National Autonomous University of Mexico

Master's and Doctoral Program in Medical, Dental and Health Sciences

FIELD OF KNOWLEDGE

Medical Sciences

Effectiveness of the numerous educational strategy interventions seeking to increase the percentage of water consumed among early elementary school students with a 1-year follow up

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GENERAL INDEX

1.0 SUMMARY

Introduction. The incidences of overweight and obesity among children in Mexico have increased at alarming rates over the past three decades, partially because of the increased intake of sugary beverages that have a high caloric content and low nutritional status. The Mexican government identified the promotion of water consumption as a major strategy to reduce the energy density of diets and thus at least partially prevent the problems of overweight, obesity, and other diseases associated with the excessive intake of sugary beverages. Therefore, the primary objective of the National Agreement for Nutritional Health (ANSA, in Spanish) sought to increase water intake and discourage the consumption of sugary beverages among the population. Schools are optimal locations to conduct healthy lifestyle intervention programs aimed at children to increase water consumption and consequently help reduce childhood obesity. To this end, the education strategy "I Prefer Plain Water" was designed. This strategy proved to effectively increase water consumption and reduce the consumption of sugary beverages in the short term; however, its ability to sustain the same pattern with regard to overall liquid consumption has not been established over the long term.

Objective. The current project seeks to evaluate the effectiveness of numerous educational strategy interventions to increase the percentage of water consumed among early elementary school students over a 1-year period.

Material and methods. A community intervention trial will be conducted at four public elementary schools of the Coyoacán Delegation in Mexico City. It will include healthy first graders during the 2017-2018 school year whose parents agree to participate through verbal informed consent and a signed privacy notice. These parents will complete a baseline 3-day beverage record (two weekdays and one weekend day). The four schools will be assigned to one of three groups: Group I will receive the educational strategy during the first grade; Group II will receive it during first and second grades; and Group III will receive it during the first, second, and third grades. All schools will have water dispensers inside the classrooms, and the children will receive a reusable 600-mL bottle so they are able to consume water on demand throughout the day. A second record of beverage consumption will be obtained by completing multiple interventions within each group, and a third record will be completed 1 year later.

Statistical analyses. Descriptive statistics will be used to summarize the numerical variables with medians, minimums, and maximums. The Kruskal-Wallis test will be applied to compare the baseline intake of beverages among the three groups. In each group, baseline water consumption will be compared with that 1 year after the end of the interventions using the Wilcoxon test.

Ethical Considerations. This research is considered to have minimal risk; thus, the Research Ethics Committee will be asked to approve a request for verbal informed consent, and the parents will be asked to sign a privacy notice. The general health law for research in Mexico will be respected, and ethical clinical practices will be followed. The authors have no conflicts of interest to declare.

2.0 RESEARCH QUESTION

Does the number of educational strategy interventions aimed at early elementary school children increase the percentage of water consumed after a 1-year follow up?

P Public early elementary school students
I Educational strategy
C Number of educational interventions
O Increase in the percentage of water consumed over the long term

3.0 INTRODUCTION

In Mexico, the prevalence of overweight and obesity has increased among children at an alarming rate over the past three decades, partially because of the increased intake of sugary beverages that have high caloric content and low nutritional status. The major types of beverages that provide the most energy intake are soft drinks, beverages made from fruit juice (with or without added sugar), flavored water, and natural juices added with sugar and whole milk.

Energy consumption from these beverages doubled for all age groups from 1999 to 2012; when added to the energy obtained from food in the diet, these drinks contributed to an excessive intake of energy linked to the development of obesity.

The Mexican government identified the promotion of water consumption as a major strategy to reduce the energy density of the diet and thus at least partially prevent the problems of overweight, obesity, and other diseases associated with the excessive intake of sugary beverages. Therefore, the National Agreement for Nutritional Health (ANSA, in Spanish) considers increasing the intake of water and discouraging the consumption of sugary beverages as priorities for this population.

Given the evidence that school provides an optimal environment to conduct nutritional promotion programs that encourage the practice of healthy lifestyles that include the promotion of water consumption, a need arose to create such an educational strategy. Ogali (Nutrition Consulting Company: www.ogali.com) designed the educational strategy “I Prefer Plain Water”, and it demonstrated short-term effectiveness by increasing the consumption of water and reducing the consumption of sugary beverages and soft drinks. However, it is unknown whether these observed changes are sustainable throughout early elementary education, a period that education specialists have established as essential to forming healthy habits for life.

Evaluating the long-term (1-year) effectiveness of this program is necessary because the knowledge gained will help determine the number of interventions that children should receive to maintain a healthy water-consumption pattern to establish public health policies that allow children to maintain a healthy lifestyle that affects their quality of life.

4.0 THEORETICAL FRAMEWORK

4.1 World Health Organization (WHO) Global Action Plan for the Prevention and Control of Non-communicable Diseases

From January 28 to February 1, 2002, a convention assembling experts in food, nutrition, and the prevention of chronic diseases was held in Geneva that included the participation of the WHO and the Food and Agriculture Organization of the United Nations (FAO). This convention continued the work of a WHO study group on diet, nutrition, and the prevention of non-communicable diseases that met in 1989 to make recommendations for the prevention of chronic diseases and the reduction of their effects (1).

The convention recognized that the growing epidemic of chronic diseases that affects both developed and developing countries is related to changes in dietary habits and lifestyles. Participants examined the considerable scientific progress made in different areas. For example, better epidemiological data now exist for determining risk factors in certain areas, and the results from controlled clinical trials are available. The mechanisms that lead to chronic diseases are clearer, and interventions that reduce risk exist. Furthermore, specific food components that increase the likelihoods of these diseases and appropriate interventions to modify their effects have been identified.

Consultations provided opportunities for the WHO and FAO to use the latest available scientific data and update their recommendations of action to governments, international agencies, and relevant public and private sector partners. The overall objective of these recommendations was to implement more effective and sustainable policies and strategies to address the growing public health challenges related to diet and health.

To achieve the best chronic disease prevention results, the strategies and policies applied must fully recognize the paramount relevance of diet, nutrition, and physical activity. This briefing calls for a change in the conceptual framework.

Diet and nutrition are important to promote and preserve good health throughout life. Its role as determinant of chronic non-communicable diseases is well established, making it a key component of prevention activities (1).

A high intake of free sugars undermines the nutritional quality of the diet because it provides a considerable amount of energy but lacks certain nutrients. The consultation considered that the restriction of free sugars most likely also contributes to reducing the risk of overweight. The working group noted the following:

Free sugars. Drinks abundant in free sugars increase total energy intake by reducing appetite control. Thus, the compensatory reduction of food intake is lower after consuming sugary beverages than that when other foods of equivalent energy content are consumed (2,3,4,5). A recent randomized clinical trial showed that soft drinks rich in free sugars are associated with a higher consumption of energy and a progressive increase in

body weight compared with calorie-free beverages with artificial sweeteners (6). Children who consume many soft drinks rich in free sugars are at greater risks of overweight and obesity (5). The consultation admitted that the goal of the population consuming less than 10% of its total energy in the form of free sugars would be difficult to meet. However, studies that show that free sugars do not influence excess weight have limitations. The CARMEN study was a randomized multicenter trial on the management of carbohydrate ratios in European national diets that analyzed the effects of altering the ratio between fats and carbohydrates as well as the relationship between simple carbohydrates and complex carbohydrates on the body weights and blood lipid levels of people with obesity. A greater weight reduction was associated with diets rich in complex carbohydrates than those rich in simple carbohydrates.

More information is available on the effects of the school environment on nutritional knowledge, dietary guidelines, and physical activity at school as well as sedentary habits at home. Some studies (7) have shown that school-based interventions affect the prevention of obesity; however, additional studies are clearly needed to provide more data about both aspects.

High intake of sugary drinks (causal factor). Low-fat diets are proportionally richer in carbohydrates (with varying amounts of sugars) and protect against harmful weight gain; however, a high intake of free sugars in beverages most likely promotes weight gain. The physiological effects of caloric intake on satiety and the satiation process appear to differ depending on the energy contained in solid foods or liquids. Perhaps because of reduced gastric distension and greater speed of transit, the energy contained in liquids is poorly "detected" by the body, and the subsequent ingestion of solid food is not adjusted for properly (8). Data from cross-sectional and longitudinal studies support this assertion (9,10,11). The high and increasing intake of sugary beverages among children in many countries is worrying. Each new can or glass of sugary beverage consumed per day is estimated to increase the risk of obesity by 60% (8). Most of the extant data concern soft drinks; however, many fruit and concentrate drinks are equally energy-rich and promote weight gain when consumed in large quantities. Overall, evidence of the contribution of the high intake of sugary beverages to weight gain is considered moderately strong.

4.2 National Strategy for the Prevention and Control of Overweight, Obesity, and Diabetes

Mexico has one of the highest consumption rates of soft drinks and sugary beverages. According to the results of the national health surveys conducted from 1999 to 2006, the number of households that consumed bottled soft drinks increased from 48% to 60% during that period. Moreover, the 2008 School Health Survey placed soft drinks among the five most consumed products in public elementary and middle schools in the country. In contrast, the results of a study conducted by the National Institute of Public Health of Mexico revealed that children reported only 28.1% of their total liquid consumption was composed of water or water infusions without caffeine or sugar, whereas 44% was

composed of high-calorie beverages such as sweetened drinks with or without carbonation, flavored water, sweetened fruit drinks, and nectars (12).

Certain non-communicable diseases are closely related to excess body weight (i.e., overweight and obesity). This situation is recognized as one of the most important public health challenges in the world given its magnitude, speed of increase, and the negative effect it has on the health of the people who suffer from it because it significantly increases the risk of non-communicable diseases (12).

As part of the commemoration of World Health Day on April 2, 2013, President Enrique Peña Nieto implemented the National Strategy for Prevention and Control of Overweight, Obesity, and Diabetes when he defined the steps that the Ministry of Health must follow in a specific and clear way: "Finally, the third priority [is] prevention. Anticipating disease and avoiding its causes is the best way to take care of [one's] health. In this sense, one of the most important prevention actions will be aimed at reducing obesity and overweight because [they] have become one of the greatest threats to the health of all Mexicans. This strategy should include the promotion of healthy lifestyles and eating habits, the generation and rescue of spaces for physical activity, the training of health personnel, and the strengthening of primary healthcare. To address obesity and diabetes, we will take the most effective measures according to [the] available scientific evidence, [thereby] prioritizing health above any other consideration. Government actions are important but will never be enough without the self-care of Mexicans" (13).

4.3 National Development Plan 2013-2018

Among elementary school-age children (5 to 11 years old), the rates of overweight and obesity are 19.8 and 14.6%, respectively. Based on reports from ENSANUT (National Health and Nutrition Survey) 2012, diabetes mellitus currently affects 9.2% of the country's population — an increase of 2.2% since 2006. Given its role as a cause of disease, obesity increases demands for health services and affects the economic and social development of the population. According to estimates from the National Autonomous University of Mexico (UNAM), the cost of obesity was 67 billion pesos in 2008. If no actions are taken, then the future cost will be greater than the investment required today to implement the policies needed to address this problem.

Three factors negatively affect the capacity of Mexico to fully enforce the right to health and therefore merit attention. First, the model with which the institutions of the sector were conceived is focused on cure rather than prevention. Second, policies have not been implemented with a multidisciplinary or interinstitutional approach regarding the improvement of the quality of health services. In this sense, confronting the diversity of the habits and customs of the population in matters of knowledge and healthcare become a challenge. Third, the current governing and structural arrangement in which the participation of vertically integrated and fragmented institutions prevails limits the operational capacity and cost effectiveness of the Public Health System (14).

4.4 General Guidelines for the Sale and Distribution of Food and Beverages in Elementary School Cafeterias

In the Official Gazette of the Federation published on August 23, 2010, an agreement established the general guidelines for the sale and distribution of food and beverages for consumption in elementary school cafeterias. This document aimed to "establish actions that promote healthy diets and environments as well as promote a culture of eating habits that favors the adoption of an appropriate diet to prevent overweight and obesity". This agreement included an appendix describing the nutritional characteristics of the type of foods and beverages that enable appropriate nutrition based on NOM-043-SSA2-2005, which includes prepared and processed foods, promotes the consumption of vegetables, fruits, and water on demand (15).

Article 2. For the purposes of this regulation, water is defined as a liquid containing no physical, chemical, or biological contaminants; it is colorless, tasteless, and odorless, and it does not cause harmful effects to humans. Water is the most recommended liquid for adequate hydration because no nutrients or ingredients have been added (15).

Chapter Thirteen of Prohibitions and Sanctions – Article 37

The preparation, sale, and distribution of foods and beverages that (by representing a source of simple sugars, refined flours, fats, or sodium) do not comply with the nutritional criteria of the appendix of this regulation and, consequently, do not favor the health of students, thereby placing them at risk, are forbidden in schools within the Federal Educational Subsystem (15).

Criteria used for snacks offered at public and private schools of the National Educational System

Snacks, as part of the diets of schoolchildren, should provide necessary nutrients and energy between meals to avoid fasting times of more than 4 hours as well as to maintain satiety. It is recommended that school snacks cover 15% of the daily recommendations for energy and nutrients. School snacks should consist of vegetables and fruits, whole grains, oilseeds and legumes, and potable water on demand (15).

The main objective in relation to beverages is to promote the consumption of water; thus, its availability must be ensured before any other drink. It is important to exclusively promote water consumption over the consumption of other types of beverages (15).

4.5 The Educational Strategy "I Prefer Plain Water"

The educational strategy "I Prefer Plain Water" was designed based on all of the above and given the scientific evidence showing that school is the optimal place to conduct healthy lifestyle intervention programs aimed at children (16), including increasing water consumption. Ogali Nutrition Consulting Company (www.ogali.com) elaborated this strategy that assembled a group of experts in research, public health, pedagogy, nutrition,

music, design, communication, social sciences, statistics, and design evaluation. The strategy is ludic and based on a collaborative scheme in which the students, teacher, and the family participate. This strategy consists of four educational sessions, with a duration of approximately 60 minutes each, which must be given every 2 weeks. The program and educational materials are specifically designed for first, second, and third graders.

4.5.1 Pedagogical support of the educational strategy "I Prefer Plain Water"

The educational strategy “I Prefer Plain Water” was designed based on the postulates of three theories of knowledge that have proved useful in behavior modification and the development of life skills, which together lead children to build a permanent foundation to acquire healthy lifestyles.

The first theory is *social cognitive* and exposes individuals to the acquisition of knowledge, rules, skills, habits, and strategies by observing others and socializing and interacting with the environment. Here, the individual modifies his or her behavior by observation and modeling. In turn, the individual influences other members of the social environment.

Albert Bandura, lead proponent of this position, argued that it is necessary to identify the influences that explain why and how a behavior is conducted to modify it. These influences are known as “determinants” or “mediators” of behavior.

This strategy uses five mediators to modify behaviors:

Expected results. The strategy enables students to easily visualize the benefits (expected results) that will be gained by simply increasing water consumption through characters in vignettes, posters, and an exchange of knowledge and experiences within the group.

Behavioral capacity. In each educational session, children set a feasible water-consumption goal, monitor themselves for the prescribed time, and acknowledge their progress. They are recognized for their effort, thereby demonstrating that they can adopt the desired behavior (behavioral change of an increase in water consumption).

Modeling and learning by observation. This strategy’s core point is the example of the teacher modeling water consumption at different times. Moreover, children can be peer models for each another.

Self-efficacy. This strategy offers students frequent opportunities to drink water and prove to themselves that they are able to change their habits with regard to the expected behavior. Self-efficacy represents a way for them to evaluate whether they are properly hydrated through observing the color of their urine.

Reinforcements. At each session, the students' achievements are recognized as they approach or meet the set goal; strategies are shared, and participants are encouraged to continue. Commitments are also made within the social circles where they belong, enabling them to strengthen their behavior in personal (strengthening self-esteem and self-care), group, and family situations.

The second theory is that of *social constructivism* posed by Vygotsky, which takes the idea that people construct their knowledge not only via the subject-object relationship but also via a subject-mediator-object triad (i.e., through social interactions with others and the influence of the culture in which they live). Therefore, the classroom activities are not individual but group activities. In addition, through the tasks that are conducted in each session, family members become involved to affect the culture in which they live to promote healthy environments.

Ausubel's theory of meaningful learning states that to promote permanent modification, it is necessary to appeal to intrinsic motivation and meaningful learning based on close situations and the actual needs and interests of children. Therefore, the strategy seeks to have children identify with one of the characters in vignettes and associate the issues presented to them with their own reality. In addition, songs and games are used to playfully assimilate important concepts that strengthen healthy behaviors.

Following the principles of competency learning, the strategy starts from the knowledge, skills, and attitudes presented in children and seeks to enhance them for use as tools that allow them to face problems related to healthcare more effectively in everyday life. Some of the competencies mentioned in the document “Competences for primary education SEP”, which are referenced in activities and games, include the capacity for expression through language, decision making, problem solving, individual responsibility, the development of self-esteem, teamwork, the promotion of a culture of prevention, and healthcare and environmental protection.

The third theory is that of *Multiple Intelligences*. Through his theory, Howard Gardner mentions that the world can be perceived via multiple ways of knowing, processing, representing, and communicating information (e.g., with images, words, numbers, body motion, rhythm, and music) as well as being in tune with oneself, with others, and with nature.

Gardner proposes a pluralistic view of the mind and a multifaceted view of intelligence. His pluralistic view of the mind recognizes that many different facets of knowledge exist and views people as possessing different cognitive potentials that lead to different styles of knowing.

His vision considers intelligence as not singular; all people have a wide range of intelligences, i.e., a repertoire of capacities necessary to solve problems.

Finally, this view takes a globalizing approach through which the contents of different subjects are reinforced and aligned with the plans and policies of the Ministry of Public Education of Mexico (SEP).

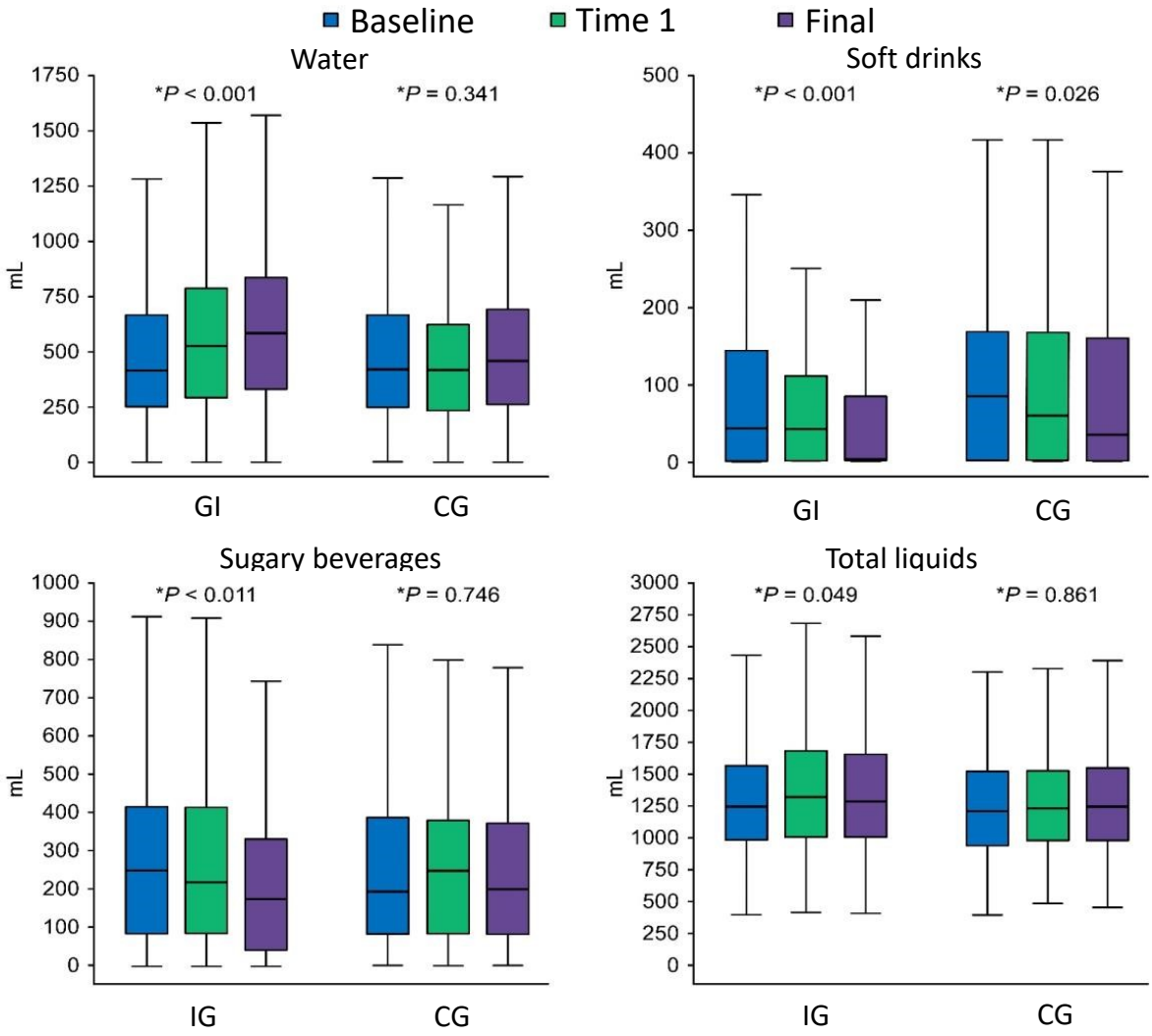
4.5.2 Effectiveness of the educational strategy "I Prefer Plain Water"

A previous study evaluated the effectiveness of the educational strategy to increase water consumption of first, second, and third graders in Mexico City. For this purpose, a community intervention test was conducted across eight elementary schools in the Coyoacán Delegation during the 2014-2015 school year. A 3-day beverage consumption record (two weekdays and one weekend day) was obtained from all participants. All schools were provided with water bottles inside the classrooms, and the children received a reusable 600-mL bottle. The schools were randomly assigned to an educational intervention group (IG) or a control group (CG). The IG had the educational strategy applied. At the end of the educational session cycle 4 months after baseline, a second record of beverage consumption was obtained, and a third was obtained at the end of the school year (4 months after the second). The strategy was considered effective if the students increased their water consumption by more than 220 mL.

For the analysis, 777 of the 1,105 children included were considered: 413/986 in the IG and 364/762 in the CG with a median age of 7.1 years (range 5.6 to 9.4 years). The children for whom the record of drinks was obtained at all three times were analyzed. From the baseline record to the end (8 months), the IG median increase in water consumption was 167 mL ($P < 0.001$) compared with the CG, which increased 37 mL. The educational strategy was effective for 166/413 of the children in the IG compared with 95/364 of the children in the CG ($P < 0.001$). The IG showed an 80 mL increase in their median total liquid consumption from baseline to first record and a 41 mL increase from the baseline record to the final record. In comparison, the CG increased 33 and 38 mL, respectively. These changes were not significant between the two groups but were significant within the IG from baseline to the first record. Significant differences were found with regard to the consumption of sugary beverages between groups ($P = 0.027$). The IG decreased 42 mL (16.8%), and the CG decreased 36 mL (14.6%) from baseline to the final record. Regarding the consumption of soft drinks, the IG decreased the consumption from 41 mL to 0 mL, whereas the CG reduced from 83 to 33 mL from baseline to the final record ($P < 0.001$). Figure 1 shows the change in beverage consumption in the groups at all three times.

After water, dairy drinks were consumed most often, with a similar median for both groups throughout the trial (i.e., no significant differences). The consumption of hot drinks, soft drinks, and functional beverages was low and did not significantly change throughout the trial.

Figure 1. Change in beverage consumption, Intervention Group (IG) vs Control Group (CG)



* Friedman related samples

The "I Prefer Plain Water" educational strategy effectively increased the consumption of water and reduced the consumption of sugary beverages and soft drinks when evaluated over the short term (4 months after its implementation); however, its long-term effectiveness (1 year later) has not been established.

According to the transtheoric model that uses the stages of change to integrate the processes and principles of change through the main theories of intervention, the maintenance stage in which the change in behavior persists occurs when the behavior is maintained for 6 months or more (17). Based on this idea, the effectiveness of this educational strategy will be evaluated 1 year after the intervention.

5.0 DESCRIPTION OF THE PROBLEM

Obesity prevention in young children should be considered a matter of the highest priority because it is necessary to promote healthy lifestyle behaviors that include (among others) an increased consumption of water and a decreased consumption of sugary drinks.
Studies have shown that school-based interventions affect obesity prevention. To date, educational strategies that promote adequate water consumption have been proposed as short-term strategies. Evidence exists of the need to reinforce these programs so that children continue with their acquired habits.

The educational strategy "I prefer plain water" favorably modifies water consumption when evaluated in the short-term; however, whether this observed change is maintained throughout early elementary education, a period that education specialists have established as essential to sustain healthy habits throughout life, is unknown.

6.0 JUSTIFICATION

The Mexican government identified the promotion of water consumption as a major strategy to reduce the energy density of the diet and thereby help prevent the problems of overweight, obesity, and other diseases associated with the excessive intake of sugary beverages. Thus, the National Agreement for Nutritional Health (ANSA) considers increasing the intake of water and discouraging the consumption of sugary beverages as a priority with regard to the population.

The educational strategy “I Prefer Plain Water” favorably affected water consumption and decreased the consumption of sugary beverages and soft drinks among early elementary school children in Mexico City when evaluated over the short term. The study of its long-term effectiveness is necessary to establish public health policies that maintain healthy lifestyles over time to enhance the quality of life of the population.

7.0 GENERAL OBJECTIVES

This proposal seeks to evaluate the effectiveness of the number of educational strategy interventions to increase the percentage of water consumed among early elementary school students over a 1-year follow-up period.

7.1 Primary Objective

This study seeks to compare the percentage of water consumed among early elementary school children receiving one, two, or three interventions of the educational strategy “I Prefer Plain Water” at a 1-year follow-up evaluation.

7.2 Secondary Objective

This study seeks to compare the monthly water consumption of participating schools during the follow-up period.

This study seeks to describe the annual body mass index (BMI) of the participating students during the follow-up period.

8.0 HYPOTHESES

The percentage of water consumed will be greater in the group of children who will receive all three interventions.

9.0 STUDY DESIGN

Experimental, analytical, longitudinal, and prospective designs will be employed. The assignment will be conducted by each school.

Community Intervention Test

10.0 POPULATION

10.1 Target Population

Children who attend elementary public schools of the Coyoacán Delegation are the target population.

10.2 Eligible Population

First graders attending public elementary schools under the epidemiological surveillance of the Ajusco and Santa Úrsula Health Centers will be recruited during the 2017-2018 school year.

11.0 SELECTION CRITERIA

11.1 Inclusion Criteria

- Healthy children (according to the investigator)
- Both girls and boys
- Children whose parents agree to participation in the study through verbal informed consent
- Children whose parents sign a privacy notice

11.2 Exclusion Criteria

- Children who present with any pathology that interferes with the free consumption of water or with the proper execution of the study
- Children for whom it is not possible to obtain a baseline record of beverage consumption

11.3 Elimination Criteria

- Children who do not attend more than two educational sessions within each grade level
- Children with incomplete or improperly completed beverage records

12.0 MATERIAL AND METHODS

12.1 Human Resources for The Preparation of the Study

- Three general Practitioners
- One odontologist
- Two nurses
- One computer technician
- One social worker
- Four nutritionists

12.2 Material Resources for the Preparation of the Study

Educational program by grade level (Appendix I)

Session	Theme
I. Water goes through my body	Importance of water for health
II. Am I drinking enough water?	The color of urine as an indicator of the volume of water consumed
III. I love water "Matarile, rile, ron"	Ecology and water care
IV. Together we take care of our health	Commitment to water consumption

Educational material (Appendix I)

- *Teacher by grade level*

- Hand puppet
- Handbook for each grade level

- *Students by grade level*

CD

- Corresponding audio-story
- Exhort "1, 2, 3... I prefer to drink more water "
- Water Song
- Cheer for healthy urine

Poster

- Individual conclusions poster

- Group conclusions poster
- Healthy urine poster "Watch the color and have control"

Games

- Group game with dice and tokens (Fountains and Waterfalls, Waterthon Water-challenge)

Others

- Wristband with the slogan “I Prefer Plain Water”
- Mobile app for personal, group, and family commitments

- *Family*

- Diptych

Method

12.3 Site and Participants

A community intervention trial will be conducted within the Coyoacán Delegation located in southern Mexico City. The four IG schools included in the previous study will be invited to participate. First graders will be recruited during the 2017-2018 school year. A medical examination (Appendix II) will be conducted for all participants within the school facilities as a direct benefit to the community. Documents regarding the original medical examination will be provided to the parents to be turned in at the school as requested, and a copy of the children’s document will be obtained for parents who consent to their participation in the study. All healthy children whose parents sign a privacy notice (Appendix IV) and complete the 3-day baseline consumption of beverages questionnaire will be included (Appendix V) after reading an information letter (Appendix III), being given the opportunity to ask questions, clarify doubts, and agree to participate in the study. The parents will express their acceptance via verbal informed consent. The verbal consent process will be documented in the file of each participant.

12.4 Intervention

At all participating schools, the principal investigator will conduct an approximately 1-hour briefing for parents to 1) explain the study's operational generalities and answer all questions and 2) provide instructions for completing the beverage consumption survey. Subsequently, the 3-day baseline record of beverage consumption will be collected.

At the beginning of the school year, first grade teachers will be trained by a nutritionist (one per school) to dispense the educational sessions (Appendix VI, VII, VIII), and the manual and materials for both teachers and students will be delivered.

The students will receive four educational sessions of approximately 1 hour. These sessions will be given every 2 weeks, and some will be supervised by a nutritionist.

The four schools will be assigned to one of the following three groups based on school enrollment and the interest of the teachers in participating:

Students in Group I will receive the education strategy only during the first grade; students in Group II will receive the educational strategy during first and second grades; and students in Group III will receive the educational strategy during first, second, and third grades.

	1st grade	2nd grade	3rd grade
Group I	X		
Group II	X	X	
Group III	X	X	X

With the delivery of the first educational session, free access to water will be initiated through Welltek water dispensers, model WT-POU-300 A (approved and certified by Cofepris and the National Institute of Physical Educational Infrastructure; INIFED), installed inside the classrooms. Children will also receive a reusable 600-mL bottle (twice) so that they may consume water throughout the day. The availability of water will be guaranteed during four school cycles.

12.5 Evaluation Process

In September 2017, the medical examination of the students and the process of inclusion will be performed; instructions will be sent to parents, and teacher training will be conducted. During October 2017, the baseline record regarding the consumption of beverages will be collected (Time 1). The educational sessions will be given from November 2017 to January 2018. A second record (Time 2) will be obtained at the end of the interventions in each group (end of June), and a third record (Time 3) will be obtained from each group 1 year after completing the interventions (end of June).

Baseline		End of 1st grade	End of 2nd grade	End of 3rd grade	End of 4th grade
Group I	X	X	X		
Group II	X	X		X	
Group III	X	X			X

Evaluation 1 year after completing the number of interventions associated with each group

In addition to measurements at baseline and at each evaluation time, body weight will be measured, and lean mass, fat free mass, fat percentage, total body water, and BMI will be analyzed using a body composition analyzer via electrical bioimpedance (TANITA TBF-310 GS). Height will be measured using a portable stadiometer (dry mark, model 213, Hambur Germany). Participants will be measured in light clothing (T-shirt and sport shorts) and without shoes. A nutritionist will be calibrated to perform the measurements. BMI will be classified using the WHO values standardized by age and gender.

The following table summarizes the procedures to be performed throughout the trial.

Procedure	**Sep 2017**	**Jun 2018**	**Sep 2018**	**Jun 2019**	**Sep 2019**	**Jun 2020**	**Sep 2020**	**Jun 2021**
School medical examination	X							
Weight, size, and body composition measurements	X	X		X		X		X
Instructions for completing the daily beverage record	X	X		X		X		X
Teacher training	X		X		X			
Daily beverage record	X	X		X		X		X
Group I intervention	X							
Group II Intervention	X							
Group III Intervention	X							

12.6 Measuring Instrument

Beverage consumption will be recorded through a beverage journal that will be completed at home by the parents for 3 days (two weekdays and one weekend day). Focus groups will be established to modify this record (Appendix IV) and make it more understandable

and practical for completing to improve the percentage of properly completed and collected journals.

The beverage categories will be based on the 2006 National Health and Nutrition Survey, as follows:

1. Water: bottled water, pitcher, mineral, or tap water;
2. Soft drinks: cola or flavored refreshment;
3. Sugary beverages: juices and nectars, "flavored water" (i.e., water made with powder or syrup), noncarbonated refreshments, and orange juice;
4. Bottled flavored waters;
5. Hot drinks: black coffee, tea, infusions, or cocoa;
6. Drinkable dairy products: milk, drinkable yogurt, milkshakes, atole, whole milk, skim milk, fat-free milk, lactose-free milk, flavored milk, or probiotic beverages;
7. Light drinks: light or zero-calorie soft drinks, zero-calorie flavored drinks, or zero-calorie teas;
8. Bottled teas with calories; and
9. Functional beverages: sports, energy, or isotonic beverages.

13.0 SAMPLE SIZE

Considering the results of the previous study where a mean difference of 80.74 mL was found with regard to water consumption with an SD of 399 mL as well as considering an α of 0.05 and a β of 0.1, we used the following formula to calculate a significant difference in means

$$n = [(Z_{1-\alpha} + Z_{1-\beta})^2 * s^2]/d^2$$

$$[(1.96 + 1.28)^2 * 399^2]/80.74^2 = 256.36$$

N = 257 children

The sample should include 329 first graders (allowing for a 28% loss margin) who will attend the 2017-2018 school year. This sample represents all of the four intervention schools that participated in the previous study.

2016-2017 school enrollment of the intervention schools participating in the previous study

School	Health Center	First grade	Total	Second grade	Total	Third grade	Total	Total school enrollment
Ramón Durand	Ajusco	32 32	64	31 32	63	26 27	53	341
Xitle	Ajusco	27 29 25	81	28 27 29	84	31 30 29	90	529
Guillén de Lampart	Santa Úrsula	28 26 27	81	31 32 30	93	27 27	54	475
Tlamatini	Santa Úrsula	34 35 34	103	36 37 36	101	33 33 33	99	600
			329		278		243	1,604

	Group I	Xitle	81
	Group II	Guillén de Lampart	81
	Group III	Ramón Durand Tlamatini	167

Based on the school enrollment of the current school year (2016-2017), schools with the same number of first graders will be assigned to Groups I and II. For Group III, the schools with the highest and lowest enrollments will be added.

14.0 STUDY VARIABLES

Variable	Operational definition	Variable type	Unit of measurement
Outcome variables			
Percentage of water consumed	Average consumption of water/average consumption of total liquids	Numeric/continuous	%
Total liquid Consumption	Average amount of total liquids consumed per child over a 3-day period	Numeric/continuous	mL
Water consumption	Average amount of water consumed per child over a 3-day period	Numeric/continuous	mL
Effectiveness of educational strategy	Increase in the percentage of water consumed, 1 year after completing the interventions within each group relative to baseline	Qualitative/dichotomous	1: yes 2: no
Secondary variables			
Age	Years old at the beginning of the school year	Numeric/continuous	Years
Gender	The sex indicated on each child's birth certificate	Qualitative/dichotomous	1: male 2: female
BMI	Indicator of the relationship between weight and height	Numeric/continuous	kg/m^2
Health condition	Health condition that (in the opinion of the investigator) enables the participant to have free consumption of water	Qualitative/dichotomous	1: healthy 2: sick
Water consumption per school	Quantity of water consumed in 1 month per participating school	Numeric/continuous	L

Operational Definitions

Educative intervention: Number of times that a student will receive the educational strategy for each elementary school year that they attend

Educational strategy: Set of activities aimed at teaching the importance of hydrating with water and promoting its consumption to maintain one's health (Appendix I)

15.0 STATISTICAL ANALYSIS

The analysis will be performed using the IBM SPSS version 22.0, and non-parametric statistics will be used.

Baseline measurement of beverage consumption (Time 1). The basal consumption of the different beverage categories will be summarized using medians, minimums, and maximums. We will apply the Kruskal-Wallis test (*K* of independent samples) to compare the differences in baseline beverage consumption among the three groups.

Baseline measurement and at the end of the interventions (Times 1 and 3). The percentage of water consumed at baseline will be compared with that 1 year after finishing the intervention for each group using the Wilcoxon test.

Comparison among the three groups. The percentage of water consumed will be compared among the three groups 1 year after the intervention is completed using Friedman's test of related samples.

16.0 ETHICAL CONSIDERATIONS

According to the Regulations of the General Law on Health in the Field of Health Research and the provisions of Article 17, this project is considered a study with minimal risk.

As a minimum risk investigation and in accordance with NOM-012-SSA3-2012 (item 11.3, paragraph 2), the Research Ethics Committee will be requested to approve the proposal that the associated researchers be allowed to request informed consent verbally. To guarantee the confidentiality of personal data, a privacy notice will be signed.

The dignity of the participants will be respected, their rights and well-being will be protected, and ethical clinical practices will be followed.

The team of researchers associated with this study has no conflicts of interest to declare. The research protocol will be submitted for approval to the Research Committee and Research Ethics Committee of the National Institute of Pediatrics.

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