Published in final edited form as:

Contemp Clin Trials. 2014 January ; 37(1): 43–57. doi:10.1016/j.cct.2013.11.003.

Talking Health, A pragmatic randomized-controlled health literacy trial targeting sugar-sweetened beverage consumption among adults: Rationale, design & methods

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Abstract

High consumption of sugar-sweetened beverages (SSB) contributes to a wide range of poor health outcomes. Further, few US adults drink less than the recommended 8 ounces per day; and individuals with low socioeconomic, low health literacy status, and in rural areas are even less likely to meet recommendations. Unfortunately, few SSB behavioral interventions exist targeting adults, and none focus on low health literacy in rural areas. Talking Health, a type 1 effectiveness-implementation hybrid trial targeting adults in rural southwest Virginia, was developed using the RE-AIM planning and evaluation framework (reach, effectiveness, adoption, implementation, maintenance). The primary aim of this pragmatic randomized-controlled trial was to determine the effectiveness of a scalable 6-month intervention aimed at decreasing SSB consumption (SIPsmartER) when compared to a matched contact physical activity promotion control group (MoveMore). SIPsmartER was developed based upon the Theory of Planned Behavior and uses health literacy strategies to improve comprehension of the intervention content among participants. MoveMore is based on a research-tested intervention that was adapted to address all theory of planned behavior constructs and health literacy principles. Secondary aims include additional health outcomes (e.g., physical activity, weight) and reach, adoption, implementation, and maintenance indicators. This paper highlights the opportunities and considerations for developing health behavior trials that aim to determine intervention effectiveness, provide all study participants an opportunity to benefit from research participation, and collect key

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information on reach and the potential for organizational adoption, implementation, and maintenance with the longer-term goal of speeding translation into practice settings.

Keywords

beverages; health literacy; research design; behavioral research; randomized controlled trial; rural population

1. Introduction

Sugar-sweetened beverages (SSB) currently contribute approximately 7% of total energy intake for United States adults [1]. Although sugar-sweetened beverages (SSB) can be defined differently, one of the most widely accepted definition includes all carbonated beverages with added sugar (e.g. soda), fruit drinks with added sugar, sports drinks, and other drinks such as sweet tea. Despite strong scientific data indicating associations among SSB and numerous health issues such as obesity, diabetes, cardiovascular disease, caries and oral health [2–6], there are few known behavioral trials that have specifically targeted SSB reduction among adults [7]. Furthermore, epidemiological data indicate low income and low educated individuals are at highest risk from excessive SSB consumption [8–10]. Yet when compared to other socioeconomic covariates, one study suggests that low health literacy status is the strongest predictor of drinking higher amounts of SSB [11]. Furthermore, when compared to observational evidence on the consequences of SSB consumption, evidence from randomized controlled trials and experimental conditions targeting SSB behaviors is limited, especially among adults [5, 12–15].

Given that health literacy status has consistently been linked with poorer health outcomes [16, 17], providing targeted intervention strategies that address health literacy may be an advantageous strategy to reduce SSB consumption. While observational and cross-sectional studies currently comprise the majority of the health literacy research, experimental skill-based approaches to address health literacy have started to emerge [17, 18]. However, these approaches have achieved mixed results, partly to a lack of focus on underlying processes of behavior change. Indeed, there is a dearth of longitudinal and experimental research studies that integrate concepts in health literacy with health behavior theory to explain the processes and casual pathways through which health literacy affects health [19, 20].

In addition to the need for health literacy frameworks that integrate behavioral processes with skill-based health literacy processes, in recent years there has been increased emphasis on the need to speed the translation of evidence-based practices into real world settings [21], the need for hybrid type research designs that simultaneously address both effectiveness and implementation in typical community settings [22], and the call for more pragmatic trials [23]. Similarly, a recent systematic review concluded that the current research on health promotion for participants with low health literacy provides insufficient information to conclude if they could attract the target population, be generalized outside of clinical setting, or achieve an effect that is sustainable [18]. Evidenced by this review and similar to other health-related fields, the health literacy field could benefit from enhanced designs with the potential to inform translation into practice.

To collectively address these opportunities, this study is guided by the RE-AIM planning and evaluative framework with the goal to develop and test interventions that have the potential to reach large proportion of the target population, effectively reduce SSB consumption, and be adopted, implemented, and maintained at a reasonable cost. This approach balances internal and external validity and can heighten the likelihood for

translation into practice [24]. In addition, the intervention content development was guided by an integrated health literacy and Theory of Planned Behavior (TPB) approach. Specifically, we hypothesize that health literacy strategies that focus on clear communication techniques, numeracy, media literacy, and teach-back methods [25–28] may influence SSB consumption directly or through changes in TPB constructs of attitude, subjective norms, perceived behavioral control, and ultimately behavioral intentions [29].

2. Study Overview & Objectives

Talking Health is a type 1 effectiveness-implementation hybrid randomized-controlled trial targeting community residents from rural southwest Virginia. In brief, a type 1 hybrid trial is one in which the primary objectives are in testing intervention effectiveness and secondary objectives are aimed at better understanding the context for implementation [22]. In addition, we took a pragmatic approach to developing a comparison condition that was matched for contact and structure, but focused on a health behavior independent of SSB consumption—physical activity. In this way all participants, even those within the comparison condition, have an opportunity to benefit from participation in the trial [23].

As such, the primary objective of this study is to determine the effectiveness of a 6-month intervention aimed at decreasing SSB consumption (SIP_{smart}ER) when compared to a matched contact comparison group targeting physical activity behaviors (MoveMore). The study is also designed to determine the intervention effectiveness in making changes in body weight, quality of life, blood pressure, glucose, and lipids. Other secondary objectives align with our RE-AIM, TPB, and health literacy approach and are intended to provide context for future implementation efforts. These include to: 1) determine the reach and representativeness, adoption feasibility, and degree to which the intervention was implemented as intended (and associated costs), and 2) explore causal pathways through which changes in nutrition literacy and nutrition-related media literacy, SSB attitudes, subjective norms, and perceived behavioral control influence behavioral intentions and SSB consumption, and 3) determine the extent to which changes in SSB consumption may be directly mediated by changes in nutrition numeracy and nutrition-related media literacy. The pragmatic approach and the goal of also providing and evaluating health benefits of the comparison participants (MoveMore), allow for a tertiary aim to determine the effectiveness of the comparison condition in the promotion of physical activity when compared to participants in the SSB condition (SIP_{smart}ER). Finally, because maintenance of behavior change has been a challenge across intervention trials [30, 31], an exploratory aim of the study is to determine the effects of a 12-month extended care maintenance intervention across conditions.

3. Theoretical and conceptual framework

One of the mostly widely accepted definition of health literacy is the “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions”[32]. While our conceptualization of health literacy includes numeracy, media literacy, oral literacy, print literacy, and cultural knowledge; our intervention and evaluation procedures will specifically focus on health numeracy and media literacy. Although defined in a variety of different ways [33], health numeracy can be summarized as “the effective use of quantitative information to guide health behavior and make health decisions.”[33–35] Media literacy can be generally defined as individuals’ ability to access, analyze, and evaluate media messages[28]. It often combines motivational components like skill-based training to prompt individuals to advocate for their own health[36].

Recent reviews on the relationships between health literacy and health outcomes illustrated the need for greater clarity in the conceptualization of health literacy, including theory-based approaches and the acknowledgement of sociocultural and psychological factors, as well as more experimental and longitudinal research to allow deeper understanding of the processes and casual pathways through which health literacy affects health [19, 20]. To address these needs we apply the TPB to understand pathways through which social cognitive and health literacy processes are related to changes in SSB consumption. The TPB is one of the most well-studied and valuable theories for understanding health behaviors and is centered on the idea that a person's behavior is codetermined by behavioral intention and perceived behavioral control. The antecedents to behavioral intentions include three independent constructs: attitudes, subjective norms, and perceived behavioral control [29, 37–39].

While there has been limited research focusing on health literacy and TPB, we propose that an intervention that improves the accessibility and understanding of the outcomes of SSB consumption and provides new skills to support decision-making (i.e., improved numeracy) would result in improved attitudes and control beliefs. Further, improvements in media literacy could influence normative beliefs and attitudes for SSB by helping participants identify methods that the media may use to distort SSB norms. Our conceptual framework (See Figure 1) addresses numerous limitations established in the health literacy literature to test the interdependence of various psychosocial, skill-based (health literacy, numeracy media literacy), and demographic factors to understand causal pathways and complex relationships impacting SSB consumption.

4. Study design

4.1. General design and randomization

This randomized-controlled community-based trial includes data collection time points at baseline, 6 months and 12 months post intervention (i.e., 18 months post baseline)(Figure 2). At baseline, eligible participants are randomized to the SIP_{smart}ER or MoveMore intervention conditions. To control for the influence of attention and intervention modality, both conditions were six-months in duration and matched in contact (Table 1). An equal number of concealed envelopes were prepared indicating SIP_{smart}ER or MoveMore conditions. To promote transparency in randomization, each participant is asked to draw from the envelope at the conclusion of baseline enrollment to indicate the randomized condition. To address the exploratory aim, at conclusion of the six-month intervention, participants are further randomized into a 12-month extended care maintenance condition.

All study procedures have been approved by the Virginia Tech Institutional Review Board. Prior to enrollment, participants were made aware of random allocation process to the SipSmartER or MoveMore groups and provided their written informed consent to participate in the study. To compensate their time to complete the data assessments, gift cards in the amount of \$25, \$50, and \$75 are provided at the baseline, six-month, and 18-month assessments, respectively.

4.2. Study population

This trial targets residents in a 14-county rural region in southwest Virginia, including Lee, Wise, Dickenson, Washington, Smyth, Tazewell, Bland, Giles, Grayson, Carol, Patrick, Wythe, Pulaski and Montgomery counties. According to US Census Bureau data, this region includes 95% Caucasian, 58% with high school education, and 18% living below the federal poverty level. There are notable socioeconomic and literacy proficiency disparities across these counties, as compared to both the state of Virginia and national averages [40,

41]. Furthermore, on the 9-point Rural-Urban Continuum Codes (1=urban, 9=completely rural), the targeted counties have an average rurality status of 6.1 (SD=2.5)(minimum=2, maximum=9) [42].

4.3. Eligibility criteria

Inclusion criteria included English-speaking adults 18 years of age, who consume 200 SSB kcals/day, self-report no contraindications for physical activity, and have regular access to a telephone. To minimize potential confounds, only one member per household is eligible to enroll and individuals cannot be concurrently enrolled in a Cooperative Extension program because these programs focus on improving nutrition. The eligibility screening consists of 7 items from the Beverage Intake Questionnaire (BEVQ-15) [43], 3 subjective health literacy questions [44–46], the 1-item Stanford Leisure-Time Activity Categorical Item (L-CAT) physical activity question [47], 6 questions related to contraindications for physical activity (as adapted from the Physical Activity Readiness Questionnaire)[48], and 11 demographic questions (Table 2). Depending on the need and preference of the individual, the screening questionnaire is either self- or interviewer-administered. Individuals with reporting possible risks to physical activity are required to obtain physician approval prior to enrollment. At enrollment, participants with measured blood pressure of 180/110 are required to get physician approval before they could be randomized and officially enrolled.

4.4. Recruitment

Although not an inclusion criteria, a primary intent of this trial was to target low socioeconomic individuals and those with limited health literacy. As such, a variety of recruitment strategies are planned and customized for each county. When possible, the first recruitment approach is to hire and train Extension Program Assistants and/or qualified community member who lived in the targeted county to assist with recruitment activities. From the RE-AIM perspective, this approach was taken to heighten the likelihood that the study would reach a broad group of eligible participants from lower socioeconomic level that are reflective of the Cooperative Extension clientele [49]. After completing Protection of Human Research Training, these individuals are trained, monitored, and compensated to help recruit and screen participants from their respective communities. In addition, trained research assistants recruit participants from a variety of organizations that serve low resource populations, including but not limited to, Free Health Clinics, Departments of Social Services, Head Start and other daycares, food pantries, and grocery stores. Recruitment strategies also include flyers posted in highly visible community venues, such as grocery and other retail stores. Furthermore, some combinations of newspaper advertisement and/or recruitment postcards mailed to residents' homes are used in each county. When using residential mailings, an existing Cooperative Extension database is used and/or a mail source company is hired to identify and target low socioeconomic neighborhoods. To adequately track and evaluate recruitment strategies, a daily recruitment log is maintained by research staff, costs are being tracked across eight categories, and upon enrollment participants are being asked where they learned about the study.

Given the random allocation to study arm, our recruitment messages focused generally on health, not specifically on SSB or physical activity behaviors. For example the three main messages included in printed recruitment materials included: 1) Be part of a research study to learn more about your health, 2) You are just one call away from a healthier you, and 3) Program includes: free health screenings, group classes and supportive phone calls.

4.5. Retention strategies

Once enrolled in the study, a baseline enrollment appointment is made and information related to the study procedures as well as a study calendar of important dates are provided to each of the participants. Following this, four main retention strategies are used including: 1) participants receive a reminder post-card one week prior, and a reminder phone call 1–2 days prior for each in-person event (i.e., data collection, small group sessions); 2) for participants that miss a small group class, a missed class packet of information is mailed to them 1–2 days after the missed class, and a research assistant calls to review the material via telephone, answers questions, and completes the personal action plan; 3) for participants that miss 2 or more consecutive intervention sessions at any time during the study, research assistants attempt to encourage continued engagement via the telephone; and 4) in the event that the participants cannot be reached via persistent telephone efforts or for telephone numbers that had been disconnected, a form letter is mailed at two different study points encouraging participation and requesting participants to confirm their address, telephone number, and alternate contact information.

5. Intervention

5.1. Intervention development

Intervention planning was based on the RE-AIM framework which included consideration of the type of intervention structure (e.g., avoid barriers associated with intervention-based travel and scheduling), delivery channel (e.g., how best to get the intervention content to the participants), and program design (e.g., involve underlying behavioral change theory and sensitive to participants' learning needs), and content (e.g., based on evidence) that would be appealing to the target population and lead to changes in SSB consumption robustly across subgroups within the target population. Planning also included addressing future issues related to the adoptability (e.g., keeping start-up costs low) and sustained implementation of the intervention (e.g., making fidelity to the intervention easy to achieve) within community organizations.

From this perspective, several formative research phases guided development of the SIP_{smart}ER condition, including the small group class sessions and the barriers and strategies programmed into the interactive voice response (IVR) telephone calls. The first was a cross-sectional study in the targeted population, which confirmed high consumption of SSB and utility of the TPB to explain SSB consumption[50]. The amount of variability ($R^2=0.38$) explained by the primary constructs of the TPB indicates that behavioral intentions, perceived behavioral control, subjective norms, and attitudes provide a good explanation for SSB intake. Based on a similar number of predictor variables, the amount of variance explained by our TPB-SSB model was stronger than the two eating behaviors papers and 35 health behavior papers reviewed by Godin, which reveal average R^2 of 0.25 and 0.34, respectively [38]. The second study was qualitative and included eight focus groups with 58 participants from the targeted population to explore cultural perspectives and in-depth attitudes, subjective norms, and perceived behavioral control for beverages (i.e. SSB, artificially-sweetened beverages, water) [51]. Across all the beverage categories and theory-grounded questions, the most notable themes that emerged included taste, availability/convenience, habit/addiction, and cost. Additionally, health consequences, water quality, and normative beliefs among peers and doctors emerged as important factors influencing SSB behaviors.

The comparison condition, MoveMore, was adapted from a previous research tested group-based physical activity (PA) intervention delivered in clinical practice settings that included 2, 2-hour sessions and a telephone follow-up, using strategies that have been shown to

improve attitudes, subjective norms, and perceived behavioral control [52–54]. Subsequent to initial development of SIP^{smart}ER and adaptations of MoveMore, a 5-week randomized control pilot test was used to evaluate participant feedback on intervention content and structure as well as understand the potential reach and preliminary effect size of the two comparison conditions [55].

A central goal in our approach is to develop a culturally sensitive intervention and to achieve a balance between health literacy skills/ability and demands/complexity of the targeted behavior [56]. Across both conditions, the approach is to minimize the complexity of making a behavior change, to avoid promoting an overwhelming degree of behavioral change at a given time, and to encourage repetition of messages for the targeted low health literate population.

5.2. Intervention overview

To address the RE-AIM issues described above, there was general agreement to deliver some of the intervention through some small class sessions to allow for a high level of interaction between the instructor and participants. There was also agreement to use automated IVR calls that could be programmed to reinforce class information, deliver brief theory-based messages, and guide participants through tracking of SSBs and action planning to promote reduced intake.

The final intervention structures, informed through the preliminary work, included 3 small-group classes, 1 live teach-back call, and 11 IVR calls. Table 1 provides an overview of the weekly structure, theoretical constructs and key learning objectives and content for each condition. The initial pilot testing demonstrated the need to enhance the structure of the intervention to include a live teach-back call to ensure that participants were comfortable with tracking their behaviors and engagement in the intervention [55].

Both of the SIP^{smart}ER and MoveMore conditions are guided by the TPB and health literacy concepts and designed for broad dissemination (Table 1). SIP^{smart}ER focuses exclusively on decreasing SSB consumption, with the primary goal of achieving the SSB recommendation of less than 8 ounces per day [57]. To sufficiently target SSB reduction, participants are educated on all beverage categories. A green light, yellow light, red light beverage strategy was developed to assist participants in making informed beverage choices. MoveMore concentrates exclusively on improving physical activity behaviors, with the primary goal of achieving 150 minutes of moderate-intensity aerobic activity and muscle-strengthening activities on two or more days per week[58].

5.2.1. Small group classes—Each of the 3 small group classes are 90–120 minutes in duration, with a class goal of approximately 6–10 participants. Clear communication techniques include hands-on demonstrations, verbal presentations, pictorial information, and materials with simplified language (i.e., <8th grade, when possible). Both conditions promote critical thinking skills to analyze and evaluate media messages[59]. That is, the SIP^{smart}ER condition evaluates SSB advertisements and the MoveMore condition evaluates PA advertisements (e.g. exercise gadgets). SIP^{smart}ER also incorporates basic, computational, and analytical nutrition numeracy skills [25].

5.2.2. Personalized action planning and behavior tracking—In class one, each participant completes a personal action plan that includes motivational factors to change behaviors, behavioral goals, as well as barriers and strategies for achieving the goals[60]. Simple behavioral diaries are provided and participants are encouraged to complete diaries each day, as this serves as the basis of the information they report to the IVR (See Figures 3a

and 3b). Reevaluation of the participants' personalized action plan is promoted at each subsequent class and IVR contact.

5.2.3. Teach back call—One week following the first class but prior to starting the IVR calls, each participant receives a live teach back telephone call. To promote comprehension of class one learning objectives, participants are asked to recall key concepts from the first class. For example, *SIPsmartER* participants are asked to recall the recommendation for ounces of SSB per day, and *MoveMore* participants are asked to recall the recommendations for cardio and strength training. To assess and promote numeracy skills, participants are also asked to explain how they track their behaviors and how they calculate weekly averages. When concepts are recalled incorrectly, the answers are provided and discussed with participants. Participants are given two additional opportunities to teach back the key concepts within the same call.

5.2.4. Interactive voice response—Participants receive 11 IVR calls, weekly for the first three weeks and then bi-weekly for the remainder of the intervention. Each of the calls was designed to reinforce key intervention messages, provide new content, and lead participants through a personal action planning procedure [61–63]. The IVR calls begin with participants entering their previous weeks behavior (i.e., *SIPsmartER* = average daily ounces of SSB; *MoveMore* = average daily minutes of PA). Based on their progress, participants are routed into one of three IVR paths: 1) meeting or exceeding goals, 2) not meeting goals, but some progress, or 3) no progress. The feedback loop and behavioral reinforcement strategies are customized for each path and intended to bolster perceptions of behavioral control and increase behavioral intentions. The action planning process uses participant reported behaviors from the current and previous call to assist the participants to set a new realistic goal for the upcoming week(s). As participants achieve the recommended level of a given behavior (i.e., 8 ounces of SSB or 150 minutes of physical activity) the calls facilitate maintenance goals. All participants are provided with the opportunity to identify new barriers that may be encountered and to change strategies used to overcome ongoing or new barriers. IVR calls 3–11 conclude with supportive messages based on specific TPB constructs, health literacy concepts, or upcoming small group classes (Table 1). Length of the IVR calls varies somewhat in duration based on the participants' need to identify new barriers and strategies with an estimated completion time range of 5–10 minutes per call.

5.3. Extended care maintenance conditions

Upon conclusion of the 6-month intervention, and framed as an exploratory aim, participants are further randomized into a 12-month extended care maintenance condition (Figure 2). Within each condition, the call frequency is standardized to one call per month. The Control-IVR is a simple reminder that participants are still enrolled in the study, and includes an entertaining science fact that is non-specific to either SSB or PA behaviors. The Behavior-IVR condition is an extension of the 6-month intervention for both the *SIPsmartER* and *MoveMore* conditions. That is, participants report behaviors (i.e., *SIPsmartER* = ounces of SSB; *MoveMore* = minutes of PA), receive customized feedback based on goal maintenance, are provided with opportunities to set a new maintenance goal, and are allowed to identify different barriers and strategies. Each month targets a specific theoretical construct(s). Months 7, 11, and 13 targeted perceived behavioral control while months 8 and 15 targeted subjective norms. Media literacy was the focus of months 9 and 16. Improving attitudes towards behavioral maintenance was the focus of months 10 and 14. Finally, the message for Month 12 focused on relapse prevention, and Month 17 was simply a summary and appointment reminder call. The content and structure of the Behavior-Live

call condition is identical to the Behavior-IVR, the distinction is that a research staff member delivers it live via telephone.

Additionally, all participants receive a birthday card and a holiday card from our research staff during the maintenance phase. Participants who actively withdraw from the 6-month intervention, or who otherwise have not participated in any aspect of the intervention, are excluded from extended care maintenance.

6. Context for adoption and implementation

Adoption and implementation issues were key considerations in the development of the interventions. The rationale to include intervention components that were typical of community health education practices (e.g., small group classes) and scalable to a large number of participants with limited personnel costs (e.g., IVR calls) are intended to improve the adoption of the programs beyond research settings. Because this trial is primarily focused on individual-level RE-AIM dimensions (reach, effectiveness, and maintenance) and delivered by research staff, we are not able to assess adoption as defined by the RE-AIM framework (i.e., the number, proportion, and representativeness of intervention delivery staff and settings). However, a key adoption consideration of start-up costs for the interventions will be captured for each of the interventions. Implementation is defined as the degree to which an intervention is delivered as intended and ongoing costs associated with intervention delivery over time. Using a cost capture template, research team members also submit project hours on a weekly basis, which are categorized (e.g., development, delivery/implementation, recruitment) to provide comprehensive information on the start-up, recruitment, and implementation costs associated with the interventions.

To facilitate consistent implementation of the small group classes, the research staff delivering the sessions participated in content development, completed practice sessions delivering the class content to the investigators, masters-level research staff, and doctoral students in nutrition and exercise science. Further, class sessions were pilot tested and study investigators provided feedback on consistency and completeness of delivery [39]. To ensure implementation consistency across cohorts, the small group sessions are manualized, including semi-structured scripts. Implementation is also assessed using session checklists and completeness of the IVR calls across the intervention. Threats to implementation fidelity (e.g. glitches in the IVR system, weather events that interrupt activities) are also tracked.

6.1. Intervention location

Locations for data collection and intervention activities vary across each cohort, mainly those centrally located venues within each community (e.g., public health buildings, Extension offices, churches). Locations were chosen to make it as easy as possible for participants to attend sessions, such as reducing transportation burden and choosing locations participants would feel comfortable going to.

6.2. Intervention staff

Three masters-level research staff (i.e., MPH, MS/RD, MSEH), as well as one PhD investigator with expertise in media literacy deliver the classes. Graduate research assistants provide additional class support, complete the live teach back calls and Behavior-Live calls for extended care maintenance, and help execute the retention strategies previously detailed. All research staff are required to complete the 5 hour on-line training in clear communication techniques [26].

7. Data collection and measures

7.1. Outcome evaluation and measures

An overview of the measures used at each time point are illustrated in Table 2. To ensure standardization and consistency, a data collection manual of procedures was developed, and all research staff are trained prior to data collection and subsequent booster sessions were held as needed. The baseline assessment consists of two appointments, each lasting approximately 45–60 minutes. Subsequent 6- and 18-month assessments are each executed in one appointment, lasting about 75–90 minutes. The order of assessment completion is randomized to either having all TPB assessments completed first and all behavior assessments completed last (i.e. dietary intake records, L-CAT and BEVQ-15) or vice versa. The randomization order of data collection is carried into 6- and 18-month assessments.

The assessment includes computer-audio assisted questionnaires, interviewer-administered questionnaires, and anthropometric and biological assessments. The computer-audio assisted assessment is specifically designed for this study, and underwent several rounds of pilot testing and revisions prior to use in this study. The first computer-audio assisted module is the BEVQ-15, a food-frequency instrument that assesses how often and how much 15 beverages are consumed on average over the past month[43]. The instrument queries seven frequencies including: never or less than 1 time/week, 1 time/week, 2–3 times/week, 4–6 times/week, 1 time per day, 2 times per day, or 3 or more times per day. Portion sizes are also reported in fluid ounces and include less than 6, 8, 12, 16, or more than 20. SSB intake is quantified by summing kilocalories from five items including regular soft drinks, sweetened juice beverage/drink, sweetened tea, coffee with sugar, and energy and sports drinks. Additionally, the computerized questionnaire includes five modules of previously validated instruments including: 1) L-CAT, a 1-item physical activity questionnaire which asks participants to select one of six statements that best describes their physical activity level over the past month [47], 2) questions guided by the constructs of the TPB that were related to SSB consumption (20-items) and physical activity (20-items) which addresses instrumental and affective attitudes, subjective norms, perceived behavioral control, behavioral intentions, and implementation intentions [50, 64], 3) media literacy, a 19-item questionnaire which inquires about media and advertisements related to SSB [65], 4) subjective numeracy, an 8-item questionnaire that assesses a person's perceived numeracy skills [66, 67], and 5) quality of life, a 4-item questionnaire that asks about physical, mental, and overall health[68]. Specific to the BEVQ and L-CAT, our data indicates that the computer-audio assisted versions of the questionnaires performed similarly to traditional pencil-paper methods [69].

Interviewer-administered methods were used to assess health literacy, dietary intake, and physical activity. The Newest Vital Sign [70] and REALM [71] were administered to assess health literacy status. Research assistants conduct three non-consecutive 24-hour dietary recalls over a two-week period, including two weekdays and one weekend day [72]. At each data collection time point, the first recall is completed during the in-person assessment and two additional unannounced recalls are completed via the phone. Instructions for the 24-hour dietary recall procedure, such as portion size determination, are explained to participants at the first in-person recall. Recall data is analyzed using nutritional analysis software (NDS-R 2011, University of Minnesota). The Godin Leisure Time Exercise Questionnaire is used to estimate time spent doing strenuous, moderate, and mild physical activity over the past 7 days [73].

A calibrated digital Tanita scale (Model: 310GS) and portable research-grade stadiometer are used to assess participants' body weight and height, without shoes and in light clothing. Fasting blood samples are obtained via routine finger sticks using a One Touch Fine Point

Lancet (Lifescan, Johnson & Johnson Company). Blood samples are collected using a capillary tube and a CardioChek PA system is used to analyze the blood samples on site to determine blood glucose, cholesterol, and triglyceride concentrations. The CardioChek conforms to the accuracy guidelines established by the National Cholesterol Education Program of the National Institutes of Health [74]. Blood pressure is always measured first, prior to the finger stick. Blood pressure measurements are made with an automated oscillometric device and conform strictly to the AHA guidelines [75]. At least 3 measurements are taken in the upright sitting position, and are two minutes apart. The OMRON (Model:HEM-907XL) blood pressure machine automatically averages the measurements. All participants' arm circumference is measured and appropriate cuff sizes are used. Participants with a reading higher than 160/100 sit quietly for 5 minutes before an additional set of readings are collected. If either number is higher than 180/110 the participant is required to get physician approval before they can be randomized (due to the possibility of being in the PA arm).

Financial cost information is being collected. The staff salary expenditure information is collected using a standard time tracking procedure that includes all research staff documenting, on a weekly basis, the amount of time spent on intervention development and delivery activities. Material costs related to intervention such as manuals, space rental, and other supplies are also collected in an ongoing fashion.

7.2. Process evaluation

The process evaluation addresses the reach and implementation aspects of the RE-AIM framework. Initial reach is operationalized as the number, proportion, and representativeness of study participants to the target population. To assess initial reach, all recruitment efforts are closely documented including a daily log of recruitment events, locations, and outcomes (e.g. number screened, number eligible). These records are jointly maintained by the research staff and hired community members who complete recruitment activities. From these records, we will estimate the number of potentially eligible community members that were exposed to recruitment activities, that responded to recruitment, and ultimately that enrolled in the trial. To assess ongoing reach we will determine the number, proportion, and representativeness of participants that receive different intervention components. In this regard, participants' class attendance and call completion are objectively tracked continuously in a password protected shared drive. Summaries are generated and the research team meets twice per month to discuss and troubleshoot any participant issues and to promote fidelity to the established intervention and retention protocols.

7.3. Summative evaluation

Upon conclusion of the 6-month assessment, participants complete an interviewer-administered summative evaluation, including 22 quantitative Likert-type questions, and 7 open-ended qualitative questions. Questions pertain to perceptions of the intervention components, including the small group sessions, personal action plans, drink diaries/exercise logs, the teach back call, IVR calls, and the various resources provided.

8. Statistical approach

8.1. Sample size

Our targeted enrollment is 340 participants, or 170 per condition. Accounting for an estimated 15% attrition rate at 6 months, our study is conservatively powered to detect a small effect (i.e., an effect size of 0.34) for 0–6 month changes in SSB intake between the SIPsmartER and MoveMore conditions (i.e., 80% power, 0.05 type 1 error). Using a

staggered enrollment process, approximately 40–45 participants will be enrolled and randomized every 4 months, for a total of 8 cohorts across the targeted counties.

8.2. Data analysis

Effectiveness of the interventions will be determined using an intention to treat approach within a mixed effect model framework [76, 77]. We will control for individual variability and time effects regardless of the group assignment and include a group by time interaction accounting for interactions between time and individual characteristics, and time and individual fixed effects. Mixed effect methods acknowledge these error components and provide better support for mitigating selection bias. A similar analytical approach will be used to examine treatment effects on other secondary outcomes (e.g. body weight, quality of life, blood pressure, glucose, and lipids), as well as test our tertiary aim to determine the effectiveness of the comparison condition in the promotion of physical activity when compared to participants in the SSB condition (SIP_{smart}ER). Likewise, while not specifically powered, mixed effect models will also be used to explore treatment effects among participants randomized in to the 12-month extended care maintenance conditions. Using both an intention to treat and present at follow-up analytical approach, we will also explore how intervention engagement (e.g. attendance at small group classes, completion of teach back calls, completion of IVR calls) influences primary and secondary outcomes, as well as evaluate intervention effects on overall caloric intake and dietary quality using the 24-hour dietary recall data.

A multivariate structural equation modeling analysis will be employed to explore proposed causal pathways. Strong theoretical support (i.e. TPB [29], Paasche-Orlow's causal model [19], von Wagner's model [20]) will be used to derive the structural models. The structural equation model will follow the mechanism flow presented in Figure 1, along with demographics and baseline variables as covariates. The causal-steps approach to testing mediation will be employed [78, 79]. Two approaches developed by MacKinnon, using tailor-made statistics, P and z' , will be used [80].

Reach will be analyzed following the recommendations of Glasgow and colleagues[81]. Specifically, the number exposed to recruitment activities will be estimated based upon local census and behavioral surveillance data. Participation rate will be calculated by dividing the total number of participants enrolled by the total number of potentially eligible residents exposed to recruitment materials. To determine representativeness, we will use multi-level mixed effect logit models with residents as nested within counties. Furthermore, nonparametric and semiparametric methods will be used to generate a summary measure of reach. These same approaches will be used to determine ongoing reach based upon participant receipt of class and IVR content. Additionally, at each time point, those who drop out of the study will be compared on key demographic variables with those retained in the study in order to understand the mechanism of participation. Pattern mixture models [82–84] will also be used to assess the degree to which important model terms (e.g. group and group by time interactions) depend on the participation and drop out pattern in our data.

A concurrent mixed methods design will be used to collect quantitative and qualitative data on implementation and triangulated for interpretation [85]. Quantitatively, implementation will be analyzed using descriptive statistics and reported as a proportion of the intervention that was delivered as intended. Qualitative data will be transcribed from participant surveys, reduced to meaning units (i.e., a word, phrase, or paragraph with a single meaning), and deductively grouped into higher order themes.

Cost data will be analyzed using descriptive statistics in categories related to development, start-up costs, and ongoing implementation costs. In addition, costs will be compared

descriptively across intervention conditions. Sensitivity analyses will be conducted to determine costs of scale up related to each intervention as a whole as well as specific intervention components.

9. Discussion

Reducing SSB intake is a clear target in promoting population health [86]. Unfortunately, individuals with low health literacy [11], low socioeconomic status [8–10], and those living in rural regions [87] drink more SSBs as compared to their counterparts. Likewise, while problems with low health literacy exist nationwide, low socioeconomic and rural populations are disproportionately burdened with poor health literacy skills [88, 89]. However, few behavioral interventions exist to decrease SSB intake among adults, and none focus on addressing the needs of low health literate audiences or those living in rural areas [12, 13]. Furthermore, the majority of health literacy studies have been conducted in primary care-based settings and the degree to which these approaches can reach low health literate individuals is unclear [18]. Importantly, Talking Health was developed to address the need to create and test interventions that have a higher likelihood of reaching rural populations and, ultimately being translated into community practice.

In addition to the primary aim focused on addressing intervention effects on SSB in a vulnerable region, this type 1 effectiveness-implementation hybrid trial has several other innovative methodological and design features. Applying the RE-AIM planning and evaluative framework promotes understanding of the contextual factors impacting the reach, adoption, implementation and maintenance for this trial, and will help inform future studies aimed at applying dissemination and implementation frameworks [24]. The pragmatic design allows for a comparison condition that is independent of SSB consumption, yet provides an opportunity for all participants, regardless of randomized condition, to benefit from participation. Given the high prevalence of physical inactivity and the Community Preventive Services Task Force recommendations for individually-adapted health behavior change programs to promote physical activity [90], findings from the MoveMore comparison condition may also have important implications for addressing disparities in meeting physical activity recommendations.

The use of scalable IVR technology among vulnerable and geographically dispersed populations is also an innovative design feature. Several other studies have demonstrated the acceptability and uptake on IVR technology among low health literate and low socioeconomic audiences [91–93], and Talking Health will help further understand the opportunities and challenges of utilizing IVR technology. Providing health information to and promoting health behavior change among hard-to-reach and low-literate populations remains an enormous challenge. Without a concerted focus on scalable strategies that are also technologically-, culturally-, and literacy-appropriate, the ability to reach health disparate populations and meet national health goals will greatly diminish [32].

Finally, Talking Health also fills an important void in the health literacy literature and can help bridge the conceptual gap between health behavior theory and health literacy. Our application draws upon the Theory of Planned Behavior (TPB) [29] and integrates motivation/intention processes with skill-based health literacy processes (e.g. numeracy, media literacy) to understand causal pathways and relationships impacting SSB consumption and physical activity behaviors. Findings may expose opportunities for more strategic approaches of simultaneously incorporating constructs in health behavior theory with concepts in health literacy when developing, implementing, and evaluating behavioral interventions.

10. Limitations

Given the unique rural southwest Virginia counties targeted by this effectiveness trial, there may be limited generalizability of study findings beyond this region. Nonetheless, our focus on reach and representativeness will help address important factors related to generalizability. While the type 1 hybrid trial is a strength of the study, the true context for implementation in real world practice settings may be limited since the interventions are being delivered by trained research staff. Additionally, there a variety of other factors that may feasibly influence changes on SSB and PA consumption that are not being measured (e.g. chronicity of behavior, medical history). As the quantitative data are interpreted, having post-program qualitative data that helps identify additional factors that influence engagement and success in the interventions will be important.

11. Conclusions

In summary, evidence is lacking regarding behavioral programs targeting SSB reduction among adults, including those at the highest risk of overconsumption. If proven effective, SIP_{smart}ER may be translated into community practice. Importantly, the contextual data generated from this trial will help inform the potential for broader dissemination and implementation into community practice.

Acknowledgments

The Talking Health trial is funded by NIH/NCI 1R01CA154364-01A1 (PI: Zoellner)

We would like to acknowledge the entire Virginia Tech research team who has been instrumental in the development and implementation of the Talking Health trial, including Ramine Alexander, Angie Bailey, Emily Cook, Erin Krzeski, Lauren Noel, Sarah Wall, and Grace Wilburn. We also appreciate the technical support in manuscript development provided by Kathleen Porter and Sherri Songer.

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Figure 1.
Theoretical and conceptual framework

Figure 2.

Talking Health Trial: Participant flow diagram, methodological overview, and considerations for RE-AIM dimensions

Note: SipSmartER, behavioral intervention targeting a reduction in sugar-sweetened beverages. MoveMore is a behavioral intervention targeting increased physical activity. IVR, interactive voice response.

SipSmartER- My Weekly Drink Diary

Each day, write down the type of sugary drink you have at each time of the day. Also record the number of ounces you drink.
At the end of the day, add up how many ounces you drank. At the end of week, calculate your average for the week.
This will help you keep track of how close you are to reaching your goal!

Day of the Week	Mon.		Tues.		Wed.		Thurs.		Fri.		Sat.		Sun.	
	Drink	# of Oz	Drink	# of Oz	Drink	# of Oz	Drink	# of Oz	Drink	# of Oz	Drink	# of Oz	Drink	# of Oz
Breakfast														
Mid-Morning														
Lunch														
Afternoon														
Dinner														
Evening														
TOTAL- for ENTIRE Day	Ounces		Ounces		Ounces		Ounces		Ounces		Ounces		Ounces	
	Weekly Average=													
	Ounces													

Figure 3a. SipSmartER daily drink diary

Move More DAILY EXERCISE LOG

Use this log to help you track the amount of activity you get each day.

WEEK #	DAY	TYPE of CARDIO	MINUTES of CARDIO	MINUTES of STRENGTH TRAINING
	Example	Walk	30 minutes	15 minutes
1	Sunday			
1	Monday			
1	Tuesday			
1	Wednesday			
1	Thursday			
1	Friday			
1	Saturday			
Total minutes of physical activity:				TOTAL=

Figure 3b. MoveMore daily exercise log

Figure 3.

Figure 3a. SipSmartER daily drink diary

Figure 3b. MoveMore daily exercise log

Table 1**Intervention Overview for the Talking Health Trial: Structure, Theoretical Constructs, and Content**

Week	Mode	Theoretical Construct	SipsmartER (SS)	MoveMore (MM)
1	Class #1	<ul style="list-style-type: none"> Attitudes Subjective Norms (SN) Perceived Behavioral control (PBC) Intentions Numeracy 	<ul style="list-style-type: none"> Understand current beverage recommendations, including sugar-sweetened beverages (SSB), and ease or difficulty of meeting recommendations Recognize health risks related to beverages, including SSB Evaluate how other's influence beverage behaviors Identify SSB and healthier options Calculate current SSB intake Develop a personal action plan to reduce SSB intake & discuss barriers and strategies to meet goals 	<ul style="list-style-type: none"> Understand current physical activity (PA) recommendations and ease or difficulty of meeting recommendations Recognize benefits of physical activity PA Evaluate how other's influence current PA Identify examples of and practice cardiovascular exercise and strength training Understand rate of perceived exertion Calculate current PA patterns Develop a personal action plan to increase PA & discuss barriers and strategies to meet goals
2	Live Teach Back Call	<ul style="list-style-type: none"> Health literacy Numeracy PBC 	Teach back 5 key concepts; when concepts were missed, concepts were reviewed and given two additional opportunities to teach back the key concepts	Teach back 8 key concepts; when concepts were missed, concepts were reviewed and given two additional opportunities to teach back the key concepts
3	IVR #1	<ul style="list-style-type: none"> PBC Intentions Numeracy 	Report SSB behaviors and evaluate progress towards goal	Report PA behaviors and evaluate progress towards goal
4	IVR #2	<ul style="list-style-type: none"> PBC Intentions Numeracy 	Report SSB behaviors and evaluate progress towards goal + Reevaluate barriers and strategies for reducing SSB	Report PA behaviors and evaluate progress towards goal + Reevaluate barriers and strategies for increasing PA
5	IVR #3	<ul style="list-style-type: none"> PBC Intentions Media literacy 	Re-evaluate personal action plan + SSB support message	Re-evaluate personal action plan + PA support message
6	Class #2	<ul style="list-style-type: none"> Media literacy Attitudes SN PBC Intentions Numeracy 	<ul style="list-style-type: none"> Review beverage and SSB guidelines from previous class lessons Recognize personal ability to not consume SSB Recognize misclaims in SSB ads Practice detecting hidden messages (truth/reality) in media about SSB 	<ul style="list-style-type: none"> Review PA guidelines from previous class lessons Learn how media messaging influences PA Recognize misclaims of PA gadgets Practice detecting hidden messages (truth/reality) in media about PA recommendations

Week	Mode	Theoretical Construct	SipsmartER (SS)	MoveMore (MM)
			<ul style="list-style-type: none"> Interpret SSB ads and compare against the nutrition label Produce counter media messages Re-evaluate personal action plan 	<ul style="list-style-type: none"> Learn and practice new cardiovascular exercise and strength training Re-evaluate personal action plan
7–8	IVR #4	<ul style="list-style-type: none"> PBC Intentions Media literacy 	Re-evaluate personal action plan + SSB support message	Re-evaluate personal action plan + PA support message
9–10	IVR #5	<ul style="list-style-type: none"> PBC Intentions SN- doctors & health care professionals 	Re-evaluate personal action plan + SSB support message	Re-evaluate personal action plan + PA support message
11–12	IVR #6	<ul style="list-style-type: none"> PBC Intentions Attitudes 	Re-evaluate personal action plan + SSB support message	Re-evaluate personal action plan + PA support message
13–14	IVR #7	<ul style="list-style-type: none"> PBC Intentions SN- friends & family 	Re-evaluate personal action plan + SSB support message	Re-evaluate personal action plan + PA support message
15–16	IVR #8	<ul style="list-style-type: none"> PBC Intentions PBC- Resources (MM) Numeracy (SS) 	Re-evaluate personal action plan + SSB support message	Re-evaluate personal action plan + PA support message
17	Class #3	<ul style="list-style-type: none"> Numeracy Attitudes SN PBC Intentions 	<ul style="list-style-type: none"> Review beverage and SSB guidelines from previous class lessons Interpret and apply information on nutrition labels Calculate the contribution of SSB calories to energy needs Calculate the costs associated with drinking SSB Re-evaluate personal action plan 	<ul style="list-style-type: none"> Review PA guidelines from previous class lessons Identify local resources for maintaining PA Discuss the the role of friends& family in maintaing PA Learn and practice new cardiovascular exercise and strength training Re-evaluate personal action plan
18–19	IVR#9	<ul style="list-style-type: none"> PBC Intentions Numeracy (SS) PBC-Enviormnet (MM) 	Re-evaluate personal action plan + SSB support message	Re-evaluate personal action plan + PA support message

Week	Mode	Theoretical Construct	SipsmartER (SS)	MoveMore (MM)
20–21	IVR #10	<ul style="list-style-type: none"> • PBC • Intentions • Relapse prevention 	Re-evalute personal action plan + SSB support message	Re-evalute personal action plan + PA support message
22–23	IVR #11	<ul style="list-style-type: none"> • PBC • Intentions • Relapse prevention 	Re-evalute personal action plan + SSB support message	Re-evalute personal action plan + PA support message

IVR, Interactive Voice Response

NOTE: During each class and IVR call, the personal action plan was re-evaluated. The personal action plan included evaluation of current behavior, goal behavior, strategies to meet goals, and potential barriers. Each support message was guided by the identified theoretical construct(s).

Table 2**Measures Overview for the Talking Health Trial**

	Screening	Baseline	6-months	18-months
Sugar-sweetened beverages (SSB) & dietary intake				
Beverage intake questionnaire (BEVQ-15) [43]	✓	✓	✓	✓
24-hour dietary recalls (3 non-consecutive days) [72]		✓	✓	✓
Physical activity				
Stanford Leisure-Time Activity Categorical Item (L-CAT) (1-item) [47]	✓	✓	✓	✓
Godin Leisure Time Exercise Questionnaire [73]		✓	✓	✓
Physical Activity Readiness Questionnaire (PAR-Q) (modified, 6-items)[48]	✓			
Health literacy, numeracy, media literacy				
Subjective health literacy (3 questions) [44–46]	✓			
Newest Vital Sign (6-items) [70]		✓	✓	✓
Rapid Estimate of Adult Literacy in Medicine (REALM) [71]		✓	✓	✓
Media literacy related to SSB (19-items) [65]		✓	✓	✓
Subjective numeracy (8-items) [66, 67]		✓	✓	✓
Theory of Planned Behavior (TPB)				
TPB for SSB consumption (20-items) [50]		✓	✓	✓
TPB for physical activity (20-items)[64]		✓	✓	✓
Anthropometric, biological & blood pressure				
Height		✓	✓	✓
Weight		✓	✓	✓
Finger stick for glucose and lipids [74]		✓	✓	✓
Blood pressure [75]		✓	✓	✓
Quality of life [68]		✓	✓	✓
Demographic questions				
gender, age, race/ethnicity, education level, income, employment status, health care coverage, marital status, number of children in the home, county of residence	✓			