A systematic review of adherence measurement methods currently used in randomised controlled trials of home-based rehabilitation interventions

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Background
Documenting participant adherence in clinical trials is paramount for assessing the extent to which effectiveness is dependent on the intervention dose. This is particularly vital in home-based therapies where greater patient commitment is required. Despite this, there are few evidence-based evaluations of the methods used and no rigorous guidance as to which is the optimum method in a given intervention.

To facilitate comparison across methods, components of adherence were considered using the following framework:

- Data
- Measurement
- Acceptability
- Validity
- Reliability

Aim
To summarise the validity, reliability and acceptability of the measurement methods currently used to assess patient adherence to home-based physiotherapy, occupational therapy and speech and language therapy rehabilitation interventions.

Methods
Phase 1 aimed to locate the adherence measurement methods currently used in home-based therapy RCTs. CENTRAL, EED and HTA databases were systematically searched for physiotherapy, occupational therapy and speech and language therapy rehabilitation studies which measured adherence. Data were independently extracted by 2 reviewers and a list of measurement methods collated and summarised.

Phase 2 aimed to locate studies of the validity, reliability or acceptability of named measurement methods located in Phase 1. Medline, CENTRAL, ProQuest Nursing & Allied Health, EMBASE, CINAHL, AMED, Web of Science and WHO ICTRP were searched. Data were independently extracted and assessed for quality by 2 reviewers using the COSMIN checklist. Studies rated Excellent and Good were included in the data analysis and synthesis. Studies rated as Fair or Poor were used as supporting data.

Study Flow

<table>
<thead>
<tr>
<th>Phase</th>
<th>Study Flow</th>
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<tbody>
<tr>
<td>Phase 1</td>
<td>1174 titles and abstracts screened</td>
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<tr>
<td></td>
<td>204 full texts screened</td>
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<tr>
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<td>56 trials included</td>
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<tr>
<td>Phase 2</td>
<td>4297 titles and abstracts screened</td>
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<tr>
<td></td>
<td>232 full texts screened</td>
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<td>67 trials included</td>
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<td>52 validated and good methods included</td>
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</tbody>
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Phase 1 Results: Adherence measurement methods used in home-based therapy randomised controlled trials

- Self report (n=98)
  - General adherence
    - Good (n=98)
    - Fair (n=98)
    - Poor (n=98)
    - Insufficient (n=98)
  - Measurement
    - Good (n=98)
    - Fair (n=98)
    - Poor (n=98)
    - Insufficient (n=98)
- Provider report (n=88)
  - General adherence
    - Good (n=88)
    - Fair (n=88)
    - Poor (n=88)
    - Insufficient (n=88)
  - Measurement
    - Good (n=88)
    - Fair (n=88)
    - Poor (n=88)
    - Insufficient (n=88)
- Electronic (n=9)
  - Frequency (n=9)
  - Reliability (n=9)
  - Acceptability (n=9)
  - Validity (n=9)

Measurement methods identified within 56 trials of home-based interventions. Those highlighted in blue were taken forward to Phase 2 of the review.

Phase 2 Results: The validity, reliability and acceptability of each named Phase 1 measurement method

- Bassett & Prapavessis’ Scale
  - Good and fair evidence for general adherence measure until further evidence of validity is available
- Problematic Experiences of Therapy Scale
  - Insufficient evidence upon which to base recommendations
- Patient Diary
  - Good evidence for moderate criterion validity
  - Fair and poor quality evidence for moderate validity and moderate to good reliability
  - Recommended as a flexible approximation of adherence to frequency, duration and/or intensity rather than an exact measure
- Borg 6-20 RPE scale
  - Good evidence for moderate criterion validity
  - Fair and poor evidence for good validity and reliability in a wide variety of populations
  - Can be recommended as a cost-effective approximate measure of adherence to intensity
- Joint Protection Behaviour Assessment
  - Low to fair quality evidence for good reliability and moderate validity
  - Can be recommended only for joint protection behaviour trials but provides a useful example of developing measures of adherence to accuracy
- Yamax Digiwalker CW-701
  - Insufficient evidence upon which to base recommendations
  - Further research and practice should focus on other models with a greater evidence base
- StepWatch Activity Monitor
  - Good evidence for good to excellent validity and moderate reliability
  - Lower quality evidence supporting high accuracy and reliability across varied populations
  - Recommended for measuring adherence to frequency, duration or intensity in walking or foot movement interventions
- Polar A1 & FS1 Heart Rate Monitors
  - Insufficient evidence upon which to base recommendations
  - Further research and practice should focus on other models with a greater evidence base

Conclusions
There is no gold standard of adherence measurement in home based therapies. Methods used to measure adherence in the subset of trials included in this review have limited evidence and require specific intervention characteristics. Adherence measurement decisions thus need to relate to the parameters and features of the interventions, be based on the available evidence and to be reported in more detail.

Further research is needed into the acceptability of adherence measurement methods. Utilising adherence measures in trials represents an opportunity to assess and report on the measurement properties and acceptability of the tool used in larger, relevant patient populations and to further develop the evidence base.

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References

Other references available on request.