Date: 10/06/2021

Official Title:

" Evaluation of a 4-month Online Lifestyle Intervention on the BMI Z-score of Mexican School Children During COVID-19 Pandemic: Randomized Controlled Pilot Trial"

NCT:

NCT04772859

Study Protocol Available[1]**:** Ramírez-Rivera DL, Martínez-Contreras R, Ruelas AL, Henry-Mejía G, Quizán-Plata T,Esparza-Romero J, Haby MM, Díaz-Zavala RG. Efecto de una intervención en línea de cambio en el estilo de vida sobre el puntaje zIMC de escolares mexicanos: protocolo de ensayo controlado aleatorizado piloto cegado a evaluadores durante la pandemia por COVID-19. Rev Esp Nutr Hum Diet. 2021; 25 (Supl. 2): e1320. doi: 10.14306/renhyd.25.S2.1320

ABSTRACT

Introduction: School closures due to the COVID-19 pandemic represent a risk factor for the development of childhood obesity, due to the increase in unhealthy behaviors. Online lifestyle interventions in schoolchildren could help to mitigate this problem. However, to our knowledge, no randomized controlled trials have been conducted to prevent obesity in schoolchildren during COVID-19. The aim of this study is to evaluate the effect of a 4-month online lifestyle intervention on the BMI Z-score of Mexican schoolchildren during the COVID-19 pandemic in an intervention group compared to a control group. **Material and Methods:** This is a protocol for an outcome assessor-blinded pilot randomized controlled trial. Schoolchildren from a public elementary school in Hermosillo, Sonora, Mexico will be invited to participate. Participants will be randomized to an intervention group (online lifestyle intervention) or a control group. The intervention will include online sessions of nutrition education and physical activity (60 minutes per session, 30 minutes for nutrition education and

30 minutes for physical activity) and nutrition information for parents. The control group will receive a digital brochure with nutrition recommendations at the beginning of the study and access to the program materials at the end of the study. The measurements will be performed at baseline and at 4 months. The primary outcome will be the BMI Z- score. Secondary outcomes: waist circumference, body fat percentage, nutrition knowledge, lifestyle parameters, participation, retention and acceptance of the intervention. The changes on the outcomes will be analyzed using an intention to treat analysis. The protocol was approved by the Research Ethics Committee of the University of Sonora Nursing Department and registered in Clinical Trials. **Conclusion:** To our knowledge, the study will provide the first evidence of the evaluation of online interventions for the prevention of obesity in schoolchildren derived from a randomized controlled trial, which could be crucial in the fight against childhood obesity.

INTRODUCTION

At the beginning of the year 2020, the World Health Organization declared the start of the COVID-19 pandemic. This is an infectious disease caused by the SARS-CoV-2 virus, which can cause mild symptoms to severe respiratory disease.[2] One of the strategies to mitigate infections has been social distancing and home confinement.[3] This, among other consequences, has caused the closure of schools in different countries, affecting millions of students in the world.[4] In Latin American and Caribbean countries, at the beginning of the pandemic it was reported that 95% of schools were closed due to COVID-19, affecting 156 million students of all levels.[5]

The schools closure can have consequences on the education and lifestyle of children and adolescents.[6] It has been seen that when children are not in school (unstructured days), they gain more weight, compared to school days. [7,8] This, due to an increase in the adoption of unhealthy behaviors, such as physical inactivity, more screen time, irregular sleep patterns and a high consumption of ultra-processed foods.[9] Similarly, during the COVID-19 lockdown, unhealthy behaviors in

children have been reported. In a study with children and adolescents from Italy, it was found that during confinement they increased an average of 4.85 h/day in front of the screen and 0.65 h/day of sleep. On the other hand, the time of physical activity decreased by 2.35 h/week.[10] In another study carried out in different countries in Europe and Latin America, it was found that children and adolescents increased their consumption of sweet beverages and fried and sweet foods, during confinement.[11]

This is concerning, because about 340 million children and adolescents worldwide are overweight.[12] In Mexico, 35.5% of schoolchildren have overweight or obesity [13], and this has both short- and long-term health consequences.[14,15]

Different agencies have proposed lines of action to prevent child malnutrition during the pandemic. One of them is about the implementation of behavior change strategies to promote healthy eating and physical activity in children, using mass communication or technological resources.[16]

One option for providing health interventions is through the use of digital media. The "eHealth" consists of the use of Information and Communication Technologies (ICT) to promote health.[17] The internet is one of the most used technologies by children and adolescents. It has been estimated that one in three children around the world uses the Internet for different entertainment and learning activities.[18,19] This provides the opportunity to use interactive communication methods for the prevention of childhood obesity through the promotion of healthy behaviors.[20]

Hamel & Robbins carried out a systematic review, of 15 studies of web based programs with children and adolescents with different change behavior theories frameworks. It was found that most of these programs were effective in modifying healthy eating behaviors such as: increased consumption of fruits, vegetables, and decreased calories and fat. Likewise, positive results in BMI and % body fat.[21]

These types of online interventions could represent a key strategy to prevent the development of childhood obesity during the current global health crisis. To our knowledge, to date there is no randomized clinical trial evaluating this type of program during the COVID-19 pandemic.

The present research group previously developed and evaluated a lifestyle change program focused on obesity prevention in Mexican schoolchildren in a face-to-face format, where positive results were obtained.[22] Given the current situation due to COVID-19, this program was adapted to an online format to evaluate its effect through a pilot randomized controlled trial.

Explanation for the choice of comparators

The control group will be of children from the same public school as the children in the intervention group. The risk of contamination is reduced by not having face-to-face classes, but it is not completely eliminated, since there may be participants who take classes in the same group and interact online. Even so, the results will be valid if significant differences between groups are observed, as we observed in a previous study, because the previous situation would reduce the effect of the intervention.

OBJECTIVES

Primary objective

- To evaluate the effect of an online lifestyle intervention on the BMI Z-score of Mexican schoolchildren at 4 months during the COVID-19 pandemic in the intervention group compared to a control group.

Secondary objectives

- To evaluate the effect of an online lifestyle change intervention on waist circumference, body fat, physical activity and sedentary behaviors, food consumption, nutrition knowledge and quality of life of Mexican schoolchildren at 4 months during the COVID-19 pandemic in the intervention group compared to a control group.

- To evaluate the effect of an online lifestyle intervention on the retention, participation and acceptance of Mexican schoolchildren at 4 months during the COVID-19 pandemic in the intervention group.

MATERIAL AND METHODS

Study desgin

This is a pilot randomized controlled trial blinded to assessors, with 4-month follow-up. It is a pilot study, because it we want to evaluate the effect and feasibility of the online intervention, to later carry out a definitive study considering an adequate sample size. The study will consist of two parallel arms, of superiority and with 1:1 allocation ratio.

To carry out this protocol, the SPIRIT 2013 guidewas followed.[23]. The protocol was approved by the Research Ethics Committee of the Nursind Department of the University of Sonora (CEI-ENFERMERIA-EPM-003-2020) and registered on the Clinical.trials.gov platform (NCT04772859).

Participants

Children from a public elementary school in Hermosillo, Sonora will be invited to participate in the study. It is worth mentioning that this public school is not representative of all the schools in Hermosillo, Sonora. Hermosillo is a city of about 884,273 inhabitants and around of 392 public elementary schools. It is located in the state of Sonora, in northwestern Mexico. Because the program is entirely online, students who agree to participate will take the intervention from home.

Sample size

No studies of online lifestyle interventions to prevent obesity in schoolchildren during the pandemic were found to obtain the effect size and standard deviation needed to estimate the study sample size. So, we decided that it would be a pilot study of at least 50 participants and no more than 70. This was decided considering our logistical capacity, which implies measuring the response variables at home in a period of 2 weeks, in addition to being able to provide intervention, among other things. The invitation will be made to all students from fourth to sixth grade of a public school in Hermosillo Sonora.

Eligibility criteria

Sign the consent and informed assent and complete the anthropometric measurements and lifestyle questionnaires.

Inclusion criteria

- 4th, 5th and 6th grade students from the participating elementary school.
- Have access to the internet.
- Have an electronic device (eg computer, laptop, tablet or smartphone).
- Nutritional status: normal weight, overweight or obesity.

Exlusion criteria

- Have a medical condition that affects body weight.
- Taking medication that affects body weight.
- Take another intervention that affects body weight.
- Have a condition that prevents physical activity.
- Withdraw informed consent or assent.
- Have a sibling participating in the study.

Implementers

The lifestyle intervention will be implemented by a Nutritionist and two interns from the Bachelor's Degree in Physical Culture and Sports from the study team. In

addition, there will be the support of interns from the Nutritional Sciences Bachelor of the University of Sonora.

Interventions of the study

Online lifestyle intervention

The intervention will be based on the "Planet Nutrition" program. This program has a handbook that was previously developed by our study group and includes nutrition, physical activity, health, and behavior change strategies (Table.1). The program will last 4 months (March to July 2021). The components of the program will be: online nutrition education sessions, physical activity and family participation. It is worth mentioning that the nutrition education and physical activity sessions will be offered in the same 1-hour class. The first 30 minutes will be for nutrition education and the remaining 30 minutes for physical activity or games that involve movement.

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 into practice the learning
26	How to prepare a salad
27	Learning to prepare healthy desserts
28	How to be active in summer holidays
29	Healthy nutrition in summer holidays
30	Balance christmas
31	Planet Nutrition challenge

Nutritional education sessions: Classes will be 3 days a week for 30 minutes each. Live sessions will be provided through the Zoom application, which is a platform for video conferencing. A code and password will be provided to access the private meeting. In addition, a web page of the study team (www.salud-nutricional.com) will be used to upload the topics that are seen in classes and activities for the participants. Presentations based on the “Planeta Nutrition” program handbook will be used. In addition, depending on the session, videos and

infographics will be made. In each class it is intended to take a little time to play a game, dynamic or workshop to reinforce learning**.**

The program will center on establishing health-related goals such as increasing consumption of fruits and vegetables, increasing physical activity time, decreasing hours spent in front of a screen, and reducing consumption of sweetened beverages. The program also will include the use of self-monitoring and positive reinforcement.

Physical activity sessions: Classes will be implemented 3 days a week for 30 minutes each. Children will work on developing different skills such as: flexibility, strength, elasticity and resistance. The Zoom digital platform will be used for the online (live) sessions. The classes will be recorded, in case the children want to do a class later.

Parent's participation: Parents who agree to participate in the program will be given a user to access a web page (www.salud-nutricional.com), where children's activities will be uploaded. This will be used to upload nutrition information, parenting activities, and study questionnaires. A private Facebook group will be created to upload teaching material (videos, infographics, messages and images) on a weekly basis. The difference between using the website and Facebook is that on the page the participants will be able to have the information ordered, upload their activities and study questionnaires. The topics addressed each week will be the same as those seen with the children in the nutrition sessions. On Facebook, they will have spaces for comments, questions, feedback and social support.

Control group: The control group will receive general nutrition recommendations at the beginning of the program, based on the Nutrition and Physical Activity Guidelines in the Context of Overweight and Obesity in Mexican Population.[24] A digital brochure will be sent in online format to the mail or through the WhatsApp application to parents. Upon completion of the study, they will be offered access to the materials from all the onlie lifestyle sessions, as well as physical activity videos for children recorded by the physical activity team.

Outcomes

The primary outcome is the change of the BMI Z-score from baseline to 4 months between the intervention group and the control group. The change in BMI Z-score for each individual will be obtained by subtracting the BMI Z-score value at 4 months minus the baseline value. The difference between groups will be obtained by subtracting the mean of the change in the intervention group minus that of the control.

Secondary outcomes will include the differences in waist circumference, body fat and relative fat mass, physical activity and sedentary lifestyle, quality of life, participation, attendance and nutrition knowledge. The categorical variables such as: food consumption and acceptance, will be evaluated with differences in proportions.

Recruitment

To invite the participants, school directors will first be contacted to invite them, inform them about the objectives and activities of the intervention. Fourth, fifth and sixth grade students from a public elementary school in Hermosillo, Sonora, Mexico will be invited to participate. It will seek to have a space in the students' online school classes, where parents will be invited to attend. A small presentation will be made with the invitation, objectives and activities of the intervention. During the same meeting, they will be sent via chat the link to a web page where they can find the the consent and informed assent and a personal data questionnaire to evaluate inclusion and exclusion criteria. They must be read and signed by parents and children online. Children may participate, even if the parents decide not to get involved in their part of the intervention.

Randomization

The measurements of the study will be carried out in a period of 2 weeks. Once the measurements are completed, the participants who meet the inclusion/exclusion criteria will be randomized to one of two groups: the “online lifestyle intervention” group or the control group. An independent person of the recruitment and

intervention of the study will receive a database, only with the codes and the basic variables of the study (BMI Z-score, sex and age) to perform the allocation of the participants. This will be based on a random block sequence, stratified by BMI Z-score and sex, with an allocation ratio of 1:1. The random number sequence will be generated using the randomization software available on the website: https://randomizer.org/. Since the assignment will be made in a single moment and without the knowledge of the participants, its concealment will be guaranteed. Participants will be explicitly informed to the assigned group.

Outcome measures

Study measurements will be performed at baseline and at 4 months. The primary outcome (BMI Z-score), waist circumference and triceps skinfold, will be measured by a person blinded to the allocation group and trained in the measurement of these variables. These anthropometric measurements will be carried out at the participants' homes in an outdoor area. Hygiene measures and recommendations will be followed to reduce the risks of contagion (use of NK95 face masks, plastic face shield, surgical suit, gloves, etc. short exposure time and disinfection of materials). Measurements will be made in less than 15 minutes. Before the home visit, a questionnaire will be sent to screen for possible symptoms related to COVID-19. Lifestyle questionnaires will be conducted online.

Primary outcome

- **BMI Z-score:** The measurement will be obtained using the sex, age, weight (kg) and height (m) of the participants.The height and weight will be combined (kg/m2) to obtain the BMI Z- score, expressed in units of standard deviation. Using The WHO Anthro Plus software.[25]

Secondary outcomes

- **Weight:** To obtain the weight (kg), a TANITA SC-240 will be used. The measurement will be used to obtain the BMI Z-score.[26]

- **Height**: The SECA 213 stadiometer will be used, following the Frankfurt plan. This measure will be used to obtain the BMI Z-score.[26]
- **Waist circumference:** A Lufkin metallic anthropometric tape will be used. The umbilical scar will be taken as reference.[26]
- **Body fat:** It will be estimated with the measurement of the tricipital skinfold, using a formula validated for Mexican children. To take the tricipital skinfold, the ISAK methodology will be followed.[27,28]
- **Relative fat mass:** This is an estimator of total body fat. A formula carried out with children (8-14 years) will be used where the data of waist circumference (cm), height and sex (0 boys and 1 girls) will be needed.[29]
- **Nutrition knowledge:** A questionnaire designed by the study team will be used to assess knowledge on nutrition. It consists of 32 questions on nutrition and health.
- **Food consumption:** Some questions from the semi-quantitative food frequency questionnaire from the National Health and Nutrition Survey were used.[30] We asked 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 was asked, considering an average portion established in the FFQ.
- **Physical activity and sedentary activities**: The physical activity and sedentary lifestyle part of the questionnaire "The Health Behavior in School-aged Children" (HBSC) was used, which is a validated lifestyle questionnaire for school-age children.[31] It consists of 9 questions, 5 questions related to the time and frequency of physical activity and 4 to sedentary activities.
- **Nutrition knowledge:** a questionnaire designed by the research team (not validated) was used to assess the knowledge on nutrition and health. It consists of 32 questions with multiple choice answers. The results were evaluated on a scale from 0 to 10, the more correct answers, the greater score.

- **Quality of life:** The PedsQL™ (Pediatric Quality of Life Inventory) questionnaire was used, which was designed to assess quality of life aspects in both healthy pediatric patients (2 to 18 years old) and those with chronic diseases. The questionnaire consists of 23 questions about physical, emotional, social and school functioning. The responses are on a 5-point likert scale (never = 0 to always = 4). The score for each item is reversed and transformed to a linear scale of 0–100, with a higher score indicating a better quality of life.[32]
- **Retention:** It will be evaluated with the percentage of participants (intervention and control group) who complete the intervention and the measurements at 4 months.
- **Participation or attendance of schoolchildren:** It will be evaluated with the percentage of attended intervention sessions and with the percentage of participants who attended all sessions.
- **Parent's participation:** At the end of the study, parents will be asked through an online questionnaire, the number of materials consulted from the program and will be reported as a percentage.
- **Acceptance.** Acceptability will be obtained with a questionnaire applied to children and parents to qualify the intervention, materials and benefits obtained with the intervention.
- **Personal information.** The first step for the screening of the participants consists of an online questionnaire of personal data. This will be sent at the time of the invitation to the program. Personal data of the child, internet access and electronic device, if they have a disease, if they take medications or perform extra interventions that may affect body weight will be asked. In addition, the email and education leve lof the parents will be asked.

Withdrawal of participants

Participants may withdraw from the study at any time they wish, being able to inform the reason or not.

Statistical Analysis

The normality of the data will be evaluated with the Shapiro Wilk test. Data will be presented as mean and standard deviation (mean ± SD) or median and interquartile ranges according to their distribution. An independent samples t-test or Mann-Whitney U test will be used to analyze the difference in BMI Z-score and changes in secondary outcomes between groups. A chi-square test will be used to make comparisons on categorical variables. Two-tailed tests with $p \leq 0.05$ will be used as the criterion for statistical significance.

Data will be analyzed with an intention-to-treat analysis. If participants decide to withdraw from the intervention, they will be asked if the measurement at 4 months can be obtained to have at least the primary outcome for inclusion in the intention-to-treat analysis. If data is not obtained for any reason or subjects were excluded due to a protocol violation, they will be replaced by their baseline measurement.

Results will focus on change in the primary study variable (BMI Z-score), while changes in secondary variables and sub-analyses (sex and BMI: normal, overweight/obese) will be considered exploratory only. For data analysis, NCSS version 10 software (Number Cruncher Statistical System for Windows, Kaysville, UT, USA) will be used.

Confidentiality

Identifiable information and will be kept confidential. Each participant will be assigned a code, therefore, their identifiable information will appear with that code and not with names. Only the physical files will keep the names, which will be kept by the principal investigator of the study, in a safe place. Only the study team may have access to the database, for their purposes.

Declaration of interest

The authors did not report any potential conflicts of interest.

REFERENCES

1. Ramírez-Rivera DL, Martínez-Contreras T, Henry-Mejia G, et al. Efecto de una intervención en línea de cambio en el estilo de vida sobre el puntaje zIMC de escolares mexicanos: protocolo de ensayo controlado aleatorizado piloto cegado a evaluadores durante la pandemia por COVID-19. *Rev Esp Nutr Hum Diet*. 2021;25(2). doi:10.14306/renhyd.25.S2.1320

2. Cucinotta D, Vanelli M. WHO declares COVID-19 a pandemic. *Acta Biomed*. 2020;91(1):157-160. doi:10.23750/abm.v91i1.9397

3. Lotfi M, Hamblin MR, Rezaei N. COVID-19: Transmission, prevention, and potential therapeutic opportunities. *Clin Chim Acta*. 2020;508(January):254-266. doi:10.1016/j.cca.2020.05.044

4. UNESCO. COVID-19 Impact on Education. Published 2020. Accessed September 24, 2020. https://en.unesco.org/covid19/educationresponse

5. UNICEF México. COVID-19: Más del 95 por ciento de niños y niñas está fuera de las escuelas de América Latina y el Caribe. Published 2020. Accessed October 26, 2020. https://www.unicef.org/mexico/comunicados-prensa/covid-19-más-del-95-por-ciento-de-niños-y-niñas-está-fuera-de-las-escuelas-de

6. UNESCO. Adverse consequences of school closures. Published 2020. Accessed September 24, 2020. https://en.unesco.org/covid19/educationresponse/consequences

7. Hippel PT Von, Workman J. From kindergarten through second grade, U.S. children's obesity prevalence grows only during summer vacations. *Obes J*. 2016;24(11):2296-2300. doi:10.1002/oby.21613

8. Díaz-Zavala RG, Castro-Cantú MF, Valencia ME, Álvarez-Hernández G, Haby MM, Esparza-Romero J. Effect of the holiday season on weight gain : A narrative review. *J Obes*. 2017;2017. doi:10.1155/2017/2085136

9. Brazendale K, Beets MW, Weaver RG, et al. Understanding differences

between summer vs. school obesogenic behaviors of children: The structured days hypothesis. *Int J Behav Nutr Phys Act*. 2017;14(1):1-14. doi:10.1186/s12966-017-0555-2

10. Pietrobelli A, Pecoraro L, Ferruzzi A, et al. Effects of COVID-19 lockdown on lifestyle behaviors in children with obesity living in Verona, Italy: a longitudinal study. *Obesity*. 2020;28(8):1382-1385. doi:10.1002/oby.22861

11. Ruiz-Roso MB, Padilha P de C, Mantilla-Escalante DC, et al. Covid-19 confinement and changes of adolescent's dietary trends in Italy, Spain, Chile, Colombia and Brazil. *Nutrients*. 2020;12(6):1-18. doi:10.3390/nu12061807

12. World Health Organization (WHO). Obesity and Overweight. Published 2018. Accessed October 10, 2019. https://www.who.int/news-room/fact-sheets/detail/obesity-and-overweight

13. Shamah-Levy T, Vielma-Orozco E, Heredia-Hernández O, Romero-Martínez M, Mojica-Cuevas J C-NL, Santaella-Castell JA R-DJ. *Encuesta Nacional de Salud y Nutrición 2018-19: Resultados Nacionales.*; 2020. Accessed September 5, 2020. https://ensanut.insp.mx/encuestas/ensanut2018/informes.php

14. Sharma V, Coleman S, Nixon J, et al. A systematic review and meta - analysis estimating the population prevalence of comorbidities in children and adolescents aged 5 to 18 years. *Obes Rev*. 2019;(April):1341-1349. doi:10.1111/obr.12904

15. Park MH, Falconer C, Viner RM, Kinra S. The impact of childhood obesity on morbidity and mortality in adulthood: a systematic review. *Obes Rev*. 2012;(5). doi:10.1111/j.1467-789X.2012.01015.x

16. Organización de las Naciones Unidad para la Alimentación y la Agricultura. *Prevención de Mala Nutrición En Niñas y Niños En México Ante La Pandemia de COVID-19. Recomendaciones Dirigidas a Tomadores de Decisiones*.; 2020. https://www.unicef.org/mexico/media/4286/file/Posicionamiento Conjunto

Nutrición.pdf

17. WHO. Global diffusion of eHealth: Making universal health coverage achievablele. Published 2016. https://www.who.int/goe/publications/global_diffusion/en/

18. UNICEF. *Children in a Digital World*.; 2017. https://www.unicef.org/publications/files/SOWC_2017_ENG_WEB.pdf

19. Mehmet B, Mustafa B. Examining the internet use aim and internet parental style of primary school students in terms of various variables. *Croat J Educ*. 2013;16(October 2014):745-778.

20. Verrotti A, Penta L, Zenzeri L, Agostinelli S, Feo P De. Childhood obesity : prevention and strategies of intervention . A systematic review of school-based interventions in primary schools. *J Endocrinol Invest*. Published online 2014. doi:10.1007/s40618-014-0153-y

21. Hamel LM, Robbins LB. Computer- and web-based interventions to promote healthy eating among children and adolescents: a systematic review. *J Adv Nurs*. 2012;69(1):16-30. doi:doi: 10.1111/j.1365-2648.2012.06086.x.

22. Ramírez-Rivera DL, Villegas-Valle RC, Martínez-Contreras T, et al. Preliminary results of the planet nutrition program on obesity parameters in Mexican schoolchildren: Pilot single-school randomized controlled trial. *Int J Environ Res Public Health*. 2021;18(2):1-15. doi:10.3390/ijerph18020790

23. Chan AW, Tetzlaff JM, Gøtzsche PC, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. *BMJ*. 2013;346:1-42. doi:10.1136/bmj.e7586

24. Bonvecchio A, Fernández AC, Plazas M, Kaufer-Horwitz M, Pérez AB, Rivera JÁ. *Guías Alimentarias y de Actividad Física En Contexto de Sobrepeso y Obesidad En La Población Mexicana*. Primera ed. Intersistemas; 2015.

25. World Health Organization (WHO). Growth reference 5-19 years. Accessed

October 1, 2019. https://www.who.int/growthref/en/

26. Gibson R. *Principles of Nutritional Assessment*. First edit. Oxford University Press; 1990.

27. Ramírez E, Valencia ME, Bourges H, et al. Body composition prediction equations based on deuterium oxide dilution method in Mexican children : a national study. *Eur J Clin Nutr*. 2012;(February):1099-1103. doi:10.1038/ejcn.2012.89

28. Marfell-Jones M, Olds T, Stewart A, Carter L. *International Standards for Anthropometric Assessment*. First edit. (ISAK, ed.).; 2006.

29. Woolcott OO, Bergman RN. Relative fat mass as an estimator of whole-body fat percentage among children and adolescents: a cross-sectional study using NHANES. *Sci Rep*. 2019;9(1):1-14. doi:10.1038/s41598-019-51701-z

30. Shamah-Levy T, Cuevas-Nasu L, Rivera-Dommarco J, Hernández-Ávila M. *Encuesta Nacional de Salud y Nutrición de Medio Camino 2016. (ENSANUT MC 2016)*.; 2016. gob.mx/salud/documentos/encuesta-nacional-de-salud-y-nutricion-de-medio-camino-2016

31. Currie C, Inchley J, Molcho M, Lenzi M, Veselska Z, Wild F. *Health Behaviour in School-Aged Children (HBSC) Study Protocol: Background , Methodology and Mandatory Items for the 2009/10 Survey*.; 2010. http://www.hbsc.org

32. Varni JW, Seid M, Kurtin PS. PedsQL™ 4.0: reliability and validity of the Pediatric Quality of Life Inventory™ Version 4.0 generic core scales in healthy and patient populations. *Med Care*. 2001;39(8):800-812. doi:10.1097/00005650-200108000-00006