

ASSESSMENT OF PARENT-REPORTED OFF-LABEL INFANT CONSUMPTION OF A PLANT-BASED TODDLER FORMULA BASED ON ALMOND AND BUCKWHEAT

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Objectives and Study.

Due to recent infant formula shortages in the United States, there has been increased off-label consumer-initiated use of toddler formulas in infants. Thus, we sought to assess reported usage trends, weight gain, and parent perception of their infant's nutrition-related symptoms during parents' elective use of a novel plant-based toddler nutritional drink based on almond and buckwheat [Else Nutrition].

Table 1: Demographic data of consumers

Gender	Male	58%
	Female	42%
Primary Reason for Choosing Else	Lifestyle or Ingredients	71%
	Clinical Reasons	29%
Details of Use	Age of Initiation (Mean)	8.7 months
	Duration of Use (Mean)	4.7 months

Methods.

Data from two waves of a cross-sectional parent survey, adapted from validated tools to address usage, demographics, and nutrition-related symptoms, were retrospectively analyzed upon IRB waiver. Out of 648 parents who completed the survey, parents of 153 participants reported off-label initiation below 12 months of age.

Figure 1: Clinical Reason Specifics for Choosing Else

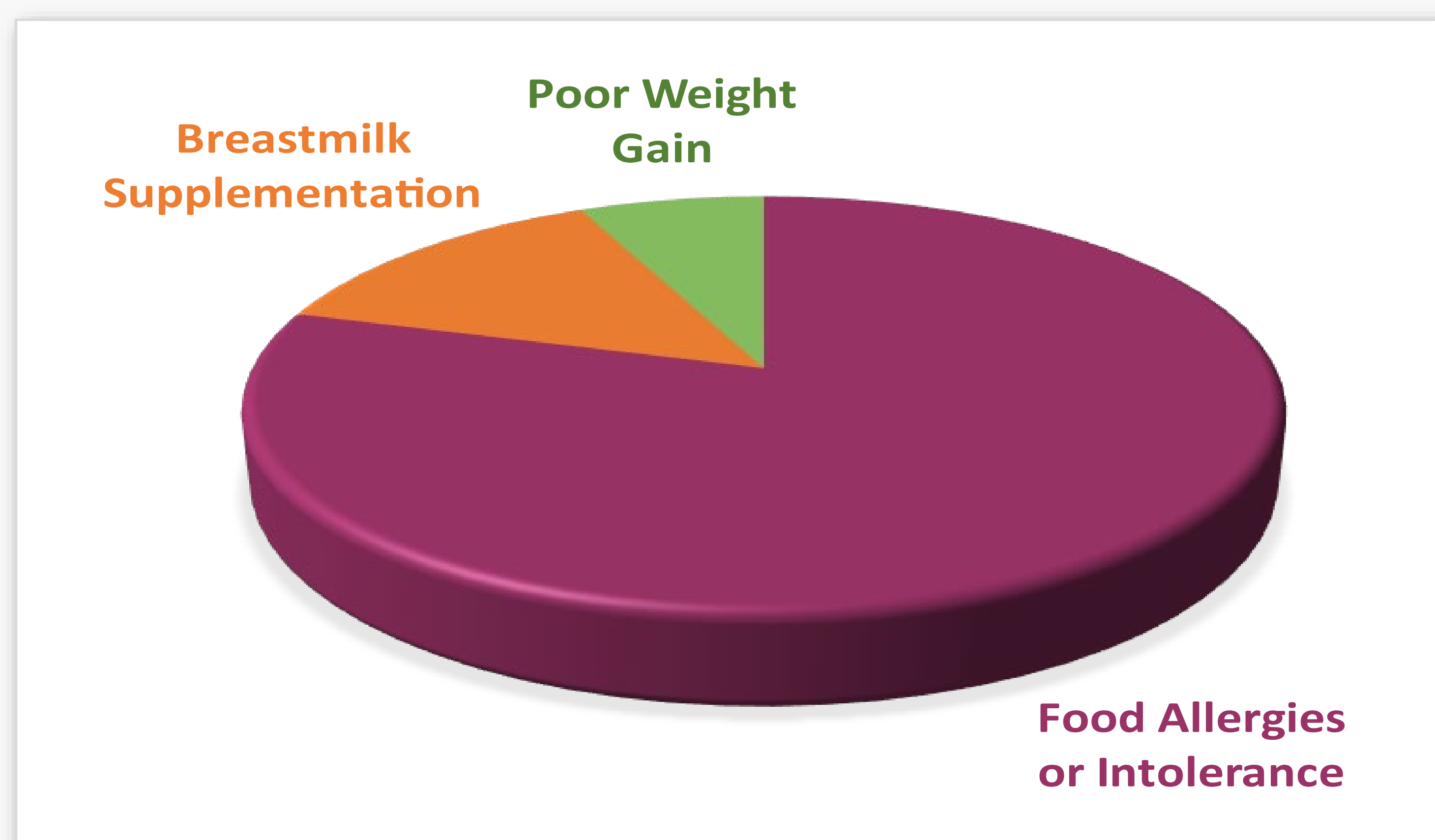
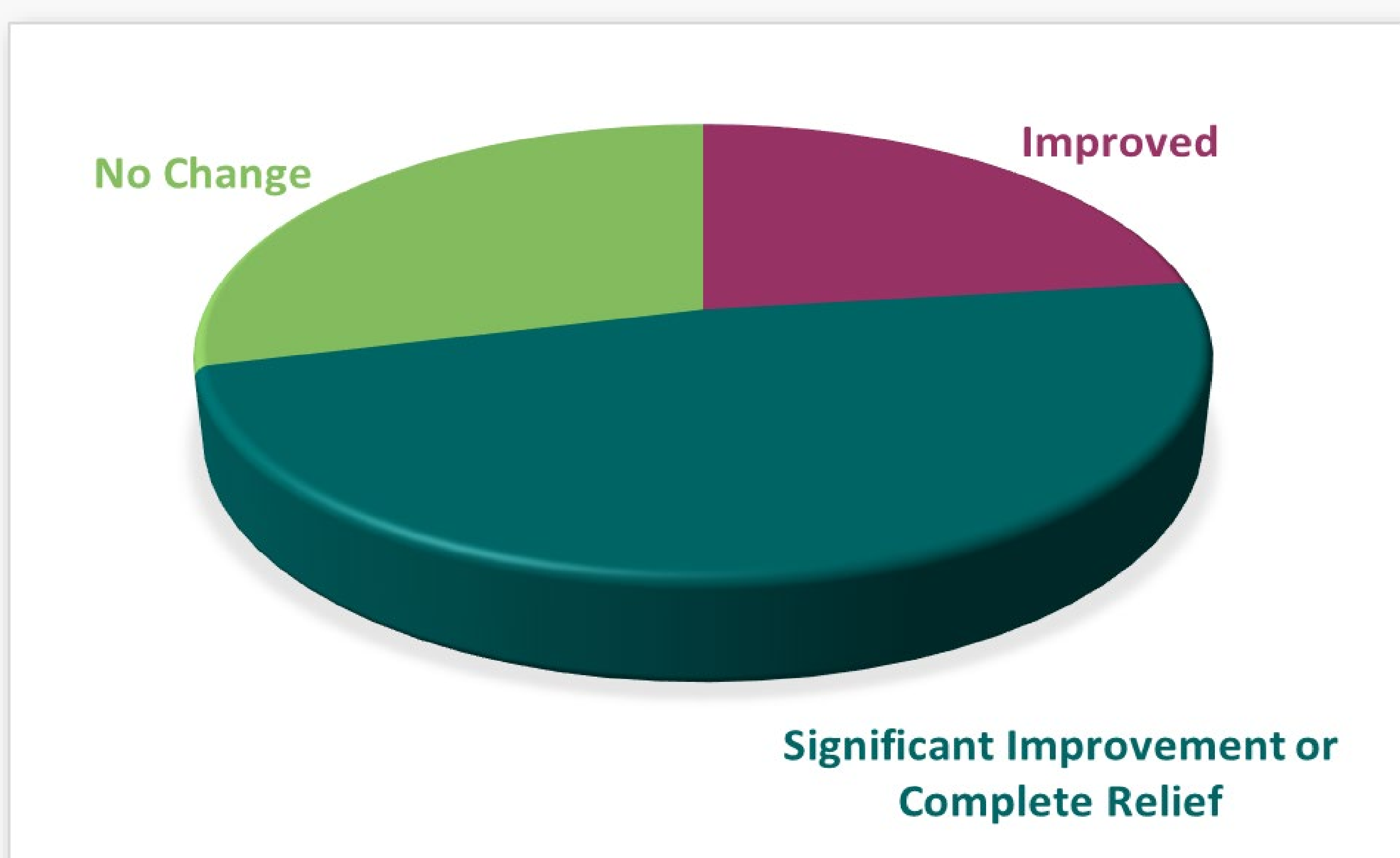


Figure 2: Improvement in Users with Reported GI Symptoms

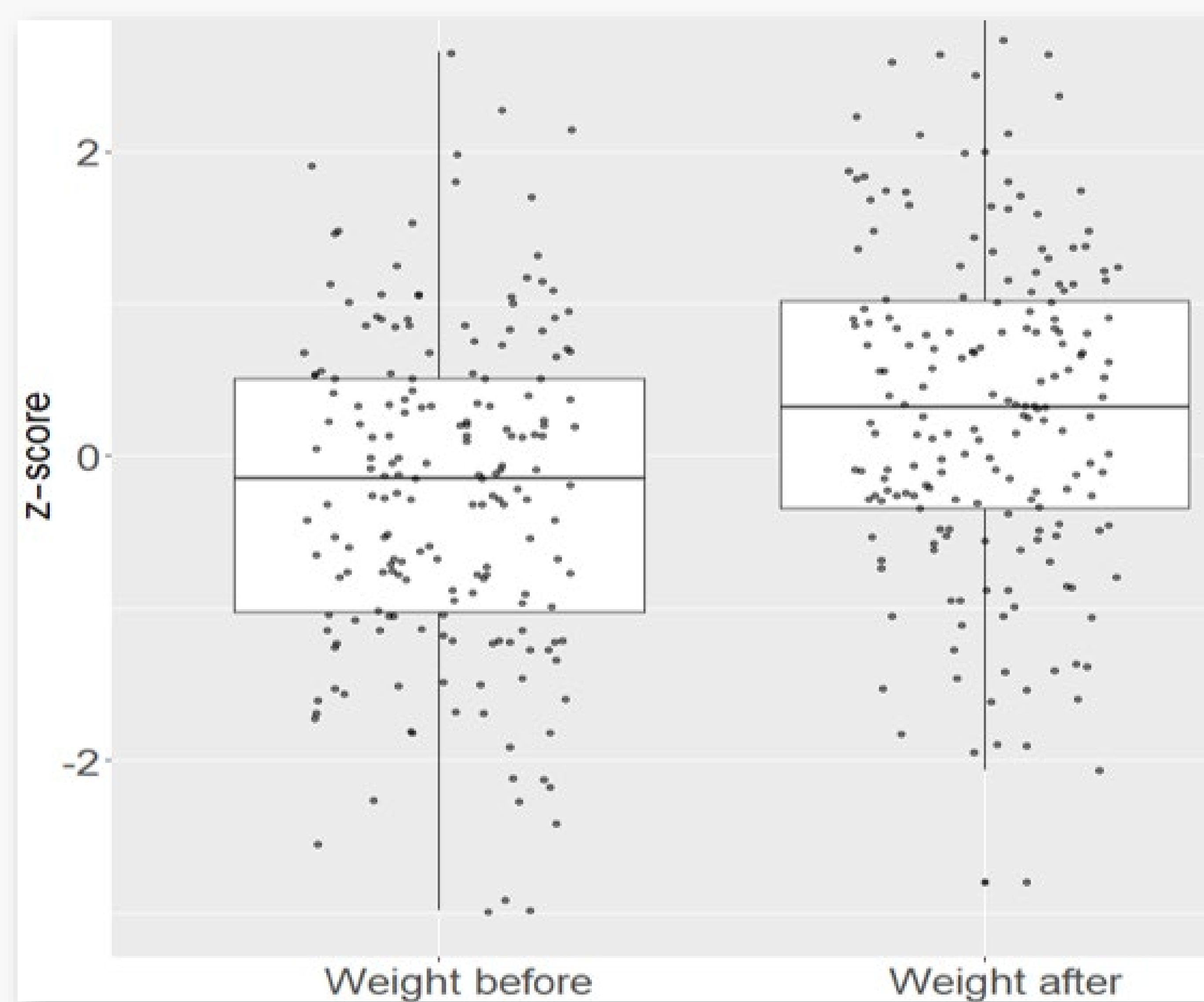


Results.

The mean age at initiation of use was 8.7±2.4 months and the mean use duration was 4.7±2.96 months. The most common reasons for use were preferred ingredients or lifestyle (71%). However, 29% reported clinical reasons for use: food allergies or intolerances (23%), breast milk supplementation (4%), and poor weight gain (2%). Of those who reported food allergies or intolerances, 60% reported dairy allergy and 17.1% reported coinciding dairy and soy allergy.

Majority (81%) of those who reported abnormal weight gain patterns with prior usage reported normal weight gain following use. Stool consistency trended toward normal stools (Type 3 or 4) after using the product; there was an 89% reduction in severely abnormal stools (Type 1 or 7). Of those who reported GI symptoms, 23% reported general improvement and 48% reported either significant improvement or complete relief of symptom.

Figure 3: Box Plot for Users with Before / After Z-Scores



Conclusion.

Analyses revealed general tolerance, reduction in reported weight gain problems, and improved parent-perception of their infant's nutrition-related symptoms following off-label use of this buckwheat/almond-based toddler drink. A well-powered, controlled clinical infant growth study, utilizing this protein source as part of an infant-intended formulation, is required to validate the results and safety/efficacy.

Conflict of Interest:

Authors RM, KB, FBY are employees of Else Nutrition; Author JVH is a scientific advisor for Else Nutrition.