

More jumping and better eating at home and school

Submission date 14/03/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 14/03/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/11/2020	Condition category 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

A lack of physical activity, skipping breakfast, and eating unhealthy and frequent snacks are three factors that play a leading role in childhood obesity. A 2007 study carried out in Buenos Aires found that more than 25% of children aged 10-11 from middle and working class families were overweight. Most of these children reported poor eating habits including skipping breakfast, and not eating enough fruit and vegetables. Early childhood is a crucial stage for promoting healthy behaviors particularly because it is during this period that habits regarding physical activity and healthy eating are established and continue into adulthood. We also know that parents' participation, both as role models and carers, is most important to the establishment and maintenance of such habits. This is a study of a school-based program, involving parents, which aims to promote healthier habits related to breakfast, snacking, and physical activity. The aim of the study is to find out whether this program can help to reduce obesity in children.

Who can participate?

Healthy first-grade children and their parents who attend one of the 12 participating schools

What does the study involve?

The 12 participating schools are randomly allocated into four groups. Parents of the first group regularly receive online tips followed by a Q & A regarding healthy eating and active play. For children in the second group, a physical activity instructor is on hand to encourage them to get enough physical activity on the school playground. Parents and children of the third group receive both interventions. Children of the fourth group receive two classroom-based lessons, teaching them about the importance of healthy eating and getting enough exercise. Before and after the study, children and parents are measured so that weight gain can be recorded, and their eating habits and physical activity levels are 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 both children and their families 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?
International Life Sciences Institute (ILSI) (Argentina)

When is the study starting and how long is it expected to run for?
January 2015 to November 2016

Who is funding the study?
The Coca Cola Foundation (USA)

Who is the main contact?
1. Prof Irina Kovalskys (ikovalskys@ilsi.org.ar)
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

MINI SALTEN: study assessing the efficacy of a virtual intervention targeted to parents and aimed at preventing obesity in 6 year old children of public schools of Buenos Aires

Acronym

MINI SALTEN

Study objectives

First grade children of public schools of Argentina are more likely to develop healthy habits related to preventing obesity if their parents are regularly exposed to a culturally appropriate educational stimuli that is delivered virtually, and monitored during 12 consecutive months.

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), 25/02/2015

Study design

Multi-centre cluster randomised trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Obesity

Interventions

The multi-component virtual and behavioral intervention aims to promote breakfast quality and uptake, healthier snacking, and increased physical activity, with the ultimate goal of preventing childhood obesity.

The 12 participating schools are randomly assigned to two groups. The nine schools in the first group (intervention group) are separated to receive one of three intervention modalities, which was randomly assigned to three schools each. Children of the three schools of the second group are the control group.

1. Virtual: Parents are instructed and followed regarding implementation of the core objectives of the program via a software platform (www.nearpod.com), delivered bi-weekly.
2. Behavioral: Physical activity (PA) of the children is promoted by a PA instructor, who is regularly present on the school playground promoting active movement during breaks.
3. Mixed: virtual + behavioral.
4. Control arm: children receive an educational intervention in the form of two classroom workshops (nutrition and PA respectively).

Intervention Type

Mixed

Primary outcome measure

1. Weight measured to the nearest 0.1 kg using a portable digital scale (SECA AURA 807)
2. Height measured to the nearest 0.1 cm with a portable stadiometer (Seca Stadiometer 206, Seca Corporation, Hamburg, Germany)
3. Waist circumference measured to the nearest 0.1 cm with an anthropometric tape (Sanny, Brasil)
4. BMI Z-score calculated using the 2007 WHO reference growth charts
5. Child's and parent's dietary intake and habits are assessed with two 24h recalls using the Multiple Pass Method completed by participating parent or guardian. 24h dietary recall data is analyzed with NDS-R (Nutrition Data System for Research – University of Minnesota)
6. Child's physical activity and sedentary behavior is assessed with accelerometers (ActiGraph wGT3X-BT) used during 7 days. Accelerometer data is analyzed with ActiLife 6.11.8 (Copyright 2009-2015 ActiGraph, LLC)
7. Parent's physical activity and sedentary behavior is assessed with the Global Physical Activity Questionnaire (GPAQ - WHO)
8. Blood pressure assessed with a digital automatic sphygmomanometer (OMRON HEM-7114EF)

Each outcome is measured at baseline and at 12 months (end of study).

Secondary outcome measures

1. Environmental characteristics are assessed with a modified and adapted version of the International Study of Childhood Obesity, Lifestyle and the Environment (ISCOLE) Questionnaire, administered to the parent
2. Social and economic levels are assessed with an adapted version of the survey elaborated by the Social Observatory of SAIMO (Argentine Society for Research of Marketing and Opinion)

Both secondary outcomes are to be assessed at 12 months (end of study).

Overall study start date

07/01/2015

Completion date

29/11/2016

Eligibility

Key inclusion criteria

All 1st grade boys and girls (typically aged 6) of participating schools whose parents or guardians also agreed to participate in the study and signed the informed consent

Participant type(s)

Healthy volunteer

Age group

Mixed

Sex

Both

Target number of participants

It was estimated that at least 200 participants were required [n=150 for the intervention group (1 cluster), and n=50 for the control group (1 cluster)]. Expecting 20% attrition, the aim was to enrol a minimum of 150 and 50 children in each cluster. Even anticipating a 60 % response rate, this was deemed feasible taking into account that more than 1000 children attended the 12 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
5. Parents who do not have access to internet
6. Parent with severe intellectual difficulties

Date of first enrolment

04/04/2015

Date of final enrolment

30/11/2015

Locations

Countries of recruitment

Argentina

Study participating centre

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Organisation

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Sponsor type

Research organisation

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Funder(s)

Funder type

Charity

Funder Name

The Coca Cola Foundation (USA)

Results and Publications

Publication and dissemination plan

The protocol has been accepted as a poster to be presented at the International Conference on Obesity (ICO), Vancouver, May 1-4, 2016.

Baseline data is being processed with the goal to publish in June 2016.

Publication of results is to be confirmed at a later date.

Intention to publish date

29/11/2017

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?
Protocol article	protocol	06/05/2017	30/11/2020	Yes	No