Health Literacy and Obesogenic Behaviors

Unique Protocol Identification Number: HLSQUARED01

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Principal Investigator: Sasha Fleary

Sponsor: CUNY Graduate School of Public Health and Health Policy

Grant Title: Health Literacy as a Vehicle to Reduce Obesogenic Behaviors Among Adolescents: A Pilot Intervention

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STATEMENT OF COMPLIANCE

The trial will be carried out in accordance with International Council on Harmonisation Good Clinical Practice (ICH GCP) and the following:

- United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812).

National Institutes of Health (NIH)-funded investigators and clinical trial site staff who are responsible for the conduct, management, or oversight of NIH-funded clinical trials have completed Human Subjects Protection and ICH GCP Training.

INVESTIGATOR'S SIGNATURE

Principal Investigator or Clinical Site Investigator:

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1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title:	Health Literacy and Obesogenic Behaviors
Grant Number:	R21DK117345
Study Description:	The goal of the proposed study is to examine the effect of adding a health literacy component to an obesity prevention intervention that addresses adolescents' obesogenic behavior-related health knowledge, motivation, and behavioral skills. The central hypothesis is adolescents receiving health literacy training as part of an obesity prevention intervention will have higher rates of prevention behaviors than those in the obesity prevention only condition.
Objectives*:	Primary Objective: Determine if the addition of HL training to an interactive digital obesity prevention intervention will improve adolescents' obesity prevention behaviors over the obesity intervention alone.
Endpoints*:	Primary Endpoint: 1-month follow-up
Study Population:	Adolescents
Phase* or Stage:	Phase 1
Description of Sites/Facilities Enrolling Participants:	Community sites in the United States
Description of Study Intervention/Experimental Manipulation:	Web-based intervention administered to individuals. The intervention contains 5 modules with an expected completion rate of 1 module per week.
Study Duration*:	5 months
Participant Duration:	3 months

1.2 SCHEDULE OF ACTIVITIES

	Week 1	Week 2	Weeks 3-7	Week 8	Week 12
Parent permission	X				
Adolescent assent		X			
Pretest survey including all		X			

outcome measures					
Randomization		X			
Control & experimental interventions			X		
Posttest survey				X	
1-month follow-up survey					X
Adverse event reporting	X	X	X	X	X

2 INTRODUCTION

2.1 STUDY RATIONALE

The prevalence of adolescent behaviors that can lead to obesity are alarming, and reduced life expectancy is the future of America's youth if behavioral changes are not implemented to improve health and reduce the obesity burden. Researchers have argued that health literacy is a precursor to health knowledge and is necessary for translating knowledge about healthy choices into behavior, with low health literacy being associated with reduced preventive health behaviors in adults. Given the lack of health literacy-specific interventions addressing adolescents' obesogenic behaviors, the purpose of this study is to examine the preliminary effectiveness of adding a health literacy module to an obesity prevention intervention that addresses adolescents' obesogenic behaviors.

2.2 BACKGROUND

The rates of pediatric obesity (~19%) and diabetes (0.24%) in the US are alarming and behaviors implicated in obesity and type 2 diabetes are highly prevalent. Approximately 69% and 73% of adolescents consume less than two fruits and vegetables daily respectively, while 53% engage in insufficient physical activity. These behaviors magnify adolescents' immediate and long-term risks for obesity and obesity-related chronic illnesses, as well as complicate the treatment of obesity-related chronic illnesses. Children and adolescents who are obese are four times more likely to be diagnosed with type 2 diabetes than normal weight children, with serious short and long-term consequences impacting quality of life. Reduced life expectancy is the future of America's youth if behavioral changes are not implemented to improve health and reduce the obesity burden. Reversing current national trends in obesity and type 2 diabetes require novel and sustainable prevention strategies to address children and adolescents' obesogenic behaviors.

Adolescence is marked by increased autonomy in decision-making, yet data suggest that adolescents are not equipped with all the skills to make effective health-related behavioral decisions. While health knowledge works in conjunction with motivation and behavioral skills to predict behavior, most existing adolescent interventions target these variables in isolation with modest success. Researchers have argued that health literacy (HL) – the ability to access, understand, and use health information to make informed health decisions – is a precursor to health knowledge and is necessary for translating health knowledge into behavior. Low HL among adults is associated with poor ability to interpret health messages, and results in reduced preventive health behaviors. Further, parent and adolescent HL is negatively related to adolescents' obesity status. Thus, while research on adding HL to existing behavior interventions to improve adolescents' obesity prevention behaviors is lacking, it is expected that the inclusion of HL into existing interventions will increase intervention effectiveness and positive behavior outcomes.

The long-term goal of this line of research is to reduce the incidence of obesity in adolescents and by extension reduce the risk for obesity-related chronic illnesses using interventions that address individual

and contextual factors related to long-term health decision-making and behavior change. The goal of the proposed study is to examine the effect of adding a HL component to an obesity prevention intervention that addresses adolescents' obesogenic behavior-related health knowledge, motivation, and behavioral skills. The central hypothesis is adolescents receiving HL training as part of an obesity prevention intervention will have higher rates of prevention behaviors than those in the obesity prevention only condition.

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 KNOWN POTENTIAL RISKS

Potential risk is primarily breach of confidentiality for low risk personal information such as participants' discussing intervention content to non-participants. Participants may feel some discomfort answering questions about their obesogenic behaviors and health literacy. Additionally, asking about obesogenic behaviors may bring up potentially sensitive issues, such as unhealthy weight control behaviors. Participants who report unhealthy weight control behaviors will be referred to their organization's youth program officer or mental health liaison for help with these problems. As part of the informed consent and assent, we will make both parents and participants aware of the purpose of the evaluation, the minimal risks described above, and make it clear that participation is voluntary.

2.3.2 KNOWN POTENTIAL BENEFITS

Potential direct benefits to all participants include education on health literacy and obesity-related health information, motivation, and behavioral skills. Specifically, participants will be provided with tools for improving health literacy and obesogenic behaviors. Indirect benefits include increased understanding of health literacy and obesogenic behaviors in adolescents can lead to more targeted interventions and health education in community settings.

2.3.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

The risks associated with participating in this study are no more than what an adolescent may experience in their daily lives. The benefits to be gained from attaining a better understanding of adolescents' health literacy and obesity-related health information, motivation, and behavioral skills and how all of this relate to their obesogenic behaviors outweigh the risks as this can have long-term consequences on what is addressed in their health curriculum, how practitioners interact with adolescents, and ultimately influence adolescents' risks for obesity and obesity-related diseases in adulthood.

4 STUDY DESIGN

4.1 OVERALL DESIGN

This is a two-arm pilot randomized control trial. Intervention conditions include (1) obesity prevention intervention without a health literacy component and (2) obesity prevention intervention with a health literacy component. This design answers the research question: “does adding a health literacy component to an obesity prevention intervention improve behavioral outcomes more than an obesity prevention intervention without a health literacy component?”

4.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

This study design will allow for determining the preliminary efficacy of the intervention and the results will be used to calculate power for a full-scale trial.

4.3 JUSTIFICATION FOR INTERVENTION

Approximately 95% of adolescents own or have access to a smartphone and ~45% are online almost constantly. Approximately 88% of adolescents have access to a computer at home. All US libraries have public-use computers with internet connectivity and 98% offer free public Wi-Fi access. These data support internet-based (eHealth) platforms for developing tools and interventions to promote health behavior change and improve adolescents’ health outcomes. EHealth interventions targeting health behavior change have increased dramatically over the last 10-20 years and eHealth interventions addressing obesity in adolescents have had favorable outcomes on reducing body mass index and improving PA and diet.

Methods for intervention delivery: The intervention will be delivered in a digital online format. This study will use the DeLP platform to deliver the intervention.

Description of Digital Platform. Created by 3C Institute, DeLP, is an online platform that uses evidence-based cognitive theory of multimedia learning to engage diverse types of online learners. The platform allows each online module to contain a mix of didactic instructions with self-assessments, demonstration videos, and interactive practice activities to apply learned skills (e.g., mini-games, second life-inspired role playing). DeLP integrates cognitive learning principles through active engagement and use of multiple sensory modalities, both of which are implicated in enhanced user engagement, learning and memory. Research has consistently supported DeLP's high quality (e.g., ratings of quality, appeal, and engagement), value (e.g., ratings of value, innovation, and likely impact), and ease of use (e.g., ratings of usability, feasibility, and acceptability in real-world settings), in addition to DeLP's ability to achieve learning objectives. Further, DeLP is built on HTML5 web standards accessible through any modern web browser and smartphone with no extra software, hardware, or technical expertise needed.

The intervention uses multiple instructional styles (e.g., illustrative role plays) and interactive elements (e.g., self-assessments, mini-games, drag-and-drops) to facilitate learning and memory of intervention content and maintain user engagement.

4.4 END-OF-STUDY DEFINITION

A participant is considered to have completed the study if he or she has completed the pretest assessments, all intervention modules, posttest assessments, and 1-month follow-up assessments. The end of the study is defined as completion of the 1-month follow-up assessment.

5 STUDY POPULATION

5.1 INCLUSION CRITERIA

Adolescents 13-16 years old at time of enrollment (may turn age 17 during the study
Must have parental consent
All weight classifications

5.2 EXCLUSION CRITERIA

Adolescents younger than 13 years or older than 16 years at time of enrollment
No parental consent
Medical conditions preventing engagement in physical activity
Medical conditions resulting in extremely restricted diets (e.g., ketogenic diet)
Already participating in an intervention related to healthy eating, physical activity and/or obesity prevention or treatment

5.3 SCREEN FAILURES

Screen failures are defined as participants who consent/assent to participate in this study but are not subsequently assigned to the study intervention or entered in the study. Individuals who do not meet the criteria for participation in this trial (screen failure) because of meeting one or more exclusion criteria that are likely to change over time may be rescreened. Screen failures will be notified that they are not eligible for the study and asked if they would like to be considered for future studies.

5.4 STRATEGIES FOR RECRUITMENT AND RETENTION

Recruitment
Study flyers will be posted in public areas at each site, announcements will be made at youth events, and study staff will table at community sites.

Retention
One of the advantages of a digital intervention is that it decreases the travel and time burdens as individuals may complete the modules based on their individual schedules. While adolescents may not prioritize the intervention or forget about it given the lack of deadline, the intervention will have a built-in point system to immediately incentivize data collection and module completion. For example, participants will be provided with a suggested schedule for completing the modules and will receive email and text prompts encouraging them to log in and complete the module prior to the scheduled date. They will be incentivized through the point system for completing the module early and according

to the schedule. Participants will also be incentivized through the point system to complete each module in one sitting to facilitate making connections across the module. Though participants will receive gift cards at each data collection completion, they will also receive points for completing data collections. These points may be redeemed for prizes at the end of the study through the points store where more desirable prizes will require more points. Collecting biometric data at posttest and follow-up may be difficult given that all other data collection will occur online. Bonus incentives for completing all aspects of the study (intervention and all data collection) should further motivate participants to maintain involvement in the project. The use of email and text prompts throughout the study should also encourage retention. We plan to collect multiple phone numbers and email address for participants and their parents to be able to reach them in the event of lost devices or changes in phone numbers or email addresses.

6 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S)

6.1 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S) ADMINISTRATION

6.1.1 STUDY INTERVENTION OR EXPERIMENTAL MANIPULATION DESCRIPTION

Comparison Arm: Vaping and Obesity Prevention Only

Arm Description: Obesity prevention and vaping

Module 1. Introduction

• Introduction to the intervention and orientation for using the web platform

• Initial goal setting

Module 2. Vaping

• Factual information about vaping devices and vaping

• Beliefs and attitudes about nicotine products

• Refusing and avoiding vaping

• Recognizing addiction and getting help

Module 3. Health information

• Factual information about healthy eating and activity (PA)

Module 4. Motivation

• Personal: Create positive attitudes toward engagement in healthy eating and PA

• Social: Enlisting social support to increase healthy eating and PA

• Social: Identification of community resources that promote and support healthy eating and PA

Module 5. Behavioral Skills

• Tips for engaging in prevention behaviors and avoiding risk behaviors in the context of existing barriers

• Skills for social situations around behaviors

• Skills for making behavior part of routine

• Build autonomy, self-efficacy and model good health decision-making for health behaviors

Experimental Arm: Health Literacy and Obesity Prevention

Arm Description: Obesity prevention and health literacy (HL).

Module 1. Introduction

• Introduction to the intervention and orientation for using the web platform

• Initial goal setting

Module 2. Health Literacy

• Functional HL: skills for reading/understanding nutrition labels and medication instructions

• Interactive HL: verbal skills for interacting with others on health issues

• Critical HL: connections between advocacy and health

• Media HL: skills for accessing and identifying reliable source of media

Module 3. Health information

• Factual information about healthy eating and activity (PA)

Module 4. Motivation

• Personal: Create positive attitudes toward engagement in healthy eating and PA

• Social: Enlisting social support to increase healthy eating and PA
• Social: Identification of community resources that promote and support healthy eating and PA
Module 5. Behavioral Skills
• Tips for engaging in prevention behaviors and avoiding risk behaviors in the context of existing barriers
• Skills for social situations around behaviors
• Skills for making behavior part of routine
• Build autonomy, self-efficacy and model good health decision-making for health behaviors

6.1.2 ADMINISTRATION AND/OR DOSING

The intervention will be administered through an interactive web-based platform. The intervention will not be proctored, rather participants may complete modules at their convenience. However, they will be provided with a suggested schedule for completing the modules. In addition to an introductory module (i.e., what is the program, instructions of navigating the website, introduction to actors, and goal setting task), the intervention includes 4 modules with 3-4 lessons per module. Lessons range from approximately 12-20 minutes long. User metrics (e.g., number of times viewed, length of time spent on page/activity) will be monitored to assess dosing.

6.2 FIDELITY

6.2.1 INTERVENTIONIST TRAINING AND TRACKING

Fidelity will be assessed by monitoring user metrics including percent of video played and length of time spent on activity (vs. predicted length of time for activity completion). No interventionist training is required as the intervention is administered through a pre-programmed digital platform and is self-paced.

6.3 MEASURES TO MINIMIZE BIAS: RANDOMIZATION AND BLINDING

Masking is not applicable to the study design. Participants will be randomized to conditions upon enrollment with the goal of balancing the number of participants in each condition (e.g., 1st participant assigned to condition 1, 2nd to condition 2, 3rd to condition 1).

6.4 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION ADHERENCE

Adherence to the protocol will be tracked by the dashboard for the web-based intervention. User metrics will include a completion rate.

7 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1 DISCONTINUATION OF STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

When a participant discontinues from study intervention, remaining study procedures will be discontinued. Attempts will be made to collect data on the participant's reason for discontinuing participation.

7.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Participants are free to withdraw from participation in the study at any time upon request.
An investigator may discontinue a participant from the study for the following reasons:

- Significant study intervention non-compliance
- Lost-to-follow up; unable to contact subject
- The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation

The reason for participant discontinuation or withdrawal from the study will be recorded.

7.3 LOST TO FOLLOW-UP

A participant will be considered lost to follow-up if he or she fails to complete the intervention or posttest and follow-up assessments and study staff are unable to contact the participant after at least 2 attempts.
The following actions must be taken if a participant fails to complete the intervention modules or assessments:

- The site will attempt to contact the participant and ascertain if the participant wishes to and/or should continue in the study
- Before a participant is deemed lost to follow-up, the investigator or designee will make every effort to regain contact with the participant (where possible, 3 text messages and/or emails). These contact attempts will be documented in the participant’s study file.
- Should the participant continue to be unreachable, he or she will be considered to have withdrawn from the study with a primary reason of lost to follow-up.

8 STUDY ASSESSMENTS AND PROCEDURES

8.1 ENDPOINT AND OTHER NON-SAFETY ASSESSMENTS

Primary outcomes. The primary outcomes of the study are the obesogenic behaviors that are expected to change as a result of participation in the intervention including:

- Diet: Within diet, we are interested in both healthy eating (e.g., fruits and vegetables, whole grain, fiber, calcium) and unhealthy eating (sugary and salty foods, fast foods, sugar-sweetened beverages, saturated fats) (healthy and unhealthy). The Dietary Screener Questionnaire and National Youth Physical Activity and Nutrition Study survey, two measures widely used in diet and obesity-related research with acceptable reliability and validity will be used to assess diet. These questionnaires assess frequency of intake in the past 7-30 days.

- Activity: Both physical activity and sedentary activity will be assessed. The Youth Activity Profile is a 15-item questionnaire designed to assess physical activity and sedentary behavior in youth. This self-report measure has been cross-validated with objective measures of physical activity and resulted in similar group estimates acquired from objective measures. The Godin and Shephard Leisure-Time Physical Activity Questionnaire is a 3-item self-report assessment of leisure time physical activity and provides corresponding metabolic equivalents. Both measures provide minutes in activity and use a 7-day recall.

Secondary outcomes. The secondary outcomes of the study is change in health literacy.

- Four types of health literacy will be assessed. Functional, interactive, and critical health literacy will be assessed using an objective measure, the Adolescent Assessments of Health Literacy. Media health literacy will be measured using an objective measure, Adolescent Media Health Literacy Scale.

All assessments are validated and will be scored per the test authors' scoring guidelines.

8.2 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

8.2.1 DEFINITION OF ADVERSE EVENTS

This protocol uses the definition of adverse event from 21 CFR 312.32 (a): any untoward medical occurrence associated with the use of an intervention in humans, ***whether or not considered intervention-related***.

8.2.2 DEFINITION OF SERIOUS ADVERSE EVENTS

An adverse event is serious when medical or surgical intervention is required to prevent any of the following, or when any of the following occur:
o Death
o A life-threatening situation
o Inpatient hospitalization
o Prolongation of existing hospitalization

o A persistent or significant disability/incapacity, or congenital anomaly/birth defect

8.2.3 CLASSIFICATION OF AN ADVERSE EVENT

8.2.3.1 SEVERITY OF EVENT

For adverse events (AEs) not included in the protocol defined grading system, the following guidelines will be used to describe severity.

- **Mild** – Events require minimal or no treatment and do not interfere with the participant's daily activities.
- **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- **Severe** – Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term "severe" does not necessarily equate to "serious".

8.2.3.2 RELATIONSHIP TO STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

All adverse events (AEs) will have their relationship to study procedures, including the intervention, assessed by an appropriately-trained clinician based on temporal relationship and his/her clinical judgment. The degree of certainty about causality will be graded using the categories below.

- **Related** – The AE is known to occur with the study procedures, there is a reasonable possibility that the study procedures caused the AE, or there is a temporal relationship between the study procedures and the event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study procedures and the AE.
- **Not Related** – There is not a reasonable possibility that the study procedures caused the event, there is no temporal relationship between the study procedures and event onset, or an alternate etiology has been established.

OR

- **Definitely Related** – There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out. The clinical event, including an abnormal laboratory test result, occurs in a plausible time relationship to study procedures administration and cannot be explained by concurrent disease or other drugs or chemicals. The response to withdrawal of the

study procedures should be clinically plausible. The event must be pharmacologically or phenomenologically definitive.

- **Probably Related** – There is evidence to suggest a causal relationship, and the influence of other factors is unlikely. The clinical event, including an abnormal laboratory test result, occurs within a reasonable time after administration of the study procedures, is unlikely to be attributed to concurrent disease or other drugs or chemicals, and follows a clinically reasonable response on withdrawal.

- **Potentially Related** – There is some evidence to suggest a causal relationship (e.g., the event occurred within a reasonable time after administration of study procedures). However, other factors may have contributed to the event (e.g., the participant's clinical condition, other concomitant events). Although an AE may rate only as "possibly related" soon after discovery, it can be flagged as requiring more information and later be upgraded to "probably related" or "definitely related", as appropriate.

- **Unlikely to be related** – A clinical event, including an abnormal laboratory test result, whose temporal relationship to study procedures administration makes a causal relationship improbable (e.g., the event did not occur within a reasonable time after administration of the study procedures) and in which other drugs or chemicals or underlying disease provides plausible explanations (e.g., the participant's clinical condition, other concomitant treatments).

- **Not Related** – The AE is completely independent of study procedures administration, and/or evidence exists that the event is definitely related to another etiology. There must be an alternative, definitive etiology documented by the clinician.

8.2.3.3 EXPECTEDNESS

A clinician with appropriate expertise in pediatric psychology or pediatrics will be responsible for determining whether an adverse event (AE) is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study procedures.

8.2.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during study visits and interviews of a study participant presenting for medical care, or upon review by a study monitor.

All AEs, not otherwise precluded per the protocol, will be captured on the appropriate case report form (CRF). Information to be collected includes event description, time of onset, clinician's assessment of severity, relationship to study procedures (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event. All AEs occurring while on study will be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

Any medical or psychiatric condition that is present at the time that the participant is screened will be considered as baseline and not reported as an AE. However, if the study participant's condition deteriorates at any time during the study, it will be recorded as an AE.

Changes in the severity of an AE will be documented to allow an assessment of the duration of the event at each level of severity to be performed. Documentation of onset and duration of each episode will be maintained for AEs characterized as intermittent.

The PI will record events with start dates occurring any time after informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. At each study visit, the investigator will inquire about the occurrence of AE/SAEs since the last visit. Events will be followed for outcome information until resolution or stabilization

8.2.5 ADVERSE EVENT REPORTING

Although the intervention in this clinical trial poses low risk to participants, adverse events information will be collected at all assessments as part of the study protocol and participants will be advised to use the "contact research staff" button to report any adverse experiences during the course of the intervention. Adverse events will be recorded on forms that are consistent with NIH and the CUNY University Integrated IRB policies. While we do not expect this research to result in adverse events that lead to a participant seeking medical care and/or hospitalization, if this should occur, then they will be reported by the PI to the IRB within 24 hours and on annual reports to the IRB. Additional reporting to the project officer at NIH will be carried out within 7 days of the incident. Study activities will also be suspended until determination of risk to other participants is made by the IRB.

8.2.6 SERIOUS ADVERSE EVENT REPORTING

In consultation with the PI, a trained member of the study team will be responsible for conducting an evaluation of a serious adverse event and shall report the results of such evaluation to the NIH and the reviewing Institutional Review Board (IRB) as soon as possible, but in no event later than 10 working days after the investigator first learns of the event.

8.3 UNANTICIPATED PROBLEMS

8.3.1 DEFINITION OF UNANTICIPATED PROBLEMS

This protocol uses the definition of Unanticipated Problems as defined by the Office for Human Research Protections (OHRP). OHRP considers unanticipated problems involving risks to participants or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-

approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;

- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

8.3.2 UNANTICIPATED PROBLEMS REPORTING

The investigator will report unanticipated problems (UPs) to the reviewing Institutional Review Board (IRB). The UP report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number
- A detailed description of the event, incident, experience, or outcome
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- UPs that are serious adverse events (SAEs) will be reported to the IRB and to the study sponsor/funding agency within 10 days of the investigator becoming aware of the event
- Any other UP will be reported to the IRB and to the study sponsor/funding agency within 10 of the investigator becoming aware of the problem
- All UPs should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and the Office for Human Research Protections (OHRP) within 30 days of the IRB's receipt of the report of the problem from the investigator

9 STATISTICAL CONSIDERATIONS

9.1 STATISTICAL HYPOTHESES

- Primary Efficacy Endpoint(s):

Adolescents in the experimental condition (obesity prevention plus health literacy) will have higher rates of obesity prevention behaviors at follow-up compared to the obesity prevention only group.

9.2 SAMPLE SIZE DETERMINATION

This is a feasibility pilot study, therefore the sample size was not determined via power calculations.

9.3 POPULATIONS FOR ANALYSES

Intention-to-Treat (ITT) analysis population (i.e., all randomized participants).

9.4 STATISTICAL ANALYSES

9.4.1 GENERAL APPROACH

Descriptive analyses will be calculated for all variables. We will compare the two study groups on baseline variables to assess whether balance was achieved through the randomization. Changes from pretest to 1-month follow-up on continuous primary and secondary outcome variables will be compared between groups using t-tests. Binary primary and secondary outcome variables (outcome improved vs. not improved) will be compared between groups using Chi-tests.

Group differences on change in physical activity (i.e., metabolic equivalents, number of days 60 minutes or more of physical activity), and diet (number of fruits and vegetables, junk food, sugar-sweetened beverages consumed per week), as well as the standard deviations of the changes in each group, will be used to calculate sample size for the next study.

10 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

10.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

10.1.1 INFORMED CONSENT PROCESS

Participants will be recruited from the community organizations that agree to participate in the study with the help of community organization personnel; community organization personnel will distribute information sheets and parent permission forms to parents and adolescents. Adolescents who return signed permission forms will be provided with assent forms. Adolescents with signed parent permission forms and who provide assent will allowed to participate in the study. The permission and assent forms will be written in simple, easy to understand language and will be reviewed by the CUNY University Integrated Institutional Review Board (IRB). Parent permission forms will be provided in both English and Spanish to accommodate Hispanic parents who are non-fluent in English. Permission from parents and assent from participants will be obtained prior to any participation in the research. The trained study research assistants will explain the purpose, methods, and extent of the study to all parents in the permission form, and ask them to call the researchers with any questions before signing. The study research assistants will also explain the purpose, methods, and extent of the study to all adolescents with signed informed consent forms, and give them an opportunity to ask any questions before providing assent. In addition, study research assistants will question potential participants to confirm their understanding of the information. Research assistants will be given a structured checklist for this purpose.

10.1.2 STUDY DISCONTINUATION AND CLOSURE

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform study participants, the IRB, and sponsor and will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance of study staff to the protocol (i.e., significant protocol violations)
- Data that are not sufficiently complete and/or evaluable
- Determination that the primary endpoint has been met
- Determination of futility

The study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the funding agency, sponsor, IRB, or other relevant regulatory or oversight bodies (OHRP, DSMB).

10.1.3 CONFIDENTIALITY AND PRIVACY

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, the safety and oversight monitor(s), and the sponsor(s) and funding agency. This confidentiality is extended to the data being collected as part of this study. Data that could be used to identify a specific study participant will be held in strict confidence within the research team. No personally-identifiable information from the study will be released to any unauthorized third party without prior written approval of the sponsor/funding agency.

All research activities will be conducted in as private a setting as possible.

The study monitor, other authorized representatives of the sponsor, representatives of the Institutional Review Board (IRB), and regulatory agencies may inspect all documents and records required to be maintained by the investigator. The clinical study site will permit access to such records.

The study participant's contact information will be securely stored at the clinical site for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB, Institutional policies, or sponsor requirements.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored at CUNY SPH. This will not include the participant's contact or identifying information. Rather, individual participants and their research data will be identified by a unique study identification number. The study data entry and study management systems will be secured and password protected. At the end of the study, all study databases will be de-identified and archived.

Measures Taken to Ensure Confidentiality of Data Shared per the NIH Data Sharing Policies It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public (see https://grants.nih.gov/policy/sharing.htm). The PI will ensure all mechanisms used to share data will include proper plans and safeguards for the protection of privacy, confidentiality, and security for data dissemination and reuse (e.g., all data will be thoroughly de-identified and will not be traceable to a specific study participant). Plans for archiving and long-term preservation of the data will be implemented, as appropriate.

Certificate of Confidentiality

To further protect the privacy of study participants, the Secretary, Health and Human Services (HHS), has issued a Certificate of Confidentiality (CoC) to all researchers engaged in biomedical, behavioral, clinical or other human subjects research funded wholly or in part by the federal government. Recipients of NIH funding for human subjects research are required to protect identifiable research information from forced disclosure per the terms of the NIH Policy (see https://humansubjects.nih.gov/coc/index). As set forth in 45 CFR Part 75.303(a) and NIHGPS Chapter 8.3, recipients conducting NIH-supported research covered by this Policy are required to establish and maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with Federal statutes, regulations, and the terms and conditions of award. It is the NIH policy that investigators and others who have access to research records will not disclose identifying information except when the participant consents or in certain instances when federal, state, or local law or regulation requires disclosure. NIH expects investigators to inform research participants of the protections and the limits to protections provided by a Certificate issued by this Policy.

10.1.4 FUTURE USE OF STORED SPECIMENS AND DATA

Data collected for this study will be analyzed and stored at CUNY SPH. Due to the small sample size that increases the identifiability of participants, data will not be stored at a repository.

10.1.5 SAFETY OVERSIGHT

Safety oversight will be under the direction of the CUNY IRB.

10.1.6 QUALITY ASSURANCE AND QUALITY CONTROL

Quality control (QC) procedures will be implemented as follows:

Parent permission and adolescent assent - Study staff will review both the documentation of the permission and assenting process as well as a percentage of the completed assent documents. This review will evaluate compliance with GCP, accuracy, and completeness. Feedback will be provided to the study team to ensure proper permission and assenting procedures are followed.

Source documents and the electronic data - Data will be captured from electronic surveys and downloaded to the study database.

Intervention Fidelity - Consistent delivery of the study interventions will be monitored throughout the intervention phase of the study. Procedures for ensuring fidelity of intervention delivery are described in **Section 6.2.1, Interventionist Training and Tracking**.

Protocol Deviations - The study team will review protocol deviations on an ongoing basis and will implement corrective actions when the quantity or nature of deviations are deemed to be at a level of concern.

Should independent monitoring become necessary, the PI will provide direct access to all trial related sites, source data/documents, and reports for the purpose of monitoring and auditing by the sponsor/funding agency, and inspection by local and regulatory authorities.

10.1.7 DATA HANDLING AND RECORD KEEPING

10.1.7.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data collection will be the responsibility of the clinical trial staff under the supervision of the PI. The PI will be responsible for ensuring the accuracy, completeness, and timeliness of the data reported.

All data will be collected using electronic survey and will be downloaded directly in the data management system. The data system includes password protection and internal quality checks, such as automatic range checks, to identify data that appear inconsistent, incomplete, or inaccurate.

10.1.7.2 STUDY RECORDS RETENTION

Study documents will be retained until at least 2 years have elapsed since the formal discontinuation of the study intervention. These documents should be retained for a longer period, however, if required by local regulations. No records will be destroyed without the written consent of the sponsor/funding agency, if applicable. It is the responsibility of the sponsor/funding agency to inform the investigator when these documents no longer need to be retained.

10.1.8 PROTOCOL DEVIATIONS

This protocol defines a protocol deviation as any noncompliance with the clinical trial protocol, International Council on Harmonisation Good Clinical Practice (ICH GCP), or Manual of Procedures (MOP) requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions will be developed by the site and implemented promptly.

These practices are consistent with ICH GCP:

- Section 4.5 Compliance with Protocol, subsections 4.5.1, 4.5.2, and 4.5.3
- Section 5.1 Quality Assurance and Quality Control, subsection 5.1.1
- Section 5.20 Noncompliance, subsections 5.20.1, and 5.20.2.

It will be the responsibility of the PI to use continuous vigilance to identify and report deviations within 5 working days of identification of the protocol deviation, or within 10 working days of the scheduled protocol-required activity. All deviations must be addressed in study source documents and reported to the NIH NIDDK Program Official. Protocol deviations must be sent to the reviewing IRB per their policies. The PI is responsible for knowing and adhering to the reviewing IRB requirements.

10.1.9 PUBLICATION AND DATA SHARING POLICY

This study will be conducted in accordance with the following publication and data sharing policies and regulations:

National Institutes of Health (NIH) Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

This study will comply with the NIH Data Sharing Policy and Policy on the Dissemination of NIH-Funded Clinical Trial Information and the Clinical Trials Registration and Results Information Submission rule. As such, this trial will be registered at ClinicalTrials.gov, and results information from this trial will be submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in peer-reviewed journals.

10.1.10 CONFLICT OF INTEREST POLICY

The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial. The study leadership in conjunction with the NIDDK has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

10.2 ADDITIONAL CONSIDERATIONS