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Jane L Holl

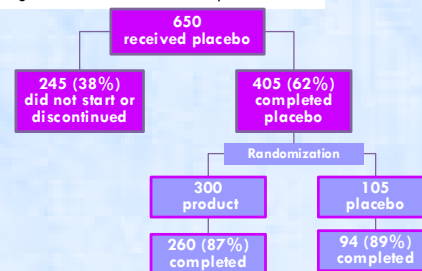
Northwestern University & Focus Pointe Global, Inc., USA

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Introduction and maintenance of early adaptive training protein blends in support of infant nutritional goals: Safety and acceptability

Childhood food allergy affects about 8% of US children. Recent research has revealed protective effects of early dietary introduction of allergenic foods on the development of food allergy for infants, including those at elevated risk. The goal of this study was to evaluate the safety and acceptability of a blend of 16 common allergenic proteins (peanut, soy, almond, cashew, hazelnut, pecan, pistachio, walnut, wheat, oat, milk, egg, cod, shrimp, salmon, and sesame) combined with 400 IU of Vitamin D into a food supplement powder. Caregivers were instructed to mix the powder into a solid or liquid feeding once a day. All procedures were deemed exempt by the Northwestern University IRB. A national sample of healthy infants, 5-11 months of age, without severe eczema participated in the 28-day placebo period followed by a 28-day randomized, blinded, placebo-controlled period. Caregivers were instructed to feed the infant one packet of the food supplement powder per day, observe their infant for 2 hours after ingestion, and record, in a web-based diary, any symptoms or allergic-type reaction including anaphylaxis occurring within 2 hours of ingestion and any reaction-related prescribed medication or medical care. Caregiver perceptions of the food supplement's smell, texture, and packaging, were also assessed. Figure 1 shows enrollment and completion rates of the study. Of the 8,400 food supplement ingestions, no infants had any allergic reaction nor received any prescribed medication or medical care. Of 14,252 placebo ingestions, 1% (N=250) resulted and 0.7% (N=61) of food supplement ingestions in a report of symptoms (e.g., cough, diarrhea). This study suggests that the food supplement is safe and feasible for infants. Future study should assess the effect of the food supplement on immunologic responses to the allergenic proteins and on the incidence of food allergy.

Figure 1. Enrollment and Completion Rates



Biography

Jane L Holl is a General Pediatrician and Health Services and Outcomes Researcher who has conducted substantial prior research on childhood food allergy in the US. She is the Director of the Center for Healthcare Studies, an interdisciplinary center at Northwestern University. She has partnered previously with Kay Savio from Focus Pointe Global, Inc., a global market research company with fully vetted, precision-targeted participants.

j-holl@northwestern.edu