The Role of Health Literacy in Intervention Engagement, Teach Back Performance, and Perceptions of Intervention Components

Lauren Noel

Thesis submitted to the faculty of the Virginia Polytechnic Institute and State University in partial fulfillment of the requirements for the degree of
Master of Science
In
Human Nutrition, Foods and Exercise

Jamie M. Zoellner (Chair)
Yvonnes C. Chen
Paul A. Estabrooks

April 4th, 2012
Blacksburg, VA

The Role of Health Literacy in Intervention Engagement, Teach Back Performance, and Perceptions of Intervention Components

Lauren Noel
MS Candidate

ABSTRACT

Background: Low health literacy is a significant problem affecting our country. While the associations between low health literacy and poorer health outcomes have been well documented (Berkman et al., 2011), the literature lacks evidence of effective strategies to address health literacy in the context of health behaviors such as diet and physical activity (PA). Likewise, few interventions have reported on how health literacy status influences performance and engagement in the intervention. Two potential intervention strategies include the teach back method or teach to goal approach and interactive voice response (IVR) technology. These strategies hold promise as a means of improving health literacy and reaching vulnerable, low health literate populations, but these strategies have not been widely explored in the literature (Paasche-Orlow et al., 2005; Baker et al., 2011; Schillinger et al., 2009; Bennett et al., 2012; Piette et al., 1999). **Primary Aims:** This research was embedded in a larger trial, Talking Health, which is a 6-month, 2 group randomized controlled trial to determine the effects of a health behavior intervention on reducing sugar-sweetened beverage (SSB) consumption in Southwest Virginians. The primary aims of this study were to examine the associations between health literacy status and 1) number of rounds of teach back needed to reinforce key concepts, 2) proportion of correct answers on the first round of teach back, 3) level of intervention engagement (i.e., completion rates for teach back call, IVR calls, and small group classes), and 4) perceptions of the intervention components. **Methods:** The data reported represent the first 3 cohorts of the Talking Health trial including participants in Lee, Giles, and Pulaski Counties. Eligibility requirements included being 18 years or older, English speaking, consuming at least 200 calories per day from SSB, able to participate in moderate intensity PA, and having reliable access to a telephone. Data were collected at baseline and at the 6-month follow-up assessment. Health literacy was assessed using the validated Newest Vital Sign. Participants were randomized to a behavioral intervention aimed at decreasing SSB consumption (SipSmartER) or to a matched-contact control group targeting PA (Move More). Both groups participated in 3 small group education sessions, received a live teach back call, and 11 supportive IVR calls. Participants completed a summative evaluation at the 6-month follow-up, which captured their perceptions of the intervention components. ANOVAs were used to measure differences in outcomes by health literacy status, randomized condition, and interactions. **Results:** Of the 125 enrolled participants, 92.0% were Caucasian, 76.8% were female, 29.6% had ≤ high school education, 64.0% had <$25,000 annual household income, and 32.8% had low health literacy skills. Eighty-five participants (68.0%) completed the teach back call. The overall model when looking at the degree to which health literacy status and randomized condition predicted the number of rounds of teach back needed to reinforce key concepts was significant (F= 8.323, p < 0.001). Out of 3 possible teach back attempts, participants in the low health literacy category required a significantly higher number of teach back attempts as compared to

those with high health literacy (F= 16.769, p <0.001), and participants randomized to Move More required a significantly higher number of teach back attempts compared to SipSmartER participants (F=7.296, p= 0.008). Similarly, the overall model when looking at the degree to which health literacy status and randomized condition predicted the proportion correct on the first round of teach back was significant (F= 9.836, p<0.001), such that those with higher health literacy status (F= 19.176, p< 0.001) and those randomized to SipSmartER condition answered a significantly higher proportion of questions correct (F= 9.783, p= 0.002). Intervention engagement including completion of the small group education sessions, the live teach back call, and the IVR calls did not vary significantly across randomized condition or literacy levels. Low health literate participants had a significantly higher overall perceived satisfaction with the IVR, as compared to high health literate participants (F= 5.849, p= 0.020). However, perceptions of other intervention components (e.g., small group sessions, teach back call, personal action plans, drink diaries/exercise logs,) were similar among participants with low and high health literacy status and across randomized conditions. **Conclusion:** These data confirm the importance for multiple teach back opportunities and additional exposure to health information to ensure participant comprehension of key intervention content—in particular for those with lower health literacy. This research also supports that IVR is an effective approach to reaching vulnerable, low health literate populations. Future research should investigate the efficacy and cost-effectiveness of utilizing teach back methods delivered using automated technologies. Future research also is needed to determine how teach back performance are related to other study factors such as retention, engagement, and health outcomes.

Chapter 1: Literature Review

Introduction

Increased sugar-sweetened beverage consumption, physical inactivity, and low health literacy are major public health concerns. A variety of health literacy strategies have been applied across health interventions, such as improving readability, limiting the number of messages, and supplementing instructions with pictures. However, there is relatively little research on the utility of the teach back and teach to goal approach. Individuals with low health literacy fit the vulnerable, hard to reach population description. Using technology is an approach to reaching and improving health behaviors in vulnerable populations. The intentions of this literature review are to provide an overview on the problem of sugar-sweetened beverage consumption and physical inactivity; health literacy interventions; the utility of the teach back or teach to goal approach; the utility of using interactive voice response systems in vulnerable populations and in health behavior interventions; the theory of planned behavior; and the target population, Southwest Virginia.

Increased Sugar-sweetened Beverage Intake and Physical Inactivity

In 2009-2010, more than 35% of U.S. adults and 17% of children were obese (CDC, 2012). Poor diet and lack of physical activity are two major contributors to the increase in the prevalence of obesity in this country. In fact, the increase in sugar-sweetened beverage (SSB) consumption over the last several decades parallels the rise in obesity (Bray, Nielsen, & Popkin, 2004; Malik, Shulze, & Hu, 2006; Vartanian, Schwartz, & Brownell, 2007). The Centers for Disease Control and Prevention defines sugar-sweetened beverages (SSB) as those that contain

caloric sweeteners (2010). These beverages, which include soft drinks, fruit drinks, sports drinks, tea and coffee drinks to which sugar has been added, energy drinks, and sweetened milk or milk alternatives, contribute approximately 80% of all added sugars to the diet (Guthrie & Morton, 2000). SSBs contribute excessive sugar and calories to the diet and offer little nutritive value. Not only are excess sugar and calories associated with weight gain and increased body mass index (BMI), SSB consumption has also been linked to several other adverse outcomes including obesity, high blood pressure, certain types of cancer, and tooth decay (Malik, Shulze, & Hu, 2006; Vartanian, Schwartz, & Brownell, 2007; Wang & Gortmaker, 2008). Additionally, increased SSB consumption is associated with decreased milk and calcium intake (Bleich, Ku, & Wang, 2011; Wang & Gortmaker, 2008).

Physical inactivity and sedentary behaviors are also associated with being overweight and obese. According to a national telephone survey conducted by the Centers for Disease Control and Prevention in 2010, 24% of the population reported no leisure time physical activity and only 48% meet the 2008 guidelines for physical activity. The associations between physical inactivity and higher risk for early death, heart disease, stroke, type 2 diabetes, depression, and some cancers have been well documented (CDC, 2012). Health behavior interventions aimed at improving beverage and physical activity behaviors are needed to help reverse the climbing rates of obesity.

Research demonstrates a consistent inverse relationship between education level and diet and physical activity. However, there is a lack of research on the implications of using health literacy strategies to influence these behaviors (Thompson et al., 2009). Interventions that aim to improve diet and physical activity behaviors are ideal for participants with low health literacy levels because these interventions focus on reading and numeracy skills. They often involve

calculating numbers like average minutes of exercise and reading information on nutrition labels. Interventions that address health literacy in the promotion of physical activity and SSB reduction could result in improved behavior change outcomes for people who may have difficulty with more traditional forms of health promotion interventions. Understanding the prevalence of low health literacy, the availability and validity of metrics used to assess health literacy, and different approaches to improve health literacy is necessary to help develop an advanced health literacy intervention targeting nutrition and physical activity behaviors.

Health Literacy

Low health literacy is a significant national problem affecting approximately 80 million Americans (Agency for Healthcare Research & Quality, 2011). Health Literacy is generally defined as "the degree to which individuals can obtain, process, and understand the basic health information and services they need to make appropriate health decisions" (AHRQ, 2011). Having low health literacy is associated with poorer health outcomes and poorer use of health care services (Berkman et al., 2011). Furthermore, low health literacy is linked to poorer access to health care; poorer health knowledge and comprehension; increased hospitalization; increased health care costs; decreased ability to take medications appropriately; and decreased ability to read and interpret medication labels and health messages. Elderly individuals, minorities, and vulnerable populations are more likely to have low health literacy (IOMC, 2004). In fact, elderly individuals with low health literacy experience poorer overall health and higher mortality. Low health literacy can also contribute to racial disparities in health outcomes (Berkman et al., 2011). Due to the burden caused by low health literacy, there is a need for effective strategies and interventions that improve health literacy.

<u>Measures of Health Literacy</u>

Although there are several instruments for measuring health literacy, including the Test of Functional Health Literacy in Adults (TOFHLA), the Rapid Estimate of Adult Literacy in Medicine (REALM) and the Newest Vital Sign (NVS), there is no gold standard for measuring health literacy (Berkman et al., 2011). These tools vary in their measurements for distinguishing different levels of health literacy and have some limitations. The TOFHLA consists of 67 items: 50 reading comprehension items and 17 items that test numerical abilities (Parker et al., 1995). The reading comprehension section includes a passage in which every fifth or seventh word is omitted. The reader chooses from a list of four words to fill in the blank. The readability levels of this section range from grades 4.3-19.5 and the score ranges from 0 to 50. The numeracy section asks readers to interpret hospital forms and labeled prescription vials. The readability of this section is grade 9.4. To create a weighted score from 0 to 50, the numeracy scores are multiplied by 2.941. Overall scores range from 0 to 100 and are determined by adding the reading comprehension and numeracy scores. A score of 75–100 indicates adequate health literacy, 60-74 is marginal health literacy, and 0–59 indicates inadequate health literacy.

The Short Test of Functional Health Literacy in Adults (s-TOFHLA) is a modified version of the TOFHLA and includes 36 reading comprehension items. A score of 23–36 indicates adequate, marginal health literacy if the score of 17–22, and inadequate health literacy if the score is 0–16. The s-TOFHLA takes only 5-7 minutes to administer, compared to the TOFHLA, which takes 22 minutes to administer (Paasche-Orlow et al., 2005, Parker et al., 1995).

The REALM is a 66-item reading recognition test that measures patients' ability to pronounce common medical terms (Murphy et al., 1993). This test can be administered and

scored in two to three minutes and requires patients to read each word aloud through a progression of easy to difficult words while an examiner records if the words are pronounced correctly. Scores are determined by adding the number of correctly pronounced words. A score of 0-18 indicates a literacy level equivalent to 3rd grade or below, 19-44 is equivalent to a 4th to 6th grade reading level, 45-60 is equivalent to 7th to 8th grade reading level, and a score of 61-66 indicates a reading level equivalent to ninth grade and above (Murphy et al., 1993).

The NVS is another instrument commonly used to measure numeracy literacy, another aspect of health literacy, and can be administered in about three minutes (Weiss, 2005). The NVS includes six questions about the nutrition label on the back of a container of one pint of ice cream (Weiss, 2005). The NVS requires patients to use nutrition numeracy skills to interpret the nutrition label, which involves performing addition, subtraction, and calculating percentages. A score of 0-1 indicates high likelihood (50% or more) of limited literacy, a score of 2-3 indicates the possibility of limited literacy, and 4-6 indicates adequate literacy.

Limitations of Health Literacy Measures

There are a number of tools used to measure health literacy, but the basic premises and limitations are the same across all of these instruments. All are designed to test health literacy status, however most do not tie back to the definition of health literacy. For example, reading recognition tests do not assess an individuals' ability to "obtain, process, and understand the basic health information and services." Additionally, basic reading, writing, and numeracy skills are needed to navigate through a complex health care system. Some tools used to measure health literacy do not address all three of these skill sets. Another major limitation of using these instruments to measure health literacy is that each instrument suggests different classifications of levels of health literacy and collapses the categories of health literacy differently. It is unclear

how patients with marginal health literacy should be treated, and the literature lacks consistency on how marginal health literacy is categorized relative to low and high health literacy. We recognize the limitations imposed by these health literacy measures and believe that using a combination of tools is the best way to assess an individual's health literacy status. For example, the REALM assesses word recognition and the NVS includes a numeracy component. Using these two tools together is a better method of assessing health literacy status because they assess different skills.

There is strong evidence of measurement reliability for the NVS. Weiss and colleagues assessed the reliability of 6 candidate items for the NVS in a sample of 250 English-speaking and 250 Spanish-speaking patients (Weiss et al., 2005). The researchers administered a previously validated instrument, the Test of Functional Health Literacy in Adults (TOFHLA), as well as candidate items for the NVS to determine how the two health literacy tests were correlated. Alternate forms reliability was determined by calculating the Pearson correlation coefficient between the equivalent tests, NVS and TOFHLA, ($r = 0.59$, $P < 0.001$). The researchers found good internal consistency for both the English and Spanish versions of the NVS (Cronbach $\alpha = 0.76$ and $\alpha = 0.69$, respectively). According to this study, the NVS also has good sensitivity and may be more sensitive than the TOFHLA in detecting marginal health literacy.

Osborn and colleagues also assessed the reliability of the NVS by comparing items from the NVS to two tests commonly used to assess health literacy status, the S-TOFHLA and the REALM (Osborn et al., 2007). The researchers used bivariate correlations to examine the relationships between scores on the NVS and REALM and between scores on the NVS and S-TOFHLA. Spearman's rank correlation coefficient was used to determine the strength of the relationship between scoring categories of the NVS and the other two tests. Lastly, the area

under the receiver operating characteristic (ROC) curve was used to determine the accuracy of the NVS to predict low and marginal health literacy as compared to the REALM and the S-TOFHLA.

The researchers found good internal consistency of the NVS (Cronbach $\alpha = 0.81$) and a moderate correlation with the REALM (r = 0.41, p<0.001). When comparing the scoring categories between the NVS and the REALM the Spearman's rank correlation coefficient was 0.41. There was also good internal consistency of the NVS (Cronbach $\alpha = 0.71$) and a strong correlation to the S-TOFHLA (r = 0.61). The Spearman's rank correlation coefficient for the strength of the relationship between the scoring categories on the NVS and the REALM was 0.59.

Consistent with Weiss and colleagues' findings, Osborn and colleagues demonstrated a strong level of reliability of the NVS to predict inadequate and marginal health literacy. Based on these findings, the NVS is a reliable instrument for assessing health literacy status.

There is strong evidence of measurement validity for the Newest Vital Sign, as demonstrated by Weiss and colleagues (Weiss, 2005). Researchers have computed ROC curves to calculate the sensitivity and specificity for the cutoff scores of the NVS test, and have determined that the NVS has good sensitivity and specificity that is better than other widely used clinical screening methods. Researchers have compared NVS scores to scores achieved on the TOFHLA. The Pearson correlation coefficient between scores on the NVS and TOFHLA show validity evidence of the NVS ($r = 0.59$, $P < 0.001$). Additionally, the NVS has good internal consistency (Cronbach $\alpha = 0.76$). Based on the validity evidence, the NVS is an appropriate instrument and the scores it produces are meaningful and useful for predicting health literacy

status. Understanding differences among health literacy measures is important when interpreting findings from interventions that have targeted health literacy.

<u>Interventions Targeting Health Literacy</u>

Sheridan and colleagues conducted a systematic literature review of interventions for low health literacy (2011). They examined 38 studies including 22 randomized controlled trials (RCTs), one cluster randomized trial, 5 non-randomized controlled trials (NRCTs), and 10 quasi-experimental studies. This review explored the effects of individual and mixed strategy interventions on health-related skills, behavioral intent, health care costs, health disparities, use of health care services, emergency department visits, hospitalizations, knowledge, self-efficacy, health behavior, adherence, and disease severity. The researchers found strong evidence that intensive self-management interventions reduced emergency department visits and hospitalizations. Additionally, disease severity was reduced by intensive self- and disease-management interventions. The success of these self-management interventions suggests that health literacy constructs can be applied to disease prevention and health promotion behaviors such as diet and physical activity.

There were mixed and limited evidence for the effectiveness of health literacy interventions on other outcomes considered. Relatively few considered behavioral knowledge or psychosocial constructs related to diet and physical activity. In light of these findings, future research should focus on developing and implementing health literacy interventions that improve knowledge, self-efficacy, and health-related skills particularly as they relate to self-management strategies specific to diet and physical activity behaviors.

In another recent review of health literacy interventions, Allen and colleagues examined the effectiveness of 14 RCTs and 10 quasi-experimental trials targeting disease self-management

and health promotion (2012). They revealed that interventions targeting health behavior changes and clinical outcomes were less likely to have significant effects. Additionally, only eight trials examined how outcomes are moderated by health literacy status. This gap in the literature is particularly important because intervention engagement can vary by health literacy status. There is evidence that individuals with higher health literacy receive more intervention components than those with low health literacy. Moreover, the studies included in this review enrolled a greater proportion of participants with high health literacy than participants low health literacy. Researchers should investigate the relationship between health literacy status and intervention effects, as well as focus on reaching low health literate individuals (Zoellner, et al., 2012; Zoellner, Allen, Motley, & Estabrooks, 2012).

Of the 24 studies reviewed, only three studies had any indicators of physical activity or dietary behaviors (Zoellner et al., 2012). This reinforces the notion that more attention is needed for health literacy as it relates to diet and physical activity.

Health Literacy Summary

This review of the health literacy literature demonstrates that health literacy interventions have primarily focused on clinical trials and outcomes such as adherence, self-efficacy, smoking, alcohol use, HIV risk and sexual behaviors, chronic disease prevalence, asthma severity and control, diabetes control and related symptoms, and hypertension control (AHRQ, 2011). The preliminary success with disease self-management in health literacy interventions suggests that health literacy may also be important for disease prevention and health promotion behaviors such as diet and physical activity. Clearly lacking are health literacy interventions that target these health behaviors. With the exception of the Taggart review, few studies have examined health literacy in the context of diet and physical activity behaviors. Given the growing need for health

promotion and prevention interventions, future health literacy research should explore how diet and physical activity may also be targeted and improved, as well as consider interventions that reach participants outside of the clinical setting.

Health literacy research should also focus on representativeness and engagement of low health literate individuals and how these vary across literacy levels. Limitations of the health literacy metrics must be considered when interpreting epidemiological and intervention studies. Nonetheless, the associations between low health literacy, poorer health knowledge, and poorer health outcomes have been well documented.

Across these reviews, several health literacy strategies have been used to improve health outcomes of these populations. For example improving readability, limiting the number of messages, supplementing instructions with pictures, and using the teach back and teach to goal method (Sheridan et al., 2011; Paasche-Orlow et al., 2005). Two potential intervention strategies that could be used to address low health literacy include the teach back or teach to goal method and IVR technology. Of the studies reviewed by Sheridan and colleagues and Allen and colleagues, only one study used the teach back approach and only one study used IVR (Paasche-Orlow et al., 2005; Schillinger et al., 2008). Theoretically, the teach back and teach to goal methods hold promise as a means of reinforcing key concepts for low health literate individuals, but there is relatively little research on this technique. The utility of IVR technology in health literacy interventions warrants further exploration because technology may enhance the capacity of healthcare providers to communicate with patients outside of the clinical setting.

Teach Back or Teach to Goal Approach

While the teach back or teach to goal method is recommended as a strategy to improve health literacy (Baker et al., 2011), the literature lacks evidence on the utility and implications of

using this method in health behavior interventions. Although there do not appear to be any standard definitions of the teach back or teach to goal method, we define the teach back method to be an opportunity to recall key concepts. This is different from the teach to goal approach, which requires participants to complete additional rounds of education until they demonstrate mastery of a concept or technique. This concept of mastery is not clearly defined in the literature. For example, does answering 90% or 100% of questions correctly indicate mastery of a concept? Future research is needed to more clearly define the teach to goal approach. To date, only two known health literacy studies have tested the effectiveness of the teach back or teach to goals approaches (Paasche-Orlow et al., 2005; Baker et al., 2011)

Paasche-Orlow and colleagues conducted a prospective cohort study to examine the relationship between inadequate health literacy and difficulties learning and recalling instructions about discharge medications and appropriate metered-dose inhaler (MDI) technique (2005). Seventy-three adults hospitalized for severe asthma exacerbations participated in the study. The mean age of participants was 41 years and the majority were African American, female, employed, and not married. Sixteen participants (22%) had inadequate health literacy. The s-TOFHLA was used to measure health literacy status at baseline. Participants' understanding of asthma medications was also assessed and participants were asked to demonstrate use of a MDI. Mastery of the asthma discharge regimen was defined as being able to describe the name of each medication, the number of tablets or actuations to be taken at each time, the number of times per day the medication should be taken, and the prescribed duration of medication use.

After two weeks, participants' asthma knowledge and MDI technique were re-assessed using the teach back method. After the first round of teach back, 59% of participants with inadequate health literacy and 73% of participants with adequate health literacy mastered the

MDI technique. Twenty-one percent of participants required one additional round of teach back and 10% required two additional rounds of teach back.

It was found that inadequate health literacy was not associated with the number of rounds of teach back needed for participants to master proper use of a MDI. After one round of teach back, 69% of participants with inadequate health literacy and 68% of participants with adequate health literacy demonstrated mastery of the asthma discharge regimen. Seventeen percent required one additional round of teach back, one required two rounds, and one required three rounds. The proportion of participants who mastered the discharge regimen was similar across health literacy levels (p=0.35). Although inadequate health literacy was not associated with difficulty in learning and retaining instructions about asthma self-care, this study signifies that the teach back method can be used to help overcome barriers to low health literacy.

Another study investigated the utility of the teach to goal method to improve self-care in heart failure (Baker et al., 2011). Baker and colleagues conducted a RCT and tested the effect of a single educational session versus a single education session combined with follow up phone calls on the adoption of self-care behaviors and on heart-failure quality of life (HFQOL). The researchers also examined whether the effects of the interventions differed by literacy level.

Six hundred and five participants were enrolled and had a mean age of 60.7 years. Fifty-two percent of participants were male, more than half were non-white, and 37% had low literacy. Participants attended an educational session about self-care for heart failure and were then assigned to the control, brief educational intervention (BEI) (n=302), or to the intervention group (TTG), which received teach to goal education (n=303). Participants were stratified by literacy level. The BEI group continued with their usual care after the class. The TTG group received additional education and self-care training. The TTG intervention was grounded in the social

cognitive theory and adult learning theory. The TTG group received 5-8 phone calls over the next 4 weeks, each call lasting about 10 minutes. For the first 2 calls, a health educator reviewed key behavior components of the program such as taking daily weights, assessing symptoms, taking the proper dose of diuretic, and calling the doctor when necessary. This material was reviewed during each call. The focus of calls 3 through 8 was reviewing the program content, assessing knowledge and behaviors using the teach to goal technique, and providing further encouragement. Literacy was assessed using S-TOFHLA.

There was a significant increase in knowledge among TTG participants (p=.008) and this improvement did not differ by literacy level. Compared to the BEI group, the TTG group had a significantly greater increase in salt knowledge (p<.001), self-efficacy (p=.006), and self-care behaviors (p<.001). The increase in knowledge, self-care behaviors, self-efficacy, and heart failure symptom scores among those with inadequate and marginal literacy as well as those with adequate literacy indicates that the TTG intervention was equally effective across literacy levels. This study provides evidence that the teach to goal approach is an effective strategy to increase knowledge and self-care behaviors for heart failure (Baker et al., 2011).

Despite their success, the teach back and teach to goal methods have not been widely explored in health behavior interventions, however, we have found two studies that suggest that this approach holds promise as an effective strategy to use in health literacy interventions. Although this is a good approach to use, it is also a resource-intensive strategy. Teaching back key concepts in person is both time- and labor-intensive. One way to make this strategy less resource-intensive would be to use technology to automate the process, for example an automated teach back call. Future research should explore other applications and implications of the teach to goal approach.

Interactive Voice Response Systems (IVR)

Ironically, low health literate individuals are known to have poorer access to clinical/medical services and less ability to navigate healthcare systems, yet this has been the primary setting to reach and implement the majority of health literacy interventions reported here. Given the potential of technology to enhance the capacity of healthcare providers to communicate with patients and reach them in non-clinical settings, there is a need to further explore the utility of technology in health literacy interventions.

One example, IVR, is emerging as a popular mode of communication in both the healthcare industry and in research. IVR allows participants to interact with a computer database using their telephone. Users listen to pre-recorded messages and are prompted to respond using their telephone keypad or speech recognition. This data is stored in a database and is used to determine the message pathways of future calls (Oake et al., 2009). IVR includes tailored responses based on current and past levels of goal achievement. In the literature, this technology has also been referred to as computer telephone interactive (CTI), computer assisted telephone interviewing (CATI), automated telephone self-management (ATSM), automated telephone disease management (ATDM), telehealth, telemedicine, and telephone-linked computer (TLC) system (Abu-Hasaballah et al., 2007; Schillinger et al., 2009; Piette et al., 1999; Pinto et al., 2002).

IVR allows participants to select times that they would like to receive their automated phone calls at their convenience. Other advantages of IVR include real-time data collection and feedback, data storage and retrieval, inbound and outbound calling, confidentiality, multilingual interfaces, access to hard-to-reach populations, and detailed longitudinal assessments (Corkrey & Parkinson, 2002). In addition, this technology does not require human contact with participants

from the research end, making it an efficient and cost effective means of communication (Pinto et al., 2002).

Over the last three decades, IVR have been used to contact patients with testing and appointment reminders (Linkins et al., 1994), promote immunizations and medication adherence (Alemi et al., 1996; Milch et al., 1992), diagnose and manage chronic disease (Piette et al., 2000), and track patient care data such as blood glucose and blood pressure (Piette et al., 1999). This technology has also been used to influence health behaviors such as promoting physical activity (Pinto et al., 2002) and smoking cessation (Regan et al., 2011), and changing dietary habits (Glasgow et al., 2008). Additionally, IVR have been used to provide a wide range of counseling such as counseling for mental health disorders (Kobak et al., 1997) and alcoholics (Perrine et al., 1995).

<u>Reviews of IVR-based Interventions</u>

Four reviews of IVR-based interventions evaluated various aspects of IVR including the effect of IVR messages on process adherence and health outcomes (Oake et al., 2009; Piette et al., 2000; Krishna et al., 2002; Corkrey & Parkinson, 2002). Krishna and colleagues conducted a review of 19 randomized controlled trials (RCT) and controlled trials published before July 2000 (2002). The primary aims of the studies were either preventive care education or chronic care. The preventive care education studies utilized IVR to promote immunizations, medication compliance, vaccinations, and healthy activities. The chronic care interventions focused on cholesterol, diabetes, hypertension, and congestive heart failure. Overall, the researchers concluded that automated telephone messages have been successful in improving health outcomes (Krishna et al., 2002).

Corkrey and Parkinson also reviewed 54 IVR-based interventions published from 1989-2000 and examined their acceptability, reliability, and feasibility (2002). Several of the studies they reviewed were related to clinical outcomes including reminder calls, consumption monitoring, and psychological studies. Five different behavioral interventions were assessed, including interventions that targeted smoking cessation, diabetes self-care, and healthy eating. However the only successful interventions were the two studies that used IVR in combination with some other form of personal contact (Corkrey & Parkinson, 2002). This finding supports the program design of the Talking Health study, which uses IVR calls in combination with small group education sessions.

Piette conducted a literature review in 2000 and found that patients are more likely to report health problems to an IVR than face-to-face to a clinician (2000). Some of the studies reviewed reported that patients were more likely to report alcohol abuse and psychiatric symptoms to an IVR than during live interviews. Additionally, patients' responses to an IVR are at least as reliable as the information they report during interviews with their healthcare provider. In two of the IVR-based interventions for diabetes care, nurses delivered follow-up telephone calls to verify patients' IVR responses. Overall, 98% of patients' reports of fair or poor general health and 98% of patients' reports of fair or poor glycemic control were affirmed (Piette, 2000). This review signifies that IVR can be used to identify health problems, and capture meaningful and reliable patient data.

In a more recent systematic review, Oake and colleagues evaluated 32 randomized and 8 controlled clinical trials that utilized IVR (2009). Twenty-five studies targeted patients' adherence with treatments, screenings, tests, or behavior modifications. Fifteen studies targeted chronic disease management, with the most common diseases being diabetes, heart failure, and

mental illness. The median effect size was 7.9% (interquartile range 2.8-19.5) for studies that measured some process of adherence (i.e., with treatments, screenings, or tests). These outcomes ranged from medication adherence to physical activity. Due to the wide range of patient-reported outcomes, these outcomes were not analyzed. However, some study information was abstracted for descriptive purposes. It was found that there were no significant differences between the intervention and control groups for two-thirds of these outcomes. The results of the remaining one third of the patient-reported of the studies that measured patient-reported outcomes favored IVR. Whether or not the IVR was used alone or as a complement to other strategies or technologies was not reported in this review. Oake and colleagues reported that although IVR-based interventions are feasible in a variety of settings and can have a modest beneficial effect, there is insufficient evidence to support that IVR-based interventions improve health outcomes (Oake et al., 2009).

Though there have been multiple reviews of IVR, the body of literature is comprised mostly of clinical trials; IVR has been used less frequently in health behavior interventions. IVR has led to improvements in health outcomes in some, but not all trials, indicating the need for more research to help understand the effectiveness of IVR-based interventions and how outcomes may be moderated by participant engagement.

Nutrition and/or Physical Activity Interventions Utilizing IVR

In evaluating the use of IVR in health behavior interventions, several factors are important to consider such as engagement, effectiveness, and participant satisfaction. Few studies have evaluated the effect of IVR on diet and physical activity (PA).

Estabrooks and Smith-Ray tested the feasibility and effectiveness of an IVR-based intervention targeting pre-diabetic patients (2007). After completing a 90-minute diabetes

prevention class, participants were randomized to receive IVR calls promoting healthy eating and PA (N=39) or to a no-contact control group (N=38). For 12 weeks, participants in the intervention group received a weekly IVR call that included health behavior messages and a tip of the week. Participants also completed a survey about their perceptions of the IVR, its functionality, and future use of the system. Participants in the IVR group completed an average of 75% of the intervention content and lost significantly more weight than those in the control group (p=.059). Furthermore, three quarters of participants in the IVR arm claimed that the IVR was easy to use and that it helped them prevent diabetes (Estabrooks & Smith-Ray, 2007).

In another RCT conducted by Estabrooks and colleagues, IVR was used to support parents of overweight children in changing their home environment and encouraging more healthful behaviors in their children (2009). Two hundred and twenty dyads of parents and their children were randomized to one of three intervention groups: workbook, group, or IVR counseling. The parents in the IVR group completed two small group sessions and then received 10 follow-up IVR calls, which included goal setting and strategies to overcome barriers. A higher level of parental engagement in IVR was associated with increased moderate physical activity and decreased BMI Z-scores in their children. The children in the IVR group significantly decreased their BMI Z-scores from baseline to 6 months and baseline to 12 months (p<.05) (Estabrooks et al., 2009). These results support that IVR-based physical activity interventions can lead to improvements in health behaviors. In addition, this study suggests that a higher level of engagement is associated with a greater effect.

Pinto and colleagues conducted a RCT of 298 sedentary adults and found that an IVR had positive short-term effects on their physical activity (2002). This intervention was guided by principles of the transtheoretical model for behavior change, and constructs of the social

cognitive theory and decision-making theory. The intervention group, TLC-PA, received counseling that promoted physical activity via a telephone-linked communication (TLC) system, or IVR. The comparison group, TLC-Eat, also used TLC technology, but was given counseling that promoted healthy eating. Physical activity and BMI were assessed at baseline. Participants were asked to call in to the system once per week for the first 3 months and then at least biweekly for the remainder of the 6-month intervention.

Participants in the TLC-PA group were more likely to meet recommendations for moderate-intensity and vigorous-intensity PA at three months (p=.04). Participants in the TLC-PA group completed a mean number of 5.6 calls (SD=7.0) versus 9.3 calls (SD=9.1) in the TLC-Eat group. Thirty-three percent of the TLC-PA group did not call into the system at all; 33% made 1 to 5 calls; 13% made 6 to 10 calls; 17% made 11 to 16 calls; and 4% made more than 20 calls. When comparing the subjects who called into the system at least once to those who did not call at all, by gender, race, age, BMI, and PA outcomes, nonusers were more likely to be African American. Regression analyses were used to control for the potential predictors simultaneously and none were statistically significant, including race. The relationship between usage of the TLC system and physical activity outcomes was examined in the TLC-PA group. Usage was categorized into nonusers, low usage (making 1 to 5 calls), and high usage (making at least 6 calls). Number of calls completed was not found to be a significant predictor of PA in any of their models (p<0.05 for all) (Pinto et al., 2002).

These results suggest that an automated physical activity counseling system can lead to improvements in physical activity and that engagement is not a significant predictor of physical activity outcomes. An important point to consider when looking at engagement as a predictor of effect in this study is that participants had to initiate contact with the system to complete their

calls. Receiving scheduled, outbound calls may have a different effect on participant engagement.

In the Community Health Advice by Telephone (CHAT) trial, King and colleagues also demonstrated that IVR is an effective approach to promoting and increasing PA in adults (2007). This three-arm RCT of 218 sedentary adults age 55 years and older aimed to evaluate the effectiveness of a telephone-based PA intervention delivered by health educator compared to messages delivered by an IVR across one year. The three arms were a human advice arm, in which PA counseling was delivered by health educators; an automated advice arm; or an attention control, in which participants attended weekly health education classes related to nutrition and home safety, but not PA. Participants in both telephone-counseling groups (human advice and IVR) significantly increased their mean minutes per week of PA (p=.01) compared to the control, and the two groups were not significantly different from each other (p=.65). Participant engagement and satisfaction with the IVR were not reported. King and colleagues concluded that IVR-based interventions could lead to moderate increases in PA over an extended period of time (King et al., 2007).

Sparrow and colleagues conducted a two-arm RCT that used IVR to promote resistance training in older adults (2012). One hundred and three middle-aged and older adults were randomized to receive IVR calls promoting resistance training (TLC-LIFT) or to an educational control TLC (attention control) for 12 months. Muscle strength, balance, walk distance, and mood were assessed at baseline, 3, 6, and 12 months. TLC-LIFT participants were called 3 times per week while attention control participants were called weekly and could choose to listen to a variety of health topics. Not only did participants in TLC-LIFT significantly increase the muscle strength and balance, most had a positive experience with the IVR.

Participants were asked to rate their impressions of the IVR calls on a 5-point likert scale with 5 being "strongly agree" and 1 being "strongly disagree." 76% of participants in TLC-LIFT "strongly agreed" or "agreed" that the IVR was easy to use. 59% responded to the statement "The telephone system's advice is right on target for me" with a 5 or 4. Lastly, 76% responded with a 5 or 4 to "The computer system motivates me to exercise" (Sparrow et al., 2012). These results suggest that IVR are viewed positively by older adults and can be used to increase promote resistance training.

Two interventions have explored using IVR to promote dietary changes (Glasgow et al., 2009; Delichatsois et al., 2001). In a RCT of 298 adults, Delichatsois and colleagues utilized an IVR to monitor participants' dietary intake, provide educational feedback, and counseling (2011). Participants in the control group received counseling for PA. The participants had a mean age of 45.9 years, were 45% white, 45% African American, and mostly women. The intervention group made numerous improvements in their diet compared to the control group. The intervention group increased their self-reported fruit and vegetable consumption by 1.1 servings per day (95% confidence interval [CI] .4, 1.7). They also improved their mean global diet quality score, which combines all five food groups and is scored from 0 to 100, by 9 (95% CI 4, 13) points more than in the control group. Lastly, the intervention group raised their dietary fiber intake 4 grams per day (95% CI .1, 7.8) and decreased their percentage of calories from saturated fat by 1.7% (95% CI -2.7, -.7). This study signifies that IVR can be used as a means to provide dietary counseling and improve overall diet.

Glasgow and colleagues described using an IVR in combination with CD-ROM as a part of an interactive diet intervention called WISE CHOICES in a process paper (2009). This program was intended to help women increase their fruit and vegetable intake and decrease their

consumption of dietary fat. The IVR calls were tailored to the participants based on their current and past levels of progress and helped them address barriers to making dietary changes. Although effects are not reported, the researchers reported on engagement (IVR completion rate) and participant satisfaction with the intervention. The results indicate that the IVR call completion rate varied from 72% for the first call to 68% for the third call. The automated phone calls were rated less helpful than the in-person and combined conditions. There is no conclusive evidence that IVR is more effective than in-person delivery. More research needs to compare the efficacy of these two delivery methods. The participants in the entirely automated arm rated their satisfaction as moderately satisfied overall while their ratings of the personalized feedback were equivalent to those of participants in the in-person arm. This study indicates that IVR can be well received by participants in a diet intervention (Glasgow et al., 2009).

Participant Engagement and Satisfaction with IVR

Although not specific to nutrition and physical activity, a few studies have reported on participants' engagement and satisfaction with IVR-based interventions. It is important to consider engagement and satisfaction because these factors may vary by class and health literacy status.

Piette reported on participant satisfaction with IVR from two RCTs (2011). The participants were 256 diabetic adults who were participants in the intervention groups of 2 RCT. More than 50% of participants were non-white and 43% had annual household incomes <$10,000. Many participants also had limited formal education and were obese. In both interventions, participants reported their self-care to an IVR every two weeks. The calls also included an opportunity to listen to tips and educational messages related to diabetes and diet. At the 12-month follow-up, participants responded to questions about their impressions of the IVR.

Three questions were single-item indicators of their satisfaction with the IVR. The other 11 questions were related to the ease of completing the calls, the perceived usefulness of the calls, and the intrusiveness of the calls.

Overall, 85% were satisfied (53% indicated that they were very satisfied and 32% were moderately satisfied) with the calls. Eighty-two percent indicated that they would be more satisfied with their care if ATDM calls were available to them and 76% would choose to receive similar calls in the future. Ratings of their satisfaction with the ease of the calls, usefulness of the calls, and intrusiveness of the calls were high. The majority of participants (80%) did not have difficulty answering the questions by pushing their touch-tone keypad. Participants who indicated that they were satisfied with the calls were more likely to complete more of the calls. Participants in the intervention groups of both RCTs had better one-year outcomes than those who received usual care. Spanish-speaking participants were more likely to report that the IVR calls were useful.

Results of bivariate and multivariate analyses revealed that satisfaction with the calls was not associated with patients' system of care, clinical characteristics at enrollment, or sociodemographic characteristics. This study demonstrates that participants generally view IVR favorably and that IVR can generate improved outcomes (Piette, 2011).

In a qualitative study of a RCT, Lambert-Kerzner and colleagues investigated patients' perspectives of an IVR that was used to monitor patients' blood pressure (BP) (2011). Of the 146 participants in the "Improving Blood Pressure in Colorado" study, 78 patients were randomized to the intervention group and received IVR calls. The majority of participants were male (81.5%) and were 50 years and older (87%). Fifty-two percent were non-Hispanic white, 23% Hispanic, 19% African American, and 4% Native American. In the intervention group, participants

performed at home BP monitoring and reported their results to an IVR every week. The IVR averaged their reported BP and provided feedback about their control of their BP. The IVR also offered the options to request a call from the pharmacist, connect to the pharmacy refill or nurse lines, and listen to educational messages. Pharmacists received reports of the participants' reported BP and worked with participants over the telephone to help them achieve their BP goals.

Eighty-six percent of participants in the intervention group reported that they had a positive experience with the study such as building a relationship with medical personnel, feeling empowered to talk to their healthcare provider, improving their health behavior, or increasing their health care knowledge. Some participants (32%) indicated that the intervention made them more motivated to be an active participant in their health care. The majority (78%) reported that IVR increased awareness of their BP and increased knowledge of BP definitions, implications of excessive salt intake and lack of exercise, and the importance of BP on health. Participants in both groups increased their self -efficacy in their ability to make behavior changes. Almost all of the participants (90%) reported that the IVR was user-friendly and supported their goal of lowering their BP as well as addressing other barriers (Lambert-Kerzner et al., 2011).

The researchers did not examine how satisfaction varied by socioeconomic status, which is a limitation of this study. However, the positive perceptions of intervention participants in this study suggest that the IVR was helpful in making behavior changes and that it increased participants' knowledge of how to self-manage their condition.

Use of IVR in Vulnerable Populations

There is some evidence to support that IVR-based interventions are feasible in vulnerable, hard-to-reach populations. Schillinger and colleagues conducted an effectiveness

study and three-arm RCT as a part of the Improving Diabetes Efforts Across Language and Literacy (IDEALL) Project (2009). The study aimed to determine the reach of automated telephone disease management (ATDM) and group medical visits (GMV) in patient participation, representativeness, and engagement. The subjects consisted of 339 diabetic adults with mean age of 56 years. More than half had some high school education or less, half were without health insurance, and the average annual income was <$30,000. Participants spoke English, Spanish, or Cantonese. Half of English and Spanish speakers had limited health literacy. Health literacy status was assessed using the short-form Test of Functional Health Literacy in Adults (S-TOFHLA). Both ATDM and GMVs focused on collaborative goal setting and action planning.

Among the ATDM participants, engagement was high. Those with communication barriers experienced a higher level of engagement. Those who were English speaking with limited literacy were more likely develop (p=.03) and report success (p=.06) with their action plans (Schillinger et al., 2009). This study suggests that participants of low health literacy status may benefit from receiving IVR-based advice for chronic disease management.

As a part of the same study, Schillinger and colleagues examined the effect of two forms of self-management support (SMS), ATDM and GMV, on outcomes (2009). ATDM is referred to as automated telephone self-management (ATSM) in this study. Both ATSM and GMV participants showed significant increases in self-management behavior. The increase was greater in the ATSM group with an effect size of 0.34, (p=.02). ATSM participants were also more likely than GMV or usual care participants to achieve the weekly minimum recommendation of at least 30 minutes of PA three times per week. Tailored support and patient-generated action plans led to better experiences with chronic illness care, increased self-efficacy, and self-

management behaviors. The ATSM model led to greater improvements in interpersonal processes of care, PA, and functional status. This supports that an automated telephone model of self-management support can be successfully used to reach vulnerable populations.

Bennett and colleagues conducted a 2-arm, 24-month randomized effectiveness trial to examine the effect of a theory and evidence based, multifaceted intervention on weight loss and hypertension (2012). The participants included 365 obese adults undergoing treatment for hypertension. Participants were 71.2% black, 13.1% Hispanic, 68.5% female, and 32.9% had less than a high school education. The majority of participants received less than a college education and made less than $25,000 per year. Participants were randomized to usual care or an intervention utilizing eHealth components to promote weight loss and self-care for hypertension. The intervention was designed to target populations with limited literacy and numeracy skills as well as limited access to resources for health. Participants set behavior change goals and chose to use a website or an IVR to monitor their progress. Both the website and the IVR provided tailored feedback. Health educators delivered monthly counseling calls guided by principles of motivational interviewing for the first year and bimonthly for the second year. The calls emphasized self-monitoring, problem solving, and behavioral skills. Twelve monthly group educational sessions were also offered.

Compared to usual care participants, intervention participants lost more weight at the 24-month assessment. The intervention resulted in modest weight loss and this was sustained over 24-months and was associated with improved blood pressure (Bennett et al., 2012). Although this intervention was not specific to using IVR, this study demonstrates that IVR can be used in combination with other eHealth components to encourage health behavior changes in vulnerable populations.

In a RCT of diabetic adults, Piette and colleagues also established that low income, low literacy patients were willing and able to use an IVR (1999). Of the 252 patients, 30 spoke Spanish as their first language. A large percentage of the patients were poor and had limited formal education. Patients received biweekly ATDM calls for 12 months and reported self-monitored blood glucose. Engagement was relatively high with patients completing an average of 69% of the ATDM calls (Piette et al., 1999).

Sarkar and colleagues reported on the results of a telephone survey of 796 adults with diabetes (2008). Participants were surveyed about their interest in three forms of self-management support: 1) telephone support, 2) group medical visits, and 3) internet-based support. With a mean age of 56 years, one third of participants were non-Hispanic white, one third were non-Hispanic African-American, and one third were Hispanic. Most patients had low education levels and were either uninsured or publically insured.

Thirty-nine percent of participants identified themselves as having low health literacy and reported having difficulty understanding written materials. Sixty-nine percent indicated that they would be interested in telephone self-management support. Self-reported limited health literacy was associated with greater interest in telephone self-management support (p<.05). There was also an association between self-reported limited health literacy and perceived communication benefit (Sarkar et al., 2008). These results signify that IVR may be an effective means of communication with vulnerable populations.

IVR Summary Table

Authors	Intervention Outcomes	Sample	Intervention	Control	Results
Estabrooks & Smith-Ray (2007)	Diabetes prevention	77 pre-diabetic patients	90 min diabetes prevention class + 1 IVR call/week for 12 weeks	No contact after class	Weight loss was significantly higher in IVR group (p=.059).
Estabrooks et al. (2009)	PA, BMI Z-scores	220 parent-children dyads	2 group classes + 10 IVR calls	Workbook, group classes	IVR group significantly ⬇ BMI Z-scores. Higher level of parental engagement was associated with a greater effect.
Pinto et al. (2002)	PA	298 sedentary adults	PA counseling via IVR (call in 1x/week for 1st 3 mo., 2x/week next 3 mo.)	Nutrition counseling via IVR	Intervention group was more likely to meet PA recommendations.
King et al. (2007)	PA	218 sedentary adults	Automated advice arm- PA counseling via IVR (12 months)	Human advice or weekly group class	Telephone counseling groups ⬆ PA compared to control.
Sparrow et al. (2012)	Resistance training	103 older adults	IVR calls 3x per week for 12 months	Educational call 1x/week	IVR group significantly ⬆ muscle strength & balance. High ratings.
Glasgow et al. (2009)	Healthy eating	_____	IVR to monitor intake, counseling	PA counseling	IVR completion rate ranged from 68%-72%.
Delichatosis et al. (2001)	Healthy eating	298 adults	IVR to monitor diet, feedback	In-person counseling	IVR group ⬆ F&V, improved diet quality.
Piette et al. (2011)	Diabetes prevention	256 diabetic adults who were participants in the intervention	Participants reported self-care to an IVR every week. Listened to educational	Usual Care	Intervention groups had better one-year outcomes than those who received usual

		arm of 2 RCTs. Many were Spanish-speaking.	messages related to diabetes and diet.		care. 85% were satisfied with the calls. Spanish-speaking participants were more likely to report that the IVR calls were useful.
Lambert-Kerzner et al., (2011)	Blood pressure	146 adults in "Improving Blood Pressure in Colorado" study.	IVR to monitor blood pressure. Could connect to a pharmacist or nurse line and listen to educational messages.	Usual care	86% a positive experience. 32% reported that they were motivated to be an active participant in their health care. 78% reported that IVRS increased awareness & knowledge. 90% reported that the IVR was user-friendly.
Schillinger et al. (2009)	Diabetes management	339 diabetic adults. >50% had some HS or less. Avg. annual income <$30,000. Spanish & Cantonese	Automated telephone disease management calls	Group medical visits	Those with communication barriers experienced a higher level of engagement. English speaking with limited literacy were more likely to use and report success on action plans.
Schillinger et al. (2009)	Diabetes management	(Same as above)	(Same as above)	(Same as above)	ATSM showed significant ↑ in self-management behaviors (p=0.02). ATSM was more likely to achieve 30 min PA three times per week.

Bennet et al. (2012)	Weight loss and self-care for hypertension	365 obese adults, 32.9% had < HS education, avg. annual income <$25,000	E-health intervention (website or IVR)	Usual care	Intervention group lost more weight at the 24-month assessment. This was associated with improved blood pressure.
Piette et al. (1999)	Diabetes management	252 adults, 30 spoke Spanish. Most were poor and limited education.	Biweekly IVR calls for 12 months. Reported BG.	Same as intervention group	Engagement was relatively high with an average completion rate of 69%.
Sarkar et al. (2008)	Preferences for self-management support	796 diabetic adults . Most had low education levels.	Telephone survey	N/A	Self-reported limited health literacy was associated with greater interest in IVR and perceived communication benefit.

IVR Summary

Socioeconomic status, education level, and health literacy status are potential barriers to reaching certain segments of the population. IVR hold promise as a means of communicating with a variety of patient populations, including those with socioeconomic and health disparities. Future research should examine the relationship between socioeconomic status and engagement and the relationship between engagement and intervention outcomes. Although most IVR-based interventions have focused on clinical outcomes rather than health behaviors, IVR is generally viewed positively by users and has been used effectively in health behavior interventions to improve physical activity and healthy eating. The fact that many people own and can use a

telephone (Oake et al., 2007) suggests that an IVR-based intervention can be easily adopted in a number of settings, including at risk populations with low socioeconomic status, low education, and low health literacy.

It is still unknown whether or not the effectiveness of IVR-based interventions is dependent on the targeted outcome (i.e., clinical, adherence, or health behavior outcomes). It is also unclear whether the effectiveness of IVR-based interventions depends on if the IVR is used in combination with some other intervention strategy such as educational classes or in-person counseling. We know that theory based interventions are more effective (Belanger-Gravel, 2011). While some of the reviewed IVR-based interventions were guided by theory, many lacked a theoretical framework. Future health literacy and IVR-based interventions need to be guided by a health behavior theory, for example the theory of planned behavior (TPB).

Theory of Planned Behavior

The TPB was developed by Icek Ajzen in 1991 and has been used to predict and explain an array of health behaviors and intentions (Ajzen, 1991). This theory posits that attitudes, subjective norms, and perceived behavioral control all directly influence an individual's behavioral intentions, and that behavioral intentions are the best predictor of actual behavior (Montaño & Kasprzyk, 2008). Attitudes are determined by an individual's behavioral beliefs, that is, their beliefs about the result of performing a specific behavior and how they positively or negatively evaluate the outcome. Subjective norms are determined by normative beliefs, which is the perceived social pressure to perform or not perform a specific behavior. Control beliefs and perceived power determine perceived behavioral control. Control beliefs are the belief in factors that serve as facilitators or barriers to performing the behavior and how much perceived power

the individual has over these factors (Montaño & Kasprzyk, 2008). It has been shown that health behavior interventions that are grounded in theory are more effective (Belanger-Gravel, 2011).

The TPB has been used to explain many different health behaviors including nutrition and physical activity. The majority of health behavior studies using the TPB are cross-sectional and quantitative studies. Future studies should use qualitative data to explore the cultural beliefs associated with health behaviors (Krzeski et al., 2012). Overall, the TPB has successfully led to behavior change in physical activity and nutrition interventions.

Southwest Virginia

One vulnerable US region that may benefit from health behavior interventions is rural Southwest Virginia. Southwest Virginia lies in the Appalachian region, which runs from Southern New York to Northern Mississippi, Alabama, and Georgia. This region has been labeled as a medically underserved area (Virginia Department of Health). Appalachian is generally characterized by high rates of poverty, low access to health care, and low educational attainment. In fact, habitants of this region suffer from economic, educational, and health disparities. Compared to the rest of the state, Southwest Virginians have higher rates of obesity, diabetes, and mortality (Virginia Department of Health). In an 11 county region of southwest Virginia, the average socioeconomic status and educational attainment of individuals in this region is lower than the state average (US Census Bureau, 2010).

On average, adults in the United States consume approximately 175 calories from SSB per day and children consume 172 calories from SSB per day (Brownell et al., 2009). Preliminary data show that SSB consumption is also a significant problem in this population (Zoellner et al., In press). A pilot study of 119 participants in Southwest Virginia revealed that

the average daily intake of SSB was 457 kilocalories (±430) kcal/day) or 38 fluid ounces per day, which is well over the recommendation of consuming 8 ounces or less of SSB per day. It was found that 82% of respondents exceeded this recommendation. This demonstrates the need for tailored interventions to reduce SSB consumption in this population.

Krzeski and colleagues conducted focus groups in the target population and used the TPB to investigate their beverage behaviors. The focus groups revealed that the top four barriers to reducing SSB consumption in this population are taste, habit/addiction, convenience/availability, and cost (Krzeski et al., 2011?). Interventions targeting SSB consumption in this population should address these barriers.

Conclusions

Across these studies reviewed, we have identified many strengths such as the potential for the teach to goal approach as an effective strategy for low health literate individuals and IVR as a strategy for reaching vulnerable populations. We have also identified several gaps in the literature including health literacy interventions that target nutrition and physical activity behaviors, health literacy interventions that explore how engagement and effect vary across health literacy levels, and the utility and implications of using the teach back and teach to goal approaches for low health literate individuals. In addition, the majority of the IVR literature focuses on clinical outcomes and not health behavior outcomes such as diet and physical activity. Future research should explore how IVR-based interventions can be used to improve nutrition and physical activity behaviors in hard to reach populations.

Primary Aims and Hypotheses

Our primary aim is to explore the relationships among health literacy and indicators of success with the teach back call and interactive voice response system. Specifically, we will account for randomized condition and explore associations among health literacy status and:

a) Level of intervention engagement (i.e., completion rates for teach back call, IVR calls, and small group classes

b) Number of rounds of teach back needed to reinforce key concepts

c) Proportion of answers correct on the first round of teach back

d) Perceptions of the intervention components

We hypothesize that participants with higher health literacy will require significantly fewer rounds of teach back and answer significantly more questions correct on the first round of teach back. We also hypothesize that engagement and perceptions of the intervention components will be the same across health literacy levels.

Chapter 2: The Role of Health Literacy in Intervention Engagement, Teach Back
Performance, and Perceptions of Intervention Components

Introduction

Low health literacy, excessive sugar sweetened beverage (SSB) consumption, and physical inactivity are significant problems affecting our country. While the associations between low health literacy and poorer health outcomes have been well documented (Berkman et al., 2011), the literature lacks evidence of effective strategies to address health literacy in the context of health behaviors such as diet and physical activity. Likewise, few interventions have explored how engagement and effect vary across literacy levels. While a variety of health literacy strategies have been applied across health interventions, such as improving readability, limiting the number of messages, and supplementing instructions with pictures, other strategies such as the teach back method and interactive voice response (IVR) technology have not been widely explored in the literature, yet hold promise as a means of improving health literacy and reaching vulnerable, low health literate populations (Paasche-Orlow et al., 2005; Baker et al., 2011; Schillinger et al., 2009; Bennett et al., 2012; Piette et al., 1999).

To date, only two known health literacy studies have tested the effectiveness of the teach back or teach to goals approaches (Paasche-Orlow et al., 2005; Baker et al., 2011). The teach back method can be defined as an opportunity to recall key concepts, while the teach to goal approach requires participants to complete additional rounds of education until they demonstrate mastery of a concept or technique. These two studies suggest that the teach back and teach to goal approaches hold promise as an effective strategy to use in health literacy interventions, yet also indicate the need for additional investigation. Particularly, the need to understand how health literacy status influences performance and perception of teach back methods.

Given that low health literate individuals are known to have poorer access to clinical/medical services and less ability to navigate the healthcare system, technology also has the potential to enhance the capacity to communicate with patients using verbal formats and in non-clinical settings. One example, IVR, is emerging as a popular mode of communication in both the healthcare industry and in research. IVR allows participants to interact with a computer database using their telephone. Users listen to pre-recorded messages and are prompted to respond using their telephone keypad or speech recognition. Data are stored in a database and are used to determine the message pathways of future calls (Oake et al., 2009). IVR includes tailored responses based on current and past levels of goal achievement.

Although IVR has been used effectively in health behavior interventions to improve physical activity and healthy eating, the majority of the IVR literature focuses on clinical outcomes. Future research should explore how IVR-based interventions can be used to improve nutrition and physical activity behaviors in hard to reach populations.

The literature indicates that IVR holds promise as a means of communicating with a variety of patient populations, including those with socioeconomic and health disparities. However, few studies have reported on the influence of health literacy status on intervention engagement and perceptions of IVR (Schillinger et al., 2009; Bennett et al., 2012; Piette et al., 1999; Sarkar et al., 2008). Future research should examine the relationship between health literacy status and engagement, and the relationship between engagement and intervention outcomes.

The primary aim of this research is to explore how health literacy status influences teach back performance, intervention engagement, and perceptions of the intervention components. This research is embedded in a larger trial, Talking Health, which is a 6-month, 2 group

randomized controlled trial to determine the effects of a health behavior intervention on reducing SSB consumption in Southwest Virginians. Our primary aims are to examine the associations between health literacy status and 1) level of intervention engagement (i.e., completion rates of teach back call, IVR calls, and small group classes), 2) number of rounds of teach back needed to reinforce key concepts, 3) proportion of correct answers on the first round of teach back, and 4) perceptions of the intervention components.

Methods

Study Design

The Institutional Review Board (IRB) at Virginia Tech approved this study. Prior to enrollment, participants gave their written informed consent to participate in the study. In this 6-month, 2-group, matched-contact randomized controlled trial, participants were randomly assigned to a behavioral intervention aimed at decreasing SSB consumption (SipSmartER) or increasing physical activity (Move More). Both groups participated in three 90-minute small group education sessions in their communities and received one approximately 20 minute teach back call, and 11 IVR calls that averaged 5-10 minutes in length. The teach back call was delivered one week following the first small group education session.

Target Population

The first three cohorts of the intervention target individuals residing in the counties of Lee, Giles, and Pulaski. The majority (93.9%) of residents in these counties are white and make an average annual income of $42,873. The average educational attainment is also low, with 55% of the population receiving less than a high school education (US Census Bureau).

<u>Recruitment, Screening, and Eligibility</u>

This study used a rolling enrollment approach in which participants were recruited for subsequent cohorts while the intervention was ongoing for earlier cohorts. A variety of recruitment methods were used. In all three cohorts, participants were recruited by flyers, newspaper and radio advertisements, and word of mouth. Two Virginia Cooperative Extension agents were hired to help recruit in Lee County. Research assistants actively recruited at a free clinic, childcare center, public library, and local festival in Giles County. In Pulaski county, two Virginia Cooperative Extension agents and one Americorp-Vista agent were hired to help recruit. In addition, research assistants recruited at a variety of community venues including but not limited to a local community college, two festivals, and the public library.

Eligibility requirements included being 18 years or older, English speaking, consuming at least 200 calories per day from SSB, able to participate in moderate intensity physical activity, and having reliable access to a telephone. If participants met eligibility criteria and agreed to participate, they were scheduled for their baseline assessment.

<u>Intervention Description</u>

Constructs of the Theory of Planned Behavior (TPB) (Ajzen, 1991; Montaño & Kasprzyk, 2008) and health literacy (AHRQ, 2011; Berkman et al., 2011; Sheridan et al, 2011; Taggart et al., 2012) were used to develop the education sessions and the script for the IVR calls. In each class, participants completed personal action plans to help them reach their sugary drink and physical activity goals. The personal action plans allowed participants to set a short-term goal, long-term goal, and identify barriers and strategies to meeting these goals. Participants were also given drink diaries or exercise logs to track their progress on meeting their goals. Sip

SmartER participants used the drink diaries to track their sugary beverage intake and Move More participants used the exercise logs to track their physical activity throughout the study.

The first Sip SmartER class focused on the recommendations for sugary drinks, health risks associated with increased SSB consumption, and strategies to overcome barriers to meeting sugary drink goals. In the second class, participants learned the impact of the media and how to interpret advertisements for sugary drinks. The third Sip SmartER class included a numeracy component and participants used math to interpret nutrition labels, calculate how much money they spend on sugary drinks, and calculate how much weight they could lose by reducing their sugary drink intake.

While the Sip SmartER classes involved more hands on activities, demonstrations, and handouts, the Move More classes focused on being physically active. Each Move More class included approximately 35 minutes of physical activity in which participants used a "Walking Indoors" exercise DVD and learned various strength training exercises using resistance bands and medicine balls. In the first class, participants learned the recommendations for physical activity and what types of activities are designated as being cardiovascular and strength training. Participants also set goals for being more physically active and chose strategies to help meet these goals. In the second class, participants learned the impact of the media and how to analyze advertisements about physical activity resources. In the third class, participants learned a different set of strength training activities as a group, learned about opportunities and resources to be physical active in their communities, and received feedback on their progress.

One week following the first class, participants received a live teach back call from a member of the research staff. The teach back call provided an opportunity for participants to teach back 5 key concepts presented in the first SipSmartER class and 8 key concepts presented

in the first Move More class. The key concepts in SipSmartER included examples of SSB and healthy alternatives, the recommendation for ounces of SSB per day, and the health risks associated with drinking too many SSB. The key concepts in the Move More class included examples of cardio and strength training exercises; the recommendations for cardio and strength training, such as minutes per week, number of sets, and number of reps; and the health benefits of being physically active. Participants were also asked to explain how they track their sugary drink intake and exercise in their diaries as well as how they calculate their weekly average ounces of sugary drinks or minutes of physical activity. These were considered key concepts because they cover the majority of the information presented in the classes and require numeracy skills. When questions were missed, participants were given the correct answer and given two additional opportunities to answer the question correctly.

Subsequent to the live teach back call, participants received an IVR call each week for the first four weeks. Calls were then delivered biweekly for the remainder of the intervention. The basic structure of the IVR calls was the same for all 11 calls. Each call asked participants to report their average SSB intake or minutes of physical activity. The calls also included goal setting and personalized feedback on progress, addressed barriers and strategies, and a weekly supportive message. The supportive messages were guided by constructs of the TPB, health literacy, media literacy, and numeracy.

Retention Strategies

Participants' class attendance and call completion and were tracked across the 6-month intervention. Several retention strategies were used. First, participants received mailed reminder post cards one week prior and a live reminder call 1-3 days prior to all data assessment and small group classes. Second, participants who missed the group sessions were mailed a packet of the

class materials and also received a live missed class call that recapped the lesson. Third, participants who missed two consecutive contacts (i.e., two IVR calls or a group session and an IVR call) received a live supportive call from our research staff. Forth, letters were mailed to hard-to-reach participants who missed several calls and did not attend the classes requesting that participants mail back the last page of the letter to confirm their address, telephone number, and alternate contact information.

Data Collection and Outcome Measures

To ensure standardization and consistency, a data collection manual of procedures was developed and all research staff were trained prior to data collection. Data collection occurred at baseline and at the 6-month follow-up assessment. The baseline assessment consisted of two appointments, each lasting 45-60 minutes. The outcome assessment included a variety of validated behavior, theory, health and media literacy, and quality of life measures (CDC, 2000; Fagerlin et al., 2007; Godin et al., 1996; Hedrick et al., 2010; Kiernan et al., 2011; Moshfegh et al., 2001; Primack et al., 2009; Zikmund-Fisher et al., 2007). The Newest Vital Sign, a validated health literacy measure, was interview-administered at baseline (Weiss, 2005). According to the NVS scoring protocol, health literacy status was collapsed into two categories, low health literacy (LHL) and high health literacy (HHL). A score of 0-3 represented LHL, or a possibility of limited literacy, and a score of 4-6 represented HHL, or adequate literacy. Participants received gift cards to Wal-Mart as an incentive to participate in the study, including $25 and $50 at the baseline and 6-month follow-up assessments, respectively.

Process and Summative Evaluation

Research assistants tracked completion rates for education sessions attendance, the teach back call, and IVR calls. IVR call completion via the IVR graphical user interface (GUI). The IVR GUI stores all IVR call data and generates reports of participants' responses.

Participants completed a summative evaluation at the 6-month follow-up assessment in which they were interviewed about their 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. Participants were asked the degree to which they agree or disagree with the statements and how satisfied (10-point Likert-scale, 1= completely dissatisfied or strongly disagree, 10 = completely satisfied or strongly agree) they were with the various components of the intervention (Appendix C).

<u>Data Analysis</u>

All quantitative analyses were conducted using SPSS version 20.0. All data were scored according to validated and standardized coding procedures. Descriptive statistics were used to summarize quantitative data. One-way ANOVAs and chi-squared tests were used to examine baseline differences between SipSmartER and MoveMore groups, as well as differences between health literacy groups. ANOVAs were used to measure differences by health literacy status, by randomized condition, and interaction effects. Cronbach's alpha test was used to assess the internal consistency of items for five sub-scales on the summative evaluation and all values are reported. In brief, three sub-scales for perceptions of the IVR, small group sessions and personalized action plans achieved good internal consistency ($\alpha > 0.7$). On the contrary, perceptions of the personalized action plan had moderate internal consistency ($\alpha > 0.567$), and the internal consistency for perceptions of the teach back call subscale increased from an α of 0.435 to 0.674 when deleting one reverse scored item.

Our hypotheses included: 1) participants with higher health literacy will require significantly fewer rounds of teach back and answer significantly more number of questions correct on the first round of teach back, 2) engagement and perceptions of the intervention components will be the same across health literacy levels.

Results

Participants

Of the 125 enrolled participants, 63 were randomized to Sip SmartER and 62 were randomized to Move More at the baseline assessment. **Table 1** illustrates the demographic information. Of participants, the majority were female (76.8%) and Caucasian (92.0%). Education status indicated that 29.6% of participants completed less than or equal to high school as their highest level of education and 70.4% of participants completed some education beyond high school. Income status indicated that 64.0% of participants made <$25,000 per year. Employment status indicated that 49.6% were employed (i.e., full time, part time, or self-employed), 9.6% were unemployed, and 40.8% were considered other (i.e., homemaker, student, retired, or unable to work). According to the NVS scoring protocol, 32.8% of participants were categorized as having LHL and 66.4% were categorized as having HHL. Insurance status indicated that 30.4% of participants were uninsured and 69.6% had some type of health insurance.

Chi-squared tests revealed no significant differences between Sip SmartER and Move More for gender, race/ethnicity, education level, income status, employment status, number of children in the home under 18 years of age, health literacy status, or insurance status. However, marital status was statistically different between groups (p= 0.050). More Move More

participants were married compared to Sip SmartER [Move More= 27 (44.3%), Sip SmartER= 22 (34.9%)].

Intervention Engagement

Participants' intervention engagement was assessed by class attendance, completion of the teach back call, and IVR call completion rate. There was no significant difference in class attendance by randomized condition [Sip SmartER 2.38 (SD=0.90) classes; Move More 2.42 (SD=0.72) classes (F= 0.027, p=0.870)] or by health literacy status [LHL= 2.47 (SD=0.62) classes; HHL= 2.36 (SD=0.90) classes (F= 0.204, p= 0.653)]. Similarly, there was no significant difference in the completion rate of the teach back call by randomized condition (68.3% of Sip SmartER; 68.9% of Move More)(p=0.903) or by health literacy status (LHL= 78.0%; HHL= 63.9%) (p=0.252). The average IVR completion rate for Lee and Giles County was 60.5%, with 59.6% of calls completed via the automated call system and 0.94% completed live. IVR call completion was not significantly different by health literacy status (F= 0.395, p= 0.532) or by randomized condition [Sip Smarter= 7.53 (SD= 3.85) calls; Move More = 6.75 (SD= 3.39) calls (F= 0.613, p= 0.437)].

Performance on the Teach Back Call

Table 2 illustrates performance on the teach back call. When looking at the degree to which health literacy status and randomized condition predicted the number of rounds of teach back needed to reinforce key concepts from the first group class, the overall model was significant (F= 8.323, p<0.001). LHL participants required significantly more rounds of teach back to as compared to HHL participants (F= 16.769, p<0.001) and Move More participants required significantly more rounds of teach back as compared to Sip SmartER participants (F=

7.296, p= 0.008). Similarly, health literacy status and randomized condition significantly predicted the proportion correct on the first round of teach back (F= 9.836, p<0.001). HHL participants answered a significantly greater proportion of questions correctly on the first round of teach back than LHL participants (F= 19.176, p<0.001). Sip SmartER participants answered a significantly greater proportion of questions correctly on the first round of teach back compared to Move More participants (F= 9.783, p= 0.002).

Summative Evaluation: Perceptions of the Intervention Components

Tables 3-7 illustrate participants' perceptions of the different intervention components by health literacy status and randomized condition. For each of the five subscales, the total summed items are presented. Due to the preliminary nature of these analyses, individual items are also presented.

As indicated in **Table 3**, there were no significant differences in perceptions about the teach back call by health literacy status or by randomized condition.

Table 4 illustrates the results of six items about participants' perceptions of the IVR calls. The overall model trended towards significant (F= 0.205, p= 0.055), whereby LHL participants' overall perception of IVR was significantly higher than HHL participants (F= 5.849, p= 0.020). Individual items related to perceptions of IVR are further illustrated and in general indicated that LHL participants were more satisfied with the IVR calls. LHL participants were more likely to indicate that the system was easy to use (F= 3.123, p= 0.035) and that they would use the automated call system again (F= 5.694, p= 0.021). Additionally, LHL participants were more satisfied with the length of the calls (F= 4.515, p= 0.039), and rated their overall satisfaction with the calls significantly higher (F= 8.829, p= 0.005) than HHL participants.

Table 5 illustrates the results for the items about their perceptions of the group classes. The only item for which there was a significant difference by group was the question about their satisfaction with how the classes were organized. Sip SmartER participants reported a significantly higher number than Move More participants for this question (F= 4.002, p= 0.051).

Table 6 illustrates the results for the items about their perceptions of the personal action plans, which were completed in each of the group classes. There were no significant differences by health literacy status or by randomized condition for the overall personal action plan score or for any of the individual items.

Table 7 illustrates the results for the items about their perceptions of the drink diaries and exercise logs. There were no significant differences in the overall diaries/logs score by randomized condition or by health literacy status. The only item for which there was a significant difference by group was the question about their satisfaction with how the drink diaries/exercise logs were set up. The overall model was significant (F= 3.487, p= 0.023) and Sip SmartER participants reported a significantly higher number than Move More participants (F= 5.707, p= 0.021).

The summative evaluation ended with a few summary questions about the various resources provided and about participants' satisfaction with the access and availability of the research staff. Participants rated their satisfaction with the access and availability of the research staff as 9.41 out of 10 (SD= 1.43) with no significant differences by literacy status (F= 0.571, p= 0.453) or randomized condition (F= 0.001, p= 0.972). Finally participants were asked which component of the intervention was the most motivating. The majority of participants (77.4%) reported that the group classes were the most motivating component. Participants also indicated

that the drink diaries/exercise logs (n=6), the automated calls (n=4), the resources (n=5), or some other component (n=13) were the most motivating.

Discussion

This is one of few known health literacy studies to employ the teach back method and IVR technology as potential strategies to use with low health literate individuals. This research adds to the health literacy body of literature because these two potential intervention strategies have not been widely explored. Only two known studies have investigated the utility and implications of the teach back and teach to goal methods in health behavior studies (Paasche-Orlow et al., 2005; Baker et al., 2011). Likewise, few IVR-based health behavior interventions have investigated the utility of using IVR in low health literate populations (Schillinger et al., 2009; Bennett et al., 2012; Piette et al., 1999; Sarkar et al., 2008).

Our analyses uncovered some interesting results about how health literacy status and randomized condition influence success with the teach back call, level of intervention engagement, and perceptions of the various intervention components. Our results indicate that LHL participants required significantly more rounds of teach back to reinforce key concepts compared to HHL participants. This supports our hypothesis, but refutes what research has been done on the effectiveness of using the teach back and teach to goal methods with LHL individuals (Paasche-Orlow et al., 2005; Baker et al., 2011). In both studies, inadequate health literacy was not associated with difficulty in learning or retaining instructions, indicating that the teach back method was equally effective across literacy levels (Paasche-Orlow et al., 2005; Baker et al., 2011). Differences between these findings and our study findings could be related to differences in the subjects explored (i.e., asthma, heart failure, SSB, and physical activity), or differences in the demographic characteristics of the study sample.

We also hypothesized that HHL participants would answer significantly more questions correct on the first round of teach back, which was supported by our study. Additionally, although not significant, LHL participants' perceptions of the teach back call indicate that this method was better received by LHL participants than by HHL participants.

Unexpectedly, Move More participants required significantly more rounds of teach back compared to Sip SmartER participants. There are a few possible explanations for the differences between the two groups' performance on the teach back call. One is the complexity of the recommendations for the behaviors. The recommendations for physical activity are more complex than the recommendations for SSB consumption thus Move More participants had to recall more information than Sip SmartER participants. Specifically, Move More participants had to recall more numbers. They were asked to recall the recommendation for minutes of physical activity each week, which is divided into days and minutes of cardio and strength training exercises, as well as the recommendation for the number of sets and reps for strength training exercises. Sip SmartER participants only had to remember one number, the recommendation for ounces of SSB per day.

Another factor that could have led to differences between groups on the teach back call is the structure of the group classes. Information was delivered differently in the two group classes. For example, the first Sip SmartER class included a PowerPoint presentation, demonstrations, visual aids, and several activities. All of these interactive components provided participants with more visual cues to the behavior. The Move More class was also interactive, but the focus of the class was on physical activity and the information was presented in more of a discussion format. Perhaps having more visual cues and a more interactive lesson helped Sip SmartER participants learn the information better in the first group class.

Another option to explore in further analyses is an item analysis of the teach back call questions. Perhaps we need to revisit the wording complexity of the questions. Future exploration of the data should include this to help us better understand why those differences existed.

Our data confirm the need for additional exposure to health information and multiple teach back opportunities to ensure participant comprehension of key intervention content—in particular for those with lower health literacy. This research supports that the teach back method is an effective strategy to overcome barriers to inadequate health literacy. The teach back method is applicable to many different patient scenarios and could be used by healthcare providers to reinforce health promotion and self-management behaviors. This technique is both time and labor intensive, which may be a barrier to applying this technique on a larger scale. Future research should investigate the efficacy of delivering the teach back method using automated technologies to make the process more cost-effective. Future research is needed to determine how teach to goal findings are related to other study factors such as retention, engagement, and health outcomes.

The results of participants' intervention engagement were what we hypothesized; health literacy status did not influence intervention engagement. Overall group class attendance and overall IVR completion rate were similar to what has been reported in other IVR-based interventions (Piette et al., 1999; Estabrooks & Smith-Ray, 2007). Further research should investigate whether using IVR in combination with a personal component improves engagement.

As supported by the findings of other IVR-based interventions (Piette et al., 2011; Lambert-Kerzner et al., 2011), overall perceptions of the automated call system were generally high (mean 7.35 out of 10, SD= 2.50). However, LHL participants had a significantly higher

overall IVR score compared to HHL participants. LHL participants also reported a significantly higher number for their satisfaction with the length of the call and for how strongly agreed that they would use this system again as tool to provide them with strategies to promote healthy living. This suggests that IVR is an effective strategy to reach vulnerable, low health literate populations, which is also supported by the literature (Schillinger et al., 2009; Bennett et al., 2012; Piette et al., 1999; Sarkar et al., 2008). The fact that the scores for the overall satisfaction with the IVR calls was significantly higher among LHL participants suggests that LHL individuals are more receptive to using an automated call system than HHL individuals.

One limitation of this study is that the Sip SmartER and Move More classes were structured differently. Sip SmartER was very engaging and hands on while Move More was also engaging, but focused more on physical activity. This may have led to differences in the two group's performance on the teach back call. Another limitation is our small sample size, which is due to having data available from the first three cohorts. As more cohorts progress through the intervention, we will have a better understanding of how health literacy status influences teach back performance, intervention engagement, and perceptions of intervention components, as well as be able to understand how health literacy status and level of engagement influence behavioral outcomes.

In conclusion, our study findings suggest that the teach back method is an effective strategy to overcome barriers to inadequate health literacy. This research helps fill an important gap in the health literacy literature because there is a need for a greater focus on health literacy in health behavior interventions.

This research also sheds light IVR as an effective strategy to reach vulnerable, hard to reach populations. Low health literate individuals are known to have poorer access to

clinical/medical services and less ability to navigate healthcare systems, yet this has been the

primary setting to reach and implement the majority of health literacy interventions reported

here. Given the potential of technology to enhance the capacity of healthcare providers to

communicate with patients and reach them in non-clinical settings, there is a need to further

explore the utility of technology in health literacy interventions. This research has examined how

participants' engagement, satisfaction, and health literacy status influenced indicators of success

with IVR. Our results indicate that IVR technology is generally viewed positively and that lower

health literate individuals are more receptive to this type of intervention strategy.

Table 1. Demographic Characteristics of Enrolled Participants at Baseline

	All Participants (N= 125)	Sip SmartER (N = 63)	Move More (N = 62)	
	(N, %)	(N, %)	(N, %)	p-value [a]
Gender				
Female	96 (76.8)	49 (77.8)	46 (75.4)	0.755
Male	29 (23.2)	14 (22.2)	15 (24.6)	
Race/Ethnicity				
White	115 (92.0)	55 (87.3)	59 (96.7)	0.054
Other	10 (8.0)	8 (12.7)	2 (3.3)	
Marital Status				
Married	50 (40.0)	22 (34.9)	27 (44.3)	
Never Married	37 (29.6)	25 (39.7)	12 (19.7)	0.050
Other (Divorced, Widowed, Separated)	38 (30.4)	16 (25.4)	22 (36.1)	
Education Level				
≤ High School	37 (29.6)	20 (31.7)	17 (27.9)	0.637
> High School	88 (70.4)	43 (68.3)	44 (72.1)	
Income Status				
< $5,000	12 (9.6)	7 (11.1)	5 (8.2)	
$5,000- 14,999	43 (34.4)	21 (33.3)	22 (36.1)	0.253
15,000-25,000	25 (20.0)	16 (25.4)	8 (13.1)	
> $25,000	45 (36.0)	19 (30.2)	26 (42.6)	
Employment Status[1]				
Employed	62 (49.6)	27 (42.9)	34 (55.7)	
Unemployed	12 (9.6)	6 (9.5)	6 (9.8)	0.307
Other (Homemaker, Student, Retired, Unable to work)	51 (40.8)	30 (47.6)	21 (34.4)	
Children in the home under 18 years of age				
0	64 (51.2)	31 (49.2)	33 (54.1)	0.778
1	34 (27.2)	19 (30.2)	15 (24.6)	
2 or more	27 (21.6)	13 (20.6)	13 (21.3)	
Health Literacy Status				
Low Health Literacy (NVS Score 0-3)	41 (32.8)	21 (33.3)	20 (32.8)	0.948
High Health Literacy (NVS Score 4-6)	83 (66.4)	42 (66.7)	41 (67.2)	
Insurance				
Uninsured	38 (30.4)	18 (28.6)	19 (31.1)	0.754
Insured	87 (69.6)	45 (71.4)	41 (68.9)	

[1]Numbers do not add up to 100% because participants could report multiple employment statuses.

Table 2. Performance on the Teach Back Call

	Sip SmartER N = 43		Move More N = 42		P (F) Difference HHL, LHL	P (F) Difference Sip, Move	P (F) Interaction	P (F) Overall Model
	LHL (mean, SD) N = 18	HHL (mean, SD) N = 25	LHL (mean, SD) N = 14	HHL (mean, SD) N = 28				
Number of Rounds of Teach Back[1]	1.89 (0.68)	1.24 (0.44)	2.14 (0.77)	1.70 (0.54)	<0.001 (16.769)	0.008 (7.296)	0.432 (0.623)	<0.001 (8.323)
Proportion Correct on First Round of Teach Back[2]	0.72 (0.27)	0.95 (0.09)	0.62 (0.24)	0.78 (0.20)	<0.001 (19.176)	0.002 (9.783)	0.452 (0.571)	<0.001 (9.836)

LHL = Low health literacy, HHL= High health literacy

[1]Number of rounds of teach back: Participants were given 3 opportunities to teach back key concepts from the first group class.

[2]The proportion correct on the first round of teach back is the proportion of questions that they answered correctly on the first attempt. Sip SmartER participants answered 5 questions and Move More participants answered 8 questions.

<p style="text-align:center">Table 3. Perceptions of the Teach Back Call (N=47)[1]</p>

Questions	Sip SmartER		Move More		P (F) Difference HHL, LHL	P (F) Difference Sip, Move	P (F) Interaction	P (F) Overall Model
	LHL (mean, SD)	HHL (mean, SD)	LHL (mean, SD)	HHL (mean, SD)				
Overall Teach Back Call Score (3 items- Scored on a scale of 0-30)[2]	26.00 (4.85)	25.19 (4.20)	27.29 (2.93)	25.79 (3.60)	0.368 (0.827)	0.463 (0.549)	0.788 (0.073)	0.730 (0.434)
Overall Teach Back Call Score (2 items- Scored on a scale of 0-20)[3]	17.78 (3.27)	15.94 (4.63)	18.57 (2.51)	17.21 (2.33)	0.150 (2.151)	0.348 (0.902)	0.826 (0.049)	0.353 (1.118)
Going through this material personally with the staff on the telephone helped me learn the material better.[4]	9.00 (1.32)	8.31 (2.15)	9.29 (1.25)	7.93 (1.91)	0.079 (3.48)	0.560 (0.345)	0.560 (0.345)	0.326 (1.186)
Answering the questions was difficult.[4,5]	8.22 (2.86)	9.25 (0.86)	8.71 (1.80)	8.13 (2.42)	0.724 (0.126)	0.622 (0.246)	0.208 (1.634)	0.440 (0.919)
For future programs, I would recommend this strategy where staff personally call and review the class materials.[4]	8.78 (1.99)	7.63 (3.01)	9.29 (1.25)	9.29 (0.914)	0.386 (0.767)	0.107 (2.715)	0.386 (0.767)	0.145 (1.893)

LHL = Low health literacy, HHL= High health literacy

[1]N= 47. Sample varies slightly across each table due to missing responses.

[2]Cronbach α = 0.435 for the 3-item Overall Teach Back Call Score.

[3]Cronbach α = 0.674 for the 2-item Overall Teach Back Call Score.

[4]Participants were asked to rate their agreement with these statements on a 10-point Likert-scale with 1 being strongly disagree and 10 being strongly agree.

[5]Item 2 was reverse coded so that the most positive response corresponded with 10 and the most negative response corresponded with 1.

Table 4. Perceptions of the IVR Calls (N= 50)[1]

Questions	Sip SmartER		Move More		P (F) Difference HHL, LHL	P (F) Difference Sip, Move	P (F) Interaction	P (F) Overall Model
	LHL (mean, SD)	HHL (mean, SD)	LHL (mean, SD)	HHL (mean, SD)				
Overall IVR Score (6 items- Scored on a scale of 0-60)[2]	48.00 (14.12)	43.67 (13.10)	49.38 (10.45)	35.17 (11.54)	0.020 (5.849)	0.358 (0.864)	0.205 (1.659)	0.055 (2.744)
The automated calls provided me with useful strategies to help reduce my sugary drinks/be more physically active.[3]	7.78 (2.54)	6.17 (3.01)	7.50 (2.62)	6.64 (1.74)	0.116 (2.575)	0.898 (0.017)	0.626 (0.240)	0.390 (1.027)
The automated telephone system was easy to use.[3]	9.33 (1.41)	9.06 (1.11)	8.38 (2.33)	7.14 (2.85)	0.217 (1.565)	0.022 (5.659)	0.433 (0.625)	0.035 (3.123)
The automated telephone system was personal.[3]	6.11 (4.11)	7.00 (2.77)	7.50 (3.12)	5.21 (3.02)	0.468 (0.536)	0.836 (0.043)	0.103 (2.768)	0.315 (1.216)
I was satisfied with the length of each call.[3]	8.00 (3.28)	7.28 (2.61)	8.88 (1.64)	5.93 (3.38)	0.039 (4.515)	0.785 (0.075)	0.204 (1.660)	0.120 (2.054)
I would use an automated telephone system again as a tool to provide me with strategies to promote healthy living.[3]	8.11 (3.52)	7.00 (3.46)	8.38 (2.77)	4.71 (3.27)	0.021 (5.694)	0.317 (1.022)	0.209 (1.626)	0.044 (2.933)
Overall, how satisfied were you with the automated telephone calls?[3]	8.67 (2.18)	7.17 (2.79)	8.75 (1.39)	6.13 (2.19)	0.005 (8.829)	0.493 (0.477)	0.422 (0.657)	0.025 (3.424)

LHL = Low health literacy, HHL= High health literacy

[1.] N= 50. Sample varies slightly across each table due to missing responses.

[2.] Cronbach α = 0.852 for the Overall IVR Score.

[3.] Participants were asked to rate their agreement/satisfaction on a 10-point Likert-scale with 1 being completely dissatisfied or strongly disagree and 10 being completely satisfied or strongly agree.

Table 5. Perceptions of the Group Classes (N= 51)[1]

Questions	Sip SmartER		Move More		P (F) Difference HHL, LHL	P (F) Difference Sip, Move	P (F) Interaction	P (F) Overall Model
	LHL (mean, SD)	HHL (mean, SD)	LHL (mean, SD)	HHL (mean, SD)				
Overall Group Classes Score (3 items- Scored on a scale of 0-30) [2]	28.22 (2.73)	28.28 (2.61)	27.12 (3.00)	27.69 (2.29)	0.697 (0.154)	0.295 (1.124)	0.749 (0.104)	0.731 (0.432)
How satisfied were you with how the classes were organized?[3]	9.33 (1.00)	9.56 (0.70)	8.75 (1.16)	9.07 (0.88)	0.320 (1.011)	0.051 (4.002)	0.861 (0.031)	0.167 (1.764)
How satisfied were you with the type of information presented in the group classes?[3]	9.67 (0.71)	9.50 (0.99)	9.38 (0.92)	9.33 (1.05)	0.716 (0.134)	0.425 (0.647)	0.827 (0.048)	0.853 (0.262)
How satisfied were you with the type of activities presented in the group classes?[3]	9.22 (1.39)	9.22 (1.17)	9.00 (1.20)	9.40 (0.74)	0.549 (0.365)	0.947 (0.005)	0.549 (0.365)	0.873 (0.233)

LHL = Low health literacy, HHL= High health literacy

[1.] N= 51. Sample varies slightly across each table due to missing responses.

[2.] Cronbach $\alpha = 0.832$ for the Overall Group Classes Score.

[3.] Participants were asked to rate their satisfaction on a 10-point Likert-scale with 1 being completely dissatisfied and 10 being completely satisfied.

Table 6. Perceptions of the Personal Action Plans (N= 53)[1]

Questions	Sip SmartER		Move More		P (F) Difference HHL, LHL	P (F) Difference Sip, Move	P (F) Interaction	P (F) Overall Model
	LHL (mean, SD)	HHL (mean, SD)	LHL (mean, SD)	HHL (mean, SD)				
Overall Personal Action Plans Score (3 items- Scored on a Scale of 0-30)[2]	26.44 (4.07)	24.17 (3.60)	24.13 (5.28)	22.75 (4.74)	0.164 (2.002)	0.155 (2.094)	0.728 (0.122)	0.256 (1.394)
How satisfied were you with how the personalized action plans were set up?[3]	9.11 (2.03)	8.83 (1.29)	8.75 (1.75)	8.50 (1.67)	0.589 (0.296)	0.478 (0.512)	0.977 (0.001)	0.835 (0.287)
You did a good job completing the personalized actin plans.[3]	7.89 (2.71)	6.84 (2.57)	7.25 (2.19)	5.81 (2.04)	0.085 (3.085)	0.244 (1.392)	0.784 (0.076)	0.194 (1.632)
Completing the personalized action plans were helpful.[3]	9.44 (1.33)	8.26 (2.08)	8.13 (2.36)	8.44 (2.10)	0.473 (0.524)	0.345 (0.911)	0.219 (1.550)	0.481 (0.836)

LHL = Low health literacy, HHL= High health literacy

[1.] N= 53. Sample varies slightly across each table due to missing responses.

[2.] Cronbach $\alpha = 0.567$ for the Overall Personal Action Plans Score.

[3.] Participants were asked to rate their agreement/satisfaction on a 10-point Likert-scale with 1 being completely dissatisfied or strongly disagree and 10 being completely satisfied or strongly agree.

Table 7. Perceptions of the Drink Diaries/Exercise Logs (N= 53)[1]

Questions	Sip SmartER		Move More		P (F) Difference HHL, LHL	P (F) Difference Sip, Move	P (F) Interaction	P (F) Overall Model
	LHL (mean, SD)	HHL (mean, SD)	LHL (mean, SD)	HHL (mean, SD)				
Overall Diaries/Logs Score (3 items- Scored on a Scale of 0-30)[2]	27.00 (6.73)	27.00 (5.34)	26.67 (4.50)	23.42 (6.64)	0.475 (0.524)	0.390 (0.761)	0.475 (0.524)	0.444 (0.919)
How satisfied were you with how the drink diaries/exercise logs were set up?[3]	9.67 (0.71)	9.10 (1.33)	8.75 (1.17)	7.53 (2.67)	0.093 (2.943)	0.021 (5.707)	0.535 (0.391)	0.023 (3.487)
You did a good job completing the drink diaries/exercise logs.[3]	7.22 (3.03)	7.30 (2.62)	7.75 (2.05)	5.47 (2.47)	0.156 (2.075)	0.398 (0.727)	0.130 (2.378)	0.122 (2.029)
Completing the drink diaries/exercise logs were helpful.[3]	8.33 (3.04)	8.20 (2.31)	8.13 (2.10)	7.60 (2.44)	0.654 (0.204)	0.582 (0.307)	0.790 (0.072)	0.872 (0.235)

LHL = Low health literacy, HHL= High health literacy

[1.] N= 53. Sample varies slightly across each table due to missing responses.

[2.] Cronbach α = 0.704 for the Overall Diaries/Logs Score

[3.] Participants were asked to rate their agreement/satisfaction on a 10-point Likert-scale with 1 being completely dissatisfied or strongly disagree and 10 being completely satisfied or strongly agree.

References

Agency for Healthcare Research and Quality (2011). Health Literacy Interventions and Outcomes: An Updated Systematic Review.

Abu-Hasaballah, K., James, A., & Aseltine, R. H., Jr. (2007). Lessons and pitfalls of interactive voice response in medical research. *Contemporary Clinical Trials, 28*(5), 593-602. doi: 10.1016/j.cct.2007.02.007

Ajzen, I. (1991). The Theory of Planned Behavior. *Organizational Behavior and Human Decision Processes*, 50,179-211.

Alemi, F., Alemagno, S. A., Goldhagen, J., Ash, L., Finkelstein, B., Lavin, A., Butts, J., Ghadiri, A. (1996). Computer reminders improve on-time immunization rates. *Medical Care, 34*(10), OS45-OS51.

Allen, K., Zoellner, J., Motley, M., & Estabrooks, P.A. (2011). Understanding the Internal and External Validity of Health Literacy Interventions: A Systematic Literature Review Using the RE-AIM Framework. *Journal of Health Communication, 16*, 55-72.

Baker, D. W., DeWalt, D. A., Schillinger, D., Hawk, V., Ruo, B., Bibbins-Domingo, K., Weinberger, M., Macabasco-O'Connell, A., Grady, K.L., Holmes, G.M., Ernman, B., Broucksou, K.A., Pignone, M. (2011). The Effect of Progressive, Reinforcing Telephone Education and Counseling Versus Brief Educational Intervention on Knowledge, Self-Care Behaviors and Heart Failure Symptoms. *Journal of Cardiac Failure, 17*(10), 789-796.

Belanger-Gravel, A., Godin G., Vezina-Im, L., Amireault S., Poirier, P. (2011). The effect of theory-based interventions on physical activity participation among overweight/obese individuals: a systematic review. *Obesity Review*, (12):430–439.

Bennett, G. G., Warner, E. T., Glasgow, R. E., Askew, S., Goldman, J., Ritzwoller, D. P., Emmons, K.M., Rosner, B.A., Colditz, G.A., Be Fit, Be Well Study, Investigators. (2012). Obesity Treatment for Socioeconomically Disadvantaged Patients in Primary Care Practice. *Archives of Internal Medicine, 172*(7), 565-574.

Berkman, N. D., Sheridan, S. L., Donahue, K. E., Halpern, D. J., & Crotty, K. (2011). Low Health Literacy and Health Outcomes: An Updated Systematic Review. *Annals of Internal Medicine, 155*(2), 97-U89.

Bleich, S., Wang, C., Wang, Y., Gortmaker. S. (2009). Increasing consumption of sugar-sweetened beverages among US adults: 1988–1994 to 1999–2004. *American Journal of Clinical Nutrition*, 89:372-381.

Bray GA, Nielsen SJ, Popkin BM. (2004). Consumption of high-fructose corn syrup in beverages may play a role in the epidemic of obesity *American Journal of Clinical Nutrition*, 79(4):537-43.

Brownell KD, Farley T, Willett WC, Popkin BM, Chaloupka FJ, Thomason JW, Ludwig DS. (2009). The public health and economic benefits of taxing sugar-sweetened beverages. *New England Journal of Medicine*, 361:1599-1605.

Centers for Disease Control and Prevention. Measuring Healthy Days. Atlanta, Georgia: CDC, November 2000**.**

Centers for Disease Control and Prevention. Facts about Physical Activity. August, 2012.

Centers for Disease Control and Prevention. The CDC Guide to Strategies for Reducing the Consumption of Sugar-Sweetened Beverages. March 2010.

Centers for Disease Control and Prevention. Physical Activity Statistics. February 2010.

Corkrey, R., & Parkinson, L. (2002). Interactive voice response: Review of studies 1989-2000. *Behavior Research Methods Instruments & Computers, 34*(3), 342-353.

Delichatsios, H. K., Friedman, R. H., Glanz, K., Tennstedt, S., Smigelski, C., Pinto, B. M., Kelley, H., Gillman, M. W. (2001). Randomized trial of a "talking computer" to improve adults' eating habits. *American Journal of Health Promotion, 15*(4), 215-224.

Duffey KJ, Popkin BM. (2007). Shifts in patterns and consumption of beverages between 1965 and 2002. *Obesity*. 15:2739-2747.

Estabrooks, P. A., Shoup, J. A., Gattshall, M., Dandamudi, P., Shetterly, S., & Xu, S. (2009). Automated Telephone Counseling for Parents of Overweight Children A Randomized Controlled Trial. *American Journal of Preventive Medicine, 36*(1), 35-42.

Estabrooks, P. A., & Smith-Ray, R. L. (2008). Piloting a behavioral intervention delivered through interactive voice response telephone messages to promote weight loss in a pre-diabetic population. *Patient Education and Counseling, 72*(1), 34-41.

Fagerlin, A., Zikmund-Fisher, B.J., Ubel, P.A., Jankovic, A., Derry, H.A., & Smith, D.M. (2007). Measuring numeracy without a math test: Development of the Subjective Numeracy Scale (SNS). *Medical Decision Making*, 27: 672-680.

Glasgow, R. E., Christiansen, S., Smith, K. S., Stevens, V. J., & Toobert, D. J. (2009). Development and implementation of an integrated, multi-modality, user-centered interactive dietary change program. *Health Education Research, 24*(3), 461-471.

Godin G, Kok G. (1996). The theory of planned behavior: a review of its applications to health-related behaviors. *American Journal of Health Promotion*, 11:87-98.

Guthrie, J. F., & Morton, J. F. (2000). Food sources of added sweeteners in the diets of Americans. *Journal of the American Dietetic Association, 100*(1), 43-51, quiz 49-50.

Hedrick V, Comber D, Estabrooks P, Salva J, Davy B. (2010). The beverage intake questionnaire: Determining initial validity and reliability. *Journal of the American Dietetic Association*, 110(8):1227-32.

Institute of Medicine Committee on Health Literacy. Health literacy: a prescription to end confusion. Washington DC: the National Academies Press, 2004.

Kiernan M, Schoffman DE, Lee K, Moore SD, Fair J, Taylor-Piliae R, Perri MG, & Haskell WL. (2011). Using the Stanford Leisure-Time Activity Categorical Item (L-Cat) to assess changes in leisure-time activity among obese women. *Annals of Behavioral Medicine*, 41:S187. Manuscript currently in preparation.

King, A. C., Friedman, R., Marcus, B., Castro, C., Napolitano, M., Alm, D., & Baker, L. (2007). Ongoing physical activity advice by humans versus computers: The community health advice by telephone (CHAT) trial. *Health Psychology, 26*(6), 718-727.

Krzeski, E. Master's Thesis, Using the Theory of Planned Behavior to Understand Drink Choices in Southwest Virginians, 2011.

Krishna, S., Balas, E. A., Boren, S. A., & Maglaveras, N. (2002). Patient acceptance of educational voice messages: A review of controlled clinical studies. *Methods of Information in Medicine, 41*(5), 360-+.

Lambert-Kerzner, A., Havranek, E. P., Plomondon, M. E., Albright, K., Moore, A., Gryniewicz, K., Magid, D., Ho, P. M. (2010). Patients' Perspectives of a Multifaceted Intervention With a Focus on Technology A Qualitative Analysis. *Circulation-Cardiovascular Quality and Outcomes, 3*(6), 668-674.

Linkins, R. W., Dini, E. F., Watson, G., & Patriarca, P. A. (1994). A Ranfomized Trial of the Effectiveness of Computer-Generated Telephone Messages in Increasing Immunization Visits Among Preschoo-Children. *Archives of Pediatrics & Adolescent Medicine, 148*(9), 908-914.

Lorig, K., Ritter, P. L., Villa, F., & Piette, J. D. (2008). Spanish diabetes self-management with and without automated telephone reinforcement - Two randomized trials. *Diabetes Care, 31*(3), 408-414.

Malik, V. S., Schulze, M. B., Hu, F. B. (2006). Intake of sugar-sweetened beverages and weight gain: a systematic review. *American Journal of Clinical Nutrition*, 84(2), 274-288.Marshall, 2003.

Montano D, Kasprzyk D. Theory of Reasoned Action, Theory of Planned Behavior, and the Integrated Beahavioral Model. In: Glanz K, Rimer BK, Viswanath K, eds. Health Behavior and Health Education: Theory, Research, and Practice. 4th edition ed. San Francisco: Jossey-Bass; 2008.

Moshfegh, A. J., Raper, N., Ingwersen, L., Cleveland, L., Anand, J., Goldman, J., & LaComb, R. (2001). An improved approach to 24-hour dietary recall methodology. *Annals of Nutrition and Metabolism*, *45*(Suppl 1), 156.

Murphy, P. W., Davis, T. C., Long, S. W., Jackson, R. H., & Decker, B. C. (1993). Rapid Estimate of Adult Literacy in Medicine (REALM) – A Quick Reading Test for Patients. *Journal of Reading, 37*(2), 124-130.

Nielsen, SJ, Popkin BM. (2004). Changes in beverage intake between 1977 and 2001. *American Journal of Preventive Medicine*, 27:205-210.

Oake, N., Jennings, A., van Walraven, C., & Forster, A. J. (2009). Interactive Voice Response Systems for Improving Delivery of Ambulatory Care. *American Journal of Managed Care, 15*(6), 383-391.

Osborn, C. Y., Weiss, B. D., Davis, T. C., Skripkauskas, S., Rodrigue, C., Bass, P. F., & Wolf, M. S. (2007). Measuring adult literacy in health care: Performance of the newest vital Sign. *American Journal of Health Behavior, 31*, S36-S46.

Paasche-Orlow, M. K., Riekert, K. A., Bilderback, A., Chanmugam, A., Hill, P., Rand, C. S., Brancati, F.L., Krishnan, J. A. (2005). Tailored education may reduce health literacy disparities in asthma self-management. *American Journal of Respiratory and Critical Care Medicine, 172*(8), 980-986.

Parker, R. M., Baker, D. W., Williams, M. V., & Nurss, J. R. (1995). The Test of Functional Health Literacy in Adults- A New Instrument for Measuring Patients Literacy Skills. *Journal of General Internal Medicine, 10*(10), 537-541.

Piette, J. D. (2000a). Interactive voice response systems in the diagnosis and management of chronic disease. [Research Support, Non-U.S. Gov't Research Support, U.S. Gov't, Non-P.H.S. Research Support, U.S. Gov't, P.H.S. Review]. *American Journal of Managed Care, 6*(7), 817-827.

Piette, J. D. (2000b). Satisfaction with automated telephone disease management calls and its relationship to their use. *Diabetes Educator, 26*(6), 1003-1010.

Piette, J. D., McPhee, S. J., Weinberger, M., Mah, C. A., & Kraemer, F. B. (1999). Use of automated telephone disease management calls in an ethnically diverse sample of low-income patients with diabetes. *Diabetes Care, 22*(8), 1302-1309.

Pinto, B. M., Friedman, R., Marcus, B. H., Kelley, H., Tennstedt, S., & Gillman, M. W. (2002). Effects of a computer-based, telephone-counseling system on physical activity. *American Journal of Preventive Medicine, 23*(2), 113-120. doi: 10.1016/s0749-3797(02)00441-5.

Primack BA, Fine D, Yang CK, Wickett D, Zickmond S. (2009). Adolescents' impressions of antismoking media literacy education: qualitative results from a randomized controlled trial. *Health Education Research*, 24(4):608-621.

Regan, S., Reyen, M., Richards, A. E., Lockhart, A. C., Liebman, A. K., & Rigotti, N. A. (2012). Nicotine Replacement Therapy Use at Home After Use During a Hospitalization. *Nicotine & Tobacco Research, 14*(7), 885-889.

Sarkar, U., Piette, J. D., Gonzales, R., Lessler, D., Chew, L. D., Reilly, B., Johnson, J., Brunt, M., Huang, J., Regenstein, M., Schillinger, D. (2008). Preferences for self-management support: Findings from a survey of diabetes patients in safety-net health systems. *Patient Education and Counseling, 70*(1), 102-110.

Schillinger, D., Hammer, H., Wang, F., Palacios, J., McLean, I., Tang, A., Youmans, S., Handley, M. (2008). Seeing in 3-D: Examining the reach of diabetes self-management support strategies in a public health care system. *Health Education & Behavior, 35*(5), 664-682.

Schillinger, D., Handley, M., Wang, F., & Hammer, H. (2009). Effects of Self-Management Support on Structure, Process, and Outcomes Among Vulnerable Patients With Diabetes A three-arm practical clinical trial. *Diabetes Care, 32*(4), 559-566.

Sheridan, S. L., Halpern, D. J., Viera, A. J., Berkman, N. D., Donahue, K. E., & Crotty, K. (2011). Interventions for Individuals with Low Health Literacy: A Systematic Review. *Journal of Health Communication, 16*, 30-54.

Sparrow, D., Gottlieb, D. J., DeMolles, D., & Fielding, R. A. (2011). Increases in Muscle Strength and Balance Using a Resistance Training Program Administered Via a Telecommunications System in Older Adults. *Journals of Gerontology Series a-Biological Sciences and Medical Sciences, 66*(11), 1251-1257.

Taggart, J., Williams, A., Dennis, S., Newall, A., Shortus, T., Zwar, N., Denney-Wilson, E., Harris, Mark F. (2012). A systematic review of interventions in primary care to improve health literacy for chronic disease behavioral risk factors. *Bmc Family Practice, 13*.

Thompson, F. E., McNeel, T. S., Dowling, E. C., Midthune, D., Morrissette, M., & Zeruto, C. A. (2009). Interrelationships of Added Sugars Intake, Socioeconomic Status, and Race/Ethnicity in Adults in the United States: National Health Interview Survey, 2005. *Journal of the American Dietetic Association, 109*(8), 1376-1383.

US Census Bureau. http://www.census.gov/, Accessed September 28, 2012.

Vartanian, L. R., Schwartz, M. B., Brownell, K. D. (2007). Effects of soft drink consumption on nutrition and health: A systematic review and meta-analysis. *American Journal of Public Health,* 97(4), 667-675.

Virginia Department of Health. http://www.vdh.state.va.us/. Accessed September 28, 2012.

Wang, Y. C., Bleich, S. N., & Gortmaker, S. L. (2008). Increasing caloric contribution from sugar-sweetened beverages and 100% fruit juices among US children and adolescents, 1988-2004. *Pediatrics, 121*(6), E1604-E1614.

Weiss B, Mays M, Martz W et al. (2005). Quick assessment of literacy in primary care: The Newest Vital Sign. *Annals of Family Medicine*. 2005;3:514-22.

Zikmund-Fisher, B.J., Smith, D.M., Ubel, P.A., Fagerlin, A. (2007). Validation of the subjective numeracy scale (SNS): Effects of low numeracy on comprehension of risk communications and utility elicitations. *Medical Decision Making*, 27: 663-671.

Zoellner J, Allen K, Estabrooks P. How effective are health literacy interventions targeting disease self-management and health promotion? A systematic literature review. Paper Session 3042. *Annals of Behavioral Medicine*, 2012.

Zoellner J, Estabrooks E, Davy B, Chen Y, You W. (2011). Exploring the Theory of Planned Behavior to Explain Sugar-sweetened Beverage Consumption. Journal of Nutrition Education and Behavior, In Press.

Appendices

Appendix A: IRB Approval

VirginiaTech
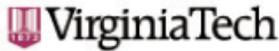
Office of Research Compliance
Institutional Review Board
2000 Kraft Drive, Suite 2000 (0497)
Blacksburg, VA 24060
540/231-4606 Fax 540/231-0959
email irb@vt.edu
website http://www.irb.vt.edu

MEMORANDUM

DATE: January 10, 2013

TO: Jamie M Zoellner Dr, Paul Andrew Estabrooks, Yvonnes Chen, Brenda Davy, Wen You

FROM: Virginia Tech Institutional Review Board (FWA00000572, expires May 31, 2014)

PROTOCOL TITLE: Talking Health- Main Trial

IRB NUMBER: 12-090

Effective January 9, 2013, the Virginia Tech Institution Review Board (IRB) Chair, David M Moore, approved the Continuing Review request for the above-mentioned research protocol.

This approval provides permission to begin the human subject activities outlined in the IRB-approved protocol and supporting documents.

Plans to deviate from the approved protocol and/or supporting documents must be submitted to the IRB as an amendment request and approved by the IRB prior to the implementation of any changes, regardless of how minor, except where necessary to eliminate apparent immediate hazards to the subjects. Report within 5 business days to the IRB any injuries or other unanticipated or adverse events involving risks or harms to human research subjects or others.

All investigators (listed above) are required to comply with the researcher requirements outlined at:

http://www.irb.vt.edu/pages/responsibilities.htm

(Please review responsibilities before the commencement of your research.)

PROTOCOL INFORMATION:

Approved As: **Expedited, under 45 CFR 46.110 category(ies) 7**
Protocol Approval Date: **February 1, 2013**
Protocol Expiration Date: **January 31, 2014**
Continuing Review Due Date*: **January 17, 2014**
*Date a Continuing Review application is due to the IRB office if human subject activities covered under this protocol, including data analysis, are to continue beyond the Protocol Expiration Date.

FEDERALLY FUNDED RESEARCH REQUIREMENTS:

Per federal regulations, 45 CFR 46.103(f), the IRB is required to compare all federally funded grant proposals/work statements to the IRB protocol(s) which cover the human research activities included in the proposal / work statement before funds are released. Note that this requirement does not apply to Exempt and Interim IRB protocols, or grants for which VT is not the primary awardee.

The table on the following page indicates whether grant proposals are related to this IRB protocol, and which of the listed proposals, if any, have been compared to this IRB protocol, if required.

Invent the Future

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY
An equal opportunity, affirmative action institution

Date*	OSP Number	Sponsor	Grant Comparison Conducted?
07/11/2012	10157901	National Institutes of Health	Compared on 01/27/2012

* Date this proposal number was compared, assessed as not requiring comparison, or comparison information was revised.

If this IRB protocol is to cover any other grant proposals, please contact the IRB office (irbadmin@vt.edu) immediately.

Appendix B: Informed Consent

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY
Informed Consent for Participants
In Research Projects Involving Human Subjects

Project Title: Talking Health Project

Principle Investigator: Jamie Zoellner, PhD, RD, Department of Human Nutrition, Foods and Exercise

Co Investigators:
Paul Estabrooks, PhD, Department of Human Nutrition, Foods and Exercise
Brenda Davy, PhD, RD, Department of Human Nutrition, Foods and Exercise
Wen You, PhD, Department of Agricultural and Applied Economics
Yvonnes Chen, PhD, Department of Communication

I.   Purpose of this Research:

Virginia Tech's Human Nutrition, Foods and Exercise Department is offering a free 6-month health program with follow-up health screenings for one year. The goal of this program is to improve your health behaviors, such as sugar intake or physical activity behaviors.

II.   Procedures

This study will include health screenings and an education program. In this study, you will be randomized- like a flip of a coin- into one of two groups, either the sugar intake group or the physical activity group. Randomization means you will not have a choice which group you belong to. You must agree to be randomized to be involved in this study.

Health Screenings
As a part of the program, you will need to attend 3 health screenings. The first one will be at the beginning of the program; the second one will be at the end of the program (6 months), and the third one will be a follow-up at 18-months. The health screening data will be collected in-person and includes:
• Surveys about your food and drink behaviors, physical activity behaviors, health status, and quality of life
• Height and weight
• Blood pressure
• Finger-stick blood sample to measure blood sugar and cholesterol levels

You will be asked to complete the screening on two different days, and each day will take about 45-60 minutes. After each of the 3 health screening, you will receive two more telephone calls where you will be asked to report your food, drink, and physical activity for the previous day. Each of these phone calls will last about 20 minutes.

The total time for the health screenings is about 7-8 hours over the course of the 18-month program.

Education Program
The education program will last for 6 months. During this time you will be asked to:
• attend 3 small group sessions, each lasting about 2 hours
• complete 11 Interactive Voice Response telephone calls to help you track your behaviors and reach your goals, each lasting about 10-15 minutes.

The total time for the education program is about 7-8 hours.

III. Compensation

You will get a gift card for your time involved in completing each of the health screenings, including:
• beginning of the program: $25 gift card
• end of the program (at 6-months): $50 gift card
• follow-up (at 18-months): $75 gift card

You will also get small non-monetary prizes at the group sessions to help you reach your goals.

IV. Risks

There are minimal risks for being involved in this study. It is possible that the health screening could cause stress or anxiety for you. You will always have the right to refuse to participate or to answer any questions in the health screening. If you become too tired during the health screening, you can take a break or finish on another day.

Possible risks related to the finger stick include a small amount of bleeding, temporary discomfort, and soreness.

The main risk of taking part in the physical activity program is a small risk associated with starting a physical activity program, if you have not been physically active. To lower this risk, you will always participate in the physical activity sessions at your own pace. Inappropriate levels of physical activity could lead to muscle and bone injuries during or following physical activity. Further, it is possible that cardiovascular and respiratory related adverse events could occur. In order to protect against these risks, the study will guide participants in selecting appropriate levels and intensity of physical activity.

Although not expected, if you must seek medical or counseling services as a direct result of your participation in this study, neither the investigator nor the University has funds to pay for such services. The costs of any such services must be paid by you.

This study may include risks that are unknown at this time. You will be informed of significant new findings that develop during the course of this study that may affect your willingness to continue to participate in this study.

V. Benefits

If you decide to take part in this study, there is no guarantee that you will experience any changes in your health, regardless of which group you are randomized to. However, participants may receive the following benefits: learning appropriate behavioral change strategies to improve their sugar intake or physical activity behaviors, modest weight loss, and/or improvement in health conditions.

At each of the health screenings you will receive a handout that explains the results of your lab values.

Furthermore, to cover your time spent completing the health screenings; you will receive a gift card incentive.

VI.   Confidentiality

Several steps will be taken to ensure confidentiality, including but not limited to adequate training of personnel. Only certified and trained study personnel will have access to information about you obtained for this study. This information will be kept confidential and will not be released without your written permission unless compelled by law. We will use study ID numbers in order to enhance the confidentiality of your information. At the start of the study you will be assigned a study ID number, so that you will only be identified by that number for study purposes. It is possible that the Institutional Review Board (IRB) may view this study's data for auditing purposes. The IRB is responsible for oversight of the protection of human subjects involved in research. All identifiable information about you will be destroyed at the earliest opportunity following the completion of the study.

VII.   Freedom to Withdraw

Participation in this study is completely voluntary. You are free to stop participating in the study at any time without penalty. If you choose to withdraw, please contact the project director to let them know of your decision. You are also free not to answer any questions or to complete any portions of the study that you choose not to without penalty. It is also possible that the study sponsor or other regulatory agencies or boards may terminate the study at any time.

VIII.   Participant's Responsibilities

I voluntarily agree to participate in this study. I agree to:
1. Complete 3 health screenings which includes surveys, height, weight, blood pressure, and a finger-stick blood sample, each lasting 45-60 minutes for 2 days
2. Complete 6 telephone recalls, each lasting about 20 minutes
3. Attend 3 small group educational sessions, each lasting about 2 hours
4. Complete 11 Interactive Voice Response telephone calls, each lasting 10-15 minutes

IX.   Participant's Permission

I have read the consent form and conditions of this project. I have had all of my questions answered. I hereby acknowledge the above and give my voluntary consent:

_____ Date:_____
Participant signature
_____
Participant Name (Please Print)

Should I have any pertinent questions about this research or its conduct, research participants' rights, and whom to contact in the event of a research related injury to the subject, I may contact:

Terri Corsi, Project Director

Department of Nutrition, Foods and Exercise
Integrated Life Sciences Building 23, Room 1032
1981 Kraft Drive (0913), Blacksburg, VA 24061
540-231-4325
540-231-5522-fax
tcorsi@vt.edu

Jamie Zoellner, Principal Investigator
Assistant Professor of Department of Nutrition, Foods and Exercise
Integrated Life Sciences Building 23, Room 1032
1981 Kraft Drive (0913), Blacksburg, VA 24061
540-231-3670
Zoellner@vt.edu

David M. Moore, Chair of Virginia Tech Institutional Review Board
For the Protection of Human Subjects
Office of Research Compliance
2000 Kraft Drive, Suite 2000, Blacksburg, VA 24060
540-231-4991
moored@vt.edu

Appendix C: Summative Evaluation

<u>Talking Health Summative Evaluation</u>

Well done, you have almost completed the 6-month health assessment. Now I would just like to ask you several more questions about your thoughts on the program. We are really interested in your honest opinions, including things you liked and things you didn't like about the program.   Please don't think you are going to hurt our feelings, because all the information you provide will really help us evaluate the program and figure out how we can make it better for members in your community in the future.

There are five sections to this final part. I will ask you about your thoughts on the small group classes, the personal actions plans, the drink diaries/exercise logs, and the telephone calls and the resources provided.

[NOW SHOW & EXPLAIN LIKERT-SCALE HANDCARD]

Any questions before we get started?

Group classes
RECORD FROM PROCESS DATA, DO NOT ASK: Number of Classes Attended:
_____

IF ATTENDED 0 CLASSES:
Sometimes it was hard for our program participant's to get to the group classes, and I noticed that you missed the classes.

> 1. What was the biggest barrier for you attending the group classes?

> 2. What could our Talking Health team have done differently increase your attendance at the group classes?

Now Skip to Question 13.
IF ATTENDED 1-3 CLASSES:
|____| 3. How satisfied were you with how the group classes were **organized**?
        [USE SATISIFACTION HAND CARD]

|____| 4. How satisfied were you with the **type of information** presented in the group classes?
        [USE SATISIFACTION HAND CARD]

|____| 5. How satisfied were you with the **type of activities** presented in the group classes?
        [USE SATISIFACTION HAND CARD]

   6. Can you please talk to me about what you liked and disliked about the small group classes.
        Probe: Anything else you liked? Anything else you disliked?

6a. Like	6 b. Dislike

IF ATTENDED 1-2 CLASSES (OR MISSED 1-2 CLASSES):
Sometimes it was hard for our program participant's to get to the group classes, and I noticed that you missed 1 or 2 classes.

7. What was the biggest barrier for you attending the group classes?

8. What could our Talking Health team have done differently increase your attendance at the group classes?

Personalized action plans

Now let's switch gears a bit and talk about the personalized action plans.

|____| 9. How satisfied were you with how the personalized actions plans were **set-up**?
      [USE SATISFACTION HAND CARD]

|____| 10. *How much do you agree or disagree with the statement*: You did a good job **completing** the
      personalized actions plan.
      [USE AGREEMENT HAND CARD]

|____| 11. *How much do you agree or disagree with the statement:* Completing the personalized
      action plans were **helpful**.
      [USE AGREEMENT HAND CARD]

12. Talk to me about what you liked and disliked about making the personalized action plans.   Probe: Anything else you liked? Anything else you disliked?

12a. Like	12b. Dislike

Diaries/Log

You're doing great, all this information you are providing is really valuable. Now let's talk about the drink diaries/exercise logs.

|____| 13. How satisfied were you with how the drink diaries/exercise logs were **set-up**?
          [USE SATISIFACTION HAND CARD]

|____| 14. *How much do you agree or disagree with the statement*: You did a good job **completing** the
          drink diaries/exercise logs.
          [USE AGREEMENT HAND CARD]

|____| 15. *How much do you agree or disagree with the statement*: Completing the drink
          diaries/exercise logs were **helpful**.
          [USE AGREEMENT HAND CARD]

|____| 16. How often did you use your drink diaries/exercise logs?
          [1] Did not use it at all
          [2] Used it some days, but not everyday
          [3] Used it everyday

IF Number 16 is '2':

|____| 16a. Did you use the drink diaries/exercise logs:
          [1] more in the first half the program
          [2] more in the second half of the program
          [3] about the same throughout the program

17. Talk to me about what you liked and disliked about drink diaries/exercise logs.
          Probe: Anything else you liked? Anything else you disliked? Did anything make it hard or easy to complete the drink diaries/exercise logs?

17 a. Like	17 b. Dislike

18. Was it hard or easy to figure out your daily averages? Why?

Teach-back call

RECORD FROM PROCESS DATA, DO NOT ASK: Teach Back Call Completed
(Y/N): _____
If no, Skip to Question 22 or 24.
Now I'm just going to ask you a few questions about the telephone calls. For these first few questions, please try to remember back to after the first class when our staff called you and personally reviewed the material covered in class. You were asked several questions about this material.

|____| 19. *How much do you agree or disagree with the statement*: Going through this material
       personally with the staff on the telephone **helped me learn** the material better.
       [USE AGREEMENT HAND CARD]
|____| 20. *How much do you agree or disagree with the statement*: Answering the questions was
       difficult.
       [USE AGREEMENT HAND CARD]
|____| 21. *How much do you agree or disagree with the statement*: For future programs, I would
       recommend this strategy where staff personally call and review the class materials.
       [USE AGREEMENT HAND CARD]

Automated calls

RECORD FROM PROCESS DATA, DO NOT ASK: Number of IVR Calls
Completed: _____
If completed 0 IVR calls:
For some of our program participants, it was really difficult for them to complete the
automated calls, and I noticed that you were not able to complete any, so I'm curious:

      22. What was the biggest barrier for completing the automated calls?

      23. What could our Talking Health team have done differently increase your completion of the
          automated calls?

If completed 1-11 IVR calls :
Okay, great, now the remaining questions are about the automated telephone messages

|____| 24. *How much do you agree or disagree with the statement:* The automated calls
provided
      me with **useful strategies** to help me reduce my sugary drinks/be more physically
active.
      [USE AGREEMENT HAND CARD]
|____| 25. *How much do you agree or disagree with the statement*: The automated
telephone system
      was **easy to use**.
      [USE AGREEMENT HAND CARD]
|____| 26. *How much do you agree or disagree with the statement:* The automated
telephone system
      was **personal.**
      [USE AGREEMENT HAND CARD]
|____| 27. *How much do you agree or disagree with the statement*: I was satisfied with
the length of
      each call.
      [USE AGREEMENT HAND CARD]
|____| 28. *How much do you agree or disagree with the statement:* I would use an
automated
      telephone system again as a tool to provide me with strategies to promote healthy
living.
      [USE AGREEMENT HAND CARD]

29. Talk to me about what you liked and disliked about the automated calls.
Probe: Anything else you liked? Anything else you disliked?

29 a. Like	29 b. Dislike

|____| 30. Overall, **how satisfied** were you with the automated telephone calls?
[USE SATISIFACTION HAND CARD]

|____| 31. Try to think back to before you began this program when our staff was explaining the
automated telephone calls. Did you think the automated telephone calls were going to be good or bad?

  [1] Good, go to 31a
  [2] Bad, go to 31b

|____| 31a. Now that we have completed that part of the program, were the automated calls
  [1] Better than I thought it would be.
  [2] Just as good as you thought it would be.
  [3] Worse than you thought it would be.

|____| 31b. Now that we have completed that part of the program, were the automated calls
  [1] Better than I thought it would be.
  [2] Just as bad as you thought it would be.
  [3] Worse than you thought it would be.

If completed <9 IVR calls.
For some of our program participants', it was difficult for them to complete the automated calls, and I noticed that you missed a few, so I'm curious:

  32. What was the biggest barrier for completing the automated calls?

  33. What could our Talking Health team have done differently increase your completion of the automated calls?

Resources (MoveMore only)
Now let's talk about the resources we provided. Talk to me about the Waling Indoors DVD provided.

|____| 34. How often did you use the DVD?
    [1] Did not use it at all

[2] Used it 1-2 x total
[3] Used it 3-5 x total
[4] Used it about 1 x month
[5] Used it about 2-3 x month
[6] Used it about 1 x week
[7] Used it about 2-3 x week
[8] Used it 4 or more x per week

35. Talk to me about what you liked and disliked about the DVD.
Probe: Anything else you liked? Anything else you disliked?

Like	Dislike

|____| 36. How often did you use the exercise bands we provided?
[1] Did not use it at all
[2] Used it 1-2 x total
[3] Used it 3-5 x total
[4] Used it about 1 x month
[5] Used it about 2-3 x month
[6] Used it about 1 x week
[7] Used it about 2-3 x week
[8] Used it 4 or more x per week

37. Talk to me about what you liked and disliked about the exercise bands.
Probe: Anything else you liked? Anything else you disliked?

Like	Dislike

Resources (SipSmartER only)

Now let's talk about the resources we provided. Talk to me about the workbook provided.

|____| 38. How often did you use the workbook/additional handouts we provided?
        [1] Did not use it at all
        [2] Used it 1-2 x total
        [3] Used it 3-5 x total
        [4] Used it about 1 x month
        [5] Used it about 2-3 x month
        [6] Used it about 1 x week
        [7] Used it about 2-3 x week
        [8] Used it 4 or more x per week

39. Talk to me about what you liked and disliked about the workbook/additional handouts we provided.
Probe: Anything else you liked? Anything else you disliked?

Like	Dislike

Summary Questions

Okay great we're almost done, just a couple more questions.
40. Of all the parts of the program, which did you find to be the most motivating?
[Do NOT read list, check all that they mention, and probe why?]

|____|[1] Group classes, why?

|____|[2] Personal action plans/goal setting, why?

|____|[3] Drink diaries/exercise logs, why?

|____|[4] Automated calls, why?

|____|[5] Live calls from research assistants, why?

|____|[6] Resources, why?

|____|[7] Other:_____, why?

|____| 41. How satisfied were you with the access and availability of the research staff?
[USE SATISIFACTION HAND CARD]

42. If we were to recruit in your community for another health study, how would you suggest that we let people know about the study? What would motivate them to consider participating?

43. Okay, great, you've made it to the end! Is there anything else that you'd like me to know?

Now let's talk about what to expect for the next 12 months. It is really important for you to remember that you are still a part of the program for the next year. We won't be seeing you in class anymore, but we will be contacting you via telephone one time a month to check in with you and see how you're doing. We will either be contacting you in person or with the automated phone system. Those calls will last about the same amount of time as the current automated calls, which is about 5-10 minutes or less. We may also send you some health information in the mail. About one month before we are scheduled to come back here, we will call and make your 18-month screening appointment. When you complete that screening appointment, we will thank you with a $75 gift card. If at any time in the next year, you happen to have any questions about the program, or if you move or change your phone number, please call our office. We don't want to lose contact with you over the next year. We hope that you will continue the healthy habits you learned from our program for the rest of your life!

Can you tell me your address and telephone number so that I can confirm this?

Address:

Phone number:

Can you provide the phone number of at least one other friend & family member that we could contact if for some reason we cannot reach you for the 18-month follow-up?

Name:

Relationship:

Phone:

Do you have any additional questions or concerns?

HANDCARD for survey
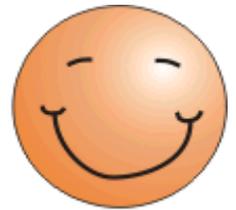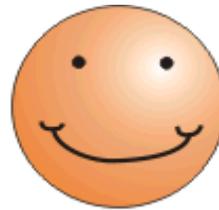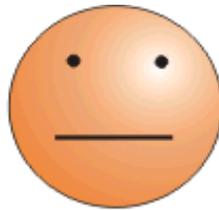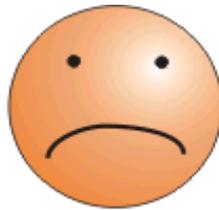
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

Completely
Completely   Neither
dissatisfied   dissatisfied or satisfied   satisfied
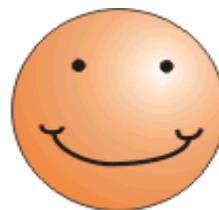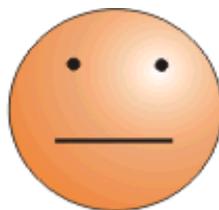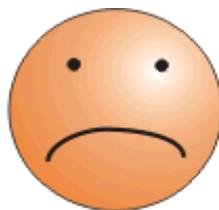
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

Strongly   Neither   Strongly
disagree   agree or disagree
agree

Appendix E: Teach Back Call Scripts

SipSmartER- Live Teach Back Call

Participant ID:_____ Date of Call:_____ Start Time of Call:_____

Black text is scripted call content

[ ] reflect content that will change within the script (e.g., [participant name])

This color text refers to information you need to add PRIOR to initiating the call

This color text in italics is instruction for the caller

		RECORD THIS INFORMATION PRIOR TO GETTING PARTICIPANTS ON PHONE
Intro_1.	|_____|[0] no |_____|[1] yes	• ***Did Participant Attend Class #1** • • *If Intro_1=0 [no], go to Intro_1a*
Intro_1a.	|_____|[0] no |_____|[1] yes	• ***Did Participant Complete Missed Class #1 Recap Call**
Intro_2.	|_____| ounces	• ***RECORD INITIAL OUNCES FROM ACTION PLAN (IAP)**
Intro_3.	|_____| ounces	• ***RECORD GOAL OUNCES FROM ACTION PLAN (GAP)** • •
Intro_4.	|_____| ounces	• ***RECORD INITIAL MINUS GOAL AMOUNT (IMG)**
Intro_5a.	Record strategy #1:	• ***Strategy from Personal Action Plan**
Intro_5b.	Record strategy #2:	• ***Strategy from Personal Action Plan**
Intro_6.	Record new strategy:	• ***Strategy from Personal Action Plan** • *randomly selected strategy from same barriers—one that participant didn't select*
Intro_7.	|_____| IVR PIN number	• ***Record IVR PIN number**
		GETTING THE PARTICIPANT ON THE PHONE •
		• Hello, this is [your name] calling from Virginia Tech for

		[participant name] she/he is expecting my call. Is he/she home right now?
		If YES, wait for them to come to the line or if the participant answers go on to number 2
• *If NO,* "Thanks, can you give me an idea when she/he may be back?" *[record time]* "Thanks, I'll try back later then. Goodbye"
•
• Hi [participant name] I'm calling to complete your first Sip Smarter telephone call. Do you have a few minutes to complete it right now? It should be about 15-20 minutes.
•
• *If YES, begin the SSB ASSESSMENT section*
• *If NO,* "That's okay, can we schedule a time that would be good for you?" *[record time]* "Thanks, I'll call back later then. Goodbye"
•
•
• *Answering Machine Response*—Only leave a message once per day on the first, second, and forth day of calling with a 3-message maximum in one week.
•
• *1st message:* This is [your name] calling from Virginia Tech for [participant name]. I'll try calling you again, but if you would like to call me back and let me know a good time for us to chat, just call me at [study line]. Thanks and I hope I catch up with you soon!
•
• *2nd & 3rd message:* This is [your name] calling from Virginia Tech for [participant name] to complete your first sip smarter call. I'll try calling you another time this week to see if we can get your call done. Again, if you would like to call me back and let me know a good time for us to chat, just call me at [study line]. Thanks and I hope we can finish up this call soon, it will just take a couple of minutes.
		INTRODUCTION
		If Intro_1 = yes: It was so great to have you at the first class- I hope that you had fun and learned a lot. Today we will be reviewing the information from that class as well as talking about your progress on reducing your sugary drink intake.

If Intro 1 = no, but Intro_1a = yes: It was so great to chat with a few days and fill you in on what you missed during class one. I hope that you have had a chance to review the packet of information. Today we will be reviewing the information from that class as well as talking about your progress on reducing your sugary drink intake. |

		TEACH BACK OPPORTUNITY #1 •
		• First, I'd like to ask you what you remember from the class [or the last time we talked, if missed class]. We went over different types of sugary drinks, talked about the recommended serving size and the health risks of drinking too many sugary drinks, and we set some goals for how many ounces folks could decrease over the next week. I'm going to ask you a few questions about you remember, if you don't know, it's okay, we can review the information shortly.
TBC1_1.	|_____|[0] incorrect |_____|[1] correct	Do you remember the maximum amount of sugary drinks recommended per day? Record response: |_____| • • *Correct = less than or equal to 8 ounces/day*
		• *If TBC1_1 = [0] incorrect:* The recommended daily amount is 8 ounces, which is the same size as the blue cup we gave you in class. Or you could use a standard 1 cup measuring cup. So 8 ounces is the maximum amount of sugary drinks that is recommended that you should consume each day. • *If TBC1_1 = [1] correct:* Yes, that's right! During that first class you learned that 8 oz is the maximum amount of sugary drinks that you should consume each day.
TBC1_2.	|_____|[0] incorrect (if any of 3 are incorrect) |_____|[1] correct (if all 3 are correct)	Can you please give me three examples of sugary drinks? Record responses: |_____| |_____| |_____|
		• *If TBC1_2= [0] incorrect:* Okay, no problem, you missed _____(state incorrect answers), those are actually non-sugary drinks. Remember, you can tell if something is sugary by looking on the back of the label, under sugar. If it has more than 0 grams of sugar, it is considered a sugary drink. You can also tell if it is a sugary drink, if you add sugar to it. • • *If TBC1_2 = [1] correct:* Yes, that's right- good job! Remember, you can always tell if something is sugary by looking on the back of the label, under sugar. If it has more than 0 grams of sugar, it is considered a sugary drink. You can also tell if it is a sugary drink, if you add sugar

		to it.
TBC1_3.	|_____|[0] incorrect (if any of 3 are incorrect) |_____|[1] correct (if all 3 are correct)	Can you please give me three examples of non-sugary drinks? • Record responses: |_____| |_____| |_____| •
		If TBC1_3= [0] incorrect: Okay, no problem, you missed _____(state incorrect answers), those are actually sugary drinks. Remember, you can tell if something is non-sugary by looking on the back of the label, if it says 0 under sugar, it is considered a non-sugary drink. It is also a non-sugary drink if you add artificial sweeteners, such as Splenda, Equal, or Sweet-N-Low. *If TBC1_3 = [1] correct:* Excellent, you got all those right. Remember, you can tell if something is non-sugary by looking on the back of the label, if it says 0 under sugar, it is considered a non-sugary drink. It is also a non-sugary drink if you add artificial sweeteners, such as Splenda, Equal, or Sweet-N-Low.
TBC1_4	|_____|[0] incorrect (if any of the 8 are incorrect) |_____|[1] correct (if all 8 are correct)	I'm going to read off a list of drinks. Just answer yes, if it is sugary, and no if it is non-sugary. • TBC1_4a. Mountain Dew |_____|[0] no |_____|[1] yes • TBC1_4b. 100% Apple Juice |_____|[0] no |_____|[1] yes • TBC1_4c. Sunny Delight |_____|[0] no |_____|[1] yes • TBC1_4d. Arizona Iced Tea |_____|[0] no |_____|[1] yes • TBC1_4e. Diet Coke |_____|[0] no |_____|[1] yes • TBC1_4f. Gatorade |_____|[0] no |_____|[1] yes • TBC1_4g. Crystal Light |_____|[0] no |_____|[1] yes • TBC1_4h. Red Bull |_____|[0] no |_____|[1] yes • ***If they say, I don't know or it depends…ask they could find out or know?*
		• *If TBC1_3= [0] incorrect:* Ok great, so you're right about _____ (state correct answers). You missed _____ (state incorrect answers). Remember the categories of sugary drink were soft drinks, 100% fruit juice, fruit drinks, energy drinks, sports drinks, and coffee

		and tea when you add sugar. Sunny delight, bottled green tea, and capri sun would be considered sugary drinks. Some examples are Coke or Mountain Dew, 100% juice such as orange or apple juice and other fruit-flavored drinks like fruit punch or Sunny D. Other sugary drinks include energy drinks like Red Bull, sports drinks like Gatorade and powerade, and coffee and tea—but only when you add sugar to it. Lastly, we talked about chocolate or other flavored milks. • Non-sugary drinks do not have sugar in them and some examples include: diet drinks, black coffee, unsweet tea, regular milk, or alcohol. • • *If TBC1_3= [1] correct:* Ok great, you really seem to understand what is and what is not a sugary drink
TBC1_5	|_____|[0] incorrect (if any of 3 are incorrect) |_____|[1] correct (if all 3 are correct)	Can you please state three health risks that are associated with drinking too many sugary drinks? Record responses: |_____| |_____| |_____|
		If TBC1_5= [0] incorrect: Remember that drinking more than the recommendation of 8 ounces per day, puts you at risk for unhealthy weight gain, diabetes, teeth decay, heart problems and even cancer. *If TBC1_5 = [1] correct:* That's right, excellent. Remember that drinking more than the recommendation of 8 ounces per day, puts you at risk for unhealthy weight gain, diabetes, tooth decay, heart problems and even cancer.
TBC1_6	Repeat teach back: |_____|[0] no |_____|[1] yes	*TBC1_6 = [1] yes - IF ANY of TBC_1 through TBC1_5 are incorrect:* You did a good job remembering information from the first class. I know there was a lot of information covered. So let's just briefly recap the ones you missed. *[Only do the LEARNING OBJECTIVE TEACH BACK #2 for those questions that were missed during TEACH BACK #1]* *TBC1_6 = [0] no - IF ALL TB1C_1 through TBC1_5 are correct:* Excellent job! You really got a lot out of the first class and you got all of those questions correct. Now let's move on and see how you're doing with your drink diary! *[Skip TEACH BACK OPPORTUNITY #2]*
		LEARNING OBJECTIVE TEACH BACK #2
TBC2_1		Do you remember the maximum amount of sugary drinks recommended per day?

	|_____|[0] incorrect |_____|[1] correct	Record response: |_____ __| • *Correct = less than or equal to 8 ounces/day*
		• *If TBC1_1 = [0] incorrect:* The recommended daily amount is 8 ounces, which is the same size as the blue cup we gave you in class. Or you could use a standard 1 cup measuring cup. So 8 ounces is the maximum amount of sugary drinks that is recommended that you should consume each day. • *If TBC1_1 = [1] correct:* Yes, that's right! During that first class you learned that 8 oz is the maximum amount of sugary drinks that you should consume each day.
TBC2_2	|_____|[0] incorrect (if any of 3 are incorrect) |_____|[1] correct (if all 3 are correct)	Can you please give me three examples of sugary drinks? Record responses: |_____ _____| |_____ _____| |_____ _____|
TBC2_3	|_____|[0] incorrect (if any of 3 are incorrect) |_____|[1] correct (if all 3 are correct)	Can you please give me three examples of non-sugary drinks? • Record responses: |_____ _____| |_____ _____| |_____ _____|

TBC2_4	|_____|[0] incorrect (if any of the 8 are incorrect)
	|_____|[1] correct (if all 8 are correct)
		I'm going to read off a list of drinks. Just answer yes, if it is sugary, and no if it is non-sugary.
		• TBC1_4a. Mountain Dew |_____|[0] no
		  |_____|[1] yes
		• TBC1_4b. 100% Apple Juice |_____|[0] no
		  |_____|[1] yes
		• TBC1_4c. Sunny Delight |_____|[0] no
		  |_____|[1] yes
		• TBC1_4d. Arizona Iced Tea |_____|[0] no
		  |_____|[1] yes
		• TBC1_4e. Diet Coke |_____|[0] no
		  |_____|[1] yes

		• TBC1_4f. Gatorade |_____|[0] no |_____|[1] yes • TBC1_4g. Crystal Light |_____|[0] no |_____|[1] yes • TBC1_4h. Red Bull |_____|[0] no |_____|[1] yes ****If they say, I don't know or it depends…ask they could find out or know?*
		• *If TBC1_3= [0] incorrect:* Ok great, so you're right about _____ (state correct answers). You missed _____ (state incorrect answers). Remember the categories of sugary drink were soft drinks, 100% fruit juice, fruit drinks, energy drinks, sports drinks, and coffee and tea when you add sugar. Sunny delight, bottled green tea, and capri sun would be considered sugary drinks. Some examples are Coke or Mountain Dew, 100% juice such as orange or apple juice and other fruit-flavored drinks like fruit punch or Sunny D. Other sugary drinks include energy drinks like Red Bull, sports drinks like Gatorade and powerade, and coffee and tea—but only when you add sugar to it. Lastly, we talked about chocolate or other flavored milks. • Non-sugary drinks do not have sugar in them and some examples include: diet drinks, black coffee, unsweet tea, regular milk, or alcohol. • *If TBC1_3= [1] correct:* Ok great, you really seem to understand what is and what is not a sugary drink
TBC2_5	|_____|[0] incorrect (if any of 3 are incorrect) |_____|[1] correct (if all 3 are correct)	Can you please state three health risks that are associated with drinking too many sugary drinks? Record responses: |_____| |_____| |_____|
		If TBC1_5= [0] incorrect: Remember that drinking more than the recommendation of 8 ounces per day, puts you at risk for unhealthy weight gain, diabetes, teeth decay, heart problems and even cancer. *If TBC1_5 = [1] correct:* That's right, excellent. Remember that drinking more than the recommendation of 8 ounces per day, puts you at risk for unhealthy weight gain, diabetes, tooth decay, heart problems and even cancer.
TBC2_6	Repeat teach back: |_____|[0] no |_____|[1] yes	*TBC2_6 = [1] yes - IF ANY of TBC2_1 through TBC2_5 are incorrect:* Okay, you did a good job remembering information from the first class. I know there was a lot of information covered. For the ones you missed again, we will briefly recap those at the end of this call. But for now let's move on and see how you're doing with

		your drink diary! *[Only do the LEARNING OBJECTIVE TEACH BACK 32 for those questions that were missed during TEACH BACK #2]* *TBC2_6 = [0] no - IF ALL REPEATED QUESTIONS for TBC2_1 through TBC2_5 are correct:* Excellent job! You really got a lot out of the first class and you got all of those questions correct. Now let's move on and see how you're doing with your drink diary! *[Skip TEACH BACK OPPORTUNITY #3]*
		.... DIARY LOG TEACH BACK ....
DD_1	|_____|[1] not using it at all |_____|[2] using it some days, but not everyday |_____|[3] using it everyday	Now we're going to talk about your drink diary. How often have you been using your drink diary to record your beverages?
		• *If DD_1 = [1] not using it all:* Remember that it's so important for you to use your diary. One of the first steps in changing you sugar drink behaviors is to understand it. The automated calls will start next week and it will ask you to report your sugary drink intake. We want to make sure you get the most out of this program by correctly recording and reporting your sugary drinks. For today, we will take some time to review how to correctly use the diary. • • *If DD_1 = [2] using it some days, but not everyday:* I'm so glad that you've started using the diary, that's great. We realize you may forget every now and then, but it is important to try and log your sugary drinks each day. The automated calls will start next week and it will ask you to report your sugary drink intake. We want to make sure you get the most out of this program by correctly recording and reporting your sugary drinks. For today, I will take some time to review how to correctly use the diary. • *If DD_1 = [1] using it every day.* Excellent, I'm so glad that you're using the diary every day. The automated calls will start next week and they will ask you to report your sugary drink intake. You will get the most out of this program if you continue to record you drinks every day and report that information to the automated calls. For today, I will take some time to review how to correctly use the diary.
DD_2	|_____|[1] using drink diary to recall intake |_____|[2] using memory to recall intake	• Okay, before we get going, do you have your drink diary and a pen handy? • *If YES, continue and mark 'using drink diary to recall intake'* • *If No,* Would you like to take a second to grab them? *If they don't know where they are, they are somewhere they cant get to*

		them, don't want to go get them, that is fine record 'using memory to recall intake' • • Ok, do you still have it, or would you like us to send you a new one
DD_3	|_____|[0] incorrect history of completely log |_____|[1] correct history of completing log	• To get started, can you please read [or recall] the beverages that you have recorded on your drink diary. • Record any **non-sugary** drinks that the participant reports: • |_____ _____| • • *Incorrect history if recording non-sugary beverages* • • *Correct history if only recording sugary beverages.*
		• *If DD_3 = 0 and participants listed non-sugary drinks:* • Remember that we only want you to record sugary drinks, so drinks that have sugar. We do not include non-sugary drinks, such as _____(state incorrect non-sugary drinks that the participant is reporting). So for now let's go ahead and cross those off your drink diary and from this point forward, you'll know not to record those non-sugary drinks • • *If DD_3 =1 and participants listed only sugary drinks:* • Great job- it seems as if you are only recording sugary drinks and that is exactly what you are supposed to be doing.
DD_4	|_____|[0] incorrect history of completely log |_____|[1] correct history of completing log	• Now think about these past few days, were there any sugary beverages that you forgot to include in your drink diary? • Record any sugary drinks that the participant now recalls: • |_____ _____| • • • *Incorrect history if participant has forgotten to record any sugary beverages.* • • *Correct history if no report of forgotten sugary beverages.*
		• *If DD_4= 0 and participants forgets sugary beverages:* • Remember that we are trying to help you remember to report all sugary drinks. Let's go ahead and add those that you missed to your drink diary and from this point forward, you'll know to remember to record those sugary drinks. • • *If DD_4 =1 and participants did not forget any sugary drinks:* • Great job- it seems as if you have really gotten the hang out of

		filling out this drink diary correctly.
DD_5	|_____|[0] incorrect history of assessing ounces |_____|[1] correct history of assessing ounces	• Now I would like you tell me how you know how many ounces to write on your drink diary? • Record how that the participant assesses ounces: |_____ _____| • *Incorrect history if participant appears to be guessing* • • *Correct history if measuring, using blue cup, or reading ounces of labels*
		• *If DD_5 = 0 and incorrect history of assessing ounces:* • Remember the blue cup we gave you in class? This represents 8 ounces. Remember, a can represents 12 ounces and a bottle usually represents 20 ounces. If you are ever unsure, you can always measure out your sugary drinks using the 8 oz cup we provided in class as a guide or you can use a standard 1 cup measuring cup. • • *If DD_5 = 1 and correct history of assessing ounces:* • Great job, remember there are lots of ways to know if you are recording the correct among of ounces. You can always measure out your sugary drinks using the 8 oz cup we provided in class as a guide, or you can use a standard 1 cup measuring cup, or you can read the ounces and serving size on the label.
DD_6	|_____|[0] incorrect history of calculating average number of ounces |_____|[1] correct history of calculating average number of ounces	• Now talk to me about how you calculate your average your weekly number of ounces? • Record any errors in calculating an average: • |_____ _____| •
		• *If DD_6 = 0 and incorrect history of calculating errors:* • *(Personalize this for the participants, and help them add each day appropriately and calculate a daily average……list below is an example script):* • *If not…let's walk through it. At the end of each day, you add up all the sugary drinks that you drank in that day. You do this for every day of the week, and at the end of the week you take each day's total and add them up. Then, you divide that number by the number of days you recorded. For example, if you drank 20 ounce on Monday + 30 on Tuesday + 40 on Wednesday+ 20 Thursday +10 Friday + 50 ounces on Saturday + 40 ounce on Sunday, you add up all of those numbers, which would be = 210 ounces. Then you divide by the number of the days in the week,*

		which would be 7. So 210/7 would be 30 ounces on average. • • As mentioned earlier, it will be very important for you to calculate this daily average each week so you can report accurately with the automated calls that start next week. • • *If DD_6 = 1 and correct history of calculating errors:* • Great job- it seems as if you really understand how to calculate your weekly average of sugary drinks. As mentioned earlier, it will be very important for you to calculate this each daily average each week so you can report accurately with the automated calls that start next week.
		• Okay before we move on, what questions do you have about completing your sugary drink diary? • Record type of question(s): • |_____ _____| *[Provide appropriate answer to the participant's question]*
		ASSESSING SSB INTAKE •
SSB_1	|_____| ounces	• Now I want to check in and see how you are doing cutting back on your sugary drinks. If you need to make some changes on your drink diary based on what you just learned or errors we found, that is completely fine. We want you to try and answer each of these next questions as accurately as possible. The more accurately your answer the better this program can help you. • • Over the past week, since the class, check out your drink diary and tell me the daily average number of ounces of sugary drinks you had? • • *If they didn't calculate or don't have the diary…* It's okay if you can't remember exactly, just go ahead and give me your best estimate.

GOAL ACHIEVEMENT & SETTING
IF PARTICIPANT IS AT 8 OUNCES OR FEWER CURRENTLY SUGGEST A GOAL TO MAINTAIN CURRENT LEVELS

ACHIEVED GOAL: I am really pleased to see that you accomplished your goal for the week! Congratulations on your success! The changes you are making are really going to help with your health in the long run. Keep up the good work! One of the best things about achieving your first week's goal is that now you know you can do it, you can cut back on your sugary drinks! You are on a great path to reduce your risk of diabetes, heart disease, and cancer. Since you are doing so well, your call is going to be really short this week! The next thing we need to do is to set a new goal for the next week.

Right now you are drinking about _____ ounces [CURRENT] and in class you set an initial goal that was about to drink _____ ounces [GAP] or less and that was cutting back by about about _____ounces [IMG].

IF PARTICIPANT IS AT 8 OUNCES OR FEWER. You are no longer drinking more than the recommended guidelines of 8 ounces. Congratulations! Does sticking where you are sound like a good goal to you?

IF PARTICIPANT IS > 8 OUNCES If you tried to reduce by that much again, your new goal would be _____ ounces[*NEW GOAL=CURRENT-_____IMG* OR *NEW GOAL=0; which ever is lower*]. Does this sound like a good goal to you?

Yes - Great! Thanks for taking the time to talk to me today. You are doing an outstanding job. Remember, your new goal to drink _____ or less ounces [*NEW GOAL]* each day over the next week. Your plan seems to be working well for you, so just stick with it and I will talk to you more about it next week! *Go to the TBM ASSESSMENT SCRIPT*

No- No problem, what do you think would be a good goal for the next week? RECORD NEW GOAL_____.
If new goal equal to current amount of ounces or fewer--Okay, that'll work fine. Thanks for taking the time to talk to me today. You are doing a good job. Remember, your goal is to drink _____or less ounces [*NEW GOAL*] each day over the next week. Your plan seems to be working well for you, so just stick with it and I will talk to you more about it next week! *Go to the TBM ASSESSMENT SCRIPT*

*If new goal higher than current amount of ounces—*Remember that ultimately, 8 ounces per day or fewer is the best goal for reducing the risk of obesity and diabetes that comes with drinking sugary drinks. If you don't want to go much lower this week that is fine, but maybe we could have a goal that you just stay at the same level you are at right now. Does that sound reasonable?
- *If yes-*Okay, thanks for taking the time to talk to me today. You are making progress. Remember, your goal is to drink _____ or less ounces [*NEW GOAL*] each day over the next week. Your plan seems to be working well for you, so just stick with it and I will talk to you more about it next week! *Go to the TBM ASSESSMENT SCRIPT.*
- *If no-*Okay, we can stick with the goal you want to set for this week. Thanks for taking the time to talk to me today. You are making progress. Remember, your goal

is to drink _____ or less ounces [*NEW GOAL*] each day over the next week. *Go to the TBM ASSESSMENT SCRIPT*.

-

MADE SOME PROGRESS: Based on what you drank on average last week, it looks like you didn't quite hit your goal, but you did make some progress, so congratulations on your success! Lots of people struggle with trying to cut back on their sugary drinks, but we know people who make even small and gradual decreases in sugary drinks improve their health and have a better chance at cutting back more than people who don't make any progress in the first week. I know you tried to
STRATEGY 1_____
_____ and
STRATEGY 2_____
_____
to help you make some progress. This week you might want to try those again and add in this strategy too
NEW STRATEGY_____
_____. [*randomly selected strategy from same barriers—one that participant didn't select*].
(if they respond with some push back use: —Just give it a try and let me know at the next class how it worked)

The next thing we need to do is to set a new goal for the next week. Right now you are drinking about _____ ounces [CURRENT] and in class you set an initial goal that was about to drink _____ ounces [GAP] or less and that was cutting back by about _____ounces [IMG].

IF PARTICIPANT IS AT 8 OUNCES OR FEWER. You are no longer drinking more than the recommended guidelines of 8 ounces. Congratulations! Does sticking where you are sound like a good goal to you?

IF PARTICIPANT IS > 8 OUNCES Do you think it would be reasonable to use the same goal you set last week? That would mean that your goal for this week would be _____ ounces [GAP]. Does this sound like a good goal to you?

Yes - Great! Thanks for taking the time to talk to me today. You are doing good job on this. Remember, your new goal is to drink _____ [GAP] or less ounces each day over the next week. Remember to try out the new strategy to help you stay on track! *Go to the TBM ASSESSMENT SCRIPT*

No- No problem, what do you think would be a good goal for the next week? RECORD NEW GOAL_____.
If new goal equal to current amount of ounces or fewer--Okay, that'll work fine. Thanks for taking the time to talk to me today. You are doing a good job. Remember, your goal is to drink _____or less ounces [*NEW GOAL*]each day over the next week. Remember to try out the new strategy to help you stay on track! *Go to the TBM ASSESSMENT SCRIPT*

*If new goal higher than current amount of ounces—*Remember that ultimately, 8 ounces per day or fewer is the best goal for reducing the risk of obesity and diabetes that comes with drinking

sugary drinks. If you don't want to go much lower this week that is fine, but maybe we could have a goal that you just stay at the same level you are at right now. Does that sound reasonable?

- *If yes-*Okay, thanks for taking the time to talk to me today. You are making progress. Remember, your goal is to drink _____[CURRENT] or less ounces each day over the next week. Your plan seems to be working well for you, so just stick with it and I will talk to you more about it next week! *Go to the TBM ASSESSMENT SCRIPT*.
- *If no-*Okay, we can stick with the goal you want to set for this week. Thanks for taking the time to talk to me today. You are making progress. Remember, your goal is to drink _____[NEW GOAL] or less ounces each day over the next week. *Go to the TBM ASSESSMENT SCRIPT*.

NO PROGRESS: Based on what you drank on average last week, it looks like you didn't cut back like you wanted to. Lots of people struggle with trying to cut back on their sugary drinks, but we know people who make even small and gradual decreases in sugary drinks improve their health. Remember the things that sugary drinks are related to—diabetes, cancer, obesity—based on the amount of sugary drinks you have each day you are putting yourself at high risk for these outcomes. I know you tried to
STRATEGY 1_____
_____ and
STRATEGY 2_____
_____
to help you make some progress. This week you might want to try those again and add in this strategy too
NEW
STRATEGY_____
_____. [*randomly selected strategy from same barriers—one that participant didn't select*].
(if they respond with some push back use: —Just give it a try and let me know at the next class how it worked)

The next thing we need to do is to set a new goal for the next week. Right now you are drinking about _____ ounces [CURRENT] and in class you set an initial goal that was about to drink _____ ounces [GAP] or less and that was cutting back by about _____ounces [IMG]. What if this week you set a goal that is about half of the one you set previously. That would mean that your goal for this week would be _____ ounces [CURRENT – (IMG_____/2]. Does this sound like a good goal to you?

Yes - Great! Thanks for taking the time to talk to me today. You are doing good job on this. Remember, your new goal is to drink _____ [CURRENT – (IMG_____/2] or less ounces each day over the next week. Remember to try out the new strategy to help you stay on track! *Go to the TBM ASSESSMENT SCRIPT*

No- No problem, what do you think would be a good goal for the next week? RECORD NEW GOAL_____.
If new goal equal to current amount of ounces or fewer--Okay, that'll work fine. Thanks for taking the time to talk to me today. You are doing a good job. Remember, your goal is to drink

_____or less ounces [*NEW GOAL*] each day over the next week. Remember to try out the new strategy to help you stay on track! *Go to the TBM ASSESSMENT SCRIPT*

*If new goal higher than current amount of ounces—*Remember that ultimately, 8 ounces per day or fewer is the best goal for reducing the risk of obesity and diabetes that comes with drinking sugary drinks. If you don't want to go much lower this week that is fine, but maybe we could have a goal that you just stay at the same level you are at right now. Does that sound reasonable?

- *If yes-*Okay, thanks for taking the time to talk to me today. You are making progress. Remember, your goal is to drink _____[CURRENT] or less ounces each day over the next week. Your plan seems to be working well for you, so just stick with it and I will talk to you more about it next week! *Go to the TBM ASSESSMENT SCRIPT*

-

- *If no-* Okay, we can stick with the goal you want to set for this week. Thanks for taking the time to talk to me today. You are making progress. Remember, your goal is to drink _____[NEW GOAL] or less ounces each day over the next week. *Go to the TBM ASSESSMENT SCRIPT*

-

-

		LEARNING OBJECTIVE TEACH BACK #3
		Okay I want to make sure I've done a good job explaining things, so I want to revisit those questions you were struggling with just one more time.
TBC3_1	|_____|[0] incorrect |_____|[1] correct	Do you remember the maximum amount of sugary drinks recommended per day? Record response: |_____ _____| • *Correct = less than or equal to 8 ounces/day*
		• *If TBC1_1 = [0] incorrect:* The recommended daily amount is 8 ounces, which is the same size as the blue cup we gave you in class. Or you could use a standard 1 cup measuring cup. So 8 ounces is the maximum amount of sugary drinks that is recommended that you should consume each day. • *If TBC1_1 = [1] correct:* Yes, that's right! During that first class you learned that 8 oz is the maximum amount of sugary drinks that you should consume each day.
TBC3_2	|_____|[0] incorrect (if any of 3 are incorrect) |_____|[1] correct (if all 3 are correct)	Can you please give me three examples of sugary drinks? Record responses: |_____ _____| |_____

		_____| |_____ _____|
TBC3_3	|_____|[0] incorrect (if any of 3 are incorrect) |_____|[1] correct (if all 3 are correct)	Can you please give me three examples of non-sugary drinks? • Record responses: |_____ _____| |_____ _____| |_____ _____|

TBC3_4	|_____|[0] incorrect (if any of the 8 are incorrect)
	 |_____|[1] correct (if all 8 are correct)
		I'm going to read off a list of drinks. Just answer yes, if it is sugary, and no if it is non-sugary.
		 • TBC1_4a. Mountain Dew |_____|[0] no
		     |_____|[1] yes
		 • TBC1_4b. 100% Apple Juice |_____|[0] no
		     |_____|[1] yes
		 • TBC1_4c. Sunny Delight |_____|[0] no
		     |_____|[1] yes
		 • TBC1_4d. Arizona Iced Tea |_____|[0] no
		     |_____|[1] yes
		 • TBC1_4e. Diet Coke |_____|[0] no
		     |_____|[1] yes
		 • TBC1_4f. Gatorade |_____|[0] no
		     |_____|[1] yes
		 • TBC1_4g. Crystal Light |_____|[0] no
		     |_____|[1] yes
		 • TBC1_4h. Red Bull |_____|[0] no
		     |_____|[1] yes
		
		 ***If they say, I don't know or it depends…ask they could find out or know?

		• *If TBC1_3= [0] incorrect:* Ok great, so you're right about _____ (state correct answers). You missed _____ (state incorrect answers). Remember the categories of sugary drink were soft drinks, 100% fruit juice, fruit drinks, energy drinks, sports drinks, and coffee and tea when you add sugar. Sunny delight, bottled green tea, and capri sun would be considered sugary drinks. Some examples are Coke or Mountain Dew, 100% juice such as orange or apple juice and other fruit-flavored drinks like fruit punch or Sunny D. Other sugary drinks include energy drinks like Red Bull, sports drinks like Gatorade and powerade, and coffee and tea—but only when you add sugar to it. Lastly, we talked about chocolate or other flavored milks.

		• Non-sugary drinks do not have sugar in them and some examples include: diet drinks, black coffee, unsweet tea, regular milk, or alcohol. • *If TBC1_3= [1] correct:* Ok great, you really seem to understand what is and what is not a sugary drink
TBC3_5	|_____|[0] incorrect (if any of 3 are incorrect) |_____|[1] correct (if all 3 are correct)	Can you please state three health risks that are associated with drinking too many sugary drinks? Record responses: |_____ _____| |_____ _____| |_____ _____|
		If TBC1_5= [0] incorrect: Remember that drinking more than the recommendation of 8 ounces per day, puts you at risk for unhealthy weight gain, diabetes, teeth decay, heart problems and even cancer. *If TBC1_5 = [1] correct:* That's right, excellent. Remember that drinking more than the recommendation of 8 ounces per day, puts you at risk for unhealthy weight gain, diabetes, tooth decay, heart problems and even cancer.
TBC3_6	Repeat teach back: |_____|[0] no |_____|[1] yes	*TBC3_6 = [1] yes - IF ANY of TBC3_3 through TB3_5 are incorrect:* Okay, great I really appreciate you hanging in there with me. I know there was a lot of information covered in the first class. For the ones you missed again, be sure and use your SipSmartER binder to find answers to these questions and review the materials. *[NO MORE TEACH BACK- Move to TPB Assessment]* *TBC3_6 = [0] no - IF ALL REPEATED QUESTIONS for TBC3_1 through TBC3_5 are correct:* Excellent job! I really appreciate you hanging in there with me. I know there was a lot of information covered in the first class and now it seems like you've really mastered all the key points. Be sure and use your SipSmartER binder to find answers to these questions and review the materials. *[NO MORE TEACH BACK- Move to TPB Assessment]*

TBM ASSESSMENT

		TBM ASSESSMENT
		The last thing we need to do today is to ask you a few questions that will help us to keep making the program better and better for you. For these questions think about drinking less than 1 cup, or 8 ounces, of sugary drinks per day. There are 4 questions we'll go

		through.

TPB_1	|____|[1] Extremely unhealthy
	|____|[2] Quite unhealthy
	|____|[3] Slightly unhealthy
	|____|[4] Neither
	|____|[5] Slightly healthy
	|____|[6] Quite healthy
	|____|[7] Extremely healthy
		1. Do you think that drinking less than 1 cup of sugary drinks each day would be healthy, unhealthy, or neither?
		   a. Healthy—Okay, do you think it would be slightly, quite or extremely healthy? RECORD _____
		   b. Unhealthy—Okay, do you think it would be slightly, quite or extremely unhealthy? RECORD_____
		   c. Neither—Go to next question

TPB_2	|____|[1] Extremely unenjoyable
	|____|[2] Quite unenjoyable
	|____|[3] Slightly unenjoyable
	|____|[4] Neither
	|____|[5] Slightly enjoyable
	|____|[6] Quite enjoyable
	|____|[7] Extremely enjoyable
		2. Do you think that drinking less than 1 cup of sugary drinks each day would be enjoyable, unenjoyable, or neither?
		   a. Enjoyable—Okay, do you think it would be slightly, quite or extremely enjoyable? RECORD _____
		   b. Unenjoyable—Okay, do you think it would be slightly, quite or extremely unenjoyable? RECORD_____
		   c. Neither—Go to next question

TPB_3	|____|[1] Strongly disagree
	|____|[2] Moderately disagree
	|____|[3] Slightly disagree
	|____|[4] Neither
	|____|[5] Slightly agree
	|____|[6] Moderately agree
	|____|[7] Strongly agree
		3. Do you agree, disagree, or neither agree or disagree that most people who are important to you want you to drink less than 1 cup of sugary drinks each day?
		   a. Agree—Okay, do you strongly, moderately, or slightly agree? RECORD _____
		   b. Disagree—Okay, do you strongly, moderately, or slightly disagree? RECORD_____
		   c. Neither—Go to next question

TPB_4	|____|[1] Extremely difficult
	|____|[2] Quite difficult
	|____|[3] Slightly difficult
	|____|[4] Neither
	|____|[5] Slightly easy
	|____|[6] Quite easy
	|____|[7] Extremely easy
		4. Do you think it would be easy, difficult, or neither for you to limit your to sugary drinks to less than 1 cup each day?
		   a. Easy—Okay, do you think it would be slightly, quite, or extremely easy? RECORD _____
		   b. Difficult— Okay, do you think it would be slightly, quite, or extremely difficult? RECORD_____
		   c. Neither—Go to goodbye text.

Next week you will start receiving automated phone calls and you will need your pin number. Can you tell me what you pin number is?

Confirm that the participant knows their pin number or provide their pin number.

Remember that the most important piece of information that you will need to complete the automated call is your daily average sugary beverage intake. So it will really helpful for you to complete your drink diary every day, calculate your average at the end of every week, and have that available when you receive the phone call. Also, please stay on the phone until the call is complete, otherwise the system will think that you did not complete the call and it will call you again.

What sort of other questions do you have for me before we hang up?

If you ever have any questions, you can always get ahold of us by calling our study phone number at _____.

Thank you for completing the call this week! I feel very confident that you are well on your way to decreasing your sugary drink intake. Also, you have helped your group move one call closer to reaching your goal and getting your prize at the next class!

Goodbye!

End Time of Call:_____   Calculate Total Minutes of Call:_____

MoveMore- Live Teach Back Call

Participant ID:_____ Date of Call:_____ Start Time
of Call:_____
Black text is scripted call content
[ ] reflect content that will change within the script (e.g., [participant name])
This color text refers to information you need to add PRIOR to initiating the call
This color text in italics is instruction for the caller

		RECORD THIS INFORMATION PRIOR TO GETTING PARTICIPANTS ON PHONE
Intro_1.	|_____|[0] no |_____|[1] yes	***Did Participant Attend Class #1** *If Intro_1=0 [no], go to Intro_1a*
Intro_1a.	|_____|[0] no |_____|[1] yes	***Did Participant Complete Missed Class #1 Recap Call**
Intro_2.	|_____| days	*** RECORD GOAL DAYS CARDIO FROM ACTION PLAN (CVDAP)**
Intro_2a	|_____| minutes	**RECORD GOAL MINUTES/DAY CARDIO FROM ACTION PLAN (CVMAP):**
Intro_2b	|_____| total minutes	**CALCULATE GOAL MINUTES X DAYS CARDIO FROM ACTION PLAN (CVWEEKLYAP):**
Intro_3.	|_____| days	**RECORD GOAL DAYS STRENGTHENING FROM ACTION PLAN (STDAP):**
Intro_3.	|_____| minutes	**RECORD GOAL MINUTES/DAY STRENGTHENING FROM ACTION PLAN (STMAP):**
Intro_3.	|_____| total minutes	**CALCULATE GOAL MINUTES X DAYS STRENGTHENING FROM ACTION PLAN (STWEEKLYAP)**
Intro_4	|_____| Goal PA total	**CALCULATE GOAL PA TOTAL (CVWEEKLYAP + STWEEKLYAP):** *Record this number on Page 9*
Intro_5.	Record strategy #1:	***Strategy from Personal Action Plan**
Intro_5a.	Record strategy #2:	***Strategy from Personal Action Plan**
Intro_6.	Record new strategy:	***Strategy from Obstacles handout** *randomly selected strategy from same barriers—one that participant didn't select*

Intro_7.	|_____| IVR PIN number	***Record IVR PIN number**
		Hello, this is [your name] calling from Virginia Tech for [participant name] she/he is expecting my call. Is he/she home right now?

If YES, wait for them to come to the line or if the participant answers go on to number 2
If NO, "Thanks, can you give me an idea when she/he may be back?" *[record time]* "Thanks, I'll try back later then. Goodbye"

Hi [participant name] I'm calling to complete your first Move More telephone call. Do you have about 15-20 minutes to complete it right now?

If YES, begin the ASSESSMENT section

If NO, "That's okay, can we schedule a time that would be good for you?" *[record time]* "Thanks, I'll call back later then. Goodbye"

*Answering Machine Response—Only leave a message once per day on the first, second, and forth day of calling with a 3-message maximum in one week.

1st message: This is [your name] calling from Virginia Tech for [participant name]. I'll try calling you again, but if you would like to call me back and let me know a good time for us to chat, just call me at [study line]. Thanks and I hope I catch up with you soon!

2nd & 3rd message: This is [your name] calling from Virginia Tech for [participant name] to complete your first Move More call. I'll try calling you another time this week to see if we can get your call done. Again, if you would like to call me back and let me know a good time for us to chat, just call me at [study line]. Thanks and I hope we can finish up this call soon, it will just take a couple of minutes. |
| | | |
| | | *If Intro_1(Attended first class) = yes:* It was so great to have you at the first class- I hope that you had fun and learned a lot. |

		Today we will be reviewing the information from that class as well as talking about your progress on increasing your physical activity minutes.
		If Intro 1(Did not attend first class) = no, but Intro_1a = yes: It was so great to chat with you a few days ago and fill you in on what you missed during class one. Today we will be reviewing the information from that class as well as talking about your progress on increasing your physical activity minutes.
		TEACH BACK OPPORTUNITY #1
		In class, we went over what physical activity is and how much you need. We also talked about the benefits of being physically active, and set some goals for how much activity folks would do over the next week. First, I'd like to ask you what you remember from the class. If you don't know, it's OK, we can review the information shortly.
TBC1_1.	|_____|[0] incorrect (if any of 4 are incorrect) |_____|[1] correct (if all 4 are correct)	Now, when we talk about physical activity we are talking about cardio and strength activities—let's start with cardio. Can you tell me four things that would let you know you are doing cardio? Record response: |_____ _____| *Correct = heart beats faster, breathing harder, using large muscles, it lasts for 10 minutes or more*
		If TBC1_1 = [0] incorrect: The way you know if you're doing cardio is your heart beats faster, you are breathing harder, you are using large muscles, and it lasts for 10 minutes or more. Remember BBLT from class? That's a quick way to remember this, the B stands for heart Beating faster, the second B stands for your Breathing harder, L stands for using Large muscles and the T stands for ten minutes. Bacon, bacon, lettuce tomato sandwich. *If TBC1_1 = [1] correct:* Yes, that's right!
TBC1_2.	|_____|[0] incorrect |_____|[1] correct	Now, do you remember how many minutes of cardio is recommended per week? _____ *record participants response*

		Correct = 150 minutes, or 30 minutes a day for 5 days out of the week.
		If TBC1_2= [0] incorrect: Okay, no problem, the recommendation is 150 minutes, or 30 minutes a day for 5 days out of the week. *If TBC1_2 = [1] correct:* Yes, that's right- good job! The recommendation is 150 minutes, or 30 minutes a day for 5 days out of the week.
TBC1_3.	|_____|[0] incorrect (if any of 6 are incorrect) |_____|[1] correct (if all 6 are correct)	Next, I'm going to read off a list of exercises. Just answer yes, if it is cardio, and no if it is not cardio. TBC1_3a. jogging for 20 minutes |_____|[0] no |_____|[1] yes TBC1_3b. watching TV on the couch |_____|[0] no |_____|[1] yes TBC1_3c. doing jumping jacks for 15 minutes |_____|[0] no |_____|[1] yes TBC1_3d. riding a bike for 30 minutes |_____|[0] no |_____|[1] yes TBC1_3e. walking to the store for 10 minutes |_____|[0] no |_____|[1] yes TBC1_3f. doing laundry for 9 minutes |_____|[0] no |_____|[1] yes ****If they say, I don't know or it depends…ask how they could find out or know?* *3a, 3c, 3d, and 3e are correct*
		If TBC1_3= [0] incorrect: Okay, no problem, you missed _____(state incorrect answers). Remember, the way to know if you're doing cardio is your heart beats faster, you are breathing harder, using large muscles, and it lasts for 10 minutes or more. Remember BBLT? *If TBC1_3 = [1] correct:* Excellent, you got all those right.
TBC1_4	|_____|[0] incorrect |_____|[1] correct	Ok, now lets talk about the other type of PA-strength training How many days a week should you do strength training every week? _____*record participants response* *It's recommended you do strength training exercise on 2 or more days per week*
		If TBC1_4= [0] incorrect: Okay, no problem, the recommendation is you do strength training exercise on 2 or more days per week and remember to work all the big muscle groups. *If TBC1_4 = [1] correct:* Yes, that's right- good job!
TBC1_5	|_____|[0] incorrect	How many sets are you suppose to do?

	|_____|[1] correct	_____record participants response *It is recommended you do 1-2 sets of each exercise.*
		If TBC1_5= [0] incorrect: Okay, no problem, it is recommended you do 1 to 2 sets of each exercise. *If TBC1_5 = [1] correct:* Excellent, you are right.
TB C1_6	|_____|[0] incorrect |_____|[1] correct	How many reps are you suppose to do? _____record participants response *It is recommended you do anywhere from 8 to 15 reps of each exercise.*
		If TBC1_6= [0] incorrect: Okay, no problem, it is recommended you do anywhere from 8 to 15 reps of each exercise. *If TBC1_6 = [1] correct:* Excellent, you are right.
TBC1_7	|_____|[0] incorrect (if any of the 8 are incorrect) |_____|[1] correct (if all 8 are correct)	Now, I'm going to read off another list of exercises, answer yes if it's strength training and no if it's not. TBC1_7a. using resistance bands |_____|[0] no |_____|[1] yes TBC1_7b. walking up a hill |_____|[0] no |_____|[1] yes TBC1_7c. lifting a gallon of milk 12 times in a row |_____|[0] no |_____|[1] yes TBC1_7d. lifting weights |_____|[0] no |_____|[1] yes TBC1_7e. 10 push ups |_____|[0] no |_____|[1] yes TBC1_7f. driving a car |_____|[0] no |_____|[1] yes ****If they say, I don't know or it depends…ask they could find out or know?* *7a, 7c, 7d, and 7e are correct.*
		If TBC1_7= [0] incorrect: Ok great, so you're right about _____ (state correct answers). You missed _____ (state incorrect answers). Remember strength training involves using a weight or other form of resistance 8-15 times in a row, for one or two sets to strengthen a muscle. *If TBC1_7= [1] correct:* Ok great, you really seem to understand what is and what is not strength training
TBC1_8	|_____|[0] incorrect	*Last question, c*an you name me three health benefits to being

	(if any of 3 are incorrect) |_____|[1] correct (if all 3 are correct)	physically active? Record responses: |_____ _____| |_____ _____| |_____ _____| *Possible answers include: Lose weight, be healthier, live longer, not getting sick, feeling better, be able to do more things, reduce risks of chronic diseases like heart disease, cancer, high blood pressure and diabetes, sleep better, maybe reduce visits to the Dr.*
		If TBC1_8= [0] incorrect: name them three benefits from the above list *If TBC1_8 = [1] correct:* That's right, excellent.
TBC1_9	Repeat teach back: |_____|[0] no |_____|[1] yes	*TBC1_9 = [1] yes - IF ANY of TBC_1 through TBC1_8 are incorrect:* You did a good job remembering information from the first class. I know there was a lot of information covered. So let's just briefly recap the ones you missed. *[Only do the LEARNING OBJECTIVE TEACH BACK #2 for those questions that were missed during TEACH BACK #1]* *TBC1_9 = [0] no - IF ALL TB1C_1 through TBC1_5 are correct:* Excellent job! You really got a lot out of the first class and you got all of those questions correct. Now let's move on and see how you're doing with your exercise log. *[Skip TEACH BACK OPPORTUNITY #2]*
		LEARNING OBJECTIVE TEACH BACK #2
TBC2_9	Repeat teach back: |_____|[0] no |_____|[1] yes	*TBC2_9 = [1] yes - IF ANY of TBC2_1 through TBC2_8 are incorrect:* Okay, you did a good job remembering information from the first class. I know there was a lot of information covered. For the ones you missed again, we will briefly recap those at the end of this call. But for now let's move on and see how you're doing with your exercise log! *[Only do the LEARNING OBJECTIVE TEACH BACK #3 for those questions that were missed during TEACH BACK #2]* *TBC2_6 = [0] no - IF ALL REPEATED QUESTIONS for TBC2_1 through TBC2_8 are correct:* Excellent job! You really got a lot out of the first class and you got all of those questions correct. Now let's move on and see how you're doing with your exercise log!

		[Skip TEACH BACK OPPORTUNITY #3]
		EXERCISE LOG TEACH BACK
DD_1	|_____|[1] not using it at all |_____|[2] using it some days, but not everyday |_____|[3] using it everyday	Now we're going to talk about your exercise log. How often have you been using your exercise log to track your activities?
		If DD_1 = [1] not using it all: Remember that it's so important for you to use your log. One of the first steps in changing your exercise behaviors is to understand it. The automated calls will start next week and it will ask you to report your average minutes of physical activity, both cardio and strength training. We want to make sure you get the most out of this program by correctly recording and reporting your minutes. For today, we will take some time to review how to correctly use the log. *If DD_1 = [2] using it some days, but not everyday:* I'm so glad that you've started using the log, that's great. We realize you may forget every now and then, but it is important to try and log physical activity each day you do it. The automated calls will start next week and it will ask you to report your average minutes of physical activity, both cardio and strength training. We want to make sure you get the most out of this program by correctly recording and reporting your minutes. For today, I will take some time to review how to correctly use the log. *If DD_1 = [1] using it every day.* Excellent, I'm so glad that you're using the log every day. The automated calls will start next week and it will ask you to report your average minutes of physical activity, both cardio and strength training. We want to make sure you get the most out of this program by correctly recording and reporting your minutes. For today, I will take some time to review how to correctly use the log.
DD_2	|_____|[1] using exercise log to recall days/minutes |_____|[2] using memory to recall intake _____send a new log	Okay, before we get going, do you have your exercise log and a pen handy? *If YES, continue and mark 'using exercise log to recall days/minutes'* *If No,* Would you like to take a second to grab them? *If they don't know where they are, they are somewhere they can't get to them, don't want to go get them, that is fine record 'using memory to recall intake'* Ok, do you still have it, or would you like us to send you a new

		one?
DD_3	|_____|[0] incorrect history of completely log |_____|[1] correct history of completing log	To get started, can you please read [or recall] the cardio and strength training exercises you put in your log. Record any **non-cardio or strength exercise** that the participant reports: |_____ _____| *Incorrect history if recording exercises that do not qualify as cardio or strength training* *Correct history if only recording cardio and strength exercises.*
		If DD_3 = 0 and participants listed non-cardio or strength exercises: Remember that we only want you to record cardio, which means your heart is beating faster, your breathing harder, you are using your large muscles and you do it for at least 10 minutes. Strength training means you work a muscle by doing 8-15 reps and 1 to 2 sets of the exercise. *If DD_3 =1 and participants listed only cardio and strength exercises:* Great job- it seems as if you are only doing true cardio and strength training exercises and that is exactly what you are supposed to be doing.
DD_4	|_____|[0] incorrect history of completely log |_____|[1] correct history of completing log	Now think about these past few days, were there any cardio or strength training exercises you forgot to record? Record any exercises that the participant now recalls: |_____ _____| *Incorrect history if participant has forgotten to record any exercises.* *Correct history if no reports of forgotten exercises.*
		If DD_4= 0 and participants forgets exercises: Remember that we are trying to help you remember to report all your physical activity. Let's go ahead and add those that you missed to your log and from this point forward, you'll know to remember to record those exercises. *If DD_4 =1 and participants did not forget any exercises:* Great job- it seems as if you have really gotten the hang out of filling out this exercise log correctly.
DD_5		How do you time your exercises?

		Record how that the participant assesses time:
	|_____|[0] incorrect history of assessing time |_____|[1] correct history of assessing time	|_____ _____| *Incorrect history if participant appears to be guessing* *Correct history if using a clock , watch, timed DVD, or some other standardized way of measuring how long he/she exercised.*
		If DD_5 = 0 and incorrect history of assessing time: You can use a watch, a clock or your cell phone at home to time your activities. Or, remember the DVD we gave you in class, if you do the warm up and 1-mile walk, that is 15 minutes. Just remember to use something that can officially tell you how long you exercised and only guess if you absolutely have to. *If DD_5 = 1 and correct history of assessing time:* Great job, remember the more accurately you record your time, the more you will get out of the program.
DD_6	|_____|[0] incorrect history of calculating average number of minutes for both cardio and strength training |_____|[1] correct history of calculating average number of minutes for both cardio and strength training	Now tell me how you calculated your average weekly minutes for both cardio and strength exercises. *Note the participants should have two separate averages, one for cardio and one for strength training.* Record any errors in calculating an average: |_____ _____|
		If DD_6 = 0 and incorrect history of calculating errors: (Personalize this for the participants, and help them add each day appropriately and calculate a daily average…… *If not…let's walk through it. (An example, please modify as you see fit)* You need to calculate weekly averages for both your cardio and strength training exercise. Let's start with cardio. Can you add together the minutes of cardio you did from all the days you have recorded in your log? OK, what is that number? Great, now, let's divide that number by the number of days you did cardio. What do you get? Great, that's the same number I get too.

		As mentioned earlier, it will be very important for you to calculate the weekly average for cardio and strength exercises each week so you can report accurately with the automated calls that start next week. *If DD_6 = 1 and correct history of calculating errors:* Great job- it seems as if you really understand how to calculate your weekly average of minutes. As mentioned earlier, it will be very important for you to calculate this weekly average so you can report accurately with the automated calls that start next week.
		Okay before we move on, what questions do you have about completing your exercise logs? Record type of question(s): |_____ _____| *[Provide appropriate answer to the participant's question]*
		ASSESSING PHYSICAL ACTIVITY
PA_1	|_____| record Current PA Minutes Total	Now I want to check in and see how you are doing increasing your minutes of physical activity. If you need to make some changes on your logs based on what you just learned or errors we found, that is completely fine. We want you to try and answer each of these next questions as accurately as possible. The more accurately your answer the better this program can help you. *If they didn't calculate or don't have the log…* It's okay if you can't remember exactly, just go ahead and give me your best estimate. 1a. Can you tell me how many days you did cardio activity last week? RECORD DAYS (CVD): _____[IF zero, go to #4] 1b. Can you also tell me, on average, how many minutes of cardio you did on each of those days? Again, this means your heart was beating a little faster, you were breathing a little deeper, and you may have even worked up a sweat. RECORD MINUTES (CVM): _____ CALCULATE DAYS X MINUTES (CVWEEKLY): _____ 1c. Can you tell me how many days you did strengthening

		activities last week?
		RECORD DAYS (STD): _____ [IF zero, go to #6] 1d. Can you tell me, on average, how many minutes of strength training activities you did on each of those days? RECORD MINUTES (STM): _____ CALCULATE DAYS X MINUTES (STWEEKLY): _____ CALCUATE Current PA Total (CVWeekly +_STWeekly:_____
PA_2	|_____|[1] Goal achieved |_____|[2] Some progress |_____|[3] No progress	|_____| record **GOAL PA TOTAL** from page 1 (USE THIS NUMBER TO HELP DETERMINE IF GOAL WAS ACHIEVED)*-*DO NOT ASK QUESTION*. ***GOAL ACHIEVED = PA TOTAL IS EQUAL TO GOAL PA TOTAL ± 5 MINUTES*** ***SOME PROGRESS = PARTICIPANT DID AT LEAST ONE DAY OF CARDIO OR STRENGTH TRAINING FOR 15 MINUTES OR MORE*** *** NO PROGRESS = PARTICIPANT DID NOTHING***

GOAL ACHIEVEMENT & SETTING
GOAL ACHIEVEMENT
ACHIEVED GOAL: I am really pleased to see that you accomplished your goal for the week! Congratulations on your success! The changes you are making are really going to help with your health in the long run. Keep up the good work! One of the best things about achieving your first week's goal is that now you know you can do it, you can increase your physical activity! You are on a great path to reduce your risk of diabetes, heart disease, and cancer. Since you are doing so well, your call is going to be really short this week! The next thing we need to do is to set a new goal for the next week. [Go to GOAL SETTING section].

MADE SOME PROGRESS: Based on what you did last week, it looks like you didn't quite hit your goal, but you did make some progress, so congratulations on that success! Lots of people struggle with trying to increase their physical activity, but we know people who make even small and gradual increases in physical activity improve their health and have a better chance at increasing more than people who don't make any progress in the first week. I know you tried to
STRATEGY
1_____
_____ and
STRATEGY
2_____
_____ to help you make some progress. This week you might want to try those again and add in this strategy too
NEW
STRATEGY_____
_____. [*randomly selected strategy from same barriers—one that participant didn't select*].
(if they respond with some push back use: —Just give it a try and let me know at the next class how it worked)

The next thing we need to do is to set a new goal for the next week. [Go to GOAL SETTING section].

NO PROGRESS: Based on what you did last week, it looks like you didn't increase you physical activity like you wanted to. Lots of people struggle with trying to increase their physical activity, but we know people who make even small and gradual increases improve their health. Remember the things that are related to not being physically active—diabetes, cancer, obesity—based on your low levels of physical activity you are putting yourself at high risk for these outcomes. I know you tried to
STRATEGY
1_____
_____ and
STRATEGY
2_____

_____ to help you make some progress. This week you might want to try those again and add in this strategy too
NEW
STRATEGY_____
_____. [*randomly selected strategy from same barriers—one that participant didn't select*].
(if they respond with some push back use: —Just give it a try and let me know at the next class how it worked)

The next thing we need to do is to set a new goal for the next week. [Go to GOAL SETTING section].
GOAL SETTING
Based on what you told me today, you are getting about: (see page 9)
_____ [CVWEEKLY) minutes of cardio activity and
_____ [STWEEKLY) minutes of strengthening activities a week [If zero strengthening say: and no strength training activities]

 [if CVWEEKLY = 0 to 19 minutes] We would like you to increase your cardio activity to 20 to 60 minutes this week. That means you would do about 10 to 20 minutes a day, 2 to 3 days this week.
[STWEEKLY= 0 to 14] We would also like you to try and get 15 to 30 minutes of strengthening activities in this week. That would be about 15 minutes a day, 1 or 2 days this week.
[STWEEKLY= 15 to 29] We would also like you to try and get 30 minutes of strengthening activities in this week. That would be about 15 minutes a day, 2 days this week.
[STWEEKLY > 29] Last week you did about _____ [STWEEKLY] minutes and that meets the recommended guidelines, so we would like you to keep that up! [Go to SET GOAL]

[if CVWEEKLY = 20 to 59] We would like you to increase your cardio activity to 60 to 90 minutes this week. That means you would do about 30 minutes a day, 2 to 3 days per week.
[STWEEKLY= 0 to 14] We would also like you to try and get 15 to 30 minutes of strengthening activities in this week. That would be about 15 minutes a day, 1 or 2 days this week.
[STWEEKLY= 15 to 29] We would also like you to try and get 30 minutes of strengthening activities in this week. That would be about 15 minutes a day, 2 days this week.
[STWEEKLY > 29] Last week you did about _____ [STWEEKLY] minutes and that meets the recommended guidelines, so we would like you to keep that up! [Go to SET GOAL]

[if CVWEEKLY = 60 to 89] We would like you to increase your cardio activity to 90 to 120 minutes this week. That means you would do about 30 minutes a day, 3 to 4 days per week.

[STWEEKLY= 0 to 14] We would also like you to try and get 15 to 30 minutes of strengthening activities in this week. That would be about 15 minutes a day, 1 or 2 days this week.

[STWEEKLY= 15 to 29] We would also like you to try and get 30 minutes of strengthening activities in this week. That would be about 15 minutes a day, 2 days this week.

[STWEEKLY > 29] Last week you did about _____ [STWEEKLY] minutes and that meets the recommended guidelines, so we would like you to keep that up! [Go to SET GOAL]

[if CVWEEKLY = 90 to 119] We would like you to increase your cardio activity to 120 to 150 minutes this week. That means you would do about 30 minutes a day, 4 to 5 days per week.

[STWEEKLY= 0 to 14] We would also like you to try and get 15 to 30 minutes of strengthening activities in this week. That would be about 15 minutes a day, 1 or 2 days this week.

[STWEEKLY= 15 to 29] We would also like you to try and get 30 minutes of strengthening activities in this week. That would be about 15 minutes a day, 2 days this week.

[STWEEKLY > 29] Last week you did about _____ [STWEEKLY] minutes and that meets the recommended guidelines, so we would like you to keep that up! [Go to SET GOAL]

[if CVWEEKLY = 120 to 149] We would like to have you increase your cardio activity to 150 minutes this week. That means you would do about 30 minutes a day, 5 days per week—and it would get you to the recommended guidelines for cardio activities!

[STWEEKLY= 0 to 14] We would also like you to try and get 15 to 30 minutes of strengthening activities in this week. That would be about 15 minutes a day, 1 or 2 days this week.

[STWEEKLY= 15 to 29] We would also like you to try and get 30 minutes of strengthening activities in this week. That would be about 15 minutes a day, 2 days this week.

[STWEEKLY > 29] Last week you did about _____ [STWEEKLY] minutes and that meets the recommended guidelines, so we would like you to keep that up! [Go to SET GOAL]

[if CVWEEKLY > 149] You are already meeting the recommended guidelines for cardio activities, so use your current cardio activity as your ongoing weekly goal.

[STWEEKLY= 0 to 14] We would also like you to try and get 15 to 30 minutes of strengthening activities in this week. That would be about 15 minutes a day, 1 or 2 days this week.

[STWEEKLY= 15 to 29] We would also like you to try and get 30 minutes of strengthening activities in this week. That would be about 15 minutes a day, 2 days this week.

[STWEEKLY > 29] Last week you did about _____ [STWEEKLY] minutes and that meets the recommended guidelines, so we would like you to keep that up! [Go to SET GOAL]

SET GOAL

Does this sound like a good goal for you?

Yes - Great! Thanks for taking the time to talk to me today.
Remember, your new goal to get _____minutes of cardio a day, _____ days per week and _____minutes of strength activities a day, _____ days per week over the next week.

[ACHIEVED GOAL] Your plan seems to be working well for you, so keep up the good work!
    [SOME/NO PROGRESS] Remember to try out the new strategy to help you stay on track!

If the participant missed a question during the 2ⁿᵈ teach-back, go to Teach Back # 3.
If the participant did not miss a teach-back question, go to TBM assessment.

		LEARNING OBJECTIVE TEACH BACK #3
		Okay I want to make sure I've done a good job explaining things, so I want to revisit those questions you were struggling with just one more time.
TBC3_1 through TBC3_8		
TBC3_9	Repeat teach back: |_____|[0] no |_____|[1] yes	*TBC3_9 = [1] yes - IF ANY of TBC3_1 through TB3_8 are incorrect:* Okay, great I really appreciate you hanging in there with me. I know there was a lot of information covered in the first class. For the ones you missed again, be sure and use your Move More binder to find answers to these questions and review the materials. *[NO MORE TEACH BACK- Move to TPB Assessment]* *TBC3_6 = [0] no - IF ALL REPEATED QUESTIONS for TBC3_1 through TBC3_8 are correct:* Excellent job! I really appreciate you hanging in there with me. I know there was a lot of information covered in the first class and now it seems like you've really mastered all the key points. Be sure and use your Move More binder to find answers to these questions and review the materials. *[NO MORE TEACH BACK- Move to TPB Assessment]*

TBM ASSESSMENT

		TBM ASSESSMENT
		The last thing we need to do today is to ask you a few questions that will help us to keep making the program better and better for you. For these questions think about moderate intensity physical activity.
TPB_1	|____|[1] Extremely unhealthy |____|[2] Quite unhealthy |____|[3] Slightly unhealthy |____|[4] Neither |____|[5] Slightly healthy |____|[6] Quite healthy |____|[7] Extremely healthy	1. Do you think that doing moderate-intensity physical activity over the next month would be healthy, unhealthy, or neither? Healthy—Okay, do you think it would be slightly, quite or extremely healthy? RECORD _____ Unhealthy—Okay, do you think it would be slightly, quite or extremely unhealthy? RECORD_____ Neither—Go to next question
TPB_2	|____|[1] Extremely unenjoyable |____|[2] Quite unenjoyable |____|[3] Slightly unenjoyable |____|[4] Neither |____|[5] Slightly enjoyable |____|[6] Quite enjoyable |____|[7] Extremely enjoyable	Do you think that doing moderate-intensity physical activity over the next month would be enjoyable, unenjoyable, oor neither? Enjoyable—Okay, do you think it would be slightly, quite or extremely enjoyable? RECORD _____ Unenjoyable—Okay, do you think it would be slightly, quite or extremely unenjoyable? RECORD_____ Neither—Go to next question
TPB_3	|____|[1] Strongly disagree |____|[2] Moderately disagree |____|[3] Slightly disagree |____|[4] Neither |____|[5] Slightly agree |____|[6] Moderately agree |____|[7] Strongly agree	Do you agree, disagree, or neither agree or disagree that most people who are important to you want you to engage in physical activity over the next month? Agree—Okay, do you strongly, moderately, or slightly agree? RECORD _____ Disagree—Okay, do you strongly, moderately, or slightly disagree? RECORD_____ Neither—Go to next question
TPB_4	|____|[1] Extremely difficult |____|[2] Quite difficult |____|[3] Slightly difficult	Do you think it would be easy, difficult, or neither for you to engage in physical activity over the next month? Easy—Okay, do you think it would be slightly, quite, or extremely easy? RECORD _____ Disagree— Okay, do you think it would be slightly, quite, or

|____|[4] Neither |____|[5] Slightly easy |____|[6] Quite easy |____|[7] Extremely easy	extremely difficult? RECORD_____ Neither—Go to goodbye text.

GOODBYE

Next week you will start receiving automated phone calls and you will need your pin number. Can you tell me what you pin number is?

Confirm that the participant knows their pin number or provide their pin number.

Remember that the most important piece of information that you will need to complete the automated call is your exercise log. So it will really helpful for you to complete your exercise log daily, calculate your average at the end of the week, and have that available when you receive the phone call. Also, please stay on the phone until the call is complete, otherwise the system will think that you did not complete the call and it will call you again.

What sort of other questions do you have for me before we hang up?

If you ever have any questions, you can always get in touch with us by calling our study phone number at 540-231-1267. **[Double-check whether this # is correct.]**

Thank you for completing the call this week! I feel very confident that you are well on your way to increasing your physical activity minutes. Also, you have helped your group move one call closer to reaching your goal and getting your prize at the next class!

Goodbye!

End Time of Call:_____   Calculate Total Minutes of Call:_____