Cardiometabolic Risk Factor Response to a Lifestyle Intervention: A Randomized Trial

D.M. Harrington, Ph.D.[1,2], C.M. Champagne Ph.D., R.D.N.[2], S.T. Broyles, Ph.D.[2], W.D. Johnson, Ph.D.[2], C. Tudor-Locke, Ph.D.[2] & P.T. Katzmarzyk, Ph.D.[2]

Author Affiliations

[1]Diabetes Research Centre, University of Leicester, Leicester, UK

[2]Pennington Biomedical Research Center, Baton Rouge, Louisiana, USA

Funding source

This study was support by ARS/USDA Cooperative Agreement #58-6251-8-038 and NIH-2P30DK072476 (NORC)

Running title

Risk Factor Response to a Lifestyle Intervention

Corresponding Author

Dr Peter Katzmarzyk, Pennington Biomedical Research Centre, 6400 Perkins Road, Baton Rouge, Louisiana 70808

E: Peter.katzmarzyk@pbrc.edu T: 225-763-2536 F: 225-763-2927

ABSTRACT

Background: Strategies to increase adherence to national dietary and physical activity (PA) guidelines to improve the health in regions such as the Lower Mississippi Delta (LMD) of the United States are needed. This paper explores the cardiometabolic responses to an education and behavior change intervention among overweight and obese adults that adapted the 2010 Dietary Guidelines (DG), with and without a PA component.

Methods: White and African-American overweight and obese adults were randomized to a DG group (n=61) or a DG+PA group (n=60). Both groups received a 12-week dietary education and behavior change intervention while the DG+PA group also received a PA education and behavior change intervention with a pedometer. Changes in individual risk factors (blood pressure, fasting glucose, triglycerides, HDL-C and LDL-C) and a continuous cardiometabolic risk score were determined. General linear models compared mean changes between groups, adjusting for covariates.

Results: No main effect of intervention group was found in completers (n=99) and those who engaged with ≥80% of the intervention (n=83) for individual risk factors or the continuous risk score. Pooling both groups, those with higher baseline risk factor values realized greater improvements in individual risk factors.

Conclusions: Adapting DG did not produce any cardiometabolic benefits even with a PA component. Although the sample was ostensibly healthy they were all overweight to mildly obese (BMI of 25-34.9 kg/m^2) and participants with higher baseline risk factor values showed more improvements. Adherence to longer-term behavior change may elicit changes in risk profile so this should be explored.

BACKGROUND

The Lower Mississippi Delta (LMD) has a higher prevalence of chronic disease including obesity, cardiovascular disease and type 2 diabetes (T2D) compared to national averages.[1] Socioeconomic factors such as lower education levels,[2] dietary habits such as low adherence to dietary reference intakes[3,4] and behavioral factors such as insufficient physical activity (PA)[1] all contribute to the disease burden. There is a need to identify strategies to increase adherence to national dietary and PA guidelines[5,6] in an effort to improve the cardiometabolic health of this population. Little work has been done in the LMD using randomized study designs to elucidate the effects of interventions that are specifically tailored for LMD residents.

The purpose of this paper was to determine whether the addition of a PA component to a dietary education and behavior change program, 'Steps Ahead', could improve cardiometabolic profiles more than the dietary education and behavior change alone in a biracial sample of overweight and obese adults from the LMD.

METHODS

The Steps Ahead study procedures were approved by the Pennington Biomedical Institutional Review Board and participants provided signed informed consent. Recruitment was via local media, web advertisements and community events. Those who

were interested in participating self-reported their age, race/ethnicity, height and weight to recruiting staff.

Potential participants were scheduled for their first visit if they reported age between 35-64 years and having a body mass index (BMI) between 25-34.9 kg/m^2. This took place in the out-patient research clinic at Pennington Biomedical Research Center, Baton Rouge, Louisiana. Additional inclusion criteria collected at this visit included: 1) objectively confirmed BMI and 2) being physically capable of undertaking PA. Exclusion criteria were: 1) blood pressure (BP) ≥160 mm/Hg systolic or ≥100 mm/Hg diastolic; 2) fasting total cholesterol ≥240 mg/dL accompanied by LDL-C ≥160 mg/dL or TG ≥300 mg/dL; 3) uncontrolled or undiagnosed T2D; 4) current/past history of a medical condition that could interfere with exercise; 5) females who were pregnant or planning to become pregnant within 4 months.

Participants reported to the study clinic following an overnight fast and having refrained from PA for 24 hours. Height, weight, waist circumference (WC) and BP were measured and a fasting blood sample was taken by blinded clinical staff. Participants wore an Actigraph GT3X+ (ActiGraph LLC, Ft. Walton Beach, FL) accelerometer for 8 days and the data were reduced as described previously.[7] Dietary intake (kcal/day) for the past month (with portion sizes) was assessed using National Cancer Institute's Diet History Questionnaire (see http://appliedresearch.cancer.gov/dhq2/webquest/). Participants were randomized into either an adapted dietary guideline group (DG) or a DG plus PA group

(DG+PA). Following the 12-week intervention, all participants underwent the same testing as at baseline. Participants received a $100 gift card as compensation.

Height was measured to the nearest 0.1 cm using a wall-mounted stadiometer and weight was measured to the nearest 0.1 kg using a calibrated digital scale using standardized procedures (light clothing, no shoes). BMI was calculated as weight in kg divided by height in m^2. 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. High WC was defined as ≥102 cm for men and ≥88 cm for women.[8] BP was measured manually using a standard mercury sphygmomanometer and an appropriately sized cuff. The participant sat alone, quietly for five minutes before the measurement was taken twice with one minute between measures. A third measurement was obtained if there was ≥10 mm/Hg difference. The means for systolic (SBP) and diastolic (DBP) blood pressure were used in analyses.

Serum triglycerides, high density lipoprotein cholesterol (HDL-C) and glucose concentrations were obtained from a Beckman Coulter DXC 600 (Brea, CA), with reagents from Beckman Coulter and Trinity (Fisher Scientific, Pittsburg, PA). LDL-cholesterol (LDL-C) was calculated using the Friedewald equation where LDL-C = total cholesterol – ((triglycerides/5) + HDL-C).[9] A cholesterol ratio was also calculated by dividing HDL-C into total cholesterol.

A continuous cardiometabolic risk score was calculated similar to previous studies.[10,11] Individual cardiometabolic risk factors were standardized for the risk factor threshold from

a recent metabolic syndrome definition.[8] The criterion was subtracted from the participant's own individual risk factor value (except for HDL-C where the participants own value was subtracted from the criterion) and this was divided by the baseline sample (n=121) standard deviation (for men and women separately). These values for HDL-C, mean arterial pressure (i.e. DBP+ [SBP-DBP]/3), triglycerides, glucose and WC were summed to create the continuous standardized cardiometabolic score for both time points. A lower score indicates a more favorable metabolic profile. Baseline scores were subtracted from follow-up scores and a negative change score indicates a favorable change over time.

The Steps Ahead intervention has been described elsewhere.[7] Briefly, the 12 week education and behavior change intervention was divided into an initial adoption phase (one group session/week) for the first four weeks and a subsequent adherence phase (biweekly telephone contact by a trained interventionist) over 8 weeks, similar to other short-term behavioral interventions.[12,13] Both groups received an adapted DG education and behavior change intervention that focused on a small steps approach to reducing fat, increasing fruits and vegetables and promoting the DASH diet,[14] all of which are consistent with the *Dietary Guidelines for Americans.*[5] The DG+PA group received an additional four PA education and behavior change lesson plans and were encouraged to increase the number of steps/day to a target of ~8300-9100 steps/day[15] using a pedometer (Omron HJ151, Omron Healthcare, Kyoko City, Japan). Strategies including goal setting, motivational interviewing and self-monitoring were included and both the

dietary and PA messages were tailored to the local population (i.e. referencing local foods and addressing barriers to being active that may be specific to the LMD).

The outcomes of interest in this analysis were change in individual cardiometabolic risk factors and change in the continuous cardiometabolic risk score. These risk factors were screened for outliers and any values that were ≥3 standard deviations above the sample mean were removed (8 individual data points removed). Descriptive baseline characteristics of were compared using t-tests. All completers were analyzed regardless of the number of sessions attended or phone calls received (completers analysis; n=99). A sub-analysis was also conducted using only data from returning participants who completed ≥80% of the intervention (80% attendance analysis; n=83). T-tests were used to highlight significant changes in the risk score within each group over time. General linear models, with least square means, were used to compare mean change scores between groups after adjustment for covariates. Model 1 included race and sex while model 2 also included the baseline value. Interaction terms (race-by-group, race-by-baseline value, sex-by-group and group-by-baseline value) were also included in the models and were subsequently removed if not significant. All analyses were completed using SAS 9.3 (SAS Institute Inc., Cary, NC, USA).

This study was powered for the primary outcome of body weight change with a sample size of 60 participants/group providing at least 81% power for detecting differences between groups of at least 1.5 kg. A post-hoc power calculation found that the sample

sizes used in this analysis (n=49 and n=42) would provide power of at least 80% to detect the difference of 1.7 in mean cardiometabolic risk score between groups.

RESULTS

Overall, 121 participants were randomized to the DG group (n=61) and DG+PA group (n=60) (Figure 1). Data were available on 99 participants and this represents a loss to follow-up rate of 14.7% in the DG group and 21.7% in the DG+PA group. No adverse events were reported to the clinic or intervention staff. Table 1 displays the participant characteristics of the 99 completers at baseline. Participants in the DG group had higher BMI ($p<0.001$), had a less favorable cardiometabolic risk score ($p=0.047$) compared to those in the DG+PA group at baseline. There were no significant differences in demographic or cardiometabolic risk factors between those who dropped (n=22) and those who completed the intervention (n = 99). Using a recent definition of metabolic syndrome,[8] at baseline 98% of the sample had high WC, 32.6% had high BP, 32.6% had low HDL-C, 16.8% had high triglycerides and 22.7% had high fasting glucose.

Both of the groups significantly decreased self-reported energy intake from baseline to follow-up (1679 to 1254 kcal/day in DG, $p<0.01$; 1705 to 1231 kcal/day in DG+PA, $p<0.01$); but the changes were not significantly different between the groups. As reported previously,[7] there were no significant differences in changes in moderate-to-vigorous physical activity (MVPA) between the two groups for all completers; however, participants

in the DG+PA group who completed >80% of the sessions significantly increased MVPA compared to the DG group.[7]

Figure 2 (panel a) shows the unadjusted change in cardiometabolic risk score.. A negative value is more favorable in this context. There were no significant changes from baseline to follow-up in the DG group (p=0.724) or the DG+PA group (p=0.076). Adjusted change scores for each risk factor from baseline to follow-up are shown in Table 2. None of the interaction terms were significant so were removed. There was no significant main effect for group or race for any risk factor but, in model 2, there was a significant main effect of baseline value for SBP, DBP, triglycerides, LDL-C, HDL-C and cholesterol ratio (all p<0.001), for fasting glucose (p=0.011), for total cholesterol and the cardiometabolic risk score (both p=0.005).

Whether adjusting for weight change would uncover significant group differences was explored. When % weight change was included in Model 2 above, the effect of % weight change was significant for triglycerides (p=0.03) and for cardiometabolic risk score (p=0.001) while the significant effects of baseline values reported for Model 2 in Table 2 remained.

The same unadjusted and adjusted analyses were completed when just those who attended ≥ 80% of the intervention were considered (n=83). Figure 2 (panel b) shows the unadjusted change in cardiometabolic risk score from baseline to follow-up in just this sample. There were no significant changes from baseline to follow-up in the DG group

(p=0.917) but there was in the DG+PA group (p=0.048). In the adjusted analysis, similar to Table 2, there were no significant main effects of intervention group (results not shown).

When the whole sample was pooled, there were no correlations between change in individual cardiometabolic risk factors and change in weight related outcomes (weight, %weight, WC) or change in MVPA (results not shown). However, change in cardiometabolic risk score was positively correlated with weight change (r=0.32; p=0.002) and % weight change (r=0.33; p=0.002). Minutes spent in MVPA was divided into 2 groups, those in the top 25% of change and bottom 75% of change. There was no significant difference in risk score change between these two groups (p=0.380) with the bottom 75% changing by -0.26 and the top 25% changing by -0.59, both improvements.

DISCUSSION

The higher prevalence of chronic disease in the LMD needs urgent attention. Adherence to national dietary and physical activity guidelines is recommended to help people attain and maintain a healthy weight, reduce the risk of chronic disease and promote overall health.[5,16] Effective adaptation and communication of these guidelines is necessary with the eventual goal of achieving their wider acceptance and use. The ultimate goal of this study was a reduction in the prevalence of overweight and obesity and parallel reductions in the prevalence of cardiometabolic risk in an LMD sample. This 12 week, low burden program found that the addition of a PA component to an adapted *Dietary Guidelines* education intervention did not confer improvements in individual risk factors. Regardless of

group allocation, those with higher baseline values and those who changed their weight over time improved their risk profile more. However, those who adhered to ≥80% of their DG+PA intervention significantly reduced their cardiometabolic risk score over the 12 week program.

In our fully adjusted analysis we found no significant effect of the addition of the PA component to an adapted DG intervention on improving cardiometabolic risk factors although, as we previously reported[7], the DG+PA group increased their PA levels more (among those with >80% adherence). Other short-term studies have reported similar lack of improvements, both with and without a dietary component, using lifestyle interventions in a variety of study designs. In a 16 week pedometer intervention to increase steps/day, Tudor-Locke et al. reported no significant changes in cardiometabolic risk factors in a sample of type 2 diabetics.[13] A 12 week intervention testing dietary advice versus PA advice versus a combination of both found a decrease in total cholesterol and LDL-C for the combination group but no significant between-group differences.[17] A 12 week cognitive behavioral pedometer intervention designed to increase daily PA found no significant intervention effects on blood pressure or cholesterol.[18] Further, in a previous intervention in the LMD, SBP (-4.3 mmHg) and HDL-C (7.9 mg/dL) levels improved after a 6-month uncontrolled community-based walking intervention.[19] Conversely, a 6-month church-based weight loss intervention in the LMD foundno clinically significant change in risk factors although participants achieved weight loss.[20]

A meta-analysis of pedometer-based interventions found that pedometer use wre an effective way to decrease SBP but evidence relating to other risk factors, including lipids and glucose, was limited.[21] A review of multi-factorial prevention strategies concluded that their effects on cardiometabolic risk factors are weak but may have effects on long-term, hard clinical end-points such as mortality or cardiac events.[22] Although studies have reported short-term improvements in outcomes including weight and PA changes, short-term lifestyle interventions appears to have limited success in improving cardiometabolic risk. This lack of efficacy may be due to the short duration of evaluated programs, clinical values being normal to begin with,[21] or the studies being inadequately powered if risk factors were not the primary outcome.[23] Similar to the effects of supervised exercise studies on common risk factors,[23] there is a large amount of heterogeneity in responses to lifestyle interventions. Longer-term interventions have had mixed success. For example, Ross et al. reported no improvements in cardiometabolic risk factors following a 2 year diet and PA behavioral intervention.[24] In one of the most intensive lifestyle interventions studying long-term cardiovascular disease outcomes, the Look Ahead intensive lifestyle intervention condition produced significant improvements in lipid and glucose levels and blood pressure in diabetic participants more than the diabetes support and education condition at 1 and 4 years.[25,26]

When looking at changes in risk factors it is important to be cognizant of the participant's baseline values and the presence of, or concurrent changes in, other health-related risk factors over the intervention time-course.[27] In Steps Ahead, the risk factor mean baseline values were within the acceptable range (Table 1) based on recent cut-points. However,

as mentioned above, 33% had high BP, 33% had low HDL-C, 17% had high triglycerides and 23% had high fasting glucose based on NHLBI definitions.[8] We have previously reported that participants improved their weight status in Steps Ahead and the DG+PA group increased their MVPA levels.[7] As such, we found that changes in the risk score were correlated with changes in weight related outcomes indicating that the more the participants improved their weight status, the more their cardiometabolic profile improved. However, this is unsurprising as WC is a component of the cardiometabolic score. Similar to other studies,[12,28] changes in risk factors were not related to MVPA changes. In the adjusted analysis, we found a significant effect of baseline value indicating that those with higher risk factor levels at baseline reduced their values to a greater extent regardless of group randomization. Chan et al. reported that changes in BP following a 12 week, workplace pedometer intervention were related to higher baseline values.[12] While this could be seen as regression to the mean, these reductions are noteworthy given that Steps Ahead did not overtly target people with elevated risk factors (other than BMI) and was a relatively healthy sample.

A number of exercise studies have reported improvements in the cardiometabolic risk score used herein of magnitudes from -0.8 to -1.4.[10,11,29] We found a modest but significant decrease in the risk score of -0.6 in the unadjusted analysis of those with ≥80% attendance to the DG+PA arm. This is notable as these improvements were based on short-term diet and PA education only and not structured, supervised exercise sessions. The clinical significance of this reduction is not known at this point. Using this cardiometabolic score allows for the detection of overall changes in metabolic risk in a

seemingly healthy sample and is important when weight related changes that we previous reported[7] are considered in tandem.

The strengths of this study are the use of established evaluation methods, including a randomized comparative design. This study consisted of a biracial sample representative of the broader LMD region (45% African-American), where 47% of those randomized and 46% of completers were African-American. Steps Ahead has specifically addressed a USDA call to action that includes the facilitation of individual behavior change through research to examine the individual factors that contribute to the adoption of healthy eating and PA behaviors and to facilitate best practice adoption.[5]

The limitations of Steps Ahead include the relatively healthy sample as, although participants were specifically recruited overweight and obese adults (BMI 25-34.9), other mean risk factor values were within the normal range. The majority of Steps Ahead participants were female or urban LMD residents. However, East Baton Rouge Parish contains neighborhoods that are representative of the broader Delta region in terms of racial diversity and poverty.[2,30] Like previous studies, Steps Ahead was powered for the primary outcome of weight change rather than individual risk factors.

We have previously shown that the addition of PA to this adapted DG education and behavior change program resulted in more weight-related improvements.[7] The addition of PA to a short-term dietary intervention did not produce any cardiometabolic benefits, but participants with baseline higher risk factor values did realize greater improvements in

their risk factors. Adherence to longer-term behavior change may elicit risk profile changes so this should be explored. Weight management behaviors such as PA and healthy eating are not short-term efforts, but rather lifelong habits which can prevent the development of disease in the longer-term.

ACKNOWLEDGEMENTS

The authors acknowledge Erma Levy RD, Kathryn Wroten MS RD and the Pennington Biomedical Clinic staff. This study is registered at clinicaltrials.gov as NCT01584596. D.M.H. is supported by the NIHR Leicester-Loughborough Diet, Lifestyle and Physical Activity Biomedical Research Unit. P.T.K. is supported, in part, by the Marie Edana Corcoran Endowed Chair in Pediatric Obesity and Diabetes. This study is registered at clinicaltrials.gov as NCT01584596. STB, PTK and WDJ are supported in part by 1 U54 GM104940 from the National Institute of General Medical Sciences of the National Institutes of Health, which funds the Louisiana Clinical and Translational Science Center. The content and views are solely the responsibility of the authors and do not necessarily represent the official views of the NHS, the NIHR or the Department of Health (all UK) and the National Institutes of Health (US).

AUTHOR DISCLOSURE STATEMENT

No competing financial interests exist related to this work

REFERENCES

1. Centers for Disease Control and Prevention (CDC), Behavioral Risk Factor Surveillance System. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention; 2011.

2. Housing Assistance Council, Taking Stock. Rural People, Poverty, and Housing in the 21st Century. Washington, DC: Housing Assistance Council; 2012.

3. Champagne C.M., Bogle M.L., McGee B.B., et al., Dietary intake in the Lower Mississippi Delta region: Results from the Foods of our Delta Study. *J Am Diet Assoc,* 2004, 104:199-207.

4. McCabe-Sellers B.J., Bowman S., Stuff J.E., et al., Assessment of the diet quality of US adults in the Lower Mississippi Delta. *Am J Clin Nutr,* 2007, 86:697-706.

5. U.S. Department of Agriculture, U.S. Department of Health and Human Services, Dietary Guidelines for Americans, 2010. Washington D.C.2010.

6. Health U.S.D.o., Human S., Physical Activity Guidelines for Americans. Atlanta, GA: CDC; 2008.

7. Harrington D.M., Champagne C.M., Broyles S.T., et al., Steps ahead: A randomized trial to reduce unhealthy weight gain in the lower mississippi delta. *Obesity,* 2014.

8. Alberti K., Eckel R.H., Grundy S.M., et al., Harmonizing the Metabolic Syndrome A Joint Interim Statement of the International Diabetes Federation Task Force on Epidemiology and Prevention; National Heart, Lung, and Blood Institute; American Heart Association; World Heart Federation; International Atherosclerosis Society; and International Association for the Study of Obesity. *Circulation,* 2009, 120:1640-1645.

9. Friedewald W.T., Levy R.I., Fredrickson D.S., Estimation of the concentration of low-density lipoprotein cholesterol in plasma, without use of the preparative ultracentrifuge. *Clin Chem,* 1972, 18:499-502.

10. Camhi S.M., Stefanick M.L., Katzmarzyk P.T., et al., Metabolic syndrome and changes in body fat from a low-fat diet and/or exercise randomized controlled trial. *Obesity,* 2009, 18:548-554.

11. Johnson J.L., Slentz C.A., Houmard J.A., et al., Exercise training amount and intensity effects on metabolic syndrome (from Studies of a Targeted Risk Reduction Intervention through Defined Exercise). *Am J Cardiol,* 2007, 100:1759-1766.

12. Chan C.B., Ryan D.A., Tudor-Locke C., Health benefits of a pedometer-based physical activity intervention in sedentary workers. *Prev Med,* 2004, 39:1215-1222.

13. Tudor-Locke C., Bell R.C., Myers A.M., et al., Controlled outcome evaluation of the First Step Program: a daily physical activity intervention for individuals with type II diabetes. *Int J Obesity,* 2004, 28:113-119.

14. Sacks F.M., Svetkey L.P., Vollmer W.M., et al., Effects on blood pressure of reduced dietary sodium and the Dietary Approaches to Stop Hypertension (DASH) diet. *New Engl J Med,* 2001, 344:3-10.

15. Harrington D.M., Tudor-Locke C., Champagne C.M., et al., Step-based translation of physical activity guidelines in the Lower Mississippi Delta. *Appl Physiol Nutr Metabol,* 2011, 36:583-585.

16. U. S. Department of Health and Human Services, Physical Activity Guidelines for Americans. Atlanta, GA: CDC; 2008.

17. Kirkwood L., Aldujaili E., Drummond S., Effects of advice on dietary intake and/or physical activity on body composition, blood lipids and insulin resistance following a low-fat, sucrose-containing, high-carbohydrate, energy-restricted diet. *Int J Food Sci Nutr,* 2007, 58:383-397.

18. De Greef K., Deforche B., Tudor-Locke C., et al., A cognitive-behavioural pedometer-based group intervention on physical activity and sedentary behaviour in individuals with type 2 diabetes. *Health Edu Res,* 2010, 25:724-736.

19. Zoellner J., Connell C.L., Santell R., et al., Fit for Life Steps: results of a community walking intervention in the rural Mississippi Delta. *Progress in Community Health Partnerships: Research, Education, and Action,* 2007, 1:49-60.

20. Kennedy B.M., Paeratakul S., Champagne C.M., et al., A Pilot church-based weight loss program for African-American adults using church members as health educators: A comparison of individual and group intervention. *Ethnic Dis,* 2005, 15:373-375.

21. Bravata D.M., Smith-Spangler C., Sundaram V., et al., Using pedometers to increase physical activity and improve health. *JAMA,* 2007, 298:2296-2304.

22. Angermayr L., Melchart D., Linde K., Multifactorial lifestyle interventions in the primary and secondary prevention of cardiovascular disease and type 2 diabetes mellitus—A systematic review of randomized controlled trials. *Ann Behav Med* 2010, 40:49-64.

23. Katzmarzyk P., Lear S., Physical activity for obese individuals: a systematic review of effects on chronic disease risk factors. *Obes Rev,* 2012, 13:95-105.

24. Ross R., Lam M., Blair S.N., et al., Trial of prevention and reduction of obesity through active living in clinical settings: a randomized controlled trial. *Arch Intern Med,* 2012, 172:414-424.

25. Pi-Sunyer X., Blackburn G., Brancati F.L., et al., Reduction in weight and cardiovascular disease risk factors in individuals with type 2 diabetes: one-year results of the look AHEAD trial. *Diabetes Care,* 2007, 30:1374-1383.

26. Wing R.R., Long-term effects of a lifestyle intervention on weight and cardiovascular risk factors in individuals with type 2 diabetes mellitus: four-year results of the Look AHEAD trial. *Arch Intern Med,* 2010, 170:1566-1575.

27. Groeneveld I.F., Proper K.I., van der Beek A.J., et al., Lifestyle-focused interventions at the workplace to reduce the risk of cardiovascular disease-a systematic review. *Scand J Work Environ Health,* 2010:202-215.

28. Zoellner J., Connell C., Powers A., et al., Does a six-month pedometer intervention improve physical activity and health among vulnerable African Americans? A feasibility study. *J Phys Activ Health,* 2010, 7:224.

29. Potteiger J., Claytor R., Hulver M., et al., Resistance exercise and aerobic exercise when paired with dietary energy restriction both reduce the clinical components of metabolic syndrome in previously physically inactive males. *Eur J Appl Physiol,* 2012, 112:2035-2044.

30. United States Census Bureau, United States Census 2012: State and Country QuickFacts. 2012; http://quickfacts.census.gov/qfd/index.html. Accessed 17 July 2013.

Table 1. Participant characteristics at baseline

	DG	DG+PA	p-value[a]
N	52	47	
Male, %	25.0	10.6	0.064
White, %	51.9	55.3	0.735
Age, yrs	50.6 (8.2)	53.3 (7.5)	0.092
Weight, kg	86.7 (11.1)	82.5 (11.1)	0.064
BMI, kg/m^2	31.3 (2.3)	29.4 (2.7)	< 0.001
Waist circumference, cm	99.5 (9.8)	95.7 (9.2)	0.050
SBP, mm/Hg	124 (13)	120 (12)	0.074
DBP, mm/Hg	79 (8)	78 (7)	0.397
Total cholesterol, mg/dL	185 (30)	188 (36)	0.702
HDL-C, mg/dL	55 (12)	57 (14)	0.363
LDL-C, mg/dL	108 (24)	109 (31)	0.810
Triglycerides, mg/dL	108 (51)	89 (52)	0.073
Fasting Glucose, mg/dL	94 (10)	93 (9)	0.656
Cholesterol ratio	3.4 (1.0)	3.5 (0.8)	0.662
	N = 49	N =42	
Cardiometabolic Risk Score†	-1.41 (2.61)	-2.49 (2.49)	0.047

Note: n = 99 with follow-up data except for SBP and HDL-C n = 98; Glucose n=97; Triglycerides n = 95; cholesterol ratio n = 98 and cardiometabolic risk score n = 91. Continuous variables presented as mean (stdev). [a] t-tests for continuous variables between groups at baseline. †negative score indicates lower risk.

Table 2. Adjusted-means (95% CIs) for change scores in both groups following a 12-week intervention

	Model 1			Model 2		
	DG+PA	DG	p-value for group	DG+PA	DG	p-value for group*
SBP, mm/Hg	-2 (-6, 2)	-2 (-5, 1)	0.897	-3 (-6, 1)	-1 (-4, 2)	0.709
DBP, mm/Hg	-1 (-3, 2)	1 (-1, 3)	0.275	-1 (-3, 2)	1 (-1, 4)	0.157
Cholesterol, mg/dL	-7 (-16, 2)	-5 (-13, 2)	0.766	-7 (-16, 2)	-6 (-13, 2)	0.811
LDL-C, mg/dL	-4.9 (-12.7, 2.9)	-3.9 (-10.6, 2.8)	0.827	-4.6 (-11.9, 2.8)	-3.9 (-10.2, 2.3)	0.887
HDL-C, mg/dL	-1.6 (-4.0, 0.8)	-0.8 (-2.8, 1.2)	0.549	-1.8 (-4.1, 0.4)	-1.3 (-3.2, 0.6)	0.677
Triglycerides, mg/dL	-3.3 (-16.6, 9.9)	-1.4 (-12.6, 9.8)	0.802	-5 (-17, 6)	3 (-7, 13)	0.227
Glucose, mg/dL	-0.8 (-3.7, 2.1)	-0.8 (-3.3, 1.7)	0.982	-0.2 (-3.0, 2.6)	-0.2 (-2.7, 2.2)	0.971
Cholesterol ratio	-0.1 (-0.2, 0.1)	-0.1 (-0.2, 0.1)	0.925	-0.1 (-0.2, 0.1)	-0.1 (-0.2, 0.1)	0.993
Risk Score	-0.43 (-0.99, 0.14)	-0.07 (-0.55, 0.41)	0.273	-0.48 (-1.0, 0.06)	0.05 (-0.41, 0.53)	0.094

Note: Model 1 – adjusting for group, race, sex. Model 2 – adjusting for group, race, sex and baseline value. *significant effect of baseline value for all outcomes $p < 0.05$

Figure Labels

Figure 1. CONSORT diagram for Steps Ahead

Figure 2. Change in cardiometabolic risk score from baseline to follow-up in (a) all completers (n = 92) and (b) those who completed ≥ 80% of the intervention (n=76). A negative value indicates an improvement. Analysis only completed on those with full risk factor data. *significant difference from baseline to follow-up in DG+PA group (p=0.048).