# Academy of Nutrition and Dietetics Nutrition Research Network: The *Saqmolo'* Project Rationale and Study Protocol for a Randomized Controlled Trial Examining the Influence of Daily Complementary Feeding of Eggs on Infant Development and Growth in Guatemala

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**ABSTRACT**

Adequate nutrition during the complementary feeding period is critical for optimal child growth and development and for promoting long-term educational attainment and economic potential. To prioritize limited public health resources, there is a need for studies that rigorously assess the influence of multicomponent integrated nutrition interventions in children younger than age 2 years in different contexts. This study aimed to describe the rationale and protocol for the Saqmolo' Project using the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines. The *Saqmolo'* (ie, "egg" in the Mayan language, Kaqchiquel) Project is an individually randomized, partially blinded, controlled comparative effectiveness trial to evaluate the influence of adding delivery of a single whole egg per day to local standard nutrition care (ie, growth monitoring, medical care, deworming medication, multiple micronutrient powders for point-of-use food fortification [*chispitas*], and individualized complementary and responsive feeding education for caregivers) for 6 months, compared with the local standard nutrition care package alone, on child development, growth, and diet quality measures in rural indigenous Mayan infants aged 6 to 9 months at baseline (N = 1,200). The study is being executed in partnership with the Wuqu' Kawoq/Maya Health Alliance, a primary health care organization located in central Guatemala. Primary outcomes for this study are changes in global development scores, assessed using the Guide for Monitoring Global Development and the Caregiver Reported Child Development Instruments. Secondary outcomes include changes in infant hemoglobin, anthropometric measures (including *z* scores for weight for age, length for age, weight for length, and head circumference for age), and diet quality as measured using the World Health Organization's infant and young child feeding indicators. The results of the *Saqmolo'* Project may help to inform public health decision making regarding resource allocation for effective nutrition interventions during the complementary feeding period.

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THE IMPORTANT INFLUENCE OF optimal diet quality during the complementary feeding period on child growth and development and long-term health has been well documented in the scientific literature.[1-3] Neurodevelopment is a complex process that proceeds in a specified developmental sequence, where timing is crucial and later compensation will not be able to retrieve all of the lost function.[4] The period from conception until age 2 years, otherwise known as the first 1,000 days, is universally recognized as a critical period for lifelong health because developing children establish metabolic and behavioral adaptations to their nutrition and overall environment.[5-7]

Despite having among the strongest economies in Latin America,[8,9] Guatemala has substantial room for improvement on several nutrition indicators tracked by the United Nations Sustainable Development Goals.[10,11] Dietary patterns for many young children in Guatemala are characterized by poor diversity and inadequate complementary feeding practices.[12-14] The diet of Guatemalan children has been shown to be low in animal-source (eg, dairy, meat, and eggs) and vitamin A-rich foods.[15] This is especially true for the rural indigenous Mayan population, who make up approximately 39% of the Guatemala population[16] and for whom historical and ongoing marginalization has resulted in limited access to sanitation and health systems, pronounced food insecurity, and high rates of poverty.[17] In fact, Guatemala's children manifest some of the poorest health indicators in the world, with 15% of neonates having low birth weight and 58% and 23% of children aged 18 to 23 months exhibiting chronic malnutrition and severe stunting (a length-for-age *z*


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score less than −2 or −3 standard deviations from the median of the World Health Organization [WHO] Child Growth Standards), respectively.[14,18,19] Furthermore, 33% of young children are anemic and more than 50% come from households living below the poverty line.[14] These outcomes disproportionately affect rural indigenous Mayan children who often experience rates of malnutrition twice as high as those reported in nonindigenous Guatemalan children.[14] In this setting, it is necessary to implement evidence-based nutrition-specific interventions, coupled with disease prevention and management interventions, to improve long-term health and development outcomes. In Guatemala and elsewhere, a common approach has been to evaluate the role of manufactured lipid-based multiple micronutrient supplements, which may have small positive influences on growth in selected settings.[20,21] Another approach is supplementation with local food commodities, with a focus on increasing consumption of animal-source foods, which are important sources of iron, zinc, and other nutrients that are often consumed in very low quantities in traditional diets in low- and middle-income countries.[22] Recent meta-analyses on this topic showed no clear influence of animal-source foods on stunting prevalence, although the analysis was limited by the low quality of studies included and significant heterogeneity between study designs, related to the foods tested and the comparison group(s).[23,24] A small 6-month randomized trial in Ecuador suggested that complementary feeding of eggs may substantially decrease the prevalence of stunting and underweight.[25,26] A similar randomized intervention in Malawi showed no overall effect of complementary feeding of eggs on child length-for-age, weight-for-age, or weight-for-length *z* scores or development.[27,28] The authors of the Malawi study also noted its close proximity to Lake Malawi. Nearly two-thirds of children were reported to have consumed fish on the previous day before assessment, which may indicate a limited benefit of egg consumption during the complementary feeding period when other animal-source foods are available.[28] Other studies examining the utility of eggs within a package of integrated interventions on the growth and development of children younger than age 2 years are present in the peer-reviewed literature[29-31] or currently underway.[32,33]

Eggs contain all nutrients considered key for neurodevelopment during the first 1,000 days of life, especially choline, which may have a major role in early brain development.[4] High choline intake during the perinatal period has been demonstrated to have lasting effects on cognition, as recently reviewed by Wallace and colleagues[34] and Derbyshire and Obeid.[35] In early life, choline plays pivotal roles in the structural integrity of membranes, neurotransmission, and methyl group metabolism. Choline passes through the blood−brain barrier via facilitated diffusion, where it is stored as membrane-bound phospholipids that are used for synthesis of the neurotransmitter acetylcholine.[34-36] Concentrations of these brain phospholipids have been suggested to increase two-fold in the cortex and three-fold in the white matter during the period between the 10th week of gestation and 2 years of age.[37] The nutritional composition and potential of eggs to improve young child nutrition has been reviewed by experts in the field.[38,39]

The objective of this individually randomized, partially blinded, controlled comparative effectiveness trial titled *Saqmolo'* (ie, "egg" in the Mayan language, Kaqchiquel), is to evaluate the influence of adding delivery of a single whole egg per day to a package of local standard nutrition care interventions, compared with the local standard nutrition care alone, on child development, growth, and diet quality measures in rural indigenous Mayan infants, aged 6 to 9 months at baseline. The study is adequately powered to detect changes in both its primary and secondary specified outcomes. The *Saqmolo'* study is a collaboration between the Academy of Nutrition and Dietetics (Academy) Nutrition Research Network, Wuqu' Kawoq/Maya Health Alliance (MHA), University of New Mexico (UNM), and Think Healthy Group. This project serves to further the Academy's vision to accelerate improvements in global health and well-being through food and nutrition and aligns with the Academy's Strategic Plan[40] by addressing the Prevention and Wellness Focus Area. The *Saqmolo'* study also addresses multiple priorities from the newly released Academy's Research Priorities,[41] including clarifying nutrient needs associated with optimal outcomes in special populations and evaluating strategies to address current diet and health disparities and related chronic disease disparities among low-income and underrepresented persons and to evaluate best practices for translating, disseminating, and scaling nutrition and dietetics interventions across community and clinical settings. This project also includes an Academy Foundation Fellow that is working with the primary study collaborator, MHA, to advance study activities on the ground in Guatemala.

## MATERIALS AND METHODS

### Study Setting

The *Saqmolo'* Project will be conducted with indigenous Mayan communities in central, rural Guatemala (departments of Chimaltenango, Sololá, Sacatepéquez, and Suchitepéquez) (Figure 1). The geographic area corresponds to the catchment area of MHA, a nonprofit primary health care organization with central offices in Tecpán, Chimaltenango, Guatemala. MHA works with vulnerable indigenous communities to provide culturally and linguistically appropriate health care services.[42] The primary language spoken in this area is Kaqchikel. MHA has been providing primary care and nutrition services in this area for over a decade and collaborates closely with the Ministry of Health and multiple other nongovernmental organizations in the region. Sixty-three percent of women in Guatemala initiate breastfeeding and approximately 53% exclusively breastfeed their infants.[43] The Global Nutrition Report indicates that 82% of infants in Guatemala have meet the WHO Infant and Young Child feeding indicators thresholds for minimum meal frequency, and 59% meet the threshold for minimum dietary diversity.[44] In 2021, Juarez and colleagues[45] demonstrated a 50% prevalence of food insecurity in rural Mayan children. Foods commonly consumed by this infant population include breastmilk, corn, bread, pasta,

rice, oatmeal, refined sugar, and eggs.[46] Study-related procedures will be conducted by MHA staff in the homes of subjects. The essential framework of the *Saqmolo'* Project's educational component has recently been shown to significantly improve diet quality indicators among children aged 6 to 24 months at baseline (n = 324).[12]

## Eligibility Criteria

Inclusion and exclusion criteria are outlined in Figure 2.

## Intervention Group

The primary caregiver of infants allocated to the intervention group will receive monthly deliveries of locally sourced whole chicken eggs, with instructions on how to prepare and serve 1 egg per day to the child, for 6 months. Caregivers will also receive suggested recipes, information on safe egg storage and preparation, and in-home education on the importance of egg consumption for early child development and growth. Each monthly egg ration will include extra eggs (~20% surplus) to account for possible consumption by other family members. Community health workers will also administer the local standard nutrition care offered by MHA to each enrolled infant, as described in Figure 3 and elsewhere.[12] Participants will be monitored for egg allergy or adverse reactions to the intervention as outlined below (see the Data Monitoring and Safety section). If an egg allergy or adverse event related to the treatment occurs, the infant will be immediately


**Figure 1.** The Saqmolo' Project logo. *Art design by Patrick Don (*https://www.patdon.com*).*

| **Inclusion criteria** |
|---|
| • Infants aged 6.0 to 9.0 mo at baseline |
| • At least one caregiver willing to provide oral informed consent and participate in study activities |
| • Planned residence in the study area for approximately the next 18 mo |
| • Singleton birth |
| **Exclusion criteria** |
| • Infants with moderate-to-severe acute malnutrition (weight-for-length *z* score $< -2$) |
| • Infants with severe anemia (hemoglobin $< 7$ g/dL per World Health Organization guidelines, with adjustments for altitude as necessary) |
| • Infants with a chronic medical condition that affects growth (eg, congenital heart disease or genetic condition) as determined by the Maya Health Alliance staff physician |
| • Infants whose caregivers have cognitive or other impairments that prevent them from being able to provide informed consent or reliably provide information required for the developmental assessments |
| • Infants with a known egg allergy |
| • Infants with recalcitrant moderate-to-severe atopic dermatitis |
| • Infants with a history of anaphylaxis or serious allergic reaction to any substance requiring emergency medical care |
| • Concurrent participation in any other clinical trial |

**Figure 2.** Inclusion and exclusion criteria for the *Saqmolo'* Project.

| Component | Description |
|---|---|
| Growth monitoring | Weight, length, and head circumference using World Health Organization growth standards to convert to *z* scores. Monitoring is monthly, in the home by community health workers, from birth to age 2 y |
| Deworming medication | Individualized, based on discussion with supervising physician. Not routinely provided before age 2 y |
| Multiple micronutrient powder | Composition includes ferrous fumarate (12.5 mg), zinc gluconate (5 mg), retinol acetate (300 μg), folic acid (160 μg), and ascorbic acid (30 mg). Provided daily beginning at age 6 mo |
| Individualized complementary and responsive feeding education for caregivers | Individualized counseling session led by community health worker, provided monthly for six sessions. Uses 24-h World Health Organization diet recall tool to focus conversation on meal frequency and food group diversity |
| Medical care | Community health workers trained in Integrated Management of Childhood Illness clinical guidelines[a] for managing acute respiratory and diarrheal illness. Urgent care/episodic care available through referral to public health post or Maya Health Alliance physicians. Vaccines on national schedule provided by public health brigades |

[a]https://www.who.int/teams/maternal-newborn-child-adolescent-health-and-ageing/child-health/integrated-management-of-childhood-illness/

**Figure 3.** Description of local standard of nutrition care components.

referred to the local health clinic and removed from the study but still continue to receive local standard of nutrition care offered by MHA. Caregivers may withdraw the infant from the study at any time and still receive local standard nutrition care in the case that it is desired.

## Control (Local Standard Nutrition Care Only) Group

Infants in the control group will receive the local standard nutrition care (Figure 3) offered by MHA for 6 months. The package of local standard nutrition care for early child nutrition provided by MHA includes growth monitoring, medical care, deworming medication, multiple micronutrient powders for point-of-use food fortification (*chispitas*), and individualized complementary and responsive feeding education for caregivers. Caregivers may withdraw the infant from the study at any time and still receive local standard nutrition care if desired.

## Outcomes

**Primary Outcomes.** Primary outcomes for this study are differences in global development scores between study arms, assessed using the Caregiver Reported Early Child Development Instruments (CREDI) long form[47] at baseline (ie, infants aged 6 to 9 months) and endline. The CREDI long form uses caregiver reports to create both a summary and subdomain scores for a child's overall development status. The CREDI included a Guatemalan sample in its validation.[47,48] The Guide for Monitoring Child Development is extensively used alongside the CREDI in low- and middle-income countries in children aged 0 to 24 months and focuses on seven areas: expressive language, receptive language, fine motor, gross motor, relating, play, and self-help.[49,50] Together the Guide for Monitoring Child Development and the CREDI show strong internal and external validity, have been tested specifically in low-resource settings, and provide complementary information about child development.[47] The primary safety end point for the study is incidence of egg allergy as discussed below (see the Data Monitoring and Safety section).

**Secondary Outcomes.** Secondary outcomes for this study include infant hemoglobin level, anthropometric measures (eg, *z* scores for weight for age, length for age, weight for length, and head circumference for age), and diet quality. For these outcomes, project investigators will compare differences in hemoglobin levels and anthropometric *z* scores, proportions of children (within inclusion criteria guidelines) who are anemic, stunted, wasted, or underweight, and proportions of children consuming a minimal acceptable diet, minimum dietary diversity, minimum meal frequency, and consuming eggs between the groups, from study enrollment to study endline (6 months postenrollment). Point-of-care hemoglobin level will be assessed using a capillary blood sample and a HemoCue Hb201+ (HemoCue AB). Infant length will be measured using a portable stadiometer to the nearest 1 mm. Weight will be monitored using a hanging Salter scale to the nearest 0.1 kg. Head circumference will be measured using nonstretchy measuring tape to the nearest 1 mm. All anthropometric measurements will be completed in triplicate. For data analysis, the mean of the first two readings will be used in the case that they did not differ more than a prespecified tolerance limit (length/height <0.5 cm, weight <0.2 kg). In the case that they differ more than

these prespecified tolerance limits, the pair of measurements that has the smallest difference will be used to calculate the mean. Infant diet quality will be measured using the WHO Infant and Young Child Feeding indicators questionnaire,[51] adapted for use in Guatemala. Although there are limitations to using the WHO Infant and Young Child Feeding indicators as the only method of dietary assessment in the study, it was believed that more rigorous methods of dietary assessment, such as repeated quantitative 24-hour dietary recalls, would not be feasible given the study complexity and anticipated participant burden.

**Other Variables.** Other variables for this study include demographic and socioeconomic characteristics, such as drinking-water access (WHO/United Nations Children's Fund)[52] and food insecurity (using the Food Insecurity Experience Scale),[53] family environment relative to promotion of child development, common morbidities, and adherence to the multiple micronutrient powders and egg consumption (intervention group) will also be assessed across all participants. A baseline demographic and family care indicators interview and questionnaire will be used to capture the above variables, aside from adherence to the multiple micronutrient powders and egg consumption. Examples of information on common morbidities and complications during and after birth to be collected within the interview and questionnaire include "infection" and "needed transfusions." Adherence to the multiple micronutrient powders and egg consumption (intervention group) will be monitored within the interview and questionnaire during the monthly in-home visits and via biweekly telephone calls to caregivers for the first 2 months.

## Participant Timeline

The *Saqmolo'* Project will use a rolling recruitment approach, as further described below (see the Recruitment and Oral Informed Consent subsection). Caregivers will have approximately 10 to 12 hours of contact with the research team across the 6-month study duration: study enrollment (ie, visits to recruit, assess eligibility, and complete informed consent; 2 hours), primary study data collection at baseline and 6 months (2 to 4 hours), and monthly 60-minute visits to administer local standard nutrition care (intervention and control groups), assess development of egg allergy (intervention group), and deliver eggs (intervention group; 6 hours). Caregivers in both groups will also receive four adherence telephone calls every 2 weeks for the first 2 months of the study (8 to 10 minutes per call). These calls will include complementary feeding messages (ie, general messages for the control group and egg-focused messages for the intervention group) and egg-related adherence questions (intervention group). A flow diagram of study milestones is presented in Figure 4.

## Sample Size Calculation

The *Saqmolo'* Project will recruit 1,200 infants. With an anticipated 20% attrition rate, based on previous studies conducted with families in this region, this provides 480 infants for each of the two treatments: egg and control. An $\alpha = .05$ and 80% power are used to determine detectable differences between treatments for the change from baseline to the end of the study.

Calculations for change in the CREDI long form are based on a standard deviation of 0.32 calculated from a validation of the score in low-resourced settings.[48] To compute the standard deviation for the difference between the baseline and the end of the study, a correlation between these two measures of 0.4 was used. The detectable difference between treatments is 0.68 for the proportion of correct responses, a design effect of 0.20. A plot of the power versus the difference is given in Figure 5.

Calculations for change in length-for-age *z* score are based on a standard deviation of 0.75 calculated from summary statistics for a randomized controlled egg feeding intervention in Ecuador.[25] To account for the block randomization, a design effect of 0.18 was assumed. The detectable difference between treatments is 0.136 *z* score units. A plot of the power versus the difference is given in Figure 6. Results for weight-for-age *z* score are similar.

Similar calculations were used to estimate the margins of error for the treatment effect based on the changes from the baseline to the end of the study. These estimates are 0.095 for length-for-age *z* score and 0.040 for the CREDI long form. Based on the power calculations and the margins of error, the investigators conclude that the sample size chosen is adequate to detect expected effects that are important, as well as to estimate the effects with confidence intervals having excellent precision.

## Recruitment and Oral Informed Consent

The *Saqmolo'* Project will seek to enroll 1,200 infants aged 6 to 9 months at baseline: intervention (n = 600) and local control (n = 600). The investigators estimate 15 months of rolling recruitment, enrolling approximately 40 infants per month. Subjects will be recruited by research study staff through referral from local public health clinics, community centers, and referring providers, including traditional midwives. Caregivers who express initial interest in study participation will undergo first-stage rapid screening to assess certain inclusion criteria, such as medical and caregiver history, that would easily exclude an infant from participation prior to scheduling an in-home visit to complete informed consent (described in the Consent Procedures section) and second-stage study screening (ie, assessment of anemia and acute malnutrition). Infants who are ineligible for enrollment in the study will still be able to receive the local standard nutrition care from MHA. Infants who are moderately or severely wasted or severely anemic based on the study exclusion criteria will not be enrolled in the study and will be immediately referred for treatment. The total number of infants excluded during the second screening step (ie, in-home visit) in aggregate by wasting and anemia status will be maintained by the study coordinator.

If the caregiver is willing, baseline data collection will occur after the informed consent process and second-stage study screening is completed; otherwise a separate home visit will be scheduled the following week. The egg feeding trial (described in more detail in the Data Monitoring and Safety section) will be performed after baseline data collection only among participants assigned to the intervention

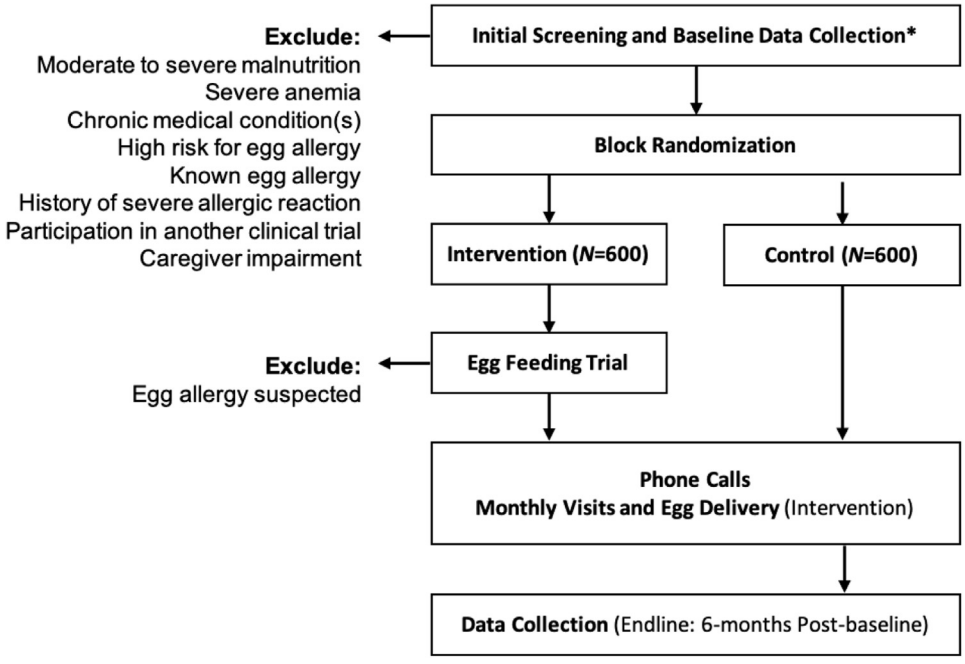


**Figure 4.** The Saqmolo' Project flow diagram. *Primary caregivers will be offered 1 week to consider enrollment and discuss participation with other individuals who need to be involved in the decision-making process, if needed.

group to complete the final aspect of the eligibility process. All research study staff and community health workers will be bilingual speakers of Spanish and Kaqchikel (or other Mayan languages, as appropriate), the anticipated language of the subjects. These recruitment strategies have been used successfully for several other studies related to early child nutrition and health in the study region.[12,43,54,55] If the recruitment progress is slower than expected through the above channels, the study team will collaborate with MHA's extensive network of local nongovernmental and community-based organizations to recruit additional participants.

## Allocation and Blinding

Once informed consent has been obtained and a child is determined to be eligible for the study (with the exception of the feeding trial), research study staff will assign a subject identification number. Eligible infants will be individually randomized using block randomization; 1:1 allocation in blocks of eight will be used to ensure a balance in sample size between study groups over time. Randomization will occur at the household level to account for rare cases where two infants within the same eligible age range might be present and thereby to allow both to participate within the same arm and prevent intrahousehold tensions. The randomization allocation sequence will be computer generated by the study statistician.[56]

Research study staff will be masked to group assignments, whereas community health workers, the MHA physician, and the project coordinator will not be able to be blinded. Other study principal investigators and statistician(s) involved in the data analysis

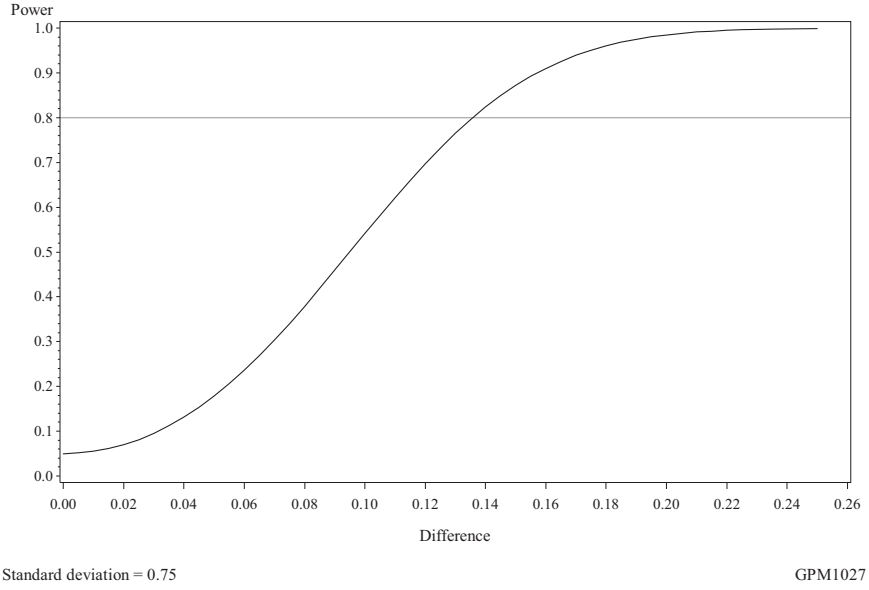


**Figure 5.** Power calculations for change in the Caregiver Reported Early Child Development Instruments[47] long form: difference between egg and control groups (n = 480 observations per group; $\alpha = .05$).

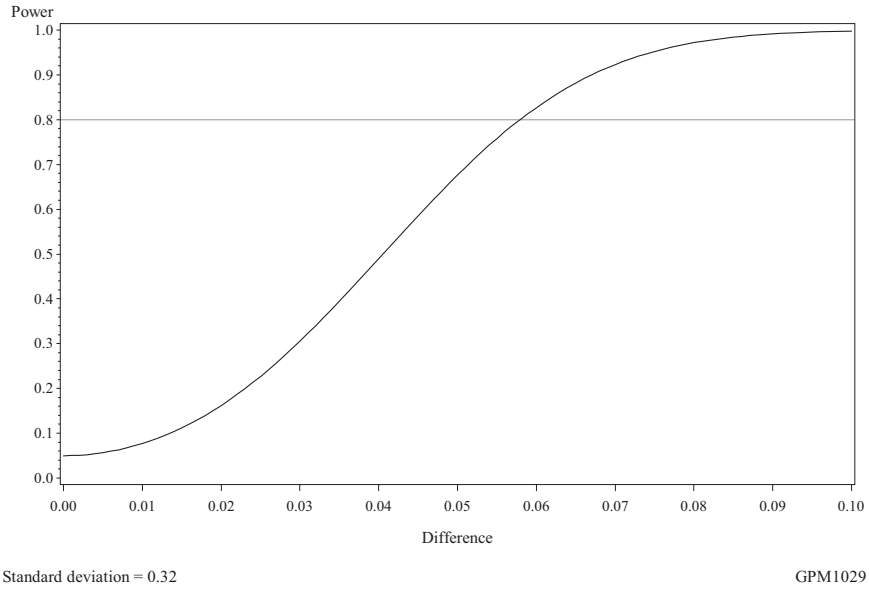


**Figure 6.** Power calculations for change in length-for-age *z* score: difference between egg and control groups using the Caregiver Reported Early Child Development Instruments[47] (n = 480 observations per group; $\alpha = .05$).

phase will be blinded to group assignment until initial data analyses are complete.

## Intervention Delivery

Families in the intervention group will be given extra eggs (about 20% extra) each month, to account for possible consumption by other family members. Prior studies, including those by MHA, have used this strategy in regular clinical programming in the area.[57] Although not a guarantee that eggs will not be directed solely to the infant, this strategy significantly increases the likelihood that a larger ration will be consumed by the target child. In addition, a recent systematic review highlighted that, behaviorally, food/micronutrient supplements may be more likely to be consumed (at least based on caregiver self-reports) when caregivers are educated specifically on the likelihood of perceptible health benefits, which is also an important part of this project's intervention interactions with caregivers.[58] Finally, the investigators note that the trial is designed as an effectiveness trial, not an efficacy trial, so under consideration is the influence of the entire intervention package, with or without leakage of the egg ration to other children. At each intervention visit, the dietary recall conducted by health workers will allow us to estimate egg consumption, a factor that can subsequently be considered when evaluating the influence of the intervention at the end of the study.

## Data Collection, Management, and Quality Assurance

Demographic, primary, and secondary outcomes will be collected in person by the research study staff at two time points: baseline (0 months) and post-intervention (6 months). An in-depth standard operating procedure manual will facilitate training, retraining, field observations, and data collection. The study data collection schedule is illustrated in Table 7. All baseline and end point demographic, primary, and secondary outcome data will be entered directly into Research Electronic Data Capture (REDCap) software, a secure cloud-based platform, via mobile app.[59,60] Data on adherence will be entered into an electronic case report form within the MHA electronic medical record (EMR) during community health worker monthly visits and biweekly telephone calls (first 2 months only) to the primary caretaker. Data quality and accuracy will be verified regularly by the study coordinator. The primary investigators (ie, authors of this article) will act as the data management committee and have access to the deidentified data through the REDCap platform. These individuals also preside over the final decision to terminate the trial.

The control group will receive a complementary basket of approximately 2 dozen eggs at the end of the study in appreciation for their participation.

## Statistical Methods

All analyses in the *Saqmolo'* Project will be conducted by the principal coinvestigators and the statistician. The MHA physician (coinvestigator P.R.) and the Academy Foundation fellow (G.M.-B.) will be unblinded to the group assignments but will refrain from participating in the initial statistical analyses. The other study principal coinvestigators (T.C.W., E.Y.J., and G.V.P.) and the study statistician (G.P.M.) will be blinded to the group assignments until initial analyses are complete. Preparation of the analysis code will begin before the termination of the trial. Statistical analyses will be conducted using SAS version 9/4 (Statistical Analysis Software Inc), Stata version 15 (StataCorp), or similar statistical software. Continuous baseline characteristics of project participants will be described using the mean and standard deviation or the median and 25th and 75th percentiles. Categorical baseline characteristics will be described using percentages. Descriptive statistics will be calculated separately for intervention and control groups at baseline.

Outcomes will be expressed as the change from baseline to the end of the study and will be analyzed using an intention-to-treat procedure. Linear mixed models will be used for the analysis of continuous variables and logistic models will be used for categorical variables. Missing data, predefined covariates, and effect modifiers of interest will be available in the online statistical analysis plan before the end of study data collection. Assumptions will be assessed for all analyses and remedial measures will be taken as needed. Differences between treatments will be analyzed using statistical significance at the 0.05 level and with 95% confidence intervals. In addition to the direct comparisons, covariance terms will be added to the models to examine possible effect modifiers.

| Outcome or variable | Method and/or instrument (citation) | Baseline | Telehone calls[a] | Monthly visits | Endline |
|---|---|---|---|---|---|
| **Primary outcome** | | | | | |
| Global development scores | Global development score tool (Caregiver Reported Early Child Development Instruments) long form[50] | Intervention group | | | Intervention group |
| | | Control group | | | Control group |
| Global development scores | Global development score tool (Guide for Monitoring Child Development)[47,48] | | | | Intervention group |
| | | | | | Control group |
| Egg allergy symptoms[a] | Caregiver-reported questions to assess food allergy symptoms | Intervention group | Intervention group | Intervention group | Intervention group |
| **Secondary outcomes** | | | | | |
| Hemoglobin | HemoCue Hb201+[b] | Intervention group | | | Intervention group |
| | | Control group | | | Control group |
| Anthropometrics | Weight using a hanging Salter scale | Intervention group | | | Intervention group |
| | Length and head circumference using a portable stadiometer | Control group | | | Control group |
| Feeding indicators | Minimum dietary diversity, minimum meal frequency, and minimum acceptable diet using the World Health Organization Infant and Young Child Feeding indicators questionnaire[51] | Intervention group | | | Intervention group |
| | | Control group | | | Control group |
| **Other variables** | | | | | |
| Demographic and socioeconomic characteristics | Demographic questionnaire | Intervention group | | | Intervention group |
| | Child's data questionnaire | Control group | | | Control group |
| | Prenatal and postnatal background of child questionnaire | | | | |

*(continued on next page)*

**Figure 7.** Data collection description and schedule.

| Outcome or variable | Method and/or instrument (citation) | Baseline | Telehone calls[a] | Monthly visits | Endline |
|---|---|---|---|---|---|
| Family environment relative to promotion of child development | Family history questionnaire | Intervention group<br>Control group | | | Intervention group<br>Control group |
| | Quick poverty score[65] | | | | |
| | Water access questionnaire[52] | | | | |
| | Food insecurity experience scale[53] | | | | |
| | Family care indicators questionnaire | | | | |
| Adherence to multiple micronutrient powder | Caregiver-reported infant consumption | Intervention group<br>Control group | Intervention group<br>Control group | Intervention group<br>Control group | Intervention group<br>Control group |
| Adherence to egg consumption | Questions to assess food allergy symptoms | Intervention group | Intervention group | Intervention group | Intervention group |
| | Caregiver-reported infant consumption | | | | |

[a]Safety outcome.

[b]HemoCue AB.

**Figure 7.** *(continued)* Data collection description and schedule.

Sensitivity analyses will be used to verify that the conclusions are robust with respect to the method of analysis chosen. Analyses based on a repeated measures design, end of study outcome with baseline as a covariate and alternative models for categorical variables will be examined.

## Data Monitoring and Safety

The primary safety end point for this study is the occurrence of egg allergy. It is widely accepted in the Guatemalan medical community that the prevalence of immunoglobulin E (IgE)-mediated food allergy in children is much lower than that observed in high-income countries. In addition, over the past decade a great deal of research has emerged suggesting that infants at average risk of food allergy need no special precautions for introducing any complementary food, including eggs. This is now the consensus represented in major pediatric society guidelines, such as those of the American Academy of Pediatrics.[61] Nevertheless, the following measures will be taken to manage potential risk and monitor for egg-related allergy.

First, all staff (ie, community health workers and research study staff) will receive training on assessment and management of potential IgE-related food allergy (ie, use of an epinephrine pen and the referral process). This training will occur at study initiation with subsequent refresher trainings each quarter. The material used in all trainings will follow guidelines published by the U.S. National Institute of Allergy and Infectious Diseases and by Food Allergy Research and Education (FARE).[62,63] Staff will carry epinephrine pens and, using the FARE guidelines for assessing and treating anaphylaxis, be capable of administering epinephrine in the event that a severe allergic reaction is observed.[62] If a serious adverse reaction is observed in the field during the observed trial or if epinephrine is given, staff will immediately transport the caregiver and infant to the nearest health post.

Second, infants at high risk for IgE-mediated egg allergy will be excluded from study participation based on the inclusion and exclusion criteria (Figure 2).

Third, during the first home visit by the community health worker, an

observed egg feeding trial with all infants allocated to the intervention group will be conducted to ensure safety. At least 2 tsp egg must be consumed without evidence of symptoms within 1 hour for an infant to be enrolled into the study.[64] Because the in-home visits are approximately 1 hour, ample time is provided for documentation of food allergy symptoms, per US National Institute of Allergy and Infectious Diseases and FARE guidelines.[62,63] Any infant exhibiting signs or symptoms of an egg allergy will be immediately withdrawn from the study, but remain eligible to receive local standard nutrition care from MHA.

Fourth, for ongoing surveillance, community health workers will ask all caregivers the following questions and record responses in the electronic case report form within the MHA EMR during all monthly in-home visits:

- At any time during the past month, have you noticed that your child has vomited or had diarrhea within a few hours of eating an egg?
- If yes, did your child have a skin rash that looks like this at the same time as they had the vomiting or diarrhea? (Note: community health workers will show caregivers a picture of what hives look like when asking the question.)

These questions are based on current evidence regarding the most likely presentation of food allergy-related reactions/anaphylaxis in infants. If the caregiver answers "yes" to both questions, the adverse event procedure outlined below will be followed and the infant will be withdrawn from the study if they are diagnosed with a probably egg allergy by MHA staff.

Adverse events or suspected adverse events reported by caregivers or observed by study staff will be promptly communicated to the study physician or an alternate delegate with equivalent medical training within 4 hours. Medical and study staff will promptly consult with the caregiver(s) of the infant subject to determine whether an event is associated with participation in the research. All adverse events related to the study that result in a visit to the local health clinic will be reported to the other primary investigators and respective institutional review boards (IRBs) within 24 hours.

## Ethics Approvals

The study protocol was reviewed and approved by the MHA IRB in Guatemala on February 17, 2020 (WK-2020-001) and by the UNM Human Research Protections Office in the United States on May 7, 2020 (20-146). The trial is registered at www.clinicaltrials.gov (NCT04316221) and will be executed in compliance with the Declaration of Helsinki.

## Protocol Amendments

Protocol modifications (eg, changes to eligibility criteria, outcomes, or planned analyses) and/or additions (eg, biological sample collection) will be discussed among the primary investigators before submission to the study IRBs. Any modification or addition will be communicated by updating the information on the www.clinicaltrials.gov website.

## Consent Procedures

Study staff will obtain verbal informed consent using the IRB-approved script. The IRBs granted waivers of documentation of informed consent, given that signed informed consent is generally not culturally appropriate in the study region. A teach-back method will be used to ensure that primary caregivers fully understand the consent information. Participants will be provided a copy of the consent document. Consent scripts are in Spanish, given that few individuals (including trained study professionals and native speakers) can read and write in Mayan languages. In lieu of written documents in the Mayan languages, expensive preparatory practice sessions and role playing will be used to ensure smooth contemporaneous translation from Spanish to Kaqchikel or K'iche'. This method was utilized previously in numerous former trials by MHA. Primary caregivers will be offered 1 week to consider enrollment and discuss participation with other individuals who need to be involved in the decision-making process. When appropriate based on family structure, verbal informed consent will be sought from multiple caregivers; however, informed consent from one biological and/or legal caregiver will be considered adequate for study enrollment because this study involves no more than minimal risk. Families that decline to participate in the study will still be eligible for the local standard nutrition care offered by MHA. IRB-approved verbal informed consent materials can be found in the **Supplementary Materials.**

## Confidentiality

Primary ownership of the study data will reside with MHA, Think Healthy Group, and the Academy. MHA will securely transfer deidentified datasets to Think Healthy Group and the Academy via the built-in REDCap secure data transfer functionality. Data sharing between MHA, Think Healthy Group, and the Academy is covered under a data use agreement (effective date January 13, 2020). MHA, Think Healthy Group, and the Academy will have primary responsibility for data management and analysis. As necessary, the Academy will transfer study data to UNM. Data sharing between the Academy and UNM is covered under contract FP7054 (effective date August 1, 2019). Per this agreement, all data shared with UNM for this study will be deidentified and transferred using the secure transfer portal provided by UNM Health Science Center Central Information Technology Support.

Research data and unique subject study IDs will be directly entered into MHA's secure REDCap interface or the MHA secure encrypted cloud-based EMR using full-disk encrypted study Android cellular telephones or laptop computers. Study personnel will each be assigned a unique username and password to the REDCap interface. Only the MHA principal investigator (P.R.), Academy fellow and study coordinator (G.M.-B.), and MHA staff will have access to the MHA EMR data.

Study personnel will be trained on standard operating procedures for key recruitment, enrollment, and data collection tasks. Native data field definition functions in REDCap will be used to ensure data quality at point of entry. The Academy Foundation fellow and study coordinator will perform ongoing quality control via frequent

database review and random audits of in-field operations (eg, recruitment, enrollment, and data collection). The Academy Foundation fellow and study coordinator will randomly and sporadically independently replicate some of the data collection to assess interrater reliability and to assist with evaluation of data collection techniques. Study staff will also participate in frequent standardization exercises during which the technique, precision, and reliability of their measurements and the way they pose questions will be evaluated and reinforced.

At enrollment into the study, each subject will be assigned a unique subject identification number. This number will be registered on the second-stage eligibility form on REDCap and in an electronic study enrollment spreadsheet, hosted on MHA's secure in-house file server. These will be the only links between subject names and their research data. Only the MHA principal investigator (P.R.) and the Academy Foundation fellow and study coordinator (G.M.-B.) will have access to the electronic study enrollment spreadsheet. Control of access to the electronic study enrollment spreadsheet on MHA's file server will be directly managed by the MHA principal investigator (P.R.) and Academy Foundation fellow and study coordinator (G.M.-B.).

Identifiable data (eg, consent forms, electronic study enrollment spreadsheet, and birthdates) will be maintained at MHA through the publication of primary study reports and manuscripts and for potential future follow-up analyses.

## Data Dissemination, Accessibility, and Sharing

Results from the *Saqmolo'* Project will be published in peer-reviewed journals and presented at scientific conferences. Deidentified data and statistical code derived from the *Saqmolo'* Project will be stored and maintained by the Academy Nutrition Research Network. Requests for access to deidentified data should be made directly to the Academy (NRN@eatright.org) and will be considered on a case-by-case basis. Publications resulting from approved analyses shall adhere to the International Committee of Medical Journal Editors "Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals" (http://www.icmje.org). Requests for statistical code may also be submitted to the Academy.

## Coronavirus disease 2019

The current coronavirus disease 2019 global pandemic has hit many facets of the world and research is no different. The investigators made the decision to delay the initiation of recruitment during April 2020 to help ensure the safety of both study participants and staff. Although the investigators believe that science will prevail in regard to an effective vaccine or treatment, it is likely that timelines may be negatively influenced for the *Saqmolo'* Project.

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### STATEMENT OF POTENTIAL CONFLICT OF INTEREST

T. C. Wallace, P. Rohloff, G. Montenegro-Bethancourt, G. P. McCabe, and A. Steiber receive salary support through the investigator-initiated grant provided to the Academy of Nutrition and Dietetics Foundation by the Egg Nutrition Center. G. Montenegro-Bethancourt is a research fellow funded by the Academy of Nutrition and Dietetics Foundation through the investigator-initiated grant from the Egg Nutrition Center. T. C. Wallace, has received other research grants and scientific consulting fees from the Egg Nutrition Center. E. Y. Jimenez and G. V. Proaño have no conflicts of interest to report.

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This study was registered at ClinicalTrials.gov identifier NCT04.

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### AUTHOR CONTRIBUTIONS

T. C. Wallace drafted the manuscript with input from P. Rohloff, E. Y. Jimenez, G. V. Proaño, G. Montenegro-Bethancourt, G. P. McCabe, and A. Steiber. T. C. Wallace, P. Rohloff, E. Y. Jimenez, G. V. Proaño, G. Montenegro-Bethancourt, and A. Steiber contributed equally to the design of the study. G. P. McCabe was responsible for the power calculations and statistical design protocol with input from E. Y. Jimenez and P. Rohloff. All authors reviewed, commented on, and approved the manuscript before submission.