# Cardiovascular Disease Risk Factors After an Employer-Based Risk Reduction Program: An Observational Cohort Study

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Submitted February 4, 2017; revision received March 16, 2017; accepted April 5, 2017. **Context:** The burden of cardiovascular disease (CVD) continues to be a public health concern. Workplace interventions that focus on modifying lifestyle habits may reduce CVD risk factors in people at risk.

**Objective:** To determine the effectiveness of a comprehensive lifestyle intervention program that integrated dietary modification, physical activity, stress management, and behavior modification counseling to reduce the risk of CVD in at-risk adults.

**Methods:** Twelve 1-year cohorts who participated in a comprehensive employer-sponsored lifestyle intervention program targeting diet, exercise, behavior modification, and stress management between 2006 and 2010 at a rural university in Appalachian Ohio were studied. Body composition, fasting glucose and lipid levels, and maximal oxygen consumption were measured at baseline, after 100 days, and at 1 year. Repeated-measures analyses of variance were conducted to compare measures at baseline with measures at 100 days and at 1 year.

**Results:** Seventy-four participants (57 women [77.1%], 17 men [22.9%]) of 97 completed the program (76.3% completion rate). Body weight (P<.001); percentage of body fat (P<.001); fat mass (P<.001); body mass index (P<.001); waist circumference (P<.001); blood levels of high-density lipoprotein (P=.035), low-density lipoprotein (P=.011), and glucose (P=.008); serum triglyceride levels (P=.019); blood pressure (systolic P=.028; diastolic, P=.001); and maximal oxygen consumption (P<.001) improved from baseline to 1 year after the intervention. Lean body mass (P=.111) and total cholesterol (P=.053) did not improve.

**Conclusions:** This employer-based lifestyle intervention program was effective in reducing CVD risk factors after 1 year of treatment. Future studies should examine the effects of the intervention at 2 and 5 years to further assess long-term adoption of the lifestyle changes and maintenance of health promoted by this program.

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ardiovascular disease (CVD) has been the leading cause of death in US adults for the past century. Despite declining mortality rates, the burden of disease due to CVD continues to be a public health concern. It has been estimated that 70% or more of CVD cases could be prevented if certain risk factors were modified. These modifiable risk factors include type 2 diabetes mellitis, high blood

pressure, hypercholesterolemia, overweight/obesity, being sedentary, and smoking/tobacco exposure.<sup>5,6</sup> Studies have shown that the presence of multiple risk factors and the severity of each risk factor act synergistically to increase the chance of CVD developing.<sup>7</sup> The American Heart Association and American College of Cardiology Foundation support the use of aggressive, comprehensive CVD risk reduction strategies.<sup>7</sup>

The Risk Reduction Program (RRP) at Ohio University was an employer-based wellness program to reduce CVD risk factors in program participants. The purpose of this study was to determine the effectiveness of the RRP in reducing CVD risk factors in at-risk adults. The research question for this study was as follows: What is the effect of the RRP on body weight; percentage of body fat; lean and fat mass; body mass index (BMI); waist circumference; blood levels of high-density lipoprotein (HDL), low-density lipoprotein (LDL), total cholesterol, and fasting glucose; serum level of triglycerides; blood pressure; and maximal oxygen uptake (Vo<sub>2</sub> max) after 100 days and at 1 year? We hypothesized that RRP would be effective in reducing CVD risk factors at both 100 days and 1 year after baseline.

### Methods

# Design, Participants, and Setting

This study was approved by the institutional review board of Ohio University in Athens. This cohort study examined a subset of data pooled from 12 cohorts of Ohio University employees and dependents who participated in the RRP between 2006 and 2010. The current study represents a convenience sample of participants who were classified as at risk for CVD and who completed the 1-year RRP program. Participants had to present with lifestyle diseases or 1 or more risk factors for CVD, such as coronary artery disease, diabetes, dyslipidemia, obesity, physical inactivity, smoking, or stress. Participants in the RRP were referred by a physician or recruited using materials distributed by the Office of Human Resources at Ohio University. Participants were treated using a comprehensive

approach that integrated personalized nutrition education and counseling, an individualized exercise regimen, behavioral modification techniques, and yoga classes to reduce existing CVD risk factors.

# Program Structure, Main Outcome Measures, and Data Collection

The RRP was implemented by an interdisciplinary team consisting of a case manager, registered dietitian nutritionist, certified personal trainer, exercise physiologist, and certified voga instructor, who worked with participants on group and individual bases. Participants were required to attend all exercise sessions, nutrition education meetings, yoga classes, and group support classes scheduled by the interdisciplinary team to remain in the program. The total cost to run the program, which included a wellness facility membership and group and individual classes was \$3000. However, because it was an employer-based program, participants were responsible for a \$300 participation fee, and the Office Of Human Resources paid the remaining \$2700. In addition, each quarter, participants could earn up to \$75 of their participation fee by meeting attendance and health goals. If the participants met the goals at 1 year, they were also eligible for a second annual membership to WellWorks, Ohio University's employee wellness facility.

The program had 2 phases. Phase I spanned the first 100 days (week 1 to week 15). During the first week of the program, participants underwent a physical assessment, including body weight; percentage of body fat; lean and fat mass; body mass index (BMI); waist circumference; blood levels of HDL, LDL, total cholesterol, and fasting blood glucose; serum level of triglycerides; blood pressure; and Vo<sub>2</sub> max. Participants also completed a medical history form. A demographic information form, a 3-day food recall sheet, and a medical outcome survey were also used to collect data during the first week. Phase II of the program was less structured than phase I, in that participants transitioned to being independent and self-directed. Measures at 1-year included waist circumference, body

composition, blood lipids, blood glucose, and an exercise stress test. Participants also completed another written medical history form at 1 year.

Body fat percentage, lean mass, and fat mass were measured by air displacement plethysmography using the BodPod Gold Standard Body Composition Tracking System (Life Measurement Inc) according to standard methods. Participants were weighed on a calibrated scale and then asked to enter the BodPod chamber. The system then calculated participants' body fat percentage, lean mass, and fat mass from the measured body density.

Vo<sub>2</sub> max was predicted from a maximal treadmill stress test using the Bruce protocol. Participants were asked to exercise to maximum volitional exhaustion, at which time maximal heart rate and rating of perceived exertion were measured and recorded. A regression equation was then used to predict Vo<sub>2</sub> max, which took into account total time accomplished during the test and maximum rating of perceived exertion. <sup>10</sup>

After a 12-hour overnight fast, blood levels of LDL, HDL, total cholesterol, and glucose, and serum triglyceride levels were measured. Blood samples were drawn by a certified phlebotomist via venipuncture and were sent to a laboratory for analysis.

The results of the baseline testing were reviewed with each participant, and individualized physical activity goals were set for weeks 2 to 15. Participants met with a case manager to review their needs, set SMART (specific, measurable, action-orientated, realistic, time-bound) goals, and design an appropriate, individualized exercise program. Participants engaged in exercise with a certified personal trainer twice weekly for 1 to 1.5 hours of aerobic and resistance training. They were also encouraged to exercise on their own. Participants were required to attend the following sessions during phase I: (1) 1 hour of a facilitated support group per week; (2) 2 hours of stress management/yoga classes with a certified yoga instructor per week; and (3) three 1-hour nutrition education groups led by a registered dietitian nutritionist.

In the nutrition education groups, participants were provided with dietary intake goals based on individual needs, focusing on decreased caloric intake (500-1000 kcal) for weight loss and specific macro- and micronutrient intake goals based on age-specific dietary reference intakes.11 Participants also set SMART goals based on nutrient intakes after each session. Nutrition counseling was also available during phase I and consisted of an initial 1-hour intake session to determine individual goals and eating plans. This initial session was followed up 7 to 14 days later with a halfhour session to gauge progress. Although this was stated not to be a weight loss-focused program, weight was one of the risk factors tracked. Dietary intake patterns were analyzed using Nutritionist Pro (First Data Bank). Behavioral modification techniques were used, including motivational interviewing, the stages of change, and cognitive behavioral therapy throughout the group and individual counseling sessions. After 2 to 3 weeks, the registered dietitian nutritionist assessed participants' progress and modified their diet therapy to meet health goals. During the last week of phase I, all tests from week 1 were repeated; these samples were collected and analyzed in the same manner as week 1.

#### **Statistical Analyses**

The data analyzed in this study were pooled from 12 cohorts of participants who completed the entire program during the same period (2006-2010). As previously noted, measurements were obtained during week 1 (baseline), after phase I (100 days), and after phase II (1 year). Repeated-measures analyses of variance were conducted to compare the aforementioned anthropometric and physiologic variables at baseline to phase I and phase II. Data were not stratified by sex for analysis, owing to the small sample size, and reasons for dropout were not tracked.

### Results

A total of 72 women (74.2%) and 25 men (25.8%) participated. Participants ranged in age from 28 to 72 years, with a mean (SD) age of 50.1 (8.8) years. No

other demographic data were collected. The Table summarizes the anthropometric, biochemical, and other characteristics and clinical outcomes.

#### **Effect of RRP on Anthropometric Measures**

The first aim of this study was to determine the effect of the RRP on body weight, body fat percentage, lean and fat mass, BMI, and waist circumference. At the completion of phase I, significant reductions were seen in most anthropometric measures, including body weight (P<.001), body fat percentage (P<.001), fat mass (P<.001), BMI (P<.001), and waist circumference (P<.001). Lean mass did not significantly change (P>.99). Similarly, at the end of phase II, participants demonstrated significant reductions in

body weight (P<.001), body fat percentage (P<.001), fat mass (P<.001), BMI (P<.001), and waist circumference (P < .001). As during phase I, lean mass did not significantly change (P=.111). No further significant reductions were observed after phase II, but the changes observed initially in body composition parameters were robust enough to persist after 1 year of program participation. Also, no anthropometric measures significantly changed from 100 days to 1 year (P > .05).

# **Effect of the RRP on Blood Laboratory Values and Cardiorespiratory Parameters**

A second aim of this study was to determine the effect of the RRP on lipid parameters, fasting glucose levels,

Table. Characteristics of Participants in a Workplace Risk Reduction Programa

n (SE) n .6 (5.9) 73 .9 (7.8) 73 .5 (1.0) 73 .7 (3.0) 73	31.3 (0.9) 40.4 (1.0)	<pre>// P Valueb &lt; .001 &lt; .001 &lt; .001</pre>	73 73 72	Mean (SE) 195.4 (5.5) 31.3 (0.9)	<.001 <.001
2.9 (7.8) 73 3.5 (1.0) 73	31.3 (0.9) 40.4 (1.0)	<.001	73	31.3 (0.9)	
5.5 (1.0) 73	40.4 (1.0)				<.001
. ,	. ,	<.001	72	40.0 (4.0)	
.7 (3.0) 73	4447(00)			40.6 (1.0)	<.001
	114.7 (2.9)	>.99	73	114.0 (2.7)	.111
.5 (0.9) 73	81.1 (3.2)	<.001	73	81.4 (3.8)	<.001
.7 (0.9) 73	37.3 (0.9)	<.001	70	37.8 (0.9)	<.001
93 (4) 73	182 (4)	<.001	70	184 (5)	.053
49 (1) 73	49 (1)	>.99	70	53 (2)	.011
17 (4) 73	109 (4)	<.001	70	109 (5)	.035
44 (11) 73	117 (7)	.004	70	119 (8)	.019
99 (4) 73	93 (2)	.085	70	93 (3)	.008
35 (2) 71	129 (2)	.001	72	131 (2)	.028
34 (1) 71	79 (1)	<.001	72	80 (1)	.001
55 (0.61) 71	32.61 (0.68)	<.001	72	32.82 (0.70)	<.001
	73 (0.9) 73 73 74 75 76 76 77 77 78 78 78 78 78 78 78 78 78 78 78	1.5 (0.9) 73 81.1 (3.2) 1.7 (0.9) 73 37.3 (0.9) 1.7 (0.9) 73 37.3 (0.9) 1.93 (4) 73 49 (1) 1.17 (4) 73 109 (4) 1.17 (4) 73 117 (7) 1.17 (7) 99 (4) 73 93 (2) 1.17 (2) 71 129 (2) 1.18 (1) 71 79 (1)	2.5 (0.9)       73       81.1 (3.2)       <.001	1.5 (0.9)     73     81.1 (3.2)     <.001	1.5 (0.9)     73     81.1 (3.2)     <.001

a Participants with missing data were not included in the analysis for that particular variable, accounting for fewer than 74 participants for some of the measures, characteristics, and clinical outcomes.

Abbreviations: BMI, body mass index; BP, blood pressure; HDL, high-density lipoprotein cholesterol; LDL, low-density lipoprotein cholesterol; Vo<sub>2</sub> max, maximal oxygen consumption; WC, waist circumference.

Baseline to 100 days.

<sup>&</sup>lt;sup>c</sup> Baseline to 1 year.

blood pressure, and Vo2 max. From baseline through phase 1, significant reductions were seen in most blood lipid parameters, including LDL (P<.001), triglycerides (P<.001), and total cholesterol (P<.001), with the exception of HDL cholesterol, which did not significantly change (P>.99). As seen with the body composition parameters, the changes in most blood lipid parameters observed during phase 1 were robust enough to persist after phase II, with LDL (P=.035) and triglyceride (P=.019) levels significantly decreasing from baseline. While it did not change during phase I, HDL level (P=.011) significantly increased after phase II. Total cholesterol did not significantly decrease (P=.053). It is also noted that no lipid measures significantly changed from 100 days to 1 year (P > .05), with the exception of HDL, which significantly increased (P<.001).

Blood glucose levels did not significantly change among participants from baseline to 100 days (P=.085) or from 100 days to 1 year (P>.99). However, blood glucose levels significantly decreased from baseline to 1 year (P=.008).

Participants demonstrated significant reductions in both systolic (P=.001) and diastolic (P<.001) blood pressure at 100 days and at 1 year (P=.028 and P=.001, respectively). Significant improvements were found in Vo<sub>2</sub> max at both 100 days (P<.001) and 1 year (P<.001). Vo<sub>2</sub> max is considered the criterion standard for determining cardiorespiratory fitness. From 100 days to 1 year, no significant changes in these measures occurred (P>.05).

### Discussion

This employer-based wellness program effectively reduced CVD risk factors in the first 100 days, and these changes were maintained at 1 year. The mean weight loss was approximately 9 lb (approximately 4.5%) at the end of the program. This amount of weight loss has been shown to be effective in reducing cardiometabolic risk. In the Diabetes Prevention Program, <sup>11</sup> a 7% weight loss resulted in more than

50% reduction in new-onset diabetes. For patients with diabetes, a 5% reduction in weight resulted in improved lipid and glucose levels and blood pressure. 12

As summarized in the **Table**, most of the weight loss occurred in the first 100 days and did not significantly change from 100 days to 1 year. The NHLBI 1998 guidelines recommended an initial goal of 10% reduction in body weight by 6 months. In the current study, after phase I, participants appeared to be on track to meet this 10% weight reduction as outlined by the NHLBI. One reason that weight loss may have slowed was because phase 2 of the program was less structured. While the RRP was not successful in achieving a 10% weight reduction, the program was successful in preventing weight regain, which is clinically important.

In addition to weight loss, statistically significant reductions were found in abdominal adiposity. Reductions in percentage of body fat and waist circumference were seen at 100 days and 1 year. The improvement of overweight/obesity, and particularly abdominal adiposity, is associated with improved metabolic function, including reduced blood cholesterol, lower blood pressure, improved insulin function, reduced risk for type 2 diabetes, and, ultimately, reduced risk for CVD. <sup>14,15</sup>

High-density lipoprotein cholesterol level did not change initially but did significantly increase at 1 year compared with baseline and 100 days (+4 mg/dL). Some studies have reported decreases in HDL cholesterol during active weight loss. Dattilo and Kris-Etherton<sup>16</sup> found that during active weight loss, small but significant decreases in HDL cholesterol can occur. However, this decrease in HDL cholesterol appears to resolve once weight reduction has stabilized.17 Since RRP participants lost the majority of weight during phase I of the current study, the finding by Dattilo and Kris-Etherton<sup>16</sup> may account for the lack of change in HDL cholesterol during that time. The significant increases in HDL cholesterol demonstrated during phase II may have been a result of prolonged weight maintenance in the sample. This finding is consistent with previous reports. 6,13,18-20

Cholesterol parameters generally improved at 100 days and were maintained at 1 year. The INTERHEART study, a study of 52 countries, identified dyslipidemia as one of the most important risk factors for CVD development. The normal mean baseline total cholesterol level of 193 mg/dL in the current study may have blunted the improvement, but the reductions in LDL cholesterol and triglyceride levels were consistent with the results of other multidisciplinary RRPs. 18-20 The reduction of other cardiometabolic risk factors, including overweight/obesity and waist circumference, have also been associated with improved blood lipid profiles. 13

Statistically significant improvement in blood glucose (-6 mg/dL) was seen only at the end of the program. However, participants had a mean glucose reading of 95 mg/dL at baseline, which was within the normal fasting range. Aizawa et al,<sup>21</sup> Kim et al,<sup>22</sup> and Oh et al<sup>23</sup> reported significant reductions in fasting blood glucose levels after 6 months. Notably, Goodpaster et al<sup>20</sup> reported results similar to the current study, with blood glucose levels reaching a statistically significant reduction after 1 year of treatment.

Weight reduction, sodium restriction, and regular physical activity have been shown to independently decrease blood pressure and reduce the risk for CVD. 23-25 In the current study, participants had improved systolic and diastolic blood pressure. Previous studies have demonstrated that a weight loss of 4.5 pounds can result in a 5 to 20 mm Hg reduction in systolic blood pressure. The current study's results are also consistent with those of the Trials of Hypertension and the recommendation of the Eighth National Joint Committee (JNC-8) on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure, which demonstrate the effectiveness of nutrition therapy, physical activity, and weight reduction to reduce blood pressure. 27

The Trials of Hypertension Prevention phase II study<sup>26</sup> demonstrated that weight loss alone, a reduced sodium diet alone, and a combination of weight loss

and diet therapy each effectively reduced systolic and diastolic blood pressure in overweight adults. However, at 6 months of treatment, the combination of weight loss and diet therapy results in the greatest reductions in both systolic and diastolic blood pressure. <sup>26</sup> The JNC-8 recommends the implementation of physical activity and dietary interventions that promote weight loss to reduce blood pressure. <sup>27</sup> In the current study, a lifestyle combination approach yielded statistically significant improvements in blood pressure.

Cardiopulmonary fitness improved in the participants in the current study. The 16% increase in  $Vo_2$  max is similar to findings of other multidisciplinary programs and reflects meaningful improvement in fitness. <sup>26,28</sup>

The cost of the RRP to the participants may have been vital to its success. The personal investment, though heavily discounted, may have improved compliance and could potentially improve insurance claims over time, particularly if participants are successful in adopting the lifestyle changes ing the long term. Chapman<sup>29</sup> concluded that worksite wellness programs can result in savings up to 25% each on absenteeism, health care, workers' compensation, and disability costs for a workplace during a 2- to 5-year period. Studies have also shown that for each dollar spent, comprehensive worksite wellness or RRPs can see a \$3 to \$6 return on investment. 29-31 In the current study, Ohio University spent a total of \$222,000 on the 74 participants who completed the RRP and could potentially earn back \$666,000 to more than \$1.3 million. Future studies should track insurance claims, health care costs, and other related variables to determine the cost-benefit of implementing an RRP. Although we are unable to generalize the results of this study because of the nature of the sample (convenience), it is likely that similar results would be seen in similar settings. As such, employers should consider developing and implementing similar programs.

There are a number of limitations to this study. It was conducted at single center in the Midwest with a single

employer. Race and ethnicity were not recorded; however, the population was largely white, which would limit generalizability to other populations. The participants volunteered to sign up for this program and thus were likely more motivated to make behavior changes than those who did not sign up. Other risk factors, such as smoking and family history, were not assessed.

Other study limitations include that there was no control group or alternative intervention group. The lack of comparison groups limits our ability to determine whether an individual portion of the RRP was more or less effective in reducing CVD risk factors. Although group nutrition education and personalized nutrition prescription were provided, dietary intake was self-reported. Therefore, initial dietary intake and subsequent adherence to nutrition prescriptions could not be accurately measured or controlled for, limiting our interpretation of the results. Physical activity prescriptions were based on the needs and abilities of each RRP participant. While frequency and duration of exercise were prescribed, they could not be controlled. Exercise adherence was not recorded but should be included in subsequent studies. This limitation hinders our ability to interpret relationships between exercise duration and risk factor improvements. Stress management was included in the RRP in the form of yoga classes. However, no psychological or psychosocial measures were used, limiting our ability to comment on the effectiveness of this component of the RRP. Without compliance data, we are unable to determine how effective the RRP is in affecting the adoption of long-term lifestyle modifications. Despite these limitations, the findings support the value of this therapeutic lifestyle program.

While this study reduced cardiovascular outcomes, a long-term prospective study is needed. Future studies should increase the duration of the program. Longitudinal studies that examine the effects of the intervention at 3 months, 6 months, 1 year, 2 years, and 5 years would result in greater information about program compliance and long-term adoption of the

lifestyle changes promoted by the RRP. We suggest that a program similar to the RRP be studied for primary and primordial prevention, as well as secondary prevention, in an effort to assess the adoption of long-term lifestyle changes.

#### Conclusion

This study underscores the potential benefits of a comprehensive employer-based lifestyle program on the wellness of patients. The most robust improvements occurred during phase I of the program, when participants had the most support. However, the changes were large enough to persist through 1 year of treatment. The improvements in risk factors that were observed are indicative of synergistic reductions in the risk for CVD,<sup>32</sup> and the persistence of those improvements at 1 year indicates that the RRP was successful. Longitudinal studies that examine the effects of the intervention at 2 and 5 years would result in greater understanding of the effects of long-term adoption of the lifestyle changes promoted by the RRP.

#### **Author Contributions**

All authors provided substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; all authors drafted the article or revised it critically for important intellectual content; all authors gave final approval of the version of the article to be published; and all authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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