

School Water Access, Food and Beverage Intake, and Obesity

Study Protocol

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The Impact of the School Water Access on Child Food and Beverage Intake and Obesity

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1. PURPOSE OF THE STUDY

a. Brief Summary

The overall goal of this cluster randomized, controlled trial involving 26 elementary schools is to examine how a drinking water promotion intervention impacts students' intake of beverages and food, and obesity. Data from this study will inform policy and practice guidelines regarding how schools can effectively decrease students' risk of obesity related to caloric intake from beverages.

The study aims are to:

1. To examine how a school-based program to promote drinking water access and consumption in low-income public schools affects caloric intake from beverages.
2. To investigate how the school-based water promotion intervention affects caloric intake from food.
3. To assess whether the school-based water promotion intervention impacts the prevalence of overweight/obesity.

b. Objectives

Our central hypothesis is that, in low-income, public elementary schools, increased access to fresh water and rigorous promotion of its consumption will reduce students' intake of caloric beverages thereby leading to lower obesity rates. We also hypothesize that the intervention will not adversely affect students' caloric intake from food.

Aim 1. To examine how a school-based program to promote drinking water access and consumption in low-income public schools affects intake of water and calories from beverages. We hypothesize that the intervention will increase intake of water and decrease intake of daily beverage calories.

Aim 2. To investigate how the school-based water promotion intervention affects caloric intake from food. We hypothesize that the intervention will decrease daily food calories consumed.

Aim 3. To assess whether the school-based water promotion intervention impacts the prevalence of overweight/obesity. We hypothesize there will be a greater decrease in the percentage of students who are overweight/obese in intervention schools as compared to control schools.

This study is significant because it is a first step toward developing effective interventions and policies that will encourage the consumption of healthy beverages among children and their families. Such improvements in beverage consumption patterns provide a unique opportunity to prevent undesired health outcomes such as obesity or dental caries via a discrete behavior change.

c. Rationale for Research in Humans

The purpose of the study is to examine the impact of improved access to safe and appealing drinking water and promotion of water intake instead of sugar-sweetened beverages on food and beverage intake and obesity among children. Schools were chosen for this research because they provide a setting for reaching a large population of children.

2. STUDY PROCEDURES

a. Procedures

Each intervention site will receive school-wide intervention activities as well as activities for students in 4th grade classes only. School-wide intervention components include: 1) installation of three new drinking water sources in high-traffic common areas, including one in the cafeteria with single-use disposable cups; 2) a promotional campaign including a kick-off musical performance. We also post signage in classes and near newly installed drinking water sources. We will also place decals (green smiley faces) in the cafeteria next to healthy beverages (water and plain milk) and reinforce water intake by providing prizes to students observed drinking water in cafeterias.

Classroom-specific intervention components include: 1) Provision of reusable water bottles for students to be filled each morning (with teacher supervision) and kept on or near students' desks. Class teachers will also facilitate weekly cleaning of reusable water bottles. The research team will lead eight brief educational classroom lessons focused on the benefits of water consumption. These lessons were developed and refined in our previous studies. Family engagement activities will include home tools to reinforce educational content in class lessons (e.g., reusable water bottle for home) and homework activities (e.g., calculation of sugar in a drink at home). We will incentivize family involvement by providing prizes to students who complete homework.

To assess how intervention activities impact caloric intake from food and beverages, we will use a multiple-pass 24-hour food and beverage diary protocol that has been adapted from a previously validated instrument. After diary completion, trained research staff will meet with students individually within 1-2 days of diary completion for approximately 20 minutes to review the diary using a multiple-pass method. Because of the cuts made to the NIH grant budget, we will not complete food and beverage diaries at 15 months but will instead add a shorter beverage frequency questionnaire to assess intervention impacts on students' beverage intake from baseline to 15 months after the start of the study (this change is approved by NIH Program officer).

To assess BMI, we will follow standard procedures for obtaining length and weight as outlined in the National Health and Nutrition Examination Survey Anthropometry Procedures Manual. We will use privacy screens to take each student's measurements one at a time in a private manner. At the same time measurements are taken, we will conduct brief surveys with students about beverage intake, physical activity and screen time behaviors. Surveys will occur at baseline and at 7 months and 15 months after the start of the study.

We will conduct surveys with the food service director and the principal at each school in order to monitor any new school-level policies or practices related to nutrition and physical activity that may impact study results. Surveys will occur at baseline and 15 months after the start of the intervention.

b. Procedure Risks

This study, which involves surveying students about beverage and food intake and screen time and physical activity behaviors, as well as taking measurements of height and weight is of minimal risk to participants and includes no procedures for which written consent is normally required outside of the research setting.

Interviews with food service directors and principals include non-sensitive information about school-level policies or practices related to nutrition and physical activity and are also of minimal risk to participants.

While childhood obesity is a major public health concern, there remain undernourished children in the US who rely on Free or Reduced Price Meals (FRPM) for their daily caloric intake. Increased water consumption amongst these underweight children holds a small but important risk of increasing satiety, thereby reducing food consumption. For these children, we will take precautions. We will work with teachers and families (through consent processes) to identify students who have chronic diseases or conditions that require special dietary accommodations or who are underweight ($BMI\% < 5$). We will then work with teachers and students' families to develop individualized plans that allow students to participate in activities that do not interfere with the dietary prescriptions of physicians or nutritionists. For example, if a student drinks a special formula such as Pediasure® for poor weight gain, he/she could participate in classroom educational lessons but opt out of drinking water in the water bottle distributed to students.

A Data Safety and Monitoring Board has been established to evaluate any adverse impact of the study on underweight children. They have determined that the study to date has not adversely affected underweight children in the intervention as compared to the control group. The board also feels that repeat measurements could stigmatize students. For this reason, we measure all students at the baseline, 7- and 15-months periods.

If students are considered to be underweight at any point during the study period, researchers will contact the student's parents to discuss strategies for healthy weight management and recommend consultation with a pediatrician.

In this study, we will collect certain basic sociodemographic information so that we can assess how these factors relate to beverage consumption patterns and obesity. Such questions, however, will be kept at a minimum to decrease risk for participants. All identifying information will be kept separate from completed surveys and will only be linked to surveys through a numerical identification number. All personal information that we access will be stored as an encrypted data file on a password-protected desktop computer located in the PI's locked office. Only trained research staff will have access to these data. All data will be coded with number-only identifiers. A name-identification number master code list (which will be destroyed once all data collection is completed) and data files will be stored in separate secure locations (computer and locked file cabinets in the PI locked office).

c. Use of Deception in the Study

NO

d. Use of Audio and Video Recordings

NO

e. Alternative Procedures or Courses of Treatment

There are no alternatives to study participation at this time.

f. Will it be possible to continue the more (most) appropriate therapy for the participant(s) after the conclusion of the study?

Schools that are selected as intervention schools will have access to changes in the built school environment that will remain at the school even after the study is complete (e.g., reusable water bottle filling stations and water dispensers in the cafeteria, physical activity area, and another common area).

Schools will also have access to educational curricula and promotional materials if they choose to implement them on their own. Most materials are low cost and can be printed and reproduced by schools for a low-cost.

Control schools will receive a reusable water bottle filling station and access to educational and promotional materials at the end of the study.

All schools will receive \$500 honoraria that can support continued education and promotion and/or any other health-related needs that the schools have at the time.

g. Study Endpoint(s)

While it is possible that there could be detectable differences in BMI outcomes during the course of the study, this is unlikely given previous studies that were used for effect size for power calculations. If there are any unanticipated impact on BMI prior to the end of the study or any adverse consequences, the Data Safety and Monitoring Board established for this study, will determine end points and action. Of note, the interventions

tested in this study (water station installation and promotion) are low-risk interventions and unlikely to have adverse consequences.

3. BACKGROUND

a. Past Experimental and/or Clinical Findings

Reducing SSB consumption by promoting fresh drinking water is a promising childhood obesity prevention strategy. Sugar-sweetened beverages (SSBs) are a major, non-nutritive calorie source. Intake of SSBs is associated with obesity and related comorbidities, such as Type 2 diabetes. Yet low-income children – the population most affected by obesity – consume more SSBs than their higher income counterparts. If children replace fruit juice and SSBs with water, they can reduce their daily caloric intake by 235 kilocalories (kcal). In randomized controlled trials (RCTs), adolescents receiving allotments of non-caloric beverages (e.g., water) at home, experience reductions in SSB intake and obesity. In the only RCT of a school-based intervention, in 32 low-income elementary schools in Germany, installation of appealing water sources, coupled with classroom-based education, led to a 31% reduction in children’s risk of being overweight. However, in the German experiment, schools did not provide alluring alternatives to water, such as sugar sweetened milk and juice. Ours will be the first study to establish how best to promote water consumption in US public schools with SSBs, including flavored milk, and juice.

US public schools are a key setting for promoting water consumption. Children spend substantial time in schools, so these settings offer an opportunity for increasing intake of water to replace SSBs. Most public schools are regulated by the 2010 Healthy Hunger-Free Kids Act (HHFKA), which requires them to offer free water where meals are served, but not outside meals. The HHFKA law has so far not sufficiently increased children’s intake of water in schools. Currently, most schools comply by providing a single fountain for hundreds of students. In our observations of students in public schools, rates of water fountain use range from 2 to 11%. Concerns about the safety and palatability of water from fountains are inhibiting factors, along with poor maintenance and inadequate access. Providing more appealing water sources along with cups and reusable bottles may increase water intake in schools. In our survey of California public schools, only 20% offered a more appealing non-fountain water source and 18% provided cups or bottles.

b. Findings from Past Animal Experiments

N/A

4. RADIOISOTOPES OR RADIATION MACHINES

N/A

5. DEVICES USED IN THE STUDY

N/A

6. DRUGS, BIOLOGICS, REAGENTS, OR CHEMICALS USED IN THE STUDY

N/A

7. DISINFECTION PROCEDURES FOR MEDICAL EQUIPMENT USED ON BOTH HUMANS AND ANIMALS

N/A

8. PARTICIPANT POPULATION

a. Planned Enrollment

1690 4th grade student participants (avg 65 per school site x 26 sites)

26 school administrators/principals (1 per school site x 26 sites)

26 food service directors/workers (1 per school site x 26 sites)

b. Age, Gender, and Ethnic Background

The age range of the participants is 7-64 years.

Gender composition: 51% male, 49% female

Ethnic background: 53% Hispanic

c. Vulnerable Populations

Children: One main aim of this study is to understand how provision and promotion of drinking water in schools affects student intake of food and beverages and child overweight/obesity. Thus, it is important to include children in this research.

Subjects unable to read, speak or understand English. Because the majority children in our study schools are Latino and may only speak Spanish, and some parents may only speak Spanish, we will not exclude Spanish-speaking populations in our study.

We will ask parents to sign an informed consent form for their child to participate in the evaluation activities. Students will also be asked to sign a written assent before participating in evaluation activities. To encourage students to complete their food and beverage diaries, they will receive a \$10-value gift card one time after completing both diaries at home with their parents. School-wide, students seen consuming water from newly installed water sources will also receive small incentives such as stickers or pencils.

d. Rationale for Exclusion of Certain Populations

We do not plan to exclude women or racial/ethnic groups from this study. Based on our previous experiences conducting research in school settings, study participants will likely be equally distributed between male and female gender. Given that one of our inclusion criteria is that schools have at least 50% of students who are eligible for free and reduced price meals (proxy for low-income households), our study population includes schools with a majority of non-White students. In our current study sample of 26 schools that have agreed to participate in the study, school populations are 66% Hispanic/Latino and 6% Black/African American.

e. Stanford Populations

None

f. Healthy Volunteers

None

g. Recruitment Details

Each school will receive an information letter describing the study and procedures. All students in 4th grade classes at participating schools will be sent home with an information letter and consent form for their parents. All principals and food service directors at participating schools will receive information letters and/or will attend meetings with research staff describing survey procedures.

h. Eligibility Criteria

i. Inclusion Criteria

School-level inclusion criteria include traditional public schools serving low-income students ($\geq 50\%$ student eligible for free/reduced price meals) that are located in the greater San Francisco Bay Area. Individual-level inclusion criteria include students in 4th grade classes in eligible intervention and control schools. We will also survey the food service director and the principal or other administrator at each participating school.

ii. Exclusion Criteria

Due to financial constraints of translation into other languages, we will exclude students or staff that cannot read and write in English and/or Spanish, and students whose parents cannot read and write in English and/or Spanish.

Students with chronic diseases or conditions that require special dietary accommodations or who are underweight, meaning their BMI% is below 5%, will also be excluded from the study classroom activities if their BMI% decreases from baseline over the course of the study period.

i. Screening Procedures

1. Students - We will send information letters and consent forms in Spanish/English to parents of students in 4th grade classes at participating schools. The information letter will inform them of the study and will include the principal investigator's contact information should they have any questions. Students who return consent forms will receive small incentives (e.g., pencils, stickers). As in our previous studies, we will visit schools to redistribute information letters and consent forms to students who have misplaced or lost forms. 4th grade students whose parents provide consent to participate in the evaluation will also be asked to provide their written assent prior to study participation.

To retain study participants, we will provide incentives to participants, use detailed confidential tracking systems for students, and use refusal conversion techniques in

which we work with school staff and students to understand and overcome non-participation and attrition.

2. Schools - School-level inclusion criteria include traditional public schools serving low-income students ($\geq 50\%$ student eligible for free/reduced price meals) that are located in the greater San Francisco Bay Area. We will recruit 13 elementary schools to serve as intervention sites and 13 elementary schools to serve as control sites

3. Food Service Director and Principal - In order to track secular trends (i.e., nutrition and physical activity policies and practices at the school or district level) that may influence study outcomes, we will conduct web-based or paper surveys with food service directors and principals at intervention and control schools at baseline and 15 months after the start of the intervention. These data will be used to conduct exploratory analyses to help account for nutrition or physical activity improvements in schools that may also affect obesity. School food service directors and principals will be provided an information letter to inform them about the study with the principal investigator's contact information if they should have any questions. Staff will be asked to sign consent forms prior to participation and they will receive a reusable water bottle for their assistance with the study.

j. Participation in Multiple Protocols

When recruiting schools, we ask school administrators about other studies the school is participating in. If the school is participating in a study that could impact our primary or secondary outcomes, we evaluate whether or not the school is eligible for the current study. At this time, there are no plans for participants to be enrolled in any other studies.

k. Payments to Participants

Participating intervention and control schools will receive a \$500 honoraria to be used for physical activity or nutrition related activities.

At intervention schools, \$200 gift cards will be given to each participating 4th grade teacher.

Participating 4th grade students at intervention and control schools will receive a \$10-value movie tickets after completing their final food/beverage diary.

At intervention and control schools, staff will receive a \$50 gift card for completing the two surveys.

l. Costs to Participants

NONE

m. Planned Duration of the Study

Entire study duration: 5 years

Food Service Director and Principal: Trained Stanford staff will interview the food service director and principal at the school at 2 time points, totaling 1.5 hours

Students: Trained Stanford staff will deliver eight 15-minute interactive lessons about the benefits of drinking water. Food and beverage diaries, short surveys of physical activity, screen time, and beverage intake, and BMI data will be collected during 3 1-hour time points (food and beverage diaries will not be completed during 15 month follow-up). Total commitment will be approximately 5 hours.

9. RISKS

a. Potential Risks

i. Investigational devices

N/A

ii. Investigational drugs

N/A

iii. Commercially available drugs, biologics, reagents or chemicals

N/A

iv. Procedures

We will measure student height and weight using a standard National Health and Nutrition Examination Survey protocol. As schools routinely measure student height and weight as a part of routine Fitnessgram testing in grades 5, 7, and 9, both school staff and students will be familiar with these assessments. We will use techniques (e.g., one student measured at a time behind a privacy screen) to make sure that we preserve student privacy while taking measurements. Study participation or non-participation will not adversely affect participants' involvement at the school and this study poses no risk greater than that encountered by students in everyday life experiences. We will take great effort to preserve participants' privacy, but in the event that a loss of privacy occurs, it is conceivable that some students may become mildly embarrassed.

v. Radioisotopes/radiation-producing machines

N/A

vi. Physical well-being

We will ask participating students in 4th grade classes to complete food and beverage diaries and a survey regarding screen time, physical activity, beverage intake, and we will also measure student height and weight using a standard National Health and Nutrition Examination Survey protocol. As schools routinely measure student height and weight as a part of routine Fitnessgram testing in grades 5, 7, and 9, both school staff and students

will be familiar with these assessments. We will use techniques (e.g., one student measured at a time behind a privacy screen) to make sure that we preserve student privacy while taking measurements. Study participation or non-participation will not adversely affect participants' involvement at the school and this study poses no risk greater than that encountered by students in everyday life experiences. We will take great effort to preserve participants' privacy, but in the event that a loss of privacy occurs, it is conceivable that some students may become mildly embarrassed.

vii. Psychological well-being

Study participation or non-participation will not adversely affect participants' involvement at the school and this study poses no risk greater than that encountered by students in everyday life experiences. We will take great effort to preserve participants' privacy, but in the event that a loss of privacy occurs, it is conceivable that some students may become mildly embarrassed.

viii. Economic well-being

N/A

ix. Social well-being

N/A

x. Overall Evaluation of Risk

Research not involving greater than minimal risk.

b. International Research Risk Procedures

N/A

c. Procedures to Minimize Risk

While childhood obesity is a major public health concern, there remain undernourished children in the US who rely on FRPM for their daily caloric intake. Increased water consumption amongst these underweight children holds a small but important risk of increasing satiety, thereby reducing food consumption. For these children, we will take precautions. We will work with teachers and families (through consent processes) to identify students who have chronic diseases or conditions that require special dietary accommodations. We will then work with teachers and students' families to develop individualized plans that allow students to participate in activities that do not interfere with the dietary prescriptions of physicians or nutritionists. For example, if a 4th grade student drinks a special formula such as Pediasure® for poor weight gain, he/she could participate in classroom educational lessons but opt out of drinking water in the water bottle distributed to students. These students, however, would be excluded from evaluation activities.

A Data Safety and Monitoring Board has been established to evaluate any adverse impact of the study on underweight children. Members of the board include experts in gastroenterology, hepatology, and nutrition, public health, general pediatrics, and epidemiology. They have determined that the study to date has not adversely affected

underweight children in the intervention as compared to the control group. The board also feels that repeat measurements could stigmatize students. For this reason, we measure all students at the baseline, 7- and 15-months periods.

In this study, we will collect certain basic sociodemographic information so that we can assess how these factors relate to beverage consumption patterns and obesity. Such questions, however, will be kept at a minimum to decrease risk for participants. All identifying information will be kept separate from completed surveys and will only be linked to surveys through a numerical identification number. All personal information that we access will be stored as an encrypted data file on a password-protected desktop computer located in the PI's locked office. Only trained research staff will have access to these data. All data will be coded with number- only identifiers. A name-identification number master code list (which will be destroyed once all data collection is completed) and data files will be stored in separate secure locations (computer and locked file cabinets in the PI locked office).

d. Study Conclusion

While it is possible that there could be detectable differences in BMI outcomes during the course of the study, this is unlikely given previous studies that were used for effect size for power calculations. If there are any unanticipated impact on BMI prior to the end of the study or any adverse consequences, the Data Safety and Monitoring Board established for this study, will determine end points and action. Of note, the interventions tested in this study (water station installation and promotion) are low-risk interventions and unlikely to have adverse consequences.

e. Data Safety Monitoring Plan (DSMC)

N/A

f. Risks to Special Populations

Research not involving greater than minimal risk.

10. BENEFITS

Students who participate in the intervention are likely to benefit from improved access to water in schools and increased knowledge about the importance of drinking water through improved beverage consumption patterns and improved weight status. Although the focus of this current proposal is to examine the effect of water provision and promotion on food and beverage intake patterns and obesity, there is also potential to impact health outcomes not measured in this study (e.g., dental caries).

Students at control schools will not benefit from this intervention during the study period. It is possible, however, that water dispensers given to control schools following the study could lead to improved beverage intake patterns in control schools as well. This study is beneficial to the larger population because study results can inform policies and programs that encourage children and their families to drink water instead of caloric beverages with added sugar. Subject risk is minimal, especially when compared to the potential benefits of this research.

11. PRIVACY AND CONFIDENTIALITY

All participant information and specimens are handled in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and privacy policies of Stanford University, Stanford Health Care, and Stanford Children's Health.