

**Exploring the Reach and Representativeness of Participants Enrolled in a Behavioral Intervention Targeting Sugar-Sweetened Beverage Consumption**

Maggie M. Reinhold

Thesis submitted to the faculty of 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  
Paul A. Estabrooks  
Wen You

November 19, 2014  
Blacksburg, VA

*Keywords: RE-AIM framework, Reach, health literacy, sugar-sweetened beverages*

# Exploring the Reach and Representativeness of Participants Enrolled in a Behavioral Intervention Targeting Sugar-Sweetened Beverage Consumption

Maggie Reinhold  
MS Candidate

## ABSTRACT

**BACKGROUND:** Understanding the reach and representativeness of participants enrolled in behavioral trials, including nutrition and physical activity trials, helps inform the generalizability of study findings and potential public health impacts. Exploring the reach and representativeness of trials that target low socioeconomic and low health literate participants in rural and medically underserved areas, such as southwest Virginia (SWVA), is especially important. The proposed research is part of Talking Health, a six-month, pragmatic randomized-control trial aimed at decreasing sugar-sweetened beverage (SSB) consumption (SIP<sup>smart</sup>ER) as compared to matched contact control targeting improving physical activity (MoveMore). This community-based trial targets an 8-county region in SWVA.

**OBJECTIVES:** Guided by the reach dimension of the RE-AIM framework, the primary objectives of this study were to determine if eligible and enrolled participants in the Talking Health trial were representative of: 1) eligible, but declined participants, and 2) the broader targeted 8-county region based on 2010 US county level census data. We hypothesized that eligible and enrolled participants would be represented in terms of age, race, ethnicity, educational attainment, income, and health literacy when compared to eligible and declined participants, as well as to the broader US census data. We also hypothesized that males would be underrepresented.

**METHODS:** Eligibility requirements for the study included being 18 years of age or older, having reliable access to a telephone, drinking  $\geq 200$  kilocalories of SSB per day, and being a resident of SWVA. A variety of recruitment strategies were used such as active recruitment at health departments, free clinics, and local businesses with help from Virginia Cooperative Extension agents along with passive methods such as flyers, newspaper ads, and word of mouth. The eligibility screener included basic demographic information such as gender, age, race, marital status, occupation, income, educational attainment, number of children in household, and insurance provider. The screener also had three validated subjective health literacy questions. Statistical analysis included descriptive statistics, independent sample t-tests, Chi-square tests, and One Way ANOVA tests to examine the representativeness of enrolled participants.

**RESULTS:** In total, 1,056 participants were screened, 620 were eligible (58.7%), and 301 (48.5%) enrolled. On average, demographic data for enrolled participants included: 93% Caucasian; 81.4% female; income of  $\$23,173 \pm \$17,144$ ; 32%  $\leq$  high school (HS) education; and health literacy score  $4.5 \pm 2.2$  (3=High, 15=Low). Among eligible participants, when comparing enrolled vs. declined participants there were significant differences ( $p < 0.05$ ) in educational attainment [enrolled=32%  $\leq$  HS, declined=48%  $\leq$  HS],

health literacy scores [enrolled=4.5(2.2), declined=5.0(3.1)], gender [enrolled=81% female, declined=73% female], age [enrolled=41.8(13.4) years, declined=38.3(13.6) years], and race [enrolled=93% white, declined=88% white]. However there were no significant differences in ethnicity and income. When compared to average US Census data across the eight counties, enrolled participants had a higher educational attainment [enrolled sample=68% $\geq$ HS, Census=58% $\geq$ HS], higher proportion of females [enrolled sample=81%, Census=48%], and lower mean income [enrolled sample= \$23,173, Census=\$36,675]. There were no meaningful differences in terms of race and ethnicity between the enrolled sample and Census data.

**DISCUSSION:** Contrary to our hypothesis, eligible and enrolled participants differed from non-enrolled participants in terms of age, race, education, and health literacy. Our enrolled sample was slightly older, predominately Caucasian, with higher educational attainment and higher health literacy. However, as hypothesized, there were no significant differences for ethnicity and income status, and men were underrepresented. When the study sample was compared to US Census data, the sample was well represented in terms of age, race, and ethnicity; however, enrolled participants had a much lower average annual income and a higher educational attainment. Men were also underrepresented when compared to the census data. There was no census data to compare health literacy status, which limits information regarding the representativeness of the enrolled sample. Importantly, this study has revealed the representativeness of individuals enrolled in this behavioral trial, helps inform the generalizability of study findings, and identifies future research for community-based studies targeting rural and medically underserved areas in SWVA. For example, future behavioral interventions need concerted recruitment strategies to target males, individuals with lower health literacy status, and individuals with less than a high school degree. Exploring and addressing barriers for study enrollment among these sub-groups is also important.

## **Acknowledgements**

I would like to thank everyone in the department of Human Nutrition, Foods and Exercise for their support through out my undergraduate and graduate career at Virginia Tech. I would especially like to thank my mentor, Dr. Jamie Zoellner, for giving me a multitude of opportunities to excel as a student, along with her continuous support and guidance through out the past three years.

I would like to thank my committee members, Dr. Paul Estabrooks and Dr. Wen You for their advice and input into this project. I would also like to express thanks to all of the members of the Talking Health team for their hard work, encouragement, and guidance. With out whom this research would not have been possible. Lastly I would like to thank my parents, Rob and Beth, my brother, Hank, and my boyfriend, Sam for their endless love and support.

## Table of Contents

<b>Chapter 1: Literature Review.....</b>	<b>1</b>
<u>Introduction.....</u>	1
<i>Sugar-sweetened Beverages.....</i>	1
<i>Physical Inactivity.....</i>	2
<i>Health and Regional Disparities.....</i>	3
<u>RE-AIM Framework.....</u>	4
<i>Reach.....</i>	8
<i>Systematic Reviews of Reach.....</i>	13
<i>Summary of Reach.....</i>	16
<u>Health Literacy.....</u>	17
<i>Health Literacy and Reach.....</i>	18
<i>Objective Health Literacy Measures.....</i>	20
<i>Health Literacy Screening Measures.....</i>	21
<i>Health Numeracy Screening Measures.....</i>	23
<u>Conclusions.....</u>	24
<u>Aims and Hypotheses.....</u>	25
<b>Chapter 2: Exploring the reach and representativeness of participants enrolled in a behavioral intervention targeting sugar-sweetened beverage consumption.....</b>	<b>26</b>
<u>Methods.....</u>	26
<i>Target Population.....</i>	26
<i>Recruitment Methods.....</i>	26
<i>Screening for Eligibility.....</i>	29
<i>Data Analysis.....</i>	30
<u>Results.....</u>	30
<u>Discussion.....</u>	35
<b>References.....</b>	<b>41</b>
<b>Appendices.....</b>	<b>50</b>
Appendix A: IRB Approval.....	50
Appendix B: Informed Consent.....	52

Appendix C: Talking Health Screener.....	55
Appendix D: Newest Vital Sign (NVS).....	66

## List of Tables

Table 1: RE-AIM Framework.....	5
Table 2: Systematic Reviews of the RE-AIM Framework.....	9
Table 3: Recruitment Methods by County.....	28
Table 4: Comparison of Eligible and Enrolled Participants vs. Eligible and Not Enrolled Participants.....	32
Table 5: Comparison of Eligible and Enrolled Participants vs. 2010 US Census Data.....	34

## Chapter 1

### Literature Review

#### INTRODUCTION

In the past few decades obesity has become an epidemic in the United States (U.S.). According to the Centers of Disease Control (CDC), 35.7% of U.S. adults are obese and 17% of U.S. children and adolescents are obese (CDC, 2014). Obesity is linked with adverse health outcomes such as cardiovascular disease (Lavie, et al. 2009), diabetes (Montonen et al., 2007), and cancer (Calle, et al., 2004). With the increase in the prevalence of obesity over the past couple of decades medical costs have also risen. It has been estimated that the annual medical cost of obesity was 147 billion dollars in 2008 (Finkelstein et al., 2009). The rise in obesity is a result of energy imbalance, including physical inactivity and increased caloric intake such as excessive sugar-sweetened beverage (SSB) consumption (CDC, 2012).

#### *Sugar-sweetened Beverages*

Sugar-sweetened beverages are defined as any beverage that contains a caloric sweetener (CDC, 2010). Examples of these beverages are soft drinks, fruit drinks, sports drinks, tea and coffee that have added sugar, energy drinks, and sweetened milk. The increase in SSB consumption over the last several decades coincides with the rise in obesity (Scarpace, et al. 2009; Vanselow, et al. 2009; Bray et al., 2004; Vartanian, et al., 2007). It has been reported that SSBs account for 6.9% of total energy intake in adults (Kit, et al. 2013). Though this is a significant amount of calorie intake from SSBs, there has been a slight decrease in SSB consumption from 1999 and 2010. The average daily kcals from SSB in 1999 was 151 kcal/d and in 2010 it decreased to 106 kcal/d (Kit, et al. 2013). In the last few years there has also been a shift in the type of SSBs consumed. That is, prevalence of soda consumption has decreased,



but consumption of nontraditional SSBs such as energy and sports drinks has increased (Han, 2013). Even though there has been a slight decrease in SSB consumption this is still a major problem that needs to be addressed.

The recommended amount of SSBs is less than or equal to eight ounces per day (CDC, 2010). This is the equivalent to one standard measuring cup. The American Heart Association (AHA) recommends that individuals consume no more than six to nine teaspoons of sugar a day (AHA, 2013). One teaspoon of sugar is equal to four grams of sugar, so individuals can have a maximum of 24-36 grams of added sugars a day. A standard eight-ounce can of soda has 26 grams of added sugar. SSBs have a large amount of added sugar and are highly caloric, but do not provide other required nutrients. Furthermore, SSBs do not contribute to satiety, which often results in excessive calorie intake, and subsequently to obesity (CDC, 2014; de Ruyter et al., 2012).

Numerous research reports implicate SSB consumption as a clear target to help reduce obesity rates in the United States (Chen, et al. 2009; Nielsen, et al. 2004). Additionally, increased SSB consumption has been linked to several other adverse health outcomes; such outcomes include increased risk for coronary heart disease (Fung et al., 2009), type II diabetes (Montonen et al., 2007), and tooth decay (Vartanian et al., 2007; Tahmassebi, et al. 2006).

### ***Physical Inactivity***

Physical inactivity is also associated with the rise in overweight and obese individuals in the United States. Furthermore; physical inactivity is associated with heart disease, stroke, type II diabetes, depression, and even cancer (CDC, 2014). Sedentary behavior is common in the US. Only 48% of all US adults meet the guidelines of 150 minutes of moderate-intensity activity per week (CDC, 2014). For weight maintenance, the Physical Activity Guidelines for Americans

recommend that adults ages 18-64 need 60 minutes of moderate-intensity aerobic activity a week along with muscle-strengthening activities on two or more days a week. There are a variety of exercises that are considered moderate-intensity aerobic activities. Examples of moderate-intensity aerobic activities include but are not limited to, jogging, swimming, cycling, and weight training. If an individual is completing vigorous-intensity aerobic activity, such as running, then individuals' need 75 minutes per week instead of 150 (CDC et al., 2014). Interventions to help individuals increase the amount of time spent being physical active are a top public health priority in the United States.

### ***Health and Regional Disparities***

Energy imbalance, such as increased consumption of SSB and physical inactivity, has led to widespread increase in obesity across the entire United States. However, some areas in the US have shown higher rates of obesity than other areas. For example, higher prevalence of adult obesity was found in the Midwest (29.5%) and the South (29.4%). Lower prevalence was found in the Northeast (25.3%) and the West (25.1%) (CDC, 2014). Likewise, individuals living in the South are less likely to meet physical activity recommendations compared to the Midwest, Northeast, and West regions of the country (CDC, 2014). Individuals with lower educational attainment and whose family income is below the poverty line are less likely to meet the physical activity recommendations (CDC, 2014). Similarly, individuals with less education and whose family income is below the poverty line are also more likely to consume SSBs (Brown et al., 2011). Furthermore, rural areas often have limited access to health foods and physical activity outlets compared to urban areas. Rural communities often fail to provide services to encourage healthy behaviors (Turner, 2006). These areas are burdened with higher rates of obesity and subject to greater economic and health disparities (Patterson, et al., 2004; Williams, et al., 2008).

Sharkey, et al. conducted a study to assess SSB consumption among rural and urban adults. Individuals were recruited by random digit dialing. SSB consumption was evaluated along with other dietary behaviors and demographic characteristics. Consumption of SSBs was higher among rural adults compared to urban adults (Sharkey, 2011). Consumption of SSBs varied across racial/ethnic subpopulations. There were also higher odds of high SSB consumption among low-socioeconomic populations. These factors should be considered when programs and policies are developed to decrease SSB consumption (Han, 2013).

Southwest Virginia is a rural, health disparate and federally designated medically underserved area (MUA) (HRSA, 2014). Southwest Virginia lies in the Appalachian region and is characterized by high rates of poverty, low access to health care, and low educational attainment. Compared to the rest of the state, Southwest Virginians have higher rates of obesity, diabetes, and mortality (Virginia Department of Health). SSB consumption is also a significant problem in this population (Zoellner et al., 2012). The Virginia Foundation for Healthy Youth administered a statewide survey on SSB consumption to 8,900 Virginia residents. Respondents who lived in SWVA self-reported consuming more SSBs than respondents from any other region of Virginia. SWVA residents were also least likely to think they drink too many SSBs (VA Foundation for Healthy Youth, 2014).

## **RE-AIM FRAMEWORK**

Developed by Glasgow and colleagues, the RE-AIM framework allows for the comprehensive planning and evaluation of health-related interventions (Glasgow, 1999). The framework has five components, which include; reach, efficacy/effectiveness, adoption, implementation and maintenance. Table 1 outlines each RE-AIM component, operational definition, and example dimension criteria from Glasgow's original definitions. The framework

allows researchers to interpret results of an intervention for its immediate impact, along with its potential for generalization. Together the RE-AIM components shape the overall public health impact of a given program or policy.

**Table 1: RE-AIM Framework**

RE-AIM	Operational Definition	Dimensions
Reach	An individual-level measure of participation. Also assesses characteristics of participants and representativeness	<ul style="list-style-type: none"> <li>• Exclusion Criteria (% excluded or characteristics)</li> <li>• Percent individuals who participate, based on valid denominator</li> <li>• Characteristics of participants compared to non-participants or to target population</li> </ul>
Effectiveness/Efficacy	The intended positive impact of the intervention and its possible unintended consequences on quality of life and related factors.	<ul style="list-style-type: none"> <li>• Primary outcome with comparison to public health goal</li> <li>• Assess outcomes for participants, staff who deliver intervention and investors</li> <li>• Potential negative outcomes</li> <li>• Participant satisfaction/quality of life</li> <li>• Short-term attrition and differential rates by treatment group/patient characteristics</li> </ul>
Adoption	The percent of potential settings and intervention agents that participate in a study and how representative they are of targeted settings/agents	<ul style="list-style-type: none"> <li>• Setting exclusions</li> <li>• Percent of settings approached that participate</li> <li>• Characteristics of settings participating</li> </ul>
Implementation	The quantity and quality of delivery of the intervention's various components	<ul style="list-style-type: none"> <li>• Adherence/consistency in delivery of program</li> <li>• Adaptions made to intervention during the</li> </ul>

			study period <ul style="list-style-type: none"> <li>• Cost of intervention (time/money)</li> </ul>
Maintenance	Organizational level: The extent to which a program or policy becomes institutionalized or part of the routine organizational practices and policies.	Individual Level: Long term effects a given intervention has on an individual	<ul style="list-style-type: none"> <li>• Primary outcome</li> <li>• Long-term attrition</li> <li>• How program was adopted long-term</li> <li>• How well the individual maintained what they learned from the intervention</li> </ul>

The RE-AIM framework as a whole has been used as a guide in the development and implementation of interventions. The framework has been successfully used to guide nutrition and physical activity interventions in both adults (Huyve, 2014) and children (Nigg, 2012). The framework has also demonstrated interventions’ potential public health impact (Evenson, 2013; Harden, 2013; Goode, 2012).

There have been numerous studies done, including a variety of studies that focus on physical activity and nutrition related outcomes, such as diabetes. For example, one study used the RE-AIM framework to evaluate the translatability of school-based physical activity intervention. Researchers identified the barriers to adopting, implementing and maintaining the intervention (Austin, et al. 2011). Another study conducted by Yank, et al. evaluated the Diabetes Prevention Program’s potential to reach their target audience and adopt the intervention. They found that there was a fair-to-good potential for primary care reach and adoption (Yank, et al. 2013). Another study conducted over a ten week period evaluated school-based nutrition education curriculum developed for third graders using the RE-AIM framework. The study demonstrated the potential for moderate to high public impact (Dunton, et al. 2014). These are a few examples that demonstrate the importance of the RE-AIM framework and its potential public health impact. Although, it has been found that most health promotion and

disease management literature underreport on participation, setting, sustainability and cost (Kessler, et al. 2013). There are currently no RE-AIM studies with a focus on SSB consumption in adult populations.

Internal and external validity are also important components involved in the RE-AIM framework and should be maximized. Internal validity identifies causal relationships and determines if a given intervention made a difference in the outcome. External validity is when findings are true beyond the controlled settings of the study (Campbell et al., 1966). Internal validity is often easier to report for researchers and is highly emphasized, because of this; external validity is repeatedly over looked and reported less often (Estabrooks et al., 2003). Lack of emphasis on external validity has slowed the dissemination of relevant research study findings (Blackman et al., 2013). For example, a systematic literature review conducted by Galaviz and colleagues examined the degree to which physical activity interventions in Latino's reported on internal and external validity using the RE-AIM framework. Of the forty-six articles reviewed, the majority recommended that the reporting of external validity needs improvement to promote translation of research into practice (Galaviz et al., 2014). A primary purpose of RE-AIM is to emphasize the importance of reporting external validity is to help close the gap between research and practice. To increase the awareness of external validity among researchers, program planners, and policy-makers, researchers should follow RE-AIM guidelines laid out by Glasgow and colleagues. The RE-AIM framework provides standard reporting criteria, information on design of interventions, and guides for program planners and potential adopters (Glasgow, 1999).

While the goal is that a program of intervention research should focus on all five constructs (CDC & Kimberly-Clark Corporation, 2008), there is often a need to provide thorough information on a limited number of constructs within a given paper (Estabrooks &

Blackman, 2013). Over the years researchers have found that there are few studies that properly report on all five dimensions of the RE-AIM framework (Gaglio, 2013). Since the primary focus of this review and research is related to Reach; this dimension is discussed in more detail below.

### ***Reach***

Reach is the absolute number, proportion, and representativeness of individuals who are willing to participate in a given intervention or program (Glasgow, 1999). Reach is an important dimension of the framework, because it allows investigators to evaluate representativeness of the studies sample and participation rate, which help to inform the generalizability of results. Table 2 provides an overview of systematic reviews done on the RE-AIM framework, and highlights findings based on the reach dimension.

**Table 2: Systematic Reviews of the RE-AIM Framework**

Author	Title	Article Reviewed (N)	Year	Outcome Measure	Reach	Dimensions of Reach (% of studies reporting)
Glasgow, R.E., Klesges, L.M, et al.	The Future of Health Behavior Change Research: What is Needed to Improve Translation of Research Into Health Promotion Practice?	119	2004	Identify barriers of translating research to practice for health behavior interventions	NA	<ul style="list-style-type: none"> <li>• Participation rate (76%)</li> <li>• Representativeness (&lt;15%)</li> </ul>
White, M.W., McAuley, E., et al.	Translating Physical Activity Interventions for Breast Cancer Survivors into Practice: An Evaluation of Randomized Controlled Trials	25	2009	Internal and external validity of studies targeting PA in breast cancer survivors	68%	<ul style="list-style-type: none"> <li>• Inclusion criteria (100%)</li> <li>• Exclusion criteria (96%)</li> <li>• Methods to identify and recruit participants (92%)</li> <li>• Sample size/participation rate (52%)</li> <li>• Representativeness/ characteristics of non-participants (0%)</li> </ul>
Akers, J.D., Estabrooks, P.A., Davy, B.M.	Translational Research: Bridging the Gap between Long-Term Weight Loss Maintenance Research and Practice	19	2010	Translation of weight loss interventions	37% (reporting on >50% of dimensions)	<ul style="list-style-type: none"> <li>• Description of target population (42%)</li> <li>• Participant demographic and behavioral information (68%)</li> <li>• Method to identify target population (68%)</li> <li>• Recruitment strategies (58%)</li> <li>• Inclusion criteria (79%)</li> <li>• Exclusion criteria (74%)</li> </ul>



						<ul style="list-style-type: none"> <li>• Target population denominator (0%)</li> <li>• Sample size (100%)</li> <li>• Participation rate (11%)</li> <li>• Characteristics of participants and non participants (5%)</li> <li>• Cost of recruitment activities (0%)</li> </ul>
Allen, K., Zoellner, J., Motley, M. & Estabrooks, P.	Understanding the Internal and External Validity of Health Literacy Interventions: A Systematic Literature Review Using the RE-AIM Framework	31	2011	Implementation of mobile technologies to increase PA	68.8%	<ul style="list-style-type: none"> <li>• Target population (100%)</li> <li>• Inclusion criteria (96%)</li> <li>• Exclusion criteria (76%)</li> <li>• Participation Rate (44%)</li> <li>• Representativeness (28%)</li> </ul>
Stellefson, M., Chaney, B., et al.	Web 2.0 Chronic Disease Self-Management for Older Adults: A Systematic Review	15	2013	Planning, implementation and effectiveness of web interventions to support chronic disease self management	Reach dimension study quality score=2.33 (highest 3)	<ul style="list-style-type: none"> <li>• Representativeness (NA)</li> <li>• Participation Rate (NA)</li> </ul>
Kohl, L.F.M., Crutzen, R., et al.	Online Prevention Aimed at Lifestyle Behaviors: A Systematic Review of Reviews	41	2013	Effectiveness of internet interventions aimed at behavior change	84.6%	<ul style="list-style-type: none"> <li>• Target Population (NA)</li> <li>• Participation Rate (NA)</li> <li>• Representativeness (NA)</li> <li>• Recruitment Strategies (NA)</li> </ul>
Gaglio, B., Shoup, A., et al.	The RE-AIM Framework: A Systematic Review of Use Over Time	77	2013	Health related interventions using the RE-AIM framework	91.5%	<ul style="list-style-type: none"> <li>• Exclusion Criteria (61.5%)</li> <li>• Participation Rate (83.1%)</li> </ul>

						<ul style="list-style-type: none"> <li>• Representativeness (58.5%)</li> <li>• Use of qualitative methods to understand recruitment (12.3%)</li> </ul>
Blackman, K.C., Zoellner, J., et al.	Assessing the Internal and External Validity of Mobile Health Physical Activity Promotion Interventions: A Systematic Literature Review Using the RE-AIM Framework	20	2013	Physical Activity and mobile technologies interventions and generalizability	53.3%	<ul style="list-style-type: none"> <li>• Target population (60%)</li> <li>• Inclusion criteria (80%)</li> <li>• Exclusion criteria (60%)</li> <li>• Participation rate (46.7%)</li> <li>• Representativeness (26.7%)</li> <li>• Recruitment Strategies (NA)</li> </ul>
O'Brien J.	The implementation of musculoskeletal injury prevention exercise programmes in team ball sports: a systematic review employing the RE-AIM framework	70	2014	Implementation of injury prevention exercise programs	34%	<ul style="list-style-type: none"> <li>• Exclusion Criteria (60%)</li> <li>• Participation Rate (48%)</li> <li>• Comparison between participants and non-participants (13%)</li> <li>• Qualitative methods (12%)</li> </ul>
Matthews, L., Alison, K., et al	Can physical activity interventions for adults with type 2 diabetes be translated into practice settings? A systematic review using the RE-AIM framework	12	2014	Translation and Implementation of physical activity interventions within routine of diabetes care	66.7%	<ul style="list-style-type: none"> <li>• Target population (NA)</li> <li>• Participation Rate (NA)</li> <li>• Recruitment strategies (NA)</li> </ul>
Galaviz K., Harden S., et al.	Physical activity promotion in Latin American populations: a systematic review on	46	2014	Internal and External Physical Activity Interventions for	48%	<ul style="list-style-type: none"> <li>• Target population (65%)</li> <li>• Inclusion criteria (72%)</li> <li>• Exclusion criteria (39%)</li> <li>• Participation Rate (52%)</li> </ul>

	issues of internal and external validity			Latin American populations		<ul style="list-style-type: none"><li>• Characteristics on non-participants and participants (11%)</li><li>• Recruitment Strategies (50%)</li></ul>
--	--	--	--	----------------------------	--	---

### ***Systematic Reviews of Reach***

Glasgow and colleagues reviewed 119 behavioral interventions and analyzed the limitations of translating research into practice. They found that less than 15 percent of the interventions reported on representativeness. Glasgow et al., also identified the lack of strict inclusion and exclusion criteria along with inappropriate recruitment strategies as reasons for poor generalizability. From the results of this review they concluded, “researchers need to identify innovative ways to enhance Reach (especially representativeness and to underserved populations)” (Glasgow et al., 2004).

White et al. organized a review and assessed the internal and external validity of 25 randomized controlled trials of physical activity and breast cancer survivors using the RE-AIM Framework. White and colleagues analysis found that the method to identify the target population, inclusion criteria and exclusion criteria were the most often reported. They also found that representativeness of the studies sample is rarely reported and characteristics of nonparticipants are not described. The generalizability of the study is limited with out this information (White et al., 2009).

Using the RE-AIM framework, Akers and colleagues reviewed 19 articles that addressed weight loss and maintenance interventions. They found that sample size, inclusion criteria, and exclusion criteria were the most often reported dimensions of reach. They identified gaps related to external validity, with only one study out of 19 that reported on representativeness. Consistent with the results of White et al. review, dimensions reflecting external validity weren't reported as often as internal validity dimensions. Akers et al., suggest that future weight status interventions define the intended population, provide the number of people who are exposed to recruitment,

and collect demographic data on both participants and nonparticipants. This information will provide the 'reach' of the program/intervention (Akers et al., 2010).

Allen and colleagues conducted a systematic literature review using the RE-AIM framework. The aim of the review was to understand the internal and external validity of health literacy interventions. 31 articles were used for the review. Among the articles reviewed, 100% reported a method to identify the target population, 96% reported inclusion criteria, 76% reported exclusion criteria, 46% reported participation rate, and 28% reported representativeness. Based on these findings, considerably fewer studies reported participation rate and representativeness (Allen, et al. 2011). Also, researchers fail to report on participants' health literacy status. Researchers often measure educational attainment and use this as a proxy for health literacy status; although it has been shown that education level is not a predictor for health literacy status (Chew, 2004). Health literacy is a key component that is often overlooked when determining the representativeness of the studies sample.

Stellefson and colleagues evaluated the planning, implementation and effectiveness of 31 web interventions to support chronic disease self-management. Regarding the reach component they focused on representativeness and participation rate. Like Allen and colleagues they also found that the majority of interventions did not report on representativeness. The demographic factors they analyzed were gender, age, and race. Across the 31 articles they found homogenous samples that were predominately white females. Stellefson and colleagues concluded that better efforts need to be made to include underrepresented, medically underserved individuals (Stellefson et al., 2013).

Similarly to Stellefson's findings, Kohl and colleagues reviewed internet intervention literature targeting behavior change, and found an undiversified study sample for all 41 articles

that were reviewed. They looked at gender, race, age, educational attainment, and income. Again, they found participants were mostly Caucasian females with high educational attainment and socioeconomic status, which is not the intended population for the majority of these interventions (Kohl et al., 2013).

Gaglio and colleagues conducted a systematic review on research articles that were published between 1999 and 2010 that evaluated the use of the RE-AIM framework, which included 71 articles. In terms of reach, 83.1% of the articles reported the percentage of individuals who participated, 61.5% reported the interventions exclusion criteria, and 58.5% of the studies reported the representativeness of those who participated in the study (Gaglio, 2013). Reach is the most often reported component of the RE-AIM framework after effectiveness, but it is also the most incorrectly used (Gaglio, et al. 2013). The denominator is how many people are eligible to participate in a given intervention/program. The denominator could also include all individuals exposed to recruitment strategies. The denominator could be an entire population or only those targeted or screened for a certain intervention (Gaglio, et al. 2013). If the denominator is defined as the entire population, reporting representativeness can be a greater challenge. It requires demographic information on non-participants as well as participants. Information on non-participants is often hard to collect (Glasgow, et al. 1999).

Consistent with other systematic reviews Blackman and colleagues found that literature often fails to compare participants to non-participants, report on recruitment strategies and representativeness. Out of the 20 articles reviewed only 27% of those reported representativeness and none of the studies reported characteristics of participants who dropped out. After the cumulative results of the review the need for better recruitment strategies was

identified. Innovative recruitment strategies need to be developed to target people who actually need the intervention (Blackman et al., 2013).

As mentioned previously, Galaviz and colleagues reviewed physical activity intervention literature in Latin American populations. Out of the 46 articles reviewed 52% reported on participation rate, while only 11% compared the characteristics on participants and non-participants. None of the studies reported on qualitative measures of reach. The lack of information on participants and reach make the results not generalizable. Galaviz et al., recommend better reporting of participants and non-participants, participation rate, and representativeness (Galaviz et al., 2014).

### ***Summary of Reach***

Since one of the first known RE-AIM reviews conducted in 2004, the numbers of systematic reviews have expanded; however the overall reporting of reach remains highly variable. There are still issues that need to be addressed when reporting reach. As shown in Table 2, the systematic reviews have found that for the Reach component of the RE-AIM framework there is less reporting on representativeness, comparison between participants and non-participants, and recruitment methods. These factors affect the generalizability of results, another key problem identified in the reviews. The majority of current RE-AIM studies do not compare study participant characteristics to the general public. There are studies that do make these comparisons and report if their sample is representative of the greater population or not. Not including health literacy status in the comparisons, limits conclusions about the representativeness of study samples. To date there are no studies that compare health literacy status of study sample to the targeted study sample or to the general population.

Though there are often problems with researchers reporting Reach there are some studies that have found ways to properly measure and report Reach. An internet-based weight loss program study conducted by Glasgow et al., was able to successfully report on recruitment methods and how that relates to participant demographic data and higher program participation (Glasgow et al., 2010).

Though representativeness is often under reported, Fjeldsoe, et al. compared participants to non-participants in a mobile phone physical activity intervention (Fjeldsoe et al. 2009). Another study conducted by Harden et al., determined the reach of physical activity programs for older adults. They tracked the different modes of recruitment along with the costs associated with each recruitment method (Harden et al., 2013). Their study determined how each of eligible and enrolled participants were recruited. The information provided will help with recruiting older adults for future studies.

As for the Reach construct, there has been research on weight loss programs (Yank, 2013; Glasgow, 2007), physical activity programs (Gainforth et al., 2014; Matthews et al., 2014; Jenkinson et al., 2012), Type 2 Diabetes (Eakin, 2003), and smoking cessation (Meyer, 2012; Glasgow, 2008). Unfortunately, there are no known SSB studies targeting adult populations that have comprehensively reported on reach and representation of the study population.

## **HEALTH LITERACY**

Affecting over 80 million individuals, low health literacy is a significant problem in the U.S. (Agency for Healthcare Research and Quality, 2011). Health literacy has been recognized as a nation wide problem, and Healthy People 2020 includes health literacy as an objective. Healthy People 2020 defined health literacy as the “degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make



appropriate health decisions” (Healthy People, 2020). Low health literacy is associated with adverse health outcomes such as higher risk of chronic disease, poorer diet quality, along with less use of health facilities (Zoellner et al., 2011; Berkman et al., 2011; von Wagner et al., 2007). Furthermore, limited health literacy has been found to be higher in certain subpopulations including those living below the poverty line, the elderly, individuals with less than a high school degree, those who live in rural areas, immigrants and those who do not speak English as their first language (Zahnd et al., 2009; Rudd, 2007).

Unfortunately, national surveillance data on health literacy is limited. Current population data on literacy and health literacy in the United States comes from the National Assessment of Adult Literacy (NAAL). The NAAL measures literacy among adults. The NAAL also measured health literacy for the first time in 2003. Over 19,000 adults were surveyed and only 12 percent of those individuals demonstrated proficient health literacy. Results also found that 14 percent of adults, over 30 million Americans, were unable to perform the most simple literacy tasks (U.S. Department of Health and Human Services, 2010). Addressing the problem of limited health literacy in the United States should be a primary health concern. There has been discussion on whether health literacy should be part of the Behavioral Risk Factor Surveillance System (Bockrath, 2013). Obtaining data and gaining a better understanding about limited health literacy and how low health literacy affects individuals’ health status is vital. There are a variety of instruments that have been developed to measure health literacy, though at this point in time none are appropriate to complete at the national level.

### ***Health literacy and Reach***

As shown in Table 2, out of 8 systematic reviews on the RE-AIM framework none of them compare health literacy status among participants and non participants, or participants to

census data. Due to the lack of national data on health literacy, comparisons on health literacy status cannot be made to the entire targeted population. However, health literacy comparison could be made between screened participants who enrolled in the trial or did not enroll, and comparisons can be made among randomized conditions. Glasgow and colleagues used Chew's three-item health literacy scale to assess health literacy status among study participants. They compared the health literacy scores of the intervention group to the control group. There were no significant differences between health literacy scores. The intervention group had a mean score of 14.1(1.6) and the control group had a mean score of 13.7(1.9) (Glasgow et al., 2008).

Understanding the overall proportion of low health literate individuals who are participating in behavioral trials is another important aspect of understanding reach. Allen and colleagues systematic review looked at interventions that targeted low health literate participants. Of the 31 articles Allen, et al. found that only two of these articles applied an inclusion criterion to ensure that participants had low health literacy status. Of 25 studies that Allen and colleagues reviewed, approximately 38% of the participants across the 25 different interventions actually had low health literacy (Allen, et al. 2013). They also found that few studies targeted individuals with low health literacy, even though they could potentially benefit the most from the health literacy interventions. These findings demonstrate the difficulty of recruiting and enrolling low health literate individuals for health behavior interventions. There should be a greater focus on recruitment efforts to target low health literate individuals, along with the administration of health literacy measures during the screening process.

Research has shown that individuals with low health literacy have less access to healthcare and are less likely to use healthcare services (U.S. Dept. of Health and Human Services). Researchers claim their interventions reduce health disparities, but we cannot

conclude that this is being done with out health literacy data. Even though there are drawbacks to the current measures of health literacy, they should still be used. The current health literacy measures available are both reliable and valid. With the current measures of health literacy, research staff can easily administer the measure during the screening process to accurately identify one's health literacy status. More efforts are needed to screen and assess health literacy in health behavioral trials, to ensure that the target populations are taking part in these interventions. This information is necessary for fully understanding the Reach component of the RE-AIM framework.

### ***Objective Health Literacy Measures***

Current health literacy instruments include: the Rapid Estimate of Adult Literacy in Medicine (REALM), the Newest Vital Sign (NVS), the Test of Functional Health Literacy in Adults (TOFHLA), the Short Test of Functional Health Literacy in Adults (S-TOFHLA), the TOFHLA abbreviated. These are commonly used instruments in health research to measure participants' health literacy. All of these measurements are useful, however there are limitations to each.

The REALM is a 66-item word recognition and vocabulary test that measures pronunciation and familiarity of relevant medical terminology and takes about 2-3 minutes to administer (Paasche-Orlow et al., 2005; Davis et al. 2006; Murphy et al., 1993). The test is scored by adding the number of words that the subject pronounced correctly. The score corresponds to the patient's estimated grade range (Murphy et al., 1993). This measurement is fast, but can cause embarrassment for individual's who cannot read certain words out loud or feel uncomfortable with some of the word choices the REALM has. The REALM also does not include numeracy components.

The NVS is a 6-item test that measures an individuals' ability to read and apply information from a nutrition label on the back of one pint of ice cream. The test takes approximately three minutes to administer and identifies patients as either having a higher probability of limited health literacy, which is indicated by a score of less than two, a possibility of limited health literacy, a score of 2-3, or adequate health literacy, a score of 4-6 (Weiss et al., 2005). The NVS does measure one's mathematical skills, but does not measure individual's reading ability of health related materials (Osborn et al., 2013).

The TOFHLA is a valid and reliable measure to identify adults' ability to read health-related materials (Parker et al., 1995; Baker, 2006). It was developed using hospital materials and consists of a 50-item reading comprehension and 17-item numerical ability test that can take up to 22 minutes to administer (Parker et al., 1995). There are two shortened versions of the TOFHLA available for use: the Short Test of Functional Health Literacy in Adults (S-TOFHLA) and the TOFHLA abbreviated. The S-TOFHLA is a 36-item reading comprehension test and takes approximately 7 minutes to administer (Chew et al., 2004). The TOFHLA abbreviated includes 36 reading comprehension items and 17 numerical ability items and takes approximately 12 minutes to administer (Paasche-Orlow et al., 2005; Parker et al., 1995). The TOFHLA and the TOFHLA abbreviated include numeracy components, but the components do not best measure health numeracy (Gong et al., 2007).

### ***Health Literacy Screening Measures***

In addition to objective measures of health literacy, there are other ways to screen for health literacy. These screening instruments are typically subjective (e.g. self-rated perception of skills). Researchers have been relatively proactive in their efforts to develop quick, low-burden, valid measures that will provide universal data on each individual's health literacy. There has

been research done to try to find the most practical method to identify one's health literacy. Wallace and colleagues administered health literacy screening questions and REALM to 305 English-speaking adults. Area under the receiver-operating characteristic (AUROC) was plotted for each item from the health literacy screening questions; and the standard scores for REALM were used as a reference. Findings indicated that one screening question that asked individuals "how confident are you filling out medical forms by yourself" might be able to identify limited and marginal health literacy skills in a clinical population (Wallace, et al. 2006). There were limitations to this study, including small sample size and clinical population.

Another study done by Jeppesen and colleagues asked 225 patients to complete S-TOFHLA and were considered to have limited health literacy with a score of less than 23. Researchers then evaluated potential predictors including self-rated reading ability, highest education level attained, single-item literacy screener (SILS) result, self-rated reading enjoyment, age, sex and race. Out of the potential predictors five were independently associated with increased odds of having limited health literacy. These five included self-rated reading ability, more frequently needed help reading written health materials, had lower education level, male, and nonwhite race. Researchers concluded that using self-rated reading ability, SILS result, highest education level, sex and race can predict whether an individual has limited health literacy (Jeppesen, et al. 2009).

Research has shown that SILS is a good predictor of an individual's limited health literacy, though in research studies it is best to follow up and complete additional assessments with those who were identified as having limited health literacy (Morris, et al. 2006). The SILS is a quick, easy, and reliable way to measure one's health literacy status. Since SILS requires minimal time and does not require research or medical staff to administer it, SILS data could be

collected quite easily. For example, there could be mailings to households or an online survey for individuals to complete, just like they would their census. Having national health literacy data could be helpful in understanding the underlying cause(s) of this national problem and help professionals develop more effective interventions. This data could also be used to further understand the representativeness of studies samples.

### ***Health Numeracy Screening Measures***

There are also several instruments that have been developed to measure health numeracy including the Subjective Numeracy Scale (SNS) and the General Health Numeracy Test (GHNT). There are other measures of numeracy available, but have little application to health, are too long for participants, and some are disease-specific (Osborn et al., 2013). The SNS is a reliable self-report measure of “perceived ability to perform various mathematical tests and preference for the use of numerical versus prose information” (Zikmund-Fisher, et al. 2007). SNS is an 8-item test with no mathematical questions. It asks participants’ four questions about their perceived mathematical ability and four questions about their preference for the way mathematical information is presented to them. The SNS takes significantly less time than other health numeracy measures (Fagerlin et al., 2007). Though a quick, valid and reliable measure; the SNS does not test specific mathematical skills. Results can also vary in how each individual interprets the 8 questions.

The GHNT is the newest measure of health numeracy. There are two forms of the GHNT, the GHNT-21 and the GHNT-6. The numbers indicate how many questions each form contains (Osborn et al., 2013). The instrument includes a variety of questions that assess a wide range of quantitative skills such as nutrition management, medication compliance, and

calculating disease risk (Osborn et al., 2013). Further research needs to be done to determine its validity and reliability.

There are strengths and limitations of each available health literacy measure. Each measure evaluates a specific component of health literacy, such as reading ability, vocabulary, health knowledge, or numeracy (Berkman et al., 2011). Current measures of health literacy are not designed to understand the underlying cause of low health literacy, are limited in approach to evaluate individual skills and not behavior change and some also lack cultural sensitivity and can be biased towards certain populations (Pleasant, 2012). Current health literacy tools also do not evaluate spoken communication skills and do not distinguish between people at very low and very high levels of health literacy. There is also so much variation among the different instruments in terms of how they are used and how level of health literacy is defined (Pleasant, 2012). With the variation in how the tool was measured makes it difficult for researchers to compare results to help understand the relationship of health literacy and health status.

## **CONCLUSIONS**

In conclusion, SSB, physical inactivity, and low health literacy skills are all noteworthy public health concerns in the US. The RE-AIM framework is a useful tool in developing, implementing and evaluating health interventions; and its application is important to help inform the generalizability of study findings and potential public health impacts. However, there is a clear gap in the literature regarding the RE-AIM framework and SSB consumption. There is also an insufficient emphasis on the importance of Reach and how to measure it comprehensively. Notably, little research has been done on the Reach component in terms of the representativeness of participants' health literacy status. For these reasons, additional research efforts are needed to understand if participants enrolled in health interventions, including those targeting SSB and

physical activity behaviors, are representative of those who were eligible and representative of the broader targeted region. This information would help inform the generalizability of study outcomes and inform future recruitment strategies.

### **AIMS & HYPOTHESIS**

The primary aims of this study are to use the Reach component of the RE-AIM framework to determine the representativeness of the studies sample by comparing eligible and enrolled participants to eligible and non-enrolled participants, and to compare enrolled participants to the U.S. Census data.

We hypothesized that eligible and enrolled participants would be represented in terms of age, race, ethnicity, educational attainment, income, and health literacy when compared to eligible and declined participants, as well as to the broader US census data. We also hypothesized that males would be underrepresented.



## Chapter 2

### Exploring the Reach and Representativeness of Participants Enrolled in a Behavioral Intervention Targeting Sugar-Sweetened Beverage Consumption

#### METHODS

Talking Health is a two-arm randomized control trial. The study includes a six-month intervention where participants are randomly assigned to a behavioral intervention aimed at reducing sugar-sweetened beverage consumption, *SIPsmartER*, or increasing physical activity, *MoveMore*. Each group participates in three small group education sessions, one teach back call, and eleven interactive voice response (IVR) calls. A complete description of the interventions can be found elsewhere (Zoellner et al., 2014). The Institutional Review Board (IRB) at Virginia Tech approved this study and all participants gave written informed consent prior to participation in this study. Given this study's focus on reach; the targeted area, recruitment methods, and screening process are detailed below.

#### *Targeted Population*

There are eight southwest Virginia cohorts in Talking Health, including Lee, Giles, Pulaski, Washington, Grayson, Wise, Wythe, and Montgomery counties. For these eight counties, United States census data was collected from the American Fact Finder and the American Community Survey. In brief, the majority of residents in these counties are white (93.9%) and make an average annual household income of \$36,675. The average educational attainment is also low, with 54% of the population receiving less than a high school degree (US Census Bureau-American Fact Finder).

#### *Recruitment Methods*

A variety of recruitment methods were used in attempts to enroll the target population (Table 3). Both active and passive recruitment methods were used. In all cohorts, participants

were recruited passively by flyers, newspaper ads, and word of mouth. Virginia Cooperative Extension agents were hired to help recruit in Lee, Pulaski, Grayson, and Wythe counties. Research assistants actively recruited at health departments and free clinics, a variety of retail stores such as Wal-Mart and Dollar General, local festivals and community events, public libraries, daycares, and some local community colleges. Most of the recruitment activities were done at health departments and free clinics. Locations were chosen based on the target population. The target population for the intervention was individuals living in rural Southwest Virginia with low socioeconomic status and low health literacy levels. For MUA a score of 0 represents completely underserved and 100 represents best served or least underserved. A score of 62.0 or less qualifies for designation as MUA (HRSA, 2014). For population density, rural is any area that is not considered urban or highly rural. An urban area is defined as any block having a population density of at least 1,000 people per square mile. Areas are considered highly rural if they have less than 7 civilians per square mile (USDA, 2014).

**Table 3: Recruitment Methods by County**

<b>County</b>	<b>Recruitment Methods</b>	<b>MUA*</b>	<b>Population Density (per sq. ml)</b>
Lee	<i>Primary active:</i> extension agents <i>Secondary active:</i> none <i>Passive:</i> newspaper ad, flyers	61.60	58.5
Giles	<i>Primary active:</i> free clinic <i>Secondary active:</i> daycare, festivals and community events <i>Passive:</i> newspaper ad, flyers	60.80	48.0
Pulaski	<i>Primary active:</i> extension agent, retail shops <i>Secondary active:</i> festivals and community events, community college <i>Passive:</i> newspaper ad, flyers, postcard mailings	60.70	105.8
Washington	<i>Primary active:</i> free clinics, Health Department/WIC <i>Secondary active:</i> Head Start, community events <i>Passive:</i> flyers, postcard mailings	56.10	97.0
Grayson	<i>Primary active:</i> Extension agent, Health Department/WIC <i>Secondary active:</i> Head Start, Retail store, Community events, Daycare <i>Passive:</i> newspaper ad, flyers, postcard mailings, emails	51.00	34.8
Wise	<i>Primary active:</i> Health Department/WIC, retail stores <i>Secondary active:</i> festivals, RAM health clinic, Head Start <i>Passive:</i> newspaper ad, flyers, postcard mailings, emails	61.10	102.3
Wythe	<i>Primary active:</i> Health Department, free clinic, extension agent <i>Secondary active:</i> Head Start, community events <i>Passive:</i> newspaper ad, Postcard mailings, flyers	61.00	62.9
Montgomery	<i>Primary active:</i> Health Department, free clinic <i>Secondary active:</i> extension agent <i>Passive:</i> flyers, emails	60.10	242.5

### *Screening for Eligibility*

At recruitment events individuals who were interested in the program filled out an eligibility screener. Eligibility requirements included being 18 years or older, consuming at least 200 calories per day from SSB, able to participate in moderate intensity physical activity, having reliable access to a telephone, and be a resident of Southwest Virginia. The screener asked individuals basic demographic information: gender, age, race, marital status, income, educational attainment, occupation, number of children in household and insurance provider. The screener included a validated modified version of the BEVQ-15, a fifteen questionnaire on SSB consumption (Hedrick, et al. 2012). There were seven questions based on type of drink consumed such as soda, sweet tea, coffee that is sweetened, sports drinks, and energy drinks. After each type of SSB category, individuals' were asked how much of each SSB they consumed. Individuals were also asked about their personal physical activity and their subjective health literacy. The screener included the L-CAT; a one-item physical activity questionnaire that asked participants to select one of six statements that best described their average physical activity level (Kieman et al., 2013). One meant physical inactive and six meant participating in moderate to vigorous intensity exercise 5 or more times a week. The screener also included three questions on health literacy (Wallace et al., 2006, Chew et al., 2004). Individuals were asked to rate their own reading ability, how often they need help filling out paperwork or forms, and how well they understand medical forms. The three questions were scored on a scale of 3 to 15, with 3 being the highest score and 15 being the lowest possible score (low health literacy) (Chew et al., 2004).

## ***Data Analysis***

All quantitative analyses were conducted using SPSS. Talking Health screening data was used for analysis. Descriptive statistics were used to summarize quantitative data and demographic characteristics including gender, race, ethnicity, age, educational attainment, income, and health literacy. One-way ANOVAs and chi-squared tests were used to examine differences in participants that were eligible and enrolled to the participants who were eligible and not enrolled.

When examining the US Census Bureau data, individuals who were older than 65 were excluded from the data analysis, because even though the Talking Health study did not have a maximum age to participate in the intervention, older individuals were not the intended target population. Therefore, data was used for individuals' ages 18-64 years old. The same statistical tests were used to examine demographic differences between the eligible and enrolled participants to the United States Census Data, with the exception of health literacy. There is no Census or surveillance data on health literacy.

## **RESULTS**

Through the recruitment efforts, 1,056 individuals were screened for eligibility, of which, 620 (58.7%) were eligible and 301 (48.5%) enrolled into the Talking Health Study. The remaining 319 were not enrolled because they either did not show up for their first appointment, could not be contacted via phone after eligibility status was determined, or otherwise chose not to participate for a variety of reasons.

Table 4 illustrates the demographic information of the eligible and enrolled participants as well as the eligible and not enrolled participants. Of the participants who were enrolled, the majority were female (81.4%), Caucasian (93%) and non-Hispanic (99%). The average age of

enrolled participants was 41.8 (13.4) years. Of those enrolled participants, 31.9% completed less than or equal to high school as their highest level of education and 68.1% completed some education beyond high school. The mean income status was \$23,172.75 (17,144.73) a year. Based on the three subjective health literacy questions, the mean health literacy score was 4.55 (2.2) for eligible and enrolled participants [health literacy score, 3=High, 15=Low].

Chi-squared and One-Way ANOVA tests revealed significant differences between eligible and enrolled participants and eligible and not enrolled participants in terms of gender, race, education status, and health literacy status. Men were underrepresented in both the eligible and enrolled sample and the eligible and not enrolled sample. The enrolled study sample was comprised of 81.4% females and the not enrolled sample had 73.4% females. The mean age was significantly higher for enrolled participants at 41.8 (13.4) compared to the eligible but non-enrolled participants with a median age of 38.3 (13.6). As for race, the majority of screened participants were Caucasian (93%).

However, enrolled participants had higher educational attainment compared to non-enrolled participants who were also eligible. 68.1% of enrolled participants had achieved more than a high school degree, where as only 52.5% of the eligible but non-enrolled participants achieved the same. There was no significant difference between income groups. Enrolled participants had a mean income of \$23,172.75 (17,144.72) compared to \$20,808.82 (15,662.27) for not enrolled participants. Mean health literacy scores were statistically significant. A score of 3 indicated the highest level of health literacy and 15 was the lowest possible score. The enrolled sample had a mean score of 4.5 (2.2). The not enrolled sample had a slightly lower mean health literacy score at 5.0 (3.1).

**Table 4: Comparison of Eligible and Enrolled Participants vs. Eligible and Not Enrolled**

Demographic Characteristics	Eligible and Enrolled N=301	Eligible and Not Enrolled N=319	Statistical Test (significance)
Gender	81.4% female 18.6% male	73.4% female 26.6% male	$X^2=5.699$ ( $p=0.021$ )*
Mean Age (SD)	41.8 (13.4)	38.3 (13.6)	$F=10.257$ ( $p<0.001$ )*
Race	93% white 7% other race	87.7% white 12.3% other race	$X^2=4.882$ ( $p=0.030$ )*
Ethnicity	99% non-Hispanic 1.0% Hispanic	98.3% non-Hispanic 1.7% Hispanic	$X^2=0.585$ ( $p=0.497$ )
Educational Attainment	68.1% beyond high school 31.9% high school or less	52.5% beyond high school 47.5% high school or less	$X^2=15.674$ ( $p<0.001$ )*

Mean Income	\$23,172.75 (17,144.73)	\$20,808.82 (15,662.27)	F=3.147 (p=0.077)
Mean Health Literacy** (SD)	4.5 (2.2)	5.0 (3.1)	F=5.122 (p=0.024)*

\*Significant p value (<0.05); \*\*Health Literacy Score 3=High, 15=Low

When eligible and enrolled participants were compared to the average of the eight Talking Health counties US census data for individuals less than 65 years old, the enrolled sample was well represented in terms of age, race and ethnicity (Table 5). However, men were underrepresented (18.6%) compared to the census data (51.9%). Likewise participants with less than a high school education are somewhat underrepresented in Talking Health (31.9%), as compared to the US census data (42.1%). On the contrary, low-income participants are overrepresented in the Talking Health sample with enrolled participants averaging a mean income of \$23,172.75 compared to \$36,674.81 in the census data.



**Table 5: Comparison of Eligible and Enrolled Participants vs. 2010 US Census Data**

Demographic Characteristics	Eligible and Enrolled N=301	2010 U.S. Census Data (<65 yo)*
Gender	81.4% female 18.6% male	48.1% female 51.9% male
Mean Age (SD)	41.8 (13.4)	40.8
Race	93% white 7% other race	93.9% white 6.1% other race
Ethnicity	99% non-Hispanic 1.0% Hispanic	98.4% non-Hispanic 1.6% Hispanic
Educational Attainment	68.1% beyond high school 31.9% high school or less	57.9% beyond high school 42.1% high school or less

Mean Income	\$23,172.75 (17,144.73)	\$36,674.81
-------------	-------------------------	-------------

\*Census Data was collected from the American Community Survey for individuals <65 years old for Lee, Giles, Pulaski, Washington, Grayson, Wise, Wythe and Montgomery counties

**DISCUSSION:**

This study has assessed the reach and representativeness of the enrolled Talking Health sample. In terms of reach, 48.5% of screened and eligible participants enrolled into the Talking Health Study. This proportion was calculated using the denominator of individual who were screened for eligibility. Participation rates in similar community based interventions that targeted physical activity and dietary behavior change, ranged from 21% to 70%, with an average of 51.8% (Pinto et al., 2005; Elley et al., 2003; Humpel et al., 2004; King et al., 1991; Albright et al., 2005; Pinto et al., 2002). When compared to the reach proportions identified in these studies that used a similar denominator our participation rate is similar.

There are a variety of factors that influence participation rate. These factors include the type of study design, characteristics of the intervention, characteristics of the target population, and the recruitment strategies that are used. Since Talking Health is a randomized controlled trial this could reduce participation rate, because there may be individuals who do not want to be randomized into a treatment condition. The way an intervention is delivered may also reduce reach. For example an intervention that is of higher intensity and requires participants to be present three times a week versus one that only requires participation three times a year will influence participation rate. Talking Health required long-term participation (18 months) with a total of three class sessions, 22 telephone calls, and three data collections. Depending on

individuals' motivation and other factors, this could have influenced the study's participation rate. Another component that may affect participation rate is the characteristics of the target population. Talking Health's target population was individuals with low health literacy and low socioeconomic status. These characteristics are associated with lower participation, which would in turn reduce participation rate. Lastly, the recruitment strategies used can also influence participation rate. Talking Health used a variety of recruitment strategies, including both active and passive methods. To determine which recruitment methods were most effective, we would have to conduct a more detailed analysis of recruitment in the Talking Health study. To adequately explore these issues, the difficult task of contacting non-participants to determine how these factors (e.g. study design, characteristics of the intervention, recruitment strategies) influenced study enrollment and reach may be needed.

This research focused on the reach component of the RE-AIM framework, but it is important to consider that researchers were primarily responsible for the recruitment of participants into the Talking Health study. As future efforts are made to translate this trial into practice, including for non-research purposes, it is unclear how reach will be influenced when practitioners try to adopt recruitment into their routine practice. Therefore, these important aspects of reach should be further examined as the Talking Health study is translated into community- and practice-based settings.

This research also adds to the literature regarding the RE-AIM framework specifically as it relates to the representativeness of participants' health literacy status. As evidenced by the systematic reviews examined, most studies that have reported on representativeness are limited to factors such as gender, age, race, ethnicity, income, and educational attainment and do not include health literacy comparison. Although we hypothesized there would be no significant

differences among the enrolled and non-enrolled participants, we found that the enrolled sample has a statistically higher health literacy score as compared to the non-enrolled. The clinical significance of this 0.5 difference on a 15-point scale is somewhat questionable and unclear. Moreover, subjective health literacy measures are typically the most practical for screening purposes; however, it is well-documented that participants perception of their health literacy skills are often higher than when using objective health literacy measures. This should be taken into consideration when interpreting the findings related to representativeness of health literacy.

Although there is no surveillance or census data to compare the health literacy data of our enrolled participants, we can compare our health literacy data to other systematic reviews. However, for pragmatic reasons, we used subjective health literacy questions in our screening protocol. The limitation with these questions is the lack of a threshold or cut-point to distinguish between low versus high health literacy status. However, when using the objective Newest Vital Sign health literacy instrument at baseline enrollment, we found that 33% of individuals enrolled had low health literacy skills. The mean score for the NVS was 3.96 (1.95), which indicates adequate health literacy. Even among a systematic review of health literacy interventions only 38% of the participants across the 25 different interventions actually had low health literacy (Allen, et al. 2013). Low health literacy individuals are a difficult target population to reach and recruitment methods need to be reconstructed so that the intended population is being reached. For our intervention, research staff thoroughly documented recruitment strategies. This data can help guide future recruitment efforts, when targeting low health literate individuals in rural areas.

In addition to health literacy, we hypothesized that there would be no significant differences between eligible and enrolled participants and eligible but not enrolled participants when comparing age, race, ethnicity, educational attainment, and income. Our data analysis

found that gender, age, race, and educational attainment showed significant differences between the eligible and enrolled sample and eligible but not enrolled individuals. Our enrolled sample had higher educational attainment than those who were eligible but declined to participate. Higher education is correlated with higher participation in behavioral trials; this correlation could explain our study outcomes (Pampel et al., 2011). In terms of age there was a significant difference, but this was only a difference of 3.5 years, which may not be clinically significant.

Even though there was a significant difference in gender between the enrolled sample and the not enrolled sample; men were underrepresented in both the enrolled sample and the eligible but not enrolled sample. This was expected as most behavioral interventions have a higher proportion of females who participate. A systematic review done by Pagoto and colleagues examined representativeness in weight loss interventions. They reviewed 244 publications and found that on average study samples consisted of 27% males and 73% females (Pagoto et al., 2012). These findings are similar to our study's sample where 54 out of 301 participants were male (18.6%). Contrary to this review, our studies sample was representative in terms of race and ethnicity, which could be due to the region in which our intervention took place, where racial/ethnic homogeneity is high and the majority of the population, is Caucasian and non-Hispanic. In terms of income, our sample had a much higher socioeconomic status. This is consistent with other behavioral trials, which found that individuals with low socioeconomic status are underrepresented in studies (Powe et al., 2004).

As mentioned through out this paper, representativeness of the studies sample is often not reported. Although we did not use inferential testing to compare our study's sample to the census data, we hypothesized that enrolled participants would be well represented in terms of age, race, ethnicity, educational attainment, and income at the individual county level as well as

across the counties when compared to the US census data. Our findings refuted our hypothesis in terms of educational attainment. Even though our recruitment strategies targeted low health literacy individuals our sample still had higher educational attainment compared to the census data. This could be due to the fact that individuals with higher education tend to participate in interventions more (Pampel et al., 2011).

Additional efforts need be made on how to reach low health literacy individuals. Jerant and colleagues used personally tailored interactive multimedia computer program to promote screening. They found that these personalized computer messages were more effective and increased screening readiness (Jerant et al., 2007). This could be one way to reach individuals with low health literacy and increase participation in health related interventions in an attempt to reduce health disparities. Researchers also need to determine appropriate recruitment strategies to recruit more males. Tailoring recruitment methods and incentives towards male populations could possibly do this.

As mentioned previously an integral part missing to determine the representativeness of a study's sample is national health literacy data. There is no national data on individual health literacy status to make the comparison. This is a limitation. Another limitation is that the demographic data collected is self-report. The screener asked individuals' about income, educational attainment, to rate their own reading ability, and other sensitive topics. This could have influenced individual's answers, which could have skewed the numbers that were analyzed.

In conclusion, this study has revealed the reach and representativeness of individuals enrolled in this behavioral trial and overall reveals a mixed picture of the representativeness of the study. Despite the findings that many of our hypothesis were rejected, this type of analysis helps inform the generalizability of study findings. This study also pinpoints future research for

community-based studies targeting rural and MUAs in SWVA. Future behavioral interventions need concerted recruitment strategies to target males, individuals with lower health literacy status, and individuals with less than a high school degree. Exploring and addressing barriers for study enrollment among these sub-groups is also important.

## References

- Agency for Healthcare Research and Quality. (2014). Health Literacy Interventions and Outcomes: An Updated Systematic Review. Retrieved from: <http://www.ahrq.gov/research/findings/evidence-based-reports/er199-abstract.htm>. Accessed July 2014.
- Akers, J.D., Estabrooks, P.A., Davy, B.M. (2010). Translational research: bridging the gap between long-term weight loss maintenance research and practice. *J Am Diet Assoc.* 110(10), 1511-22.
- Albright, C.L., Pruitt, L., Castro, C., Gonzalez, A., Woo, S., King, A.C. (2005). Modifying physical activity in a multiethnic sample in low-income women: one-year results from the IMPACT (Increasing Motivation for Physical ACTivity) project. *Ann Behav Med.* 30(3), 191-200.
- 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. *J Health Commun.* 16(3), 55-72.
- American Heart Association. (2014 September). Sugars, Added Sugars and Sweeteners. Retrieved from: <http://www.heart.org/HEARTORG/GettingHealthy/NutritionCenter/HealthyDietGoals/Sugars>. Accessed July 2014.
- Austin, G., Bell, T. Caperchione, C. Mummery W.K. (2011). Translating research to practice: using the RE-AIM framework to examine an evidence-based physical activity intervention in primary school settings. *Health Promot Pract.* 12(6), 932-41.
- Baker, D.W., Wolf, M.S., Feinglass, J., Thompson, J.A., Gazmararian, J.A., Huang, J. (2007). Health literacy and mortality among elderly persons. *Arch Intern Med.* 167(14), 1503-9.
- 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. *Ann Intern Med,* 155(2), 97-107. doi: 10.7326/0003-4819-155-2-201107190-00005.
- Blackman, K.C., Zoellner, J., Berrey, L.M., Alexander, R., Fanning, J., Hill, J.L., Estabrooks, P. (2013). Assessing the Internal and External Validity of Mobile Health Physical Activity Promotion Interventions: A Systematic Literature Review Using the RE-AIM Framework. 15(10):e224.
- Bray, G.A., Nielsen, S.J., Popkin, B.M. (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.



Brown, I.J., Stamler, J., Van Horn, L., Robertson, C.E., Chan, Q.N., Dyer, A.R., Huang, C.C., Rodriguez, B.L., Zhao, L.C., Daviglius, M.L., Ueshima, H., Elliott, P. (2011). Sugar-sweetened beverage, sugar intake of individuals, and their blood pressure: International study of macro/micronutrients and blood pressure. *Hypertension*. 57(4), 695.

Bockrath, S. (2013). Implications of Health Literacy for Public Health: Workshop Summary: Current Health Department Efforts in Health Literacy. *Institute of Med.* 34-38.

Calle, E.E. and Kaaks, R. (2004). Overweight, obesity and cancer: epidemiological evidence and proposed mechanisms. *Nature Reviews Cancer*. 4, 579-591.

Campbell, D.T. and Stanley, J.C. (1966). Experimental and quasi-experimental designs for Research. Chicago, IL: Rand McNally.

Centers for Disease Control and Prevention. (2014, September 3). Overweight and Obesity Facts. Retrieved from: <http://www.cdc.gov/obesity/data/facts.html>. Accessed July, 2014.

Centers for Disease Control and Prevention. (2014). "The RE-AIM Framework. A Public Approach to Translating Research to Practice." 1-60.

Centers for Disease Control and Prevention. (2014). Physical activity. *National Center for Chronic Disease Prevention and Health Promotion*. Retrieved from <http://www.cdc.gov/physicalactivity/everyone/guidelines/adults.html>. Accessed July, 2014.

Centers for Disease Control and Prevention. (2010). The CDC Guide to Strategies for Reducing the Consumption of Sugar-Sweetened Beverages. 1-41.

Chen, L., Appel, L.J., Loria, C., Lin, P.H., Champagne, C.M., Elmer, P.J., Ard, J.D., Mitchell, D., Batch, B.C., Svetkey, L.P., Caballero, B. (2009). Reduction in consumption of sugar-sweetened beverages is associated with weight loss: the PREMIER trial. *Am J Clin Nutr.* 89, 1299–306.

Chew, LD., Griffin, JM., Partin, MR., Noorbaloochi, S., Grill, J.P., Snyder, A., Bradley, K.A., Nugent, S.M., Baines, A.D., Vanryn, M. (2008). Validation of Screening Questions for Limited Health Literacy in a Large VA Outpatient Population. *J Gen Intern Med.* 23(5), 561-566.

Davis, T.C., Wolf, M.S., Arnold, C.L., Byrd, R.S., Long, S.W., Springer, T., Kennen, E., Bocchini, J.A. (2006). Development and validation of the Rapid Estimate of Adolescent Literacy in Medicine (REALM-Teen): a tool to screen adolescents for below-grade reading in health care settings. 118(6), 1707-14.

Dietary Guidelines Advisory Committee. (2010). Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans. Washington, DC:U.S. Department of Agriculture.

- Dunton, G.F., Liao, Y., Grana, R., Laglorie, R. Riggs, N. Chou, C.P., Robertson, T. (2014). State-wide dissemination of a school-based nutrition education programme: a RE-AIM (Reach, Efficacy, Adoption, Implementation, Maintenance) analysis. *Public Health Nutr.* 17(2), 422-30.
- Eakin, E.G., Bull, S.S., Glasgow, R.E., Mason, M. (2003). Reaching those most in need: A review of diabetes self-management interventions in disadvantaged populations. *Diabetes Metab Res Rev.* 18(1), 26-35.
- Elley, C.R., Kerse, N., Arroll, B., Robinson, E. (2003). Effectiveness of counseling patients on physical activity in general practice: cluster randomized controlled trial. *Brit Med J.* 326, 793-8.
- Estabrooks, P., Dzewaltowski, D.A., Glasgow, R.E., Klesges, L.M. (2003). Reporting of validity from school health promotion studies published in 12 leading journals, 1996-2000. *J Sch Health.* 73(1), 21-8.
- Evenson, K.R., Brownson, R.C., Satinsky, S.B., Eyler, A.A., Kohl, H.W. (2013). The U.S. National Physical Activity Plan: dissemination and use by public health practitioners. *Am. Journal Preventative Medicine.*44(5), 431-8.
- 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. *Med Decis Making.* 27(5), 672-80.
- Finklestein, E.A., Trogdon, J.G., Cohen, J.W., Dietz, W. (2009). Annual medical spending attributable to obesity: Payer-and service specific estimates. *Health Affairs.* 28(5), 822-31.
- Fjeldsoe, B.S. (2009). MobileMums: a physical activity intervention delivered via SMS for disadvantaged postnatal women. *School of Psychology.* 376-395.
- Fung, T. T., V. Malik, K. M. Rexrode, J. E. Manson, W. C. Willett, Hu, F.B. (2009). Sweetened Beverage Consumption and Risk of Coronary Heart Disease in Women. *American Journal of Clinical Nutrition* 89(4),1037-042.
- Gaglio, B., Shoup, JA., Glasgow, RE. (2013). The RE-AIM Framework: A Systematic Review of Use Over Time. *American J Public Health.* 103(6), 38-46.
- Gainforth, H.L., Latimer-Cheung, A.E., Athanasopoulos, P. Martin Ginis, K.A. (2014). Examining the Feasibility and Effectiveness of a Community-Based Organization Implementing an Event-Based Knowledge Mobilization Initiative to Promote Physical Activity Guidelines for People with Spinal Cord Injury Among Support Personnel. *Health Promot Pract.* 9:29. Epub 2014 May 22.
- Galaviz, K.I., Harden, S.M., Smith, E., Blackman, K.C., Berrey, L.M, Mama, S.K., Almeida, F.A., Lee, R.E., Estabrooks, P.A. (2014). Physical activity promotion in Latin American

populations: a systematic review on issues of internal and external validity. *Int J Behav Nutr Phys Act.* 11(77). doi: 10.1186/1479-5868-11-77.

Glasgow, R., T. Vogt, and S. Boles. (1999). "Evaluating the Public Health Impact of Health Promotion Interventions: The RE-AIM Framework." *Am. J. Public Health* 89(9),1322-327.

Glasgow, R., Boles, S., Lichtenstein, E., Lee, M., Foster, L. (2004). Adoption, reach, and implementation of a novel smoking control program: analysis of a public utility-research organization partnership. *Nicotine Tob Res.* 6(2), 269-74.

Glasgow, R.E., Strycker, L.A., Kurz, D., Faber, A., Bell, H., Dickman, J.M., Halterman, E., Estabrooks, P.A., Osuna, D. (2010). Recruitment for an internet-based diabetes self-management program: scientific and ethical implications. *Ann Behav Med.* 40(1), 40-8.

Glasgow, R.E., Nelson, C.C., Kearney, K.A., Reid, R., Ritzwoller, D.P., Stretcher, V.J., Couper, M.P., Green, B., Wildenhaus, K. (2007). Reach, Engagement, and Retention in an Internet-Based Weight Loss Program in Three Healthcare Systems. *J Med Internet Res.* 9(2), e11.

Glasgow, R.E., Estabrooks, P.A., Marcus, A.C., Smith, T.L., Gaglio, B., Levinson, A.H., Tong, S. (2008). Evaluating Initial Reach and Robustness of a Practical Randomized Trial of Smoking Reduction. *Health Psychol.* (6), 78-788.

Gong, D.A., Lee, J.Y., Rozier, R.G., Pahel, B.T., Richman, J.A., Vann, W.F. (2007). Development and testing of the Test of Functional Health Literacy in Dentistry (TOFHLiD). *J Public Health Dent.* 67(2), 105-12.

Goode, A.D., Owen, N., Reeves, M.M., Eakin, E.G. (2012). Translation from research to practice: community dissemination of a telephone-delivered physical activity and dietary behavior change intervention. *Am Journal of Health Promotion.* 26(4), 253-9.

Han, E. Powell, L.M. (2014). Consumption Patterns of Sugar Sweetened Beverages in the United States. *J Acad Nutr Diet.* 113(1), 43-53.

Harden, S.M., Burke, S.M., Halle, A.M., Estabrooks, P.A. (2013). Generalizing the Findings From Group Dynamics-Based Physical Activity Research to Practice Settings: What Do We know?. *Eval Health Prof.* Epub: 2013 May 28.

Hedrick, V.E., Savla, J., Comber, D.L., Flack, K.D., Estabrooks, P.A., Nsiah-Kumi, P.A., Ortmeier, S., Davy, B.M. (2012). Development of a brief questionnaire to assess habitual beverage intake (BEVQ-15): Sugar-sweetened beverages and total beverage energy intake. *J Acad Nutr Diet.* 112(6), 840-849.

Health Resources and Services Administration. (2014). Find Shortage Areas: MUA/P by State and County. *U.S. Dept of Health and Human Services.*

- Humpel, N., Marshall, A.L., Iverson, D., Leslie, E., Owen, N. (2004). Trial of print and telephone delivered interventions to influence walking. *Prev Med.* 39, 635-41.
- Huye, H.F., Connell, C.L., Crook, L.B., Yadrick, K., Zoellner, J. (2014). Using the RE-AIM Framework in Formative Evaluation and Program Planning for a Nutrition Intervention in the Lower Mississippi Delta. *Health Promotion International.* 46(1), 34-42.
- Jenkinson, K.A., Naughton, G., Benson, A.C. (2012). The GLAMA (Girls! Lead! Achieve! Mentor! Activate!) physical activity and peer leadership intervention pilot project: a process evaluation using the RE-AIM framework. *BMC Public Health.* 12(55), 2-15.
- Jeppesen, K.M., Coyle, J.D., Miser, W.F. (2009). Screening questions to predict limited health literacy: a cross-sectional study of patients with diabetes mellitus. *Ann Fam Med.* 7(1), 24-31.
- Jerant, A., Kravitz, R.L., Rooney, M., Amerson, S., Kreuter, M., Franks, P. (2007). Effects of a tailored interactive multimedia computer program on determinants of colorectal cancer screening: a randomized controlled pilot study in physician offices. *Patient Educ Couns.* 66(1), 67-74.
- Kessler, R.S., Purcell, E.P., Glasgow, R.E., Klesges, L.M., Benkeser, R.M., Peek, C.J. (2012), What Does It Mean to "Employ" the RE-AIM Model?. *Eval Health Prof.* 36(1):44-66.
- Kiernan, M., Schoffman, D.E., Lee, K., Brown, S.D., Fair, J.M., Perri, M.G., Haskell, W.L. (2013). The Stanford Leisure-Time Activity Categorical Item (L-CAT): a single categorical item sensitive to physical activity changes in overweight/obese women. *Int J Obes.*
- Kimberly-Clark Corporation. 2008. "Assuring Healthy Caregivers. A Public Approach to Translating Research Into Practice.1-60.
- King, A.C., Haskell, W.L., Taylor, C.B., Kraemer, H.C., Debusk, R.F. (1991). Group- vs home-based exercise training in healthy older men and women: a community-based clinical trial. *JAMA.* 266, 1535-42.
- Kit, B.K., Fakhouri, T.H.I., Park, S., Nielsen, S.J., Ogden, C.L. (2013). Trends in sugar-sweetened beverage consumption among youth and adults in the United States: 1999-2010. *Am J Clin Nutr.* 98(1), 180-188.
- Kohl, L.F., Crutzen, R., Vries, N.K. (2013). Online Prevention Aimed at Lifestyle Behaviors: A Systematic Review of Reviews. *J Med Internet Res.* 15(7), 146.
- Lavie, C., Milani, R.V., Hector, O. (2009). Obesity and Cardiovascular Disease. *J of Am College of Cardiology.* 53(21), 1925-32.

Matthews, L., Kirk, A., Macmillan, F., Mutrie, N. (2014). Can physical activity interventions for adults with type 2 diabetes be translated into practice settings? A systematic review using the RE-AIM framework. *Transl Behav Med.* 4(1), 60-78.

Meyer et al., (2012). Adoption, reach and effectiveness of computer-based, practitioner delivered and combined smoking interventions in general medical practices: a three-arm cluster randomized trial. *Drug Alcohol Depend.* 121(102), 124-32.

Montonen, J., R. Jarvinen, P. Knekt, M. Heliovaara, and A. Reunanen. (2007). Consumption of Sweetened Beverages and Intakes of Fructose and Glucose Predict Type 2 Diabetes Occurrence. *J. Nutr.* 137(6), 1447-454.

Morris, N.S., MacLean, C.D., Littenberg, B. (2006). Literacy and health outcomes: a cross-sectional study in 1002 adults with diabetes. *BMC Fam Pract.* 7(49).

Murphy, P.W., Davis, T.C., Long, S.W., Jackson, R.H., Decker, B.C. (1993). Rapid Estimate of Adult Health Literacy in Medicine (REALM): A quick reading test for patients. *Journal of Reading.* 37(2), 124-130.

Nielsen, S. J., and Popkin, B. M. (2004). Changes in beverage intake between 1977 and 2001. *American Journal of Preventive Medicine,* 27(3), 205-210.

Nigg, C., Geller, K., Adams, P., Hamada, M., Hwang, P., Chung, R. (2012). Successful dissemination of Fun 5 —a physical activity and nutrition program for children. *Translational Behavioral Medicine.* 2(3), 276-285.

Office of Disease Prevention and Health Promotion. (2014). Health People 2020. Available at: <https://www.healthypeople.gov/2020/data-search/Search-the-Data>. Accessed July 2014.

Osborn, C.Y., Wallston, K.A., Shpigel, A., Cavanaugh, K., Kripalani, S., Rothman, R.L. (2013). Development and validation of the General Health Numeracy Test (GHNT). *Patient Educ Couns.* 91(3), 350-356.

Osborn, C.Y., Wallston, K.A., Shpigel, A., Cavanaugh, K., Kripalani, S., Rothman, R.L. (2013). Development and validation of the General Health Numeracy Test (GHNT). *Patient Educ Couns.* 91(3), 350-356.

Paasche-Orlow, M.K., Parker, R.M., Gazmararian, J.A., Nielsen-Bohlman, L.T., Rudd, R.R. (2005). The prevalence of limited health literacy. *J Gen Intern Med.* 20(2), 175-184.

Pagoto, S.L., Schneider, K.L., Oleski, J.L., Luciani, J.M., Bodenlos, J.S., Whited, M.C. (2012). Male inclusion in randomized controlled trials of lifestyle weight loss interventions. *Obesity.* 20(6), 1234-9.

Pampel, F.C., Krueger, P.M., Denney, J.T. (2011). Socioeconomic Disparities in Health Behaviors. *Annu Rev Sociol.* 36, 349-370.

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. *J Gen Intern Med.* 10(10), 537-41.

Patterson, P.D., Moore, C.G., Probst, J.C., Shinogle, J.A. (2004). Obesity and physical inactivity in rural America. *J Rural Health.* 20(2), 151-9.

Pinto, B.M., Friedman, R.M., Marcus, B.H., Kelley, H., Tennstedt, S., Gillman, M.W. (2002). Effects of a computer-based, telephone-counseling system on physical activity. *Am J Prev Med.* 23(2),113-20.

Pinto, B.M., Frierson, G.M., Rabin, C., Trunzo, J.J., Marcus, B.H. (2005). Home-based physical activity intervention for breast cancer patients. *J Clin Oncol.* 23, 3577-87.

Pleasant (2012). Health literacy around the world: Part 1 health literacy efforts outside of the United States. Washington, DC: Institute of Medicine.

Rudd, R.E. (2007). Health literacy skills of U.S. adults. *Am J Health Behav.* 31 (Suppl 1), S8-18.

Ruyter, J.M., Olthof, M.R., Seidell, J.C., Katan, M.B. (2012). A trail of Sugar-free or Sugar-sweetened beverages and body weight in children. *New England J of Medicine.* 367, 1397-406.

Scarpace PJ, Zhang Y. (2009). Leptin resistance: a predisposing factor for diet-induced obesity. *Am J Physiol Regul Integr Comp Physiol.* 296(3), 493-500.

Sharkey J.R., Johnson, C.M., Dean, W.R. (2011). Less-healthy eating behaviors have a greater association with a high level of sugar-sweetened beverage consumption among rural adults than among urban adults. *Food Nutr Res.* 55(10), 5819.

Stellefson, M., Chaney, B., Barry, A.E., Chavarria, E., Tennant, B., Walsh-Childers, K., Sriram, P.S., Zagora, J. (2013). Web 2.0 chronic disease self-management for older adults: a systematic review. *J Med Internet Res.* 15(2), 35.

Tahmassebi, J., Duggal, M., Malik-Kotru, G., et al. (2006). Soft Drinks and Dental Health: A review of the Current Literature. *J. of Dental Research.* 34(1), 2-11.

Turner, K. M. and M. R. Sanders, "Help When It's Needed First: A Controlled Evaluation of Brief, Preventive Behavioral Family Intervention in a Primary Care Setting," *Behavior Therapy.* 37(2),131-142.

U.S. Department of Health and Human Services. (2010). What is Health Literacy? Available at: <http://www.health.gov/communication/literacy/quickguide/factsbasic.htm>. Accessed July 2014.

U.S. Census Bureau. (2013). State and county quickfacts (American Community Survey). Available from: <http://quickfacts.census.gov/qfd/states/51000.html>. Accessed September 24, 2014.

United States Department of Agriculture. What is Rural? *National Agricultural Library*. Available from: <http://ric.nal.usda.gov/what-is-rural>. Accessed July 2014.

VA Foundation of Healthy Youth (2014). Available from: <http://www.vfhy.org/about-us/press-releases/one-third-virginians-consume-least-one-sugar-sweetened-beverage-day>. Accessed July 2014.

Vanselow, P., Neumark-Sztainer, R. (2009). Adolescent beverage habits and changes in weight over time: findings from Project EAT. *Am J Clin Nutr.* 10(1), 68-75.

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. *Am J Public Health.* 97(4), 667-75.

Von Wagner, C., Knight, K., Steptoe, A., Wardle, J. (2007). Functional health literacy and health-promoting behavior in a national sample of British adults. *J Epidemiol Commun H.* 61(12), 1086-90.

Wallace, L.S., Rogers E.S., et al. (2006). Brief Report: Screening Items to Identify Patients with Limited Health Literacy Skills. *J Gen Intern Med.* 21(8), 874-877.

White, S.M., McAuley, E., Estabrooks, P.A., Courneya, K.S. (2009). Translating physical activity interventions for breast cancer survivors into practice: an evaluation of randomized controlled trials. *Ann Behav Med.* 37(1), 10-9.

Weiss, B.D., Mays, M.Z., Martz, W., Castro, K.M., DeWalt, D.A., Pignone, M.P., Mockbee, J., Hale, F.A. (2005). Quick assessment of literacy in primary care: The Newest Vital Sign. *Ann Fam Med.* 3(6), 514-522.

Williams, K.J., Taylor, C.A., Wolf, K.N., Lawson, R.F., Crespo, R. (2008). Cultural perceptions of healthy weight in rural Appalachian youth. *Rural Remote Health.* 8(2), 932.

Yank, V., Stafford, R.S., Rosas, L.G., Ma, J. (2013). Baseline reach and adoption characteristics in a randomized controlled trial of two weight loss interventions translated into primary care: A structured report of real-world applicability. *Contemp Clin Trials.* 34(1), 126-35.

Zahnd, W.E., Scaife, S.L., Francis, M.L. (2009). Health literacy skills in rural and urban populations. *Am J Health Behav.* 33(5), 550-557.

Zikmund-Fisher, B.J., Smith, D.M., Ubel, P.A., Fagerlin, A. (2007). Validation of the Subjective Numeracy Scale: Effects of low numeracy on comprehension of risk communications and utility elicitation. *Med Decis Making*. 27(5), 663-71.

Zoellner, J., You, W., Connell, C., Smith-Ray, R.L., Allen, K., Tucker, K.L., Davy, B.M., Estabrooks, P. (2011). Health literacy is associated with healthy eating index scores and sugar-sweetened beverage intake: Findings from the rural Lower Mississippi Delta. *J Am Diet Assoc*. 111(7), 1012-20.

Zoellner, J., Estabrooks, P.A., Davy, B., Chen, Y., You, W. (2012). Exploring the theory of planned behavior to explain sugar-sweetened beverage consumption. *J Nutr Ed Behav*. 44(2), 172-7.

Zoellner, J., Krzeski, E., Harden, S., Cook, E., Allen, K., Estabrooks, P.A. (2012). Qualitative application of the theory of planned behavior to understand beverage consumption behaviors among adults. *J Acad Nutr Diet*. 112(11), 1774-84.

Zoellner, J., Cook, E., You, W., Davy, B., Estabrooks, P. (2014). Mixed methods evaluation of a randomized control pilot trial targeting sugar-sweetened beverage behaviors. *Open J Prev Med*. 3(1), 51-57.



## Appendices

### Appendix A: IRB Approval



Office of Research Compliance  
Institutional Review Board  
2000 Kraft Drive, Suite 2000 (0497)  
Blacksburg, VA 24098  
540/231-4006 Fax 540/231-0969  
email [irb@vt.edu](mailto:irb@vt.edu)  
website <http://www/irb.vt.edu>

#### MEMORANDUM

**DATE:** January 10, 2013  
**TO:** Jamie M Zoelner Dr, Paul Andrew Estabrooks, Yvonne 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 Institutional 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 (ibadmin@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  
Yvonne 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

Virginia Tech Institutional Review Board Project No. 12-090  
Approved January 6, 2014 to January 31, 2015

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  
540-231-4991  
moored@vt.edu



## Human Nutrition, Foods & Exercise

### Talking Health Screening Survey

Remember that all the answers you provide are private. Only the researcher's will have access to your answers. You will not be singled out as a result of this study.

This first set of questions is about the types of beverages you have drank in the past **month**. Please feel free to ask any question you have regarding the beverages or serving size options.

1. How often do you drink **sweetened juice beverages/drinks (such as fruit aides, lemonade, punch, or Sunny Delight)**?

- Never or less than 1 time per week
- 1 time per week
- 2-3 times per week
- 4-6 times per week
- 1 time per day
- 2 times per day
- 3 or more times per day

1a. When you drink **sweetened juice beverages/drink**, how much do you normally drink?

- less than 6 fluid ounces (or  $\frac{3}{4}$  cup)
- 8 ounces (1 cup)
- 12 ounces (1  $\frac{1}{2}$  cups)
- 16 ounces (2 cups)
- more than 20 ounces (2  $\frac{1}{2}$  cups)

2. How often do you drink **regular soft drinks** (NOT diet)?

- Never or less than 1 time per week
- 1 time per week
- 2-3 times per week
- 4-6 times per week
- 1 time per day
- 2 times per day
- 3 or more times per day

2a. When you drink **regular soft drinks**, how much do you normally drink?

- less than 6 fluid ounces (or  $\frac{3}{4}$  cup)
- 8 ounces (1 cup)
- 12 ounces (1  $\frac{1}{2}$  cups)
- 16 ounces (2 cups)
- more than 20 ounces (2  $\frac{1}{2}$  cups)

3. How often do you drink **diet soft drinks**?

- Never or less than 1 time per week
- 1 time per week
- 2-3 times per week
- 4-6 times per week
- 1 time per day
- 2 times per day
- 3 or more times per day

3a. When you drink **diet soft drinks**, how much do you normally drink?

- less than 6 fluid ounces (or  $\frac{3}{4}$  cup)
- 8 ounces (1 cup)
- 12 ounces (1  $\frac{1}{2}$  cups)
- 16 ounces (2 cups)
- more than 20 ounces (2  $\frac{1}{2}$  cups)

4. How often do you drink **sweetened tea** (sweetened with sugar)?

- Never or less than 1 time per week
- 1 time per week
- 2-3 times per week
- 4-6 times per week
- 1 time per day
- 2 times per day
- 3 or more times per day

4a. When you drink **sweetened tea**, how much do you normally drink?

- less than 6 fluid ounces (or  $\frac{3}{4}$  cup)
- 8 ounces (1 cup)
- 12 ounces (1  $\frac{1}{2}$  cups)
- 16 ounces (2 cups)
- more than 20 ounces (2  $\frac{1}{2}$  cups)

5. How often do you drink **unsweetened tea**? (This includes tea with **NO** sugar **OR** tea that may have artificial sweeteners such as Splenda or Sweet and Low)

- Never or less than 1 time per week
- 1 time per week
- 2-3 times per week
- 4-6 times per week
- 1 time per day
- 2 times per day
- 3 or more times per day

5a. When you drink **unsweetened tea**, how much do you normally drink?

- less than 6 fluid ounces (or  $\frac{3}{4}$  cup)
- 8 ounces (1 cup)
- 12 ounces (1  $\frac{1}{2}$  cups)
- 16 ounces (2 cups)
- more than 20 ounces (2  $\frac{1}{2}$  cups)



6. How often do you drink **tea or coffee, with cream and/or sugar (includes non-dairy creamer)**?

- Never or less than 1 time per week
- 1 time per week
- 2-3 times per week
- 4-6 times per week
- 1 time per day
- 2 times per day
- 3 or more times per day

6a. When you drink **tea or coffee, with cream and/or sugar**, how much do you normally drink?

- less than 6 fluid ounces (or  $\frac{3}{4}$  cup)
- 8 ounces (1 cup)
- 12 ounces (1  $\frac{1}{2}$  cups)
- 16 ounces (2 cups)
- more than 20 ounces (2  $\frac{1}{2}$  cups)

7. How often do you drink **energy and sports drinks (such as Red Bull, Rockstar, Gatorade, Powerade, etc)**?

- Never or less than 1 time per week
- 1 time per week
- 2-3 times per week
- 4-6 times per week
- 1 time per day
- 2 times per day
- 3 or more times per day

7a. When you drink **energy and sports drinks**, how much do you normally drink?

- less than 6 fluid ounces (or  $\frac{3}{4}$  cup)
- 8 ounces (1 cup)
- 12 ounces (1  $\frac{1}{2}$  cups)
- 16 ounces (2 cups)
- more than 20 ounces (2  $\frac{1}{2}$  cups)

**This next question is about your physical activity.**

**During the past month, which statement best describes the kinds of physical activity you usually did during your **FREE TIME** (or time spent other than working at a job)? Please read all six statements before selecting one.**

- 1. You did not do much physical activity. You mostly did things like watching television, reading, playing cards, or playing computer games. Only occasionally, no more than once or twice a month, did you do anything more active such as going for a walk or playing tennis.
- 2. Once or twice a week, you did light activities such as getting outdoors on the weekends for an easy walk or stroll. Or once or twice a week, you did chores around the house such as sweeping floors or vacuuming.
- 3. About three times a week, you did moderate activities such as brisk walking, swimming, or riding a bike for about 15-20 minutes each time. Or about once a week, you did moderately difficult chores such as raking or mowing the lawn for about 45-60 minutes. Or about once a week, you played sports such as softball, basketball, or soccer for about 45-60 minutes.
- 4. Almost daily, that is five or more times a week, you did moderate activities such as brisk walking, swimming, or riding a bike for 30 minutes or more each time. Or about once a week, you did moderately difficult chores or played sports for 2 hours or more.
- 5. About three times a week, you did vigorous activities such as running or riding hard on a bike for 30 minutes or more each time.
- 6. Almost daily, that is five or more times a week, you did vigorous activities such as running or riding hard on a bike for 30 minutes or more each time.

**These next 3 questions will help us understand the reading needs of people taking this survey.**

1. How confident are you filling out medical forms by yourself?

- Extremely confident
- Quite a bit confident
- Somewhat confident
- A little bit confident
- Not at all confident

2. How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?

- Never
- Rarely
- Sometime
- Often
- Always

3. How would you rate your ability to read?

- Excellent or very good
- Good
- Okay
- Poor
- Terrible or very poor

**This next set of questions is about your health as it relates to exercise.**

**Please check ONE answer, yes or no.**

1. Do you have any chest pain or lightheadedness when you exercise?

- Yes, please explain: \_\_\_\_\_
- No

2. Do you have any joint pain that is worsened by exercise?

- Yes, please explain: \_\_\_\_\_
- No

3. Have you ever experienced any allergic reactions from exercise (hives or wheezing )?

- Yes, please explain: \_\_\_\_\_
- No

4. In the past month, have you been told by your doctor not to exercise for any reason?

- Yes, please explain: \_\_\_\_\_
- No

5. Do you have a pacemaker or internal defibrillator?

- Yes, please explain: \_\_\_\_\_
- No

6. Is there any other reason we have not asked or you have not told us that would prevent you from participating in an exercise program?

- Yes, please explain: \_\_\_\_\_
- No

**This final set of questions is needed to help us understand the people taking this survey.**

1. What is your gender?

- Male
- Female

2. What is your marital status (please choose only one)?

- Married
- Divorced
- Widowed
- Separated
- Never married
- A member of an unmarried couple

3. Please indicate which of the following best describes you (choose all that apply).

- White
- Black or African American
- Asian
- American Indian/Alaskan Native
- Native Hawaiian or Other Pacific Islander
- Not sure
- Other: \_\_\_\_\_

4. Please indicate which of the following best describes you (please choose only one).

- Hispanic or Latino
- Not Hispanic or Latino
- Not sure

5. What is your age? \_\_\_\_\_

6. Please indicate which county you live in from the list below.

- Alleghany
- Bland
- Buchanan
- Carroll
- Craig
- Dickenson
- Floyd
- Giles
- Grayson

- Lee
- Pulaski
- Russell
- Smyth
- Tazewell
- Washington
- Wise
- Wythe
- Other: \_\_\_\_\_

7. Please mark the highest grade of school that you have completed (please choose only one).

- Grades 0-8
- Grades 9-11
- High school
- Some college
- College graduate
- Graduate school

8. Are you currently (choose all that apply)?

- Employed for wages full-time
- Employed for wages part-time
- Self-employed
- Out of work for more than 1 year
- Out of work for less than 1 year
- A homemaker
- A student
- Retired
- Unable to work

9. Of these income groups, please choose which number best represents your family's total income (before taxes) in the last 12 months (please choose only one).

- Less than \$5,000
- \$5,000-9,999
- \$10,000-14,999
- \$15,000-19,999
- \$20,000-24,999
- \$25,000-29,999
- \$30,000-34,999
- \$35,000-39,999
- \$40,000-44,999
- \$45,000-49,999
- \$50,000-54,999
- More than \$55,000

10. How many children under the age of 18 years do you have that currently live in your home (please choose only one)?

- 0
- 1
- 2
- 3
- 4
- More than 4

11. What kind of health care coverage do you have?

- None
- Private health insurance, including HMOs
- Medicare
- Medicaid
- Other, please specify\_\_\_\_\_

Please let us know when you are usually able to attend an education session.

1. Please check which **mornings** you can usually attend an education session (check all that apply):

- Monday
- Tuesday
- Wednesday
- Thursday
- Friday

Comments:

2. Please check which **evenings** you can usually attend an education session (check all that apply):

- Monday
- Tuesday
- Wednesday
- Thursday
- Friday

Comments:

3. May we contact you to provide you with more information on the Talking Health Program?

- No
- Yes, please provide your contact information:

Name: \_\_\_\_\_

Address: \_\_\_\_\_

Do you have regular access to a telephone (landline or cellphone)? \_\_\_\_\_

Home Telephone Number: \_\_\_\_\_

Cell Phone Number: \_\_\_\_\_

Email Address: \_\_\_\_\_



**Appendix D: Newest Vital Sign (NVS)**

<b>Nutrition Facts</b>			
Serving Size		½ cup	
Servings per container		4	
Amount per serving			
Calories	250	Fat Cal	120
			%DV
<b>Total Fat</b>	13g		20%
Sat Fat	9g		40%
<b>Cholesterol</b>	28mg		12%
<b>Sodium</b>	55mg		2%
<b>Total Carbohydrate</b>	30g		12%
Dietary Fiber	2g		
Sugars	23g		
<b>Protein</b>	4g		8%

\*Percentage Daily Values (DV) are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

**Ingredients:** Cream, Skim Milk, Liquid Sugar, Water, Egg Yolks, Brown Sugar, Milkfat, Peanut Oil, Sugar, Butter, Salt, Carrageenan, Vanilla Extract.

[PARTICIPANT ID Number]:

[DATA COLLECTOR Initials]:

Newest Vital Sign (NVS)

[SHOW NUTRITION LABEL HANDCARD]

[READ TO RESPONDENT]: "This next section only takes a few minutes because there are only 5-6 questions. Please use the nutrition label provided to answer the following questions. This information is on the back of a container of one pint of ice cream."

[NOTE: Provide respondent with scratch paper if necessary.]

NVS1. If you eat the entire container, how many calories will you eat?

[RECORD ANSWER or check below]

[98] I don't know/Refused to answer

NVS2. If you are allowed to eat 60 grams of carbohydrate as a snack, how much ice cream could you have?

[RECORD ANSWER or check below]

[NOTE: IF PARTICIPANT ANSWERS 'Two servings' ASK "How much ice cream would that be if you were to measure it into a bowl?"]

[98] I don't know/Refused to answer

NVS3. Your doctor advises you to reduce the amount of saturated fat in your diet. You usually have a total of 42 grams of saturated fat each day, which includes one serving of ice cream. If you stop eating the one serving of ice cream, how many grams of saturated fat would you be eating each day?

[RECORD ANSWER or check below]

[98] I don't know/Refused to answer

[PARTICIPANT ID Number]: |||||

NVS4. If you usually eat 2500 calories in a day, what percentage of your daily value of calories will you be eating if you eat one serving?

\_\_\_\_\_  
[RECORD ANSWER or check below]

[98] I don't know/Refused to answer

NVS5. Pretend that you are allergic to the following substances: Penicillin, peanuts, latex gloves, and bee stings. Is it safe for you to eat this ice cream?

\_\_\_\_\_  
[RECORD ANSWER or check below]

[98] I don't know/Refused to answer

NVS6. [ASK ONLY IF THE PATENT RESPONDS "NO" TO QUESTION 5].  
Why not?

\_\_\_\_\_  
[RECORD ANSWER or check below]

[98] I don't know/Refused to answer