

STUDY PROTOCOL:

Participatory intervention to improve the nutrition and physical activity of school children in Acatlan de Juarez, Jalisco

Summary

Introduction

This is a community project carried out in partnership between the Technologic Institute of Higher education in the West (ITESO, in Spanish: Instituto Tecnológico de Estudios Superiores de Occidente), the Tonalá University Center of the University of Guadalajara (CUTonala, in Spanish: Centro Universitario de Tonalá de la Universidad de Guadalajara) and the University center of health science from Guadalajara University (CUCS, in Spanish: Centro Universitario de Ciencias de la Salud de la Universidad de Guadalajara) with consultancy of the National Institute of public health (INSP, in Spanish: Instituto Nacional de Salud Pública), financed by the company Tresmontes Lucchetti and endorsed by the Jalisco Association of Nutritionists, A.C. (AJANUT, in Spanish: Asociación Jalisciense de Nutriólogos). The present Project complies with the “National Strategy for the Prevention and control of Overweight, obesity and diabetes” (In Spanish: “Estrategia Nacional para la Prevención y el control del Sobrepeso, la Obesidad y la Diabetes”) signed by the Federal Government executive. It also follows the accords that establishes the general guidelines for sale and distribution of processed and cooked food and beverage in Schools from the National Education System, suggested by the national ministries of health and public education. The references mentioned before have the objective of protecting and improve health in Mexican kids.

General Objective

Assess the functionality and effect of a participatory intervention to improve nutrition and physical activity within the school environment in kids between 6 and 10 years old from public elementary schools in Acatlan de Juarez, Jalisco, Mexico.

Proposed Methods

The project is a community trial with a three-year duration that includes an intervention group and a control group of 3 different schools each. Acatlan de Juarez has a total of 11 elementary schools.

The strategies will be implemented in collaboration with local authorities from Acatlan de Juarez, school campus authorities, personnel from ITESO, CUTonala, CUCS, and AJANUT. Key actors will be included in all study stages from both school and community settings, with the goal to adapt the strategies to be social and culturally acceptable and promote community ownership of the project. There will be an initial study of the project's viability and the actual conditions of food intake and physical activity in schools, including a community perception. The research team will design the contents and materials for the intervention, considering the intakes of opinion and suggestions of the community and the initial study results. The schools from the control group will be selected from the municipality of Villa Corona, Jalisco, which is similar to the Acatlan de Juarez municipality.

The strategies proposed for intervention from the research team, that will be consensed with the community, goes as follow:

- Vigilance in the compliance with the regulation of food sales on the school ground in accordance with official guidelines.
- Sensibilization of children, parents, teachers (especially the ones in charge of Physical Education), and food supply staff (in the school food store) to improve acceptance and compromise to food sales regulation.
- Training on hygiene and nutritious food preparations for personnel in charge of the school's food store.
- Promotion of consumption of simple water and healthy food.
- Rescue and promotion of consumption of local foods
- Refurbishment of infrastructure for the consumption of simple water for free and healthy foods, as well as the realization of physical activities.
- Event organization and support on group coordination that promotes physical activity at the community level.
- Optimization of Physical Education Classes at school.
- Implementation of health promotion and care actions in the school context.
- Skill development in school community for health care and the generation of healthy school environments.

- Creation and/or strengthening of health and nutritional committees in school, with principals, teachers, and parents' participation to generate primary and permanent conditions that favor healthy contexts.

A member of the research team will be in charge of implementing and monitoring each of the schools' strategies from the intervention community during the study.

Monitoring and evaluation of the impact of the intervention will be assessed through a community trial. There will be three schools as a study group and three as a control. There will be three different periods of measurements:

- a baseline measurement in the 2015-2016 school year
- an intermediate measurement in the 2016-2017 school year
- a final measurement in the 2017-2018 school year

The measurement periods will have an estimated duration of two months each.

During the measurement periods, the body composition of children from 1st to 4th grade will be obtained, and they will be followed up during the next two years; the dynamics of water and food consumption, physical activity, functional physical capacities, as well as availability and accessibility of food in school will be identified. In addition, a sub-sample of study subjects will provide questionnaires on food consumption frequency, additional anthropometric measures, and blood samples to determine blood glucose and lipid levels.

To obtain a bigger approach with the population, instruments of qualitative nature will be implemented prior to the intervention, such as focus groups and in-depth interviews, that will identify barriers and possible solutions to improve food habits and encourage the physical activity of the population. During the periods of intermediate and final measurements, there will be similar qualitative strategies applied to procure successes and find possible improvement points of the intervention.

During the implementation of the strategies, there will be a thorough monitoring of the locations that will allow identifying the critical changes that can affect eating and physical activity habits in any of the two groups (intervention and control)

Introduction

For 20 years, in Mexico, a growing problem of overweight and obesity has been observed in all life stages, including children. Jalisco is one of the states with the highest prevalence of overweight/obesity in the school population, surpassing the national average (Instituto Nacional de Salud Pública, 2013). Excess body weight (from body fat) is a risk factor for many chronic diseases; it is also associated with emotional, psychological, economic, and social problems, both for the individual, their families, and the community. The sooner in life this condition of excessive weight occurs, the greater the risk of developing concomitant diseases and the difficulty in reversing these conditions (Reilly & Kelly, 2011).

The most successful interventions in modifying behaviors and environments that promote the development of childhood overweight are those that have within their strategies the empowerment of the actors involved, from the planning of the intervention, monitoring, and follow-up once the research team is withdrawing from the scenario (Hawkes et al., 2015; Hung et al., 2015; Vasques et al., 2014). Also, they seek to modify factors related to individual food consumption and the availability of food and beverages, policies, knowledge, beliefs, and others (Roberto et al., 2015; Swinburn et al., 2015).

A conceptual framework has recently been proposed to study overweight/obesity development and strategy planning, which has three levels of influence on which various risk factors are grouped (Figure 1). The following describes each of the levels; this study will base its strategies on these:

The **basic causes** are the most “distant” to the individual; that is, they have more relation with the epidemiological and nutritional transition than the individual's decisions. Within this group of causes, we find industrialization, urbanization, globalization, technological changes for food production and processing, as well as modifications in transportation, media, work, and recreational activities. In addition, here are the regulations surrounding the food and physical activity issued by the state.

The **underlying causes** refer to the environment's characteristics closest to the subject; these are determined by the basic causes. The availability and accessibility to food and beverage with high amounts of energy intake and low micronutrients are the causes within this group that have the most significant relationship with the development of overweight and obesity. Another causal factor within this group is the change in eating patterns, where

local dietary habits have been modified to adopt new ones. This has its origin in lifestyle modifications since there is a diminution in the time dedicated to the selection, preparation, and consumption of food. Therefore, it relates to the preferences of acquiring processed and energy-dense food, which results more convenient, and has advertising and marketing with a bigger social penetration.

At last, the **Immediate causes** are directly related to the subjects' behavior and are primarily influenced by the underlying causes and, consequently, are also influenced by the basic causes. This group of causes, specifically for the development of obesity, results in a positive balance of energy, which means higher consumption of energy in comparison to the energy utilized by the body, which leads to energy storage, mainly as body fat. The two factors responsible for energy balance are diet and physical activity. The higher the intake of high energy food/beverage and less time spent on physical activity, the imbalance energy will be more pronounced, and the fat tissue gain will be more significant. On the other hand, the genetic and epigenetic factors can contribute to make the energy balance of each individual more complicated (or simple) to maintain.

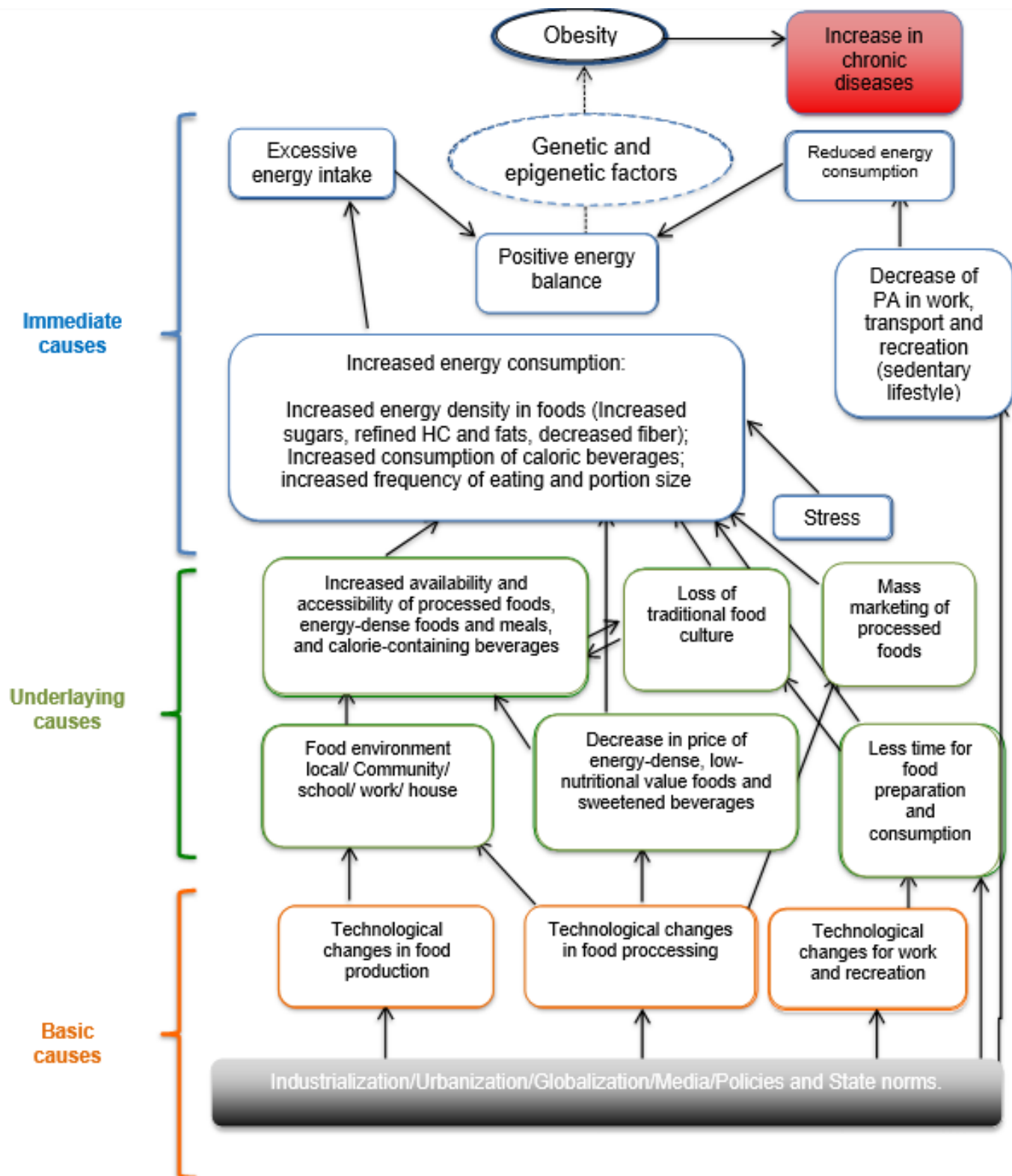


Figure 1 Conceptual framework of obesity causes

In Mexico, efforts have been made to fight the increasing prevalence of overweight/obesity and its consequences on the population through regulations (sale, formulation of products, taxes, advertising) and public awareness (media campaigns) (Roberto et al., 2015). Currently, the documents containing guidelines to fight and prevent overweight/obesity are the "National Strategy for the Prevention and control Overweight, Obesity and Diabetes" (In Spanish: "Estrategia Nacional para la Prevención y el control del Sobrepeso, la Obesidad y la Diabetes") (Gobierno de la República de México, 2013a) and the "National Plan of development 2013-2018" (in Spanish: "Plan Nacional de Desarrollo 2013 – 2018") (Gobierno de la República de México, 2013b). In the school environment, specifically, guidelines were developed for the sale of food inside the schools of the National Education System (Secretaría de Educación Pública de México & Secretaria de Salud de México, 2014). The present study proposes to evaluate the functionality and effect of a participatory intervention to improve nutrition and physical activity within the school environment for children 6-10 years of age from public elementary schools. The current project aims to apply the general guidelines for sale and distribution of prepared and processed foods and beverages in schools from the national education system, including the promotion of physical activity in school hours and the implementation of an educational component, among other actions at the community level, planed in conjunction with key actors, in Acatlan de Juarez, Jalisco, Mexico. Acatlan de Juarez has eleven elementary schools (including public, private, rural, and urban).

Background

Obesity is a public health problem in Mexico. Results of representative surveys at a national level in 1999, 2006, and 2012 show high increases in the prevalence of overweight and obesity in children, teenagers, and adults (Gutiérrez et al., 2012). The prevalence of overweight and the combined obesity rate is 34.3% among school children (ages 5-11) nationally. In the State of Jalisco, this number has increased and raises to 39.6% (in 2006 it was 37.4% in boys and 34.9% in girls) (Instituto Nacional de Salud Pública, 2013).

Weight gain from the early stages of life is detrimental to individuals' physical and psychological health. Developing obesity in childhood significantly increases the risk of remaining overweight in adulthood, the risk of presenting chronic diseases, fewer job

opportunities, self-esteem conflicts, lower overall quality of life, and higher cost for both the individual and the health care system (Lobstein et al., 2015; Paulis, Silva, Koes, & van Middelkoop, 2014).

Over the last decade, there has been increased public and private interest in preventing childhood overweight and obesity. Interventions based on individual behavior change have been implemented, such as increased physical activity and dietary changes and environmental issues that promote healthier lifestyles. Similarly, a significant number of studies have been developed to identify risk factors for obesity. In Mexico, there have been efforts to improve the health of the population, including the children (Roberto et al., 2015). In September of 2013, the federal government and the health ministry issued the National Strategy for the Prevention and Control of Overweight, Obesity, and Diabetes, a document that establishes action plans to fight these diseases from different approaches. The objectives of the strategies are:

- Promote the consolidation of a culture that facilitates the **adoption of lifestyles** that maintain people's health.
- **To detect** timely and massively the universe of overweight, obesity, and diabetes cases to guarantee its proper **control and management**.
- Generate a platform that allows for trained human resources and inputs sufficient to **make adequate access to health services**.
- **Increase** the number of patients in **metabolic control** with type 2 diabetes.

In addition, within the strategy, there are established axes to achieve the objectives mention above, one of which is the Health Promotion. This axis, in turn, includes four groups of specific actions for its application.

1. Promotion of **correct nutrition** on an individual and collective level (family, school, place of work, and community)
2. Promotion of **physical activity** on an individual and collective level (family, school, place of work, and community)
3. **Educational communication**
4. Generate **social participation** processes with emphasis on community participation

On the other hand, in May 2014, was published in the Official Federal Diary the “Agreements to establish the general guidelines for the sale and distribution of food and beverage made and processed in schools of the national education system” (Secretaría de Educación Pública de México & Secretaría de Salud México, 2014) for all schools, public and private, in which prepared and processed foods and beverages are sold and distributed (Appendix 1). The main objective of the accord is to promote the health of students in terms of nutritional content and hygienic conditions of food and drinks. It is important to mention that the guidelines should be implemented from the second semester of 2014.

The interventions within the school settings that are most successful against overweight and obesity in children are the ones that take into account both individual and environmental issues, without neglecting the politicians and procure the involvement of the school community (Lobelo et al., 2013). It has been observed that interventions that only include one component from the listed above have less impact and probability of success than the programs with an effort to cover the majority of causes (immediate, subjacent, and basics) (Aguilar Cordero et al., 2014; Anuradha et al., 2015; Rocha-Silva, Martiñ -Matillas, Carbonell-Baeza, Aparicio, & DelgadoFernandez, 2014; Williams et al., 2013).

To achieve a decrease in overweight and obesity within Mexican childhood, and its wide range of consequences, it is required to design and implement interventions that take into account a variety of factors involved in its development. The current project proposes following the actions signaled by the National Strategy for the Prevention and Control of Overweight, Obesity, and Diabetes, which include diet-related strategies (also based on the guidelines for the food sale and beverages), promotion and increase of physical activity, scholarly communication and community involvement in decision making.

General objective

Assess the effect and functionality of a participatory intervention to improve nutrition and physical activity within the school environment in children from six to ten-year-old's from public elementary schools in Acatlan de Juarez, Jalisco, Mexico

Specific objectives

1. Determine the viability, restrictions, and possible solutions from locals to improve nutrition and physical activity on school-aged children

2. Implement and monitor strategies for the promotion of adequate diet and physical activity of children between six and ten years old at the community and school level
3. Evaluate the effect of the strategies implemented to promote an adequate diet and physical activity for children between six and ten.

Proposed methods

The project will have a total duration of 3 years (figure 2). The outcome variables will be the change in consumption and availability of food and drinks, time spent on physical activity within school settings, knowledge, and attitudes regarding the consumption of healthy food, water, and realization of physical activity, as well as the empowerment of community actors involved about their health. On the other hand, it is expected to find serum lipids and glucose modifications in the prevalence of children's overweight and obesity and physical abilities (endurance, strength, and speed). Finally, it is intended that the present project establishes a background of the need to maintain a permanent health promoter in all schools of primary education.

The strategies will be carried out on a community and school level. The proposed actions will be developed at three local elementary public schools during the morning shift; meanwhile, the other three, belonging to the municipality of Villa Corona, Jalisco, will only be evaluated (control group). Table 1 presents the general characteristics of the intervention and control schools.

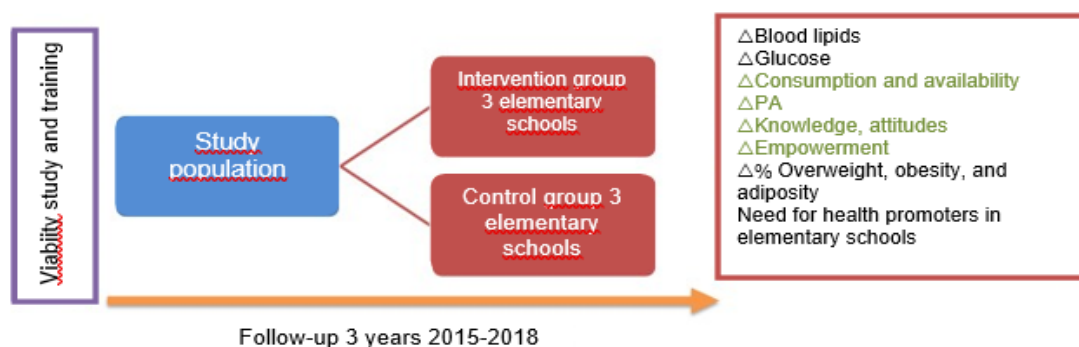


Figure 2 Study design in Acatlan de Juarez, Jalisco

Table 1. General characteristics of elementary schools in the intervention and control group

School	Municipality	Type	schedule	students	teachers	groups
David G. Berlanga	Acatlan	Intervention	8:00 to 12:30	571	19	18
Cauhtémoc	Acatlan	Intervention	8:00 to 12:30	238	9	9
Justo Sierra	Acatlan	Intervention	8:00 to 12:30	353	12	12
Benito Juarez	Villa Corona	Control	8:00 to 12:30	380	12	12
Roberto Quiroz Guerra	Villa Corona	Control	8:00 to 12:30	277	9	9
Manuel López Cotilla	Villa Corona	Control	8:00 to 12:30	251	9	9

The study will have three moments of evaluation: baseline, intermediate, and final, and an initial evaluation of viability and formative research (Figure 3). In the measurement periods, simple instruments will be used in the school setting to obtain information on the dynamics of water and food consumption within the school ground, the dynamics, and infrastructure for realizing physical activity, quality of physical education classes, and the availability of food in schools. In each measurement period, anthropometric measurements will also be taken on all children from 1st to 4th year of elementary (six to ten years of age). Qualitative methodologies will be applied to obtain information on the community's satisfaction level and the benefits and restrictions observed to that point. In addition, at the request of the municipal president of Acatlan de Juarez, a diagnosis of the nutritional status of children in the eight elementary schools that will not have intervention through the measurement of height and weight.

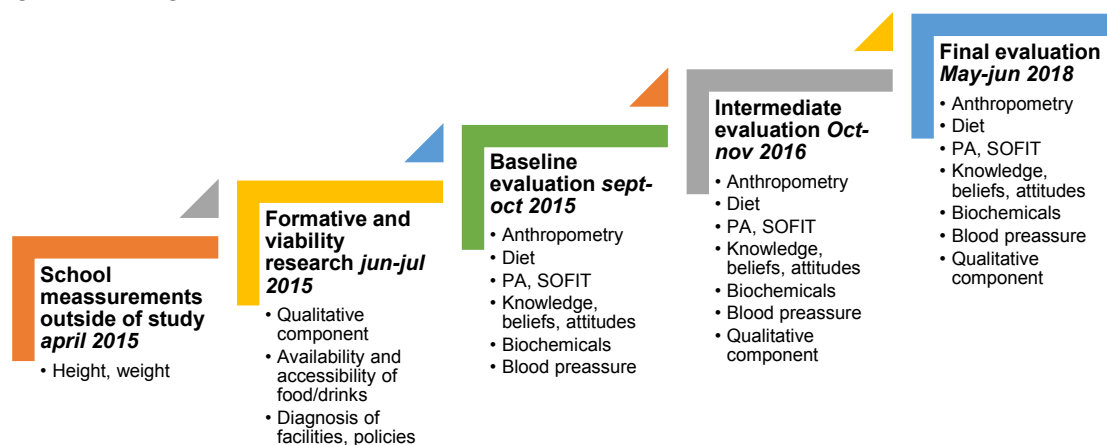


Figure 3 Measurement moments during the project

PA: physical activity, endurance, strength and speed evaluation
SOFIT: System for Observing Fitness Instruction Time

Table 2 Description of GENERAL evaluation instruments

Instrument	Description	Information to obtain	To whom it is addressed	Place of application	Application period
Focus groups	Group technique with the support of audio and video recorders for its registration and transcription.	Opinions, prejudices and beliefs. Restrictions and possible solutions to improve their eating habits and encourage physical activity. Improvement points during the implementation of the project. Impact perception of the intervention	Sample of children selected by convenience and separated by age. Sample of key actors selected by convenience (Parents, teachers, principals, health authorities)	Intervention and control schools	Viability study (prior to baseline measurements) Intermediate evaluation period Final evaluation period For convenience until information saturation is reached.
In-depth interviews	Individual interviews	Opinions, prejudices and beliefs. Restrictions and possible solutions to improve their eating habits and encourage physical activity in the population. Improvement points during the implementation of the project. Impact perception of the intervention	Sample of key actors selected by convenience (Parents, teachers, principals, health authorities)	Place selected for convenience of the interviewee	Viability study (prior to baseline measurements) Intermediate evaluation period Final evaluation period For convenience until information saturation is reached.
Inventory of food and drinks	Format of availability of water	Availability of pure free water in school grounds	-	Intervention and control schools	Baseline, intermediate and final measurements. Evaluations will be performed twice in not consecutive days in each measurement period
Inventory of food and drinks	Registration form of available food. Support material: Food scale	Availability of food and beverages in schools; quantities, ingredients or brand, portion size and prices.	All food stores in schools	Intervention and control schools	Baseline, intermediate and final measurements. Evaluations will be performed twice in not consecutive days in each measurement period

Instrument	Description	Information to obtain	To whom it is addressed	Place of application	Application period
Observation of the food sales at entering and exiting the school ground	Direct observation registration form.	Availability of food and beverages outside the schools, as well as the most demanded foods.	-	Surroundings of the intervention and control schools	Baseline, intermediate and final measurements.
Observation of food consumption within the school	Survey of food consumption in classrooms	Classroom food consumption and teachers' attitudes towards it	Teachers	Classrooms (all groups from 1 st to 4 th)	Baseline, intermediate and final measurements.
	Observation during recess	Activities generally performed by most children during recess	Information regarding schedules, duration and implementation of phased recess	Intervention and control schools	Baseline, intermediate and final measurements.
SOFIT	Registration forms recording children's and teacher's activities during physical education classes	Quality of the physical education class and teacher's behavior.	Follow-up groups of the study schools	Intervention and control schools	Baseline, intermediate and final measurements.
Anthropometry	OMS and ISAK methodology with plicometers, metallic anthropometric tapes, electronic scales and portable stadiometers.	Weight, size, folds (tricipital, abdominal and calf) and perimeters (neck, relaxed arm, flexed arm, waist, calf)	Follow-up groups of the study schools	Intervention and control schools	Baseline, intermediate and final measurements.

Table 2 describes the assessment instruments to be used per measurement period, the information to be obtained with each one of them, the target population of each one, and the periods of application.

For the project's logistic and financial considerations, a random sub-sample of children will have additional measurements taken to complement the information (Table 3). The additional measurements include:

- Household socio-economic characteristics questionnaire.
- Questionnaires (semi-quantitative) of the child's food consumption frequency, applied to his mother.
- Questionnaire and observation of the consumption of school lunch/refreshments applied to the child in school.
- Breakfast questionnaire and observation of school breakfast consumption (if the school counts with the service).
- Blood pressure
- A blood sample to determine glucose and lipid levels
- Evaluation of physical endurance capacities with the application of Eurofit Battery and the realization of endurance and speed¹ tests.
- Twenty-two detailed anthropometric measurements according to ISAK methodology, to obtain body composition.

Prior to applying the test, the informed consent of the children's parents will be requested.

Table 3 Measurements to be applied in the sub-sample

Instrument	Description	Information to obtain	To whom it is addressed	Place of application	Application period
Household questionnaire	Validated questionnaire of family and housing characteristics	Household and child identification data. Socioeconomic information of the family	Mother or person in charge of the care of selected children	Home	Baseline, intermediate and final measurements
Food consumption frequency questionnaire	Semi-quantitative questionnaire of the consumption of one week	Characterization of the usual diet of the child	Mother or person in charge of the care of selected children	Home	Baseline, intermediate and final measurements

¹ By performing the 6-minute walking test and the maximum speed test.

Instrument	Description	Information to obtain	To whom it is addressed	Place of application	Application period
Breakfast questionnaire	Semi-quantitative record of the consumption of one mealtime	Accurate information on the breakfast consumed by the child at home or at school on the day of the interview.	Children from the sub-sample	Intervention and control schools	Baseline, intermediate and final measurements
School lunch questionnaire	Semi-quantitative record of habitual consumption at lunch break	Food consumption preferences and average spending on food during lunch break	Children from the sub-sample	Intervention and control schools	Baseline, intermediate and final measurements
Observation of school breakfast and lunch	Direct observation of the food consumed	Semi-quantitative registration. Precise observation of the food consumption of the selected children in the school cafeteria	Children from the sub-sample	Schoolyard of Intervention and control schools	Baseline, intermediate and final measurements
Blood pressure	Automatic baumanometers	Recordings of systolic and diastolic blood pressure	Children from the sub-sample	Intervention and control schools	Baseline, intermediate and final measurements
Blood sample	Technical description in appendixes	Blood glucose and lipid levels	Children from the sub-sample	Intervention and control schools	Baseline, intermediate and final measurements
Physical evaluation	6-minute pediatric walking test	Tolerance level to exercise and subjective feeling of fatigue	Children from the sub-sample	Intervention and control schools	Baseline, intermediate and final measurements
	Flexibility test "Back-saber sit & reach"	Trunk and hip mobility (representative of global flexibility)	Children from the sub-sample	Intervention and control schools	1 Evaluation period per year (Baseline, intermediate and final measurements)
	Explosive force test for lower body (standing broad jump)	Maximum power reached by the lower body	Children from the sub-sample	Intervention and control schools	1 Evaluation period per year (Baseline, intermediate and final measurements)

Instrument	Description	Information to obtain	To whom it is addressed	Place of application	Application period
	Endurance test "Course-Navette 20m shuttle run test" to estimate the maximum oxygen consumption <VO2max>	Maximum oxygen consumption (VO2max), maximum cardiorespiratory capacity	Children from the sub-sample	Intervention and control schools	1 Evaluation period per year (Baseline, intermediate and final measurements)
	Maximum speed test	Subjective feeling of fatigue using the modified Borg scale	Children from the sub-sample	Intervention and control schools	1 Evaluation period per year (Baseline, intermediate and final measurements)
	Step registration for one day	Number of steps during the day (The pedometer will be placed at the entrance of the classroom and will be removed the next day at the same time, making an observation at the end of the day)	Children from the sub-sample	Intervention and control schools	1 Evaluation period per year (Baseline, intermediate and final measurements)
Anthropometry	ISAK methodology with plicometers, anthropometric metal strips, electronic scales, portable stadiometers and anthropometers for long and short limbs	22 measurements of which: Basic (3 measurements) Folds (6 measurements) Perimeters (9 measurements) Diameters (4 measurements)	Children from the sub-sample	Intervention and control schools	1 Evaluation period per year (Baseline, intermediate and final measurements)

Each test will be realized on a different day during school hours before lunch break. Each child's results will be compared with the standard parameters, and they will be given to the children's parents confidentially.

In order to achieve a greater approach to the population, qualitative tools will also be implemented, such as non-participating observation, focus groups, and semi-structured interviews, that will aim to generate new strategies suggested by the population, as well as to identify barriers and possible solutions to improve eating habits and encourage physical activity in the community. The aim is to carry out three qualitative measurements, one before the baseline, as part of the feasibility study, one in the intermediate period to acknowledge the population's perception of the intervention and improvement areas, and at the end of the study to gather the satisfaction level among the community and the perceived impact of the intervention. The qualitative component will be implemented by specialized personnel in qualitative methodologies.

Questionnaires, formats, and interview guides are presented in full as appendixes in this protocol, in separate documents.

In addition, close and careful observation of the events will be maintained inside the communities during the project that could affect the results (Table 4)

Table 4 Description of evaluation instruments at the LOCAL LEVEL

Instrument	Description	Information to obtain	To whom it is addressed	Place of application	Application period
Observation log	Detailed registration of events, without specific format	Relevant related events that may affect the dynamics of food and physical education in schools and communities	-	Schools and communities	Constant recording of relevant events
Registry of process indicators of activities at the community level	Indicator registry format according to the implemented actions proposed by the locality	Number of effective events carried out, attendance, duration, etc.	-	Schools and communities	Depending on the regularity of the actions proposed by the community

Population description and sample selection

Study location:

Acatlan de Juarez is a small town and municipality in the central region of the state of Jalisco state, Mexico. Its located approximately 45.7 km south of Guadalajara, in the Lagunas region. It has an area of 176.85 km². According to the 2010 census, it has a population of 23,241 inhabitants, of which 9.88% are children between 6 and 10 years old. The main economic activities are agriculture of cane, corn, beans, peanuts, sunflower, and tomatoes. Within the cattle raising, the main breeding is from dairy and beef cattle, pigs, sheep, goats, horses, and various birds, beehives, and rabbits; the main branches of the Acatlan de Juarez industry are sugar and alcohol. For commerce, the municipality counts with various commercial establishments, where one can find basic necessities. There are five medical units and 11 elementary schools (Gobierno del Estado de Jalisco, 2015; Instituto Nacional de Estadística y Geografía, 2010).

Selection of study schools:

The strategies will be implemented in all three intervention schools. A nutrition diagnosis will be offered as a community service to the rest of the schools in Acatlan de Juarez in a previous stage of the study; none of the described strategies will be implemented. The schools were chosen at the convenience of the size of the student body. In addition to having a sufficient population, each school's authorities needed to be willing to participate.

Selection of control schools:

There were three elementary schools selected from the municipality of comparison (Villa Corona, Jalisco). The schools were chosen for their similarities in social, economic, and geographic contexts to the intervention municipality. These schools were selected for the similarity in the student body size for the intervention schools.

Subjects of study:

Depending on the different strategies, is pretended to incorporate:

- Children from six to ten years of age (completed at the beginning of the study) who attend public schools from the intervention community

- Mothers and fathers from families with kids of school-age
- Personnel in charge of school cooperatives
- Key actors and members of different groups involved in the implementation of the strategies.

Sample size:

All schools and retail outlets of food in and around the schools will be evaluated. The anthropometric measures (height, weight, waist, and three basic folds) will be taken from students from 1st to 4th year of elementary schools.

For the calculation of the sample size, data of a similar study realized by Li and Col. were used. In 2014 (Li et al., 2014), a total sample size of 288 children among the six schools (three control and three intervention) took into account a loss in the follow-up of 30%. It was considered a type I error of .05, power of 80%, and six clusters.

Selection of the sub-sample

One cluster will be randomly selected from each grade level of the schools chosen, listed in Table 1, and within each cluster chosen, 12 children will be randomly selected per cluster (48 children total per school)

The exclusion criteria are:

- Chronic disease with confirmed diagnosis (Cancer, diabetes type 1 or type 2)
- Physical limitations that could affect the development and standard nutritional patterns.
- Use of medications that may influence energy consumption and expenditure (antidepressant drugs, antipsychotics, and steroids).
- Children who are or have been in a weight reduction program in the past year.
- Use of medications or confirmed diagnosis of illnesses that could alter laboratory values.

Fieldwork logistics in evaluation periods

The field strategy for information gathering in the three evaluation periods will be organized with a single brigade of six people (during the evaluation periods, there will be two more people to complement the 6-member brigade and facilitate the collection of information; while four members will stay in the project during the implementation of strategies). In addition, some of the project's researchers and undergraduate nutritionists will participate as support in the measurement period. The brigade will work in each of the schools for approximately one week, starting with the intervention schools. It is expected that in 2 months, all the required information will be completed. The responsibilities will be distributed inside the brigade to optimize the time. The qualitative component will be implemented by different brigade personnel to ensure their specialization in qualitative methodologies. The project will count with one general field supervisor to ensure that the brigade personnel is advised and supported at all times.

Field staff will receive the appropriate training in interviewing techniques, ethical considerations, filling out specific questionnaires, training in the anthropometric measures, and blood pressure. One researcher will be trained in the SOFIT method. Only the standardized personnel with the specific techniques will be responsible for gathering the information.

Blood sampling

Glucose and lipid determinations on blood will be made by the laboratory of clinical analysis of the University Center of Exact Sciences and Engineering (CUCEI; in Spanish Centro Universitario de Ciencias Exactas e Ingeniería) of the University of Guadalajara, who will be going to the schools, take the samples, analyze them and deliver the results. The determination of blood chemistry analytes is done by spectrophotometry in liquid chemistry. The hematic biometry is done with the SISMEEX equipment by impedance. The laboratory is registered on the external quality control PACAL (Quality Assurance Program) company certified in ISO 9001:2008 and certified by System ISO 9001. In addition, it has Notice of Laboratory Operation at the Jalisco Ministry of Health and the University of Guadalajara. They are also registered with the Ministry of Environment and Natural Resources (SEMARNAT. In Spanish: Secretaría de Medio Ambiente y Recursos Naturales) and have transportation and reception of biologically hazardous waste with the company Corporate

Techno Ambien. For the collection of blood samples, children and their parents will be asked to have fasting of food and caloric beverages for 12 hours before intake (usually the night before), which must be suspended as soon as the measurement is made. The blood samples collection will be conducted on school premises by qualified CUCEI staff (described at the beginning of this section) at the end of the baseline, intermediate, and final measurement period. It is estimated that the measurements are taken during the first hours of the school day (between 8:00 and 10:00 hours), and approximately 10 ml of blood will be taken per child.

Action strategies

Strategy implementation

The strategies of the project are aimed to improve nutrition and increase the physical activity of the children. They are mainly based on the implementation of the guidelines of the “National Strategy for the Prevention and Control of Overweight, Obesity, and Diabetes” in a guided and supervised way by the research team of this project; In addition, it is intended to incorporate strategies suggested by the own community of intervention. In the control community, as in the rest of the country, it is expected that the actions of the “National Strategy for the Prevention and Control of Overweight, Obesity, and Diabetes” are gradually implemented under the capacities of local authorities in education and health.

In both intervention and control communities, results will be presented by the school after each measurement period, and parents will be given the results of their child’s nutritional status.

To achieve a better acceptance of the strategies by the population in the intervention locality, these will be implemented in collaboration with municipal authorities, schools, parents, and staff from ITESO, UdeG, and AJANUT. The aim is to involve the key actors of both the school environment and community, from early stages of the project, in order to adapt the strategies to be cultural and socially acceptable, generating strategies that could contribute to the achievement of the goals and promote the appropriation of the project from the community. Key actors include parents, school principals, teachers, food service concessionaires within the school grounds, and municipal authorities of Acatlan de Juarez in contact with the school-age children from six to ten years old.

Initially, the strategies to be implemented will include the following:

- Regulation of food sales within school grounds
- Awareness of children, parents, teachers, and staff in charge of the food supply to improve acceptance and commitment to food sales regulation.
- Training of staff in charge of food supply within the school, to help support the preparation of healthy foods.
- Promotion of the consumption of water.
- Organization of events and support in the coordination of groups that promote physical activity at the community level.
- Implementation of healthy spaces inside the school
- Improve the quality of the physical education classes within schools
- Physical activities outside school hours and during vacations to promote physical activity all year round.
- Offering different types of support for the implementation and promotion of health care actions within the school context.
- Development of skills in the educational community for health care and the generation of healthy school environments.
- Creation and/or strengthening of health and nutrition committees in schools, with school principals, teachers, and parents to generate primary conditions that favor healthy environments.

Table 5 lists possible intervention strategies taken from the study realized before in Tlaltizapan, Morelos; however, in the current project, some strategies may be modified once the result of the formative investigation and viability are known.

For the implementation of the strategies, the population will be actively involved; it will be established on a common agreement the times, responsibilities, and activities for the organization and convening of courses and events. The research team will design the contents and didactic materials for the courses and workshops, considering the community's opinions and suggestions.

Table 5 Description of strategies proposed in the previous project carried out in Tlaltizapan, Morelos

Strategy	Implementation
Regulation of food sales on school grounds	Compliance with food sales guidelines in schools will be monitored. Non-compliance will be reported to school principals and they will be encouraged to limit sales to permitted products, advising those in charge to do so.
Awareness of children, parents, teachers and staff in charge of food offering to improve the acceptance and commitment to the regulations	<p>There will be an opening event at the beginning of the project activities, which will include the community and various recreational activities that promote healthy food and physical activity.</p> <p>Meetings will be held with parents and teachers to explain in detail the purpose of the regulation, the process of elaboration of the guidelines, to make known the benefits of good nutrition, the risks of consuming food that is dense in calories and high fat content, and answer questions about it.</p> <p>Similar guidance will be provided to food sales staff but during the time of the school day, with the help of the teachers. They will be informed that they will be able to access workshops and training to adapt their food supply to the guidelines.</p> <p>Children will have an explanation during classes, complementing the nutrition content marked by SEP. Each group will be asked for a space to explain the new regulations and to answer their questions about them.</p>
Training of the staff in charge of the food offer in the schools, to support the preparation of healthy food	Free workshops will be provided to adapt the food supply to the guidelines. The main topics to be discussed will be portion sizes, healthy cooking methods, hygiene in the preparation and healthy ingredients. It is aimed to offer the workshops for each school, on campus, and at times that result convenient to vendors. To integrate food vendors from around the schools, the support of the Municipal President will be sought.
Organization of events and support in the coordination of groups that promote the physical activity at the community level.	In coordination with the key actors, support will be given to the organization of sports tournaments, walks, dance competitions, etc. (depending on children's preferences). Schools will be

	supported in the purchase of some games that encourage physical activity that can be used by all children during recess.
Improve the quality of physical education classes on school campuses	Physical education teachers will be provided with manuals for class development of physical education adapted to the Mexican context. As an additional tool to existing classroom programs. Each group will be monitored to take at least 2 physical education classes per week and the effective time of each class. Principals will be encouraged to comply with the regarding physical education classes.
Implementation of healthy spaces on school campuses	In coordination with local key actors, actions such as food fairs, healthy lunch contests, gastronomic exhibitions or conferences, nutrition week, etc. will be organized.
Physical activation outside of class and outside of the school calendar (Not applicable in Tlaltizapan)	Activities will be planned so that children can go to their schools (or community centers) outside of their school hours and during vacations to stay active even at times outside of their school hours. For the above, the support of social service providers of the Bachelor of Physical Culture and Sport (or similar) will be sought.
To offer diverse support for the implementation of health promotion and care actions in the school context	Courses will be developed for teachers to give them useful tools in the health and nutrition sessions that they must give to their students as part of the modifications to the school curriculum that SEP has made. These courses will be based on the contents of the official textbooks. It will be coordinated with the school zone supervisor and with the principals of each school on the schedules and duration of the courses; and if possible, incentives or recognition to the teachers.
Creation and/or strengthening of health and nutrition committees in schools, with the participation of principals, teachers and parents to generate basic conditions that favor healthy environments.	The formation of committees will be encouraged in schools where they have not been previously integrated. The support of the principals of each school will be requested for the invitations. A member of the project team will join each school's committee and participate in the meetings.

During the periods of strategy implementation, the project will have four people who will stay permanently in the locality for the duration of the intervention. A member of the project will be permanently in charge of implementing and monitoring the strategies at one of the community interventions schools, keeping direct contact with key actors. The same person will be a member of the health and nutrition committee of the school. In addition, monitoring activities will be carried out in the comparison schools, which will be systemized into indicators for the evaluation process. On the other hand, it is contemplated the support of nutritionists and other undergraduate professionals to support the elaboration of material, application of interventions, events, workshops, and measurements, with previous training and standardization.

Additionally, formative research will enrich the proposed strategies. This will be carried out with the support of personnel specialized in qualitative methodologies. Two people will be in charge of implementing the qualitative component, which will consist of non-participating observation, focus groups, and semi-structured interviews with children and key actors (parents, teachers, school principals, municipal authorities, and community leaders); to inquire about opinions, prejudices, and beliefs regarding the implementation of the guidelines that regulate food sales within school grounds. The same staff will be responsible for analyzing the information and determining the barriers and possible solutions to improve eating habits and encourage physical activity in the population (during the qualitative instruments' application, one more person will be supporting the research team). The focus group among children will be held inside the schools, working mainly with fifth and sixth-grade students. In addition, all teachers at each school will be invited to participate in a focus group that will be held at the school campus with the support of the principals. Semi-structured interviews will be conducted with children, parents, and teachers. The specialized staff in qualitative methodologies will personally arrange with each of the interviewees the day, time, and place where interviews will be held, supporting the interviewees' convenience.

Monitoring and evaluation

Table 6 describes the outcome variables. The conceptual framework of obesity causes (Figure 1) specifies a wide variety of factors that influence this pathology's immediate causes. To modify these factors, it is necessary to implement strategies that will impact the outcome variables, but whose impact is not direct. These strategies are mainly oriented towards modifying the food supply, increasing opportunities to make physical activity,

creating healthy environments, and community participation, among others; not precisely modifying the body composition. Many of the strategies proposed for the project will reflect on the outcome variables; however, their monitoring during the intervention will be given through process indicators, among which stand out:

- Number of parent's reunions, for each topic of health and nutrition
- Number and percentage of parents that assist the reunions about topics of health and nutrition (total of parents per group/number of parents that assist per group)
- Number of events outside school hours realized with health and nutrition topics
- Number of sports events realized
- Number of assistants and participants on sports events and health and nutrition topics
- Effective classes of physical education per group (physical education classes programmed per group / physical education classes realized per group)
- Duration pf physical education classes (minutes)
- Application grade of the guidelines
- Number of non-recommended foods present at the school campus

These are some of the indicators proposed; however, with the formative and viability investigation results, it will be possible to propose various actions for which indicators of the specific process will be designed.

During the implementation of the strategies, detailed records will be kept of relevant related events that may affect food and physical education dynamics in the schools and the locality (Table 4), both in the intervention and control localities. Similarly, a detailed registry will be kept of the agreements reached in meetings with key actors and the support given by the municipality and school authorities.

Table 6 Outcome variables

Category			
Basic causes			Underlying causes
Diet	Physical activity	Interpersonal factors	Environment
Energy consumption	Number of steps	Beliefs	Availability and accessibility of food and beverages
Fat consumption	Speed	Knowledge	Quality of infrastructure for physical activity and meals

Recommended and non-recommended food consumption	Resilience	Attitudes	Length and quality of physical education classes
Beverage consumption	Strength	Motivation, intention to change	Policies to regulate the sale and consumption of food
Local foods consumption		Social empowerment	

Information analysis plan

It is pretended to analyze the information in 3 different sections. One section with impact results, one section with process results, and one section with qualitative results.

The section with impact results will present central tendency measures and dispersion of the information obtained during the measurement periods, having as main outcome variables:

- Score in beliefs, attitudes, and knowledge questionnaires.
- The average consumption of energy and fat
- Consumption of healthy foods (recommended)
- Consumption of non-healthy foods (Not recommended)
- Number of steps during the day
- Availability of healthy foods and non-healthy foods at school
- Availability of drinking water at schools
- Number and quality of spaces to develop physical activity
- Score in endurance, speed, and strength test

As for the process results section, six-month reports will be elaborated and delivered to the financing company, presenting information on the process indicators mentioned in the previous section; as well as the summary of the activities and relevant events that have taken place in the community and the agreements reached with the key actors.

The section on qualitative results will be presented once the formative research has concluded, and after each measurement phase. This section will present the barriers and

possible solutions to improve eating habits and encourage physical activity in the population provided by the key actors and elements of the actors' perception of the intervention's progress and satisfaction.

Ethical aspects

Parent meetings will be held at the intervention and comparison sites for each grade at each school to explain the project and request oral consent from children's parents who have not been selected in the sub-sample, to obtain measurements of weight, waist, neck, basic folds, and height. Copies of the designed informed consent letter will be made available upon request. Different informed consent letters will be read to parents of children in the intervention community and the control locality. In addition, a written informed consent letter will be requested from the parents of the children selected to take the additional measurements (Appendix 1). The signing of the consent letters will be realized at smaller meetings and/or home visits to obtain their contentment regarding the collection of blood samples and questionnaires of diet and physical activity in children, blood pressure measurements, and step counts. The assent of all children over 7 years of age will be obtained with an informed assent letter (Appendix 2). Both letters of consent and assent will be read and explained to participants to ensure that they have understood their content. These letters are written specifically for the intervention and comparison locality.

Participating key actors will be asked for informed consent to participate in interviews and will be provided with a copy of the contact information from the researchers responsible for the project (Appendix 3).

Reunions will be carried out with different community groups, the school community, and the decision-makers separately to present the results after each measurement period. The reunion will help maintain the community involved in the process, as well as receive feedback. Parents will be given the results of their children's nutritional state, blood pressure, glucose, cholesterol, triglyceride levels, and the results of the physical abilities test. In the case of detecting that any child requires medical attention, it will be referred to Acatlan Health Services for treatment. If the found condition is severe, the kid will have a secured place for its special treatment at the New Civilian Hospital of Guadalajara "Juan I. Menchaca" in Guadalajara Jalisco.

Schedule

The intervention is scheduled to begin in September 2015; however, in June and July of 2015, the formative research and the viability study will be carried out within the schools. It is contemplated a training period for staff before each of the 3 periods of evaluation. The total duration is 3 years (2015-2018), with the last field evaluation scheduled at the end of the 2017-2018 school year. There is also a 6-month period for data analysis and the elaboration of the final report at the end of the project. Table 7 describes the estimated times on which each of the project periods will be developed.

Year	Month	Activities	School year
2015	April	Measurement of non-participating schools in the intervention location	2014-2015
	June-July	Formative research and viability study	
	July- August	Analysis of formative research and staff training	
	August	Planning of intervention strategies	
	September	Presentation of strategies before a group of experts and corrections. Preparation of material for initial evaluation	2015-2016
	October – November	Baseline evaluation	
	November	Opening event	
	December	Formative research article School vacations	
2016	January – July	Baseline measurement article Strategy implementation	2016-2017
	Easter	School vacation	
	July – August	School vacation	
	July – August	Staff training	
	September – October	Intermediate measurement	2017-2018
	November – December	Strategy implementation	
	December	School vacation	
2017	January – March	Intermediate measurement article Implementation of strategies	2016-2017
	Easter	School vacation	
	April – July	Implementation of strategies	
	July – August	School vacation	2017-2018
	September – December	Implementation of strategies	
	December	School vacation	
2018	January – April	Implementation of strategies	2017-2018
	Easter	School vacation	
	March – April	Implementation of strategies Staff training	
	May – June	Final evaluation	
	July - December	Analysis of information	
2019	January	Final report evaluation Final evaluation article	2019

Budget

Table 8 describes the different items considered for the budget per year, which considers the necessary costs for developing all the stages of the project, including from staff training, to the end of the collection and analysis of the information. The work team includes a project coordinator, who will be in charge, along with the operative responsible for the quality of the information and the development of the fieldwork. A coordinator for the qualitative component is also included. There will be an additional person who will support the qualitative research. The team will have 2 social service providers in charge of collecting quantitative information during the different stages, as well as implementing and evaluating the intervention.

Due to the type of methodology used in this study, the totality of strategies to be implemented during the intervention is unknown; however, previous experience of INSP groups in similar interventions indicate that it will be necessary to develop materials and campaigns to promote the consumption of fruits and vegetables, as well as the creation of healthy spaces within the school. All materials and equipment for the design of an educational campaign are included, including the ones that will need reproduction and the materials for its implementations.

On the other hand, expenses for transportation (gasoline) and travel of personnel in charge of collecting information and implementing strategies are included in the items of transportation and travel expenses, respectively. Finally, the administrative cost of the projects is included in the budget, which represents 15% of the total cost of the intervention, requested by ITESO's administration.

	2015	2016	2017	2018			
	May	January	July	January	July	January	TOTAL
PERSONNEL/STAFF	\$132,000.00	\$237,000.00	\$222,000.00	\$174,000.00	\$174,000.00	\$249,000.00	\$1,188,000.00
TRANSPORTATION	\$7,000.00	\$12,500.00	\$9,000.00	\$9,000.00	\$9,000.00	\$7,500.00	\$54,000.00
TRAVEL EXPENSES	\$6,000.00						\$6,000.00
BIOCHEMICAL DETERMINATIONS	\$105,000.00		\$105,000.00			\$105,000.00	\$315,000.00
MATERIAL & EQUIPMENT	\$16,200.00	\$88,420.00	\$3,600.00	\$15,000.00	\$3,600.00	\$15,000.00	\$141,820.00
OTHER EXPENSES		\$15,000.00				\$15,000.00	\$30,000.00
STATIONERY AND OTHERS		\$10,000.00	\$10,000.00	\$10,000.00	\$10,000.00	\$10,000.00	\$50,000.00
EVENTS	\$15,000.00					\$10,000.00	\$25,000.00
SUBTOTAL	\$281,200.00	\$362,920.00	\$349,600.00	\$208,000.00	\$196,600.00	\$411,500.00	\$1,809,820.00
ADMINISTRATIVES ITESO 15% (OVERHEAD)	\$49,623.53	\$64,044.71	\$61,694.12	\$36,705.88	\$34,694.12	\$72,617.65	\$319,380.00
TOTAL IN PESOS	\$330,823.53	\$426,964.71	\$411,294.12	\$244,705.88	\$231,294.12	\$484,117.65	\$2,129,200.00
TOTAL IN DOLLARS	\$21,505.23	\$27,754.90	\$26,736.23	\$15,907.14	\$15,035.31	\$31,470.13	\$138,408.93

Appendixes

October 2015

**CONSENT LETTER: Parent's consent for their child to participate in an interview
and Acceptance of the child to participate.**

**PARTICIPATORY INTERVENTION TO IMPROVE THE NUTRITION AND PHYSICAL
ACTIVITY OF SCHOOL CHILDREN IN ACATLAN DE JUAREZ, JALISCO**

Dear Sir / Mrs.:

On behalf of the Technological Institute of Higher Studies of the West (ITESO), the University of Guadalajara (UdeG), and the Ministry of Public Education (SEP), we extend a warm invitation to you and your child to participate in a study that has as its purpose the implementation and evaluation of a strategy to modify the environment of school-aged children and promote adequate physical activity and healthy eating, thus improving their body composition and physical fitness.

Procedure:

In case you agree to participate in the study, your child will be asked a series of questions related to feeding, observations about the foods your child eats at school, body measurements (weight, height, folds, waist, hip, and neck), physical fitness tests: flexibility, aerobic capacity (the child is asked to walk for 6 minutes, as far as he or she can walk) strength (the child is asked to do horizontal jumps) and a venous blood sample to check glucose levels, and blood lipids. Observations, interviews, and measurements will be conducted by ITESO and UdeG trained staff within the school facilities.

It will take approximately half an hour to ask your child these questions. The body measurements are estimated to take 25 minutes, and the physical fitness test will take approximately 15 minutes. For blood sampling, about 10 ml (equivalent to 2 teaspoons) of blood from an arm vein, under controlled circumstances. The blood collection will be performed by experts in the area, within the school facilities, with new and sterile material and under rigorous quality control. These measurements will be performed on 3 occasions throughout the project (from 2015 to 2018).

Benefits:

The main benefit for you and your child will be to know the child's nutritional and physical status and blood test results free of charge for three years. If you agree to participate, you will be collaborating with ITESO, UdeG, and SEP in a mission to research and find solutions for the promotion of adequate physical activity and healthy eating in schools. This study can help us better understand how to improve the school environment and our children's health in the future.

In addition, we are committed to sending regular reports on your child's nutritional status and overall progress of the study and working throughout the three years to improve children's nutrition and physical activity.

Possible risks:

The study does not pose any risk to your child's health since the amount of blood drawn will be the same as that required for a regular blood test. Drawing the blood sample may cause a burning sensation at the point where the needle is inserted into the skin and may result in a small bruise that disappears within a few days. On rare occasions, it can cause temporary dizziness.

Fitness tests are low impact; however, medical care will be available at all times.

Participation / Voluntary Withdrawal:

Children participating in this study will be those in grades 1-4. Participation in this study is entirely voluntary. You have the right to refuse to participate and to withdraw from the study at any time. Whether or not you participate will not affect your child's benefits from the school or any future services.

You do not give up any of your legal rights by signing this informed consent document.

Cost of Participation:

There will be no cost to you or the school for participating in this study. All measurements, tests, and activities related to the study will be given to you at no cost for the duration of the project.

Confidentiality:

The information that we obtain will be completely confidential and transported directly to the Technological Institute of Higher Studies of the West (ITESO), to Dr. Laura Arellano Gómez's office, and will be for the exclusive use of the researchers participating in this project.

Contacts:

You have the right to receive answers to any questions about the procedures, risks, and benefits related to this project. For this purpose, you may contact **Professor Roberto Paulo Orozco Hernández**, responsible for the project, at **(01 - 33) 36 69 34 34 ext. 3989**.

Sincerely,

Professor Roberto Paulo Orozco Hernández

ITESO Project Coordinator

Parent or Guardian Consent for their Child's Participation

Your signature indicates your agreement for your child to voluntarily participate in this study.

Date:

Month / Day / Year

Name of participant's parent/guardian:

Name of the child participating:

Parent/Guardian's Signature:

Family relationship to the child: _____

Acceptance of the Child to Participate

(To be obtained orally when the child is interviewed)

Date:

Month / Day / Year

Name of the child:

The child has received an explanation and has agreed to participate:

1. Yes
2. No

Witness #1:

Family relationship to the child:

Witness #2:

Family relationship to the child:

Name and signature of researcher obtaining consent

October 2015

LETTER OF CONSENT: Principal's consent for the elementary school to participate in the project:

PARTICIPATORY INTERVENTION TO IMPROVE THE NUTRITION AND PHYSICAL ACTIVITY OF SCHOOL CHILDREN IN ACATLAN DE JUAREZ, JALISCO

Dear Director:

On behalf of the Technological Institute of Higher Studies of the West (ITESO), the University of Guadalajara (UdeG), we request your consent for the educational facility you lead to participate in this study, which has the following objective: To evaluate the functioning and effect of a participatory intervention to improve nutrition and physical activity within the school environment in children aged 6 to 10 years from public elementary schools in Acatlan de Juarez, Jalisco, Mexico.

Procedure:

The project will have a total duration of 3 years (Start 2015, end 2018). Outcome variables will be: change in consumption and availability of food and beverages, time invested in physical activity within the school environment, knowledge and attitudes towards the consumption of healthy food, simple water, and physical activity, as well as the empowerment of community actors involved on their health. On the other hand, it is expected to find modifications in serum lipids and glucose, the prevalence of overweight and obesity, and the physical capacities (resistance, strength, and speed) of children. Finally, it is intended that the present project establishes a background of the need to maintain a health promoter permanently in all basic education schools.

The study will have three moments of evaluation: baseline, intermediate, and final, and an initial evaluation of viability and formative research. The measurement periods will use simple instruments in the school context to obtain information at the school level about the dynamics of food and water consumption within the schools, the dynamics and infrastructure for physical activity, the quality of physical education classes, and food availability.

In each measurement period, anthropometric measurements will also be taken of all elementary school children. Qualitative methodologies will be applied to obtain information on community satisfaction and the benefits and barriers observed.

After each measurement period, a report with the overall results of the school will be provided to the school principal and any members of the school community considered relevant by the principal.

In addition to the procedures described in the previous paragraphs, a random subsample of children in grades 1-4 will be selected and the following additional measurements will be taken to complement the information:

- Household socio-economic characteristics questionnaire.
- Questionnaires (semi-quantitative) of the child's food consumption frequency, applied to his mother.
- Questionnaire and observation of the consumption of school lunch/refreshments applied to the child in school.
- Breakfast questionnaire and observation of school breakfast consumption (if the school counts with the service).
- Blood pressure
- A blood sample to determine glucose and lipid levels
- Evaluation of physical endurance capacities with the application of Eurofit Battery and the realization of endurance and speed tests.

- Twenty-two detailed anthropometric measurements according to ISAK methodology, to obtain body composition.

Prior to applying the test, the informed consent of the children's parents will be requested. Each test will be realized on a different day during school hours. Each child's results will be compared with the standard parameters, and they will be given to the children's parents confidentially.

In order to achieve a greater approach to the population, qualitative tools will also be implemented, such as non-participating observation, focus groups, and semi-structured interviews, that will aim to generate new strategies suggested by the population, as well as to identify barriers and possible solutions to improve eating habits and encourage physical activity in the community.

Possible risks:

The study does not pose any risk to students' health since the amount of blood drawn will be the same as that required for regular blood testing. Drawing the blood sample may cause a burning sensation at the point where the needle is inserted into the skin and may result in a small bruise that disappears within a few days. On rare occasions, it can cause temporary dizziness. Fitness tests are low impact; however, medical care will be available at all times.

Participation / Voluntary Withdrawal:

Participation in this project is entirely voluntary; however, the permanence of the elementary school is fundamental to obtain reliable results that will allow us to propose actions that will improve the nutrition and physical activity of both this campus and the rest of the country. The school has the right to refuse to participate and to abandon the study at any time.

Cost of Participation:

There will be no cost to any member of the school community for being part of this study. All measurements, tests, and activities related to the study will be provided at no cost to you for the duration of the project. Also, no food or other products will be sold or promoted as part of the project.

Confidentiality:

The information that we obtain will be completely confidential and transported directly to the ITESO or UdeG facilities, under the supervision and analysis of Dr. Laura Arellano Gómez, and will be for the exclusive use of the researchers participating in this project.

Contacts:

You and any member of the school community have the right to receive answers to any questions about the procedures, risks, and benefits related to this project. You may contact Professor Roberto Paulo Orozco Hernández, responsible for this project, at (01 - 33) 36 69 34 34 ext. 3989.

Sincerely,

Professor Roberto Paulo Orozco Hernández

ITESO Project Coordinator

Principal's Consent for the Elementary School to Participate in the Project: *Participatory Intervention to Improve Nutrition and Physical Activity in School Children in Acatlan de Juarez, Jalisco*

Your signature indicates your agreement to allow the elementary school you lead to participate in this study voluntarily.

Date:

Month / Day / Year

School Name and code:

Principal's name

Signature of the Director
