

Food and nutrition education to reduce obesity among school-age children in Panama

Submission date 27/03/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 29/03/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 28/06/2023	Condition category Nutritional, Metabolic, Endocrine	<input checked="" type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

This is a study to prevent and reduce the prevalence of overweight and obesity in school-age children in Panama which is a growing problem. The study seeks to develop, validate and evaluate a comprehensive intervention program in food and nutrition education (FNE) at public schools under the perspective of an intersectoral public health and education policy. It is thought that FNE could be effective in school environments. However, the country does not have a national policy to prevent malnutrition problems in school population. The main aim of this study is to collect data that will inform the design of a large and national intersectoral public policy to promote healthy dietary practices in public and private schools against overweight and obesity in Panama.

Who can participate?

School-age children in elementary schools in Panama.

What does the study involve?

Participants are distributed in three healthy program schools or two regular schools (without healthy program) plus FNE activities. The student under the Healthy Program are expected to achieve an adequate state of physical, mental and social health; and create an environment of institutional and communal well-being through the promotion of healthy lifestyles. The FNE involves a comprehensive package of interventions during the school period 2019 such as games, theater plays, regulation of unhealthy products in the schools, publicity prohibition of unhealthy foods, use of pedagogical school gardens, etc. Follow-up interviews and measurements are conducted by field research assistants 12 and 30 weeks later, who assess anthropometric, dietary, and psychometric indicators. Interviews with student, teachers and parents are also conducted to assess the acceptability of the interventions.

What are the possible benefits and risks of participating?

This study does not involve any physical risks or harm to participants or the researchers.

Where is the study run from?

The selected educational schools correspond to the Victoria D'Spinay and La Herradura schools located in the District of La Chorrera; the Hernando Bárcenas school located in the District of

Capira; and El Espavé and Berta Elida Fernández schools, located in the District of Chame. La Herradura, Hernando Bárcenas and Berta Elida Schools are part of the intersectoral program called "Healthy Schools".

When is the study starting and how long is it expected to run for?
April 2019 to December 2019.

Who is funding the study?

Food and Agriculture Organization (FAO) of the United Nations in Panama; and also funds has been provided by the Mesoamerica without Hunger Program of the FAO and Mexican international Cooperation Agency (AMEXID).

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

TCPPAN3606

Study information

Scientific Title

Food and nutrition education against overweight and obesity in school-age children designing a public policy against malnutrition in school-age children in Panama

Acronym

FNE

Study objectives

A multisectoral food and nutrition policy improves anthropometric and psychosocial indicators in school-age children in Panama.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 25/03/2019, the Bioethics Committee of the University of Panama, (University Post Office (Estafeta Universitaria), Panama, Republic of Panama; comitebioetica.invup@up.ac.pa; +507 523-5769), ref: N°CBUP/075/2019.

Study design

Quasi-experimental, non-randomised study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Malnutrition

Interventions

This is a quasi experimental, prospective and non-controlled study to develop and validate a comprehensive food and nutrition education against overweight and obesity among school-age children in Panama. The follow-up will be the school year 2019 (approximately 9 months, from April to December 2019). The measurements include three points, at the beginning (April 2019); intermediate evaluation (July 2019); and final evaluation (Nov-Dec 2019).

This is a non-controlled study because it is not ethical to carry out this type of studies that include benefits on the health of children, so a pre-post design is proposed prospective intervention, being the pre period the control of each student. The universe for this study are

1458 students from fourth to sixth grade in the five public schools selected in Panama West Province. The sample size was calculated to determine a change, pre to post intervention, of 5% in the overweight prevalence under the following criteria: 95% of confidentiality, an estimation error of 3%, and using an estimate prevalence of overweight reported by a national survey in 2008 of 26.9%. The total sample estimated is 768 students of both gender, this sample include an additional of 20% for potential losses during the following.

The nutritional education interventions under a policy framework include the implementation of:

1. Kiosk regulation, in which the sale of unhealthy products is prohibited (MoH Resolution N°49 of 2018 and Ministry of Education Resolution N°3623 of 2018)
2. Cooking workshops involving teachers, parents and students to promote healthy dietary practices and based on the national food dietary guidelines
3. Ludic activities such as games, plays, etc. to promote healthy dietary practices, water consumption and physical activities
4. Using of pedagogical school gardens as part of subjects and as science laboratory
5. Increasing physical activities and team games during all days
6. Ensuring safe water at school. It is also highlighted the recent national law of tax for sodas, drinks and high sugar juices; and the law N°75 of 2017 that propose healthy dietary practices at schools (https://www.gacetaoficial.gob.pa/pdfTemp/28406/GacetaNo_28406_20171115.pdf).

All the food and nutrition activities were developed and validated before the trial implementation in two short-term pilots in 2018 (data not published). As well as, the KAP instrument was validated using psychometric measurements such as factor analysis, Kaiser-Mayer Olkin and Cronbach Alpha. All these analysis provides a tested instrument, with acceptable psychometric properties, which can be potentially used to measure healthy eating habits and lifestyles in school-age children in Panama.

Intervention Type

Behavioural

Primary outcome measure

1. Nutritional status is measured at baseline, 20 and 30 weeks and using:
 - 1.1. BMI-for-age z-scores (BAZ).
 - 1.2. Waist circumference.
 - 1.3. Percentage of body fat.
 - 1.4. Proportion of overweight children.
 - 1.5. Proportion of obese children.
2. Knowledge of, attitude to, perception of and behaviour regarding dietary practices is measured using a valid and reliable instrument with 51 items (14 of knowledge about the national food-based dietary guidelines, and 37 items for attitude, perception and behaviour regarding healthy dietary practices) at baseline, 20 and 30 weeks.

Secondary outcome measures

1. Dietary intake of micro and micronutrients is measured using a valid method of 24-hour recall, the analysis and interpretation will be based on the food composition table and dietary requirements for age and sex, both instruments of the Institute of Nutrition of Central America and Panama (INCAP, for its acronyms in Spanish) at baseline, 20 and 30 weeks.
2. Household food insecurity is measured using the Latin America and the Caribbean food insecurity scale (ELCSA, for its acronyms in Spanish) (<http://www.fao.org/3/a-i30651.pdf>) at

baseline, 20 and 30 weeks.

3. Dietary diversity is measured using the household and individual dietary diversity index (<http://www.fao.org/3/a-i1983e.pdf>) at baseline, 20 and 30 weeks.

Overall study start date

19/08/2018

Completion date

15/12/2019

Eligibility

Key inclusion criteria

Fourth to sixth grade (9-12 years old)

Participant type(s)

Healthy volunteer

Age group

Child

Lower age limit

9 Years

Upper age limit

12 Years

Sex

Both

Target number of participants

700

Total final enrolment

504

Key exclusion criteria

none

Date of first enrolment

08/04/2019

Date of final enrolment

10/05/2019

Locations

Countries of recruitment

Panama

Study participating centre

Victoria D'Spinay Public School

La Chorrera, Panama West Province

La Chorrera

Panama

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Study participating centre

La Herradura Public School

District of La Chorrera, Panama West Province

La Chorrera

Panama

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Study participating centre

Hernando Bárcenas Public School

District of Capira, Panama West Province

Capira

Panama

-

Study participating centre

El Espavé Public School

District of Chame, Panama West Province

Chame

Panama

-

Study participating centre

Berta Elida Fernández Public School

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Chame

Panama

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Sponsor information

Organisation

FAO

Sponsor details

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Sponsor type

Other

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Funder(s)

Funder type

Other

Funder Name

Food and Agriculture Organization of the United Nations

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

31/12/2020

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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Abstract results	instrument development abstract	01/07/2019	18/07/2019	No	No
Protocol article	protocol	13/06/2020	12/06/2020	Yes	No
Other publications	instrument development paper	18/06/2020	15/06/2020	Yes	No
Dataset	Stata dataset file		28/06/2023	No	No
Other publications	Validation of materials	01/01/2022	28/06/2023	Yes	No
Results article		06/05/2023	28/06/2023	Yes	No
Thesis results			28/06/2023	No	No