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A weight-neutral versus weight-loss approach for health promotion in women with high BMI: A randomized-controlled trial

Janell L. Mensinger [a, *], Rachel M. Calogero [b], Saverio Stranges [c], Tracy L. Tylka [d]

[a] Reading Health System, Sixth Avenue and Spruce Street, West Reading, PA, 19611, USA
[b] School of Psychology, University of Kent, UK
[c] Department of Population Health, Luxembourg Institute of Health, Luxembourg
[d] Department of Psychology, The Ohio State University, USA

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ABSTRACT

Weight loss is the primary recommendation for health improvement in individuals with high body mass index (BMI) despite limited evidence of long-term success. Alternatives to weight-loss approaches (such as Health At Every Size – a weight-neutral approach) have been met with their own concerns and require further empirical testing. This study compared the effectiveness of a weight-neutral versus a weight-loss program for health promotion. Eighty women, aged 30–45 years, with high body mass index (BMI $\geq$ 30 kg/m^2) were randomized to 6 months of facilitator-guided weekly group meetings using structured manuals that emphasized either a weight-loss or weight-neutral approach to health. Health measurements occurred at baseline, post-intervention, and 24-months post-randomization. Measurements included blood pressure, lipid panels, blood glucose, BMI, weight, waist circumference, hip circumference, distress, self-esteem, quality of life, dietary risk, fruit and vegetable intake, intuitive eating, and physical activity. Intention-to-treat analyses were performed using linear mixed-effects models to examine group-by-time interaction effects and between and within-group differences. Group-by-time interactions were found for LDL cholesterol, intuitive eating, BMI, weight, and dietary risk. At post-intervention, the weight-neutral program had larger reductions in LDL cholesterol and greater improvements in intuitive eating; the weight-loss program had larger reductions in BMI, weight, and larger (albeit temporary) decreases in dietary risk. Significant positive changes were observed overall between baseline and 24-month follow-up for waist-to-hip ratio, total cholesterol, physical activity, fruit and vegetable intake, self-esteem, and quality of life. These findings highlight that numerous health benefits, even in the absence of weight loss, are achievable and sustainable in the long term using a weight-neutral approach. The trial positions weight-neutral programs as a viable health promotion alternative to weight-loss programs for women of high weight.

The prevailing paradigm in clinical medicine and public health focuses on weight management as a key determinant of health promotion and chronic disease prevention. This paradigm guides the clinical recommendations made by health professionals for individuals with a body mass index over 30 kg/m^2 (hereafter referred to as high BMI) to lose weight (Kushner & Ryan, 2014), and it encourages the implementation of large-scale dieting interventions (e.g., Wing et al., 2013). Moreover, the weight-management paradigm has dominated the wider societal discourse that presumes a linear relationship between weight and all-cause mortality (Olshansky et al., 2005).

However, increasing evidence supports a paradigm shift away from focusing on weight management as the only pathway to health. For instance, epidemiological data suggest secular changes in the obesity-disease relationship, indicating that those with high BMI today have less disease than prior decades (Gregg et al., 2005; Mehta et al., 2014). Furthermore, there is a U-shaped weight-

* Corresponding author. Present address: 1601 Cherry Street, MS 9503, 3 Parkway Building, 9th floor, Department of Health Sciences, College of Nursing and Health Professions, Drexel University, Philadelphia, PA, 19102, USA.
E-mail address: jlm448@drexel.edu (J.L. Mensinger).

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mortality association with the most protected group being in the "overweight" BMI category (Flegal, Kit, Orpana, & Graubard, 2013; Hotchkiss & Leyland, 2011). Inconsistent evidence for the weight-health relationship (e.g., Karahalios et al., 2014; Romero-Corral et al., 2006) has led to recent attention on metabolically healthy obesity (e.g., Hamer & Stamatakis, 2012; Stefan, Haring, Hu, & Schulze, 2013) and the obesity paradox (e.g., Hainer & Aldhoon-Hainerová, 2013; Stokes & Preston, 2015). Even when the most conservative definition of metabolic health is employed, findings from large representative datasets show that close to one-third of obese adults exhibit no indication of cardio-metabolic abnormalities (Tomiyama, Hunger, Nguyen-Cuu, & Wells, 2016; Wildman et al., 2008).

In light of these patterns, weight scientists have questioned the effectiveness of weight loss as a method for improving long-term health (Brown & Kuk, 2015; Tomiyama, Ahlstrom, & Mann, 2013). In their systematic analysis of 21 randomized controlled trials (including participants without metabolic abnormalities) that involved a weight loss intervention and a minimum of one-year follow-up, Tomiyama et al. (2013) found inconsistent patterns between weight loss and health improvement. Two of the five studies produced reductions in stroke for individuals randomized to the weight-loss groups compared to a control condition. In the two diabetes prevention trials included in the analysis, individuals randomized to the weight-loss groups had a lower incidence of diabetes than those in the control conditions. However, of the five studies that examined coronary morbidity or mortality, none of the groups randomized to the weight-loss interventions demonstrated benefits on these variables. Overall, even when weight loss was maintained among dieters, there was no corresponding improvement in fasting blood glucose, blood pressure, or blood lipids.

In addition, recent evidence from a sample of over 3000 patients with cardiovascular disease from the National Health and Nutrition Examination Survey (NHANES) cohorts indicated that those who moved from the high BMI categories to the "normal" BMI category had the highest mortality risk of all groups (Stokes & Preston, 2015). Similarly, Køster-Rasmussen et al. (2016) found the lowest mortality rates among "overweight" and "obese" (BMI $\geq$ 25) type 2 diabetics who had maintained the same weight status during the 6-year intervention period, and no reductions in mortality rates for individuals who intentionally lost weight during this period. Dieting has also been shown to be ineffective for sustaining lost weight in the long-term (Fildes et al., 2015; Kraschnewski et al., 2010; Mann et al., 2007), and, it increases the health risks associated with weight-cycling (Montani, Schutz, & Dulloo, 2015). The stigma associated with obesity and weight loss failures can also negatively impact health via increased physiological stress responses (Schvey, Puhl, & Brownell, 2014; Sutin, Stephan, Luchetti, & Terracciano, 2014; Tomiyama et al., 2014), thus increasing allostatic load for those with high BMI (for reviews see Puhl & Suh, 2015; Tomiyama, 2014). In fact, even after controlling for disease burden, body weight, and additional covariates, Sutin et al. (2015) demonstrated that experiences of weight stigmatization subject individuals to higher mortality risk.

Given the inconsistent evidence to support the traditional weight-loss paradigm for health improvement, poor weight maintenance statistics, and the need to lessen the burdens of stigma on individuals with high BMI, alternative approaches to improve health and well-being that do not include weight loss goals have been developed (e.g., Bacon & Aphramor, 2011; Miller & Jacob, 2001; Tylka et al., 2014). Weight-neutral approaches to health are grounded in mindfulness skills and emphasize intuitive eating, self-care, pleasurable exercise, and size-acceptance. These approaches do not require reductions in BMI, thus mitigating the inherent stigmatization of recommending weight loss for those with high BMI (Bombak, 2014; Calogero, Tylka, & Mensinger, 2016; O'Hara & Gregg, 2014; Tylka et al., 2014). Systematic reviews of the literature evaluating the health impact of weight-neutral approaches have revealed effectiveness on a range of physiological (e.g., blood lipids, blood pressure), psychological (e.g., self-esteem, depression), and/or behavioral outcomes (e.g., dietary quality, disordered eating, physical activity) (Clifford et al., 2015; Schaefer & Magnuson, 2014).

Despite the promise of weight-neutral approaches for health improvement, there are few randomized controlled trials that directly compare weight-neutral approaches to conventional weight-loss approaches, and no randomized controlled trials, to our knowledge, have looked at intuitive eating as an outcome. As noted in a recent "Framing Health Matters" publication in the *American Journal of Public Health,* missing empirical evidence leaves the potential for a paradigm shift around medical management of obesity at an impasse (Penney & Kirk, 2015). To address these gaps in the literature, and evaluate whether weight loss is necessary for improvements in health and well-being, the present study examined the long-term effectiveness of a manualized weight-neutral program and a manualized weight-loss program on a variety of outcomes related to cardio-metabolic fitness, psychological well-being, and lifestyle behaviors.

Given that traditional weight-loss approaches involve calorie restriction and increased energy expenditure, we predicted greater weight and BMI reductions in the weight-loss program compared to the weight-neutral program at post-intervention. Since participants in the weight-neutral program were instructed to forego restrained eating and alternatively eat according to their internal hunger and satiety cues, they were not expected to lose weight during this shorter (6-month) period. However, because reductions in weight loss are rarely sustained long-term in traditional weight-loss approaches (Douketis, Macie, Thabane, & Williamson, 2005; Fildes et al., 2015; Mann et al., 2007), we predicted no difference in weight and BMI between programs at the follow-up (24-month post-randomization) assessment.

Positive lifestyle changes and improved self-worth often accompany weight loss (Teixeira et al., 2010), yet cardio-metabolic parameters can be improved without weight loss (Bacon, Stern, Van Loan, & Keim, 2005); therefore, we predicted similar improvements in both programs on all other variables measured at post-intervention. However, because participants in the weight-neutral program would not be relying on weight loss to drive lifestyle changes and facilitate improved psychological well-being, we anticipated more stability in health parameter changes for the weight-neutral compared to the weight-loss program participants. Hence, at 24 months, we predicted the weight-neutral program would have sustained more health and well-being improvements than the weight-loss program.

1. Method

1.1. Design and procedure

This study was a 1:1 parallel-group randomized design comparing the effectiveness of two 6-month group-based "healthy living programs" (weight-neutral or weight-loss). Folded index cards containing program assignments from a computer-generated randomization scheme were placed into sealed and sequentially numbered opaque envelopes. Upon completion of the baseline assessments where informed consent

was obtained, participants were given an envelope containing a welcome letter with their assignment and instructions. Participants were not informed of the difference between the programs. Only the administrative assistant had access to the allocation sheet during the recruitment phase of the study. Follow-up assessments occurred immediately post-intervention (6 months) and at 24-months post-randomization. We gave incentives of $20 for attending follow-up assessments. The study was approved and monitored by the Institutional Review Board of the Reading Health System in Pennsylvania.

1.2. Participants

Participants were recruited in Fall 2008 from the community surrounding the Reading Health System in Southeastern Pennsylvania using advertisements placed in physician offices, local coupon magazines, and the hospital's website. Telephone screens were conducted to determine preliminary eligibility based on the following criteria: 30–45 years old, female, BMI 30–45, physically inactive (i.e., scoring in one of the bottom two categories on the Stanford Brief Activity Survey) (Taylor-Piliae et al., 2006), and practicing birth control if heterosexual and pre-menopausal. Women were excluded if they: were current smokers; did not speak fluent English; were taking medications known to effect weight; were presently participating in a weight-loss program or diet; were pregnant or intending to become pregnant; had or were planning to have bariatric surgery; had type 1 or insulin-dependent type 2 diabetes; had an active neoplasm; or had a history of myocardial infarction, congestive heart failure, cerebrovascular disease, renal disease, or cirrhosis. Specific psychological contraindications included bulimia nervosa, anorexia nervosa, alcohol or substance abuse, and psychiatric disturbances that significantly disrupt daily functioning (e.g., suicide ideation, current manic episode, schizophrenia). Prior to attending the study intake session where baseline measurements occurred, applicants were required to submit a clearance form that included a description of the study and its eligibility criteria, and was signed by their primary care physician.

Of 252 women who were screened, 80 were enrolled and randomized to the weight-neutral or weight-loss program. Both programs commenced in early January 2009 and ran through late June 2009. Seventy-two participants were available at post-intervention, and 40 participants completed the 24-month assessments. Fig. 1 displays the detailed flow of participant involvement throughout the study.

1.3. Interventions

Participants were divided into two cohorts of 20 within each respective program. Cohorts met weekly for 90-min sessions on a weekday evening for the duration of 6 months.

The weight-neutral program employed was the *HUGS Program for Better Health* (Omichinski, 2007); HUGS stands for **H**ealth-focused, **U**nderstanding lifestyle, **G**roup supported, and **S**elf-esteem building. This integrated approach is based on an evidence-based (Omichinski & Harrison, 1995) manualized curriculum that incorporates the key components of popular weight-neutral approaches (Bacon & Aphramor, 2011; O'Hara & Gregg, 2014; Robison, Putnam, & McKibbin, 2007; Tylka et al., 2014). The HUGS Program emphasized the principles of eating for well-being *and* pleasure, size acceptance, and the importance of engaging in physical activity for personal enjoyment and fulfillment. Participants received the books, *Staying Off of the Diet Roller Coaster* (Omichinski, 2000) and *Tailoring Your Tastes* (Omichinski & Hildebrand, 1995), in addition to a booklet of psycho-educational worksheets and a set of affirmation CDs produced by HUGS Inc. At the end of the program, participants were encouraged to maintain their non-dieting lifestyles and self-affirming attitudes about their bodies by utilizing the social support network developed during the program. Participant email and phone number lists were distributed and conference call lines were created to help facilitate this network. The weight-neutral program was led by a psychotherapist and fitness professional with 15 years of experience working with high BMI clients from a Health At Every Size framework.

The weight-loss program employed was the *LEARN Program for Weight Management* (Brownell, 2000); LEARN is a behavior modification approach to weight loss that stands for **L**ifestyle, **E**xercise, **A**ttitudes, **R**elationships, and **N**utrition. While the program emphasizes weight loss as an ultimate goal, the focus is on changing diet and lifestyle and gaining skills to overcome weight-loss barriers. It is an evidence-based curriculum and has been referred to as the gold standard in weight-management approaches (Gardner et al., 2007). Participants in the LEARN program received the *LEARN Program for Weight Management* manual (Brownell, 2000), the *LEARN Weight Stabilization and Maintenance Guide* (Brownell, 2008), and the LEARN Program CD set. As with the weight-neutral program, at the end of the weight-loss program, participants were encouraged to maintain their lifestyle changes by utilizing their new social support network. Participant email and phone number lists were distributed and conference call lines were created to help facilitate this network. This program was delivered by a registered dietician with over 15 years of experience working with bariatric populations and patients with type 2 diabetes.

The two programs shared many common principles, and both emphasized the importance of healthy lifestyle choices and gradual sustainable change. However, in the weight-loss program, food intake recommendations were based on *external* prescriptions and caloric restriction, and weight loss was an explicit goal. In contrast, the weight-neutral program taught strategies to recognize and respond to *internal* physiological signs of hunger and satiety to determine food intake, and, size acceptance was promoted in lieu of weight-loss goals. We ensured fidelity of the programs by using checklists derived from the leaders' manuals and randomly selecting sessions for audit by trained research technicians.

1.4. Measurements

1.4.1. Cardio-metabolic fitness

Venous blood samples were drawn after an overnight fast in order to obtain glucose levels and lipid panels (total cholesterol, LDL cholesterol, HDL cholesterol, total cholesterol-HDL ratio, and triglycerides). We followed standardized methods established by the National High Blood Pressure Education Program and averaged two blood pressure (BP) readings using a Welch Allyn cuff with an aneroid sphygmomanometer (Chobanian et al., 2003). Body weight and height were recorded without shoes using a Detecto balance beam scale and a wall-mounted stadiometer to the nearest 0.1 kg and 0.1 cm, respectively. Waist circumference was measured to the nearest quarter inch with a flexible tape measure on bare skin at the narrowest point between the iliac crest and the lower rib margin. Hip circumference was measured to the nearest quarter inch with a flexible tape measure at the maximal circumference of the buttocks over under garments.

1.4.2. Psychological well-being

Global self-esteem was measured using the Rosenberg Self-Esteem Scale (RSE) (Rosenberg, 1979). The RSE consists of 10 statements with Likert style responses ranging from 1 (*strongly*

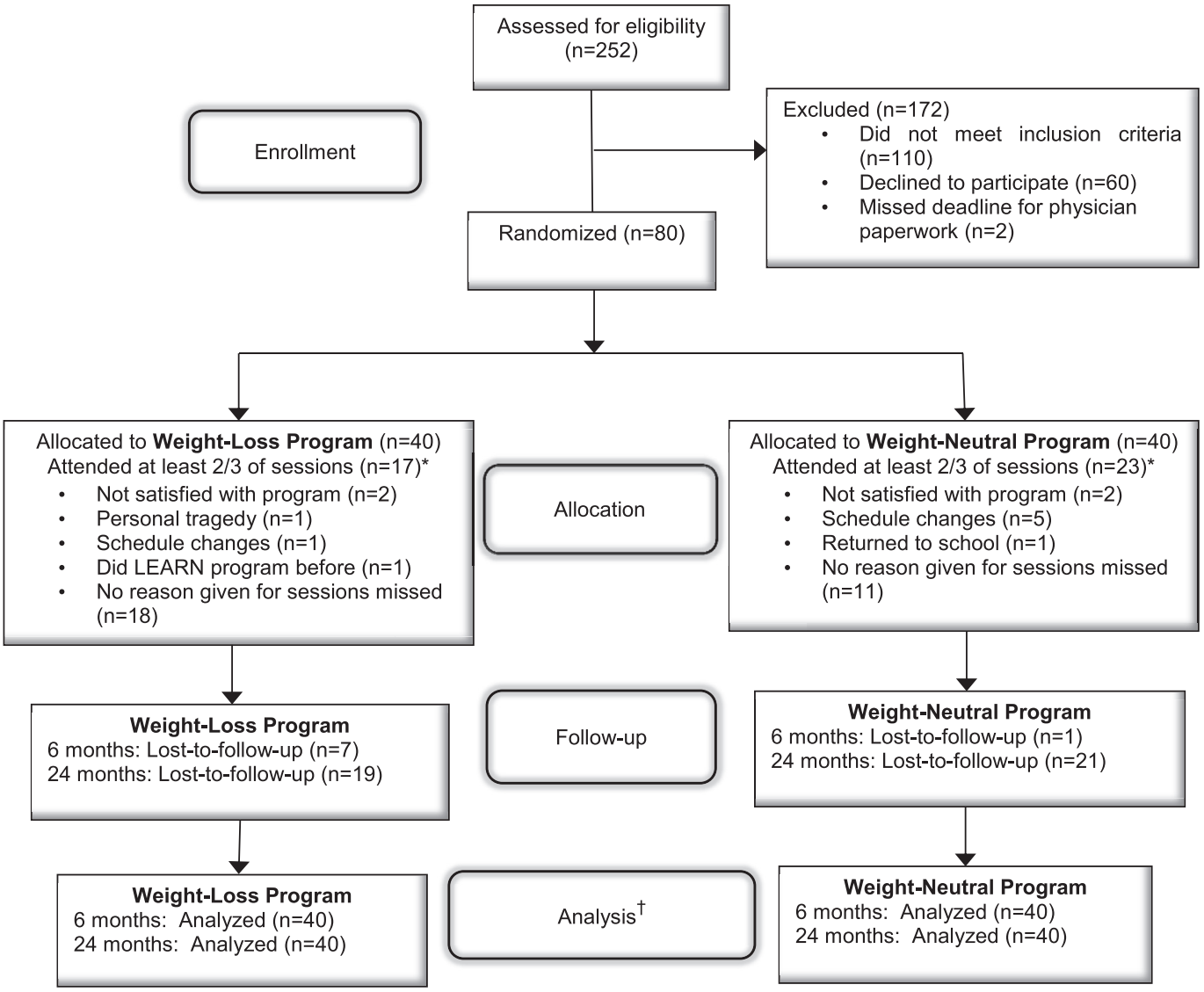

Fig. 1. Diagram of participant flow through study. *No significant differences were observed between groups on completion rates; $p = 0.37$. †We used a full ITT analysis with SPSS MIXED and the Restricted Maximum Likelihood (REML) option. This method uses information from all available data to provide parameter estimates that are robust against bias. Therefore, despite loss-to-follow-up at the 6-month and 24-month assessments, the n analyzed at each time point is the complete dataset since everyone had at least baseline data considered in the estimation procedures for the 6-month and 24-month parameters.

disagree) to 4 (*strongly agree*). Item scores are summed and range from 10 to 40; higher composite scores indicate higher self-esteem.

Distress was measured using the abbreviated Depression Anxiety Stress Scale (DASS-21) (Lovibond & Lovibond, 1995). The DASS-21 contains 21 items assessing depression, anxiety, and stress. Participants are asked to indicate the degree to which the statement applied to them in the past week on a scale from 0 (*did not apply at all*) to 3 (*applied most of the time*). Item scores are summed and range from 0 to 63; higher composite scores indicate higher distress.

Quality of life (QOL) was assessed using the current state of health and well-being subscale of the Red Lotus Health and Well-Being Questionnaire (RL-QOL) (Gregg & O'Hara, 2007; McKinnon, 2008). This 15-item measure utilizes 5-point Likert responses ranging from 0 (*poor*) to 5 (*excellent*) or 0 (*none of the time*) to 5 (*all of the time*). Item scores are summed and range from 15 to 75; higher composite scores indicate higher QOL.

1.4.3. Lifestyle behaviors

Physical activity levels were measured utilizing a single item on the health behaviors subscale of the RL-QOL. The item asked each participant to rank the question, "I participate in moderate physical activities (activities that make me breathe a bit harder or puff and pant) for about 30 min on average, most days of the week" on a 5-point Likert scale ranging from 1 (*never true*) to 5 (*always true*). Higher scores indicate more physical activity.

To measure dietary habits, we administered the Dietary Risk Assessment, a screening tool created for primary care settings to identify individuals who require further nutritional counseling (Olendzki et al., 1999). It contains four subsections on types of food consumption: meats, side dishes/desserts/snacks, dairy/eggs, and spreads/oils. A point system, established by Olendzki et al. (1999), was given for specific food types in each subsection to derive a score. For example, those who consume more skinless meats like chicken and turkey, fish (not fried), and beans will earn less points on this scale than a person who consumes more hot

Table 1
Baseline characteristics of the study sample.

Characteristic	Weight-neutral program *n* (%)	Weight-loss program *n* (%)	*p*-value
Education			0.066
High school diploma, or some high school	8 (20)	14 (35)	
Some college (or technical school)	17 (43)	21 (53)	
College graduate (bachelor's degree)	10 (25)	4 (10)	
Graduate or professional degree	5 (13)	1 (3)	
Employment status, *n* (%)			0.378
Employed for wages full-time	22 (55)	31 (78)	
Employed for wages part-time	11 (28)	6 (15)	
Not working	7 (18)	3 (8)	
Race/ethnicity			0.644
African American/black non-hispanic	0 (0)	1 (3)	
Hispanic	3 (8)	1 (3)	
White non-hispanic	37 (93)	38 (95)	
Relationship status			0.962
Married	28 (70)	28 (70)	
Member of an unmarried couple	4 (10)	4 (10)	
Divorced	2 (5)	3 (7)	
Never been married	6 (15)	5 (12)	
Mean age (*SD*), *y*	39.83 (4.34)	39.35 (3.91)	0.609
Mean body mass index (*SD*), kg/m^2	37.42 (0.57)	38.56 (0.65)	0.191
Median household income (min-max), *US$*	68.75K (18K–180K)	60K (12K–130K)	0.504
Median individual income (min-max), *US$*	29.5K (0K–120K)	30K (5K–75K)	0.916

Note. Percentages are rounded to the higher integer when value => 0.5 causing totals to exceed 100%; *p*-values based on *t*-tests, chi-squares, and Mann-Whitney *U* tests as appropriate for variable types; Household income data missing for 2 Weight-Neutral Program participants; Individual income data missing for 1 Weight-Loss Program participant; 1K = 1000 US$.

dogs, bacon, and sausage. Adding the four subsections derives a composite score of dietary risk; higher scores indicate poorer dietary quality.

Two additional items from the health behaviors subscale of the RL-QOL questionnaire assessed fruit and vegetable intake. The items ask participants to rate how often they ate two or more servings of fruits (or five or more of vegetables) on an average day, 1 (*none of the time*) to 5 (*all of the time*). Item scores are summed and range from 2 to 10; higher composite scores indicate more consumption of fruits and vegetables.

We assessed eating by internal cues using the Intuitive Eating Scale (IES) (Tylka, 2006). The IES contains 21 items measuring participants' ability to recognize hunger and satiety cues, eat in accordance to physical rather than emotional cues, and give themselves unconditional permission to eat. Items are rated along a 5-point scale ranging from 1 (*strongly disagree*) to 5 (*strongly agree*) and as recommended by Tylka (2006), item scores are averaged. Higher scores correspond to higher levels of intuitive eating.

1.5. Data analysis

Statistical tests were performed in SPSS (Version 22.0, Armonk, NY: IBM Corp.). Linear mixed-effects models (Singer & Willet, 2003)[1] were used to determine the group-by-time interactions, as well as the between-group (weight-neutral versus weight-loss program) and within-group (repeated time points) differences. As recommended in the CONSORT statement for parallel-group randomized trials, participants were analyzed according to the intention-to-treat principle (Schulz, Altman, & Moher, 2010). Intent-to-treat analyses compare study participants in the groups to which they were randomly allocated, regardless of whether or not they fully completed the program protocol[2]. All models fit a covariance matrix using the compound symmetry assumption. In cases where there was a statistically significant group-by-time interaction, we also examined within-group *post hoc* comparisons using the Least Significant Difference test. The *p*-values reported in the text for within-group changes over time refer to the *post hoc* comparisons, while the *p*-values in the tables refer to the omnibus tests for either the simple effects of time or the group-by-time interactions (labeled accordingly). Sample size determination was based on data from a previous trial comparing a weight-neutral to a weight-loss program with 78 obese women and a 50% attrition rate at the 24-month follow-up (Bacon, Stern, Loan, & Keim, 2005).

2. Results

Demographic characteristics of the study participants separated by program are shown in Table 1. No meaningful group differences emerged, suggesting that the randomization was successful.

[1] We analyzed the data with SPSS MIXED utilizing Restricted Maximum Likelihood estimation (REML) on all available data points. This advances the techniques of earlier generation approaches (e.g., repeated measures ANOVA) whereby missing cases are deleted listwise resulting in a significant loss of power and introducing more potential bias. Estimates of treatment effects under REML in SPSS MIXED are assumed to be unbiased when data are 'missing at random' (MAR) or 'missing completely at random' (MCAR) (Bell, Kenward, Fairclough, & Horton, 2013). To determine the degree to which we could assume data as MAR or MCAR, we performed a series of sensitivity analyses with the complete dataset. No meaningful differences (i.e., differences that changed the study findings) between participants who completed long-term follow-up and those who did not were revealed.

[2] Intention-to-treat (ITT) analysis is primarily aiming to ensure no systematic differences exist between groups beyond what we would expect with random variation (Hollis & Campbell, 1999). In contrast, per protocol analysis examines how treatments differ *only* for those who fully comply with the program, which introduces the potential bias that individuals who do not complete a treatment protocol are generally different from those who do not. In most cases of randomized controlled trials reporting use of the ITT principle, loss-to-follow-up on outcome variables precludes the *fully* unbiased analysis that the ITT approach was intended to offer. We estimated parameters using the REML option in SPSS MIXED. This method is especially robust when data are MAR and allows for the completion of a full ITT analysis. Although missing data is ignored, baseline and 6-month observations inform the estimates (even for the participants who did not complete 24-month assessments) and hence give us reasonably unbiased values for treatment effects (Gallop & Tasca, 2009).

Table 2
Predicted means and changes from baseline for cardio-metabolic parameters.

Outcome Variable	Estimated marginal means (SE)				Change from baseline			
	Weight-neutral (WN) program		Weight-loss (WL) program		WN program	WL program	Mean difference in change (95% CI)	Group-by-time interaction
	n		*n*					
Body mass index (kg/m^2)								
Baseline	40	37.4 (0.61)	40	38.6 (0.61)	–	–		$p = 0.008$
6 months	37	37.2 (0.61)	33	36.9 (0.62)*	−0.25	−1.6	−1.4 (−2.3 to −0.5)	
24 months	19	37.2 (0.67)	21	37.2 (0.66)*	−0.26	−1.3	−1.1 (−2.2 to 0.0)	
Simple effect of time		$p = 0.668$		$p < 0.001$				
Weight (kg)								
Baseline	40	102.1 (2.1)	40	105.3 (2.1)	–	–		$p = 0.004$
6 months	37	101.6 (2.1)	33	100.7 (2.1)*	−0.56	−4.6	−4.1 (−6.5 to −1.7)	
24 months	19	101.3 (2.2)	21	101.6 (2.2)*	−0.83	−3.7	−2.8 (−5.9 to 0.2)	
Simple effect of time		$p = 0.683$		$p < 0.001$				
Waist circumference (inches)								
Baseline	40	45.4 (0.8)	40	46.2 (0.8)	–	–		$p = 0.314$
6 months	37	43.1 (0.8)*	33	45.1 (0.8)*	−2.3	−1.1	1.1 (−1.1 to 3.4)	
24 months	19	44.4 (1.0)	21	44.3 (1.0)	−0.97	−1.9	−0.9 (−3.7 to 1.8)	
Simple effect of time		$p = 0.018$		$p = 0.127$				
Hip circumference (inches)								
Baseline	40	51.0 (0.6)	40	51.7 (0.6)	–	–		$p = 0.678$
6 months	37	49.5 (0.6)*	33	49.9 (0.6)*	−1.5	−1.9	−0.3 (−1.3 to 0.7)	
24 months	19	51.1 (0.7)‡	21	51.3 (0.7)‡	0.05	−0.46	−0.5 (−1.7 to 0.7)	
Simple effect of time		$p < 0.001$		$p < 0.001$				
Waist-to-hip ratio								
Baseline	40	0.89 (0.01)	40	0.89 (0.01)	–	–		$p = 0.662$
6 months	37	0.87 (0.01)*	33	0.89 (0.01)	−0.02	−0.01	0.01 (−0.01 to 0.03)	
24 months	19	0.87 (0.01)*	21	0.87 (0.01)*	−0.02	−0.02	−0.00 (−0.03 to 0.02)	
Simple effect of time		$p = 0.020$		$p = 0.047$				
Systolic blood pressure (mmHg)								
Baseline	40	124.1 (1.7)	40	128.4 (1.7)	–	–		$p = 0.722$
6 months	37	124.3 (1.8)	33	126.4 (1.9)	0.21	−2.0	−2.2 (−7.9 to 3.4)	
24 months	19	124.2 (2.3)	21	126.8 (2.3)	0.10	−1.7	−1.8 (−8.7 to 5.2)	
Simple effect of time		$p = 0.995$		$p = 0.591$				
Diastolic blood pressure (mmHg)								
Baseline	40	78.8 (1.4)	40	80.6 (1.4)	–	–		$p = 0.385$
6 months	37	79.4 (1.5)	33	78.6 (1.5)	0.67	−2.0	−2.6 (−6.6 to 1.4)	
24 months	19	78.9 (1.9)	21	78.3 (1.8)	0.09	−2.3	−2.4 (−7.3 to 2.6)	
Simple effect of time		$p = 0.885$		$p = 0.289$				
Low-density lipoprotein (mg/dL)								
Baseline	40	122.8 (5.1)	40	117.4 (5.1)	–	–		$p = 0.009$
6 months	39	114.0 (5.1)*	33	124.0 (5.3)	−8.8	6.6	15.4 (5.5–25.3)	
24 months	18	112.8 (6.0)*	21	118.4 (5.9)	−10.0	1.0	11.0 (−1.8 to 23.8)	
Simple effect of time		$p = 0.017$		$p = 0.176$				
High Density lipoprotein (mg/dL)								
Baseline	40	47.2 (1.8)	40	46.7 (1.8)	–	–		$p = 0.608$
6 months	39	43.0 (1.9)*	33	44.4 (1.9)	4.2	2.3	2.0 (−1.9 to 5.8)	
24 months	18	43.9 (2.2)	21	44.5 (2.2)	3.3	2.2	1.1 (−3.9 to 6.1)	
Simple effect of time		$p = 0.007$		$p = 0.239$				
Total cholesterol (mg/dL)								
Baseline	40	197.7 (6.8)	40	196.3 (6.8)	–	–		$p = 0.353$
6 months	39	189.1 (6.8)	33	200.9 (7.2)	−8.7	4.6	13.3 (−4.9 to 31.4)	
24 months	18	178.8 (8.8)*	21	183.6 (8.7)‡	−19.0	−12.6	6.3 (−17.0 to 29.7)	
Simple effect of time		$p = 0.070$		$p = 0.122$				
Total cholesterol- HDL ratio								
Baseline	40	4.4 (0.20)	40	4.4 (0.20)	–	–		$p = 0.789$
6 months	39	4.6 (0.21)	33	4.7 (0.21)	0.13	0.28	0.15 (−0.28 to 0.57)	
24 months	18	4.2 (0.25)	21	4.3 (0.24)‡	−0.25	−0.15	0.09 (−0.45 to 0.64)	
Simple effect of time		$p = 0.166$		$p = 0.063$				
Triglycerides (mg/dL)								
Baseline	40	135.1 (13.5)	40	151.7 (13.5)	–	–		$p = 0.383$
6 months	39	152.9 (13.6)	33	143.8 (14.4)	17.9	−7.9	−25.8 (−62.5 to 10.9)	
24 months	18	118.8 (17.7)‡	21	122.0 (17.4)	−16.3	−29.7	−13.4 (−60.6 to 33.8)	
Simple effect of time		$p = 0.108$		$p = 0.210$				
Fasting glucose (mg/dL)								
Baseline	40	100.0 (4.7)	40	99.6 (4.7)	–	–		$p = 0.623$
6 months	39	104.8 (4.8)	33	99.2 (5.0)	4.8	−0.35	−5.2 (−15.8 to 5.4)	
24 months	18	102.9 (5.8)	21	99.0 (5.7)	2.9	−0.52	−3.4 (−17.2 to 10.3)	
Simple effect of time		$p = 0.418$		$p = 0.993$				

Note. CI = confidence interval; *Significant within-group difference from baseline ($p < 0.05$); ‡Significant within-group difference from 6-months ($p < 0.05$).

2.1. Cardio-metabolic fitness (Table 2)

2.1.1. Group-by-time interactions

Between-group differences in weight loss and BMI change were observed from baseline to post-intervention ($p = 0.001$; $p = 0.002$, respectively), with greater reductions in the weight-loss program post-intervention. However, these between-group differences in weight loss and BMI were no longer significant at 24 months ($p = 0.063$; $p = 0.057$, respectively). Between-group differences in LDL cholesterol change were observed from baseline to post-intervention ($p = 0.003$), with a greater reduction in the weight-neutral program. However, these between-group differences were also no longer significant at 24 months ($p = 0.090$).

2.1.2. Within-group effects of time

Participants in the weight-loss program showed reductions in body weight post-intervention ($p < 0.001$), and maintained these reductions in body weight at the 24-month assessment ($p = 0.001$, compared to baseline). Weight-loss program participants also lowered their BMI post-intervention ($p < 0.001$), and maintained a lower BMI at 24 months ($p = 0.001$, compared to baseline). No BMI or weight changes were evident for participants in the weight-neutral program at post-intervention or at 24 months (all $ps > 0.447$). Participants in the weight-loss program did not have lower LDL cholesterol at post-intervention ($p = 0.074$, with trends indicating higher LDL levels at this time point) or at 24 months ($p = 0.824$, compared to baseline). Participants in the weight-neutral program significantly lowered their LDL cholesterol levels post-intervention ($p = 0.010$), and maintained this reduction at 24 months ($p = 0.031$, compared to baseline).

2.1.3. Main effects of time

Given that no additional between-group differences were observed in other cardio-metabolic parameters, the main effects of time, as well as parameter estimates for baseline to post-intervention and baseline to 24 months, are presented. Time point was statistically significant for waist circumference, F (2, 119) = 4.91, $p = 0.009$, hip circumference, F (2, 109) = 25.61, $p < 0.001$, waist-to-hip ratio, F (2, 111) = 6.56, $p = 0.002$, HDL cholesterol, F (2, 111) = 5.90, $p = 0.004$, total cholesterol, F (2, 114) = 3.79, $p = 0.026$, and total cholesterol-HDL ratio, F (2, 110) = 4.51, $p = 0.013$. At post-intervention, participants decreased their waist circumference, $B = -2.25$, SE = 0.78, $p = 0.005$, hip circumference, $B = -1.55$, SE = 0.34, $p < 0.001$, and waist-to-hip ratio, $B = -0.02$, $SE = 0.01$, $p = 0.018$, as well as their HDL cholesterol, $B = -4.22$, SE = 1.34, $p = 0.002$. At 24 months, waist-to-hip ratio changes remained significant, $B = -0.02$, SE = 0.01, $p = 0.024$; however, changes in waist circumference, $B = -0.97$, SE = 1.00, $p = 0.337$, hip circumference, $B = 0.05$, SE = 0.45, $p = 0.906$, and HDL cholesterol, $B = -3.27$, SE = 1.81, $p = 0.073$, were no longer evident. While no changes in total cholesterol were found at post-intervention, $B = -8.67$, SE = 6.26, $p = 0.169$, decreases were evident at 24 months, $B = -18.96$, SE = 8.40, $p = 0.026$. Despite a significant time point value, total cholesterol-HDL ratio was not significantly different at post-intervention, $B = 0.13$, SE = 0.14, $p = 0.376$, or 24 months, $B = -0.24$, SE = 0.20, $p = 0.215$. Finally, there were no significant changes over time in systolic or diastolic blood pressure, fasting blood glucose, or triglyceride levels.

2.2. Lifestyle behaviors (Table 3)

2.2.1. Group-by-time interactions

Between-group differences in intuitive eating were observed from baseline to post-intervention ($p = 0.002$), with greater improvements in the weight-neutral program. Although, these differences were non-significant at 24 months ($p = 0.076$). Between-group differences in dietary risk changes were observed from baseline to post-intervention ($p < 0.001$), with greater improvements initially observed in the weight-loss program. These differences were not sustained at 24 months ($p = 0.625$), however. No additional between-group differences were observed in lifestyle behaviors.

Table 3
Predicted means and changes from baseline for psychological and behavioral outcomes.

Outcome Variable	Estimated marginal means (SE)				Change from baseline			
	Weight-neutral (WN) program		Weight-loss (WL) program		WN program	WL program	Mean difference in change (95% CI)	Group-by-time interaction
	n		*n*					
Intuitive eating								
Baseline	40	2.9 (0.07)	40	3.0 (0.07)	–	–		$p = 0.006$
6 months	37	3.4 (0.07)*	33	3.1 (0.07)*	0.43	0.15	−0.29 (−0.47 to −0.11)	
24 months	19	3.2 (0.08)*	21	3.0 (0.08)	0.28	0.08	−0.20 (−0.42 to 0.02)	
Simple effect of time		$p < 0.001$		$p = 0.090$				
Quality of life								
Baseline	40	53.8 (1.1)	40	52.7 (1.1)	–	–		$p = 0.189$
6 months	37	56.9 (1.1)*	33	55.7 (1.2)*	3.1	3.0	−0.17 (−3.2 to 2.9)	
24 months	19	57.1 (1.4)*	21	52.6 (1.4)‡	3.3	−0.1	−3.3 (−7.2 to 0.5)	
Simple effect of time		$p = 0.006$		$p = 0.018$				
Self-esteem								
Baseline	40	19.0 (0.65)	40	19.2 (0.65)	–	–		$p = 0.707$
6 months	37	21.3 (0.66)*	33	20.8 (0.69)*	2.3	1.7	−0.61 (−2.0 to 0.8)	
24 months	19	20.9 (0.79)*	21	20.7 (0.77)*	1.9	1.5	−0.36 (−2.2 to 1.4)	
Simple effect of time		$p < 0.001$		$p = 0.005$				
Fruit & vegetable intake								
Baseline	40	4.5 (0.29)	40	4.4 (0.29)	–	–		$p = 0.121$
6 months	37	6.1 (0.29)*	33	6.6 (0.31)*	1.5	2.2	0.70 (−0.10 to 1.50)	
24 months	19	6.0 (0.37)*	21	5.7 (0.36)*‡	1.5	1.3	−0.18 (−1.17 to 0.81)	
Simple effect of time		$p < 0.001$		$p < 0.001$				
Dietary risk assessment								
Baseline	40	32.7 (1.2)	40	34.4 (1.2)	–	–		$p = 0.001$
6 months	37	26.8 (1.2)*	33	22.6 (1.3)*	−5.9	−11.7	−5.9 (−8.8 to −2.9)	

Table 3 (*continued*)

Outcome Variable	Estimated marginal means (SE)				Change from baseline			
	Weight-neutral (WN) program		Weight-loss (WL) program		WN program	WL program	Mean difference in change (95% CI)	Group-by-time interaction
	n		*n*					
24 months	19	27.0 (1.5)*	21	27.8 (1.5)*‡	−5.6	−6.5	−0.9 (−4.5 to 2.7)	
Simple effect of time		$p < 0.001$		$p < 0.001$				
Physical activity								
Baseline	40	2.4 (0.15)	40	2.2 (0.15)	–	–		$p = 0.546$
6 months	37	3.3 (0.15)*	33	3.0 (0.16)*	0.96	0.82	−0.14 (−0.68 to 0.41)	
24 months	19	3.0 (0.21)*	21	3.1 (0.20)*	0.66	0.90	0.24 (−0.42 to 0.90)	
Simple effect of time		$p < 0.001$		$p < 0.001$				
Distress								
Baseline	40	14.2 (2.6)	40	17.2 (2.1)	–	–		$p = 0.820$
6 months	37	13.4 (2.1)	33	15.3 (2.3)	−0.8	−1.8	−1.1 (−8.1 to 6.0)	
24 months	19	17.4 (2.9)	21	22.1 (2.8)‡	3.2	4.9	1.7 (−6.9 to 10.4)	
Simple effect of time		$p = 0.445$		$p = 0.093$				

Note. CI = confidence interval; *Significant within-group difference from baseline ($p < 0.05$); ‡Significant within-group difference from 6-months ($p < 0.05$).

2.2.2. Within-group effects of time

Significant increases in intuitive eating were evident for both the weight-neutral ($p < 0.001$) and weight-loss programs ($p = 0.029$) at post-intervention. At 24 months however, only the weight-neutral program maintained improvements in intuitive eating behaviors ($p = 0.001$, compared to baseline; weight-loss program $p = 0.310$). Participants in both programs also reported significant improvement in dietary risk scores at post-intervention (both *ps* < 0.001). However, between post-intervention and 24 months, dietary risk scores significantly increased (a negative change) for the weight-loss program ($p < 0.001$), whereas the weight-neutral program maintained improvements across time points. The baseline to 24-month comparisons showed significant improvements in the weight-neutral and weight-loss programs (both *ps* < 001).

2.2.3. Main effects of time

Since no additional between-group differences were observed in lifestyle behaviors, the main effects of time, as well as the parameter estimates for baseline to post-intervention and baseline to 24 months, are presented. Significant improvements were demonstrated over time for physical activity, $F(2, 123) = 23.55$, $p < 0.001$, and fruit and vegetable consumption, $F(2, 116) = 45.90$, $p < 0.001$. At post-intervention, participants increased their physical activity levels, $B = 0.96$, SE = 0.19, $p < 0.001$, and fruit and vegetable consumption, $B = 1.53$, SE = 0.28, $p < 0.001$. At 24 months, increases in physical activity, $B = 0.66$, SE = 0.24, $p = 0.007$, and fruit and vegetable consumption, $B = 1.51$, SE = 0.36, $p < 0.001$, remained significant.

2.3. Psychological well-being (Table 3)

2.3.1. Group-by-time interactions

No between-group differences were observed in mean change over time for psychological well-being outcomes.

2.3.2. Main effects of time

Since between-group differences were not observed in psychological well-being, the main effects of time, as well as the parameter estimates for baseline to post-intervention and baseline to 24 months, are presented. Time point was statistically significant for self-esteem, $F(2, 112) = 16.20$, $p < 0.001$, and quality of life, $F(2, 117) = 7.71$, $p = 0.001$. At post-intervention, participants increased their self-esteem, $B = 2.27$, SE = 0.50, $p < 0.001$, and quality of life, $B = 3.13$, SE = 1.06, $p = 0.004$, and these changes were maintained at 24 months, $B = 1.91$, SE = 0.66, $p = 0.004$, and $B = 3.29$, SE = 1.39, $p = 0.020$, respectively. Overall changes in distress throughout the study were non-significant.

3. Discussion

In light of increasing evidence for the poor long-term success rate of weight loss for improving health in people with high BMI (Køster-Rasmussen et al., 2016; Tomiyama et al., 2013; Wing et al., 2013), alternative weight-neutral approaches for health promotion have been developed and employed (e.g., Bacon et al., 2002, 2005; Katzer et al., 2008; Leblanc et al., 2012). However, to date, only one randomized controlled trial has directly compared a weight-loss program to a weight-neutral program on a wide range of health and well-being factors (Bacon et al., 2002, 2005). The current RCT helps to fill this important gap in the literature and compare different frameworks for health in people with high BMI (Penney & Kirk, 2015). While some clinicians and researchers have expressed concern over the use of weight-neutral approaches, and of the Health At Every Size® model in particular (Sainsbury & Hay, 2014), the findings presented here suggest concerns about the use of weight-neutral approaches for health improvement are unwarranted. Despite the fact that weight and BMI did not significantly change for participants in the weight-neutral program, by the end of the study, there were no instances where the weight-neutral program produced inferior outcomes relative to the weight-loss program. For the majority of health and well-being indicators, the programs did not differ from each other post-intervention and at the two-year follow-up assessment.

To summarize the findings, post-intervention reductions in weight and BMI were significantly greater for participants in the weight-loss program, while improvements in intuitive eating were significantly greater for participants in the weight-neutral program. This pattern of results was expected and indicates that the programs were indeed effective in their respective aims. Both programs were successful in changing healthy lifestyle behaviors (i.e., physical activity, fruit and vegetable intake), as well as certain parameters of psychological well-being (i.e., quality of life, self-esteem) and cardio-metabolic fitness (i.e., total cholesterol, waist-to-hip ratio) which were maintained at 24 months; however, the programs did not differ from one another in terms of their relative impact on these variables. Neither program decreased blood pressure, fasting blood glucose, or triglyceride levels.

Although participants in the weight-neutral program did not lose weight, they reduced LDL cholesterol levels to a greater extent than participants in the weight-loss program. More specifically, participants in the weight-neutral program demonstrated an overall decrease of 10 mg/DL in LDL cholesterol. In contrast, while participants in the weight-loss program sustained a reduction in weight and BMI over the follow-up period, they experienced no change in LDL cholesterol over the duration of the study. These findings are consistent with Bacon et al. (2002, 2005) and highlight the capacity for certain cardio-metabolic fitness variables, namely LDL and total cholesterol, to improve with weight-neutral health promotion strategies.

The patterns observed in dietary composition also deserve mention. While both programs showed improvement in dietary risk between baseline and post-intervention, findings initially indicated greater improvement among participants in the weight-loss program. However, at 24 months, participants in the weight-loss program demonstrated within-group *negative* changes in dietary risk, while participants in the weight-neutral program maintained the improvements seen between post-intervention and the 6-month assessment. Paralleling patterns were found for weight-loss program participants in the fruit and vegetable intake. Nevertheless, despite the significant decrements seen in the weight-loss program during follow-up, the baseline to 24-month change in dietary composition was improved for both groups. Future research is needed to explore intervening or buffering variables that help explain the negative changes in dietary composition during long-term follow up periods for weight-loss program participants. These patterns could eventually lead to reversal of lost weight, which often is accompanied by secondary health consequences (Montani et al., 2015).

To our knowledge, this study is the first randomized controlled trial to examine intuitive eating in a weight-neutral versus weight-loss program, thereby addressing another gap recently noted in a systematic review of this literature (Schaefer & Magnuson, 2014). Research has shown that intuitive eaters benefit from greater body appreciation, emotional awareness, interoceptive sensitivity, self-compassion, and distress tolerance, while displaying less maladaptive behaviors and traits such as perfectionism, self-silencing, and disordered eating, compared to individuals who engage in eating restraint (Brown, Parman, Rudat, & Craighead, 2012; Herbert et al., 2013; Schoenfeld & Webb, 2013; Shouse & Nilsson, 2011; Tylka, Calogero, & Danielsdottir, 2015; Tylka & Kroon Van Diest, 2013). In the present study, as expected, participants in the weight-neutral program demonstrated greater improvement in intuitive eating compared to the weight-loss program post-intervention, and they sustained improvements in intuitive eating over the follow-up. Moreover, as mentioned above, the findings for dietary risk in the present study suggest that the dietary prescriptions of the weight-loss program were not sustainable in the long-term, which could explain why participants in the weight-loss program did not improve LDL cholesterol or many of the other cardio-metabolic factors thought to be a direct consequence of weight loss even though they did lose weight. In the context of a growing body of literature showing the positive correlates of intuitive eating (see Bruce & Ricciardelli, 2016 for a review), the evidence presented here suggests an intuitive eating lifestyle as a promising and sustainable alternative for health improvement in people with high BMI.

Similar to other RCTs, this study is not without limitations. The sample of women was predominantly White and within a narrow age range, limiting the generalizability of these results beyond this particular demographic group. Future studies should examine weight-neutral approaches with larger samples that include people of color, and men and women across various developmental stages of life. While the total trial length of 24 months is indeed a strength of this study, perhaps not enough time was given for between-group differences to emerge and/or for changes to become evident in certain cardio-metabolic variables, such as blood pressure and blood glucose. Longer trials are needed to know the enduring effects of weight-loss and weight-neutral programs, and whether or not they differ from each other over time. However, we consider the primary limitation of this study to include the 50% attrition rate at the 24-month assessment and the fact that only 50% of the participants adhered to the complete study protocol by attending over two-thirds of the program sessions. It is important to note that this pattern of attrition is not atypical in studies involving weight and health outcomes (Bacon et al., 2005; Douketis et al., 2005; Katzer et al., 2008). Nevertheless, because the full sample was unavailable for final assessment, we recommend a cautious interpretation of the results. Given that sensitivity analyses suggested dropout did not impact the findings, and our use of intention-to-treat based linear mixed model analysis with restricted maximum likelihood estimation strengthens the study, this research builds on existing RCT literature comparing a standard weight-loss to a weight-neutral approach on a variety of health outcomes, which used earlier generation repeated measures analytic strategies (Bacon et al., 2005).

In conclusion, if our goal is to improve and sustain health and well-being, this study provides novel evidence supporting an alternative approach to weight loss in the promotion of health for high BMI individuals. We need to use methods that do not aggravate weight stigma and dieting pressures, often which further compound the problems of restrictive eating and weight cycling for those with high BMI (Montani et al., 2015; Tomiyama, 2014). Weight-neutral approaches that emphasize intuitive eating and size acceptance, although they may not lead to weight-loss as shown here, are still effective for improving a range of health indicators (LDL cholesterol, total cholesterol, dietary composition, physical activity, quality of life, self-esteem, waist-to-hip ratio), and they warrant serious attention from researchers and clinicians seeking non-stigmatizing health promotion strategies.

Conflict of interest statement

The authors declare no conflicts of interest regarding this work.

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