Introduction to the series “Best (but Oft-Forgotten) Practices”¹

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The reliability of science as an enterprise has been challenged of late (1, 2). Although it is difficult to ascertain whether the implementation of good research practices is better or worse than in the past, the fact remains that there is still room for making the scientific enterprise stronger. This month, the Journal is unveiling the first in a series of articles to help reinforce important scientific and statistical principles that should be useful for researchers in general and for those in nutrition in particular. The series, titled “Best (but Oft-Forgotten) Practices,” is meant to highlight topics related to statistical design and analysis. The conduct and analysis of scientific endeavors are constantly changing, and much like there is continuing medical education, we, the editors, hope that this series will serve in a way as “continuing scientific education.”

The first article in the series is about designing, analyzing, and reporting cluster randomized controlled trials (cRCTs) (3). cRCTs are also called group randomized trials, among other names, and include experiments in which the randomization and intervention are applied at a cluster level, such as a family, a school, or a community, whereas the observations are taken at the individual level. Such cRCTs are becoming attractive venues to test and apply nutritional and obesity interventions. However, the appropriate level. Such cRCTs are becoming attractive venues to test and apply nutritional and obesity interventions. However, the appropriate design and analysis of cRCTs are imperative to the validity and inferential value of this approach. Therefore, with the rationale provided in the article by Brown et al. (3), the CONSORT (Consolidated Standards of Reporting Trials) guidelines for cRCTs (4), and the further reading included in the article by Brown et al., the editors recommend that, going forward, authors and reviewers of articles submitted to the Journal should consider the following:

- Follow CONSORT guidelines for cRCTs. This is in line with the Journal’s compliance with the “Recommendations for the conduct, reporting, editing, and publication of scholarly work in medical journals” (see the “Information for Authors” at http://ajcn.nutrition.org/site/misc/ifa.xhtml), including the recommendation to “consult guidelines for the reporting of specific study types” (5). Compliance with many of the cRCT-specific CONSORT guidelines will improve the design, conduct, analysis, and reporting of such studies.

- The design and analysis of cRCTs may not be intuitive, so we strongly advise that people obtain specific training in the conduct of cRCTs or have professional statisticians working on such trials at the outset.

- Analysis of cRCTs submitted to the Journal must take clustering into account. Small intraclass correlation coefficients or small design effects are not considered justifications for not taking clustering into account.

- Given the point above, >1 cluster must be assigned to each group to be considered a cRCT. Studies that include only 1 cluster per group will have 0 df if clustering is taken into consideration during the analysis. Studies with only 1 cluster in a treatment arm may be considered quasi-experiments or other types of designs, but in the Journal they cannot be identified as cRCTs.

These recommendations apply to most common cases, but of course in science special circumstances sometimes prevail. Authors who believe that their case constitutes a valid exception to these recommendations are encouraged to articulate such exceptions; in most cases, however, these recommendations undergird the validity of cRCTs.

The editors envision that following these recommendations and becoming familiar with the contents of our first “Best (but Oft-Forgotten) Practices” series will strengthen the field of nutrition science. Some of the topics we expect to include in future installments of this series represent recurring issues for the analysis of nutrition studies, such as regression analysis, multiple comparisons, and randomization. We expect this series of articles to strengthen submissions to the Journal and to be of use to all authors who analyze nutrition studies in the same manner as the series “Statistics Notes,” which the British Medical Journal has published since 1994 (6).

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REFERENCES