Randomization by Cluster, But Analysis by Individual Without Accommodating Clustering in the Analysis Is Incorrect: Comment

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We recently read the article by Morgan et al. addressing the important topic of physical activity and obesity among girls [1]. The article focused on testing a novel program designed to increase physical activity levels among fathers/male guardians and their daughters. The study design involved a cluster randomized controlled trial involving 115 fathers and 153 daughters where family units were randomized into either the Dads And Daughters Exercising and Empowered (DADEE) intervention group or a wait-list control group. The primary outcome of interest, physical activity levels among fathers and daughters, was assessed at baseline, 2 months post-intervention, and also at 9 months post-intervention. Thus, clusters of families were randomized into their respective intervention groups while longitudinal data were collected on all study participants. Intention-to-treat mixed effects models were used by the authors to determine the intervention effects and according to the Morgan et al., paper was done without taking the clustering into account. This would be an incorrect approach to analyze cluster randomized trials. We therefore have contacted the authors, alerted them to the issue, and advised that different analyses were needed than those described in the published article.

Clustering occurs when data are collected on multiple related units from a given set of units [2]. Collection of data on subjects within a given cluster can lead to correlated data, where observations collected within clusters are more similar when compared with observations taken across clusters. Correlations between units within clusters can either be positive or negative therefore leading to either inflated or deflated estimated variances [3]. Not accounting for potential clustering effects can lead to incorrect estimates of variances, confidence intervals, and biased assessments of treatment effects where the p values appear smaller than they really are [4].

The results reported were described by the authors as being based on analyses performed at the individual level that did not account for potential impacts of clustering on the statistical analyses.

As the use of cluster-randomized trials continues to increase among public health researchers, it is imperative that statistical approaches used to assess treatment effects adequately account for correlations induced by the collection of data on multiple subjects within clusters.

We look forward to the authors correcting the record on this analysis.

Compliance with Ethical Standards

Author's (or Authors') Statement of Conflict of Interest Authors Carmen D. Tekwe and David B. Allison declare that they have no conflict of interest.

References


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