Winfood Data from Kenya and Cambodia: Constraints on Field Procedures.

Victor O. Owino*[1]; Jutta Skau[2]; Selina Omollo[3]; Silvenus Konyole[3]; John Kinyuru[4]; Benson Estambale[5]; Bethwel Owuor[6]; Roos Nanna[2]; Henrik Friis[2].

***[1]Department of Nutrition and Dietetics. The Technical University of Kenya**,
[2] the University of Copenhagen, Denmark; [3] University of Nairobi, Kenya;
[4] Jomo Kenyatta University of Agriculture and Technology, Nairobi, Kenya; [5]Jaramogi Oginga Odinga University, Bondo, Kenya;
[6]Catholic University of East Africa, Nairobi, Kenya

Abstract

Background. Researchers face myriad challenges in the design and implementation of randomized, controlled trials. Apart from summaries on limitations, these challenges are rarely documented in detail to inform future research projects.
Objective. To describe methodological challenges encountered during randomized, controlled trials (WinFood Study) designed to assess the efficacy of locally produced complementary foods based on traditional animal-source foods (edible termites and spiders) to support growth and nutritional status in Kenyan and Cambodian infants.
Methods. In a randomized, controlled design, infants received WinFood or corn–soy blend (CSB) for 9 months from 6 to 15 months of age. Lean mass accrual and blood nutrition indicators (lipid profile, iron and zinc status) were measured cross-sectionally at 9 and 15 months of age, respectively. Lean mass was determined by measuring deuterium oxide enrichment in saliva samples following a standard dose of deuterium solution (0.5 g/kg body weight) to infants. Blood nutrition indicators were determined following the drawing of 3 mL of blood by venipuncture.
Results. Challenges included rapid depletion of food rations, high rate of loss to follow-up, delayed ethical approval, lack of local food-processing capacity, low capacity among staff to draw blood, and lack of laboratory capacity to perform both deuterium oxide and micronutrient status measurements. Spillage of deuterium oxide solution during dosing was a major challenge in the Kenya context. A high rate of morbidity among infants made some assessments very difficult, especially drawing of blood and saliva samples.
Conclusions.
The challenges were largely contextual. Improvement of local laboratory capacity, training of staff, and sensitization of the communities and the Ethics Review Committee are highly recommended.
Key words:
Cambodia; field challenges; Kenya; randomized, controlled trial; WinFood

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