Abstract

Objective. To describe the design, methods, and challenges encountered during a randomized clinical trial aimed to promote water intake for reducing risks of metabolic syndrome in Mexican women. Materials and methods. In a randomized clinical trial in Cuernavaca, Mexico, overweight and obese (body mass index \[\text{BMI} \leq 39\]) women, 18 - < 45 years old with an intake of sugar-sweetened beverages 250 kilocalories per day (kcal/day) were randomly allocated to the water and education provision group (n = 120) or the education provision only group (n = 120). Results. We screened 1756 women. The main difficulties encountered were identifying participants with the recruitment criteria, delivering water to participants, and the time demanded from the study participants. Conclusions. The trial’s main challenges were difficulties surrounding recruitment, delivery of the intervention, and the time demanded from the study participants. Modifications were effectively implemented without jeopardizing the original protocol.

Keywords

Clinical trials, sugar, beverages, triglycerides, body mass index, diet, women, Mexico.