

Abstract

Landscape of Nutrition- or Diet-Related Randomised Controlled Trials: Data from Protocols Published between 2012 and 2022 [†]

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Abstract: Background and aims: As part of a project to consolidate reporting guidance for randomised controlled trials (RCTs), protocols of RCTs, and systematic reviews of nutritional interventions, it was important to understand the nutritional interventions research landscape over the past decade. We aimed to assess the nutrition or diet-related interventions research landscape using data from RCT protocols published as research articles between 2012 and 2022. Methods: We searched six databases for eligible protocols published between January 2012 and March 2022. Data extracted included bibliometrics, study scope (population, intervention, comparator, outcome, study design), and research transparency practices (protocol registrations, conflicts of interest and funding statements, mentions of reporting guidelines). We screened the “Instructions for Authors” webpages of each journal contributing publications to our sample to check whether they endorsed reporting guidelines. Results: We included 1068 protocols. The frequency of publication of RCT protocols as research articles increased annually, with a mean of 161 (range: 155 to 163) publications/year. Healthy (n = 342; 32.0%) adults and elderly people (n = 350; 32.7%) composed the most frequent target population. Isolated nutrition- or diet-related interventions (n = 724; 67.8%) were most frequently studied, with supplementation (n = 405; 37.9%) being the most common type of intervention. The most frequent primary outcome reported was clinical status (n = 308; 28.8%). Most protocols described a single-centre (n = 838; 78.5%), two-arm (n = 844; 79.1%), parallel (n = 1014; 94.9%) RCT. Of the 148 journals in which the included protocols were published, general medical journals (n = 518; 48.5%) contributed more publications compared to methods journals (n = 479; 44.9%) and nutrition journals (n = 71; 6.6%). The SPIRIT statement was endorsed by 33.8% (n = 50) of the journals, CONSORT by 75.3% (n = 111), and TIDieR by 2.7% (n = 4). In 32.1%, 27.8%, and 1.9% of publications, the authors mentioned SPIRIT, CONSORT, and TIDieR, respectively. Most protocols (n = 1006; 94.2%) reported the study registration and included conflicts of interest (n = 952; 89.1%) or funding (n = 994; 93.2%) statements. Conclusions: The number of nutrition- or diet-related RCT protocols being published as research articles is increasing over time, showing the importance of this type of publication. The adoption of research transparency practices by researchers and journals can still improve.



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