

DIARIES –ARE THEY VALID?

Hypothesis / aims of study

Adherence measurement in clinical trials is paramount to assess the extent to which the effectiveness of a particular intervention depends on the received intervention dose and to determine whether null results arise from suboptimal adherence or ineffectiveness. Adherence can be defined in general terms, such as the World Health Organisation definition – the extent to which a patient follows recommendations agreed with the provider or as components of the prescribed behaviour e.g. adherence to frequency, intensity, duration and the type or accuracy of behaviour¹. Adherence is vital where interventions contain unsupervised home-based therapeutic activities, such as pelvic floor muscle exercises, however, measurement is difficult as observing these behaviours is usually infeasible. Systematic reviews have found adherence diaries to be one of the most commonly used adherence measures in unsupervised exercise-based rehabilitation, home-based rehabilitation and non-pharmacological self-management interventions². Diaries are advantageous as they require only limited retrospection, can measure a wide range of behaviours in differing levels of detail and can display patterns of change over time. They are additionally both economical and simple to administer. Despite their potential importance adherence diaries are vulnerable to two major problems: reduced validity from back- and forward-filling, social desirability and simple forgetfulness; and missing data arising from non-completion and non-return. The authors undertook a systematic review and found that adherence diaries had evidence for moderate to excellent validity and acceptability, suggesting that whilst they can be used well in some situations, this was not always the case. However, the reasons behind this were unclear. Qualitative and quantitative assessments of questionnaire return rates highlighted several potential factors that may apply to diaries, including participants' opinions of the trial, personal factors such as forgetfulness, pre-warning participants about the questionnaires, question order, question content and monetary incentives. However, despite their popularity there is little evidence to support optimal design or use of adherence diaries within a trial. As stated previously adherence diaries are a commonly used method of measuring adherence in trials, including pelvic floor muscle training, yet their completion and validity appears to vary widely. We aimed to: 1) explore how this variation arises and develop ways to optimise adherence diaries, 2) evaluate whether one or more of these increased the validity and completeness of diary data.

Study design, materials and methods

Development: We adopted a multiple case study approach, collecting interviews with diaries from seven purposively sampled UK trials, including one reporting on pelvic floor muscle exercise home programme. We explored return rates, diary designs and researchers' ideas as to what improved or hindered diary completion and validity.

Evaluation: We conducted a randomised trial, comparing a diary optimised according to several model components developed from the results of our case study, to one non-optimised diary. Healthy older adults undertook a home-based eight-week walking program. They completed each diary for four weeks, recording walk duration and frequency. The primary outcome was the validity of self-reported adherence to walking duration, compared to an ActiVpal accelerometer. Secondary outcomes included test-retest reliability and acceptability.

Results

33 participants were recruited. Diaries did not significantly differ in their validity, reliability or acceptability. On average, both diaries closely matched the ActiVpal when assessing duration adherence, however there were high levels of inter- and intra-individual variation in validity (mean difference (95% limits of agreement (LOA) optimised diary = 3.09% (-103.3% to 109.5%), non-optimised diary = -0.34% (-131.1% to 130.5%), $p=0.732$). The diaries were rated as low burden and equal numbers of participants favoured each diary or were neutral.

Interpretation of results

Group level data is valid, however at an individual level diaries are likely to be inaccurate. This raises concerns if they are to be used in individual-level calculations, e.g. bladder, bowel or PFM adherence. Different designs of adherence diaries appear to be interchangeable, but this study was underpowered to detect a difference.

Concluding message

Currently, self-report questionnaires have little evidence to support their use and though some electronic methods are valid and reliable, they are costly and are mostly limited to walking activity³. Increasingly electronic methods are being developed to record adherence to pelvic floor muscle exercises and will require validation in robust clinical trials.

References

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Disclosures

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