



Published in final edited form as:

*Contemp Clin Trials*. 2021 November ; 110: 106566. doi:10.1016/j.cct.2021.106566.

## Study protocol for *iSIPsmarter*: A randomized-controlled trial to evaluate the efficacy, reach, and engagement of a technology-based behavioral intervention to reduce sugary beverages among rural Appalachian adults

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### Abstract

Sugar-sweetened beverage (SSB) consumption is disproportionately high among rural Appalachian adults, with intakes double the national average and nearly four times the recommended amount. This trial targets this major dietary risk factor and addresses notable gaps in the rural digital health intervention literature. *iSIPsmarter* is a technology-based behavior and health literacy intervention aimed at improving SSB behaviors. It is comprised of six Internet-delivered, interactive Cores delivered weekly, an integrated short message service (SMS) strategy to engage users in tracking and reporting SSB behaviors, and a cellular-enabled scale for

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Credit author statement

JMZ, LMR, KJP, WY and DFT were responsible for the conceptualization, methodology, and acquisition of funding; JMZ, LMR, KJP, ALR, CF and MH were responsible for developing the intervention resources; JMZ and ALR prepared the first draft of the manuscript; all authors provided critical review and editing of the manuscript.

Declaration of interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Dr. Deborah Tate serves on the scientific advisory board for Weight Watchers and WondrHealth.

Yet, all other authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

ClinicalTrial registry: [NCT05030753](https://clinicaltrials.gov/ct2/show/study/NCT05030753)

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in-home weighing. *Δ*SIPsmarter is adapted from an evidence-based intervention and is grounded by the Theory of Planned Behavior and health literacy, numeracy, and media literacy concepts. The RCT is guided by the RE-AIM framework and targets 244 rural Appalachian adults. The goal is to examine the efficacy of *Δ*SIPsmarter to reduce SSB in a two-group design [*Δ*SIPsmarter vs. static Participant Education website] with four assessment points. Changes in secondary outcomes (e.g., diet quality, weight, quality of life) and maintenance of outcomes will also be evaluated. Additional secondary aims are to examine reach and representativeness, patterns of user engagement, and cost. Two tertiary aims are exploratory mediation analyses and a systems-level, participatory evaluation to understand context for future organizational-level adoption of *Δ*SIPsmarter. The long-term goal is to sustain an effective, scalable, and high reach behavioral intervention to reduce SSB-related health inequities and related chronic conditions (i.e., obesity, diabetes, some obesity-related cancers, heart disease, hypertension, dental decay) in rural Appalachia and beyond.

## Keywords

Beverages; Behavioral research; Digital technology; Randomized controlled trial; Health literacy; Rural population

## 1. Introduction

In the United States, sugar-sweetened beverages (SSB, e.g., soda/pop, sweet tea, sports and energy drinks, fruit drinks, sweetened coffee) are the largest single food source of calories, contributing approximately 7% of total energy intake for adults.<sup>1</sup> There are 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.<sup>2–12</sup> The intake of SSB is disproportionately high in the southwest Virginia region of Appalachia. Specifically, adults drink ~38 ounces (~475 calories) of SSB per day<sup>13</sup> that contributes to about 14% of total daily energy intake.<sup>14,15</sup> This intake is more than double national average intakes<sup>1</sup> and more than four times the recommended amount of 8 ounces or less per day.<sup>16,17</sup>

Further compounding the challenges of SSB, the Appalachian region lacks access to medical services and evidence-based behavioral prevention programs.<sup>18–20</sup> Historically, extending evidence-based interventions into Appalachia has been hindered by lack of providers, geographical dispersion and limited transportation resources, and a digital divide.<sup>18,21</sup> In recent years, progress has been made in shrinking the digital divide.<sup>22–25</sup> Rural adults are becoming increasingly connected through mobile phones with short message service (SMS) capability; nationally, mobile phone ownership is 91% in rural areas<sup>23</sup> with dramatic increases in smartphone ownership.<sup>22</sup> Similar adoption rates are found in Appalachia Virginia. Estimates indicate that approximately 85% of southwest Virginians have access to Internet and 99.9% of Virginians have mobile coverage.<sup>24,25</sup> This digital expansion offers an opportunity to address challenges that have remained relatively static in Appalachia, including provider shortages and transportation barriers.

Although there is a large body of literature documenting the effectiveness of health-related Internet-based interventions, including for nutrition-related outcomes,<sup>26–32</sup> there is limited data on Internet-based interventions in medically-underserved rural regions, especially in Appalachia. Because of this gap, there is a great need to understand how rural, Appalachian adults may engage with technology-based behavioral programs.

Previous research findings document the effectiveness of *SIPsmarter*, a behavioral and health literacy intervention, at improving SSB behaviors in rural, Appalachian adults.<sup>33,34</sup> Furthermore, *SIPsmarter* significantly decreased weight,<sup>33</sup> as well as improved overall dietary and beverage quality,<sup>15,35</sup> delta13C biomarker (i.e., a biomarker of added sugar),<sup>36</sup> and quality of life (QOL).<sup>33</sup> A meta-analysis of 12 controlled interventions targeting SSB intake among adults found that *SIPsmarter* demonstrated the largest effects and significantly improved SSB behaviors relative to the matched contact control condition focused on physical activity (−413.98 mL SSB, 95% CI −665.32, −162.64).<sup>37</sup> Despite promising effects, in a follow-up pilot dissemination and implementation trial of *SIPsmarter*, the small group class modality limited the reach and scalability of this effective intervention.<sup>38</sup>

The current *SIPsmarter* trial was conceptualized to address the need for scalable and effective SSB reduction strategies that can reach large numbers of low SES, rural residents with the highest SSB consumption rates. This study builds on prior SSB trials in rural Appalachia and is adapted from an evidence-based SSB reduction program for adults.

## 2. Materials and methods

### 2.1. Study overview and objectives

*SIPsmarter* is a randomized-controlled trial (RCT) guided by the RE-AIM (reach, efficacy/effectiveness, adoption, implementation, maintenance) planning and evaluation framework.<sup>39,40</sup> The primary objective is to examine the efficacy of an Internet-based intervention aimed at decreasing SSB consumption (*SIPsmarter*) in a two-group [*SIPsmarter* vs. static Participant Education (PE) website] design with four assessment time points including baseline (pre-intervention), week 9 (post-intervention), 6-months post-intervention, and 18-months post-intervention. The primary hypothesis is that *SIPsmarter* will be more efficacious at reducing SSB consumption than a PE website at the week 9 post-intervention. Secondary objectives are to determine efficacy on secondary outcomes (e.g., diet quality, weight, QOL, behavioral theory constructs) and maintenance of outcomes at 6- and 18-months post intervention. Additional secondary aims include evaluating reach and representativeness of enrolled participants and describing patterns of user engagement. Exploratory aims are to explore the influence of engagement on efficacy outcomes and explore mediators to engagement and efficacy outcomes. Finally, to inform future organizational-level adoption and implementation, costs will be estimated and factors that influence sustainable SSB screening and referral processes among rural, Appalachian systems will be explored.

## 2.2. Study region and population

This study targets adults living in and around the rural southwest Virginia region of Appalachia. In this region, about 94% of adults are white, 56% have beyond a high school education, the median income is around \$40,200, and the poverty rate is approximately 19%.<sup>18</sup> The region is disproportionately burdened by health disparities and has among the poorest scores for health behaviors in the state,<sup>41</sup> with the majority of the region scoring low in terms of health opportunity level.<sup>42</sup> The Appalachian region has high prevalence and mortality from numerous SSB-related chronic conditions (i.e., obesity, diabetes, some obesity-related cancers, heart disease, hypertension, dental decay) and limited access to medical care.<sup>18,43</sup> This disproportionate burden is compounded by compromised determinants of health: high poverty rates,<sup>44</sup> low educational attainment,<sup>45</sup> and low health literacy.<sup>46</sup>

## 2.3 Intervention development and adaptation

The *ΔSIPsmarter* intervention was adapted from the effective *SIPsmarter* intervention focused on SSB behaviors.<sup>33</sup> Both interventions target rural Appalachian adults. *SIPsmarter* is a 6-month intervention with three in-person group classes and 11 interactive voice response (IVR) calls. It also includes a 12-month maintenance phase with monthly IVR calls. Alternatively, *ΔSIPsmarter* is a 9-week intervention with six Internet-based Cores and a recurring maintenance Core lasting 18-months post intervention. SSB self-monitoring, action planning, and feedback are key features of both programs.

Like *SIPsmarter*, *ΔSIPsmarter* is also grounded by the Theory of Planned Behavior (TPB) and health literacy, numeracy and media literacy concepts (Figure 1). The TPB is one of the most well-studied and useful theories for understanding and improving health behaviors. This theory postulates that an individual's behavioral intentions are shaped by attitudes, subjective norms, and perceived behavioral control.<sup>47,48</sup> *ΔSIPsmarter* integrates skill-based health literacy concepts, such as numeracy and media literacy. This focus on health literacy is important because low SES and rural residents are more likely to have low health literacy. Further, low health literacy has consistently been linked with adverse health outcomes, and low numeracy has been shown to influence chronic disease management and correlate with nutrition- and weight-related outcomes.<sup>49–55</sup> *ΔSIPsmarter* integrates health numeracy skills to help participants use and apply SSB nutrition facts label information. Media literacy skills are targeted to mitigate the overexposure and negative influence of SSB marketing, to foster skepticism toward advertising, and to develop critical thinking skills needed to identify misclaims in SSB advertising.<sup>56–61</sup>

The core content of *SIPsmarter* and *ΔSIPsmarter* are remarkably similarly. The main exception is the addition of evidence-based weight related strategies that were incorporated into *ΔSIPsmarter* during the adaptation process. Specifically, behavioral content related to the specific role of SSB in energy balance, weight self-monitoring as an additional self-regulation strategy, and personalized action planning and feedback pertaining to weight were added.

A user-centered development process was employed to adapt *SIPsmarter* to *ΔSIPsmarter*. An *ΔSIPsmarter* Advisory Team was established at the outset to engage individuals who represent the user population and get their feedback during the adaptation process. Researchers conducted field study and usability interview sessions to inform development efforts. Twelve 1-hour telephone calls were conducted with seven Advisory Team members. Sessions were focused on three main areas: 1) accessibility (e.g., Internet access, device and mobile phone ownership, computer literacy, SMS use), 2) Core content, and 3) usability and functionality. From the Advisory Team calls, improvements to the *ΔSIPsmarter* dashboard were made in order to increase usability and functionality for participants. Further, Advisory Team members provided important feedback on stories (modeled from past *SIPsmarter* participants) that are woven throughout the Cores. Members identified stories that were relevant and described situations related to setting SSB goals, making behavioral changes, and overcoming barriers to drinking less SSB. Feedback from Advisory Team members was integral in developing relevant, culturally-sensitive Core content. Likewise, member feedback helped inform the development of *ΔSIPsmarter* technology components, including built-in flexibility to account for varying Internet and SMS accessibility among participants.

## 2.4 Study design

**2.4.1 Design and randomization**—This RCT includes a two-group by four assessment design. After the baseline assessment, a simple randomization process with a 1:1 allocation ratio is used to assign participants to the *ΔSIPsmarter* or PE conditions. Participants will be emailed a unique link to set their password in order to log on and securely access their assigned program.

All study procedures have been approved by the University of Virginia Institutional Review Board. Prior to enrollment, participants will be made aware of the random allocation process to *ΔSIPsmarter* or PE groups and provide their informed consent to participate in the study. To compensate their time to complete the data assessments, online gift cards in the amount of \$50, \$50, and \$100 will be provided at the week 9, 6-month, and 18-month post-intervention assessments, respectively. Additionally, participants will be mailed an electronic cellular-enabled scale (valued at \$110) for data collection which is theirs to keep.

**2.4.2 Eligibility criteria**—Study eligibility criteria includes English-speaking adults 18 years of age and older, who live in Southwest Virginia or surrounding Appalachian counties. Eligible adults must consume >200 SSB calories per day, as assessed by a validated beverage intake questionnaire.<sup>62–64</sup> Additional eligibility criteria include the ability and willingness to access an Internet-enabled computer or tablet at least one time per week to check and receive email and willingness to receive SMS-based stepped care reminders.

**2.4.3 Recruitment**—This study will recruit, enroll, and randomize 244 participants. An *ΔSIPsmarter* Leadership Council was formed to engage stakeholders in proactively addressing recruitment and sustainability planning. The Leadership Council is comprised of four organizations that service Southwest Virginia, including two Federally-Qualified Health Center networks, the Virginia Department of Health, and a multi-service community agency.

Recruitment strategies will include a variety of different approaches within each partnering organization and across the broader Southwest Virginia. Examples include distribution of study brochures, provider referrals, and flyers with information directing individuals to an interest website. A participant interest website will include information on the study, eligibility, incentives, privacy, and how to join. Adults who are interested in the study will complete a brief online interest screener which will be available on the study website. The screener is used to determine initial eligibility in the study.

## 2.5 Interventions Overview

*Δ*SIPsmarter and the PE websites both include the provision of scientifically accurate and evidence-based SSB behavioral content as well as the ability to track SSB and weight diaries. All content within *Δ*SIPsmarter and the PE website is written using clear communication strategies and at or below an 8th grade reading level. The digital interventions are built on a proprietary Research Infrastructure Containing ehealth (RICE) platform and the website structure is modeled off an evidenced-based behavioral intervention for adults with insomnia.<sup>65,66</sup>

**2.5.1 Participant Education (PE) website**—The PE website control condition includes relevant content from the *Δ*SIPsmarter intervention. The website provides users with self-guided information that is presented all at once, allowing the user to complete the website at their own pace. The PE website is organized by pages and includes 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 about SSB advertisements. Printable forms are available in order to assist participants in tracking their SSB and weight; however, this data is not entered or stored on the website. Also, PE participants do not set SSB or weight goals or have personalized feedback.

**2.5.2 *Δ*SIPsmarter**—*Δ*SIPsmarter is a highly interactive, structured, and self-guided program. It is comprised of six Internet-based Cores and a recurring maintenance Core, personalized action planning, and behavioral tracking. The Cores include an interactive and media rich format of text, audio, graphics, animation, and video. The Cores utilize stories and testimonials modeled from past *SIPsmarter* participants in the region to make the content more relevant. Each of the six Cores are be metered out to the user, with a new Core unlocked and available seven days after completion of the previous Core. Anticipated time to complete the program is less than one hour each week. Because *Δ*SIPsmarter Cores are delivered online, users have convenient access to the program from anywhere the Internet is available. And, while it is not a native mobile application, it is usable through a smartphone browser, making it functional on a mobile device. Automated email reminders alert users when new Cores are available in order to promote Core completion. Users receive up to two automated email reminders to complete the Cores.

As shown in Figure 1, *Δ*SIPsmarter integrates numerous skill-building and evidence-based strategies across the Cores: behavior change techniques (e.g., goal setting, action planning, feedback and monitoring, comparison of outcomes)<sup>67</sup> and health literacy techniques (e.g.,



clear communication, message repetition, visual learning, experiential learning, building health numeracy skills, media message critiques).<sup>57,68–71</sup> As guided by the TPB, *iSIPsmarter* targets participants' SSB-related attitudes, subjective norms, and perceived behavioral control to improve behavioral intentions and SSB behaviors. A few TPB application examples include: 1) attitudes - participants examine the health and financial implication of their SSB behaviors, 2) subjective norms - participants consider the influence of family and friends on their SSB behaviors, 3) perceived behavioral control - participants are encouraged to work on two self-selected SSB barriers per week and to achieve small weekly goals (i.e., decrease SSB by 20–50% per week), and 4) behavioral intentions - participants set week goals and develop a personalized action plan.

Each *iSIPsmarter* Core includes behavioral content, personalized action planning pertaining to both SSB behaviors and weight, and personalized follow-up and feedback. Participants complete personalized action planning throughout *iSIPsmarter*, starting with Core 2. Action planning is specifically designed to provide behavioral support to users and help troubleshoot behavioral barriers. All participants are encouraged to work towards the recommendation of drinking less than 8 ounces of SSB per day. However, participants set their own program and weekly SSB goals based on their current SSB intake. While participants are encouraged to set a weekly goal of a 20–50% SSB ounce decrease from their previous week's average (until they meet recommendations), they are allowed to choose a goal outside of the recommended range. Participants have the option of setting personal goals to 'maintain weight' or 'lose weight', and Core content (e.g., personalized recommendations for calories and added sugar) is customized to their goals.

SSB tracking is a key component of *iSIPsmarter*. The program will provide daily prompts for users to report SSB intake (in ounces) from the previous day. Participants have the option of receiving daily prompts by email only or by both email and SMS; participants do not have to opt into daily SMS prompts for tracking. The email directs participants to enter their ounces by logging into the website. The SMS prompts users to respond with their number of SSB ounces and an encouraging and/or confirmation SMS will be sent back. When users log into the website, personalized SSB feedback will be provided. Further, users are provided a cellular enabled ©BodyTrace scale along with encouragement via e-mail, SMS, and Dashboard content to weigh daily to track progress towards weight loss or maintenance goals. Weigh-ins from the ©BodyTrace scale are synced with *iSIPsmarter*. For participants who are unable to sync their scales, they may also log into the website and enter their weight on the Dashboard. Similar to SSB, personalized weight feedback is provided when users log into the website.

**2.5.2.1 *iSIPsmarter* stepped care engagement strategy:** Engagement and retention issues are prevalent in technology-based interventions,<sup>72–75</sup> including those pertaining to lifestyle habits and weight.<sup>30</sup> Therefore, *iSIPsmarter* uses a human-supported stepped care engagement strategy to provide support and encouragement to complete each of the six Cores. The timing of the delivery of stepped care coincides with the Core timing and participants will be identified as either adherent or non-adherent in completing their assigned Core. When participants complete their assigned Core, no additional support will be provided, and the participant will continue to the next Core. When participants fail to

complete a Core, they will receive a human-supported text. The text message includes: 1) content stating that the user did not complete the 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. If participants have not completed the Core by the following week, they will be stepped-up to receive a phone call. Research staff will call the participant to provide encouragement, technical assistance, and strategies to promote task completion. When possible, reasons for non-adherence will be documented. If the participant still does not complete the Core, they will be considered non-adherent. To encourage reengagement, non-adherent participants will continue to weekly receive automated email reminders to complete Cores and daily prompt reminders to track.

**2.5.3 Interventions Summary**—Although there is overlap between groups, *ASIPsmarter* is a multi-component intervention that differs from standard PE 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. Also, participants randomized to the *ASIPsmarter* condition will complete behavioral tracking using SMS and online tools whereas the PE website provides printable forms. Finally, both interventions are fully digital, with the exception of *ASIPsmarter* human-supported stepped care engagement strategies to promote Core completion. The PE website was chosen as the control condition to provide evidence-based SSB behavioral content and some potential benefit to all eligible Appalachian adults who join the trial, while also maximizing web program differentiation to appropriately test our hypotheses.

## 2.6 Data collection and measures

Data collection to assess efficacy of the intervention will be managed by research team members. An overview of the measures used at each of the four time points are illustrated in Table 1.

**2.6.1. Efficacy and maintenance measures**—Before enrollment, the online interest screener will collect information on potential participant demographics and SSB intake. Two 24-hour telephone dietary recalls and an online questionnaire are administered at baseline. At the initial telephone call, participants who consent to join the study are asked to complete their first telephone 24-hour dietary recall. After the first recall, participants will be emailed a link to complete the online baseline survey and mailed a cellular-enabled ©BodyTrace scale with instructions. After the baseline survey is complete, research staff will call participants for a second dietary recall and then participants will be randomized into the *ASIPsmarter* or PE conditions. Participants will be emailed a unique link to set their password in order to log on and securely access their assigned program.

The 9 week post-intervention assessment time point allows participants a reasonable amount of time to complete all six Cores. At the start of week 9, regardless of intervention progress or intervention group, participants will be instructed to complete the online



post-assessment battery, weigh-in, and two 24-hour dietary recalls. After completing the assessments, individuals will have continued access to their assigned online program. The same assessment procedures will be followed again at the 6- and 12-months post-intervention maintenance assessments.

**2.6.2. Reach and engagement measures**—Participation reach will be determined by dividing the total number of enrolled participants by the total number eligible to enroll. The process engagement variables are automatically collected and stored in the database (e.g., number of logins, time/date of use, average session length, content viewed, completion and mode of SSB and weight tracking). The Internet Intervention Evaluation Measure<sup>94,95</sup> and Internet Intervention Adherence Measure<sup>94,96</sup> will be adapted and administered at week 9 post assessment to examine users' experiences with and perceived efficacy of the programs.

**2.6.3. Adoption and implementation measures**—Process data include meeting minute notes from the Leadership Council and process notes on recruitment strategies. Leadership Council members will be interviewed at the conclusion of active recruitment in order to identify strategies for sustainability and improve recruitment and enrollment protocols. To determine costs, research staff use a real-time tracking process to document time spent for the stepped care components, including texts and phone calls.<sup>97</sup>

**2.6.4. Power calculation**—The *Δ*SIPsmarter power calculation is based on the existing *SIPsmarter* effectiveness trial that found an effect size of 0.55 for the primary 6-month SSB reduction. It is expected that *Δ*SIPsmarter will also lead to significant improvements given the added enhancements of stepped care, daily SSB tracking, and the shorter time to follow-up assessment. However, 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), a smaller *Δ*SIPsmarter ES may be found. Based on these considerations, the current study is powered to detect a reasonably conservative effect size 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).

## 2.7 Data analysis

The efficacy analysis will be on the individual level and will address potential self-selection occurrence across program participation, engagement, and stepped care provision. 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 analyses 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.

**2.7.1 Efficacy and maintenance**—A general linear mixed model (GLMM) will be used 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.<sup>98–101</sup> We will also model attrition specifically in GLMM and estimate it through full-information maximum likelihood as one approach for conducting intention-to-treat analysis.

**2.7.2. Reach and engagement**—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, we will follow the multiple testing correction procedures in mixed models proposed in Joo et al.<sup>102</sup> and examine the potential efficiency gained through hierarchical Bayesian procedure in Gelman et al.<sup>103</sup>

Reach will be analyzed following recommendations of Glasgow et al.<sup>104</sup> Participation rate will be determined by dividing the total number of enrolled participants by the total number of eligible inquiries. 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.<sup>105</sup> 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).

To explore how engagement influences efficacy outcomes, the GLMM will be expanded to include engagement variables (e.g., number of log-ins/Core completion). Furthermore, the GLMM will be modified to explore potential mediating effects of variables (e.g., behavioral theory constructs) on engagement and efficacy outcomes. The procedure for testing mediation will closely follow suggestions of Zhao et al.<sup>106</sup> and Imai et al.<sup>107</sup>

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, potential stratification, and targeted power calculation.

**2.7.3. Adoption and implementation**—Data sources will include meeting artifacts (e.g., agendas, minutes, memos) and key informant interview transcripts. Aided by NVivo software, a hybrid deductive (i.e., utilizing RE-AIM<sup>39,40</sup> and Consolidated Framework for Implementation Research<sup>108</sup> constructs as coding categories) and inductive (i.e., identifying specific emergent codes within each category) qualitative analysis approach will be used.<sup>109–112</sup> Coding will occur in pairs, and 80% agreement will be sought. In an iterative process, meaning units will be reduced into emerging themes then organized back to the guiding frameworks. To facilitate a deeper understanding of our processes, organizational-

level data will be triangulated to check for consistency between and within sources.<sup>111,113</sup> When feasible, efforts will be made to draw out distinctions by organizational site.

Implementation costs will be assessed as the incremental cost of delivering *ASIPsmarter* with stepped care relative to the PE website. Since the primary cost additions are due to the added stepped care component of *ASIPsmarter*, 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.<sup>97</sup> 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.<sup>114</sup> This will provide necessary parameters for a future full-scale effectiveness trial that assess cost-effectiveness of *ASIPsmarter* in rural systems.

### 3. Discussion

Despite the pervasive SSB problem in Appalachia and nationally, as well as clear obesity and health consequences, solutions surrounding excessive consumption of SSB intake remain a critical public health challenge. While emerging evidence from enacted policy-level SSB taxation strategies are promising,<sup>115–117</sup> SSB taxation also remains highly debated and resisted.<sup>118–121</sup> Likewise, culturally engrained SSB behaviors will not be solved solely from a top-down, macro-level approach. Our RCT is the first known study to test the efficacy and reach of a behavioral and technology-based SSB reduction intervention in rural communities, while also seeking to understand the context for potential future organizational-level adoption and implementation.

Importantly, our study builds on an existing evidence-based intervention and utilizes an individual-level behavioral, health literacy, and technology-based approach. In distinction from the other SSB studies that have been found ineffective among adults,<sup>37</sup> we attribute *SIPsmarter*'s effectiveness to the underlying conceptual and theoretical approach, use of evidence-based behavioral change techniques, as well as our targeted strategy focused exclusively on SSB. Each of these attributes have been carried forward in the adaption process and user-centered development of *ASIPsmarter*. Despite strong intervention evidence in both the health literacy and behavioral medicine fields, there remains a dearth of lifestyle interventions guided, implemented, and evaluated within both behavioral change theory and a health literacy framework<sup>49,50,54,55,122</sup> (e.g., only 3 of 74 recently reviewed community-based health literacy studies used behavior change theory).<sup>122</sup> *ASIPsmarter*'s comprehensive integration of evidence from both disciplines, including behavioral change and skill-build techniques, is a unique approach.

The shrinking digital divide among rural communities presents an opportunity for the use of technology-based interventions in rural areas, as a means to overcome barriers

(e.g., transportation, small population sizes) that have limited evidence-based lifestyle interventions in rural areas. However, to fully capitalize on this opportunity, it is important to explore how rural residents engage with the technology. The integrated SMS tracking of daily SSB behaviors and remote weight tracking are additional innovative iSIPsmarter components designed to further augment real-time personalization of Internet-based Cores. There is a clear lack of data in the literature on these components in rural regions, especially in Appalachia. Furthermore, engagement and retention issues are prevalent in technology-based interventions.<sup>30,72–75</sup> However, the literature on engagement in digital behavior change interventions is complex and lacks clear and consistent solutions.<sup>72–75</sup> Our stepped care strategies will provide important data on promoting engagement in technology-based behavioral interventions, in rural and lower SES regions.

#### 4. Limitations

Several limitations of this study should be noted. First, the targeted rural Appalachia region and exclusion of non-English speakers may limit the generalizability of findings. Second, given this study is an Internet-based intervention, the inclusion criterion limits the sample to those with access to technology. Third, the primary outcome is self-report SSB, which may suffer from reporting errors. However, our findings are based on comparative efficacy (i.e., comparing iSIPsmarter and PE). Therefore, as long as the reporting errors are randomly distributed across the two groups, the comparative efficacy findings will not be subject to this limitation. Despite these limitations, our RCT targets a high-need rural Appalachia region with documented excessive SSB intake, is adapted from an evidence-based intervention, applies innovative technology and a stepped care approach to optimize participant engagement, uses state-of-the art dietary assessment approaches to evaluate outcomes, and is being implemented with guidance from four local health and community-based service organizations to identify sustainable recruitment and implement strategies.

#### 5. Conclusions

Clearly missing from the literature are scalable and effective SSB reduction strategies that can reach large numbers of low SES, rural residents with the highest consumption rates. Moreover, the prevention and treatment of chronic diseases are typically most successful when paired with other multi-level strategies and systems-oriented approaches.<sup>123,124</sup> If iSIPsmarter is found to be efficacious, and reach and engagement shows strong potential, a future goal will be to integrate this intervention within healthcare systems and with higher macro-level approaches (e.g., policies to limit access, taxation). Given the magnitude of excessive SSB consumption and consequences, this future work would be applicable in rural Appalachia and beyond.

#### Funding sources

This study was funded by the National Institutes of Health (NIH), National Institute on Minority Health and Health Disparities [R01MD015033]. NIH was not involved in the design of this study or writing of this manuscript.

## Abbreviations:

<b>SSB</b>	sugar-sweetened beverages
<b>SMS</b>	short service message
<b>RE-AIM</b>	reach, adoption, effectiveness, implementation, and maintenance
<b>TPB</b>	Theory of Planned Behavior
<b>RCT</b>	randomized controlled trial
<b>PE</b>	participant education
<b>GLMM</b>	general linear mixed model

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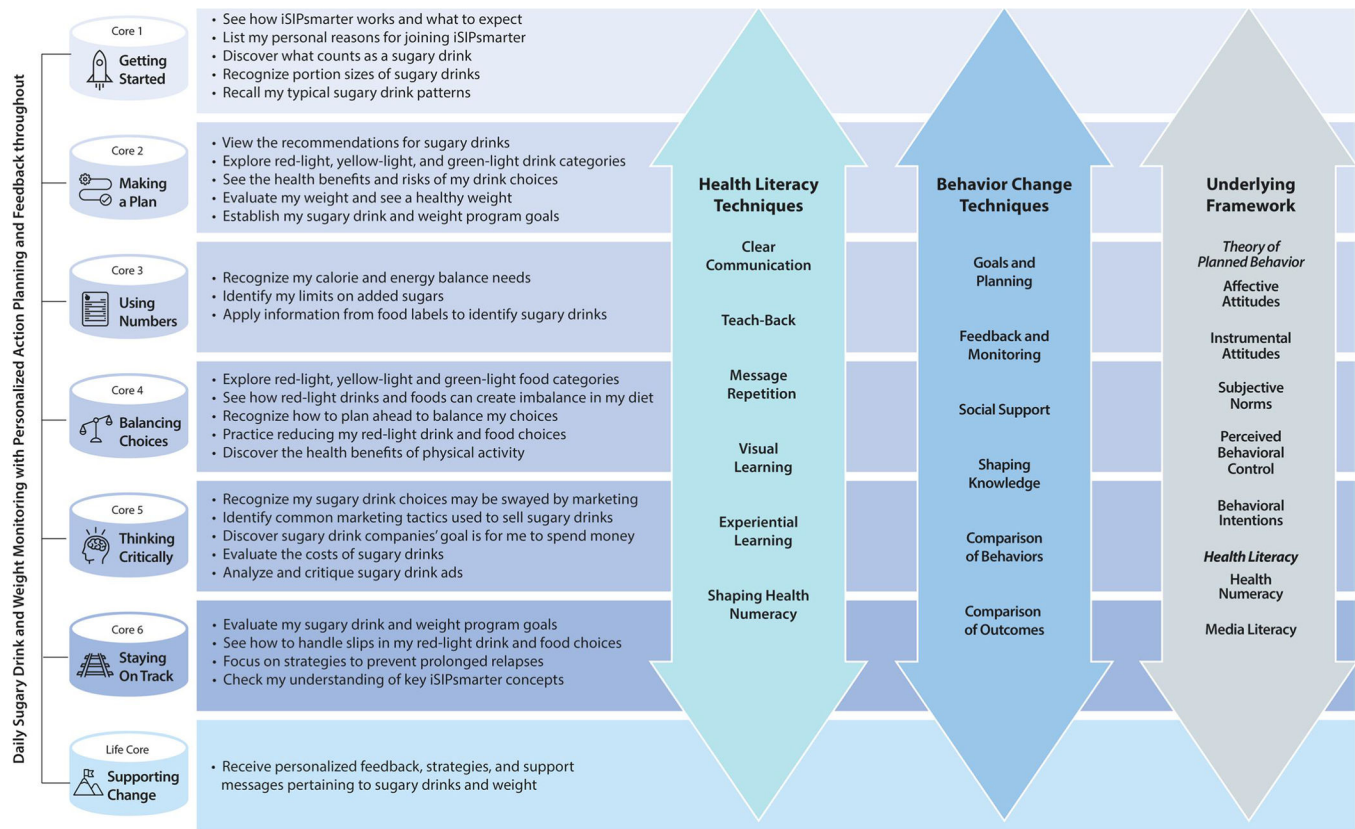
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**Figure 1.**  
iSIPsmarter Overview

**Table 1.**

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, <sup>76-78</sup> 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) <sup>62-64</sup>
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 <sup>79</sup>
Weight	X	X	X	X	SA1	Assessed via study provided cellular/WIFI enabled in-home digital scale
Height	X				SA1	Self-reported
QOL	X	X	X	X	SA1	Assessed using 4-item Centers for Disease Control Healthy Days core questions <sup>80</sup>
SSB TPB	X	X	X	X	SA1	SSB-related TPB with 4 subscales: attitudes, subjective norms, perceived behavioral control, and behavioral intentions <sup>13</sup>
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 <sup>81</sup>
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 <sup>82</sup>
eHealth Literacy	X	X	X	X		Assessed using the eHealth Literacy Scale (eHEALS) <sup>83</sup>
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) <sup>84-86</sup>
Other Health Habits	X	X	X	X	SA1	Weighing frequency, weight perceptions, <sup>87</sup> and weight and SSB avoidance adapted from the Information Avoidance Scale <sup>88,89</sup> ; Physical activity using Stanford Leisure-Time Activity Categorical Item (L-Cat) <sup>90-92</sup> ; Sleep quality using the Pittsburgh Sleep Quality Index (PSQI) <sup>93</sup> ; Tobacco history <sup>87</sup>
Health History, Medication, & Health care access	X	X	X	X	SA1	History of chronic disease and medication use; 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 <sup>87</sup>

Pre = baseline (pre-intervention); Post = week 9 (post-intervention); 6 M = 6-months post-intervention; 18 M = 18-months post-intervention

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