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Effectiveness of a school-based obesity prevention program on the BMI Z-score and body fat at 6 months in Mexican children: Pilot study of a cluster randomized controlled trial

Efectividad de un programa escolar de prevención de obesidad sobre el puntaje Z de IMC y grasa corporal a 6 meses en niños mexicanos: estudio piloto de un ensayo controlado aleatorio por conglomerados

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ABSTRACT

School-based obesity prevention programs show positive effects on obesity and lifestyle parameters. However, the most efficient way to implement them is unknown. In Mexico, available studies present methodological limitations. The aim of this study is to evaluate the feasibility and effectiveness of a school-based obesity prevention program 1) implemented by advanced undergraduate nutrition and physical activity students, and 2) the same program implemented by schoolteachers and advanced undergraduate physical activity students, each compared to a control group of Mexican children. This study is a cluster randomized controlled trial. Children from several schools in Hermosillo, Sonora, Mexico will be invited to participate. The schools will be randomly assigned to one option: 1) the Planet Nutrition Program (PNP) delivered by advanced undergraduate nutrition and physical activity students, 2) PNP by schoolteachers, or 3) a control group. The intervention will consist of nutritional education and physical activity sessions for children and nutrition information for parents. The BMI Z-score, body fat, and lifestyle parameters will be evaluated at baseline and at 6 months. If successful, we expect that the program turns out a model for obesity prevention in this age group, with a potential for dissemination in Mexican schools.

Keywords: Schools, Prevention, Childhood obesity, Lifestyle, Randomized controlled trial

RESUMEN

Los programas escolares de prevención de obesidad muestran efectos positivos sobre parámetros de obesidad y estilo de vida. Sin embargo, se desconoce cuál es la forma más efectiva de implementación y en México los estudios disponibles muestran limitaciones metodológicas. El objetivo del estudio es evaluar la factibilidad y efectividad de un programa escolar de prevención de obesidad 1) implementado por estudiantes avanzados de nutrición y actividad física y 2) implementado por maestros escolares y estudiantes avanzados de actividad física, ambos en comparación a un grupo control de niños mexicanos. El presente es un ensayo controlado aleatorio por conglomerados. Se invitará a participar a escolares de distintas primarias públicas de Hermosillo, Sonora. Las escuelas se asignarán aleatoriamente a: 1) Programa Planeta Nutrición (PPN) brindado por estudiantes avanzados, 2) PPN por maestros escolares y 3) grupo control. La intervención consistirá en sesiones de nutrición y actividad física para escolares e información de nutrición para padres. Se medirá el puntaje Z de IMC, grasa corporal y variables de estilo de vida al inicio y a los 6 meses. Se espera que el presente programa pueda ser un modelo de prevención de obesidad con un alto potencial de diseminación en las escuelas de México.

Palabras clave: Escuelas, Prevención, Obesidad infantil, Estilo de vida, Ensayo controlado aleatorio

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INTRODUCTION

Childhood obesity is a global public health problem. About 158 million children and adolescents are affected by obesity worldwide (World Health Organization, 2018). This public health burden continues to increase, mainly in low- and middle-income countries (NCD Risk Factor Collaboration, 2017), such as Mexico, where 1.9 million school-age children and 3.3 million adolescents have obesity (Shamah-Levy *et al*., 2020) and it is estimated that by 2030, Mexico will be the seventh country ranked with the highest childhood obesity burden all over the world for the total number of children with obesity (Obesity Evidence Hub, 2021).

One of the strategies to mitigate childhood obesity is the implementation of school-based obesity prevention programs (World Health Organization, 2012). Different studies have been conducted to evaluate the effect of obesity prevention programs. A systematic review estimated the effect of different interventions which included physical activity and/or nutrition components. They found that, in schoolchildren, this type of program significantly reduced BMI in the intervention group compared to control (-0.05 kg/m^2, 95 % CI -0.10, -0.01), however, most of such studies were carried out in high-income countries (Brown *et al*., 2019). In a systematic review that include 29 Mexican programs aimed at preventing obesity in children or adolescents, only 3 of them were found to included both a nutrition and physical activity component, and only 9 of 16 studies that evaluated BMI as an outcome showed a significant effect of the intervention. Additionally, most of the studies were rated as low methodological quality i.e. (non-randomized controlled trial, lack of blinding, no intention to treat analysis for the data, no reporting of conflict of interest and funding) (Aceves *et al*., 2021). Such shortcomings suggest the need to pursue more robust scientific evidence.

Previously, our research group developed a school-based obesity prevention program called "Planet Nutrition". The feasibility and effect of the program were evaluated through two pilot randomized controlled trials with schoolchildren from Hermosillo, Sonora; in face-to-face and online formats (Ramírez-Rivera *et al*., 2021b; Ramírez-Rivera *et al*., 2021a). The face-to-face program lasted 9 weeks and identified favorable trends in BMI Z-score changes at 9 weeks (-0.11, 95% CI, -0.23, 0.01) compared to a control group. Additionally, significant differences were observed in waist circumference, body fat, physical activity, and nutrition knowledge. The study also showed that after the summer holidays (23-week follow-up) both groups increased their BMI Z-score (Ramírez-Rivera *et al*., 2021b). This is consistent with evidence wich suggest that summer holidays periods result in weight gain in children (Díaz-Zavala *et al*., 2017; Franckle *et al*., 2014). The online version of the program that continued for 4 months during the COVID-19 pandemic did not show a significant effect or trend in BMI Z-score, but both fruit consumption and quality of life improved significantly compared to the control group.

The implementers of any health program are crucial to warrant success because they can impact the delivery and effect of the programs (Fernandez *et al*., 2019). For instance, it has been observed that nutrition education programs delivered by trained schoolteachers or external healthcare personnel show the greatest effect (Murimi *et al*., 2018). The participation of advanced students in nutrition and physical activity in undergraduate programs could enhance such effect. In most of Mexican Universities, students must participate in a social service program targeting the community (Diario Oficial de la Federación, 1981). Therefore, in Mexico such students could offer obesity prevention programs at a low cost.

Although, there is evidence of the importance of the qualifications and training of implementers, to our knowledge, the effect of school-based obesity prevention programs delivered by different implementers has not been evaluated. Furthermore, in middle-income countries, including Mexico, there is a lack of studies of school-based obesity prevention programs with adequate methodological quality (Aceves *et al*, 2021; Singhal *et al*., 2021).

Thus, the aim of the study is to evaluate the feasibility and effectiveness of a school-based obesity prevention program in Mexican schoolchildren implemented by 1) advanced undergraduate nutrition and physical activity students or 2) schoolteachers and advanced undergraduate physical activity students. The study will be conducted in two phases, the first will be a 6-month pilot study and the second a definitive study of 6 months with a follow-up at 12 months. The present protocol is mainly focused on the methods for the pilot study (phase 1). The complete process for the definitive study (phase 2), will be based on the pilot study results.

OBJECTIVES

Primary objective

To evaluate indicators of feasibility (retention, adherence, fidelity and acceptability) of a school-based obesity prevention program implemented by advanced undergraduate nutrition and physical activity students, or implemented by schoolteachers and advanced undergraduate physical activity students at 6 months.

Secondary objectives

To evaluate the effect of a school-based obesity prevention program on health indicators i.e., body size (BMI Z-score), body fat, waist circumference, relative fat mass, physical activity, sedentary behaviors, food consumption, nutrition knowledge, and quality of life at 6 months, and the BMI Z-score and body fat after the summer holidays (at 8 months). The following comparisons will be made:

1. Intervention implemented by advanced undergraduate nutrition and physical activity students compared to a control group.
2. Intervention implemented by schoolteachers and advanced undergraduate physical activity students compared to a control group.
3. Intervention implemented by advanced undergraduate nutrition and physical activity students compared to schoolteachers and advanced physical activity students.

MATERIAL AND METHODS

Trial design

This study is a cluster randomized controlled trial of three parallel groups with a 1:1:1 allocation ratio. To develop this protocol, the SPIRIT 2013 guide was followed (Figure 1) (Chan *et al*., 2013). The study was approved by the Research Ethics Committee of the Nursing Department from the Universidad de Sonora (EPD-007-2022) and registered in Clinical Trials: NCT05461703.

Study setting

Schoolchildren (ages 9 to 11 y, boys and girls) from different public elementary schools in Hermosillo, Sonora, Mexico will be invited to participate in the pilot study. The schools will be selected by convenience by blinded authorities (not involved in study recruitment or intervention) from the Ministry of Education and Culture of Sonora [Secretaría de Educación y Cultura (SEC) del Estado de Sonora]. The inclusion and exclusion criteria of schools will be evaluated and those that meet

	STUDY PERIOD									
	Enrolment	Allocation	Post-allocation						6 months	8 months
TIMEPOINT**	$-t_1$	0	t_1	t_2	t_3	t_4	t_5	t_6	t_6	t_8
ENROLMENT										
Eligibility Screen	X									
Informed consent	X									
Allocation		X								
INTERVENTIONS										
"Planet Nutrition" program			←	—	—	—	—	→		
Control group			X							
ASSESSMENTS										
BMI Z-score (weight and height)	X								X	X
Waist circumference	X								X	
Body fat	X								X	X
Relative fat mass	X								X	
Physical activity and sedentary behavior	X								X	
Food frequency consumption	X								X	
Quality of life	X								X	
Nutrition knowledge										
Feasibility (retention, adherence, acceptability, and Fidelity)									X	

Figure 1. Enrolment, interventions, and assessments of the study.
Figura 1. Reclutamiento, intervenciones y evaluaciones del estudio.

the inclusion criteria will be randomized to one of the three groups.

Eligibility criteria

To be eligible for this study an informed consent and assent form must be signed by the parents and children respectively, and anthropometric measurements and lifestyle questionnaires must be completed.

Schools

Inclusion criteria: school principals and 4th-grade teachers willing to participate, availability of space for physical activity classes, and 4th grade groups with a minimum of 20 students. *Exclusion criteria*: participating in a similar study.

Schoolchildren

Inclusion criteria: to be a 4th grade student (9 to 11 years).
Exclusion criteria: A personal condition that prevents conducting physical activity or a condition that parents consider should exclude their child from participating.
Elimination criteria: Withdrawal of consent or assent. Development of a medical condition that prevents continuation of study activities.

While only children with informed consent will participate in the baseline and follow-up measurements, all children in the class will participate in the intervention activities.

Implementers

Inclusion criteria: Receiving 80 % of the program training. Respond satisfactorily to a questionnaire that assesses their knowledge of the program.

Study Intervention Components

School-based obesity prevention program: The intervention will be the same in the two different intervention groups: a program implemented by nutrition and physical activity advanced undergraduate students and program implemented by schoolteachers, both based on the "Planet Nutrition" Program (PNP), which was previously designed. This program has manuals specially designed for children; it include different nutrition topics (Table 1) and applies some behavior change strategies. The components of the program are the following:

Nutrition education sessions: They will consist of 1 face-to-face group session of 1 h per week in the school classroom during the regular school class schedule. The PNP manual will be used to present the different topics, workshops, games, and dynamics to reinforce learning. The program will be focused on establishing health-related goals, such as increasing the consumption of fruits and vegetables, increasing physical activity time, decreasing hours spent in front of a screen, and reducing the consumption of sweetened beverages. The program will also include the use of self-monitoring and positive reinforcement.

Physical activity sessions: Three 1-hour classes per week will be implemented by physical activity undergraduate students at the school during the regular school class schedule, independent of the school's curricular physical activity classes. A physical activity manual designed by the study team will be used.

Table 1. Sessions and topics of the "Planet Nutrition" program
Tabla 1. Sesiones y temas del programa "Planeta Nutrición"

Sessions	Topics
1	Creating healthy habits
2	What is excess weight?
3	Is it really bad to eat ultra-processed food?
4	The bitter truth of sweetened beverages
5	The importance of physical activity
6	Sedentary behaviors
7	Food Guidelines: My plate
8	Analyzing my healthy lunch
9	Jar for healthy drinking
10	Sweetened beverages vs. healthy lunch
11	Reading food labels
12	Importance of healthy nutrition
13	Ultra-processed food
14	Sustainable lifestyle
15	Traditional Mexican diet
16	Healthy lunch
17	Identifying good and bad fats
18	What is important to know about sodium?
19	Smoking
20	Learning about Cancer
21	Importance of consuming fruits and vegetables
22	Vitamins and minerals
23	Why is fiber consumption important
24	Gut microbiota
25	Jeopardy: Let's put the learning into practice
26	How to prepare a salad
27	Preparing healthy desserts
28	How to be active during summer holidays
29	Healthy nutrition in summer holidays
30	Sleep and growth
31	Planet Nutrition Challenge

Parents' participation: Parents will receive weekly nutrition and health information through WhatsApp or email, depending on parent's preference. The topics for which information is sent will be similar to what the children see in the nutrition sessions, and are designed to reinforce the children's learning. In addition, recommendations for healthy eating at home will be provided. The implementers (advanced nutrition students or schoolteachers) will send the information.

Control group: Schoolchildren will continue with their normal school nutrition and physical activity classes. At the

end of the study, they will have access to the program materials through a web page.

Implementers

PNP implemented by students: The program will be delivered by a team of advanced Nutrition undergraduate students of Universidad de Sonora, and advanced undergraduate students of the Sports Training degree from Universidad Estatal de Sonora. We define advanced students (or interns) as those who are studying the last 3 semesters of the degree or who offer a service but do not have their professional title yet.

PNP implemented by schoolteachers: The program will be delivered by the 4th grade teachers of the eligible schools and the same physical activity advanced undergraduate students of the student implemented group.

Both groups of implementers will receive previous training from a registered nutritionist and a physical activity teacher with experience in this program. The nutrition training will be delivered in 3 d of 1 h each, separately for each group of implementers. The nutrition advanced students will have the training at the university and the schoolteachers at the school (individually for each teacher) in their free time. The main purpose of the tutoring will be to provide the objectives and activities of the program, to explain the topics of nutrition and health and to review the schedule of the study.

The Physical activity students will have their training for 1 month in their University. In this training, they will plan the classes and to study general concepts.

Sample size

Fifteen public schools (350 to 400 students) from Hermosillo, Sonora, Mexico will be invited to participate in the pilot study. The sample size was determined based on the feasibility of providing the program, and finding possible positive effects on the variables of interest (BMI Z-score and body fat). The calculation of the sample size is not essential in a pilot study, its main objective is to explore the feasibility of the intervention to later perform the sample calculation for a future definitive trial (Eldridge *et al*., 2016).

Recruitment

The nutrition team of the study will visit the schools to provide the information and the informed consent and assent forms. One 4th grade group of the participating schools will be randomly chosen. In general, public schools in Mexico have 3 groups of each grade; but for this phase, it is intended to work with one group per school due to the sample size.

Allocation of groups

The schools that meet the inclusion/exclusion criteria will be randomized to one of the three groups: 1) PNP implemented by advanced undergraduate students in nutrition and physical activity, 2) PNP by schoolteachers and advanced undergraduate students in physical activity, and 3) control group. A person independent of the recruitment and the intervention will perform the random allocation of the schools, stratified by the census-tract level of socioeconomic status (SES) where the school is placed; the SES will be based on the social marginalization index (CONAPO, 2020), this at a single point in time – thus ensuring allocation concealment. The random number sequence will be generated using the software "Research Randomizer" https://randomizer.org/ (Urbaniak and Plous *et al*., 2013).

Data collection

Measurements will be made at baseline and at 6 months by a team of advanced nutrition students that are independent of recruitment and intervention, over a 4-week period at each time point in the schools. The BMI Z-score and body fat will also be measured after the summer holidays (8 months from baseline). The questionnaires on physical activity and sedentary behaviors, diet, and quality of life will be answered by parents through Google Forms online questionnaires. Children will answer the questionnaires on quality of life and nutrition knowledge at school under the supervision of the measurement team.

Primary outcome

Feasibility

Feasibility will be evaluated at the end of the study (6 months) and consists of the evaluation of participant retention, adherence, fidelity, and program acceptability:

Retention: number of schools and participants that complete the final measurements. A retention of participants and schools > 80 % at 6 months will be considered excellent, 50 – 80 % moderate and < 50 % low.

Adherence: An attendance list will be taken in the nutrition and physical activity classes. At the end of the study, the parents of children in intervention group will also be asked about the number of sent materials that they readthrough an online questionnaire. Attendance at program activities > 80 % at 6 months will be considered excellent, 50 - 80 % moderate and <50 % low attendance.

Fidelity: Fidelity will be evaluated through a monitoring list. The implementers must mark the session provided, date, and duration. There will be a monthly visit to the school by the nutritionist of the team to verify how the program is being provided in accordance with the established protocol. An adequate fidelity will be considered when ≥ 60 % of the program is provided, moderate from 40 - 60% and low <40 %.

Acceptability: a questionnaire will be applied to children, parents, and implementers to qualify the program and materials in a scale from 0 to 10. In addition, they will be interviewed about the perceived obtained benefits or barriers. Good acceptance will be considered from 10 - 8 points, moderate acceptance from 8 - 5 points, and poor acceptance ≤ 5 points.

Secondary outcomes

BMI Z-score: Calculated using the weight, height, sex, and date of birth of the children, using the "Anthro Plus" v.1.0.4 software, which uses the WHO reference tables (World Health Organization, 2007).

Body fat: Body composition will be obtained using electrical bioimpedance RJL Quantum II (Clinton Township, Michigan) following the methodology recommended by the manufacturer (RJL Systems, Inc. 2013). With the data obtained (resistance and reactance values in ohms), an equation designed to estimate fat-free mass in Mexican children will be used (Ramírez *et al*., 2012). The fat mass will be obtained by difference; by subtracting the kilograms of fat-free mass from the total kilograms of the subject and its percentage will be calculated later.

Waist circumference: The measurement will be taken at the umbilical scar level, with the participant standing, using a metallic anthropometric tape (Lufkin Executive Thineline W606PMM). Participants will be asked to indicate their umbilical scar location and to inhale and exhale (Marfell *et al*., 2006).

Relative fat mass: Estimated using a formula validated in American children aged 8 to 14 years. Data of waist circumference (cm), height (cm), and sex will be included in the formula to obtain the value (Woolcott *et al*., 2019).

Food consumption: Some questions from the semi-quantitative food frequency questionnaire (FFQ) from the National Health and Nutrition Survey (ENSANUT) will be used. We will ask about the frequency of consumption of ultra-processed foods (sweet beverages, fried foods, cakes, and cookies) and healthy foods (fruits, vegetables, and water) in the previous 7 days. For each food, the size of the portion consumed will be asked, considering an average portion established in the FFQ (Shamah-Levy *et al*., 2020).

Physical activity and sedentary behavior: The questions on physical activity and a sedentary lifestyle will be used from "The Health Behavior in School-Age Children" (HBSC) questionnaire. The questionnaire includes the days and time (intensity, duration, and frequency) dedicated to physical activity in the last 7 days. In addition, the questionnaire includes a section of time dedicated to sedentary activities during the week and on the weekend (Currie *et al*., 2014).

Quality of life: The PedsQL™ questionnaire (Pediatric Quality of Life Inventory) will be used. This generic health status instrument assesses the frequency of problems experienced in the past month in the following aspects: physical, emotional, social, and school functioning. Responses are on a 5-point Likert scale (never = 0 to always = 4). The score for each item is inverted and converted to a linear scale from 0 to 100, with a higher score indicating a better quality of life (Varni *et al*., 2001).

Nutrition knowledge: A questionnaire designed by the study team will be used to assess knowledge on nutrition issues. It consists of 32 questions about nutrition and health. Knowledge will be evaluated on a scale from 0 to 10, with the more correct answers, the higher the score.

Statistical Analysis

The difference in baseline characteristics between groups will be analyzed using an ANOVA analysis for the quantitative variables with Fisher LSD tests for post-hoc analyses and a chi-square test for the categorical outcomes. If there are significant differences between groups at baseline, an adjustment will be made in the follow-up analysis; otherwise, adjustment for additional relevant covariates will be considered based on previous works to account for the possibility of residual confounding. To evaluate the differences between groups in feasibility and the change of the BMI Z-score, body fat, and secondary variables at the beginning and at the end of the intervention, a mixed effects lineal model will be used to evaluate the effect between groups and within groups considering individual changes amongst subjects as a random intercept in the model. All analyses will be performed by intention-to-treat (ITT). If follow-up data is not obtained for any reason or subjects were excluded due to a protocol violation, only their baseline measurement will be considered within the model and a sensitivity analysis will be conducted to assess the impact of their removal into the model estimates. The R studio software will be used to perform the analysis (Allaire, 2011).

Data management

Data obtained through physical documents will be transferred to a digital database. Two people from the study team will be in charge of entering the data through double verification to avoid errors. Physical documents will be kept at Universidad de Sonora. Only the study team will have access to the physical and digital documents for study purposes. The database will not obtain identifiable data (complete names, telephone numbers, etc.), only codes will be used.

Data Monitoring

This study does not have an external monitoring committee. The progress of the work will be presented to the group of researchers participating in the study. Likewise, once the final evaluations of the program are completed, the results will be presented to the Research Ethics Committee of the Nursing Department of the Universidad de Sonora, the Ministry of Education and Culture of Sonora [Secretaría de Educación y Cultura (SEC) and to directors and schoolteachers. It is intended to publish the results of the study in a peer-reviewed journal.

Risks

None of the measurements or activities in the study have a negative effect on the participant's health, neither in the short nor in the long term. The physical activity sessions are designed for children, with a moderate intensity level, which minimizes any risk of injury.

DISCUSSION

Strengths

One of the advantages of the present study is the cluster randomized controlled trial design. This design minimizes the risk of contamination between the groups of the study by having different schools. Second, a pilot study will be conducted to test feasibility before conducting a larger study.

Finally, the study team has previous experience in the Planet Nutrition program.

Limitations

Due to the nature of the study, the intervention will not be blinded. Moreover, the lifestyle variables will be self-reported and not evaluated through objective measurements, which increases the risk of bias.

CONCLUSION

If successful, we expect that the program could be a model for obesity prevention with a high potential for dissemination in Mexican schools.

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CONFLICTS OF INTEREST

The authors report having no potential conflicts of interest.

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