iSIPsmarter: An RCT to evaluate the efficacy, reach, and engagement of a technology-based behavioral and health literacy intervention to reduce sugary beverages among rural Appalachian adults

Study Protocol

NCT#: NCT05030753

Date: March 25, 2022

PROTOCOL

Background

1. Provide the scientific background, rationale and relevance of this project.

INSTRUCTIONS

- This should include a referenced systematic evidenced-based review when possible.
- If this study involves qualitative research explain the major constructs of your study.
- Do not state in this section what you plan to do in this study. This information should be entered later under "What will be done in this protocol?"
- Do not include the bibliography in this section.
- For studies submitted under the Expedited review criteria, this section need not be more than a few paragraphs.
- For those studies where data will be analyzed collaboratively by multiple sites doing a similar study for which there is no common protocol (Collaborative Site Analysis Study) include a description of the common scientific goals/ procedures/data points.
- If this is a FIVE YEAR UPDATE make sure the information throughout the protocol includes the most current information.

Answer/Response:

In the United States (US), sugar-sweetened beverages (SSB) is the largest single food source of calories and contributes approximately 7% of total energy intake.[1] The intake of SSB is disproportionately high in in the southwest Virginia region of Appalachia with data indicating that adults drink ~38 ounces (~475 calories) of SSB per day[2] and SSB contributes about 14% of total daily energy intake.[3, 4] This intake is more than double national average intakes[1] and more than four times the recommended amount.[5, 6] There are also strong and consistent data documenting relationships among high SSB consumption and numerous health issues, including obesity, diabetes, some obesity-related cancers, heart disease, hypertension, and dental decay.[7-17 2122]

Further compounding the challenges of SSB, the Appalachian region lacks access to providers, medical services, and evidence-based behavioral prevention programs.[23-25] Although there is a large body of literature documenting the effectiveness of health-related Internet-based intervention, including for nutrition-related outcomes,[26-32] there is limited data on Internet-based interventions in medically-underserved rural regions, especially in Appalachia. Because of this gap, little is known about how rural, Appalachian adults may engage with technology-based behavioral programs. Historically, extending evidence-based interventions into Appalachia has been hindered by lack of providers, physical barriers (e.g. rural geographical dispersion, limited transportation resources), and a digital divide.[23, 33] Given the progress in shrinking the digital divide in recent years,[34-37] the timing is ideal to evaluate technology-based behavioral interventions in this region.

The current proposal is designed to target this major SSB dietary risk factor and public health challenge, as well as address notable gaps in the rural e/m-Health literature. ***i*SIPsmarter**

is a technology-based behavioral and health literacy intervention targeting SSB reduction that has already been developed by this research team. It is comprised of six Internet-delivered Cores, an integrated short message service (SMS) strategy to engage users in tracking SSB behaviors, and the incorporation of a cellular enabled scale for in-home weight tracking. ***i*SIPsmarter** is a highly interactive, structured, and self-guided program that uses strategies previously proven to promote behavior change. Knowing some participants have difficulties staying engaged with technology-based interventions,[38-41] ***i*SIPsmarter** also incorporates a stepped care approach to users who struggle to complete components of the intervention.

Importantly, this ***i*SIPsmarter** proposal builds on our team's expertise with e/m-Health interventions and decades of SSB behavioral intervention research in rural Appalachia. Specifically, ***i*SIPsmarter** has been adapted from our evidence-based SSB reduction program for Appalachian adults, SIP*smart*ER,[4, 42-52] that included in-person classes and interactive voice response calls. In the full-scale RCT, SIP*smart*ER improved 6-month SSB behaviors[43] and sustained improvements across a 12-month maintenance phase.[50] Furthermore, SIP*smart*ER significantly decreased weight,[43] and improved overall dietary and beverage quality,[4, 44] an added sugar biomarker,[45] and quality of life (QOL).[43] The effective SIP*smart*ER content and behavioral change strategies have been carried forward in the adaption process and user-centered development of ***i*SIPsmarter.**

Objectives/Hypothesis

INSTRUCTIONS:
If this study involves biomedical research clearly state the objectives and hypotheses and clearly define the primary and any secondary outcome measures. If this study involves qualitative research clearly state your research hypothesis or question.

This section should not include information already included in other sections such as background information or information from the procedures section.

Answer/Response: The purpose of this study is to help people decrease their sugary drinks. The study is also trying to help people improve their diet, weight, and quality of life.

PRIMARY AIM: To determine the efficacy of ***i*SIPsmarter** at reducing SSB consumption. We hypothesize that ***i*SIPsmarter** will be more efficacious at reducing SSB consumption than a static patient education (Sugary Drink Education Website) website at post assessment.

SECONDARY AIMS: Using ***i*SIPsmarter**, we will:

- Determine its efficacy on secondary outcomes (overall dietary quality, weight, QOL, behavioral theory constructs) and the maintenance of all primary and secondary outcomes at 6- and 18-months follow-up.
- Evaluate its reach and representativeness.
- Describe patterns of user engagement (number of log-ins, number of cores completed, diary entries).
  Estimate the added cost of delivering stepped care in ***i*SIPsmarter** and its associated value to intervention adherence and efficacy outcomes.

EXPLORATORY AIMS:

- Explore the influence of engagement on efficacy outcomes and explore mediators to engagement and efficacy outcomes.

Study Design: Biomedical

1. Will controls be used?

Answer/Response: Yes

►**IF YES, explain the kind of controls to be used.**

Answer/Response:

The Sugary Drink Education website will include scientifically accurate information that is typical of nutrition education websites and relevant content as adapted from our SIP*smart*ER intervention. The Sugary Drink Education website will include information about SSB recommendations, types of SSB and portion size, SSB-related health risks, energy balance information, identifying motivators and barriers to reducing SSB intake, interpreting SSB nutrition labels, and recognizing media influences and misclaims in SSB advertisements, as well as printable forms to track SSB and weight. Unlike ***i*SIPsmarter**, the content will not be tailored and will be presented all at once.

2. What is the study design?

Example: case series, case control study, cohort study, randomized control study, single-blind, double-blind, met-analysis, systematic reviews, other. You may also view the IRB-HSR Learning Shot on this topic to help you answer this question. (http://www.virginia.edu/vpr/irb/learningshots/Writing_protocol_June09/player.html

Answer/Response:

This is a randomized controlled trial. The overall goal is to examine the efficacy of ***i*SIPsmarter** in a 2 group [***i*SIPsmarter** vs. Sugary Drink Education website] by 4 assessment (Pre, Post, 6- and 18-month follow-up) design:

3. Does the study involve a placebo?

Answer/Response: No

►**IF YES, provide a justification for the use of a placebo**

Answer/Response:

Human Participants

Ages: at least 18 years old

Sex: male and female

Race: all races, no race inclusion/exclusion criteria

Subjects- see below

INSTRUCTIONS: For question 1-4 below insert an exact #. Ranges or OPEN is not allowed. This # should be the maximum # you expect to need to enroll (i.e. sign consent) If you are only collecting specimens the number of participants should equate to the # of specimens you need. If you are collecting only data from a chart review the number should designate the number of subjects whose medical records you plan to review. Age/ Sex/Race criteria should designate the demographics of participants from whom you will obtain the specimen/data.

1. **Provide target # of subjects (at all sites) needed to complete protocol.**

INSTRUCTIONS: If this is NOT a database protocol, this number should be the same as the number of subjects needed to obtain statistically significant results.

Answer/Response: 97 participants per condition are needed to complete the protocol (Total = 194)

2. **Describe expected rate of screen failure/ dropouts/withdrawals from all sites.**

Answer/Response: We anticipate a 20% attrition at the post intervention assessment

3. **How many subjects will be enrolled at all sites?**

INSTRUCTIONS: This number must be the same or higher than the # from question # 1 in order to account for the # of screen failures, dropouts, withdrawals described in question # 2.

Answer/Response: 122 participants per condition are needed to enroll in the study (Total = 244)

4. **How many subjects will sign a consent form under this UVa protocol?**

INSTRUCTIONS: If the protocol does not have a consent form- the number listed here should reflect such things as the number of subjects from whom specimens will be obtained, the number of charts to be reviewed etc.

Answer/Response: 244

Inclusion/Exclusion Criteria

INSTRUCTIONS:

- The inclusion and exclusion criteria should be written in bullet format.
- *This item applicable if the study will require consent (verbal or written).* Unless there is a scientific reason for not recruiting a certain type of vulnerable population(e.g. not enrolling fetuses, neonates or children in a study regarding Alzheimer's) list the following vulnerable populations under either Inclusion or Exclusion criteria below: pregnant women, fetuses, neonates, children, prisoners, cognitively impaired, educational or economically disadvantage, non- English speaking subjects .
- If you will not enroll subjects who do not speak English because certain procedures cannot be carried out if the subject does not speak English (e.g. a survey is not validated

in other languages) insert the following as an Inclusion Criteria: Willingness and ability to comply with scheduled visits and study procedures.
- If this is a collection of only retrospective* specimens or data, the inclusion criteria must include a start and stop date for when specimens/ data will be collected.
- The stop date must be prior to the version date of this protocol.
- *Retrospective: all specimens are in a lab at the time this protocol is approved by the IRB. All data exists in medical records or records from previous studies at the time this protocol is approved by the IRB.

1. List the criteria for inclusion

Answer/Response:

- English speaking
- at least 18 years old
- consume >200 kcals of SSB/day
- live in the targeted southwest Virginia or surrounding Appalachia county region
- be able and willing to access an internet-enabled device at least one time per week
- willing to receive text message reminders to complete program tasks
- willing to check emails regularly for reminders to complete program tasks
- willing and able to comply with study procedures

2. List the criteria for exclusion

Answer/Response:

- Non-English speaking
- ages <18 years
- consume <200 kcals of SSB/day
- live outside of the targeted southwest Virginia or surrounding Appalachia county region
- unable to access an internet-enabled device at least one time per week
- unwilling to receive text message reminders to complete program tasks
- unwilling to check emails regularly for reminders to complete program tasks
- unwilling or unable to comply with study procedures

3. List any restrictions on use of other drugs or treatments.

INSTRUCTIONS: List only those drugs or treatments that are prohibited while on study, not those listed as an exclusion criteria.

Answer/Response: None

Statistical Considerations

1. Is stratification/randomization involved?

Answer/Response: No

►IF YES, describe the stratification/ randomization scheme.

INSTRUCTIONS:

The stratification factors and/or the randomization plan should be identified. If there is no randomization component or important patient characteristics that will be used in treatment allocation or data analysis, a statement to this effect should be included.

Stratification factors: These are pretreatment patient characteristics which could be balanced across treatment arms by design or may be used to determine starting dose or treatment allocation.

If randomization is going to be used, the details of the randomization plan should be described.

The description should include:
--the method and timing of randomization
--the type of randomization scheme that will be used in the study
--whether or not the randomization masked/blinded/if so, then to whom is it masked/blinded
--who has access to the randomization scheme

Answer/Response:

►**IF YES, who will generate the randomization scheme?**

_____ Sponsor
__X__ UVa Statistician. Insert name Answer/Response: Dr. Wen You
_____ UVa Investigational Drug Service (IDS)
_____ Other*:* Specify Answer/Response:

2. What are the statistical considerations for the protocol?

The objectives section and the statistical section should correspond, and any objective for which analysis is unfeasible should be deleted. Also, the estimates and non-statistical assumptions of the statistical section should be supported by discussion in the background section.

The answer to this question should include:
--Study Design/Endpoints
--Recap of study objectives and endpoint definitions. An assessment of how study objectives will be assessed by identifying & defining which endpoints will be used to assess each component of the study objectives.
--The study design should include contingencies for early stopping, interim analyses, stratification factors (If applicable), and any characteristics to be incorporated in analyses.
--The power/precision of the study to address the major study endpoint(s), the assumptions involved in the determination of power/precision.
--If statistical hypothesis testing is included then specify the null and alternative hypotheses, the test statistic, and the type I and II error rates
--If precision of an estimate, then provide a definition for precision

--If other, then specify

Answer/Response:

Our efficacy analysis will be on the individual level and the analysis will address potential self-selection occurrence across program participation, engagement, and stepped care provision. Appropriate descriptive, parametric, and non-parametric statistical methods will be used to summarize continuous and categorical variables between the intervention conditions at baseline. Data will be examined for the presence of outliers, violations of normality (for continuous variables), and missing data. Major violations of normality will be corrected with an appropriate transformation procedure. All analysis will use county-level cluster robust standard error adjustment to account for correlation of behavioral outcomes within the county who are likely to share similar food and beverage preferences, food environments, and SSB consumption norms.

3. Provide a justification for the sample size used in this protocol.

Include sample size calculations or statistical power estimation. If not applicable, please provide explanation.
Also include the anticipated accrual rate, the accrual goal for the study, including accrual goals by strata if appropriate, adjustments for drop-outs etc. and study duration.

Answer/Response:

This ***i*SIPsmarter** power calculation is based on our SIP*smart*ER effectiveness trial that found an ES of 0.55 for the primary 6-month SSB outcome [i.e., SIP*smart*ER decreased SSB intake by 227 (95% CI=-326, -127, p<0.001) kcals/day when compared to the decrease of 53 (95% CI=-88, -17, p<0.01) kcals/day among MoveMore (p<0.001); see Section 4b]. We anticipate that ***i*SIPsmarter** will lead to a change at least as strong as that found with SIP*smart*ER, given the added enhancements of stepped-care, daily SSB tracking, and the shorter time to follow-up assessment. Yet, one might expect a somewhat smaller ***i*SIPsmarter** ES given the remote delivery, more limited human exchange, and less discrepancy of provision of content provided between the experimental and control conditions (PE website provides SSB content). Based on these considerations, we are powering our study to detect a reasonably conservative ES of 0.4. To achieve 80% power with a 0.05 type I error rate, 97 participants/condition are needed. Accounting for 20% attrition at the post intervention assessment, a total of 122 participants/condition will be enrolled (Total enrolled = 244).

4. What is your plan for primary variable analysis?

Include primary outcome(s)/predictor variable(s), statistical methods/models/tests to be employed, or descriptive summaries as appropriate. If not applicable, please provide explanation.

Answer/Response:

A General Linear Mixed Model (GLMM) will be employed to control errors of non-independence and heteroscedasticity caused by individual and county heterogeneity, and potential covariates identified a priori based on the existing literature and theory that are relevant to SSB consumption outcome, and include: age, gender, race/ethnicity, income level,

education level, health literacy level.[53-56] Furthermore, GLMM will allow us to model attrition specifically through a structural approach. A time indicator that identify post-assessment time points will be created and included in the model with baseline as the base. A treatment group indicator will be included to identify ***i*SIPsmarter** group with PE group as the base. The time and group interaction term will be included in the model with its coefficient capturing the over time relative effect (***i*SIPsmarter** vs. PE) on SSB intakes. The model will allow county level random effects to capture the source of variability that comes from county-level unobserved differences.

5. What is your plan for secondary variable analysis?

Include the following:
--Secondary outcome(s)/predictor variables, statistical methods/models/tests to be employed, or descriptive summaries as appropriate. If not applicable, please provide explanation.
--For phase III studies, the power/precision of the study to address the secondary objective(s).

Answer/Response:

The multi-level mixed effect model used for the primary aim will be modified to assess secondary outcomes and maintenance time points. For those discrete outcomes, nonlinear mixed effect models will be used with appropriate link functions chosen to capture the nonlinear outcomes' distribution; additional time indicators will be added to the model that will capture 6- and 18-months follow-up assessment time points. Due to the multiple outcomes treatment effect analysis nature, we will follow the multiple testing correction procedures in mixed models proposed in Joo et al.[57] and examine the potential efficiency gained through hierarchical Bayesian procedure in Gelman et al.[58] **SA2:** Similar to our teams' other reach papers,[49, 59-61] reach will be analyzed following recommendations of Glasgow et al.[62] Participation rate will be determined by dividing the total number of enrolled participants by the total number eligible to enroll. Representativeness will be assessed by comparing demographics of those enrolled to: 1) those screened, eligible, and not enrolled and 2) the demographics of the targeted Appalachia Virginia region using county-level Census Bureau data.[63] **SA3:** We will report descriptive statistics and qualitative findings on patterns of user engagement (e.g., number of log-ins, number of cores completed, diary entries), requirement for stepped care, and participants' perceptions of the intervention (e.g., usability, satisfaction, and barriers to web program use). **SA4:** The incremental cost of ***i*SIPsmarter** with stepped care relative to the PE website will be assessed. Since the primary cost additions are due to the added stepped care component of ***i*SIPsmarter**, we will focus on those associated added costs, including time to construct and send texts and time to prepare for and talk on the phone.[64] Beyond those incremental costs, we will also capture costs per participant and explore marginal costs per SSB kcal reduction. Non-research-related intervention resource use will be valued at competitive market rates (e.g., the labor costs of stepped care will be valued at the market wage rate for the associated occupation). All costs will be estimated and evaluated in the constant dollars adjusted by appropriate index. Recognizing that we do not have a second treatment group without stepped care enhancement, we will use Monte Carlo simulations to alter adherence rate and changes in characteristics of the participants in order to simulate

changes in stepped care demands.[65] This will provide necessary parameters for a future full-scale effectiveness trial that assess cost-effectiveness of ***i*SIPsmarter** in rural systems. **Exploratory Aim (EA)1:** The GLMM will be expanded to include engagement variables (e.g., number of log-ins/core completion) and explore engagement effect on efficacy outcomes. Furthermore, the GLMM will be modified to explore potential mediating effects of variables (e.g., behavioral theory constructs) on engagement and efficacy outcomes. Specific procedure for testing mediation will closely follow suggestions of Zhao et al.[66] and Imai et al.[67] Although not specifically powered for these exploratory mediation analyses, findings will provide necessary preliminary results to inform a future effectiveness trial in terms of block randomization and targeted power calculation.

6. Have you been working with a statistician in designing this protocol?

Consultation with a professional statistician is highly recommended to ensure good science of the study and facilitate the review process.

Answer/Response: Yes

IF YES, what is their name?

Answer/Response: Dr. Wen You

7. Will data from multiple sites be combined during analysis?

Answer/Response: No

INSTRUCTIONS: IF YES, answer the following questions

7(a). Does the study involve randomization?

Answer/Response:

IF YES, will randomization be done at each site or among sites?

Answer/Response:

7(b). Has the sample size calculation considered the variation among sites?

Answer/Response:

7(c). When combining the data from multiple sites to assess the study results, is the effect of the treatment to be tested (or the association to be tested) assumed to be the same across sites or vary among sites? What is the modelling strategy?

Answer/Response:

7(d). Is there a common protocol used in all sites?

Answer/Response:

IF NO, how will differences among sites, such as those related to the implementation, inclusion criteria, patient characteristics, or other sites characteristics, be considered to assess the study results?

Answer/Response:

Study Procedures-Biomedical Research

1. What will be done in this protocol?

INSTRUCTIONS:
This should include everything that will be done as part of this protocol. Do not repeat information that is included in other sections such as Background or Hypothesis sections.
This section should include an indication of which research interventions if any offer a prospect for direct benefit and which interventions (invasive measurements, collection of blood, tissue, data, surveys, etc.) are being done solely to answer a research question and generate generalizable knowledge. If the interventions done solely for research purposes are associated with greater than minimal risk they need to be justified. Describe and justify any control and experimental arm and include method, dose, and duration of drug administration. Reference any claim of clinical equipoise if applicable.

If you are obtaining specimens or data, provide information regarding the type of specimen/data, amount of specimen needed and how the specimen/data will be obtained and what analysis will be done with the specimen/data.

Special note for studies with waiver of consent/waiver of documentation of consent:
Include a statement regarding how subjects will be recruited. For other studies this information is captured in Recruitment does not need to be duplicated in this section.

Answer/Response:

The intervention will be tested in a 2 group (***i*SIPsmarter** vs. Sugary Drink Education website) by 4 assessment (pre, post, 6-months post, and 18-months post).

After the initial eligibility screening and consent are performed, the following procedures are conducted for research purposes:

Step	Weeks	Study Phase	What will I do?	Time required?
1	0	Screening	Complete Interest Form Review/Sign Consent Form Phone Interview & Dietary Recall Telephone Call 1	60 minutes
2	2	Baseline	Complete Questionnaire Dietary Recall Telephone Call 2 Weight with Cellular Scale	90 minutes
3	3-12	Intervention	Use assigned website	
4	12	Post-Assessment 9 weeks	Complete Questionnaire Dietary Recall Telephone Call 1 Dietary Recall Telephone Call 2 Weight with Cellular Scale	90 minutes
5	38	Post-	Complete Questionnaire	90

		Assessment 6 months	Dietary Recall Telephone Call 1 Dietary Recall Telephone Call 2 Weight with Cellular Scale	minutes
6	96	Post- Assessment 18 months	Complete Questionnaire Dietary Recall Telephone Call 1 Dietary Recall Telephone Call 2 Weight with Cellular Scale	90 minutes

OUTCOME MEASURES

- **SEE ATTACHMENTS: 15337 iSIP Outcome Assessment Packet** (and Table below)
  - The BEV-Q 15, 24-hour dietary recalls, objective body weights, quality of life, and validated measures that have been used in our prior SIP*smart*ER and Internet-based interventions will be administered.
  - The BEV-Q 15 and two 24-hour dietary recalls will be used to understand changes in beverage behaviors, total caloric intake, and overall diet quality.
  - Secondary outcome measures are directly related to the ***i*SIPsmarter**'s underlying theoretical and conceptual framework. Acceptable psychometric properties have been established for our measures.[2, 68-80]

Table 4. **Outcome measures for each aim and the assessment timing schedule**

Measures	Pre	Post	6 M	18 M	Aim	Description
Eligibility Screener	X				SA2	SSB screener, demographics, subjective health literacy,[161-163] and access to and use of Internet and text messaging
Beverage Intake, BEV-Q 15	X	X	X	X	PA, SA1	Frequency and portion sizes of 15 beverage categories over the past month, including 5 SSB specific categories (e.g., regular soft drinks, sweetened juice drinks, tea with sugar, coffee with sugar, energy drinks)[164-166]
24-hour Dietary Recalls	X	X	X	X	SA1	Two unannounced 24-hour dietary recalls (one weekend and one weekday) using state-of-the-art Nutrition Data System for Research (NDSR) software and multiple pass methods[178]
Weight	X	X	X	X	SA1	Assessed via cellular enabled in-home ©BodyTrace digital scale[179]
Height	X				SA1	Self-reported
QOL	X	X	X	X	SA1	Assessed using SF-12, a multi-dimensional measure of health-related QOL[167,168]
Health Disparity	X	X	X	X	SA1	Health access to care variables such as: health insurance, unmet health needs, usual source health care, routine check-up, delayed or missed care due to cost[180]
SSB TPB	X	X	X	X	SA1	SSB-related TPB with 4 subscales: attitudes, subjective norms, perceived behavioral control, and behavioral intentions[2]
SSB Media Literacy	X	X	X	X	SA1	Perceptions of SSB-related media and advertisements with 3 subscales: authors and audience, messages and meanings, and representation and reality[169]
Health Literacy	X	X	X	X	SA1	Assessed using the Newest Vital Sign, an objective health literacy & numeracy, based off 6 questions from nutrition facts panel[170]
SSB Home Environment	X	X	X	X	SA1	Home availability frequency of 15 beverage categories from the BEVQ-15 (modeled from home food availability measures)[181-183]
Physical Activity	X	X	X	X	SA1	Stanford Leisure-Time Activity Categorical Item (L-Cat), a single item with six physical activity categories[171-173]

PA = Primary Aim; SA = Secondary Aim; QOL = quality of life; SSB = sugar-sweetened beverages; TPB = Theory of Planned Behavior

BASELINE PROCEDURES (Health Assessment 1)

- **Telephone interview #1 completed by participant with a trained research assistant** *(at baseline only, this is completed with the first screening interview phone call and after the consent form is signed)*
  - First 24-hour dietary recall
  - Self-reported height
  - Self-reported weight
- **On-line Questionnaire self-completed by participants**
  - See table below and modules A-J of attachment

  - *Mail welcome packet mailed to participant, including ©BodyTrace scale, after first telephone interview and on-line questionnaire is completed*
- **Telephone interview #1 completed by participant with a trained research assistant**
  - Second 24-hour dietary recall
  - Objective body weight using the cellular ©BodyTrace scale that is mailed to participants. Research staff will help troubleshoot ©BodyTrace scale procedures, including cellular connection.
  - Collect SSN for gift card issue purposes

RANDOMIZATION

Once participants sign the informed consent they are randomized into their assigned condition:

  - GROUP 1: Sugary Drink Education Website
  - GROUP 2: *i*SIPsmarter Program Website

Participants are notified of their randomized condition once their above baseline procedures are completed.

INTERVENTIONS

- **Both websites (*i*SIPsmarter and Sugary Drink Education)** will include the provision of evidence-based SSB behavioral content and the ability to track SSB and weight diaries (although ***i*SIPsmarter** groups will do this using online and SMS tools whereas the Sugary Drink Education site will provide printable documents). These features allow us to control for certain elements (e.g., self-monitoring through diaries), but it is necessary to balance issues of controlling for these constructs while still ensuring the ability to maximize web program differentiation and appropriately test our hypotheses. Although there is overlap between groups, ***i*SIPsmarter** will be a multi-component intervention that differs from standard patient education websites in the following ways: (1) Individually tailored SSB and weight recommendations based on user input; (2) High levels of interactivity to increase user engagement; (3) Structured implementation of the program through use of metered (distributed) content over the intervention period rather than content presented all at once; and (4) Provision of comprehensive user specific content rather than more general information.
- **Sugary Drink Education website** will include scientifically accurate information that is typical of nutrition education websites and relevant content as adapted from our SIP*smart*ER intervention. The Sugary Drink Education website will include information about SSB recommendations, types of SSB and portion size, SSB-related health risks, energy balance information, identifying motivators and barriers to reducing SSB intake, interpreting SSB nutrition labels, and recognizing media influences and misclaims in SSB advertisements, as well as printable forms to track SSB and weight. Unlike ***i*SIPsmarter**, the content will not be tailored and will be presented all at once.
  - **Time:** There are no set time commitments, but participants are able to continue to review the website content as often as they would like over the course of the 18 months.

- ***i*SIPsmarter** is comprised of six Internet-based Cores and a recurring maintenance Core. Each Core includes behavioral content and personalized action planning pertaining to both SSB behaviors and weight, is personalized to the user, and provides follow-up and feedback. As such, ***i*SIPsmarter** is a highly interactive, structured, and self-guided program. Providing automated reminders to alert users when the cores are available is useful in promoting Core completion, and all users will receive up to two automated email reminders to complete the Cores.
    - ***i*SIPsmarter Diaries**
        - Related to SSB tracking, users are prompted daily to report their SSB intake (in ounces). For SSB prompts and diary entry, users can select between an online or SMS option.
        - Users will also be encouraged to weigh daily using their cellular enabled ©BodyTrace. Weigh-ins from the ©BodyTrace scale are synced with ***i*SIPsmarter** allowing for personalized weight feedback when users log into the website. If cellular connection does not work in the participants' home, they will be allowed to enter their weight through the website.
    - **Time:**
        - During the 1st six weeks, the Internet Program will take approximately 1 – 2 hours of the participant's' time each week.
        - After the 1st six weeks, there are no specified time requirements for use of the Internet program, but the participant is able to continue to review the program's content over the course of the year.
    - Online task completion for ***i*SIPsmarter** is tagged and stored in our database, providing a standardized metric for determining and providing stepped care support. The timing of the delivery of stepped care will coincide with the timing of the six ***i*SIPsmarter** Cores. The decision to provide stepped care throughout all six Cores is driven by our previous SIP*smart*ER trials, where we observed fluctuations in user engagement and dropouts throughout the entire course of the intervention.[52] Given that each ***i*SIPsmarter** Core is unlocked and available 7 days after completion of the previous Core, these time points will be used as adherence check points. Operationally, the first time point occurs one week after the participant has been granted access to the program. Participants will be identified as either adherent or non-adherent with the automated email instructions to complete Core 1. If they have completed it, no additional support will be made and the participant will move on to the second intervention week (continue to receive the automated Core email prompts, as is standard for all ***i*SIPsmarter** Cores). If they have not completed the first Core, they will be identified as requiring stepped care and will receive Step 1-Text. This human-supported text will include: (1) content stating that the user did not complete the Overview Core; (2) encouragement to log back in and complete the Core as soon as possible; and (3) support by asking if there were any concerns or obstacles to completing the assigned task for that week. Participants receiving this support would then be tagged as Step 1-Text. Their progress would be

followed over the next week, and they would be re-evaluated at time 2. If they have completed the assignment by time 2, they would continue using the program. Yet, if they still did not complete the assignment, they would be stepped up to Step 2-Phone. When this occurs, the participant would be contacted by phone and again provided encouragement, technical assistance, and strategies to promote task completion. If this participant still does not complete the Core, they would be considered non-adherent. This process will continue for each participant at each of the six Core time points.

- The process engagement variables, for specific aims 3, are automatically collected and stored in the database (e.g. number of logins, time/date of use, average session length, content viewed). SSB diaries and ©BodyTrace weight tracking are also captured within the ***i*SIPsmarter** database. Although participants in the Sugary Drink Education website condition may track SSB and weight diaries via printable forms, this data will not be entered or stored, nor will they have access to web-based ©BodyTrace data.

FOLLOW-UP (Health Assessments 2-4)

- Follow-up health assessments will occur at 9 weeks, 6 months, and 18 months. Participants will receive email and phone call reminders for each approaching follow-up health assessments.
- Each of the follow-up health assessments will be the same as the first baseline health assessments and will include: an on-line questionnaire and 2 telephone interviews that include dietary recalls and weight. Variations to this are as follows:

  9 Week Follow-Up Assessment

  In addition, the on-line questionnaire the Internet Intervention Evaluation Measure[81, 82] and Internet Intervention Adherence Measure[81, 83] will be administered at post (9-week) assessment to examine users' experiences with and perceived efficacy of the programs. These measures are limited to the 9-week follow-up assessment.**(SEE ATTACHMENT: 15337 iSIP Outcome Assessment Packet_v1)**

  6 Month Follow-Up Assessment

  - At the six month follow-up assessment the on-line questionnaire will include a four item Van Westendorp Price Sensitivity Meter to determine acceptability and feasibility of a future fee based intervention (Van Westendorp P. H. (1976). NSS-Price sensitivity meter: A new approach to study consumer perceptions of prices, ESOMAR (European Society for Opinion and Marketing Research) Congress, Venice, Italy. 139-167). There will also be an additional 6 items includes to access how participants accessed their assigned web-based programs and if they experienced any technical difficulties. These measures are limited to the 6-month follow up assessment. (**SEE ATTACHMENT: 22130 NEW 6-MONTH QUALTRICS QUESTIONS AMENDMENT 3.25.22)**
  - At the six month follow-up assessment a brief summative interview will be conducted during the first dietary recall to obtain feedback on decision making processes for consenting or declining the optional Biobank Study (IRB# 210186) linked to the current iSIPsmarter study. Questions are designed to solicit information

about their experience with iSIPsmarter and the Biobank and to help provide insight into future recruitment of rural populations into Biobank studies. Responses will be summarized via interviewer notes. (**SEE ATTACHMENT: 22130 BIOBANK SUMMATIVE EVALUATION FOR CONSENTED PARTICIPANTS 3.25.22 and 22130 BIOBANK SUMMATIVE EVALUATION FOR DECLINED PARTICIPANTS 3.25.22**)

Please note that variations to the online survey and phone interviews fall within the original consent form time and description parameters. Time estimates to complete assessments at 9 weeks and 6 months continue to fall within 90 minutes and additional questions refer to feedback and satisfaction regarding their experience in the study. (**SEE ATTACHMENT: 22130 ASSESSMENT MEASURES AND TIME COMPLETION ESTIMATES ACROSS THE ISIPSMARTER PROJECT 3.25.22**)

Participants can continue using their online program between each follow-up assessment until the 18-month follow-up. After the 18-month follow-up:

- Participants can have the option of continuing to use their assigned website until the end of grant funding.
- Or they have the option of using the other version of the website that they did not use during the trial.

2. If this protocol involves study treatment, explain how a subject will be transitioned from study treatment when they have completed their participation in the study.

Example: If the subject will be taking an investigational drug, will they need to be put back on an approved drug when they have completed the study? If yes, explain how this will be accomplished and who will cover the cost. If the subject has a device implanted will it be removed? Again- who will cover the cost of the removal?
Instructions: Answer NA if this study does not involve a study treatment.

Answer/Response:

Once the behavioral interventions have ended, the participants will resume their usual medical care, at their own cost.

Bibliography

INSTRUCTIONS: Provide a current bibliography supporting the hypothesis, background and methodology including references to papers and abstracts that have resulted from previous work by the investigator and references to the work of others.

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APPENDIX: Non- UVa Personnel

1. **Explain the duties of non-UVA personnel on this protocol.**

   - **Undergraduate/Graduate Volunteers:** These include students studying in the Human Nutrition, Food, and Exercise Department and MPH program at Virginia Tech University. Current students include: Jayme Price (undergraduate), Baily Steele (MPH Student). All students have completed UVA CITI Human Subjects training.

2. **Explain your plans for training and oversight of these personnel**.
   Students will be supervised by the study coordinator, Donna Brock, and trained by appropriate research team members on data entry, procedural tracking, dissemination of study materials, and recruitment processes as necessary.

3. **How do you plan to access any study records the non-UVA personnel might maintain?**
   All data will be maintained on-site by UVA personnel.

4. **Will the non- UVA personnel be exposed to any additional risk while working on this protocol?**
   No.

5. **List name of any other institution with which they have an affiliation**.
   Non-UVa study team members have affiliations listed above.

6. **Will the non- UVa personnel have access to UVa patients or their health information along with any HIPAA identifiers prior to consent?**
   These are not UVA patients. However, the volunteer students will have access to participant contact information for the purpose of disseminating study materials via FedEx mailings.

YES	NO	
X		1. Name
X		2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of the zip code if, according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same 3 initial digits contains more than 20,000 people and (2) The initial 3 digits of a zip code for all such geographic units containing 20,000 is changed to 000.
	X	3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year)

		indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older. *[This means you may record the year but not record the month or day of any date related to the subject if the subject is under the age of 89. In addition if the subject is over the age of 89 you may not record their age and you may not record the month, day or year of any date related to the subject]*
X		4. Telephone numbers
	X	5. Fax numbers
	X	6. Electronic mail addresses
	X	7. Social Security number
	X	8. Medical Record number
	X	9. Health plan beneficiary numbers
	X	10. Account numbers
	X	11. Certificate/license numbers
	X	12. Vehicle identifiers and serial numbers, including license plate numbers
	X	13. Device identifiers and serial numbers
	X	14. Web Universal Resource Locators (URLs)
	X	15. Internet Protocol (IP) address numbers
	X	16. Biometric identifiers, including finger and voice prints
	X	17. Full face photographic images and any comparable images
	X	18. Any other unique identifying number, characteristic, code that is derived from or related to information about the individual (e.g. initials, last 4 digits of Social Security #, mother's maiden name, first 3 letters of last name.)
	X	19. Any other information that could be used alone or in combination with other information to identify an individual. (*e.g. rare disease, study team or company has access to the health information and a HIPAA identifier or the key to the code* .)

7. If any items above are checked YES, list names of non- UVa affiliated individuals who will have access.

Bailey Steele, student volunteer (Virginia Tech MPH program)
Jayme Price, student volunteer (Virginia Tech, undergraduate in HNFE program)