Changes in Cardiometabolic Risk Among Older Adults with Obesity: An Ancillary Analysis of a Randomized Controlled Trial Investigating Exercise Plus Weight Maintenance and Exercise Plus Intentional Weight Loss by Caloric Restriction

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Changes in cardiometabolic risk among older adults with obesity: an ancillary analysis of a randomized controlled trial investigating exercise plus weight maintenance and exercise plus intentional weight loss by caloric restriction

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Abstract

Background: Obesity imposes risk to cardiometabolic health; however, intentional weight loss among older adults with obesity remains controversial.

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Objective: To explore the impact of exercise plus weight maintenance and exercise plus intentional weight loss by caloric restriction on changes in cardiometabolic risk among older adults with obesity assessed by four risk-scoring tools.

Design: Using longitudinal data from the CROSSROADS study (#NCT00955903; May 2009 – October 2014), scores were calculated using baseline and 12-month data according to criteria from the International Diabetes Federation (IDF), National Cholesterol Education Program's Adult Treatment Panel (ATPIII), Framingham Risk Score (FRS), and Cardiometabolic Disease Staging (CMDS).

Participants/Setting: Participants (39% male, 23% African American, 70.2 ± 4.7 y) were randomized to exercise (n=48), exercise + nutrient-dense weight maintenance diet (n=44), or exercise + weight loss by moderate caloric restriction (n=42).

Main Outcome Measure: To evaluate effects of exercise plus weight maintenance and exercise plus intentional weight loss on changes in cardiometabolic risk.

Statistical Analyses Performed: Generalized Estimating Equations were used to assess changes in risk with ethnicity, biological sex, and age as covariates.

Results: Group-time interaction was only significant for Framingham and CMDS (p=0.005 and 0.041, respectively). Upon post-hoc analysis, significant within-group improvements in Framingham scores were observed for exercise + weight maintenance (p<0.001, r = −1.682) and exercise + weight loss (p=0.020, r = −0.881). In analysis of between-group differences in Framingham scores, significant decreases were observed in the exercise + weight maintenance group (p=0.001, r = −1.723) compared to the exercise group. For CMDS, the exercise + weight loss group had significant within-group improvements (p=0.023, r = − 0.102). For between-group differences in CMDS, the exercise + weight loss group showed significant risk reduction (p=0.012, r = −0.142) compared to the exercise group.

Conclusions: Among risk scores evaluated, Framingham and CMDS showed significantly greater sensitivity to change in cardiometabolic risk. Older adults with obesity can significantly lower cardiometabolic risk through exercise + weight maintenance or exercise + weight loss by moderate caloric restriction.

Keywords

cardiometabolic risk; obesity; older adults; weight loss; exercise

Introduction

Cardiovascular diseases (CVD) are the leading cause of death in the United States, as well as the number one cause of death globally[1]. Major risk factors for developing CVD include age, biological sex, high blood pressure, smoking habits, dyslipidemia, and impaired fasting glucose[2]. While these risk factors may present individually, it is well accepted that risk factors cluster and interact multiplicatively, occurring more often together than alone[3]. As a result, the term cardiometabolic disease is often used to describe a clustering of disorders including hypertension, dyslipidemia, glucose intolerance, and abdominal adiposity, that together have the potential to lead to CVD as well as type 2 diabetes[4].

Acknowledging the inter-connectedness of these risk factors, multivariable risk prediction tools have been developed to assess risk for developing cardiometabolic disease albeit with varying diagnostic criteria.

Three commonly used risk-scoring methods include the Framingham Risk Score (FRS) which assess cardiovascular disease risk along with two methods to diagnose metabolic syndrome - National Cholesterol Education Program Adult Treatment Panel (ATPIII) Score and the International Diabetes Federation (IDF) Score[2, 5, 6]. For the FRS, the following risk outcomes are factored into a final numerical score: age, biological sex, high-density lipoprotein cholesterol (HDL-C), total cholesterol, presence of diabetes, smoking habits, and treated versus non-treated systolic blood pressure[2]. This final score represents a percent risk of having a severe cardiovascular event within the next 10 years. ATPIII scores are calculated based on waist circumference, blood pressure, triglyceride levels, HDL-C, and blood glucose measurements[5]. A diagnosis of metabolic syndrome is given if three out of the five criteria are met. IDF scores are calculated based on fasting glycemia, triglycerides, HDL-C, blood pressure, and waist circumference[6]. A metabolic syndrome diagnosis based on IDF criteria requires the presence of abnormal glycemia and at least two other risk factors.

In recent years, a new cardiometabolic screening tool has been developed. The Cardiometabolic Disease Staging (CMDS) Score was created as a way to predict CVD mortality and categorize cardiometabolic risk levels of obese adults in order to better target which individuals would benefit from intensive weight loss therapy[7]. The score is comprised of five different stages of cardiometabolic disease risk. CMDS scoring has been validated in the Coronary Artery Risk Development in Young Adults (CARDIA) Study and the Atherosclerosis Risk in Communities (ARIC) Study. CMDS scores are calculated using measurements for waist circumference, blood pressure, HDL-C, fasting triglycerides, and fasting glucose. Table 1 provides an overview of these four screening tools.

As these scoring tools are comprised of unique variables and biological cut points, it is unknown if each would identify similar changes in cardiometabolic risk resulting from clinical interventions. Thus, these four scoring tools were employed to investigate the effects of exercise with and without intentional weight loss by caloric restriction on changes in cardiometabolic risk among older adults with obesity. In order to assess differences in risk scoring, the current study evaluated data from a randomized controlled trial (#NCT00955903), wherein participants were randomized to one of three groups for one year: 1) exercise, 2) exercise combined with a nutrient-dense weight maintenance diet, or 3) exercise combined with moderate caloric restriction[8]. It must be acknowledged that although weight loss has been shown to lower cardiometabolic risk factors, weight loss among older adults with obesity remains a highly controversial topic[9, 10]. Nevertheless, in the parent study, the weight loss group demonstrated significant weight loss at six months that was maintained through the 12-month intervention (4.1% ± 0.7%, $p<0.001$)[11]. In contrast, neither the exercise only or the exercise + weight maintenance groups showed significant weight changes at six or twelve months. Regardless of intervention arm, there were no significant changes in total lean mass or total bone mineral density among participants following the 12-month intervention.

Although the parent study demonstrated significant weight loss when modest caloric restriction was combined with multimodal exercise, the influence of these interventions on cardiometabolic disease risk remains unknown. As such, the purpose of this exploratory ancillary study was to investigate the impact of exercise plus weight maintenance and exercise plus intentional weight loss by caloric restriction on changes in cardiometabolic risk among older adults with obesity as assessed by four risk-scoring tools.

Materials and Methods

Sample

This study was an ancillary analysis of data collected as part of a randomized controlled trial conducted between May 2009 and October 2014 investigating the effects of a 12-month diet and exercise intervention among older adults with obesity at risk for cardiometabolic disease (ClinicalTrials.gov #NCT00955903)[8]. Although 164 participants were randomized, to the parent study, only 134 participants had complete data for assessing each risk score at month 12 (Figure 1). The parent study enrolled community-dwelling males and females ages 65 years and older from the Birmingham, Alabama area. By study design, all participants were obese (BMI 30–40 kg/m^2) and taking at least one medication to control lipids, blood pressure, or blood glucose. Exclusion criteria included weight change greater than +/− 4.5 kg in the previous year as well as any psychiatric or physical limitations that would preclude participation. The Institutional Review Boards at the University of Alabama at Birmingham and the University of Alabama provided study approval; furthermore, all participants provided written informed consent for the parent study and for use of their data in ancillary analyses of data collected.

In the parent study, participants were randomized to one of the following three groups: 1) exercise, 2) exercise + nutrient-dense weight maintenance, or 3) exercise + nutrient-dense weight loss by moderate caloric restriction. A blocked randomization was used to assign participants to intervention group using a computer-based algorithm stratified by age category, sex, and race[7]. Study personnel involved in data collection were blinded to group assignment to minimize potential bias during collection of outcome measures.

All participants engaged in a standardized exercise program including both aerobic and resistance training. Previous research demonstrated the effectiveness of this training protocol[12–14]. Briefly, the exercise intervention was prescribed and overseen by an exercise physiologist. Exercise for all three groups consisted of a combination of resistance and aerobic training. Participants received tailored recommendations for two days per week of resistance exercise training and 90–150 minutes per week of moderate-intensity aerobic exercise. The exercise regimen consisted of both home-based and gym-based activities where participants attended supervised exercise sessions at the gym twice weekly for the first twelve weeks of the intervention and twice monthly thereafter. All participants were provided with resistance bands and guidelines for activities to be done at home.

For the dietary component of the study, participants in the exercise only group met one time with a Registered Dietitian Nutritionist (RDN), and at baseline, they received written instructions for a healthy diet based on the Dietary Guidelines for Americans[15]. Participants

in both the weight maintenance and weight loss group were given daily calorie goals based on estimates of total energy expenditure (TEE) determined by resting metabolic rate at baseline using a ReeVue indirect calorimeter (KORR Medical Technologies, Inc., Salt Lake City, UT). Additionally, both groups received counseling from the RDN on improving their diet quality and comprehensive behavioral counseling. For example, participants attended small group sessions facilitated by the RDN weekly for the first six months and then every other week for the remaining six months. The behavioral sessions focused on goal setting, self-monitoring, problem-solving, and motivational interviewing. Furthermore, both the weight maintenance and weight loss groups received instruction on selection and intake of nutrient-dense foods such as fruits, vegetables, whole grains, and low-fat dairy. Detailed education was provided for a target macronutrient ranges of 25% kcals from protein, 47% kcals from carbohydrate, and 28% kcals from fat. Participants randomized to the exercise + weight maintenance group received recommendations for kcal intake based on TEE. calculated by multiplying measured resting energy expenditure (REE) by an activity factor of 1.7 to account for the prescribed exercise regimen. Compliance to the study was assessed through three unannounced 24-hour dietary recalls collected at baseline, month 6, and month 12 to monitor dietary adherence. Additionally, adherence to the exercise regimen was monitored by physical activity diaries and accelerometry.

Participants randomized to the exercise + weight loss group received a dietary prescription with a reduction of 500 kcals/day from baseline TEE. The reduction of 500 kcal/day was based on weight loss recommendations for older adults outlined in the Position Statement of the American Society for Nutrition and The Obesity Society[9]. Regardless of TEE, recommendations were not decreased below 1000kcals/day. Participants in the exercise + weight loss group were also encouraged to take a daily multivitamin and mineral supplement to ensure adequate intake of micronutrients.

Risk Scoring

Risk scores were calculated using the following participant data collected at baseline and at month 12: age, biological sex, waist circumference, and blood pressure along with fasted blood samples for analysis of serum glucose and lipids. Cardiometabolic risk was assessed by applying the criteria of the FRS, ATPIII, IDF, and CMDS (Table 1). Among these, the ATPIII and IDF employ a binary classification of risk (yes or no). In contrast, the FRS is a continuous scale with higher values indicating increased risk, and the CMDS is ordinal scale with levels 1–4 in order of increasing risk.

Statistical Analysis

Generalized Estimating Equations (GEE) with a Bonferroni correction were used to determine changes in risk scores across intervention groups from baseline to month 12. GEE was chosen due to its proficiency in handling semiparametric data and the ability to account for within-subject correlation expected from repeated measurements. Link functions for the models were chosen according to the nature of the outcome variable. The identity function was used for FRS, logit for ADPIII and IDF, and the log function (Poisson) for CMDS. Self-reported ethnicity was treated as a covariate for all risk scores. Biological sex and age were treated as covariates for ATPIII, IDF, and CMDS as these variables were not

accounted for in the respective scores. SPSS version 25 was used for statistical modeling (IBM, Armonk, NY).

The parent study was powered to detect 10% difference in visceral adipose tissue between the exercise and weight loss group compared to the exercise and weight maintenance group[8]. While statistical power is a probability concept, probability applies only to an event that is yet to occur. Thus, reporting post-hoc power (i.e. observed power) adds no more information than reporting p-values. Given the ancillary, exploratory nature of these analyses, exact p-values are presented along with reporting of outcomes that have p-values less than 0.05.

Results

Participants (n=134, 39% male, 23% Black/African American, 70.2 ± 4.7 y) were randomized to exercise (n=48), exercise + nutrient-dense weight maintenance (n=44), or exercise + nutrient-dense caloric restriction of 500 kcals/day (n=42). Although 148 participants had measured weight at 12 months, only 134 participants had complete data for assessing each risk score. At baseline, mean FRS were 13.9 and 17.2 for females and males, respectively. These scores represent an approximate elevated CVD risk of approximately 10% for females and 29.4% risk for males. In application of ATPIII and IDF criteria, 72 participants were classified with metabolic syndrome by both classification systems. According to CMDS scoring, the mean score at baseline was 2.3 or Stage 2 presentation of metabolic syndrome or pre-diabetes. Change scores for each risk scoring tool by intervention group are provided in Figure 2. Intervention-time interaction was not significant in application of ATPIII or IDF risk scores; however, intervention-time interaction was significant for FRS and CMDS risk staging (p=0.005 and 0.041, respectively).

Upon post-hoc analysis, significant within-group improvements in FRS were observed for exercise + weight maintenance ($p<0.001$, $r = -1.682$) and exercise + weight loss ($p=0.020$, $r = -0.881$) (Table 2). In analysis of between group differences in FRS, a significant decrease was observed in the exercise + weight maintenance group ($p=0.001$, $r = -1.723$) compared to the exercise group. For CMDS, the exercise + weight loss group had significant within intervention group improvements ($p=0.023$, $r = -0.102$), and the same group showed significant risk score reduction ($p=0.012$, $r = -0.142$) compared to the exercise group.

Discussion

The purpose of this study was to assess the impact of exercise plus weight maintenance and exercise plus intentional weight loss by caloric restriction on changes in cardiometabolic disease risk among older adults with obesity. Results of this study suggest that exercise with or without weight loss contributed to an overall decrease in cardiometabolic disease risk. Results reported herein are supported by another randomized controlled trial in which a 40% reduction in cardiometabolic disease risk was observed when exercise was combined with a weight loss intervention among older adults with obesity[16]. Thus, the complementary effect of exercise cannot be underestimated as exercise has been shown to benefit overall cardiometabolic health by decreasing blood pressure and inflammation and by improving glucose tolerance, insulin sensitivity, and HDL-C levels[17–19]. Results of this study further

suggest that some risk scoring methods might be more sensitive to detecting changes in disease risk as a result of individual risk factors assessed and variance in scoring as FRS and CMDS are not binary scoring tools. However, despite the widespread use of risk scoring tools, it should be noted that some may over- or under-estimate risk as a result of the populations of validation[20]. This is further complicated by the disagreement over the diagnostic criteria that should be used for defining metabolic syndrome[3].

Although four risk scoring methods were employed, significant changes were only observed in the FRS and the CMDS scores as a result of the intervention. Further, among variables assessed in the parent study, significant improvements were only observed in glucose and HDL-C among the exercise + weight loss group as compared to the exercise group alone ($p = 0.023$ and 0.007, respectively)[11]. These findings may be explained by the fact that FRS and CMDS account for unique biological variables coupled with non-binary scoring allowing for greater distribution of scores to assess change (Table 1). Specifically, FRS accounts for smoking status as well as both treated and non-treated systolic blood pressure. Regarding CMDS scoring, this method accounts for use of medications for dyslipidemia, blood pressure, and diabetes. In short, it is plausible that both FRS and CMDS provided a more holistic approach to assessing total risk in comparison to IDF and ATPIII. Nevertheless, IDF and ATPIII are validated measures of diagnosing cardiometabolic disease, and both are widely used for providing a quick overview into an individual's cardiometabolic disease risk.

Strengths of this study include a near-equal distribution of males and females, rigorous study design, and monitoring of adherence in the CROSSROADS Study including weekly check-ins with participants along with in-clinic exercise sessions. Additionally, this study is strengthened by the use of multiple validated cardiometabolic screening tools and robust statistical analyses. It should be noted that this is the first study of its kind to comparatively assess cardiometabolic disease risk changes using multiple validated risk scores among older adults with obesity. However, this study is not without limitations, namely inclusion of participants from the same geographical region with high levels of physical function at baseline. Additionally, it must be acknowledged that the exploratory nature of this ancillary analysis may be a limitation to detect variable level of risk among individuals. Lastly, the four validated risk scores applied in this study do not take into account the more stringent 2017 guidelines for high blood pressure in adults[21]. As such, re-development of risk scoring tools utilizing the most current hypertension guidelines is warranted.

Conclusions

Although there is an ongoing debate about weight loss among older adults with obesity, the CROSSROADS Study demonstrated that participants in the exercise + weight loss group lost a significant amount of body weight (4.1%) and fat mass (2.6kg) while loss of lean body mass in all groups was negligible[11]. In extension of these findings, results of this ancillary study suggest that older adults with obesity can lower cardiometabolic disease risk by engaging in exercise in combination with a nutrient-dense diet with or without weight loss. The clinical implications of these findings should not be underestimated, but rather

add to the body of evidence about the benefit of regular physical activity and diet quality to improve cardiometabolic health.

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Research Snapshot

Research Question:

What is the effect of a 12-month exercise plus weight maintenance and exercise plus intentional weight loss by caloric restriction on cardiometabolic risk factors among older adults with obesity?

Key Findings:

This exploratory ancillary study demonstrated the effects of exercise plus weight maintenance and exercise plus intentional weight loss on changes in cardiometabolic risk assessed by four risk-scoring tools. Comparatively, only the Framingham Risk Score and the Cardiometabolic Disease Staging reflected changes in cardiometabolic risk as a result of the intervention. Results suggest older adults with obesity can significantly lower cardiometabolic risk by engaging in either exercise + weight maintenance or exercise + weight loss by moderate caloric restriction.

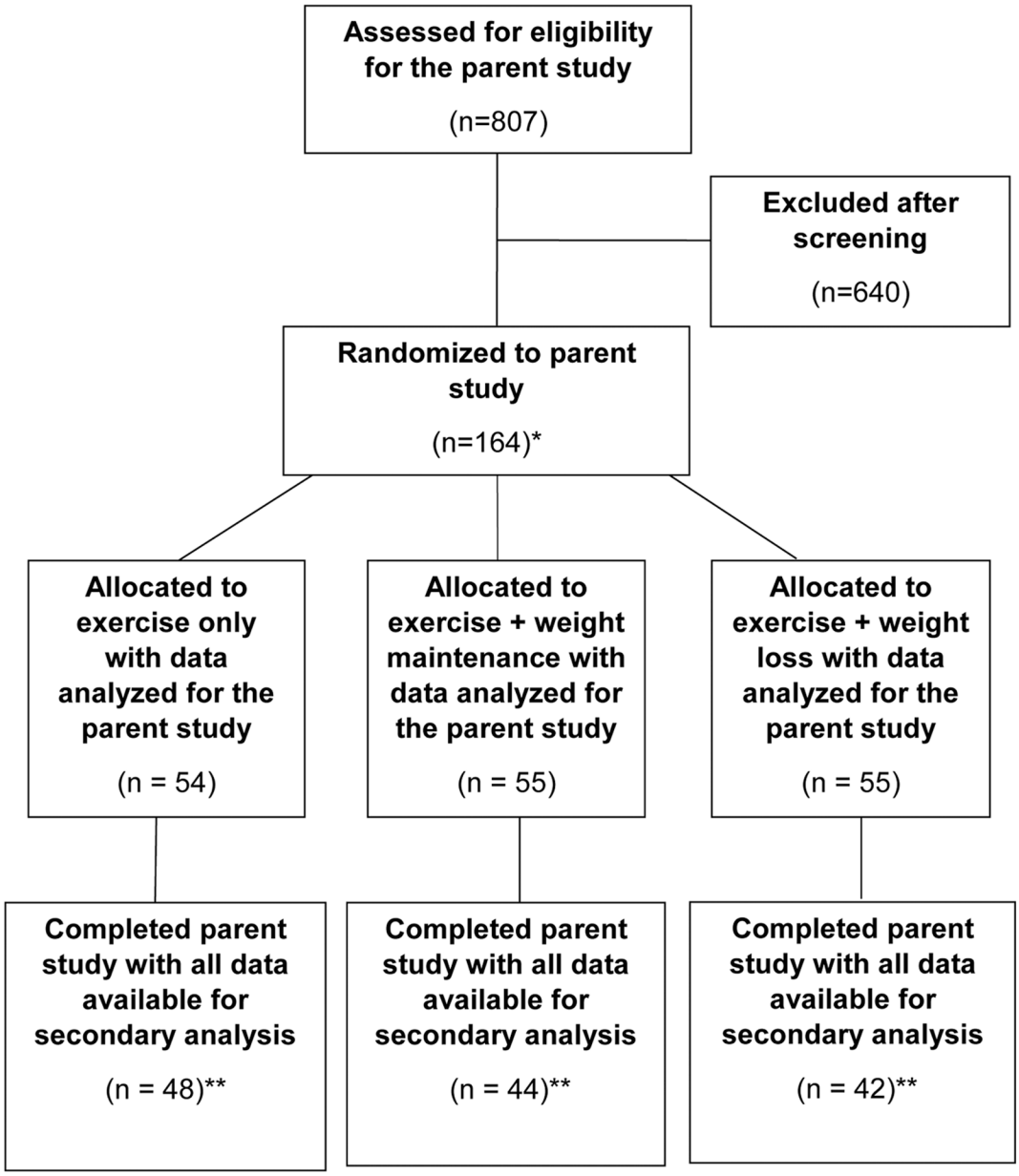

Figure 1. Flow Diagram for Inclusion in an Ancillary Analysis of a Randomized Controlled Trial Investigating Exercise plus Weight Maintenance and Exercise plus Intentional Weight Loss by Caloric Restriction

** Initially, 167 participants were randomized, but before the study began, three were diagnosed with cancer thus disqualifying them for eligibility.

*Reduction in participant numbers due to loss to follow-up, withdrew from intervention, or missing data at study completion.

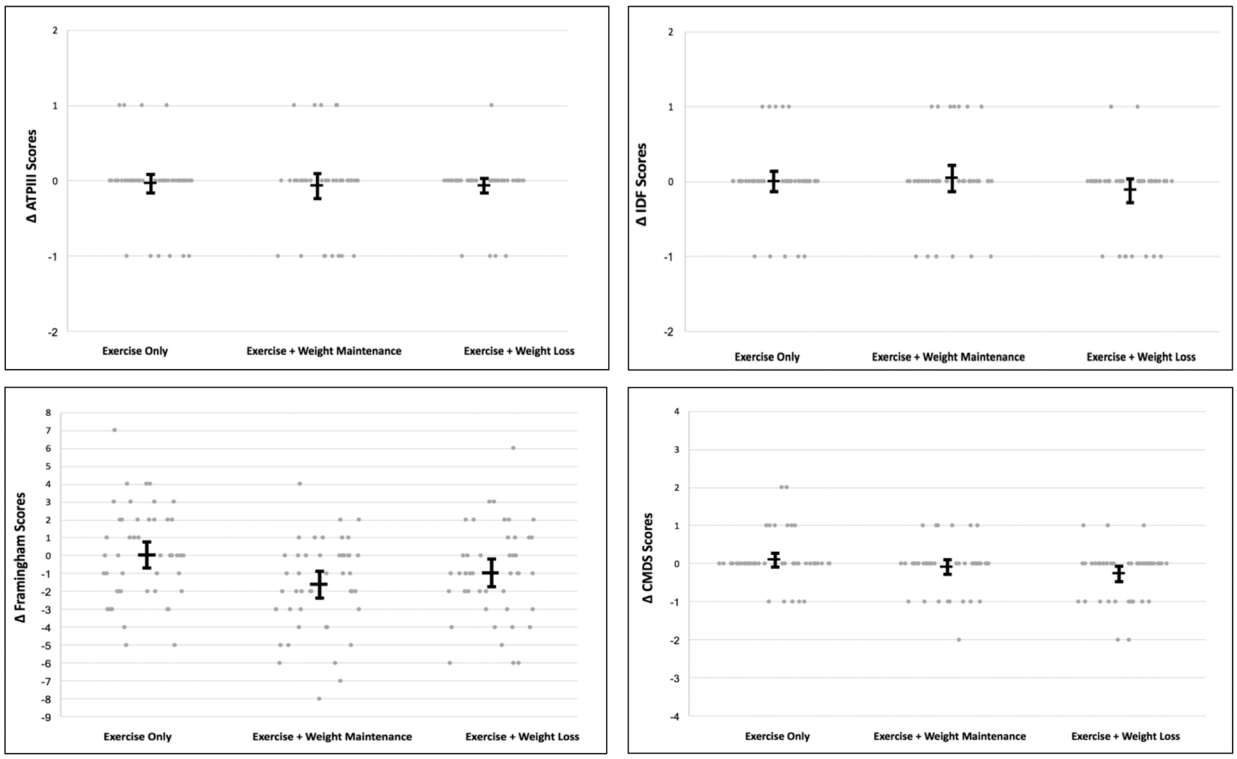

Figure 2. Individual Changes in Cardiometabolic Risk Scores after a 12-Month Intervention Investigating Exercise plus Weight Maintenance and Exercise plus Intentional Weight Loss by Caloric Restriction

Framingham – Framingham Risk Score; CMDS – Cardiometabolic Disease Staging; IDF International Diabetes Federation Score; ATPIII - National Cholesterol Education Program Adult Treatment Panel III Score; Exercise Only - Group 1; Exercise + Weight Maintenance - Group 2; Exercise + Weight Loss - Group 3

Table 1.

Comparison of Commonly Utilized Cardiometabolic Risk Scores

Screening Tool	Risk Factors Assessed	Biological Cut Points for Scoring	Points of Uniqueness among Scoring Tools
Framingham Risk Score (2)	**10-year cardiovascular risk is determined by a point tally based on scoring brackets for each risk factor**		Different scoring by agex Different scoring by biological sex Accounts for treated and non-treated SBP Smoking consideration Incorporates a risk percentage score
	Age (y)		
	HDL-C (mg/dL)	<35, 35–44, 45–49, 50–59, 60+	
	Total cholesterol (mg/dL)	<160, 160–199, 200–239, 240–279, 280+	
	SBP treated vs not treated (mmHg)	<120, 120–129, 130–139, 140–159, 160+	
	Smoker?	yes/no	
	Diabetic?	yes/no	
National Cholesterol Education Program Adult Treatment Panel III (ATPIII) Score (4)	**Diagnosed with metabolic syndrome if 3 out of 5 criteria are present**		Medication not considered Binary scoring for diagnosis of metabolic syndrome (yes or no)
	High glycemia (mg/dL)	>110–125	
	High waist circumference (cm)	Men >102, Women >88	
	High triglycerides (mg/dL)	≥150	
	Low HDL-C (mg/dL)	Men <40, Women <50	
	High blood pressure (mmHg)	≥130/≥85	
International Diabetes Federation (IDF) Score (5)	**Diagnosed with metabolic syndrome if glycemia is abnormal and 2 further criteria are present**		Factors in diabetes and blood pressure medication Binary scoring for diagnosis of metabolic syndrome (yes or no)
	High fasting glycemia (mg/dL)	100–125 or medication use	
	High waist circumference (cm)	Men ≥94, Women ≥80	
	High triglycerides (mg/dL)	≥150	
	Low HDL-C (mg/dL)	Men <40, Women <50	
	High blood pressure (mmHg)	≥130/≥85 or medication use	
	Stage 0 - Metabolically healthy, no risk factors		
Cardiometabolic Disease Staging (CMDS) Score (6)	**Stage 1 - Have up to two of the following risk factors**		Accounts for lipid- and blood pressure-lowering medications Uses a stepwise ordinal scale with levels 1–4 to ascribe increasing risk
	High waist circumference (cm)	Men ≥112, Women ≥88	
	High blood pressure (mmHg)	≥130 and/or ≥85 or medication use	
	Low HDL-C (mg/dL)	Men <40, Women <50 or medication use	
	High triglycerides (mg/dL)	≥150 or medication use	
	Stage 2 - Metabolic syndrome or prediabetes; have one of the following three conditions in isolation		

Screening Tool	Risk Factors Assessed	Biological Cut Points for Scoring	Points of Uniqueness among Scoring Tools
	Metabolic syndrome diagnosis - based on three or more risk factors:	High waist circumference, High blood pressure, Low HDL-C, High triglycerides	
	Impaired fasting glucose (IFG)	Fasting glucose ≥5.6 mmol/L or ≥100 mg/dL	
	Impaired glucose tolerance (IGT)	2-hour glucose ≥7.8 mmol/L or 140 mg/dL	
	Stage 3 - Metabolic syndrome + prediabetes; have two of the three following conditions		
	Metabolic syndrome		
	Impaired fasting glucose (IFG)		
	Impaired glucose tolerance (IGT)		
	Stage 4 - Have type 2 diabetes mellitus (T2DM) and/or cardiovascular disease (CVD)		
	T2DM	Fasting glucose ≥126 mg/dL OR 2-hour glucose ≥200 mg/dL or medication use	
	Active CVD	Angina pectoris or status post a CVD event such as acute coronary artery syndrome, stent placement, coronary artery bypass, thrombotic stroke, nontraumatic amputation due to peripheral vascular disease	

Table 2:

Changes in Cardiometabolic Risk Scores Between and Within Intervention Groups after a 12-Month Intervention Investigating Exercise plus Weight Maintenance and Exercise plus Intentional Weight Loss by Caloric Restriction

	Framingham			CMDS			IDF			ATPIII		
	r	**SE**	***P***	**r**	**SE**	***P***	**r**	**SE**	***P***	**r**	**SE**	***P***
Group 1: Exercise Only	0.042	0.364	0.909	0.040	0.035	0.251	0.000	0.274	1.000	−0.254	0.253	0.316
Group 2: Exercise + Weight Maintenance	−1.682	0.383	**<0.001** *	−0.030	0.041	0.466	0.197	0.368	0.592	−0.292	0.346	0.399
Group 3: Exercise + Weight Loss	−0.881	0.380	**0.020** *	−0.102	0.045	**0.023** *	−0.537	0.356	0.131	−0.364	0.205	0.076
Group 3 vs Group 2	0.801	0.539	0.137	−0.072	0.061	0.235	−0.734	0.512	0.152	−0.072	0.402	0.857
Group 2 vs Group 1	−1.723	0.528	**0.001** *	−0.070	0.054	0.194	0.197	0.459	0.667	−0.038	0.429	0.930
Group 3 vs Group 1	−0.923	0.526	0.080	−0.142	0.057	**0.012** *	−0.537	0.449	0.232	−0.110	0.326	0.735

* *Indicates P<0.05.* r values are represent the coefficient of the General Estimating Equations with similarity to coefficients of a traditional linear regression in that they indicate the expected difference in scores. Negative values indicate reduction in risks scores. Framingham – Framingham Risk Score; CMDS – Cardiometabolic Disease Staging; IDF International Diabetes Federation Score; ATPIII - National Cholesterol Education Program Adult Treatment Panel III Score; SE – standard error; Group 1 – exercise only; Group 2 – exercise + weight maintenance; Group 3 – exercise + weight loss