BMJ Open

Effect of an innovative behavioural change strategy and small-quantity lipid-based nutrient supplements on stunting and obesity in children in Baja Verapaz, Guatemala: protocol for a randomised control trial

Carolina González Acero,[1] Sebastian Martinez ,[2] Ana Pérez-Expósito,[1] Solis Winters[2]

To cite: González Acero C, Martinez S, Pérez-Expósito A, *et al*. Effect of an innovative behavioural change strategy and small-quantity lipid-based nutrient supplements on stunting and obesity in children in Baja Verapaz, Guatemala: protocol for a randomised control trial. *BMJ Open* 2020;**10**:e035528. doi:10.1136/bmjopen-2019-035528

► Prepublication history and additional material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2019-035528).

Received 05 November 2019
Revised 09 April 2020
Accepted 18 May 2020

For numbered affiliations see end of article.

Correspondence to
Dr Sebastian Martinez; SMARTINEZ@iadb.org

ABSTRACT

Introduction In Latin America, a rapid increase in obesity alongside persistent malnutrition has resulted in a double burden of disease that affects the most vulnerable segments of the population. Infant and young child feeding practices are important factors that affect both sides of the growth curve. Interventions such as behavioural change strategies and home fortification using products like small-quantity lipid-based nutrient supplements (SQ-LNS) have the potential to reduce the presence of both these conditions, especially if they are implemented during the first 1000 days of life. This paper details the protocol for SPOON: Sustained Programme for Improving Nutrition, an innovative strategy to prevent stunting and reduce risk for obesity in children under 24 months old in high-poverty areas in Baja Verapaz, Guatemala.

Methods and analysis SPOON: Sustained Programme for Improving Nutrition Guatemala is a three-arm randomised control trial: treatment group 1 will receive the programme behavioural change strategy and SQ-LNS, treatment group 2 will receive the programme behavioural change strategy and micronutrient powders; the control group will receive the standard of care provided by the Ministry of Health, which includes micronutrient powders. A modified formula of SQ-LNS has been especially developed for this trial. A total of 76 communities are included in the study and 1628 households with a pregnant woman in the third trimester or a child under 4.5 months were recruited at baseline. Baseline data were collected between September and November 2018. Follow-up data will be collected 2 years after the start of the intervention. The primary outcomes of interest are related to mothers' infant feeding knowledge and practice, and indicators of children's nutritional status and growth including height, weight, weight gain rate and prevalence of stunting, overweight, obesity and anaemia. After follow-up data have been collected, differences of simple means and regression models including covariates such as child's age and sex, characteristics of the primary caregiver and household socioeconomic indicators will be estimated. Heterogeneous effects will also be estimated within subgroups of age at exposure, sex, caregiver characteristics and household socioeconomic status.

Ethics and dissemination This study was approved by the National Health Ethics Committee of the Ministry of Health of Guatemala (resolution 10–2018). Informed consent was obtained from all mothers and caregivers prior to enrolment in the programme. Results will be submitted to a peer-reviewed medical or public health journal, and disseminated internally at the Inter-American Development Bank, with the Government and Stakeholders in Guatemala and through international conferences and seminars.

Trial registration number NCT03399617

Strengths and limitations of this study

- ⇒ The three-arm randomised design allows us to assess the joint and individual impacts of small-quantity lipid-based nutrient supplements and the behavioural change strategy compared with the standard of care currently provided by the Ministry of Health in Guatemala.
- ⇒ The programme is specifically designed to reduce the risk of overweight and malnutrition simultaneously, and targets children at a critical period of growth and development.
- ⇒ The data include a rich set of nutrition, growth, demographic and socioeconomic variables.
- ⇒ A primary limitation is that, given most children in the study are were not yet born or were younger than 6 months old, feeding practices and anthropometric measures could not be measured at baseline.
- ⇒ Due to operational limitations, the goal of recruiting 2000 households for the sample could not be met.

INTRODUCTION

In the last two decades, Latin America has made substantial advancements in reducing malnutrition, decreasing stunting

(height-for-age z-score ≤2 SD) by 10 percentage points in most countries.[1] However, the prevalence of stunting among children under 5 years old, especially in areas of high poverty, remains high, at 6 million children in total.[2]

Over the same period, while the region continues to face challenges in reducing stunting, obesity has rapidly increased.[3] An estimated 4 million children under 5 and 22 million adolescents in Latin America are overweight or obese.[4] Moreover, in middle-income and low-income countries, the obesity rate is increasing 30% faster than in richer nations, a rate higher than the decreasing rate of underweight.[5]

Both undernutrition and overweight/obesity present serious problems for public health, especially when manifested in childhood. Undernutrition is responsible for the majority of deaths in children around the world and is also related to a series of conditions in adulthood: it increases the probability of obesity; it is related to insulin resistance and hypertension; it compromises the function of the autonomic nervous system; and it is linked to poor mental development and school achievement, as well as behavioural abnormalities.[6] Childhood obesity is a risk factor for many adverse health outcomes in adulthood, such as premature mortality, physical morbidity and the development of non-communicable diseases, including diabetes, hypertension, ischaemic heart disease and strokes.[7]

Despite high rates of overweight and obesity in the region, the implementation of strategies to prevent obesity during the first years of life has been limited.[4] Instead, resources have been directed at the implementation of interventions with the sole objective to reduce malnutrition. However, the rapid increase in obesity alongside persistent malnutrition has resulted in a double burden of disease that affects the most vulnerable and that should be attended to in an integrated manner.

Both stunting and overweight are the result of inadequate child growth during the first years of life, which is directly related to infant feeding practices and the quantity and quality of diet.[8 9] In Latin America, the quantity of food consumed by children once they are 6 months old is not generally a problem; however, the quality of diet in many areas is poor.[10] Changes in consumption patterns and lifestyles, together with an increase in income in the region, have led to an overconsumption of calories along with a limited intake of healthy foods. Many children are exposed to high-fat, high-sugar and high-carb foods that tend to be cheaper but are low in essential nutrients and fatty acids, resulting in a sharp increase in obesity while simultaneously perpetuating undernutrition.[10–12] Additionally, the prevalence of anaemia in children under 2 years old is over 40% in the poorest quintiles in Colombia, Guatemala, Mexico and Peru, a reflection of widespread micronutrient deficiencies.[13]

For these reasons, interventions to improve the quality of infant and young children's diets would reduce the presence of both these conditions, especially if they are implemented during the first 1000 days (from conception to 2 years old), a critical period of growth in which nutrition interventions have been demonstrated to have a greater impact.[14 15] Several interventions aimed at improving infant and young child feeding (IYCF) practices have been recommended at the international level. Most of these interventions are related to food fortification and supplementation, maternal education and behavioural change strategies.[9]

Behavioural change strategies that include carefully designed, evidence-based messaging and are delivered in an interactive way have shown important successes in IYCF practices in Bangladesh, Vietnam and Peru.[16–18] Additionally, home fortification with products like small-quantity lipid-based nutrient supplements (SQ-LNS) has been used successfully to improve nutritional status in Africa.[19–22] These supplements are given to children between 6 and 24 months along with their normal food to improve the quality of diet and increase their consumption of essential micronutrients and fatty acids. In its standard formulation, the micronutrients are incorporated in a paste made of vegetable fat, peanuts, powdered milk and sugar. The evidence of LNS in improving nutritional status is mixed: studies in Ghana and Malawi found that LNS increased height, reduced anaemia and improved motor development, while a study conducted in Guatemala found no detectable effects of LNS supplementation alone on linear growth in children 6–24 months old.[19–23]

This paper details the protocol for SPOON: Sustained Programme for Improving Nutrition Guatemala, an innovative strategy to prevent stunting and reduce risk for obesity in children under 24 months old in high-poverty areas in Baja Verapaz, Guatemala. Guatemala, much like the rest of Latin America, suffers from the double burden of malnutrition. One in every two children is stunted and, in some indigenous regions, the rate of malnutrition is as high as 70%. At the same time, 4.7% of children under 5 years old in Guatemala are overweight.[24] The prevalence of anaemia in children under 5 is 32.4%, and in children under 2 years the anaemia rate is even higher: 70.1% among children under 18 months and 40.1% among children between 18 and 24 months old.[24]

Programme aims and objectives

The programme has short-term objectives to improve mothers' knowledge of recommended IYCF practices and increase the percentage of mothers that follow the recommendations. In the long term, the programme aims to achieve optimal child growth by reducing the risk of stunting, overweight/obesity and anaemia among children enrolled in the programme. The programme hopes to achieve these objectives through an innovative behavioural change strategy directed at mothers and caregivers and the distribution of SQ-LNS to children 6–24 months old. The theory of change, presented in figure 1, describes the logic of how the programme intends to achieve these results.

According to evidence in the field of behavioural science, the development of messages that stimulate

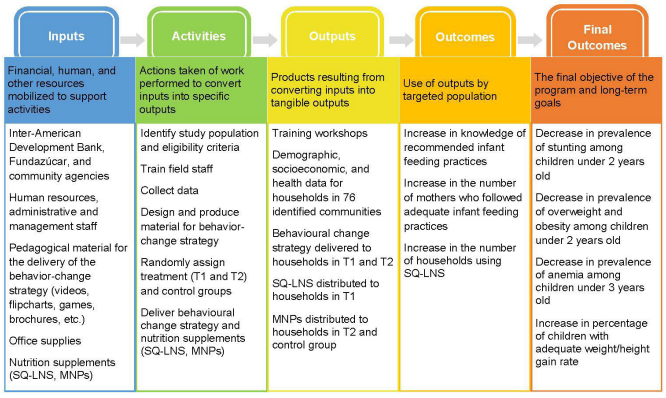

Figure 1 SPOON: Sustained Programme for Improving Nutrition Guatemala theory of change. MNPs, micronutrient powders; SQ-LNS, small-quantity lipid-based nutrient supplements.

cognitive and emotional factors have the power to influence decisions made regarding infant feeding.[25 26] Knowledge of adequate feeding practices and the application of these practices are necessary to improve child growth and development. However, meeting these recommendations presents a serious challenge, given that nutritional requirements at this age are high and gastric capacity is low. For this reason, the programme includes the distribution of SQ-LNS to provide the needed additional nutrients to improve nutritional status. By combining these two interventions, the programme looks to increase infant and young child feeding knowledge and practice among caregivers, improve the diet of children, and, consequently, achieve optimal child growth.

It is important to note that SQ-LNS is a manufactured food product that is available for a limited period of time, and therefore, is not intended for reducing long-term family food security. However, the consumption of these key nutrients during the first 1000 days of life may have long-term, intergenerational effects on health and income.[27 28]

Evaluation questions

The primary objective of the evaluation is to empirically identify the effect of the programme on intermediate outcomes related to knowledge and practice, as well as final outcomes related to the nutritional status of children. More specifically, the evaluation of the study is designed to answer the following questions:

1. What is the joint impact of SQ-LNS and the programme behavioural change strategy on mother/caregiver's IYCF knowledge and practice and on growth (height, weight, weight gain rate) and prevalence of anaemia among children enrolled in the programme?
2. What is the effect of the programme behavioural change strategy on mother/caregiver's IYCF knowledge and practice and on growth (height, weight, weight gain rate) and prevalence of anaemia among children enrolled in the programme?
3. What is the cost-effectiveness of SQ-LNS supplementation provided along with the programme behavioural change strategy compared with the implementation of the programme behavioural change strategy with standard micronutrient powders (MNPs)?

METHODS AND ANALYSIS

Study design

SPOON: Sustained Programme for Improving Nutrition Guatemala is a three-arm randomised control trial implemented in the department of Baja Verapaz, where the prevalence of stunting is 50.2% and anaemia in children under 5 is 25.5%.[23] Participants were randomly assigned at the community level to one of two groups: a control group and a treatment group. Households in the control communities will receive the standard of care provided by the Ministry of Health through their local health services. This care includes the provision of MNPs and growth monitoring. Households in the treatment communities will be randomly assigned at the household level to receive one of two different treatments. The first treatment group (T1) will receive SQ-LNS supplementation and the programme behavioural change strategy. The second treatment group (T2) will receive the programme behavioural change strategy along with MNPs. To guarantee a regular supply of supplements, SQ-LNS and MNPs will be delivered to participating households in all groups by the programme's implementing agency. All children will receive the standard healthcare protocol provided by the Ministry of Health in their communities, with the exception of MNPs in T1. Project implementation teams will work closely with local health services to guarantee that no children receive double supplementation during the length of intervention.

Interventions

The programme consists of two main interventions: SQ-LNS distribution and an innovative behavioural change strategy. These interventions are explained in detail below, along with a description of the MNP supplementation provided by the Ministry of Health as part of the standard protocol.

Small-quantity lipid-based nutrient supplement

SQ-LNS is a peanut-based ready-to-use home-fortification product to improve diet quality. It includes peanuts and other ingredients such as vegetable oils, skim milk powder and complex vitamins and minerals. The formulation of SQ-LNS specifically designed for this study, Enov'Nutributter Vitalito produced and packaged in France by Nutriset®, does not include sugar. Additionally, the formulation for the programme in Guatemala does not include vitamin A, given that sugar distributed in the country is already highly fortified. The specific nutrition formulation for Enov'Nutributter Vitalito is presented in table 1. The programme will distribute 60 sachets of SQ-LNS every 2 months. Children 6–24 months will consume 20 g daily for a total of 18 months. This

Table 1 SQ-LNS nutrition formulation for SPOON: Sustained Programme for Improving Nutrition Guatemala*

	100 g Enov'Nutributter Vitalito		20 g Enov'Nutributter Vitalito (recommended daily dose)
	Minimum	Maximum	
Energy	590 kcal	620 kcal	118 kcal
Proteins	12 g	16 g	2.6 g
Lipids	46 g	50 g	9.6 g
Calcium	1400 αmg	1600 mg	280 mg
Linoleic acid	13.5 g	14.6 g	2.81 g
α-linolenic acid	2.9 g	3 g	0.58 g
Phosphorous	950 mg	1070 mg	190 mg
Potassium	1000 mg	1190 mg	200 mg
Magnesium	200 mg	230 mg	40 mg
Zinc	40 mg	45 mg	8 mg
Copper	1.7 mg	1.8 mg	0.34 mg
Iron	45 mg	50 mg	9 mg
Iodine	450 µg	590 µg	90 µg
Selenium	100 µg	105 µg	20 µg
Manganese	6 mg	6.4 mg	1.2 µg
Vitamin A			0 mg
Vitamin B_1	1.5 mg	2 mg	0.3 mg
Vitamin B_2	2 mg	2.6 mg	0.4 mg
Niacin	20 mg	24 mg	4.0 mg
Pantothenic acid	9 mg	10.3 mg	1.8 mg
Vitamin B_6	1.5 mg	1.8 mg	0.3 mg
Folic acid	400 µg	480 µg	80 µg
Vitamin B_{12}	2.5 µg	5 µg	0.5 µg
Vitamin C	150 mg	190 mg	30 mg
Vitamin D	25 µg	45 µg	5 µg
Vitamin E	30 mg	48 mg	6.0 mg
Vitamin K	150 µg	190 µg	30 µg
Sodium	–	150 mg	20 mg

*Source: Nutriset®. Enov'Nutributter Vitalito - Nutritional specifications. SPOON: Sustained Programme for Improving Nutrition Project - Guatemala. 2019.
SQ-LNS, small-quantity lipid-based nutrient supplements.

supplementation strategy was designed to take advantage of the full window of opportunity from 6 to 24 months. The supplement is not a product currently produced or distributed in Guatemala, and therefore, it had to be especially registered for this intervention as a nutritional supplement at the Department of Food Regulation and Control.

SPOON: Sustained Programme for Improving Nutrition behavioural change strategy

Ethnographic and marketing methods were used to develop a novel, multilevel participatory behavioural change strategy that uses parallel and synergistic communication channels to promote recommended IYCF practices and the use of SQ-LNS and MNPs. Messages were designed based on formative research in Baja Verapaz and literature reviews that helped prioritise desired IYCF practices, identify common barriers and facilitators to adhering to practices, and optimise the delivery of messages. Recommended practices centre around breastfeeding, complementary feeding and the use of supplements. Table 2 presents desired practices and examples of some of the main barriers and facilitators that were identified and used to inform the behavioural change strategy.

The strategy will be delivered to mothers or caregivers through monthly individual home visits, interactive and playful group sessions led by trained staff, and community mobilisation activities using flipcharts, brochures and games. Group sessions will be held in each community and will include a minimum of 5 and a maximum of 30 participants. Additionally, the behavioural change strategy incorporates products including calendars, boxes to store supplements and videos as a communication tool to support home visits. Products are used to incentivise and support adoption of recommended practices. Communication materials are simple, attractive and use a branding design especially developed for the programme. The programme's behavioral change approach includes mothers, caretakers, families, and communities. The programme also involves community leaders and encourages the use of health services. The nutrition messages are incorporated into a 14-module strategy on a wide-range of topics including self-esteem and women's empowerment, reproductive health, household budget management, maternal and child health, community organisation and hygiene. Families establish commitments and goals related to each topic, which are then discussed during home visits. Nutrition messages are delivered according to the child's age. The multilevel participatory and market-based characteristics of the behavioural change strategy, its interactive and playful approach, the wide-range of topics known to be related to nutritional impact, community participation and the intensity of delivery (monthly home visits and 14 group sessions) differentiate the programme from other interventions conducted with LNS in Guatemala.[23]

Micronutrient powders

MNPs (15-micronutrient formulation) are currently provided by the Guatemalan Ministry of Health. Children 6 months old will receive 1 g of powdered micronutrients for 60 days every 6 months until 24 months, according to national policy. Children in T1 group receiving SQ-LNS will not receive MNPs during the duration of the intervention.

Study sample and recruitment

Rural and periurban areas (excluding the urban centres) that were accessible by the implementing agency were considered for the sample. Due to budgetary restrictions,

Table 2 Examples of desired improving infant and young child feeding (IYCF) practices, barriers, and facilitators identified and used to design the behavioural change strategy

IYCF categories	Desired practices	Main barriers*	Main facilitators*
Breastfeeding	► Exclusively breastfeed during the first 6 months of life	► Exclusive breastfeeding also includes water and teas ► Children need food before 6 months	► Breastfeeding is the best food for their babies ► Breastfeeding is free ► Breastfeeding can be done everywhere ► Breastfeeding is an accepted practice in communities ► Grandmothers support breastfeeding ► Breastmilk is better than formula ► Formula is expensive
	► Do not provide water or tea during the first 6 months of life	► Tea can prevent stomach ailments ► Water is necessary for hydration ► Grandmothers support tea provision	
	► Continue breastfeeding from 6 to 24 months	► After 1 year, breastmilk is not good for children; it can even cause diarrhoea	
Complementary feeding	► Introduce food at 6 months	► Children need food before 6 months ► Children are not ready to eat at 6 months ► Breastmilk provides everything the baby needs; there is no need for food ► It is easier to breastfeed than feed solid foods	► Mothers have time to prepare foods ► Mothers offer food several times a day
	► Ensure adequate quantity, consistency and frequency of food	► Small children should eat soft foods and purees ► Liquid foods are soft and therefore good for the children ► Caregivers don't have information about frequency	
	► Introduce a variety of foods	► There is a lack of variety in family diet ► Families lack resources to buy food ► Animal source foods are not good to eat before 1 year	
	► Motivate the child and feed them with patience and love	► Children know when to eat ► There is no need to insist on feeding when the child does not want to eat	
	► Avoid sugar-sweetened beverages and food with high sugar and fat content	► Cookies are commonly given to children under 2 years old ► Intake of traditional non-industrialised sugar sweetened beverages is common	
Use of SQ-LNS and MNPs	► Provide SQ-LNS to children 6–24 months of age every day, even if not at home ► Give the entire sachet every day ► Provide SQ-LNS alone or with a small portion of food that the child will like ► Motivate the child to eat the supplement with patience ► Do not interrupt SQ-LNS use even when the child is sick ► Provide MNPs to children 6–24 months old (60 sachets, every 6 months) ► Mix MNPs with a small portion of food and give it to the child	► Children get tired of taking supplements ► Caregivers forget to give SQ-LNS to their children ► SQ-LNS cause diarrhoea and vomit ► Children don't need to eat while sick ► It is not possible to give the supplement during harvest because mothers work outside the home	► Health personnel promote the use of supplements ► Population has previous experience using LNS and MNPs ► Mothers value supplements ► Supplements are practical ► Supplements benefit children ► Mothers are willing to use SQ-LNS ► MNPs protect against disease ► Supplements have vitamins that are good ► Giving MNPs is easy

*Based on the perceptions, values and beliefs of mothers and grandmothers.
MNPs, micronutrient powders; SQ-LNS, small-quantity lipid-based nutrient supplements.

a maximum of 40 communities was able to receive the intervention. With the objective of maximising the number of households in the sample and balancing the number of communities assigned to the treatment and control groups (40 each), the 80 communities with the largest population and that met access criteria were recruited. Based on the available census and health centre information, the expectation was to find approximately 2000 eligible households in the 80 communities.

Eligibility criteria

Households were eligible if:

- They had a pregnant woman in the third trimester or a child under 4.5 months old at the time of the household listing exercise.
- They were a resident of one of the study sample communities.
- The child had no chronic diseases or congenital malformations.
- They were not planning on moving far from the intervention area in the next 24 months.

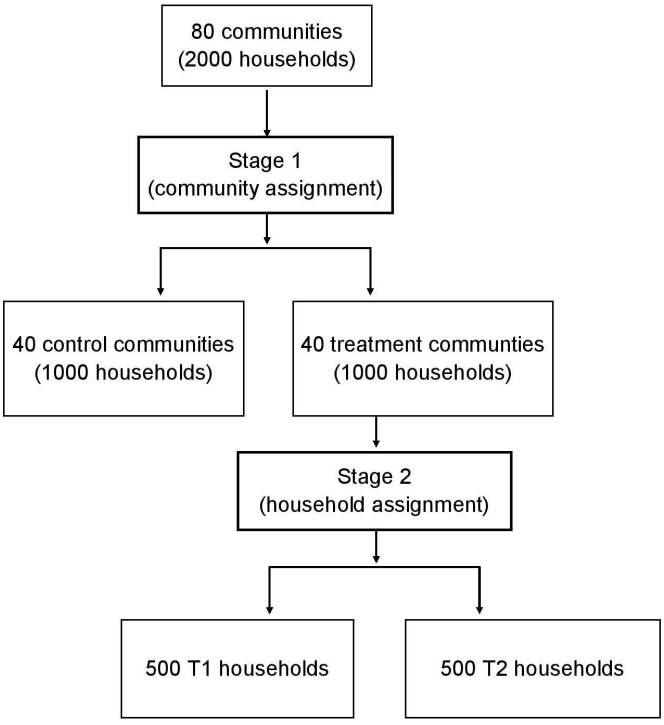

Figure 2 Original random assignment protocol.

Patient and public involvement

A sample of households from the research area was consulted during the development of the behavioural change strategy. Prior to the start of the intervention, a census of each community was conducted to identify potential participants, and potential participants were invited to community assemblies where eligible mothers could voluntarily enrol in the study. Risks and benefits of study participation, as well as the randomised nature of the study was presented during the community assemblies, and all participants provided informed consent. During the trial period, the implementing agency provides the community with monitoring results on an ongoing basis. At conclusion, the study results will be disseminated in intervention communities. The authors acknowledge support from local authorities and community leaders, as well as local and national health services during the development of the behavioural change strategy and recruitment of participants.

Randomisation

The original design for the random assignment of the programme proposed two stages (figure 2). In the first stage, half of the communities (40) were randomly assigned to the treatment group to receive the intervention and the 40 remaining communities form the control group. In the second stage, half of the households within the treatment group were randomly assigned to treatment 1 (T1) and the remaining households in the treatment group were assigned to treatment 2 (T2).

Due to operational limitations in the implementation of the behavioural change strategy, the programme determined that each community needed to have at least 5 eligible households to be included in the sample. This constraint required a slight alteration of the original evaluation design. Four of the 80 communities identified at baseline did not have the required 5 households, resulting in 76 eligible communities in total for randomisation. In these 76 communities, there were 1628 total households, below the goal of 2000. Due to an operational requirement to provide at least 500 households with SQ-LNS, and in the interest of maximising the statistical power of the study, the number of communities and households initially considered for treatment 1 was adjusted.

The actual random assignment protocol was implemented as follows:

Stage 1: Random assignment of communities was decided by generating a random number between 0 and 1 with a uniform distribution for every community in the sample. The 40 communities with the highest random numbers were assigned to the treatment group and the remaining 36 were assigned to the control group.

Stage 2: Random assignment of households to T1 and T2 was decided by generating a random number between 0 and 1 with a uniform distribution for every household in the treatment communities, using the random number generator on the website 'www.random.org'. Sixty per cent of households with the highest random numbers were assigned to T1 (to reach the 500-household requirement) and the rest were assigned to T2.

The random assignment, as actually implemented, is presented in figure 3.

Sample size and power

The original power calculations were estimated using height-for-age z-scores for children under 2 years old. The programme set a minimum detectable effect of 0.2 SD as the goal. The prevalence and intracluster correlation (ICC) for this indicator in Guatemala were estimated using the 2009 National Maternal-Child Health Survey (ENSMI, for its abbreviation in Spanish). The power analyses were performed under standard thresholds (80% statistical power at the 5% significance level). As presented in table 3, the minimum detectable effect for estimating the impact of the SQ-LNS intervention with 30 households per community on average, randomly assigned to T1 or T2 with a probability of 0.5, is 0.19 SD, taking into account a minimum participation of 70% of households in the community (minimum of 420 households per group). For the impact on the behavioural change strategy, assuming 40 communities per treatment and control group, the minimum detectable effect originally projected was 0.31 SD.

After updating power calculations based on the baseline sample, the minimum detectable effect at the household level for the detection of the impact of SQ-LNS remains at 0.19 SD with no sample attrition. However, under a scenario of 20% attrition, the minimum detectable effect is 0.21 SD. At the community level, assuming 10 households per community and based on the actual samples of 40 treatment and 36 control communities,

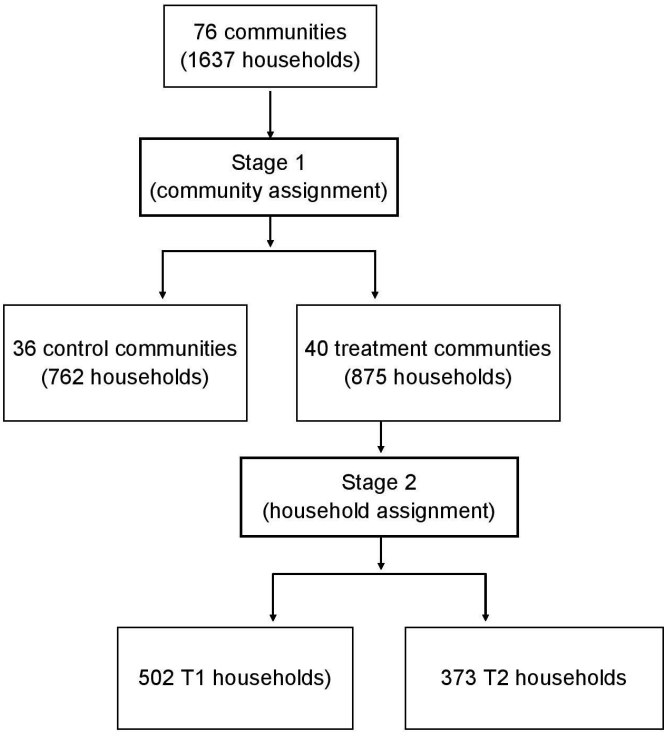

Figure 3 Actual random assignment.

Table 3 Sample size and power

	SQ-LNS	Programme's behavioural change strategy
Panel A. Power calculations in design phase		
	Household randomisation (T1 and T2) n=420 households per group Participation rate: 70%	Community randomisation (T and C) n=40 communities, 600 households per group (assume 15 households per community) Intercluster correlation=0.19 Participation rate: 50%
Minimum Detectable Effect (SE)	0.19	0.31
Panel B. Power calculations post-baseline		
	Household randomisation (T1 and T2) T1=500 households T2=370 households	Community randomisation (T and C) T=40 communities C=36 communities (assume 10 households per community) Intercluster correlation=0.19
Minimum Detectable Effect with no attrition (SE)	0.19	0.34
Minimum Detectable Effect with 20% attrition (SE)	0.21	0.35

SQ-LNS, small-quantity lipid-based nutrient supplements.

the minimum detectable effect rises to between 0.34 and 0.35 SD. Subsequent to the original power calculations, the ICC for height-for-age z-score was computed for the study sample using routine monitoring data collected by the project in February 2020. The empirical ICC was calculated as 0.076, below the value of 0.19 calculated for rural areas with ENSMI. Thus, community level minimum detectable effect sizes are expected to be smaller than the original estimates.

Additionally, the measurement of effects on final outcomes such as height for age of children will be carried out using regression analysis on a longitudinal panel of mothers and children surveyed at baseline, allowing the inclusion of baseline controls that may reduce the residual variance of the impact estimates. The availability of a baseline survey and longitudinal measurements of outcome indicators will increase the final statistical power of the study, so the projections in table 3 should be considered upper bounds (assuming that the dropout rate in the sample does not exceed the projection of 20%).

Data collection

Baseline data were collected between September and November 2018, prior to the implementation of the programme. Follow-up data will be collected in the first half of 2021, 2 years after the start of the interventions (March 2019). In addition, routine anthropometric measurements will be collected throughout the duration of the programme, approximately every 2 months. The programme will also monitor and record data on treatment compliance.

The household surveys include a rich set of demographic, socioeconomic and nutrition variables. Given a large portion of the baseline sample includes pregnant women, child anthropometric measures were not measured at baseline. A self-reported measure of the amount of SQ-LNS consumed by the child will be added to the final survey as an additional measure of compliance.

Outcomes (to be analysed at endline)

Primary outcome measures:

- Infant and young child feeding knowledge (self-reported).
- Infant and young child feeding practices (self-reported).
- Height-for-age z score (calculated using height measurements).
- Weight-for-age z score (calculated using weight measurements).
- Height gain rate (calculated using repeated height measurements).
- Weight gain rate (calculated using repeated weight measurements).
- Haemoglobin (measured using a portable photometer).
- Prevalence of obesity (calculated using body mass index measurements).

- Prevalence of stunting (calculated using height-for age z-scores).
- Prevalence of anaemia (calculated using haemoglobin concentration in capillary blood).

Secondary outcome measures:.

- Adherence to nutritional supplement regimen (measured as the number of packets consumed in 1 month).
- Exclusive breastfeeding (self-reported).

Analysis plan

Baseline balance

To ensure treatment and control groups are balanced across individual and household characteristics, as would be expected in a randomised experiment, simple differences in means are calculated for a variety of indicators. The results of these balance tests are presented in the online supplementary appendix in table A1.

Panel A includes maternal characteristics, such as age, education, indigenous status and marital status. In addition to these demographic characteristics, the baseline survey has detailed measurements on 'soft traits' that could influence a mother's ability or capacity to apply recommended nutrition practices. These include quantitative measures for empowerment, grit and self-esteem. Empowerment is measured with an index that represents the percentage of decisions a mother makes surrounding different family and household matters, including clothing, expenses, food, children's education, contraception, work and health-related decisions.[29–31] Grit is measured using the Grit test, which is scored on a scale between 1 and 5, where 5 indicates a high level of grit.[32] Finally, self-esteem is measured using the Rosenberg test, which uses a scale between 0 and 30, where a score below 15 indicates low self-esteem.[33 34] Mothers' knowledge and practice of infant and young child feeding practices are a primary outcome of interest. To determine whether any differences in baseline knowledge exist between groups, a knowledge index between 0 and 1 was constructed that measures the percentage of correct answers in the knowledge survey out of the total. The index includes 33 questions that focus on breastfeeding and complementary feeding. The components of the knowledge index and the correct answers are detailed in online supplementary appendix table A2. A similar practice index could not be calculated since 36% of children were not yet born and, of those born, most were not old enough to measure the mother's adherence to recommended practices (exclusive breastfeeding up to 6 months, the introduction of solid and semisolid foods, continued breastfeeding at 1 year and 2 years of life, minimum dietary diversity, consumption of iron-rich foods, duration of breastfeeding, among other indicators of infant feeding practices recommended by WHO).[35]

Panels B through D include demographic information for fathers and children, such as age, education and sex, as well as indicators related to household size and composition. Socioeconomic characteristics, including income, wealth, asset ownership, home tenancy and materials, energy and electricity and water and sanitation are included in panels E through I.

In general, baseline characteristics are well balanced. There are significant differences in 19 of 97 total variables and 291 tests, a ratio of 6.5% statistically significant differences at baseline, as expected by chance. Nine per cent of the 97 variables were significant at the 10% level, 8% at the 5% level and 2% at the 1% level. Additionally, the magnitude of these differences is relatively small and there is no systematic pattern in the direction of the differences. Overall, the tests support the random assignment assumption of balance on observed and unobserved covariates.

Primary analysis

After follow-up data have been collected, impact estimation will be done comparing the average results and the distribution of indicators between the treatment and control groups. Differences of simple means and regression models including covariates of the child's age and sex, and characteristics of the primary caregiver and household will be estimated. In addition to potential changes in indicator averages, changes in the distribution of variables will be explored under the hypothesis that the intervention might not only improve average value for a given indicator but compress the distribution over a range of values closer to an optimal range. Changes to distributions will be checked by applying the Kolmogorov-Smirnov test.

Secondary analysis

As a secondary analysis, heterogeneous treatment effects will be analysed by time of exposure to treatment, child sex, maternal baseline characteristics (age, education, empowerment, grit, self-esteem and baseline knowledge) and household socioeconomic status at baseline. Furthermore, the cost-effectiveness of T1 and T2 will be compared.

ETHICS AND DISSEMINATION

Ethical approval and consent

The study was approved by the National Health Ethics Committee of the Ministry of Health of Guatemala (resolution 10–2018). Informed consent was obtained from all mothers and caregivers prior to baseline data collection and participation in the study.

Dissemination plan

Results will be submitted to a peer-reviewed medical or public health journal. We will also disseminate results internally at the Inter-American Development Bank, with the Government and Stakeholders in Guatemala and through international conferences and seminars. Deidentified data will be shared among participating research institutions and made available to the public on the Inter-American Development Bank's publication website 2 years after finalising the study.

Author affiliations
[1]Social Protection and Health Division, Inter- American Development Bank, Washington, District of Columbia, USA
[2]Office of Strategic Planning and Development Effectiveness, Inter- American Development Bank, Washington, District of Columbia, USA

Acknowledgements We thank the Ministry of Health of Guatemala and Fundazucar (implementation agency) for their support with the implementation of this study. We also thank Nutriset® for its technical assistance and SQ-LNS production.

Contributors CGA, SM, AP-E and SW. Conceived and designed the study: CGA, SM and AP-E. Wrote the paper: CGA, SM, AP-E and SW. Discussed, critically revised and approved the study protocol: CGA, SM and AP-E. Responsible for the organisation and conduct of the study: SM. Supervised the study: SM. Responsible for the statistical analysis: SW and SM. Contributed to data analysis: SW. Drafted the first version of the report: SW. Elaborated, discussed and approved the final version of the paper for publication: CGA, SM, AP-E and SW.

Funding This study was financed by the Inter-American Development Bank (IDB) through the grants RG-X1200 (ATN/CF-14540-RG) and RG-X1192 (GRT/CF-14713-RG), 'SPOON: Sustained Programme for Improving Nutrition' supported by PepsiCo Foundation; and GU-T1242 (ATN/JO-15413-GU)'Facing the Challenge of Undernutrition and Obesity in Guatemala' supported by the Japanese Special Fund Poverty Reduction Programme Found (JPO). The IDB team worked with technical assistance partners and partners in the field to design this intervention.

Competing interests The Inter- American Development Bank uses the term SPOON solely to identify the title of the project "SPOON: Sustained Program for Improving Nutrition" without any association to existing registered trademark(s) or their holders, and without any endorsement from such trademark holders. All authors were employed by the Inter-American Development Bank at the time of the study's conception and implementation. AP-E reports grants from PepsiCo Foundation, grants from The Government of Japan, provided to the Inter-American Development Bank to implement and evaluate the Programme. AP-E was a staff and subsequently a paid consultant for the programme at the Inter-American Development Bank. All opinions in this paper are those of the authors and do not necessarily represent the views of the Government of Guatemala or the Inter-American Development Bank, its Executive Directors or the governments they represent.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

ORCID iD
Sebastian Martinez http://orcid.org/0000-0002-7651-6674

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Correction: *Effect of an innovative behavioural change strategy and small-quantity lipid-based nutrient supplements on stunting and obesity in children in Baja Verapaz, Guatemala: protocol for a randomised control trial*

González Acero C, Martinez S, Pérez-Expósito A, *et al*. Effect of an innovative behavioural change strategy and small-quantity lipid-based nutrient supplements on stunting and obesity in children in Baja Verapaz, Guatemala: protocol for a randomised control trial. *BMJ Open* 2020;10:e035528. doi: 10.1136/bmjopen-2019-035528

This article was previously published with errors.
References to the acronym SPOON have been adjusted throughout the article.
SPOON disclaimer added in the Competing interests section.

BMJ Open 2022;**12**:e035528corr1. doi:10.1136/bmjopen-2019-035528corr1