

# Jumping to Health

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<b>Registration date</b> 08/10/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 08/10/2015	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Childhood obesity is a growing concern worldwide, which can lead to serious health problems such as diabetes, heart disease and even cancer. A study in 2007 showed that in Buenos Aires more than 25% of middle and working class children aged 10-11 were overweight. Many of these children showed unhealthy eating habits, such as skipping breakfast and not getting enough fruit and vegetables in their diet. It is important to make sure that children have a healthy, balanced diet and plenty of exercise to ensure that grow and develop properly, without becoming overweight or obese. There is evidence that its spread can be prevented and even reversed when eating and physical activity habits are improved. SALTEN is a school-based programme which aims to educate children about healthy eating, as well as encouraging them to be more active. The aim of this study is to find out whether the applying the SALTEN programme in schools can help to reduce obesity in children.

### Who can participate?

Healthy children in fourth and fifth grade, who attend one of the eight participating schools.

### What does the study involve?

The eight participating schools are randomly allocated into two groups. Schools in the first group (intervention group) apply the SALTEN programme, providing the children with fruit during breaks and install water fountains in the playground. A physical activity instructor is also in place to encourage children to get enough physical activity in the playground. Children attending these schools also take part in 13 lessons in which teachers educate them about healthy lifestyle choices. Children attending schools in the second group (control group) receive two classroom-based lessons, teaching them about the importance of healthy eating and getting enough exercise. Before and after the study, children are measured so that weight gain can be recorded, as well as having their eating habits and physical activity levels measured before and after the study.

### What are the possible benefits and risks of participating?

A benefit of taking part in the study is that children may have a healthier lifestyle which improves their general health. There are no risks of participating in this study.

### Where is the study run from?

Eight public schools located in Argentina.

When is the study starting and how long is it expected to run for?  
January 2013 to November 2014

Who is funding the study?

1. The Coca Cola Foundation (USA)
2. International Life Sciences Institute (Argentina)

Who is the main contact?

1. Professor Irina Kovalskys (Scientific)  
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2. Dr Cecile Rausch Herscovici (Scientific)  
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### **Study website**

www.salten.com.ar

## **Contact information**

### **Type(s)**

Scientific

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## **Additional identifiers**

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N/A

## **Study information**

### **Scientific Title**

Comprehensive Study for the Prevention of Obesity and Non-Communicable Chronic Disease, SALTEN!

### **Acronym**

SALTEN

### **Study objectives**

Children of public schools of Argentina, aged 9-11 years, are more likely to develop healthy eating habits and improve physical activity levels if they are exposed to culturally appropriate environmental and educational stimuli during two consecutive school years.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Institutional Review Board of the Argentine Medical Association (Comité de Ética de la Asociación Médica Argentina), 19/04/2013

### **Study design**

Multi-centre cluster randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Cluster randomised trial

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

School

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

Prevention

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Obesity

## **Interventions**

A multi-component behavioural and educational intervention aimed to improve physical activity and healthy eating habits of 4th and 5th grade boys and girls of 8 schools (4 intervention; 4 control) matched for socio demographic characteristics.

Intervention arm: Children receive daily access to fruits during school-breaks; water fountains are installed in the school playgrounds, and a physical activity (PA) instructor encourages moderate to vigorous physical activity during school breaks on playgrounds that were accordingly re-designed, painted and equipped for this goal. The educational component consists of 13 units focused on healthy lifestyle that are delivered by their teachers.

Control arm: Children receive 2 classroom workshops aimed at providing knowledge regarding healthy eating and physical activity respectively.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

1. Anthropometric measures (weight, height, waist circumference and BMI Z-score) measured at baseline and at 18 months (end of follow-up)
  - 1.1. Weight measured using an electronic scale to the nearest 0.1kg
  - 1.2. Height measured with a wall-mounted stadiometer to the nearest 0.1cm
  - 1.3. Waist circumference measured using an anthropometric tape to the nearest 0.1cm
  - 1.4. BMI z-score calculated using the 2007 WHO reference growth charts
2. Dietary intake was measured using a modified and trans-culturally adapted version of the Child Nutrition Questionnaire at baseline and subsequently at 6, 12 and 18 months
3. Physical activity level (during school-breaks, after school, and during weekend) was assessed with the interviewer based part of a culturally adapted and modified version of the Child and Adolescent Physical Activity and Nutrition Survey at baseline, 6, 12 and 18 months

## **Secondary outcome measures**

Dietary habits and attitudes, and level of engagement and attitudes towards physical activity measured using the self-report part of the Child Nutrition Questionnaire and the Child and Adolescent Physical Activity and Nutrition Survey at baseline, 6, 12 and 18 months.

## **Overall study start date**

07/01/2013

## **Completion date**

28/11/2014

## **Eligibility**

### **Key inclusion criteria**

1. Children in 4th and 5th grade (aged 9-11 years)
2. Attending participating schools
3. Received parental consent

### **Participant type(s)**

Healthy volunteer

**Age group**

Child

**Lower age limit**

9 Years

**Upper age limit**

11 Years

**Sex**

Both

**Target number of participants**

It was estimated that at least 508 participants were required [n=254 for the intervention group (1 cluster), and n=254 for the control group (1 cluster)]. Expecting 20% attrition, the aim was to enrol a minimum of 317 children in each group. Even anticipating a 60 % response rate, this was deemed feasible taking into account that more than 1000 children attended the eight participating schools.

**Key exclusion criteria**

1. Children with severe intellectual difficulties
2. Children with limitations to engage in physical activity
3. Children suffering from illnesses compromising nutrition or food selection
4. Children taking medication known to affect body weight

**Date of first enrolment**

18/03/2013

**Date of final enrolment**

31/05/2013

**Locations****Countries of recruitment**

Argentina

**Study participating centre**

**Teniente General Julio A. Roca**

San Martín 620

Morón

Argentina

1708

**Study participating centre**

**Tomás Espora**

Arredondo 2465

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## Sponsor information

### Organisation

International Life Sciences Institute (ILSI), Argentina

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### Sponsor type

Research organisation

### Website

[www.ilsil.org.ar](http://www.ilsil.org.ar)

## Funder(s)

### Funder type

Charity

### Funder Name

The Coca Cola Foundation

### Funder Name

International Life Sciences Institute (ILSI) Argentina

## Results and Publications

Publication and dissemination plan

An original paper under the title "Findings from SALTEN, a pilot intervention designed to improve healthy eating and recreational physical activity in public schools of Argentina" to be submitted to the International Journal of Obesity.

**Intention to publish date**

30/10/2015

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

**IPD sharing plan summary**

Available on request