Assessing Health Behavior Modification for Participants in the OSU-Coriell Personalized Medicine Collaborative Following Genomic Counseling

THESIS

Presented in Partial Fulfillment of the Requirements for the Degree Master of Science in the Graduate School of The Ohio State University

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2017

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Abstract

Health behavior change is a complex and dynamic process, and remains difficult to predict. Many studies examine the theoretical framework that influences health behavior change; however, few exist to explain the effect of genomic counseling (GC) on health behavior change. The purpose of this study was to assess the impact of genomic testing and GC on health behavioral attitudes, intentions and outcomes for participants following receipt of multiple actionable complex disease reports. This study focuses on health behavior change related to health literacy, the transtheoretical model, social support theory and receipt of GC. Sixty-four participants completed surveys to assess health literacy, desires to change behaviors, confidence to change behaviors, stages of change and perceived utility of GC and genomic risk. No discrepancies in health literacy were found. Assessment of desire to change found that those who perceived the utility of genomic risk as most useful identified most with the maintenance stage of change. Additionally, participants who most identified with the contemplation and preparation stages of change had the most intended behavioral changes. Lastly, participants who received informational and instrumental support from GC least identified with being in the action stage of the transtheoretical model. These results provide evidence to support the theory that the stage(s) of behavior change in which a participant exists could

influence their behavioral attitudes and modifications, and may be influenced by the types of social support provided by healthcare professionals.

Acknowledgments

I would like to acknowledge the efforts of the faculty, staff and students of the Division of Human Genetics at the Ohio State University. Additionally, I would like to acknowledge my committee members who work closely with the OSU-Coriell Personalized Medicine Collaborative to provide our cohort and foundation for study.

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Chapter 1: Introduction

Disease Risk

Cardiovascular disease, specifically coronary artery disease (CAD) has reached near epidemic proportions in the United States. The American Heart Association estimated that in 2010, 1 in every 6 deaths in the United States (US) were attributable to manifestations of CAD (Go et al., 2014). This same year, it was estimated that 19.7 million U.S. adults had a diagnosis of Type 2 diabetes mellitus (DM2), with another 8.2 million with undiagnosed DM2 (Tarver, 2014). These statistics paint a grim picture for the health of many Americans afflicted with these diseasess. CAD and DM2 are multifactorial diseases that have complex etiology, meaning that there are multiple risk factors that may lead to development of these diseases. A few of these risk factors include family history, obesity, and genomic biomarkers. Fortunately for risk factors like obesity, there are lifestyle actions (e.g. weight loss) that can be implemented by the participant to potentially lower risk.

Ohio State University, in collaboration with the Coriell Institute for Medical Research has partnered on a personalized medicine collaborative (OSU-CPMC). This study seeks to provide participants with chronic disease access to online actionable complex disease reports, including CAD and DM2, in the context of genomic counseling (Sweet, et al., 2014). Test reports utilize single nucleotide polymorphisms (SNPs), paired

with lifestyle and family history risk factors (Appendix B) to illustrate risk, and actions that the participant can take to potentially lower risk. The OSU-CPMC study provides tools to empower modification of the potentially actionable non-genetic risk factors over which participants may have some control (e.g. diet, exercise, smoking cessation). These tools include the disease risk reports—which instructs participants on the multiple risk factors; the threshold of risk that they have for developing these diseases; and the actions they can take to lower risk—and genomic counseling (GC)—which provides participants with support to both answer questions about their disease risk and, potentially, foster an environment of health enhancing behavior change. The adoption and maintenance of health-enhancing behaviors has a two-fold purpose—to prevent development of illness, such as CAD and DM2, and to decrease likelihood of premature death (Joseph, Daniel, Thind, Benitez, & Pekmezi, 2016).

External Factors Influencing Health Behavior

There is currently little evidence to suggest that provision of genetic/genomic risk alone encourages risk-reducing behavior change (Evans, Meslin, Marteau, & Caulfield, 2011; Hollands, French, Griffin, Prevost, & Sutton, 2016). Multiple studies have shown that simple communication of genetic risk information has minimal impact on health behavior change. This includes results of a recent cohort study reporting no impact on diet or physical activity of direct-to-consumer genome-wide testing for common complex disease (Bloss, Schork, & Topol, 2011), and a recent systematic review that suggested providing genetic-based disease risk estimates has little or no effect on risk-reducing health behaviors (Hollands et al., 2016). For this latter meta-analysis, of the 18 studies examined, only one study incorporated genetic counselor intervention in the results

delivery process, and the focus was on phenotypically high-risk and low-risk participants followed for only 12-weeks (Grant et al. 2013; Wu, et al., 2016). Given the limited evidence, it is difficult to predict outcomes based upon a few studies, especially since many of these studies followed participants over a limited timeframe. Additional studies need to be done to develop more effective techniques for delivery of genetic/genomic risk information. One review even postulates that alteration of the participant's social environment may even be more beneficial than simply communicating genetic risk as a technique of behavioral modification (Evans et al., 2011). Incorporating health care professionals (e.g. genetic counselors) as educators and facilitators using this technique of transformation of the participant's social environment to offer more support may foster a system of health-enhancing behaviors (Ginting, Ven, Becker, & Na Ring, 2014). By acting as a supportive resource, a genetic counselor may encourage potential modification of health behaviors, and, in turn, reduction of risk.

Social support theory has four constructs: instrumental, informational, emotional and appraisal (Tardy, 1985). In a review of social support by Demaray (2013), instrumental support includes the provision of time and resources; informational support the provision of information and advice; emotional support the provision of caring behaviors; and appraisal, providing feedback. Strom & Egede (2012) suggest that social support is both a perception of the participant being accepted and cared for and a realization of the actual support received. Using the social support construct as a mediator may improve self-management practices and overall healthcare outcomes. One study measuring social support in a population of African American participants with DM2 found that satisfaction with support received was a predictor for improved diabetes-

specific quality of life and intended practices for blood glucose monitoring (Tang, Brown, Funnell, & Anderson, 2008). One pitfall of this study, and much of the research that exists on this topic, is that the ill-defined types of social support that can be given (e.g. emotional, appraisal, instrumental, and informational), as well as the timing of this support. Another study tried to define the type of social support by looking at the influence of emotional and instrumental support in physical activity behavior change in adolescent girls (Laird, Fawkner, Kelly, Mcnamee, & Niven, 2016); they found significant difference in physical activity of participants when receiving instrumental support from parents, in particular their mothers. However, when observing emotional support, and effects, limited statistical significance was found on physical activity (Laird, et al., 2016). One of the drawbacks to this particular study was the lack of analysis for the support provided by healthcare providers, although these investigators did have encouraging findings about behavioral modification with the use of instrumental support. By analyzing the limitations of these studies and expanding upon the literature that exists on social support and GC, there may be a more effective means to influence behavior change. To better understand the types of support that should be provided, and increase efficacy for behavior change, more work needs to be done to understand the cognitive barriers underlying participant perception of genetic and non-genetic risk factors for development of disease. Analysis of these cognitive barriers may provide the genetic counselor (and other health professionals) with additional tools and approaches to tailor risk assessment and intervention to each participant with which they interact.

Internal Factors Influencing Behavior Change

Influencing behavior from an external platform might be a difficult task if the internal processes effecting health behavioral attitudes, perception of risk and determination to change are not considered. To do this, perhaps the most important factors to study are the impact of perceived lack of control and health literacy on attitude certainty and processing of readiness to change.

Some underlying cognitive barriers that can influence behavior change include the principles of perceived risk and perceived personal control. The efficacy of these constructs on behavior change has been analyzed (Avis, Smith, & Mckinlay, 1989). For example, it has been shown that participants with stronger family history of DM2 have an increased perception of DM2 risk (Avis, et al., 1989). However, those who are at predicted increased risk for DM2 may also feel less able to control their risk of developing the disease, and therefore, less likely to attempt behavior change (Wu, et al., 2016).

Abstracting from this theory, participants who are at increased risk for diseases (e.g. DM2) may have decreased motivation to implement behavior change due to underlying assumptions that they may already have health complications related to an eventual diagnosis. This behavior may be explained by maladaptive coping styles that exist in the common-sense model of illness cognition. This model suggests that there are two ways for participants' perception of risk to guide prevention behaviors: reduce the threat of impending illness by adopting healthy behaviors or adopt maladaptive mechanisms including fatalistic response (Leventhal, Diefenbach, & Leventhal, 1992).

This fatalistic mentality that predisposition will predict health outcome demonstrates a persistent cognitive barrier for health behavior change.

Limitations of these cognitive construct analyses are also apparent in the lack of increased disease risk awareness within families. One study that evaluated the impact of genetic risk on risk perception for DM2 found that there was no difference between families that had a strong versus a weak family history (Grant et al., 2013). This lack of increased risk perception in families with strong family history may be due to the lack of disease risk awareness. Family dynamics and communication may also play a large role in these cognitive constructs, as those with increased perceived personal risk may have more family communication and therefore, a better knowledge base to increase personal risk awareness. This could, in turn, affect personal risk perception. In addition, personal experience with a certain disease within one family may be different than that in another family, and subsequently, affect perceived level of control. In participants who feel they have less control due to their increased predicted risk, personal experience based on strong family history could contribute to this perceived lack of control. If perceived risk does not strongly influence behavior change, due to perceived lack of control, then there must be outlying factors that contribute to behavior change (Li et al., 2016).

Contributory elements to perceived lack of control may also include the participant's health literacy. One study demonstrated that participants with limited health literacy had poorer health outcomes and higher cost to the health system (Sørensen, et al., 2012). Health literacy is defined as the participant's acknowledgment and comprehension of their health status and potential risk for developing disease, and their ability to act upon this information in the appropriate manner (Ratzan & Parker, 2000). Limited health

literacy can impair the comprehension of health-related information and therefore affect the participant's attitudes and intentions towards health behavior change. One study suggests that awareness of a participant's literacy skills can help to adjust and tailor health information for delivery in a format the participant understands (Weiss et al., 2005). Aspects of health literacy that have been shown to encourage health behavior awareness include increased self-advocacy and knowledge (Abrams, McBride, Hooker, Cappella, & Koehly, 2015). However, this awareness may not always translate into health behavior change. Evidence that awareness alone may not change health behaviors is provided by one study which found that 38% of college-educated US adults accurately interpret their genetic risk for DM2, and even fewer accurately interpreted this information when their genetic risk was delivered online (Haga et al., 2014).

There are other influences which may affect health literacy, and as such, have a downstream effect on health behavior awareness and modification. One such factor may be the involvement of health professional support. In fact, several professional organizations discourage models of healthcare practice that exclude health professional intervention and support in the risk communication process (Li, Ye, Whelan, & Truby, 2016), possibly due to the lowered efficacy of personalization of risk. A meta-analysis compared different forms of personalized risk information and the delivery of this information to determine the impact on dietary change. They found significant dietary changes observed in the group of participants who had genetic risk information given through genetic counseling, rather than general health advice (Li et al., 2016). To extrapolate, personalizing genetic risk through health professional intervention (e.g. genetic counseling) may have more influential impact on motivating change in various

health behaviors, which, in turn may enhance health outcomes. The education and participatory support provided by a genetic counselor regarding disease risk, may, therefore be one avenue to improve health literacy and overall health behavioral outcomes.

In addition to improving health literacy, genetic counselor intervention may also actively engage the participant in developing an attitude of change. As attitude is a predictive precursor to behavior, it is important to first seek attitude change (Gökbayrak, Paiva, Blissmer, & Prochaska, 2015). One such construct to engage participants is that of attitude certainty. Attitude certainty has been described as an unwavering sense of self-assurance and strong beliefs (Petrocelli, Tormala, & Rucker, 2007). It has been shown that increasing attitude certainty encourages predictive behavior (Clarkson, Tormala, & Rucker, 2008). Through this technique, one could hypothesize that a provider's influence over affirmation of positive attitude may have a positive effect on the participant's ability to make healthy behavior change (Clarkson et al., 2008).

Attitude certainty may fuel the participant's desire to modify their health behaviors. From this foundational support, it could be argued that behavioral modification may grow and push the participant to make the necessary modifications that improve health outcomes. This is not a small task, as behavior change is multifaceted, and personally and professionally challenging. One such challenge for the healthcare provider is recognizing the type of supportive care that they can provide to participants to encourage health behavioral modification. Davies et al. suggests that provider interventions employing techniques such as social learning theory and modeling increase self-efficacy and provides the most effective means for changing health behaviors

(Davies et al., 2015). It is thought that combining this methodology with continuous information given to participants regarding risk factors for a given disease (e.g. BMI, blood pressure, and serum cholesterol levels for CAD) might modify behavior.

Techniques aimed at changing health behavior outcomes by increasing attitude certainty also must keep in mind the internal stage in which a participant perceives their readiness to change (Prochaska & DiClemente, 1982). The transtheoretical model (TTM) of behavior change, or modification, is a process of identifiable stages through which participants progress (Zimmerman et al., 2000). The TTM consists of four constructs: stage of change, processes of change, self-efficacy, and decisional balance. (Koyun & Eroğlu, 2013). Each of these stages presents an opportunity for healthcare providers, specifically the genetic counselor, to intervene with appropriate social support to guide the participant through the process.

Blending the ideologies of the theory of planned behavior—relating intention to the perceived behavior control—and the transtheoretical model of change, the balance of behavioral intentions with behavioral outcomes in a population receiving disease risk information may be better measured.

Study Aims

The goal of this study was to determine the utility of GC as a means of social support and the influence of GC intervention on behavioral attitude, intentions and modification on participants receiving multiple actionable disease reports. We hypothesize that decisions to engage in behavioral modification (e.g. diet, exercise, reducing alcohol intake, etc.) will be positively associated with social support received from GC intervention. Moreover, we postulate that participants who received GC will be

more likely to have intended behaviors to change than participants who did not receive GC. This study also seeks to describe the relationship between the current stage of behavioral change and participant perception of the support provided by the genetic counselor (e.g. emotional, instrumental, informational or appraisal). We hope to discover any correlation between perception of the type of support offered by a genetic counselor and the utility of this support by the participant, and whether the participant incorporated the support provided in any decision to modify health behaviors. Although we seek to determine overall desire to enact behavioral modifications for all eight diseases under study, we purposefully focus on the complex diseases of DM2 and CAD, as a preponderance of study participants received increased risk results for these diseases (e.g. 89% had at least one risk factor for CAD; 94% had at least one risk factor for DM2; Appendix B).

The study themes will be evaluated in three aims, which include specific hypotheses:

Aim 1: Understand the influence of GC on health-related attitudes, behaviors and behavioral intentions, and assess differences based on level of health literacy.

- Hypotheses: Participants receiving GC will have greater confidence to change behaviors and greater intention to change behaviors than those not receiving GC (H1). Additionally, participants receiving GC will perceive their genomic risk to be more useful and applicable to their lives than those who did not receive GC. Finally, those with lower health literacy will have a lower perceived utility of GC (H2).

Aim 2: Determine the stage of behavior change (pre-contemplation, contemplation, etc.) at which GC is perceived to be most helpful.

- Hypothesis: GC will be perceived to be most useful for participants who identify most with the contemplation stage of behavior change (H3).

Aim 3: Examine participant perceptions of the social support provided by the genetic counselor and whether this support has any effect on their behaviors or behavioral intentions.

- Hypothesis: Participants who received active (instrumental) support from their genetic counselor will be more confident in their ability to change behaviors and will have a greater intention to change behavior than participants who received other types of support (e.g. informational, appraisal, emotional; H4).

Chapter 2: Methods

Participants

Participants (n= 250) were enrolled in the OSU-Coriell Personalized Medicine Collaborative (OSU-CPMC) for which each received 8 online personalized complex disease reports (e.g. DM2). 199 OSU-CPMC study participants were part of a randomized controlled trial (RCT). Of 98 intervention arm participants (mean age = 57.8; 39% female) randomized for in-person GC, 76 (78%) were seen. In contrast, control arm participants (n=101; mean age = 58.5; 54% female) were not initially offered GC as part of the study protocol but were able to access in-person GC, if they requested it, 3-months post viewing of at least one test report and post-completion of the study-specific follow-up survey. A total of 15 control arm participants subsequently had in-person GC as part of the RCT. In a second OSU-CPMC trial (R21 study), GC was offered to 51 newly accrued participants, of which 44 had GC (37 phone GC; 7 in-person GC).

Methods

Participants in the OSU-CPMC trials were provided baseline and follow up surveys per parent study protocol. All 250 participants completed baseline surveys, with 161 completing follow up surveys (105 counselees; 59 control arm subjects). Five of the original 250 participants were lost to follow-up. Therefore, for this current study, 245 participants were invited to complete a 33-question Qualtrics survey (Appendix C)

designed to assess health behavioral modifications made after receipt of test results, with specific focus on DM2 and CAD.

The e-mail to solicit volunteer participation in the Qualtrics survey provided informed consent. A $10 Amazon.com gift card incentive was offered to those who completed the survey. Surveys were sent a total of three times, with three week increments between each e-mail in order to allow participants ample opportunity to answer the survey.

All data collected was stored on secure software associated with the Qualtrics survey. De-identified data was analyzed on SPSS software. Analyses were performed regarding attitudes towards and changes in health behaviour and behavioural outcomes. Comparative analysis was also performed on the 3 separate surveys (baseline, follow-up, Qualtrics) to assess health behaviour modifications and other measures in this study population. The study was approved by the Ohio State University's biomedical research IRB.

Measures

Study measures are found in Appendix A (Qualtrics Survey**)**

Receipt of GC

Participants selected on the survey whether they received GC during the RCT or R21 studies. Participants were categorized on a bivariate scale. Those who answered that they received GC were assigned a "1", and participants who answered that they did not receive GC or were unsure of whether they received GC were assigned a "0". Using this

bivariate format, we analyzed the influence of receipt of GC on confidence to change behaviors, perceived utility of genomic risk and intentions to change behaviors.

Social Support

Social support was defined using the following measures: instrumental support includes the provision of time and resources; informational support the provision of information and advice; emotional support the provision of caring behaviors; appraisal includes providing feedback. This social support was measured through quantitative questioning based upon social support theory (Demaray et al., 2013). Participants were asked "What type of support would you say your genetic counselor provided to you?" and "What type of support would you say your genetic counselor used most during your genetic counseling session?" Participants selected from one of four categories; instrumental as "Active support through asking questions that made me self-reflect, informational as "Resource support through providing information on my genetic risk", emotional as "Emotional support through expression of empathy and care", or appraisal as "Verbal support through advice giving and suggestions". Determining whether the participant has had GC and what type of social support they felt their genetic counselor provided, may offer insight on the best method of social support to provide participants during GC.

Health Literacy

Health literacy was measured utilizing a validated health literacy scale called "The Newest Vital Sign" (Weiss, et al., 2005). This measure was used to better assess participant's comprehension of health-related information. The intention was to provide

evidence about the potential for discrepant health literacy between participants under study, which could impact outcome data (Appendix C).

Health Behaviors

Health behaviors were measured in three ways. First, we measured *desire to change*, which encompassed the health behaviors that participants wanted to change prior to study enrollment, after study enrollment and current behaviors that they intend to change. Second, *confidence to change behaviors* was measured within two time frames—six months and one year after the conclusion of the survey. Finally, a Likert scale using descriptors of the stages of change in the transtheoretical model was used to measure the *stage of behavior change* with which participants most strongly identify. Specifics regarding the measures of health behavior attitudes and intentions are provided next.

Desire to Change was measured using three similar categorical variables. These variables were analyzed across time periods (prior to enrolling in study—3 years to 1 year ago; after GC/ receiving genomic risk summary—2 years to 6 months ago; and intentioned behaviors desired to still change) to determine what health behaviors were the most common desired changes. We used 8 categorical variables of health behavior change, where participants were able to select all that applied to the given time period (Appendix C).

Confidence to Change behavior was assessed with the following question, "How confident are you that in the following time frames you can make health behavior modifications, such as those listed in the previous question, based on your genetic risk that you discussed with your genetic counselor?". A Likert scale was used to measure

from least confident (1) to most confident (5) based on two time periods—six months and one year (Appendix C).

Stage of Behavior Change measures were adapted from Koyun & Eroğlu, 2013, which measured participants' readiness to cease smoking by using descriptors of each stage of change in the TTM, rather than the terminology of that stage. Since smoking cessation was one of our desired behaviors assessed, we used similar descriptors (Koyun & Eroğlu, 2013) for each stage of change as follows: pre-contemplation-" I do not intend to modify my health behaviors within the next six months"; contemplation-"I am thinking about starting to modify my health behaviors within the next six months"; preparation-"I am currently trying to modify my health behaviors, but I don't always practice healthy behaviors"; action-"I am currently modifying my health behaviors, but have only begun to do so within the past six months"; maintenance-"I am currently modifying my health behaviors and have done so for more than six months". Since these stages of behavior change are continuous, and participants may be in more than one stage of change at a time, this was measured using Likert scales, from strongly disagree (1) to strongly agree (5) with descriptors given on each stage of change (Appendix C). Although the TTM includes six separate stages, for purposes of our study, relapse was not measured as this is an external influencing factor on movement between stages, not as a stage of its own.

Utility of Genomic Risk and GC

Additional questions on the Qualtrics survey included a few follow-up questions from the original parent RCT survey. These questions compared beliefs and attitudes about the utility of genetic risk results and GC. Questions included; "To what extent do you consider the information about your genetic risk results useful and applicable to your

life?" and "To what extent do you consider the support that you received from your genetic counselor relevant and helpful to changing your health behavior?". A Likert scale was used to select perceived utility from "not at all useful" (1) to "very useful" (5). This allowed for comparison between subgroups to look at significant differences between perceived utility of genetic risk results received and perceived utility of GC.

Statistical Analyses

Descriptive statistics were used to describe and analyze the sample population (demographics using means, standard deviations, etc.), and to summarize survey values. Analysis of variance (ANOVA) and independent t-test calculations were used to examine study aims, as most of our outcome variables are bivariate and continuous variables. For analysis of continuous variables, ANOVA was used to determine if the group of variables was jointly significant. Bivariate variables were analyzed using independent t-test, as significance of a single variable was called into question. For the purposes of data analysis, we reported the t-statistic/ F-statistic, degrees of freedom and *p* value. In some cases, mean value was reported as well.

Chapter 3: Results

Demographics

Of the original cohort of 250 OSU-CPMC participants, five were lost to follow up, two are deceased and 11 e-mails were undeliverable. Therefore, of the 232 eligible participants, 67 (28.9%) completed the Qualtrics survey. Two participants did not provide a correct ID number on the Qualtrics survey, and therefore, their response data was not analyzed. Another provided incomplete data. Of the remaining 64, 39 (60.94%) participants were from the parent RCT; and 25 (39.06%) from the R21 study. Of the 64 participants, 35 (54.68%) were female and 29 (45.31%) were male; 36 (56.25%) received GC and 28 (43.75%) did not. On average, the Qualtrics survey (33-questions) took participants 38.8 minutes to complete.

Category of genomic risk

When queried on the Qualtrics survey, participants self-selected into risk categories based upon their recall of the OSU-CPMC genomic test result (n=64) for CAD and DM2. Through the self-selection process, participants chose which category of risk they fell into—high risk for CAD, high risk for DM2, high risk for both CAD and DM2, or high risk for neither CAD nor DM2. This allowed us to assess both the accurate selection and recall of specific disease risk by the participant. These categories included; increased risk for CAD (n=19, 27.5%), increased risk for DM2 (n=4, 5.8%), increased

risk for both CAD and DM2 (n=12, 17.4%), increased risk for neither CAD nor DM2 (n=29, 42%). Given the skewed split in participant recall of their genomic risk for CAD and DM2, and the small sample size, the reproducibility of these findings related to disease risk would be limited.

Analysis regarding the accuracy of self-selected genomic risk result (CAD, DM2) was performed. Of 64 participants, 14 (21.9%) accurately selected the correct risk category for each disease for which they received a high-risk report. Of the 14 participants that accurately identified the correct risk category, nine received GC as an intervention. Upon analysis by independent t-test, those who received GC were no more likely to accurately identify the correct risk category than those who did not receive GC, $t(62)=0.677$, $p=0.50$. However, independent t-test analysis of the accuracy of genomic risk selection in participants who were affected with disease revealed statistical significance, $t(62)=2.43$, $p=0.02$. All 14 participants who accurately self-selected the disease category for which they actually received high risk results were affected with either CAD, DM2 and/or heart failure (HF); however, not all affected participants identified their disease category correctly.

We also examined the influence of affected status on health behavioral intentions and confidence to change. For example, participants with a diagnosis of CAD may be more actively aware of health behaviors that could benefit their current disease, and confident that they could change health behaviors than unaffected participants. Therefore, we elicited how many of the 64 participants had a diagnosis of CAD, HF and/or DM2; we found that 28 (43.75%) were affected. By t-test, no statistically significant differences were found between affected and unaffected participants on confidence to change health

behaviors at 6 months, t(58)=-0.3, *p*=0.76 or one year, t(51)=0.54, *p*=0.59. Additionally, no significant difference was found regarding intended behaviors (Table 1). Therefore, for purposes of our study, there was no significant difference between affected and unaffected participants regarding health behavioral attitudes or intentions.

Table 1

Independent t-test Analysis of Affected Status and Health Behavioral Intentions

Health Behavior	Affected		Unaffected			
	M	SD	M	SD	*t*	*df*
Intended Diet	0.21	(0.42)	0.28	(0.45)	-0.57	62
Intended Exercise	0.32	(0.48)	0.36	(0.49)	-0.33	62
Intended Maintaining Weight	0.25	(0.44)	0.25	(0.44)	0	62
Intended Reducing Alcohol	0.04	(0.19)	0.11	(0.32)	-1.1	62
Intended Weight Loss	0.46	(0.51)	0.44	(0.50)	0.16	62
Intended Quit Smoking	0.00	(0.00)	0.03	(0.17)	-0.88	62
Intended Other	0.04	(0.19)	0.03	(0.17)	0.18	62
Intended None	0.25	(0.44)	0.11	(0.32)	1.4	47.36

Note. *t* statistic was used to explain the likelihood of affected status affecting the intended behavior, the greater the magnitude of the absolute value of t, the greater the evidence against the null hypothesis.
Mean (M) and Standard deviations (SD) of each intended health behavior are described.
df is the number of values in the calculations that are free to vary.
**p*>0.05 level.

Social support

For the 36 participants who received GC, their response to questions on social support were as follows: 1 (1.4%) reported the genetic counselor used emotional support; 19 (27.5%) resource support; 4 (5.8%) reported active support was used most frequently,

and 12 (17.4%) reported verbal support. Upon independent t-test, we found a significant difference, p=0.02, between participants who recieved resource support and those who did not, based on their confidence to change health behaviors within the next 6 months. We also found that those who received resource support were less confident to change health behaviors within 6 months than participants who did not t(33)=-2.51, p=0.02. Participants receiving resource support had a mean score of 3.22 in their confidence to change behavior in 6 months, whereas those who did not had a mean score of 3.61. We did not find additional significant associations between social support and health behavior change. There were no significant differences between participants receiving different types of social support and their intentions to change health behaviors.

Additionally, social support was investigated in accordance with perceived utility of GC and perceived utility of genomic risk. A trend in the data showed that mean perceived utility of GC was marginally decreased in relation to mean perceived utility of genomic risk (Figure 1), however, no statistical significance was found (p=0.56 and p=0.82 respectively). One limiting factor for this and other analyses of social support was the decreased sample size (n=36) from an already small sample size (n=64).

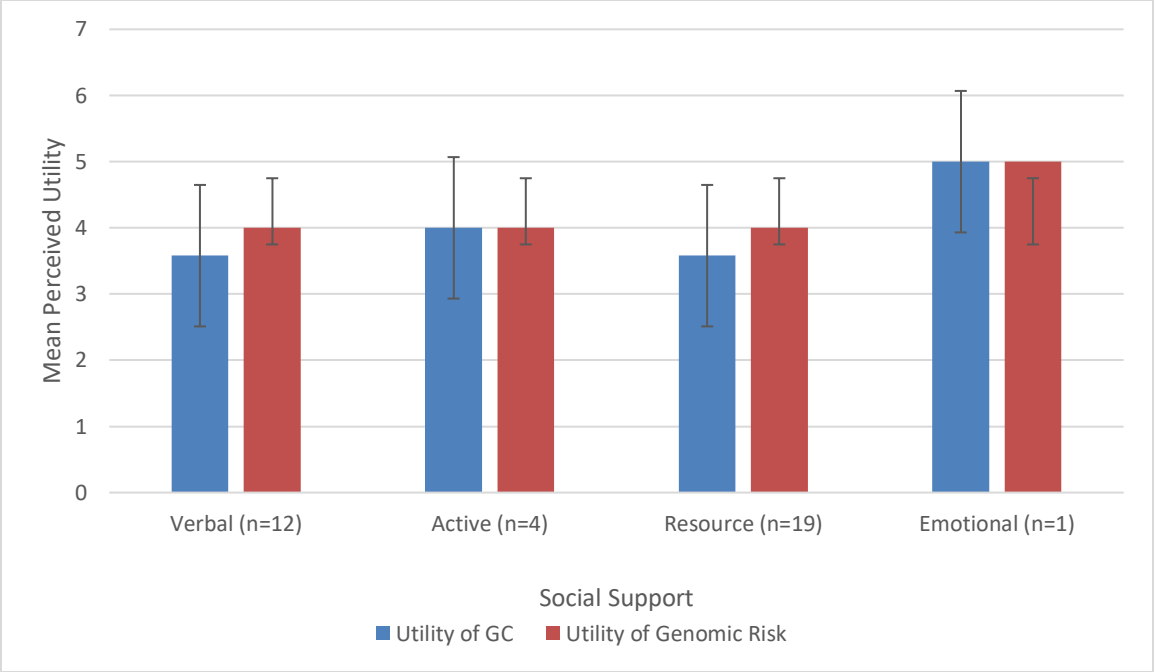

Figure 1. *Mean Perceived Utility of GC and Utility of Genomic Risk vs. Social Support* displays the trend of mean perceived utility of GC decreased in relation to mean perceived utility of genomic risk in participants who received verbal and resource support most in GC.

Health Literacy

For each correct answer on the Health Literacy measure, a score of "1" was given, whereas a score of "0" was given for each incorrect answer. Scores for all answers were totaled and the composite score was analyzed. If the participant scored a total of 4-6, this was taken to indicate *adequate* health literacy. If the participant scored 2-3, they were considered at *possibly limited* health literacy. With scores of 0-1, the participant was considered at high likelihood (>50%) to be health literacy *limited*. Using this scoring system, participants were placed into the 3 health literacy categories; *adequate* health literacy (n=53, 81.53%), *possible limited* health literacy (n=8, 11.6%) and high likelihood (>50%) of *limited* health literacy (n=3, 4.61%).

Although we postulated that health literacy was a confounding factor between participants who received GC and those who did not, we found no significant difference between these two groups t(63)=0.26, $p = 0.79$. It was hypothesized that those participants with *possibly limited* or *highly likely limited* health literacy, would have a lower perceived utility for GC than those who had *adequate* health literacy. After controlling for those with GC and a high likelihood of limited health literacy, we were left with n=1. We combined the *possibly limited* and *highly likely limited* groups into one category: *limited* health literacy. Upon t-test analysis, no statistically significant difference was found between those with *adequate* health literacy and those with *limited* health literacy in their perception of the utility of GC, t(35)=-1.78, p=0.08, or their perception of the utility of genomic risk, t(60)=-1.93, p=0.06. Therefore, we postulate that those with *limited* health literacy did not have a decreased perceived utility of GC, which refutes our hypothesis. In fact, the mean score for perceived utility of GC and genomic risk was lower, 3.52 and 3.71 respectively, than those of *possibly limited* or *limited* health literacy, 4.33 and 4.36 respectively. This could be due to the skewed sampling, as most participants (n=53, 82.81%) are of *adequate* health literacy.

Health behaviors

Participants reported health behaviors that they *desired to change* prior to enrolling in the OSU-CPMC study (n=64), health behaviors that they were already modifying after enrollment (n=63) and health behaviors that they still intend to modify (n=64). Frequencies of intended health behavior change selection can be found in Table 2 (Appendix D).

Table 2

Frequency of Health Behaviors Desired to Modify Prior to Enrolling, After Receipt of GC and/or Genomic Risk Result and Behaviors Still Intended

Health Behavior Variable	Number of Participants (%)
Prior Desired Modification	
Diet	16 (23.2%)
Exercise	22 (31.9%)
Maintaining Healthy Weight	16 (23.2%)
Reduce Alcohol Consumption	5 (7.2%)
Lose Weight	29 (42.0%)
Quit Smoking	1 (1.4%)
Other	2 (2.9%)
None	11 (15.9%)
Current Modification	
Diet	32 (46.4%)
Exercise	24 (34.8%)
Maintaining Healthy Weight	13 (18.8%)
Reduce Alcohol Consumption	4 (5.8%)
Lose Weight	22 (31.9%)
Quit Smoking	0 (0%)
Other	5 (7.2%)
None	13 (18.8%)
Intended Modification	
Diet	39 (60.94%)
Exercise	37 (57.81%)
Maintaining Healthy Weight	30 (46.87%)
Reduce Alcohol Consumption	0 (0%)
Lose Weight	39 (60.94%)
Quit Smoking	0 (0%)
Other	3 (4.68%)
None	6 (9.37%)

Note. n is the number of participants who answered the desired behavior changes at each time period. Percentages of the total n are in parentheses.

Upon t-test analysis, no significance was found to be associated between those who received GC and their intentioned behaviors (Table 3). Therefore, we can

extrapolate that the GC intervention did not influence intention to change behavior (H3 was not supported).

Table 3

Independent t-test Analysis Between Those Who Receive GC and Those Who Do Not on Health Behavioral Intentions

	Received GC		Did not have GC			
	M	SD	M	SD	*t*	*df*
Intended Diet	0.22	0.42	0.29	0.46	-0.57	62
Intended Exercise	0.28	0.45	0.43	0.50	-1.24	55
Intended Maintaining Weight	0.28	0.45	0.21	0.42	0.57	62
Intended Reducing Alcohol	0.08	0.28	0.07	0.26	0.17	62
Intended Weight Loss	0.47	0.51	0.43	0.50	0.34	62
Intended Quit Smoking	0.00	0.00	0.03	0.19	-1.14	62
Intended Other	0.06	0.23	0.00	0.00	1.43	35
Intended None	0.14	0.35	0.21	0.42	-0.78	47.36

Note. t statistic was used to explain the effect of receipt of GC on the intended behavior, where the greater the magnitude of the absolute value of t, the greater the evidence against the null hypothesis.
Standard deviations (SD) are
df is the number of values in the calculations that are free to vary.
**p*>0.05

Participants reported their *confidence to change* on a Likert scale of 1-5, 1 being *not at all confident* and 5 being *very confident*. Within a 6-month time period (n=60), the mean response value was 3.45, which corresponds between *moderately confident* and *confident*. In the one-year time period (n=53), the mean response value was 3.7 which corresponds between *moderately confident* and *confident*. It was hypothesized that GC intervention would serve to increase the confidence level: however, no significance was

found on confidence level at 6 months, t(58)=1.64, p=0.11 or at one year, t(51)=1.59, p=0.12 for participants who received GC. Although this negates our hypothesis (H1), this does suggest that GC intervention alone may not positively influence confidence to change behaviors. ANOVA was calculated on participants' confidence levels using the stage of change with which they identified most. We found that participants who were most confident in changing behaviors identified with the pre-contemplation, contemplation and maintenance stages of change (Tables 4, 5). Participants in these stages may be more likely to progress along the stage of change continuum due to their confidence level.

Table 4

ANOVA of Stage of Change Underlying Confidence to Change Behaviors in the Six Months

Stage of Change	*df*	*F*	*p*
Pre-contemplation			
Between	4	4.36	0.004*
Within	55		
Contemplation			
Between	4	5.35	0.001*
Within	54		
Preparation			
Between	4	0.97	0.43
Within	55		
Action			
Between	4	0.96	0.45
Within	54		
Maintenance			
Between	4	3.86	0.008*
Within	55		

Note. F statistic was used to explain the difference between stage of change groups in the confidence level to change behavior in the next 6 months; the greater the magnitude of *F*, the greater the evidence against the null hypothesis.
df is the number of values in the calculations that are free to vary.
*p>0.05 level.

Table 5

ANOVA of Stage of Change Underlying Confidence to Change Behaviors in the Next Year

Stage of Change	*df*	*F*	*p*
Pre-contemplation	4	6.17	0.000*
Between	48		
Within			
Contemplation			
Between	4	4.86	0.002*
Within	48		
Preparation			
Between	4	1.44	0.24
Within	48		
Action			
Between	4	0.96	0.44
Within	48		
Maintenance			
Between	4	4.14	0.006*
Within	48		

Note. F statistic was used to explain the difference between groups in the confidence level to change behavior in the next year; the greater the magnitude of *F*, the greater the evidence against the null hypothesis.
df is the number of values in the calculations that are free to vary.
*$p>0.05$ level.

Participants were asked to self-select their *stage of change* based upon the transtheoretical model, based upon measures used in Koyun & Eroğlu, 2013. These categories were designed as Likert scales, as participants could be in more than one stage at a time. Participants stated their agreement, with each descriptive category, 1 being "strongly disagree" to 5 being "strongly agree. Mean values were then measured to determine with which stages of change participants most identified. We found that participants more strongly identified with the stages of contemplation, mean value=3.62;

preparation, mean value=3.68; and maintenance, mean value=3.32. Participants least identified with action, mean value=2.7; and pre-contemplation, mean value=1.73. One limitation of this analysis was the inability to look at individual cases, as these means scores were calculated on a basis of the study population rather than a participant's mean scores. As such, we were unable to determine on an individual level if there was an association between stage of change and other measures. Therefore, all measures in relation to stage of change were generalized to the population at hand.

We also looked at intervention of GC on stage of change (TTM). We found that those who received GC were more likely to identify with the contemplation stage of behavior change, $t(59)=2.05$, $p=0.045$. We can reason from this that those who have received GC may be more likely to be thinking about behavior change, and may begin to contemplate behavior change sooner than those participants who did not receive GC. Using independent t-test, the differences between stages of behavior change in the TTM and behavioral intentions was analyzed (Table 6.) We found that participants who intended to diet were more likely to identify with the preparation stage of change and least likely to identify with the pre-contemplation stage of change, than those who didn't intend to diet. Participants who intended to exercise were more likely to identify with the contemplation and preparation stages of change. Those who intended to maintain weight were more likely to identify with the contemplation stage than those who did not intend to maintain weight. Participants intending to lose weight were more likely to identify with contemplation or preparation stages and less likely to identify with the pre-contemplation stage than those who were not intending to lose weight. Finally, participants who were intending to do nothing were more likely to identify with pre-

contemplation and less likely to identify with contemplation, preparation, or action than those who do not intend to modify nothing. To extrapolate, those identifying most with a pre-contemplation stage may not be thinking of health behavior modifications, and therefore, may intend to do nothing. Another trend suggests that participants who intend to exercise and lose weight most identify with the contemplation and preparation stages of change, which could be related to their active thought process and plans to change health behaviors.

Table 6

Multiple Independent t-test Analyses of Health Behavioral Intentions and Stage of Change

Health Behaviors	Stage of Change							
	Precontemplation		Contemplation		Preparation		Action	
	t	*df*	*t*	*df*	*t*	*df*	*t*	*df*
Intended Diet	-2.01*	60	1.97	59	2.49*	60	1.59	59
Intended Exercise	-1.93	60	2.35*	59	2.24*	60	1.63	59
Intended Maintaining Weight	-1.38	60	1.65	59	2.49*	60	1.81	59
Intended Weight Loss	-2.75*	60	3.16*	59	3.29*	60	1.79	59
Intended None	3.8*	60	-2.44*	59	-3.26*	60	-2.64*	59

Note. *t* statistic was used to explain the difference between groups of stages of change and intended behaviors, where the greater the magnitude of the absolute value of t, the greater the evidence against the null hypothesis.

df is the number of values in the calculations that are free to vary.

*$p>0.05$

Maintenance stage and the intended behaviors of reducing alcohol, smoking cessation and other were omitted, due to lack of evidence of statistical significance between stage of change and intended health behaviors.

Utility of Genomic Risk and GC

Data was also collected on utility of genetic risk results and GC. On a scale of 1-5, 1 being *not at all useful* and 5 being *extremely useful*, participants were asked to what extent they felt that their genomic risk information was useful. The number of participants and the percentage of total participant answers from 1-5 are as follows: 0 (0%), 10 (14.5%), 11 (15.9%), 23 (33.3%), and 19 (27.5%). Overall, participants (n=62) had a mean score of 3.82 for perceived utility of genomic risk which suggests participants generally valued genomic risk between *moderately useful* and *very useful*. The same scale was then used to assess participants' perception of the utility of GC. This was reported s number of participants and the percentage of total participant answers on a scale of 1-5 respectively; 0 (0%), 8 (11.6%), 5 (7.2%), 16 (23.2%), and 8 (11.6%). Again, participants (n=37) had a collective mean score of 3.65 meaning that they perceived the utility of GC to be between *moderately useful* and *very useful*. It was hypothesized that GC intervention would increase the perceived utility of genomic risk. No significance was found, $t(60)=2.33$, $p=0.23$, between those who received GC—mean score of 4.09—and those who did not receive GC—mean score of 3.48—and their perceived utility of genomic risk. This nullifies our hypothesis and suggests that GC intervention does not increase the perceived utility of genomic risk.

An analysis of variance was conducted looking at the differences between each stage of the TTM, perceived utility of GC and perceived utility of genomic risk. No

statistical significance was discovered between groups for perceived utility of GC (Table 7). However, there was a significant difference, at the $p>0.05$ level, between stage of change and perceived utility of genomic risk (Table 8). Participants who most identified with maintenance stage of change viewed their genomic risk as more applicable and useful than those who identified with other stages most. Participants who identified with the maintenance stage of change had a mean score of 3.34 associated with *moderately useful*, whereas those who did not had a mean score of 2.95, which corresponds between *somewhat useful* and *moderately useful*. We extrapolate that those in the maintenance stage of TTM may believe that their genomic risk is more useful and applicable to their healthcare than those participants in other stages, and therefore may utilize this risk in their personal evaluation of behavior.

Table 7

ANOVA of Perceived Utility of GC and Stage of Change

Stage of Change	*df*	*F*	*p*
Precontemplation			
Between	3	0.82	0.49
Within	32		
Contemplation			
Between	3	2.9	0.83
Within	31		
Preparation			
Between	3	0.72	0.55
Within	32		
Action			
Between	3	1.78	0.17
Within	31		
Maintenance			
Between	3	2.01	0.13
Within	33		

Note. F statistic was used to explain the difference between groups of stages of change and perceived utility of genomic counseling; the greater the magnitude of *F*, the greater the evidence against the null hypothesis.
df is the number of values in the calculations that are free to vary.
*Significance found at the $p>0.05$ level.

Table 8

ANOVA of Perceived Utility of Genomic Risk and Stage of Change

Stage of Change	*df*	*F*	*p*
Precontemplation			
Between	3	0.96	0.42
Within	57		
Contemplation			
Between	3	0.55	0.65
Within	56		
Preparation			
Between	3	0.81	0.49
Within	57		
Action			
Between	3	0.44	0.72
Within	56		
Maintenance			
Between	3	4.16	0.01*
Within	58		

Note. F statistic was used to explain the difference between groups of stages of change and perceived utility of genomic risk; the greater the magnitude of *F*, the greater the evidence against the null hypothesis.
df is the number of values in the calculations that are free to vary.
*Significance found at the $p>0.05$ level.

Chapter 4: Discussion

The overall purpose of this study was to assess the impact of genomic testing and genomic counseling on health behavioral attitudes, intentions and outcomes on participants in a personalized medicine study receiving multiple online actionable complex disease reports. More specifically, we sought to assess the utility of genomic counseling as a means of social support and determine its influence on behavioral attitude, intentions and short term behavioral modification. We attempted to determine correlations between perception of the type of support offered by a genetic counselor and the utility of this support by the participant—whether the participant incorporated the support provided in their decision to modify/not modify their health behaviors. Further, we sought to describe the relationship between the current stage of behavioral change and participant perception of the support provided by the genetic counselor (i.e. emotional).

Regarding genomic risk, we posited that participants who received genomic counseling would be more likely to accurately remember their genomic risk, as compared to controls. We found that there was no significant difference between those who received genomic counseling and those who did not on their retention of their genomic disease risk. Although there is limited literature regarding genomic risk information retention for common complex disease, Sweet et al. found that participants in this OSU-CPMC study receiving in-person genomic counseling believed they knew their

genetic risk status better than control arm subjects when surveyed one month post counseling (Sweet, et al., 2017). Additionally, studies for Mendelian disease have shown similar findings. Dicastro et al. noted that 61.8% of *BRCA1* carriers versus 30% of non-carriers, accurately recalled personal and offspring cancer risk post genetic counseling (Dicastro, et al., 2002). Since this study observed differences between those who received counseling as well as those who are affected, we looked at the accuracy of genomic risk selection for participants with a diagnosis of CAD, DM2 and/or heart failure. We found that all 14 participants who correctly identified their genomic risk category were affected with one or more of these diseases. However, only half (14/28) of the affected participants correctly identified their disease risk given on the test reports received during the OSU-CPMC study. This lack of retention might be due to the differing timing of genomic counseling in the OSU-CPMC study, as some participants received genomic counseling more than 3 years ago (RCT), while others received genomic counseling within the last six months (R21). However, no significant difference in retention of risk information was found between those in the RCT and R21 cohorts. Further studies evaluating the ability to retain genomic information after counseling intervention are essential to develop better techniques in genomic counseling to convey genomic information, as retention of this risk information can strongly influence behavioral attitudes and intentions.

Another construct that is influenced by genomic counseling and impacts these behavioral attitudes and intentions is that of stage of change. Non-significant trends were observed between those who received genomic counseling and their stage of change. Participants who received genomic counseling more strongly identified with the

contemplation stage of change than those who did not receive genomic counseling. This suggests that the genomic counseling intervention may stimulate the thought process surrounding healthy behavior change. Subsequently, we found that participants identifying with contemplation and preparation stages indicated an increased intention to change behaviors. It may then be reasonable to deduce an indirect relationship between receipt of genomic counseling and increased intentions to change behavior, though a direct relationship was not observed (H1 not supported).

Due to the significance found between stage of change and intended behaviors, we extrapolate that participants existing in the contemplation and preparation stages of change may have a stronger desire to change health behaviors than participants in other stages. Other studies have observed similar findings. A 2010 study found significant interaction between participants who received special intervention of education surrounding the methods to reduce dietary saturated fat and the contemplation stage of change (Mochari-Greenberger, Terry, & Mosca, 2010). These investigators also found that participants in the contemplation stage have an increased potential to achieve positive dietary changes if moved along to the preparation and action stages. Taken together with our data, this could suggest that there is efficacy for genomic counseling intervention during or shortly after the contemplation stage of change. Although there were no differences observed in perceived utility of genomic counseling in these various stages (H3 not supported), we postulate that reaching participants in the contemplation and preparation stages of the transtheoretical model, may have positive impact on their desire and action to change behavior.

Genomic counseling intervention was postulated to be useful in these stages of change also to combat discrepancies in health literacy that may exist for participants in each stage of change. However, no significant differences in health literacy in our population were found. This suggests that effects of health literacy on health behavior change in our cohort were limited as compared to that found in the literature. Sørensen, et al., 2012 also found that participants with limited health literacy skills had poorer health outcomes and higher health system costs. Since our study sample does not appear to have health literacy limitations, we can neither support nor refute what has been observed in other studies. Furthermore, no significant differences were found between participants of limited health literacy and adequate health literacy in perception of the utility of genomic counseling or genomic risk (H2 not supported).

Since perception of genomic risk is grounded in the ability to comprehend risk, health literacy is easily analyzed against this construct. However, perception of genomic counseling is a psychological construct difficult to juxtapose against health literacy. It may then be reasoned that subjective interpretations of counseling could create a barrier in comprehension of the risk information and application of that risk to behavioral attitudes and intentions. One study suggests that when counseling is conducted, we must be able to define for the participant subjective risk from objective risk (Shiloh & Saxe,1989). As important as appropriate delivery of this objective risk information is, we must also be able to better measure objective and subjective interpretations of genomic counseling. One way to evaluate perceptions of this counseling objectively is to compare the social support provided by genomic counseling to the stage of change in which the participant exists.

We found that participants receiving instrumental and informational support identified least with the action stage of behavior change. We reason that participants in the action stage, may be less receptive to information that contributes to the initiation of behavioral modification, as they have already implemented health behavior changes. A qualifying factor that may have influenced our findings is the type of social support provided by genomic counseling in our study. These genomic counseling sessions were focused on discussion of the prevention of disease risks, and interpretation of actionable risk factors contributing to these disease types, instead of a focus on a pre-existing disease. This differs from the more traditional genetic counseling approach for which more directed emotional and psychosocial support may be provided. We postulate there may be less need for this type of social support in the genomic counseling sessions that were done for the OSU-CPMC study. Further research into traditional genetic counseling approaches, with regard to the social support provided by the counselor, may be advantageous to see if this inverse association with the action stage of change exists in the traditional setting. If so, it may be postulated that providing participants in the action stage of change with different types of social support may be more effective in conveying risk.

Another factor that was found to contribute to efficacy of social support in the stages of change model was the confidence of the participants to change behaviors in the next 6 months and upcoming year. We found that participants in the precontemplation, contemplation and maintenance stages were more confident to change behaviors within six months and within a year. Therefore, it can be inferred that participants in these stages of change may be able to best progress to the next stage of change and therefore would be

more amenable to social support provided by the genomic counselor. In the context of social support provided by the genomic counselor, no statistical significance was observed for those receiving instrumental support on confidence to change (H4 not supported). Additional analysis showed that participants receiving informational support were significantly less confident to make behavioral modifications in the next six months than those who did not receive this type of support. One study contrasting this finding showed that participants provided with informational support were most likely to have positive self-care maintenance (Cené, et al., 2013), albeit, social support was not provided by genomic counseling. Given these conflicting findings, we suggest further investigation into the role of social support, stage of change, and confidence in changing behaviors to provide a better genomic counseling delivery model.

Limitations

Our findings suggest that additional work needs to be done to determine the most effective means to deliver genetic/genomic counseling to encourage participant engagement and participation in healthy behavior modification. Specifically, for our study, we were unable to determine if tools such as social support are effective in delivery of genomic risk during certain stages of change mainly due to the small sample size. Statistical power was not achieved for many calculations due to the limited number of participants that completed the Qualtrics survey. This may have been due to survey fatigue, the fact that many of these participants (especially those in the RCT) have been on study for several years, or have been involved with other OSU-CPMC online surveys beyond those included in this study. Additionally, some participants who answered the Qualtrics survey provided only partial response to aspects of the survey, such that all

sections of the analysis were not equally weighted. An extension of this limitation included the attempt to further categorize this sample population into those who received genomic counseling and those who did not, making our sample size even smaller. In addition to sample size, we were limited by validated measures to study both social support and stages of change, as literature surrounding use of social support in genetic counseling is absent. Social support as a means of counseling and stages of change of participants in counseling studies is very limited.

Finally, our study reports trends in a specific cohort that may not be descriptive of a more generalized population. Our participants consisted of many participants that were affected with disease already, as well as motivated participants seeking out research studies, meaning that there are significant selection biases occurring in this cohort. Collecting this data in other cohorts may result in other findings.

Chapter 5: Conclusion

The importance of genomic counseling on perception of health-related attitudes, behaviors and behavioral intentions has not been well reported. The intention of this pilot study was to further investigate the influence of genomic counseling on these effects. Significant differences found between those who received genomic counseling and the identification with the contemplation stage of change provides insight into effect of genomic counseling on progression through the Transtheoretical model. Additionally, determining that participants existing in the contemplation and preparation stages of change have an increased intention to change behavior, may indicate that participants in these stages have a stronger desire to change health behaviors than those in the other stages. Therefore, individuals in these stages may be amenable to genomic counseling to influence their ability to initiate behavior change.

Although there were no differences observed in perceived utility of genomic counseling in these stages, it can be postulated that reaching participants in these stages of the transtheoretical model may have positive impact on desire and action to change behavior. Additionally, as a novel study on social support, we found that participants receiving informational and appraisal support were least likely to identify with the action stage of change. In addition to observing differences in stages of change depending on social support type used, we found that there were also significant differences between types of social support provided and participants' confidence to change. For participants

receiving informational support were least confident in their ability to change behaviors. It can be postulated that the efficacy of informational support may be better when used in conjunction with another type of support, as alone it may have a negative impact on confidence to change, which could have an indirectly negative impact on behavioral intentions and ability to enact the change.

Confidence to change was also impacted by identity of stage of change. Participants in the precontemplation, contemplation and maintenance stages were more confident to change behaviors within six months and within a year. Therefore, it can be inferred that participants in these stages of change may be able to best progress to the next stage of change. For participants in the maintenance stage, their confidence level could be tied to their active and sustained behavior change. However, for participants in the precontemplation and contemplation stages of change, there may be more encouragement and support that goes into their ability to initiate and sustain behavior change. Therefore, it may be advantageous for genetic counselors to reach participants in these stages of change to actively engage them in the process of planning and initiating health-enhancing behaviors.

Overall, our study suggests that the stage(s) of behavior change in which a participant exists can both influence their behavioral attitudes and modifications, and are influenced by actions of healthcare providers in the type of social support provided.

Future Directions

As a pilot study, this research was intended to lay ground work for future endeavors into exploration of the role of genomic counseling in behavioral modification for participants receiving multiple potentially actionable complex disease genomic

reports. To the best of our knowledge, this was the first study to analyze social support in context of genomic counseling intervention. Although we found limited significance of our data on social support, our study provided a solid platform for further studies evaluating the importance of the types of social support provided by the genetic counselor and the timeframe in which this social support is given.

To reach statistical significance for a future study assessing similar measurable outcomes, sample size would have to be larger, and time between participants receiving GC and answering surveys better controlled. In addition, the use of validated, measurable outcomes related to the transtheoretical model is warranted. Other variables to consider in future analyses include the long-term compliance of care that participants receiving these actionable disease reports follow, as well as analysis of the association between perceived GC utility and family and peer influence on behavior change. In order to provide the best care for our participants, there needs to be a standard of care established for longitudinal follow-up. Understanding more about participant's perceptions of their own health-related attitudes, behaviors and behavioral modifications will provide the foundation for more focused follow up.

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Appendix A: E-mail Announcing Study

Subject: New Survey for the OSU-Coriell study – Assessing Your Health Behavior Change!

Dear participant,
We hope all is well and thank you for your continued participation in the OSU-Coriell Personalized Medicine study!

We are excited to announce a new survey. We are sending this survey to better understand outcomes for some of the test results that you have received through the research study. Specifically, you will be asked about health behaviors, and how the test results may have modified any health behaviors such as changes in your diet or lifestyle.

We will use the information gained to improve on how genetic counseling for complex disease is provided.

Completion of the survey is voluntary.

To participate, please click on this link. It should take approximately 20-25 minutes to complete the survey. You will receive a $10 Amazon.com gift card for your participation.

Choosing not to participate in this survey will not affect your participation in the OSU-Coriell Personalized Medicine study or your medical care at Ohio State.

If you should have any questions about this survey or study participation, please feel free to contact the study PI: Kevin Sweet at Kevin.Sweet@osumc.edu

Sincerely,
Megan McMinn,
OSU-CPMC Liaison

Appendix B: Number of participants with at least one risk factor from the OSU-CPMC RCT and R21 data

Table 9

Participant reportable risk factor data from RCT and R21 studies

Disease	Risk Factor	RR	Number of counts for each risk variable *	% of Participants With At Least One Risk Variable
AMD	Smoking (former history)	1.4	77	
	Smoking (current history)	2.0	9	
	Family History (at least one first-degree relative)	4.0	17	
	Variant (heterozygous)	2.4	77	
	Variant (homozygous)	6.0	11	
				73.1
CAD	Diabetes	1.7	29	
	Smoking	2.1	7	
	Family History (one or both parents)	1.4	100	
	Variant (heterozygous)	1.3	101	
	Variant (homozygous)	1.7	39	
				89.3
DM1	Family History (one first-degree relative)	6.6	43	
	Variant (heterozygous)	0.08	28	
	Variant (homozygous)	0.3	98	
				11.7
DM2	BMI (BMI 25-29.9)	2.3	69	
	BMI (BMI $\geq$ 30)	5.9	85	
	Family History (one or both parents)	1.3	35	
	Variant (heterozygous)	1.2	90	
	Variant (homozygous)	1.3	22	
				92.4

continued

Table 9 Continued

Disease	Risk Factor	RR	Number of counts for each risk variable *	% of Participants With At Least One Risk Variable
HH	Variant (homozygous)	27	1	
				0.5
LUP	Smoking	1.5	9	
	Family History (one-first degree relative)	4.1	36	
	Family History (two first-degree relatives)	11.3	20	
	Variant (heterozygous)	1.4	68	
	Variant (homozygous)	2.0	15	
				0.518
MEL	Family History (one-first degree relative)	2.2	26	
	Variant (heterozygous)	1.7	32	
	Variant (homozygous)	3.0	1	
				0.269
PRO	Family History (father or brothers diagnosed with prostate cancer)	1.9	9	
	Variant (heterozygous and homozygous risk)	1.5	13	
				0.107

Note. Some participants had more than one risk variable for a given disease
AMD: Age Related Macular Degeneration
CAD: Coronary Artery Disease
DM1: Type 1 Diabetes
DM2: Type 2 Diabetes
HH: Hemochromatosis
LUP: Systemic Lupus Erythematosus
MEL: Melanoma
PRO: Prostate cancer
RR: Relative risk

Appendix C: Qualtrics Survey

OSU-CPMC study 2 chronic disease cohort updated survey

Slider:

1. About how much do you weigh without shoes? (2011 BRFSS)

_____ Pounds

2. About how tall are you without shoes? (2011 BRFSS)

_____Feet

_____Inches

*Allows us to calculate BMI and compare to their BMI from the start of the Coriell study

Multiple Choice: *(Skip Logic, if yes then go onto 4, if no, not sure or prefer not to answer go on to 5)*

3. Did you receive genetic counseling while participating in the Coriell study?
   - Yes
   - No
   - Not sure
   - Prefer not to answer

Likert Scale:

4. The following questions ask you to state your agreement about your experience with genetic counseling and receiving your results.

	Strongly disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly agree
The genetic counseling I received helped me understand my risk.					

Understanding my results helped me to change my behaviors and reduce my disease risk.					
Understanding my results helped me seek proper medical attention and reduce my disease risk.					
I have told my family members about my OSUMC-CPMC results.					
I feel as though my family members would benefit from genetic counseling.					
5. Next, we would like to know more about your opinions of your health and healthy behaviors. A health behavior is defined as any activity or action undertaken for the purpose of preventing or detecting disease and to improve overall health and well-being (such as getting regular exercise, eating healthier and stopping smoking).					
	Strongly disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly agree
My health behaviors have an influence on my family.					
My family plays an active role in changing my health behaviors.					

My health behaviors limit the activities I can participate in with my family.					
I am motivated to change my health behaviors based upon my CPMC risk results.					
I am confident in my ability to understand most health related information.					
I have shared my OSUMC-CPMC results with my health care providers.					
I have asked my doctor for help in changing my health behaviors.					

Multiple Choice with skip logic: (2011 BRFSS)
6. Have you smoked at least 100 cigarettes in your entire life? (5 packs=100 cigarettes) *(Skip logic, if yes, not sure or prefer not to answer, then go onto 7, if no, go onto 10)*

- Yes
- No
- Not sure
- Prefer not to answer

7. Do you now smoke cigarettes every day, some days or not at all? *(Skip logic, if every day, some days or not sure, go onto 8, if not at all, or prefer not to answer, go onto 10)*

- Everyday
- Some days
- Not at all
- Not sure
- Prefer not to answer

8. Are you seriously thinking of quitting smoking? *(Skip logic, if prefer not to answer go onto 10)*

- Yes, within the next 30 days
- Yes, within the next 6 months
- No, not thinking of quitting
- Prefer not to answer

9. During the past 6 weeks, have you stopped smoking for one day or longer because you were trying to quit smoking?

- Yes
- No
- Not sure
- Prefer not to answer

Slider: (2011 BRFSS)

10. On average, how many times per week do you participate in a physical activity or exercise, other than your regular job, such as running, walking for exercise, calisthenics, golf or gardening?
____Times a week
11. And when you take part in these activities, for how many minutes do you usually keep at it?
____Minutes
12. On average, how many servings of fruits and vegetables do you eat each day? (One serving is a small piece of fruit, ½ cup of vegetables, ¼ cup of dried fruit, ¾ cup of 100% fruit juice, ½ cup of beans)
____Servings

Open Ended fill in the blank: (2005 Weiss, Newest Vital Sign)

For the next set of questions, we are interested in understanding how you interpret and understand health information. Please type in your answers to the question using the nutrition information below. Imagine that this information appears on the back of a pint-sized container of ice cream.

Nutrition Facts	
Serving Size	1/2 cup
Servings per container	4
Amount per serving	
Calories 250	Fat Cal 120
	%DV
Total Fat 13g	20%
Sat Fat 9g	40%
Cholesterol 28mg	12%
Sodium 55mg	2%
Total Carbohydrate 30g	12%
Dietary Fiber 2g	
Sugars 23g	
Protein 4g	8%

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

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

13. Looking at the above package label, if you eat the entire container, how many calories will you eat? _____(in calories)

14. If you are following a diet that allows for you to eat 60 g of carbohydrates as a snack, how many servings of ice cream could you have? _____(in servings)

15. Your doctor advises you to reduce the amount of saturated fat in your diet. You usually have 42 g of saturated fat each day, which includes 1 serving of this ice cream. If you stop eating this ice cream, how many grams of saturated fat would you now be consuming each day?

_____(in grams)

16. If you usually eat 2,500 calories in a day, what percentage of your daily value of calories will you be eating if you eat one serving of this ice cream?_____(in %)

Now, imagine that you are allergic to the following substances: Penicillin, peanuts, latex gloves, and bee stings. Looking at the same label, please answer the questions below.

17. Is it safe for you to eat this ice cream? (check one)

- Yes
- No
- Prefer not to answer

18. If it is not safe for you to eat this ice cream, why not? (note: the label you saw on the previous page appears again below) _____

Nutrition Facts	
Serving Size	1/2 cup
Servings per container	4
Amount per serving	
Calories 250	Fat Cal 120
	%DV
Total Fat 13g	20%
Sat Fat 9g	40%
Cholesterol 28mg	12%
Sodium 55mg	2%
Total Carbohydrate 30g	12%
Dietary Fiber 2g	
Sugars 23g	
Protein 4g	8%

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

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

Multiple Choice: Adapted from Sweet et al. 2014

19. Before enrolling in the Coriell study, were there any health behaviors that you wanted to improve or change? (**Adapted from Sweet et al. 2014)**

- Yes
- No
- Not sure
- Prefer not to answer

20. In what areas were the health behaviors that you wanted to improve or change **prior** to enrolling in the Coriell study? Check all that apply. (**Adapted from Sweet et al. 2014)**

- Diet-related (such as eating more servings of vegetables and cutting down on sweets)
- Exercise (such as walking for an hour every day)
- Quitting Smoking
- Reducing Alcohol Consumption
- Maintaining a Healthy Weight
- Losing Weight
- Other (specify)
- None

21. Which result best describes your Coriell genetic risk result? (*Skip logic Diabetes, go to 22, 23 and 32 c, if Heart Disease, go to 22, 23 and 32 a, if both, go to 22, 23 and 32 b, if neither, go to 23 d.*) (**NEW)**

- High risk for Diabetes
- High risk for Heart Disease
- Neither of these describe my Coriell genetic risk result

Likert Scale: (skip logic to either one of these)
(22A-C, 23 A-D AND 27-31 & 33 will only appear if the answer to number three is yes, not sure or prefer not to answer)

22a. How much do you agree with this statement? **(NEW)**

I made changes in my health behavior based on the information about my **HEART DISEASE** genetic risk, based on what my genetic counselor discussed with me as part of the Coriell study.

(1=strongly disagree, 5=strongly agree)

22b. How much do you agree with this statement? **(NEW)**

I made changes in my health behavior based on the information about my **HEART DISEASE and DIABETES** genetic risk, based on what my genetic counselor discussed with me as part of the Coriell study.

(1=strongly disagree, 5=strongly agree)

22c. How much do you agree with this statement? **(NEW)**
I made changes in my health behavior based on the information about my **DIABETES** genetic risk, based on what my genetic counselor discussed with me as part of the Coriell study.

(1=strongly disagree, 5=strongly agree)

Multiple Choice:
23a. What health behaviors have you changed *ALREADY* due to the results that your genetic counselor discussed with you about **HEART DISEASE**? Check all that apply. (**Adapted from Sweet et al. 2014)**

- Diet-related (such as eating more servings of vegetables and cutting down on sweets)
- Exercise (such as walking for an hour every day)
- Quitting Smoking
- Reducing Alcohol Consumption
- Maintaining a Healthy Weight
- Losing Weight
- Other (specify)
- None

23b. What health behaviors have you changed *ALREADY* due to the results that your genetic counselor discussed with you about **HEART DISEASE and DIABETES**? Check all that apply. (**Adapted from Sweet et al. 2014)**

- Diet-related (such as eating more servings of vegetables and cutting down on sweets)
- Exercise (such as walking for an hour every day)
- Quitting Smoking
- Reducing Alcohol Consumption
- Maintaining a Healthy Weight
- Losing Weight
- Other (specify)
- None

23c. What health behaviors have you changed *ALREADY* due to the results that your genetic counselor discussed with you about **DIABETES**? Check all that apply. (**Adapted from Sweet et al. 2014)**

- Diet-related (such as eating more servings of vegetables and cutting down on sweets)
- Exercise (such as walking for an hour every day)
- Quitting Smoking
- Reducing Alcohol Consumption
- Maintaining a Healthy Weight
- Losing Weight
- Other (specify)
- None

23d. Are there any health behaviors you have *ALREADY* changed due to the results that your genetic counselor discussed with you about your genetic risk? Check all that apply. (**Adapted from Sweet et al. 2014)**

- Diet-related (such as eating more servings of vegetables and cutting down on sweets)
- Exercise (such as walking for an hour every day)

- Quitting Smoking
- Reducing Alcohol Consumption
- Maintaining a Healthy Weight
- Losing Weight
- Other (specify)
- None

24. Are there any health behaviors you *INTEND* to change due to the results that your genetic counselor discussed with you about your genetic risk? Check all that apply. (**Adapted from Sweet et al. 2014)**

- Diet-related (such as eating more servings of vegetables and cutting down on sweets)
- Exercise (such as walking for an hour every day)
- Quitting Smoking
- Reducing Alcohol Consumption
- Maintaining a Healthy Weight
- Losing Weight
- Other (specify)
- None

Likert Scale:
25. How confident are you that in the following time frames you can make health behavior modifications, such as those listed in the previous question, based on your genetic risk that you discussed with your genetic counselor? (**Adapted from Sweet et al. 2014)**

	Not at all confident 1	Somewhat confident 2	Neither Agree Nor Disagree 3	Confident 4	Very Confident 5
In the next 6 months					
In the next year					

26. For each statement below, please state your agreement. (**Adapted from Koyun & Eroğlu, 2013)**

	Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
I do not intend to modify my health behaviors within the next six months.					

I am thinking about starting to modify my health behaviors within the next six months.					
I am currently trying to modify my health behaviors, but I don't always practice healthy behaviors.					
I am currently modifying my health behaviors, but have only begun to do so within the past six months.					
I am currently modifying my health behaviors and have done so for more than six months.					

Slider:
27. What percentage of the genetic counseling session do you estimate was spent talking about health behaviors and changes that you might make? **(NEW)**
_____percent

Multiple Choice:
28. What type of support would you say your genetic counselor provided you?
(Generated from information in Demaray & Malecki, 2013). Check all that apply.

- Emotional support through expression of empathy and care
- Resource support through providing information on my genetic risk
- Engaging support through actively asking question that made me self-reflect
- Verbal support through advice giving and suggestions

29. Which type of support would you say your genetic counselor used the most during your genetic counseling session? **(Generated from information in Demaray, et al., 2013).**

- Emotional support through expression of empathy and care
- Resource support through providing information on my genetic risk
- Engaging support through actively asking question that made me self-reflect
- Verbal support through advice giving and suggestions

30. My genetic counselor encouraged me to talk to my doctor about my health behaviors. **(NEW)**

- Yes
- No

31. If yes, with whom did they encourage you to talk? **(NEW)**
- Dietician
- Primary care doctor
- Psychologist
- Cardiologist
- Endocrinologist
- Other (specify)
- None

Likert Scale: (**Adapted from Sweet et al. 2014)**

32a. To what extent do you consider the information about your **HEART DISEASE** genetic risk results useful and applicable to your life?

Not at all Useful 1	Somewhat Useful 2	Moderately useful 3	Useful 4	Very Useful 5

32b. To what extent do you consider the information about your **HEART DISEASE and DIABETES** genetic risk results useful and applicable to your life?

Not at all Useful 1	Somewhat Useful 2	Moderately useful 3	Useful 4	Very Useful 5

32c. To what extent do you consider the information about your **DIABETES** genetic risk results useful and applicable to your life?

Not at all Useful 1	Somewhat Useful 2	Moderately useful 3	Useful 4	Very Useful 5

33. To what extent do you consider the support that you received from your genetic counselor relevant and helpful to changing your health behavior? *(Will only appear if the answer to number three is yes, not sure or prefer not to answer)*

Not at all Useful 1	Somewhat Useful 2	Moderately useful 3	Useful 4	Very Useful 5

Appendix D: Graphical Representation of Intended Behavior Change

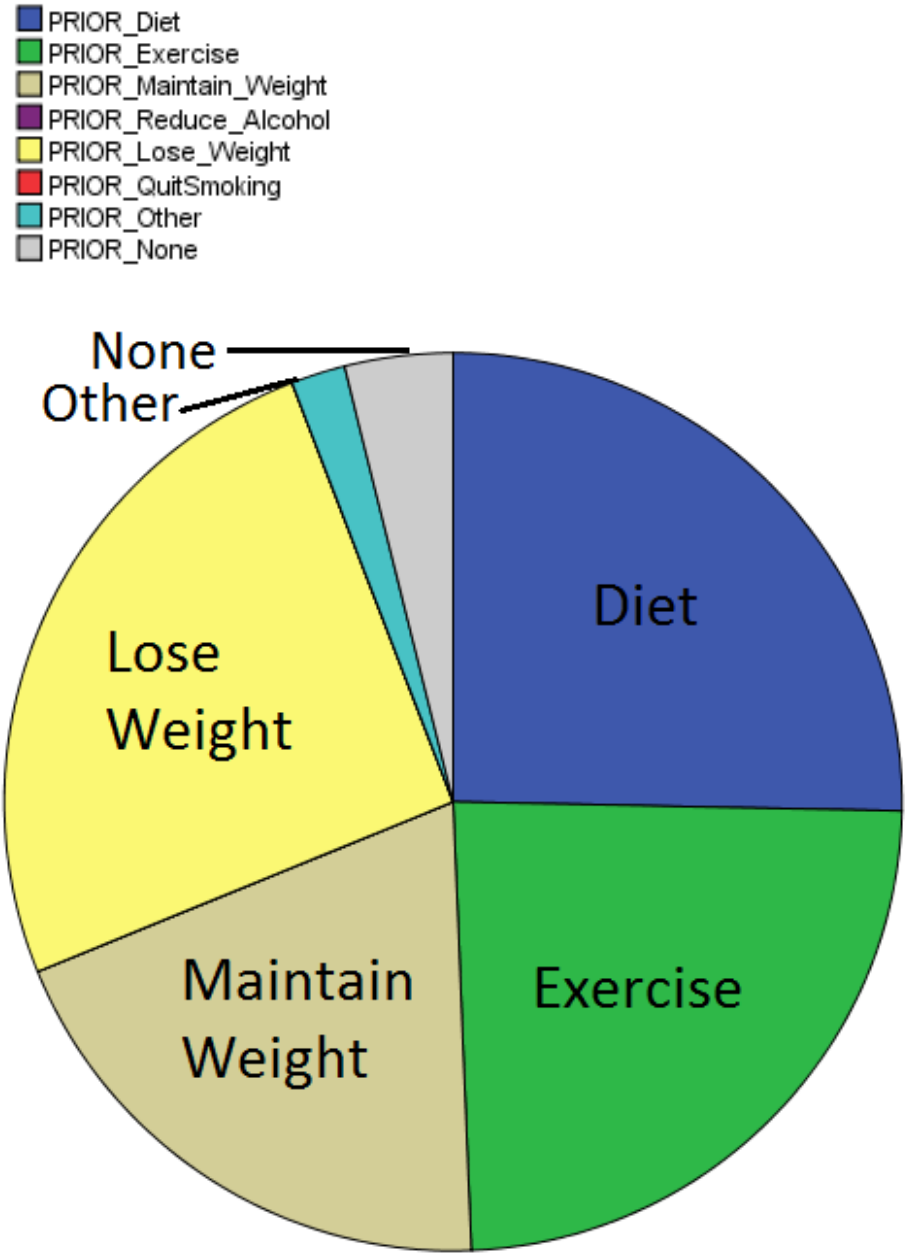

Figure 2. *Percentage of Prior Desired Behaviors*

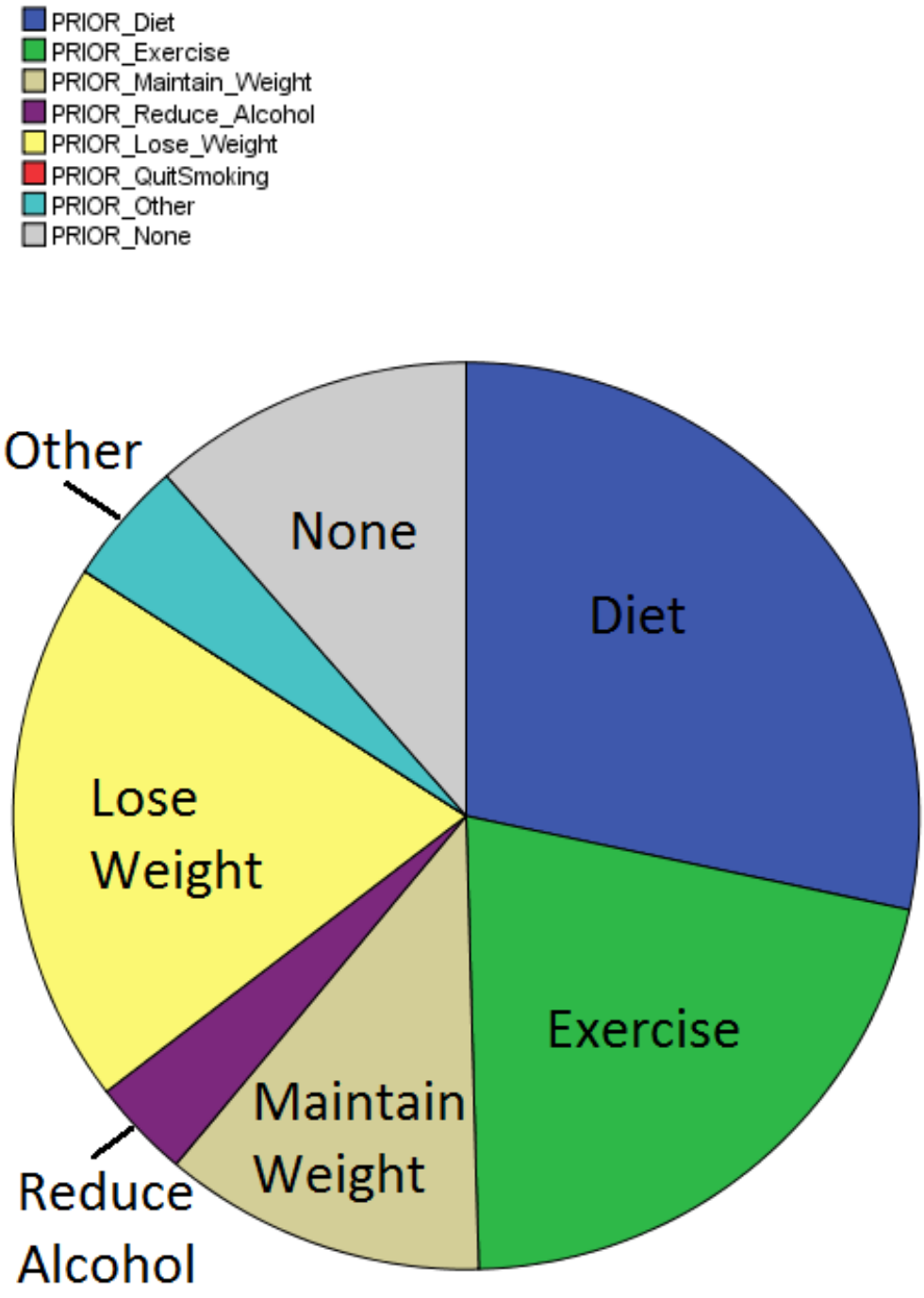

Figure 3. *Percentage of Behaviors Changed After Receipt of GC and/or Genomic Risk*

Figure 4. *Percentages of Behaviors Still Intended To Change*