Optimising the use of adherence diaries in RCTs of home-based AHP rehabilitation interventions: A multiple case study

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Improving health through research

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Background

• Important to measure adherence in rehabilitation trials
  ➢ If null results, ineffective or not undertaken?
  ➢ If positive results, are effects dose-dependent?
Previous work

• Systematic reviews - adherence diaries are the most commonly used adherence measure
• But diaries had variable validity
• Why?
Questions

1. How is an optimal adherence diary characterised in trials?

2. What are the processes within trials that facilitate or inhibit this?

3. How can adherence diaries be optimised in trials?
Case Studies

An empirical in-depth inquiry which investigates a phenomenon in its real-world context where the boundaries between the phenomenon and context may not be clear (Yin, 2014).

Aimed to generate theory to explain the variation in diaries

Data collection and analysis

**Cases**
- Purposive sample
- 7 UK AHP clinical trials
- PT, OT and SLT, pilot and full trials, range of diary designs and return rates

**Data collected**
- Interviews with researchers
- Blank diary and sample of anonymous completed diaries
- Published trial protocols, surveys, qualitative data and results
- Unpublished reports

**Data Analysis**
- Within- and cross-case analysis
- Coding
- Modelling
- Matrices
- Pattern matching
- Triangulation
- Member checking
<table>
<thead>
<tr>
<th>Cases (n=7)</th>
<th>Condition</th>
<th>Home-based activity measured</th>
<th>N using the diary</th>
<th>Duration of recording</th>
</tr>
</thead>
</table>
| **NONSPEX (pilot)** | Dysarthria following stroke | ▪ Words and sentence practice  
▪ Conversation practice  
▪ With/out non-speech oromotor exercises.  
▪ 10-15min 2-3 times a day, 5 days a week | 39 | 7 weeks |
| **SCORD (substantive)** | Dupuytren’s contracture | ▪ Night-resting thermoplastic splint wear  
▪ Every night | 77 | 6 months |
| **ENVISAGE-WP2 (pilot)** | Secondary falls prevention | ▪ Exercise games, computer visualisations or a booklet  
▪ 3 times per week | 22 | 12 weeks |
| **SELF (pilot + substantive)** | Rotator cuff tendinopathy | ▪ Single self-managed shoulder exercise  
▪ 2 times per day | 12 | 3 months |
| **SELF (pilot + substantive)** | Pelvic organ prolapse | ▪ Individualised prescription of pelvic floor muscle exercises  
▪ Daily | 42 | 3 months |
| **SUPER (pilot)** | Pelvic organ prolapse | ▪ Individualised prescription of pelvic floor muscle exercises  
▪ Daily | 28 | 12 weeks |
| **EVIDEM-E (substantive)** | Behavioural and psychological symptoms of dementia | ▪ Walking  
▪ 5 times a week, 20-30mins per time, RPE of 12-14  
▪ Control group activity recorded | 131 | 12 weeks |
| **TOMAS (substantive)** | Post-stroke mobility limitations | ▪ PT/OT intervention to improve outdoor mobility  
▪ Number of journeys made (daily)  
▪ Control group journeys recorded | 568 | 12 months |
What is an optimal diary?

<table>
<thead>
<tr>
<th>Optimal</th>
<th>High return</th>
<th>Medium return</th>
<th>Low return</th>
</tr>
</thead>
<tbody>
<tr>
<td>Highly accurate</td>
<td>ENVISAGE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unclear</td>
<td>SCORD SELF pilot</td>
<td>TOMAS EVIDEM-E</td>
<td>SUPER SELF substantive</td>
</tr>
<tr>
<td>Inaccurate</td>
<td>NONSPEX</td>
<td></td>
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</table>
How can diaries be optimised?

FAVOURABLE TRIAL AND ORGANISATIONAL CONTEXT

INDIRECT INCENTIVISATION

PARTICIPANT CAPABILITIES

DIARY SALIENCE

ACTIVITY SALIENCE

DIARY COMPLEXITY

ACTIVE DATA RETRIEVAL

PARTICIPANT MOTIVATION

LEVEL OF DATA COLLECTED
Favourable organisational and trial context

“in the NHS study what we saw was more loss to follow up, more patents not attending treatment...at least one of the centres had other research studies going on at the same time.
(Case 4: interview)
Indirect incentivisation

“I suppose there’s a broader thing is what, what did we do actively to keep people in the trial so that we would get data, cos to some extent that, that feeds into a response.” (Case 2: interview)

Trial context effects

Participation effects e.g. access to resources

Satisfaction with the trial and processes
Participant capabilities

**Participant abilities**
(level of impairments)

“they were physically not able to do it…particularly that was the case for people who were physically not in good shape and living alone.” (Case 1: interview)

**Competing life interests**
e.g. employment, being a carer, social life

“The majority of trial participants were retired (65% of trial sample)…many stated that because they had time or no other commitments this made trial participation easy.” (Case 2: survey publication)
Diary salience

Initial emphasis on the diary by researchers and professionals

Positive and negative effects of completing the diary

Ongoing encouragement to complete the diary

“get the physios to emphasise it more that they have to bring them back and try and make it as part of an outcome you know and reinforce it as such rather than just they have to complete this diary as well.” (Case 5: interview)
“some people said that it was very difficult to quantify the amount of conversation, because people would say things like “Och I talk all day!” or you know “My wife and I are, you know, are chitter-chattering all the time”. (Case 1: interview)
Diary complexity

- Information required
- Frequency of completion
- Amount of data on one page

“it’s no challenge to us to fill in this kind of thing, but erm some people are, are put off by anything that requires the completion of a form.” (Case 1: interview)
Active data retrieval

“to some extent we came to get the data from them. Do you see what I mean? We weren’t waiting for responses by post.” (Case 2: interview)
How can diaries be optimised?

- Smooth trial implementation
- Participant benefits
- Low impairment levels
- Few other commitments
- Emphasise importance
- Memorable activity
- Simple
- Active strategies
Implications

- Researchers need to:
  - Be aware of factors that might reduce the level of data collected
  - Build in strategies to optimise diaries

- Similar concepts in questionnaire literature
  - use similar principles
Next steps

• Only theoretical - needs testing
• EXACT – randomised crossover trial
• Does optimising diaries according to diary complexity and salience principles produce more valid diaries?
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