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Impact of a playful family education strategy with information and communication technology on childhood obesity prevention

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03/07/2024

Recruitment status
Recruiting

Registration date
08/07/2024

Overall study status
Ongoing

Last Edited
05/07/2024

Condition category
Other

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
One of the main worldwide health problems is adult and childhood obesity, due to the complications arising from this. As World Obesity Federation (WOF) reported that in 2020, a total of 1.39 billion of adults were overweight and 81 billion were obese; while 260 million of children were overweight and 175 million had obesity. Additionally, in 2022 according to the Encuesta Nacional de Salud y Nutrición (ENSANUT) 2020-2022, an 19.2% of childhood overweight prevalence was reported, and 18.1% of childhood obesity, which places our country as the second place in childhood obesity worldwide, only preceded by the USA.
Although it is well-known that the main etiological factor are the poor eating habits, promoted by the excessive consumption of sweetened beverages and ultra-processed foods. Additionally, to the nutritional educational programs and guidelines, some strategies have been proposed in Mexico, in an attempt to reduce its consumption, such as the tax to soft drinks and junk food, and the front labelling of foods.

However, previous studies have demonstrated that a family program with the participation of children and parents is required, but not only by the implementation of integrative workshops, but through the reinforcement and support with the use of current technologies that have confirmed an improvement in learning processes.

The main objective is that the overweight children workshop group achieve a normal weight or maintain in an overweight status, and those with childhood obesity and digital reinforcement become overweight or reduce body weight, fat mass and waist circumference, as secondary objectives.

Who can participate?
Children aged 9 to 12 years diagnosed with childhood obesity (BMI Z-score 3 standard deviations above the median for age and sex according to established growth patterns, and a BMI above the 97th percentile as per WHO and CDC standards) or diagnosed with overweight (BMI Z-score

1 to 2 standard deviations above the median for age and sex according to established growth patterns, and a BMI above the 85th percentile), from Family Medicine Unit No. 23 (IMSS, Mexico City) and Family Medicine Units No. 1 and 3 (IMSS, Morelos).

What does the study involve?
In a pursuit of lowering childhood obesity and overweight prevalence and incidence, we created a non-randomized multicentric clinical trial to assess the efficacy of a technologically reinforced playful family educational workshop, on the treatment and prevention of this public health problem.

For this, a total of 196 participants will be allocated into four interventional groups:
1. Overweight children control group (n = 49 children).
2. Overweight children workshop group (n = 49 children).
3. Childhood obesity control group (n = 49 children).
4. Childhood obesity digitally reinforcement group (n = 49 children).

What are the possible benefits and risks of participating?
Possible benefits:
- Reduction in childhood obesity rates: Which could have a significant impact on public health and reduced healthcare costs, by decreasing associated health risks as cardiovascular diseases, diabetes or insulin resistance, high blood pressure, and other complications.
- Improved Dietary habits: By involving children and their families in educational workshops and digital reinforcement, promoting healthier eating habits.
- Enhanced Learning and engagement: By technological reinforcement, leading to better retention of information and behaviour changes among children.
- Sustainability and adherence: The possible observed benefits during the study may be sustained over a long term.
- Evidence-Based Strategies: The study could provide valuable data on the effectiveness of technology integration with family-based educational programs.
- Public health and policies development: Positive outcomes of the study could support the development of policies and programs that emphasize family involvement and the use of digital tools in children health education.

Risks of participating.
- According to the Article 17 of General Health Law of Mexico that addresses risks in research, the current clinical trial must be considered as a minor risk since enrolled children might be at risk of minor injuries while participating in physical activities or exercises. However, risk minimization will be considered by researchers by the implementation of safe exercise guidelines.

Where is the study run from?
Centro Medico Nacional Siglo XXI (Mexico)

When is the study starting and how long is it expected to run for?
May 2020 to December 2029

Who is funding the study?
Mexican Social Security Institute, IMSS. Convocatoria para el Financiamiento de protocolos de Investigación y desarrollo Tecnológico del programa de Investigación Traslacional “Traslada” 2024. Funding Reference Number: 0594.

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT06486493

Secondary identifying numbers
R-2020-785-036

Study information

Scientific Title
Effectiveness of a family playful/ludic educational strategy reinforced with the use of information and communication technologies in the prevention and reduction of childhood obesity

Study objectives
The implementation of a family-based educational and recreational strategy, enhanced by the use of Information and Communication Technologies, could reduce the incidence and prevalence of childhood obesity and improve dietary habits in children aged 9 to 12 years.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/05/2020, Centro Medico Nacional Siglo XXI Research Ethics Committee (Av. Cuauhtémoc 330, Doctores, 4th Floor, Block B of the Congress Unit, National Medical Center Century XXI, Cuauhtémoc., Mexico City, 06720, Mexico; +52 56276900 Ext: 21230; ccnis@cis.gob.mx), ref: CONBIOÉTICA 09 CEI-00920160601

Study design
Multicenter interventional non-randomized controlled trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home, Hospital, Medical and other records

Study type(s)
Prevention, Treatment, Efficacy

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Childhood obesity prevention

Interventions
This clinical trial consists of a 4-arm non-randomized intervention, assigned as follows:
1. Overweight conventional treatment group:
A total of 49 children between 9 to 12 years old, from the Family Medicine Unit No. 1 and 3 (IMSS, Morelos) with a BMIZ-score 1 to 2 standard deviations above the median of the established growth patterns by age and sex, and a BMI above the 85th percentile, according to the World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC).

This will be considered as an active comparator with conventional medical treatment by their physicians, following the Clinical Practice Guideline for the Prevention and Diagnosis of Overweight and Obesity in Children and Adolescents (SS-025-08) and the Guideline for the Diagnosis, Treatment, and Prevention of Overweight and Obesity in Adults (IMSS 46-08), over six months, with a follow-up of 18 months post-intervention.

2. Overweight workshop group:
An aggregate of 49 children between 9 to 12 years old, from the Family Medicine Unit No. 23 (IMSS, Mexico City) with a BMI Z-score 1 to 2 standard deviations above the median of the established growth patterns by age and sex, and a BMI above the 85th percentile according to WHO and CDC. Treated with a workshop based on national and international guidelines for the management of overweight and obesity, and best practices for the control and reduction of overweight and obesity in school-aged children, by the Food and Agriculture Organization (FAO).

This workshop will be proposed as a Playful Family Education Strategy, in addition to the conventional medical; based on national and international guidelines for overweight and obesity management in school-aged children, by the Food and Agriculture Organization (FAO). consisting of a monthly session over six months for parents and children, with a follow-up of 18 months post-intervention.
Estimated workshop sessions.
For parents:
-First session focuses on raising awareness about childhood obesity through counselling and nutritional advice, promoting water consumption over sugary drinks.
-Subsequent sessions use 'case study' technique to discuss common food and nutrition challenges.
For children:
-Sessions follow the 'Nutritional Guidance Intervention Guide' by the National System for Integral Family Development (DIF).
-First session encourages healthy eating habits through activities and educational games.
-Later sessions emphasize healthy eating patterns and physical activity.

3. Obesity conventional treatment group:
Second active comparator, with an overall amount of 49 children between 9 and 12 years old, from the Family Medicine Unit No. 1 and 3 (IMSS, Morelos) with a BMI Z-score 3 standard deviations above the median of the established growth patterns by age and sex, and a BMI above the 97th percentile according to WHO and CDC. Treated with conventional medical treatment by their physicians, according to the Clinical Practice Guideline for the Prevention and Diagnosis of Overweight and Obesity in Children and Adolescents (SS-025-08) and the Guideline for the Diagnosis, Treatment, and Prevention of Overweight and Obesity in Adults (IMSS 46-08), over six months, with a follow-up of 18 months post-intervention.

4. Obesity reinforcement group:
A group of 49 children between 9 to 12 years old, from the Family Medicine Unit No. 23 (IMSS, Mexico City) with a BMI Z-score 3 standard deviations above the median of the established growth patterns by age and sex, and a BMI above the 97th percentile according to WHO and CDC. Treated with conventional medical treatment by their physicians, the previously mentioned workshop The previously created and INDAUTOR registered workshop, with monthly sessions over six months for parents and children, and the technological reinforcement through two-week digital algorithms, such as videogames, educational videos, and digital challenges, for the children, that they must complete through their smartphone of tablet. Followed by an 18-month post-intervention follow-up.

Intervention Type
Behavioural

Primary outcome measure
Reduction of childhood obesity incidence and prevalence:
Assessed by the baseline, 3-month and 6-month evaluation from the start of intervention, and subsequently, at 6-, 12- and 18-months post-intervention of the proportion of children transitioning from obesity to overweight, according to the CDC criteria for childhood obesity. And the incidence will be determined by the proportion of overweight children who maintain their overweight status over time.

Secondary outcome measures
1. Body weight:
It will be measured at baseline, 3-month and 6-month evaluation from the start of intervention, and subsequently, at 6-, 12- and 18-months post-intervention, using a Seca scale with an accuracy of 0.1 kg, following standardized international procedures.

2. Body Mass Index (BMI)
It will be assessed at baseline, 3-month and 6-month evaluation from the start of intervention, and subsequently, at 6-, 12- and 18-months post-intervention, using body weight, and height (measured with a stadiometer with an accuracy of 0.1 cm, Weighing and Measuring Station with Frankfort line, SECA model 284), following standardized international procedures. Using these data, BMI (kg/m^2) will be calculated, and children will be classified according to their BMI percentile based on WHO and CDC charts.

3. Fat Mass
It will be assessed at baseline, 3-month and 6-month evaluation from the start of intervention, and subsequently, at 6-, 12- and 18-months post-intervention, by bioimpedance with the TANITA Iron Kids BF 689 body composition analyser.

4. Waist circumference
Measured at baseline, 3-month and 6-month evaluation from the start of intervention, and subsequently, at 6-, 12- and 18-months post-intervention, with a Seca 201 Ergonomic Waist Circumference Measuring Tape, collocated around the stand up children body between the middle point of the anterior superior iliac spine and the costal margin, after breathing out. They will be classified according to the Third National Health and Nutrition Examination Survey (NHANES III) waist circumference tables for Mexican American children, and a percentile above 90 will be considered as an elevated risk.

5. Dietary habits
It will be assessed at baseline, 3-month and 6-month evaluation from the start of intervention, and subsequently, at 6-, 12- and 18-months post-intervention, by a 24 hour Food Frequency Questionnaire (FFQ) to capture children's usual food and drinks consumption by querying the frequency at which a predefined food list items are consumed, including portion sizes, nutrient intake (calories, fats, proteins, carbohydrates, vitamins and minerals), eating patterns (timing, frequency, and types of meals or snacks), food diversity and diet quality.

Overall study start date
15/05/2020

Completion date

31/12/2029

Eligibility

Key inclusion criteria
1. School-age children aged 9 to 12 years from the Family Medicine Unit Number 23 (IMSS, Mexico City) and the Family Medicine Units Number 1 and 3 (IMSS, Morelos)
2. Children accompanied by their parents who consent to participate in the study
3. Children with a BMI equal to or greater than the 85th percentile (indicating overweight or obesity) according to CDC classification
4. Children who have agreed to participate through informed consent and assent forms
5. Families with access to Wi-Fi connection or mobile internet
6. Children with digital device (Smartphone or Tablet) access, supervised by their parents

Participant type(s)
Patient

Age group
Child

Lower age limit
9 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
196

Key exclusion criteria
1. Children undergoing in any type of weight reduction program, whether pharmacological or non-pharmacological treatment
2. Children with a prior diagnosis of endocrinological or congenital diseases, associated with obesity, such as hypothyroidism, Prader-Willi syndrome, growth hormone deficiency, Cushing's syndrome, trisomy 21, among others
3. Children with abnormal thyroid function test results
4. Children with physical limitations, such as congenital malformations, that may prevent them from engaging in moderate to intense physical activity included in the intervention
5. Participants enrolled in another research protocol of any kind

Date of first enrolment
06/01/2025

Date of final enrolment
31/12/2028

Locations

Countries of recruitment
Mexico

Study participating centre
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ROR
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Funder(s)

Funder type
Government

Funder Name
Instituto Mexicano del Seguro Social

Alternative Name(s)
Mexican Social Security Institute, IMSS

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Mexico

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/06/2030

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available upon request from the principal investigator Dr. José de Jesús Peralta Romero, at the current email addresses drjperalta@hotmail.com and drjjperalta@gmail.com

IPD sharing plan summary
Available on request