Optimizing clinical trial design for assessing the efficacy of functional foods.

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Abstract

Randomized clinical trial data are capable of providing strong experimental evidence to establish causal relationships between functional food components and health and disease/disease risk. However, clinical studies must be well designed in order to optimize the quality of the data they provide. The purpose of this review is to identify design elements that maximize the quality of clinical trials examining the efficacy of functional foods. Both observational studies and experimental trials can provide useful data for identifying diet-disease relationships. Two experimental designs are conventionally used: parallel and crossover. Each of these designs possesses advantages and disadvantages. For certain functional ingredients, selection of an appropriate control arm is straightforward, while for others it is challenging. Studies should be short enough to optimize subject compliance, be cost effective, and avoid high subject dropout rates, while being lengthy enough to ensure biological efficacy. The dose, frequency, and diurnal timing of intake of the active food ingredient all need to be chosen carefully. Randomized clinical trials testing the efficacy of functional foods may use both validated and emerging surrogate endpoints and should employ suitable statistical tests for data analysis. Paying attention to all these factors is crucial to the design of quality clinical trials that reliably evaluate food-health relationship validity. Accordingly, clinical studies that incorporate the optimal design elements discussed will yield robust results appropriate for the substantiation of health claims on functional foods.