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Steps Ahead: A Randomized Trial to Reduce Unhealthy Weight Gain in the Lower Mississippi Delta

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Abstract

Objective—The Lower Mississippi Delta (LMD) region of the U.S. is characterized by high levels of obesity and physical inactivity. The objective was to test the effectiveness of adapting the 2010 *Dietary Guidelines for Americans* (DG), with and without a physical activity (PA) component, for attenuating weight gain.

Design and Methods—Overall, 121 white and African-American adults (35–64 y; BMI 25–34.9 kg/m^2) were randomized to a DG only group (n=61) or a DG+PA group (n=60). Both groups received a 12-week dietary education and behavior change intervention. The DG+PA also received PA education and a pedometer. Changes in weight (kg), %weight and waist circumference (WC; cm) were determined. Analyses considered all completers (n=99) and those who engaged with ≥80% of the intervention (n=83). General linear models compared mean changes between groups after adjustment for baseline values, race and sex.

Results—Weight, %weight and WC significantly decreased from baseline to follow-up in both groups ($p<0.05$; unadjusted values). Adjusted analysis showed a main effect of group for weight ($p=0.041$) and %weight ($p=0.047$) in the completers analysis and WC ($p=0.046$) in the ≥80% attendance analysis, with the DG+PA group improving weight-related outcomes more.

Conclusions—Low-burden behavioral interventions could be effective strategies in attenuating unhealthy weight gain in the LMD.

Keywords

Intervention; Obesity; Physical Activity; Dietary Recommendations

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DISCOLOSURE
The authors have no competing interests to disclose.

D.M.H. carried out the data collection and wrote the manuscript. All authors conceived the study design, analyzed the data and all authors critically reviewed the manuscript for content and had final approval of the submitted version.

INTRODUCTION

Compared to the rest of the United States, the Lower Mississippi Delta (LMD) is a region characterized by larger proportions of the adult population living below the poverty threshold (16.7% vs. 11.8%) and lower education levels (1). Adherence to healthy eating guidelines are lower, and the dietary composition and eating patterns of LMD residents differs from national averages (2, 3). Furthermore, the proportion of adults who report being physically active >150 min/week is lower than the national average (4). As a result, there is a higher prevalence of obesity and related chronic disease compared to the national average (5). Although it is well-established that the obesity epidemic in the LMD needs urgent attention, few studies have investigated strategies to improve the obesity status of this population using randomized study designs. A particular research need is to identify strategies to increase adherence to national health guidelines, specifically the *Dietary Guidelines for Americans, 2010* (6) and the *Physical Activity Guidelines for Americans, 2008* (7).

The purpose of this study was to determine whether adding physical activity (PA) education to adapted dietary education could attenuate unhealthy weight gain more than providing adapted dietary education alone. A secondary aim was to determine whether those who increase PA demonstrate a more favorable weight-related change than those who do not.

DESIGN AND METHODS

Sample

This study was conducted according to the guidelines provided in the Declaration of Helsinki, study procedures were approved by the Pennington Biomedical Research Center Institutional Review Board and all participants provided written informed consent. Recruitment was conducted via local and electronic media and distribution of flyers at community events in Baton Rouge, Louisiana.

Inclusion and Exclusion Criteria

Potential participants were scheduled for a clinic visit if they reported being 35–64 years old and having a body mass index (BMI) within the inclusionary range to recruiting staff. Inclusionary criteria included 1) clinic measured BMI of 25–34.9 kg/m^2; 2) being physically capable of undertaking PA; and 3) acceptance of randomized group assignment. Exclusion criteria collected at the clinic included: 1) blood pressure ≥ 160 mmHg systolic or ≥100 mmHg diastolic; 2) fasting total cholesterol ≥ 6.2 mmol/L with LDL-C ≥ 4.1 mmol/L or ≥ triglycerides 3.4 mmol/L; 3) uncontrolled or undiagnosed Type 2 diabetes; 4) pregnant females; 5) using weight loss medications, taken a medication known to affect weight in the past 30 days, or those who had started taking a new prescription medication in the last 3 months; and 6) being regularly physically active based on International Physical Activity Questionnaire (IPAQ) questions 1–4 (8).

Test Schedule

At baseline, participants had height, weight and waist circumference (WC) measured at the study clinic. Participants were provided an accelerometer and given verbal and written instructions for wear. Once the participant provided valid accelerometry data (defined as ≥ 600 minutes on ≥4 days of the week) 8 days later, study enrollment and random allocation to one of the two intervention groups occurred. A 15 minute group-specific orientation, including the intervention schedule for the subsequent 12 weeks, was provided by the interventionist. Following the 12-week intervention, all participants underwent the same testing as at baseline.

Anthropometric Measures

Anthropometric measures were taken without shoes and heavy items of clothing. Height was measured to the nearest 0.1 cm using a wall-mounted stadiometer. Weight was measured to the nearest 0.1 kg using a calibrated Seca digital scale, and BMI was calculated. WC was measured midway between the inferior border of the rib cage and the superior aspect of the iliac crest to the nearest 0.1 cm. Each measurement was taken twice by the same pair of observers with a third measurement taken if the first two measurements were greater than 0.1 cm, 0.1 kg and 0.5 cm, respectively, apart, with the average of the two (or the two closest) used in the analysis.

Physical Activity Assessment

Moderate to vigorous PA (MVPA) was estimated using the Actigraph GT3X+ (ActiGraph LLC, Ft. Walton Beach, FL) accelerometer using a 7-day (waking hours only) protocol. Participants wore the accelerometer on an elastic belt around the hip, over the right hip bone in the mid-axillary line. Data were sampled at a rate of 80 Hz with the low frequency extension turned on. Files were downloaded at a 1 second epoch and converted to a 60 second epoch file for analysis. A SAS program modified from the NHANES accelerometer SAS program (9) was used to reduce the accelerometer data. Non-wear time was calculated in minutes for activity counts of zero. MVPA intensity was defined as ≥2020 activity counts/min (10).

Randomization and Power

Participants were randomized into an adapted dietary guideline education only group (DG) or an adapted dietary guideline plus PA education group (DG+PA). Participants received a $25 gift card after returning the accelerometer at baseline and another $75 after the final follow-up visit. Investigators and assessment staff were blinded to group assignment.

A power analysis was conducted based on findings from two studies that used similar study designs and follow-up durations (11, 12). Thus, an estimated between group difference in 12-week weight change of 1.5 kg and an estimated standard deviation for change of 2.9 kg were used to determine that a sample size of 60 participants per group would provide at least 81% power.

Intervention

The 12-week intervention was based on the First Step Program (13). The programme included an initial adoption phase where participants met for group sessions at the study center once a week for the first four weeks. This was followed by an adherence phase of 8 weeks of biweekly telephone contact from the interventionist. Group sessions lasted 90 minutes for the DG group and 120 minutes for the DG+PA group. Education was delivered using a variety of strategies including printed materials, slide presentations, group discussions and individual telephone discussion. Each cohort of participants within each group was assigned one of two trained interventionists, who were also registered dieticians, for the duration of the 12 weeks.

Adapted Dietary Guidelines Education (DG)—Both groups received an adapted DG education intervention in person and over the telephone. The design and implementation of the DG education followed previous weight-loss trials which included behavioral techniques (e.g. food diaries) that have been successful for weight loss (14). The intervention was consistent with the recommendations for preventing weight gain in the *Dietary Guidelines* (6) and with suggestions that a small-changes approach could prevent weight gain (15). The emphasis was on reducing total and saturated fat, increasing fruits and vegetables (16, 17), and promoting the DASH diet (18), all of which are consistent with the *Dietary Guidelines* (6). At the group sessions, each participant's weight was recorded, discussions surrounding participant's food diaries took place and challenges and solutions were identified. Presentation and discussion sessions used standardized content adapted for the LMD, referencing the dietary guidelines and MyPlate, portion control and label reading and how to eat on a budget or when dining out. During the adherence phase participants continued diet self-monitoring and discussed progress with the interventionist over the telephone.

Physical Activity Education (PA)—This portion of the intervention was designed to increase the number of daily steps taken by the participants to achieve the goal of 30 min/day of MVPA. Target step levels specific for the LMD population have been defined using data from a feasibility study in the LMD where ~8300–9100 steps/day equated to 30 min/day of MVPA (19) with the aim of making the PA targets achievable (20).

At the first group session participants received a pedometer (Omron HJ151, Omron Healthcare, Kyoko City, Japan) to wear for the duration of the intervention. It displayed the number of total steps taken (volume) and the number of steps taken over a moderate intensity threshold. The first meeting included a short supervised walk providing a mastery experience of walking at MVPA. Participants were taught how to monitor steps and asked to log daily steps taken. Although the pedometer was used as a tracking and motivational tool for steps/day, there was continued emphasis on the 30 min/day MVPA guideline. Each session involved a review of the participants' step logs with individual, incremental goal-setting with assistance from the interventionist. Educational content for the 4-week session included presentations and discussion on walking goals and strategies to increase PA, incorporating PA as a way of life, planning ahead and addressing relapse. During the adherence phase, participants continued their self-monitoring and goal-setting (using pedometers and step logs) and discussed progress with the interventionist over the telephone.

Statistical Analysis

The primary outcome for this study was change in weight, while %weight, WC and MVPA were secondary outcomes. Descriptive characteristics of the two groups at baseline were compared using χ^2 tests and t-tests. Data for those who returned for week 12 follow-up were analyzed regardless of the number of sessions attended or phone calls (completers analysis; n = 99). A subsequent analysis was conducted using data from returning participants who completed ≥80% of the intervention (80% attendance analysis; n = 83). General linear models, with least square means, were used to compare mean weight change between groups after adjustment for corresponding baseline value, sex and race. Interactions were included in the model but were subsequently removed when not significant (except where noted in Table 2). Additional separate analytical models were used to investigate weight, % weight and WC change stratified by change in MVPA (≥75th vs. <75th percentile). All analyses were conducted using SAS 9.3 (SAS Institute Inc., Cary, NC, USA).

RESULTS

Overall, 121 participants were randomly assigned to the DG group (n = 61) and the DG+PA group (n = 60). Figure 1 demonstrates the flow of participants through the study from screening to 12-week follow-up, indicating at various stages the number excluded or lost to follow-up. For the completers analysis we relied on data from 99 participants who returned for the 12-week follow-up visit. For the analysis of accelerometer data, we relied on data from 90 of the 99 participants who returned a full set of valid baseline and follow-up data. For the 80% attendance analysis we relied on 83 participants. No adverse events were reported to the clinic or intervention staff. The mean percent of attended visits by participants was higher, but not significantly, for the DG group (88% for DG versus 79% for DG+PA, p = 0.19).

Table 1 summarizes the characteristics of the 99 completers including outcome means for weight, BMI, WC and MVPA. The DG group had significantly higher BMI ($p < 0.001$) and WC (p = 0.049) at baseline and this difference in BMI also existed when the original 121 randomized participants were compared. There were no significant mean differences at baseline between those who completed the 12-week follow-up (n = 99) and those who did not (n = 22) for any outcome or demographic variables (all $p > 0.05$). Those who attended ≥80% of the intervention were more likely to be older than those who did not (52.8 vs. 47.6 years; p = 0.017).

Figure 2 presents unadjusted change means for the completers analysis (top panel) and the 80% attendance analysis (bottom panel). Weight decreased significantly in the DG group ($p < 0.05$) and the DG+PA group ($p < 0.001$) from baseline to follow-up based on both the completers and 80% attendance groups. WC decreased significantly by −1.4 cm (p = 0.007) in the DG group and by −2.4 cm ($p < 0.001$) in the DG+PA group. Based on both the completers and 80% attendance analyses, MVPA levels increased significantly in the DG +PA group only (+8 min/day; p = 0.013 and +10 min/day; p = 0.005, respectively).

Adjusted-means for weight, %weight, WC and MVPA change are presented in Table 2 for the completers analysis and the 80% attendance analysis with adjustments to remove extraneous variability attributable to baseline value, sex and race. P-values relate to significance of between-group differences. The general linear model analysis revealed an intervention group significant main effect for weight change ($p = 0.041$) and %weight change ($p = 0.047$) in the completers analysis with the DG+PA group improving these outcomes more than the DG group. Significant effects of race ($p = 0.003$), baseline value ($p = 0.026$) and baseline-by-race interaction ($p = 0.004$) were observed for WC only. The race effect showed that, overall, white participants reduced their WC more than African-Americans. The significant interaction indicated that African-American participants with a higher baseline WC reduced their WC to a greater extent. With respect to the 80% attendance group, a main effect for intervention group was found for % weight change ($p= 0.043$) and changes in WC ($p = 0.046$) and MVPA ($p = 0.024$), again with the DG+PA group improving these outcomes significantly more than the DG group. A significant baseline-by-race interaction was observed for WC only ($p = 0.019$). Again, African-American participants with a higher baseline WC reduced their WC to a greater extent

MVPA change for the 90 completers who had full accelerometer data ranged from −38 to 76 min/day. Within each group and when both groups were pooled there was no difference by race or sex. With the groups pooled, MVPA change was stratified as change ≥ 75th percentile (n = 22; mean MVPA R Δ−3 min/day) and < 75th percentile (n = 68; mean MVPA R Δ28 min/day). The 75th percentile corresponded to 10 min/day. Mean weight, %weight and WC change by MVPA change group is shown in Figure 3. Those who changed their MVPA by >10 min/day reduced their WC significantly more than those who did not ($p = 0.018$).

DISCUSSION

There is a need to determine strategies to effectively communicate national health guidelines with the ultimate goals of achieving use and improving obesity status. This 12-week, low-burden program demonstrated that adapted *Dietary Guidelines* education, with and without a PA component, was effective in reducing weight related outcomes and thus attenuating unhealthy weight gain. The addition of the PA component produced greater weight loss compared to the DG only group. Those in the DG+PA group who adhered to the program more (≥80%) increased MVPA more than those in the DG group. In the sample as a whole, those who increased their MVPA by more than 10 min/day had a greater reduction in waist circumference than those who did not.

The mean weight loss of −1.7 kg (unadjusted analysis) of the DG+PA group compares well to weight (−1.7 kg) and WC (3 cm) decreases in a study conducted among diabetic post-menopausal women, who undertook supervised moderate walking 3 times/week for 14 weeks, while maintaining regular dietary patterns (11). However, a 16-week pedometer intervention demonstrated a non-significant decrease in weight and WC in both the intervention (−0.7 kg, −1.8 cm) and control (−0.6 kg, −0.4 cm) groups (13). Further, De Greef *et al*. reported no significant changes in weight following a 12-week cognitive-behavioral lifestyle intervention that incorporated pedometers without dietary instruction

(21). In the present study the addition of the PA component (education plus a pedometer) to the diet education resulted in an extra ~0.9 kg of weight loss (unadjusted and adjusted analyses) over the 12 week intervention. Whether education/advice based interventions can be just as, or more, successful than structured, supervised exercise programs is an important consideration in terms of cost-effectiveness and burden on staff. A number of studies have shown that a program of lifestyle advice and education is as successful in terms of weight outcomes as structured exercise programs (22, 23).

LMD community members have identified lack of diet knowledge, intake of unhealthy foods and lack of PA as the top three problems associated with poor health (24). Much work has been done to describe LMD dietary intake and eating patterns (2, 3, 25). Less work has focused on changing PA behaviors in the context of weight loss and maintenance in LMD adults. Kennedy *et al*. reported a 3.3 kg weight loss after a 6-month church-based program for African-Americans (26). Although weight was not a primary outcome, WC decreased by 3.5 cm after an quasi-experimental 6-month LMD walking intervention reporting increased minutes spent walking after 3 months (27). Another short-term LMD intervention demonstrated an MVPA increase of ~3 min/day following a single week PA education intervention in 43 rural LMD participants (28). In the context of these past results, our increase of up to 11 min/day is encouraging but further work is required to elucidate why some participants are more successful than others at increasing their MVPA.

Pedometer-based interventions consistently elicit short-term increases in steps/day. Specifically, a meta-analysis reported that pedometer-based interventions increase steps/day by 26.9% over baseline and decrease BMI levels by 0.38 kg/m^2 (29). Although the *Physical Activity Guidelines* are based around an intensity and duration target (min/week), the impact of pedometer-based interventions on MVPA (rather than steps/day) is not well understood. An earlier pedometer-based intervention reported significant increases in accelerometer-determined steps/day but no significant increases in MVPA, possibly because baseline MVPA were already at recommended levels (mean 31 min/day) prior to intervention (21). We previously reported that LMD participants accumulated an extra ~3 min/day of MVPA with just a single week of a pedometer-based intervention (28). Ayabe *et al* delivered a 3-week intervention in a chronic disease exercise program where one group was given a 30 min/day MVPA target while the other was given a 10,000 step/day target. Although both groups increased steps/day to over 10,000 steps, only the MVPA target group increased their minutes spent in MVPA (30). It is unclear whether pedometer-based interventions may need an intensity component to encourage participants to achieve PA recommendations. Although a pedometer was used as a motivational and tracking tool in the present study, the overall message was to achieve 30 min/day of PA at a moderate intensity; step goals reflected previously determined values indicative of this amount of MVPA in LMD adults (19).

African-Americans were well represented herein. Overall, 49% (n = 99) of those screened, 47% (n = 57) of randomized participants and 46% (n = 46) of the final completed sample were African-American. In the context of pedometer-based interventions, Zoellner *et al*. pointed to a lack of efficacious evidence for African American participants changing their PA behaviors through pedometers (20), evidenced by the 93% sample of white participants in the pedometer meta-analysis (29). In the present study we found no significant differences by race in the increased amount of MVPA. Overall, White participants reduced their WC more than African-Americans in the present study, and African-Americans with higher WC at baseline had more success in reducing their WC.

Overall, incorporating pedometers as self-monitoring tools and promoting walking within the context of an education program is feasible in LMD populations (20, 28). However, large variability in participants' responses to this intervention program exists. For instance, when data were pooled across groups, mean % weight change was −2.0% (−6.3% to 2.4%) for males and −0.8% (−5.8% to 5.1%) for females (difference p = 0.047). It is possible that even within the LMD, dietary and PA programs need to be tailored specifically to address the needs of cultural sub-groups (31) to remove any disconnect between the education delivered and subsequent actions of some participants.

The strengths of this study include the use of standardized and objective assessments, as well as a randomized design with adequate statistical power. Accelerometry was used to evaluate the effects of both intervention strategies, ensuring that estimates of MVPA could be directly compared with the guidelines. We experienced 18.2% attrition and 83% adherence to the program. This compares well to other LMD studies reporting completion rates of 80 to 90% (26, 27). Unlike past pedometer-based interventions (29), African-American participants were well represented in the study and participation rates appear representative of the broader LMD region (1, 32).

The limitations of this study include the urban LMD location that mainly attracted urban LMD residents. However, East Baton Rouge Parish contains communities and neighborhoods with racial diversity and poverty levels representative of the broader LMD region. Steps Ahead focused on delivering PA education material and motivating participants towards both step-based and intensity based PA goals, which may not be preferred by African-Americans in the LMD (31). Similar to other LMD (26, 28) and pedometer-based studies (29, 33), the majority of our participants were female. Finally, the education level of our sample was relatively high compared to the broader LMD (1). Considering health literacy improves with increased educational attainment (34), and heath literacy has been linked to healthier eating in the LMD (35), an intervention in the broader LMD may need to address health literacy as a barrier.

The United States Department of Agriculture has called for research examining individual behavior change strategies to identify and facilitate adoption of best practices to increase healthy eating and PA behaviors (6). Steps Ahead has addressed this research need. The interventional strategies to deliver adapted *Dietary Guidelines* were successful in reducing weight-related outcomes and addressing our primary objective of preventing unhealthy weight gain. The addition of the PA component resulted in additional changes consistent with preventing unhealthy weight gain, including an increase in MVPA. Both interventions were low-burden and well accepted (based on good adherence) by randomized participants. Future work should evaluate this model in rural regions of the LMD, expand the model to families and children to extend reach, and use Steps Ahead to set the stage for lifelong health and weight management behaviors.

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What is already known about this subject

- The obesity epidemic is more pronounced in the Lower Mississippi Delta (LMD) region of the U.S.
- Adherence to healthy eating and physical activity guidelines in this region is low
- There is a need to identify strategies to reduce unhealthy weight gain in the LMD using diet and physical activity

What this study adds

- Adapting the *Dietary Guidelines for Americans* to suit the LMD resulted in improvements in weight-related outcomes in both intervention groups
- The addition of a physical activity component resulted in additional weight-related benefits
- A low-intensity intervention was a well-accepted strategy for reducing unhealthy weight gain in the LMD

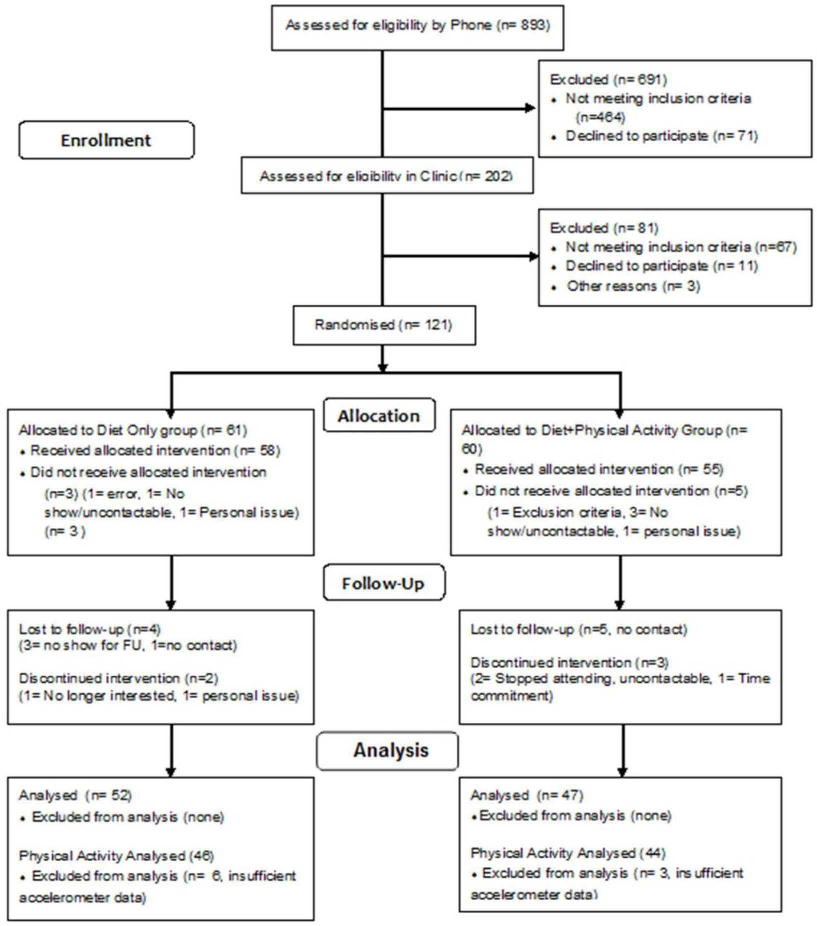

Figure 1.

CONSORT diagram showing the flow of participants through the randomized trial.

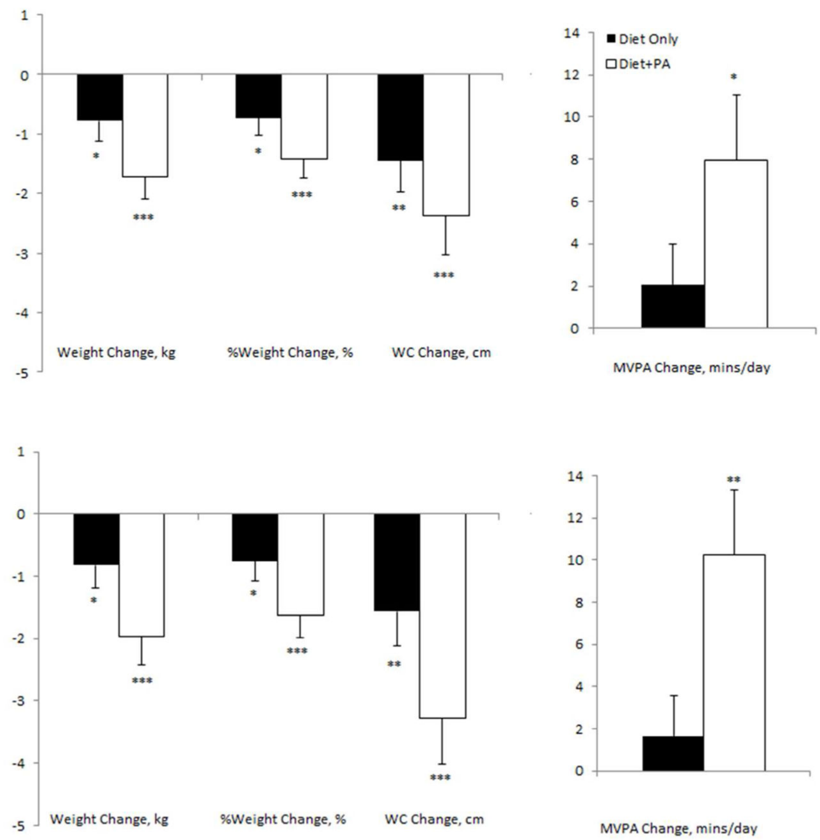

Figure 2.

Unadjusted mean change scores for the completers (top panel, n=99) and those with ≥80% attendance subset (bottom panel, n=83). Bars represent standard errors. Difference within groups from baseline to follow-up (t-test) notated by ***for $p < 0.001$; ** for $p < 0.01$; and * for $p < 0.05$.

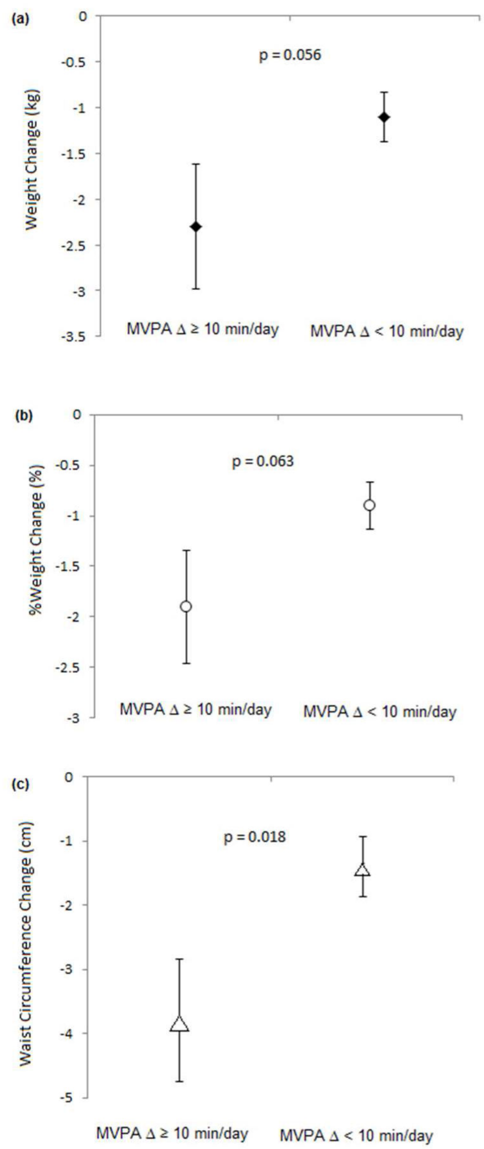

Figure 3.
Mean changes (± standard error) in (a) weight ◆; (b) % weight ○; (c) waist circumference △ by MVPA change group.

Table 1

Participant characteristics

	Completers (n = 99)			80% Attendance (n = 83)		
	DG+PA (n=47)	DG (n=52)	p-value[a]	DG+PA (n= 37)	DG (n= 46)	p-value[a]
Male, %	10.6	25.0	0.064	10.8	26.1	0.079
White, African-American, %	44.7	48.1	0.735	37.8	47.9	0.361
Education, %			0.080			0.108
< Some High School	4.3	0		5.4	0	
High School Diploma/GED	14.9	15.7		13.5	17.8	
1–3 Years in College	17.0	31.4		13.5	28.9	
College Degree	40.4	17.6		43.3	20.0	
Postgraduate Degree	23.4	35.3		24.3	33.3	
Household Income (USD), %			0.622			0.661
< 30,000/yr	13.1	17.6		16.7	17.7	
30,000 – 49,000/yr	21.7	19.6		11.1	20.0	
50,000 – 69,999/yr	17.5	19.6		22.2	17.8	
70,000 – 89,999/yr	13.0	15.7		16.7	15.6	
90,000 – 109,999/yr	21.7	9.8		19.4	8.9	
≥110,000	13.0	17.7		13.9	20.0	
Age, yrs	53.3 (7.5)	50.6 (8.2)	0.092	55.1 (5.7)	50.9 (7.9)	0.008
Weight, kg	82.5 (11.1)	86.7 (11.1)	0.064	82.7 (11.7)	86.2 (11.1)	0.166
BMI, kg/m^2	29.4 (2.7)	31.3 (2.3)	< 0.001	29.4 (2.9)	31.2 (2.3)	0.003
WC, cm	95.7 (9.2)	99.5 (9.8)	0.049	96.5 (9.8)	99.0 (9.8)	0.249
Accelerometer	n=44	n=46		n=35	n=41	
Wear-time, min/day	896 (105)	867 (94)	0.154	897 (101)	858 (69)	0.060
MVPA, min/day	16 (17)	15 (12)	0.676	16 (18)	16 (12)	0.824
Steps/day	6331 (2544)	5859 (1797)	0.315	6157 (2272)	5843 (1758)	0.499

Note: Continuous variables presented as mean (standard deviation).

[a] $\chi 2$ test for categorical variables and t-tests for continuous variables between groups at baseline.

Table 2

Adjusted means (95% CIs) for changes in weight-related outcomes and physical activity in those who completed the intervention and those with ≥ 80% attendance

	Completers (n=99)			80% Attendance Subset (n=83)		
Variable	**DG+PA (n=47)**	**DG (n=52)**	**p-value**	**DG+PA (n= 37)**	**DG (n=46)**	**p-value**
Weight, %	−1.9 (−2.6, −1.1)	−1.0 (−1.7, −0.3)	0.047	−2.0 (−3.0, −1.1)	−1.0 (−1.8, −0.2)	0.043
Weight, kg	−2.1 (−3.1, −1.2)	−1.1 (−1.9, −0.2)	0.041	−2.2 (−3.3, −1.0)	−1.1 (−2.0, −0.1)	0.071
Waist, cm	−2.9 (−4.3, −1.4)	−1.4 (−2.7, −0.1)	0.075[a]	−3.3 (−5.0, −1.6)	−1.3 (−2.7, 0.1)	0.046[c]
MVPA[†]	8 (3, 14)	3 (−2, 8)	0.119[b]	11 (5, 18)	3 (−2, 8)	0.023[b]

Note: All means adjusted for corresponding baseline value, sex and race; moderate to vigorous physical activity (MVPA) is also adjusted for change in wear time from baseline to follow-up;

[†]MVPA using accelerometer cut-point of ≥2020 Actigraph counts/min in groups specific sample sizes from left to right of n = 44, n = 46, n = 35 and n = 41; p-value is for main effect of group ($p < 0.05$);

[a]significant race (p = 0.003), baseline value (p = 0.026) and race*baseline value interaction (p = 0.004);

[b]MVPA changed significantly with change in wear-time (p <0.001);

[c]significant baseline value-by-group interaction (p= 0.019).