Jumping to Health

Submission date	Recruitment status	Prospectively registered		
06/10/2015	No longer recruiting	Protocol		
Registration date	Overall study status	Statistical analysis plan		
08/10/2015	Completed Condition category	☐ Results		
Last Edited		Individual participant data		
08/10/2015	Nutritional, Metabolic, Endocrine	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?

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Additional identifiers

Protocol serial number

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

Study type(s)

Prevention

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(s)

- 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

Key secondary outcome(s))

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.

Completion date

28/11/2014

Eligibility

Key inclusion criteria

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

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Child

Lower age limit

9 years

Upper age limit

11 years

Sex

All

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 Castelar Argentina 1708

Study participating centre Alte. Guillermo Brown

Rio Piedras 290 Morón Argentina 1708

Study participating centre José de San Martín

Maison 531

Castelar Argentina 1712

Study participating centre Gral. Manuel Belgrano

Gutierrez 453 Moron Argentina 1706

Study participating centre Monseñor Miguel de Andrea

Santa María de Oro 2547 Castelar Argentina 1712

Study participating centre José Hernández

Luis Antonio Beruti 488 Moron Argentina 1708

Study participating centre Manuel Dorrego

José María Casullo 125 Moron Argentina 1708

Sponsor information

Organisation

International Life Sciences Institute (ILSI), Argentina

Funder(s)

Funder type

Charity

Funder Name

The Coca Cola Foundation

Funder Name

International Life Sciences Institute (ILSI) Argentina

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes