Title: Preventing Childhood Obesity Through Youth Empowerment: A Cluster RCT of the H2GO! Program

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3. Background, Rationale, and Purpose

3.1 Background

Childhood obesity remains a major public health challenge in the United States, with more than one-third of children classified as overweight or obese. Excess body weight during childhood is associated with numerous adverse health outcomes, including increased risk for type 2 diabetes, hypertension, cardiovascular disease, and several cancers later in life. Early prevention strategies are therefore critical for reducing long-term morbidity and improving population health. Sugar-sweetened beverages (SSBs) are the largest source of added sugars in children's diets and represent an important modifiable contributor to excess caloric intake and obesity. Consumption of SSBs is disproportionately high among children from low-income households and racial and ethnic minority populations, groups that also experience higher rates of childhood obesity and obesity-related chronic disease. Consequently, reducing SSB consumption has emerged as a key behavioral target for childhood obesity prevention interventions.

Although numerous behavioral interventions have attempted to reduce SSB intake, relatively few have demonstrated sustained effectiveness among early and pre-adolescent youth in community settings. Traditional educational approaches frequently rely on passive information delivery and often fail to engage youth as active participants in behavior change. Innovative intervention approaches that empower youth to influence both their own behaviors and those of their families may offer greater potential for sustained behavior change.

Youth empowerment interventions are grounded in the premise that children can serve as important agents of change within their families and communities. Empowerment-based approaches emphasize increasing knowledge, developing critical thinking skills, enhancing confidence and self-efficacy, and creating opportunities for youth to take leadership roles in promoting healthy behaviors. Despite their promise, few rigorous randomized controlled trials have evaluated youth empowerment interventions for childhood obesity prevention or examined empowerment as a mechanism through which behavioral changes occur.

The H2GO! intervention was developed collaboratively with the Massachusetts Alliance of Boys & Girls Clubs (BGCs) to address this gap. The intervention is grounded in Empowerment Theory and combines interactive health education, narrative development, and youth-led family engagement activities designed to reduce sugar-sweetened beverage consumption while increasing water intake. The intervention is delivered within existing BGC programming by trained BGC staff, increasing its potential for sustainability and future dissemination.

Pilot work demonstrated the feasibility of implementing the H2GO! intervention within BGC settings and provided encouraging evidence regarding participant engagement and behavioral outcomes. Building upon these findings, the present study evaluates the efficacy of the H2GO! intervention using a cluster randomized controlled trial conducted across BGC sites throughout Massachusetts.

3.2 Rationale and Purpose

The purpose of this study is to evaluate the efficacy of a community-based youth empowerment intervention designed to prevent childhood obesity by reducing sugar-sweetened beverage consumption among children participating in Massachusetts BGC.

Using a cluster randomized controlled trial, BGC sites will be randomized to either receive the H2GO! intervention or continue usual BGC programming during the study period. Parent-child dyads will be followed for 12 months to determine whether participation in H2GO! results in improvements in child body mass index (BMI), beverage consumption behaviors, and youth empowerment. The study also seeks to determine whether increases in youth empowerment mediate intervention effects on obesity-related outcomes. Findings from this study will provide evidence regarding the effectiveness of a scalable community-based intervention delivered through an established national youth-serving organization.

4. Objectives

4.1 Study Objectives

The overall objective of this study is to determine the efficacy of the H2GO! youth empowerment intervention for preventing childhood obesity among children participating in Massachusetts BGCs.

Primary Objective - Evaluate the effect of the H2GO! intervention on child BMI z-score over a 12-month follow-up period.

Secondary Objective - Evaluate the effect of the intervention on child sugar-sweetened beverage consumption and child water consumption over 12 months.

Exploratory Objective - Examine youth empowerment as a potential mediator through which the intervention influences BMI z scores.

4.2 Study Outcome Measures

4.2.1. Primary Outcome Measures

The primary outcome is change in child body mass index (BMI) z-score from baseline to 12 months. Standing height and weight will be measured by trained study staff using standardized procedures with a portable stadiometer and a calibrated medical-grade digital scale. Children will be measured in light clothing without shoes in a semi-private setting. Two measurements of height and weight will be obtained, and the average of the two measurements will be used for analysis. BMI (kg/m^2), age- and sex-specific BMI percentiles, and BMI z-scores will be calculated using the Centers for Disease Control and Prevention (CDC) growth charts.

4.2.2. Secondary Outcome Measures

The secondary outcomes are change in child sugar-sweetened beverage intake and water intake over 12 months. Beverage consumption will be assessed using the validated 15-item Beverage Intake Questionnaire (BEVQ), which measures the quantity of beverage consumption and estimates energy intake from SSBs. The BEVQ has demonstrated acceptable reliability and validity for assessing habitual beverage intake among children. Participants will complete the questionnaire electronically using a REDCap-enabled tablet during study visits. To maximize completion of follow-up assessments, participants who are unable to complete surveys in person will have the option of completing the questionnaire online or by telephone.

4.2.3. Exploratory Outcome Measures

The exploratory outcome is youth empowerment**.** Youth empowerment will be assessed using the abbreviated Sociopolitical Control Scale for Youth (SPCS-Y)**.** The SPCS-Y is an 8-item self-report measure that assesses youths' perceived leadership competence and policy control using a 10-point phrase-completion response scale. Higher scores indicate greater perceived empowerment.

5. Study Design

This study is a cluster-randomized controlled trial designed to evaluate the efficacy of the $H_2GO!$, a 6-week in-person, group-based behavioral intervention to prevent childhood obesity by reducing sugar-sweetened beverage (SSB) consumption among early and pre-adolescent youth. The intervention will be implemented in collaboration with BGCs in Massachusetts.

Ten BGC sites will participate in the study and serve as the unit of randomization. Sites will be randomized in a 1:1 ratio to either the $H_2GO!$ intervention (n = 5 sites) or a wait-list usual care control condition (n = 5 sites). Comparison sites will continue standard BGC programming throughout the study period and will receive the $H_2GO!$ intervention following completion of the study. Approximately 450 parent-child dyads (an average of 45 dyads per site) will be enrolled across the 10 participating BGC sites, with approximately 225 dyads assigned to each study condition. Recruitment, intervention implementation, and outcome assessments will take place at the participating BGC sites.

The primary outcome is child body mass index (BMI) z-score. Secondary outcomes include child sugar-sweetened beverage intake and water intake, and the exploratory outcome is youth empowerment. Outcome assessments will be conducted at baseline, 2 months, 6 months, and 12 months. Child anthropometric measurements will be obtained by trained study staff using standardized procedures, and survey-based outcomes will be collected using validated instruments. The entire duration for participation of a single participant is approximately 12 months.

6. Potential Risks and Benefits

6.1. Risks

Potential risks to both parent and child participants are minimal. Study procedures include behavioral and psychosocial surveys completed by parent and child participants and anthropometric measurements obtained from child participants. The intervention promotes reducing sugar-sweetened beverage consumption and increasing water consumption. To minimize risk, child and parent participants will be screened for eligibility, including confirmation that they have no medical condition that would limit their ability to modify beverage consumption behaviors.

The primary risks associated with study participation are loss of confidentiality and potential discomfort associated with child anthropometric measurements. Some participants may have concerns regarding the confidentiality of their survey responses and study records. Appropriate safeguards will be implemented to protect participant confidentiality, and study staff will provide an environment that allows participants to ask questions or express concerns. Height and weight measurements will be obtained in a semi-private setting by trained study staff using standardized

procedures. Participant safety will be monitored throughout the study, and all study personnel will receive appropriate training and supervision.

Additional risks are minimal and may include discomfort associated with answering questions about dietary and physical activity behaviors. During the informed consent process and prior to survey administration, participants will be informed that they may decline to answer any question they do not wish to answer without penalty. No significant physical, psychological, social, cultural, financial, or legal risks are anticipated. Individuals who choose not to participate will continue to receive standard BGC programming.

Risks Associated with Remote Study Procedures. If study activities are conducted remotely because of public health restrictions, participants may experience minor inconvenience or discomfort associated with receiving the intervention or completing study assessments remotely. Participants will be informed during the consent process that study procedures may transition to a remote format if necessary.

Privacy Risks Associated with Remote Study Procedures. If intervention sessions are delivered virtually, there is a minimal risk of loss of privacy because study staff cannot control the privacy of participants' home environments. Because the intervention is educational in nature, these risks are expected to be minimal. To reduce potential privacy concerns, participants will be informed before each virtual session that they may turn off their camera at any time if they do not wish to appear on screen. Secure, password-protected videoconferencing procedures will be used for all remote intervention sessions.

6.2 Potential Benefits

Potential benefits to child participants include access to health education that may result in reduced sugar-sweetened beverage consumption, increased water consumption, and a reduced risk of excessive weight gain and obesity. Parent participants may also benefit from access to health education and resources promoting healthier beverage consumption behaviors. Participation in this study will contribute to scientific knowledge regarding the efficacy of youth empowerment interventions for reducing sugar-sweetened beverage consumption and preventing childhood obesity. Findings from this study may inform the development, implementation, and dissemination of evidence-based obesity prevention interventions in youth-serving community settings, including BGCs.

6.3 Analysis of Risks in Relation to Benefits

The risks associated with study participation are anticipated to be minimal and primarily include the potential for loss of confidentiality, temporary discomfort associated with child anthropometric measurements, and discomfort when responding to questions regarding dietary and physical activity behaviors.

Potential benefits to participants assigned to the intervention group include access to health education that may promote healthier beverage consumption behaviors, including reduced sugar-sweetened beverage intake and increased water consumption, which may contribute to improved dietary behaviors and obesity prevention. Participants in both study groups will contribute to the

evaluation of a community-based intervention designed to reduce sugar-sweetened beverage consumption and childhood obesity risk.

Potential societal benefits include generating evidence regarding the effectiveness and scalability of a youth empowerment intervention that may be disseminated through youth-serving organizations to support childhood obesity prevention. Given the minimal risks associated with study participation, the anticipated benefits to participants and society are considered to outweigh the potential risks.

7. Study Subject Selection

7.1. Subject Inclusion Criteria

Child Participants
Children will be eligible to participate if they meet all of the following criteria:

1. Are 9 to 12 years of age at enrollment.
2. Are current members of a participating BGC in Massachusetts.
3. Are able to understand and communicate in English.
4. Are able and willing to provide assent.
5. Have parent or caregiver permission to participate.
6. Have no medical condition that would limit their ability to modify beverage consumption behaviors.
7. Have access to a Wi-Fi-enabled device at home.

Parent/Caregiver Participants
Parents or caregivers will be eligible to participate if they:

1. Are the parent or primary caregiver of an eligible child participant.
2. Are 18 years of age or older.
3. Are able to understand and communicate in English.
4. Are able and willing to provide informed consent.
5. Have no medical condition that would limit their ability to modify beverage consumption behaviors.
6. Do not anticipate changing their child's BGC membership during the 12-month study period.

7.2 Subject Exclusion Criteria
N/A (covered under inclusion criteria)

8. Study Conditions
8.1. Intervention condition
Child participants - Intervention procedures for child participants (those who agree to be in the study and who have parental permission and consent to participate) include participating in a 12-session behavioral intervention consisting of group-based in-person sessions over 6 weeks (1-hour sessions twice a week) delivered by trained BGC program staff in the BGC setting. Each week consisted of a 1-hour health session and a 1-hour narrative session (delivered on separate days). See Table below for session topics and activities. Child participants will also receive

reusable water bottles and a pictorial intervention booklet. Developed by the PI and the research team, the intervention booklet includes activity worksheets, parent-child take-home activities (e.g., complete a nutrition label reading activity at home, conduct a scavenger hunt of different types of beverages at home, fun facts and quizzes, and water and SSB consumption tracking sheets. Activity worksheets were completed by participants during intervention sessions, and parent-child take-home activities were completed at home following each session.

Parent participants - Intervention procedures for parent participants include exposure to intervention messages (e.g., reduce SSB intake) through weekly parent-child take-home activities, child sharing of narratives produced, and a culminating open house event at the BGC. Parents will also attend an in-person open house event, where they will hear and see messages and materials that encourage them to drink less sugary drinks and drink more water.

<table>
<tr><th colspan="3">H₂GO! Intervention Session Topics and Activities</th></tr>
<tr><th>Weekly BGC-staff led health sessions</th><th>Weekly BGC-staff led narrative sessions</th><th>Weekly youth-led activities</th></tr>
<tr><td>1. Water is Good for You! (hydration demonstration)</td><td>Develop print narratives to promote water intake</td><td rowspan="7">Teach parents information and skills learned through parallel weekly parent-child activities

Engage parents in critical dialogues on target behavioral messages through weekly sharing of narratives</td></tr>
<tr><td>2. Re-Think Your Drink (blinded taste tests of flavored water)</td><td>Develop print narratives to encourage non-SSB alternatives</td></tr>
<tr><td>3. Find the Facts (label reading, SSB measuring activity)</td><td>Develop print narratives to explain how to identify SSBs</td></tr>
<tr><td>4. Explore the Corner Store (scavenger hunt of SSBs and non-SSBs)</td><td>Develop audio narratives to explain how to identify SSBs</td></tr>
<tr><td>5. Water, Water, Everywhere (role play skits to find ways to drink water)</td><td>Develop video narratives to find opportunities to drink water</td></tr>
<tr><td>6. SSB Triggers (role play skits to manage SSB triggers</td><td>Develop video narratives to manage SSB triggers</td></tr>
<tr><td colspan="3">7. Culminating youth-led BGC community event featuring display of narratives and flavored water taste tests</td></tr>
</table>

In the event that BGC sites close public health restrictions, the intervention will be delivered through Boston University's secure video conference platform, Zoom, and have added protective measures (password protection, enabled waiting rooms). BGC site staff will be provided with a separate version of the Staff Manual that will describe specific instructions on how to deliver the intervention virtually. Study staff will be available to provide any technical assistance during these sessions.

8.2. Comparison condition

Child participants in the comparison site will receive usual care (standard, existing programming at the Boys and Girls Club) during the study and will receive an intervention toolkit and training after study completion.

9. Recruitment and Retention Procedures

9.1.1. Recruitment Procedures

Participants will be recruited from participating BGC sites in Massachusetts. BGC staff will distribute recruitment packets containing a study flyer and parental permission information to eligible families during BGC programming, during parent pick-up hours (approximately 3:00–7:00 PM on weekdays), during routine parent orientation sessions, and electronically through BGC e-newsletters and list servs. Interested parent-child dyads will be referred to trained study staff who will provide additional information about the study and review eligibility and consent procedures. Recruitment and enrollment activities may be conducted in person at participating BGC sites, by telephone, or electronically using REDCap.

9.1.2 Retention Procedures

Multiple strategies will be used to promote participant retention throughout the 12-month follow-up period. Parent participants will receive up to two email reminders and up to two telephone reminders before each follow-up assessment at 2, 6, and 12 months.

Participants will receive compensation for completing each assessment. Child and parent participants will each receive a $20 Amazon gift card after completion of the baseline assessment, $25 after the 2-month assessment, $30 after the 6-month assessment, and $50 after the 12-month assessment, for a maximum of $125 per participant. Participants who withdraw from the study will be compensated for all assessments completed before withdrawal. Beginning in April 2022, participant incentives were increased to a tiered schedule to improve retention. In December 2022, the 12-month incentive was increased to $50, and participants completing the 12-month assessment became eligible to enter a raffle for a $100 prize to further enhance retention.

10. Screening Procedures

Interested parent-child dyads will be referred to trained study staff, who will review the study, determine eligibility, and answer questions regarding participation onsite at the BGC sites during recruitment periods. Eligibility for both parent and child participants will be assessed by study staff using the approved inclusion criteria. No identifiable private information will be collected and no medical records will be reviewed for the purpose of determining eligibility. Interested and eligible parent-child pairs will then be referred to the consent procedures.

11. Consent Procedures

The BGC (BGC) study sites will serve as the primary setting for recruiting study participants and obtaining informed consent and assent. Trained study staff will be responsible for all recruitment and consent procedures. Written parental permission will not be obtained, as the study is educational in nature, presents no more than minimal risk to participants, and involves no procedures for which written consent would ordinarily be required outside of the research setting.

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BGC staff will distribute recruitment packets containing a study flyer and parental permission information to children 9–12 years of age during BGC programming, to parents during pick-up hours (approximately 3:00–7:00 PM on weekdays), during routine BGC parent orientation sessions, and electronically through BGC e-newsletters. Interested parent-child dyads will be referred to study staff to learn more about the study and begin the enrollment process. Parents will review the eligibility criteria for themselves and their children using the study flyer and then contact study staff. Study staff will confirm eligibility, review study details, and answer questions either in person at the BGC, by telephone, or electronically using REDCap. No identifiable private information will be collected and no medical records will be reviewed to determine eligibility; therefore, no separate screening visit will be conducted.

During the consent process, participants will be informed of the study condition to which their BGC site has been assigned (H_2GO! intervention or usual care) prior to enrollment.
Prior to obtaining verbal child assent, study staff will explain the purpose of the study using age-appropriate language, describe the child's role in the study, and explain that confidentiality of all collected information will be maintained to the greatest extent possible. Children will be reminded that participation is voluntary, that they may decline participation or withdraw at any time without affecting their experience at the BGC, and that they may speak privately with study staff regarding their decision to participate. Children will be provided up to one week to consider participation before providing verbal assent.

Prior to obtaining parental permission, study staff will explain the study purpose, procedures, potential risks and benefits, and the roles of both the parent and child participants. Parents will be informed that participation is voluntary, that they may decline participation without affecting their child's participation in BGC programming, and that confidentiality will be maintained to the greatest extent possible. Study staff will answer all questions, and parents will be provided up to one week to consider participation before providing parental permission.

Parental permission and child verbal assent may be obtained through one of three methods:

(1) in person at the participating BGC, with verbal parental permission and verbal child assent
(2) by telephone, with verbal parental permission and verbal child assent documented by study staff using a REDCap form and a corresponding progress note documenting participant names and the date of consent
(3) electronically through a REDCap form documenting parental permission and child verbal assent.

These procedures are intended to facilitate participation for families who are unable to complete the consent process in person. Parents and children completing the consent process by telephone or electronically will receive electronic access to the study flyer and parental permission materials and will have up to one week to consider participation. The majority of consent procedures are expected to occur in person. For telephone consent, study staff will ask parents to reference the parental permission form previously distributed through the BGC recruitment materials while the consent information is reviewed.

Once verbal parental permission and verbal child assent have been obtained, the parent-child dyad will be enrolled in the study.

If in-person study activities cannot be conducted because of public health restrictions or other circumstances that limit access to participating BGC (BGC) sites, parental permission and child assent will be obtained remotely using the procedures described above (i.e., by telephone or electronically through REDCap). If BGC sites remain open but outside personnel are not permitted on site, study staff will conduct parental permission and child assent procedures in an alternative location that protects participant privacy, such as a designated outdoor or other approved area adjacent to the BGC.

12. Study Procedures

12.1. Data collection procedures

Child and parent participants in both the intervention and comparison groups will complete self-administered study questionnaires (approximately 15–30 minutes) using a REDCap-enabled tablet during in-person study visits at participating BGC sites at baseline, 2 months, 6 months, and 12 months. To maximize follow-up completion, participants who are unable to complete assessments in person will have the option of completing questionnaires online or by telephone. Child participants will undergo standardized height and weight measurements at baseline, 2 months, 6 months, and 12 months. Anthropometric measurements will be obtained by trained study staff in a semi-private setting using standardized equipment and procedures.

Data collection contingency procedures – In the event BGC sites are closed because of public health restrictions, child and parent participants will have the option of completing study questionnaires online or by telephone. Study staff will mail standardized height stadiometers and digital scales to participants' homes and provide parents or caregivers with remote training on measurement procedures. Study staff will observe anthropometric measurements via secure video conference to promote standardized measurement procedures and will record measurements during the session.

If BGC sites remain open but outside personnel are not permitted on site, identical stadiometers and digital scales will be provided to participating BGC sites. Study staff will provide virtual training to designated BGC staff on standardized anthropometric measurement procedures and will remain available remotely via secure video conference or telephone to provide technical assistance as needed.

If participants are unable to attend in-person follow-up visits despite normal BGC operations, they will be offered the option of completing anthropometric assessments at home. When feasible, participants may complete measurements at a participating BGC site using standardized equipment. Alternatively, participants without appropriate equipment at home may be mailed a study-issued digital scale and measuring tape for home use in lieu of one participant incentive. Study staff will observe all home anthropometric assessments via secure video conference and record measurements in real time. If measurements are obtained using equipment other than the standardized study equipment, the brand and model of the equipment will be documented in the study database, and this deviation will be considered during data analysis and reported as a study

limitation, as appropriate. Child participants completing home assessments will complete study questionnaires electronically through a secure survey link provided to the parent or caregiver.

13. Data and Safety Monitoring Plan

The proposed study is a multi-site, cluster-randomized behavioral clinical trial evaluating a youth empowerment intervention to reduce sugar-sweetened beverage consumption and prevent childhood obesity. The intervention and study procedures present no more than minimal risk to participants. Because the intervention is educational in nature and participants are not blinded to study assignment, a formal Data and Safety Monitoring Board (DSMB) is not warranted.

Participant safety and data integrity will be monitored by the Principal Investigator (PI) in collaboration with an independent Safety Officer. Safety monitoring activities include ongoing review of participant recruitment, protocol adherence, adverse events, data quality, participant retention, and study conduct. Serious adverse events, unanticipated problems, and any significant safety concerns will be reported to the Boston University Medical Campus Institutional Review Board (IRB) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) in accordance with institutional and NIH requirements.

The Safety Officer is Richard Saitz, MD, MPH, FACP, an experienced physician-scientist who is independent of the study team and has no scientific, financial, or supervisory relationship with the study. The Safety Officer will review scheduled safety reports, evaluate participant safety, scientific integrity, and ethical conduct, and advise the PI regarding any corrective actions or recommendations related to study continuation

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13.1. Definitions for Safety Assessment

Adverse Event (AE) - An adverse event (AE) is any unfavorable physical or psychological change experienced by a study participant that is temporally associated with study participation, regardless of whether it is considered related to the study.

Serious Adverse Event (SAE) - A serious adverse event (SAE) is an event that results in death, is life-threatening, requires inpatient hospitalization or prolongation of hospitalization, results in persistent or significant disability or incapacity, or constitutes another important medical event based on clinical judgment.

Adverse events will be classified by:

- severity (mild, moderate, severe); and
- relationship to the study intervention (definitely, probably, possibly, or unrelated).

Because this is a minimal-risk behavioral intervention, adverse events are not anticipated.

Potential risks are limited primarily to:

- loss of confidentiality;
- temporary discomfort associated with anthropometric measurements;
- minor discomfort associated with answering behavioral or psychosocial survey questions.

Participants will be instructed to notify study staff of any adverse events, serious adverse events, or unanticipated problems occurring during study participation.

13.2 Safety Review

The Principal Investigator will have primary responsibility for ongoing safety oversight and will work with the Safety Officer throughout the study. The Study Coordinator will prepare routine monitoring reports for review by the PI and Safety Officer. Monitoring activities will include:

- participant accrual;
- adherence to eligibility criteria;
- intervention fidelity and protocol adherence;
- participant retention and withdrawals;
- anthropometric data quality;
- adverse events, serious adverse events, and unanticipated problems;
- protocol deviations;
- completeness and quality of study data.

Safety reports will be reviewed according to the following schedule:

Data	Review Frequency
Participant accrual and eligibility	At the end of each recruitment wave
Adverse events	As events occur
Intervention compliance	Quarterly
Anthropometric data	Quarterly
Participant retention and dropout	Quarterly
Statistical power implications of missing data	Annually

The annual safety review will summarize:

- recruitment and retention;
- protocol adherence;
- adverse events;
- serious adverse events;
- unanticipated problems;
- protocol deviations;
- study progress toward completion.

13.2.1 Multi-Site Safety Monitoring

Because this study is conducted across multiple BGC sites, safety monitoring procedures will be standardized across all participating sites. Study staff will receive standardized training before participant enrollment and ongoing supervision throughout the study. The research team will monitor intervention delivery through attendance records, intervention fidelity assessments, staff training documentation, and refresher training as needed. Participant recruitment, retention, protocol adherence, and data quality will be reviewed across individual sites and in aggregate to identify any site-specific concerns requiring corrective action.

13.3. Reporting Plans

All adverse events (AEs), serious adverse events (SAEs), unanticipated problems (UPs), and protocol deviations meeting reporting criteria will be documented by the study team. Every event reported by a participant, intervention staff, or research staff to the Principal Investigator (PI) or designated study personnel that meets the criteria for an AE or SAE will be documented.

An adverse event report will be completed for each reportable event and will include a description of the event, the date and method by which the event was reported, any supporting documentation (when applicable), an assessment of severity, determination of relatedness to the study, and any actions taken.

The PI will be notified immediately of all AEs, SAEs, and unanticipated problems identified by study staff. Although the study poses minimal risk and adverse events are not anticipated because of the educational nature of the intervention, all reportable events will be managed according to the following procedures:

- The PI will review and evaluate all AEs within 72 hours of notification.
- All SAEs will be reviewed by both the PI and the Safety Officer within 24 hours of notification.
- Study-related SAEs will be reported to the NIDDK within 2 weeks of the study team's awareness of the event. All other AEs will be summarized in the annual progress report submitted to NIDDK.
- Unexpected safety events and unanticipated problems involving risks to participants or others will be reported promptly to the Boston University Medical Campus Institutional Review Board (IRB) and NIDDK in accordance with institutional and NIH reporting requirements.
- Any action resulting in the temporary or permanent suspension of the study will be reported immediately to the appropriate NIDDK Program Official and the IRB.

Recipients of safety reports, as appropriate, include the PI, the independent Safety Officer, the Boston University Medical Campus IRB, and the NIDDK Program Official. Annual continuing review reports submitted to the IRB will include summaries of participant recruitment and retention, adverse events, serious adverse events, unanticipated problems, protocol deviations, and an overall assessment of study progress, participant safety, and data integrity.

13.4. Stopping Rules

Given the minimal-risk nature of this educational behavioral intervention, no formal interim efficacy analyses or predefined stopping rules are planned. Although it is unlikely that new information will emerge during the study that would warrant early termination, the study team will continuously monitor participant safety, study conduct, recruitment, retention, and data quality.

If unexpected safety concerns arise or other issues threaten the scientific integrity or feasibility of the study, the Principal Investigator, in consultation with the Safety Officer, will determine whether modifications to the study or suspension of study activities are warranted. Baseline participant characteristics will be reviewed following completion of baseline enrollment to assess balance between study groups. In addition, participant retention and missing data will be

monitored quarterly to evaluate their potential impact on study power and the ability to detect differences in the primary outcome.

The study was powered assuming a 25% dropout rate. Dropout rates exceeding this threshold will trigger additional review by the study investigators and Safety Officer. Alert thresholds have been established at dropout rates of 25% (low alert), 30% (mid-level alert), 40% (high-level alert), and 50% (extreme alert). At each alert level, appropriate corrective actions will be implemented to minimize further participant loss:

- Mid-level alert (30% dropout): Study investigators will convene to identify and implement strategies to improve participant retention and reduce further losses to follow-up.
- High-level alert (40% dropout): Study investigators will review study procedures and determine whether protocol modifications are needed to preserve study integrity and improve retention.
- Extreme-level alert (50% dropout): If a 50% dropout rate occurs before completion of the 6-month follow-up assessments, the study investigators and Safety Officer will evaluate whether continuation of the study remains scientifically justified. If this level of dropout occurs during the 12-month follow-up period, the study team will determine whether completion of the remaining follow-up assessments remains appropriate given the study objectives and available data.

The study team recognizes that unforeseen circumstances not specified above may also warrant modification, temporary suspension, or termination of the study. Any such events will be documented in the safety reports and communicated promptly to the Principal Investigator, Safety Officer, Institutional Review Board (IRB), and NIDDK, as appropriate.

14. Data Handling and Record Keeping

14.1 Confidentiality

A number of strategies will be used to maintain confidentiality to the highest extent possible. Each participant will be assigned a unique study identification number. The participant database will only be accessible to authorized study personnel via password-protected computer programs. Collected data will be stored in a password-protected database, with access limited to investigators and key data management staff. For the purposes of scheduling follow-up study visits, we also will collect contact information. Tracking information will be stored in a separate database that is password protected and not linked to an individual's study data or results.

All known members on our research team have completed Collaborative IRB Training (CITI) requirements. New hires will be required to pass this program. Data in all analytic databases are coded by number instead of name, and participant files will be kept in locked offices. All scheduled video conference meetings will be password-protected.

14.2. Study Documentation and Source Data

Study data will be recorded using study-specific source documents and electronic data capture forms within the REDCap data management system. Source data will include participant-completed study questionnaires, anthropometric measurements, study logs, consent

documentation, adverse event reports, protocol deviation reports, and other study records generated during the conduct of the trial.

Each participant will be assigned a unique study identification number. All study data, documents, and electronic study records will be identified using the study identification number rather than direct participant identifiers. A master code linking study identification numbers to participant identifiers will be maintained separately from study data and will be accessible only to authorized study personnel.

Electronic study data will be stored on secure, password-protected Boston University servers with access restricted to the Principal Investigator and authorized study team members. Any paper study records will be maintained in locked file cabinets within the Principal Investigator's secured office. Appropriate administrative, physical, and technical safeguards will be implemented to protect the confidentiality and integrity of study records.

14.3 Study Records Retention
Study records will be retained for 7 years following completion of the study in accordance with institutional requirements. At the end of the retention period, documents containing direct participant identifiers and the master code linking participant identities to study identification numbers will be securely destroyed.

15. Statistical Plan
15.1. Study Hypotheses
Primary Hypothesis - Children enrolled at intervention sites will demonstrate a greater reduction in BMI z-score from baseline to 12 months than children enrolled at comparison sites.

Secondary Hypotheses - Compared with children enrolled at comparison sites, children enrolled at intervention sites will demonstrate:

- Reduced sugar-sweetened beverage (SSB) consumption from baseline to 12 months; and
- Increased water consumption from baseline to 12 months.

Exploratory Hypothesis - Changes in youth empowerment will mediate the effects of the intervention on child BMI z-score, SSB consumption, and water consumption.

15.2.Sample Size Determination
A total of 450 parent-child dyads (900 participants) will be enrolled across 10 Boys & Girls Club (BGC) sites, with an average of 45 parent-child dyads per site. The sample size was determined based on the primary hypothesis that children enrolled at intervention sites will demonstrate a greater reduction in BMI z-score from baseline to 12 months than children enrolled at comparison sites.

Preliminary data from the pilot study demonstrated an intervention effect of 0.22 BMI z-score units over 6 months. To provide a conservative estimate that accounts for potential attenuation of intervention effects over a longer follow-up period, the study is powered to detect a 0.10-unit difference in BMI z-score over 12 months, assuming a standard deviation of 0.15 in both study groups. Prior school-based and community-based childhood obesity prevention interventions

have reported between-group differences in BMI z-score ranging from approximately 0.00 to 0.16 units over 12–18 months, supporting the selected effect size for the present study.

The sample size calculation assumes an intra-class correlation coefficient (ICC) of 0.05, based on previous studies reporting ICCs between 0.01 and 0.05. Assuming a two-sided significance level of $\alpha = 0.05$ and 75% participant retention, enrollment of 450 parent-child dyads provides greater than 80% power to detect a 0.10-unit difference in BMI z-score and greater than 90% power to detect a 0.20-unit difference between study conditions.

Recruitment feasibility is supported by the study team's pilot work and by the participating BGC network. Ten BGC sites have committed to participate in the study. Collectively, these sites enroll more than 7,500 children annually within the target age range (9–12 years), providing an adequate pool of eligible participants to achieve the target sample size. If a participating site withdraws prior to enrollment, the study team will work with the Massachusetts Alliance of BGCs to identify a replacement site.

15.3 Statistical Methods

Primary analysis - Distributions, descriptive statistics, and missing values will be examined for child BMI z-scores. Bivariate analyses will compare intervention and comparison group characteristics using chi-square tests for categorical variables and t-tests for continuous variables. These results will identify clinically relevant or statistically notable ($p<0.1$) imbalances between groups that will be adjusted for in multivariable analyses. Analyses will utilize an intent-to-treat approach, with each participant enrolled in the intervention site analyzed as part of the group.To test our primary hypothesis that children in intervention sites will have decreased BMI z-scores compared to children in comparison sites, we will apply generalized linear mixed models using BMI z-scores as the main outcome. The hierarchical structure of the data (repeated measures on youth nested within sites) will be modeled by including participant- and site-level random intercepts. A more complex covariance structure for repeated measures over time on participants (e.g. unstructured covariance) will be incorporated into the analysis if necessary.

The main predictors of the model include study condition (intervention vs. control), all time points (baseline, 2, 6, and 12 months), and the interaction term between study condition and time points. Intervention effects will be evaluated over the entire study period by testing the interaction term of time and study condition, and by specifically comparing change from baseline to 12 months via a statistical contrast. We will also compare changes from baseline to earlier time points using this approach. Covariates associated with child BMI (e.g., gender, race, other dietary intake, physical activity, screen time) will be examined for balance between groups and incorporated into multivariable analyses if imbalances ($p<0.1$) occur.

Potential moderating effects of gender, age, and race/ethnicity on intervention effects will be examined via a three-way interaction with the moderator, the study condition indicator and time. A significant interaction term signals possible moderating effects. In such cases, we will analyze and report intervention effects by appropriate subgroups (e.g., males vs. females). Participants with incomplete follow-up can be included in analyses, which are valid under a missing at random assumption. We will also assess the likelihood of nonignorable missing data using a pattern mixture model.

Secondary Analysis - To test our Aim 2 hypothesis that children in intervention sites will have decreased SSB intake and increased water intake than children in control sites over 12 months, we propose to compare SSB and water intake using linear mixed models and similar approaches for hypothesis testing described in Aim 1 (see above). Comparisons of group mean changes from baseline to 2 and 6 months will also utilize this approach. We will additionally examine changes in child self-efficacy, parental beverage intake, SSB home availability, and spontaneous changes in other BMI-related behaviors (other dietary intake, physical activity, screen time, sleep) over time and by study condition using methods described above.

Exploratory analysis - For our mediation hypothesis, we will follow the framework of Baron and Kenney using our linear mixed model approach described in Aim 1. We will examine the impact of including youth empowerment in the primary models on estimating change in child BMI z-scores (primary outcomes) and child SSB and water intake (secondary outcomes) by first examining the intervention effect on youth empowerment using a linear mixed model, i.e., testing whether the pattern of change in youth empowerment over time differs by study condition via a statistical interaction. Next, we will examine the effect of youth empowerment on primary and secondary outcomes by incorporating an empowerment by time interaction, i.e. testing whether patterns of change over time in outcomes depend on level of empowerment. Finally, we will incorporate both interaction terms (study condition by time and empowerment by time) to determine if the intervention effect is partially or fully mediated by empowerment. We will examine empowerment as a mediator regardless of statistical significance of the intervention effect, recognizing that this is not necessary for mediation to have occurred.

16. Ethical Considerations

This study will be conducted in accordance with the ethical principles outlined in the Declaration of Helsinki, applicable federal regulations governing research involving human participants, and Boston University Institutional Review Board (IRB) policies and procedures.
The study protocol, informed consent and assent documents, recruitment materials, and all participant-facing materials will receive approval from the Boston University Medical Campus IRB prior to implementation. Any protocol modifications affecting study procedures or participant protections will receive IRB approval before implementation, except where necessary to eliminate an immediate hazard to participants.

The study involves parent-child dyads, including children ages 9–12 years, who are considered a vulnerable research population. Appropriate protections include parental permission, child assent, age-appropriate explanation of study procedures, opportunities for children to ask questions privately, and clear communication that participation is voluntary. Parents and children will be informed that declining participation or withdrawing from the study will not affect participation in BGC programs or access to services.

Participant privacy and confidentiality will be protected through the use of unique study identification numbers, secure storage of identifiable information, restricted access to study records, and procedures described in prior sections. Participant safety will be monitored throughout the study in accordance with the Data and Safety Monitoring Plan described above.

The study is considered minimal risk because it evaluates an educational behavioral intervention promoting healthy beverage consumption. Potential risks are minimized through appropriate eligibility screening, trained study personnel, established confidentiality protections, and ongoing safety monitoring.