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Intervention Completion Rates among African Americans in a Randomized Effectiveness Trial for Diet and Physical Activity Changes

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Abstract

Background—The intervention completion rate is an important metric in behavioral and intervention research; trials with limited intervention completion rates may have reduced internal validity. We examined intervention completion rates among 530 African Americans who had been randomized to an integrated (INT) or disease-specific (DSE) risk education protocol as part of a comparative effectiveness trial from September 2009 to August 2012.

Methods—The interventions were developed by an academic-community partnership using community-based participatory research. Intervention completion rates were determined based on attendance at all four intervention sessions. Intervention completers were participants who

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completed all four sessions and non-completers were those who did not complete any session or only completed one to three sessions following randomization.

Results—73% of participants were intervention completers and 27% were non-completers. There were no differences in intervention completion based on randomization to INT (72%) or DSE (75%), sociodemographic factors, or BMI in the total sample. Different factors were associated significantly with intervention completion within study groups. Among participants randomized to INT, the odds of intervention completion were greater with higher levels of intrinsic motivation, less exposure to information about diet and cardiovascular disease, and greater BMI. Among participants randomized to DSE, the odds of completing the intervention were associated significantly with older age and greater dietary self-efficacy.

Conclusions—Many African Americans are likely to complete risk education interventions.

Impact—Psychological characteristics should be considered when determining intervention completion rates following randomization in behavioral and intervention trials.

INTRODUCTION

Obesity and excess weight are significant clinical and public health issues that disproportionately affect African Americans (1, 2). A goal of obesity-related interventions developed for African Americans is to identify the most effective approaches for reducing excess weight and obesity so that the risk of developing chronic disease is reduced and the potential for adverse outcomes is lowered (3–6). Considerable investments are made to ensure that intervention staff are trained appropriately and protocols are delivered with fidelity to ensure their internal validity. Efforts are also made to ensure that interventions have sufficient reach and that the study sample is demographically representative of the target population (7). However, attrition is an important threat to internal validity.

The retention rate is an important metric in clinical trials and other intervention research that reflects the ratio of the number of participants retained relative to those enrolled. The retention rate is one metric that is used to assess an intervention's effectiveness and these data are required in study reports (8). The first element of retention is based on the number of participants who received or completed the intervention relative to the total number who were allocated to study arms; this rate is relevant for determining if the intervention's efficacy is likely to be underestimated (8–10). Studies have shown that intervention completion rates following randomization is variable depending on the type of study and the setting in which it is delivered. For instance, intervention completion rates ranged from 79% to 90% among African American church members who were randomized to different protocols as part of a motivational interviewing intervention that targeted fruit and vegetable intake (5). But, it is not always feasible to implement obesity-related health behavior interventions in churches and programs implemented in this setting may have limited reach to and completion among general community members.

We developed a community-based risk education intervention in which participation was open to African American adults who were residents in an urban metropolitan area. The intervention was developed through an academic-community partnership using principles of community-based participatory research (CBPR) (11). Previously, we demonstrated the

feasibility of recruiting a sample of residents that is demographically representative of the community to participate in risk education (7), however, our pilot did not include randomization to study arms and participation only involved completing one intervention session. Intervention completion rates may differ in protocols that involve randomization to different study arms and attendance at more than session.

The purpose of this report was to characterize completion rates for our health behavior intervention that targeted concerns and priorities about diet and physical activity in a community-based sample of African American adults (11). While it is common practice to compare intervention completion rates following randomization based on allocation to study arms and sociodemographic and personal characteristics (8), we determined if completion differed based on motivation to make behavioral changes and the extent to which the information delivered was likely to be novel. To do this, we measured prior exposure to information about cancer and cardiovascular disease because these were the diseases targeted in the intervention and compared completion rates based on how much participants had heard or read about these conditions. We predicted that participants with greater motivation and those with less exposure would be most likely to complete the intervention. We also examined whether these factors had different effects on intervention completion within study arms.

MATERIALS AND METHODS

Overview of Study Design and Population

We completed a randomized trial to compare the effectiveness of two forms of risk education among African Americans from September 2009 to August 2012. To be eligible for participation, individuals had to self-identify as being African American, be ages 18–75, and be a current resident in the Philadelphia, PA metropolitan area. We excluded individuals who self-reported a personal history of cancer or a cardiovascular event (e.g., heart attack, stroke). Individuals who had a history of an eating disorder, those enrolled in a commercial weight loss program, and individuals who had a physical condition that restricted their physical activity were also ineligible. Since this was a community-based sample, more than one person from a household and those who were related were eligible for participation.

Eligible participants were randomized to one of two study arms: integrated risk education (INT) or disease-specific risk education (DSE) following self-referral from community-based recruitment mechanisms (7). The study was described as a research program that would provide information about risk factors for chronic disease and ways to live a healthier lifestyle. Following self-referral, a screening interview was completed to determine eligibility. Those who were eligible completed a structured baseline telephone interview after providing verbal informed consent. The baseline obtained sociodemographics, exposure to information about cancer and cardiovascular disease, and motivation to make behavior changes. At the end of the baseline, individuals were invited to participate in the intervention; those who agreed were randomly assigned to either DSE or INT. Individuals who lived in the same household or were related to another participant were assigned to the same intervention group. Written informed consent was obtained for intervention

completion. The study was approved by the Institutional Review Boards at the University of Pennsylvania and the Medical University of South Carolina.

Both study arms consisted of four sessions that were delivered using a semi-structured format. We limited the intervention to four sessions to facilitate future dissemination to community organizations and primary care settings. Each session in INT and DSE lasted about 1 ½ to 2 hours. Intervention sessions were delivered in a group format at a university office building once per week over a 4-week period; these groups included an average of five participants. Participants were scheduled for the intervention depending on their availability and they remained with the same group once the 4-week intervention period was started except for a small number (n=43) who changed to a different group after the first session because they had a scheduling conflict or were unable to obtain child care. As in other intervention studies (12, 13), there were two primary Master's level health educators who delivered the intervention. There were also two adjunct facilitators: the study PI (CHH) and a community health educator, who had been trained by the study team. These adjunct health educators delivered the intervention to 39 participants (7% of our total sample) at the university office building or a community site. As stated previously, the intervention was developed collaboratively by the partnership to address concerns and priorities about diet and physical activity that were identified by community residents (11). In addition to including strategies from motivational interviewing (MI) from a previous MI intervention (5), both protocols incorporated evidence-based strategies to promote health behavior change in fruit and vegetable intake and physical activity and materials adapted from the Supporting Healthy Activity and Eating Right Everyday Study lifestyle weight loss program (14) and the Diabetes Prevention Program (15). Participants were given a \$35 incentive per session to defray travel and other expenses.

Measures

Sociodemographic and medical history characteristics—We obtained gender, age, marital status, education, employment, and income by self-report using items from our previous research (7). Participants were asked if they had a personal history of hypertension and diabetes (yes or no) and we calculated BMI using self-reported height and weight. We calculated travel distance to the intervention site using the participant's self-reported zip code.

Self-efficacy for diet and physical activity—We used validated instruments to evaluate dietary and physical activity self-efficacy (16, 17). These instruments asked participants how confident they were in terms of their ability to eat fruits and vegetables and to be physically active under a variety of circumstances.

Motivation for behavior change—We used a 12-item version of the Treatment Self-Regulation Questionnaire (18) that was adapted by Resnicow and colleagues (4) to evaluate the extent to which an individual's motivation to eat more fruits and vegetables was for intrinsic, self-determined, personal reasons or was because of external or extrinsic rewards or a punishment. This version included two 6-item Likert style sub-scales that measured intrinsic and extrinsic motivation; higher scores reflected greater motivation.

Prior exposure to information about cancer and cardiovascular disease—We adapted items from our previous research to measure how much participants had heard or read about cancer and cardiovascular disease (19). Similar items were used to evaluate exposure to information about nutrition and cardiovascular disease and physical activity and cardiovascular disease. We re-coded responses to these items as having less (almost nothing and a little bit) or more (a lot and a fair amount) of exposure to information about cancer and cardiovascular disease.

Intervention completion rates—We determined intervention completion rates based on completion of all four sessions. Specifically, participants who completed all four sessions were categorized as intervention completers and those who only completed one to three sessions were categorized as non-completers. Participants who declined to complete the intervention, those who withdrew after completing one to three sessions, and those who did not complete any session after being scheduled were categorized as non-completers.

We also created a variable for intervention health educator based on who delivered the first session. Participants whose first intervention session was completed by one of the two primary health educators were categorized as having a primary facilitator. Those whose session was not completed the primary health educators were categorized as having an adjunct facilitator. Participants were scheduled for the first session based on their availability; those who did not schedule this session because they declined or could not be reached after multiple contact attempts did not have an assigned health educator. Since the primary health educators completed the first session for 93% of participants, we categorized participants who did not complete the first session as having one of the primary health educators. This is a reasonable assumption because the adjunct health educators facilitated groups only for a limited time (e.g., 1-month) and a small number of participants (n=39), whereas the primary health educators completed intervention sessions for close to 100% of participants.

Data Analysis

First, we generated descriptive statistics to characterize participants in terms of sociodemographics and intervention completion. Next, we used Chi Square Tests of Association and T-Tests to evaluate the univariate relationship between completion and sociodemographics, exposure, and motivation, respectively. Last, we used logistic regression analysis to identify factors having significant independent associations with intervention completion. Variables that had a univariate association of $p < 0.10$ with completion were included in the model. Since this was a randomized trial, we also generated a stratified logistic regression models based on study arm to identify factors having significant independent associations with completion based on randomization to INT or DSE.

RESULTS

Table 1 shows the characteristics of participants who were randomized to INT and DSE. Overall, 73% (n=389) completed all four intervention sessions. Of the 27% (n=141) who were intervention non-completers, 10 declined to complete any intervention session and six

withdrew from the study. The majority of non-completers were those who we were unable to contact because their telephone number had been disconnected and/or they had moved (n=37) or they could not be reached after making several contact attempts (n=88). Importantly, many participants who were non-completers were still exposed to the intervention: 2.6% (n=14) completed one session, 3% (n=16) completed two sessions, and 1.5% (n=8) completed three sessions. Figure 1 shows intervention completion after randomization to INT and DSE; these rates did not differ between study arms. For subsequent analyses, we compared intervention completers (n=389) to non-completers (n=141).

Table 1 shows the univariate analysis of intervention completion. Older age and less prior exposure to information about diet and cardiovascular disease had significant associations with intervention completion. Intervention completers also had higher mean levels of intrinsic and extrinsic motivation compared to non-completers (see Table 2). Based on the multivariate logistic regression model in the total sample, the likelihood of intervention completion was increased with older age (OR=1.34, 95% CI=1.09, 1.64, p=0.005), greater intrinsic motivation (OR=1.24, 95% CI=1.01, 1.52, p=0.04), and less prior exposure to information about diet and cardiovascular disease (OR=1.87, 95% CI=1.06, 3.29, p=0.03).

Since intervention completion rates were not equivalent between study arms, we re-ran the logistic regression analysis stratified by INT or DSE to determine if variables that were associated with completion in the total sample had different associations among participants randomized to each arm. We also included BMI and all of the exposure variables in these models. As shown in Table 3, older age and greater levels of dietary self-efficacy had significant independent associations with intervention completion among participants randomized to DSE. Among participants randomized to INT, increased intrinsic motivation, higher BMI, and less prior exposure to information about diet and cardiovascular disease were associated significantly with intervention completion.

DISCUSSION

The purpose of this study was to characterize intervention completion rates in a community-based sample of African American adults who were enrolled in a randomized trial that compared the effects of alternate risk education strategies to enhance obesity-related health behaviors. Overall, 73% of participants completed all four intervention sessions. Our intervention completion rates were lower, but comparable to those reported in similar types of intervention trials that were implemented in a specific community organization and participation was limited to organization members (5). These differences may be due to the number of sessions included in the protocols and the need to travel to attend intervention sessions. However, travel distance did not have a significant association with intervention completion in the total sample or among study arms. Similarly, there were no differences in intervention completion based on whether the groups were facilitated by a primary or adjunct health educator. Of those who did not complete any intervention sessions, many were unable to contact to schedule the first session because their telephone number had been disconnected or they had moved and others could not be reached after multiple contact attempts. Importantly, there were no differences in intervention completion between

participants randomized to INT and DSE. But, different factors were associated with intervention completion among those randomized INT and DSE. Among participants randomized to DSE, older age and greater dietary self-efficacy had significant independent associations with intervention completion, whereas increased levels of intrinsic motivation, higher BMI, and less exposure to information had significant independent associations with intervention completion among those randomized to INT. Since there were no differences between study arms in these factors, it is not likely that the randomization process contributed to these findings. Rather, intervention completion may be due to different motivations for obtaining information about how to make health behavior changes among those in each study arm.

Intrinsic motivation is defined as the extent to which individuals want to make behavioral changes because it is personally relevant and meaningful, and making these changes is linked one's beliefs and values (6). Increasing intrinsic motivation is a primary goal of MI (6); recent research has shown that African Americans who have low intrinsic motivation may be the most responsive to MI interventions (20). The primary question for our study is whether or not differences in factors that are associated with intervention completion is likely to affect the generalizability and efficacy of our intervention. As such, it is important to consider the context and focus of our intervention: a community-based sample of adults who were recruited using self-referrals to participate in a health behavior intervention that was designed to increase fruit and vegetable consumption and physical activity. Given these features, it is not surprising that there would be differences in reasons for wanting to make behavior change among participants in INT and DSE. This is because individuals are likely to vary in terms of when and why they want to make health behavior changes. Differences in intervention completion rates based on intrinsic motivation among those randomized to INT could be because behavior change is an ongoing process (21); individuals have to have some level of desire to before behavior changes are initiated. Overall, many participants in our study were overweight or obese and did not meet the recommended guidelines for fruit and vegetable intake or physical activity (22), but were concerned about obesity and indicated a need for educational interventions that would facilitate health behavior change (11). Since greater BMI was also associated with intervention completion among participants randomized to INT, it could be that intervention completion was the initiation of the behavior change process. When viewed in this way, it does not seem that differences in factors that were associated with intervention completion among study arms would limit the generalizability of our study, especially since they did not differ in these variables. Our intervention completion rates also did not differ significantly based on sociodemographics. Nevertheless, our findings show that psychological factors should be considered when evaluating intervention completion rates overall and within study arms so that these variables can be taken into account.

In considering the results of this study, some limitations should be noted. First, only African Americans from an urban geographic area were included; it was not possible to compare intervention completion rates by race or ethnicity or residency in a different city or state. Intervention completion rates may be lower in rural geographic areas that do not have multiple resources for public transportation. Relatedly, we provided a financial incentive to defray expenses that were incurred to travel to the sessions. It could be argued that providing

a financial incentive adversely affects the generalizability of our study. Our decision to provide a financial incentive was based on the strategies that are recommended to enhance the retention of minorities in medical research (23, 24). Further, our findings suggest that the incentive may not have been the only or most important factor in intervention completion. Previous research on retaining African American women in a genetic counseling intervention (25) and barriers to African American participation in research (26) found that provision of a tangible benefit is important both recruitment and retention. The financial incentive we gave provided a tangible benefit to study participation and also addressed the logistical and financial realities of our study population (e.g., low income). More importantly, perhaps, our data show that the primary reasons for not completing the intervention is because participants could not be reached to schedule sessions, either because their telephone number had been disconnected or they no longer lived at the address provided. This trend was not surprising because of the high rates of unemployment and low household income levels in our sample. A small number of participants declined to complete any intervention session or withdrew following randomization. Nevertheless, future studies should determine if intervention completion rates after randomization differ among African Americans depending on if a financial incentive is provided and their satisfaction with the health educator's communication skills, knowledge, and experience level. Despite these limitations, our study has important implications for the retention of African Americans in research protocols.

Recruitment and retention are critical to the success of any research that involves human participants. Many studies have documented challenges recruiting and retaining African Americans in research (23, 24,27, 28). Our study demonstrates that some issues may be insurmountable. But, our findings also show that many African Americans are likely to complete a health behavior intervention. It may be important to evaluate psychological characteristics when determining intervention completion rates following randomization and at other points so that the effects of these variables can be considered as part of evaluating the trial's efficacy and effectiveness.

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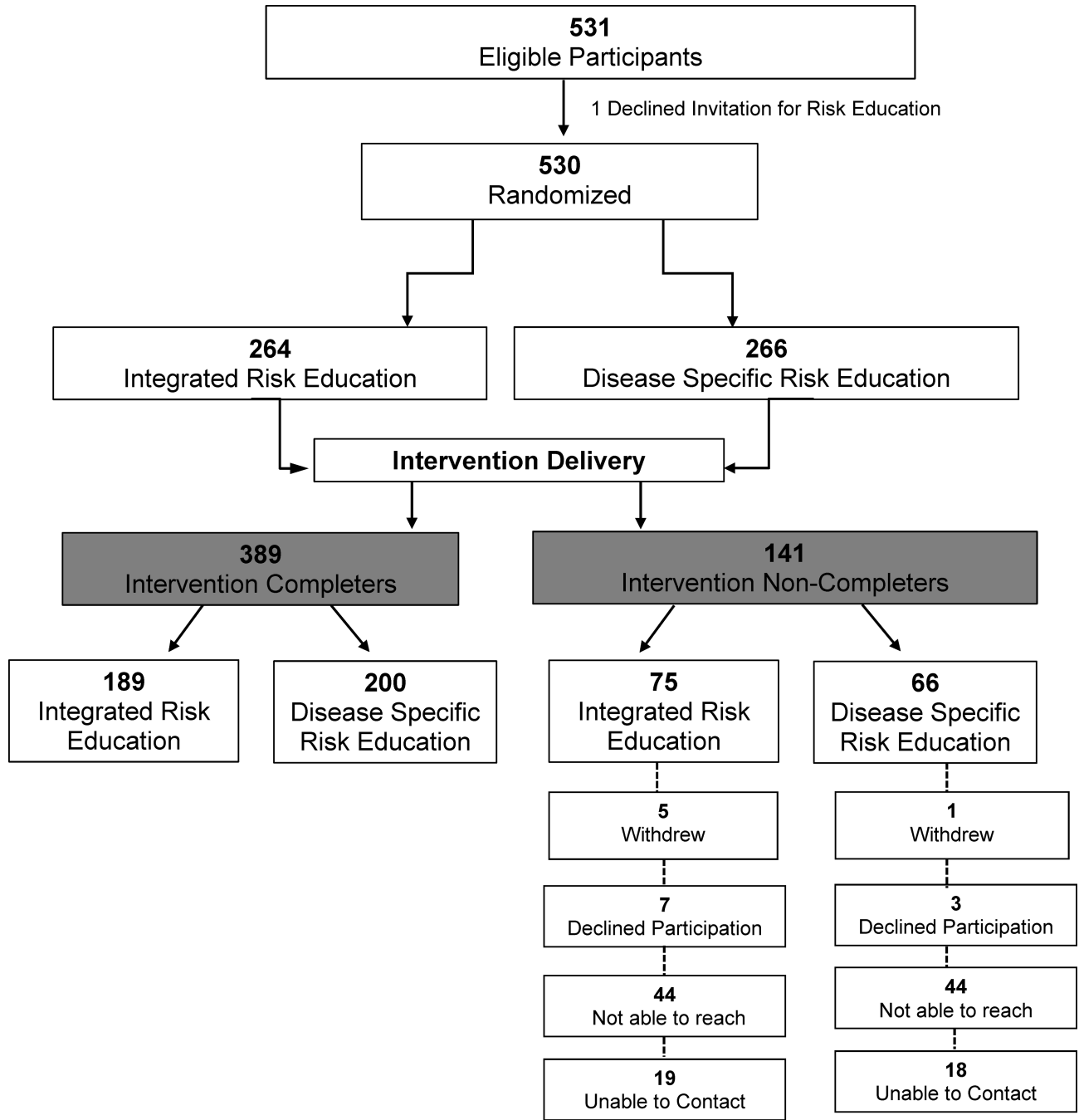


Figure 1. Intervention Completion Rates after Randomization

Could Not Be Reached= Telephone and/or address was valid, but was not able to contact to schedule session after multiple attempts.

Unable to Contact= Telephone and/or address was not valid; participant was no longer at the address or the telephone number disconnected.

Table 1

Sample Characteristics and Intervention Completion by Sociodemographics and Exposure Variables

Variable	Level	n (%)	% Complete Intervention	Chi Square
Gender	Male	227 (43%)	74%	0.006
	Female	303 (57%)	73%	
Marital Status [†]	Married	62 (12%)	81%	1.91
	Not Married	467 (88%)	72%	
Education Level	Some College	260 (49%)	74%	0.18
	High School Graduate	270 (51%)	72%	
Employment Status [†]	Employed	177 (34%)	69%	2.71 [‡]
	Not Employed	349 (66%)	76%	
Income Level [†]	>\$20,000	237 (48%)	72%	0.31
	<\$20,000	254 (52%)	75%	
Health Insurance [†]	Yes	414 (78%)	75%	3.07 [‡]
	No	115 (22%)	67%	
Diabetes	Yes	55 (10%)	73%	0.01
	No	475 (90%)	73%	
Hypertension	Yes	159 (30%)	75%	0.50
	No	371 (70%)	73%	
Same household	Yes	12 (2%)	83%	0.62
	No	518 (98%)	73%	
Know someone in study [†]	Yes	50 (9%)	68%	0.87
	No	479 (91%)	74%	
Randomization	Integrated	264 (50%)	72%	0.88
	Disease Specific	266 (50%)	75%	
Health educator	Primary	491 (93%)	73%	1.61
	Adjunct	39 (7%)	82%	
Diet and CVD ^{††}	A lot/fair amount	240 (45%)	68%	5.76 [*]
	Almost nothing/a little bit	290 (55%)	78%	
Diet and Cancer	A lot/fair amount	236 (44%)	71%	1.06
	Almost nothing/a little bit	294 (56%)	75%	
Physical activity and cancer	A lot/fair amount	201 (38%)	73%	0.08
	Almost nothing/a little bit	328 (62%)	74%	

Variable	Level	n (%)	% Complete Intervention	Chi Square
Physical Activity and CVD ^{††}	A lot/fair amount	288 (54%)	70%	2.64 [‡]
	Almost nothing/a little bit	241 (46%)	77%	
	Mean (SD)	Completer Mean (SD)	Non-Completer Mean (SD)	t-value
Age	48.2 (10.7)	49.0 (10.4)	45.8 (11.2)	-3.09 _(t) **
Body Mass Index	29.9 (6.6)	30.0 (6.5)	29.5 (6.8)	-0.74 _(t)
Travel distance	5.0 (3.6)	4.9 (3.6)	5.2 (3.5)	0.99

[†] 1 participant refused to provide marital status, 4 refused to provide employment status, 39 participants refused to provide income, 1 refused health insurance, 1 refused to report if they knew someone else in the study

^{††} CVD=Cardiovascular disease

** p<0.01;

* p<0.05;

[‡] p<0.10

Table 2

Intervention Completion by Motivation and Self-Efficacy

Variable	Intervention Completers Mean (SD)	Intervention Non Completers Mean (SD)	t-value
Intrinsic Motivation [§]	26.8 (3.4)	25.9 (3.6)	-2.66 ^{**}
Extrinsic Motivation ^{§§}	16.4 (4.7)	15.4 (4.8)	-2.28 [*]
Diet Self-Efficacy ^{§§§}	33.0 (8.1)	31.9 (9.2)	-1.40
Physical Activity Self-efficacy ^{§§§§}	23.6 (5.2)	22.56 (5.2)	-2.15 [*]

^{**} p<0.01;

^{*} p<0.05

[§] Cronbach's alpha=0.92

^{§§} Cronbach's alpha=0.78

^{§§§} Cronbach's alpha=0.92

^{§§§§} Cronbach's alpha=0.80

Table 3

Logistic Regression Analysis of Intervention Completion by Study Group

Variable	Integrated Risk Education Odds Ratio (95% CI) [†]	Disease Specific Risk Education Odds Ratio (95% CI) ^{††}
Age	1.20 (0.89, 1.61)	1.51 (1.09, 2.08)**
Employment Status	0.97 (0.52, 1.82)	0.66 (0.34, 1.26)
Marital Status	3.05 (0.92, 10.14) [‡]	0.89 (0.35, 2.25)
Health Insurance	0.61 (0.31, 1.20)	0.85 (0.41, 1.79)
Physical Activity Self-Efficacy	1.11 (0.82, 1.51)	1.08 (0.78, 1.50)
Dietary Self-Efficacy	0.77 (0.56, 1.06)	1.44 (1.04, 2.01)*
Intrinsic Motivation	1.71 (1.20, 2.43)**	1.03 (0.74, 1.44)
Extrinsic Motivation	1.07 (0.79, 1.46)	1.38 (0.98, 1.94) [‡]
Diet and Cancer Exposure	0.74 (0.28, 2.00)	0.84 (0.32, 2.25)
Physical activity and Cancer Exposure	1.84 (0.67, 5.03)	1.23 (0.47, 3.21)
Diet and CVD Exposure	3.31 (1.32, 8.29)**	1.67 (0.70, 4.02)
Physical activity and CVD Exposure	0.79 (0.34, 1.81)	1.04 (0.43, 2.49)
BMI	1.46 (1.06, 1.13)*	0.82 (0.59, 1.12)

[†]
n=259;^{††}
n=259;**
p<0.01;*
p<0.05;[‡]
p<0.10

ORs for continuous variables reflect the OR for a 1-SD unit change in the covariate.