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Review

Rates of attrition, non-compliance and missingness in randomized controlled trials of child physical activity interventions using accelerometers: A brief methodological review

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ABSTRACT

Objectives: The purpose of this brief review was to describe the missingness, from both attrition and non-compliance, during physical activity randomized controlled trials among children which have used accelerometers to measure physical activity.
Design: Systematic review.
Methods: Using a previously published search strategy, an updated search of the literature was performed in the MEDLINE database for articles published from 1996 to February 2015 identifying physical activity RCTs in children (ages 2–18) measuring physical activity using accelerometers. Rates of attrition and non-compliance were extracted from identified articles. Twenty-three independent studies provided complete attrition and non-compliance data and were included.
Results: The mean attrition rate was 11.5% (SD 10.1%, range 0–30.9%). The mean accelerometer non-compliance rate at baseline was 22.7% (SD 16.4%, range 1.7–67.8%) and 29.6% (SD 19.4%, range 3.3–70.1%) at follow-up. The mean total study missingness was 37.4% (SD 20.2%, range 3.3–75.4%) and ranged from 3.3% to 75.4%. There was large variation in how missingness was accounted for between studies. There were no statistically significant differences in missingness between study characteristics including sample size, participant age, intervention setting, duration of follow-up, whether physical activity was the primary outcome, and weartime compliance criteria.
Conclusions: Missingness is common among randomized controlled trials using accelerometry in children and is currently handled inconsistently. Researchers must plan for high levels of missingness in study design and account for missingness in reporting and analyses of trial outcomes.

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1. Introduction

To improve poor physical activity levels of children, high quality research trials are needed to evaluate intervention strategies.[1] To improve the quality and transparency of randomized controlled trial (RCT) reporting, the Consolidated Standards of Reporting Trials (CONSORT) statement was developed in 1996.[2] In physical activity intervention trials, it is commonly anticipated that all participants who begin the trial may not provide complete data at follow-up, creating 'missingness' in trials. The CONSORT checklist requires a flow diagram including the number of participants at each stage including the number of participants randomly assigned to treatments and those included in the final analysis. According to the CONSORT website, over 585 journals have endorsed CONSORT reporting guidelines. Thus missingness should be reported for all RCTs to enable readers to judge the quality of the evidence reported.

There are two components of missingness in trials: attrition and non-compliance. For the purposes of this study, attrition is defined as those participants who entered the study and who did not remain in the study at follow-up. It is important to note, that as part of this definition, missingness does not include whether a participant followed the intervention protocol, otherwise known as adherence, but whether or not they were still available for measurement at follow-up. In addition to attrition, there is non-compliance with measurement, in this case accelerometer protocols. Non-compliance is defined as participants who remained in the study at follow-up but did not participate in outcome assessment or did not provide valid physical activity outcome data. Together, attrition and non-compliance create missingness, or those who entered the study but were not included in the final results of the study.

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Accelerometers are currently and commonly being used for objective measurement of physical activity in children, and thus are often the primary outcome of physical activity trials. However, non-compliance with accelerometer protocols is known to be high,[3,4] though limited information is available on precise estimates. As objective measures, accelerometers require substantial participant burden compared to the majority of self-report measures. While protocols vary, participants are usually required to provide three to four days of 8 to 10 h per day to have data considered valid for youth.[5] In a recent meta-analysis of controlled trials that measured physical activity using accelerometers among children,[6] the median "losses to follow-up" was 11% and ranged from zero to 46%. It is unclear, however, how attrition and non-compliance specifically contributed to 'losses to follow-up'. Additionally, issues of how researchers dealt with the missingness and if it varied by study characteristics was not explored.

The combination of attrition and non-compliance with accelerometer protocols may be resulting in a significant percentage of study samples missing from the findings of physical activity studies and thus findings are at risk of biased study findings. The purpose of this review was to examine the missingness, both attrition and non-compliance, during physical activity RCTs among children which have used accelerometers to measure physical activity.

2. Methods

Using the published search strategy from the EarlyBird 54 review of physical activity RCTs with objective measures of physical activity,[6] an updated search of the literature was performed in the MEDLINE database. Articles were searched that had been published from February 2015 to 1996, when CONSORT reporting guidelines were established. Reference lists were cross-checked.

To be included, articles had to be the primary report of the RCT, excluding duplicate or secondary analyses articles. Study design was restricted to randomized controlled trials as they are currently considered the highest quality study design and should follow CONSORT reporting guidelines, thus increasing the chance of required information being reported.

Participants needed to be between the ages of 2 and eighteen. To reduce the inclusion of preliminary studies or small studies where higher than normal effort may be applied to decrease attrition and non-compliance, studies with an $n < 50$ were excluded.

The intervention duration had to be a minimum of two weeks, thus providing a minimum duration of two weeks between baseline and follow-up measures. This was to allow for the natural process of attrition.

The reported outcome (primary or secondary) of the study had to include child physical activity as measured by accelerometer. The accelerometer had to be used for measuring full day physical activity (excluding studies that only measured school day physical activity where research staff supervised accelerometer wear at school thus create an artificial weartime compliance). The same children had to be measured at two time points as part of the experimental design and studies where a random sample of children were selected at each time point were excluded. These two previous points would lead to different samples used to calculate attrition and non-compliance, thus precluding the ability to calculate total missingness from these studies.

To calculate the attrition, non-compliance and overall missingness, four numbers were extracted from the articles.

- N available at baseline = participants present for baseline testing and randomized (not excluded).

- N with valid PA at baseline = participants with valid accelerometer data at baseline as defined by author.
- N available at follow-up = participants who were available at the first follow-up assessment following completion of intervention delivery. If not reported, taken as measure with the highest n at follow-up.
- N with valid PA at follow-up = participants with valid accelerometer wear at follow-up, only of those available at follow-up. Technical failure of accelerometers resulted in non-valid data and these participants were not included as having valid data.

If the published study included some, but not complete non-compliance data, the corresponding authors were contacted and given the opportunity to provide the data. Five authors were contacted and two authors provided additional data (De Craemer, Verloigne).

Four variables to assess missingness were calculated from the extracted variables using the following formulas:

(1) Attrition (%) = 100 − (N available at follow-up/N available at baseline).
(2) Non-compliance at baseline (%) = 100 − (N with valid PA at baseline − N available at baseline).
(3) Non-compliance at follow-up (%) = 100 − (N with valid PA at follow-up − N available at follow-up).
(4) Missingness (%) = 100 − (N with valid PA at follow-up − N available at baseline).

The relationships between the study characteristics of sample size, participant age, intervention setting, intervention duration, whether physical activity was a primary or secondary outcome and compliance criteria (total hours needed for wear ranging from 12 h (2 days with a minimum of 6 h) to 53 h (4 days with 800 min per day) with missingness were examined using Spearman correlations for continuous data or ANOVA between stratified categorical variables.

3. Results

A total of 8699 articles were retrieved and titles were screened. 272 abstracts were reviewed of which 100 full text articles were examined. 21 of the articles were excluded for using physical activity measures other than accelerometry, 15 studies were non-randomized, 9 did only measured partial day physical activity using accelerometers, 9 measured PA in a only a subsample of participants, 5 were not the report of the primary study outcome, 3 had no measure of physical activity, 2 did not measure PA in the same children at two time-points, and one did not provide enough information to be assessed. Thirty-five original studies were eligible.

Of the 35 eligible studies, twenty-three studies provided complete attrition and non-compliance data and were included in the analysis. One study only reported the total n at baseline. Seven studies did not provide compliance data at either timepoint (only reported attrition data). Four studies were missing baseline compliance data. One study reported compliance as "not enough to assess" but did not provide numbers. One study did not report follow-up numbers and the cited Appendix was unable to be obtained.

Characteristics of included studies can be seen in Table 1. The average sample size was 517 (SD 565, range 60–2221). Sixteen of the studies had accelerometer measured physical activity as a primary outcome. Three studies were conducted with young children (<6 years of age), 17 were conducted with children (ages 6 to 11 years), and three were conducted with adolescents (11+). The majority ($n = 13$) of the interventions were conducted in a school setting. The duration ranged from 6 weeks to two school years with a mean of 34 weeks.