

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

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<b>Registration date</b> 05/09/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/12/2016	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N/A

## 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

### **Study design**

Interventional randomised and controlled cluster study carried out in multiple schools

### **Primary study design**

Interventional

### **Secondary study design**

Cluster randomised trial

### **Study setting(s)**

School

### **Study type(s)**

Prevention

### **Participant information sheet**

N/A

### **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 measure**

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

### **Secondary outcome measures**

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

This outcome will be measured during November 2014.

### **Overall study start date**

15/03/2014

### **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

### **Age group**

Child

### **Lower age limit**

6 Years

### **Upper age limit**

10 Years

**Sex**

Both

**Target number of participants**

1,655 children

**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)

**Sponsor details**

c/o Christian Aliste

Dirección INTA Universidad de Chile

Santiago

Chile

7810000

+56 (0)2 2978 1411

caliste@inta.uchile.cl

**Sponsor type**

University/education

**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**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

**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?
<a href="#">Protocol article</a>	protocol	03/12/2016		Yes	No