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RAPID COMMUNICATION

Small Changes in Nutrition and Physical Activity Promote Weight Loss and Maintenance: 3-Month Evidence from the ASPIRE Randomized Trial

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Abstract

Background Current obesity interventions use intensive behavior changes to achieve large initial weight loss. However, weight regain after treatment is common, and drop out rates are relatively high. Smaller behavioral changes could produce initial weight loss and be easier to sustain after active treatment.

Purpose We examined the efficacy of an intervention that targeted small but cumulative participant-chosen changes in diet and physical activity (ASPIRE) and compared this treatment to standard didactic and wait-list control groups. The primary outcome measures were body weight, waist circumference, and intra-abdominal fat.

Methods Fifty-nine overweight or obese sedentary adults were randomized to one of three groups: (1) the ASPIRE group (n=20), (2) a standard educationally-based treatment group (n=20), or (3) a wait list control group (n=19) for 4 months. Active treatment groups received identical resistance and aerobic training programs.

Results Intention-to-treat analyses showed that participants in the ASPIRE group lost significantly more weight than the standard and control groups (−4.4 vs. −1.1 and +0.1 kg, respectively), and the greater initial weight loss in the ASPIRE group was sustained 3 months after active treatment (4.1 kg). An alternative analytic strategy (0.3 kg/month weight gain for those lost to follow-up) showed continued weight loss (−0.2 kg after active treatment; −4.6 kg from baseline) at follow-up in the ASPIRE group. Similar patterns were observed for the other adiposity measures.

Conclusion More modest behavioral changes are capable of promoting weight loss, decreasing adiposity markers and sustaining these changes over 3 months. Longer-term studies comparing this approach with traditional behavioral weight loss treatments are warranted.

Keywords ASPIRE · Weight loss · Nutrition

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Introduction

Developing effective weight loss programs is imperative given the obesity epidemic and its associated health consequences [1]. Traditional behavioral therapy programs involving dietary restriction (1,000–1,200 kcals/day), physical activity (60 min most days of the week), and behavioral self-management achieve about 10% initial weight loss over 6 months [2]. However, long-term maintenance of weight loss remains elusive, as most intervention participants regain one-third of their weight during the first year and within 5 years return to pre-intervention levels [3, 4].

Even with extended 'continuous care' interventions, using different contact modalities and different self-regulation strategies [5–8], some weight regain is imminent. Therefore, pursuing additional treatment avenues in an attempt to achieve lasting weight loss needs to be considered.

One treatment issue concerns the amount of weight loss necessary to be considered successful. While most treatments focus on large initial weight losses, more modest, maintained weight losses (~5%) have been shown to have clinically important health benefits for reducing disease risk [3]. Moreover, recently published population-based data showed that losing a greater percentage of maximum weight was one factor associated with greater weight regain across time [9]. As a result, some researchers have begun to question weight loss protocols, particularly the initial 'dieting' phase (i.e., large caloric reduction; [10]). Some recent alternative approaches include "nondieting," "antidieting," or "undieting" approaches [11–14]. A review of the effectiveness of non-dieting studies [10] showed that, while these approaches had favorable impacts on self-esteem, mood, and body image, they had little or no impact on weight.

The one exception to these findings was a small randomized clinical trial by Sbrocco et al. [15]. The Sbrocco et al. [15] program featured a behavioral choice model, coupled with smaller but potentially maintainable changes in eating behaviors that was compared to a traditional behavioral weight loss program. At the end of the 3-month treatment program, the traditional behavioral therapy program showed greater weight loss compared to the behavioral choice group. However, across a 9-month follow-up period, the behavioral choice program participants continued to lose weight, while the traditional program began to regain their lost weight. While these results were provocative, several notable limitations exist including: The dietary changes were fairly restricted, all participants were female, there was a significant run-in period to be eligible for randomization, and perhaps, most importantly, the findings have yet to be replicated.

The present study extended this promising approach by including men and women, broadening choice by allowing participants to include different foods, target caloric amounts, and by equally increasing exercise across treatment groups. The *ASPIRE* (Aspiring for Lifelong Health) program represented a blending of traditional and non-dieting approaches. *ASPIRE* program participants were told that, to promote a negative energy balance (lose weight), only small caloric reductions and small increases in physical activity were required. Participants were provided brief instruction about nutrition and physical activity and asked each week to choose and make one small, potentially permanent change in food choices and caloric intake and one small change in physical activity. Small changes were cumulative and made within the context of healthful foods and increasing step counts [16]. Overall, the goal was to lose at least 5% of total body weight and to maintain that loss without continued treatment. It was hypothesized that the *ASPIRE* program would result in greater initial weight loss and improved short-term maintenance of weight loss than both a waiting-list control and a standard educational weight loss program.

Methods

Participants

The 59 participants were recruited through newspaper articles and a radio interview featuring the *ASPIRE* study in the fall of 2001. A flow diagram depicting the number of eligible participants for the trial, the number randomized to each treatment group, and the number completing each assessment is shown in Fig. 1 [17]. Eligibility criteria included being overweight or obese (body mass index [BMI—weight in kilograms/height in square meters] 26–40) and having a sedentary lifestyle (<30 min of moderate to vigorous exercise per week). Participants were excluded for the following reasons: (1) presence of any cardiopulmonary or metabolic disease (i.e., diabetes, thyroid, liver, or kidney disease); (2) blood pressure > 160/100 mmHg, (3) medications that could affect body weight, other metabolic parameters, or both; (4) lack of active health insurance; (5) recent pregnancy or plans to become pregnant in the next 10 months, and (6) BMI greater than 40 kg/m^2. The study population consisted mostly of middle-aged, Caucasian (94%), obese (31.66±3.05%) men (41%) and women (59%). The study took place in 2002.

Design

The protocol was approved by the Institutional Review Board at Virginia Polytechnic Institute and State University. Written informed consent was obtained from all participants. After successful completion of the baseline assessment, 59 participants, stratified by gender and BMI, were randomly assigned using a random-numbers table by the first author to one of the three treatment groups: (1) A *standard* group focused on an educationally based, didactically delivered US Department of Agriculture (USDA) nutrition and physical activity program coupled with a center-based resistance and aerobic training program (n=20); (2) *ASPIRE*, a choice-approach (no pre-set goals) focused on small, cumulative changes in physical activity and nutrition, including the same center-based resistance and aerobic training program (n=20); or (3) a *control* group, who was asked to continue life as usual (n=19). After randomization, participants that completed a 16-

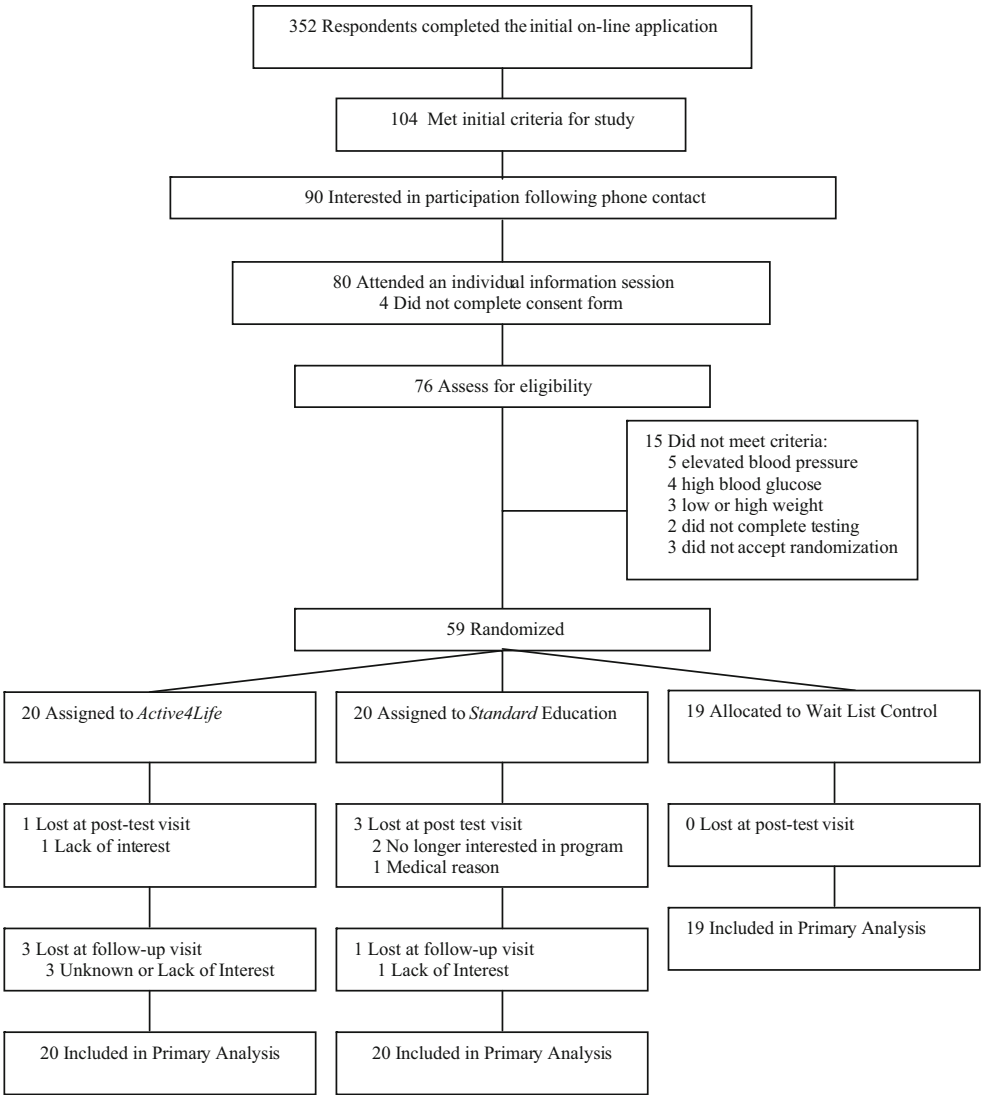

Fig. 1 Participant flow chart through enrollment to follow-up testing

week initial period were reassessed and then were again followed up 3 months after the completion of treatment.

Procedures

Common Treatment Components

To minimize any differential effects of aerobic and resistance training between the two treatment groups, participants in both treatment arms completed the same progressive aerobic and resistance training protocols. Each training session was conducted with a personal trainer and included a 10- to 12-min graded exercise protocol (GXP) focusing on improving aerobic fitness using either a treadmill or cycle ergometer and a 15- to 20-min resistance training protocol with a 5-min stretching period at the end of every session. Both the aerobic and resistance training protocols have both tested in our lab and shown to be time efficient and effective protocols for increasing fitness and strength [18]. The total time for the entire aerobic and resistance training session was 40–45 min, performed twice per week. Overall, participants in both treatment groups received approximately 24 h of personal training supervision across the treatment program.

Standard Treatment

In addition to their two center-based visits per week, once a week, participants met with a nutritionist for 20 min to receive the education-based program "Dietary Guidelines for Americans" developed by the US Department of Health and Human Services [19], which included topics and handouts related to fitness, building a healthy base of food knowledge, and making nutritionally sound food choices. Consistent with these guidelines, women in the program

were encouraged not to eat more than 1,600 kcal/day, and men were encouraged not to eat more than 2,000 kcal/day. Participants also were encouraged to engage in at least 30 min per day of physical activity on most days of the week. Participants received didactic behavioral counseling for approximately 5 h across the duration of the study.

ASPIRE Treatment

Participants randomized to the *ASPIRE* treatment received the same center-based aerobic- and resistance-training program as people randomized to the *Standard* group. In addition, participants met weekly, one on one, with a lifestyle coach for approximately 20 min. Participants set challenging, yet achievable goals in relation to nutrition and physical activity involving small changes that were presented as choices each week. For the nutrition portion, participants were asked to complete a 1-week baseline record to serve as a basis for subsequent goals. Energy intake range/calorie goals were individualized based on each participant's resting energy expenditure using the Harris–Benedict equation [20], total energy expenditure (activity level based on participants' step counts at baseline), and total energy intake at baseline from food records. Based on these guidelines, daily energy intake goals in the *ASPIRE* ranged from 1,500 to 2,200 kcal/day for women (−200 to 500 kcal/day from baseline) and from 1,900 to 2,600 kcal/day for men (−200 to 600 kcal/day from baseline). The nutrition program stressed smaller, healthful targeted changes and substitutions such as increasing fruits and vegetables and whole grains, decreasing high fat dairy and meat products, soft drinks, higher calorie snacks, and portion sizes, and maintaining consistent kcal/day consumption [16]. For physical activity, all participants were given a pedometer to first assess their current volume of physical activity. After the baseline period, participants were asked to set weekly goals to slowly increase steps to eventually reach 3,000 steps/day greater than baseline or a total of 10,000 steps/day. Participants kept a detailed daily step count and calorie log. Participants also received guidance in selecting and using a venue to continue exercising after the intervention ended. This choice-oriented program lasted approximately 5 h across the duration of the study.

Control

Control participants were asked to continue life as usual during the first 16-week study period, to attend an assessment, and then to continue life as usual for an additional 12-weeks. Participants were told they would then receive the most effective treatment program.

Measures

Anthropometrics and Body Composition Total body weight, waist circumference, and intra-abdominal fat (%) were the primary outcome variables. An experienced investigator with extensive assessment experience, blind to treatment condition, performed all body composition assessments with the exception of waist measurements. Weight (without shoes) was measured to the nearest 0.25 lb using a calibrated balance-beam scale. Height (without shoes) was measured to the nearest 0.5 cm using a calibrated stadiometer. Waist measurements were taken to the nearest 0.1 cm using a Gulick anthropometric tape (Perform Better, Cranston, RI, USA). Intra-abdominal fat was measured by a dual energy X-ray absorptiometry (DXA; Hologic QDR 4500A, Hologic, Inc., Bedford, MA, USA).

Manipulation Checks

To more precisely partition the adiposity differences between the *ASPIRE* and *standard* treatment groups, both groups engaged in structured aerobic and resistance training activities. We used markers of these activities to determine whether the groups were indeed comparable on these dimensions after active treatment.

Cardiorespiratory Fitness Cardiorespiratory fitness was determined by predicting aerobic capacity (VO_2max) from heart rate and VO_2 responses obtained in a progressive multistage sub-maximal exercise test, performed on a stationary cycle ergometer (Monark 818E, Varberg, Sweden) and using an automated respiratory gas analysis system (MedGraphics® CPX-D, Minneapolis, MN, USA). Because a strong linear relation exists between heart rate and VO_2 response in exercise, even in overweight adults, VO_2 was regressed on heart rate responses and extrapolated to the level of predicted maximal heart rate to obtain a VO_2max value [21].

Strength Total body strength (total kilograms lifted/number of machines) was assessed by trainers using eight air-powered Keiser resistance exercise machines. Participants completed a full strength test on each machine, and the total was then divided by eight (the number of machines) to obtain their total strength at each testing period.

Physical Activity Participants used step counter pedometers (Accusplit 120E, Accusplit, San Jose, CA, USA) to log the number of steps taken each day for 1 week. The pedometer was worn on the waistband directly above the knee.

Table 1 Baseline participant characteristics by treatment group

	ASPIRE (n=20)		Standard (n=20)		Control (n=19)		p value
	M	SD	M	SD	M	SD	
Mean age (years)	39.8	8.0	41.1	7.6	40.5	5.9	0.84
BMI (kg/m^2)	31.8	3.0	31.4	2.7	31.8	3.6	0.86
Weight (kg)	90.5	16.2	89.9	15.7	90.7	14.0	0.98
Number of men/women	8/20		7/20		9/19		0.73
Percent with college education or less (n)	32	(16)	50	(11)	44	(10)	0.25
Aerobic Fitness (ml kg^{-1} min^{-1})	21.8	5.9	22.1	5.6	26.1	8.2	0.10
Strength (kg)	52.4	13.5	51.4	20.5	54.8	20.5	0.85
Intra-abdominal fat (%)	35.6	4.3	36.5	5.0	34.9	8.9	0.73
Waist circumference (cm)	104.6	12.1	105.4	10.1	106.6	14.5	0.87

Education values were missing for one, four, and three participants in the ASPIRE, standard, and control groups, respectively.

Statistical Analyses

For the primary outcome variables (weight, waist circumference, and percent abdominal fat), all randomized participants were analyzed regardless of completion. Specifically, we replaced any posttreatment or follow-up missing values with the baseline value. We used separate regression analyses to evaluate changes in body weight, waist circumference, and intra-abdominal fat. Although no baseline differences in the primary outcome measures were detected across treatment groups (see Table 1), we included baseline (or the posttreatment measurement for the 3-month follow-up comparisons) values as covariates in our estimation of treatment effects. Because these analyses were similar to those using simple change scores, we report unadjusted means in the tables. Test statistics reflect focused treatment group contrasts that compared either active treatment groups versus the control group or the *ASPIRE* group versus the *standard* treatment group. Treatment maintenance after 3 months was examined using within groups t-tests.

Given that the test statistics for treatment effects are extremely conservative, particularly for the 3-month follow-up analyses, we also analyzed a primary outcome variable (weight) using an alternative operational definition of weight gain across time (0.3 kg per month) based on a recent meta-analysis [4] and published studies [8] of treatment non-completers.

In addition to p values, we also report Cohen's [22] standardized effect sizes (d) for simple change scores. Analyses were performed using the Statistical Package for the Social Sciences (SPSS, Chicago, IL, USA) for Windows version 15 and Stata 10.0 (Stata Corp, College Station, TX, USA). Post hoc power analysis for our highly correlated repeated measure (r=.97) revealed that the trial had power > 0.90 to detect a 6-lb posttreatment weight change between the active treatment groups.

Results

Baseline Comparisons and Attendance

Participants in the three conditions did not differ on any demographic or outcome measures at baseline (see Table 1). Participants in each group adhered well to their in-person behavioral and exercise sessions, 98% for *ASPIRE* and 91% for *standard* (z=−0.97, P=0.33).

Effectiveness of Fitness Matching

To evaluate the posttreatment similarity of the intervention groups, we compared strength, cardiorespiratory fitness, and step counts for those with complete data. As shown in Table 2, the active treatment groups had similar increases in strength and cardiorespiratory fitness [F(1,33)=3.28, p= 0.08; F(1,34)=.21, p=0.65, respectively], increases that were significantly greater than the control group [F(1,51)= 143, p<0.001; F(1,51)=9.94, p=0.003, respectively]. Finally, while participants in *ASPIRE* increased their pedometer steps/day by 68% from baseline, compared to participants in the *Standard* treatment who increased their steps/day by 40% and to the 21% increase in steps observed among *control* participants, only the difference between *ASPIRE* and *control* group was significant, F(1,20)=7.30, p<0.05.

Immediate Posttreatment Effects on Adiposity Measures

As shown in Table 2, both active treatment groups showed improvements in adiposity measures at the end of Phase 1, while the *control* group showed no change. In addition, changes in the *ASPIRE* group were significantly greater than the *standard* treatment condition for all three primary outcome measures. Both active treatment groups lost more weight than the *control* group [F(1,56)=10.70,

Table 2 Adiposity, fitness, and strength changes (±SD) by treatment group

	Baseline	Posttreatment	Change	3-month follow-up	Overall change
Primary outcome measures (intention-to-treat)					
Body weight (kg)					
ASPIRE	90.3±16.1	85.8±15.9	−4.5±3.4	86.2±15.8	−4.1±5.8
Standard	89.7±15.6	88.6±15.3	−1.1±2.7	88.4±15.3	−1.3±2.5
Control	90.5±14.0	90.6±14.3	+.1±2.4	N/A	N/A
Intra-abdominal/trunk fat (%)					
ASPIRE	35.6±4.3	32.9±5.1	−2.8±2.8	33.6±5.6	−2.0±3.7
Standard	36.5±5.0	35.7±5.9	−0.84±1.6	36.0±5.7	−0.46±1.2
Control	34.9±8.9	34.8±9.0	−0.05±1.8	N/A	N/A
Waist circumference (cm)					
ASPIRE	104.6±12.0	97.8±11.6	−6.8±3.4	97.4±11.6	−7.2±8.8
Standard	105.4±10.1	105.0±9.2	−0.42±4.4	105.5±8.9	+0.05±6.6
Control	106.6±14.5	106.4±14.5	−0.16±3.6	N/A	N/A
Manipulation checks (completers)					
Aerobic fitness (ml kg^{-1} min^{-1})					
ASPIRE	20.4±5.0	25.9±7.3	+5.4±3.4	26.0±5.5	+5.5±4.1
Standard	22.4±5.0	27.1±5.8	+4.7±2.3	24.5±6.2	+2.0±4.4
Control	26.7±8.6	27.7±8.0	+1.0± 5.8	N/A	N/A
Total strength (total of weight lifted on 8 machines/8) % change					
ASPIRE	51.2±11.4	100.3±28.4	+97.1±45.5	109.5±31.9	+110.4±44.2
Standard	51.9±19.3	112.8±32.2	+123.4±32.6	108.2±35.6	+111.2±38.2
Control	56.4±21.9	53.0±21.5	−6.4±2.7	N/A	N/A

Intention-to-treat used the baseline value carried forward for any missing follow-up data.

p=0.002, d=0.84], and participants in the *ASPIRE* group lost more weight than the *standard* participants [F(1,37)= 11.78, p=0.002, d=0.96]. The *control* group experienced a nonsignificant increase in weight [t(18)=−0.26, p= 0.80, d=0.01]. Active treatment groups lost more intra-abdominal fat at the end of Phase 1 [F(1, 55)=7.68, p=0.008, d=0.73], while the *ASPIRE* group lost more intra-abdominal fat than the *standard* group participants [F(1, 36)=6.01, p=0.02, d=0.76], and the *control* participants showed no change [t(18)=.11, p=0.91, d= 0.01]. For waist circumference, active treatment groups had significantly greater reductions [F(1,56)=7.71, p=0.008, d=0.71], and the *ASPIRE* group reduced waist circumference more than the *standard* condition [F(1,37)=29.60, p< 0.001, d=1.26], while the *control* group was unchanged for fat and waist circumference [t's(18)=0.11 and 0.20, p's> 0.84, respectively].

At the end of the 4 months, participants in both treatment groups were told that they would have no contact for 3 months and then would be asked to return for follow-up testing at that time. Participants in the *control* condition were provided with an abbreviated *ASPIRE* program at that time.

Maintenance of Treatment Effects

Generally, both active treatment groups were able to maintain the positive changes achieved after active treatment (see Table 2). Based on the intention-to-treat model, the *ASPIRE* group maintained their weight loss [t (19)=−0.41, p=0.67], waist circumference decreases [t (19)=.21, p=0.83], and abdominal fat loss [t(19)=−1.44, p=0.16]. Although the initial change was significantly smaller, those in the *standard* condition were also able to maintain their more modest posttreatment changes [t(19)= 0.73, p=0.48; t(19)=−0.52, p=0.61; t(18)=−1.45, p=0.17 for weight, waist, and abdominal fat, respectively]. The abdominal fat measurements appeared to regress the most, but this was because of the relatively large number of baseline values (n=5 in each group) carried over for those who were unable to complete this assessment at follow-up. We detected no differences in the rate of change after active treatment between the two active treatment arms for any of the three primary outcome measures (F's from 0.18–1.17, p's>0.29).

We also examined weight change across time using an alternative, empirically justified estimate of weight regain for non-completers (0.3 kg per month [4]). According to this analysis, participants in the *ASPIRE* group exhibited significantly greater weight loss across treatment compared to either the *standard* or *control* groups [−4.5±3.5 vs. −1.1±2.9 and +.1±2.4 kg, respectively; F(1,37)= 11.27, p<0.001, d=0.97 for the *ASPIRE* vs. *standard* group] and continued to lose weight across the 3-month follow-up (−0.2±3.7 vs. −0.1±1.2). From baseline to 3-month follow-up, participants in the *ASPIRE* group lost significantly more weight compared to the *standard* group [−4.6±5.7 vs. −1.2±2.7 kg; F(1,37)=6.12, p=0.02, d=0.97].

Discussion

The present study hypothesized that having participants choose small but cumulative changes in nutrition, caloric consumption, and physical activity would result in modest but sustainable weight loss. This treatment blended traditional behavioral therapy with a non-dieting behavioral choice approach. Participants in this *ASPIRE* program achieved statistically and clinically significant reductions in total body weight (4.62 kg; 5% of body weight), intra-abdominal fat, and waist circumference. Perhaps more notably, across a 3-month follow-up period, these participants were able to maintain all treatment-based improvements.

The present study had several strengths. First, the study was a randomized controlled trial with both treatment and wait-list comparison groups. Second, we matched resistance and aerobic training across *standard* and *ASPIRE* groups to control for adiposity changes unrelated to the behavioral treatment element. These groups were also matched on treatment contact time to more clearly partition the unique effects of the *ASPIRE* approach. Thus, we can reasonably assume that the favorable adiposity changes in the *ASPIRE* group after treatment and the maintenance of these changes 3 months after treatment were attributable to the intervention rather than nonspecific attention effects or changes in fitness. Finally, the *ASPIRE* effects were robust despite a very conservative analytic approach, one that carried the pretreatment values forward for those participants who did not complete the study.

Despite these strengths, limitations should be considered. First, the follow-up was only 3 months rather than at least 1 year [23]. Second, although the *standard* USDA comparison group was useful because of the similar caloric and activity goals relative to *ASPIRE*, it would be desirable to compare *ASPIRE* to more traditional behavioral weight loss programs that emphasize greater caloric restriction and more rapid weight loss. Regarding the repeatability of the *ASPIRE* approach, it is notable that our *control* group, who received a 12-week version of the *ASPIRE* program after the other active treatments ended, achieved and maintained (3 months) improvements in adiposity that were comparable to the original *ASPIRE* group (data not shown).

While no one treatment approach can address the obesity epidemic, the development and testing of novel approaches, such as the 'small changes' approach, will provide an evidence base for effective and enduring risk reduction interventions.

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