

Effectiveness of an intervention on diet and physical activity, aimed at controlling the increase in childhood obesity in public schools from three Chilean regions

Submission date 29/07/2014	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 05/09/2014	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 05/12/2016	Condition category Nutritional, Metabolic, Endocrine	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Obesity (being very overweight) among children is considered one of the most important public health problems in Chile. It is caused by eating food that is high in calories, sugars, fats and salts and is most commonly seen in children from poorer backgrounds (low socio-economic areas). Children that are obese are much more likely to develop serious health problems as adults, such as heart disease, diabetes and some forms of cancer. It can also lead to low self-esteem, lack of confidence and the development of eating disorders. There is evidence to suggest that controlling food intake and physical activity in schools is a good way to tackle childhood obesity. With that in mind, we are looking at how teaching children about good nutrition (nutritional education) and giving them specialised physical education classes may prevent childhood obesity among children from low socio-economic areas.

Who can participate?

Children between 6 and 10 years of age attending schools in low socio-economic areas.

What does the study involve?

The study is carried out over the course of one school year. It involves 12 schools with a total of 1,655 children in grades 1 to 4. Each school is randomly allocated into one of four groups, resulting in three schools being allocated to each group. Schools in group 1 are provided with a Healthy Kiosk from which nutritional education sessions take place. Schools in group 2 are provided with physical education classes taught by a specialised teacher. Schools in group 3 are provided with the Healthy Kiosk and both the nutritional education and physical education sessions. Schools in group 4 are in the control group and not provided with the Healthy Kiosk, nutritional education sessions or physical education sessions.

What are the possible benefits and risks of participating?

The immediate benefit of this study for the participants will be learning about how healthy their diet is and how fit they are. In the long term, this study should provide scientific evidence to

influence political decisions related to public health. The main risks are involved with the physical education classes in the form of falls and minor injuries.

Where is the study run from?

Institute of Nutrition and Food Technology (Instituto de Nutrición y Tecnología de los Alimentos, or INTA), University of Chile (Chile)

When is the study starting and how long is it expected to run for?

March 2014 to December 2014

Who is funding the study?

1. Tres Montes Lucchetti (Chile)
2. FOSIS (Fondo de Solidaridad e Inversión Social from the Chilean Government) (Chile)
3. University of Chile (Universidad de Chile) (Chile)

Who is the main contact?

Nelly Bustos

nbustos@inta.uchile.cl

Contact information

Type(s)

Scientific

Contact name

Ms Nelly Bustos

Contact details

El Libano 5524

Macul

Santiago

Chile

7810000

+56 (0)2 2978 1436

nbustos@inta.uchile.cl

Additional identifiers

Study information

Scientific Title

Effectiveness of an intervention on diet and physical activity, aimed at controlling the increase in childhood obesity in public schools from three Chilean regions: a interventional randomised and controlled cluster study

Study objectives

Integrated interventions that address nutrition education, the implementation of a healthy kiosk and 4 hours per week of physical education classes in different blocks, where 50% of the time

corresponds to physical activity of moderate to vigorous intensity, are more effective than each of these interventions separately for the control of childhood obesity in children between the ages of 6 and 10 years of age during a school year.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institute of Nutrition and Food Technology (Instituto de Nutrición y Tecnología de los Alimentos), 12/05/2014, ref. Acta de Aprobacion Numero 5

Primary study design

Interventional

Study design

Interventional randomised and controlled cluster study carried out in multiple schools

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Childhood obesity

Interventions

Intervention:

1. Healthy kiosk and nutritional education: With regards to the nutritional education there will be 16 sessions of 90 minutes each covering the eating guidelines for the Chilean population (Reference: Que rico es comer sano). The Healthy kiosk are based on the guidelines described in Manual de Implementación de un Espacio y Punto de Venta Saludable en Escuelas Básicas de Chile published Bustos et.al.
2. Optimised physical activity: Physical education classes will be taught by a specialised physical education teacher. The classes will be run twice a week and will have duration of 90 minutes each with a minimum effective duration of 70 minutes during which 50% of the time children will undertake physical activity of moderate to high intensity.
3. Complete intervention combining items 1 and 2 above: Healthy kiosk, nutritional education and optimised physical activity.

Control:

1. Students in schools that are allocated as controls do not participate in any of the above interventions.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Nutritional status: Overweight > 1 Z of BMI; Obese > 2 Z of BMI; Normal between -1 and 1 Z of BMI

Where Z score is calculated from the entire BMI distribution of the study participants. BMI is calculated by dividing the children weight (kg) by the height (m) squared. This outcome will be measured during March 2014

Key secondary outcome(s)

1. Waist perimeter ($\geq$ to 90th percentile)
2. Body fat percentage ($\geq$ to 90th percentile)

This outcome will be measured during November 2014.

Completion date

19/12/2014

Eligibility

Key inclusion criteria

Children from public schools between the ages of 6 and 10 years, attending schools classed as high social vulnerability

Participant type(s)

Other

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 Years

Upper age limit

10 Years

Sex

All

Key exclusion criteria

Children with any heart related pathologies

Date of first enrolment

15/03/2014

Date of final enrolment

19/12/2014

Locations

Countries of recruitment

Chile

Study participating centre

El Libano 5524

Santiago

Chile

7810000

Sponsor information

Organisation

Institute of Nutrition and Food Technology (Instituto de Nutrición y Tecnología de los Alimentos) (Chile)

ROR

<https://ror.org/047gc3g35>

Funder(s)

Funder type

Government

Funder Name

Tres Montes Lucchetti (Chile)

Funder Name

FOSIS (Fondo de Solidaridad e Inversión Social from the Chilean Government) (Chile)

Funder Name

Universidad de Chile

Alternative Name(s)

University of Chile, udechile, Uchile, UC

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Chile

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	03/12/2016		Yes	No