RESEARCH PARENTAL PERMISSION FORM

Basic Information

Title of Project: Preventing Childhood Obesity Through Youth Empowerment: a Cluster RCT of the H_2GO! Program

IRB Number: H-39841 NCT04265794

Sponsor: Boston University Medical Campus

Principal Investigator: Monica wang, ScD
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Study Phone Number: (617)-358-1571

Overview

We are asking you to agree for you and your child to be in a research study. A research study is an organized way of collecting information about scientific questions. This form will tell you what you and your child should expect if you agree for you and your child to be in the study. There are programs in place to make sure that investigators fulfill their obligations listed in this form.

It is your decision whether or not to agree for you and your child to join the study. We are doing the research to understand how children can establish healthy habits with their families and to test a youth empowerment program on childhood obesity risk

If you agree, your child will: participate in a 6-week program called H_2GO! at the Boys & Girls Club during regular Club hours; complete a study survey 4 times (once before the study begins, 2 months later, 6 months later, and 12 months later); and have his or her height and weight measured by study staff 4 times (once before the study begins, 2 months later, 6 months later, and 12 months later).

If you agree to participate, you will complete a study survey 4 times (once before the study begins, 2 months later, 6 months later, and 12 months later). You and your child will be in the study for 12 months if you and your child decide to stay for the whole study. You will find more information about what will happen in this study later in this form.

In the event that the Boys & Girls Club closes due to coronavirus related guidelines, your child will continue the program virtually (BGC site staff will continue the program through Zoom). You and your child will complete study surveys remotely (online or over the phone).

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You and your child might benefit from being in the study because you and your child may learn information about how to develop healthier eating habits. You will find more information about benefits later in this form.

The main risks of being in the study is breach of confidentiality. You will find more information about risks later in this form.

Purpose

The purpose of the study is to understand how children can establish healthy habits with their families and to test a youth empowerment program on childhood obesity risk. program. Health issues that will be targeted include drinking water and sugary drinks (e.g., soda, juice, sports drinks).

What Will Happen in This Research Study

The research involves a 6-week, 12-session youth empowerment program called H_2GO!. The youth empowerment program will focus on helping youth gain confidence and skills to make healthy behavior changes around reducing sugar-sweetened beverage consumption and increasing water consumption. Your child will be invited to participate in the H_2GO! Program, which will be delivered by trained staff in the BGC setting during regular Club hours, unless the Boys & Girls Club site close due to coronavirus related guidelines, in which case they will take place remotely. Each session is approximately 1 hour long and will be delivered twice a week for 6 weeks. The program includes interactive, hands-on learning activities that focus on health, hydration, and storytelling. Your child will receive reusable water bottles and a pictorial booklet. Your child will be instructed to complete take-home activities with you each week. At the end of the program, child and parent participants will be invited to attend a BGC open house featuring stories (written, audio, and video) that children created and to celebrate the conclusion of the program.

The entire duration for participation in this study is approximately 12 months.

Your child will be asked to complete surveys and measurements at four time points (at the beginning of the study, 2 months later, 6 months later, and 12 months later). Your child will be asked to fill out a survey asking them about their eating patterns, exercise, sleep, screen time, how empowered they feel, and sociodemographics. The child surveys take about 15-30 minutes to complete. Your child will also have their height and weight measured by trained study staff in a semi-private setting.

In the event that you and your child are unable to attend the club during follow-up data collection periods, you will have the option of measuring your child's height and weight measurements in a home setting using your own tools. If you do not have tools, you will have the option of having a scale and tape measure mailed to your home that you may keep in lieu of one incentive. This will not affect future incentives. Study staff will be required to be present via a video conferencing tool (BU Zoom) when your child's height and weight are measured.

In the event that the Boys & Girls Club sites close as a result of COVID-related policies, we will ask parents to measure and report their child's height and weight to study staff. Study staff will provide families with necessary tools and guidance on how to record child's body measurements.

You will be asked to fill out a parent survey asking about your sugary drink and water consumption, the availability of sugary drinks at home, and your sociodemographics information at four time points (at the beginning of the study, 2 months later, 6 months later, and 12 months later). The parent surveys take about 10-15 minutes to complete.

At the end of the study, we will post the results, briefs with findings, and publications on our project website, as well as share findings via BGC newsletters and social media.

The ways we will protect your and your child's privacy and confidentiality are described in a separate section later in this form.

Risks and Discomforts

Potential risks to both you and your child are minimal. Possible risks may include discomfort having measurements taken or in answering particular questions on surveys. You or your child do not have to answer any questions that you do not feel comfortable answering. No physical, psychological, social, cultural, financial, or legal risks are anticipated.

Potential Benefits

The benefits of being in this study for you and your child may be having access to health information, reduced sugar-sweetened beverage consumption, and increased water consumption. Additional benefits for your child may be prevention of excessive weight gain. However, you and your child may not receive any benefit. You and your child being in the study may help the investigators learn what kind of programming may be most helpful to establish healthy eating habits among children and families.

Costs

There are no costs to you or your child for your child being in this research study.

Payment

Your child will receive a Amazon gift card each time he or she completes a study assessment, which includes a survey and having his or her height and weight measured. There are a total of 4 study assessments (at the beginning of the study and 2, 6, and 12 months later) and the incentive amounts are as follows:

- Baseline: $20 Amazon gift card

- 2-month: $25 Amazon gift card
- 6-month: $30 Amazon gift card
- 12-month: $35 Amazon gift card

You will receive a Amazon gift card each you complete a study assessment. There are a total of 4 study assessments (at the beginning of the study and 2, 6, and 12 months later) and the incentive amounts are as follows:

- Baseline: $20 Amazon gift card
- 2-month: $25 Amazon gift card
- 6-month: $30 Amazon gift card
- 12-month: $35 Amazon gift card

Should you or your child withdraw from the study before the study is completed, you and your child will be compensated for any study assessments completed.

Confidentiality

We must use information that shows your and your child's identity to do this research. Information already collected about you and your child will remain in the study record even if you and your child later withdraw.

We will store your and your child's information in ways we think are secure. We will store paper files in locked filing cabinets. We will store electronic files in computer systems with password protection and encryption. We will conduct remote visits over BU Zoom or the telephone. However, we cannot guarantee complete confidentiality.

In the event that the BGC sites close due to COVID-related guidelines and the intervention is delivered via Zoom, there are instances where the Zoom sessions will be audio- or video- recorded for research purposes. The recording will be utilized to fulfill the objectives of the lessons and will be saved on a password protected device. Video and audio recordings will not be shared with any individuals other than those listed below (research staff, people from federal and state agencies who audit research, any people who give us separate permission to share your child's information). The recordings will be shared only when absolutely necessary to fulfill research objectives. However, we cannot guarantee complete confidentiality.

This study is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. All studies funded by the National Institutes of Health that involve identifiable information are covered by a CoC**.** The CoC provides how we can share research information. Because we have a CoC, we cannot give out research information that may identify you or your child to anyone that is not involved in the research except as we describe below. Even if someone tries to get your or your child's information in connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you or your child from sharing your or your child's own research information.

If you agree for you and your child to be in the study and sign this form, we will share information that may show your and your child's identity with the following groups of people:

- People who do the research or help oversee the research, including safety monitoring.

- People from Federal and state agencies who audit or review the research, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.

- Any people who you give us separate permission to share your or your child's information.

We will share research data where we have removed anything that we think would show your or your child's identity. There still may be a small chance that someone could figure out that the information is about you or your child. Such sharing includes:

- Publishing results in a public health book or journal.

- Adding results to a Federal government database.

- Using research data in future studies, done by us or by other scientists.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Subject's Rights

By consenting for you and your child to be in this study, you do not waive any of your or your child's legal rights. Consenting means that you have been given information about this study and that you agree to participate and to have your child participate in the study. You will be given a copy of this form to keep.

If you or your child do not agree for you and your child to be in this study or if at any time you or your child withdraws from this study, you or your child will not suffer any penalty or lose any benefits to which you or your child are entitled. Your and your child's participation is completely up to you and your child. Your decision and your child's decision will not affect your or your child's ability to get health care or payment for your or your child's health care. It will not affect your or your child's enrollment in any health plan or benefits you or your child can get.

We may decide to have you or your child stop being in the study even if you and your child want to stay. Some reasons this could happen are if staying in the study may be bad for you or your child, or if the study is stopped.

Questions

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, contact the Research Project Manager, Selenne Alatorre, by phone at (617)-358-1571 or via email at salatorr@bu.edu. Also call if you need to report an injury to your child during this research.

You may also call 617-358-5372 or email medirb@bu.edu. You will be talking to someone at the Boston Medical Center and Boston University Medical Campus IRB. The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your child's rights as a research subject. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

By agreeing for you and your child to be in this research, you are indicating that you have read this form (or it has been read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate and to allow your child to participate in this research study.

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