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At Last-Best Practices for Conducting Human Nutrition Randomized Controlled Trials: A Brief Review and Commentary

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Introduction

Best practices for designing, conducting, documenting, and reporting human nutrition Randomized Controlled Trials (RCT) were developed [1-5]. This comprehensive resource serves as a reference for investigators, funders, regulators, institutions, assessors, trainees, and others in research. The papers also include examples of situations that can occur in the conduct of human RCTs and present strategies for effectively addressing them. The goal was to provide guidance that, if followed, should improve the rigor of human nutrition clinical studies that will result in a greater impact on policy decisions and, ultimately, human health. The effort was undertaken by a working group called Nutrition Intervention Research (NURISH), with members identified through the NIH Clinical and Translational Sciences Award (CTSA) program. A workshop was organized by the Tufts Clinical and Translational Science Institute (CTSI), Indiana CTSI, and Pennsylvania State University CTSI. The NURISH working group was comprised of three subgroups: Design and conduct of human nutrition Randomized Controlled Trials (RCTs), U.S. documentation and regulation of human nutrition RCTs, and Laboratory considerations and clinical data management for human nutrition RCTs. The latter subgroup also discussed planning and conducting statistical analyses for human nutrition RCTs. The manuscripts that have been published are co-authored by all workshop participants [1-5]. Diet-related interventions can include diet and/or behavioural manipulation; provision of foods-single foods, meals or entire diets, or delivery of specific components incorporated into single food items or as supplements.

Design and conduct of human nutrition RCTS

Human nutrition RCTs are the gold standard for establishing causal relations between exposure to nutrients, foods, or dietary patterns and health outcome measures, from disease endpoints to intermediary markers such as body composition, blood pressure, serum lipids, and bone mineral density. Core principles for design and conduct of clinical nutrition RCTs were addressed and recommendations offered to maximize quality and generalizability of the findings while maintaining the highest levels of ethics and scientific integrity [2].

Documentation and regulation of human nutrition RCTs

Considerations involved in nutrition research, are essential when conducting human nutrition RCTs and sometime were addressed in one of the papers in the series on guidance for human nutrition RCTs [3]. Training in the broad scope of documentation and regulation is limiting in human nutrition research and mostly focuses on approval of the protocol by the Institutional Review Board or ethics committee. Development of Standard Operating Procedures, training of staff, and certifications of good clinical practices and conflicts of interest must be completed prior to initiating a study. Comprehensive documentation practices are necessary for replicability of a study and to allow independent

verification of study procedures and data integrity, where appropriate.

Laboratory considerations and clinical data management for human nutrition RCTs

Best practices for data collection and fundamentals of clinical data management to ensure data integrity and quality were the theme of another paper in the series [4]. The article covered key steps for bio specimen collection and analysis and for clinical data management. Included were preparation and study starting up; data collection, entry, cleaning, and authentication; and database lock. When followed, these tools and strategies are necessary to ensure the quality and preservation of data, which is crucial to building a database that accurately informs food and nutrition policy.

Statistical analysis planning for human nutrition RCTs

A critical component for research transparency, validity, and reproducibility is the statistical analysis plan, which must be developed as part of the study protocol. The final paper for conducting human nutrition RCTs summarizes best practices for developing a statistical analysis plan, conducting statistical analyses, and reporting statistical methods and results for human nutrition RCTs [5]. The analysis plan emphasizes the importance of linking a priori study results and outcomes, thereby defining the impact of the study.

Future directions

The American Society of Nutrition plans to host webinars to train on the guidance developed and published in Advances in Nutrition later this year [1-5]. It will be important to keep updating this guidance. A recent workshop sponsored by the National Academy's Forum on Drug Discovery, Development, and Translation on Envisioning a Transformed Clinical Trials Enterprise for 2030 addressed goals and priorities for increasing efficiency, effectiveness, and putting patients at the centre [6]. The outcome may lead to significant changes in the design and conduct of future RCTs. For example, one article focused on large-scale hybrid RCTs him current clinical trials enterprise is very impressive with the many discoveries that have benefitted human health. Clearly, progress still needs to made in achieving the highest standard of human nutrition RCT research and, also, to assure that the research conducted serves all populations in society.

Conclusion

Clinical nutrition trials have unique considerations including documentation of the safety, efficacy, integrity, and sometimes assurances or permissions from federal agencies such as the FDA about the diet intervention. Unique design considerations include the difficulty of blinding the intervention, the lack of a deficient nutritional status, or absence of a bioactive in diets of participants at baseline, carry over effects, and benefit of a run-in period.

Conflicts of Interest and Source of Funding

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