Design of Clinical Trials Evaluating Dietary Interventions in Patients With Functional Gastrointestinal Disorders

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Abstract

Clear guiding principles for the design and conduct of dietary intervention trials in functional gastrointestinal disorders (FGID) are lacking. This narrative review examines the specific challenges associated with the design and reporting in dietary intervention trials. Dietary intervention trials need to address the collinearity between food, nutrients, and bioactive components that obscure the relationship between food and their effects in the gut. Randomized, double-blinded, placebo-controlled studies remain the gold standard for dietary trials, but are limited by difficulties in adequate masking of study food or inappropriate choice of placebo food / diets. Provision of study diets as the preferred delivery method can somewhat address these limitations, although allowing good adherence compared with education-based dietary interventions. Issues associated with participant expectancies and dietary behaviors can alter the true effectiveness of a diet. In addition, failure to adjust for or report baseline intake of nutrients of interest can reduce their magnitude of benefit. Bias in subjective reports and choice of measurement tools can preclude accurate assessment of food-intake data. In the design of elimination and rechallenge studies, sufficient time period and adequate exclusion of dietary triggers are essential to ensure symptoms are well-controlled before rechallenging. The route and frequency of challenging, design of test food, and / or placebo should match the aims of the rechallenge phase. Long-term efficacy data of such therapeutic diets has been poorly documented in most studies. Standardized guidelines that address many of the challenges outlined above are suggested to strengthen the quality of evidence for dietary therapies in FGID.

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