PERSONAL UTILITY: EXAMINING THE EFFECTS OF GENOMIC RISK KNOWLEDGE ON MOTIVATION TOWARD DIET AND PHYSICAL ACTIVITY BEHAVIOR CHANGES

Harlyn Gynette Skinner

A dissertation submitted to the faculty at the University of North Carolina at Chapel Hill in partial fulfillment of the requirements for the degree of Doctor of Philosophy in the Department of Nutrition in the Gillings School of Global Public Health.

Chapel Hill
2017

Approved by:

Alice Ammerman

Thomas Keyserling

Jonathan C Schisler

Dianne Ward

Carmen Samuel-Hodge

ABSTRACT

Harlyn Gynette Skinner: Personal Utility: Examining The Effects Of Genomic Risk Knowledge On Motivation Toward Diet And Physical Activity Behavior Changes
(Under the direction of Alice Ammerman)

The National Institutes of Health and the Centers for Disease Control and Prevention have jointly indicated urgency in researching the use of personal genomics in the assessment of disease prevention. One research priority is the use of genomic information in behavior change research for reducing the risk for common chronic disease (e.g., cardiovascular disease—CVD). Research suggests improvements in motivation toward behavior change with counseling based on one gene (genetic counseling) and even better outcomes with counseling based on two or more genes (genomic or polygenetic counseling). Currently, little is known about the effect of genetic or genomic counseling in minority populations.

This study examines whether genomic-risk knowledge increases motivation towards diet and physical activity changes to reduce CVD-risk in African-American participants from a rural, low-income county in eastern North Carolina. To meet this goal, we conducted three inter-related research projects. First, focus groups were conducted with African-Americans and Whites to assess community needs and wants regarding a genomics project (n=35). Findings indicated community interest in participation and interest in receiving personalized genomic results. Second, intervention messages on the return of personalized CVD genomic-risk were developed following the principles of The Protection Motivation Theory and Leventhal's

Common Sense Model. Messages were tested within the target population for comprehension and acceptance (n=32).

Using a 2-arm randomized controlled trial design, returning CVD genomic results were compared to an attention control group in sixty-two (n=62) African-Americans. The primary outcome was the difference in motivation towards diet and physical activity at 1-month follow-up compared using a general linear regression model. There were no significant between- or within-group results (p=0.51). There was significant within-group moderation by genomic-risk category for the intervention group. Those with low genomic CVD-risk self-reported increased motivation towards diet and physical activity (0.31 ± 0.18, p=0.09), and increased weekly consumption of fruit and vegetables (1.34 ± 0.36, p=0.001). Those with average genomic CVD-risk self-reported less motivation and no change in fruit and vegetable consumption. Findings suggest that genomic-risk knowledge may impact the perceived threat of CVD, but more research needs to be done to better understand the best use for this approach.

I dedicate this work to my family (blood and chosen) who supported me throughout this process.

TABLE OF CONTENTS

LIST OF TABLES xiii

LIST OF FIGURES xv

LIST OF ABBREVIATIONS xvi

CHAPTER 1: INTRODUCTION 1

A. Overview 1

B. Formative Aims and Rationale 2

B.1. Formative Aim 1 2

B.2. Formative Aim 2 2

C. Experimental Aims and Hypotheses 3

C.1. Experimental Aim 1 3

C.2. Experimental Aim 2 3

C.3. Experimental Aim 3 4

CHAPTER 2: LITERATURE REVIEW 5

A. Cardiovascular Disease Disparities — Region & Race 5

B. Lifestyle Change — Part Of The Solution But Does NOT Eliminate Disparity 6

B.1. Lifestyle 6

B.2. Genetics 7

B.3. Lifestyle & Genetics 8

C. Personalized Risk Communication 8

C.1. Personalized Risk Communications And Health Literacy 10

D. Personalized Genomic Risk Communication 11

D.1. Direct-To-Consumer 11

D.2. Diet And Physical Activity 12

D.3. Type 2 Diabetes Mellitus and CVD 14

E. Psychosocial Impact 18

F. Gaps in Knowledge 19

G. Heart Healthy Lenoir 20

H. Summary 20

CHAPTER 3: A CONCEPTUAL MODEL DEPICTING A HYPOTHESIS FOR THE COMMUNICATION OF GENOMIC RISK 21

A. Protection Motivation Theory 21

CHAPTER 4: USING COMMUNITY-BASED PARTICIPATORY RESEARCH PRINCIPLES TO DEVELOP MORE UNDERSTANDABLE RECRUITMENT AND INFORMED CONSENT DOCUMENTS IN GENOMIC RESEARCH 25

A. Overview 25

B. Introduction 26

C. Methods 28

C.1. Participants 28

C.2. Focus Group Guide Development 29

C.3. Focus Group Protocol 29

C.4. Analysis 30

D. Results 31

D.1. Demographics 31
D.2. Defining Genomics 33
D.3. Focus Group Themes 33
D.3.1. Theme 1: Transparent Communication 34
D.3.2. Theme 2: Privacy 35
D.3.3. Theme 3: Participation Incentives and Barriers 36
D.3.4. Theme 4: Knowledge 38
D.3.5. Theme 5: The Impact of Knowing 39
E. Discussion 41
CHAPTER 5: COMMUNICATING GENOMICS RESULTS FOR A MINORITY AUDIENCE: DEVELOPMENT OF A PROTOCOL 45
A. Overview 45
B. Introduction 46
C. Methods 47
C.1. Background 47
C.2. Adaptation of Original Protocol 49
C.3. Participants 49
C.4. Message-Testing Protocol 50
C.5. Analysis 51
D. RESULTS 53
D.1. Demographics 53
D.2. Key Lessons Learned 54
D.2.1. Lesson 1: Genomics Education 54
D.2.2. Lesson 2: Personal Utility 58

D.2.3. Lesson 3: Language Usage 61

E. Discussion 61

E.1. Conclusions 63

CHAPTER 6: THE RETURN OF RESULTS STUDY: RESULTS FROM A RANDOMIZED CONTROLLED TRIAL TO EVALUATE THE CONCEPT OF USING PERSONALIZED GENOMIC RESULTS FOR MOTIVATION TO CHANGE DIET AND PHYSICAL ACTIVITY BEHAVIORS 64

A. Overview 64

B. Introduction 65

C. Methods 66

C.1. Parent Study 66

C.2. Risk Estimates 67

C.2.1. Phenotypic Risk Estimate 67

C.2.2. Genetic Risk Estimate 67

C.3. Intervention 71

C.3.1. Participant Screening and Recruitment 71

C.3.2. Randomization 71

C.3.3. Interventions 71

C.4. Outcome Measures 75

C.5. Analysis 76

D. Results 79

D.1. Participant Characteristics 79

D.2. Primary Outcome 81

D.3. Secondary Outcomes 84

D.3.1. Motivation Towards Stress Reduction 84

D.3.2. Protection Motivation Theory Constructs 84

D.3.3. Health Behaviors 86

E. Discussion 87

CHAPTER 7: SUMMARY OF FINDINGS AND RECOMMENDATIONS FOR FUTURE RESEARCH 94

A. Summary of Findings 94

B. Recommendations for Future Research 95

C. Recommendations for Theory 97

D. Conclusions 98

APPENDIX 4: SUPPLEMENTAL MATERIALS FOR ESTABLISHING COMMUNITY NEED 99

APPENDIX 4.1: ADDITIONAL QUOTATIONS ABOUT KNOWLEDGE 99

APPENDIX 4.2: FOCUS GROUP CONSENT FORM 102

APPENDIX 4.3: FOCUS GROUP GUIDE 105

APPENDIX 4.4: DEMOGRAPHICS SURVEY 108

APPENDIX 4.5: FOCUS GROUPS CODEBOOK 110

APPENDIX 5: RETURN OF RESULTS PROTOCOL DEVELOPMENT MATERIALS 111

APPENDIX 5.1 EXAMPLE ADAPTED RETURN OF RESULTS PROTOCOL 111

APPENDIX 5.2 KEYWORDS SHEET USED WITH RETURN OF RESULTS PROTOCOL 121

APPENDIX 5.3 TAKE HOME MATERIALS WITH RETURN OF RESULTS PROTOCOL 122

APPENDIX 5.4 PHASE 1 CONSENT FORM 125

APPENDIX 5.5 PHASE 1 RECRUITMENT BROCHURE 129

APPENDIX 5.6 PHASE 1 STRUCTURED "COGNITIVE" INTERVIEW AND FOCUS GROUP PROTOCOL 131

APPENDIX 5.7 RAPID ESTIMATE OF ADULT LITERACY IN GENETICS 138

APPENDIX 6: RANDOMIZED CONTROLLED TRIAL SUPPLEMENTAL MATERIALS 140

APPENDIX 6.1: CONTROL GROUP MATERIALS 140

A. Script 140

APPENDIX 6.2 GENOTYPING METHODS 148

APPENDIX 6.2.1a: FINE-MAPPING AND ADMIXTURE PAPERS REVIEWED 150

A. BMI 150

B. Dyslipidemia 150

C. T2DM 150

D. Blood Pressure 151

E. CVD 152

F. Smoking 152

APPENDIX 6.2.1.b: LIST OF POTENTIAL SNPS 153

APPENDIX 6.3: OUTCOME MEASURES 156

A. Baseline Surveys 156

B. Post-Test Survey 175

C. 1-Month Follow-Up Survey 182

APPENDIX 6.4: BASELINE VARIABLES 197

A. The Short Test of Functional Health Literacy in Adults (STOFHLA) 197

APPENDIX 6.5: REGRESSION ANALYSES FOR SECONDARY AND TERTIARY OUTCOMES 209

A. Motivation Towards Stress Reduction 209

B. Threat Appraisal 210

C. Coping Appraisal 214

D. Maladaptive Coping 219

E. Diet 223

F. Physical Activity 224

REFERENCES 226

LIST OF TABLES

Table 2.1: Odds Ratios from Previous Research on Personalized Risk Information 9

Table 2.2: Type 2 Diabetes Mellitus and Cardiovascular Disease Return of Genomic Results Studies 16

Table 4.1. Characteristics Of Focus Group Sample (N=35) 32

Table 5.1. Focus Group Descriptions 52

Table 5.2. Focus Group Demographics 53

Table 6.1. Heart Healthy Lenoir CVD Genomic Risk Signature for African-Americans 70

Table 6.2. Measures Used In Randomized Controlled Trial 77

Table 6.3. Participant Characteristics 82

Table 6.4. Phenotypic Risk by Genomic Risk—Overall 83

Table 6.5. Phenotypic Risk by Genomic Risk—Intervention Group 83

Table 6.6. Regression Analysis For Motivation Towards Diet And Exercise 83

Table A6.1. GWAS Significant SNPs From Fine-Mapping And Admixture Studies 153

Table A6.2. Candidate SNPs From Fine-Mapping And Admixture Studies 154

Table A6.3. STOFHLA Frequency Table 197

Table A6.4. STOFHLA Means 197

Table A6.5. Demographics – Means 197

Table A6.6. Demographics – Frequency Table 198

Table A6.7. Phenotypic Risk – Frequency Table 204

Table A6.8. Phenotypic Risk – Means 206

Table A6.9. Genomic Risk – Frequency Table 207

Table A6.10. Regression Analysis For Motivation Towards Stress Reduction 209

Table A6.11. Regression Analysis For Perceived Threat 210

Table A6.12. Regression Analysis For Perceived Vulnerability 211
Table A6.13. Regression Analysis For Perceived Severity 212
Table A6.14. Regression Analysis For Perceived Fear 213
Table A6.15. Regression Analysis For Coping Efficacy 214
Table A6.16. Regression Analysis For Diet Response Efficacy 215
Table A6.17. Regression Analysis For Diet Response Cost 216
Table A6.18. Regression Analysis For Physical Activity Response Efficacy 217
Table A6.19. Regression Analysis For Physical Activity Response Cost 218
Table A6.20. Regression Analysis For Fatalism 219
Table A6.21. Regression Analysis For Fatalism Subscale—Predetermination 220
Table A6.22. Regression Analysis For Fatalism Subscale—Luck 221
Table A6.23. Regression Analysis For Fatalism Subscale—Pessimism 222
Table A6.24. Regression Analysis For Fruit And Vegetable Servings 223
Table A6.25. Regression Analysis For Total Walking Time 224
Table A6.26. Regression Analysis For Total Minutes Of Physical Activity 225

LIST OF FIGURES

Figure 3.1. Conceptual Model 24

Figure 4.1. Transparent Communication Quotations 34

Figure 4.2. Privacy Quotations 35

Figure 4.3. Privacy Quotation—African-American Mistrust 36

Figure 4.4. Participation Incentives and Barriers Quotations 36

Figure 4.5. Participation Incentives and Barriers Quotation 37

Figure 4.6. Knowledge Quotations 38

Figure 4.7. Knowledge Quotation 38

Figure 4.8. The Impact of Knowing Quotation—Value of Knowing 40

Figure 4.9. The Impact of Knowing Quotation—Perceived Control 40

Figure 5.1. Genomics Education In ROR Script 55

Figure 5.2. "What Are SNPs?" Video 56

Figure 5.3. Take Home Genomic Education Resources 57

Figure 5.4. Phenotypic Risk Representation Using Framingham Risk Score 59

Figure 5.5. Genotypic Risk Presentation 60

Figure 6.1. SNP Decision Tree 3/4/16 69

Figure 6.2. Study Flow Diagram 74

LIST OF ABBREVIATIONS

AA	African-American
BRFSS	Behavioral Risk Factors Surveillance System
C	Control
CBPR	Community-Based Participatory Research
CDC	Centers for Disease Control and Prevention
CVD	Cardiovascular Disease
DTC-GT	Direct-to-Consumer Genetic Testing
FG	Focus Group
FRS	Framingham Risk Score
GRS	Genomic Risk Signatures
GWAS	Genome-Wide Association Studies
HDL	High-Density Lipoprotein
HHL	Heart Healthy Lenoir
I	Intervention
IRB	Institutional Review Board
LDL	Low-Density Lipoprotein
M	Mean
MHI-5	Mental Health Inventory
NC	North Carolina
NHGRI	National Health Genomic Research Institute
NIH	National Institutes of Health
PMT	Protection Motivation Theory

RCT	Randomized Controlled Trial
REAL-G	Rapid Estimate of Adult Literacy in Genetics
RESIDE	RESIDential Environment project
ROR	Return of Results
SD	Standard Deviation
SES	Socioeconomic Status
SF-12	Short Form Health Survey
SNP	Single Nucleotide Polymorphism
SNS-3	Subjective Numeracy Scale
STOFHLA	Short Test of Functional Health Literacy in Adults
T2DM	Type 2 Diabetes Mellitus
W	White
YRI	Yoruba In Ibadan, Nigeria

CHAPTER 1: INTRODUCTION

A. OVERVIEW

The National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) have jointly indicated urgency in researching the use of personal genomics in the assessment of disease risk and prevention. Chief among the research priorities is the establishment of an evidence base for effective ways of communicating personal genomic information as an approach to behavior change particularly in chronic disease risk reduction (e.g., cardiovascular disease—CVD).[1,2] High rates of CVD and its risk factors are found in (1) minorities,[3] (2) those of low socioeconomic status, [3,4] and (3) by geographic boundary (Southeastern states);[3,4] all such vulnerable populations can be found in rural North Carolina (NC). CVD mortality and morbidity can be effectively decreased by improvements in diet and physical activity, but this does not ameliorate CVD disparity. Disparity can be partially explained by genetic variation.

Research demonstrates positive improvements in motivation toward behavior change when individuals receive counseling based on one gene (genetic counseling) and even better outcomes when individuals receive counseling based on two or more genes (genomic counseling).[5-7] CVD is polygenic in nature.[8,9] The full constellation of SNPs (single nucleotide polymorphisms) involved in the development of CVD, and many other common chronic diseases, has yet to be fully elucidated. *Very few studies have been conducted investigating the effect of genomic counseling in motivating health behavior change in common chronic diseases*;

even fewer specifically in CVD.[10] To our knowledge, none have been conducted exclusively in an African-American population. Comparing participants' genomic profile to existing genomic risk markers for CVD identified from fine mapping and admixture studies, and then returning that genomic information to the participant, provides the basis for the current proposal. This study concentrates on the most vulnerable population—African-Americans living in a low socioeconomic area in the Southeastern United States. The primary goal of this study is to **determine if genomic knowledge will increase motivation towards CVD risk reduction health behaviors as compared to the control group** in a randomized proof-of-concept study with 62 African-American (AA) residents from the vulnerable population of Lenoir County, NC.

B. FORMATIVE AIMS AND RATIONALE

B.1. FORMATIVE AIM 1

Determine acceptance of genomic research in the African-American community in Lenoir County.

RATIONALE: There is a historical context of mistreatment by and lack of consent for medical research in AA communities. This has led to a culture of mistrust. To determine if a genomics study would be acceptable to the community, focus groups were conducted with AAs and Whites in Lenoir County.

B.2. FORMATIVE AIM 2

Adapt CVD genomic risk intervention materials for African-Americans in Lenoir County.

RATIONALE: To our knowledge, previous genomic risk communication literature largely focused on Whites. Given that ancestry is linked to genomic variation and that the most effective communication strategies can vary across cultural lines, adaptation of the current methods in the literature was necessary.

C. EXPERIMENTAL AIMS AND HYPOTHESES

C.1. EXPERIMENTAL AIM 1

Using a randomized controlled design, determine the effect of conveying CVD genomic risk via culturally and literacy appropriate materials on motivation toward changing diet and physical activity behaviors relative to no genomic risk communication (using an attention-control delayed intervention approach).

HYPOTHESIS: Motivation to change diet and physical activity will increase for AAs receiving genomic knowledge relative to those receiving no genomic information. Effects will be moderated by genomic-risk category.

C.2. EXPERIMENTAL AIM 2

Determine the effect of receiving genomic risk information versus no risk communication on psychosocial factors—constructs of Protection Motivation Theory: threat appraisal, perceived vulnerability, perceived severity, perceived fear, perceived efficacy, response cost, response efficacy, and fatalism.

HYPOTHESIS: Threat appraisal, perceived vulnerability, perceived severity, perceived fear, perceived efficacy, and response efficacy will increase while response cost will decrease among

AAs receiving genomic knowledge relative to those receiving no genomic information. Fatalism will not change. Effects will be moderated by genomic-risk category.

C.3. EXPERIMENTAL AIM 3

Determine the effect of receiving genomic risk information versus no risk communication on self-reported change in diet and physical activity behaviors.

HYPOTHESIS: Reported diet quality will become more healthful but reported physical activity will not change for AAs receiving genomic knowledge relative to those receiving no genomic information. Effects will be moderated by genomic-risk category.

CHAPTER 2: LITERATURE REVIEW

A. CARDIOVASCULAR DISEASE DISPARITIES — REGION & RACE

Cardiovascular disease (CVD) is the most common cause of morbidity and mortality in the United States.[11] In 2014, 614,348 people died from CVD[11] and at least 200,000 of those deaths could have been prevented.[12]

The risk of suffering from CVD is 49% higher than the U.S. average for those living in the Stroke Belt—an 11-state region of the southeastern United States, which includes North Carolina.[4,13] Residents in the Stroke Belt have poorer health outcomes and a higher prevalence of obesity compared to the rest of the country.[4] Situated in the heart of the Stroke Belt is Lenoir County, North Carolina. CVD is the leading cause of death in Lenoir County of adults aged 35 years and older (ranked 1st with 365.1 deaths per 100,000 compared to 192.7 deaths per 100,000 statewide).[3,14,15] Lenoir County residents report their most pressing health concerns as obesity, Type 2 Diabetes Mellitus (T2DM), and heart disease.[15] Additionally, the age-adjusted obesity rate (BMI $\geq$ 30) in Lenoir County is 37.0% compared to 29.7% statewide.[3,16] These facts illustrate disparity in CVD and its risk factors within Lenoir County and define residents as a vulnerable population.

Nationwide, African-Americans (AAs) are at 20% higher risk of CVD mortality compared to Whites and are nearly twice as likely to die from preventable CVD.[11,12] AAs also have higher rates of CVD risk factors compared to Whites—hypertension, T2DM, obesity, and smoking; hypercholesterolemia prevalence (as measured by statin use) is lower compared to

Whites.[3,13] The disparity in CVD and its risk factors widens in the Stroke Belt; in Lenoir County, AAs are at a 90% higher risk for CVD mortality than their White counterparts.[4,13,14]

B. Lifestyle Change — Part Of The Solution But Does NOT Eliminate Disparity

B.1. Lifestyle

Environmental risk factors for CVD have been well established: smoking status, hypertension, hypercholesterolemia, type 2 diabetes, and obesity.[17-19] These risk factors are strong predictors of CVD morbidity and mortality. A multitude of studies have demonstrated that lifestyle change targeting these risk factors lowers CVD risk.[19-23] The Nurses' Health Study suggests that a healthy lifestyle can lead to an 83% reduction in the risk of CVD; participants with a healthful lifestyle, noted the following healthy behaviors: not smoking, having a BMI < 25, consuming $\leq$ ½ alcoholic beverage per day, engaging in moderate to vigorous physical activity for 30 minutes per day, and scoring in the highest 40% for 'a good diet'.[19] (A good diet was defined as high consumption of cereal fiber, fish fatty acids, folate, and a high ratio of polyunsaturated to saturated fat; and low consumption of foods high in trans-fats and low glycemic load.) In particular, studies of Mediterranean diets have demonstrated a beneficial effect of such diets on the prevention of CVD and further CVD events.[23-26] The Mediterranean diet is characterized by olive oil as the main source of dietary oil, generous consumption of fruits and vegetables, lots of fish, little red meat (i.e., beef, lamb, pork), and modest consumption of alcohol. Meta-analysis confirms that focusing on diet and physical activity is critical in reducing CVD risk.[21]

Despite the evidence that eating a healthy diet and engaging in physical activity lowers CVD risk, there is a widening disparity between North Carolinians and average United States

behavior with regard to these lifestyle behaviors. According to the Behavioral Risk Factors Surveillance System (BRFSS) Survey, North Carolinians consumed 5 or more fruits or vegetables a day and engaged in the recommended levels of physical activity at lower rates compared to the average American.[3] The disparity gap has also widened between AAs and Whites in the past 30 years.[27] According to the BRFSS North Carolina Survey, fewer AAs than Whites consumed 5 or more fruits and vegetables or engaged in the recommended levels of physical activity.[28] Overall, despite an effective prescription for lifestyle change to reduce CVD risk, AAs are less successful in making diet and physical activity changes that would reduce disparity in CVD risk factors and CVD mortality.

B.2. GENETICS

Studies have established a genetic component to the development of CVD.[29-31] Genome-wide association studies (GWAS) have detected direct associations of genomic variations—called single nucleotide polymorphisms (SNPs)—with CVD.[32] The effect size attributable to a single CVD-related SNP is modest at best.[33] However, the large number of CVD-related SNPs identified in GWAS each explains a small amount of risk meaning that *CVD is polygenic in nature*. CVD genomic risk signatures (GRS)—aggregates of SNPs identified through GWAS that contribute to a genetic predisposition towards CVD—can be used to calculate an individual's CVD related genomic risk. These CVD genomic risk signatures are both independent predictors of CVD events and predictors of phenotypic risk.[34-38]

While there is not racial or regional disparity in the presence of CVD-related SNPs in the populous, it is important to mention the limitations of GWAS research. There are many more studies with White participants than AA participants. SNPs identified as relevant in sample populations of European-ancestry may not be relevant in AAs because of the reliance of GWAS

results on ancestral background. However, studies with AA participants have identified a multitude of CVD and CVD risk factor related SNPs in those of African-ancestry.[39-49] Additionally, AAs are admixed descendants of European and African ancestors. Admixture and fine-mapping studies exist specifically to investigate SNP variations in those of non European-ancestry.[42,44,46-48,50-75]

B.3. LIFESTYLE & GENETICS

Researchers are looking for new ways to motivate health behavior change. Studies demonstrate that patients who have previously suffered myocardial infarctions are more motivated to make diet and physical activity changes because they perceive themselves more vulnerable to further CVD.[76] However, public health practitioners want to encourage lifestyle change *before* a myocardial infarction. Protection Motivation Theory postulates that personal genomic knowledge may increase perceived vulnerability and motivate lifestyle change before a myocardial infarction in a similar manner to what is seen in myocardial infarction patients after their first CVD event.[77]

C. PERSONALIZED RISK COMMUNICATION

There is a paucity of research on the combined effect of personal genomic risk knowledge *and* lifestyle change on the reduction of CVD risk; none of this research has been conducted with AAs in the Stroke Belt. More broadly, there is research on personalized risk communication and some research on the effects of genomic risk knowledge.

In a Cochrane review by Edwards et al (2013), it was demonstrated that personalized risk communication has a positive effect over general risk information.[78] After receiving tailored messages, individuals were 15% more likely to undergo health protective screening (Pooled

Odds Ratio: 1.15 [1.02,1.29]).[78] These health behavior changes are confirmed by meta-analyses which indicates that personalized risk communication messages are shown to be more effective over generic comparison messages in affecting health behavior change.[79]

In addition to health behavior changes, there are cognition changes in those who receive personalized risk communications (Table 2.1). Individuals who receive tailored messages are more than four-times as likely to make informed decisions about undergoing screening tests (Pooled Odds Ratio: 4.48 [3.62,5.53]).[78] Personalized risk communication also affects an individual's understanding of risk perception making the participant's understanding of their risk 46% more accurate (Pooled Odds Ratio: 1.46[1.13,1.88]).[78,80] Knowledge has been shown to increase 2- to 7-fold as the result of tailoring.[78] Across studies, anxiety was non-significantly decreased implying that personalized risk communications might lessen anxiety about health behavior change (Standard Mean Difference: -0.13 [-0.29,0.03]).[78] In summary, personalized risk communication increases knowledge about risk and engenders more accurate risk perception leading to increased informed decision making about health behavior change.

Table 2.1: Odds Ratios from Previous Research on Personalized Risk Information

	Type of Risk Communication		
	Numerical	Categorical	List of Risk Factors
Uptake of Screening	0.95 [0.78,1.15][81-86]	1.29 [1.11,1.51][87-92]	----
Informed Decision	2.08 [1.14,3.81][81]	---	4.98 [3.97,6.24][93,94]
Perceived Risk	1.22 [0.91,1.64][82,95]	2.50 [1.48,4.20][96]	
Knowledge	2.11 [1.52,2.91][81-83]		7.13 [5.79,8.79][93,94]

C.1. Personalized Risk Communications And Health Literacy

As noted in Table 2.1, there are several different modalities through which risk can be presented—numerical, categorical, or a list of risk factors. The least effective modality is numerical. This may due to poor health literacy.

According to Berkman et. al. (2011), 'health literacy' is defined as the ability to: 1) "read and understand text to locate and interpret information in documents (print literacy)"; 2) "use quantitative information for tasks (numeracy)"; and 3) "speak and listen effectively (oral literacy)."[97] The 2003 National Assessment of Adult Literacy found that 14% of adults (approximately 30 million people) have below basic health literacy.[98] Low health literacy has long been associated with low health knowledge, poor disease self-management, and poor health outcomes.[99-103] Specifically, those with low health literacy have poorer skills in taking medications,[104-106] interpreting medication and nutrition labels,[107-109] and have higher all-cause mortality rates in the elderly.[110-112] Similarly, low numeracy has been associated with poor self-management of chronic disease, including higher utilization of emergency department services.[113-116]

Low numeracy is also a concern in personalized risk communications. According to the 2003 National Assessment of Adult Literacy, 22% of adults have below basic quantitative skills.[98] Even highly educated adults have been shown to have inadequate understanding of probabilities and risks.[117-121] These miscomprehensions of numerical information are suggested to result in poor risk estimation (regardless of format), improper calculation of disease probability, and inconsistent treatment decisions when outcomes are expressed in terms of absolute versus relative risk.[118,120,122,123] Poor numeracy and subsequent disease risk perceptions have been shown to affect health behaviors.[120,124-126] In cancer research, low numeracy has been

associated with the overestimation of risk leading to either increased cancer screening or fatalistic avoidance of cancer screening.[120,127-131] All of these numeracy concerns could contribute to the non-significant change in health behavior seen when providing numerical risk estimates.

Tailored communication efficacy is thought to be more relevant to the individual and therefore more comprehensible.[132] Evidence shows that literacy and numeracy must be taken into consideration when conveying risk information. Additionally, research suggests that giving both verbal and written information increases comprehension.[133] Making informed choices about health behaviors and increasing adherence to those behaviors is seen as the goal for personalized risk communication.[78]

D. Personalized Genomic Risk Communication

Personalized risk communication has been applied to the field of genomics both in commercial industry and in public health.

D.1. Direct-To-Consumer

Direct-to-consumer genetic testing (DTC-GT) companies provide personalized genomic risk information for common diseases to the public for-profit. In 2008, DTC-GT was become a $70.2 million global market and the number of companies offering DTC-GT services has risen dramatically.[134-136] While there is clear public interest in genomic testing, research suggests that testing of this kind can be confusing to patients and has yet to be proven definitively useful to population health. Studies demonstrate that genomic knowledge in the populous is low and consumers often still have questions about their DTC-GT results.[137-142] Given these knowledge

deficits, questions have been raised as to whether DTC-GT marketing encourages inappropriate applications of genetic tests, as well as questions about the ramifications of communicating genomic results in the absence of a knowledgeable professional to help interpret results.[2,143] Additionally, research suggests that DTC-GT may have limited public health impact. To this writer's knowledge, very few studies have been performed that systematically test health behavior change in response to DTC-GT. The few studies that have been performed show little evidence that the provision of DTC-GT results alone result in sustained behavior change.[144-146]

D.2. Diet And Physical Activity

In the field of public health, some studies have been performed on personalized genomic risk information's effect on health behaviors. Past studies have mostly been in the fields of smoking cessation and cancer (not discussed here). However, there are limited numbers of studies on personalized genomic risk information's impact on an individual's diet and physical activity behaviors.

In a Cochrane review by Marteau et al (2010), genomic based risk communications were found to more than double uptake of a healthful diet (Pooled Odds Ratio: 2.24 [1.17,4.27]) and to have no effect on physical activity (Pooled Odds Ratio: 1.03 [0.59,1.80]).[5] These results are based on findings from two studies: Marteau et al (2004) and Chao et al (2008).

Marteau et al (2004) performed a randomized controlled trial (RCT) on the impact of genomic risk communication for familial hypercholesterolemia on perceived control and health behavior change—diet, physical activity, adherence to statin medications, and smoking.[147] Intervention participants received routine clinical diagnosis and behavioral advice plus, findings for point mutations in the *LDLR* and *APOB* genes. Control participants received routine clinical

diagnosis and behavioral advice. Dietary measurement was self-reported fat intake measured at baseline and the 6-month follow-up. Physical activity measurement was self-reported frequency of vigorous physical activity measured at baseline and the 6-month follow-up. Results showed a trend towards genomic risk recipients being more than twice as likely to have a lower fat diet (Odds Ratio: 2.10 [0.99, 4.43]) and no change in physical activity at the 6-month measurement (Odds Ratio: 0.99 [0.55,1.790]).[5]

Chao et al (2008) performed a RCT on the impact of genetic risk communication for Alzheimer's disease on health behavior change—diet, physical activity, medication and vitamin use.[148] Intervention participants received Alzheimer's education, *APOE* genotype, and their lifetime risk based on their *APOE* genotype. Control participants received Alzheimer's education and a numerical risk estimate based on family history and gender. Dietary measurement was self-reported diet changes aimed at reducing Alzheimer's risk measured at baseline and 1-year follow-up. Physical activity measurement was self-reported physical activity changes aimed at reducing Alzheimer's risk measured at baseline and 1-year follow-up. Results demonstrated a trend towards genetic risk recipients being more than twice as likely to alter their diet to reduce Alzheimer's risk (Odds Ratio: 2.69 [0.75,9.70]) and no change in physical activity to reduce Alzheimer's risk at 1-year (Odds Ratio: 1.40 [0.27,7.19]).[5]

Also of note is the Arkadianos et al study (2007).[7] In a non-randomized design, this study investigated the impact of genomic risk communication for diet (nutrigenetics) on weight management. Participants in a weight management clinic were offered genotyping for 24 SNPs, and a personalized diet and exercise plan based on that information. The comparison group received standard diet and exercise plans from the weight management clinic. There was no difference between intervention and comparison groups at most time points—45 days, 100 days,

and 300 days. However at > 300 days post return of results, weight management clinic patients who received nutrigenetic diet and exercise plans lost significantly more weight compared to weight management clinic patients with standard diet plans (Odds Ratio 5.74 [1.74,22.52]). Put another way, nutrigenetics subjects lost 5.6% of their original body weight compared to a 2.2% weight gain in comparison subjects.[7]

Results from these three studies, combined, imply that receiving personalized genomic risk communications may result in dietary change, however genomic risk assessment effects 1) may require a long-term intervention (~ 1 year), and 2) may be most beneficial in conjunction with lifestyle skill training. Results imply that physical activity behaviors are not affected by genomic risk assessment. It is important to note several key limitations of these studies: 1) It is unclear how risk was conveyed (i.e., verbally, written, using numerical estimates, using categorical estimates, taking into account literacy, etc.); 2) Most of these studies were low intensity lifestyle programs that did not teach lifestyle change skills; 3) Participants tended to be White, highly educated women, thereby limiting generalizability.

D.3. Type 2 Diabetes Mellitus and CVD

There is an emerging body of literature on personalized genomic risk assessments applied to Type 2 Diabetes Mellitus (T2DM) and cardiovascular disease (CVD) interventions. To our knowledge, there are only four of these types of studies, two of which have yet to report results (Table 2.2).

Godino et al (2012) investigated the effect communicating personalized T2DM genomic risk results on objectively measured physical activity measured using the Actiheart® monitor (N=569).[149] Intervention group one received a genomic risk estimate and standard T2DM

prevention lifestyle advice. Intervention group two received a phenotypic risk estimate and standard T2DM prevention lifestyle advice. The control group received no risk information, only standard T2DM prevention lifestyle advice. Participants were followed for eight weeks. There were no significant between-group findings.[150]

Grant et al investigated the effect of personalized genomic risk on motivation towards diabetes prevention (N=108).[151] In their intervention, they included a 12-week lifestyle intervention program modeled after the Diabetes Prevention Program.[152] At the end of the intervention, program attendance and motivation were measured as the main outcomes. There were no differences between intervention and control groups for either outcome at 12-weeks. A major strength of this research compared to the studies mentioned above is the use of a proven-effective lifestyle program. There were no differences between groups with this short-term study.

The Arkadianos study, described above, suggests that a longer-term study coupled with the intensive lifestyle program might be more effective. Additionally, Arkadianos et al found that when giving genomic results in conjunction with an intensive lifestyle program, intervention participants with fasting blood glucose levels >100mg/dl were almost twice as likely to have fasting blood glucose levels <100 mg/dl at >300 days when compared to the control group (Odds Ratio: 1.98 [1.01,3.87]).[7]

Other related studies, including Cho et al (2012), and Knowles et al (2012) have yet to publish study results.

The five studies mentioned above promise to yield interesting results. However, these studies have several key limitations: 1) most assessed short-term programs; 2) most are low-intensity lifestyle programs, if any counseling at all; 3) most do not take into account health

literacy or numeracy issues in their genomic counseling; and 4) the study populations are largely highly educated White populations.

There are also research projects underway on how to use genomic risk information to improve health behaviors in common diseases at National Human Genome Research Institute (NHGRI) Centers for Excellence in the Ethical, Legal, and Social Implications Research Centers across the country. The application of personal genomic risk assessments to common diseases is an upcoming research field, which has been deemed an urgent priority by the NIH and the CDC.[1,2] This proposal seeks to answer that call by contributing to the evidence base of effective ways of communicating personal genomic information as an approach to behavior change in CVD disease risk reduction.

TABLE 2.2: TYPE 2 DIABETES MELLITUS AND CARDIOVASCULAR DISEASE RETURN OF GENOMIC RESULTS STUDIES

T2DM								
Study (N)	Design	Follow-up	Intervention	Control	Primary Outcome	Secondary Outcome	Primary Results	Secondary Results
Grant 2013[151,153] N=108	2-arm RCT In-person	12-weeks	Genetic risk + 12-week diabetes prevention program	12-week diabetes prevention program	Program attendance Motivation	Weight change Weekly exercise and diet logs Diabetes risk perception Stages of change for: low fat diet, exercise, and weight loss	No differences between groups	Increased stage of change for exercise
Godino 2012[149,150] N=569	3-arm RCT Mail	After receipt of letter	Genetic risk estimate + standard lifestyle advice sheet	Standard lifestyle advice sheet	Objectively measured physical activity	Self-reported: Diet	No differences between groups	More accurate estimates of perceived risk in

		8-weeks	Phenotypic risk estimate + standard lifestyle advice sheet			Weight Intentions to be physically active Intentions to engage in a healthy diet Anxiety Diabetes-related worry Self-rated health Perceived risk		intervention groups compared to control group
Cho 2012[154] N≅506	3-arm RCT In-person	3 months 1 year	Genetic risk + one counseling session with healthcare staff at participant's physician's office One counseling session with healthcare staff at participant's physician's office	One counseling session with healthcare staff at participant's physician's office	Insulin resistance (HOMA-IR) BMI	Diet pattern Physical activity Waist circumference Perceived risk	Not reported yet	Not reported yet
CVD								
Study	Design	Follow-up	Intervention	Control	Primary Outcome	Secondary Outcome	Primary Results	Secondary Results
Knowles 2012[10] N≅100	2-arm RCT In-person	3 months 6 months	Genetic risk + 3 clinic visits	3 clinic visits	LDL cholesterol	Blood pressure Weight Diet Hemoglobin A1c	Not reported yet	Not reported yet

						Exercise patterns Smoking Stages of change Risk perception Medication compliance Attitudes towards medications Anxiety		

E. PSYCHOSOCIAL IMPACT

The psychological impact of returning genomic results has been measured across many studies. The most frequently studied concept is perceived risk and intention to change health behavior. Findings for these measures are inconsistent.

A Cochrane review reports that perceived risk becomes more accurate as a result of genomic information (Pooled Odds Ratio: 1.46[1.13,1.88]).[78] However meta-analysis suggests there is no change in perceived risk over time.[146] Perceived risk has also been found to affect other psychosocial measures—anticipated worry and test-induced distress. However, this effect is not linearly related with genomic risk nor is it related to interest in undergoing genomic testing or perceived benefits from genomic testing.[155] Perceived risk has yet to be fully elucidated in genomic studies. Therefore, further research is needed to better understand perceived risk's relationship with genomic risk results.

Likewise, intention has yielded contradictory results across previous studies. A Cochrane review reports no change in intention towards a more healthful diet or increased physical activity

in response to genomic risk information (Standardized mean difference: 0.18 [-0.02,0.38]).[5] However, when analyzing intention to change health behaviors by genomic risk categories, some studies have found that participants who are told they are at low genomic risk then have lower intentions towards healthy behaviors.[89,156] For this reason, experts have cautioned against the promotion of "genetic invulnerability" in participants with "lower" genetic risk. Some experts suggest that stressing gene-environment interaction and personal control in message framing will counteract the effect of lowered healthy behavior intentions.[157]

Other psychosocial constructs have been measured, but the research thus far is either inconsistent or suggests there is no effect. These measures include anxiety,[5,78] outcome expectations,[5] perceived control,[158] motivation.[151] While genomic risk information may motivate health behavior change, the psychological underpinnings motivating such a change have yet to be fully elucidated.

F. GAPS IN KNOWLEDGE

Review of the literature has highlighted four critical gaps in knowledge. ***First***, the impact of personal genomic knowledge on psychological changes, health behavior change, and disease prevention has yet to be fully elucidated. ***Second***, the motivational effect of personal genomic knowledge to lessen health disparities has yet to be addressed. ***Third***, current translational genomic studies efforts have not taken into account best practice lifestyle change methods with the accompanying individual- and community-level supports. ***Fourth*** most current translational genomic studies have not created communications that are comprehensible by the general public. Therefore, the overarching goal of this proposed research project is to fill those research gaps.

G. Heart Healthy Lenoir

This investigation was conducted as ancillary study to the Heart Healthy Lenoir (HHL) study. HHL was a five-year three-project coordinated study spanning the CVD care continuum from prevention to treatment to genomics research aimed at reducing CVD risk disparities in a rural, low-income county in eastern North Carolina: the HHL Lifestyle Study was a community-based lifestyle intervention program designed to reduce CVD risk disparity by improving eating patterns, promoting physical activity, and supporting weight loss; the HHL Hypertension Study was a clinic-based lifestyle intervention program designed to improve blood pressure control of patients through their primary care practices by targeting medication and lifestyle management at the patient and practice level; and the HHL Genomics Study explored genomic factors associated with CVD risk and intervention success. All HHL Genomics participants were also enrolled in the Lifestyle or Hypertension studies.

H. Summary

Enrolling AAs from The HHL Genomics Study, this proposal seeks to determine if genomic-risk knowledge will increase motivation towards diet and physical activity as compared to no risk communication.

CHAPTER 3: A CONCEPTUAL MODEL DEPICTING A HYPOTHESIS FOR THE COMMUNICATION OF GENOMIC RISK

A. PROTECTION MOTIVATION THEORY

Protection Motivation Theory (PMT) suggests that engaging in risk-reducing lifestyle changes is governed by an individuals' perception of risk of the disease.[124,159] PMT is based on expectancy-value theory which states that adoption of behavior is a function of expectancy regarding the consequences of the behavior and the value of those consequences.[160] In PMT, these cognitive mediational processes take two forms—threat appraisal and coping appraisal. Threat appraisal is the process of evaluating a fear appeal—information developing a disease state—relevant to the individual's perception of how threatened the person feels. Threat appraisal consists of the following constructs: perceived vulnerability, perceived severity, and fear arousal. Coping appraisal is the process of evaluating a fear appeal relevant to the individual's perception of the recommended behavior change to address the fear appeal. Coping appraisal consists of the following constructs: response efficacy (Will the behavior change be effective?) and self-efficacy (Do I believe I'm capable of performing the behavior?). Threat and coping appraisal is predictive of protection motivation which is predictive of concurrent behavior.[161] However, activating threat appraisal without providing the skills necessary for positive coping appraisal may result in maladaptive coping responses—i.e., fatalism. Research has shown that individuals at high genetic risk could be fatalistic which results in the lack of motivation to make diet and physical activity lifestyle changes.[158,162] However, very few studies have empirically measured fatalism resulting in insufficient current evidence for fatalism as a

mediating mechanism of motivation. This type of maladaptive response has been theorized to inhibit protection motivation.

Research has shown that patients who have just suffered a cardiac event have higher motivation towards diet and physical activity changes.[77,163] According to PMT, the fear appeal is the healthcare provider warning of another cardiac event, the threat appraisal is the patient's perceived risk of another cardiac event, and the coping appraisal is the patient's perception of diet and physical activity change. In cardiac patients, PMT has shown that increased feelings of vulnerability results in higher levels of motivation towards diet change.[77] This relationship does not exist with physical activity.[163] However, coping appraisal is strongly associated with both diet and physical activity motivation.[77,163] Parallel mechanisms to threat and coping appraisals have been suggested in the study of personalized genomic risk communications.[5,78] Additionally, deeper exploration of the mechanisms of motivation towards behavior change due to genomic knowledge has been named as a priority in the literature.[164,165] For these reasons, PMT is the central theorem of this study.

In summary, genomic risk information may be internalized as more personally relevant than general non-personalized risk information. This could lead to a higher threat appraisal based on: 1) increased perceived vulnerability due to the use of genomics, 2) increased perceived severity of CVD because the genomic results are about CVD, and/or 3) increased fear due to increased perceived vulnerability and severity. This could also lead to higher coping appraisal: 1) increased perceived response efficacy of diet and/or physical activity changes, and/or 2) decreased perceived response-cost of diet and/or physical activity changes. Both threat-appraisal and coping-appraisal could lead to protection motivation. Threat-appraisal might also activate maladaptive coping-appraisal, which would inhibit protective motivation. Activation of coping-

appraisal might also inhibit maladaptive coping-appraisal. Overall, protection motivation could lead to changes to diet and exercise.

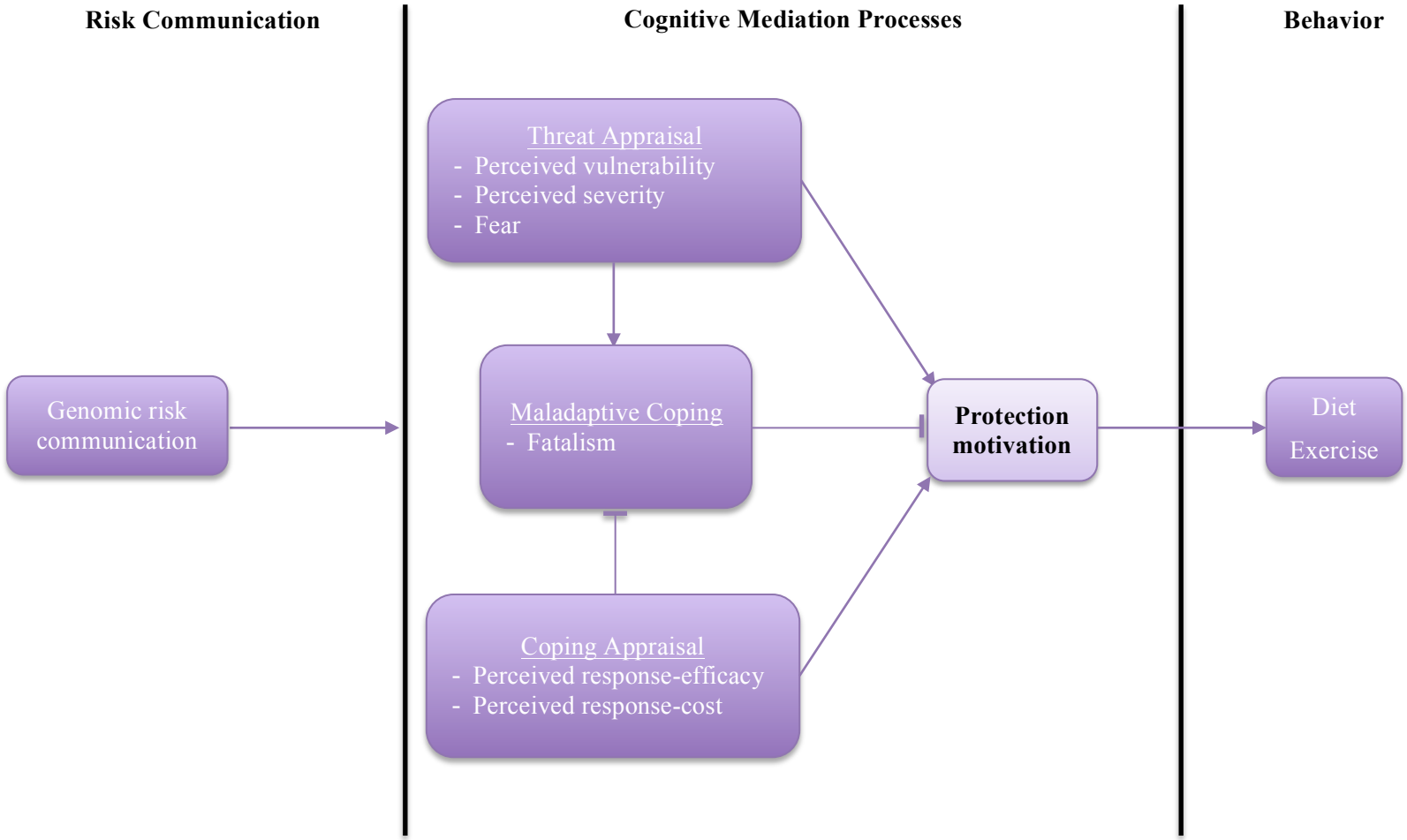


FIGURE 3.1. CONCEPTUAL MODEL

CHAPTER 4: USING COMMUNITY-BASED PARTICIPATORY RESEARCH PRINCIPLES TO DEVELOP MORE UNDERSTANDABLE RECRUITMENT AND INFORMED CONSENT DOCUMENTS IN GENOMIC RESEARCH[1]

A. OVERVIEW

Heart Healthy Lenoir is a transdisciplinary project aimed at creating long-term, sustainable approaches to reduce cardiovascular disease risk disparities in Lenoir County, North Carolina using a design spanning genomic analysis and clinical intervention. We hypothesized that residents of Lenoir County would be unfamiliar and mistrustful of genomic research, and therefore reluctant to participate; additionally, these feelings would be higher in African-Americans. To test our hypothesis, we conducted qualitative research using community-based participatory research principles to ensure our genomic research strategies addressed the needs, priorities, and concerns of the community.

African-American (n=19) and White (n=16) adults in Lenoir County participated in four focus groups exploring perceptions about genomics and cardiovascular disease. Demographic surveys were administered and a semi-structured interview guide was used to facilitate discussions. The discussions were digitally recorded, transcribed verbatim, and analyzed in ATLAS.ti. From our analysis, key themes emerged: transparent communication, privacy, participation incentives and barriers, knowledge, and the impact of knowing. African-Americans were more concerned about privacy and community impact compared to Whites, however,

[1] Skinner HG, Calancie L, Vu MB, et al. Using community-based participatory research principles to develop more understandable recruitment and informed consent documents in genomic research. PloS one 2015;10:e0125466.

African-Americans were still eager to participate in our genomic research project. The results from our formative study were used to improve the informed consent and recruitment processes by: 1) reducing misconceptions of genomic studies; and 2) helping to foster participant understanding and trust with the researchers. Our study demonstrates how community-based participatory research principles can be used to gain deeper insight into the community and increase participation in genomic research studies. Due in part to these efforts 80.3% of eligible African-American participants and 86.9% of eligible White participants enrolled in the Heart Healthy Lenoir Genomics study making our overall enrollment 57.8% African-American. Future research will investigate return of genomic results in the Lenoir community.

B. INTRODUCTION

This paper discusses the Heart Healthy Lenoir (HHL) Genomics Study and the use of community-based participatory research (CBPR) to engage a rural at-risk community in a genomic research study. The HHL Genomics Study is one-third of a larger project designed to create long-term, sustainable approaches to reduce cardiovascular disease (CVD) risk disparities in Lenoir County, North Carolina. The primary aim of the study is to explore the genomic factors associated with CVD risk, clinical outcomes, and responsiveness to CVD risk reduction interventions. Participants were recruited from two clinical interventions, the HHL Lifestyle Study (ClinicalTrials.gov number: NCT01433484) and the HHL Hypertension Control Study (ClinicalTrials.gov number: NCT01425515).[166,167]

Lenoir County, North Carolina was chosen for the HHL study for a variety of factors including its geographical location in eastern North Carolina, high poverty levels, and the community infrastructure. Situated in the heart of the "Stroke Belt", North Carolina has heart

disease, stroke and obesity rates well above the national averages;[168,169] Lenoir County rates are elevated further still over North Carolina's averages.[170] According to 2014 U.S. Census Bureau estimates, 24.9% of Lenoir County residents lived in poverty between 2008 to 2012 which is 8.1% higher than state averages for the same period.[171] The county is also home to many clinical and public health efforts, including a community hospital, a federally-funded community health center, multiple primary care practices, a local public health department, a revitalized farmers' market, and a community alliance dedicated to improving the county's health.[172]

To our knowledge, prior to our study there have been no genomic studies performed in Lenoir County. As such, we used CBPR to engage the community and to learn how best to implement our study. Minkler (2010) defines CBPR as "a process that involves community members or recipients of interventions in all phases of the research process".[173] The CBPR method not only strengthens the relationship between research institutions and their communities, but also increases community ownership of health-promoting programs.[174] In addition, the use of CBPR is an important component of medical research when trying to overcome the mistrust of health researchers by vulnerable groups.[175,176] According to 2013 U.S. Census reports, 40.9% of Lenoir County residents are African-American, compared to 22.0% statewide.[171] African-Americans are considered a vulnerable group due to a history of mistreatment by and lack of consent for medical research conducted on this population (e.g., Henrietta Lacks and the Tuskegee Syphilis Study). Therefore, researchers need to be sensitive to issues of power and historical context when conducting studies on populations that include African-Americans. Corbie-Smith et al. (1999) observed high levels of mistrust regarding medical research amongst African-American focus group (FG) participants.[176] Many in that study mentioned concerns stemming from the Tuskegee Syphilis Study, as well as having a

general feeling that they are exploited within the medical research field. The Tuskegee Syphilis Study has a continuing legacy that can impact the relationship between African-Americans and medical research.[176-179] CBPR provides a way for university researchers to hear and address community concerns including any historic misgivings in order to promote program feasibility, acceptability, and success within the community. These methods can be used to develop study materials for the whole community with particular salience for vulnerable groups within the community.[180-183] In particular, improvements to recruitment and informed consent documents can be guided through the use of CBPR methods.[184]

In this paper, we present our findings from a CBPR study where we engaged members of a rural community that includes a high proportion of African-Americans. Our objective was to learn how to design study materials that would instill trust and encourage participation in potential research participants, particularly those that are historically under-represented in genomic research using feedback and knowledge derived directly from the community.

C. METHODS

C.1. PARTICIPANTS

We conducted four FG discussions attended by a total of 35 individuals from Lenoir County that were organized into two African-American and two White FGs. We used purposeful sampling to ensure that the predominant racial groups in the county, African-American and White, were equally represented in our sample. Our recruitment goal was to have racially homogenous groups with a balance of men and women. Eligibility criteria included being an adult aged 18 and older, English-speaking, and a current resident of Lenoir County. Participants

were recruited by key community members (e.g., the Health Director), or through flyers posted in the community. Interested participants were screened by phone to determine eligibility.

C.2. Focus Group Guide Development

Since we were unaware of any previous genomic studies conducted in Lenoir County, we wanted to understand the thoughts, feelings, and concerns both about genomics and heart health from Lenoir residents. Co-investigators with experience in the Lenoir community and community member assistants worked together to develop a semi-structured discussion guide to explore the acceptability of genomic research in Lenoir County based on input from discussions with key community residents. The community member assistants were either referred by our Community Advisory Council or recruited through a job advertisement in the community. The two community member assistants reflected the racial makeup of each FG, either African-American or White. The community residents who helped develop the guide included Lenoir County Health and Human Services agency employees. Based on community input and existing literature, we constructed our guide with the hypothesis that there would be unfamiliarity and mistrust of genomic research in Lenoir County, and reluctance to participate in a genomics study; furthermore, the mistrust and reluctance would be higher in African-Americans.

C.3. Focus Group Protocol

The University of North Carolina Chapel Hill Institutional Review Board reviewed and approved the study protocol (IRB # 10-0395). The FGs were conducted in winter 2011 with each session lasting approximately 90 minutes. Groups were held in a private location at the community hospital. A trained co-investigator with extensive qualitative expertise moderated

discussions, assisted by a community member of the research team. At the beginning of each group, the moderator read the consent form aloud and gave participants the opportunity to ask study-related questions before those interested signed the written informed consent form. Next, demographic information was collected via survey (e.g., age, race, and education level). Word association was then used to assess baseline familiarity with the term 'genomics'. The FG leader then provided an analogy that investigators and community research team members developed to help participants define genomics. Next, participants were asked to verbally rate on a scale from 1 to 10, with 10 being "completely important," how important genomics is to their health. The discussion then commenced covering the following topics: (1) community concerns about genomics; (2) thoughts and perceptions about genomics and heart health; and (3) community concerns about participation in genomic research. Participants were each paid $25 upon completion of the session.

C.4. Analysis

FGs were digitally recorded and reviewed for quality and completeness. Files were transcribed verbatim then verified by listening to the original recordings. To analyze our data, we first created a coding scheme using both deductive and inductive methods.[185,186] A codebook was developed and applied to organize text and assist with interpretation. Using a deductive *a priori* approach, we developed a codebook based on the discussion topics, the hypothesis, and a preliminary reading of the transcripts before beginning an in-depth analysis of the data. We then incorporated data-driven inductive coding techniques as described by Strauss and Corbin,[187] and Crabtree and Miller [188] to explore patterns. We applied the codes from the codebook to each line of transcript text to identify meaningful units of text, connected the codes and identified themes,

and confirmed the findings through a process of clustering the themes.[188] While codes were mutually exclusive, lines of text could have been marked with multiple codes if more than one theme was represented.

We used a qualitative data analysis software program, ATLAS.ti 6.2, to facilitate analysis. After each transcript was imported into the software and coded, we retrieved text on specific codes or combination of codes to enable thematic analysis of particular topics.[189] From this, we looked at the quotes in the context of the documents and assessed the levels of agreement and saliency of themes. Finally, we summarized our findings and chose quotes representative of each theme for presentation.

D. RESULTS

D.1. DEMOGRAPHICS

A total of 35 participants attended the FGs, with 8-10 attendees per group (Table 4.1). Across all FGs, participant ages ranged from 22 to 86 years with the average age being 57 years. Over half the participants were self-identified African-Americans (n=19). The majority of participants were females (n=23). All participants finished high school with approximately half having a college degree or higher. Compared to 2013 U.S. Census Bureau statistics for Lenoir County,[171] our FGs had more African-Americans (due to purposeful sampling), more females (66% in the FGs versus 52.2% in Lenoir County), and a higher education level (100% finishing high school and 51% having a Bachelor's degree or higher in the FGs versus 77.8% and 14.1%, respectively, in Lenoir County). The majority of FG participants also had a known family history of heart disease (n=23) and had health insurance (n=24).

TABLE 4.1. CHARACTERISTICS OF FOCUS GROUP SAMPLE (N=35)

Characteristic		FG1 N=9	FG2 N=10	FG3 N=8	FG4 N=8	All FGs N=35
Race						
	African-American	100% N=9	100% N=10	---	---	54% N=19
	White	---	---	100% N=8	100% N=8	46% N=16
Age (SD) Age Range		48 y (10) 22y – 56y	57 y (5) 48y – 67y	65 y (13) 47y – 85y	60 y (20) 38y – 86y	57 y (14) 22y – 86y
Gender						
	Male	56% N=5	10% N=1	38% N=3	38% N=3	34% N=12
	Female	44% N=4	90% N=9	62% N=5	62% N=5	66% N=23
Education						
	High School Graduate	100% N=9	100% N=10	100% N=8	100% N=8	100% N=35
	Bachelor's Degree or higher	56% N=5	50% N=5	25% N=2	75% N=6	51% N=18
Family History of Heart Disease						
	Yes	33% N=3	70% N=7	75% N=6	88% N=7	66% N=23
	No	45% N=4	20% N=2	25% N=2	12% N=1	26% N=9
	Don't know	22% N=2	10% N=1	---	---	8% N=3
Health Insurance						
	Yes	44% N=4	70% N=7	62% N=5	100% N=8	69% N=24
	No	44% N=4	30% N=3	38% N=3	0% N=0	29% N=10
	Non-response	12% N=1	---	---	---	2% N=1

Table 4.1 provides demographic characteristics of all focus groups. Data are presented as mean (standard deviation), range, or percent and N.

D.2. Defining Genomics

Only one to two people per FG were familiar with the term "genomics." Soliciting words and ideas participants associated with "genomics" prior to providing the analogy yielded widely varied responses such as "*geometry,*" "*informative,*" and "*a continuing of possibilities.*" The genomics analogy was then given to provide a conceptual framework for participants to better articulate their perspectives during the remainder of the focus group.

> "Genomics is a term that describes the study of all of a person's genes (their genome), including how genes interact with each other and with the person's environment. This is different from genetics, which is the study of a single gene in isolation. Think of genomics as a garden and genetics like a plant in your garden. If the plant is not flowering, you could study just the plant itself (genetics) or look at the surroundings to see if it is too crowded or there is not enough sun (genomics)."

Following the provision of the analogy, participants verbally reported finding the analogy helpful in understanding what we meant by genomics for our discussion. Participants also made connections between our genomics analogy and family history of common chronic diseases (e.g., CVD, type 2 diabetes, or cancer). Participants' responses suggest that they understood the distinction between single gene diseases and genomics, which was the purpose of our analogy. Participants then verbally reported genomics as being highly important to their health ranking it an 8.5 out of 10, with 10 being "completely important." This importance did not vary across racial groups.

D.3. Focus Group Themes

Five themes emerged from the discussion about genomics: transparent communication, privacy, participation incentives and barriers, knowledge, and the impact of knowing. There were no major thematic differences between FGs or racial groups; therefore the results for each theme are representative of all participants regardless of race. Places where one racial group spoke on

additional information (e.g., Theme 2: Privacy and Theme 4: Knowledge) are noted within the theme. Below we present a summary of each theme and how we used that information to tailor our materials.

D.3.1. Theme 1: Transparent Communication

D.3.1.a. Results

Participants found genomics to be a highly "*technical word*" and requested that researchers use simple, non-technical language instead. This theme arose when discussing how to describe the project to the community as well as how to describe the risks and benefits of participation. Many people wanted plain-speak, and specificity regarding research aims and the possibility of receiving negative health information. Specifically, they wanted research staff to be up-front about any risks involved with the study. Participants felt that technical language could obfuscate the presence of risk either through poor communication of what would happen to their genomic data or poor communication of what could happen to their health as a result of their "genomics." Contrary to our hypothesis, there were no major thematic differences between racial groups.

"I would like to know what you're really looking for. Talk to me" ~ AA "Be honest and tell it like it really is, and don't try to sugar coat it." ~ W

Figure 4.1. Transparent Communication Quotations

D.3.1.b. Implications

Based on this finding, we incorporated transparent communication into HHL Genomics materials. As such, we were purposeful in using non-technical language in study recruitment and informed consent materials. Our goal was to have transparent communication that fostered trust

between researchers and the community. Working with our community team members, we honed language that was easily understood. For example, instead of describing the HHL Genomics study aim as "determining whether genomic signatures can be used to predict responsiveness to interventions that underlie CVD disparities," the aim was described as "wanting to learn more about genetic factors related to heart disease and needed treatments."

D.3.2. Theme 2: Privacy

D.3.2.a. Results

Many participants discussed privacy concerns about the handling of personal information and blood. Participants wanted transparent communication about who would have access to their data and that "qualified" professionals would handle blood draws (e.g., research staff, physicians, or nurses). Participants also wanted explicit assurances that their personal information would be protected, particularly regarding how their blood was handled after the study. If these privacy concerns were addressed, the majority of participants stated that they would not have barriers against participation in a genomics study.

"I would like to know about the privacy part [as an incentive to participate]." ~ W

"At the hospital though, after they test your blood or use your blood for whatever purpose, isn't that blood destroyed? ... How do you know that's what's happening [here]? They show [information leaks] on TV on the Sci-Fi channel and everything." ~ AA

FIGURE 4.2. PRIVACY QUOTATIONS

African-Americans spoke of a mistrust of medical research that Whites did not. Many African-Americans voiced mistrust of science in general and of medical professionals even mentioning conspiracy theories. Their main privacy concern was of being identified from their genetic information. Despite this and in contrast to expectations, most African-American

participants voiced great trust in HHL researchers and even eagerness to participate in our genomic study.

> "Even though we're not identifying ourselves and you say after this you know nobody would know anybody. How do we know down the road somebody won't find out who we are? And that's the only inhibitions that I have." ~ AA

Figure 4.3. Privacy Quotation—African-American Mistrust

D.3.2.B. IMPLICATIONS

The finding about privacy led to the stressing of de-identification of samples and participant rights under the Genetic Information Non-discrimination Act (GINA) in the informed consent form. Also, recruitment and informed consent materials explicitly discuss the handling of blood samples. While the study did decide to keep samples for future research, it was emphasized that these samples are de-identified and that participants have the right to withdraw their blood from the study at any point in time.

D.3.3. THEME 3: PARTICIPATION INCENTIVES AND BARRIERS

D.3.3.A. RESULTS

Receipt of money was named as an incentive for the time and financial costs of study participation (e.g., travel to the study site). Conversely, the concern that participation would require payment for genomic analyses and blood draws was stated as a barrier to participation.

> "[A participation incentive would be that] the services are gratis and medicine can be that way. And they cover travel." ~ W
>
> "Prevention. It's like…be real positive about prevention, heart disease and prevention of heart disease." ~ AA

Figure 4.4. Participation Incentives and Barriers Quotations

Once the FG moderator explained that study participation would be free, participants stressed the importance of explicitly stating that in study materials so that financial concerns would not be a barrier to participation. Participants also repeatedly spoke of receiving CVD results from our genomic study. Not only was this an important incentive unto itself, but participants also spoke of using this information to change their lifestyle. Participants wanted incentives that would support lifestyle changes, such as improving diet or increasing physical activity. For example, health center memberships, gym shoes, and support in preparing healthy meals were mentioned. There were no major differences between racial groups for this theme.

"[Researchers would benefit from] just recognizing that people are different before you go through with the study. I would figure out if people do want an incentive with money or people just want to do it just to figure out the information about their genes." ~ AA

Figure 4.5. Participation Incentives and Barriers Quotation

D.3.3.B. IMPLICATIONS

From this finding, we learned the importance of stating all monetary gifts and expenses (or lack thereof) upfront and explicitly in our recruitment materials. In addition to the monetary incentive payment schedule, our materials also included explicit statements that participation in our program, which included blood draws and genomic analysis, would not cost participants anything, though transportation to the study site was at the participants' expense. For example, after explaining the study protocols, the informed consent document stated, "The program is free, but travel costs to and from the measurement visits are not covered." Additionally, we learned that participants saw value in their genomic CVD results and wanted that information returned to them. Lifestyle supports were strengthened in the two HHL clinical studies as a result of these FGs. HHL Lifestyle participants were provided with healthy recipes and HHL Hypertension Control participants were provided with home blood pressure monitors.

D.3.4. THEME 4: KNOWLEDGE

D.3.4.A. RESULTS

Participants stated interest in genomics for societal, health, and individual benefits. Contributing to the larger genomics knowledge pool was named as important by both White and African-American participants. Additionally, African-Americans spoke specifically of adding to the knowledge pool about African-Americans. All participants stated interest in the perceived health benefits of genomic knowledge. Particularly, they believed that genomics could yield knowledge about disease states like CVD and Type 2 Diabetes and could then be used to improve their own health and the health of future generations of their family. Again, African-Americans shared this sentiment but were also interested in the perceived health benefits of genomic research for the African-American community at large. Lastly, participants were interested in genomics for the perceived individual benefits. In general, participants viewed personal genomic information as an added catalyst to make lifestyle changes, and the vast majority of participants wanted individualized genomic feedback from the study. The desire for returning genomic results was evident irrespective of race. (Additional quotes can be found in Appendix 4.1. Additional Quotations About Knowledge.)

"I would love to be part of the solution." ~ W

"We need to know these things [results of genomics research] and we need more support in these [African-American] communities, they're not as tight knit as they used to be . . . we need a lot of this education." ~ AA

Figure 4.6. Knowledge Quotations

"If I was to do it [the study] I would want some feedback on my results and also the overall findings on what I could do to change if I had to do any changes." ~ AA

Figure 4.7. Knowledge Quotation

D.3.4.B. IMPLICATIONS

This finding led us to explicitly state in our recruitment and informed consent materials that the HHL Genomics study was being performed to help *society*. We did this to avoid 'therapeutic misconception' in our materials since our FG participants seemed equally if not more motivated to participate in genomic research due to perceived health benefits or the possibility of receiving genomic results. Appelbaum defines therapeutic misconception as the conflation of research goals with therapeutic treatment.[190] Furthermore, we also stated in our recruitment and informed consent materials that participants would not receive their individual results. Materials stated that since "the results of the blood tests for genomics is not a routine test and would not be easy to understand by either you or your doctor, *we will not send you the results of these tests.*"

D.3.5. THEME 5: THE IMPACT OF KNOWING

D.3.5.A. RESULTS

VALUE OF KNOWING

The consensus among the FGs was that the knowledge gained in genomic studies would benefit both society and the individual; furthermore, this information would lead to better health decisions. Some participants expressed negativity about receiving personal genomic information. Concerns regarding genomic knowledge revolved around the fear of a "pre-determined" disease state, confusion around what genomic results would mean, and possible depression and stress from thinking about their "genomics" all the time.

"You have some that want to know the future, you have some that don't want to know the future. And I guess [knowledge] can be harmful in some ways too, knowing too much." ~ W

Figure 4.8. The Impact of Knowing Quotation—Value of Knowing

PERCEIVED CONTROL

The majority of participants reported feeling that they were ultimately in control of their health no matter what their "genomics" said. Repeatedly, participants alluded to genomic knowledge as something to empower them in making health decisions. Alternatively, others took the perspective that they could not change what was in their genes, sometimes citing family disease history as justification. However, the vast majority of participants, regardless of race, felt that lifestyle choices were controllable (e.g., smoking, diet, and exercise), and that having genomic information would empower them to make lifestyle choices.

"It's not really a study but it's a group that's helping us to more [or] less take charge of our well-being as far as our health, eating right, and doing the right things as far as you know keeping our health intact. So I would try to participate in as many studies as I have to, to take care of me." ~ AA

Figure 4.9. The Impact of Knowing Quotation—Perceived Control

D.3.5.B. IMPLICATIONS

Our findings suggest that knowing individualized genomic results is highly valuable and empowering to our FG participants, therefore we explicitly addressed this in our recruitment and informed consent materials. Materials explicitly stated that individualized results would not be returned. HHL made this decision due to researchers not anticipating return of genomic results being so coveted in this community and not having genetic counselors in our research plan. Given the range of responses about knowing genomic information, counselors and other forms of

support were deemed to be ethically necessary if HHL were to return individualized results to the community.

E. DISCUSSION

The goal of HHL is to reduce CVD risk disparities in Lenoir County, NC. In order for our interventions to succeed, we needed a strong relationship with the community as well as the ability to enroll a representative sample of the population into our study. Our approach was to use CBPR principles to tailor the recruitment and informed consent processes to both foster trust and transparency in our relationship with the community and meet our recruitment goals.

Through FGs, we found that participants were not very familiar with the term genomics. This is consistent with previous studies, which demonstrate genetic knowledge to be low nationwide.[137,138] Christianson et al. (2010) replicated this finding in North Carolina and also demonstrated a racial difference in understanding where African-Americans more frequently reported less genomic knowledge.[191] Regardless, this did not seem to diminish our participants' desire to participate in genomic research. Our hypothesis was that Lenoir County residents would be unfamiliar and mistrustful of genomic research and would therefore be reluctant to participate; we believed this mistrust and reluctance would be higher in African-Americans. All participants voiced trust in HHL researchers and a willingness to participate in our genomic study. While African-Americans did speak of a legacy of mistrust and their privacy concerns stemming from that, they simultaneously voiced trust in HHL researchers and a willingness to participate in our genomic study. Other studies have also reported positive attitudes towards participation in genomic research.[192] However contrary to some published reports,[193] our FG participants did not report a difference in willingness to participate by race. (Enrollment into

HHL Genomics by our 35 FG participants was not tracked.) Irrespective of race, participants expressed two distinct sentiments about genomic knowledge: knowledge as empowering and knowledge as predetermination. The Protection Motivation Theory could explain these divergent viewpoints. The theory postulates that those with increased perceived threat may engage in protective health behaviors while those who believe that people have no control over their health may lose motivation to engage in protective health behaviors.[159] Research shows that an individual's threat beliefs can predict their perceived control in response to genomic knowledge.[194] Genomics knowledge was a major participation incentive for our FG participants. The majority of participants wanted the option to obtain individualized genomic results. Returning genomic data has been documented in other several populations.[195-198] In accordance with CBPR principles, investigators explored ways to address community wants while being cognizant of debate in the field as to whether individual results should be returned and how that should be done.[199,200] Ultimately, we determined that HHL did not have the infrastructure to responsibly return results (e.g., genetic counselors), but as a result of the findings presented here, we did initiate an ancillary study investigating methods to return the HHL Genomics Study results to the Lenoir community. Future genomic research studies may consider the question of returning results early in the planning process in order to be responsive to community wants.

Limitations in this study include positive bias towards research since our participants live in an area with many public health interventions and opted to join the FGs, indicating at least some level of trust and interest in medical research. Some participants were also already participating in the HHL Lifestyle or Hypertension Control studies. Another limitation is that after providing our analogy, participants verbally reported finding the analogy helpful but we did not perform word associations or use any other method to determine if participants' descriptions

of genomics changed after receiving the analogy. Lastly, this data is representative only of the individuals in the FG, which was purposefully sampled to ensure equal representation of the predominant racial groups in the county; all possible opinions of the larger populations may not have been captured. Experienced moderators ensured that all voices were heard in the group to gain the broadest representation of opinions possible. Future studies may benefit by utilizing other data collection methods that allow anonymity, such as a survey, which may elicit divergent views that people may be uncomfortable voicing within a group.

Strengths of this study include that, to our knowledge, this is the first study to include a lay-analogy in defining genomics for participants, which seemed to help frame the conversation. Another strength of this study is the use of CBPR. Community research team members helped develop the FG guide and administer the FGs. Also, our study engaged populations traditionally under-represented in medical research, specifically African-Americans and those from underserved rural areas. Employing CBPR methods of co-learning to build trust between researchers and community members allowed researchers to explore the presence of and remedies to misconceptions and suspicions about medical research within the Lenoir community.

Overall, this study provided valuable information on the motives of potential genomic research participants in Lenoir County as well as ways to use that information to tailor informed consent and recruitment materials. These efforts resulted in not only high participation in our study, but also more African-American than White participants, which is contrary to much of the previous literature.[192,193] The HHL Genomics Study enrolled 253 African-American participants and 185 White participants, which captures 82.8% of the eligible participant pool. Of the eligible African-American participants, 80.3% enrolled in our study thereby making the HHL Genomics participant population 58% African-American. We believe that using CBPR methods to elicit the

community voice and accordingly adjust study materials and communications yielded a meaningful consent and recruitment process that enabled us to recruit a high percentage of our eligible population and particularly the eligible African-American population. We also believe that CBPR methods are generalizable to other genomic research endeavors and could be used to improve genomic study participation in historically underserved areas as well as in minority populations.

CHAPTER 5: COMMUNICATING GENOMICS RESULTS FOR A MINORITY AUDIENCE: DEVELOPMENT OF A PROTOCOL

A. OVERVIEW

Since 2003 there has been a call to include more minorities in genomic research. Given the historical context of African-American (AA) exploitation for medical research, this can be a challenge in the AA community. Applying participatory research principles to genomic research suggests that including return of results in genomic studies may be warranted. However, few studies exist to guide the return of genomic results (ROR). This study describes the participatory development of a ROR protocol for use in a general African-American audience.

Six message-testing groups were conducted with AA individuals from a rural southern community. Individual interviews were held to return fictional genomic results, and then focus groups were conducted for line-by-line participant feedback. Genetic literacy was assessed at baseline.

Thirty-two African-Americans participated. The group was mostly female (n=30); average age was 52 years; most had a high school degree or higher (n=29); and most were high genetic literacy (n=24). Three key lessons were learned. 1) Participants preferred the use of specialized genetic terms. 2) Participants wanted all self-relevant information. 3) Participants wanted genomics education. The final result is an ROR protocol that uses precise scientific terminology that is supported by various supplemental materials to introduce and reinforce genomic concepts.

B. INTRODUCTION

Since the sequencing of the human genome in 2003, the field of genomic research has grown tremendously.[201,202] Genomic research holds tremendous promise for illuminating the biological bases of disease, identifying pharmacological treatment targets, and birthing the field of personalized medicine.[30,203-205] However, to date, most genomic research studies focus on participants with European ancestry. This leaves other populations, such as African-Americans (AAs), underrepresented in genomics studies and subject to ineffective or less effective genomics-based health advances.[206] This unequal inclusion of AAs in genomic research may contribute to race-based health inequalities. The call for more minorities in genomic research studies has been a long-standing one,[207] but it is imperative to fulfill such goals given the applications of genomics research to the public health and assessing genomic-based risk of disease, especially in a growing direct-to-consumer market for genetic health products.[207,208]

However, in AA communities, the history of misuse and exploitation of the AA community by medical researchers, healthcare providers and/or academic researchers has led to a culture of mistrust and suspicion towards medical research initiatives.[176-178,209-213] Community-Based Participatory Research (CBPR), a paradigm of research in which clinicians or academic researchers partner with research participants to investigate scientific research questions,[173] has been used in the past to establish relationships and trust and encourage study participation in minority communities.[214,215] Unfortunately, CBPR techniques are not often applied to genomic research studies, though some of our previous work demonstrates that the application of CBPR principles to genomic studies may increase AA participation rates.[216]

Genomic studies are increasingly investigating the impact of returning personalized genomic health information to participants.[5,10,148,150,151,217] Particularly, the return of results

(ROR) is being researched as a tool to help communicate and therefore affect risk for common chronic diseases such as cardiovascular disease (CVD). Research studies investigating *how* to return results to participants in a manner that promotes understanding are few in number, leaving a gap in the literature. Additionally, participants in existing ROR studies come from the same pool as genomic studies—white, urban, highly educated, high health-literate individuals. Therefore, an additional gap in the literature exists regarding how to create ROR information that works appropriately with minority communities. The purpose of the current study is to help fill those gaps by developing a ROR protocol suitable for use in an AA rural population with literacy and numeracy heterogeneity.

C. METHODS

C.1. BACKGROUND

This protocol was developed for use in a larger study investigating the personal utility of personalized genomic results in motivating participants toward health-protective behaviors related to CVD (ClinicalTrials.gov number: NCT02208180). The larger study is a proof-of-concept randomized controlled trial whose primary outcome is motivation towards diet and exercise. The focus of the work presented here is the design and testing of the ROR protocol.

Our ROR approach was guided by previously published protocols.[151,154,157] We were interested in developing a protocol that conveyed risk verbally rather than numerically. Numerical representation of absolute risk is the most common method for reporting perceived risk.[218] However, numerical risk estimates can be difficult to understand, even for high literacy individuals.[219] Given the expected literacy and numeracy heterogeneity of our population, we searched for published protocols that considered numeracy and/or literacy issues when reporting

genetic information for common chronic diseases. Through a literature review conducted in 2013, several potential studies were identified.[10,149,151,153,154] The Grant and Cho protocols were thought to be the best protocol to fit our study population as the approach used in their ROR protocols best addressed heterogeneity in numeracy and literacy levels[153,154]. The Grant protocol was used as the core of our protocol with elements of the Cho protocol incorporated.

In brief, the Grant ROR protocol draws from Leventhal's Common Sense Model in motivational psychology.[220] The goals of the session are to increase motivation with a focus on risk perception and self-efficacy. Visual aids are used to help bridge genomic literacy and numeracy gaps.[157] The Cho risk summary was used at the conclusion of our protocol.[154] The summary was presented in the fashion of a stoplight: Red for summary of genomic information, yellow for summary of lifestyle information and statistics about CVD mortality, and green for lifestyle recommendations to reduce CVD risk. The lifestyle recommendations given were the same as in the Heart Healthy Lenoir (HHL) Project—the parent project for this study.[221] (Appendix 5.1)

The ROR genomics protocol was designed as a "teachable moment to encourage behavior change" in those already at high environmental risk.[157] Feelings of fatalism in those at high genetic risk and feelings or invulnerability in those at low genetic risk have been shown to reduce motivation to change.[222] Evidence suggests that balanced messages between risk and personal control, such as in this protocol, can pre-empt these extreme mindsets.[151,194,223] The emphasis on personal control at the end of the protocol was designed to simultaneously motivate and avoid harm in participants.

C.2. Adaptation of Original Protocol

We made the following adaptations to the Grant Study protocol: changing the gene-environment educational statistics from representing Type 2 Diabetes to CVD, including an additional educational page explaining SNPs at the beginning of the protocol, and a detailed verbal script of the ROR protocol was created. Also, instead of presenting a combined phenotype and genotype risk as in the original Grant protocol, these representations were separated because of the limited evidence on how to accurately represent a combined risk. The Framingham Risk Score (FRS) was used to represent phenotypic risk for CVD.

In contrast to the Grant study, the protocol in our study was to be administered by researchers, not certified as genetic counselors. Therefore, free access to a genetic counselor was available as an additional resource for participants. Participants were able to make an appointment for a future session with the counselor if they wanted additional counseling after the research session.

Once the initial ROR protocol was designed and scripted, it was then tested in a sample from the target population to assess comprehensibility, particularly genomic literacy and cultural appropriateness.

C.3. Participants

In order to test the feasibility and acceptability of the modified Grant/Cho ROR protocol in a rural, African American population, we conducted six message-testing groups over the course of three weeks. Participants were recruited from HHL—a CVD risk reduction study in Lenoir County, North Carolina (details described elsewhere [221,224]). Eligibility criteria included being African-American, being enrolled in both the Lifestyle Weight Loss groups and the

Genomics sub-studies of HHL,[221] completing the 24-month HHL follow-up visit, and providing express written consent to be contacted for further HHL study opportunities. Mailings and phone calls were used for recruitment. Participants were each paid $30 upon completion of the message-testing session. The Institutional Review Board at the University of North Carolina at Chapel Hill approved this study (IRB# 14-1500).

C.4. Message-Testing Protocol

The message testing protocol consisted of a structured cognitive interview followed by a focus group.[107,108,225-228] All sessions, interviews and focus groups were digitally recorded. In brief, the moderator read the consent form aloud and gave participants an opportunity to ask questions before signing the written informed consent. The agenda, individual interviews followed by reconvening for a focus group, was explained to the group. It was made clear that all "results" returned in the sessions were fictional and did not pertain to any actual participant. Trained research assistants conducted the individual interviews in a private room with each participant. The cognitive interview session was approximately 20 minutes long. At the beginning of the interview, the REAL-G (The Rapid Estimate Of Adult Literacy In Genetics) was used to assess genomic literacy;[229] an 8-item scale with possible scores ranging from 0 – 8 with 8 indicated the highest genetic literacy. The research assistant then administered the ROR protocol using fictional genomic results. A brief check for comprehension was then assessed, asking participants to provide feedback on the clarity of the ROR protocol and any thoughts on edits to the materials.

Participants then reconvened as a group to comment on the protocol. This focus group lasted approximately 1 hour and was held in a private location. The primary investigator served

as the facilitator and a research assistant served as note-taker. Participants were given a copy of the ROR script to help aid the discussion. The moderator then led the group in a page-by-page review of the ROR protocol, soliciting participant feedback on script wording, clarity of the script and the images, additional genomic education materials desired, and any other text changes participants felt would increase comprehension. Genomic and phenotypic risk categories were randomly varied among the participants to get feedback on differing risk categories (Table 5.1).

After two focus groups, participant feedback was incorporated to produce an updated protocol, which was presented alongside the original protocol in the following 2 focus groups until a final protocol was achieved after 6 groups.

C.5. Analysis

Notes and digital recordings were reviewed to ensure accuracy and consensus of protocol modifications. After completion of all focus groups, digital recordings were transcribed verbatim. A second reviewer verified the transcripts by listening to the original recordings. A list of protocol modifications requested by the sample population was developed based on discussion topics.

TABLE 5.1. FOCUS GROUP DESCRIPTIONS

Week	Groups	Phenotypic Risk Presented	Genomic Risk Presented	Resulting Protocol Tailoring
1	1 & 2	Average	High Average Low	• Begin protocol with 23andMe "What is a SNP?" video. Link also provided on last page of protocol. • Visual aid for genetic education added. • Physical cues added to script to call attention to visual aids. • Chart explaining components of FRS and change in components over the course of HHL added. • For each SNP added: odds risk score, general information about metabolic pathway. • Keyword sheets added. 23andMe sheet added to take-home packet. Sheet with SNP definition added during protocol presentation. • NHGRI "Guide to your Genome" added to take-home packet. • Language adjustment: genetic words added, numerical words removed. • Color adjustment in summary chart. Red to orange.
2	3 & 4	High	High Average Low	• Cookbook added to take-home packet. • Body mass index added to keyword sheet during protocol. • More genomic education added regarding the SNPs in this study. • Language adjustment: explanations added, numerical words adjusted.
3	5 & 6	Low	High Average Low	• None.

D. RESULTS

D.1. DEMOGRAPHICS

A total of 32 participants attended the message testing groups, with 3-8 attendees per group. All participants self-identified as African-American. Participant ages ranged from 27 to 68 years, mean age was 52 years (*Standard Deviation [SD]* 10). Most participants were females. The majority of participants finished high school with approximately a quarter having a college degree or higher (n=7). This population was of average high genetic literacy (*Mean [M]* 5.0, *SD* 2.7; *Median* 6.0). High literacy participants (n=24) mainly drove this score (*M* 6.3, *SD* 1.4; *Median* 6.0). (Table 5.2).

TABLE 5.2. FOCUS GROUP DEMOGRAPHICS

Characteristic	Group 1 N = 3	Group 2 N = 3	Group 3 N = 8	Group 4 N = 7	Group 5 N = 7	Group 6 N = 4	All Groups N = 32
Age *M*(*SD*) Age Range	56y (3) 53y – 58y	50y (17) 31y – 62y	50y (13) 33y – 68y	54y (6) 43y – 61y	55 (7) 46y – 65y	46 (14) 27y – 59y	52y (10) 27y – 68y
Gender Male	---	---	N = 1	---	N = 1	---	N = 2
Female	N = 3	N = 3	N = 7	N = 7	N = 6	N = 4	N = 30
Education Less than High School	---	N = 1	---	N = 1	---	N = 1	N = 3
High School Degree or higher	N = 3	N = 2	N = 7	N = 6	N = 7	N = 3	N = 29
REAL-G Score *M*(*SD*)	7.3 (0.6)	4.3(3.8)	4.3 (2.7)	4.7 (3.1)	5.9 (1.9)	4.0 (3.6)	5.0 (2.7)
High Literacy *M*(*SD*)	7.3 (0.6) N = 3	6.5 (0.7) N = 2	5.5 (1.5) N = 6	6.4 (1.5) N = 5	6.3 (1.5) N = 6	7.0 (1.4) N = 2	6.3 (1.4) N = 24
Low Literacy *M*(*SD*)	--- ---	0 N = 1	0.5 (0.7) N = 2	0.5 (0.7) N = 2	3 N = 1	1 (0) N = 2	0.9 (1.0) N= 8

D.2. Key Lessons Learned

Three key lessons emerged from the discussion about return of genomics results protocol around genomics education, personal utility, and language usage. Below we present a summary of each lesson learned and how we used that information to tailor our materials.

D.2.1. Lesson 1: Genomics Education

Participants requested expanded genomics education materials both within the ROR script and as a resource to take home.

D.2.1.a. Within the ROR Script

The initial script contained one page of SNP education at the beginning of the protocol. The information was conveyed primarily verbally using a visual aid. This was done to educate participants about SNPs, however, participants wanted more information. Therefore, the first page was expanded to include an explanation of genes, DNA, and transcription (Figure 5.1).

Participants also indicated it was helpful to precede the ROR script with "What are SNPs?" "What are SNPs?" is a publically available animated educational video created by 23andMe.[230] Participants found this to be a non-intimidating introduction to the topic as well as to have memorable images to help conceptualize the concept of SNPs (Figure 5.2).

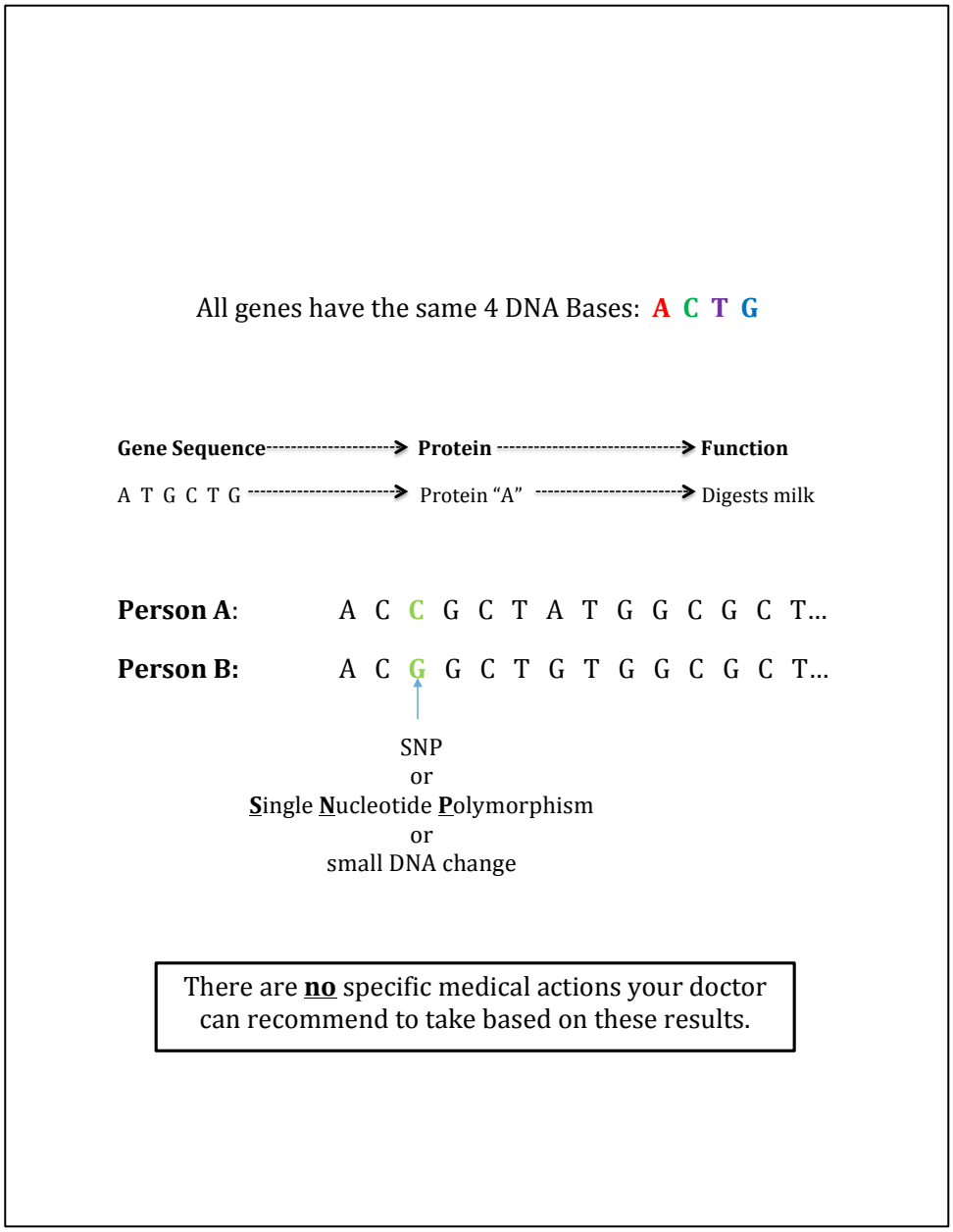


FIGURE 5.1. GENOMICS EDUCATION IN ROR SCRIPT

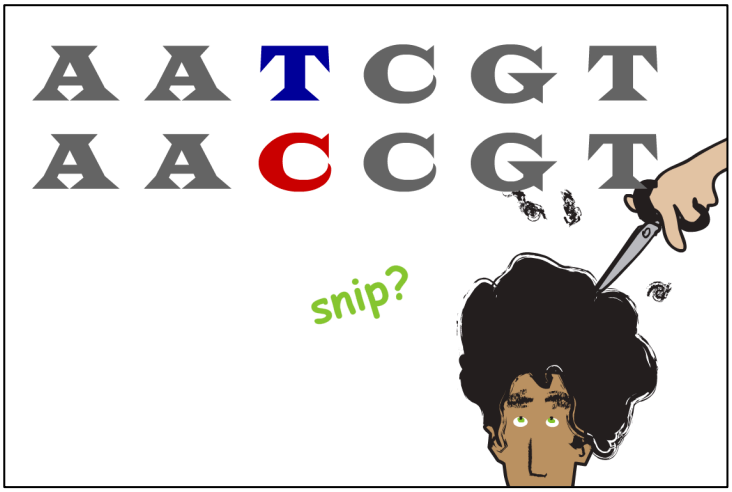
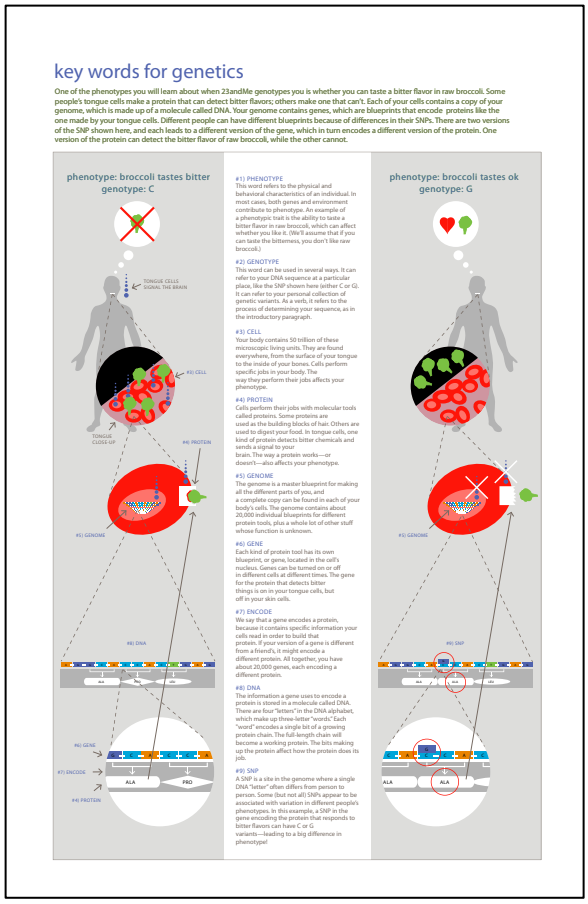
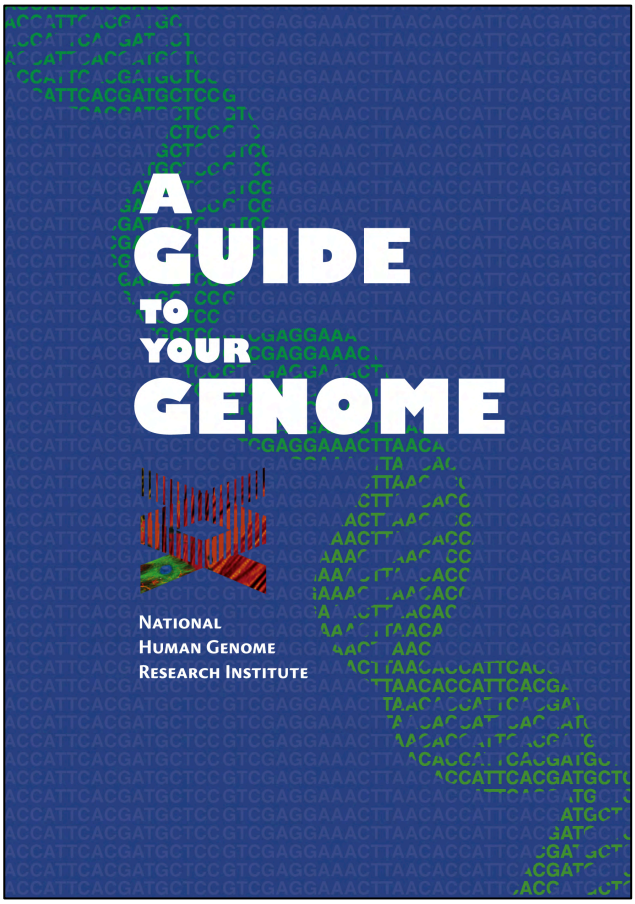


Figure 5.2. "What Are SNPs?" Video

D.2.1.B. TAKE-HOME RESOURCES

Participants were provided with two educational resources to take home. The first was a publically available "Key Word for Genetics" guide created by 23andMe that explains SNPs and phenotypes. The second was a pamphlet entitled "A Guide to Your Genome" created by the National Health Genomic Research Institute (NHGRI) (Figure 5.3). Most participants reported they liked this information, as additional resources to learn more at home; some participants said the extra information did not matter to them. All participants agreed these materials were most useful as additional resources rather than as part of the return of results protocol.





3a. 23andMe Keywords sheet
https://www.23andme.com/gen101/graphics/genetics/

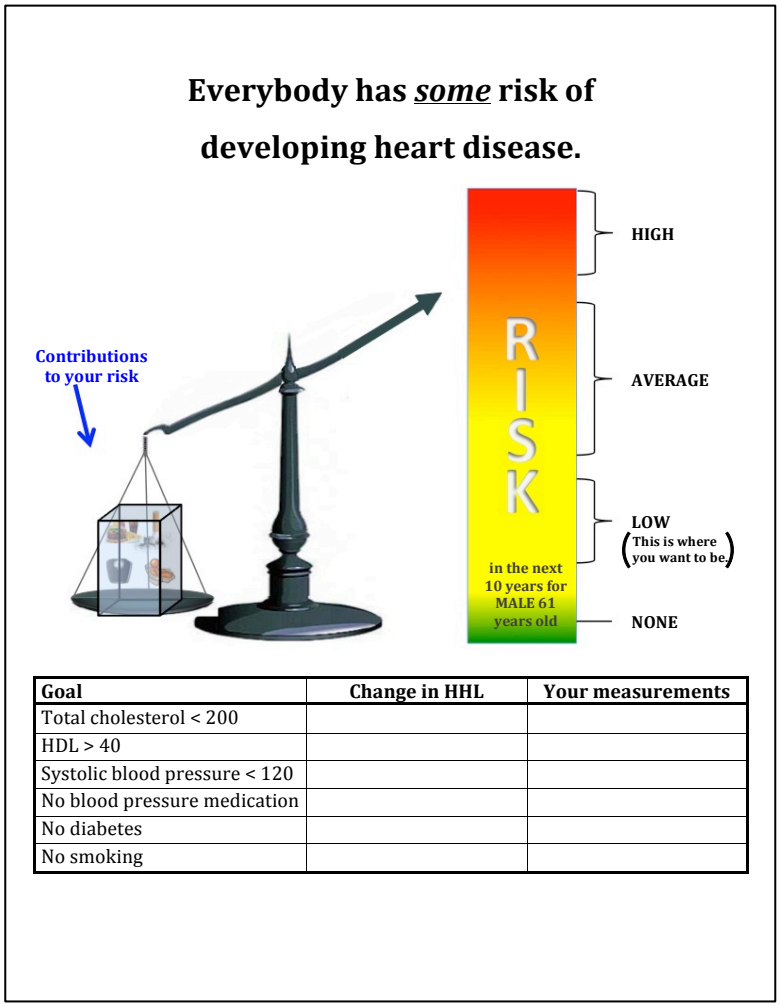
3b. NHGRI pamphlet
https://www.genome.gov/pages/education/allaboutthehumangenomeproject/guidetoyourgenome07.pdf

FIGURE 5.3. TAKE HOME GENOMIC EDUCATION RESOURCES

D.2.2. Lesson 2: Personal Utility

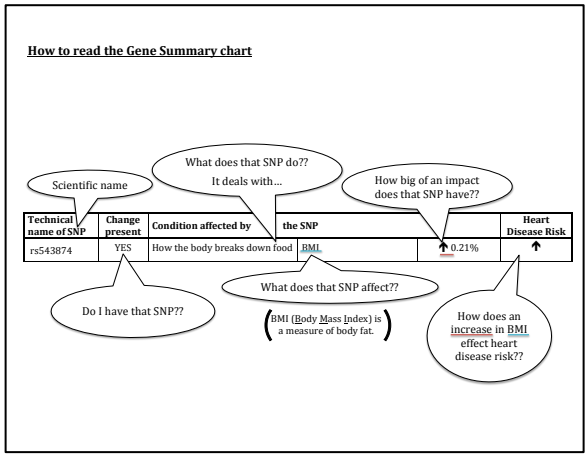
Phenotypic and genomic risks were represented separately within the ROR protocol. Through message testing, we learned participants wanted more information about the data used for calculating each type of risk. Participants wanted to know all of the information involved in the score derivation (e.g., total cholesterol, HDL, blood pressure, A1c, smoking status, and medication status), as well as how these values changed over the course of their two years in HHL (Figure 5.4).

The presentation of the SNP information also evolved over the course of message testing (Figure 5.5). Participants requested more information on each SNP; specifically, they wanted to know more about the function of each SNP and to what degree each SNP affected their phenotype. Additionally, participants requested the exact odds ratios associated with each SNP. An instruction sheet on how to read the SNP information was also developed in collaboration with participants so they remembered how to interpret this information at home. Participants felt all of these modifications would help them understand the protocol both during the presentation and when reflecting upon it at home.



Goal	Change in HHL	Your measurements
Total cholesterol < 200		
HDL > 40		
Systolic blood pressure < 120		
No blood pressure medication		
No diabetes		
No smoking		

Figure 5.4. Phenotypic Risk Representation Using Framingham Risk Score

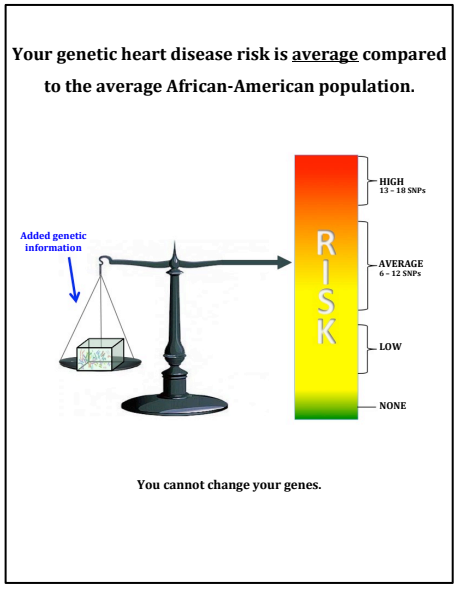


5a. Gene Summary Chart Instruction Sheet

Gene Summary

Technical name of SNP	Change present	Condition affected by the SNP			Heart Disease Risk
rs543874	NO	How the body breaks down food	BMI	↑ 0.21%	
rs6567160	YES	How the body breaks down food	BMI	↑ 0.07%	↑
rs2258119	YES	How the heart pumps blood	Systolic blood pressure (the top number)	↑ 1.84 mm Hg	↑
rs7903146	YES	How the body breaks down sugar	Type 2 diabetes (T2DM)	23.3% ↑ chance of T2DM	↑
rs6511720	YES	How the body breaks down fat	LDL-C (bad cholesterol)	8.10 mg/dL ↑ LDL	↑
rs646776	NO	How the body breaks down fat	LDL-C (bad cholesterol)	4.46 mg/dL ↑ LDL	
rs3764261	YES	How the body breaks down fat	HDL-C (good cholesterol)	2.79 mg/dL ↓ HDL	↑
rs16942887	NO	How the body breaks down fat	HDL-C (good cholesterol)	1.27 mg/dL ↓ HDL	
rs2036527	YES	How much you smoke	Cigarettes smoked per day	0.04 more cigarettes	↑

5b. Gene Summary Chart



5c. Graphic representation of genomic risk

FIGURE 5.5. GENOTYPIC RISK PRESENTATION

D.2.3. Lesson 3: Language Usage

Two main lessons arose about language usage surrounding genomic literacy and numeracy.

The language in the original and adapted protocols was designed for low literacy. In developing the exact script with the genetic counselor, we opted for the simplest terms to make the protocol comprehensible to the widest possible audience. For example, we used the term "small DNA change" instead of "SNP." Our message testing revealed that participants preferred the use of the specialized genomic words, such as SNP. Many participants identified the 23andMe video as helpful in conceptualizing and remembering the term. However, participants still said the simpler definition of SNP would be helpful on a keyword sheet as a reminder. This keyword sheet was created in response and placed behind the ROR materials so that is was visible during the presentation.

The Grant protocol was also chosen for the low numeracy considerations inherent in the presentation. Participants suggested wording changes when numerical words arose in the protocol. For example, on the scales it was suggested that the word "average" be changed to "normal". Ultimately, we decided not to make that change due to the different connotations of "average" and "normal." Conversely, participants requested more numerical information about the SNPs. It was decided the presentation of this information should be in percentages as participants felt this to be most understandable.

E. Discussion

With rapidly advancing technologies available for studying the human genome, the field of genomic research is expanding quickly and holds great promise for developing more effective

and more personalized treatments for common chronic diseases such as CVD. Despite this incredible advancement in genomic technologies and research, African-Americans remain underrepresented in genomic studies—a fact which may perpetuate widely observed health disparities since pharmacological targets are discovered using primarily European DNA. In order to produce appropriate and inclusive treatment options, more African-Americans must be included in genomic research studies. However, given the national history of exploitation of African-Americans for medical research, it is most appropriate to conduct genomic research among this population in a thoughtful manner, guided by the principles of Community-Based Participatory Research (CBPR). A central tenet of CBPR is the return of results to the participant, particularly when the community requests results.[173,216]

To our knowledge, we present here the first ROR protocol explicitly developed for genomic research in African American populations, as well as a process for collaboratively developing ROR protocols that can be used for other outcomes and populations. We found that these research participants prefer to discuss genomic concepts using specialized genomic terms even if those terms are discipline specific and initially unfamiliar to participants.

As such, others seeking to develop similar ROR protocols may consider using scientifically precise vocabulary for important concepts while using various visual aids (handouts, videos) to explain the concepts behind those terms in an accessible way.

Future genomic research using this or a similar ROR protocol should evaluate the cognitive value and acceptability of the protocol in AA populations outside of the American South, and additional studies should investigate how knowledge of genomic risk, as communicated by this ROR protocol, affects motivation for health-related behavior change outcomes.

E.1. Conclusions

This study is unique in that it concentrates on an AA population. The ROR protocol presented here is designed specifically to fill the gap of communication research in AA populations using CBPR principles with the goal of using the ROR to study the personal utility of personalized CVD genomic results (ClinicalTrials.gov number: NCT02208180).

CHAPTER 6: THE RETURN OF RESULTS STUDY: RESULTS FROM A RANDOMIZED CONTROLLED TRIAL TO EVALUATE THE CONCEPT OF USING PERSONALIZED GENOMIC RESULTS FOR MOTIVATION TO CHANGE DIET AND PHYSICAL ACTIVITY BEHAVIORS

A. OVERVIEW

With the rise of personalized genomics, participants are more frequently asking for or expecting their personalized genomic results to be available to them. However an evidence base for the communication and effects of personalized genomics has yet to be fully established. This study attempts to contribute to that evidence base by evaluating the effect of communicating personalized cardiovascular disease genomics risk on motivation towards cardiovascular disease (CVD) risk reduction in an African-American (AA) population in rural North Carolina using a randomized controlled design.

A total of 62 participants were randomized to either receive personalized genomic information or to an attention control group. Participants were followed for one month at the end of which the control group also received their results. Outcomes assessed were self-reported motivation, Protection Motivation Theory constructs, fruit and vegetable servings, and physical activity. Four groups were planned for, but only three were formed due to the lack of high genomic risk participants: average genomic risk intervention group (n=12), low genomic risk intervention group (n=19), and control group (n=31). The control group received no genomic risk information, regardless of genomic risk status.

There were no significant differences in between- or within-group motivation towards diet and physical activity between baseline and 1-month follow-up (p=0.51). Moderation by

genomic risk category for the intervention group revealed some significant findings. The low genomic risk intervention group self-reported being more motivated towards diet and physical activity (0.3 ± 0.2, p=0.09), and consuming more fruits and vegetables per week (1.3 ± 0.4, p=0.001). The average genomic risk intervention group less motivation, and no change in diet. Findings suggest that genomic-risk knowledge may impact the perceived threat of CVD. Specifically, those of low genomic risk may not be demotivated and those of average risk may be demotivated, both of which are contrary to hypotheses in the literature. Future research is needed to replicate these findings and further investigate the mechanisms behind this phenomenon.

B. INTRODUCTION

Personalized genetic information has been commercially accessible since 2007.[201,203,231] The usefulness of this genetic information depends on the clinical utility and validity of the SNPs (single nucleotide polymorphisms) involved. Clinical utility concerns the availability and efficacy of treatment based on the genetic information. Clinical validity is the accuracy with which the genomic information predicts clinical disease.[232] Though it is reasonable to hypothesize that knowledge of personalized genetic risk factors may be an important motivator for health-related behavior change, this remains underexplored.

The National Institutes of Health and Centers for Disease Control and Prevention have jointly called for more evidence regarding the use of personal genomics in disease prevention; specifically, there is a need to "assess how genome profiles affect behavior of individuals."[233] This can be used in addressing common chronic diseases. This paper attempts to address that priority by giving evidence on the use of personal genomics to promote behavior change for cardiovascular disease prevention. Enrolling a rural, African-American population in North

Carolina, this study evaluates the effect of returning personalized cardiovascular disease genomic risk results on motivation towards diet and physical activity. We hypothesized that motivation towards diet and physical activity would increase for AAs receiving genomic knowledge relative to those receiving no genomic information. Protection Motivation Theory (PMT) constructs were theorized to increase; all save for fatalism, which was theorized to remain flat. Fruit and vegetable servings were hypothesized to increase with no change in physical activity behaviors. All findings were theorized to interact with genomic risk category. Findings were supposed to different—or moderated—based on the genomic risk communications received.

C. METHODS

C.1. PARENT STUDY

The current study is an ancillary project of the Heart Healthy Lenoir (HHL) study. In brief, the primary aim of HHL was to create long-term, sustainable approaches to reducing cardiovascular disease (CVD) risk disparities in Lenoir County, North Carolina—a rural, low-income county in eastern North Carolina. HHL included three coordinated studies: The Lifestyle Study, The Hypertension Control Study, and The Genomics Study. The Lifestyle Study evaluated a community-based lifestyle intervention aimed at reducing CVD risk and disparities in risk through the improvement of eating patterns, promotion of physical activity, and weight loss support.[221] (ClinicalTrials.gov number: NCT01433484) The Hypertension Control Study evaluated a clinical intervention testing a medication and lifestyle management system to improve blood pressure control and reduce disparities in blood pressure control among patients diagnosed with poorly controlled high blood pressure.[224] (ClinicalTrials.gov number:

NCT01425515) The Genomics Study explored genomic factors associated with CVD risk and treatment success.

C.2. Risk Estimates

Risk estimates were calculated for all participants.

C.2.1. Phenotypic Risk Estimate

Phenotypic CVD risk was calculated using the Framingham Risk Score (FRS),[234] which uses age, systolic blood pressure, total cholesterol, HDL (high-density lipoprotein), gender, smoking status, diabetes status, and blood pressure medication status to calculate a 10-year risk estimate. To remain consistent with the parent study, the same method of calculation was used in this study used the participant's 24-month measurement values from the parent study.[235] If a participant reported a cardiac event during HHL, the 2-year FRS estimate was used.[236] All estimates were framed in comparison to the average risk for the participant's age and sex group.

C.2.2. Genetic Risk Estimate

C.2.2.a. Genotyping

Whole genome genotyping was performed as a part of the HHL Genomics Study. That genotyping information was used for the current study. (See Appendix 6.1 for additional information about genotyping methods.)

C.2.2.B. GENETIC RISK SIGNATURE

To compile a genomic risk signature (GRS) we consulted with a genetics epidemiologist, who guided our procedures. Fine mapping and admixture papers were analyzed for the presence of genome-wide association study significant SNPs ($p \leq 5x10^{-8}$) in those of African ancestry for the following conditions: blood pressure, dyslipidemia, T2DM, BMI, smoking, and CVD. (See Appendix 6.2 for the full list.) Allele frequencies for each SNP were taken from the 1000 Genomes Project using the YRI (Yoruba in Ibadan, Nigeria) population.[237] SNP imputation was in progress through the beginning of this study; therefore, those SNPs not imputed by the cutoff date of the end of February 2016 were not included in this study (Figure 6.1). In total, 9 SNPs were identified (Table 6.1).

An additive risk model was used for the CVD GRS. To compute genomic risk for study participants, each SNP genotyped was represented as 0/1/2, indicating the participant's number alleles for a total possible score of 18. Participants were categorized into "high genomic CVD risk" (upper quartile; 13-18 SNPs), "average genomic CVD risk" (middle two quartiles; 6-12 SNPs), and "low genomic CVD risk" (lowest quartile; 0-5 SNPs).

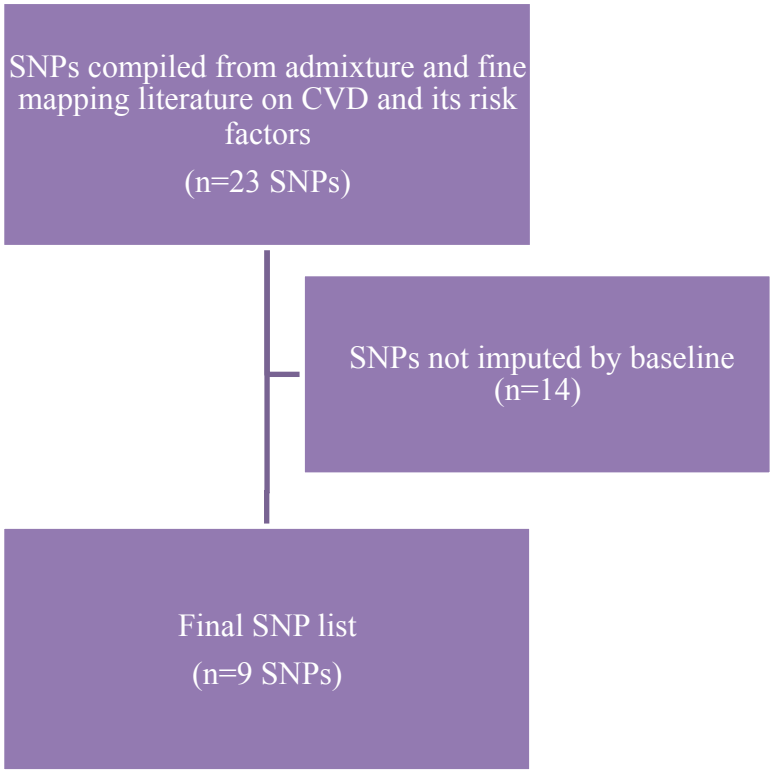


FIGURE 6.1. SNP DECISION TREE 3/4/16

TABLE 6.1. HEART HEALTHY LENOIR CVD GENOMIC RISK SIGNATURE FOR AFRICAN-AMERICANS

SNP	Pheno-type	Gene	Chro-mo-some	Effect Allele	Effect Allele Fre-quency	Study N	Effect size ± S.E.	p-value	Refer-ence
rs16942887	HDL	LCAT	16	G	0.70	8,061	1.27 ± 0.11 mg/dL	$1.00x10^{-10}$	Teslovich 2010[56]
rs3764261	HDL	CETP	16	C	0.74	8,061	3.39 ± 0.09 mg/dL	$3.00x10^{-18}$	Teslovich 2010[56]
						8,318	2.79 ± 0.25 mg/dL	$5.91x10^{-28}$	Carlson 2013[55]
rs543874	BMI	SEC16B	1	G	0.25	45,704	0.060 ± 0.008	$2.00x10^{-13}$	Monda 2013[53]
						29,151	−0.0110	$2.40x10^{-09}$	Gong 2013[50]
rs646776	LDL	CELSR2/PSRC1/SORT1	1	T	0.69	7,724	4.46 ± 0.63 mg/dL	$1.48x10^{-12}$	Carlson 2013[55]
rs6511720	LDL	LDLR	19	G	0.87	8,061	-6.99 ± 0.30 mg/dL	$5.00x10^{-08}$	Teslovich 2010[56]
						9,291	-8.10 ± 0.80 mg/dL	$7.05x10^{-24}$	Carlson 2013[55]
rs6567160	BMI	MC4R	18	C	0.23	45,920	0.059 ± 0.009	$2.96x10^{-11}$	Monda 2013[53]
rs7903146	T2DM	TCF7L2	10	T	0.24	9,844	0.23 ± 0.04	$3.98x10^{-10}$	Carlson 2013[55]
rs2258119	SBP	C21orf91	21	C	0.23	8,591	1.84 ± 0.34	$4.69x10^{-08}$	Fox 2011[44]
rs2036527	cigarettes smoked per day	CHRNA5	15	A	0.15	32,389	0.04 ± 0.01	$1.84x10^{-08}$	David 2012[42]

C.3. INTERVENTION

C.3.1. PARTICIPANT SCREENING AND RECRUITMENT

Participants for the current study were recruited from the HHL Study. In February 2016, invitations were sent to HHL participants who met the following criteria: 1) African-American (AA), 2) completed the HHL 24-month follow-up visit, 3) agreed to be contacted for future studies, 4) were enrolled in the HHL Genomics Study, and 5) were not enrolled in the HHL Lifestyle Weight Loss program. Participants from the HHL Lifestyle Weight Loss program were excluded from this study because they had more contact with HHL compared to other participants, and this group was used as the participant pool for formative research for the current study.

C.3.2. RANDOMIZATION

After providing informed consent, participants completed the baseline questionnaire including a health literacy questionnaire. Participants were then randomized to the intervention or control group using block randomization by health literacy status (high or low).

C.3.3. INTERVENTIONS

Participants attended a baseline study visit in the Kinston, North Carolina field office in March 2016. After informed consent and the baseline survey, participants were randomized to receive either their CVD genomic results (intervention group) or financial management counseling (control group). The intervention protocol was designed to be a one-on-one low-risk educational session. (See Chapter 5 for more detail.) An attention control group protocol was chosen to match the amount and intensity of participant contact. Trained research assistants

delivered all interventions during one individual face-to-face counseling session. A post-test survey was then administered to assess immediate participant response. Participants were brought back to the field office one-month later (April 2016) for a follow-up measurement visit. (Figure 6.2)

C.3.3.A. CONTROL GROUP

An attention control, delayed intervention design was implemented in this study, with the control group receiving their genetic information after follow-up measures. During the intervention period, the control group did not receive information about diet and exercise, but received a modified financial management module. The module was one 15-minute, self-directed educational session on how to set and achieve financial goals. Participants were given brief educational materials about whatever financial topic they chose—saving, budgeting, creating assets, or credit. Then participants were led through how to create a financial goal. Control group participants participated in the genomics intervention protocol at the close of the intervention period, and after completing final measurements.

C.3.3.B. INTERVENTION GROUP

The return of results protocol has been described elsewhere (See Chapter 5.) In brief, the protocol is a 15-minute empowering, educational session designed to motivate risk reduction behaviors by focusing on risk perception and self-efficacy. Materials were crafted to minimize feelings of invulnerability in those of low genomic risk.[157] Invulnerability concerns center around the fear of demotivating participants to make lifestyle changes. A brief genomics education unit is completed prior to receiving results. Separate genomic and phenotypic risk

estimates were then provided using verbal risk estimates (i.e., "high," "average," or "low" risk). Visual aids were used to help bridge genomic literacy and numeracy gaps. After receiving results, written lifestyle advice from HHL was provided on reducing environmental CVD risks such as diet and physical activity. Participants were encouraged to follow the HHL lifestyle advice as well as advice from their doctors. A genetic counselor was also available for additional follow-up at the participant's request.

C.3.3.c. Lifestyle Advice

This study is unique in that our population had already received the lifestyle change instruction in HHL. We capitalized on that by reminding participants of the counseling previously received, which can be found elsewhere.[221] In brief, the advice focused on dietary and physical activity behaviors. The "Med-South Diet" advice focused on fruit and vegetable consumption, carbohydrate quality, lean meats, and high quality fats in keeping with a Mediterranean dietary pattern. The physical activity advice set goals of walking ≥ 7,500 steps/day or 150 minutes a week broken up into as small as ten-minute segments.

Advice information is available at http://www.hearthealthylenoir.com/sites/default/files/imce/documents/HealthyEatingMaterials.pdf.

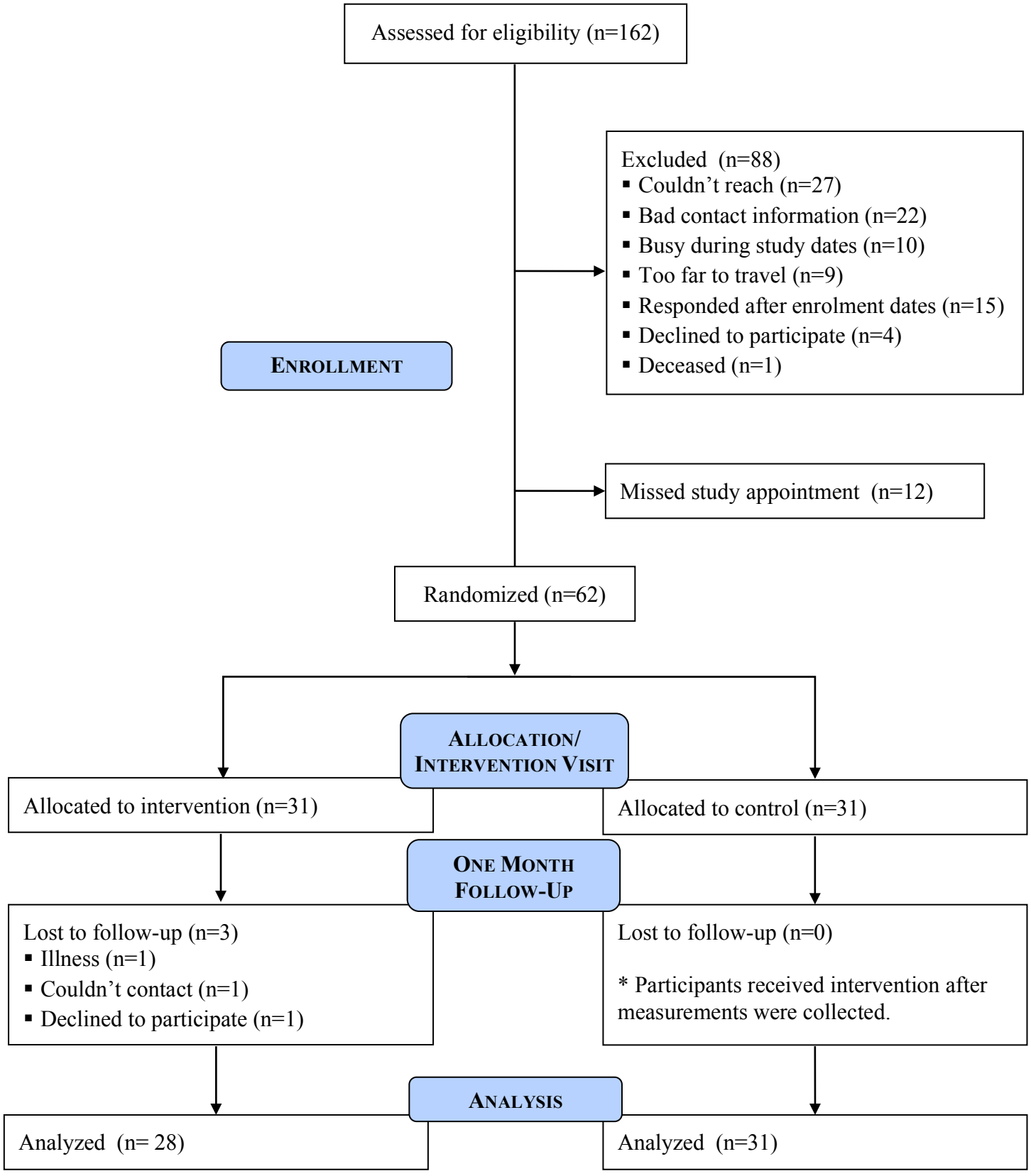


Figure 6.2. Study Flow Diagram

C.4. OUTCOME MEASURES

The primary study outcome was motivation towards changing diet and physical activity behaviors. It was assessed via self-report using the Prevention and Planning Behaviors measure developed by Rini et al; this instrument has never been published, however it has been used by another translational genomic research study.[238] This scale assesses degrees of influence on participants' motivation to change their health behavior in translational genomic studies, and takes into consideration that behaviors could become less healthful rather than more healthful. Using a larger genomics study (n=513) with a White, high income, high health and genetic literacy population, factor analysis was conducted on this scale. The following subscales were created: motivation towards diet and physical activity (n=8; α=0.86), motivation towards stress reduction (n=3; α=0.82).

Secondary outcomes were self-reported as well. They include: motivation sub-scales, fruit and vegetable consumption, physical activity, Protection Motivation Theory (PMT) constructs, and fatalism. The fatalism scale was comprised of three subscales: predetermination, luck, and pessimism. (Table 6.2) (See Appendix 6.3 for data collection instruments.) The post-test administered immediately after intervention, consisted only of PMT constructs and health behaviors.

The Institutional Review Board at the University of North Carolina at Chapel Hill approved this study (IRB# 14-1500). The trial is also registered with ClinicalTrials.gov (ClinicalTrials.gov number: NCT02208180). Participants were provided $60 in incentives for their participation.

C.5. Analysis

The primary outcome was the 1-month change in motivation for healthy diet and exercise behaviors in the intervention group, relative to the control group. We estimated 2-4 participants per scale item for this 14-item scale. Using the median estimate, we estimated needing 42 subjects per arm, or 84 subjects in total.

A general linear mixed model was used for analysis. We looked at time (baseline and follow-up), and intervention group (intervention and control) in a 2x2 model to estimate the effect on the outcomes. Moderation analyses were also performed to test interactions with genomic risk signature (GRS).[239] For this, we used a 2x2x1 model (time x GRS x intervention treatment group). Significance for all analyses was set at $p \leq 0.05$. A complete-case analysis approach was used however some missingness was allowed in variables for which the mean was calculated. All analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC). The Consolidated Standards of Reporting Trials guidelines were followed in the conducting and reporting of this study.[240]

TABLE 6.2. MEASURES USED IN RANDOMIZED CONTROLLED TRIAL

Measure(s)	Description		Point Assessed		
		HHL	Baseline	Post-test	1-month
Demographics					
Age	Used to establish demographics.	X			
Gender	Used to establish demographics.	X			
Race	Used to establish demographics.	X			
Genomic Literacy	The Rapid Estimate of Adult Literacy in Genetics (REAL-G)[229]: 8-item measure administered by a research assistant		X		
Health Literacy	The Short Test of Functional Health Literacy in Adults (STOFHLA)[241]: 36-item measure	X	X (If unavailable from HHL.)		
Health Related Quality Of Life	Short Form Health Survey (SF-12)[242]: 12-item measure		X		X
Mental Health	Mental Health Inventory (MHI-5)[243]: 5-item measure		X		X
History Of Genetic Testing	Used to asses if participant or any close relatives have ever had genetic testing.[244]: 3-item measure		X		
Numeracy	Subjective Numeracy Scale (SNS-3)[245]: 3-item measure		X		
Education	Used to establish demographics[221]				X*
Marital/Partner Status	Used to establish demographics[221]				X*
Employment Status	Used to establish demographics.				X*
Income	Used to establish demographics.				X*
Health Insurance Status	Used to establish demographics.				X*
Household Composition	Used to establish demographics.				X*

Measure(s)	Description		Point Assessed		
		HHL	Baseline	Post-test	1-month
Risk Estimates					
Diabetes	Hemoglobin A1c was measured from a blood draw at baseline and 24 months.	X			
Cholesterol	Total cholesterol, HDL, and LDL (low-density lipoprotein) were measured from a blood draw at baseline and 24 months.	X			
Systolic Blood Pressure	Blood pressure was measured in triplicate at baseline and 24 months.	X			
Hypertension Medication Status	"Do you take medicine for high blood pressure or hypertension?" Measured at baseline and 24 months.	X			
Smoking Status	"Do you smoke cigarettes now?" Measured at baseline and 24 months.	X			X
History Of Heart Disease	"Has a doctor ever told you that you have had a heart attack?" Measured at baseline.	X			
Genotyping	Whole genome genotyping at baseline.	X			
Protection Motivation Theory Constructs					
Motivation	Prevention and Planning Behaviors[238]: 12-item measure		X	X	X
Threat Appraisal	Participant identifies the how they perceive CVD threat on a 5-point Likert scale[246]: 1-item		X	X	X
Perceived Vulnerability	Participant identifies 10-year CVD risk on a percentage scale[247]: 1-item		X	X	X
Perceived Severity	Participant identifies severity of CVD on self-referenced questions covering range of factors using a 5-point Likert scale[248]: 8-items		X	X	X
Perceived Fear	Participant identifies feelings of fear on a 5-point Likert scale[249]: 4-items		X	X	X

Measure(s)	Description		Point Assessed		
		HHL	Baseline	Post-test	1-month
Coping appraisal	Coping Efficacy subscale of the Psychological Adaptation Scale used in previous genomic research[250]: 5-items			X	X
Perceived Response Efficacy	Participant identifies the efficacy of diet and physical activity on a 5-point Likert scale[251]: 6-items		X	X	X
Perceived Response Cost	Participant identifies the cost of diet and physical activity on a 5-point Likert scale[251]: 6-items		X	X	X
Fatalism	Fatalism scale with predetermination, luck and pessimism subscales[252]: 20-items		X	X	X
Health Behaviors					
Fruit and Vegetable Servings	A 10-item Block screener[253]		X		X
Physical Activity	RESIDE (RESIDential Environment project) Neighborhood Physical Activity Questionnaire[254]:16-item measure		X		X

* Demographic information available from the parent study and unlikely to change significantly since the parent study was measured at follow-up to reduce subject fatigue during the baseline survey.

D. RESULTS

D.1. PARTICIPANT CHARACTERISTICS

Between February 2016 and March 2016, invitations were sent to 162 HHL participants to participate in the Heart Healthy Lenoir Return of Results (HHL ROR) Study; 74 participants (46%) responded positively and were scheduled for a baseline study visit. The most common reason for a non-positive response to the study invitation was being unable to reach the

participant (17%), followed by incorrect contact information (14%). An additional 12 participants (7%) did not keep their study appointments after a positive invitation response leaving 62 participants to be randomized. Three participants in the intervention group were lost to follow-up. (See Figure 6.2.)

Approximately 15% (n=25) of the target population was either unavailable during the study dates or responded after enrollment closed. Analysis was performed to see if the study population differed from these possible participants in terms of demographics or HHL study enrollment. No significant differences were found.

There were no significant differences between groups in baseline characteristics in this study except where otherwise noted (Table 6.3). There were also no significant differences in baseline characteristics between the low and average GRS intervention groups. (See Appendix 6.4 for additional statistics.)

Participants in the current study came largely from the HHL Hypertension Study (n=56) with 21 participants from the HHL Lifestyle study including 9 participants in both studies. On average, about 1 year and 9 months had elapsed between the last HHL visit and the baseline HHL ROR Study visit. All participants were self-identified as African-Americans. The majority of participants were female (n=44; 71%). The average age was 61 years (*Standard Deviation [SD]* 9). Most participants had graduated 12^{th} grade or higher (n=48; 77%).

This sample was mostly high literacy (n=46). The average literacy score was 27.8 (*SD* 10.1) on a scale from 0 – 36. Likewise, the sample was of high genetic literacy (*Mean [M]*±*SD* 4.3 ± 2.7 on a scale from 0 – 8). Subjective numeracy scores were ranked average on a scale from 1 – 6 (*M* ± *SD* 3.2 ± 1.4).

Genomic CVD risk was mostly low (n=40; 65%) across all study participants (n=19; 61% in the intervention group). There were no significant differences in the allele numbers of the SNPs between the intervention and control groups. Phenotypic risk was almost evenly split between low (n=14; 23%) and high (n=13; 21%) across all study participants. (See Tables 6.4 and 6.5 for population breakdown by FRS and GRS.) Over the course of the 2-year HHL intervention, there were no significant differences in the component variables of the Framingham Risk Score (i.e., age, systolic blood pressure, total cholesterol, HDL, sex, smoking status, A1c values, or blood pressure medication status) when comparing the intervention and control groups in this study. However, there was a significant difference between groups in the change in HDL (*Control vs. Intervention [C vs. I] M ± Standard Error [SE]:* -4.2 ± 8.1 vs. 2.0 ±8.6, p = 0.0111)

D.2. Primary Outcome

Post-test measurements were administered to determine the initial reaction of participants. Analysis of post-test results did not show any difference between baseline and post-test. Therefore only baseline (Time 1) and follow-up (Time 3) were used for analysis, except where noted otherwise.

At baseline, participants reported being "a little more" motivated to change their diet and physical activity habits. There were no differences between groups (p=0.99). Over time, there were no significant between-group differences in motivation toward diet and exercise (*C vs I:* 0.06 ± 0.15 vs. -0.08 ± 0.15, p=0.51). The positive value for the control group indicates a non-significant movement towards increased motivation over the course of the study; the negative value for the intervention group indicates the opposite. Moderation analyses showed a significant effect of moderation in the intervention group (p=0.01). The low genomic risk signature (GRS)

group self-reported being between neutral motivation and "a little more" motivated to change their diet and exercise habits at baseline. Over the course of this study, that motivation trended towards increasing (0.3 ± 0.2, p=0.09). The average GRS group self-reported being "a little more" motivated to change their behaviors at baseline; this regressed towards neutral by follow-up (-0.5 ± 0.2, p=0.06). (Table 6.6).

TABLE 6.3. PARTICIPANT CHARACTERISTICS

Characteristic	Overall (n=62)	Intervention Group (n=31)	Control Group (n=31)	p-value
Age *M*(*SD*)	60.9 ± 8.6	60.2 ± 9.5	61.5 ± 7.8	0.55
Male Gender *N (%)*	18 (29%)	10 (32%)	8 (26%)	0.78
Education *N (%)**				0.80
< High School	11 (19%)	6 (11%)	5 (16%)	
High School	37 (63%)	18 (64%)	19 (61%)	
College and Beyond	11 (19%)	7 (25%)	4 (13%)	
Genomic Risk *N (%)*				0.79
Low	40 (65%)	19 (61%)	21 (68%)	
Average	22 (36%)	12 (39%)	10 (32%)	
High	0 (0%)	0 (0%)	0 (0%)	
Phenotypic Risk *N (%)*				0.50
Low	29 (47%)	14 (45%)	15 (48%)	
Average	11 (18%)	4 (13%)	7 (23%)	
High	22 (36%)	13 (42%)	9 (29%)	
Subjective Numeracy *M*(*SD*)	3.2 ±1.4	3.2 ± 1.4	3.1 ± 1.5	0.75
Health Literacy *M*(*SD*)	27.8 ± 10.1	27.9 ± 9.6	27.7 ± 10.7	0.95
Real-G Score *M*(*SD*)	4.3 ± 2.7	3.8 ± 2.5	4.7 ± 2.8	0.18
Time Since HHL *M*(*SD*)	1.8 ± 0.3	1.8 ± 0.3	1.8 ± 0.3	0.59

*N=59 Overall; N=31 Control; N=28 Intervention

TABLE 6.4. PHENOTYPIC RISK BY GENOMIC RISK—OVERALL

Genomic Risk *N (%)*	Phenotypic Risk *N (%)* Low	Average	High	Total
Low	20 (69%)	8 (73%)	17 (77%)	40 (65%)
Average	9 (31%)	3 (27%)	5 (23%)	22 (36%)
High	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Total	29 (47%)	11 (18%)	22 (36%)	62 (100%)

TABLE 6.5. PHENOTYPIC RISK BY GENOMIC RISK—INTERVENTION GROUP

Genomic Risk *N (%)*	Phenotypic Risk *N (%)* Low	Average	High	Total
Low	10 (71%)	3 (75%)	9 (69%)	19 (61%)
Average	4 (29%)	1 (25%)	4 (31%)	12 (39%)
High	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Total	14 (45%)	4 (13%)	13 (42%)	31 (100%)

TABLE 6.6. REGRESSION ANALYSIS FOR MOTIVATION TOWARDS DIET AND EXERCISE

Label	*Estimate*	*Standard Error*	*DF*	*t Value*	*Pr > |t|*
Control Time 1	3.9509	0.2304			
Control Time 3	4.0141	0.2304			
Intervention Time 1	3.9306	0.2365			
Intervention Time 3	3.8556	0.2365			
Control: Time 3 vs. Time 1	0.06318	0.1474	113	0.43	0.6691
Intervention: Time 3 vs. Time 1	-0.07500	0.1513	113	-0.50	0.6212
Control vs. Intervention: Time 3 vs. Time 1	0.1382	0.2113	113	0.65	0.5144
Intervention Low GRS Time 1	3.6736	0.2827			
Intervention Low GRS Time 3	3.9861	0.2827			
Intervention Average GRS Time 1	4.1875	0.3793			
Intervention Average GRS Time 3	3.7250	0.3793			
Intervention Low GRS: Time 3 vs. Time 1	0.3125	0.1809	113	1.73	0.0868
Intervention Average GRS: Time 3 vs. Time 1	-0.4625	0.2427	113	-1.91	0.0592
Intervention: Low GRS vs. Average GRS: Time 3 vs. Time 1	0.7750	0.3027	113	2.56	0.0118

This measurement used a 5-point bi-polar Likert scale. A score of 3 indicates “no change in motivation.”

D.3. Secondary Outcomes

See Appendix 6.5 for regression analyses tables.

D.3.1. Motivation Towards Stress Reduction

At baseline, participants reported being "a little more" motivated to adopt stress reduction behaviors, with no differences between groups (p=0.64). Between-group analysis revealed a trend towards a difference in motivation between the two groups over time. Over the course of the study, the control group trended towards slightly increased motivation to reduce stress while the intervention group trended towards slightly decreased motivation to reduce stress (*C vs I:* 0.2 ± 0.2 vs. -0.2 ± 0.2, p=0.11). There was no significant effect of moderation by GRS in the intervention group. However, the trend seen in the between group analysis was probably driven by the average GRS group which trended towards regressing towards neutral by follow-up (-0.5 ± 0.3, p=0.08).

D.3.2. Protection Motivation Theory Constructs

D.3.2.a. Threat Appraisal

At baseline, participants self-reported that CVD was a "very serious" health threat. When asked to rate their chances of developing CVD in the next 10 years, the median percentage was 40% (range 0 – 100%; Mean 43 ± 29%). Thoughts of CVD made participants feel "somewhat" fearful. When queried about the perceived severity of CVD using self-referenced statements naming possible consequences of CVD, participants self-reported as neutral on a 5-point bipolar Likert scale of agreement. (Sample statement: "My feelings about myself would change if I got heart disease.") Over time, there were no significant between- or within-group differences for

threat appraisal, perceived vulnerability, perceived severity or perceived fear. There was a trend towards a between-group effect for perceived vulnerability; the control group trended towards feeling less vulnerable by one-month while the intervention group trended towards feeling more vulnerable (p=0.06). Moderation analysis also revealed a significant effect of moderation by GRS but only for perceived vulnerability (p=0.05). The average GRS group significantly increased their perceived vulnerability to develop CVD within the next 10 years from baseline to follow-up (from 16 ± 9% to 35 ± 9%, p=0.05). The low GRS group started at 49% perceived vulnerability that decreased to 46%— not a significant change over time (p=0.58). Related, no participants sought consultation with the genetic counselor after their study appointment.

D.3.2.B. COPING APPRAISAL

Coping efficacy questions self-referred to the information received, therefore the analyses for this variable were between post-test (Time 2) and follow-up (Time 3). At post-test, participants reported that the information they received in the intervention somewhat helped them cope better. (For the control group this was the financial management information. For the intervention group this was the CVD genomic information.) In terms of healthful diet changes, participants agreed with statements about healthful diet changes being feasible and effective in preventing CVD. The same pattern was seen with physical activity changes to prevent CVD. There were no between group differences in coping efficacy at post-test (p=0.69) or the other variables at baseline [diet response cost (p=0.31), physical activity response cost (p=0.91), diet response efficacy (p=0.70), and physical activity response efficacy (p=0.68)].

By one-month follow-up, there were no significant between- or within-group differences, or significant effects of moderation for coping efficacy, or diet or physical activity response cost

or response efficacy. There was a trend towards a between group difference of diet response cost with the control group regressing slightly towards neutral and the intervention group rating healthful diet changes as slightly more feasible (*C vs I:* -0.1 ± 0.1 vs. 0.1 ± 0.1, p = 0.09). A trend was also seen in physical activity response efficacy (p=0.09). The low GRS group non-significantly regressed towards neutral (-0.05 ± 0.14, p=0.70). The average GRS group trended towards a small increase in the perceived efficacy of physical activity in preventing CVD (0.3 ± 0.2, p=0.07).

D.3.2.c. Maladaptive Coping

The study population self-described themselves as disagreeing with fatalistic statements in the measurement scale at baseline with no differences between groups (2.35±0.63, p=0.66). The same pattern was seen in the fatalism sub-scales: predetermination (2.47±0.67, p=0.46), luck (2.04±0.73, p=0.76), and pessimism (2.34±0.73, p=0.73). At follow-up, there were no between-group effects of fatalism (*C vs. I:* 0.1 ± 0.07 vs 0.1 ± 0.07, p=0.93). Likewise, moderation analysis showed no interaction between GRS, and time for the intervention group (0.08 ± 0.15, p=0.58). Analysis of the subscales over time did not reveal any significant findings.

D.3.3. Health Behaviors

D.3.3.a. Diet: Fruit and Vegetable Servings

At baseline, this population reported consuming 3.5±1.9 servings of fruits and vegetables per week, with no difference between groups (p=0.94). Over time, there were no between-group effects for fruit and vegetable servings (p=0.37). There was a significant within-group effect for the intervention group (0.6±0.3, p=0.04). Closer investigation via moderation analysis revealed a

significant effect of moderation (p=0.03). This was driven by the low GRS group that self-reported an increase in fruit and vegetable consumption from 3±0.5 servings per week at baseline to 4.3±0.5 servings per week at 1-month follow-up (p=0.0005). There was a non-significant decrease in self-reported fruit and vegetable consumption in the average GRS group (-0.04±0.48, p = 0.94).

D.3.3.B. PHYSICAL ACTIVITY

Physical activity was categorized by walking time and active time. Walking time included walking for transportation and exercise. Active time included walking time plus all other types of moderate and vigorous physical activity. At baseline, the median time spent walking per week was 50 minutes (range: 0 – 1200 minutes; average 108±207), and the median active time per week was 120 minutes (range: 0 – 4740 minutes; average 242±623); there were no differences between groups (p=0.85 and 0.32, respectively). By follow-up, no significant between-group, within-group, or moderation effects were found for either of these categories.

E. DISCUSSION

Recent, rapid advances in genomic technologies have made personalized genomic information less expensive, more comprehensive, and more widely available than before, but how this information affects health-related behaviors is widely unknown. This personalized genomic information could be an important tool to affect individual behavior change, either to promote the adoption of healthy behaviors, or to dis-incentivize less healthy behaviors. The present study contributes to the evidence base regarding the effect of personalized genomic CVD risk knowledge on motivation towards healthy behaviors in a rural African-American population

that has historically experienced disproportionate rates of CVD morbidity and mortality.[3,11-13] Importantly, the present study collected data on both motivation towards a healthy diet and physical activity behaviors, as well as measures of the behaviors themselves.

In this small pilot study, we did not observe any significant differences in the 1-month change in motivation for healthy diet and physical activity behaviors in the intervention group, relative to the control group. However, when we stratified analysis by GRS, we found that those in the lowest genomic risk category exhibited self-reported decreases in perceived vulnerability, increases in motivation towards diet and physical activity changes, and increases in fruit and vegetable consumption. Feelings of fatalism did not change. This may indicate that individual knowledge of lower-than-average genomic CVD risk may encourage a focus on healthy lifestyle behaviors in order to preserve one's perceived genomic advantage, or that those with knowledge of their own lower-than-average risk may simply be encouraged by the lack of genomic impediments to cardiovascular health.

Compared to theory, this finding is notable in two ways. First, this finding is consistent with Protection Motivation Theory. Protection Motivation Theory posits that when an individual receives information about their health, this information is then evaluated in terms of the severity of the disease (threat appraisal) and the efficacy of the prevention actions (coping appraisal). This evaluation can either lead to motivation towards health protective behaviors or maladaptive coping (e.g., fatalism). In theory, decreased threat appraisal, and/or increased coping appraisal will lead to health protective motivation and behaviors. In this study, the low GRS group self-reported high coping appraisal (which did not change), decreased threat appraisal, increased health protective motivation and increased health behaviors, without any maladaptive coping. This suggests that the mechanism of action of this type of health communication may act through

the individual's sense of CVD threat activated by the receipt of genomic information. Particularly, it might act through perceived vulnerability since perceived threat and perceived fear of CVD was high for this group and did not change. More research is needed to fully elucidate the theory constructs behind this phenomenon.

This finding in the low GRS group is also noteworthy since the literature frequently posits that individuals receiving low genomic risk information may develop a sense of 'invulnerability.' This means that the participant would feel like since their genome does not predispose them to a disease state that they are less likely—or invulnerable—to developing the disease state. This could, in turn, demotivate participants from engaging in common environmental risk factor protective behaviors (e.g., smoking cessation, or not eating a high fat diet). Our findings suggest the opposite phenomenon in our sample. Instead of feeling demotivated, the low GRS group was the most motivated group in this study. Additional qualitative research is required to investigate why this group felt more motivated. However, we theorize that this phenomenon might have, in part, to do with the way in which the information was communicated. The communications protocol used was specifically designed to minimize feelings of invulnerability in those of low genomic risk. Instead of simply receiving genomic risk information, the protocol also discusses that environmental risk factors contribute more to the development of CVD than genomics and that individuals have control over these environmental risk factors. In addition, the protocol concludes by offering participants support for making environmental risk factor changes in the form of take-home reading materials which included a cookbook. These communications materials were designed with participation from the study target population. The use of techniques focusing on risk perception and self-efficacy may have avoided feelings of invulnerability in this sample.

Opposite findings were seen in the average GRS group. Those in the average genomic risk category self-reported increases in perceived vulnerability, decreases in motivation towards diet and physical activity changes, and no significant change in fruit and vegetable consumption without any changes in fatalism. This may indicate that individual knowledge of average genomic CVD risk may demotivate focus on healthy lifestyle behaviors.

Once again, these findings are consistent Protection Motivation Theory. The average GRS group self-reported unchanged high coping appraisal, increased threat appraisal, decreased health protective motivation, and stable health behaviors, without any maladaptive coping. Based on theory, maladaptive coping should have been activated however that is not what was observed in this study. Even though there is demotivation, these findings indicate a lack of harm even with negative results. The average GRS participants were eating an average of 4.3 servings of fruits and vegetables a week at baseline and this did not change. (This is the same level to with the low GRS group increased by the end of the intervention.) Perhaps fatalism is not the proper maladaptive coping construct and/or perhaps returning genomic results does not have detrimental behavioral effects even when it fails to motivate. Further research can more fully explore these questions.

We also posit that the lack of motivation and behavior change may be due to the normalization of unhealthy.[255-257] In formative research for the communications protocol for this study, participants suggested that when receiving results, the word "average" be replaced with "normal." That would mean that phenotypic and genomic results would be contextualized as "high," "*normal*," or "low." We decided not to make this suggested change, but the idea itself is suggestive of a linguistic conflation between "average" and "normal". For CVD, the ideal phenotypic state is not "average" but rather "low". Many in North Carolina and in Lenoir County

are at "average" or even "high" phenotypic risk. These risk states may have become normalized because they are frequently socially experienced.[256,257] These risk states are not normal, but the sense of normality may psychologically reduce the threat of the disease state.[258-263] Perhaps this sense of normality may also demotivates people towards taking additional steps to change diet and physical activity habits. We might be seeing that phenomenon in this study. However, rigorous qualitative research is needed to further explore the psychology behind these findings.

Our findings agree with previous research in this area which have found that knowledge of personalized genomic information has not impacted health-related behavior.[264,265] Study limitations include a low overall sample size and a short follow-up period. Follow-up periods for ROR studies can vary greatly, from as little as two months[150] to one year.[7,154] Longer follow-up periods of up to one year have shown that knowledge of personalized genomic data may be more effective in maintaining behavior change than it is in initiating behavior change.[7] Future studies should follow participants for longer periods to assess adherence to lifestyle changes.

An additional limitation was the primary outcome measure. While designed specifically for and used in previous ROR genomics studies, it was not a validated measure. Measures were also self-report instead of objective measures. Furthermore, the lack of a rigorous examination of non-responders limits our ability to understand if the study population differed in some way from the larger population in relation to their views on genomics.

Lastly, our sample included zero participants who qualified as high genomic risk based on the 9 included SNPs, which reduced variation in the sample. Sufficient variation may have been necessary to detect any relationship between knowledge of personalized genomic risk and motivation toward health-related behaviors. Though we hypothesized that knowledge of high

genomic risk may strongly motivate changes in health-related behavior, we are unable to fully test this hypothesis using the present study population.

Strengths of this study include recruitment and retention of a minority population in a genomics study. Only three participants (<5%) were lost to follow-up, and more participants were interested in joining than could be accommodated by the end of the enrollment period. The community-based participatory research (CBPR) principles on which this study was founded may serve as a model for future genomics studies trying to recruit and retain a large minority population.

An additional strength is that this study included lifestyle intervention in its ROR. A limitation of many studies is the return genomic information without lifestyle change skills for disease prevention. Alternatively, this study recruited from an existing research study that taught lifestyle change skills to reduce CVD risk. While not a full-scale lifestyle intervention in this study, participants received reminders about the skills learned during their previous HHL research study participation. The average time elapsed between the original HHL research studies and the baseline visit for the current study was likely long enough that any observed changes in motivation for health-related behaviors was likely due to the present study, and not residual effects from the previous studies. Future studies may investigate returning genomic results before or in conjunction with lifestyle interventions rather than after those interventions have concluded.

While only a pilot study, we believe that this study has important implications for the recruitment and retention of minorities in genomics research, the use of CBPR principles in genomics research, and the modality of ROR communications when studying its effects on behavior change. Future studies should more closely examine the theoretical underpinnings of

ROR mode of action. Studies should also examine whether motivation differs by type of behavior—whether knowledge of personalized genetic risk affects adopting vs. ceasing health-related behaviors, and should include a longer follow up period if possible.

As genomic consumer products become more available to the public, it is imperative to better understand how the public understands knowledge of personalized genomic information, and whether and how it motivates changes in health-related behavior.

CHAPTER 7: SUMMARY OF FINDINGS AND RECOMMENDATIONS FOR FUTURE RESEARCH

Evidence of the use of personal genomics in risk reduction for common chronic diseases is needed. Cardiovascular disease (CVD) is still the number one cause of death in the United States. African-Americans, those of low socioeconomic status, and those living in the Southeastern United States are most at risk of CVD mortality. Many of those deaths are preventable. The findings from this dissertation research contribute to the literature concerning health disparity, genomics communication, and the use of personal genomics in health behavior research by (1) establishing the acceptability and want of genomic research when working in *partnership* with rural African-American communities, (2) creating an accessible return of genomics results communication protocol for use with a general African-American audience, and (3) reporting on the findings of a pilot study conducted to test the impact of returning personalized cardiovascular genomics results on motivation towards diet and physical activity in a rural African-American population. The sections below summarize these contributions and discuss potential implications for future research.

A. SUMMARY OF FINDINGS

The history of medical research in minority communities is a long and complicated one out of which much mistrust has grown.[176-178,209-213] But, as medical and public health research forges forward into the world of genomics, we need to make sure that minority communities are not being left out of these innovations. Aim One focus groups established that participation in

genomic research was acceptable in Lenoir County, North Carolina and that participants wanted their results returned. Aim Two used participatory methods to create an approachable and comprehensible genomics return of results (ROR) communication protocol for use in a general African-American audience. Aim Three was a pilot study of return of personalized cardiovascular genomic results study for African-Americans, using a randomized-controlled attention-controlled delayed-intervention design. While there were no significant between-group findings, intervention group moderation analyses suggests that ROR may work primarily through variation in perceived threat and that those at lowest genomic risk may demonstrate positive motivation and behavior changes with both no impact and no harm done to those of average genomic risk.

B. Recommendations for Future Research

Meta-analysis on previous ROR research has found that knowledge of personalized genomic information has not impacted health-related behavior.[264] Included in this meta-analysis by Cochrane Reviews were diet (n=7 studies) and physical activity behaviors (n=6 studies), but no research focusing on these behaviors as they relate to CVD prevention. Additionally, not all ROR studies were considered. For example, the Grant study returning T2DM results was not included in the Cochrane Review. While mounting evidence suggests a lack of efficacy of ROR in behavior change, we suggest that this line of inquiry is still worthwhile.

The communications methods used to return results is an understudied area and is often a weakness in ROR studies. Literacy (health and genomic), numeracy, and genomic knowledge issues abound in most previous research. The most common method for ROR is a numerical representation, which has suggested as difficult to comprehend.[219] Additionally, little educational

context is given when providing results. The current study addressed those issues in our ROR protocol. Without these communications issues being addressed, an accurate assessment of the effect of ROR cannot be done, in our opinion. Future research should be sure to address communications concerns in partnership with the target communities for the most accurate results.

The current study was limited in several ways that should be addressed by future research, namely the small sample size. The follow-up period and intervention timing were also limitations of the current study that could be corrected by future research. Adherence to risk-reducing health-behaviors may be the true value of ROR—a variable that no studies included in the Cochrane Reviews or this study address. Most ROR studies only follow participants for 6 to 12 months but findings from Arkadianos suggest that a follow-up period of at least one year is advisable to see the largest effect of ROR.[7] Additionally, the lack of life skills support is a limitation of most ROR studies. Participants want this genomic information to learn more about themselves and use it to make lifestyle changes.[204,216] Therefore, lifestyle change skills are advisable to have participants make health-behavior changes. The current study provided results after the conclusion of lifestyle change instruction. Anecdotally, many participants mentioned that they ideally would have liked to receive their results at the beginning of their two years in HHL. Future research might explore the impact of these results when given at the beginning of a high-intensity lifestyle program with periodic references to their genomic risk category. (High intensity as this is most efficacious in promoting health behavior change.)[266] This combined an extended follow-up period (1 year+) and a measure of adherence to behavior changes might yield evidence as to the efficacy of ROR.

Another consideration for future research is the cost involved in ROR. Few cost-effective studies have been conducted on this mode of health communication. Unlike other types of counseling based on the latest efficacious research, this type of communication requires biomedical analyses to be done for every single participant. This type of analysis is much cheaper now than it was 10 years ago, but still is an additional cost in addition to the man-hours to interpret these results. More hours still are needed to input the information into the communications protocol and then implement the one-on-one protocol with participants. Cost-benefit and cost-efficacy analyses should be performed to balance the expense of this counseling with participant demand.

C. Recommendations for Theory

Protection Motivation Theory was the most applicable theory for the return of genomic results in health behavior research. However, more should be done on the conceptualization and measurement of theory constructs as it relates to genomic results. For example, there is much supposition in the literature about fatalism in response to genomic results. Findings from this study suggest that this is not a concern. As such, perhaps the conceptual model should be revising to not consider fatalism as a consequence of receiving results. Instead we posit that it should be a measure of disposition. Accounting for fatalism in this manner could change the conceptualization of which participants might and might not be receptive to genomic results as a health behavior change tool. For example, control participants in Aim Three were no different from intervention participants on overall fatalism, but where significantly more pessimistic than the intervention group. This effect was stable over all three time-points. More study should be done to examine this effect and its implications in return of results research.

An additional concern is the type of research design used to study ROR. Most studies are 2- or 3-arm RCTs. While this is generally considered the ideal study design, we suggest that a Solomon 4-square design might be of more use in this new field. This type of design would allow for better control of the effects of measurement tools. Constructs like diet and physical activity response cost and response efficacy are difficult to measure without asking directly what participants think about those behaviors. Therefore there might be some reactivity in the operationalization of the PMT constructs. A Solomon 4-square design would reveal if this supposition has merit; the findings could then be used to refine PMT construct measurement to be used in later ROR studies.

With these refinements to the PMT conceptual model as it applies to ROR and refinements in the operationalization of PMT constructs, future studies could more effectively study the mechanism of action of ROR.

D. CONCLUSIONS

The current study is a small but novel exploration of cardiovascular return of genomic results in an understudied, high-risk population—African-Americans. This work lays foundational evidence for future work in this field, and importantly future work in this field with *African-Americans*. While much more work needs to be done in the field of return of results, we have demonstrated the power of participatory research in the field of genomics. With community partnership, minority communities can be recruited and actively engaged in genomics research.

APPENDIX 4: SUPPLEMENTAL MATERIALS FOR ESTABLISHING COMMUNITY NEED

APPENDIX 4.1: ADDITIONAL QUOTATIONS ABOUT KNOWLEDGE

Societal Benefits	• *"If people are willing to contribute in a study that would help somebody, […] as a human of humanity or humane person, I think people should." (AA)*
	• *"[For] the individual impact on the study or individual, and the information that will be provided. And then also the benefits the overall benefits that it's going to make on the community and society in general the study will impart." (AA)*
	• *"There needs to be some more research and study on African American community stress and the heart . . . we worry more and it [has] got to do with economics a whole lot of the time . . . the alcohol consumption, the smoking cigarettes, the over-eating [of] comfort foods. Those are our stress relievers" (AA).*
	• *"The overall benefits that it's going to make on the community and society in general" (AA)*
	• *"I wouldn't need anything [to participate in a genomics study]. Just to know that you might be helping." (W)*
	• *"It might prolong somebody else's [life]." (W)*
	• *"Might save somebody's life" (W)*

	• *"Wouldn't need any incentive" (W)*
Health Benefits	• *"Find out if you have personal disposition to heart disease." (W)*
	• *"And if you have the knowledge, [you have] accountability for your own self, for your own actions." (AA)*
	• *"[To] prevent some things from ever happening" (W)*
	• *"I would like to have more information too because just like he said there's 14 of us [children] . ... It's probably 10 of us is diabetic because Mama and Daddy [are] diabetics. ... And if I could do something to stop that. If I just know some more information to help me so my grandbabies won't get it, I'd like that" (AA)*
	• *"What would motivate me is that if I could do anything to help somebody else." (AA)*
	• *"if I knew I was susceptible to a certain disease I wouldn't claim it but I […] would try to learn more about it. I wouldn't be afraid. I would learn something about it what I do to prevent that." (AA)*
Individual Benefits	• *"I definitely would like the report back. […] That would be payment enough." (W)*
	• *"Like the history. You know where you are coming from and you [are] going to know where you are going." (AA)*

	• *"I think knowledge is the best incentive." (AA)*
	• *"So the more I know the better off I am." (AA)*
	• *"I would like somebody to follow up with me and tell me what I could do to change." (W)*
	• *"[I'd like to] make the changes [to] live longer […] or comfortabler." (W)*
	• *"My brother was 36 he died of cancer. And if I had more information to prevent from getting it, I would do it." (AA)*

APPENDIX 4.2: FOCUS GROUP CONSENT FORM

University of North Carolina-Chapel Hill
Consent to Participate in a Research Study
Consent Form for Participants (Phase 1)—Genetics

IRB Study # 10-0363
Consent Form Version Date: 1/20/2011

Title of Study: Improving Lifestyle to Reduce the Risk of Heart Attack and Stroke

Principal Investigator: Thomas C. Keyserling, MD, MPH (UNC-Chapel Hill)
UNC-Chapel Hill Department: Center for Health Promotion and Disease Prevention
UNC-Chapel Hill Phone number: 919-966-2276, Ext 238
Co-Investigators:
-- UNC-Chapel Hill: Alice Ammerman, DrPH, MPH, RD; Katrina Donahue, MD, MPH; Kelly Evenson, PhD; Jacquie Halladay, MD, MPH; Alexandra Lightfoot, EdD; Carmen Samuel-Hodge, PhD, MPH, RD; Maihan Vu, DrPH, MPH
--East Carolina University, Greenville, NC: Doyle Cummings, PharmD; Stephanie B. Jilcott, PhD
Funding Source and/or Sponsor: National Institutes of Health
Study Contact telephone number: 919-966-6088
Study Contact email: Beverly.Garcia@unc.edu

What are some general things you should know about research studies? You are being asked to take part in a research study. You are free to join the study or not. If you don't want to take part in the study at all, or if you don't want to answer some questions, that's okay. There is no penalty if you change your mind after you start the study. If you decide not to join the study, it will not affect the care you receive at this health clinic.

Research studies are designed to obtain new facts. These new facts may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

We want you to understand the details about the study so that you can make an informed choice about being in it. You will be given a copy of this consent form. Please ask questions if there is anything you do not understand.

Being in the Study is Your Choice
Before you learn about the study, you should know that:
1. Your choice to be in the study is voluntary.
2. You may decide not to join the study.

3. If you choose to be in the study, you may stop at any time.

What is the purpose this study? Our main study goal is to try to understand how our genes and family history work together with our environment to affect health. Before we begin the study, we want to talk with men and women who live in Lenoir County to better understand their thoughts, feelings, and concerns about genetics and heart health. You are being asked to take part in this discussion group.

How many people will take part in Phase 1 of the study? In this study, we will talk to four groups of 10 to 12 men and women who live in Lenoir County.

How long will your part in Phase 1 of the study last? It should take about two hours to answer the questions.

What will happen if you take part in Phase 1 of the study? A member of our research team will lead the group discussion which should last no more than two hours. The group will be asked some questions about their thoughts and feelings about genetics and heart health. No questions will be directed to you individually, but instead will be posed to the group. You may choose to respond or not respond at any point during the discussion. The group discussion will be audiotaped so we can capture comments in a transcript for analysis. Your information will not be shared with anyone but the research staff.

What are the possible benefits from being in this study? Research like this helps others by making clear how we can best help men and women like you. You may not benefit directly from this study.

What are the possible risks or discomforts involved from being in this study? You should not have any discomfort from being in this study. We think you will be at ease answering the questions we will ask you. Although we will be careful to protect your privacy, loss of privacy is a potential risk of being in this study. Also, there is always a chance of unknown risks. You should report any problems to the research staff.

How will your privacy be protected? To make sure what you say is confidential, you can use a different name during the project so that nobody connected with the study will know your real name. Also, what other people say during the discussions is confidential, so you should not share anything you hear or see in the group with people outside the group. Your name will not appear on the transcript from the tape recording. Instead, we will make up and use an ID number. The key that links your name and ID number and the study data we collect from you will be stored in a locked file cabinet and/or password protected computer. The tape recording of the discussion session will be promptly transferred to a password protected computer and will be erased from storage in the tape recorder.

Will you receive anything for being in this study? You will receive a $25 gift card for taking part in this study. You will also be given an information sheet about the Heart-Healthy Lenoir Project.

Will it cost you anything to be in this study? It is free for you to be in this study, other than your costs to travel to the meeting site or child care if needed.

What if you have questions about this study? You have the right to ask and have answered any questions you may have about this research. If you have questions, or concerns, you should contact Thomas Keyserling, MD, MPH (919-966-2276, Ext. 238; jato@med.unc.edu). He is the leader of this project and will be happy to answer your questions.

What if you have questions about your rights as a research participant?
All human research is reviewed by a group of people that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the Institutional Review Board at the UNC-Chapel Hill at 919-966-3113 or by email to IRB_subjects@unc.edu.

Title of Study: Improving Lifestyle to Reduce the Risk of Heart Attack and Stroke

Principal Investigator: Thomas C. Keyserling, MD, MPH

Participant's Agreement: I have read the information above. I have had all of my questions answered.

☐ By placing a check here, I agree that the researchers may call me by phone to see if I am willing to take part in a follow-up study or interview. (If you check yes, we will ask for your phone number.)

By signing this form, I agree to be in the study. If I decide I do not want my information to be used, I will tell you in writing.

Signature of participant Date

Printed name of participant

Signature of person obtaining consent Date

Printed name of person obtaining consent

APPENDIX 4.3: FOCUS GROUP GUIDE

Procedures:

1. The project staff (moderator and facilitator) will greet individuals as they enter the room and check off their name on the attendance sheet.
2. Project staff will give each participant a consent form and survey
3. The moderator will provide an explanation of the purpose of the focus group meeting and introduce him/herself as well as the co-moderator.

   Thank you for being here. My name is _____ and today I will be leading our focus group discussion. A focus group is a meeting where questions are asked to a group of people in order understand a specific topic. The purpose of this focus group is for me to listen to your thoughts and experiences about genetics and heart health and suggestions for how we can make our study better.

   You should feel free to make any sort of comments – positive or negative – about what we are talking about today. There are no right or wrong answers

4. The moderator will review each of the key sections of the consent form.

   As you came in today, you were each given a consent form. Let's go over this form now and make sure there are no questions.

   Important points to note:
   - Purpose of the study and what participants are being asked to do
   - Length of participation
   - Risks, benefits and compensation
   - Protection of privacy
     - Be sure to note that discussions will be recorded if all participants are willing. Recording can be stopped at any time at any participant's request.
   - Who to call with questions

   Are there any questions? If you are willing to continue, please sign this form and return it to one of the project staff.

5. The moderator will review the ground rules.
   We want everyone to have the chance to share their opinions or experiences. We want this to be a very open discussion. There are just a few ground rules we want to go over that will help everything go more smoothly:
   1. *Talk one at a time.*
   2. *Be respectful of others. You don't have to agree with what's said.*
   3. *Keep today's discussions private. What is said in this room should stay here.*
   4. *Remember that you can choose a 'fake' name for this discussion.*
   5. *Does anyone have any questions?*

[Administer survey questions]

(START THE RECORDER)

Ice-breaker: Let's begin by going around the table and have each person say their first name (fake or real) and then tell the group your **favorite place in Kinston**.

Section 1: Perception of Genomics

One of the terms some people may use when they talk about genetics and health is "**GENOMICS.**"

1. How many of you have ever heard of this term?

2. **(Moderator: Look for how many people raise their hands)**. It looks like we have _____ people who have raised their hand.

3. This may be a term that you may or may not have heard before. Now, if someone were to say the word "GENOMICS" to you, tell me what comes to your mind. What have you heard about it? **LIST**

For the rest of this discussion, I am going to share with you what we mean by Genomics so that we are all on the same page:
Genomics is a term that describes the study ofall of a person's genes (their genome) including how genes interact with each other and with the person's environment. This is different from genetics which is the study of a single gene in isolation. Think of genomics as a garden and genetics like a plant in your garden. If the plant is not flowering, you could study just the plant itself (genetics) or look at the surrounding to see if it is too crowded or there is not enough sun (genomics).

Genomics is……

1. What might be some **benefits or positive** things about genomics?

2. What might be some **drawbacks or negative** things about genomics?

3. On a scale of 1-10, (1=not at all important and 10=completely important), How important is genomics to your health?

   PROBE: Do you feel pre-determined or destined to get certain diseases like heart disease?

   PROBE: What factors might affect whether or not you get heart disease?

4. What changes, if any, would you make in your lifestyle if you knew you had inherited traits that increase your chances of getting heart disease?

Section 2: Safety and Security Concerns

1. If you were asked to participate in research that involves using your genetic make-up to develop better ways to detect, treat, and prevent things like heart disease, would you participate?

2. What things would you need to consider or would want to know about the study?

3. What are some things that would be helpful for you in making this decision?

4. How comfortable are you with the idea of medical researchers having your genetic information?

5. What safeguards or protections do you feel are necessary and appropriate for someone to participate in this kind of research study?

Section 3. Promotion

1. How should this study be advertised to the community?

2. If we put you in charge of getting the word out to others about this study, what would you do to make sure everyone knows about this?

PROBE: What would you say?

PROBE: Where would you put materials and messages?

Section: Closing

Based on our discussion today, what do you feel are two main things I should take back to our team?

Is there anything else you feel we did not cover that I need to know?

We would like to thank you for your time. Your answers have greatly helped us. If you have any questions about what we have done today, don't hesitate to call the phone number on the bottom of the consent form. We will be happy to talk with you about the study.

APPENDIX 4.4: DEMOGRAPHICS SURVEY

Patient Demographic Form

1. Gender
   - ☐ Male
   - ☐ Female

2. What is your age?

   ☐☐ Years

3. What ethnic group do you consider yourself?
   - ☐ Hispanic or Latino
   - ☐ Not Hispanic or Latino

4. What race do you consider yourself? [Mark all that apply.]
   - ☐ American Indian or Alaska Native
   - ☐ Asian
   - ☐ Black or African American
   - ☐ Native Hawaiian or Other Pacific Islander
   - ☐ White
   - ☐ unknown
   - ☐ refused

5. What is the highest level of education you have completed?
   - ☐ I never went to school
   - ☐ Some primary school (K-8)
   - ☐ Finished primary school (K-8)
   - ☐ Some high school (9-12)
   - ☐ Finished high school (9-12)
   - ☐ Some college
   - ☐ College degree
   - ☐ Graduate degree
   - ☐ Unknown
   - ☐ Other _____

6. Does anyone in your family have heart disease?
   - ☐ Yes
   - ☐ No
   - ☐ Don't know

7. How important is genetics to your overall health?
   - ☐ Not at all important
   - ☐ Somewhat important

- ☐ Mostly important
- ☐ Completely important

8. Do you have any kind of health care coverage, including private health insurance, prepaid plans such as HMOs, or government plans such as Health Check, Medicaid Program for Children, or NC Health Choice?

- ☐ Yes
- ☐ No

If yes, what is your primary health insurance plan? This is the plan which pays the medical bills first or pays most of the medical bills.

- ☐ The State Employee Health Plan
- ☐ Blue Cross/Blue Shield of North Carolina
- ☐ Other private health insurance plan purchased from an employer or directly from insurance company
- ☐ NC Health Choice
- ☐ Medicaid
- ☐ Carolina ACCESS
- ☐ Health Check
- ☐ South Care
- ☐ The military, CHAMPUS, TRI CARE or the VA
- ☐ The Indian Health Service
- ☐ Other
- ☐ Don't know/Not sure
- ☐ Refused

APPENDIX 4.5: FOCUS GROUPS CODEBOOK

Code-Filter: All

HU: PSO Genetics FG
File: [C:\Users\mvu\Documents\Scientific Software\ATLASti\TextBank\PS0 Genetics FG.hprS] Edited by: Admin
Date/Time: 2012-03-2109:21:27

Advertisement
Comfort Level
Communication
Factors Affecting Heart Disease
Final Thoughts
Genomics Benefits
Genomics Drawbacks
Genomics Perceptions
Importance Of Genomics
Knowledge
Knowledge Value
Lifestyle Changes
Participation
Placement
Perceived Control
Predetermination
Privacy
Promotion
Safeguards

APPENDIX 5: RETURN OF RESULTS PROTOCOL DEVELOPMENT MATERIALS

APPENDIX 5.1 EXAMPLE ADAPTED RETURN OF RESULTS PROTOCOL

Heart Healthy Lenoir

Return of Results

Participant ID _____

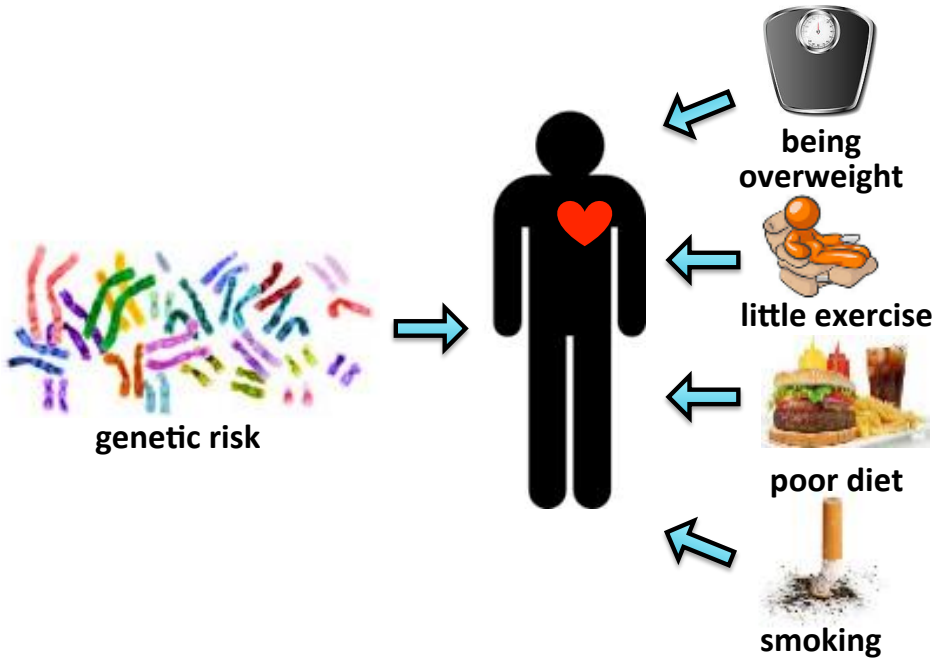
Most people have this DNA sequence: A C C G C T A T G G C G C T…

A few people have a SNP (small change): A C G G C T G T G G C G C T…

Single **N**ucleotide **P**olymorphism (SNP)

Participant ID _____

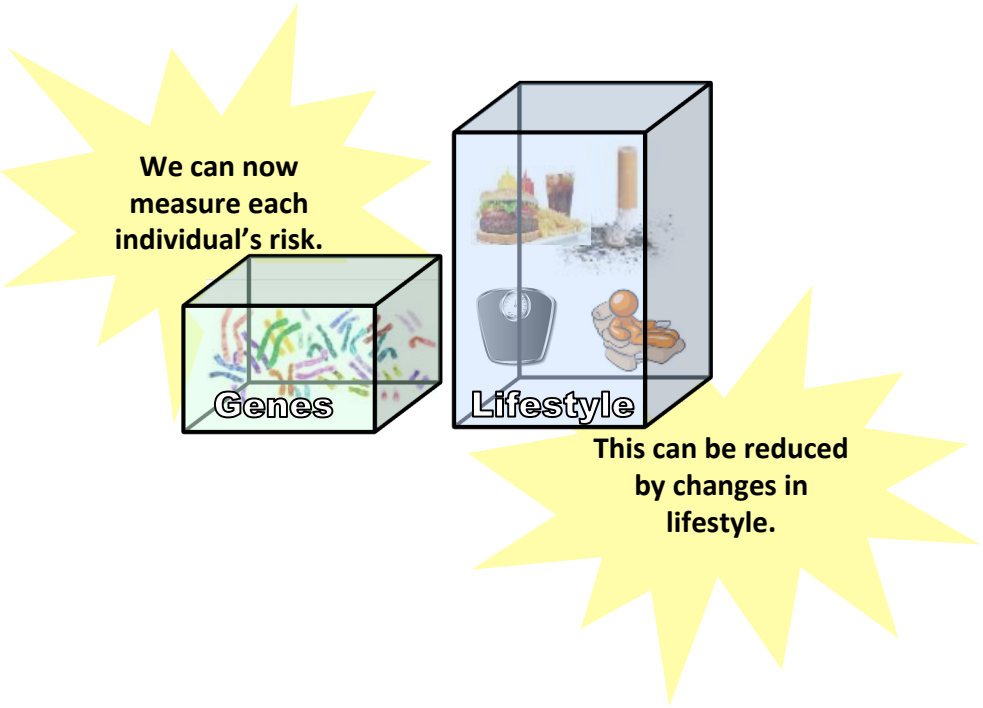
Your heart disease risk is made up of genetics and lifestyle choices.



2

Participant ID _____

Both genes and lifestyle choices contribute to your overall risk of developing heart disease.



3

Participant ID _____

Everybody has *some* risk of developing heart disease.

4

Participant ID _____

Gene Summary

SNP	Condition	Risk for Heart Disease Compared to Other African-Americans
rs10913469	BMI	<< high / average / low >>
rs2568958	BMI	<< high / average / low >>
rs29941	BMI	<< high / average / low >>
rs12970134	BMI / Weight	<< high / average / low >>
rs6499640	BMI / Weight	<< high / average / low >>
rs7561317	BMI / Weight	<< high / average / low >>
rs7647305	BMI / Weight	<< high / average / low >>
rs8050136	BMI / Weight	<< high / average / low >>
rs925946	BMI / Weight	<< high / average / low >>
rs10830963	Fasting plasma glucose	<< high / average / low >>
rs7903146	Type 2 diabetes	<< high / average / low >>
rs12740374*	LDL-C	<< high / average / low >>
rs3729639*	HDL-C	<< high / average / low >>
* Protective from heart disease		

Participant ID _____

Your genetic heart disease risk is ***average***

with the African-American population.

6

Participant ID _____

Summary

Item	Result
Genetic Testing	You are at << high / average / low >> genetic risk for heart disease • You have **xx** out of **13** possible small DNA changes tested in fifteen genes linked to higher risk for heart disease in a number of large studies.
Other Things About You that Raise Your Risk	• *<< insert CVD risk increasing factors>>*
Why This is Important	**Heart disease is the #1 cause of death in the U.S.** • North Carolina has a higher death rate than the US average. • Lenoir County has a higher death rate than the North Carolina average. • African-Americans have higher death rates in Lenoir County and across the U.S. compared to Caucasians. **BUT, heart disease can be delayed, or even prevented.**
What You Can Do to Lower Your Risk of Developing Heart Disease	Follow the prescription from Heart Healthy Lenoir.

7

Thank you!

For questions please contact:

Harlyn Skinner

hskinner@ad.unc.edu

252-643-5150

If you would like to speak with a genetic counselor, please contact Harlyn Skinner for an appointment with

Julianne O'Daniel, M.S., C.G.C.

The Return of Results Research Study is sponsored by UNC-CH, ECU, National Institutes of Health, and the Heart-Healthy Lenoir Community Advisory Committee.
This study was reviewed and approved by the University of North Carolina Institutional Review Board:
IRB # 14-1500

Nuts, Oils, Dressings, and Spreads | Tips

✔ Check the goals you want to work on for the next contact.

☐ **1. Choose nuts and nut butters often. Try to eat three or more servings each week.**

- Enjoy a variety of nuts (pecans, peanuts, walnuts, almonds, cashews) and nut butters, like peanut butter.
- A serving is a handful of nuts (one quarter cup or about one ounce) or two tablespoons of nut butter (about the size of a ping-pong ball).
- Try a peanut butter sandwich on whole grain bread, or peanut butter on celery or an apple. These can make a tasty lunch or snack!
- Unsalted or lightly salted nuts or all natural nut butters are good choices, but regular nuts and nut butters are also good choices.

☐ **2. Choose trans fat free margarine.**

- For spreads, trans fat free margarine is preferred because it contains healthy vegetable oil, but butter on occasion is okay.
- When you use margarine look for tub or squeeze margarines that say trans fat free.
- Don't use regular stick margarines, which are usually high in trans fats.

☐ **3. Use healthful toppings like trans fat free margarine or vegetable oil for bread and other foods. Aim for three or more servings per week.**

- Margarine that does not contain trans fat is a healthful choice for topping bread and other foods.
- Consider dipping bread in olive oil or a mix of olive oil and balsamic vinegar.

Continued ➔

Heart Healthy Lenoir Healthy Eating Tips can be found at: http://www.hearthealthylenoir.com/sites/default/files/imce/documents/HealthyEatingMaterials.pdf

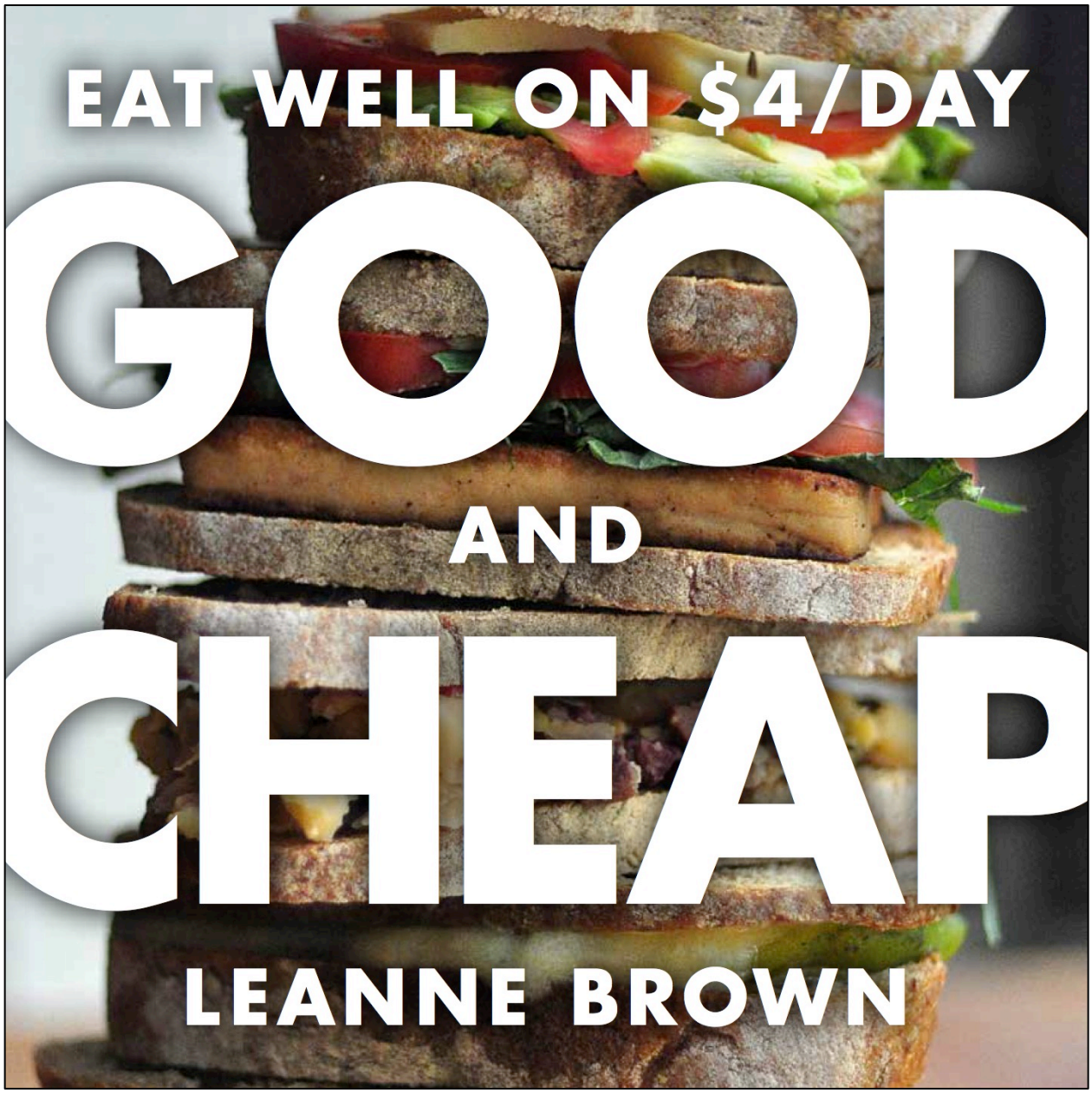
APPENDIX 5.2 KEYWORDS SHEET USED WITH RETURN OF RESULTS PROTOCOL

Key Words

SNP (**S**ingle **N**ucleotide **P**olymorphism): a small DNA change

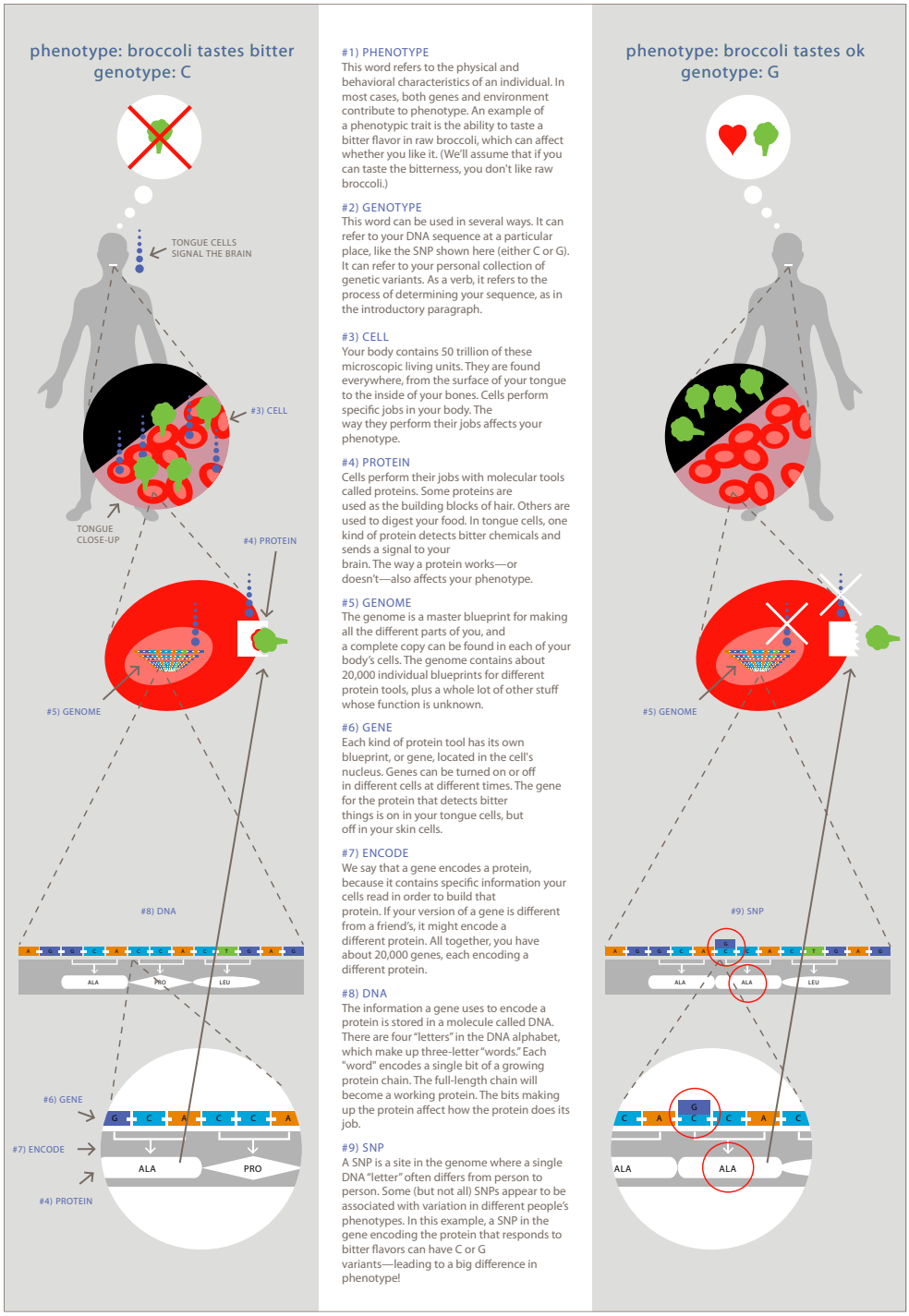
BMI (**B**ody **M**ass **I**ndex): a measure of body fat

APPENDIX 5.3 TAKE HOME MATERIALS WITH RETURN OF RESULTS PROTOCOL



key words for genetics

One of the phenotypes you will learn about when 23andMe genotypes you is whether you can taste a bitter flavor in raw broccoli. Some people's tongue cells make a protein that can detect bitter flavors; others make one that can't. Each of your cells contains a copy of your genome, which is made up of a molecule called DNA. Your genome contains genes, which are blueprints that encode proteins like the one made by your tongue cells. Different people can have different blueprints because of differences in their SNPs. There are two versions of the SNP shown here, and each leads to a different version of the gene, which in turn encodes a different version of the protein. One version of the protein can detect the bitter flavor of raw broccoli, while the other cannot.



#1) PHENOTYPE
This word refers to the physical and behavioral characteristics of an individual. In most cases, both genes and environment contribute to phenotype. An example of a phenotypic trait is the ability to taste a bitter flavor in raw broccoli, which can affect whether you like it. (We'll assume that if you can taste the bitterness, you don't like raw broccoli.)

#2) GENOTYPE
This word can be used in several ways. It can refer to your DNA sequence at a particular place, like the SNP shown here (either C or G). It can refer to your personal collection of genetic variants. As a verb, it refers to the process of determining your sequence, as in the introductory paragraph.

#3) CELL
Your body contains 50 trillion of these microscopic living units. They are found everywhere, from the surface of your tongue to the inside of your bones. Cells perform specific jobs in your body. The way they perform their jobs affects your phenotype.

#4) PROTEIN
Cells perform their jobs with molecular tools called proteins. Some proteins are used as the building blocks of hair. Others are used to digest your food. In tongue cells, one kind of protein detects bitter chemicals and sends a signal to your brain. The way a protein works—or doesn't—also affects your phenotype.

#5) GENOME
The genome is a master blueprint for making all the different parts of you, and a complete copy can be found in each of your body's cells. The genome contains about 20,000 individual blueprints for different protein tools, plus a whole lot of other stuff whose function is unknown.

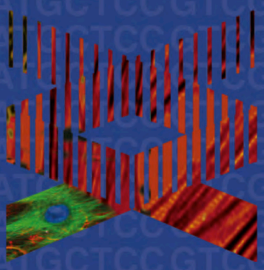
#6) GENE
Each kind of protein tool has its own blueprint, or gene, located in the cell's nucleus. Genes can be turned on or off in different cells at different times. The gene for the protein that detects bitter things is on in your tongue cells, but off in your skin cells.

#7) ENCODE
We say that a gene encodes a protein, because it contains specific information your cells read in order to build that protein. If your version of a gene is different from a friend's, it might encode a different protein. All together, you have about 20,000 genes, each encoding a different protein.

#8) DNA
The information a gene uses to encode a protein is stored in a molecule called DNA. There are four "letters" in the DNA alphabet, which make up three-letter "words." Each "word" encodes a single bit of a growing protein chain. The full-length chain will become a working protein. The bits making up the protein affect how the protein does its job.

#9) SNP
A SNP is a site in the genome where a single DNA "letter" often differs from person to person. Some (but not all) SNPs appear to be associated with variation in different people's phenotypes. In this example, a SNP in the gene encoding the protein that responds to bitter flavors can have C or G variants—leading to a big difference in phenotype!

A GUIDE TO YOUR GENOME



National Human Genome Research Institute

APPENDIX 5.4 PHASE 1 CONSENT FORM

University of North Carolina-Chapel Hill
Consent to Participate in a Research Study
Adult Participants – General
Consent Form for Participants (Phase 1) version 2

Consent Form Version Date: 10/21/14
IRB Study #14-1500
Title of Study: Heart Healthy Lenoir Study: Return of Results

Principal Investigator: Harlyn Skinner, MS
UNC-Chapel Hill Department: Nutrition
UNC-Chapel Hill Phone number: (919) 966-6088

Faculty Advisor: Alice Ammerman, DrPH, RD
UNC-Chapel Hill Department: Center for Health Promotion & Disease Prevention
UNC-Chapel Hill Phone number: 919-966-6082

Co-Investigators: Alice Ammerman, DrPH, RD; Tom Keyserling, MD; Jonathan Schisler, PhD; Jacquie Halladay, MD, MPH

Funding Source and/or Sponsor: National Institutes of Health
Study Contact telephone number: 252-643-5150
Study Contact email: hskinner@ad.unc.edu

About Heart Healthy Lenoir Return of Results
Introduction
We invite you to take part in this research project. This form tells you about the project so you can decide if you want to take part in it. If you do, it is fine to change your mind and withdraw from the study at any time. We think you will benefit from taking part in this study, but you may not, as the purpose of research studies is to gain new knowledge that may help others in the future. There also may be risks to being in a research project and these are noted on this form. It will not be a problem for your doctors or other health care providers if you do not take part in this study or if you start the project and then decide to stop taking part before it is done.

What is the purpose of this new part of the study?
Some participants have expressed interest in receiving their information from the Genomics study. So, we would like to give participants an opportunity to learn about some genomic variations that contribute to heart disease risk. We have searched the literature for genomic variations that have been shown to be associated with heart disease and its risk factor. We have identified 13 genomic variations that contribute to heart disease risk in African-Americans. Research has shown that giving people genomic risk information can affect their diet and exercise choices. We would like to know if genomic information affects people's choices about diet and exercise to reduce heart disease risk.

Our main goal is to try to understand the best way to give African-Americans information about genomic variations that contribute to heart disease risk. To do so, we have developed materials that provide information on genomic information and heart disease risk. We want to talk with African-Americans who live in Lenoir County to better understand their thoughts, feelings, and concerns about these materials. You are being asked to take part in this discussion group.

Taking part in this new part of the Study is Your Choice
Before you learn about the study, you should know that:

4. Your choice to be in the study is voluntary.
5. You may decide not to join the study.
6. If you choose to be in the study, you may stop at any time.

We want you to understand the details about the study so that you can make an informed choice about being in it. You will be given a copy of this consent form. Please ask questions if there is anything you do not understand.

How many people will take part in this phase of the study? In this study, we will talk to up to 40 African-American men and women who live in Lenoir County.

How long will your part in this phase of the study last? It should take about two hours to answer the questions. We will first speak to each person individually for about 30 minutes, then as a group for about one and a half hours.

What will happen if you take part in this phase of the study? First, you will review and sign this consent form. Then, there will be an individual and a group discussion. Both discussions will be audiotaped so we can capture comments to help improve our materials. You will not be identified on the tapes and discussion information will not be shared with anyone but the research staff.

First, a member of our research team will speak with you individually. You'll take a brief survey then we'll present our materials and ask your thoughts about them. Then we will gather everyone as a group to ask the group their thoughts about the materials. A member of our research team will lead the group discussion, which should last no more than one and a half hours. The group will be asked some questions about what they find unclear, what they would change, and how to make our materials easier to understand. In the group session, no questions will be directed to you individually, but instead will be posed to the group. You may choose to respond or not respond at any point during the discussion.

What are the possible benefits from being in this phase of the study? Research like this helps others by making clear how we can best help men and women like you. You may not benefit directly from this study.

What are the possible risks or discomforts involved this phase of the study? You should not have any discomfort from being in this study. We think you will be at ease answering the questions we will ask you. Although we will be careful to protect your privacy; loss of privacy is

a potential risk of being in this study. Also, there is always a chance of unknown risks. You should report any problems to the research staff.

How will your privacy be protected? To make sure what you say is confidential, you can use a different name during the group session so that others who take part in this group, who do not already know you, will not know your real name. Also, what other people say during the discussions is confidential, so you should not share anything you hear or see in the group with people outside the group. Your name will not appear on the transcript from the tape recording. Instead, we will make up and use an ID number. The key that links your name and ID number and the study data we collect from you will be stored in a locked file cabinet and/or password protected computer. The tape recording of the discussion session will be promptly transferred to a password-protected computer and will be erased from storage in the tape recorder.

Will you receive anything for being in this phase of the study? You will receive a $30 gift card for taking part in this study.

Will it cost you anything to be in this this phase study? It is free for you to be in this study, other than your costs to travel to the meeting site or childcare if needed.

What if you have questions about this study? You have the right to ask and have answered any questions you may have about this research. If you have questions, or concerns, you should contact Harlyn Skinner, MS (252-643-5150; hskinner@ad.unc.edu). She is the leader of this project and will be happy to answer your questions.

What if you have questions about your rights as a research participant?
All human research is reviewed by a group of people that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the Institutional Review Board at the UNC-Chapel Hill at 919-966-3113 or by email to IRB_subjects@unc.edu.

Title of Study: Heart Healthy Lenoir Study: Return of Results

Principal Investigator: Harlyn Skinner, MS
Faculty Advisor: Alice Ammerman, DrPH, RD

Participant's Agreement: I have read the information above. I have had all of my questions answered.

☐ By placing a check here, I agree that the researchers may call me by phone to see if I am willing to take part in the follow-up study of the return of genomic information to study participants. (If you check yes, we will ask for your phone number.)

By signing this form, I agree to be in the study. If I decide I do not want my information to be used, I will tell you in writing.

Signature of participant Date

Printed name of participant

Signature of person obtaining consent Date

Printed name of person obtaining consent

APPENDIX 5.5 PHASE 1 RECRUITMENT BROCHURE

Heart-Healthy
Lenoir
Return of Results
Research Study
Focus Groups
Participant Brochure

Heart-Healthy Lenoir Return of Results Research Project: This project's goal is to understand how people respond to genomic risk information.

1. What is this study all about?
Some people wanted to know their heart disease risk results from Heart Healthy Lenoir. This study aims to learn what people think about their genomic risk information for heart disease. But first, we need help refining our materials to return risk information.

2. Who can participate?
African-American participants from Heart Healthy Lenoir.

3. How many people can join?
Up to 40 people.

4. How long does the study last?
The study lasts for 1 month.

5. What happens if I decide to participate?
If you decide to participate, we will ask you to:

- Sign a consent form, saying you agree to participate in the project
- Attend 1 focus group for 2 hours to
  - Answer a 1-2 minute survey
  - Speak individually about our materials
  - Speak in a focus group about our materials

6. How can I enroll in the study?
- A study team member will give you a call to see if you're interested.

OR

- Call the study office to say you're interested.

252-643-5150

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

CPHHD
CENTERS FOR POPULATION HEALTH AND HEALTH DISPARITIES
http://cancercontrol.cancer.gov/cphhd/

East Carolina UNIVERSITY

7. When do the Return of Results Focus Groups start?
- Study enrollment begins July 2014.
- Study appointments will begin to be scheduled in July 2014.

8. What will it cost me?
The program is free, but travel costs to and from the study office are not covered.

9. Will I be paid to be in this study?
You will be paid for your time completing the study visit. You will receive:
- $30 gift card for completing the focus group (120 minutes).

10. Are there any possible benefits to joining?
We think you'll enjoy taking part in the discussion. You will help us understand how people respond to receiving genomic risk information about heart disease.

11. Where can I get more information?
Contact Harlyn Skinner, at hskinner@ad.unc.edu or call 252-643-5150

www.hearthealthylenoir.com

The Return of Results Research Study is sponsored by UNC-CH, ECU, National Institutes of Health, and the Heart-Healthy Lenoir Community Advisory Committee.
This study was reviewed and approved by the University of North Carolina Institutional Review Board: IRB # 14-1500

APPENDIX 5.6 PHASE 1 STRUCTURED "COGNITIVE" INTERVIEW AND FOCUS GROUP PROTOCOL

Procedures

Participants will be greeted by the moderator and/or note taker upon their arrival. They will be asked to sign-in and they will be encouraged to help themselves to refreshments while we wait for participants to arrive. The session will begin 10 minutes after participants are asked to arrive. Should a participant arrive late, the note taker will assist the participant in checking in and getting settled.

Note: Each individual interviewer should have a folder ready with this script, the REAL-G, pens, and a ROR script for participants. Each folder will be labeled with the participant's ID number.

Introduction

Good (morning/afternoon/evening). My name is _____ and I'll be leading our discussion today. This is (*introduce other research staff*). First thank you for taking time to join us. The purpose of this discussion is to hear your thoughts and opinions about a program we're planning to help African-Americans understand their personalized risk for heart disease. Today, we'd like to learn more about the best ways to talk about 13 small DNA changes that contribute to heart disease risk. Specifically, we are interested in creating a final product that has language and phrasing that everyone can connect to.

This session should last about two hours. First we'll talk to you individually for thirty minutes. We'll present our materials and get your initial impressions. Then we'll gather everyone together for a group discussion for about an hour and a half. There, we'll speak more in-depth about the materials. At the end of the group discussion you will receive a Wal-Mart gift card for $30 for your time.

We'll be audiotaping both parts of our discussion for report writing purposes. Everything you say is important to us and we want to make sure we don't miss any of your comments. However, I want to assure you that all of your comments are confidential and that nothing you say will be connected with your name.

Before we begin, I can take your consent forms from you if you have them. You would have received it as part of the packet that was mailed to you. If you don't have it, I have a copy here you can sign and extra copies in case anyone wants to take another one home.

Moderator Instructions: Collect consent forms and place them in the dedicated consent forms folder.

Now we're going to break into our individual sessions. We'd like you to experience this like you were a participant in our proposed study. A research team member will take you to a private area and give you made-up individual results about your risk for heart disease from the Heart Healthy Lenoir study. We *have not* looked at any of your personal information. We made things up to give you the experience of being in our proposed study. When we come back together as a

group, we'll talk about your experience getting "your" results and your opinions about our presentation of the information.

Individual Interview

Hi. My name is _____ and I appreciate your time to be here today. Today, I'm going to have you take a brief survey, and then I'll give you some made-up individual results like you were a participant in our proposed study. Our meeting today should take about 30 minutes. Feel free to ask me questions along the way. I also have a pen for you to write notes for things to discuss with the group later. I'll ask you about your overall impressions at the end.

I'd like to tape our discussion today. Is it OK to start the recorder now?

You'll hear me say a series of numbers that will allow us to identify you without me saying your name. I do that to maintain your confidentiality. And again, *none* of the results I'm talking about after I start the recorder are real; they are *completely* made-up.

Interviewer Instruction: Start recorder and state participant number, initials of interviewers, date, and time.]

Now I'm going to give you a survey that looks at people's level of comfort with medical jargon. This survey is to help us figure out the best type of materials to develop. The survey only takes 1-2 minutes to do.

Interviewer Instruction: Hand participant REAL-G questionnaire

I want to hear you read as many words as you can from this list. Begin with the first word and read aloud. When you come to a word you cannot read, do the best you can or say "pass" and go on to the next word.

Note: If the participant takes more than five seconds on a word say "It's okay to pass" and point to the next word, if necessary, to move the participant along. If the participant begins to miss every word; have him/her pronounce only known words.

Thank you. Again, that is to help us figure out the best type of materials to develop.

Now, I'm going to give you individual heart disease risk results from Heart Healthy Lenoir. I also have a written copy here for you to keep.

Interviewer Instruction: Read return of results script. Turn the pages of the participant's copy as well as yours.

That is the end of the script! Before we go back to the group, I have just one question.

Take out 1 – 9 scale sheet. Record participant answer on notes page.

Q1. On a scale of 1-9, (1=completely unclear and 9=completely clear), how understandable is the information in this document?

Thank you very much for your time. We'll gather together in the main office now for the group discussion.

Encourage participants to help themselves to refreshments while we wait for all participants finish their interviews.

Focus Group Introduction

Welcome back! For this part of our discussion I'd like to go through our materials more in-depth. This part will last about an hour and a half. Please feel free to excuse yourself anytime if you need to use the restroom (describe location). Once we're done with our discussion you will receive your gift card to Wal-Mart as a thank you for your time.

Before we start the tape, I'd like to go over a few ground rules that will help everything go more smoothly. We want this to be an open discussion and for everyone to have the chance to share their opinions or experiences.

6. Talk one at a time.
7. Be respectful of others. You don't have to agree with what's said.
8. Keep today's discussions private. What is said in this room should stay here.
9. Remember that you can choose a 'fake' name for this discussion.

Does anyone have any questions before we get started?

Part A: General Impressions

I'd like everyone to get acquainted a bit. Let's go around the room and everyone give me a first name and one word to describe your experience receiving the genetic information. (Q1)

Q2. Could anyone expand on that?

Probe(s): What were your thoughts and feelings when you got the information?
What things made you feel positive about the experience?
What things made you feel negative about the experience?
What do you find repetitive?
What needed more explaining?

Part B: Breaking Down the Script

Now I'm going to give you a copy of our script so you can help us with the wording. This is your opportunity to tell me *everything* I need to change.

The first page is an introduction to the idea of looking at genetics for small DNA changes, or SNPs.

Interviewer Instruction: Read first page of return of results script.

Q3. What other background information about SNPs do you want before the discussion?

Q4. We've tried to use non-technical terms to explain things. What words do you find to be jargon or that we need to do a better job explaining?

Q5. I also wanted to ask you about a few specific words:

a. Genetic. How can we make the use of that word more clear?

b. SNP. How can we make the use of that phrase clearer?
c. Variant. We've used the phrase "small DNA change" or "changes" instead. Does that phrase make the conversation clearer?

Let's move to Page 2.

Interviewer Instruction: Read second page of return of results script.

Q6. What did you understand the message to be from this page?

Probe(s): My goal was to talk about the factors that contribute to heart disease. How could that message be clearer?
What things did you find repetitive or in need of more explanation?
What would you change about the picture?

Let's move to Page 3.

Interviewer Instruction: Read third page of return of results script.

Q7. What did you understand the message to be from this page?

Probe(s): My goal was to talk about how genetics and lifestyle choices contribute to heart disease. How could that message be clearer?
What things did you find repetitive or in need of more explanation?
What would you change about the picture?

Let's move to Page 4.

Interviewer Instruction: Read four page of return of results script.

Q8. What did you understand the message to be from this page?

Probe(s): My goal was to talk about lifestyle contributions to heart disease risk. How could that message be clearer?
What things did you find repetitive or in need of more explanation?
What would you change about the picture?

Let's move to Pages 5 & 6.

Interviewer Instruction: Read five and six page of return of results script.

Q9. What did you understand the message to be from these pages?

Probe(s): My goal was to talk about genetic contributions to heart disease. How could that message be clearer?

What things did you find repetitive or in need of more explanation?
What would you change about the picture?

Let's move to Page 7.

Interviewer Instruction: Read seven page of return of results script.

Q10. What did you understand the message to be from these pages?

Probe(s): My goal was to talk summarize your risk of heart disease, why it's important, and
what you can do. How could that message be clearer?
What things did you find repetitive or in need of more explanation?
What would you change about the picture?

Let's move to next pages.

These pages are designed to remind you of your personal goals and to remind about the tips on how to eat better to reduce your heart disease risk.

Q11. How effective is it to end the discussion with these tips? Do you think there is a better way to end the conversation?

Let's move to the last page.

On the last page, I've given you my contact information and told you a genetic counselor is available.

Q12. What sorts of questions do you still have after having this discussion?

Probe(s): Would you want to speak to the genetic counselor?
What sorts of questions would you ask her?

Interviewer instructions: Hand out NHGRI *A Guide to Your Genome*. Give them a minute to flip through it.

We are also considering including a publication from the National Institutes of Health on understanding your genome for participants to take home.

Q13. Do you think this would be helpful to take home? How so?

Part C: Recruitment

For this last section, I'd like to ask how your opinions about how you would like to be recruited into this study. We're planning on inviting African-Americans from Heart Healthy Lenoir to enroll in our study to get their genetic information.

Q14. How should we describe the study to you to peak your interest?

Probe(s): What questions would you like answered about the risks and benefits of this
study before you participate?
Would you like to be contacted by mail or phone?

Q15. Are there any last comments or suggestions anyone would like to make?

Thank you very much for your time. We appreciate you coming out to share your thoughts with us. (Name of note taker) will give you each a gift card for $30 for your participation today.

APPENDIX 5.7 RAPID ESTIMATE OF ADULT LITERACY IN GENETICS

RAPID ESTIMATE OF ADULT LITERACY IN GENETICS (REAL-G)

Erby, L.H. et al. (2008). The rapid estimate of adult literacy in genetics (REAL-G): a means to assess literacy deficits in the context of genetics. *American Journal American Journal of Medical Genetics*; 146A(2): 174-181.

Focus Group No. _____

Participant # _____

Date _____

Time _____

Interviewer ID _____

List	
Genetic	
Sporadic	
Mutation	
Variation	
Chromosome	
Hereditary	
Abnormality	
Susceptibility	
# of (+) Responses:	

LEGEND: (+) = Correct (—) = Word not attempted (/) = Mispronounced word

List
Genetic
Sporadic
Mutation
Variation
Chromosome
Hereditary
Abnormality
Susceptibility

APPENDIX 6: RANDOMIZED CONTROLLED TRIAL SUPPLEMENTAL MATERIALS

APPENDIX 6.1: CONTROL GROUP MATERIALS

A. SCRIPT

Introduction

Hi. My name is _____ and I appreciate you taking the time to be here today. Today, we're going to talk about health and wealth, take a brief survey, and then schedule your next appointment. Our meeting should take about 45 minutes. Feel free to ask me questions along the way. I also have a pen for you to write notes for yourself if you'd like.

Do you have any questions before we get started?

I'd like to tape our discussion today. Is it OK to start the recorder now?

Interviewer Instruction: Start recorder and state participant number, initials of interviewers, date, and time.] (E.g. 001, CF, Nov 15, 10am)

Part A: Are Health and Wealth Related?

Q1. What does economic empowerment look like for people in Lenoir County?

Probes: What does that phrase make you think of?
How would you define it?

Here we have some maps of North Carolina. I've stared Lenoir County on each map. The first map is people living in poverty. The second map is the obesity rate. The third map is preventable heart disease deaths.

Q2. Why are people in Lenoir county poor?

Q3. How do you think money and health are related?

Probes: Looking at the maps, what comes to mind?

Q4. How is stress and money related in your life?

Q5. What are some ways to increase individual, family, and community wealth?

Ideas: Money management and budgeting
Getting out of debt and saving
Buying a home
Education and training for better jobs
Starting a business
Becoming involved in the political system.

Part B: Values

Here is a list of values some people think are important.

Interviewer Instruction: Have participant mark the three most important to them.

Q6. Of these values, which are the three most important to you?
Q7. What do these values mean to you?
Q8. How might these values relate to your life and financial goals?

Part C: Saving / Budgeting / Creating Assets / Credit

Today we're going to talk about economic empowerment and how that fits with your most important values. We can talk about saving, budgeting, creating assets, or credit. What's of interest to you today?

Interviewer Instruction: Remind the participant that these topics all related to money and health buy you are asking them to choose the one to emphasize.

Part C-1: Saving

Interviewer Goal: Begin a discussion about the importance of saving. Identify potential reasons for not saving and items that require savings by using the discussion questions below. This should lead into a discussion on the importance of saving (i.e.: having money in emergency situations)

Q1. What ways were you taught to save?

Probes: Who taught you to save? Parents, grandparents, etc
Were you ever taught to save?

Q2. What have you saved money for in the past?

Interviewer Instruction: Show participants simple ways for them to continue saving by discussing the "saving tips" worksheet.

Q3. What are some ways you could save money?

Having a saving account can also help you build wealth. For example, if you save $70 a month, you will have $840 at the end of the year.

Interviewer Instruction:
- Use the "Different types of savings accounts" page to talk about the options of saving.
- Use "Why keep your money in a bank?" to help explain the real benefit of a savings account—how your money can grow!
  - Give an example of when your money does not grow (i.e. when you put $1000 in your closet for a year)
- Have participants use what they have learned to fill out the "Pay Yourself First Action Plan" worksheet.

Q3. What is one piece of advice you would give to your children about the importance of savings, and how to save?

Interviewer Instruction: Skip to Part D.

Part C-2: Budgeting

Interviewer Goal: Talk about budgeting in relation to a recipe.

Creating a budget is like a recipe. Our income is the sum of the ingredients, your expenses are the quantities to use, and a recipe or budget are both how you put it all together. If you add too much flour or spend too much on something, the final product or your income will not work out.

There are four steps to preparing a budget.

Step 1: Keep track of your daily spending.

Interviewer Instruction: Discuss “Daily Spending Diary”.

Step 2: Determine what your monthly income and expenses are the month before they are due.

Interviewer Instruction: Discuss “Monthly Income and Expense” and “Monthly Payment Schedule” worksheets

Step 3: Find ways to decrease spending.

Interviewer Instruction: Discuss “Tips to Help You Decrease Spending" handout.

Q1. What are some different budgeting techniques that have worked for you?

Interviewer Instruction: Fill out “My ideas for decreasing spending”

Step 4: Find ways to increase income.

This last sheet is a few more ideas to help you budget.

Interviewer Instruction: Discuss “Other Budgeting Tools" handout.

Interviewer Instruction: Skip to Part D.

Part C-3: Creating Assets

Interviewer Goal: Lead a discussion on the importance of having a savings account and how it can guild wealth.

Q1. What does wealth mean to you?
Probe(s): Can you give me an example?

Q2. I have a definition here of wealth as when "the value of the things you own is greater than the amount of money you owe (assets)". What are your thoughts on that?

Q3. What are some assets that don't help generate wealth?

Q4. What are some assets that do contribute to wealth?

Interviewer Instruction: Discuss examples of wealth creating assets (i.e. house, retirement plan, savings account) as well as assets that don't contribute to wealth (i.e. car, stereo, clothes).

Q5. What is a benefit of saving money in a bank?

Having a saving account can help you build wealth. For example, if you save $70 a month, you will have $840 at the end of the year.

Interviewer Instruction:
- Use the "Different types of savings accounts" page to talk about the options of saving.
- Use "Why keep your money in a bank?" to help explain the real benefit of a savings account—how your money can grow!
  - Give an example of when your money does not grow (i.e. when you put $1000 in your closet for a year)
- Have participants use what they have learned to fill out the "Pay Yourself First Action Plan" worksheet.

Coming back to the idea of assets, some debt can also help you build wealth.

Q6. What are some examples where debt is good?

Q7. What are some examples where debt is bad?

Interviewer Instruction:
- Discuss debt and use "Not all debt is bad debt" to demonstrate cases in which debt is contributing positively to your future!
- Talk about increasing your assets through home ownership. Discuss 3 ways in which investing in a home can help you financially by referring to "Using Home Equity to Build Wealth."

Interviewer Instruction: Skip to Part D.

Part C-4: Credit

Interviewer Goal: Lead a discussion on credit and debt

Q1. What does having credit mean to you?
Probes: Is it good or bad to have credit?

Q2. Would you say you have good or bad credit? Why?

Q3. Sometimes you can have too much debt, which could make your credit bad. Do you think you are in too much debt?

Interviewer Instruction: Use the "15 signs of debt trouble" handout to have a discussion on how to tell if you could be in too much debt.

It's important to stay out of debt and have a good credit history.

Interviewer Instruction: Use the "Tips for Building Your Credit History" handout to talk about ways to build one's credit history

You can find out if your credit is good or bad with a credit report.

Interviewer Instruction: Use the "What is a Credit Report" handout to discuss the importance of a credit report, what it is used for, how to get one and how to read one

Interviewer Instruction: Skip to Part D.

Part D: Financial Goals

There are two types of goals: Life and Financial.
1). Life: This type includes things like getting an education, improving job skills, getting out of debt, or starting business.
2.) Financial: This type includes things like saving money, budgeting, creating assets, or improving your credit.

We're going to talk about financial goals today.

Q1. Now that we've talked some about finances, what hopes do you have for your finances?

Q2. Why are these important to you?

Q3. In order to live out these hopes, what do you need to do?

You can help work towards those hopes by setting a goal.

Interviewer Instruction:
- Use "Setting Goals" to discuss setting goals.

SMART goals can help you figure out and reach your goals.

Interviewer Instruction:
- Use "How to Increase the Success Rate of Your Goals" to introduce SMART Goals.
- Just mention the detailed SMART goals rules. They can read them on their own time.
- Review the example SMART goal.

This next page gives you more information on exactly how to set a SMART goal. Let me give you an example of one.

Interviewer Instruction: Review the example SMART goal.

Setting a financial goal to work toward using these guidelines will help you become economically empowered. I'm going to give you a copy of the Financial Goal Tip sheets and planning worksheets so you can create your own SMART goal at home.

The handouts from the other topics we didn't discuss today are also in this book for you to read on your own time.

Q4. Do you have any questions for me?

Part E: Ending

Thank you so much for taking the time to let me talk with you today. I'm going to ask you to take one last quick survey, and then we'll get you scheduled for your next visit.

APPENDIX 6.2 GENOTYPING METHODS

Dr. Schisler, primary investigator for the HHL Genomics Study, and his laboratory team at the medical school of the University of North Carolina, Chapel Hill performed whole genome genotyping as a part of the HHL Genomics Study. The following is a description of study procedures for HHL Genomics.

Three milliliters of whole blood were obtained from fasted participants at HHL Genomics study entry. DNA was extracted from circulating leukocytes using a single monophasic reagent containing a chaotropic cell disrupter and a noncorrosive phenol free extraction reagent (DNA STAT-60, Tel-Test) as described by Alcorta, Preston and Munger.[267] DNA aliquots were maintained in a dedicated, locked ultra-low freezer at -80°C. Total genomic DNA (500 ng) was processed with standard Illumina reagents and protocols, and hybridized to a Human Omni-Express Exome BeadChip.

The Human Omni-Express Exome BeadChip measures > 700,000 SNPs derived from previous generation arrays, the HapMap project, with representation on chromosomes X and Y, mitochondrial SNPs, known regions of copy number variation, recombination hotspot SNPs, and > 240,000 exonic variants. This chip captures 73% of CEU variation and 40% of YRI variation (MAF > 5% compared against the June 2011 1kGP data release, $r^2 > 0.8$). The Illumina platform has a high level of quality control through the use of three pre-hybridization checkpoints as well as Quality Control probes on the array. The Human Omni-Express Exome BeadChip was used in conjunction with the Illumina® GenomeStudio software, which allowed automated quality control that sorts samples by quality control call rate, visualization of quality control metrics across samples, SNP cluster visualization and signature SNP list for tracking. Flexible SNP filter and export are also included to enable downstream analysis.

Before performing the genetic analyses, the data were examined from each group individually for population substructure to ensure that variation was negligible. Identification of local elements associated with selected variables (either categorical-such as ancestry, or continuous-such as BMI, blood pressure, etc.) including outcome of treatment regimens was performed with logistical or linear modeling tools, respectively, in the software package R. For a given gene, all SNPs within 10 kb of the untranslated region were tested. Each SNP was tested by grouping the selected variable level based on the genotype, and assuming an additive relationship between number of 'B' alleles and the variable of interest, using the two-sided Cochran-Armitage trend test.[268-271] This combination may have inflated the theoretical number of false positives from the model. In order to minimize bias, the regression analysis was repeated after randomizing the gene-SNP pairs. After 100 such randomizations the permuted statistics were compared to actual statistics in order to estimate the empirical false discovery rate at each theoretical p-value threshold. This permutation procedure was specific for identifying local-acting SNPs since it assumes no distant-acting SNPs, and thus was a conservative estimate in the presence of the potential selection bias.

APPENDIX 6.2.1A: FINE-MAPPING AND ADMIXTURE PAPERS REVIEWED

A. BMI

- Gong J, Schumacher F, Lim U, Hindorff LA, Haessler J, Buyske S, et al. Fine mapping and identification of BMI loci in African Americans. The American Journal of Human Genetics 2013;93(4):661-671.
- Liu C-T, Monda KL, Taylor KC, Lange L, Demerath EW, Palmas W, et al. Genome-wide association of body fat distribution in African ancestry populations suggests new loci. PLoS Genet 2013;9(8):e1003681.
- Locke AE, Kahali B, Berndt SI, Justice AE, Pers TH, Day FR, et al. Genetic studies of body mass index yield new insights for obesity biology. Nature 2015;518(7538):197-206.
- Monda KL, Chen GK, Taylor KC, Palmer C, Edwards TL, Lange LA, et al. A meta-analysis identifies new loci associated with body mass index in individuals of African ancestry. Nature genetics 2013;45(6):690-696.
- Peters U, North KE, Sethupathy P, Buyske S, Haessler J, Jiao S, et al. A systematic mapping approach of 16q12. 2/FTO and BMI in more than 20,000 African Americans narrows in on the underlying functional variation: results from the Population Architecture using Genomics and Epidemiology (PAGE) study. PLoS Genet 2013;9(1):e1003171.

B. DYSLIPIDEMIA

- Carlson CS, Matise TC, North KE, Haiman CA, Fesinmeyer MD, Buyske S, et al. Generalization and dilution of association results from European GWAS in populations of non-European ancestry: the PAGE study. PLoS biology 2013;11(9):e1001661.
- Teslovich TM, Musunuru K, Smith AV, Edmondson AC, Stylianou IM, Koseki M, et al. Biological, clinical and population relevance of 95 loci for blood lipids. Nature 2010;466(7307):707-713.

C. T2DM

- Cheng C-Y, Reich D, Haiman CA, Tandon A, Patterson N, Elizabeth S, et al. African ancestry and its correlation to type 2 diabetes in African Americans: a genetic admixture analysis in three US population cohorts. PloS one 2012;7(3):e32840.
- Haiman CA, Fesinmeyer MD, Spencer KL, Bůžková P, Voruganti VS, Wan P, et al. Consistent Directions of Effect for Established Type 2 Diabetes Risk Variants Across Populations The Population Architecture using Genomics and Epidemiology (PAGE) Consortium. Diabetes 2012;61(6):1642-1647.
- Hasstedt SJ, Highland HM, Elbein SC, Hanis CL, Das SK. Five linkage regions each harbor multiple type 2 diabetes genes in the African American subset of the GENNID Study. Journal of human genetics 2013;58(6):378-383.

- Jeff JM, Armstrong LL, Ritchie MD, Denny JC, Kho AN, Basford MA, et al. Admixture Mapping and Subsequent Fine-Mapping Suggests a Biologically Relevant and Novel Association on Chromosome 11 for Type 2 Diabetes in African Americans. PloS one 2014;9(3):e86931.
- Long J, Edwards T, Signorello LB, Cai Q, Zheng W, Shu X-O, et al. Evaluation of genome-wide association study-identified type 2 diabetes loci in African Americans. American journal of epidemiology 2012;176(11):995-1001.
- McCormack S, Grant SF. Genetics of obesity and type 2 diabetes in African Americans. Journal of obesity 2013;2013.
- Ng MC, Saxena R, Li J, Palmer ND, Dimitrov L, Xu J, et al. Transferability and Fine Mapping of Type 2 Diabetes Loci in African Americans The Candidate Gene Association Resource Plus Study. Diabetes 2013;62(3):965-976.
- Palmer ND, McDonough CW, Hicks PJ, Roh BH, Wing MR, An SS, et al. A genome-wide association search for type 2 diabetes genes in African Americans. PloS one 2012;7(1):e29202.
- Saxena R, Elbers CC, Guo Y, Peter I, Gaunt TR, Mega JL, et al. Large-scale gene-centric meta-analysis across 39 studies identifies type 2 diabetes loci. The American Journal of Human Genetics 2012;90(3):410-425.
- Waters KM, Stram DO, Hassanein MT, Le Marchand L, Wilkens LR, Maskarinec G, et al. Consistent association of type 2 diabetes risk variants found in europeans in diverse racial and ethnic groups. PLoS genetics 2010;6(8):e1001078.

D. BLOOD PRESSURE

- Fox ER, Young JH, Li Y, Dreisbach AW, Keating BJ, Musani SK, et al. Association of genetic variation with systolic and diastolic blood pressure among African Americans: the Candidate Gene Association Resource study. Human molecular genetics 2011;20(11):2273-2284.
- Franceschini N, Fox E, Zhang Z, Edwards TL, Nalls MA, Sung YJ, et al. Genome-wide association analysis of blood-pressure traits in African-ancestry individuals reveals common associated genes in African and non-African populations. The American Journal of Human Genetics 2013;93(3):545-554.
- Hall JL, Duprez DA, Barac A, Rich SS. A review of genetics, arterial stiffness, and blood pressure in African Americans. Journal of cardiovascular translational research 2012;5(3):302-308.
- Nguyen K-DH, Pihur V, Ganesh SK, Rakha A, Cooper RS, Hunt SC, et al. Effects of Rare and Common Blood Pressure Gene Variants on Essential Hypertension Results From the Family Blood Pressure Program, CLUE, and Atherosclerosis Risk in Communities Studies. Circulation research 2013;112(2):318-326.
- Shetty PB, Hua T, Bamidele T, Morrison AC, Hanis CL, Rao DC, et al. Variants in CXADR

and F2RL1 are associated with blood pressure and obesity in African-Americans in regions identified through admixture mapping. Journal of hypertension 2012;30(10):1970.

- Studies ICfBPG-WA. Genetic variants in novel pathways influence blood pressure and cardiovascular disease risk. Nature 2011;478(7367):103-109.
- Zhu X, Cooper RS. Admixture mapping provides evidence of association of the VNN1 gene with hypertension. PLoS One 2007;2(11):e1244.

E. CVD

- Lettre G, Palmer CD, Young T, Ejebe KG, Allayee H, Benjamin EJ, et al. Genome-wide association study of coronary heart disease and its risk factors in 8,090 African Americans: the NHLBI CARe Project. PLoS genetics 2011;7(2):1-11.
- Tekola-Ayele F, Adeyemo AA, Rotimi CN. Genetic epidemiology of type 2 diabetes and cardiovascular diseases in Africa. Progress in cardiovascular diseases 2013;56(3):251-260.
- Zhang L, Buzkova P, Wassel CL, Roman MJ, North KE, Crawford DC, et al. Lack of associations of ten candidate coronary heart disease risk genetic variants and subclinical atherosclerosis in four US populations: the Population Architecture using Genomics and Epidemiology (PAGE) study. Atherosclerosis 2013;228(2):390-399.

F. SMOKING

- David S, Hamidovic A, Chen G, Bergen A, Wessel J, Kasberger J, et al. Genome-wide meta-analyses of smoking behaviors in African Americans. Translational psychiatry 2012;2(5):1-8.
- Hamidovic A, Goodloe RJ, Bergen AW, Benowitz NL, Styn MA, Kasberger JL, et al. Gene-centric analysis of serum cotinine levels in African and European American populations. Neuropsychopharmacology 2011;37(4):968-974.
- Han S, Yang BZ, Kranzler HR, Oslin D, Anton R, Gelernter J. Association of CHRNA4 polymorphisms with smoking behavior in two populations. American Journal of Medical Genetics Part B: Neuropsychiatric Genetics 2011;156(4):421-429.

APPENDIX 6.2.1.B: LIST OF POTENTIAL SNPS

TABLE 7. GWAS SIGNIFICANT SNPS FROM FINE-MAPPING AND ADMIXTURE STUDIES

SNP	Phenotype	Gene	Chromosome Region	$p \leq 5x10^{-8}$	Reference
rs543874	BMI	SEC16B	1q25	$2.00x10^{-13}$	Monda 2013[53]
rs7586879	BMI	ADCY3	2	$3.60x10^{-08}$	Monda 2013[53]
rs348495	BMI	GNPDA2	4p12	$1.60x10^{-10}$	Monda 2013[53]
rs17817964	BMI	FTO	16q12	$1.05x10^{-10}$	Monda 2013[53]
rs6567160	BMI	MC4R	18q21	$2.96x10^{-11}$	Monda 2013[53]
rs7708584	BMI, WC (unadjusted to BMI)	GALNT10	5q33	$3.37x10^{-11}$	Monda 2013[53]
rs629301	LDL	SORT1	1	$2.00x10^{-14}$	Teslovich 2010[56]
rs3764261	HDL	CETP	16	$3.00x10^{-18}$	Teslovich 2010[56]
rs16942887	HDL	LCAT	16	$1.00x10^{-10}$	Teslovich 2010[56]
rs6511720	LDL	LDLR	19	$5.00x10^{-08}$	Teslovich 2010[56]
rs3764261	HDL	CETP	16	$5.91x10^{-28}$	Carlson 2013[55]
rs6511720	LDL	LDLR	19	$7.05x10^{-24}$	Carlson 2013[55]
rs646776	LDL	CELSR2/PSRC1/SORT1	1p13.3	$1.48x10^{-12}$	Carlson 2013[55]
rs3135506	HDL, TG	APOA1; APOA1/C3/A4/A5 cluster	11	$2.02x10^{-10}$	Carlson 2013[55]
rs7903146	T2DM	TCF7L2	10	$3.98x10^{-10}$	Carlson 2013[55]
rs328	HDL	LPL	8	$2.55x10^{-08}$	Carlson 2013[55]
rs543874	BMI	SEC16B	1q25.2	$2.40x10^{-09}$	Gong 2013[50]
rs116612809	BMI, BMI adjusted for TG	BRE	2p23.2	$3.60x10^{-08}$	Gong 2013[50]
rs10474346	DBP	GPR98/ARRDC3	5	$3.56x10^{-08}$	Fox 2011[44]
rs2258119	SBP	C21orf91	21	$4.69x10^{-08}$	Fox 2011[44]
rs437470	SBP	CXADR	21q21	$4.00x10^{-04}$*	Shetty 2012[69]
rs437470	DBP	CXADR	21q21	$6.00x10^{-04}$*	Shetty 2012[69]
rs2036527	Smoking (cigarettes smoked per day)	CHRNA5	15q25.1	$1.84x10^{-08}$	David 2012[42]

* A GWAS significant p in this study is $9.8x10^{-4}$

TABLE 8. CANDIDATE SNPS FROM FINE-MAPPING AND ADMIXTURE STUDIES

SNP	Phenotype	Gene	Chromosome Region	$p \leq 1x10^{-6}$	Reference
rs10261878	BMI, WC (unadjusted to BMI)	MIR148A-NFE2L3	7p15	$4.57x10^{-07}$	Monda 2013[53]
rs974417	BMI, WC (unadjusted to BMI)	KLHL32	6q16	$6.88x10^{-08}$	Monda 2013[53]
rs10938397	BMI	GNPDA2	4	$1.81x10^{-08}$	Monda 2013[53]
rs7138803	BMI	FAIM2	12	$4.37x10^{-06}$	Monda 2013[53]
rs1558902	BMI	FTO	16	$2.69x10^{-07}$	Monda 2013[53]
rs1320330	BMI	TMEM18	2	$2.05x10^{-06}$	Monda 2013[53]
rs10501087	BMI	BDNF	11	$2.51x10^{-07}$	Monda 2013[53]
rs1558902	BMI	FTO	16	$2.69x10^{-07}$	Monda 2013[53]
rs2075064	WC adjusted for BMI	LHX2	9	$6.50x10^{-08}$	Liu 2013[51]
rs6931262	WHR adjusted for BMI	RREB1	6	$5.70x10^{-08}$	Liu 2013[51]
rs6867983	WC (unadjusted for BMI)	MAP3K1	5	$2.70x10^{-07}$	Liu 2013[51]
rs7601155	WC (unadjusted for BMI)	BRE	2	$4.90x10^{-07}$	Liu 2013[51]
rs10894604	WHR adjusted for BMI	OPCML	11	$7.70x10^{-07}$	Liu 2013[51]
rs17213965	WHR adjusted for BMI	MYH11	16	$1.30x10^{-06}$	Liu 2013[51]
rs2570467	WC (unadjusted for BMI)	PCSK1	5	$2.10x10^{-06}$	Liu 2013[51]
rs11777345	WHR adjusted for BMI	CSMD1	8	$4.80x10^{-06}$	Liu 2013[51]
rs4730779	WC adjusted for BMI	ASZ1	7	$6.30x10^{-06}$	Liu 2013[51]
rs6739392	WHR adjusted for BMI	ETAA1	2	$6.20x10^{-06}$	Liu 2013[51]
rs1345301	WC (unadjusted for BMI)	IL1RL2; IL1RL1	2	$7.90x10^{-06}$	Liu 2013[51]
rs1294410	WHR adjusted for BMI	LY86	6	$1.80x10^{-06}$	Liu 2013[51]
rs737337	HDL	LOC55908	19	$6.00x10^{-06}$	Teslovich 2010[56]
rs56137030	BMI	FTO	16q12.2	$8.30x10^{-06}$	Peters 2013[54]
rs6548240	BMI	TMEM18	2p25.3	$1.10x10^{-07}$	Gong 2013[50]
rs6548238	BMI	TMEM18	2p25.3	$3.80x10^{-07}$	Gong 2013[50]
rs2867125	BMI	TMEM18	2p25.3	$5.60x10^{-06}$	Gong 2013[50]
rs10938397	BMI	GNPDA2	4p12	$1.70x10^{-07}$	Gong 2013[50]
rs2744475	BMI	TFAP2B	6p12.3	$2.80x10^{-06}$	Gong 2013[50]
rs1519480	BMI	BDNF	11p14.1	$7.80x10^{-07}$	Gong 2013[50]
rs62048402	BMI	FTO	16q12.2	$5.10x10^{-06}$	Gong 2013[50]
rs1421085	BMI	FTO	16q12.2	$6.50x10^{-06}$	Gong 2013[50]
rs6567160	BMI	MC4R	18q21.32	$4.70x10^{-06}$	Gong 2013[50]
rs114584581	BMI, BMI adjusted for TG	BRE	2p23.2	$5.90x10^{-08}$	Gong 2013[50]
rs74941130	BMI, BMI adjusted for TG	BRE	2p23.2	$6.90x10^{-08}$	Gong 2013[50]

rs79329695	BMI, BMI adjusted for TG	BRE	2p23.2	$3.70x10^{-08}$	Gong 2013[50]
rs4802349	BMI, HDL adjusted for BMI, BMI adjusted for HDL	DHX34	19q13.32	$1.20x10^{-07}$	Gong 2013[50]
rs17428471	SBP	EVX1-HOXA	7	$1.40x10^{-04}$	Franceschini 2013[66]
rs1401454	SBP	SOX6	11	$9.70x10^{-04}$	Franceschini 2013[66]
rs1401454	DBP	SOX6	11	$5.00x10^{-03}$	Franceschini 2013[66]
rs1990151	SBP	IPO13	1	$7.39x10^{-07}$	Fox 2011[44]
rs13413144	SBP	FMNL2	2	$5.55x10^{-07}$	Fox 2011[44]
rs592582	SBP	GPD2	2	$4.46x10^{-07}$	Fox 2011[44]
rs1858309	DBP	GPR98	5	$8.76x10^{-08}$	Fox 2011[44]
rs7709572	DBP	GPR98	5	$7.41x10^{-08}$	Fox 2011[44]
rs7724489	DBP	GPR98	5	$1.17x10^{-07}$	Fox 2011[44]
rs243601	SBP	C21orf91	21	$2.61x10^{-07}$	Fox 2011[44]
rs243603	SBP	C21orf91	21	$3.91x10^{-07}$	Fox 2011[44]
rs243605	SBP	C21orf91	21	$3.83x10^{-07}$	Fox 2011[44]
rs243607	SBP	C21orf91	21	$1.99x10^{-07}$	Fox 2011[44]
rs243609	SBP	C21orf91	21	$4.41x10^{-07}$	Fox 2011[44]
rs2220511	SBP	C21orf91	21	$4.68x10^{-07}$	Fox 2011[44]
rs12408339	SBP	RHBG	1	$8.64x10^{-06}$	Fox 2011[44]
rs214070	SBP	NUCB2	11	$8.65x10^{-06}$	Fox 2011[44]
rs6511018	SBP	SLC25A42	19	$5.83x10^{-06}$	Fox 2011[44]
rs12985799	SBP	SLC25A42	19	$3.24x10^{-06}$	Fox 2011[44]
rs2012318	SBP	SLC25A42	19	$6.42x10^{-06}$	Fox 2011[44]
rs11666627	SBP	SLC25A42	19	$3.00x10^{-06}$	Fox 2011[44]
rs10417974	SBP	SLC25A42	19	$3.71x10^{-06}$	Fox 2011[44]
rs11187065	Smoking (serum cotinine)	IDE	10	$8.91x10^{-06}$	Hamidovic 2012[74]
rs667282	Smoking (cigarettes smoked per day)	CHRNA5	15	$1.81x10^{-07}$	David 2012[42]
rs3101457	Smoking (cigarettes smoked per day)	C1orf100	1q44	$2.63x10^{-07}$	David 2012[42]
rs938682	Smoking (cigarettes smoked per day)	CHRNA3	15	$3.75x10^{-07}$	David 2012[42]
rs547843	Smoking (cigarettes smoked per day)	LOC503519	15q12	$6.16x10^{-07}$	David 2012[42]
rs3813570	Smoking (cigarettes smoked per day)	PSMA4	15	$9.85x10^{-07}$	David 2012[42]
rs1678618	Smoking (age of smoking initiation)	SPOCK2	10q22.1	$8.25x10^{-07}$	David 2012[42]
rs1245577	Smoking (age of smoking initiation)	SPOCK2	10q22.1	$8.30x10^{-07}$	David 2012[42]
rs1612028	Smoking (age of smoking initiation)	SPOCK2	10q22.1	$9.28x10^{-07}$	David 2012[42]

APPENDIX 6.3: OUTCOME MEASURES

A. BASELINE SURVEYS

9832385895 **Return of Results**
Baseline Information

1 / 9

ENR1 v. 1.0

Section A:

Date enrolled: ☐☐ / ☐☐ / 2 0 1 ☐
month *day* *year*

Form completed by:
○ participant only
○ interviewer only → Interviewer ID: ☐☐
○ both

Section B: About You

RAPID ESTIMATE OF ADULT LITERACY IN GENETICS (REAL-G)*

Now I'm going to give you a survey that looks at people's level of comfort with medical jargon. This survey is to help us figure out the best type of materials to develop. The survey only takes 1-2 minutes to do.

	correct	*mispronounced word*	*word not attempted*
1. Genetic	○	○	○
2. Sporadic	○	○	○
3. Mutation	○	○	○
4. Variation	○	○	○
5. Chromosome	○	○	○
6. Hereditary	○	○	○
7. Abnormality	○	○	○
8. Susceptibility	○	○	○

*Erby, L.H. et al. (2008). The rapid estimate of adult literacy in genetics (REAL-G): a means to assess literacy deficits in the context of genetics. American Journal American Journal of Medical Genetics; 146A(2): 174-181.

Developed by the Data Capture Services Unit in the UNC-CH Center for Health Promotion & Disease Prevention
www.hpdp.unc.edu/services/datacapture

Section C: Health

I'm going to start by asking you some questions about your health right now and your current daily activities. Please try to answer every question as accurately as you can.

1. In general, would you say your health is:

   ○ excellent ○ very good ○ good ○ fair ○ poor

*The following two questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?*

2. **moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf:

   ○ yes, limited a lot ○ yes, limited a little ○ no, not limited at all

3. climbing **several** flights of stairs:

   ○ yes, limited a lot ○ yes, limited a little ○ no, not limited at all

*During the **past 4 weeks**, have you had any of the following problems with your work or other regular activities **as a result of your physical health**?*

4. **accomplished less** than you would like:

   ○ yes ○ no

5. were limited in the **kind** of work or other activities:

   ○ yes ○ no

*During the **past 4 weeks**, were you limited in the kind of work you do or other regular activities **as a result of any emotional problems** (such as feeling depressed or anxious)?*

6. **accomplished less** than you would like:

   ○ yes ○ no

7. didn't do work or other activities as **carefully** as usual:

○ yes ○ no

8. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

○ not at all ○ a little bit ○ moderately ○ quite a bit ○ extremely

*The next few questions are about how you feel and how things have been **during the past 4 weeks.** For each question please give the one answer that comes closest to the way you have been feeling.*

*How much of the time during the **past 4 weeks . . .***	***all of the time***	***most of the time***	***a good bit of the time***	***some of the time***	***a little of the time***	***none of the time***
9. have you felt calm and peaceful?	○	○	○	○	○	○
10. did you have a lot of energy?	○	○	○	○	○	○
11. have you felt downhearted and blue?	○	○	○	○	○	○
12. During the **past 4 weeks**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)	○	○	○	○	○	○

*How much of the time during the **last month** have you . . .*	***all of the time***	***most of the time***	***a good bit of the time***	***some of the time***	***a little of the time***	***none of the time***
13. been a very nervous person?	○	○	○	○	○	○
14. felt so down in the dumps that nothing could cheer you up?	○	○	○	○	○	○
15. been a happy person?	○	○	○	○	○	○

Section D: Genetic Testing

Now I'd like to talk about genetics. Genetics is a term that describes the study of a single gene in isolation. Think of genetics like a plant. If the plant is not flowering, you could study the plant (genetics) to see if there's a problem (genetic testing). I'm going to ask you a few questions about your experience with genetic testing now.

1. Have you ever had a genetic test? (It's usually a blood test) *[Mark only one.]*

   - ○ no
   - ○ yes--just one time
   - ○ yes--more than one time
   - ○ not sure

   1a. If yes, what kind of genetic test was performed?

   _____

2. Have you ever had genetic counseling from someone who talked to you about possible genetic causes of health problems, such as how genes are inherited in families? *[Mark only one.]*

   - ○ no
   - ○ yes--just one time
   - ○ yes--more than one time
   - ○ not sure

   2a. If yes, what was the health concern that led you to genetic counseling?

   _____

3. Has anyone else in your family had genetic testing or counseling? *[Mark only one.]*

   - ○ no
   - ○ yes
   - ○ not sure

Section E: Health Behaviors

In this part, I'm going to ask you about a few health-related behaviors like diet. Thinking about your eating habits over the **past month**, about how often do you eat each of the following foods? Remember breakfast, lunch, dinner, snacks and eating out

	less than 1/WEEK	*once a WEEK*	*2-3 times a WEEK*	*4-6 times a WEEK*	*once a DAY*	*2+ a DAY*
1. Fruit juice, like orange, apple, grape, fresh, frozen or canned (not sodas or other drinks)	○	○	○	○	○	○
2. How often do you eat any fruit, fresh or canned (not counting juice)?	○	○	○	○	○	○
3. Vegetable juice like tomato juice, V-8, or carrot	○	○	○	○	○	○
4. Green salad	○	○	○	○	○	○
5. Potatoes, any kind, including baked, mashed or french fried	○	○	○	○	○	○
6. Vegetable soup, or stew with vegetables	○	○	○	○	○	○
7. Any other vegetables, including string beans, peas, corn, broccoli or any other kind	○	○	○	○	○	○
8. Fiber cereals like Raisin Bran, Shredded Wheat or Fruit-n-Fiber	○	○	○	○	○	○
9. Beans such as baked beans, pinto, kidney, or lentils (not green beans)	○	○	○	○	○	○
10. Dark bread such as whole wheat or rye	○	○	○	○	○	○

Section F: Neighborhood Physical Activity Questionnaire

Walking

Now I'd like to ask you about two types of walking: walking for transportation (e.g., to the store or work), then walking for recreation, health and fitness. If the walking that you do for transportation is also for recreation, health or fitness, please tell me about it only once.

For example:

Linda lives 20 minutes away from work. She chooses to walk there rather than drive mainly because she wants to improve her fitness. If Linda says that she walks for transportation (3 times per week for a total of 120 minutes), she would not repeat that information under walking for recreation, health or fitness.

1. In a **usual week**, do you walk to get to or from somewhere (such as walking to a store or bus stop) or for recreation, health or fitness (including walking your dog)?

   ○ yes ○ no

Walking for Transportation

2. In a **usual week**, how many times do you walk **as a means of transportation**, such as going to and from work, walking to the store, or walking to a bus stop?

   ☐☐ ➔ ***if 0, skip to Q. 5***
   times

3. Please estimate the total time you spend walking as a **means of transportation** in a **usual week**. (e.g., 5 times by 10 minutes = 50 minutes)

   ☐☐ ***hours*** ☐☐☐ ***minutes***

4. Let me know which of the following places you walk to as a **means of transportation** in a **usual week**. *[Mark all that apply.]*

   ☐ to or from work (or study)
   ☐ to or from bus stop
   ☐ to or from store
   ☐ to or from restaurant
   ☐ to or from friend's house
   ☐ other place #1 ➔ _____
   ☐ other place #2 ➔ _____

Walking for Recreation, Health or Fitness:

If you have already reported recreational walking, please do not report it again for the following questions.

5. In a **usual week**, how many times do you walk for **recreation, health** or **fitness** (including walking your dog)?

☐☐ *times* ➔ ***if 0, skip to Other Leisure Time Physical Activities***

6. Please estimate the total time you spend walking for **recreation, health** or **fitness** in a **usual week**. (e.g., 5 times by 10 minutes = 50 minutes)

☐☐ *hours* ☐☐☐ *minutes*

7. Could you tell me where you walk for **recreation, health** or **fitness** in a **usual week**? *[Mark all that apply.]*

- ☐ park
- ☐ neighborhood
- ☐ school
- ☐ to or from restaurant
- ☐ to or from a store
- ☐ fitness center
- ☐ other place #1 ➔ _____
- ☐ other place #2 ➔ _____

Other Leisure Time Physical Activities

The next set of questions is about **other leisure time physical activities** that you do in a **usual week**, besides what you have already mentioned. Do not include walking.

8. In a **usual week**, do you do any other vigorous or moderate intensity leisure time physical activities? Do not include any walking.

○ yes ○ no ➔ ***Skip Section G***

9. Could you tell me where you do these leisure time physical activities in a **usual week**?
[Mark all that apply.]

☐ park
☐ neighborhood
☐ school
☐ fitness center
☐ other place #1 ➔ _____
☐ other place #2 ➔ _____

10. In a **usual week**, do you do any vigorous intensity leisure time physical activities like jogging, aerobics, swimming laps, or competitive tennis? Do not include walking or moderate intensity physical activities. Vigorous intensity physical activities cause a large increase in breathing and heart rate.

○ yes ○ no ➔ ***if no, skip Q. 13***

11. In a **usual week**, how many times do you do vigorous intensity leisure time physical activities which cause a large increase in breathing and heart rate?

☐☐ ***times*** ➔ ***if 0, skip to Q. 13***

12. What do you estimate is the total time you spend doing vigorous intensity leisure time physical activities in a **usual week**.
(e.g., 3 times by 20 minutes = 60 minutes)

☐☐ ***hours*** ☐☐☐ ***minutes***

13. Apart from what you have already mentioned, in a **usual week** do you do any other moderate intensity leisure time physical activities like dancing, cycling, social tennis, golf, or gardening? Moderate intensity physical activities cause a moderate increase in breathing and heart rate.

○ yes ○ no ➔ ***if no, skip to Section G***

14. In a **usual week**, how many times do you do moderate intensity leisure time physical activities which cause a moderate increase in breathing and heart rate?

☐☐ ***times***

15. What do you estimate is the total time you spend doing moderate intensity leisure time physical activities in a **usual week**?
(e.g., 1 time for 1 hour = 1 hour)

☐☐ ***hours*** ☐☐☐ ***minutes***

Section G: Dealing with Numbers

Now I'd like to know how comfortable you are dealing with numbers. Some people are more comfortable than others. For each of the following questions, please choose the answer that best reflects ***how good you are at doing the following things:***

1. How good are you at working with fractions?

not at all good					***extremely good***
○	○	○	○	○	○

2. How good are you at working with percentages?

not at all good					***extremely good***
○	○	○	○	○	○

3. How good are you at calculating a 15% tip?

not at all good					***extremely good***
○	○	○	○	○	○

4. How good are you at figuring out how much a shirt will cost if it is 25% off?

not at all good					***extremely good***
○	○	○	○	○	○

5. How **often** do you find numerical information to be useful?

never					***very often***
○	○	○	○	○	○

4019143967

Return of Results
PMT1 Survey

PMT1 v. 1.0

Date: ☐☐ / ☐☐ / 2 0 1 ☐
month *day* *year*

Section A

Now I'll read a list of things some people do after learning new information. ***Thinking about how you feel right now****, how motivated are you to…*

	a lot less motivated	*a little less motivated*	*no change in motivation*	*a little more motivated*	*a lot more motivated*
1. Eat more fruits and vegetables	○	○	○	○	○
2. Eat more fish and lean meat rather than meats that are high in fat	○	○	○	○	○
3. Eat more fiber in your diet	○	○	○	○	○
4. Eat fast food less often	○	○	○	○	○
5. Reduce sugar in your diet	○	○	○	○	○
6. Eat a special diet that might help manage your health	○	○	○	○	○
7. Get more exercise or be more physically active	○	○	○	○	○
8. Spend less time sitting or being sedentary (like when you're watching TV or using a computer)	○	○	○	○	○
9. Move closer to family who can help take care of you as you get older	○	○	○	○	○
10. Reduce stress in your everyday life	○	○	○	○	○
11. Try new methods for relaxing, such as meditation, progressive relaxation, or	○	○	○	○	○
12. Get more sleep	○	○	○	○	○
13. Drink less alcohol or stop drinking it	○	○	○	○	○
14. If you smoke, quit smoking	○	○	○	○	○
15. Is there anything else you feel motivated to do or to stop doing?	○ yes ➔ ☐ ○ no				

Developed by the Data Capture Services Unit in the UNC-CH Center for Health Promotion & Disease Prevention
www.hpdp.unc.edu/services/datacapture

Section B

Now I'd like to talk to you about heart disease. People think different things about heart disease. We would like to know what you think.

	not at all serious	*slightly serious*	*somewhat serious*	*moderately serious*	*very serious*
1. How serious a threat to health is heart disease?	○	○	○	○	○

	not at all strong	*slightly strong*	*somewhat strong*	*moderately strong*	*very strong*
2. My chances of developing heart disease in the future are:	○	○	○	○	○

3. What is the *percent chance* that you will develop heart disease in the next 10 years?

○ 0% ○ 10% ○ 20% ○ 30% ○ 40% ○ 50% ○ 60% ○ 70% ○ 80% ○ 90% ○ 100%

	strongly disagree	*disagree*	*neither agree or disagree*	*agree*	*strongly agree*
4. My financial security would be endangered if I got heart disease.	○	○	○	○	○
5. I believe that heart disease would be a very serious illness for me to develop.	○	○	○	○	○
6. If I had heart disease, my whole life would change.	○	○	○	○	○
7. If I got heart disease, it would be more serious than other diseases.	○	○	○	○	○
8. Heart disease would endanger my marriage (or a significant relationship).	○	○	○	○	○
9. If I had heart disease my career would be endangered.	○	○	○	○	○
10. Heart disease is a hopeless disease.	○	○	○	○	○
11. My feelings about myself would change if I got heart disease.	○	○	○	○	○
12. Problems I would experience from heart disease would last a long time.	○	○	○	○	○
13 I am unlikely to develop heart disease in the future.	○	○	○	○	○

Section C

In Heart Healthy Lenoir, we talked about a healthy eating plan. Healthy eating means eating more:
- Healthy fats. Healthy fats are fats such as those found in vegetable oils, nuts, and fish.
- Fruits and vegetables.
- Whole grains such as whole wheat bread and brown rice.

And eating less:
- Unhealthy fats. Unhealthy fats are trans fats that are found in some baked goods, packaged snack foods, band fried foods at restaurants.
- Processed meats like bacon, hot dogs, and cold cuts.
- Foods with added sugar and salt-like, sugar-sweetened beverages and some prepared foods.

*Thinking about **that healthy eating plan**, please answer the following questions.*

	strongly disagree	***disagree***	***neither agree or disagree***	***agree***	***strongly agree***
1. Healthy eating is effective in preventing heart disease.	○	○	○	○	○
2. The benefits of following the healthy eating plan outweigh the costs.	○	○	○	○	○
3. I have the time to follow the healthy eating plan to prevent heart disease.	○	○	○	○	○
4. I would be discouraged from following at least one of the steps of the healthy eating plan during the next week because I would feel silly doing so.	○	○	○	○	○
5. If I follow the healthy eating plan, I am less likely to get heart disease.	○	○	○	○	○
6. Following at least one of the steps of the healthy eating plan during the next week would cause me too many problems.	○	○	○	○	○
7. I am able to follow the healthy eating plan to prevent getting heart disease.	○	○	○	○	○
8. Healthy eating works in preventing heart disease.	○	○	○	○	○
9. I would be discouraged from following at least one of the steps of the healthy eating plan during the next week as it would take too much time.	○	○	○	○	○
10. I can easily follow the healthy eating plan to prevent heart disease.	○	○	○	○	○

Section D

In Heart Healthy Lenoir, we talked about walking as aerobic physical activity. The program recommended walking briskly for 150 minutes a week. This would be about 30 minutes of walking on five days of the week. This can be divided into ten-minute segments of walking.

*Thinking about **that recommendation**, please answer the following questions.*

	strongly disagree	*disagree*	*neither agree or disagree*	*agree*	*strongly agree*
1. I would be discouraged from taking at least one 30-minute walk during the next week as it would take too much time.	○	○	○	○	○
2. I would be discouraged from taking at least one 30-minute walk a week because I would feel silly doing so.	○	○	○	○	○
3. Walking for 30 minutes a day is effective in preventing heart disease.	○	○	○	○	○
4. Walking for 30 minutes a day works in preventing heart disease.	○	○	○	○	○
5. If I walk for 30 minutes a day, I am less likely to get heart disease.	○	○	○	○	○
6. I am able to walk 30 minutes a day to prevent getting heart disease.	○	○	○	○	○
7. I have the time to walk for 30 minutes a day to prevent heart disease.	○	○	○	○	○
8. I can easily walk for 30 minutes a day to prevent heart disease.	○	○	○	○	○
9. The benefits of taking at least one 30-minute walk a week outweigh the costs.	○	○	○	○	○
10. Taking at least one 30-minute walk during the next week would cause me too many problems.	○	○	○	○	○

Section E

These questions are again about your thoughts about heart disease.

The thought of developing heart disease makes me feel:

	not at all	*slightly*	*somewhat*	*mosderately*	*very*
1. Frightened	○	○	○	○	○
2. Anxious	○	○	○	○	○
3. Worried	○	○	○	○	○
4. Scared	○	○	○	○	○

Section F

	strongly disagree	*disagree*	*neither agree or disagree*	*agree*	*strongly agree*
1. If someone is meant to get a serious disease, it doesn't matter what kinds of food they eat, they will get that disease anyway.	○	○	○	○	○
2. I will get diseases if I am unlucky.	○	○	○	○	○
3. If someone is meant to get a serious disease, they will get it no matter what they do.	○	○	○	○	○
4. Everything that can go wrong for me does.	○	○	○	○	○
5. If someone gets a serious disease, that's the way they were meant to die.	○	○	○	○	○
6. My health is a matter of luck.	○	○	○	○	○
7. If someone is meant to have a serious disease, they will get that disease.	○	○	○	○	○
8. I will have a lot of pain from illness.	○	○	○	○	○
9. If someone has a serious disease and gets treatment for it, they will probably still die from it.	○	○	○	○	○
10. How long I live is a matter of luck.	○	○	○	○	○

	strongly disagree	disagree	neither agree or disagree	agree	strongly agree
11. If someone was meant to have a serious disease, it doesn't matter what doctors and nurses tell them to do, they will get the disease anyway.	○	○	○	○	○
12. I will suffer a lot from bad health.	○	○	○	○	○
13. How long I live is predetermined.	○	○	○	○	○
14. I will stay healthy if I am lucky.	○	○	○	○	○
15. I will die when I am fated to die.	○	○	○	○	○
16. I often feel helpless in dealing with the problems of life.	○	○	○	○	○
17. My health is determined by fate.	○	○	○	○	○
18. Sometimes I feel that I'm being pushed around in life.	○	○	○	○	○
19. My health is determined by something greater than myself.	○	○	○	○	○
20. There is really no way I can solve some of the problems I have.	○	○	○	○	○

6264475756

Return of Results
STOFHLA

1 / 4

STOF1 v. 1.0

Date: ☐☐ / ☐☐ / 2 0 1 ☐
month *day* *year*

Instructions

Here are some other medical instructions that you or anybody might see around the hospital. These instructions are in sentences that have some of the words missing. Where a word is missing, a blank line is drawn, and 4 possible words that could go in the blank appear just below it. I want you to figure out which of those 4 words should go in the blank, which word makes the sentence make sense. When you think you know which one it is, fill in the bubble next to that word and then go on to the next one. When you finish the page, turn the page and keep going until you finish all the pages.

Stop at the end of 7 minutes

Start time: ☐☐ : ☐☐ ○ a.m. ○ p.m.

Interviewer: ☐☐

Stop time: ☐☐ : ☐☐ ○ a.m. ○ p.m.

QC done by: ☐☐ *UNC to review?* ○ yes ● no

Developed by the Data Capture Services Unit in the UNC-CH Center for Health Promotion & Disease Prevention
www.hpdp.unc.edu/services/datacapture

Passage A: X-ray Preparation

Your doctor has sent you to have a _____ X-ray. You must have an _____ stomach

○ stomach	○ asthma
○ diabetes	○ empty
○ stitches	○ incest
○ germs	○ anemia

when you come for _____ . The X-ray will _____ from 1 to 3 _____ to do.

○ is	○ take	○ beds
○ am	○ view	○ brains
○ if	○ talk	○ hours
○ it	○ look	○ diets

The Day Before the X-ray

For supper have only a _____ snack of fruit, _____ and jelly, with coffee or tea.

○ little	○ toes
○ broth	○ throat
○ attack	○ toast
○ nausea	○ thigh

After _____ , you must not _____ or drink anything at _____ until **after**

○ minute	○ easy	○ ill
○ midnight	○ ate	○ all
○ during	○ drank	○ each
○ before	○ eat	○ any

you have _____ the X-ray.

- ○ are
- ○ has
- ○ had
- ○ was

The Day of the X-ray

Do not eat _____ . Do not _____ , even _____ .

○ appointment	○ drive	○ heart
○ walk-in	○ drink	○ breath
○ breakfast	○ dress	○ water
○ clinic	○ dose	○ cancer

If you have any _____ ,call the X-ray _____ at 616-4500.

○ answers	○ Department
○ exercises	○ Sprain
○ tracts	○ Pharmacy
○ questions	○ Toothache

Passage B: Medicaid Rights & Responsibilities

I agree to give correct information to _____ if I can receive Medicaid. I _____ to provide

○ hair	○ agree
○ salt	○ probe
○ see	○ send
○ ache	○ gain

the county information to _____ any statements given in this _____ and hereby

○ hide	○ emphysema
○ risk	○ application
○ discharge	○ gallbladder
○ prove	○ relationship

give permission to the _____ to get such proof. I _____ that for Medicaid I must report

○ inflammation	○ investigate
○ religion	○ entertain
○ iron	○ understand
○ county	○ establish

any _____ in my circumstances within _____ (10) days of becoming _____ of the change.

○ changes	○ three	○ award
○ hormones	○ one	○ aware
○ antacids	○ five	○ away
○ charges	○ ten	○ await

I understand _____ if I **do not** like the _____ made on my case,

○ thus	○ marital
○ this	○ occupation
○ that	○ adult
○ than	○ decision

I have the _____ to a fair hearing. I can _____ a hearing by writing or _____

○ bright	○ request	○ counting
○ left	○ refuse	○ reading
○ wrong	○ fail	○ calling
○ right	○ mend	○ smelling

the county where I applied. If you _____ TANF for any family _____ , you will have to

○ wash	○ member
○ want	○ history
○ cover	○ weight
○ tape	○ seatbelt

_____ a different application form. _____ ,we will use the _____

○ relax	○ Since	○ lung
○ break	○ Whether	○ date
○ inhale	○ However	○ meal
○ sign	○ Because	○ pelvic

on this form to determine your _____ .

- ○ hypoglycemia
- ○ eligibility
- ○ osteoporosis
- ○ schizophrenia

B. POST-TEST SURVEY

2978258876

Return of Results
PMT2 Survey

PMT2 v. 1.0

Date: ☐☐ / ☐☐ / 2 0 1 ☐
month *day* *year*

Section A

Now I'll read a list of things some people do after learning new information. ***Thinking about how you feel right now****, how motivated are you to…*

	a lot less motivated	*a little less motivated*	*no change in motivation*	*a little more motivated*	*a lot more motivated*
1. Eat more fruits and vegetables	○	○	○	○	○
2. Eat more fish and lean meat rather than meats that are high in fat	○	○	○	○	○
3. Eat more fiber in your diet	○	○	○	○	○
4. Eat fast food less often	○	○	○	○	○
5. Reduce sugar in your diet	○	○	○	○	○
6. Eat a special diet that might help manage your health	○	○	○	○	○
7. Get more exercise or be more physically active	○	○	○	○	○
8. Spend less time sitting or being sedentary (like when you're watching TV or using a computer)	○	○	○	○	○
9. Move closer to family who can help take care of you as you get older	○	○	○	○	○
10. Reduce stress in your everyday life	○	○	○	○	○
11. Try new methods for relaxing, such as meditation, progressive relaxation, or	○	○	○	○	○
12. Get more sleep	○	○	○	○	○
13. Drink less alcohol or stop drinking it	○	○	○	○	○
14. If you smoke, quit smoking	○	○	○	○	○
15. Is there anything else you feel motivated to do or to stop doing?	○ yes ➔ ○ no				

Developed by the Data Capture Services Unit in the UNC-CH Center for Health Promotion & Disease Prevention
www.hpdp.unc.edu/services/datacapture

Section B

Now I'd like to talk to you about heart disease. People think different things about heart disease. We would like to know what you think.

	not at all serious	*slightly serious*	*somewhat serious*	*moderately serious*	*very serious*
1. How serious a threat to health is heart disease?	○	○	○	○	○

	not at all strong	*slightly strong*	*somewhat strong*	*moderately strong*	*very strong*
2. My chances of developing heart disease in the future are:	○	○	○	○	○

3. What is the *percent chance* that you will develop heart disease in the next 10 years?

○ 0% ○ 10% ○ 20% ○ 30% ○ 40% ○ 50% ○ 60% ○ 70% ○ 80% ○ 90% ○ 100%

	strongly disagree	*disagree*	*neither agree or disagree*	*agree*	*strongly agree*
4. My financial security would be endangered if I got heart disease.	○	○	○	○	○
5. I believe that heart disease would be a very serious illness for me to develop.	○	○	○	○	○
6. If I had heart disease, my whole life would change.	○	○	○	○	○
7. If I got heart disease, it would be more serious than other diseases.	○	○	○	○	○
8. Heart disease would endanger my marriage (or a significant relationship).	○	○	○	○	○
9. If I had heart disease my career would be endangered.	○	○	○	○	○
10. Heart disease is a hopeless disease.	○	○	○	○	○
11. My feelings about myself would change if I got heart disease.	○	○	○	○	○
12. Problems I would experience from heart disease would last a long time.	○	○	○	○	○
13 I am unlikely to develop heart disease in the future.	○	○	○	○	○

Section C

In Heart Healthy Lenoir, we talked about a healthy eating plan. Healthy eating means eating more:
- Healthy fats. Healthy fats are fats such as those found in vegetable oils, nuts, and fish.
- Fruits and vegetables.
- Whole grains such as whole wheat bread and brown rice.

And eating less:
- Unhealthy fats. Unhealthy fats are trans fats that are found in some baked goods, packaged snack foods, band fried foods at restaurants.
- Processed meats like bacon, hot dogs, and cold cuts.
- Foods with added sugar and salt-like, sugar-sweetened beverages and some prepared foods.

*Thinking about **that healthy eating plan**, please answer the following questions.*

	strongly disagree	***disagree***	***neither agree or disagree***	***agree***	***strongly agree***
1. Healthy eating is effective in preventing heart disease.	○	○	○	○	○
2. The benefits of following the healthy eating plan outweigh the costs.	○	○	○	○	○
3. I have the time to follow the healthy eating plan to prevent heart disease.	○	○	○	○	○
4. I would be discouraged from following at least one of the steps of the healthy eating plan during the next week because I would feel silly doing so.	○	○	○	○	○
5. If I follow the healthy eating plan, I am less likely to get heart disease.	○	○	○	○	○
6. Following at least one of the steps of the healthy eating plan during the next week would cause me too many problems.	○	○	○	○	○
7. I am able to follow the healthy eating plan to prevent getting heart disease.	○	○	○	○	○
8. Healthy eating works in preventing heart disease.	○	○	○	○	○
9. I would be discouraged from following at least one of the steps of the healthy eating plan during the next week as it would take too much time.	○	○	○	○	○
10. I can easily follow the healthy eating plan to prevent heart disease.	○	○	○	○	○

Section D

In Heart Healthy Lenoir, we talked about walking as aerobic physical activity. The program recommended walking briskly for 150 minutes a week. This would be about 30 minutes of walking on five days of the week. This can be divided into ten-minute segments of walking.

*Thinking about **that recommendation**, please answer the following questions.*

	strongly disagree	*disagree*	*neither agree or disagree*	*agree*	*strongly agree*
1. I would be discouraged from taking at least one 30-minute walk during the next week as it would take too much time.	○	○	○	○	○
2. I would be discouraged from taking at least one 30-minute walk a week because I would feel silly doing so.	○	○	○	○	○
3. Walking for 30 minutes a day is effective in preventing heart disease.	○	○	○	○	○
4. Walking for 30 minutes a day works in preventing heart disease.	○	○	○	○	○
5. If I walk for 30 minutes a day, I am less likely to get heart disease.	○	○	○	○	○
6. I am able to walk 30 minutes a day to prevent getting heart disease.	○	○	○	○	○
7. I have the time to walk for 30 minutes a day to prevent heart disease.	○	○	○	○	○
8. I can easily walk for 30 minutes a day to prevent heart disease.	○	○	○	○	○
9. The benefits of taking at least one 30-minute walk a week outweigh the costs.	○	○	○	○	○
10. Taking at least one 30-minute walk during the next week would cause me too many problems.	○	○	○	○	○

Section E

These questions are again about your thoughts about heart disease.

The thought of developing heart disease makes me feel:

	not at all	*slightly*	*somewhat*	*mosderately*	*very*
1. Frightened	○	○	○	○	○
2. Anxious	○	○	○	○	○
3. Worried	○	○	○	○	○
4. Scared	○	○	○	○	○

Section F

	strongly disagree	*disagree*	*neither agree or disagree*	*agree*	*strongly agree*
1. If someone is meant to get a serious disease, it doesn't matter what kinds of food they eat, they will get that disease anyway.	○	○	○	○	○
2. I will get diseases if I am unlucky.	○	○	○	○	○
3. If someone is meant to get a serious disease, they will get it no matter what they do.	○	○	○	○	○
4. Everything that can go wrong for me does.	○	○	○	○	○
5. If someone gets a serious disease, that's the way they were meant to die.	○	○	○	○	○
6. My health is a matter of luck.	○	○	○	○	○
7. If someone is meant to have a serious disease, they will get that disease.	○	○	○	○	○
8. I will have a lot of pain from illness.	○	○	○	○	○
9. If someone has a serious disease and gets treatment for it, they will probably still die from it.	○	○	○	○	○
10. How long I live is a matter of luck.	○	○	○	○	○

	strongly disagree	disagree	neither agree or disagree	agree	strongly agree
11. If someone was meant to have a serious disease, it doesn't matter what doctors and nurses tell them to do, they will get the disease anyway.	○	○	○	○	○
12. I will suffer a lot from bad health.	○	○	○	○	○
13. How long I live is predetermined.	○	○	○	○	○
14. I will stay healthy if I am lucky.	○	○	○	○	○
15. I will die when I am fated to die.	○	○	○	○	○
16. I often feel helpless in dealing with the problems of life.	○	○	○	○	○
17. My health is determined by fate.	○	○	○	○	○
18. Sometimes I feel that I'm being pushed around in life.	○	○	○	○	○
19. My health is determined by something greater than myself.	○	○	○	○	○
20. There is really no way I can solve some of the problems I have.	○	○	○	○	○

Section G

*People are affected in different ways by health information. We would like to know how the information you have learned has affected **you.***

	strongly disagree	*disagree*	*neither agree or disagree*	*agree*	*strongly agree*
1. This information helped you accept the way things work out in life.	○	○	○	○	○
2. This information helped you learn to deal better with uncertainty.	○	○	○	○	○
3. This information taught you how to adjust to things you cannot change.	○	○	○	○	○
4. This information helped you take things as they come.	○	○	○	○	○
5. This information helped you look at things in a more positive way.	○	○	○	○	○

C. 1-MONTH FOLLOW-UP SURVEY

8970061573 **Return of Results**
Follow-up Information

1 / 15

ENR2 v. 1.0

Section 1:

Date enrolled: ☐☐ / ☐☐ / 2 0 1 ☐
month *day* *year*

Form completed by:
- ○ participant only
- ○ interviewer only → Interviewer ID: ☐☐
- ○ both

Section 2: Health

I'm going to start by asking you some questions about your health right now and your current daily activities. Please try to answer every question as accurately as you can.

1. In general, would you say your health is:

○ excellent ○ very good ○ good ○ fair ○ poor

*The following two questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?*

2. **moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf:

○ yes, limited a lot ○ yes, limited a little ○ no, not limited at all

3. climbing **several** flights of stairs:

○ yes, limited a lot ○ yes, limited a little ○ no, not limited at all

*During the **past 4 weeks**, have you had any of the following problems with your work or other regular activities **as a result of your physical health**?*

4. **accomplished less** than you would like:

○ yes ○ no

5. were limited in the **kind** of work or other activities:

○ yes ○ no

Developed by the Data Capture Services Unit in the UNC-CH Center for Health Promotion & Disease Prevention
www.hpdp.unc.edu/services/datacapture

*During the **past 4 weeks**, were you limited in the kind of work you do or other regular activities **as a result of any emotional problems** (such as feeling depressed or anxious)?*

6. **accomplished less** than you would like:

○ yes ○ no

7. didn't do work or other activities as **carefully** as usual:

○ yes ○ no

8. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

○ not at all ○ a little bit ○ moderately ○ quite a bit ○ extremely

*The next few questions are about how you feel and how things have been **during the past 4 weeks.** For each question please give the one answer that comes closest to the way you have been feeling.*

*How much of the time during the **past 4 weeks . . .***	***all of the time***	***most of the time***	***a good bit of the time***	***some of the time***	***a little of the time***	***none of the time***
9. have you felt calm and peaceful?	○	○	○	○	○	○
10. did you have a lot of energy?	○	○	○	○	○	○
11. have you felt downhearted and blue?	○	○	○	○	○	○
12. During the **past 4 weeks**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)	○	○	○	○	○	○

*How much of the time during the **last month** have you . . .*	*all of the time*	*most of the time*	*a good bit of the time*	*some of the time*	*a little of the time*	*none of the time*
13. been a very nervous person?	○	○	○	○	○	○
14. felt so down in the dumps that nothing could cheer you up?	○	○	○	○	○	○
15. been a happy person?	○	○	○	○	○	○

Section 3: Health Behaviors In this part, I'm going to ask you about a few health-related behaviors like diet. Thinking about your eating habits over the **past month**, about how often do you eat each of the following foods? Remember breakfast, lunch, dinner, snacks and eating out

	less than 1/WEEK	*once a WEEK*	*2-3 times a WEEK*	*4-6 times a WEEK*	*once a DAY*	*2+ a DAY*
1. Fruit juice, like orange, apple, grape, fresh, frozen or canned (not sodas or other drinks)	○	○	○	○	○	○
2. How often do you eat any fruit, fresh or canned (not counting juice)?	○	○	○	○	○	○
3. Vegetable juice like tomato juice, V-8, or carrot	○	○	○	○	○	○
4. Green salad	○	○	○	○	○	○
5. Potatoes, any kind, including baked, mashed or french fried	○	○	○	○	○	○
6. Vegetable soup, or stew with vegetables	○	○	○	○	○	○
7. Any other vegetables, including string beans, peas, corn, broccoli or any other kind	○	○	○	○	○	○
8. Fiber cereals like Raisin Bran, Shredded Wheat or Fruit-n-Fiber	○	○	○	○	○	○
9. Beans such as baked beans, pinto, kidney, or lentils (not green beans)	○	○	○	○	○	○
10. Dark bread such as whole wheat or rye	○	○	○	○	○	○

Section 4: Neighborhood Physical Activity Questionnaire

Walking

Now I'd like to ask you about two types of walking: walking for transportation (e.g., to the store or work), then walking for recreation, health and fitness. If the walking that you do for transportation is also for recreation, health or fitness, please tell me about it only once.

For example:

Linda lives 20 minutes away from work. She chooses to walk there rather than drive mainly because she wants to improve her fitness. If Linda says that she walks for transportation (3 times per week for a total of 120 minutes), she would not repeat that information under walking for recreation, health or fitness.

1. In a **usual week**, do you walk to get to or from somewhere (such as walking to a store or bus stop) or for recreation, health or fitness (including walking your dog)?

   ○ yes ○ no

Walking for Transportation

2. In a **usual week**, how many times do you walk **as a means of transportation**, such as going to and from work, walking to the store, or walking to a bus stop?

   ☐☐ *times* ➔ ***if 0, skip to Q. 5***

3. Please estimate the total time you spend walking as a **means of transportation** in a **usual week**. (e.g., 5 times by 10 minutes = 50 minutes)

   ☐☐ *hours* ☐☐☐ *minutes*

4. Let me know which of the following places you walk to as a **means of transportation** in a **usual week**. *[Mark all that apply.]*

   ☐ to or from work (or study)
   ☐ to or from bus stop
   ☐ to or from store
   ☐ to or from restaurant
   ☐ to or from friend's house
   ☐ other place #1 ➔ _____
   ☐ other place #2 ➔ _____

Walking for Recreation, Health or Fitness:

If you have already reported recreational walking, please do not report it again for the following questions.

5. In a **usual week**, how many times do you walk for **recreation, health** or **fitness** (including walking your dog)?

   ☐☐ *times* ➔ ***if 0, skip to Other Leisure Time Physical Activities***

6. Please estimate the total time you spend walking for **recreation, health** or **fitness** in a **usual week**. (e.g., 5 times by 10 minutes = 50 minutes)

   ☐☐ *hours* ☐☐☐ *minutes*

7. Could you tell me where you walk for **recreation, health** or **fitness** in a **usual week**? *[Mark all that apply.]*

   ☐ park
   ☐ neighborhood
   ☐ school
   ☐ to or from restaurant
   ☐ to or from a store
   ☐ fitness center
   ☐ other place #1 ➔ _____
   ☐ other place #2 ➔ _____

Other Leisure Time Physical Activities

The next set of questions is about **other leisure time physical activities** that you do in a **usual week**, besides what you have already mentioned. Do not include walking.

8. In a **usual week**, do you do any other vigorous or moderate intensity leisure time physical activities? Do not include any walking.

   ○ yes ○ no ➔ ***Skip to Section 5***

9. Could you tell me where you do these leisure time physical activities in a **usual week**?
[Mark all that apply.]

☐ park
☐ neighborhood
☐ school
☐ fitness center
☐ other place #1 ➔ _____
☐ other place #2 ➔ _____

10. In a **usual week**, do you do any vigorous intensity leisure time physical activities like jogging, aerobics, swimming laps, or competitive tennis? Do not include walking or moderate intensity physical activities. Vigorous intensity physical activities cause a large increase in breathing and heart rate.

○ yes ○ no ➔ ***if no, skip Q. 13***

11. In a **usual week**, how many times do you do vigorous intensity leisure time physical activities which cause a large increase in breathing and heart rate?

☐☐ ***times*** ➔ ***if 0, skip to Q. 13***

12. What do you estimate is the total time you spend doing vigorous intensity leisure time physical activities in a **usual week**.
(e.g., 3 times by 20 minutes = 60 minutes)

☐☐ ***hours*** ☐☐☐ ***minutes***

13. Apart from what you have already mentioned, in a **usual week** do you do any other moderate intensity leisure time physical activities like dancing, cycling, social tennis, golf, or gardening? Moderate intensity physical activities cause a moderate increase in breathing and heart rate.

○ yes ○ no ➔ ***if no, skip to Section 5***

14. In a **usual week**, how many times do you do moderate intensity leisure time physical activities which cause a moderate increase in breathing and heart rate?

☐☐ ***times***

15. What do you estimate is the total time you spend doing moderate intensity leisure time physical activities in a **usual week**?
(e.g., 1 time for 1 hour = 1 hour)

☐☐ ***hours*** ☐☐☐ ***minutes***

Section 5

Now I'll read a list of things some people do after learning new information. ***Thinking about how you feel right now****, how motivated are you to…*

	a lot less motivated	*a little less motivated*	*no change in motivation*	*a little more motivated*	*a lot more motivated*
1. Eat more fruits and vegetables	○	○	○	○	○
2. Eat more fish and lean meat rather than meats that are high in fat	○	○	○	○	○
3. Eat more fiber in your diet	○	○	○	○	○
4. Eat fast food less often	○	○	○	○	○
5. Reduce sugar in your diet	○	○	○	○	○
6. Eat a special diet that might help manage your health	○	○	○	○	○
7. Get more exercise or be more physically active	○	○	○	○	○
8. Spend less time sitting or being sedentary (like when you're watching TV or using a computer)	○	○	○	○	○
9. Move closer to family who can help take care of you as you get older	○	○	○	○	○
10. Reduce stress in your everyday life	○	○	○	○	○
11. Try new methods for relaxing, such as meditation, progressive relaxation, or	○	○	○	○	○
12. Get more sleep	○	○	○	○	○
13. Drink less alcohol or stop drinking it	○	○	○	○	○
14. If you smoke, quit smoking	○	○	○	○	○
15. Is there anything else you feel motivated to do or to stop doing?	○ yes ➔ ○ no				

Section 6

Now I'd like to talk to you about heart disease. People think different things about heart disease. We would like to know what you think.

	not at all serious	*slightly serious*	*somewhat serious*	*moderately serious*	*very serious*
1. How serious a threat to health is heart disease?	○	○	○	○	○

	not at all strong	*slightly strong*	*somewhat strong*	*moderately strong*	*very strong*
2. My chances of developing heart disease in the future are:	○	○	○	○	○

3. What is the *percent chance* that you will develop heart disease in the next 10 years?

○ 0% ○ 10% ○ 20% ○ 30% ○ 40% ○ 50% ○ 60% ○ 70% ○ 80% ○ 90% ○ 100%

	strongly disagree	*disagree*	*neither agree or disagree*	*agree*	*strongly agree*
4. My financial security would be endangered if I got heart disease.	○	○	○	○	○
5. I believe that heart disease would be a very serious illness for me to develop.	○	○	○	○	○
6. If I had heart disease, my whole life would change.	○	○	○	○	○
7. If I got heart disease, it would be more serious than other diseases.	○	○	○	○	○
8. Heart disease would endanger my marriage (or a significant relationship).	○	○	○	○	○
9. If I had heart disease my career would be endangered.	○	○	○	○	○
10. Heart disease is a hopeless disease.	○	○	○	○	○
11. My feelings about myself would change if I got heart disease.	○	○	○	○	○
12. Problems I would experience from heart disease would last a long time.	○	○	○	○	○
13 I am unlikely to develop heart disease in the future.	○	○	○	○	○

Section 7

In Heart Healthy Lenoir, we talked about a healthy eating plan. Healthy eating means eating more:
- Healthy fats. Healthy fats are fats such as those found in vegetable oils, nuts, and fish.
- Fruits and vegetables.
- Whole grains such as whole wheat bread and brown rice.

And eating less:
- Unhealthy fats. Unhealthy fats are trans fats that are found in some baked goods, packaged snack foods, band fried foods at restaurants.
- Processed meats like bacon, hot dogs, and cold cuts.
- Foods with added sugar and salt-like, sugar-sweetened beverages and some prepared foods.

*Thinking about **that healthy eating plan**, please answer the following questions.*

	strongly disagree	***disagree***	***neither agree or disagree***	***agree***	***strongly agree***
1. Healthy eating is effective in preventing heart disease.	○	○	○	○	○
2. The benefits of following the healthy eating plan outweigh the costs.	○	○	○	○	○
3. I have the time to follow the healthy eating plan to prevent heart disease.	○	○	○	○	○
4. I would be discouraged from following at least one of the steps of the healthy eating plan during the next week because I would feel silly doing so.	○	○	○	○	○
5. If I follow the healthy eating plan, I am less likely to get heart disease.	○	○	○	○	○
6. Following at least one of the steps of the healthy eating plan during the next week would cause me too many problems.	○	○	○	○	○
7. I am able to follow the healthy eating plan to prevent getting heart disease.	○	○	○	○	○
8. Healthy eating works in preventing heart disease.	○	○	○	○	○
9. I would be discouraged from following at least one of the steps of the healthy eating plan during the next week as it would take too much time.	○	○	○	○	○
10. I can easily follow the healthy eating plan to prevent heart disease.	○	○	○	○	○

Section 8

In Heart Healthy Lenoir, we talked about walking as aerobic physical activity. The program recommended walking briskly for 150 minutes a week. This would be about 30 minutes of walking on five days of the week. This can be divided into ten-minute segments of walking.

*Thinking about **that recommendation**, please answer the following questions.*

	strongly disagree	*disagree*	*neither agree or disagree*	*agree*	*strongly agree*
1. I would be discouraged from taking at least one 30-minute walk during the next week as it would take too much time.	○	○	○	○	○
2. I would be discouraged from taking at least one 30-minute walk a week because I would feel silly doing so.	○	○	○	○	○
3. Walking for 30 minutes a day is effective in preventing heart disease.	○	○	○	○	○
4. Walking for 30 minutes a day works in preventing heart disease.	○	○	○	○	○
5. If I walk for 30 minutes a day, I am less likely to get heart disease.	○	○	○	○	○
6. I am able to walk 30 minutes a day to prevent getting heart disease.	○	○	○	○	○
7. I have the time to walk for 30 minutes a day to prevent heart disease.	○	○	○	○	○
8. I can easily walk for 30 minutes a day to prevent heart disease.	○	○	○	○	○
9. The benefits of taking at least one 30-minute walk a week outweigh the costs.	○	○	○	○	○
10. Taking at least one 30-minute walk during the next week would cause me too many problems.	○	○	○	○	○

Section 9

These questions are again about your thoughts about heart disease.

The thought of developing heart disease makes me feel:

	not at all	*slightly*	*somewhat*	*moderately*	*very*
1. Frightened	○	○	○	○	○
2. Anxious	○	○	○	○	○
3. Worried	○	○	○	○	○
4. Scared	○	○	○	○	○

Section 10

	strongly disagree	*disagree*	*neither agree or disagree*	*agree*	*strongly agree*
1. If someone is meant to get a serious disease, it doesn't matter what kinds of food they eat, they will get that disease anyway.	○	○	○	○	○
2. I will get diseases if I am unlucky.	○	○	○	○	○
3. If someone is meant to get a serious disease, they will get it no matter what they do.	○	○	○	○	○
4. Everything that can go wrong for me does.	○	○	○	○	○
5. If someone gets a serious disease, that's the way they were meant to die.	○	○	○	○	○
6. My health is a matter of luck.	○	○	○	○	○
7. If someone is meant to have a serious disease, they will get that disease.	○	○	○	○	○
8. I will have a lot of pain from illness.	○	○	○	○	○
9. If someone has a serious disease and gets treatment for it, they will probably still die from it.	○	○	○	○	○
10. How long I live is a matter of luck.	○	○	○	○	○

	strongly disagree	disagree	neither agree or disagree	agree	strongly agree
11. If someone was meant to have a serious disease, it doesn't matter what doctors and nurses tell them to do, they will get the disease anyway.	○	○	○	○	○
12. I will suffer a lot from bad health.	○	○	○	○	○
13. How long I live is predetermined.	○	○	○	○	○
14. I will stay healthy if I am lucky.	○	○	○	○	○
15. I will die when I am fated to die.	○	○	○	○	○
16. I often feel helpless in dealing with the problems of life.	○	○	○	○	○
17. My health is determined by fate.	○	○	○	○	○
18. Sometimes I feel that I'm being pushed around in life.	○	○	○	○	○
19. My health is determined by something greater than myself.	○	○	○	○	○
20. There is really no way I can solve some of the problems I have.	○	○	○	○	○

Section 11 *People are affected in different ways by health information. We would like to know how the information you have learned has affected* ***you.***

	strongly disagree	disagree	neither agree or disagree	agree	strongly agree
1. This information helped you accept the way things work out in life.	○	○	○	○	○
2. This information helped you learn to deal better with uncertainty.	○	○	○	○	○
3. This information taught you how to adjust to things you cannot change.	○	○	○	○	○
4. This information helped you take things as they come.	○	○	○	○	○
5. This information helped you look at things in a more positive way.	○	○	○	○	○

Section 12: Demographics

1. What is the highest grade or year of regular school you have completed? *[Mark only one.]*

○ never attended school
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 ○ 11
○ 12 ○ 13 ○ 14 ○ 15 ○ 16 ○ 17 ○ 18 ○ 19 ○ 20 ○ 21+

2. Are you now: *[choose one]*

○ married
○ widowed
○ divorced
○ separated
○ never married
○ living with partner

3. Do you smoke cigarettes now?

○ every day
○ some days

8a. If every day or some days, on average, how many packs of cigarettes do you now smoke a day? ☐.☐☐ ***packs per day***

○ not at all

4. Do you currently have health insurance?

○ yes ○ no

5. During the past 12 months, was there any time when you had no health insurance at all?

- ○ yes ➔
- ○ no

5a. For how many months of the past 12 months did you have no health insurance?

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6
○ 7 ○ 8 ○ 9 ○ 10 ○ 11 ○ 12

5b. What is the **one main** reason why you did not have any health insurance?

- ○ can't afford/too expensive
- ○ not eligible due to working status/changed employer/lost job
- ○ not eligible due to citizenship/immigration status
- ○ family situation changed
- ○ can get health care for free/pay for own care
- ○ not eligible due to health or other problems
- ○ don't believe in insurance
- ○ switched insurance companies, delay between jobs
- ○ other ➔ _____

6. Which of the following best describes your current main daily activities and/or responsibilities? *[Choose one.]*

- ○ working full time (30 or more hours/week)
- ○ working part time (less than 30 hours/week)
- ○ unemployed or laid off
- ○ looking for work
- ○ student
- ○ keeping house or raising children full-time
- ○ do not work due to health reasons
- ○ retired

7. What type of work do/did you do in your current or most recent job? *[Choose one.]*

- ○ management, business, and financial (chief executives, financial managers, etc.)
- ○ professional and related (engineer, architect, dentist, etc.)
- ○ service (waitress, cook maintenance, house or hotel cleaner, etc.)
- ○ sales (cashier, counter clerk, telemarketing, etc.)
- ○ administrative support, clerical (file clerk, answering service, hotel clerk, etc.)
- ○ construction (carpentry, electrician, painter, plumber, etc.)
- ○ installation, maintenance and repair (auto mechanic, building maintenance, electronic installation & repair, etc.)
- ○ production (assembly line, meat packing, printing, farming, etc.)
- ○ transportation & material moving (bus or truck driver, railroad, service station or parking lot attendant, garbage or recycling collector, etc.)
- ○ other ➔ *specify* _____

The next questions are important to help us understand your economic situation. Please answer as accurately as possible. The information will not be reported in any way that allow you to be personally identified.

8. What was the total combined income of your household in the past year including income from all sources such as wages, salaries, Social Security, or retirement benefits, help from relatives and so forth? Please tell us the total income before taxes.

○ less than $5000	○ $30,000 to $39,999	○ $80,000 to $89,999
○ $5,000 to $9,999	○ $40,000 to $49,999	○ $90,000 to $99,999
○ $10,000 to $14,999	○ $50,000 to $59,999	○ $100,000 or more
○ $15,00 to $19,999	○ $60,000 to $69,999	○ don't know
○ $20,000 to $29,999	○ $70,000 to $79,999	○ refused to answer

9. How many people live in your household, including you? ☐☐ ***number of people***

10. Of the persons living in your household (including you), how many are 18 years and older? ☐☐ ***number of people***

11. Of the persons living in your household how many are under 18 years of age? ☐☐ ***number of people***

APPENDIX 6.4: BASELINE VARIABLES

A. THE SHORT TEST OF FUNCTIONAL HEALTH LITERACY IN ADULTS (STOFHLA)

TABLE 9. STOFHLA FREQUENCY TABLE

Variable	*Value*	*Overall*	*Control*	*Intervention*	*Pr > |ChiSq|*
Literacy	Low Literacy	16 (25.81%)	8 (25.81%)	8 (25.81%)	1.0000
	High Literacy	46 (74.19%)	23 (74.19%)	23 (74.19%)	

N (%)

TABLE 10. STOFHLA MEANS

Variable	*Overall*	*Control*	*Intervention*	*Pr > |t|*
Overall Literacy Score	27.79±10.09	27.71±10.72	27.87±9.59	0.9504
Low Literacy Participants' Score	12.50±7.62	11.50±8.42	13.50±7.15	0.6165
High Literacy Participants' Score	33.11±2.55	33.35±2.31	32.87±2.80	0.5307
Administration Time (Minutes)	6.49±1.17	6.62±1.32	6.37±1.00	0.4072

Mean ± Standard Deviation

TABLE 11. DEMOGRAPHICS – MEANS

Variable	*Overall*	*Control*	*Intervention*	*Pr > |t|*
Age When Enrolled In Current Study	60.86±8.62	61.51±7.80	60.20±9.46	0.5543
Years Spent In HHL	2.09±0.14	2.07±0.13	2.10±0.15	0.3882
Years Since HHL	1.79±0.29	1.77±0.30	1.81±0.29	0.5923
What Is The Highest Grade You Have Completed?	12.31±2.18	12.48±2.28	12.11±2.10	0.5128
How Many People Live In Your Household, Including You?	2.00±1.27	1.97±1.30	2.04±1.26	0.8398
Number Of People In Your Household >= 18 Years Old	1.56±0.82	1.61±0.76	1.50±0.88	0.5996
Number Of People In Your Household < 18 Years Old	0.31±0.75	0.35±0.80	0.25±0.70	0.5956

Mean ± Standard Deviation

TABLE 12. DEMOGRAPHICS – FREQUENCY TABLE

Variable	*Value*	*Overall*	*Control*	*Intervention*	*Pr > |ChiSq|*
What Is Your Sex?	Male	18 (29.03%)	8 (25.81%)	10 (32.26%)	0.7802
	Female	44 (70.97%)	23 (74.19%)	21 (67.74%)	
Enrolled In Hypertension Arm Of HHL?	Yes	56 (90.32%)	29 (93.55%)	27 (87.10%)	0.6713
	No	6 (9.68%)	2 (6.45%)	4 (12.90%)	
Enrolled In Lifestyle Arm Of HHL?	Yes	21 (33.87%)	9 (29.03%)	12 (38.71%)	0.5921
	No	41 (66.13%)	22 (70.97%)	19 (61.29%)	
Enrolled In Genomics Arm Of HHL?	Yes	62 (100.0%)	31 (100.0%)	31 (100.0%)	
	No	0 (0.00%)	0 (0.00%)	0 (0.00%)	
What Is The Highest Grade You Have Completed?*	8	3 (5.08%)	1 (3.23%)	2 (7.14%)	0.8019
	10	5 (8.47%)	3 (9.68%)	2 (7.14%)	
	11	3 (5.08%)	1 (3.23%)	2 (7.14%)	
	12	37 (62.71%)	19 (61.29%)	18 (64.29%)	
	14	3 (5.08%)	3 (9.68%)	0 (0.00%)	
	15	2 (3.39%)	1 (3.23%)	1 (3.57%)	
	16	4 (6.78%)	2 (6.45%)	2 (7.14%)	
	18	1 (1.69%)	0 (0.00%)	1 (3.57%)	
	21	1 (1.69%)	1 (3.23%)	0 (0.00%)	
Marital Status*	Married	14 (23.73%)	5 (16.13%)	9 (32.14%)	0.7208

Variable	*Value*	*Overall*	*Control*	*Intervention*	*Pr > |ChiSq|*
	Widowed	11 (18.64%)	6 (19.35%)	5 (17.86%)	
	Divorced	15 (25.42%)	9 (29.03%)	6 (21.43%)	
	Separated	4 (6.78%)	3 (9.68%)	1 (3.57%)	
	Never Married	12 (20.34%)	6 (19.35%)	6 (21.43%)	
	Living with a Partner	3 (5.08%)	2 (6.45%)	1 (3.57%)	
Do You Smoke Cigarettes Now?*	Every Day	4 (6.78%)	1 (3.23%)	3 (10.71%)	0.5983
	Some Days	6 (10.17%)	3 (9.68%)	3 (10.71%)	
	Not at All	49 (83.05%)	27 (87.10%)	22 (78.57%)	
Do You Currently Have Health Insurance?*	Yes	54 (91.53%)	28 (90.32%)	26 (92.86%)	1.0000
	No	5 (8.47%)	3 (9.68%)	2 (7.14%)	
During The Past 12 Months, Was There Any Time When You Had No Health Insurance At All?*	Yes	11 (18.64%)	4 (12.90%)	7 (25.00%)	0.3204
	No	48 (81.36%)	27 (87.10%)	21 (75.00%)	

Variable	*Value*	*Overall*	*Control*	*Intervention*	*Pr > |ChiSq|*
Which Of The Following Best Describes Your Current Main Daily Activities And/Or Responsibilities?*	Working Full Time (>= 30 hours)	15 (25.42%)	9 (29.03%)	6 (21.43%)	0.9512
	Working Part Time (< 30 hours)	7 (11.86%)	3 (9.68%)	4 (14.29%)	
	Unemployed or Laid Off	2 (3.39%)	1 (3.23%)	1 (3.57%)	
	Looking for Work	1 (1.69%)	1 (3.23%)	0 (0.00%)	
	Student	3 (5.08%)	2 (6.45%)	1 (3.57%)	
	Keeping House or Raising Children	1 (1.69%)	1 (3.23%)	0 (0.00%)	
	Do Not Work Due to Health Reasons	12 (20.34%)	6 (19.35%)	6 (21.43%)	
	Retired	18 (30.51%)	8 (25.81%)	10 (35.71%)	

Variable	*Value*	*Overall*	*Control*	*Intervention*	*Pr > |ChiSq|*
What Type Of Work Do/Did You Do In Your Current Or Most Recent Job?*	Management, Business, and Financial	3 (5.08%)	1 (3.23%)	2 (7.14%)	0.4264
	Professional and Related	6 (10.17%)	4 (12.90%)	2 (7.14%)	
	Service	6 (10.17%)	2 (6.45%)	4 (14.29%)	
	Administrative Support, Clerical	2 (3.39%)	2 (6.45%)	0 (0.00%)	
	Construction	3 (5.08%)	1 (3.23%)	2 (7.14%)	
	Production	9 (15.25%)	7 (22.58%)	2 (7.14%)	
	Transportation & Material Moving	3 (5.08%)	2 (6.45%)	1 (3.57%)	
	Other	27 (45.76%)	12 (38.71%)	15 (53.57%)	

Variable	*Value*	*Overall*	*Control*	*Intervention*	*Pr > |ChiSq|*
Income*	Less Than $5,000	7 (12.07%)	5 (16.13%)	2 (7.41%)	0.9017
	$5,000-$9,999	6 (10.34%)	2 (6.45%)	4 (14.81%)	
	$10,000-$14,999	8 (13.79%)	5 (16.13%)	3 (11.11%)	
	$15,000-$19,999	11 (18.97%)	5 (16.13%)	6 (22.22%)	
	$20,000-$29,999	5 (8.62%)	2 (6.45%)	3 (11.11%)	
	$30,000-$39,999	4 (6.90%)	2 (6.45%)	2 (7.41%)	
	$40,000-$49,999	2 (3.45%)	2 (6.45%)	0 (0.00%)	
	$50,000-$59,999	6 (10.34%)	4 (12.90%)	2 (7.41%)	
	$60,000-$69,999	3 (5.17%)	1 (3.23%)	2 (7.41%)	
	$70,000-$79,999	2 (3.45%)	1 (3.23%)	1 (3.70%)	
	$100,000 or more	1 (1.72%)	1 (3.23%)	0 (0.00%)	
	Don't Know	2 (3.45%)	1 (3.23%)	1 (3.70%)	
	Refused to Answer	1 (1.72%)	0 (0.00%)	1 (3.70%)	

Variable	*Value*	*Overall*	*Control*	*Intervention*	*Pr > |ChiSq|*
How Many People Live In	1	25 (42.37%)	15 (48.39%)	10 (35.71%)	0.6592
Your Household, Including	2	21 (35.59%)	9 (29.03%)	12 (42.86%)	
You?*	3	7 (11.86%)	3 (9.68%)	4 (14.29%)	
	4	3 (5.08%)	2 (6.45%)	1 (3.57%)	
	5	1 (1.69%)	1 (3.23%)	0 (0.00%)	
	6	1 (1.69%)	1 (3.23%)	0 (0.00%)	
	7	1 (1.69%)	0 (0.00%)	1 (3.57%)	
Number Of People In Your	0	2 (3.39%)	0 (0.00%)	2 (7.14%)	0.3815
Household >= 18 Years Old*	1	31 (52.54%)	17 (54.84%)	14 (50.00%)	
	2	18 (30.51%)	9 (29.03%)	9 (32.14%)	
	3	7 (11.86%)	5 (16.13%)	2 (7.14%)	
	4	1 (1.69%)	0 (0.00%)	1 (3.57%)	
Number Of People In Your	0	49 (83.05%)	25 (80.65%)	24 (85.71%)	0.9241
Household < 18 Years Old*	1	4 (6.78%)	2 (6.45%)	2 (7.14%)	
	2	4 (6.78%)	3 (9.68%)	1 (3.57%)	
	3	2 (3.39%)	1 (3.23%)	1 (3.57%)	

N (%)

*N=59 Overall; N=31 Control; N=28 Intervention

TABLE 13. PHENOTYPIC RISK – FREQUENCY TABLE

Variable	*Value*	*Overall*	*Control*	*Intervention*	*Pr > |ChiSq|*
Framingham Risk Score	Low Over 10 Years	23 (37.10%)	13 (41.94%)	10 (32.26%)	0.5014
	Average Over 10 Years	11 (17.74%)	7 (22.58%)	4 (12.90%)	
	High Over 10 Years	22 (35.48%)	9 (29.03%)	13 (41.94%)	
	Low Over 2 Years	6 (9.68%)	2 (6.45%)	4 (12.90%)	
Do You Take Medicine For High Blood Pressure Or Hypertension? (Baseline)	Yes	56 (98.25%)	28 (100.0%)	28 (96.55%)	1.0000
	No	1 (1.75%)	0 (0.00%)	1 (3.45%)	
Do You Take Medicine For High Blood Pressure Or Hypertension? (24mo)	Yes	56 (98.25%)	28 (96.55%)	28 (100.0%)	1.0000
	No	1 (1.75%)	1 (3.45%)	0 (0.00%)	
Change In Hypertension Medication Status Over The Course Of HHL	Stopped Meds Since HHL Baseline	1 (1.69%)	1 (3.45%)	0 (0.00%)	1.0000
	No Change/Still On Meds	57 (96.61%)	28 (96.55%)	29 (96.67%)	
	Started Meds Since HHL Baseline	1 (1.69%)	0 (0.00%)	1 (3.33%)	
Participant Has Diabeties (A1c>6.5)	Yes	22 (35.48%)	7 (22.58%)	15 (48.39%)	0.0620
	No	40 (64.52%)	24 (77.42%)	16 (51.61%)	

Variable	*Value*	*Overall*	*Control*	*Intervention*	*Pr > |ChiSq|*
Smoking Status At 24mo	Every Day	5 (8.06%)	1 (3.23%)	4 (12.90%)	0.4791
	Some Days	6 (9.68%)	3 (9.68%)	3 (9.68%)	
	Not At All	51 (82.26%)	27 (87.10%)	24 (77.42%)	
Change In Smoking Status Over HHL	No Change/Non-Smoker	47 (75.81%)	26 (83.87%)	21 (67.74%)	0.7052
	Stopped Smoking	4 (6.45%)	1 (3.23%)	3 (9.68%)	
	Decreased Smoking	2 (3.23%)	1 (3.23%)	1 (3.23%)	
	No Change/Still Smoker	7 (11.29%)	3 (9.68%)	4 (12.90%)	
	Increased Smoking	1 (1.61%)	0 (0.00%)	1 (3.23%)	
	Started Smoking	1 (1.61%)	0 (0.00%)	1 (3.23%)	
Has A Doctor Ever Told You That You Have Had A Heart Attack? (Baseline)	Yes	6 (9.68%)	2 (6.45%)	4 (12.90%)	0.6713
	No	56 (90.32%)	29 (93.55%)	27 (87.10%)	

N (%)

TABLE 14. PHENOTYPIC RISK – MEANS

Variable	*Overall*	*Control*	*Intervention*	*Pr > |t|*
Change In Total Cholesterol Over HHL (Baseline Carried Forward If Missing)	-8.79±35.98	-13.89±42.25	-3.28±27.52	0.2926
Total Cholesterol Lab Value At 24mo	177.37±29.03	179.89±27.69	174.64±30.74	0.5201
Change In HDL Over HHL (Baseline Carried Forward If Missing)	-1.21±8.81	-4.15±8.12	1.96±8.57	0.0111
HDL Lab Value At 24mo	51.27±18.33	49.78±12.17	52.88±23.41	0.5472
Change In SBP Over HHL (Baseline Carried Forward If Missing)	-8.55±21.66	-10.29±20.84	-6.76±22.69	0.5286
SBP Lab Value At 24mo	127.75±18.09	127.51±16.89	128.00±19.54	0.9160
Change In A1c Over HHL (Baseline Carried Forward If Missing)	-0.16±0.97	-0.11±0.47	-0.21±1.32	0.7117
A1c Lab Value At 24mo	6.76±1.48	6.44±1.08	7.10±1.78	0.1096

Mean ± Standard Deviation

TABLE 15. GENOMIC RISK – FREQUENCY TABLE

Variable	*Value*	*Overall*	*Control*	*Intervention*	*Pr > |ChiSq|*
Genomic Risk Score (Additive)	Low	40 (64.52%)	21 (67.74%)	19 (61.29%)	0.7911
	Average	22 (35.48%)	10 (32.26%)	12 (38.71%)	
	High	0 (0.00%)	0 (0.00%)	0 (0.00%)	
rs543874 – BMI SNP	No Deleterious Alleles	30 (48.39%)	14 (45.16%)	16 (51.61%)	0.6995
	One Allele	29 (46.77%)	16 (51.61%)	13 (41.94%)	
	Two Alleles	3 (4.84%)	1 (3.23%)	2 (6.45%)	
rs6567160 – BMI SNP	No Deleterious Alleles	41 (66.13%)	20 (64.52%)	21 (67.74%)	1.0000
	One Allele	20 (32.26%)	10 (32.26%)	10 (32.26%)	
	Two Alleles	1 (1.61%)	1 (3.23%)	0 (0.00%)	
rs2258119 – SBP SNP	No Deleterious Alleles	29 (46.77%)	15 (48.39%)	14 (45.16%)	0.7649
	One Allele	27 (43.55%)	14 (45.16%)	13 (41.94%)	
	Two Alleles	6 (9.68%)	2 (6.45%)	4 (12.90%)	
rs7903146 – T2DM SNP	No Deleterious Alleles	29 (46.77%)	13 (41.94%)	16 (51.61%)	0.7816
	One Allele	25 (40.32%)	14 (45.16%)	11 (35.48%)	
	Two Alleles	8 (12.90%)	4 (12.90%)	4 (12.90%)	

Variable	*Value*	*Overall*	*Control*	*Intervention*	*Pr > |ChiSq|*
rs6511720 – LDL SNP	No Deleterious Alleles	45 (72.58%)	19 (61.29%)	26 (83.87%)	0.1046
	One Allele	15 (24.19%)	10 (32.26%)	5 (16.13%)	
	Two Alleles	2 (3.23%)	2 (6.45%)	0 (0.00%)	
rs646776 – LDL SNP	No Deleterious Alleles	29 (46.77%)	15 (48.39%)	14 (45.16%)	1.0000
	One Allele	24 (38.71%)	12 (38.71%)	12 (38.71%)	
	Two Alleles	9 (14.52%)	4 (12.90%)	5 (16.13%)	
rs3764261 – HDL SNP	No Deleterious Alleles	26 (41.94%)	12 (38.71%)	14 (45.16%)	0.6774
	One Allele	32 (51.61%)	16 (51.61%)	16 (51.61%)	
	Two Alleles	4 (6.45%)	3 (9.68%)	1 (3.23%)	
rs16942887 – HDL SNP	No Deleterious Alleles	46 (74.19%)	22 (70.97%)	24 (77.42%)	0.8786
	One Allele	14 (22.58%)	8 (25.81%)	6 (19.35%)	
	Two Alleles	2 (3.23%)	1 (3.23%)	1 (3.23%)	
rs2036527 – Smoking SNP	No Deleterious Alleles	32 (51.61%)	18 (58.06%)	14 (45.16%)	0.6654
	One Allele	23 (37.10%)	10 (32.26%)	13 (41.94%)	
	Two Alleles	7 (11.29%)	3 (9.68%)	4 (12.90%)	

APPENDIX 6.5: REGRESSION ANALYSES FOR SECONDARY AND TERTIARY OUTCOMES

A. MOTIVATION TOWARDS STRESS REDUCTION

TABLE 16. REGRESSION ANALYSIS FOR MOTIVATION TOWARDS STRESS REDUCTION

Label	*Estimate*	*Standard Error*	*DF*	*t Value*	*Pr > |t|*
Control Time 1	4.0090	0.2395			
Control Time 3	4.1865	0.2361			
Intervention Time 1	4.1000	0.2424			
Intervention Time 3	3.8685	0.2424			
Control: Time 3 vs. Time 1	0.1775	0.1787	111	0.99	0.3229
Intervention: Time 3 vs. Time 1	-0.2315	0.1788	111	-1.29	0.1981
Control vs. Intervention: Time 3 vs. Time 1	0.4090	0.2528	111	1.62	0.1086
Intervention Low GRS Time 1	4.0000	0.2897			
Intervention Low GRS Time 3	4.0370	0.2897			
Intervention Average GRS Time 1	4.2000	0.3887			
Intervention Average GRS Time 3	3.7000	0.3887			
Intervention Low GRS: Time 3 vs. Time 1	0.03704	0.2137	111	0.17	0.8627
Intervention Average GRS: Time 3 vs. Time 1	-0.5000	0.2867	111	-1.74	0.0839
Intervention: Low GRS vs. Average GRS: Time 3 vs. Time 1	0.5370	0.3575	111	1.50	0.1359

B. THREAT APPRAISAL

TABLE 17. REGRESSION ANALYSIS FOR PERCEIVED THREAT

Label	*Estimate*	*Standard Error*	*DF*	*t Value*	*Pr > |t|*
Control Time 1	4.9048	0.2473			
Control Time 3	4.7571	0.2473			
Intervention Time 1	4.7167	0.2539			
Intervention Time 3	4.7611	0.2539			
Control: Time 3 vs. Time 1	-0.1476	0.1655	113	-0.89	0.3743
Intervention: Time 3 vs. Time 1	0.04444	0.1699	113	0.26	0.7941
Control vs. Intervention: Time 3 vs. Time 1	-0.1921	0.2372	113	-0.81	0.4198
Intervention Low GRS Time 1	4.8333	0.3035			
Intervention Low GRS Time 3	4.7222	0.3035			
Intervention Average GRS Time 1	4.6000	0.4071			
Intervention Average GRS Time 3	4.8000	0.4071			
Intervention Low GRS: Time 3 vs. Time 1	-0.1111	0.2031	113	-0.55	0.5854
Intervention Average GRS: Time 3 vs. Time 1	0.2000	0.2725	113	0.73	0.4644
Intervention: Low GRS vs. Average GRS: Time 3 vs. Time 1	-0.3111	0.3398	113	-0.92	0.3618

TABLE 18. REGRESSION ANALYSIS FOR PERCEIVED VULNERABILITY

Label	*Estimate*	*Standard Error*	*DF*	*t Value*	*Pr > |t|*
Control Time 1	47.9048	5.4015			
Control Time 3	40.0952	5.4015			
Intervention Time 1	32.7222	5.5448			
Intervention Time 3	40.2778	5.5448			
Control: Time 3 vs. Time 1	-7.8095	5.7025	113	-1.37	0.1736
Intervention: Time 3 vs. Time 1	7.5556	5.8538	113	1.29	0.1994
Control vs. Intervention: Time 3 vs. Time 1	-15.3651	8.1723	113	-1.88	0.0627
Intervention Low GRS Time 1	49.4444	6.6273			
Intervention Low GRS Time 3	45.5556	6.6273			
Intervention Average GRS Time 1	16.0000	8.8915			
Intervention Average GRS Time 3	35.0000	8.8915			
Intervention Low GRS: Time 3 vs. Time 1	-3.8889	6.9966	113	-0.56	0.5794
Intervention Average GRS: Time 3 vs. Time 1	19.0000	9.3870	113	2.02	0.0453
Intervention: Low GRS vs. Average GRS: Time 3 vs. Time 1	-22.8889	11.7076	113	-1.96	0.0530

TABLE 19. REGRESSION ANALYSIS FOR PERCEIVED SEVERITY

Label	*Estimate*	*Standard Error*	*DF*	*t Value*	*Pr > |t|*
Control Time 1	3.4759	0.1873			
Control Time 3	3.3224	0.1873			
Intervention Time 1	3.4901	0.1923			
Intervention Time 3	3.4418	0.1923			
Control: Time 3 vs. Time 1	-0.1536	0.1037	113	-1.48	0.1413
Intervention: Time 3 vs. Time 1	-0.04830	0.1064	113	-0.45	0.6508
Control vs. Intervention: Time 3 vs. Time 1	-0.1053	0.1486	113	-0.71	0.4801
Intervention Low GRS Time 1	3.5247	0.2298			
Intervention Low GRS Time 3	3.3642	0.2298			
Intervention Average GRS Time 1	3.4556	0.3083			
Intervention Average GRS Time 3	3.5194	0.3083			
Intervention Low GRS: Time 3 vs. Time 1	-0.1605	0.1272	113	-1.26	0.2096
Intervention Average GRS: Time 3 vs. Time 1	0.06389	0.1707	113	0.37	0.7088
Intervention: Low GRS vs. Average GRS: Time 3 vs. Time 1	-0.2244	0.2128	113	-1.05	0.2940

TABLE 20. REGRESSION ANALYSIS FOR PERCEIVED FEAR

Label	*Estimate*	*Standard Error*	*DF*	*t Value*	*Pr > |t|*
Control Time 1	2.9738	0.2565			
Control Time 3	2.7239	0.2572			
Intervention Time 1	2.7917	0.2633			
Intervention Time 3	2.9528	0.2633			
Control: Time 3 vs. Time 1	-0.2499	0.1807	111	-1.38	0.1694
Intervention: Time 3 vs. Time 1	0.1611	0.1844	111	0.87	0.3842
Control vs. Intervention: Time 3 vs. Time 1	-0.4110	0.2582	111	-1.59	0.1142
Intervention Low GRS Time 1	3.0833	0.3147			
Intervention Low GRS Time 3	3.0556	0.3147			
Intervention Average GRS Time 1	2.5000	0.4222			
Intervention Average GRS Time 3	2.8500	0.4222			
Intervention Low GRS: Time 3 vs. Time 1	-0.02778	0.2204	111	-0.13	0.8999
Intervention Average GRS: Time 3 vs. Time 1	0.3500	0.2957	111	1.18	0.2391
Intervention: Low GRS vs. Average GRS: Time 3 vs. Time 1	-0.3778	0.3688	111	-1.02	0.3079

C. COPING APPRAISAL

TABLE 21. REGRESSION ANALYSIS FOR COPING EFFICACY

Label	*Estimate*	*Standard Error*	*DF*	*t Value*	*Pr > |t|*
Control Time 2	11.0262	0.6402			
Control Time 3	10.5548	0.6402			
Intervention Time 2	11.2500	0.6572			
Intervention Time 3	11.2889	0.6572			
Control: Time 3 vs. Time 2	-0.4714	0.4139	113	-1.14	0.2571
Intervention: Time 3 vs. Time 2	0.03889	0.4249	113	0.09	0.9272
Control vs. Intervention: Time 3 vs. Time 2	-0.5103	0.5932	113	-0.86	0.3915
Intervention Low GRS Time 2	11.0000	0.7855			
Intervention Low GRS Time 3	11.2778	0.7855			
Intervention Average GRS Time 2	11.5000	1.0539			
Intervention Average GRS Time 3	11.3000	1.0539			
Intervention Low GRS: Time 3 vs. Time 2	0.2778	0.5079	113	0.55	0.5855
Intervention Average GRS: Time 3 vs. Time 2	-0.2000	0.6814	113	-0.29	0.7697
Intervention: Low GRS vs. Average GRS: Time 3 vs. Time 2	0.4778	0.8498	113	0.56	0.5751

TABLE 22. REGRESSION ANALYSIS FOR DIET RESPONSE EFFICACY

Label	*Estimate*	*Standard Error*	*DF*	*t Value*	*Pr > |t|*
Control Time 1	4.0881	0.2023			
Control Time 3	3.9480	0.2023			
Intervention Time 1	4.0537	0.2077			
Intervention Time 3	4.0398	0.2077			
Control: Time 3 vs. Time 1	-0.1401	0.1154	113	-1.21	0.2273
Intervention: Time 3 vs. Time 1	-0.01389	0.1185	113	-0.12	0.9069
Control vs. Intervention: Time 3 vs. Time 1	-0.1262	0.1654	113	-0.76	0.4470
Intervention Low GRS Time 1	4.0741	0.2482			
Intervention Low GRS Time 3	3.8796	0.2482			
Intervention Average GRS Time 1	4.0333	0.3330			
Intervention Average GRS Time 3	4.2000	0.3330			
Intervention Low GRS: Time 3 vs. Time 1	-0.1944	0.1416	113	-1.37	0.1724
Intervention Average GRS: Time 3 vs. Time 1	0.1667	0.1900	113	0.88	0.3822
Intervention: Low GRS vs. Average GRS: Time 3 vs. Time 1	-0.3611	0.2369	113	-1.52	0.1303

TABLE 23. REGRESSION ANALYSIS FOR DIET RESPONSE COST

Label	*Estimate*	*Standard Error*	*DF*	*t Value*	*Pr > |t|*
Control Time 1	4.1262	0.2067			
Control Time 3	3.9771	0.2071			
Intervention Time 1	3.8736	0.2122			
Intervention Time 3	3.9861	0.2122			
Control: Time 3 vs. Time 1	-0.1491	0.1065	112	-1.40	0.1643
Intervention: Time 3 vs. Time 1	0.1125	0.1087	112	1.03	0.3029
Control vs. Intervention: Time 3 vs. Time 1	-0.2616	0.1522	112	-1.72	0.0884
Intervention Low GRS Time 1	3.9722	0.2537			
Intervention Low GRS Time 3	3.9722	0.2537			
Intervention Average GRS Time 1	3.7750	0.3403			
Intervention Average GRS Time 3	4.0000	0.3403			
Intervention Low GRS: Time 3 vs. Time 1	0	0.1299	112	0.00	1.0000
Intervention Average GRS: Time 3 vs. Time 1	0.2250	0.1743	112	1.29	0.1995
Intervention: Low GRS vs. Average GRS: Time 3 vs. Time 1	-0.2250	0.2174	112	-1.03	0.3029

TABLE 24. REGRESSION ANALYSIS FOR PHYSICAL ACTIVITY RESPONSE EFFICACY

Label	*Estimate*	*Standard Error*	*DF*	*t Value*	*Pr > |t|*
Control Time 1	3.7294	0.1883			
Control Time 3	3.7048	0.1883			
Intervention Time 1	3.8715	0.1933			
Intervention Time 3	4.0130	0.1933			
Control: Time 3 vs. Time 1	-0.02460	0.1119	113	-0.22	0.8263
Intervention: Time 3 vs. Time 1	0.1415	0.1148	113	1.23	0.2205
Control vs. Intervention: Time 3 vs. Time 1	-0.1661	0.1603	113	-1.04	0.3024
Intervention Low GRS Time 1	3.8796	0.2311			
Intervention Low GRS Time 3	3.8259	0.2311			
Intervention Average GRS Time 1	3.8633	0.3100			
Intervention Average GRS Time 3	4.2000	0.3100			
Intervention Low GRS: Time 3 vs. Time 1	-0.05370	0.1372	113	-0.39	0.6963
Intervention Average GRS: Time 3 vs. Time 1	0.3367	0.1841	113	1.83	0.0701
Intervention: Low GRS vs. Average GRS: Time 3 vs. Time 1	-0.3904	0.2297	113	-1.70	0.0919

TABLE 25. REGRESSION ANALYSIS FOR PHYSICAL ACTIVITY RESPONSE COST

Label	*Estimate*	*Standard Error*	*DF*	*t Value*	*Pr > |t|*
Control Time 1	3.9839	0.1904			
Control Time 3	3.9458	0.1904			
Intervention Time 1	3.9778	0.1954			
Intervention Time 3	4.1278	0.1954			
Control: Time 3 vs. Time 1	-0.03810	0.1028	113	-0.37	0.7117
Intervention: Time 3 vs. Time 1	0.1500	0.1055	113	1.42	0.1580
Control vs. Intervention: Time 3 vs. Time 1	-0.1881	0.1474	113	-1.28	0.2044
Intervention Low GRS Time 1	4.0556	0.2336			
Intervention Low GRS Time 3	4.1806	0.2336			
Intervention Average GRS Time 1	3.9000	0.3134			
Intervention Average GRS Time 3	4.0750	0.3134			
Intervention Low GRS: Time 3 vs. Time 1	0.1250	0.1262	113	0.99	0.3239
Intervention Average GRS: Time 3 vs. Time 1	0.1750	0.1693	113	1.03	0.3034
Intervention: Low GRS vs. Average GRS: Time 3 vs. Time 1	-0.05000	0.2111	113	-0.24	0.8132

D. Maladaptive Coping

Table 26. Regression Analysis For Fatalism

Label	*Estimate*	*Standard Error*	*DF*	*t Value*	*Pr > |t|*
Control Time 1	2.3488	0.1626			
Control Time 3	2.4581	0.1626			
Intervention Time 1	2.2689	0.1669			
Intervention Time 3	2.3697	0.1669			
Control: Time 3 vs. Time 1	0.1093	0.07162	113	1.53	0.1298
Intervention: Time 3 vs. Time 1	0.1008	0.07352	113	1.37	0.1730
Control vs. Intervention: Time 3 vs. Time 1	0.008452	0.1026	113	0.08	0.9345
Intervention Low GRS Time 1	2.3528	0.1995			
Intervention Low GRS Time 3	2.4944	0.1995			
Intervention Average GRS Time 1	2.1850	0.2677			
Intervention Average GRS Time 3	2.2450	0.2677			
Intervention Low GRS: Time 3 vs. Time 1	0.1417	0.08788	113	1.61	0.1097
Intervention Average GRS: Time 3 vs. Time 1	0.06000	0.1179	113	0.51	0.6118
Intervention: Low GRS vs. Average GRS: Time 3 vs. Time 1	0.08167	0.1470	113	0.56	0.5797

TABLE 27. REGRESSION ANALYSIS FOR FATALISM SUBSCALE—PREDETERMINATION

Label	*Estimate*	*Standard Error*	*DF*	*t Value*	*Pr > |t|*
Control Time 1	2.5338	0.1807			
Control Time 3	2.5933	0.1807			
Intervention Time 1	2.3522	0.1855			
Intervention Time 3	2.4950	0.1855			
Control: Time 3 vs. Time 1	0.05952	0.09462	113	0.63	0.5306
Intervention: Time 3 vs. Time 1	0.1428	0.09713	113	1.47	0.1443
Control vs. Intervention: Time 3 vs. Time 1	-0.08325	0.1356	113	-0.61	0.5405
Intervention Low GRS Time 1	2.4944	0.2217			
Intervention Low GRS Time 3	2.7000	0.2217			
Intervention Average GRS Time 1	2.2100	0.2975			
Intervention Average GRS Time 3	2.2900	0.2975			
Intervention Low GRS: Time 3 vs. Time 1	0.2056	0.1161	113	1.77	0.0793
Intervention Average GRS: Time 3 vs. Time 1	0.08000	0.1558	113	0.51	0.6085
Intervention: Low GRS vs. Average GRS: Time 3 vs. Time 1	0.1256	0.1943	113	0.65	0.5194

TABLE 28. REGRESSION ANALYSIS FOR FATALISM SUBSCALE—LUCK

Label	*Estimate*	*Standard Error*	*DF*	*t Value*	*Pr > |t|*
Control Time 1	1.9333	0.1627			
Control Time 3	2.0143	0.1627			
Intervention Time 1	2.0361	0.1670			
Intervention Time 3	2.1653	0.1670			
Control: Time 3 vs. Time 1	0.08095	0.1046	112	0.77	0.4406
Intervention: Time 3 vs. Time 1	0.1292	0.1074	112	1.20	0.2315
Control vs. Intervention: Time 3 vs. Time 1	-0.04821	0.1499	112	-0.32	0.7483
Intervention Low GRS Time 1	2.0972	0.1996			
Intervention Low GRS Time 3	2.1806	0.1996			
Intervention Average GRS Time 1	1.9750	0.2678			
Intervention Average GRS Time 3	2.1500	0.2678			
Intervention Low GRS: Time 3 vs. Time 1	0.08333	0.1283	112	0.65	0.5175
Intervention Average GRS: Time 3 vs. Time 1	0.1750	0.1722	112	1.02	0.3116
Intervention: Low GRS vs. Average GRS: Time 3 vs. Time 1	-0.09167	0.2147	112	-0.43	0.6703

TABLE 29. REGRESSION ANALYSIS FOR FATALISM SUBSCALE—PESSIMISM

Label	*Estimate*	*Standard Error*	*DF*	*t Value*	*Pr > |t|*
Control Time 1	2.3175	0.1728			
Control Time 3	2.5286	0.1728			
Intervention Time 1	2.2852	0.1774			
Intervention Time 3	2.2972	0.1774			
Control: Time 3 vs. Time 1	0.2111	0.09481	113	2.23	0.0279
Intervention: Time 3 vs. Time 1	0.01204	0.09732	113	0.12	0.9018
Control vs. Intervention: Time 3 vs. Time 1	0.1991	0.1359	113	1.47	0.1456
Intervention Low GRS Time 1	2.2870	0.2120			
Intervention Low GRS Time 3	2.3611	0.2120			
Intervention Average GRS Time 1	2.2833	0.2845			
Intervention Average GRS Time 3	2.2333	0.2845			
Intervention Low GRS: Time 3 vs. Time 1	0.07407	0.1163	113	0.64	0.5255
Intervention Average GRS: Time 3 vs. Time 1	-0.05000	0.1561	113	-0.32	0.7493
Intervention: Low GRS vs. Average GRS: Time 3 vs. Time 1	0.1241	0.1946	113	0.64	0.5251

E. DIET

TABLE 30. REGRESSION ANALYSIS FOR FRUIT AND VEGETABLE SERVINGS

Label	*Estimate*	*Standard Error*	*DF*	*t Value*	*Pr > |t|*
Control Time 1	3.6074	0.3960			
Control Time 3	3.8796	0.3960			
Intervention Time 1	3.6813	0.4065			
Intervention Time 3	4.3308	0.4065			
Control: Time 3 vs. Time 1	0.2722	0.2934	55	0.93	0.3575
Intervention: Time 3 vs. Time 1	0.6496	0.3011	55	2.16	0.0354
Control vs. Intervention: Time 3 vs. Time 1	-0.3773	0.4204	55	-0.90	0.3733
Intervention Low GRS Time 1	3.0006	0.4859			
Intervention Low GRS Time 3	4.3367	0.4859			
Intervention Average GRS Time 1	4.3620	0.6519			
Intervention Average GRS Time 3	4.3250	0.6519			
Intervention Low GRS: Time 3 vs. Time 1	1.3361	0.3599	55	3.71	0.0005
Intervention Average GRS: Time 3 vs. Time 1	-0.03700	0.4829	55	-0.08	0.9392
Intervention: Low GRS vs. Average GRS: Time 3 vs. Time 1	1.3731	0.6023	55	2.28	0.0265

F. Physical Activity

Table 31. Regression Analysis For Total Walking Time

Label	*Estimate*	*Standard Error*	*DF*	*t Value*	*Pr > |t|*
Control Time 1	80.5357	64.5957			
Control Time 3	151.45	64.5957			
Intervention Time 1	123.99	66.3095			
Intervention Time 3	85.1389	66.3095			
Control: Time 3 vs. Time 1	70.9167	89.7040	55	0.79	0.4326
Intervention: Time 3 vs. Time 1	-38.8556	92.0839	55	-0.42	0.6747
Control vs. Intervention: Time 3 vs. Time 1	109.77	128.55	55	0.85	0.3969
Intervention Low GRS Time 1	123.89	79.2550			
Intervention Low GRS Time 3	94.7778	79.2550			
Intervention Average GRS Time 1	124.10	106.33			
Intervention Average GRS Time 3	75.5000	106.33			
Intervention Low GRS: Time 3 vs. Time 1	-29.1111	110.06	55	-0.26	0.7924
Intervention Average GRS: Time 3 vs. Time 1	-48.6000	147.66	55	-0.33	0.7433
Intervention: Low GRS vs. Average GRS: Time 3 vs. Time 1	19.4889	184.17	55	0.11	0.9161

TABLE 32. REGRESSION ANALYSIS FOR TOTAL MINUTES OF PHYSICAL ACTIVITY

Label	*Estimate*	*Standard Error*	*DF*	*t Value*	*Pr > |t|*
Control Time 1	145.49	134.56			
Control Time 3	277.31	134.56			
Intervention Time 1	285.11	138.13			
Intervention Time 3	274.28	138.13			
Control: Time 3 vs. Time 1	131.82	100.96	55	1.31	0.1971
Intervention: Time 3 vs. Time 1	-10.8278	103.64	55	-0.10	0.9172
Control vs. Intervention: Time 3 vs. Time 1	142.65	144.69	55	0.99	0.3285
Intervention Low GRS Time 1	416.11	165.09			
Intervention Low GRS Time 3	395.06	165.09			
Intervention Average GRS Time 1	154.10	221.50			
Intervention Average GRS Time 3	153.50	221.50			
Intervention Low GRS: Time 3 vs. Time 1	-21.0556	123.88	55	-0.17	0.8657
Intervention Average GRS: Time 3 vs. Time 1	-0.6000	166.20	55	-0.00	0.9971
Intervention: Low GRS vs. Average GRS: Time 3 vs. Time 1	-20.4556	207.28	55	-0.10	0.9217

REFERENCES

1. Khoury MJ, Bowen MS, Burke W, et al. Current priorities for public health practice in addressing the role of human genomics in improving population health. American journal of preventive medicine 2011;40:486-93.

2. McBride CM, Bowen D, Brody LC, et al. Future health applications of genomics: priorities for communication, behavioral, and social sciences research. American journal of preventive medicine 2010;38:556-65.

3. BRFSS Prevalance & Trends Data [online]. 2015. (Accessed Jun 21, 2017, at https://www.cdc.gov/brfss/brfssprevalence/.)

4. Liao Y, Greenlund KJ, Croft JB, Keenan NL, Giles WH. Factors explaining excess stroke prevalence in the US Stroke Belt. Stroke; a journal of cerebral circulation 2009;40:3336-41.

5. Marteau TM, French DP, Griffin SJ, et al. Effects of communicating DNA-based disease risk estimates on risk-reducing behaviours. Cochrane database of systematic reviews (Online) 2010:CD007275.

6. Sanderson SC, O'Neill SC, White DB, et al. Responses to online GSTM1 genetic test results among smokers related to patients with lung cancer: a pilot study. Cancer epidemiology, biomarkers & prevention : a publication of the American Association for Cancer Research, cosponsored by the American Society of Preventive Oncology 2009;18:1953-61.

7. Arkadianos I, Valdes AM, Marinos E, Florou A, Gill RD, Grimaldi KA. Improved weight management using genetic information to personalize a calorie controlled diet. Nutrition journal 2007;6:29.

8. Simonson MA, Wills AG, Keller MC, McQueen MB. Recent methods for polygenic analysis of genome-wide data implicate an important effect of common variants on cardiovascular disease risk. BMC Med Genet 2011;12:146.

9. O'donnell CJ, Nabel EG. Genomics of cardiovascular disease. New England Journal of Medicine 2011;365:2098-109.

10. Knowles JW, Assimes TL, Kiernan M, et al. Randomized Trial of Personal Genomics for Preventive Cardiology Design and Challenges. Circulation: Cardiovascular Genetics 2012;5:368-76.

11. Kochanek KD MS, Xu JQ, Tejada-Vera B. Deaths: Final data for 2014. National vital statistics reports. Hyattsville, MD: National Center for Health Statistics; 2016.

12. Vital Signs: Avoidable Deaths from Heart Disease, Stroke, and Hypertensive Disease — United States, 2001–2010. Morbidity and Mortality Weekly Report (MMWR): Centers for Disease Control and Prevention; September 6, 2013:721-7.

13. National Heart Lung and Blood Institute. Morbidity & Mortality: 2012 Chart Book on Cardiovascular, Lung, and Blood Diseases. Washington, DC: National Institutes of Health; 2012.

14. Heart Disease Death Rates, 2013-2015. All Ages 35+, by County. May 12, 2017 ed: National Vital Statistics System. National Center for Health Statistics; 2017.

15. Lenoir County 2014 Community Health Assessment. 2014. (Accessed June 21, 2017, at http://lenoirmemorial.thehcn.net/content/sites/lenoirmemorial/Lenoir_CHA_2014.pdf.)

16. Obesity Age-Adjusted Percentage [online]. 2013. (Accessed Jun 21, 2017, at https://www.cdc.gov/diabetes/atlas/countydata/atlas.html.)

17. Hubert HB, Feinleib M, McNamara PM, Castelli WP. Obesity as an independent risk factor for cardiovascular disease: a 26-year follow-up of participants in the Framingham Heart Study. Circulation 1983;67:968-77.

18. Gregg EW, Cheng YJ, Cadwell BL, et al. Secular trends in cardiovascular disease risk factors according to body mass index in US adults. JAMA 2005;293:1868-74.

19. Stampfer MJ, Hu FB, Manson JE, Rimm EB, Willett WC. Primary prevention of coronary heart disease in women through diet and lifestyle. New England Journal of Medicine 2000;343:16-22.

20. Mente A, de Koning L, Shannon HS, Anand SS. A systematic review of the evidence supporting a causal link between dietary factors and coronary heart disease. Archives of internal medicine 2009;169:659-69.

21. Iestra J, Kromhout D, Van der Schouw Y, Grobbee D, Boshuizen H, Van Staveren W. Effect Size Estimates of Lifestyle and Dietary Changes on All-Cause Mortality in Coronary Artery Disease Patients A Systematic Review. Circulation 2005;112:924-34.

22. Hu FB, Willett WC. Optimal diets for prevention of coronary heart disease. JAMA: the journal of the American Medical Association 2002;288:2569-78.

23. De Lorgeril M, Renaud S, Salen P, et al. Mediterranean alpha-linolenic acid-rich diet in secondary prevention of coronary heart disease. The Lancet 1994;343:1454-9.

24. Barringer TA. Mediterranean diets and cardiovascular disease. Current atherosclerosis reports 2001;3:437-45.

25. Goulet J, Lapointe A, Lemieux S, Lamarche B. Mediterranean Diet and Cardiovascular Disease. Current Nutrition & Food Science 2006;2:265-73.

26. Michel de Lorgeril M, Salen P, Martin J-L, Monjaud I, Delaye J, Mamelle N. Mediterranean diet, traditional risk factors, and the rate of cardiovascular complications after myocardial infarction. Heart failure 1999;11:6.

27. Romero CX, Romero TE, Shlay JC, Ogden LG, Dabelea D. Changing trends in the prevalence and disparities of obesity and other cardiovascular disease risk factors in three racial/ethnic groups of USA adults. Advances in preventive medicine 2012;2012.

28. Risk Factors and Health Indicators by Race/Ethnicity, Gender, and Trend. Center for Disease Control and Prevention, 2011. (Accessed Oct 8, 2013, at http://wwwn.cdc.gov/sortablestats/.)

29. Arking DE, Chakravarti A. Understanding cardiovascular disease through the lens of genome-wide association studies. Trends in Genetics 2009;25:387-94.

30. Hindorff LA, Sethupathy P, Junkins HA, et al. Potential etiologic and functional implications of genome-wide association loci for human diseases and traits. Proceedings of the National Academy of Sciences 2009;106:9362-7.

31. Larson M, Atwood L, Benjamin E, et al. Framingham Heart Study 100K project: genome-wide associations for cardiovascular disease outcomes. BMC medical genetics 2007;8:S5.

32. A Catalog of Published Genome-Wide Association Studies. National Institutes of Health Genomic Research Institute.

33. Burton PR, Clayton DG, Cardon LR, et al. Genome-wide association study of 14,000 cases of seven common diseases and 3,000 shared controls. Nature 2007;447:661-78.

34. Thanassoulis G, Peloso GM, Pencina MJ, et al. A Genetic Risk Score Is Associated With Incident Cardiovascular Disease and Coronary Artery Calcium The Framingham Heart Study. Circulation: Cardiovascular Genetics 2012;5:113-21.

35. Ripatti S, Tikkanen E, Orho-Melander M, et al. A multilocus genetic risk score for coronary heart disease: case-control and prospective cohort analyses. The Lancet 2010;376:1393-400.

36. Kathiresan S, Melander O, Anevski D, et al. Polymorphisms associated with cholesterol and risk of cardiovascular events. New England Journal of Medicine 2008;358:1240-9.

37. Simonson M, Wills A, Keller M, McQueen M. Recent methods for polygenic analysis of genome-wide data implicate an important effect of common variants on cardiovascular disease risk. BMC medical genetics 2011;12:146.

38. Van Hoek M, Dehghan A, Witteman JC, et al. Predicting type 2 Diabetes based on polymorphisms from genome-wide association studies a population-based study. Diabetes 2008;57:3122-8.

39. Adeyemo A, Gerry N, Chen G, et al. A genome-wide association study of hypertension and blood pressure in African Americans. PLoS genetics 2009;5:1-11.

40. Chen G, Bentley A, Adeyemo A, et al. Genome-wide association study identifies novel loci association with fasting insulin and insulin resistance in African Americans. Human molecular genetics 2012;21:4530-6.

41. Barbalic M, Reiner AP, Wu C, et al. Genome-wide association analysis of incident coronary heart disease (CHD) in African Americans: a short report. PLoS genetics 2011;7:1-5.

42. David S, Hamidovic A, Chen G, et al. Genome-wide meta-analyses of smoking behaviors in African Americans. Translational psychiatry 2012;2:1-8.

43. Doumatey AP, Chen G, Ayele FT, et al. C-reactive protein (CRP) promoter polymorphisms influence circulating CRP levels in a genome-wide association study of African Americans. Human molecular genetics 2012;21:3063-72.

44. Fox ER, Young JH, Li Y, et al. Association of genetic variation with systolic and diastolic blood pressure among African Americans: the Candidate Gene Association Resource study. Human molecular genetics 2011;20:2273-84.

45. Irvin MR, Wineinger NE, Rice TK, et al. Genome-wide detection of allele specific copy number variation associated with insulin resistance in African Americans from the HyperGEN study. PloS one 2011;6:1-6.

46. Lettre G, Palmer CD, Young T, et al. Genome-wide association study of coronary heart disease and its risk factors in 8,090 African Americans: the NHLBI CARe Project. PLoS genetics 2011;7:1-11.

47. Ng MC, Hester JM, Wing MR, et al. Genome‐Wide Association of BMI in African Americans. Obesity 2012;20:622-7.

48. Palmer ND, McDonough CW, Hicks PJ, et al. A genome-wide association search for type 2 diabetes genes in African Americans. PloS one 2012;7:1-14.

49. Smith NL, Felix JF, Morrison AC, et al. Association of Genome-Wide Variation With the Risk of Incident Heart Failure in Adults of European and African Ancestry A Prospective Meta-Analysis From the Cohorts for Heart and Aging Research in Genomic Epidemiology (CHARGE) Consortium. Circulation: Cardiovascular Genetics 2010;3:256-66.

50. Gong J, Schumacher F, Lim U, et al. Fine mapping and identification of BMI loci in African Americans. The American Journal of Human Genetics 2013;93:661-71.

51. Liu C-T, Monda KL, Taylor KC, et al. Genome-wide association of body fat distribution in African ancestry populations suggests new loci. PLoS Genet 2013;9:e1003681.

52. Locke AE, Kahali B, Berndt SI, et al. Genetic studies of body mass index yield new insights for obesity biology. Nature 2015;518:197-206.

53. Monda KL, Chen GK, Taylor KC, et al. A meta-analysis identifies new loci associated with body mass index in individuals of African ancestry. Nature genetics 2013;45:690-6.

54. Peters U, North KE, Sethupathy P, et al. A systematic mapping approach of 16q12. 2/FTO and BMI in more than 20,000 African Americans narrows in on the underlying functional variation: results from the Population Architecture using Genomics and Epidemiology (PAGE) study. PLoS Genet 2013;9:e1003171.

55. Carlson CS, Matise TC, North KE, et al. Generalization and dilution of association results from European GWAS in populations of non-European ancestry: the PAGE study. PLoS biology 2013;11:e1001661.

56. Teslovich TM, Musunuru K, Smith AV, et al. Biological, clinical and population relevance of 95 loci for blood lipids. Nature 2010;466:707-13.

57. Cheng C-Y, Reich D, Haiman CA, et al. African ancestry and its correlation to type 2 diabetes in African Americans: a genetic admixture analysis in three US population cohorts. PloS one 2012;7:e32840.

58. Haiman CA, Fesinmeyer MD, Spencer KL, et al. Consistent Directions of Effect for Established Type 2 Diabetes Risk Variants Across Populations The Population Architecture using Genomics and Epidemiology (PAGE) Consortium. Diabetes 2012;61:1642-7.

59. Hasstedt SJ, Highland HM, Elbein SC, Hanis CL, Das SK. Five linkage regions each harbor multiple type 2 diabetes genes in the African American subset of the GENNID Study. Journal of human genetics 2013;58:378-83.

60. Jeff JM, Armstrong LL, Ritchie MD, et al. Admixture Mapping and Subsequent Fine-Mapping Suggests a Biologically Relevant and Novel Association on Chromosome 11 for Type 2 Diabetes in African Americans. PloS one 2014;9:e86931.

61. Long J, Edwards T, Signorello LB, et al. Evaluation of genome-wide association study-identified type 2 diabetes loci in African Americans. American journal of epidemiology 2012;176:995-1001.

62. McCormack S, Grant SF. Genetics of obesity and type 2 diabetes in African Americans. Journal of obesity 2013;2013.

63. Ng MC, Saxena R, Li J, et al. Transferability and Fine Mapping of Type 2 Diabetes Loci in African Americans The Candidate Gene Association Resource Plus Study. Diabetes 2013;62:965-76.

64. Saxena R, Elbers CC, Guo Y, et al. Large-scale gene-centric meta-analysis across 39 studies identifies type 2 diabetes loci. The American Journal of Human Genetics 2012;90:410-25.

65. Waters KM, Stram DO, Hassanein MT, et al. Consistent association of type 2 diabetes risk variants found in europeans in diverse racial and ethnic groups. PLoS genetics 2010;6:e1001078.

66. Franceschini N, Fox E, Zhang Z, et al. Genome-wide association analysis of blood-pressure traits in African-ancestry individuals reveals common associated genes in African and non-African populations. The American Journal of Human Genetics 2013;93:545-54.

67. Hall JL, Duprez DA, Barac A, Rich SS. A review of genetics, arterial stiffness, and blood pressure in African Americans. Journal of cardiovascular translational research 2012;5:302-8.

68. Nguyen K-DH, Pihur V, Ganesh SK, et al. Effects of Rare and Common Blood Pressure Gene Variants on Essential Hypertension Results From the Family Blood Pressure Program, CLUE, and Atherosclerosis Risk in Communities Studies. Circulation research 2013;112:318-26.

69. Shetty PB, Hua T, Bamidele T, et al. Variants in CXADR and F2RL1 are associated with blood pressure and obesity in African-Americans in regions identified through admixture mapping. Journal of hypertension 2012;30:1970.

70. International Consortium for Blood Pressure Genome-Wide Association Studies. Genetic variants in novel pathways influence blood pressure and cardiovascular disease risk. Nature 2011;478:103-9.

71. Zhu X, Cooper RS. Admixture mapping provides evidence of association of the VNN1 gene with hypertension. PLoS One 2007;2:e1244.

72. Tekola-Ayele F, Adeyemo AA, Rotimi CN. Genetic epidemiology of type 2 diabetes and cardiovascular diseases in Africa. Progress in cardiovascular diseases 2013;56:251-60.

73. Zhang L, Buzkova P, Wassel CL, et al. Lack of associations of ten candidate coronary heart disease risk genetic variants and subclinical atherosclerosis in four US populations: the Population Architecture using Genomics and Epidemiology (PAGE) study. Atherosclerosis 2013;228:390-9.

74. Hamidovic A, Goodloe RJ, Bergen AW, et al. Gene-centric analysis of serum cotinine levels in African and European American populations. Neuropsychopharmacology 2011;37:968-74.

75. Han S, Yang BZ, Kranzler HR, Oslin D, Anton R, Gelernter J. Association of CHRNA4 polymorphisms with smoking behavior in two populations. American Journal of Medical Genetics Part B: Neuropsychiatric Genetics 2011;156:421-9.

76. Condon C, McCarthy G. Lifestyle changes following acute myocardial infarction: patients perspectives. European Journal of Cardiovascular Nursing 2006;5:37-44.

77. Plotnikoff RC, Higginbotham N. Protection motivation theory and the prediction of exercise and low-fat diet behaviours among Australian cardiac patients. Psychology and Health 1998;13:411-29.

78. Edwards AG, Naik G, Ahmed H, et al. Personalised risk communication for informed decision making about taking screening tests. Cochrane database of systematic reviews (Online) 2013.

79. Noar SM, Benac CN, Harris MS. Does tailoring matter? Meta-analytic review of tailored print health behavior change interventions. Psychological bulletin 2007;133:673.

80. Ahmed H, Naik G, Willoughby H, Edwards A. Communicating risk. BMJ 2012;344:40-4.

81. Nagle C, Gunn J, Bell R, et al. Use of a decision aid for prenatal testing of fetal abnormalities to improve women's informed decision making: a cluster randomised controlled trial [ISRCTN22532458]. BJOG: An International Journal of Obstetrics & Gynaecology 2008;115:339-47.

82. Rimer BK, Halabi S, Sugg Skinner C, et al. Effects of a mammography decision-making intervention at 12 and 24 months. American journal of preventive medicine 2002;22:247-57.

83. Trevena LJ, Irwig L, Barratt A. Randomized trial of a self-administered decision aid for colorectal cancer screening. Journal of Medical Screening 2008;15:76-82.

84. Bloom JR, Stewart SL, Chang S, You M. Effects of a telephone counseling intervention on sisters of young women with breast cancer. Preventive medicine 2006;43:379-84.

85. Glazebrook C, Garrud P, Avery A, Coupland C, Williams H. Impact of a multimedia intervention “Skinsafe” on patients' knowledge and protective behaviors. Preventive medicine 2006;42:449-54.

86. Schwartz MD, Rimer BK, Daly M, Sands C, Lerman C. A randomized trial of breast cancer risk counseling: the impact on self-reported mammography use. American Journal of Public Health 1999;89:924-6.

87. Bastani R, Maxwell AE, Bradford C, Das IP, Yan KX. Tailored risk notification for women with a family history of breast cancer. Preventive medicine 1999;29:355-64.

88. Bodurtha J, Quillin JM, Tracy KA, et al. Mammography screening after risk-tailored messages: the women improving screening through education and risk assessment (WISER) randomized, controlled trial. Journal of Women's Health 2009;18:41-7.

89. Bowen DJ, Powers D. Effects of a mail and telephone intervention on breast health behaviors. Health Education & Behavior 2010;37:479-89.

90. Glanz K, Steffen AD, Taglialatela LA. Effects of colon cancer risk counseling for first-degree relatives. Cancer Epidemiology Biomarkers & Prevention 2007;16:1485-91.

91. Lee CY. A randomized controlled trial to motivate worksite fecal occult blood testing. Yonsei medical journal 1991;32:131-8.

92. Sequist TD, Zaslavsky AM, Colditz GA, Ayanian JZ. Electronic patient messages to promote colorectal cancer screening: a randomized controlled trial. Archives of internal medicine 2011;171:636.

93. Smith SK, Trevena L, Simpson JM, Barratt A, Nutbeam D, McCaffery KJ. A decision aid to support informed choices about bowel cancer screening among adults with low education: randomised controlled trial. BMJ: British Medical Journal 2010;341.

94. Steckelberg A, Hülfenhaus C, Haastert B, Mühlhauser I. Effect of evidence based risk information on “informed choice” in colorectal cancer screening: randomised controlled trial. BMJ: British Medical Journal 2011;342.

95. Lerman C, Lustbader E, Rimer B, et al. Effects of individualized breast cancer risk counseling: a randomized trial. Journal of the National Cancer Institute 1995;87:286-92.

96. Skinner CS, Schildkraut JM, Berry D, et al. Pre-counseling education materials for BRCA testing: does tailoring make a difference? Genetic Testing 2002;6:93-105.

97. Berkman ND, Sheridan SL, Donahue KE, Halpern DJ, Crotty K. Low health literacy and health outcomes: an updated systematic review. Annals of Internal Medicine 2011;155:97-107.

98. Kutner M, Greenburg E, Jin Y, Paulsen C. The Health Literacy of America's Adults: Results from the 2003 National Assessment of Adult Literacy. NCES 2006-483. National Center for Education Statistics 2006.

99. Baker DW, Parker RM, Williams MV, Clark WS, Nurss J. The relationship of patient reading ability to self-reported health and use of health services. American journal of public health 1997;87:1027-30.

100. Baker DW, Parker RM, Williams MV. Health literacy and the risk of hospital admission. Journal of general internal medicine 1998;13:791-8.

101. Gazmararian JA, Williams MV, Peel J, Baker DW. Health literacy and knowledge of chronic disease. Patient education and counseling 2003;51:267-75.

102. Schillinger D, Grumbach K, Piette J, et al. Association of health literacy with diabetes outcomes. JAMA: the journal of the American Medical Association 2002;288:475-82.

103. Wolf MS, Gazmararian JA, Baker DW. Health literacy and functional health status among older adults. Archives of Internal Medicine 2005;165:1946.

104. Kripalani S, Henderson LE, Chiu EY, Robertson R, Kolm P, Jacobson TA. Predictors of Medication Self‐management Skill in a Low‐literacy Population. Journal of General Internal Medicine 2006;21:852-6.

105. Waldrop-Valverde D, Jones DL, Jayaweera D, Gonzalez P, Romero J, Ownby RL. Gender differences in medication management capacity in HIV infection: the role of health literacy and numeracy. AIDS and Behavior 2009;13:46-52.

106. Raehl CL, Bond C, Woods TJ, Patry RA, Sleeper RB. Screening tests for intended medication adherence among the elderly. The Annals of pharmacotherapy 2006;40:888-93.

107. Davis TC, Wolf MS, Bass PF, et al. Literacy and misunderstanding prescription drug labels. Annals of internal medicine 2006;145:887-94.

108. Wolf MS, Davis TC, Shrank W, et al. To err is human: patient misinterpretations of prescription drug label instructions. Patient education and counseling 2007;67:293-300.

109. Rothman RL, Housam R, Weiss H, et al. Patient understanding of food labels: the role of literacy and numeracy. American journal of preventive medicine 2006;31:391-8.

110. Baker DW, Wolf MS, Feinglass J, Thompson JA, Gazmararian JA, Huang J. Health literacy and mortality among elderly persons. Archives of Internal Medicine 2007;167:1503.

111. Baker DW, Thompson JA. Health literacy, cognitive abilities, and mortality among elderly persons. Journal of General Internal Medicine 2008;23:723-6.

112. Sudore RL, Yaffe K, Satterfield S, et al. Limited literacy and mortality in the elderly: the health, aging, and body composition study. Journal of General Internal Medicine 2006;21:806-12.

113. Estrada CA, Martin-Hryniewicz M, Peek BT, Collins C, Byrd JC. Literacy and numeracy skills and anticoagulation control. The American journal of the medical sciences 2004;328:88-93.

114. Cavanaugh K, Huizinga MM, Wallston KA, et al. Association of numeracy and diabetes control. Annals of Internal Medicine 2008;148:737-46.

115. Baker DW, Gazmararian JA, Williams MV, et al. Functional health literacy and the risk of hospital admission among Medicare managed care enrollees. American Journal of Public Health 2002;92:1278-83.

116. Apter AJ, Cheng J, Small D, et al. Asthma numeracy skill and health literacy. Journal of Asthma 2006;43:705-10.

117. Estrada C, Barnes V, Collins C, Byrd JC. Health literacy and numeracy. JAMA: The Journal of the American Medical Association 1999;282:527-.

118. Lipkus IM, Samsa G, Rimer BK. General performance on a numeracy scale among highly educated samples. Medical Decision Making 2001;21:37-44.

119. Reyna VF, Lloyd FJ, Whalen P. Genetic testing and medical decision making. Archives of Internal Medicine 2001;161:2406.

120. Reyna VF, Nelson WL, Han PK, Dieckmann NF. How numeracy influences risk comprehension and medical decision making. Psychological bulletin 2009;135:943-73.

121. Sheridan SL, Pignone M. Numeracy and the medical student's ability to interpret data. Effective clinical practice: ECP 2002;5:35.

122. Weinstein ND. What does it mean to understand a risk? Evaluating risk comprehension. JNCI Monographs 1999;1999:15-20.

123. Forrow L, Taylor WC, Arnold RM. Absolutely relative: how research results are summarized can affect treatment decisions. The American journal of medicine 1992;92:121-4.

124. Brewer NT, Weinstein ND, Cuite CL, Herrington JE. Risk perceptions and their relation to risk behavior. Annals of Behavioral Medicine 2004;27:125-30.

125. Klein WM, Stefanek ME. Cancer risk elicitation and communication: lessons from the psychology of risk perception. CA: A Cancer Journal for Clinicians 2007;57:147-67.

126. Mills B, Reyna VF, Estrada S. Explaining contradictory relations between risk perception and risk taking. Psychological science 2008;19:429-33.

127. Black WC, Nease RF, Tosteson AN. Perceptions of breast cancer risk and screening effectiveness in women younger than 50 years of age. Journal of the National Cancer Institute 1995;87:720-31.

128. Davids SL, Schapira MM, McAuliffe TL, Nattinger AB. Predictors of pessimistic breast cancer risk perceptions in a primary care population. Journal of general internal medicine 2004;19:310-5.

129. Gurmankin AD, Baron J, Armstrong K. Intended message versus message received in hypothetical physician risk communications: exploring the gap. Risk Analysis 2004;24:1337-47.

130. Schwartz LM, Woloshin S, Black WC, Welch HG. The role of numeracy in understanding the benefit of screening mammography. Annals of internal medicine 1997;127:966-72.

131. Woloshin S, Schwartz LM, Black WC, Welch HG. Women's Perceptions of Breast Cancer Risk How You Ask Matters. Medical Decision Making 1999;19:221-9.

132. Barratt A, Irwig L, Glasziou P, et al. Users' Guides to the Medical Literature. JAMA: the journal of the American Medical Association 1999;281:2029-34.

133. Johnson A, Sandford J, Tyndall J. Written and verbal information versus verbal information only for patients being discharged from acute hospital settings to home. Cochrane database of systematic reviews (Online) 2003;4.

134. Direct-to-Consumer Testing and Its Impact on the Lab Market. G2 Reports, 2008. at http://www.g2reports.com/issues/advisory/advisory/mark_terry/235-1.html.)

135. Freese J, Shostak S. Genetics and social inquiry. Annual Review of Sociology 2009;35:107-28.

136. Credence Research Inc. Direct-to-Consumer Genetic Testing: Market Growth, Future Prospects and Competitive Analysis, 2016-2022. San Jose, CA2016. Report No.: 57820-05-16.

137. Christensen KD, Jayaratne T, Roberts J, Kardia S, Petty E. Understandings of basic genetics in the United States: results from a national survey of black and white men and women. Public health genomics 2010;13:467-76.

138. Lanie AD, Jayaratne TE, Sheldon JP, et al. Exploring the public understanding of basic genetic concepts. Journal of genetic counseling 2004;13:305-20.

139. McBride CM, Wade CH, Kaphingst KA. Consumers' views of direct-to-consumer genetic information. Annual review of genomics and human genetics 2010;11:427-46.

140. Condit CM. Public understandings of genetics and health. Clinical genetics 2010;77:1-9.

141. Bates BR. Public culture and public understanding of genetics: a focus group study. Public Understanding of Science 2005;14:47-65.

142. Smerecnik CM, Mesters I, de Vries NK, de Vries H. Educating the general public about multifactorial genetic disease: applying a theory-based framework to understand current public knowledge. Genetics in Medicine 2008;10:251-8.

143. McGuire AL, Diaz CM, Wang T, Hilsenbeck SG. Social networkers' attitudes toward direct-to-consumer personal genome testing. The American journal of bioethics 2009;9:3-10.

144. Bloss CS, Madlensky L, Schork NJ, Topol EJ. Genomic information as a behavioral health intervention: can it work? Personalized medicine 2011;8:659-67.

145. Bloss CS, Schork NJ, Topol EJ. Effect of Direct-to-Consumer Genomewide Profiling to Assess Disease Risk. The New England Journal of Medicine 2011;364:524-34.

146. Heshka JT, Palleschi C, Howley H, Wilson B, Wells PS. A systematic review of perceived risks, psychological and behavioral impacts of genetic testing. Genetics in Medicine 2008;10:19-32.

147. Marteau T, Senior V, Humphries SE, et al. Psychological impact of genetic testing for familial hypercholesterolemia within a previously aware population: a randomized controlled trial. American Journal of Medical Genetics Part A 2004;128:285-93.

148. Chao S, Roberts JS, Marteau TM, Silliman R, Cupples LA, Green RC. Health behavior changes after genetic risk assessment for Alzheimer disease: The REVEAL Study. Alzheimer disease and associated disorders 2008;22:94.

149. Godino JG, van Sluijs EM, Marteau TM, Sutton S, Sharp SJ, Griffin SJ. Effect of communicating genetic and phenotypic risk for type 2 diabetes in combination with lifestyle advice on objectively measured physical activity: protocol of a randomised controlled trial. BMC public health 2012;12:444.

150. Godino JG, van Sluijs EM, Marteau TM, Sutton S, Sharp SJ, Griffin SJ. Lifestyle Advice Combined with Personalized Estimates of Genetic or Phenotypic Risk of Type 2 Diabetes,

and Objectively Measured Physical Activity: A Randomized Controlled Trial. PLoS medicine 2016;13:e1002185.

151. Grant RW, O'Brien KE, Waxler JL, et al. Personalized Genetic Risk Counseling to Motivate Diabetes Prevention A randomized trial. Diabetes care 2013;36:13-9.

152. Diabetes Prevention Program Research Group. The Diabetes Prevention Program (DPP) description of lifestyle intervention. Diabetes care 2002;25:2165-71.

153. Grant RW, Meigs JB, Florez JC, et al. Design of a randomized trial of diabetes genetic risk testing to motivate behavior change: the Genetic Counseling/lifestyle Change (GC/LC) Study for Diabetes Prevention. Clinical trials 2011;8:609-15.

154. Cho AH, Killeya-Jones LA, O'Daniel JM, et al. Effect of genetic testing for risk of type 2 diabetes mellitus on health behaviors and outcomes: study rationale, development and design. BMC health services research 2012;12:16.

155. Cameron LD, Sherman KA, Marteau TM, Brown PM. Impact of genetic risk information and type of disease on perceived risk, anticipated affect, and expected consequences of genetic tests. Health Psychology 2009;28:307-16.

156. Helmes AW, Culver JO, Bowen DJ. Results of a randomized study of telephone versus in-person breast cancer risk counseling. Patient education and counseling 2006;64:96-103.

157. Waxler JL, O'Brien KE, Delahanty LM, et al. Genetic counseling as a tool for type 2 diabetes prevention: a genetic counseling framework for common polygenetic disorders. Journal of genetic counseling 2012;21:684-91.

158. Collins RE, Wright AJ, Marteau TM. Impact of communicating personalized genetic risk information on perceived control over the risk: a systematic review. Genetics in Medicine 2011;13:273-7.

159. Boer H, Seydel ER. Protection motivation theory. In: Conner M, Norman P, eds. Predicting Health Behaviour: Research and Practice with Social Cognition Models: Open University Press; 1996:95-120.

160. Glanz K, Rimer BK, Viswanath K. Health Behavior and Health Education2008.

161. Milne S, Sheeran P, Orbell S. Prediction and Intervention in Health‐Related Behavior: A Meta‐analytic Review of Protection Motivation Theory. Journal of Applied Social Psychology 2000;30:106-43.

162. Bates BR, Templeton A, Achter PJ, Harris TM, Condit CM. What does "a gene for heart disease" mean? A focus group study of public understandings of genetic risk factors. American Journal of Medical Genetics 2003;119A:156-61.

163. Plotnikoff R, Higginbotham N. Protection Motivation Theory and exercise behaviour change for the prevention of heart disease in a high-risk, Australian representative community sample of adults. Psychology, health & medicine 2002;7:87-98.

164. McBride CM, Koehly LM, Sanderson SC, Kaphingst KA. The behavioral response to personalized genetic information: will genetic risk profiles motivate individuals and families to choose more healthful behaviors? Annual review of public health 2010;31:89-103.

165. Marteau TM. Communicating genetic risk information. British medical bulletin 1999;55:414-28.

166. Halladay JR, Donahue KE, Hinderliter AL, et al. The heart healthy lenoir project-an intervention to reduce disparities in hypertension control: study protocol. 2013;13:441.

167. Pitts SBJ, Smith TW, Thayer LM, et al. Addressing rural health disparities through policy change in the stroke belt. Journal of Public Health Management and Practice 2013;19:503-10.

168. Wing S, Casper M, Davis WB, Pellom A, Riggan W, Tyroler H. Stroke mortality maps. United States whites aged 35-74 years, 1962-1982. Stroke 1988;19:1507-13.

169. Heyman A, Tyroler HA, Cassel JC, O'Fallon W, Davis L, Muhlbaier L. Geographic differences in mortality from stroke in North Caroline. 1. Analysis of death certificates. Stroke 1976;7:41-5.

170. Behavioral Risk Factor Surveillance System Survey Data. Atlanta (GA): U.S. Department of Health and Human Services, Centers for Disease Control and Prevention; 2012:Risk Factors and Health Indicators by Race/Ethnicity, Gender, and Trend.

171. U.S. Census Bureau: State and County QuickFacts.Data derived from Population Estimates, American Community Survey, Census of Population and Housing, State and County Housing Unit Estimates, County Business Patterns, Nonemployer Statistics, Economic Census, Survey of Business Owners, Building Permits.

172. Lenoir County 2011 Community Health Assessment. 2011. at http://www.co.lenoir.nc.us/documents/2011CHAFFINAL_000.pdf.)

173. Minkler M, Wallerstein N. Community-based participatory research for health: From process to outcomes. 2nd ed ed. San Francisco (CA): Jossey-Bass; 2010.

174. Viswanathan M, Ammerman A, Eng E, et al. Community‐Based Participatory Research: Assessing the Evidence: Summary. Rockville (MD): Agency for Healthcare Research and Quality (US); 1998-2005; 2004 Aug. Report No.: 99.

175. Israel BA, Schulz AJ, Parker EA, Becker AB, Allen A, Guzman JR. Critical issues in developing and following CBPR principles. In: Minkler M, Wallerstein N, eds. Community-based participatory research for health: From process to outcomes. San Francisco (CA): Jossey-Bass; 2010:47 - 66.

176. Corbie‐Smith G, Thomas SB, Williams MV, Moody‐Ayers S. Attitudes and beliefs of African Americans toward participation in medical research. Journal of General Internal Medicine 1999;14:537-46.

177. Corbie-Smith G. The continuing legacy of the Tuskegee Syphilis Study: considerations for clinical investigation. The American journal of the medical sciences 1999;317:5-8.

178. Gamble VN. Under the shadow of Tuskegee: African Americans and health care. American Journal of Public Health 1997;87:1773-8.

179. Thomas SB, Quinn SC. The Tuskegee Syphilis Study, 1932 to 1972: implications for HIV education and AIDS risk education programs in the black community. American journal of public health 1991;81:1498-505.

180. Corneli AL, Bentley ME, Sorenson JR, et al. Using formative research to develop a context-specific approach to informed consent for clinical trials. Journal of empirical research on human research ethics: JERHRE 2006;1:45.

181. Poureslami I, Nimmon L, Doyle-Waters MMR, FitzGerald JM. Using community-based participatory research (CBPR) with ethno-cultural groups as a tool to develop culturally and linguistically appropriate asthma educational material. Diversity in Health and Care 2011;8:203-15.

182. FitzGerald J, Doyle-Waters M, Poureslami I. "Using Community-Based Participatory Research (CBPR) To Develop Culturally And Linguistically Appropriate Educational Materials To Assess Asthma Patients" Knowledge And Health Literacy In Ethno-Cultural Groups. American Thoracic Society International Conference; 2011 May 13-18; Denver (CO). p. A1429.

183. Chang C, Minkler M, Salvatore AL, Lee PT, Gaydos M, San Liu S. Studying and Addressing Urban Immigrant Restaurant Worker Health and Safety in San Francisco's Chinatown District: A CBPR Case Study. Journal of Urban Health 2013;90:1026-40.

184. Faden RR, Beauchamp TL, King NM. A history and theory of informed consent. New York (NY): Oxford University Press; 1986.

185. Ulin PR, Robinson ET, Tolley EE. Qualitative methods in public health: a field guide for applied research. San Francisco, CA: Jossey-Bass; 2005.

186. Miles MB, Huberman AM. Qualitative Data Analysis. Thousand Oaks (CA): Sage; 1994.

187. Strauss AL, Corbin J. Basics of qualitative research. Newbury Park (CA): Sage Publications 1990.

188. Crabtree BF, Miller WL. Doing qualitative research. 2nd ed ed. Thousand Oaks, CA: Sage Publications; 1999.

189. Braun V, Clarke V. Using thematic analysis in psychology. Qualitative research in psychology 2006;3:77-101.

190. Appelbaum PS, Roth LH, Lidz C. The therapeutic misconception: informed consent in psychiatric research. International journal of law and psychiatry 1982;5:319-29.

191. Christianson CA, Powell KP, Hahn SE, et al. Findings from a community education needs assessment to facilitate the integration of genomic medicine into primary care. Genetics in Medicine 2010;12:587-93.

192. Henderson G, Garrett J, Bussey-Jones J, Moloney ME, Blumenthal C, Corbie-Smith G. Great expectations: views of genetic research participants regarding current and future genetic studies. Genetics in Medicine 2008;10:193-200.

193. Sterling R, Henderson GE, Corbie-Smith G. Public willingness to participate in and public opinions about genetic variation research: a review of the literature. American journal of public health 2006;96:1971-8.

194. Parrott R, Kahl ML, Ndiaye K, Traeder T. Health communication, genetic determinism, and perceived control: The roles of beliefs about susceptibility and severity versus disease essentialism. Journal of health communication 2012;17:762-78.

195. Bollinger JM, Scott J, Dvoskin R, Kaufman D. Public preferences regarding the return of individual genetic research results: findings from a qualitative focus group study. Genetics in Medicine 2012;14:451-7.

196. Beskow LM, Burke W. Offering individual genetic research results: context matters. Science translational medicine 2010;2:1-5.

197. Roberts JS, Shalowitz DI, Christensen KD, et al. Returning individual research results: development of a cancer genetics education and risk communication protocol. Journal of empirical research on human research ethics : JERHRE 2010;5:17-30.

198. Wolf SM, Crock BN, Van Ness B, et al. Managing incidental findings and research results in genomic research involving biobanks and archived data sets. 2012;14:361-84.

199. Evans JP, Rothschild BB. Return of results: not that complicated? Genetics in Medicine 2012;14:358-60.

200. Wolf SM. The past, present, and future of the debate over return of research results and incidental findings. Genetics in Medicine 2012;14:355-7.

201. Collins FS, McKusick VA. Implications of the Human Genome Project for medical science. Jama 2001;285:540-4.

202. Wright CF, MacArthur DG. Direct-to-consumer genetic testing. Molecular Genetics and Personalized Medicine: Springer; 2012:215-36.

203. Burke W, Burton H, Hall AE, et al. Extending the reach of public health genomics: what should be the agenda for public health in an era of genome-based and "personalized" medicine? Genetics in Medicine 2010;12:785-91.

204. Pinker S. My genome, my self. New York Times Magazine 2009;7.

205. Pan S, Knowles JW. Exploring predisposition and treatment response--the promise of genomics. Progress in cardiovascular diseases 2012;55:56-63.

206. Need AC, Goldstein DB. Next generation disparities in human genomics: concerns and remedies. Trends in Genetics 2009;25:489-94.

207. Collins FS, Green ED, Guttmacher AE, Guyer MS. A vision for the future of genomics research. Nature 2003;422:835.

208. Bustamante CD, Francisco M, Burchard EG. Genomics for the world. Nature 2011;475:163-5.

209. Skloot R. The immortal life of Henrietta Lacks. New York, NY: Crown Publishers; 2010.

210. Corbie-Smith G, Moody-Ayers S, Thrasher AD. Closing the circle between minority inclusion in research and health disparities. Archives of Internal Medicine 2004;164:1362-4.

211. Corbie-Smith G, Thomas SB, George DMMS. Distrust, race, and research. Archives of internal medicine 2002;162:2458-63.

212. Durant RW, Davis RB, George DMMS, Williams IC, Blumenthal C, Corbie-Smith GM. Participation in research studies: factors associated with failing to meet minority recruitment goals. Annals of epidemiology 2007;17:634-42.

213. Williams IC, Corbie-Smith G. Investigator beliefs and reported success in recruiting minority participants. Contemporary clinical trials 2006;27:580-6.

214. Sussman AL, Montoya C, Werder O, Davis S, Wallerstein N, Kong AS. An Adaptive CBPR Approach to Create Weight Management Materials for a School-Based Health Center Intervention. Journal of obesity 2013.

215. Wallerstein NB, Duran B. Using community-based participatory research to address health disparities. Health promotion practice 2006;7:312-23.

216. Skinner HG, Calancie L, Vu MB, et al. Using community-based participatory research principles to develop more understandable recruitment and informed consent documents in genomic research. PloS one 2015;10:e0125466.

217. van Oostrom I, Meijers-Heijboer H, Duivenvoorden HJ, et al. The common sense model of self-regulation and psychological adjustment to predictive genetic testing: a prospective study. Psycho-Oncology 2007;16:1121-9.

218. Cameron LD. Can our health behaviour models handle imagery-based processes and communications? European Health Psychologist 2009;11:56-8.

219. Vassy JL, O'Brien KE, Waxler JL, et al. Impact of literacy and numeracy on motivation for behavior change after diabetes genetic risk testing. Medical decision making : an international journal of the Society for Medical Decision Making 2012;32:606-15.

220. Leventhal H, Brissette I, Leventhal E. The common-sense model of self-regulation of health and illness. In: Cameron LD, Leventhal H, eds. The self-regulation of health and illness behaviour. New York: Routledge; 2003:42-65.

221. Keyserling TC, Samuel-Hodge CD, Pitts SJ, et al. A community-based lifestyle and weight loss intervention promoting a Mediterranean-style diet pattern evaluated in the stroke belt of North Carolina: the Heart Healthy Lenoir Project. BMC public health 2016;16:732.

222. Marteau TM, Lerman C. Genetic risk and behavioural change. BMJ : British Medical Journal 2001;322:1056.

223. Gamm JL, Nussbaum RL, Biesecker BB. Genetics and alcoholism among at‐risk relatives I: Perceptions of cause, risk, and control. American Journal of Medical Genetics Part A 2004;128:144-50.

224. Halladay JR, Donahue KE, Hinderliter AL, et al. The heart healthy lenoir project-an intervention to reduce disparities in hypertension control: study protocol. BMC health services research 2013;13:441.

225. Davis TC, Wolf MS, Bass PF, et al. Low literacy impairs comprehension of prescription drug warning labels. Journal of general internal medicine 2006;21:847-51.

226. Davis TC, Federman AD, Bass PF, et al. Improving patient understanding of prescription drug label instructions. Journal of general internal medicine 2009;24:57-62.

227. Wolf MS, Davis TC, Bass PF, et al. Improving prescription drug warnings to promote patient comprehension. Archives of internal medicine 2010;170:50-6.

228. Wolf MS, Davis TC, Tilson HH, Bass III PF, Parker RM. Misunderstanding of prescription drug warning labels among patients with low literacy. American Journal of Health-System Pharmacy 2006;63.

229. Erby LH, Roter D, Larson S, Cho J. The rapid estimate of adult literacy in genetics (REAL‐G): A means to assess literacy deficits in the context of genetics. American Journal of Medical Genetics Part A 2008;146:174-81.

230. What are SNPs? at https://www.23andme.com/gen101/snps/.)

231. Khoury MJ, Bowen S, Bradley LA, et al. A decade of public health genomics in the United States: centers for disease control and prevention 1997-2007. Public health genomics 2009;12:20-9.

232. Burke W. Clinical validity and clinical utility of genetic tests. Current Protocols in Human Genetics 2009:9.15. 1-9.. 7.

233. Khoury MJ, McBride CM, Schully SD, et al. The Scientific Foundation for personal genomics: recommendations from a National Institutes of Health-Centers for Disease Control and Prevention multidisciplinary workshop. Genetics in medicine : official journal of the American College of Medical Genetics 2009;11:559-67.

234. D'Agostino RB, Vasan RS, Pencina MJ, et al. General cardiovascular risk profile for use in primary care the Framingham Heart Study. Circulation 2008;117:743-53.

235. Heart to Heart - Framingham Risk Score 10 Year Risk. at https://med-decisions.com/.)

236. D'Agostino RB, Russell MW, Huse DM, et al. Primary and subsequent coronary risk appraisal: new results from the Framingham study. American heart journal 2000;139:272-81.

237. 1000 Genomes Project. (Accessed March 4, 2016, at https://www.ncbi.nlm.nih.gov/variation/tools/1000genomes/.)

238. Rini C. Prevention and Planning Behaviors Scale. University of North Carolina Chapel Hill; 2012.

239. Jose PE. Doing statistical mediation and moderation: Guilford Press; 2013.

240. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. BMC medicine 2010;8:18.

241. Parker RM, Baker DW, Williams MV. The test of functional health literacy in adults. Journal of general internal medicine 1995;10:537-41.

242. Ware Jr JE, Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. Medical care 1996;34:220-33.

243. Berwick DM, Murphy JM, Goldman PA, Ware Jr JE, Barsky AJ, Weinstein MC. Performance of a five-item mental health screening test. Medical care 1991:169-76.

244. Henderson G, Evans JP, Berg JS. NCGENES: North Carolina Clinical Genomic Evaluation by Next-generation Exome Sequencing. 2010.

245. Fagerlin A, Zikmund-Fisher BJ, Ubel PA, Jankovic A, Derry HA, Smith DM. Measuring numeracy without a math test: development of the Subjective Numeracy Scale. Medical Decision Making 2007;27:672-80.

246. Croyle RT, Sun Y-C, Louie DH. Psychological minimization of cholesterol test results: Moderators of appraisal in college students and community residents. Health Psychology 1993;12:503.

247. Cameron LD, Leventhal H. Vulnerability Beliefs, Symptom Experiences, and the Processing of Health Threat Information: A Self‐Regulatory Perspective. Journal of Applied Social Psychology 1995;25:1859-83.

248. Perceived Severity. at http://cancercontrol.cancer.gov/brp/research/constructs/perceived-severity.pdf.)

249. Milne S, Orbell S, Sheeran P. Combining motivational and volitional interventions to promote exercise participation: Protection motivation theory and implementation intentions. British journal of health psychology 2002;7:163-84.

250. Biesecker BB, Erby LH, Woolford S, et al. Development and validation of the Psychological Adaptation Scale (PAS): Use in six studies of adaptation to a health condition or risk. Patient education and counseling 2013.

251. Redd BR. Using the protection motivation theory to examine the effects of obesity fear arousal on the physical activity of young adult female college students: Wayne State University; 2012.

252. Shen L, Condit CM, Wright L. The psychometric property and validation of a fatalism scale. Psychology and Health 2009;24:597-613.

253. Block G, Gillespie C, Rosenbaum EH, Jenson C. A rapid food screener to assess fat and fruit and vegetable intake. American journal of preventive medicine 2000;18:284-8.

254. Giles-Corti B, Timperio A, Cutt H, et al. Development of a reliable measure of walking within and outside the local neighborhood: RESIDE's Neighborhood Physical Activity Questionnaire. Preventive medicine 2006;42:455-9.

255. Lin L, McFerran B. The (Ironic) Dove Effect: How Normalizing Overweight Body Types Increases Unhealthy Food Consumption and Lowers Motivation to Engage in Healthy Behaviors. ACR North American Advances 2012.

256. Christakis NA, Fowler JH. The spread of obesity in a large social network over 32 years. n engl j med 2007;2007:370-9.

257. McFerran B, Dahl DW, Fitzsimons GJ, Morales AC. I'll have what she's having: Effects of social influence and body type on the food choices of others. Journal of Consumer Research 2009;36:915-29.

258. Boyington JE, Carter-Edwards L, Piehl M, Hutson J, Langdon D, McManus S. Cultural attitudes toward weight, diet, and physical activity among overweight African American girls. Preventing chronic disease 2008;5.

259. Killion L, Hughes SO, Wendt JC, Pease D, Nicklas TA. Minority mothers' perceptions of children's body size. Pediatric Obesity 2006;1:96-102.

260. Tovée MJ, Swami V, Furnham A, Mangalparsad R. Changing perceptions of attractiveness as observers are exposed to a different culture. Evolution and Human behavior 2006;27:443-56.

261. Kumanyika SK. Environmental influences on childhood obesity: ethnic and cultural influences in context. Physiology & behavior 2008;94:61-70.

262. Christakis NA, Fowler JH. Social contagion theory: examining dynamic social networks and human behavior. Statistics in medicine 2013;32:556-77.

263. Kernper KA, Sargent RG, Drane JW, Valois RE, Hussey JR. Black and white females' perceptions of ideal body size and social norms. Obesity 1994;2:117-26.

264. O'Donovan CB, Walsh MC, Gibney MJ, Brennan L, Gibney ER. Knowing your genes: does this impact behaviour change? Proceedings of the Nutrition Society 2017:1-10.

265. Hollands GJ, French DP, Griffin SJ, et al. The impact of communicating genetic risks of disease on risk-reducing health behaviour: systematic review with meta-analysis. Bmj 2016;352:i1102.

266. Patnode CD, Evans CV, Senger CA, Redmond N, Lin JS. Behavioral counseling to promote a healthful diet and physical activity for cardiovascular disease prevention in adults without known cardiovascular disease risk factors: updated evidence report and systematic review for the US Preventive Services Task Force. JAMA 2017;318:175-93.

267. Alcorta D, Preston G, Munger W, et al. Microarray studies of gene expression in circulating leukocytes in kidney diseases. Experimental nephrology 2002;10:139-49.

268. Beecham GW, Martin ER, Li Y-J, et al. Genome-wide association study implicates a chromosome 12 risk locus for late-onset Alzheimer disease. The American Journal of Human Genetics 2009;84:35-43.

269. Cochran WG. Some methods for strengthening the common χ 2 tests. Biometrics 1954;10:417-51.

270. Armitage P. Tests for linear trends in proportions and frequencies. Biometrics 1955;11:375-86.

271. Ahn K, Haynes C, Kim W, Fleur RS, Gordon D, Finch SJ. The Effects of SNP Genotyping Errors on the Power of The Cochran‐Armitage Linear Trend Test for Case/Control Association Studies. Annals of human genetics 2007;71:249-61.