Kids SipSmartER, an Intervention to Reduce Sugar-sweetened Beverages

Study Protocol

NCT#: NCT03740113

Date: 09/04/2024

Human Research Protection Program
Institutional Review Board for Social & Behavioral Sciences
iProtocol

Current User: **Porter, Kathleen (kjp9c)**

Protocol Number: 2371

IRB of Record: UVA

Title: Kids SipSmartER

Descriptive Title: sugar beverages, behavioral intervention, schools, Appalachia

Previous IRB-SBS Protocol Number: 2018-0195

Date Approved: **2024-09-04**

This protocol record was electronically approved on 2024-09-04

This protocol record is currently Approved.

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2021-01-18 - Conflicts of Interest - Stage 1
2016-12-08 - Conflicts of Interest - Stage 1
2023-01-09 - GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)
2023-02-17 - IRB-HSR RESEARCHER BASIC COURSE
2020-01-14 - IRB-HSR RESEARCHER BASIC COURSE
2020-01-20 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
2016-12-15 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
2023-02-17 - IRB-SBS RESEARCHER REFRESHER COURSE
2022-02-20 - Undue Foreign Influence: Risks and Mitigations

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2020-01-20 - IRB-HSR RESEARCHER BASIC COURSE
2017-01-12 - IRB-HSR RESEARCHER BASIC COURSE
2022-12-20 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS

2020-01-14 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
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2020-09-08 - Conflicts of Interest - Stage 1
2016-08-30 - Conflicts of Interest - Stage 1
2022-03-09 - IRB-HSR RESEARCHER BASIC COURSE
2019-01-29 - IRB-HSR RESEARCHER BASIC COURSE
2016-01-08 - IRB-HSR RESEARCHER BASIC COURSE
2022-03-09 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
2018-07-31 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
2015-07-21 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
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CITI Training:
2022-12-19 - GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)
2022-11-22 - GCP for Social and Behavioral Research Best Practices for Clinical Research - Basic Course
2022-11-22 - IRB-HSR RESEARCHER BASIC COURSE

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2024-05-14 - GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)
2024-05-14 - IRB-HSR RESEARCHER BASIC COURSE
2024-05-14 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS

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2023-08-01 - GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)
2024-07-26 - IRB-HSR RESEARCHER BASIC COURSE
2021-07-28 - IRB-HSR RESEARCHER BASIC COURSE
2018-07-29 - IRB-HSR RESEARCHER BASIC COURSE

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2023-07-27 - GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)
2021-09-27 - IRB-HSR RESEARCHER BASIC COURSE
2024-08-30 - IRB-HSR RESEARCHER REFRESHER COURSE

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Title: E0:Assistant Professor of Research

CITI Training:
2021-06-03 - Conflicts of Interest - Stage 1
2017-05-31 - Conflicts of Interest - Stage 1
2022-09-05 - GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)
2022-04-27 - IRB-HSR RESEARCHER BASIC COURSE
2018-11-09 - IRB-HSR RESEARCHER BASIC COURSE
2017-01-11 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
2022-01-13 - Undue Foreign Influence: Risks and Mitigations

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CITI Training:
2022-06-27 - Conflicts of Interest - Stage 1
2018-06-16 - Conflicts of Interest - Stage 1
2014-07-15 - Conflicts of Interest - Stage 1
2023-02-18 - GCP FDA Refresher
2017-04-19 - GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)
2019-05-07 - IRB-HSR RESEARCHER BASIC COURSE
2016-04-20 - IRB-HSR RESEARCHER BASIC COURSE
2022-05-27 - IRB-HSR RESEARCHER REFRESHER COURSE
2021-12-01 - Undue Foreign Influence: Risks and Mitigations

Department Chair: Bernheim, Ruth (rg3r)

non-UVA Research Team (Sub-Investigators)

non-UVA Sub-Investigator: Abedin, Naveen
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Training Documentation

View File: Abedin_Naveen - Completion Certificate.pdf
date uploaded: 2023-08-21, by: Porter, Kathleen *(kjp9c)*
This file is approved.
date approved: 2023-08-31

non-UVA Engaged Institutions (in the United States)

Use this section for non-UVA Institutions which are located in the United States.

Use the International Research section, farther down this page, for non-UVA Institutions located outside of the United States.

Is more than one institution located in the United States (another university, commercial institution, etc.) engaged in this research proposal? Yes

Institution Name: Virginia Tech

PI at Institution: Abedin, Naveen - naveenabedin@vt.edu, 469-544-6312

IRB Contact at Institution: Abedin, Naveen - naveenabedin@vt.edu , 469-544-6312

Institution Type: US Postsecondary Institution

Institution Activities: The activities at this institution are different from the research activities at the other institution in this study.

Institution Review: This institution does not require IRB review for this protocol.

Institution Activities Description:

Ms. Abedin will conduct analyses using de-identified databases and contribute to related manuscripts.

Study Overview

Anticipated end date for collecting data: 2023-12-30

Anticipated end date for analyzing data: 2024-12-30

Is this research funded? Yes

Funding Source(s): Federal government, Virginia Commonwealth (Non-UVA State fund)

Supply all Agency Grant Numbers & Titles currently associated with this protocol:

R01MD012603

Kids SIPsmartER: A multi-level behavioral and health literacy intervention to
reduce sugar-sweetened beverages among Appalachian middle-school students

&

Virginia Foundation for Healthy Youth Funding [full title: Fostering Healthy Beverage Choices to Reduce Obesity Risk: Tazewell County Public Schools HCAT]

Do any of the Funding Sources create a Conflict Of Interest for the Principal Investigator, Faculty Sponsor or Research Team (Sub-Investigators) listed on this protocol? No

What is the purpose in conducting this research? How does this study contribute to the advancement of knowledge and why is it worth doing?

Purpose The overarching goal of this proposal is to work in partnership with Appalachian middle schools to implement and evaluate Kids SIPsmartER. Kids SIPsmartER is a school-based, behavior and health literacy curriculum aimed at improving SSB behaviors among middle school students, which also engages parents/guardians to support SSB reductions at home.

Our team has been working on SSB-related behaviors in Appalachia for over 8 years. We have recently conducted a systematic literature review on youth SSB interventions34 and a feasibility study of Kids SIPsmartER in one Appalachia middle school.1,2,35 Adapted from our evidence-based SSB reduction program for Appalachian adults,36-44 Kids SIPsmartER is grounded by the Theory of Planned Behavior as well as health literacy, media literacy, numeracy, and public health literacy concepts.45-49 In our Kids SIPsmartER feasibility study we found significant improvements in SSB behaviors, media literacy and public health literacy among middle school students.1,2 Also, students and teachers found Kids SIPsmartER acceptable, in-demand, practical, and implementable within existing school resources.1,2 For this R01, Kids SIPsmartER will be a 12 session, 6-month program with an integrated two-way short service message (SMS) strategy to engage parents/guardians in SSB role modeling and supporting home SSB environment changes. Our data from the targeted counties indicate approximately 76-82% adults use SMS. Our SMS message bank will be adapted from our current interactive voice response system37,43 that has 102 SSB reduction strategies, specific to 14 barriers identified specifically for this region though formative and qualitative research phases.50-52

Our study is guided by the RE-AIM (reach, adoption, effectiveness, implementation, maintenance) framework, which enables evaluation at the individual-level (i.e., student and parents/guardians) and organization-level (i.e., teachers and schools).53 Our cluster-randomized controlled trial targets 12 middle schools in medically underserved, Central Appalachian counties in Virginia. Specifically, our proposed R01 is a type 1 hybrid design with a primary aim of evaluating effectiveness among 7th grade students and with secondary aims of exploring caregiver outcomes and implementation factors among teachers and schools.54 In each school's first year of implementation, Kids SIPsmartER will be co-delivered by researchers and ~24 teachers. In the school's second year of implementation, teachers will be trained and supported to deliver Kids SIPsmartER with reduced in-class support. We anticipate enrolling ~3420 students and ~3180 parents/guardians.

- Primary effectiveness aim: assess changes in SSB behaviors at 7-months (immediately post program) among students receiving Kids SIPsmartER, as compared to control schools. Secondary aims:

- Secondary effectiveness & maintenance outcomes: determine changes in secondary student outcomes (e.g. quality of life,

BMI z-score, theory-related variables, health and media literacy); changes in caregiver SSB behaviors and home environment; and maintenance of outcomes at 19-months post-baseline.

- Reach: assess the reach and representativeness of Kids SIPsmartER, among students and parents/guardians.

- Implementation, adoption, and school-level maintenance: using a mixed-methods approach with interviews, surveys, observation, and process evaluation strategies, assess the degree to which teachers implement Kids SIPsmartER as intended and the potential for institutionalization within the schools.

If found to be effective among students, and if implementation at the school level shows strong potential, our mid-term goal is scale up Kids SIPsmartER to reach additional middle schools. The long-term goal of this line of health promotion and prevention research is to sustain multi-level strategies to reduce SSB-related health inequities and chronic conditions (e.g. obesity, cancer, diabetes, dental decay) in rural Appalachia.

Why is it important? The intake of sugar-sweetened beverages (SSB) is disproportionately high in Appalachian adolescents. Our data show this population drinks ~34 ounces (~425 kcals) of SSB per day.1,2 This intake is more than double national average intakes3 and more than 4 times the recommended daily amount of less than 8 ounces per day.4 There are strong and consistent scientific data and systematic reviews documenting relationships among high SSB and numerous health issues such obesity, some types of obesity-related cancers, diabetes, cardiovascular disease, and dental erosion and decay,5-12 including among children and adolescents.13-17 For example, a seminal 19-month prospective study of diverse school age children found that for each additional serving of SSB, frequency of obesity significantly increases (odds ratio = 1.6, CI=1.14-2.24).18 Further compounding this SSB problem, the Appalachian region lacks access to medical services and to evidence-based prevention programs.19,20 Likewise, rural Appalachia is challenged by transportation issues, geographical isolation, and the digital divide.21-23 Therefore, schools provide the best opportunity to reach the largest proportion and most representative sample of adolescents. Reaching adolescents with behaviorally-focused health programs where they spend most of their time, at school, shows promise;24 yet engaging parents/guardians who are one of their child's strongest role models and gatekeeper for the SSB home environment is also important.25-30 Finally, there is great need to understand how to support schools and teachers to implement and maintain evidence-based health education programs,31-33 especially among rural schools.34

What will participants do in this study? Please provide an overall summary of the study plan. Where and when it will be conducted? What do you hope to learn from these activities? If the study has more than one phase, clearly map out the different phases. You will b required to describe the study components in more detail in later sections but use this paragraph to help your IRB reviewer to understa the general outline of the study. Other sections in the protocol form can be seen below.

Study Logistics This study began in the 2018-19 school year and will run for 7 years. All human subjects will come from 12 middle schools. To be eligible for the study, schools should be in the geographical Central Appalachia catchment area in southwest Virginia, have approximately 80 to 200 students in the 7th grade, and have an 8th grade within the same school building. The latter eligibility criteria is in effort to promote student retention at the 19-month data point. We have identified at least 22 schools that meet this criteria. If more schools are needed, we can also extend our catchment area in Central Appalachia, including to qualified schools in West Virginia.

A key intent of our design is to allow schools equal opportunity to benefit, regardless of randomized treatment allocation. For pragmatic reasons, we are not proposing a simple randomization approach in which all 12 schools (clusters) are randomized at the out-set of the study. Due to turnover in administration/teachers and fluctuations in resources, our school informants indicated it is unrealistic for a school to enter into an agreement for a research project that is as far as 3-4 years out. Therefore, to promote sound randomization and school retention, we propose to recruit and randomize 4 schools [2 Intervention Schools (IntS) and 2 Control Schools (ConS)] in 3 separate blocks. Among Intervention Schools (IntS), both students and parents complete the evaluation components and receive Kids SIPsmartER. In Control Schools (ConS), both students and parents only complete the evaluation components, they do not receive the Kids SIPsmartER program. Control schools become Delayed Intervention Schools (DIntS) schools in the following academic year and receive the Kids SIPsmartER program (See Attachment in Study Overview file).

[MODIFICATION August 10 2021]: Throughout the execution of in-person study activities, researchers will abide by current UVA policy regarding masks as well as any school-level policies that exceed UVA policy.

Within each block of our stepped wedge design, we will use pure randomization. IntS and Delayed Intervention Schools (DIntS) are co-delivered by researchers and 7th grade teachers, whereas Support Schools (SupS) and Organizational Maintenance (OrgM) School are delivered by 7th grade teachers. Student and caregiver individual-level data is collected during IntS, DIntS, ConS and

SupS years, but not OrgM years. The primary 7-month SSB outcome is completed by May 2021. Individual-level 19-month maintenance data is collected as students matriculate into 8th grade. Implementation indicators are tracked in IntS, DIntS, and SupS years.

There will be 30 cohorts of students and parents/guardians in the 12 schools: 6 Intervention cohorts, 6 Delayed Intervention cohorts, 12 Supported cohorts, and 6 Control cohorts.

In each school's first year of implementation, Kids SIPsmartER will be co-delivered by researchers and ~24 teachers. In the school's second year of implementation, teachers will be trained and supported to deliver Kids SIPsmartER with reduced in-class support. We anticipate enrolling ~3420 students and ~3180 parents/guardians. The ~24 teachers and 12 principals will also be research participants.

Additional funding to support the implementation and evaluation of Kids SIPsmartER in three of the middle schools was awarded through a Virginia Foundation for Health Youth (VFHY) grant. This grant was secured with support from the school district office that oversees these three Block 1 schools. Due to this additional funding, these middle schools will continue to receive support and engage in delivery and data collection activities, instead of going into the OrgM years (limited support, no evaluation). We are calling these years Continued Support Schools (SupS2).

It is important to note, that as surveys and curriculum activities will be during a normal class period, all students, regardless of consent, will participate in the classroom component. However, height/weight data will only be recorded for research purposes from students with parental consent and student assent to participate in this research. Furthermore, only data from consented/assented will be used for research purposes.

Kids SIPsmartER program:

Kids SIPsmartER is a multi-level intervention that uses both individual- and micro-level strategies to target students and their parents/guardians. For this R01, Kids SIPsmartER will be a 12 session, 6-month program with an integrated two-way short service message (SMS) strategy to engage parents/guardians in SSB role modeling and supporting home SSB environment changes. See Attachment in Study Overview for the program student curriculum and parent SMS messages. The parent consent and child assent processes, as described in more detail below, will occur prior to any other study activities.

Students: The Kids SIPsmartER student curriculum and data activities will be deliver during the normal school day. Schools will have the flexibility to identify different subjects where Kids SIPsmartER might best fit in their school, including science, health, physical education, and homeroom class periods. Due to COVID-19 and specific school opening plans that include distance learning, Kids SIPsmartER may also be delivered electronically using prerecorded videos that teachers will share with their students.

Parents/guardians: At the beginning of the program, all enrolled parents/guardians will receive a one-time newsletter highlighting key SSB educational, role modeling, and home environment concepts. Thereafter, parents/guardians will receive 2 text messages per week, for a total of 6 months. One SMS per week will contain educational information related to SSB and will align with the content of the student curriculum and will be based on content from the empirically supported adult SIPsmartER program. The other will alternate between collecting data from parents/guardians about SSB behavior and availability in the home environment and sharing strategies to reduce SSB intake and availability. UVA's Qualtrics Research Suite will be used to exchange and manage text messages.

Teachers & Principals: In addition to participating in training and teaching the Kids SIPsmartER curriculum, teachers and principals will also take part in reflective interviews and complete surveys during the years their schools deliver SIPsmartER (IntS, DIntS, SupS, SupS2, OrgM). Each year, principals will complete a survey and interview at the end of the school year. Teachers will complete two interviews and surveys. The first time will be after the first 9 lessons (mid-year) have been delivered and the second time will be at the end of the school year.

Data activities:

Students: For students in IntS, DIntS, and SupS schools, we will administer the survey instruments during class time at 4 times [baseline, 3-, 7- (immediately post program), and 19-months (maintenance)]. At 3-months, only the self-reported SSB behaviors will be assessed. (See below for more details)

Students (SupS2). In these schools, students will complete the survey instruments at 3 time points - [baseline, 3-, 7- (immediately post program)] [AMENDMENT JULY 2021] The baseline and immediately post surveys will be shorter versions of the survey collected during IntS, DIntS, and SupS. (See below for more details) At 3-months, only self-reported SSB behaviors will be assessed.

MODIFICATION 3/16 DUE to coronavirus and school closure: We are requesting a modification to allow for flexibility in working with each of our enrolled schools to distribute and collect student surveys for our primary outcome data point. There will be no change to the content of the survey, but the student survey may be distributed and returned via mail or via an on-line Qualtrics links (using UVA Qualtrics Research Suite) sent to the students. Knowing that each school and student's within schools will have different capabilities for an on-line survey, we will work closely with each school to follow their recommendations.

Students (focus group subset) Within each school during the first two years of intervention delivery, a sub-set of students (n~20) will take part in focus groups after the completion of Kids SIPsmarter. It is expected that there will be two focus groups (~8-12 students) per intervention, delayed intervention, and support school. Focus groups will be one class period long (40-50 minutes), and students will be pulled from their normal classes to be part of the focus group. Teachers will help research staff identify the best times for the focus groups. Focus groups will assess students' satisfaction with the program and what they think could be done to make it better. Focus groups will be run by one or two trained researchers.

Parents/guardians: For parents/guardians enrolled in IntS, DIntS, and SupS schools, survey packets will be sent home from school to those who have signed consent to participate in the research at 3 times (baseline, 7- and 19-months).

MODIFICATION 3/16 DUE to coronavirus and school closure: We are requesting a modification to allow for flexibility in working with each of our enrolled schools to distribute and collect parent surveys. The caregiver survey may be distributed and returned via mail or via an on-line Qualtrics links (using UVA Qualtrics Research Suite) sent to the parents via either text or email. The only change to the survey will be an addition of a current mailing address so that the gift card can be mailed directly to the parent, instead of going home with the student via school.

Parents/guardians enrolled during SupS2 schools not complete separate survey packets. Yet, they will participate in the SMS program which already includes embedded questions pertaining to sugary beverage behaviors.

Parent/guardian (interview subset) Within each school during the first two years of intervention delivery, a sub-set of parent/guardian (n~20) will take part in interviews after the students complete Kids SIPsmarter. After receiving consent, research staff will text or call parents to schedule the interview time. This will allow for the interview to be at a convenient time for the parent/guardian. Interviews will be ~30 minutes long and will assess their satisfaction with the program and how they made behavior changes.

Middle Schools: The research grant will cover expenses for all the necessary supplies to implement the program that would not be normally found in a classroom. School will also receive an incentive for participation: • $1,500 during the year in which teachers co-deliver Kids SIPsmartER with the UVA research team • $1,500 during the year teachers lead deliver Kids SIPsmartER with technical assistances from the UVA research team • Should schools be randomized into the control condition, they would receive $1,000 that year • If schools choose to maintain Kids SIPsmartER, they would receive an additional $1,000 that year • In total, each middle school will receive $3,000-$5,000

Teachers and Principals: Teacher and principals in IntS, DIntS, SupS, SupS2, and OrgM schools will complete surveys and take part in reflective interviews. Teachers will complete surveys and interviews twice (middle and end of the year) while principals will complete them once (end of the year). The content areas addressed in the surveys and interviews are highlighted this table below. Teachers are hired as consultants and will paid to complete the surveys and interviews. There is no compensation for the principals to complete the survey or interview.

Is this study topic relevant to cancer risk factors, prevention, cancer treatment, or survivorship (e.g., pain, financial toxic etc.), or will the study purposefully include participants currently or previously diagnosed with cancer, or their caregivers
Yes

(optional) **Study Overview file upload**: Below you have the option to upload additional files to help the Board better understand your study. You are not required to provide any additional explanation beyond completing the text boxes provided in this Study Overview section; however, for example, if you are using a new technology or a complicated process that would be more easily demonstrated witl image or video, you can upload the file here.

Study Overview
View File: KSS_CancerLink.docx
date uploaded: 2022-11-01, by: Porter, Kathleen *(kjp9c)*
This file is approved.
date approved: 2022-11-04

Study Overview
View File: KSS_IRB_Attachment1_Study Overview and CurriculumOverview_mod4.docx
date uploaded: 2019-03-11, by: Zoellner, Jamie *(jz9q)*
This file is approved.
date approved: 2019-04-01

Participant Groups

Participant Group Name: Parents/guardian - paper consent

Age Range (years): >18 years

Vulnerable populations: no vulnerable population (none)

Maximum number of participants, in this group, expected to enroll over the life of the study: 2745

Minimum number of participants, in this group, expected to enroll over the life of the study: 0

Total number of participants, in this group, ever enrolled: 170

Approximate number of participants, in this group, currently enrolled: 170

Future Enrollment: We will enroll participants, in this group, during the next twelve months

Approximate number of participants, in this group, expected to enroll in the next twelve months: 614

Have participants, in this group, withdrawn from the study in the past year? No

Describe the participants in this group.

One parent/caregiver per 7th grade student enrolled in Kids SIPsmartER is eligible to participate.

The students' parents/guardians who are >18 years of age or older will be invited to participate in the study. Parents/guardians will be excluded if they are non-English speaking.

We anticipate 3180 parents/caregivers to be enrolled in the NIH funded cohorts of the study (IntS, SupS, ConS) and 742 in the Virginia Foundation for Healthy Youth SupS2 cohorts. Of these participants, we anticipate ~70% (2745) will complete paper consent forms.

Parent/guardian (interview subset)
A convenience sample of parents/guardians who consented to participate in the SMS component in intervention, delayed interventior and support schools will be identified by research staff and asked to participate in the interviews. Only parents/guardians who completed the SMS component will be included because the purpose of the interviews is to understand their experience in and satisfaction with the component.

Will participants in this group be *compensated* for taking part in your study? Yes

Are any of the participants US citizens or US residents? Yes

This question applies only to participants who are US citizens or US residents.
Will participant payments be processed through an account administered by UVA? Yes

Participants are paid using UVA funds issued as: F

F: other form of payment (i.e. cash, gift card, gift) for value $100 or less.
Provide a justification for not issuing payments using UVA issued checks.

Due to the number of expected participants and the timing and small amount for each check, gift cards are more pragmatic to use compared to UVA-issued checks.

Describe your payment process, including information about the amount participants will be paid and how payment will b issued and delivered to participants.

Parents/guardians enrolled in IntS, DIntS, and SupS schools will receive $10 gift card when they return a baseline, 7-month, and 19-months (for a total of $30). Gift cards will be sent home with students once the caregiver surveys are returned.

For caregivers participating in interviews, they will receive an additional $10 gift card. Gift cards will be mailed or sent home with students.

Parents/guardians enrolled in SupS2 schools who return a consent form will be entered into a lottery to win a $25 gift card. Parents/guardians will be entered into the lottery regardless of whether they choose to participate or not. For each SupS2 school, there will be two gift cards per school year.

Participant Group Name: Parents/guardian - Qualtrics consent

Age Range (years): >18 years

Vulnerable populations: no vulnerable population (none)

Maximum number of participants, in this group, expected to enroll over the life of the study: 1177

Minimum number of participants, in this group, expected to enroll over the life of the study: 0

Total number of participants, in this group, ever enrolled: 170

Approximate number of participants, in this group, currently enrolled: 170

Future Enrollment: We will enroll participants, in this group, during the next twelve months

Approximate number of participants, in this group, expected to enroll in the next twelve months: 614

Have participants, in this group, withdrawn from the study in the past year? No

Describe the participants in this group.

One parent/caregiver per 7th grade student enrolled in Kids SIPsmartER is eligible to participate.

The students' parents/guardians who are >18 years of age or older will be invited to participate in the study. Parents/guardians will be excluded if they are non-English speaking.

We anticipate 3180 parents/caregivers to be enrolled in the NIH funded cohorts of the study (IntS, SupS, ConS) and 742 in the Virginia Foundation for Healthy Youth SupS2 cohorts. Of these participants, we anticipate ~30% (1177) will complete Qualtrics consent forms. Parents/guardians will access the Qualtrics consent option using a QR code on the principal letter that is sent home; no emails will be collected.

Parent/guardian (interview subset)
A convenience sample of parents/guardians who consented to participate in the SMS component in intervention, delayed interventior and support schools will be identified by research staff and asked to participate in the interviews. Only parents/guardians who completed the SMS component will be included because the purpose of the interviews is to understand their experience in and satisfaction with the component.

Will participants in this group be *compensated* for taking part in your study? Yes

Are any of the participants US citizens or US residents? Yes

This question applies only to participants who are US citizens or US residents.
Will participant payments be processed through an account administered by UVA? Yes

Participants are paid using UVA funds issued as: F

F: other form of payment (i.e. cash, gift card, gift) for value $100 or less.
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Parents/guardians enrolled in IntS, DIntS, and SupS schools will receive $10 gift card when they return a baseline, 7-month, and 19-months (for a total of $30). Gift cards will be sent home with students once the caregiver surveys are returned.

For caregivers participating in interviews, they will receive an additional $10 gift card. Gift cards will be mailed or sent home with students.

Parents/guardians enrolled in SupS2 schools who return a consent form will be entered into a lottery to win a $25 gift card. Parents/guardians will be entered into the lottery regardless of whether they choose to participate or not. For each SupS2 school, there will be two gift cards per school year.

Participant Group Name: Students

Age Range (years): 12-15

Vulnerable populations: includes minors

Maximum number of participants, in this group, expected to enroll over the life of the study: 4218

Minimum number of participants, in this group, expected to enroll over the life of the study: 0

Total number of participants, in this group, ever enrolled: 297

Approximate number of participants, in this group, currently enrolled: 297

Future Enrollment: We will enroll participants, in this group, during the next twelve months

Approximate number of participants, in this group, expected to enroll in the next twelve months: 714

Have participants, in this group, withdrawn from the study in the past year? No

Describe the participants in this group.

Students (IntS, DIntS, SupS, SupS2) 7th grade students in the 12 enrolled schools during the years their school is randomized to on of these cohorts are eligible to participate. Parents/guardians agreeing to participate in the texting component is not an eligibility requirement for students to participate. Based on average number of students per school (n=133) and consenting rates from past work in the region (86%), we anticipate that 114 students per school will participate in each cohort for a total of 4218 students. Of these students, 3420 will take part in the NIH funded portion of the trail, with 2736 taking part in both data collection and curriculur activities as part of Intervention, Delayed Control, and Supported cohorts and another 684 will participate in data collection activities without receiving Kids SIPsmartER as part of Control cohorts. Within the Virginia Foundation for Healthy Youth funded Continued Support cohorts, 798 students will participate.

Data from students with major cognitive disabilities that could compromise self-report behavioral data quality will also be excluded; we will rely on information provided by the teachers to make this decision.

Students (focus group subset)
The research staff will work with classroom teachers in intervention, delayed intervention, and support schools to identify ~20

students across their classes to join the focus groups. Considerations when selecting students will include limiting disruption to the school day and selecting students who it is anticipate will be able to contribute to group discussion.

Will participants in this group be *compensated* for taking part in your study? No

Participant Group Name: Teacher & Principals

Age Range (years): >18 years

Vulnerable populations: no vulnerable population (none)

Maximum number of participants, in this group, expected to enroll over the life of the study: 36

Minimum number of participants, in this group, expected to enroll over the life of the study: 0

Total number of participants, in this group, ever enrolled: 8

Approximate number of participants, in this group, currently enrolled: 8

Future Enrollment: We will enroll participants, in this group, during the next twelve months

Approximate number of participants, in this group, expected to enroll in the next twelve months: 8

Have participants, in this group, withdrawn from the study in the past year? No

Describe the participants in this group.

We anticipate that an average of 2 teachers per school will be selected to deliver Kids SIPsmartER and that each principal from the 1 schools will participate. Therefore, we expect ~24 teachers and 12 principals to enroll in the study.

The principal of each school is eligible to participate based on her/his position. Teachers from the participating schools are eligible if they are a teacher selected by the principal to deliver SIPsmartER.

Participating in this project is not voluntary, in the sense of how human subjects research must be in a voluntary approach. Rather principals agree for the schools to participate and select which teacher(s) will assist in the project. The teachers are then hired as 'consultants' for time they spend on this project outside of normal classroom hours.

Teachers will not be limited to certain subjects, as schools will have the flexibility to identify different subjects where Kids SIPsmartE might best fit in their school, including science, health, physical education, and homeroom class periods.

Due to the design of this study and the participation of teachers, it does not seem logical to have a consent approach for teachers, since this is not completely voluntary (see below).

Will participants in this group be *compensated* for taking part in your study? No

Participant Summary

Participant Group Name: Parents/guardian - paper consent

Maximum number of participants, in this group, expected to enroll over the life of the study: 2745

Participant Group Name: Parents/guardian - Qualtrics consent

Maximum number of participants, in this group, expected to enroll over the life of the study: 1177

Participant Group Name: Students

Maximum number of participants, in this group, expected to enroll over the life of the study: 4218

Participant Group Name: Teacher & Principals

Maximum number of participants, in this group, expected to enroll over the life of the study: 36

What special experience or knowledge does the Principal Investigator, Faculty Sponsor, and the Research Team (Sub-Investigators) have that will allow them to work productively and respectfully with the participants in this protocol and/c participant data?

Dr. Zoellner has ~15 years of experience conducting nutrition focused research in rural and health disparate communities, including 8 years of experience in the targeted districts in Virginia. Dr. Porter also has ~15 years of experience conducting nutrition focused research in schools. They have had numerous federally funded grants in the target region, working to understand and intervene on nutrition related health behaviors. Dr. Zoellner is also the Associate Director of UVA's Cancer Center without Walls and is working to expand the outreach and community-based research efforts in Southside and southwest Virginia.

All of the study investigators will have undergone CITI IRB training. Prior to starting the recruitment process, the CITI training certificate of all UVA investigators will be documented through the CITI Program website.

Furthermore, this project has already been approved by SBS-IRB for over a year and running in accordance to IRB approved protoco

What is the relationship between the participants of this study, and the Principal Investigator, Faculty Sponsor, and the Research Team (Sub-Investigators)? Does the Principal Investigator, Faculty Sponsor, or the Research Team (Sub-Investigators) know any of the participants personally or hold any position of authority over the participants (including b not limited to: grading authority, professional authority, etc.)? Do any of the researchers listed on the protocol stand to g financially from any aspect of this research?

There are no personal or financial relationships among the research team and study participants. The research team does not hold any position of authority over the participants.

Recruitment & Consent

How will participants be approached or contacted for recruitment into the study?

Our recruitment materials have been finalized and previously approved. See attachments:
- KSS_IRB_Attachement8_overview for introducing to schools
- KSS_IRB_Attachement9_Principal letter_Kids SipSmartER Program
- KSS_IRB_Attachement10_Principal letter_Sugary Drink Control
- KSS_IRB_Attachement11_Flyer_Kids SipSmartER Program
- KSS_IRB_Attachement12_Flyer_Kids SipSmartER Control

For COVID related adjustments and the new Continued Support/VFHY (SupS2) schools, we have adpated to approved Kids SIPsmartER Program flyer to show differences (i.e., no heights and weights in both, no parent evaluation and incententives in the Continued Support/VFYH schools.) Images have also been ajdusted in new Continued Support/VFHY (SupS2) flier so it can be distinguished from the other versions
- KSS_IRB_Attachment30_Flyer_Sugary Drink Study Brochure_COVIDmod6
- KSS_IRB_Attachment31_Flyer_ContinuedSupportVFHY

[AMENDMENT July 2021] To reflect student data collection during SupS2 and OrgM years, we have adapted the previous approved Kids SIPsmartER Program flyer for SupS2 year to reflect these changes.
- KSS_IRB_Attachment39_SupSOrgM_Flier_Mod7

Schools will be approached and Attachement 8 will be used as a guide to informing the schools of this research project.

Principal letters, flyers and the informed consent documents will be sent home with the students to give to their parents.

Do participants have any limitations on their ability to *consent* **?** Yes

Describe the limitations on their ability to consent:

Study involves minors.

Since children are unable to consent, an assent process will be used. There will be two three different assent forms:
- Children receiving the SipSmartER program. See Attachment 6. Minor Informed Assent Agreement for Kids SipSmartER Prograr
- Children in the control schools. See Attachment 7. Minor Informed Assent Agreement for Sugary Drink Survey
- Children involved in the focus groups. See Attachment 21. Minor Informed Assent Agreement for Focus Groups

All consented students will complete an assenting process before the first data collection activity. A member of the research staff will describe the study to the students by explaining the different activities, risks, and benefits. This staff member will also explain that, although their parents/guardians provided them with legal permission to participate, they also have the right to agree or disagree to participate. Students will sign forms identifying their assent or dissent to participate. A copy of the form will be given to each student

What are the consent processes for this study?

[AMENDMENT JULY 2021] Due to the different years of implementation and expectations of data collection during those years, consent/assent and data collection processes for students and parents vary by year of intervention implementation (i.e., ConS, IntS, DIntS, SupS, SupS2, OrgM). These processes have also changed as a result of COVID-19 pandemic's impact on schools during the school years this project has been active. To reduce complication, we have summarized the timeline and changes of these modifications in Attachment 38, along with the related consent and data collection documents. The specific consent processes by yea are described in detail below.

Students and Parents (ConS, IntS, DIntS, SupS years):
After verbal introduction in the classrooms, consent forms and instructions regarding the informed consent will be sent home with students to give to their parents/guardians approximately one or two weeks after recruitment and promotional/recruitment activities In collaboration with our UVA research staff, we anticipate that teachers in all schools will be involved with distributing student and parent/caregiver consent forms, collecting forms, and following-up with students who have not returned consent forms twice a week for two weeks. For students who have not returned consent forms at this time, research staff will contact their parent/guardian up to three times to in attempt to obtain verbal consent.

Due to school schedule changes due to COVID-19 precautions, we will also provide a third approach for distributing and completing the consenting process: via a Qualtrics link or a QR code that directs the parent/caregiver to the Qualtrics survey. This approach would be used if the other methods distributing paper consents in schools, returning paper consents, and/or completing verbal consents by calling parents using the school phone are not possible due to school closures and restrictions on visitors to the schools. Specific consent distribution and collection procedures will be determined school by school to ensure that the procedure best meets the school's needs.

There will be eight different consent forms:
- Intervention, Delayed Intervention, Supported schools: Schools that will have the Kids SIPsmartER as a part of regular classroom activities and the option to participate in the research. On the consent forms, parents/guardians will be able to identify if they want their child child's survey data and height and weight to be used for the research and if they want to participate in the research (including completing the surveys and text message program). See Attachment 4. Parent/Guardian Informed Consent Agreement for Kids SIPsmartER Program.
  - Hybrid version for Intervention, Delayed Intervention, Supported school: Same as original version except for the option of virtual classroom activities and removal of measuring heights and weights. See Attachment 22. Parent/Guardian Informed Consent Agreement for Kids SIPsmartER Program COVID.
  - Qualtrics Hybrid Version for Intervention, Delayed Intervention, Supported school: Same as COVID version except language at the end of the consent form has been adjust to reflect submitting through Qualtrics (e.g., type in your name, directions for signing). See Attachment 23. Parent/Guardian Informed Consent Agreement for Kids SIPsmartER Program COVID Qualtrics
  - [ADMENDMENT JULY 2021] Qualtrics Version for Intervention, Delayed Intervention, Supported school: Same as original versio (Attachment 4) except language at the end of the consent form has been adjust to reflect submitting through Qualtrics (e.g., type in your name, directions for signing). See Attachment 33. Parent/Guardian Informed Consent Agreement for Kids SIPsmartER Program Qualtrics.

- Control schools: Schools were only data collection activities are available. On the consent forms, parents/guardians will be able to identify if they want their child child's survey data and height and weight to be used for the research and if they want to participat in the research (including completing the surveys only). See Attachment 5. Parent/Guardian Informed Consent Agreement for Sugary Drink Survey.
  - [ADMENDMENT JULY 2021] Qualtrics Version for Intervention, Delayed Intervention, Supported school: Same as original versio (Attachment 5) except language at the end of the consent form has been adjust to reflect submitting through Qualtrics (e.g., type in your name, directions for signing). See Attachment 34. Parent/Guardian Informed Consent Agreement for Kids SIPsmartER Program Qualtrics.

Student Focus Groups: A sub-sample of students in intervention, delayed intervention, and support schools identified by their teachers as potential participants in the focus groups. On the consent forms, parents/guardians will identify if they want their child to participate or not. See Attachment 19. Parent/Guardian Informed Consent Agreement for Student Focus Groups.
- Parent Interviews: A sub-sample of parents/caregivers in intervention, delayed intervention, and support schools that have agreed to participate in the SMS Component. On the consent forms, parents/guardians will identify if they want to participate or not. See Attachment 20. Parent/Guardian Informed Consent Agreement for Parent/Caregiver Interviews.
- Continued Support schools: The three schools that will be enrolled in Continued Support cohorts will have the Kids SIPsmartER

as a part of regular in-person or virtual classroom activities and the option to participate in the research. On the consent forms, parents/guardians will be able to identify if they want their child child's survey data to be used for the research and if they want to participate in the research (including text message program and using their data from the text messaging program). See Attachment 24. Parent/Guardian Informed Consent Agreement for Kids SIPsmartER Program Continued Support.

o Qualtrics Version for Continued Support Schools: Same as original version except language at the end of the consent form has been adjust to reflect submitting through Qualtrics (e.g., type in your name, directions for signing). See Attachment 25. Parent/Guardian Informed Consent Agreement for Kids SIPsmartER Program Continued Support Qualtrics.

o [AMENDMENT JULY 2021] Because of the other changes noted above, Attachments 24 and 25 were only used in the 2020-2021 academic school year, and we do not anticipate using these for future schools.

If consent is provided verbally, researchers will follow the Verbal Consent protocol (Attachment 16). This procedure will help ensure understanding while allowing the same consent form to be used.

- KSS_IRB_Attachment16_VerbalConsentProtocol_Mod4

Parents/guardians will be able to keep a copy of the sent form.

Since children are unable to consent, an assent process will be used. There will be three different assent forms:

- Children receiving the SipSmartER program. See Attachment 6. Minor Informed Assent Agreement for Kids SipSmartER Prograr

o Hybrid version of the assent for children receiving the SipSmartER program. Same as original consent except has in-person anc virutal delivery options and heights and weights removed. See Attachment 26. Minor Informed Assent Agreement for Kids SipSmartER Program_COVID

o Qualtrics Hybrid version of the assent for children receiving the SipSmartER program. Same as COVID version except for language at the end of the consent form has been adjust to reflect submitting through Qualtrics (e.g., type in your name, directions for signing). See Attachment 27. Minor Informed Assent Agreement for Kids SipSmartER Program_COVID

- Children receiving the SipSmartER program in SupS2 schools. See Attachment 28. Minor Informed Assent Agreement for Kids SipSmartER Program Continued Support

o Qualtrics version of the assent for children receiving the SipSmartER program in SupS2 schools. Same as original version excep for language at the end of the consent form has been adjusted to reflect submitting through Qualtrics (e.g., type in your name, directions for signing). See Attachment 29. Minor Informed Assent Agreement for Kids SipSmartER Program Continued Support Qualtrics.

- Children in the control schools. See Attachment 7. Minor Informed Assent Agreement for Sugary Drink Survey
- Children involved in the focus groups. See Attachment 21. Minor Informed Assent Agreement for Focus Groups

All consented students will complete an assenting process before the first data collection activity. A member of the research staff will describe the study to the students either in person or by distance (e.g., video, Zoom call) by explaining the different activities, risks, and benefits. This staff member will also explain that, although their parents/guardians provided them with legal permission to participate, they also have the right to agree or disagree to participate. Students will sign forms identifying their assent or dissent to participate. A copy of the form will be given to each student.

[MODIFICATION August 10 2021]: Students in SupS2 years will be informed by the teacher to let them know if they do not want the data included in the study. This will occur during the baseline survey administration.

Students who return the Intervention, support, or Control consent form (normal, COVID-19, Qualtrics), regardless of permission granted or denied), will receive a nominal prize, valued at $1.50 (such as Kids SIPsmartER water bottle). Additionally, each school-year year in IntS, SupS, and ConS, two students per school who have returned the consent form will receive a larger incentive: gift cards valued at $25. Within each active IntS, SupS, and ConS school, student names will be selected at random. Not all schools are required to adopt this strategy and leaving this as an optional strategy for each school is important. If students are not physically in school because of COVID-19 restrictions, distributing these nominal prizes will not be possible.

[AMENDMENT JULY 2021] Students and Parents (SupS2, OrgM years):
Consent and student assent will not be collected for student data during SupS2 and OrgM years, as the research conducted during meets requirements for waiver of consent and assent and not including consent and assent will not adversely impact the rights and welfare of participants. For students in these years, the research poses minimal risk and, given the design and intention of these years – to implement and evaluate the program under "real world" conditions with limited researcher support, the incorporation of th consent and assent process would limit the practicality of executing the research. During these years, the Kids SIPsmartER program and will be delivered as part of the students' normal Health/PE curriculum by the teachers. and, during SupS2 years, all student data will be collected by teachers as a class assignment and without identifiers (i.e., no names will be collected). No student level data wil be collected during OrgM years.

Students will be informed by their teachers that Kids SIPsmartER will be part of their Health/PE curriculum for the upcoming year. All students receiving Kids SIPsmartER will receive a water bottle as part of the program.

During SupS2 and OrgM years, consent will be collected for parents to participate in the SMS program. After verbal introduction in

the classrooms approximately two weeks prior to the start of the classroom program, consent forms and instructions regarding the informed consent will be sent home with students to give to their parents, along with a letter describing the text message program. Teachers in all SupS2 and OrgM schools will be involved with distributing student and parent/caregiver consent forms, collecting forms, and following-up with students who have not returned consent forms twice a week for two weeks. Parents will be able to complete the consent form via a physical or virtual form.
o Parent Only Consent for Continuing Support and Organizational Maintenance years. Intervention, Delayed Intervention, Supported school: See Attachment 35. Parent/Guardian Only Informed Consent Agreement for Kids SIPsmartER Program.
o Qualtrics Parent Only Consent for Continuing Support and Organizational Maintenance years: Same as paper version except language at the end of the consent form has been adjust to reflect submitting through Qualtrics (e.g., type in your name, directions for signing). See Attachment 36. Parent/Guardian Informed Consent Agreement for Kids SIPsmartER Program Qualtrics.

Parents, at each school, will be incentivized to return the consent form, with the chances of winning one of two $25 gift cards.

Teachers and Principals:
Due to the design of this study and the participation of teachers, it does not seem logical to have a consent approach for teachers, since this is not completely voluntary. The teachers are selected to participate by the principals, who have agreed to have their schoc participate in this research and be randomized. Participating teachers will register as vendors/consultants with UVA to allow them to be compensated for their time in activities related to the preparation of and reflection on the delivery of SIPsmartER in their classrooms (e.g., training, completing lesson debrief forms). The surveys and interviews are also included in this time compensated time. Principals are not directly compensated from this project, since they salaried, unable to receive payments, and their time commitment is minimal. As described further below, teachers and principals will be informed that they have the right to refuse to answer any specific questions throughout the evaluation process.

Will participants be deceived and/or have information withheld from them about the study? No

Will participants be debriefed? No

Recruitment & Consent Tools

Consent or Assent (signature required)
View File: KSS_IRB_Attachment19_StudentFocusGroupConsent_Mod4_v3.docx
date uploaded: 2019-03-20, by: Zoellner, Jamie *(jz9q)*
This file is approved.
date approved: 2019-04-01

Consent or Assent (signature required)
View File: KSS_IRB_Attachment20_CaregiverInterviewConsent_Mod4_v2.docx
date uploaded: 2019-03-19, by: Zoellner, Jamie *(jz9q)*
This file is approved.
date approved: 2019-04-01

Consent or Assent (signature required)
View File: KSS_IRB_Attachment21_MinorAssentStudentFocusGroup_Mod4_v3.docx
date uploaded: 2019-03-20, by: Zoellner, Jamie *(jz9q)*
This file is approved.
date approved: 2019-04-01

Consent or Assent (signature required)
View File: KSS_IRB_Attachment22_InterventionConsent_Hybrid2_Mod6.docx
date uploaded: 2020-08-06, by: Porter, Kathleen *(kjp9c)*
This file is approved.
date approved: 2020-08-19

Consent or Assent (signature required)
View File: KSS_IRB_Attachment23_InterventionConsent_HybridQualtrics3_Mod6.docx
date uploaded: 2020-08-06, by: Porter, Kathleen *(kjp9c)*
This file is approved.
date approved: 2020-08-19

Consent or Assent (signature required)
View File: KSS_IRB_Attachment24_Consent_ContinuedSupportVFHY_Mod6.docx
date uploaded: 2020-08-04, by: Porter, Kathleen *(kjp9c)*
This file is approved.
date approved: 2020-08-19

Consent or Assent (signature required)
View File: KSS_IRB_Attachment25_Consent_ContinuedSupportVFHYQualtrics2_Mod6.docx
date uploaded: 2020-08-05, by: Porter, Kathleen *(kjp9c)*
This file is approved.
date approved: 2020-08-19

Consent or Assent (signature required)
View File: KSS_IRB_Attachment26_InterventionAssent_Hybrid2_Mod6.docx
date uploaded: 2020-08-06, by: Porter, Kathleen *(kjp9c)*
This file is approved.
date approved: 2020-08-19

Consent or Assent (signature required)
View File: KSS_IRB_Attachment27_InterventionAssent_HybridQualitrics3_Mod6.docx
date uploaded: 2020-08-06, by: Porter, Kathleen *(kjp9c)*
This file is approved.
date approved: 2020-08-19

Consent or Assent (signature required)
View File: KSS_IRB_Attachment28_Assent_ContinuedSupportVFHY2_Mod6.docx
date uploaded: 2020-08-06, by: Porter, Kathleen *(kjp9c)*
This file is approved.
date approved: 2020-08-19

Consent or Assent (signature required)
View File: KSS_IRB_Attachment29_Assent_ContinuedSupportVFHYQualtrics3_Mod6.docx
date uploaded: 2020-08-06, by: Porter, Kathleen *(kjp9c)*
This file is approved.
date approved: 2020-08-19

Consent or Assent (signature required)
View File: KSS_IRB_Attachment33_InterventionConsentQualtrics_Mod7_submit2 (1).docx
date uploaded: 2021-08-02, by: Monroe, Jeff *(mjm6ny)*
This file is approved.
date approved: 2021-08-10

Consent or Assent (signature required)
View File: KSS_IRB_Attachment34_ControlConsentQualtrics_Mod7_submit21.docx
date uploaded: 2021-08-02, by: Monroe, Jeff *(mjm6ny)*
This file is approved.
date approved: 2021-08-10

Consent or Assent (signature required)
View File: KSS_IRB_Attachment35_ParentOnlyConsent_Mod7_submit21.docx
date uploaded: 2021-08-02, by: Monroe, Jeff *(mjm6ny)*
This file is approved.
date approved: 2021-08-10

Consent or Assent (signature required)
View File: KSS_IRB_Attachment36_ParentOnlyConsentQualtrics_Mod7_submit22.docx
date uploaded: 2021-08-02, by: Monroe, Jeff *(mjm6ny)*
This file is approved.
date approved: 2021-08-10

Consent or Assent (signature required)
View File: KSS_IRB_Attachment4_InterventionConsent_v4_Mod 4_v211.docx
date uploaded: 2021-08-02, by: Monroe, Jeff *(mjm6ny)*
This file is approved.
date approved: 2021-08-10

Consent or Assent (signature required)
View File: KSS_IRB_Attachment5_ControlConsent_Mod4_v2.docx
date uploaded: 2019-03-19, by: Zoellner, Jamie *(jz9q)*
This file is approved.
date approved: 2019-04-01

Consent or Assent (signature required)
View File: KSS_IRB_Attachment6_InterventionAssent_SUBMITTED_Mod4_v2.docx

date uploaded: 2019-03-19, by: Zoellner, Jamie *(jz9q)*
This file is approved.
date approved: 2019-04-01

Consent or Assent (signature required)
View File: KSS_IRB_Attachment7_ControlAssent_Mod4_v2.docx
date uploaded: 2019-03-19, by: Zoellner, Jamie *(jz9q)*
This file is approved.
date approved: 2019-04-01

Consent or Notification (no signature required)
View File: KSS_IRB Attachment16_VerbalConsentProtocol_Mod4_v2.docx
date uploaded: 2019-03-11, by: Zoellner, Jamie *(jz9q)*
This file is approved.
date approved: 2019-04-01

Recruitment
View File: KSS_IRB_Attachement 8_overview for introducing to schools_version2.docx
date uploaded: 2019-03-11, by: Zoellner, Jamie *(jz9q)*
This file is approved.
date approved: 2019-04-01

Recruitment
View File: KSS_IRB_Attachment 10_Principal Letter_Sugary Drink Control.docx
date uploaded: 2019-03-11, by: Zoellner, Jamie *(jz9q)*
This file is approved.
date approved: 2019-04-01

Recruitment
View File: KSS_IRB_Attachment 11_19-182345 Cancer Sugary Drink Study Brochure_updated image.pdf
date uploaded: 2019-03-11, by: Zoellner, Jamie *(jz9q)*
This file is approved.
date approved: 2019-04-01

Recruitment
View File: KSS_IRB_Attachment 12_Flyer_control1.docx
date uploaded: 2019-03-11, by: Zoellner, Jamie *(jz9q)*
This file is approved.
date approved: 2019-04-01

Recruitment
View File: KSS_IRB_Attachment30_Flyer_Sugary Drink Study Brochure_COVIDmod6.pdf
date uploaded: 2020-08-04, by: Porter, Kathleen *(kjp9c)*
This file is approved.
date approved: 2020-08-19

Recruitment
View File: KSS_IRB_Attachment31_Flyer_ContinuedSupportVFHY.pdf
date uploaded: 2020-08-04, by: Porter, Kathleen *(kjp9c)*
This file is approved.
date approved: 2020-08-19

Recruitment
View File: KSS_IRB_Attachment32_Recruitment_PrincipalLetter_HybridQualitrcis_Mod6.docx
date uploaded: 2020-08-06, by: Porter, Kathleen *(kjp9c)*
This file is approved.
date approved: 2020-08-19

Recruitment
View File: KSS_IRB_Attachment39_SupSOrgM_Flier_Mod7_submit_2108_2.pdf
date uploaded: 2021-08-10, by: Porter, Kathleen *(kjp9c)*
This file is approved.
date approved: 2021-08-10

Recruitment
View File: KSS_IRB_Attachment9_Principal Letter_Kids SipSmartER Program.docx
date uploaded: 2019-03-11, by: Zoellner, Jamie *(jz9q)*

This file is approved.
date approved: 2019-04-01

Associate Recruitment & Consent Tools with Participant Groups

Participant Group Name: **Parents/guardian - paper consent**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachment19_StudentFocusGroupConsent_Mod4_v3.docx**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachment20_CaregiverInterviewConsent_Mod4_v2.docx**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachment22_InterventionConsent_Hybrid2_Mod6.docx**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachment24_Consent_ContinuedSupportVFHY_Mod6.docx**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachment28_Assent_ContinuedSupportVFHY2_Mod6.docx**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachment35_ParentOnlyConsent_Mod7_submit21.docx**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachment4_InterventionConsent_v4_Mod 4_v211.docx**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachment5_ControlConsent_Mod4_v2.docx**
✓ Recruitment & Consent Tool: **KSS_IRB Attachment16_VerbalConsentProtocol_Mod4_v2.docx**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachement 8_overview for introducing to schools_version2.docx**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachment 10_Principal Letter_Sugary Drink Control.docx**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachment 11_19-182345 Cancer Sugary Drink Study Brochure_updated image.pd**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachment 12_Flyer_control1.docx**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachment30_Flyer_Sugary Drink Study Brochure_COVIDmod6.pdf**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachment31_Flyer_ContinuedSupportVFHY.pdf**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachment32_Recruitment_PrincipalLetter_HybridQualitrcis_Mod6.docx**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachment39_SupSOrgM_Flier_Mod7_submit_2108_2.pdf**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachment9_Principal Letter_Kids SipSmartER Program.docx**

Participant Group Name: **Parents/guardian - Qualtrics consent**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachment23_InterventionConsent_HybridQualtrics3_Mod6.docx**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachment25_Consent_ContinuedSupportVFHYQualtrics2_Mod6.docx**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachment27_InterventionAssent_HybridQualitrics3_Mod6.docx**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachment29_Assent_ContinuedSupportVFHYQualtrics3_Mod6.docx**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachment33_InterventionConsentQualtrics_Mod7_submit2 (1).docx**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachment34_ControlConsentQualtrics_Mod7_submit21.docx**

Participant Group Name: **Students**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachment21_MinorAssentStudentFocusGroup_Mod4_v3.docx**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachment26_InterventionAssent_Hybrid2_Mod6.docx**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachment27_InterventionAssent_HybridQualitrics3_Mod6.docx**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachment28_Assent_ContinuedSupportVFHY2_Mod6.docx**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachment29_Assent_ContinuedSupportVFHYQualtrics3_Mod6.docx**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachment6_InterventionAssent_SUBMITTED_Mod4_v2.docx**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachment7_ControlAssent_Mod4_v2.docx**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachment 10_Principal Letter_Sugary Drink Control.docx**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachment 11_19-182345 Cancer Sugary Drink Study Brochure_updated image.pd**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachment 12_Flyer_control1.docx**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachment9_Principal Letter_Kids SipSmartER Program.docx**

Participant Group Name: **Teacher & Principals**
✓ Recruitment & Consent Tool: **KSS_IRB_Attachement 8_overview for introducing to schools_version2.docx**

Data Sources

Data Source Name: Caregiver Assessment Packets

When will the data be collected? Some data are collected but new data may be added to the data set after IRB-SBS approval of this protocol.

Who will collect the data? Primary data source

Describe this Data Source.

Parents/guardians (Cons, IntS, DIntS, SupS). Survey packets will be sent home from school to those who have signed consent to participate in the research at 3 times (baseline, 7- and 19-months).

The measurement packets are the same regardless of intervention or control schools. With the exception of intervention school participants answering questions about their experience with the Kids SIPsmartER program.

See Attachment #3. Data consists of:

Beverage Behaviors, including SSBs (BEV-Q)
SSB Theory of Planned Behavior
SSB Media Literacy
Health Literacy, 3-items valid for self-administration
Public Health Literacy
Quality of Life
SSB Home Environment
SSB Parenting Practices/Rules
Satisfaction Questions

MODIFICATION 3/16 DUE to coronavirus and school closure: We are requesting a modification to allow for flexibility in working with each of our enrolled schools to distribute and collect parent surveys. The caregiver survey may be distributed and returned via mail or via an on-line Qualtrics links (using UVA Qualtrics Research Suite) sent to the parents via either text or email. The only change to the survey Attachment #3 will be an addition of a current mailing address so that the gift card can be mailed directly to the parent, instead of going home with the student via school.

The changes the survey instrument have been changed and tracked, see:
View File: KSS_IRB_Attachment3_CaregiverPacket_v3_SUBMITTED_mod5_add mailing address.docx

Parents/guardians (SupS2). Parents/guardians enrolled during in SupS schools will not complete survey packets.

Will a recording device (e.g. audio, video, photographic) be used to collect data/materials from participants? No

Are the participant's identifying information included as part of the data at any time? Yes, and participant identifiers will NOT retained

What identifiers will be connected to the data and will you have access to those identifiers?

Names and dates of birth

Describe the process for stripping participant identifiers from the data.

Confidentiality will also be promoted by assigning a 6-digit identification number for each participant at the time of enrollment. All ID numbers will be stored in password protected computers and this information will be limited to the PI and research staff. A limited data set will be developed and all identifiers will be destroyed at the conclusion of the study. No identifiable data will be disclosed outside the organization.

Several steps will be taken to ensure confidentiality, such as ensuring all research team members complete human subjects training have been adequately trained to de-identify data. Trained research staff members will be responsible for collecting all outcome data. All field computers will be password protected; filing cabinets will have locks and be in locked rooms. Confidentiality will also be promoted by assigning a 6-digit identification number for each participant at the time of enrollment. All ID numbers will be stored in password protected computers and this information will be limited to the PI and research staff. A limited data set will be developed and all identifiers will be destroyed at the conclusion of the study. No identifiable data will be disclosed outside the organization.

Data Source Name: Parent Exit Interview

When will the data be collected? Some data are collected but new data may be added to the data set after IRB-SBS approval of this protocol.

Who will collect the data? Primary data source

Describe this Data Source.

Within each school during the first two years of intervention delivery, a sub-set of parent/guardian (n~20) will take part in interviews after the students complete Kids SIPsmarter. After receiving consent, research staff will text or call parents to schedule the interview time. This will allow for the interview to be at a convenient time for the parent/guardian. Interviews will be ~30 minutes long and wil assess their satisfaction with the program and how they made behavior changes.

- KSS_IRB_Attachment19_ CaregiverInterviewProtocol_Mod4

Will a recording device (e.g. audio, video, photographic) be used to collect data/materials from participants? Yes

What type(s) of recording device(s) will be used in this data tool? Audio

Describe each recording device(s) and provide a justification for using the recording device.

We will be audio recording parent interviews to allow members of the research team to fully participate in the interview process and ensure that recollections/notes of statements and/or conversations are accurate. Each interview will be transcribed verbatim.

Are the participant's identifying information included as part of the data at any time? Yes, and participant identifiers will NOT retained

What identifiers will be connected to the data and will you have access to those identifiers?

Names and voices

Describe the process for stripping participant identifiers from the data.

For all digital audio files and the transcribed text will be stored in password protected laptop and desktop computers. Computers are kept in a room only accessible by key. Once the digitial audio files have been uploaded onto the computer, they will be erased from the recorder. Recordings will either be transcribed by members of the research team or by a transcription service. Digital audio files will be erased from the recorder once they have been uploaded onto a password protected, study computer. De-identified transcripts will be retained for five years after completion of all data analysis in order to inform future research.

Data Source Name: Student Assessment Packet

When will the data be collected? Some data are collected but new data may be added to the data set after IRB-SBS approval of this protocol.

Who will collect the data? Primary data source

Describe this Data Source.

Students (ConS, IntS, DIntS, SupS). For students, during these years, we will administer the survey instruments during class time at 4 times [baseline, 3-, 7- (immediately post program), and 19-months (maintenance)]. At 3-months, only the self-reported SSB behaviors will be assessed. To ensure efficiency and improve the quality of data, the survey will be delivered and student response recorded using an Audience Response System. Based on our experiences with the feasibility testing,1,2 we anticipate that each survey assessment data point will take one class period, or 45-50 minutes. On a subsequent day, students will be pulled from class for height and weight assessments [also measured at 3 times baseline, 7- (immediately post program), and 19-months (maintenance)]. Height and weight will be assessed with a research-grade calibrated digital Tanita scale and portable stadiometer wil measure student height and weight and BMI percentiles calculated based on CDC growth charts. At each of the three data time points, trained staff members will conduct these assessments following established procedures. Heights and weights are already collected in many of our schools as a part of normal activities in health and PE class (and a consent process is not required). However, this may not always be the case in each school. Also, some schools only collect height and weight in the beginning of the school year, but not at the end of the school year. Per request of our schools, we need to be flexible in our protocol to allow for schools to use the researcher collected height and weight data for school reporting purposes. We will coordinate with each school to avoid unnecessary overlap in collecting height and data twice among students. If requested by schools, it is likely that our research team will assist the teachers and be responsible for measuring height and weight as a part of the normal class activity; however, our UVA research team will only record height/weight for research purposes for those students participating in the study.

For years in which school operations are impacted by COVID-19 (e.g., virtual or hybrid instructional approaches, restrictions on visitors), student heights and weights will not be assessed.

The measurement packets are the same regardless of intervention or control schools. With the exception of intervention school participants answering questions about their experience with the Kids SIPsmartER program.

See Attachment #2. Data consists of:

Beverage Behaviors, including SSBs (BEV-Q)
SSB Theory of Planned Behavior
SSB Media Literacy
Health Literacy & Numeracy, Newest Vital Sign
Public Health Literacy
Quality of Life
SSB Home Environment
SSB Parenting Practices/Rules
Satisfaction Questions

At the 7-month assessment, students will receive a nominal prize, valued at $5.50 (such as Kids SIPsmartER t-shirt, see budget).

MODIFICATION 3/16 DUE to coronavirus and school closure: We are requesting a modification to allow for flexibility in working with each of our enrolled schools to distribute and collect student surveys for our primary outcome data point. There will be no change to the content of the survey, but the student survey may be distributed and returned via mail or via an on-line Qualtrics links (using UV Qualtrics Research Suite) sent to the students. Knowing that each school and student's within schools will have different capabilities for an on-line survey, we will work closely with each school to follow their recommendations.

[AMENDMENT July 2021] Student Assessment Packet (SupS2)

Describe this Data Source. What does/will the data consist of? If a data set will be used, include the data fields to be used.

Students (SupS2). For students during these years, we will administer the survey instruments during class time at 3 times [baseline, 3-months, and 7-months]. At 3-months, only the self-reported SSB behaviors will be assessed. To ensure efficiency and improve the quality of data, the survey will be delivered and student response recorded using an Audience Response System. Based on our experience, we anticipate that each survey assessment data point will take half of one class period, or ~20-25 minutes.

See Attachment #37. Survey questions include Beverage Behaviors, including SSBs (BEV-Q), SSB Theory of Planned Behavior, SSB Media Literacy, Public Health Literacy, Quality of Life, SSB Home Environment, and
Satisfaction Questions [7-month only]. Compared to the original student survey (Attachment #2), 36 items were removed. Items were removed to streamline the survey to focus on SSB related questions and remove identifiers. Removed items relate to specifics o household rules about sugary drinks (9 items), household availability of food items (3 items), perceptions of weight (2 items), physical activity behaviors (3 items), dietary pattern (11 items), oral health behaviors (3 items), sleep behaviors (3 items), school performance (1 item), and month and day of birth (1 item)

[August 2024 Modification] See Attachment #40. This shortened version of the survey replaces Attachment #37. Survey questions include Beverage Behaviors, including SSBs (BEV-Q), SSB Theory of Planned Behavior, SSB Home Environment, and Satisfaction Questions [included at 7-month only]. Compared to the previously used survey (Attachment #37), 36 items were removed. Items were removed to streamline the survey to focus on key SSB-related questions and reduce burden on teachers. Removed items relate to specifics of household rules about sugary drinks (15 items), media liteacy (6 items), health literacy (6 items), public health literac (4 items), and quality of life (5 items).

To be flexible to school preference for survey distribution and in case of future virtual learning due to school closures to in-person learning (i.e., COVID-19 related closures), there will be two modes of delivery for student surveys: pen and paper and on-line via a Qualtrics link (using UVA Qualtrics Research Suite). Knowing that each school and student's within schools will have different capabilities for an on-line survey, we will work closely with each school to follow their recommendations.

[MODIFICATION August 10 2021]" We collect MM/DD/YYYY on surveys for consented/assented students and enrolled parents/caregivers but only collect YYYY for the students who have waiver of consent. Birthdate detail is needed to calculate student BMI.

Will a recording device (e.g. audio, video, photographic) be used to collect data/materials from participants? No

Are the participant's identifying information included as part of the data at any time? Yes, and participant identifiers will NOT retained

What identifiers will be connected to the data and will you have access to those identifiers?

Names and dates of birth. These identifiers are not collected in SupS2 years.

Describe the process for stripping participant identifiers from the data.

Confidentiality will also be promoted by assigning a 6-digit identification number for each participant at the time of enrollment. All ID numbers will be stored in password protected computers and this information will be limited to the PI and research staff. A limited data set will be developed and all identifiers will be destroyed at the conclusion of the study. No identifiable data will be disclosed outside the organization.

Several steps will be taken to ensure confidentiality, such as ensuring all research team members complete human subjects training have been adequately trained to de-identify data. Trained research staff members will be responsible for collecting all outcome data. All field computers will be password protected; filing cabinets will have locks and be in locked rooms. Confidentiality will also be promoted by assigning a 6-digit identification number for each participant at the time of enrollment. All ID numbers will be stored in password protected computers and this information will be limited to the PI and research staff. A limited data set will be developed and all identifiers will be destroyed at the conclusion of the study. No identifiable data will be disclosed outside the organization.

Data Source Name: Student focus groups

When will the data be collected? Some data are collected but new data may be added to the data set after IRB-SBS approval of this protocol.

Who will collect the data? Primary data source

Describe this Data Source.

Within each school during the first two years of intervention delivery, a sub-set of students (n~20) will take part in focus groups afte the completion of Kids SIPsmarter. It is expected that there will be two focus groups (~8-12 students) per intervention, delayed intervention, and support school. Focus groups will be one class period long (40-50 minutes), and students will be pulled from their normal classes to be part of the focus group. Teachers will help research staff identify the best times for the focus groups. Focus groups will assess students' satisfaction with the program and what they think could be done to make it better. Focus groups will be run by one or two trained researchers.

For participating in focus groups, students will be able to choose one of the following Kids SIPsmartER branded materials: draw string back, water bottle, highlighter, or pen.

- KSS_IRB_Attachment18_ StudentFocusGroupProtocol_Mod4

Will a recording device (e.g. audio, video, photographic) be used to collect data/materials from participants? Yes

What type(s) of recording device(s) will be used in this data tool? Audio

Describe each recording device(s) and provide a justification for using the recording device.

We will be audio recording student focus groups. This practice will allow members of the research team to fully participate in the focu group process and will also ensure that recollections/notes of statements and/or conversations are accurate. Each focus group will be transcribed verbatim.

Are the participant's identifying information included as part of the data at any time? Yes, and participant identifiers will NOT retained

What identifiers will be connected to the data and will you have access to those identifiers?

Names and voices.

Describe the process for stripping participant identifiers from the data.

For all digital audio files and the transcribed text will be stored in password protected laptop and desktop computers. Computers are kept in a room only accessible by key. Once the digitial audio files have been uploaded onto the computer, they will be erased from the recorder. Recordings will either be transcribed by members of the research team or by a transcription service. Digital audio files

will be erased from the recorder once they have been uploaded onto a password protected, study computer. De-identified transcripts will be retained for five years after completion of all data analysis in order to inform future research.

Data Source Name: Teacher & Principal Assessements

When will the data be collected? Some data are collected but new data may be added to the data set after IRB-SBS approval of this protocol.

Who will collect the data? Primary data source

Describe this Data Source.

Teacher and principals will complete surveys and take part in reflective interviews. Teachers will complete surveys and interviews twice (middle and end of the year) while principals will complete them once (end of the year). The content areas addressed in the surveys and interviews are highlighted this table below. Teachers are hired as consultants and will paid to complete the surveys and interviews. There is no compensation for the principals to complete the survey or interview.

- KSS_IRB_Attachement14_ MidYear_Survey+InterviewProtocol_mod3
- KSS_IRB_Attachement15_ EndYear_Survey+InterviewProtocol_mod3

Data consists of:
Perceptions of training and technical support provided by research staff
Perceived importance of KSS
Perceptions about implementing KSS
Perceptions about maintaining KSS
Implementation experience
Organizational capacity

Will a recording device (e.g. audio, video, photographic) be used to collect data/materials from participants? Yes

What type(s) of recording device(s) will be used in this data tool? Audio

Describe each recording device(s) and provide a justification for using the recording device.

We will be audio recording interviews with teachers and principals. This practice will allow members of the research team to more full participate in the interviews and will also ensure that recollections/notes of statements and/or conversations are accurate. Each interview will be transcribed verbatim.

Are the participant's identifying information included as part of the data at any time? Yes, and participant identifiers will NOT retained

What identifiers will be connected to the data and will you have access to those identifiers?

Names and voices.

Describe the process for stripping participant identifiers from the data.

For all digital audio files and the transcribed text will be stored in password protected laptop and desktop computers. Computers are kept in a room only accessible by key. Once the digitial audio files have been uploaded onto the computer, they will be erased from the recorder. Recordings will either be transcribed by members of the research team or by a transcription service. Digital audio files will be erased from the recorder once they have been uploaded onto a password protected, study computer. De-identified transcripts will be retained for five years after completion of all data analysis in order to inform future research.

Confidentiality will also be promoted by assigning a 6-digit identification number for each participant at the time of enrollment. All ID numbers will be stored in password protected computers and this information will be limited to the PI and research staff. A limited data set will be developed and all identifiers will be destroyed at the conclusion of the study. No identifiable data will be disclosed outside the organization.

Several steps will be taken to ensure confidentiality, such as ensuring all research team members complete human subjects training have been adequately trained to de-identify data. Trained research staff members will be responsible for collecting all outcome data.

All field computers will be password protected; filing cabinets will have locks and be in locked rooms. Confidentiality will also be promoted by assigning a 6-digit identification number for each participant at the time of enrollment. All ID numbers will be stored in password protected computers and this information will be limited to the PI and research staff. A limited data set will be developed and all identifiers will be destroyed at the conclusion of the study. No identifiable data will be disclosed outside the organization.

Associate Data Sources with Data Sources

If you are you linking the participants in a data set with their content in a different data set, use this section to associate and describe t linked Data Sources.

Data Source Name: **Caregiver Assessment Packets**
✓ Data Source Name: **Parent Exit Interview**
✓ Data Source Name: **Student focus groups**

Data Source Name: **Parent Exit Interview**
✓ Data Source Name: **Caregiver Assessment Packets**
✓ Data Source Name: **Student focus groups**

Data Source Name: **Student Assessment Packet**
✓ Data Source Name: **Caregiver Assessment Packets**
✓ Data Source Name: **Student focus groups**

Data Source Name: **Student focus groups**
✓ Data Source Name: **Parent Exit Interview**
✓ Data Source Name: **Student Assessment Packet**

Data Source Name: **Teacher & Principal Assessements**
(not associated with other Data Source)

Describe the processes for linking the data:

All sources of an individual students data is linked. All sources of an individual caregiver data is linked. Within households, student & caregiver data are linked.

Associate Data Sources with Participant Groups

Participant Group Name: **Parents/guardian - paper consent**
✓ Data Source Name: **Caregiver Assessment Packets**
✓ Data Source Name: **Parent Exit Interview**

Participant Group Name: **Parents/guardian - Qualtrics consent**
✓ Data Source Name: **Caregiver Assessment Packets**

Participant Group Name: **Students**
✓ Data Source Name: **Student Assessment Packet**
✓ Data Source Name: **Student focus groups**

Participant Group Name: **Teacher & Principals**
✓ Data Source Name: **Teacher & Principal Assessements**

Data Sources Upload

Instrument
View File: KSS_IRB_Attachment 15_EndYear_Survey+InterviewProtocol_submitted.doc
date uploaded: 2019-03-11, by: Zoellner, Jamie *(jz9q)*
This file is approved.
date approved: 2019-04-01

Instrument
View File: KSS_IRB_Attachment17_StudentFocusGroupProtocol_Mod4.docx
date uploaded: 2019-03-12, by: Zoellner, Jamie *(jz9q)*
This file is approved.
date approved: 2019-04-01

Instrument
View File: KSS_IRB_Attachment18_CaregiverInterviewProtocol_Mod4.docx
date uploaded: 2019-03-11, by: Zoellner, Jamie *(jz9q)*
This file is approved.
date approved: 2019-04-01

Instrument
View File: KSS_IRB_Attachment2_StudentPacket_v5_SUBMITTED_mod4.docx
date uploaded: 2019-03-11, by: Zoellner, Jamie *(jz9q)*
This file is approved.
date approved: 2019-04-01

Instrument
View File: KSS_IRB_Attachment3_CaregiverPacket_v3_SUBMITTED_mod5_add mailing address.docx
date uploaded: 2020-03-16, by: Zoellner, Jamie *(jz9q)*
This file is approved.
date approved: 2020-03-23

Instrument
View File: KSS_IRB_Attachment37_Student Survey_SupS2_Mod7_submit.pub
date uploaded: 2021-07-20, by: Porter, Kathleen *(kjp9c)*
This file is approved.
date approved: 2021-08-10

Instrument
View File: KSS_IRB_Attachment40_Student Survey_SupS2_Mod8_submit.pub
date uploaded: 2024-08-26, by: Porter, Kathleen *(kjp9c)*
This file is approved.
date approved: 2024-09-04

Instrument
View File: KSS_IRB_Attchement 14_MidYear_Survey+InterviewProtocol_submitted.doc
date uploaded: 2019-03-11, by: Zoellner, Jamie *(jz9q)*
This file is approved.
date approved: 2019-04-01

Permission to Access Data Source and Participant Group

Are there any rules or restrictions to access Data Sources and/or Participant Groups? No

Permissions and/or Agreements

Proof of Permission
View File: IRB-SBS School Admin Form.docx
date uploaded: 2019-03-11, by: Zoellner, Jamie *(jz9q)*
This file is approved.
date approved: 2019-04-01

Reliance Agreement - non-UVA Institution - Signed IAA
View File: VT IRB-23-888 Letter of Non-Engagement.pdf
date uploaded: 2023-08-30, by: Monroe, Jeff *(mjm6ny)*
This file is approved.
date approved: 2023-08-31

Data Reports & Storage

How will data/materials be stored? What measures will be taken to secure these data during collection and analysis? If th data includes recordings, what will be done with the recordings (including if/when the recordings will be destroyed)? Describe the long-term plan for maintaining the data when the active research phase is completed. Please note that you n need additional "material release" consent forms if you are using recordings for purposes beyond the study.

> Data will be stored in filing cabinets that have locks and be in locked rooms. Data linked to a participant will be destroyed following the study completion. De-identified data will be retained for five years after completion of all data analysis in order to inform future

research.

For all digital audio files and the transcribed text will be stored in password protected laptop and desktop computers. Computers are kept in a room only accessible by key. Once the digitial audio files have been uploaded onto the computer, they will be erased from the recorder. Recordings will either be transcribed by members of the research team or by a transcription service. Digital audio files will be erased from the recorder once they have been uploaded onto a password protected, study computer. De-identified transcripts will be retained for five years after completion of all data analysis in order to inform future research.

How will data/materials be reported for this study? Will the results be reported in aggregate or will individual data be discussed?

Reported study findings will be reported in aggregated form, individual data will be released or reported.

If a participant decides to withdraw from the study, how will you handle their data?

All participants can withdraw from the study at any time. There is no penalty for withdrawing. If participants withdraw from the study the information collected will not be used.

Do you plan to publish your raw data after the study is completed *(i.e. open-access or open source publishing)*? No

Will other parties (i.e. other corporations, institutions, researchers) have access to or retain a copy of the data? No

International Research

Risks & Benefits

You have indicated that this study will include the **2 items** displayed in the list below. These **2 items** are areas that often require more scrutiny from the Board. When framing your responses regarding the risks in this study, address the study as a whole, and also conside the **2 items** specifically as well.

Items:
1. includes minors
2. limits on ability to consent

Is loss of confidentiality and/or privacy a risk to participants? Yes

What will be done to protect participants from loss of confidentiality and/or privacy?

It is important to note, that as surveys and curriculum activities will be conducted during a normal class period, all students, regardless of consent, will participate in the classroom component. However, height/weight data will only be recorded for research purposes from students with parental consent and student assent to participate in this research. Furthermore, only data from consented/assented will be used for research purposes.

Additionally, the research staff will be trained to minimize students' anxiety associated with completing the study measures. Notably, the PI will develop and train research staff on a scripted protocol to help ensure all participants are adequately informed about the research and their confidentiality protected.

Several steps will be taken to ensure confidentiality, such as ensuring all research team members complete human subjects training have been adequately trained to de-identify data. Trained research staff members will be responsible for collecting all outcome data. All field computers will be password protected; filing cabinets will have locks and be in locked rooms. Confidentiality will also be promoted by assigning a 6-digit identification number for each participant at the time of enrollment. All ID numbers will be stored in password protected computers and this information will be limited to the PI and research staff. A limited data set will be developed and all identifiers will be destroyed at the conclusion of the study. No identifiable data will be disclosed outside the organization.

We will be audio recording student focus groups. This practice will allow members of the research team to fully participate in the focu group process and will also ensure that recollections/notes of statements and/or conversations are accurate. Each focus group will be transcribed verbatim.

We will be audio recording parent interviews to allow members of the research team to fully participate in the interview process and ensure that recollections/notes of statements and/or conversations are accurate. Each interview will be transcribed verbatim.

We will be audio recording interviews with teachers and principals. This practice will allow members of the research team to more full participate in the interviews and will also ensure that recollections/notes of statements and/or conversations are accurate. Each interview will be transcribed verbatim.

[MODIFICATION August 10 2021]: All digital audio files will be stored on either UVA Box (sensitive data) or on a highly secure shared drive (es3.eservices.virginia.edu; highly sensitive data). Determination of the drive will be based on determination of data sensitivity using UVA guidelines. UVA Box may be synced to individual password-protected laptop and desktop computers. Computers are kept i a room only accessible by key. Once the digital audio files have been uploaded onto the computer, they will be erased from the recorder. Recordings will either be transcribed by members of the research team or by a transcription service. Digital audio files will be erased from the recorder once they have been uploaded into the proper storage site. De-identified transcripts will be retained for five years after completion of all data analysis in order to inform future research.

Data will be stored in filing cabinets that have locks and be in locked rooms. Data linked to a participant will be destroyed following the study completion. De-identified data will be retained for five years after completion of all data analysis in order to inform future research. Reported study findings will be reported in aggregated form, individual data will be released or reported.

Describe any remaining potential risks to participants. For example, are any of your participants or participant groups "ris sensitive"? Include information about the probability of harm (i.e. how likely it is that harm will occur). What will be done reduce risk to participants? If something unexpected involving risk happens, how will you handle it?

Students:
There are minimal risks for students involved in this study. It is possible that completing the assessments could cause stress or anxiety. However, the surveys contain minimally sensitive questions. Nonetheless, all research staff will be trained to deal with this anticipated anxiety and each individual will be informed that they always have the right to refuse to participate or to answer any questions on the survey.

Students (focus group subset):
In addition to the risks that apply to the whole sample of students, students participating in the focus groups might also feel stress o anxiety about answering questions in front of their peers. To mitigate this, students will be told that they can skip questions they are uncomfortable answering and allowed to ask to turn of audio-recording for responses they do not want to have taped. Also, participants agree to respect one another's privacy and confidentiality by not disclosing anything said within the context of the discussion as part of the consenting process as part of the consenting process. Nonetheless, all staff involved in data collection activities will be trained to deal with this anticipated anxiety.

Parents/guardians:
There are minimal risks for parents/guardians involved in this study. The time it takes to complete the survey may be an inconvenience. Other risks revolve around feelings of stress and anxiety related to answering survey questions and responding to SMS questions. This stress or anxiety could be due to the content of questions (e.g., household behaviors) and the possible costs of receiving and sending text messages. To mitigate potential stress and anxiety, parents/guardians will be informed that their participation in the component is voluntary, will be notified that they always have the right to refuse to answer any questions on the survey or text, and will be ensured that their data will be kept confidential and will not be shared with school staff.

Parents/caregivers (interview subset):
In addition to the risks that apply to the whole sample of parents/caregivers, parents/caregivers participating in the interviews might also feel stress or anxiety about having their responses recorded. To mitigate this, they will be told that they can skip questions they are uncomfortable answering and allowed to ask to turn of audio-recording for responses they do not want to have taped.

Teachers and Principals:
There is minimal risk to teachers and principals in this study. There may be some inconvenience of time to complete reflective interviews and surveys. Teachers and principals will be informed that they have the right to not answer specific questions. Teachers and principals can also ask the researchers to turn off the audio-recorder if there is a response they would not want taped. Additionally, these activities will be scheduled at times that do not conflict with the participant's other professional responsibilities.

All groups:
The seriousness of this risk to privacy and confidentiality of personal information is low. Several steps will be taken to ensure confidentiality from the research end and participant ends. Research staff will be adequately trained to de-identify data and will have completed human subjects training. Also, based on the security software on internal computer hard and software within our research lab, the likelihood of these risks is low.

Are there direct benefits to the participants in this study? Yes

Describe the overall benefit of this study and the direct benefits to the participants.

Intervention students & parents/guardians:
There are no direct benefits to for students & parents/guardians joining this research study. But, it is our hope that everyone will benefit from the Kids SIPsmartER program and reduce their sugary drink intake and improve their quality of life.

Control students and parents/guardians:
While there are no direct benefits for students and parents/guardians in the control schools, participants could indirectly benefit from the knowledge gained and potential for Kids SIPsmartER to be integrated into their school in the future in and impact the health of students and parents/guardians.

Teachers and Principals:
Teachers and principals will benefit from understanding key processes necessary to promote the successful adoption, implementation and maintenance of an evidence-based health education curriculum into their school. These understandings will build capacity, which could improve other health education efforts within the school.

Findings from this project will have research and practice implications. Research implications include peer-review publications related to developing and testing SMS messages for cultural appropriateness, and the practical use of SMS for health interventions in rural areas. Practice implications include the refining of an evidenced-based health education program to make it compatible with the region's needs so it could be disseminated into the region.

Continuation

Are you applying for a continuation of your protocol's approval? No

Modification

Does this protocol version include any changes that were made to the previously approved protocol (protocol form, conse documents, etc)? *Minor edits are considered changes!* Yes

Has the level of risk changed (either increased or decreased) since the last submission? No

Provide the rationale for changing the protocol described in this study. Note that the program is able to detect changes m in the text boxes so it is not necessary to report every edit.

We have modified the survey used in the SupS2 year to reduce the number of items on the survey. TThis items will allow us to continue to evaluate Kids SIPsmartER's impact without collecting unnecessary data. In doing this, this change will also reduce burder on students and teachers.

Unexpected Adverse Events

Did a negative event associated with the research occur and does it meet one of the following conditions:

is not described as a possibility in the previously approved protocol OR;

did not occur within the parameter described (i.e. an increase in frequency or severity)?

No