

Feasibility Study of Behavioral Weight-Loss Program for African-American Women
Aged 35-75 Years

A Dissertation
SUBMITTED TO THE FACULTY OF
UNIVERSITY OF MINNESOTA
BY

Naira R. Zargarian, MSN, RN, FNP

IN PARTIAL FULFILLMENT OF THE REQUIREMENTS
FOR THE DEGREE OF
DOCTOR OF PHILOSOPHY

Ruth Lindquist, PhD, RN, FAAN, Adviser

August 2015

© Naira R. Zargarian

Acknowledgements

I would like to thank my academic advisor Dr. Ruth Lindquist for her incredible mentorship, tireless support and encouragement, and priceless contributions to this dissertation. Her incredible work ethics, wealth of expertise, gentle personality, yet, strong leadership have made my being in the doctoral program very memorable and life-changing. I would also like to thank my dissertation committee members Drs. Cynthia Gross, Diane-Treat Jacobson, Erica Schorr and Kay Savik for their guidance and expertise as I was progressing through my studies. I would like to thank Michelle Mathiason for her invaluable statistical advice and wealth of knowledge that she shared with me, along with patience and encouragement throughout this process. I would like to express my deepest gratitude to my friends Rodica Catrava, Sohye Lee, Christine Myers, and Lindsay Snyder for helping me in the conduct of my research; without your participation this research project would have not been completed. I would also like to thank the River of Life/Waters of Life church members for welcoming me to be a part of the S.O.A.R. project, and participating in my research.

Dedication

This dissertation is dedicated to my incredible family; without your support and encouragement I would have not been where I am now.

Abstract

Background: Obesity and being overweight are associated with many comorbid conditions, and are major contributing factors to cardiovascular disease (CVD). The increased proportion of overweight and obese individuals in Western societies over the past few decades has been attributed largely to behaviors including sedentary lifestyle and dietary excess. While genetics and aging may increase the risk of obesity and being overweight, individual, social, and environmental factors may play a significant role in the development of CVD risk factors among women. Women are at an increased risk during perimenopause when hormones change and metabolism slows. African American (AA) women are particularly at a high risk.

Objectives and Aims: Incorporating the behavioral principles identified in a review of literature, a study was conducted to determine the feasibility and potential efficacy of a 10-week weight-loss program, and to determine whether adopting healthy behaviors by focusing on creating a structured healthy environment, will improve clinical outcomes and reduce risk factors of CVD among AA women ages 35-75 compared to randomized active, control group; barriers, facilitators and lessons learned are presented.

The first aim (**Aim 1**) of the dissertation was to describe the results of a literature review that explored current research that focused on modification of behaviors of diet and physical activity, to identify short-term outcome measures that would be appropriate, feasible, and achievable for weight-loss intervention in primary care for midlife women to reduce risks and improve their cardiovascular health. A second aim (**Aim 2**) was to determine if it is feasible to operationalize and successfully implement a cohesive weight-loss program, and to foster enduring adoption of healthy nutrition and physical activity behaviors. A third aim (**Aim 3**) of this study was to determine the effect size of the program by employing additional structured content that targets the external social/environmental aspects of their life. Another aim (**Aim4**) was to

determine if, when operationalized in the context of a 10-week behavioral weight-loss program, the structured content would result in greater changes in weight and selected secondary bio-behavioral outcomes among AA women 35-75 years old compared to a group receiving unstructured, individual-focused/peer discussions. Lastly, another aim (**Aim 5**) was to evaluate satisfaction with the program and identify subjectively perceived challenges and facilitators in participation and meeting goals of the weight-loss intervention in this AA community.

Methods: Twenty-three AA women from one AA church of two campuses were recruited into a quasi-experimental randomized controlled trial that was conducted to achieve the objective and aims. Twenty-two women completed the study of the 10-week bio-behavioral weight loss program which had common dietary and physical activity content as well as separate time for structured discussion (experimental treatment group, n=11) and unstructured discussion (control group, n=11). Bio-behavioral outcomes included: adopting behavior to increase and/or meet goals of nutritional intake; adopting behavior to increase and/or meet goals of physical activity; and improving fasting blood sugar (FBS), systolic blood pressure (SBP), diastolic blood pressure (DBP), body mass index (BMI), weight, hip circumference (HC), waist circumference (WC), and waist-to-hip ratio (WHR). Challenges, facilitators and satisfaction were also assessed via a short self-administered survey with both open-ended and non-open-ended questions. Both parametric and non-parametric statistics were used to describe baseline characteristics and results and to test for within and between group differences in outcomes, and changes from pre- to post when groups were combined, and to examine correlations of selected variables. Effect sizes of the intervention for the primary and selected secondary outcome variables were calculated and expressed with Cohen's *d* statistics.

Results: The study described in this dissertation was informed by the review of literature (Chapter 2), and generated empirical findings (Chapter 3). Lessons learned and recommendations for future research (Chapter 4). Empirical results by aim are described:

Aim 1: A combination of vigorous exercise and a modified diet approach appears to be the best obesity management strategy. If confirmed in larger studies, it may be an effective non-pharmacological approach for the reduction of risk factors in the prevention and treatment of CVD.

Aim 2: The results of this study showed that it was feasible, and standard behavioral strategies were well - received, but not consistently applied by participants to attain desired weight loss. However, despite good attendance (5.9 ± 2.5 ($p=0.62$) days for experimental group, and 5.5 ± 1.7 days ($p > .05$) for active, control group), and because of a number of challenges encountered during the study, it is impossible to measure adoption of enduring healthy nutrition and physical activity behaviors.

Aim 3: The estimated effect size for change in SBP was small (0.2), and small-to-moderate (0.3) for change in weight; however, for change in DBP it was moderate (0.5), suggesting that the addition of a structured group intervention component could potentially yield a clinically significant effect on blood pressure and other variables. However, large-scale studies are needed to test this hypothesis.

Aim 4: The primary outcome measure was weight. Statistical analysis demonstrated that even though there appeared to be a small difference in weight loss between the experimental and active, control groups (2.16 ± 5.2 lbs. vs. 0.40 ± 6.4 lbs.), it was not statistically significant ($p=0.49$) due to high variability. When groups were combined, the average weight loss for the 22 women was 1.28 ± 5.8 lbs., albeit not statistically different ($p=0.31$) from baseline. There were no significant differences between groups in any of the secondary measures. The overall change in

BMI was not significant when both groups were combined (0.22 ± 0.98 , $p=0.31$). The SBP reduction for the groups when combined was 4.95 ± 14.51 mm/Hg, which was also not statistically significant ($p=0.12$). However, participants in the combined analysis were found to have statistically significant DBP improvement (6.45 ± 9.71 mm/Hg decrease, $p= 0.005$). Analyses showed statistically significant decrease in HC when the intervention groups were combined (0.7 ± 1.4 in., $p=0.03$), as well as statistically significant WC reduction (pre to post) (1.34 ± 1.6 in., $p< 0.001$).

Importantly, there was a correlation between the number of attended meetings and weight loss. Five out of 22 participants who attended at least 8 out of 10 sessions, lost more weight (6.3 lbs on average) than their counterparts attending fewer than 8 out of 10 meetings who gained an average of 0.2 lbs ($p= 0.02$). Analysis showed that there was no significant difference in the baseline weight of participants who attended the meetings 8 or more times versus less than 8 times ($p=0.82$).

Aim 5: Satisfaction with the program was excellent. All participants responded positively to the satisfaction questionnaire (100%), except for one participant in structured group (10%) and 2 in unstructured group (20%) who found it difficult to fit meetings into their schedule.

Conclusion: The study was judged overall to be feasible, and standard behavioral strategies were well- received, but not consistently applied by participants to attain desired weight loss. No statistically significant differences were observed between groups, so the groups were combined to examine overall outcomes. In combined analyses, DBP, HC and WC showed statistically significant improvements. The structured versus unstructured discussion approach as implemented in this study is a novel approach. If further developed and tested, this type of program has the potential to be a valuable non-pharmacological approach to facilitate weight loss and weight management. This study adds to the existing literature on obesity management among

AA women. Efforts to implement the protocol successfully could lead to better patient outcomes and improved quality of life for AA women.

Recommendations: Several recommendations can be made for the design of future weight-loss studies. Setting realistic goals and expectations and reviewing them throughout the study are important to maintain self-efficacy of participants. In future research, this could be measured and tracked to confirm. A change in time for conducting a study from summer when everybody is busy with other activities and taking care of children and grandchildren who are out of school, to the fall when people are ready to return to more structured routine, might yield more favorable results, including even better attendance. In future studies, it is recommended that make-up sessions be planned or other forms of content delivery (e.g., email, text messaging, and posting information on designated websites). Mid-week phone follow-up, more peer-to-peer interaction, and determination of readiness to change prior to the study enrollment and selecting only those with readiness to change could also be helpful in increasing attendance, anticipating that such participants would make an explicit commitment to the intervention schedule which would improve attendance, engagement in the protocol and improve outcomes. If possible, a “run-in” period in which women attend and perform study activities could be implemented to exclude women who do not adhere to minimal protocol requirements. This may ensure that women are recruited who are truly ready to change their lifestyle and behavior, and who may utilize study resources more fruitfully.

Table of Contents

	<u>Page</u>
Acknowledgments	i
Dedication	ii
Abstract	iii
Background	iii
Objectives and Aims	iii
Methods	iv
Results	v
Aim 1	v
Aim 2	v
Aim 3	v
Aim 4	v
Aim 5	vi
Conclusion	vi
Recommendations	vii
Table of Contents	viii
List of Tables	xii
List of Figures	xiii
Chapter 1: Introduction	1
Combat Ready: 10-10-10	2
Purpose	2
Dissertation Aims	3
Aim 1	3
Aim 2	3
Aim 3	3
Aim 4	3
Aim 5	3
Significance	3
Organization of Dissertation	4
Chapter 2: Manuscript One	6
Outcome Measures of Behavioral Weight Loss Programs in Perimenopause	7
Summary	7
Methods	10
Results	10
Study Characteristics	10
Sample Characteristics	11
Intervention Strategies	11
Exercise Only Intervention	11
Diet Only Intervention	13
Diet and Exercise Combination Intervention	31
Discussion	32
Conclusions	34

Table of Contents

	<u>Page</u>
Chapter 3: Manuscript Two.....	41
Feasibility of a Community-Based Behavioral Weight-Loss Program for African-American Woman	42
Summary	43
Theoretical Framework	46
Purpose	46
Methods	47
Design.....	47
Subjects and Setting.....	47
Power/Sample Size	48
Study Interventions	48
Structured Discussion (Experimental) Intervention Group.....	49
Unstructured Discussion (Active Control Group) Intervention	50
Study Measures.....	50
Demographic and Health-Related Variables	50
Safety.....	50
Attendance.....	51
Retention	51
Blood Pressure (mm/Hg)	51
Blood Glucose (mg/dL)	51
Weight (Pounds)	51
Height (Inches)	52
Body Mass Index (kg/m ²)	52
Waist Circumference (Inches).....	52
Hip Circumference (Inches).....	52
Waist-to-Hip Ratio.....	52
Study Procedures	52
Statistical Analysis.....	53
Human Subject Considerations	54
Results	54
Sample Characteristics.....	54
Attendance	56
Clinical Outcomes.....	57
Primary Outcome Measures.....	57
Secondary Outcome Measures	58
Effect Size Calculation.....	60
Discussion.....	60
Limitations.....	63
Conclusions.....	64

Table of Contents

	<u>Page</u>
Chapter 4: Manuscript Three	71
A Community-Based Behavioral Weight-Loss Study for African-American Women: Satisfaction, Challenges and Lessons Learned	72
Summary	73
Study Context	75
Weight-Loss Study Description	76
Participants' Perceptions	77
Participant Satisfaction	77
Participant-Perceived Obstacles to Weight Loss	78
Participant-Perceived Facilitators of Weight Loss.....	80
Investigators' Challenges, Lessons Learned and Recommendations	81
Challenges.....	81
Recruitment.....	81
Attendance	81
Dietary Interventions	82
Physical Activity.....	83
Commitment	84
Lessons Learned and Recommendations	84
Recruitment.....	84
Lesson Learned.....	85
Attendance	85
Lesson Learned.....	85
Lesson Learned.....	86
Lesson Learned.....	86
Dietary Interventions	87
Lesson Learned.....	87
Lesson Learned.....	88
Physical Activity.....	89
Lesson Learned.....	89
Conclusion	89
Chapter 5: Discussion.....	99
Chapter 2 (Manuscript One) Results	99
Chapter 3 (Manuscript Two) Results.....	100
Chapter 4 (Manuscript Three) Results.....	100
Synthesis	101
Conclusions.....	102
Recommendations for Future Research.....	102
References.....	105
Appendix A: Southern Medical Journal Release	120

Table of Contents

	<u>Page</u>
Appendix B: Topical Outline of Weekly Shared Behavioral Weight-Loss Sessions	121
Appendix C: Topical Outline of Weekly Optimized Environmental Changes	122
Appendix D: IRB Approval.....	124

List of Tables

	<u>Page</u>
Chapter 2: Manuscript One	
Table 1 <i>Trials Utilizing Exercise as Weight-Loss Intervention to Minimize Risks Factors for CVD</i>	15
Table 2 <i>Trials Utilizing Dietary Weight-Loss Interventions to Minimize Risk Factors for CVD</i>	20
Table 3 <i>Trials Utilizing Dietary and Exercise Weight-Loss Interventions to Minimize Risk Factors for CVD</i>	25
Chapter 3: Manuscript Two	
Table 1 <i>Self-Reported Baseline Characteristics and Medical Demographics of Randomized Participants</i>	55
Table 2 <i>Baseline and Post-Intervention Measures and Comparison of Changes by Group</i>	58
Table 3 <i>The Effect Size of Intervention for the Primary and Two Secondary Outcome Variables</i>	59
Chapter 4: Manuscript Three	
Table 1 <i>Satisfaction Questionnaire</i>	78

List of Figures

	<u>Page</u>
Chapter 3: Manuscript Two	
<i>Figure 1.</i> Attendance versus weight loss scatterplot for the treatment and control groups combined	57
Chapter 4: Manuscript Three	
<i>Figure 1.</i> Perceived obstacles to successful weight loss. Perceived obstacles to weight loss are presented by the frequency with which they were identified	79
<i>Figure 2.</i> Perceived facilitators of successful weight loss.....	80

Chapter 1: Introduction

Obesity has become a global health problem and has reached an epidemic level in the world. In the United States and Europe, obesity, defined as a body mass index (BMI) $> 30 \text{ kg/m}^2$, affects approximately one-third of the total population (Liu, Hay, & Fraught, 2013). Obesity is a cause of many co-morbid conditions including depression, low self-esteem, sleep apnea, osteoarthritis, certain forms of cancer, diabetes type 2 (DM2) (Bray, 2004), and is a major contributing factor to cardiovascular disease (CVD), a leading cause of death and disability among women (American Heart Association [AHA], 2009). CVD claims the lives of almost 500,000 American women each year (Go et al., 2013). In 2007, CVD caused about 1 death per minute among women in the United States (Roger et al., 2011).

Obesity raises risks for CVD partly through effects on blood pressure, blood sugar, and blood cholesterol. It also affects insulin resistance and elevations in thrombotic markers, such as fibrinogen, and inflammatory markers, such as interleukin-6, and C-reactive protein (CRP) (Bassuk & Manson, 2008).

Weight management is now considered an essential intervention in dealing with the epidemic of obesity, and decreasing risks of CVD and all-cause mortality (Bassuk & Manson, 2008; Carroll & Dudfield, 2004). Evidence from randomized controlled trials (RCTs) indicates that exercise and dietary modifications decrease blood pressure as well as improve the lipid profile by raising high-density lipoprotein (HDL), lowering triglycerides (TG) and low-density lipoprotein (LDL) in overweight and obese adults with metabolic abnormalities (Carroll & Dudfield, 2004), and should be considered an essential part of 'behavioral or therapeutic lifestyle change'.

Peri- and postmenopausal women are at a higher risk of CVD compared with their premenopausal counterparts. Contributors to weight gain at menopause include declining

estrogen level, age-related loss of bone and muscle tissues, and lifestyle factors such as diet and decrease in energy expenditure (Lovejoy, 2008). The change in fat accumulation around the abdomen has also been implicated as the primary cause of CVD seen in women (Gohlke-Barwolf, 2000).

Combat Ready: 10-10-10

Combat Ready: 10-10-10 is a study component of the large Midwest metropolitan-area church health initiative that examined the effect of a 10-week structured educational diet and physical activity program on weight loss. Participants were randomly assigned into one of two groups. Both groups met once a week for 1-1.5 hours. During the first hour, both groups stayed together for general information about diet and exercise and behavioral strategies for weight loss (like portion size; label reading, calorie content information; calorie intake and caloric expenditures, weight maintenance strategies). For the second part, the groups were split into the experimental and control groups. These peer groups processed the information and weight-loss program materials in either a structured or an unstructured format. Each group was led by a research team member together with a designated church member.

There were weekly assignments to monitor dietary intake and physical activity in a diary or online with the aid of a smart phone application. Weekly, the research team weighed participants, and discussed physical activity and caloric/nutritional intake before the session, answered questions, and addressed concerns or difficulties participants might be having.

Purpose

The purpose of the study was to determine the feasibility and potential efficacy of a 10-week weight-loss program, and to determine whether adopting healthy behavior by focusing on creating healthy environment, will improve clinical outcomes and reduce risk factors of CVD among AA women ages 35-75 compared to a matched active control group.

Dissertation Aims

Aim 1: Describe the results of a literature review that explored current research that focused on modification of behaviors of diet and physical activity, to identify short-term outcome measures that would be appropriate, feasible, and achievable for weight-loss intervention in primary care for midlife women to reduce risks and improve their cardiovascular health.

Aim 2: Determine if it is feasible to operationalize and successfully implement a cohesive weight-loss program, to foster enduring adoption of healthy nutrition and physical activity behaviors.

Aim 3: Determine the effect size of a 10-week behavioral weight-loss program employing additional structured content that targets the external social/environmental aspects of life.

Aim 4: Determine if, when operationalized in the context of a 10-week behavioral weight-loss program, the structured content would result in greater changes in weight and selected secondary bio-behavioral outcomes among AA women 35-75 years old compared to a group receiving unstructured, individual-focused/peer discussions.

Bio-behavioral outcomes included improving fasting blood sugar (FBS), systolic blood pressure (SBP), diastolic blood pressure (DBP), body mass index (BMI), weight, hip circumference (HC), waist circumference (WC), and waist-to-hip ratio (WHR).

Aim 5: Evaluate satisfaction and subjectively perceived obstacles and facilitators in participation and meeting the goals of the program of weight-loss intervention amongst this AA community, and lessons learned by investigators through the implementation.

Significance

Despite increasing awareness of the role of obesity in CVD, weight loss remains a problem, particularly among AA women who are largely underrepresented in the behavioral

lifestyle intervention literature (Welch, 2003; Tussing-Humphreys, Fitzgibbon, Kong, & Odoms-Young, 2013). Despite clear benefits of weight-loss programs, especially for AA women, physician care of obese patients is inadequate (Ma, Xiao, & Stafford, 2008). The study presented in this dissertation will be an invaluable non-pharmacological approach to facilitate weight loss and weight management, and will add to the existing literature on obesity management among AA women, that will lead to better patient outcomes and improved quality of life. The “lessons learned” from the conduct of the study offer helpful insights and recommendations for future studies in the area.

Organization of Dissertation

This dissertation is organized into five chapters. Chapter 1 introduces an overview of the dissertation and its aims. Chapter 2 comprises a published manuscript that reviews current research that is focused on modification of behaviors of diet and physical activity to identify short-term outcome measures that would be appropriate, feasible, and achievable for weight-loss intervention in primary care for midlife women to reduce risks and improve their cardiovascular health. In this manuscript, the relationships between strategies comprising exercise only, dietary modifications only, and exercise and dietary modifications combined, and changes in the clinical outcome measures such as body weight, HgbA1C, endothelial function, insulin resistance, cholesterol, C-reactive protein, insulin, glucose, triglycerides, and leptin, were examined. Chapter 3 comprises the manuscript that presents the intervention study that examined whether adopting healthy behavior by focusing on creating a healthy environment is feasible; it presents effect sizes, and evaluates whether the experimental environmental intervention achieves improved clinical outcomes and reduced risk factors of CVD among AA women ages 35-75 years compared to a randomized active, control group. It also discusses the major findings, and provides recommendations for future research necessary to reduce the burden of CVD risk among

AA women 35-75 years old. Chapter 4 comprises the manuscript that discusses satisfaction, facilitators and obstacles that women encountered while participating in the study, and lessons learned by the investigators that may be beneficial to other investigators who might undertake similar research. Chapter 5 presents a discussion and synthesis of the knowledge from the literature and incorporates the new knowledge gleaned from the review (Chapter 2), the feasibility study (Chapter 3) and the discussion of barriers, facilitators, and lessons learned (Chapter 4). While each chapter ends with references supporting the text of the chapter, a final cumulative, encompassing reference list is located at the end of Chapter 5.

Chapter 2: Manuscript One

Chapter 2 consists of the results of Aim 1 of the dissertation. In this chapter, a literature review that explored current research that focused on modification of behaviors of diet and physical activity to identify short-term outcome measures that would be appropriate, feasible, and achievable for weight-loss intervention in primary care for midlife women to reduce risks and improve their cardiovascular health is presented in manuscript form, as submitted to Southern Medical Journal. The copyright permission to reproduce in this dissertation is included in Appendix A. This manuscript also establishes the relationships between intervention strategies comprising exercise only, dietary modifications only, and exercise and dietary modifications combined, and changes in the clinical outcome measures.

Chapter 2: Manuscript One

Review Article

Outcome Measures of Behavioral Weight Loss Programs in Perimenopause

Naira Zargarian, MSN, RN, Ruth Lindquist, PhD, RN, Cynthia R. Gross, PhD, and

Diane Treat-Jacobson, PhD, RN

From the University of Minnesota School of Nursing, Minneapolis.

Reprint requests to Naira Zargarian, University of Minnesota School of Nursing 5-140 WDH, 308 Harvard St SE, Minneapolis, MN 55455-0342. E-mail: zarg0002@umn.edu

The authors have no financial relationships to disclose and no conflicts of interest to report.

Accepted June 17, 2014.

Southern Medical Journal, Volume 107, Number 8, August 2014

Copyright * 2014 by The Southern Medical Association 0038-4348/0-2000/107486

DOI: 10.14423/SMJ.0000000000000147

Reprinted with permission from The Southern Medical Journal

Summary: Obesity and being overweight are associated with many comorbid conditions and are major contributing factors to cardiovascular disease. The increased proportion of overweight and obese people in Western societies has been attributed largely to behaviors that include sedentary lifestyle and dietary excess. Women are at particular risk during perimenopause, when hormones change and metabolism slows. The purpose of this review was to examine published studies of weight-loss programs for perimenopausal women using behavioral change strategies of diet alone, regular physical activity alone, or both in combination to determine the range of

potential outcomes and reduction of cardiovascular risks. Based on the findings from this review, practice applications and recommendations for future research are proposed.

Key Words: behavioral weight loss interventions, obesity, perimenopausal women

Key Points

- Weight management in perimenopause is critical to prevent excess cardiovascular risk.
- Effectiveness of behavioral strategies depends on intervention intensity, adherence to physical activity and dietary recommendations, length of time, and ongoing maintenance.
- The primary care setting is ideal for identification of perimenopausal women who are overweight and obese, for implementation of behavioral lifestyle strategies to prevent the development and progression of cardiovascular disease, and the promotion of overall health and functioning.

Obesity has become a global health problem and has reached an epidemic level. In the United States and Europe, obesity, generally accepted as a body mass index (BMI) $>30 \text{ kg/m}^2$, affects approximately one-third of the total population.¹ Obesity is a cause of many comorbid conditions, including depression, low self-esteem, sleep apnea, osteoarthritis, certain forms of cancer, type 2 diabetes mellitus (DM2),² and is a major contributing factor to cardiovascular disease (CVD), a leading cause of death and disability among women.³ CVD claims the lives of almost 500,000 women each year.⁴ In 2007, CVD caused, on average, one death per minute among women in the United States.⁵

Obesity raises risks for CVD partly through effects on blood pressure, blood sugar, and blood cholesterol. It also affects insulin resistance and elevations in thrombotic markers, such as fibrinogen, and inflammatory markers, such as interleukin-6, and C-reactive protein (CRP).⁶ The Heart Disease Prevention Guidelines for Women⁷ recommend maintaining a BMI of $<25 \text{ kg/m}^2$; quitting smoking; performing 150 minutes of moderate exercise or 75 minutes of vigorous exercise

per week; eating a diet of fruits and vegetables, whole grains, and high-fiber foods; and limiting intake of saturated fat, trans fats, cholesterol, alcohol, sodium, and sugar. According to the 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults,⁸ people with hypertension aged 60 years or older need to work to achieve a blood pressure (BP) of <150/90 mm Hg and for people younger than 60 years and/or with DM or nondiabetic chronic kidney disease a BP of 140/90 mm Hg.⁸

Weight management is now considered an essential intervention in addressing the epidemic of obesity and decreasing the risks of CVD and all-cause mortality.^{6,9} Evidence from randomized controlled trials (RCTs) indicates that exercise and dietary modifications decrease blood pressure as well as improve the lipid profile by raising high-density lipoprotein (HDL) and lowering triglycerides (TG) and low-density lipoprotein (LDL) in adults with metabolic abnormalities⁹ who are overweight and obese and should be considered an essential part of behavioral or therapeutic lifestyle changes.

Perimenopausal women are at a higher risk of CVD compared with their premenopausal counterparts. Contributors to weight gain at menopause include declining estrogen level, age-related loss of bone and muscle tissues, and lifestyle factors such as diet and a decrease in energy expenditure.¹⁰ The change in fat accumulation around the abdomen also has been implicated as the primary cause of CVD seen in women.^{10,11}

Theoretical frameworks underlying obesity interventions often address motivation as a facilitating factor. There are several theories explaining behavioral changes related to obesity interventions. Bandura's self-efficacy theory emphasizes how cognitive, behavioral, personal, and environmental factors interact to determine a person's motivation and behavior.¹² Prochaska's transtheoretical model of behavior change has been the basis for developing effective interventions to promote change in health behaviors.¹³ Self-determination theory addresses

personality development, the relation of culture to motivation, and the impact that social environment has on motivation, affect, behavior, and well-being.¹⁴

Encouraging behavior to improve dietary habits and increasing physical activity are essential keys to manage weight and promote the heart health of perimenopausal women in primary care; however, it can be challenging. As such, the purpose of this review was to examine research focused on modification of diet and physical activity behaviors to identify short-term outcome measures that would be appropriate, feasible, and achievable for weight-loss intervention in primary care for women in midlife to reduce risks and improve their cardiovascular health.

Methods

Computerized and manual searches were performed using the electronic databases of PubMed, MEDLINE, CINAHL, Scopus, PsycINFO, and Google Scholar. Key words “menopause,” “obesity,” and “cardiovascular disease” were entered to retrieve the literature for the period 2003 - 2013. A manual search of article reference lists retrieved also was completed. Inclusion criteria were RCTs of exercise, diet, and a combination of exercise and diet, English language, and women 45 to 75 years old at risk for CVD.

Results

Study Characteristics

Of the 50 articles identified through the search, 13 met the inclusion criteria. The main reasons for exclusion of other articles were lack of relevance to the research question (16), duplicate studies (4), studies conducted and published before 2003 (9), and not RCTs (8). The characteristics of the included studies are presented in Tables 1 to 3. Articles identified as relevant were selected, followed by an extraction of the needed information, including authors; place of the study; trial characteristics including design, randomization, and duration; characteristics of

participants such as age group; inclusion and exclusion criteria; treatment interventions; attrition; outcome measures; and key findings.

The quality of selected RCTs was assessed by blinding, randomization, and dropouts, as it is described for each of the studies. All of the studies reported no significant differences in the main characteristics of the participants at baseline. Dropouts in the intervention and control groups ranged from 0%¹⁵ to 15%.¹⁸ Reasons for dropouts were the inability to continue training, dissatisfaction with randomization, loss to follow-up, relocation, time constraints, voluntary withdrawal, adverse effects, and equipment failure. The participants were people at risk for CVD and therapeutic interventions used were behavioral changes; dietary interventions alone; and different-intensity exercise, both alone and in combination with diet. Principal outcome measures were weight loss and biomarkers of CVD such as abnormal blood pressure, cholesterol, glucose, insulin, hemoglobin A1c (Hgb A1c), inflammatory markers, and BMI. In this review, the focus was on changes of these outcome measures that could be used in primary care to monitor intervention effectiveness.

Sample Characteristics

Participants included women and men 45 to 75 years old. The majority of studies we selected were conducted using female subjects. The literature search revealed that few trials recruit only female subjects.^{16,18,21} The data from these trials (Tables 1-3) were extracted from the female subgroup only.

Intervention Strategies

The behavioral intervention strategies for weight loss were categorized and are presented by type of intervention: exercise only, diet only, and diet and exercise combined.

Exercise Only Intervention

All exercise only studies reviewed included physical activities: high amount/vigorous-

intensity exercise (65% - 80% peak maximum oxygen consumption), low amount/vigorous intensity, low amount/moderate intensity (40% - 55% peak maximum oxygen consumption),¹⁶ and moderate-intensity exercise (45 min 5 days/week).¹⁹ One study had four groups with moderate intensity and vigorous intensity exercise with the same calorie restrictions for all groups (approximately 400 kcal/day deficit).²⁰ All exercise sessions were supervised by a certified physiologist or physician.

The value of exercise only was based on changes in the following outcome measures: body weight, Hgb A1c, endothelial function, insulin resistance, adipocytokines, total cholesterol (TC), HDL, LDL, CRP, insulin, glucose, TG, and leptin.

A study by Stensvold et al¹⁶ found that exercise alone did not contribute to weight loss or statistically significant improvement of CVD biomarkers, even though it exerted some beneficial effect on physiological abnormalities. Another study¹⁹ found no statistically significant differences between exercisers and controls in fasting blood sugar or postprandial blood sugar levels, triglyceride levels, and lipid profile, at 3 and 12 months. Results of one RCT²⁰ revealed that both exercise groups (various-intensity exercise plus calorie restriction) and control (calorie restriction only) lost weight, but found no statistically significant differences between groups. Changes in lipids, fasting glucose, insulin, or postprandial blood sugar level were similar across all of the groups. Because most of these outcomes improved in each group, the effect of weight loss itself appears to be more favorable for improving cardiovascular status than for improved fitness.²⁰ A study by Okada et al²¹ revealed that HDL and adiponectin improved in both exercise and control group ($P < 0.01$); however, CRP was not significantly changed in either group. The contradictory results of these studies suggest that exercise alone may not be effective in CVD risk reduction, and other factors such as diet modification, improved sleeping habits, stress and depression management, and smoking cessation may account for substantial decrease in CVD risk

factors.

Articles reviewed^{16,19,21} clearly demonstrated that there were no statistically significant changes in cardiac biomarkers between exercise and control groups, apart from one study²¹ that showed a slight decrease in the LDL level in both groups ($P < 0.05$). Primary care providers should be aware, however, that although exercise by itself may not affect all CVD risk factors, weight loss as a result of exercise appears to significantly improve the health and well-being of women who are overweight.

Diet Only Intervention

Strategies for weight control generally recommend the adoption of a low-fat diet, which is associated with cardiovascular risk reduction.²² Noakes et al,²² Howard et al,²³ Shai et al,¹⁸ and Azadbakht et al¹⁵ conducted studies to investigate the effects of different diets on CVD risk factors, and these resulted in consistent findings: improvement in outcome measures ($P < 0.001$) owed to weight loss rather than dietary composition. The study by Howard et al²³ revealed that a diet consisting of low-fat food plus behavioral modifications had a modest effect on weight loss and other outcome measures. Similar results were achieved by Shai et al,¹⁸ who compared the effects of low-fat diets (30%) versus moderately low-fat diets (35%), versus the Mediterranean diet with the same amount of calories, on weight loss and other CVD risk factors. Women in the Mediterranean diet group lost more weight (-6.2 kg) than women in the low-fat diet group (-0.1 kg; $P < 0.001$). Improvement in BMI, Hgb A1c, CRP, and cholesterol were noted; however, LDL did not change significantly within or among groups. In the study conducted by Azadbakht et al,¹⁵ subjects in the intervention group following a Dietary Approaches to Stop Hypertension diet experienced statistically significant improvement ($P < 0.01$) in weight loss and other outcome measures, when red meat was replaced by soy nut protein, compared with controls who ate red meat as the only source of protein.

The results of reviewed studies^{15,18,22,23} suggest that better reduction of CVD risk factors were achieved with the Mediterranean diet¹⁸ and that modest improvements in some outcome measures such as CRP, HDL, TC, and fasting blood sugar were the result of weight loss rather than dietary composition ($P < 0.05$). None of the reviewed studies showed significant changes in LDL.

Table 1. Trials using exercise as weight-loss intervention to minimize risks factors for CVD

Ref, location	Design method/duration	Sample characteristics	Inclusion/exclusion criteria	Intervention/Dosage	Attrition	Outcome measures	Key findings	
							Intervention group	Control group
Stensvold et al, 2009, Norway ¹⁶	RCT, randomization by age and sex stratification; 12 wk	Obese men and women (n = 43); age 50.2 T 9.5 y	Inclusion criteria: MetS Exclusion criteria: unstable angina, HF, MI, kidney failure	Group 1: AIT treadmill walking for 43 min 3x/wk Group 2: ST for approx. 50 min 3x/wk Group 3: AIT (2x/wk) + ST (1x/wk) Group 4: ControlYregular exercise. All training was supervised by physiologist	3 subjects for refusal to train and traumatic pain	WT, FBG, HDL, Hgb A1c, TC, TG	Women: no statistically significant changes in body weight, FBG, HDL, LDL, Hgb A1c, TC	Women: no statistically significant changes in body weight, FBG, HDL, LDL, Hgb A1c, TC

Ref, location	Design method/duration	Sample characteristics	Inclusion/exclusion criteria	Intervention/Dosage	Attrition	Outcome measures	Key findings	
							Intervention group	Control group
Okada et al, 2010, Japan ²¹	RCT, simple randomization without permuted block, blinding not reported; 3 mo + 24 mo f/u	38 patients: 21 men and 17 women ages 53.3 - 70.5 y	Inclusion criteria: DM 2 Exclusion criteria: CAD, diabetic retinopathy, proteinuria, autonomic, and orthopedic disorders	Group 1: exercise Exercise: 3Y5x/wk for 75 min for 3 months with supervision Group 2: control-sedentary Both groups received comparable dietary and medical interventions for 3 mo	5 subjects in exercise group, 1 in control group (attended different clinic, angina, cerebral infarction)	BMI, HDL, Hgb A1c, LDL, CRP, FMD	Group 1: BMI: 25.7±3.2-25.3±3.4 (<i>P</i> <0.05); FMD: 7.3%±4.7% -10.9%±6.2% (<i>P</i> < 0.05); HDL: 1.17±0.22-1.33 ±0.36 (<i>P</i> <0.01); LDL: 3.34 ±0.64-2.88 T 0.79 (<i>P</i> < 0.01); CRP: no change; Hgb A1c decreased (<i>P</i> <0.01)	Group 2: women BMI: no change; FMD: no change; HDL: 1.23±0.26-1.35±0.28 (<i>P</i> < 0.05); LDL: 3.26 ±1.25-2.50± 0.74 (<i>P</i> <0.01); CRP: no change; Hgb A1c decreased (<i>P</i> < 0.01)

Ref, location	Design method/duration	Sample characteristics	Inclusion/exclusion criteria	Intervention/Dosage	Attrition	Outcome measures	Key findings	
							Intervention group	Control group
Frank et al, 2005, USA ¹⁹	RCT, randomized by BMI stratification	Postmenopausal women ages 50-75 y	Inclusion criteria: sedentary, BMI >25 kg/m ² Exclusion criteria: avid exercisers, DM 1 and 2, smoking, HT significant comorbidities	Group 1: exercise Moderate intensity (45 min 5 d/wk) for 12 mo; started at 40% of max HR for 16 min/session and increased to 60%-75% for 45 min/session by wk 8 Group 2: control: usual daily activities	3 subjects at 12 mo, reasons not indicated	Insulin, glucose, TG, leptin, IR	Group 1: insulin: 3 mo -6% ($P = 0.002$), 12 mo -4% ($P = 0.0002$); leptin: 3 mo -11% ($P = 0.001$), 12 mo -7% from baseline; IR: 3 mo -7% ($P = 0.0024$), 12 mo -2% ($P = 0.0005$); TG and glucose concentration: no change	Group 2: insulin:3 mo 9% ($P = 0.002$), 12 mo 12% ($P = 0.0002$); leptin: 3 mo -1% ($P = 0.001$), 12 mo no change ($P = 0.03$); IR: 3 mo 10% ($P = 0.0024$), 12 mo 14% ($P = 0.0005$); TG and glucose

Ref, location	Design method/duration	Sample characteristics	Inclusion/exclusion criteria	Intervention/Dosage	Attrition	Outcome measures	Key findings	
							Intervention group	Control group
								concent.
Nicklas et al., 2009, USA ²⁰	RCT, random number generation; 20 wk	112 postmenopausal women ages 50-70 y	Inclusion criteria: BMI 25-40, no HT, no smoking, sedentary (<15 min 2x/wk for 6 mo), stable weight Exclusion criteria: BP >160/90 mm Hg, depression, TG >400 mg/dL, DM 1 and 2, cancers, impaired cognition, medications affecting body weight (except thyroid statins, oral	Group 1: CR + MI exercise Group 2: CR + VI exercise Group 3: CR only Diet: - 400 kcal/d or -2800 kcal for all groups; all exercise sessions (3 d/wk) supervised	17 subjects from illness, change in work schedule, new time constraints, relocation, family circumstances, diet problems	WT, PPBS, FBS, HDL, LDL, TC	WT, PPBS, FBS, HDL, LDL, TC Group 1: CR + MI: no statistically significant changes Group 2: CR + VI: no statistically significant changes Group 3: CR: no statistically significant changes	

Ref, location	Design method/ duration	Sample characteristics	Inclusion/ exclusion criteria	Intervention/ Dosage	Attrition	Outcome measures	Key findings	
							Intervention group	Control group
			DM medication)					

AIT, aerobic interval training; BMI, body mass index; BP, blood pressure; C, control; CAD, coronary artery disease; CR, calorie restriction; CRP, C-reactive protein; CVD, cardiovascular disease; DM, diabetes mellitus; EX, exercise; FBS, fasting blood sugar; FMD, flow-mediated dilation; f/u, follow-up; HDL, high-density lipoproteins; HF, heart failure; Hgb A1c, hemoglobin A1c; HR, heart rate; HT, hormone therapy; IR, insulin resistance; LDL, low-density lipoproteins; MaxHR, maximum heart rate; MetS, metabolic syndrome; MI, myocardial infarction; PPBS, postprandial blood sugar; RCT, randomized controlled trial; ST, strength training; TC, total cholesterol; TG, triglycerides; VI, vigorous intensity; WT, weight.

Table 2. Trials using dietary weight-loss interventions to minimize risk factors for CVD

Ref, location	Design method/duration	Sample characteristics	Inclusion/exclusion criteria	Intervention/dosage	Attrition	Outcome measures	Key findings	
							Intervention group	Control group
Noakes et al, 2005, Australia ²²	RCT, randomization by parallel design: HP/LSF diet and HC/LSF diet; 12 wk	119 women ages 49±9y	Inclusion criteria: BMI 27-40 kg/m ² , Exclusion criteria: DM 1 and 2, MetS	Group 1: HP group 34% protein, 20% fat (<10% from saturated fat) and 46% from carbohydrates Group 2: HC group 17% protein, 20% fat, and 64% carbohydrates; individual consultations with 2 dietitians, alternately every 4 wk throughout study 5600 kJ (approx.. 1340 kcal)	19 subjects, reasons not indicated	WT, LDL, HDL, FBS, insulin, CRP, HCY	Group 1: weight loss; HP diet: 6.8± 3.9 kg (<i>P</i> = 0.041); LDL: -6%; HDL: -7%; Glucose: -4% as a result of weight loss (<i>P</i> <0.001); CRP -19% (<i>P</i> <0.001) with no effect on diet (<i>P</i> <0.447); HCY: no change	Group 2: HC diet: 5.4 ± 4.3 kg (<i>P</i> = 0.041); HC diet: LDL: -6%; HDL: -7%; glucose: -4% as a result of weight loss (<i>P</i> <0.001); CRP: -19% (<i>P</i> <0.001) with no effect on diet (<i>P</i> <0.447); HCY: no change

Ref, location	Design method/duration	Sample characteristics	Inclusion/exclusion criteria	Intervention/dosage	Attrition	Outcome measures	Key findings	
							Intervention group	Control group
Howard et al, 2006, USA ²³	RCT, randomized permuted block algorithm with blocks of size 5, 10, or 15, stratified by clinical center site and age; 6 y with f/u approx 8.1 y	48,835 women ages 50-79 y who participated in Women's Health Initiative Dietary Modification Trial; IG: n = 19,541 (40%); CG: n = 29,294 (60%)	Inclusion criteria: post-MI, diet with 32% fat Exclusion criteria: breast or colorectal cancer, melanoma, survival rate <3 y, alcoholism, DM 1, and frequent eating out	Group 1: IG: intensive behavior modification in groups (18 sessions 1st y and then quarterly), and individual sessions (by mail or telephone): reduce fat to 20%, increase vegetables/fruits to 5 servings and grains to 6 servings/d Group 2: CG: received diet-related educational materials	Deceased 4.9%; LTFU 1.1%; withdrew; IG: 4.7%; CG: 4.0%	WT, fatal and nonfatal CHD, fatal and nonfatal stroke, and CVD (CHD and stroke); BMI, BP, TG, lipids, glucose	Group 1: WT: -0.7 (9.0); BMI: -0.2 (2.7); WC: -0.4 (7.3); DBP: -2.6 (9.4); TG: -10.2 (32.0; <i>P</i> G 0.05); LDL: -9.7 (29.3; <i>P</i> G 0.05) Modified diet did not significantly reduce risk of CHD, stroke, or CVD, and achieved modest effects on CVD risk factors at 3 y (<i>P</i> < 0.01)	Group 2: WT: 0.6 (9.2); BMI: 0.3 (2.7); WC: 0.5 (7.7); DBP: -2.3 (9.4); TG: -6.9 (31.9; <i>P</i> < 0.05); LDL: -9.1 (29.1; <i>P</i> < 0.05)

Ref, location	Design method/du ration	Sample characteristi cs	Inclusion/exclu sion criteria	Intervention/dos age	Attrition	Outcome measures	Key findings	
							Intervention group	Control group
Shai et al, 2008 Israel ¹⁸	RCT, double-blinded, randomi zation stratified by sex, age, BMI, history of CAD and DM 2, and current statin use; 2 y	322 obese men (n = 277, 86%) and women (n = 51, 14%)	Inclusion criteria: ages 40-65 y; BMI >27 kg/m ² ; DM 2 or CAD, regardless of age and BMI Exclusion criteria: pregnant or lactating, CC 92 mg/dL, liver or GI problems, cancer, participating in another diet trial	Group 1: LFD: 1500 kcal/d for women, 1800 kcal/d for men; 30% fat, 10% SF, 300 mg cholesterol/d Group 2: MD: 1500 kcal/d for women 1800 kcal/d for men, 35% fat Group 3: LCD: 20 g carbohydrate/d for 2 mo, then up to 120 g/d; dietitian at wk 1, 3, 5, and 7 and thereafter at 6-wk intervals; total of 18 sessions/90 min each, 10 to 15 min motivational	50 subjects, reasons not indicated	Weight loss, BMI, Hgb A1c, CRP, TG, LDL, HDL, TG	Women: WT loss (kg): MD: -6.2; LCD: -2.4 (<i>P</i> <0.001) BMI: MD: -1.5 ±2.2; LCD: 1.5±2.1(<i>P</i> = 0.05) CRP: MD: -21%, LCD: -29% (<i>P</i> <0.005); SBP (mm Hg): MD: 5.5±14.3; LCD: 3.9±12.8 HDL (mg/dL): MD: 6.4; LCD: 8.4 (<i>P</i> <0.01) TG: LCD (23.7; <i>P</i> =0.03); LDL: no sign. change within or between groups FBS with DM 2: MD: -32.8 mg/dL; Hgb A1c: MD: -0.5% T 1.1%; LCD: -	Women: WT loss (kg): LFD: -0.1 (<i>P</i> <0.001); BMI: LFD: -1.0±1.4 CRP: LFD: no sign. Change; SBP: LFD: 4.3±11.8 mmHg HDL: LFD: 6.3 mg/dL TG: LFD: 2.7 LDL: no sign. changes within or between groups Hgb A1c: LFD:

Ref, location	Design method/duration	Sample characteristics	Inclusion/exclusion criteria	Intervention/dosage	Attrition	Outcome measures	Key findings	
							Intervention group	Control group
				telephone calls 6x/2 y by dietitian			.9%±0.8%	-0.4% ±1.3%
Azadbakht, et al, 2007 Iran ¹⁵	RCT, randomization not described 12 mo	42 postmenopausal women with MetS	Inclusion criteria: MetS Exclusion criteria: use of estrogen, medications for DM 1 and 2, untreated hypothyroidism, smoking, kidney or liver diseases, breast cancer	Group 1: control group; diet A (red meat DASH) Group 2: diet B (soy protein DASH) Group 3: diet C (soy nut protein DASH) Daily sessions with nutritionist by telephone; participants were visited every 2 wk for 45-60 min each	0 subjects	WT loss, FBS, HDL, LDL, TG, SBP, DBP	WT: diet B: 70.0 ± 1.8 -70.7 ± 0.9; diet C: 70.1± 0.8 -70.4± 0.8 (<i>P</i> = 0.58) FBS: diet B: 119 T 0.6Y111 T 0.9 (<i>P</i> <0.01); diet C: 118 ± 0.5 - 103 ± 0.5 (<i>P</i> < 0.01) LDL: diet B: 127 ± 2.4; diet C: 118 ± 3.0 (<i>P</i> < 0.01) TG: diet B: 239 ± 0.9 - 217 ± 0.5 (<i>P</i> < 0.01); diet C: 238 ± 0.9 - 209 ± 0.6 (<i>P</i> < 0.01) SBP, DBP: no statistically sign. changes	WT: diet A: 70.0 ± 1.9 -70.1 ± 0.9 (<i>P</i> = 0.58) FBS: diet A: 112 ± 1.0 -120 ± 0.6 (<i>P</i> < 0.01) LDL: diet A: 134 ± 3.3 (<i>P</i> < 0.01) TG: diet A: 238 ± 1.0 -228 ± 0.9 (<i>P</i> < 0.01) SBP, DBP: no statistically sign. changes

BMI, body mass index (kg/m²); CAD, coronary artery disease; CG, control group; CHD, coronary heart disease; CRP, C-reactive protein; CVD, cardiovascular disease; DASH, Dietary Approaches to Stop Hypertension; DBP, diastolic blood pressure; DM, diabetes mellitus; FBS, fasting blood sugar; f/u, follow-up; HC, high carbohydrate; HCY, homocysteine; HDL, high-density lipoprotein; Hgb A1c, hemoglobin A1c; HP, high protein; IG, intervention group; LCD, low-carbohydrate diet; LDL, low-density lipoprotein; LFD, low fat diet; LSF, low saturated fat; LTFU, lost to follow-up; MD, Mediterranean diet; MetS, metabolic syndrome; RCT, randomized controlled trial; SBP, systolic blood pressure; SF, saturated fat; TG, triglycerides; WC, waist circumference; WT, weight.

Table 3. Trials using dietary and exercise weight-loss interventions to minimize risk factors for CVD

Ref. location	Design method/duration	Sample characteristics	Inclusion/exclusion criteria	Intervention/dosage	Attrition	Outcome measures	Key findings	
							Intervention group	Control group
Imayama et al, 2012, USA ²⁵	RCT, double-blinded, computer-generated stratification by BMI and race/ethnicity; permuted blocks size 4; 12 mo	Postmenopausal women ages 50-75 y (n = 439)	Inclusion criteria: BMI >25.0 (if Asian >23.0); sedentary (<100 min/wk of moderate activity) Exclusion criteria: HT, history of breast cancer, heart disease, DM 2, smoking; alcohol intake of >2 drinks/d; unable to attend intervention sessions at study facility; abnormal exercise tolerance test	Group 1: D: goal 10% weight reduction (n = 118), BM, 2 to 4 individual sessions, then weekly in groups (5-10) until wk 24, then monthly; e-mail or phone contacts Group 2: E: 225 min/wk of MI to VI exercise (n = 117), 3 sessions/wk at facility and 2 sessions/wk at home Group 3: D, E (n = 117) Group 4: C (n = 87)	39 subjects; reasons not indicated	WT, CRP, IL-6, Leukocyte and neutrophil levels; glucose	Group 1: WT: D, E, and D + E: -8.5%, -2.4%, and -10.8%, respectively, all $P < 0.01$ CRP: E: -36.1%, $P < 0.0353$ (D + E), E: -8.5%, $P < 0.001$ (D + E), D + E: -41.7%, $P < 0.001$ (E) IL-6: D: -23.1%, $P < 0.001$ (C, D + E), E: -4.5%, $P < 0.001$ (D + E), D + E: -24.3%, $P < 0.001$ (C, D + E) Neutrophils: D: -9.6%, $P < 0.006$ (C), E: -9.0%, $P < 0.002$ (D), $P < 0.003$ (D + E), D + E: -9.0%, $P < 0.005$ (C), $P < 0.003$	Group 2: no significant changes in weight, CRP, IL-6, and leukocyte and neutrophil levels at 12 mo

Ref. location	Design method/duration	Sample characteristics	Inclusion/exclusion criteria	Intervention/dosage	Attrition	Outcome measures	Key findings	
							Intervention group	Control group
							Leukocytes: D: – 5.3%, $P < 0.019$ (C), E: -8%, $P < 0.023$ (E), D + E: – 7.2%, $P < 0.001$ (C)	
Oh et al, 2011, South Korea ²⁶	RCT, randomization by 1:2:1 ratio	Postmenopausal women ages 66.5 ± 9.5 (n = 29); mean BMI 27.3	Inclusion criteria: MetS: hypertension, diabetes, or hyperlipidemia; abdominal obesity (WC > 80 cm)	Group 1: Treatment group (n = 16): health screening (blood pressure, body weight check), education (risk factors, role of diet/exercise), exercise (supervised group exercise), diet (– 300 kcal), and counseling (30 min each)	7 subjects: because of skin problem, travel, and failure to show up for blood test	WT, IR inflammatory cytokines, FBG	Group 1: WT loss: – 4.7 kg (7.3%) MCP-1: – 16 pg/mL (5.17%, $P < 0.038$) RBP-4: no significant group x time interaction ($P < 0.871$) Fasting insulin and IR: – 0.9 IU/mL, 14.8%, $P = 0.022$ and – 0.508, 28.6%, $P = 0.006$, respectively FBS: no significant decrease ($P < 0.335$)	Group 2: WT: – 2.0 kg (3.1%) MCP-1: 71 pg/mL, 23.7% RBP-4: no significant group x time interaction ($P < 0.871$) Fasting insulin and IR: 0.9 IU/mL,

Ref. location	Design method/duration	Sample characteristics	Inclusion/exclusion criteria	Intervention/dosage	Attrition	Outcome measures	Key findings	
							Intervention group	Control group
				session) 12 sessions (3x/wk, 2 h/session) Group 2: C (n = 13)				14.8%, and 0.222, 12.4%, respectivel yFBS: no significant decrease ($P < 0.335$)
Anderson et al, 2006, Australia ³⁷	RCT, random allocation of surveys to group 1 (IG) or group 2 (C) as they were received; 12 wk	N = 113 women (IG: n = 47, C: n = 66)	Inclusion criteria: speak and understand English, 45 - 60 y	Group 1: CBS: 2 nurse Meetings (40 min each): Wk 1: individual health education, outcome measures collected, and goal setting; Wk 12: outcome measures collected	21 subjects; reasons: family health priorities, planned travel, and perceived lack of time to complete program	WT, BMI, SBP, DBP, RHR	Group1: WT:— 1.00±2.46, $P < 0.02$; BMI: — 0.37± 0.94, $P < 0.02$; DBP: 3.91±10.27, $P < 0.02$; SBP, RHR: —4.7, $P < 0.08$ and —2.61, $P < 0.19$, but did not reach significance	Group 2: WT, BMI, DBP, SBP, RHR: no significant changes

Ref. location	Design method/duration	Sample characteristics	Inclusion/exclusion criteria	Intervention/dosage	Attrition	Outcome measures	Key findings	
							Intervention group	Control group
				and records collected; e-mail and telephone calls encouraged Group 2: continue usual daily activities				
Eriksson et al., 2006, Sweden ¹⁷	RCT, random allocation by computer generated random numbers to IG (n = 75) or C (n = 76); 3 mo with 1-y f/u	N = 151 middle-aged men and women	Inclusion criteria: HTN, dyslipidemia, DM 2, obesity Exclusion criteria: CHD, stroke, TIA, uncontrolled BP, dementia, or severe psychiatric disease	Group 1: IG: E: supervised endurance and circuit training in groups 3x/wk for 3 mon; D: 5 group counseling sessions with dietitian, f/u monthly meetings with	28 subjects; IG: n = 15, C: n = 13; reasons: workload, other diseases, moved out of area, MI, pain, no show, dissatisfaction with randomization	VO ₂ , WT, LDL, BMI, SBP, DBP, TG, Hgb A1c	Women: group 1: f/u 1 y data: WT: -1.5 kg, P<0.001; DBP: -2.3 mm Hg (-4.04 to -0.51; P< 0.05) between groups (C - IG) mean change: BMI: -0.5±1.0 (P< 0.001); SBP: -4.7 ±10.5 (P< 0.001); DBP: -3.8±5.0 (P< 0.001); LDL:	Women: group 2: f/u 1 y data: WT: -0.7 kg BMI, SBP, DBP, LDL, TG, and FBG: no significant changes

Ref. location	Design method/duration	Sample characteristics	Inclusion/exclusion criteria	Intervention/dosage	Attrition	Outcome measures	Key findings	
							Intervention group	Control group
				physiotherapist Group 2: C: usual care and single meeting with doctor, dietitian, and physiotherapist			0.36 ± 0.83 (<i>P</i> < 0.01); TG: -0.28 ± 1.00 (<i>P</i> < 0.05); Hgb A1c: -0.54 ± 0.74 (<i>P</i> < 0.05)	
Foster-Schubert et al., 2012, USA ²⁴	RCT, 4-arm design, computerized program, stratified to BMI (930 and G30) and race; permuted block randomization with blocks of	N = 439 postmenopausal women	Inclusion criteria: BMI >25 exercising <100 min/wk at MI or greater Exclusion criteria: DM or medications, use of HT, history of breast cancer; alcohol in	Group 1: D WT loss (1200-to 2000-kcal diet) (n = 118) Group 2: MI to VIE (n = 117) Group 3: both interventions combined (n = 117) Group 4: no lifestyle change group (n = 87); 2 meetings with dietitian,	40 subjects; reasons: family demands, dissatisfaction with randomization, work or family demands, or injury, other medical issues unrelated	WT loss, body composition	WT loss: D: 7.2 kg (-8.5%, <i>P</i> < 0.0001); E: 2.0 kg (-2.4%, <i>P</i> = 0.034); D + E: 8.9 kg (-10.8%, <i>P</i> < 0.0001) BMI: D: -8.6% E: 2.4%; D + E: -10.3% Among postmenopausal women, lifestyle change involving diet, exercise, or both combined for 1 y improves body	WT loss: C: -0.8% BMI: -0.7%

Ref. location	Design method/duration	Sample characteristics	Inclusion/exclusion criteria	Intervention/dosage	Attrition	Outcome measures	Key findings	
							Intervention group	Control group
	4		excess of 2 drinks/d, smoker, weight-loss medications	followed by weekly meetings in groups of approx. 5-10 women, for 6 mo; mo 7-12 dietitian: 2x/mo: face-to-face and 1 by telephone or e-mail; 45 min E 5x/wk for 12 mo	to intervention		weight, BMI, and adiposity, with greatest change arising from combined intervention	

BM, behavior modification; BMI, body mass index (kg/m²); BP, blood pressure; C, control group; CBS, cognitive behavioral strategies; CHD, coronary heart disease; CRP, C-reactive protein; DBP, diastolic blood pressure; D, calorie-restricted diet; DM, diabetes mellitus; E, aerobic exercise; FBG, fasting blood glucose; f/u, follow-up; HDL, high-density lipoprotein; Hgb A1c, hemoglobin A1c; HT, hormone therapy; HTN, hypertension; IG, intervention group; IL-6, interleukin 6; IR, insulin resistance; LDL, low-density lipoprotein; MCP-1, monocyte chemoattractant protein-1; MI, moderate intensity; RBP-4, retinol-binding protein-4; RCT, randomized controlled trial; RHR, resting heart rate; SBP, systolic blood pressure; TG, triglycerides; TIA, transient ischemic attack; VI, variable intensity; VO2, maximal oxygen consumption; WC, waist circumference; WT, weight.

Primary care providers should focus more on behavioral counseling and modified dietary approaches that yield better reduction of CVD risk factors than the generally adopted low-fat-diet approach.

Diet and Exercise Combination Intervention

An RCT demonstrated that a diet and exercise combination intervention is more effective than either diet or exercise alone.²⁴ In this study, postmenopausal women were randomized to four groups: a dietary intervention (1200-2000 kcal diet) group, a moderate-to-vigorous exercise group, a diet and exercise group, and a no lifestyle change group. Results revealed that subjects in the diet and exercise group lost more weight than either diet or exercise-alone groups (-8.9 kg [-10.8%], $P < 0.0001$ vs. -7.2 kg [-8.5%], $P < 0.0001$, and -2.0 kg [-2.4%], $P = 0.034$, respectively). The control group experienced a non-significant decrease in weight (-0.8%) and BMI.

Two RCTs provided data about changes in the level of inflammatory cytokines in response to a combination of diet and exercise.^{25,26} The intervention consisted of a calorie-restricted diet (-300 kcal) with a goal of 10% weight reduction, and three sessions of supervised different-intensity exercise. Participants received health education regarding behavioral modification. Results of the first study showed that subjects in the diet and exercise group lost more weight than their counterparts ($P < 0.01$). Inflammatory biomarkers responded in a similar way: significantly greater decrease in CRP and interleukin-6 levels in the diet and exercise group compared with the diet only group or the controls (-41.7% , $P < 0.001$ vs. -36.1% , $P < 0.001$, and -24.3% , $P < 0.001$ vs. -23.1% , $P < 0.001$, respectively). In the second study, more weight loss also was achieved in the diet and exercise group than in the control group (-4.7 kg [7.3%] vs -2.0 kg [3.1%]); better reduction of the inflammatory biomarker monocyte chemoattractant protein-1 (-16 pg/mL [5.17%], $P < 0.038$ vs. 71 pg/mL [23.7%]); insulin resistance (-0.508 , 28.6% , $P = 0.006$ vs. 0.222 , 12.4%). There

was a non-significant fasting insulin decrease in both groups ($P < 0.335$).

The findings of these studies show that a combination of moderate-to-vigorous exercise and a modified diet consisting of a moderate caloric restriction is the most effective strategy for achieving clinically meaningful weight loss and has the biggest impact on reduction of CVD risk factors, especially CRP and other inflammatory biomarkers.

Not many studies provide long-term follow-up with participants of aggressive behavior modification trials. Okada et al²¹ conducted a 2-year follow-up during which it was shown that the control group developed cardiovascular events more frequently than did the exercise group ($P < 0.05$). The beneficial effect of exercise to reduce cardiovascular events persisted up to 24 months.

Shai et al¹⁸ concluded that at the 24-month mark, the overall weight changes among the 45 women were -0.1 kg (95% confidence interval [CI] -2.2 to 1.9) for the low-fat group, -6.2 kg (95% CI -10.2 to -1.9) for the Mediterranean diet group, and -2.4 kg (95% CI -6.9 to 2.2) for the low-carbohydrate group ($P < 0.001$).

Howard et al²³ determined that during a mean of 8.1 years, reduced total fat intake and increased intake of vegetables, fruits, and grains did not significantly decrease the risk of coronary heart disease, stroke, or CVD in postmenopausal women and achieved only modest effects in CVD risk factors, suggesting that more focused diet and lifestyle interventions may be needed to improve risk factors and reduce CVD risk.

Lifestyle changes involving weight loss through diet and exercise reduce risks of CVD, with the greatest change arising from weight loss resulting from the combined diet and exercise intervention.

Discussion

The findings of the present review showed that exercise alone and dietary modifications

alone were not as effective in the reduction of CVD risk factors as those interventions combined; however, weight loss as a result of these single interventions was beneficial in improving blood pressure, lipid profile, CRP, insulin resistance, Hgb A1c, and quality of life and in reducing the morbidity and mortality rates in perimenopausal women.²⁶

Evidence increasingly supports women becoming vulnerable to CVD as early as perimenopause and that risks increase after menopause. Estrogen loss in perimenopause and associated abdominal obesity and insulin resistance contribute to dyslipidemia, oxidative stress, inflammation, altered coagulation, and atherosclerosis. These changes can set the stage for the modifiable cardiovascular risk factors of hypertension, dyslipidemia, and impaired glucose tolerance.²⁷

The epidemic of obesity has been attributed largely to behaviors that include sedentary lifestyle and dietary excess; however, it would be unwise to view these environmental factors in isolation from the biological factors that normally control body weight and composition. There is compelling evidence that inter-individual differences in susceptibility to obesity have strong genetic determinants,²⁸ and that the major impact of genes on human obesity may directly affect hunger, satiety, and food intake in addition to metabolic rate or nutrient breakdown.^{28,29} Monogenetic defects causing human obesity actually disrupt hypothalamic pathways and have a profound effect on satiety and food intake. Eventually, it may be necessary to reclassify obesity from a metabolic disorder to a neurobehavioral one.^{28,29}

Because known genetic defects do not fully explain the heritability of obesity, other forms of variation, such as epigenetics marks, or imprinting, must be considered.³⁰ Imprinting affects gene expression without changing the DNA sequence. Genomic imprinting is involved in differentiation, development, viability, and metabolic functions. Failures in imprinting are known to cause extreme forms of obesity and are associated with susceptibility to obesity.³¹ The

epigenetic contribution to common forms of obesity are still largely unknown, but from rare syndromes and animal models it can be concluded that likely both genetic and environmental effects on epigenetics will in turn be associated with obesity.³¹

This review provides evidence of the beneficial effects of lifestyle modifications and weight loss on the prevention of CVD among perimenopausal women. One of the limitations of the study is a small sample size. Longer and larger RCTs are needed to evaluate the dose - response relation of exercise, weight loss, and risks of CVD development. Conducting studies with extended follow-up (>12 months) also may be helpful. Additional RCTs involving obese minority populations at risk for CVD are needed. Clinical manifestations of CVD risk factors among different ethnic groups may vary.

Healthcare professionals can play a pivotal role in managing obesity by diagnosing patients at risk and providing psychosocial support to encourage therapeutic adherence.³² Although some aspects of CVD risk such as age, sex, and family history are non-modifiable, others are a result of lifestyle, which can be influenced by appropriate changes in diet and activity, as well as early pharmacologic interventions.³³

Awareness of heart disease as a leading cause of death among women is suboptimal and a gap in awareness exists between whites and racial/ethnic minorities.³³ The US Preventive Services Task Force³⁴ notes that weight loss is associated with a lower incidence of health problems and death and recommends that clinicians screen all of their patients for obesity and offer counseling and behavioral interventions to promote sustained weight loss. Despite the guidelines, physician-provided obesity care is inadequate.^{35,36}

Conclusions

A combination of vigorous exercise and a modified diet appears to be the best obesity-management strategy. If confirmed in larger studies, it may be an effective non-pharmacologic

approach for the reduction of risk factors in the prevention and treatment of CVD. Prompt recognition, diagnosis, and intervention in cases of overweight and obesity may prevent progression to DM2 and major coronary events, which are leading causes of morbidity and mortality in the world, as well as significantly improve the quality of life of perimenopausal women while reducing medical costs and the worldwide economic burden.

Little is known about genetic and obesity-related diseases among minority populations. Research is needed to determine whether public health messages aimed at reducing obesity and its consequences in racially and ethnically diverse populations may benefit from incorporating an acknowledgment of the role of genetics and epigenetics in these conditions.

References

1. Liu J, Hay J, Faught B. The association of sleep disorder, obesity status, and diabetes mellitus among US adults-The NHANES 2009-2010 survey results. *Int J Endocrinol* 2013;2013:234129.
2. Bray GA. Medical consequences of obesity. *J Clin Endocrinol Metab* 2004;89:2583-2589.
3. American Heart Association (2009). Cardiovascular disease: women's No.1 health threat. <http://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm:462778.pdf>. Accessed June 20, 2014.
4. Go AS, Mozaffarian D, Roger VL, et al. Heart disease and stroke statistics-2013 update: a report from the American Heart Association. *Circulation* 2013;127:e6-e245.
5. Roger VL, Go AS, Lloyd-Jones DM, et al. Heart disease and stroke statistics-2011 update: a report from the American Heart Association. *Circulation* 2011;123:e18-e209.
6. Bassuk S, Manson J. Lifestyle and risk of cardiovascular disease and type 2 diabetes in women: A review of the epidemiologic evidence. *Am J Lifestyle Med* 2008;2:191-213.
7. Mosca L, Benjamin EJ, Berra K, et al. Effectiveness-based guidelines for the prevention of cardiovascular disease in women-2011 update: a guideline from the American Heart Association. *Circulation* 2011;123:1243Y1262.
8. James PA, Oparil S, Carter BL, et al. 2014 evidence-based guideline for the management of high blood pressure in adults: report from the panel members appointed to the Eighth Joint National Committee (JNC 8). *JAMA*; 2014;311:507-520.
9. Carroll S, Dudfield M. What is the relationship between exercise and metabolic abnormalities? A review of the metabolic syndrome. *Sports Med* 2004;34:371-418.
10. Lovejoy JC, Champagne CM, de Jonge L, et al. Increased visceral fat and decreased

- energy expenditure during the menopausal transition. *Int J Obes (Lond)* 2008;32:949-958.
11. Gohlke-Ba'rwolf C. Coronary artery disease Vis menopause a risk factor? *Basic Res Cardiol* 2000;95(Suppl I):I77-I83.
 12. Crothers LM, Hughes TL, Morine KA. *Theory and Cases in School-Based Consultation: A Resource for School Psychologists, School Counselors, Special Educators, and Other Mental Health Professionals*, New York: Taylor & Francis, 2008.
 13. Velicer WF, Prochaska JO, Fava JL, et al. Smoking cessation and stress management: applications of the transtheoretical model of behavior change. *Homeost Health Dis* 1998;38:216-233.
 14. Deci EL, Ryan RM. Self-determination theory: a macrotheory of human motivation, development, and health. *Can Psychol* 2008;49:182-185.
 15. Azadbakht L, Kimiagar M, Mehrabi Y, et al. Soy inclusion in the diet improves features of the metabolic syndrome: a randomized crossover study in postmenopausal women. *Am J Clin Nutr* 2007;85:735-741.
 16. Stensvold D, Tjonna A, Skaug E, et al. Strength training versus aerobic interval training to modify risk factors of metabolic syndrome. *J Appl Physiol* 2010;108:804-810.
 17. Eriksson KM, Westborg CJ, Eliasson MC. A randomized trial of lifestyle intervention in primary healthcare for the modification of cardiovascular risk risk factors. *Scand J Public Health* 2006;34:453-461.
 18. Shai I, Schwarzfuchs D, Henkin Y, et al. Weight loss with a low- carbohydrate, Mediterranean, or low-fat diet. *N Engl J Med* 2008;359: 229-241.
 19. Frank LL, Sorensen BE, Yasui Y, et al. Effects of exercise on metabolic risk variables in overweight postmenopausal women: a randomized clinical trial. *Obes Res* 2005;13:615-625.

20. Nicklas BJ, Wang X, You T, et al. Effect of exercise intensity on abdominal fat loss during calorie restriction in overweight and obese postmenopausal women: a randomized, controlled trial. *Am J Clin Nutr* 2009;89:1043-1052.
21. Okada S, Hiuge A, Makino H, et al. Effect of exercise intervention on endothelial function and incidence of cardiovascular disease in patients with type 2 diabetes. *J Atheroscler Thromb* 2010;17:828-833.
22. Noakes M, Keogh JB, Foster PR, et al. Effect of an energy-restricted, high-protein, low-fat diet relative to a conventional high-carbohydrate, low-fat diet on weight loss, body composition, nutritional status, and markers of cardiovascular health in obese women. *Am J Clin Nutr* 2005;81: 1298-1306.
23. Howard BV, Van Horn L, Hsia J, et al. Low-fat dietary pattern and risk of cardiovascular disease: the Women's Health Initiative Randomized Controlled Dietary Modification Trial. *JAMA* 2006;295:655-666.
24. Foster-Schubert KE, Alfano CM, Duggan CR, et al. Effect of diet and exercise, alone or combined, on weight and body composition in overweight- to-obese postmenopausal women. *Obesity (Silver Spring)* 2012;20:1628-1638.
25. Imayama I, Ulrich CM, Alfano CM, et al. Effects of a caloric restriction weight loss diet and exercise on inflammatory biomarkers in overweight/ obese postmenopausal women: a randomized controlled trial. *Cancer Res* 2012;72:2314-2326.
26. Oh EG, Chu SH, Bang SY, et al. Effects of a therapeutic lifestyle modification program on inflammatory chemokines and insulin resistance in subjects with metabolic syndrome. *Biol Res Nurs* 2011;13:182-188.
27. Villareal DT, Miller BV 3rd, Banks M, et al. Effect of lifestyle intervention on metabolic coronary heart disease risk factors in obese older adults. *Am J Clin Nutr* 2006;84:1317-

1323.

28. O’Rahilly S, Farooqi IS. Genetics of obesity. *Philos Trans R Soc Lond B Biol Sci* 2006;361:1095-1105.
29. Alfredo Martínez J, Enríquez L, Moreno-Aliaga MJ, et al. Genetics of obesity. *Public Health Nutr* 2007;10:1138-1144.
30. Sanderson SC, Diefenbach MA, Streicher SA, et al. Genetic and lifestyle causal beliefs about obesity and associated diseases among ethnically diverse patients: a structured interview study. *Public Health Genomics* 2013;16:83-93.
31. Herrera BM, Keildson S, Lindgren CM. Genetics and epigenetics of obesity. *Maturitas* 2011;69:41-49.
32. Collins P, Rosano G, Casey C, et al. Management of cardiovascular risk in the perimenopausal woman: a consensus statement of European cardiologists and gynecologists. *Climacteric* 2007;10:508-526.
33. Mosca L, Mochari-Greenberger H, Dolor RJ, et al. Twelve-year follow-up of American women’s awareness of cardiovascular disease risk and barriers to heart health. *Circ Cardiovasc Qual Outcomes* 2010;3: 120-127.
34. US Preventive Services Task Force. Screening for and management of obesity in adults. <http://www.uspreventiveservicestaskforce.org/uspstf11/obeseadult/obesers.htm>. Published June 2012. Accessed October 24, 2013.
35. Ma J, Xiao L, Stafford RS. Adult obesity and office-based quality of care in the United States. *Obesity (Silver Spring)* 2009;17:1077-1085.
36. Fujioka K, Bakhru N. Office-based management of obesity. *Mt Sinai J Med* 2010;77:466-471.
37. Anderson D, Mizzari K, Kain V, et al. The effects of a multimodal intervention trial to

promote lifestyle factors associated with the prevention of cardiovascular disease in menopausal and postmenopausal Australian women. *Health Care Women Int* 2006;27:238-253.

Chapter 3: Manuscript Two

Chapter 3 was written as a manuscript to address the dissertation's Aims 2, 3, and 4 in the presentation of the methods and findings of the dissertational quasi-experimental randomized controlled trial of an intervention employing behavioral weight loss strategies and additional discussion components (structured application versus unstructured discussion). The common content of the intervention is included in Appendix B, and the experimental structured application component is in Appendix C. The Institutional Review Board approval to conduct the protocol is in Appendix D.

Aim 2 was to determine if it is feasible to operationalize and successfully implement a cohesive community-based behavioral weight-loss study, to foster enduring adoption of healthy nutrition and physical activity behaviors.

Aim 3 was to determine the effect size of a 10-week behavioral weight-loss program employing additional structured content that targets the external social/environmental aspects.

Aim 4 was to determine whether the implementation of the program will result in greater changes in weight and selected bio-behavioral outcomes among AA women ages 35-75 years compared to a group having unstructured, individual-focused/peer discussions, when measured from baseline to 10 weeks. Bio-behavioral outcomes include: adopting behavior to increase and/or meet goals of nutritional intake; adopting behavior to increase and/or meet goals of physical activity; and improving fasting blood sugar, blood pressure, body mass index, weight, hip and waist circumference, and waist-to-hip ratio.

**Feasibility of a Community-Based Behavioral Weight-Loss Program for
African-American Women**

Naira Zargarian, MSN, RN, FNP, PhD Candidate; Ruth Lindquist, PhD, RN, FAAN, Professor;

Cynthia R. Gross, PhD, Professor; Erica Schorr, PhD, RN, Assistant Professor;

Kay Savik, MS, Senior Statistician; Michelle Mathiason Moore, MS, Statistician;

Diane Treat-Jacobson, PhD, RN, FAAN, Associate Professor;

University of Minnesota School of Nursing, Minneapolis, MN

Corresponding author:

Naira Zargarian, MSN, RN, FNP, PhD Candidate

University of Minnesota School of Nursing

5-140 WDH

308, Harvard Street SE

Minneapolis, MN

zarg0002@umn.edu

Manuscript in preparation for submission to *Western Journal of Nursing Research*

The authors have no financial disclosures to declare and no conflicts of interest to report.

Summary

This study examined the feasibility of a behavioral weight-loss program for women as a part of health initiative at an African-American church. Women (N=23) were randomized into structured versus unstructured discussion groups. The primary outcome was weight loss; secondary outcomes included fasting blood sugar, systolic and diastolic blood pressure, body mass index, hip and waist circumference, and waist-to-hip ratio. No statistically significant differences were observed between groups, so groups were combined to examine overall outcomes. Diastolic blood pressure, and hip and waist circumferences showed statistically significant decreases. The study was feasible; standard behavioral strategies well received, but not consistently applied. For both experimental and control groups combined, the estimated effect size for change in weight was small (0.2), small-to-moderate for change in SBP (0.3), and moderate for change in DBP (0.5). Larger-scale studies are needed to test the hypothesis that a structured discussion group would have significant additional effects on these variables.

Keywords: obesity, behavioral weight-loss, African American, women, feasibility study

Feasibility of a Community-Based Behavioral Weight-Loss Program for African-American Women

Obesity has become a major global health problem and has reached an epidemic level in the world (Liu, Hay, & Faight, 2013). In the United States and Europe, obesity, defined as a body mass index (BMI) $> 30 \text{ kg/m}^2$, occurs in approximately one-third of the total population (Liu, Hay, & Faight, 2013). Obesity is a major contributing factor to cardiovascular disease (CVD), which is the leading cause of death and disability among women, claiming the lives of nearly 500,000 American women each year (American Heart Association [AHA], 2013). The rise in obesity is a key contributor to the epidemic of type 2 diabetes mellitus, greatly increasing the risk for myocardial infarction and stroke in women (AHA). Obesity raises the risk for CVD, partly through its effects on established risk factors such as high cholesterol, hypertension, high blood sugar, and several novel risk factors, including insulin resistance, and inflammatory markers, such as interleukin-6, tumor necrosis factor- α , and C-reactive protein (Bassuk & Manson, 2008).

It has been demonstrated that when women go through menopause, they specifically gain visceral fat (Lovejoy, Champagne, de Jonge, Xie, & Smith, 2008). This change in fat accumulation coincides with an expected decrease in serum estradiol and decrease in energy expenditure. The increase in visceral body fat during menopause, combined with other related metabolic changes, has been implicated as the primary cause of CVD in middle-aged women (Gohlke-Barwolf, 2000). While genetics and aging may increase the risk of obesity and being overweight, individual, social, and environmental factors may also play a significant role in the development of CVD risk factors among women (Keller et al., 2010). Low socioeconomic status, low educational attainment, unemployment, and poverty have also been associated with obesity and being overweight (Kaplan, Huguet, Newsom, & McFarland, 2004).

Members of specific ethnic groups, including African Americans (AA), are at an increased risk of CVD. In 2009, CVD caused the deaths of 48,070 AA females. While the overall death rate from CVD per 100,000 was 236 in 2009, the death rate for AA females was 268 (American Heart Association, 2013).

Mensah, Mokdad, Ford, Greenlund, and Croft (2005), and Williams (2009) found marked health disparities across racial groups exist in the prevalence, morbidity, and mortality associated with CVD and their major risk factors. Their analysis indicates that these disparities are explained by both biological risk factors and social and environmental determinants of CVD, and appear to play a key role in the differences in the overall decreased life expectancy and lower quality of life of AA relative to Caucasian counterparts.

Weight management is now considered an essential strategy to combat the epidemic of obesity and type 2 diabetes, and to decrease risks of CVD and all-cause mortality. Behavioral weight-loss interventions have been studied for over 30 years (Wadden, Butryn, & Byrne, 2004) and typically consist of diet, exercise, and behavior therapy. Typical behavioral modification strategies include self-monitoring, goal setting, shaping, reinforcement, and stimulus control (Wadden & Butryn, 2003). These strategies were operationalized in the weight-loss program delivered to participants in the present study.

AA women struggle with both weight loss and maintenance. It has been proposed that the inherent biology and social and environmental constraints of AA women unfavorably impact their adoption of behavioral lifestyle changes (Fitzgibbon, 2012). Research suggests that the inclusion of cultural adaptations (e.g., family-oriented approaches to changing eating habits, cooking healthier versions of staple foods, and communal exercise behavior) may result in more favorable weight loss and maintenance outcomes for AA women (Fitzgibbon, 2012; Fitzgibbon et al., 2005). Thus, cultural adaptations were carefully considered in the present study.

Theoretical Framework

A recent theoretical environmental approach to weight loss and weight management, “System Change Theory,” developed by Moore and Charvat (2002) informed the treatment strategy in the present work. Moore et al. proposed that instead of changing people’s minds as was historically attempted by health care professionals, efforts should be made to change their “systems” at individual, interpersonal, and environmental levels (Webel, Moore, Hanson, & Salata, 2013). Consistent with this approach, interventions were designed that emphasized strategies of “systems thinking.” It was reasoned that change could more successfully occur by conducting a series of small, self-created applications to improve health by modifying small discrete aspects of the immediate environment or to change small components of daily routines. In this process, the most successful ideas are implemented while those that do not work are discarded. Individuals self-monitor ongoing application to promote the sustainability of chosen strategies.

Purpose

The purpose of this study was to determine the feasibility and potential efficacy of a 10-week weight-loss program among AA women aged 35-75 years old, to explore whether individuals in a structured group discussion focused on applied change strategies (experimental) would exhibit improved clinical outcomes and a reduction in risk factors of CVD compared to those receiving the standard weight-loss information with unstructured discussion (control).

A secondary purpose of this study was to determine the effect size to test this intervention in a larger future clinical trial. The primary outcome was weight; secondary outcomes included fasting blood sugar, systolic blood pressure, body mass index, hip circumference, waist circumference, and waist-to-hip ratio.

The study aims were based on findings of previous studies that mainly focused on adhering to dietary and physical activity guidelines by motivating behavior change. This approach has been shown to be of limited value because of its short-lasting nature (Moore et al., 2011). Moore's work was a first of its kind, focusing on structuring changes in the environment and behavioral responses to elicit desired and more enduring weight-loss and maintenance-related behavior.

Methods

Design

This feasibility study used a two-group randomized controlled experimental design (intervention and control) with measures collected at baseline and 10 weeks. In the present work, the analysis focused on estimating the effect size. Of interest was whether the experimental treatment (structured group discussions) would add to the effectiveness of a standard behavioral weight-loss intervention on weight-loss outcomes and selected secondary variables.

Subjects and Setting

Twenty-three obese or overweight AA females 35-75 years old were recruited through a Twin Cities area church comprising two campuses. Investigators were invited to deliver a weight-loss program as a part of a church health initiative. All potential participants who expressed a desire to lose weight were screened for eligibility. The study took place on the church campus and at the church's community center.

Inclusion criteria for participation were: AA females aged 35-75 years, obese or overweight, and sedentary defined as exercise less than 2 times a week in the last 3 months. Exclusion criteria were: significant metabolic disorders (e.g., untreated hypothyroidism and diabetes type I); use of medications affecting glucose metabolism; uncontrolled blood pressure (SBP >160 mm/Hg) (unless cleared by primary care provider); dementia or other chronic mental

illness, active cancer (chemo, radiation); and previously diagnosed medical issues or other serious health problem potentially interfering with participation in the study, including conditions limiting physical activity. Physical activity eligibility/exclusion was assessed by the Physical Activity Readiness Questionnaire (PAR-Q), a 7-item ‘yes’ or ‘no’ self-screening tool that can be used to determine the safety or possible risk of exercising for an individual based upon their answers to specific health history questions (presence of heart disease; chest pain during physical activity or at rest; dizziness, balance issues, or loss of consciousness and bone or joint problems that could worsen by a change in physical activity). The PAR-Q has been found to have acceptable reliability and validity when evaluated in studies (Luz, Neto, & Farinatti, 2007; Warburton et al., 2011).

Power/sample size

This feasibility study was not powered to detect significant differences; it was conducted to generate effect sizes for variables of interest. It was established by investigators in consultation with the statistician *a priori* with support of the literature that the conduct of the protocol with the proposed sample of 10-15 per group should provide sufficient information about protocol feasibility (Hertzog, 2008) when conducted over 10 weeks.

Study Interventions

Experimental and active control groups met for shared content weekly, during which they learned standard behavioral weight-loss strategies, including goal-setting; self-monitoring; maintaining motivation; problem-solving skills; dietary and physical activity recording; reading nutritional labels, recognizing hidden sources of salt and sugar, and avoiding them; portion control and serving sizes, daily recommendations of nutrients; and relapse prevention techniques. One session was led by a personal trainer who provided physical activity recommendations, discussed ways to increase levels of activity, how to keep activity logs, how to exercise safely,

and how to overcome challenges to increasing physical activity. Another session was led by a registered dietitian, who introduced ways of healthy cooking, holiday meal preparations, overcoming negative thinking, and modifying recipes to make healthier meals.

Physical activity increase (walking) was encouraged. Each participant was given a pedometer, and it was suggested to increase walking to a goal of 10,000 steps a day (Choi, Pak, Choi, & Choi, 2007). Participants were also encouraged increase other activities as they chose.

One of the most accurate methods to calculate dietary intake is using a food record (Willett, 1998). Participants were provided education on understanding of body functioning and weight loss based on calories consumed and expended: basal metabolic rate (BMR) and total energy expenditure (TEE). To promote adherence to the recommended caloric intake calculated by the principal investigator (based on participant's BMR), and as an aid to track, monitor, and to calculate intake, HealthCheques® Daily Log (a paper check-book size tool for calculating calories and recording intake that also provides nutritional/caloric information for the most commonly consumed foods) was used. Using the log, participants were able to identify serving and portion sizes, count calories consumed daily, and track their daily physical activity: type of activity, time spent doing it, and steps taken as measured by pedometer.

The protocol called for the separation of the participants for delivery of unstructured discussion (control) and structured discussion (experimental) after a shared meeting time:

Structured discussion (experimental) intervention group (n=11) participants were assigned to receive 10 weeks of a structured group discussion intervention during which attempts were made to teach participants how to make small experimental changes (try-out changes) to their daily routine that would help them to gradually adopt new, healthier habits that would make permanent weight loss possible; with the discussions based on the weekly topics. For illustration, to increase regular physical activity, women in this group would participate in a structured

discussion to propose actual ways in which they could realistically incorporate more physical activity into their daily lives—for example, recruiting a family member or a friend and having scheduled time for daily exercise, or walking a pet daily. After a ‘mini-experiment’ was trialed and adapted, participants were encouraged to move on to the next experiment. The discussion was facilitated by a primary investigator with a designated participant as co-facilitator.

Unstructured discussion (Active control group) intervention (n=11) participants were to receive unstructured facilitated peer group discussion/interaction in conjunction with the behavioral health education for weight loss. In this group, participants were encouraged to discuss personal weight-loss experiences or their feelings and responses to the information and content of the weekly presentation. The discussion was facilitated by an investigator with a participant designated as co-facilitator.

Study Measures

Demographic and health-related variables. Standard self-reported demographic variables and health-related variables were recorded on an investigator-developed form. Variables included age, marital status, employment, education, living arrangements, and health conditions.

Safety. Safety of dietary intake was fostered by explaining the need to maintain adequate nutritional and caloric intake. Total energy expenditure, basal metabolic rate, and calories per day, based on those rates and participants’ weight-loss goals were calculated. Safety of physical activity was assessed with the use of the PAR-Q. Participants were asked at each weekly session if they had had any falls, sprains, or other pains (including chest pain) during physical activity. They were also asked to report any new energy or fatigue issues experienced, or any potential untoward symptoms experienced that could be attributable to weight-loss efforts.

Attendance was monitored by investigators at weekly meetings. A sign-in sheet was available for participants upon arrival. Individual program attendance was measured by frequency of physical presence during the 10-week program.

Retention was measured by the number of participants who completed the study. Percent retention was calculated as the number of those completing divided by number enrolled.

Blood pressure (mm/Hg) was measured using a Welch Allyn manual blood pressure monitor at baseline and upon completion of the 10-week intervention. Systolic and diastolic blood pressure were measured and recorded by investigators from the digital display per American Heart Association-recommended protocol (Smith, 2005). The owner's manual for equipment maintenance and calibration was adhered to. The validity and reliability of the blood pressure monitor was assessed and evaluated by dabl® Educational Trust Limited (2015).

Blood glucose (mg/dL) readings were obtained using the One Touch® UltraMini® blood glucose monitoring system at baseline and 10 weeks. Fasting blood glucose via finger stick and recorded by investigators. Reliability and accuracy of the One Touch® UltraMini® meter was in accordance with FDA requirements of having glucose values within $\pm 20\%$ of the laboratory measurement. Some specific situations could cause a difference of more than $\pm 20\%$, including non-fasting, dehydration, and temperature variations (<http://www.onetouch.com>). Non-fasting samples were noted in the database and were not analyzed with fasting blood glucose.

Weight (pounds) was measured using a Taylor glass digital scale at the time of enrollment and at 10 weeks without shoes wearing light clothes, at approximately the same time of a day with a scale calibrated to zero prior to use. Participants could weigh-in weekly to monitor their goal achievement of 1-2 pound weight loss per week over the 10-week period, and to assess progress toward their goal. Participants who did not lose weight discussed their physical activity, and dietary intake and eating patterns with staff. The validity of the scale was checked by placing

a standard 12-pound weight repeatedly on the scale to verify that the correct number was consistently displayed. The same scale was used for all measurements.

Height (inches) was measured using a non-stretchable tape measure attached to the wall. Per Center for Disease Control and Prevention (CDC) guidelines, subjects were standing on the floor, without shoes, and back of the head, shoulders, buttocks, and heels in contact with the wall with the tape attached to it. The ruler was positioned on the top of the head with sufficient pressure to compress the hair, and measurements were taken.

Body Mass Index (kg/m²) was measured by calculating weight in kilograms divided by height in meter squared, at the beginning and at the completion of the study.

Waist circumference (inches). To define the level at which the waist circumference was measured, the lateral border of the ilium was palpated. The measuring tape was then placed around the trunk horizontally, at the approximate midpoint between the lower margin of the last palpable rib and the top of the ileac crest (World Health Organization [WHO], 2008b).

Hip circumference (inches) was taken with a non-stretch measuring tape around the widest portion of the buttocks. Subjects were standing upright, with arms along the sides, feet spread evenly, and the weight evenly distributed across the feet (WHO, 2008b).

Waist-to-hip ratio was calculated by dividing waist circumference by hip circumference.

Study Procedures

Subjects were screened for eligibility and the reasons for exclusion were recorded. The PAR-Q was administered to potential participants to assess the safety of participation in physical activity during the study. Eligible subjects were oriented to the study; all study-related questions were addressed, and consent forms signed. Baseline measurement of weight, systolic and diastolic blood pressure, fasting blood glucose, body mass index, waist and hip circumference and waist to hip ratio were obtained. Twenty-two subjects were randomized into the active control

group (Group 1) and intervention (Group 2) and by simple randomization: pulling participant numbers from a “hat,” alternating assignment to the groups. Due to extended recruitment, and unwillingness or inability of participants to stay for the second part of each session, the planned half-hour structured and unstructured individualized weight-loss strategy sessions were implemented in full only 2 out of 9 times. Shortening the length of meetings from 2 hours to 1 hour was helpful to retain participants, maximizing the delivery of content to a fuller cohort of women.

Upon completion of the study, post-tests were administered to all participants, and findings were analyzed to evaluate potential differences in interventions, and in overall (combined group) changes in primary and secondary measures. The effect sizes of the interventions for the primary and two secondary measures were calculated.

Statistical analysis

The effect of intervention was evaluated by intention-to-treat analysis. Baseline measurements were done during the first 2-3 weeks based on participants’ attendance. Post intervention measurements were assessed at week 10 or as soon as possible for non-attendees. Potential between-group differences in baseline characteristics were examined by Student’s t-tests for continuous variables, and Fisher Exact tests were used for categorical variables. To determine whether there were within and between group differences in change from pre to post for each outcome variable, changes in the combined group from pre to post were also examined via paired t-tests for each outcome variable. Cohen’s *d* (small, $d=0.2$; medium, $d=0.5$; and large, $d=0.8$) was used to calculate effect sizes for each group (structured and unstructured) for the primary outcome variable and SBP and DBP. A *p*-value of ≤ 0.05 was considered statistically significant. Results were reported as means \pm SD. All analyses were performed with SAS software (2011).

Human subject considerations

The study was reviewed and approved by the Institutional Review Board of the University of Minnesota prior to the recruitment of subjects.

Results

Twenty-three (N=23) AA women met the eligibility criteria and signed a consent form; however, one participant did not complete pre- and post-assessments, or participate after the first session, leaving 22 women for analysis.

Sample characteristics

Even small differences between groups can be clinically important, albeit, not always statistically significant, especially with small groups. In this study, the overall distributions of baseline characteristics were quite similar in the study groups. There were no statistically significant differences between the groups for self-reported demographic and medical variables at baseline (Table 1). The participants were AA women ranging in age from 37 to 75 years, with an average BMI of 33.96 (SD=5.27). Almost half were married (45.0%); 91.0% of participants had college and graduate degrees, and 17 of 22 (73%) were employed full-time or part-time.

Table 1

Self-Reported Baseline Characteristics and Medical Demographics of Randomized Participants

Variables	Structured interventions (experimental group n=11)	Unstructured interventions (control group n=11)	Total (n=22)	P-value
Age (years)	58.4(11.0)	53.8(9.0)	56.1(10.0)	0.30
Marital status (%):				0.2
Married	7(63)	3(73)	10(45)	
not married (divorced/separated, single, widowed)	4(36)	8(27)	12(55)	
Employment (%):				0.63
full-time	7(64)	5(45)	12(55)	
part-time	1(9)	4(36)	5(23)	
Unemployed	1(9)	1(9)	2(9)	
Retired	2(18)	1(9)	3(14)	
Education (%):				1.0
high school or less	2(18)	0	2(9)	
some college and college graduate degree	7(64)	10(91)	17(77)	
graduate degree	2(18)	1(9)	3(14)	
Living arrangements (%):				1.0
Alone	2(18)	3(27)	5(23)	
with a spouse	3(27)	2(18)	5(23)	
with a family	6(55)	6(55)	12(55)	
Health conditions (%):				
high blood pressure	7(64)	6(55)	13(59)	0.67
high cholesterol	4(36)	1(9)	5(23)	0.31
heart disease	1(9)	1(9)	2(9)	0.99
diabetes type 2	3(27)	3(27)	6(27)	0.99
Other (depression, thyroid, lupus, kidney, Sjogren's disease)	3(27)	2(18)	5(23)	1.0
Medications (%):				
for blood pressure	7(64)	5(46)	12(55)	0.67
for blood sugar	1(9)	3(27)	4(18)	0.59
for cholesterol	4(36)	1(9)	5(23)	0.31
Number of medications (%):				0.56
Multiple	4(36)	3(27)	7(32)	
One	5(45)	3(27)	8(36)	
None	2(18)	5(45)	7(32)	

Note. Values are means \pm SD or N (%); $p \leq .05$

Attendance

The lowest attendance was in the mid-summer (end of June – beginning of July), when many participants were on vacation. During the summer, participants' children and grandchildren were home from school, which may have prevented them from regularly attending weekly meetings due to having to take care of them. There were also family celebrations, birthday parties, sporting events and travel that interfered with regular participation. Among other reasons was a once-a-month 'food shelf' event held by the church that many participants regularly assisted in. Occasional unanticipated unavailability of the room for meetings might have been another contributing factor; participants left before alternative arrangements were made. The mean overall attendance for the experimental group was 5.9 ± 2.5 ($p=0.62$) days, whereas the active control group was 5.5 ± 1.7 days ($p > .05$). There was a moderate-to-strong positive correlation ($R=0.446$) between the number of attended meetings and weight loss among all participants (see Figure 1). Five out of 22 participants who attended at least 8 out of 10 sessions, lost more weight (6.3 lbs. on average) than their counterparts attending fewer than 8 out of 10 meetings who gained an average of 0.2 lbs. ($p= 0.02$). There was no significant difference in baseline weights of participants who attended the meetings 8 or more times versus less than 8 times ($p=0.82$).

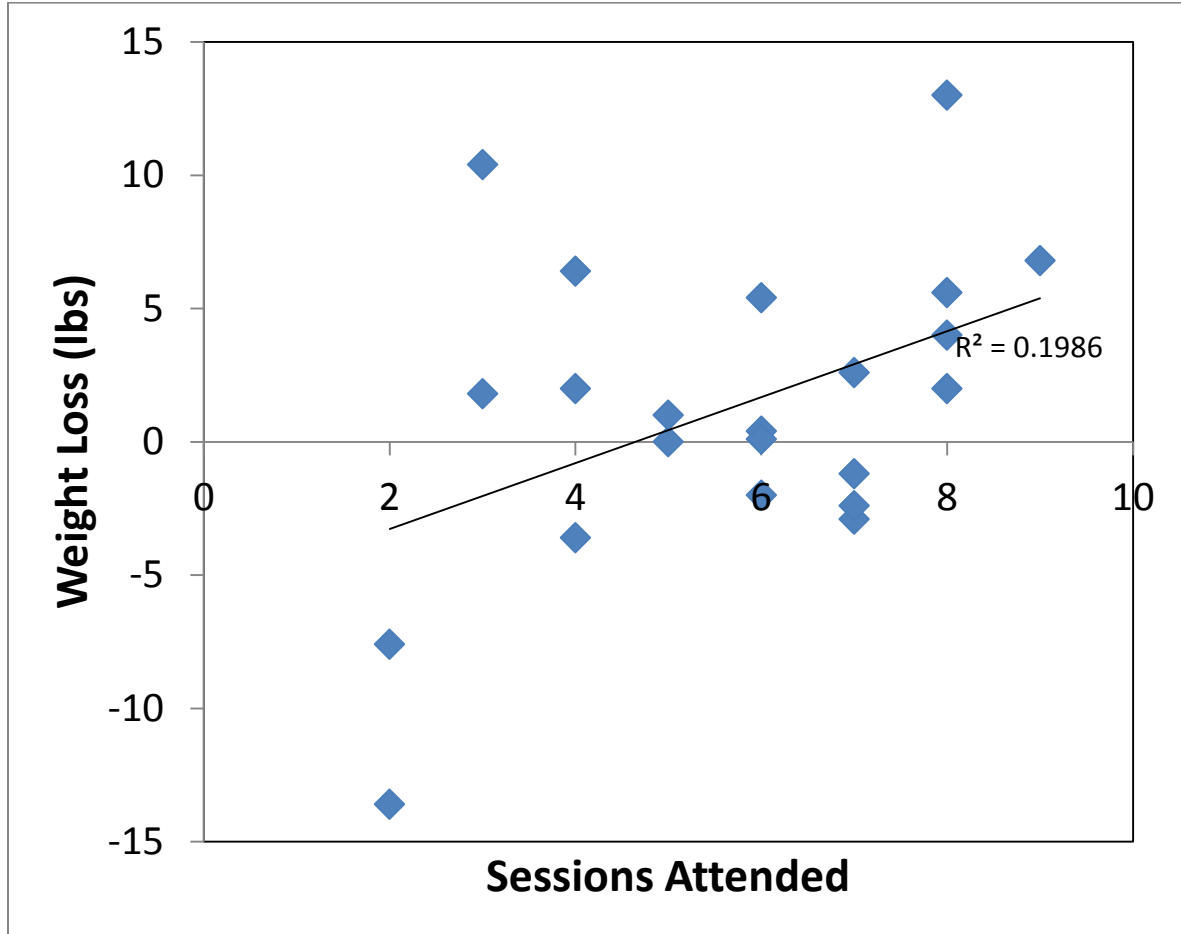


Figure 1. Attendance versus weight loss scatterplot for the treatment and control groups combined.

Clinical outcomes

Primary outcome measures. The primary outcome measure was weight. There were no significant differences between groups in baseline weights (Table 2). Although there appeared to be a small difference in weight loss between the experimental and active control groups (2.16 ± 5.2 lbs. vs. 0.40 ± 6.4 lbs.), it was not statistically significant ($p=0.49$) due to high variability. Weight change in experimental group ranged from (-6.8 lbs.) to (+7.4 lbs.), whereas the control group had weight loss change ranging from (-13.0 lbs.) to (+10.0 lbs.). When the groups were

combined, the average weight loss for the 22 women was 1.28 ± 5.8 lbs., which was also not statistically different from zero ($p=0.31$) when compared to baseline values.

Table 2

Baseline and Post-Intervention Measures and Comparison of Changes by Group

Variables	Before/After		Before/After		Baseline to post-intervention between group comparisons, p-value
	Experimental group (n=11)	Experimental group (n=11)	Active control group (n=11)	Active control group (n=11)	
Body weight (lbs.)	197.6(29.4)	195.4(31.5)	207.4(33.1)	207.0(32.1)	0.49
BMI (lbs.x703/in ²)	33.0(4.2)	32.7(4.5)	34.9(6.3)	34.8(6.1)	0.47
SBP (mmHg)	138.3(12.2)	131.6(13.2)	138.6 (15.9)	135.4(13.1)	0.58
DBP (mmHg)	81.4(11.2)	77.2(10.1)	89.8(9.2)	81.1(7.0)	0.28
FBS*(mg/dL)	93.5(10.1)	89.1(12.6)	98.9(19.0)	101.1(14.1)	0.18
Hip circ (in)	48.3(3.8)	47.1(3.7)	48.1(5.6)	48.0(5.3)	0.08
Waist circ (in)	41.8(6.4)	40.7(6.3)	42.7(4.7)	42.7(4.7)	0.40
WHR	0.86(0.09)	0.86(0.09)	0.89(0.08)	0.86(0.05)	0.12

Note. $P \geq 0.05$ for all comparisons at baseline and at post-intervention between groups; BMI, body mass index; SBP, systolic blood pressure; DBP, diastolic blood pressure; FBS,* fasting blood sugar (N=8 Group 1; N=8 Group 2), only non-diabetics; in, inches; lbs., pounds; circ, circumference; WHR, waist-to-hip ratio.

Secondary outcome measures. There were no significant differences between groups in any of the secondary measures (Table 3). Therefore, changes from pre to post-intervention for the combined groups were also examined. Body mass index ranged from normal (≤ 25 [n=2]), overweight (25-29.9 [n=2]), to obese (≥ 30 [n=18]). The overall change in body mass index was not significant when both groups were combined (0.22 ± 0.98 , $p=0.31$). Systolic blood pressure reduction (4.95 ± 14.51 mm/Hg) for the combined groups was not statistically significant ($p=0.12$);

however, there was significant decrease in diastolic blood pressure (-6.45 ± 9.71 mm/Hg, $p=0.005$).

Table 3

The Effect Size of Intervention for the Primary and Two Secondary Outcome Variables

Group/Variable	Mean change pre to post intervention	SD	Cohen's <i>d</i>
1/weight	0.4	6.4	0.3
2/weight	2.16	5.2	
1/SBP	3.2	13.6	0.2
2/SBP	6.7	15.8	
1/DBP	8.7	8.2	11.0
2/DBP	4.2	0.5	

Note. Cohen *d* interpretation of effect size: 0.2- small; 0.3-small-to-medium; 0.5-moderate.

Six diabetic and 16 non-diabetic women were enrolled in the study. Fasting blood glucose overall for both groups ($n=21$; one missing) showed no reduction (0.29 ± 12.85 mg/dL, $p=0.92$). Blood sugar on average decreased slightly (2.4 ± 12.3 mg/dL) for non-diabetics, and increased slightly (5.0 ± 14.2 mg/dL) for diabetic women albeit not statistically significant.

There was a statistically significant decrease in hip circumference when the intervention groups were combined (0.7 ± 1.4 in., $p=0.03$), in addition to a significant reduction in waist circumference (pre to post-intervention) for all women (1.34 ± 1.6 in., $p < 0.001$). The waist-to-hip ratio in the combined analysis decreased by 0.016 ± 0.046 , which was not statistically significant ($p=0.11$).

Effect size calculation

In this feasibility study, the estimated effect size for change in weight in experimental versus control groups was small for change in SBP at 0.2; small-to-moderate at 0.3 for change in weight; and moderate for change in DBP at 0.5 suggesting that the addition of a structured group intervention component could potentially yield a clinically significant effect on weight loss and other variables. For future studies, the sample size required for a two-sample t-test with an effect size of 0.2 is 394 subjects per group. Similarly, for an effect size of 0.3, each group would need to have 176 subjects. And for an effect size of 0.5 the sample size required per group is 64 subjects.

Discussion

This study examined the effects of lifestyle interventions (diet and exercise) and behavioral change on weight and other clinical outcomes. This feasibility study addressed the issue of body weight with a basic understanding of energy balance; people lose weight when energy expenditure exceeds energy intake over a defined period of time (Catenacci & Wyatt, 2007). Although these states of energy balance are clear, identifying the optimum strategies to achieve them is challenging. It is well known that the most common approach to obesity treatment includes lifestyle interventions that target both diet and physical activity and some form of behavioral self-management (Svetkey et al., 2012; Kim, Park, & Lim, 2007). The finding of this feasibility study revealed non-statistically significant differences in the outcomes between groups. When the two groups were combined, there were modest, statistically significant decreases in diastolic blood pressure, and hip and waist circumferences. However, there were no significant changes in weight, fasting blood sugar, systolic blood pressure, and body mass index.

Calculation of Cohen's *d* for the structured (treatment) versus the unstructured (control) groups determined that even though the structured intervention was not delivered as was

intended, the estimated effect size for change in weight was 0.3; diastolic blood pressure 0.5; and systolic blood pressure 0.2, suggesting that addition of a structured discussion group component could potentially produce a clinically significant additional effect on weight loss and other variables. It is crucial to realize that finding "non-significance" is not the same as finding "no effect," as it is quite possible for a meaningful effect to be present although the statistical test lacks sufficient power to detect it at the desired significance level due to a modest sample size or an imprecise research design (Zakzanis, 2001). In the case of AA women, even a small effect size for changes in blood pressure, and only modest-to-moderate sustained weight loss may have a significant impact on metabolic risk reduction, diabetes prevention, and CVD outcomes (Wing et al., 2011; Van Gaal, Mertens, & Ballaux, 2005).

Unfortunately, due to inconsistent attendance and participants' other priorities, the content of the structured intervention was not delivered as intended; the added component of structured versus unstructured discussion occurred only 2 out of 10 times, on weeks 2 and 5. This likely affected the findings of the study, potentially diminishing any salutary effect of the structured intervention, and likewise, any potential positive effects of the unstructured intervention. Based on the results of weight loss, it was determined that low weight loss was especially noted among participants with lower attendance, which resonates with Fitzgibbon et al. (2012), who concluded that attention to cultural preferences, behavioral management strategies, and session attendance were important factors to successful weight loss. Self-efficacy is important in behavior change interventions studies. Byrne, Barry, and Petry (2013) indicated that change in self-efficacy during treatment was the strongest predictors of weight loss. Other studies have also found that increases in self-efficacy from pre- to post-treatment are associated with greater weight loss (Bas & Donmez, 2009; Warziski et al., 2008).

Even though the structured intervention was not delivered as intended due to above-mentioned reasons, and the weight-loss intervention did not produce statistically significant results, the conduct of the trial demonstrated that the behavioral protocol was feasible. In this study, there were a number of women who were recruited late (after the first week). Certainly, there is a learning curve to acquire and incorporate information about diet and physical activity and the application of that information as a means to lose weight. It is clear that a longer period of time would be necessary to demonstrate significant weight loss. Nine weeks of content after the baseline may be too short, given the fact that late recruitment and variable attendance may have further limited the amount of information acquired that could have been used for weight loss. In future studies, it is recommended that make-up sessions be planned or other forms of content delivery (e.g., email, text messaging, posting information on designated websites) be offered. Mid-week phone follow-up, more peer-to-peer interaction, and determination of readiness to change prior to the study enrollment as well as recruitment of women who will make an explicit commitment to the intervention schedule could improve attendance. If possible, a “run-in” period in which women attend and perform study activities could be implemented to exclude women who do not adhere to minimal protocol requirements. This may ensure that women are recruited who are truly ready to change their lifestyle and behavior, and who may utilize study resources more fruitfully.

In future studies, schedules should be made to enable the full time of content and participant discussion to fully implement and more fairly test the intervention strategies. Perhaps, shorter duration of shared meeting time would make it easier for participants to stay for the structured intervention. It would be helpful to replicate this study on a larger scale and over a longer period of time to evaluate the effectiveness of this novel intervention. Studies indicate that

only long-term behavior-modification strategies can substantially enhance and maintain weight lost, so obesity treatment can have a good outcome (Binks & O'Neil, 2002).

Limitations

This feasibility study had a number of limitations that can be addressed in future studies. It was difficult to measure waist and hip circumference since many of the women were obese; folded skin around the waistline made it difficult to identify the landmarks. In future studies, more accurate recording of precise landmarks and measurements for each woman would be documented in the record along with the measured value. The small sample was another limitation, which increased variability and made effect size calculations less precise. The convenience sample was another limitation, affecting generalizability of study findings; the sample was not representative of all AA women. Another limitation was conducting the study during the summertime when many participants could not commit themselves fully to weekly Saturday meetings for 1.5 hours, resulting in inconsistent attendance. It may be more effective to have meetings in the fall, with meetings broken down into shorter 1-hour meetings that include half-hour general sessions followed by the half-hour structured and unstructured group sessions. The study provided only limited opportunity to test the unstructured versus structured intervention components. The underutilization of dietary and physical activity tools by the women was another limitation which could be improved in future studies by recruiting women who exhibit self-efficacy and readiness for change, which could be assessed *a priori* (Parker & Parikh, 2001).

Despite increasing awareness of the role of obesity in CVD, weight loss remains a problem, particularly among AA women (Welch, 2003; Tussing-Humphreys, Fitzgibbon, Kong, & Odoms-Young, 2013). The awareness of heart disease as the leading cause of death among women is suboptimal and a gap in awareness exists between Caucasians and racial/ethnic

minorities (Mosca et al., 2010). Minorities, including AA women, are largely underrepresented in the behavioral lifestyle intervention literature (Tussing-Humphreys et al., 2013). Despite clear benefits of weight-loss programs, especially for AA women, physician care of obese patients is inadequate (Ma, Xiao, & Stafford, 2008).

Conclusions

The study was judged overall feasible, and standard behavioral strategies were well received, but not consistently applied by participants to attain desired weight loss. No statistically significant differences were observed between groups, so the groups were combined to examine overall outcomes. In combined analyses, diastolic blood pressure, and hip and waist circumferences showed statistically significant improvements. The structured versus unstructured discussion approach as implemented in this study is a novel approach. If further developed and tested, this type of program has potential to be a valuable non-pharmacological approach to facilitate weight loss and weight management. This study adds to the existing literature on obesity management of AA women. Efforts to implement the protocol successfully could lead to better health and improved quality of life for AA women. If the weight loss is effective in managing obesity in AA women aged 35-75 years, it can become an easy and cost-effective way to reduce the dramatic and devastating consequences of diabetes, hypertension, heart disease and other comorbid conditions with attendant medical cost and economic burden.

References

- American Diabetic Association (2014). Retrieved from <http://www.diabetes.org/living-with-diab>
- Anthropometry Procedure Manual (Revised 2004). Retrieved from http://www.cdc.gov/nchs/data/nhanes/nhanes_03_04/BM.pdf
- American Diabetes Association (2013). Blood glucose meters 2013. *Diabetes: The Healthy Living Magazine (January)*. Retrieved March 17, 2015 from: <http://www.diabetesforecast.org/2013/jan/blood-glucose-meters-2013.html>
- Bas, M., & Donmez, S. (2009). Self-efficacy and restrained eating in relation to weight loss among overweight men and women in Turkey. *Appetite*, 52, 209-216
- Bassuk, S. & Manson, J. (2008). Lifestyle and risk of cardiovascular disease and type 2 diabetes in women: A review of the epidemiologic evidence. *American Journal of Lifestyle Medicine*, 2(3), 191-213.
- Binks, M. & O'Neil, M. (2002). Referral sources to a weight management program: Relation to outcome. *Journal of General Internal Medicine*, 17, 596-603.
- Byrne, S., Barry, D., & Petry, N. (2012). Predictors of weight loss success: Exercise vs. dietary self-efficacy and treatment attendance. *Appetite*, 58(2), 695-698.
- Catenacci, V. & Wyatt, H. (2007). The role of physical activity in producing and maintaining weight loss. *Nature Clinical Practice Endocrinology & Metabolism*, 3, 518-529.
- Center for Disease Control and Prevention (CDC). Measuring height accurately at home. Retrieved from: http://www.cdc.gov/healthyweight/assessing/bmi/childrens_bmi/measuring_children.htm
- 1
- Choi, B., Pak, A., Choi, J., & Choi, E. (2007). Daily step goal of 10,000 steps; A literature review. *Clinical Investigative Medicine*, 30(3), E146-151.

- dabl[®] Educational Trust (2015). Blood pressure monitors – Validations, papers and reviews.
Retrieved April 12, 2015 @ <http://www.dableducational.org/index.html>
- Fitzgibbon, M., Tussing-Humphreys, L., Porter, J., Martin, I., Odoms-Young, A., & Sharp, L. (2012). Weight loss and African-American women: A systematic review of the behavioral weight loss intervention literature. *Obesity Reviews*, 13(3), 193-213.
- Gohlke-Barwolf, C. (2000). Coronary artery disease - Is menopause a risk factor? *Basic Research in Cardiology*, 95 (Suppl 1), I77-83.
- Heart disease and stroke statistics - 2013 update: A report from the American Heart Association. *Circulation*. Published online before print December 12, 2012, 10.1161/CIR.0b013e31828124ad. Accessed December 29, 2013.
- Hedley, A., Ogden, C., Johnson, C., Carroll, M., Curtin, L., & Flegal, K. (2004). Prevalence of overweight and obesity among US children, adolescents, and adults, 1999-2002. *JAMA*, 291, 2847-2850.
- Hertzog, M. (2008). Considerations in determining sample size for pilot studies. *Research in Nursing and Health*, 31(2), 180-191.
- Kadam, P. & Bhaler, S., (2010). Sample size calculation. *International Journal of Ayurveda Research*, 1(1), 55-57.
- Kaplan, M., Huguet, N., Newsom, J., & McFarland, B. (2004). The association between length of residence and obesity among Hispanic immigrants. *American Journal of Preventative Medicine*, 27, 323-326.
- Keller, C., Larkey, L., Distefano, J., Boehm-Smith, E., Records, K., Robillard, A., ...O'Brian, A. (2010). Perimenopausal obesity. *Journal of Women's Health*, 19(5), 987-997.
- Kim, J., Park, S., & Lim, Y. (2007). Analysis of the factors affecting the success of weight reduction programs. *Yonsei Medical Journal*, 48(1), 24-29.

- Liu, J., Hay, J., & Faught, B. (2013). The association of sleep disorder, obesity status, and diabetes mellitus among US adults-The NHANES 2009-2010 survey results. Retrieved from: <http://dx.doi.org/10.1155/2013/234129>
- Lovejoy, J., Champagne, C., de Jonge, L., Xie, H., & Smith, S. (2008). Increased visceral fat and decreased energy expenditure during the menopausal transition. *International Journal of Obesity*, 32(6), 949–958.
- Luz, L., Neto, G., & Farinatti, P. (2007). Validity of the Physical Activity Readiness Questionnaire (PAR-Q) in elder subjects. *Brazilian Journal of Kinanthropometry and Human Performance*, 9(4), 367-371
- Ma, J., Xiao, L., & Stafford, R. (2008). Adult obesity and office-based quality of care in the United States. *Obesity*, 17, 1077-1085.
- Mensah, J., Mokdad, A., Ford, E., Greenlund, K., & Croft, J. (2005). State of disparities in cardiovascular health in the United States. *Circulation*, 111, 1233-1241.
- Moore, S., Charvat, J., Alemi, F., Gordon, N., Ribisl, P., & Rocco, M. (2011). Improving lifestyle exercise in cardiac patients: Results of the SystemCHANGE Trial. *Circulation*, 124, A13341.
- Moore, S. & Charvat, J. (2002). Using the CHANGE Intervention to enhance long-term exercise. *Nursing Clinics of North America*, 37(2), 272-283.
- Mosca, L., Benjamin, E., Berra, K., Bezanson, J., Dolor, R., Lloyd-Jones, D., ... Wenger, N. (2011). Effectiveness-based guidelines for the prevention of cardiovascular disease in women-2011 Update (2011). *Circulation*, 123(11), 1243–1262.
- Mosca, L., Mochari-Greenberger, H., Dolor, R., Newby, L., & Robb, K. (2010). Twelve-year follow-up of American women's awareness of cardiovascular disease risk. Retrieved from: <http://circoutcomes.ahajournals.org> on December 29, 2013.

- One Touch Ultra Mini blood glucose monitoring system user guide. Retrieved from
http://www.onetouch.com/sites/default/files/file/UltraMini_English_06629001B_OTUM_UG_US_en_R1_web1.pdf
- Pampel, F., Krueger, P., & Denney, J. (2010). Socioeconomic disparities in health behaviors. *Annual Review of Sociology*, 36, 349-370. doi: 10.1146/annurev.soc.012809.102529
- Parker, K. & Parikh, S. (2001). Applying Prochaska's model of change to needs assessment, programme planning and outcome measurement. *Journal of Evaluation in Clinical Practice*, 7(4), 365-371.
- SAS Institute Inc. 2011. Base SAS® 9.3 Procedures Guide: Statistical Procedures. Cary, NC: SAS Institute Inc.
- Smith, L. (2005). New AHA recommendations for blood pressure measurement. *American Family Physician*, 72(7), 1391-1398.
- Statistical Fact Sheet 2013 Update. American Heart Association. Retrieved from:
http://www.heart.org/idc/groups/heart-public/@wcm/@sop/@smd/documents/downloadable/ucm_319568.pdf. Accessed December 29, 2013.
- Svetkey, L., Ard, J., Stevens, V., Loria, C., Young, D., Hollis, J., ... Vollmer, W. (2012). Predictors of long-term weight loss in adults with modest initial weight loss, by sex and race. *Obesity*, 20(9), 1820-1828.
- Tsai, A. & Wadden, T. (2005). Systematic review: An evaluation of major commercial weight loss programs in the United States. *Annals of Internal Medicine*, 142(1), 56-66.
- Tussing-Humphreys, L., Fitzgibbon, M., Kong, A., & Odoms-Young, A. (2013). Weight loss maintenance in African American women: A systematic review of the behavioral lifestyle

- intervention literature. *Journal of Obesity*, Article ID 437369, 31 pages. Retrieved from:
<http://www.hindawi.com/journals/job/2013/437369/>
- Van Gaal, L., Mertens, I., & Ballaux, D. (2005, 7 Suppl. L). What is the relationship between risk factor reduction and degree of weight loss? *European Heart Journal*, L21-L26.
- Wadden, T., Butryn, M., & Byrne, K. (2004). Efficacy of lifestyle modification for long-term weight control. *Obesity Research*, 12, 151S-162S.
- Wadden, T. & Butryn, M. (2003). Behavioral treatment of obesity. *Endocrinology and Metabolism Clinics of North America*, 32, 981-1003.
- Warburton, D., Gledhill, N., Jamnik, V., Bredin, S., McKenzie, D., Stone, J., Charlesworth, S., ... Shephard, R. (2011). Evidence-based risk assessment and recommendations for physical activity clearance: Consensus Document. Retrieved from
<https://idp2.shib.umn.edu/idp/umn/login>
<http://www.nrcresearchpress.com.ezp1.lib.umn.edu/doi/pdf/10.1139/h11-062>
- Warziski, M., Sereika, S., Styn, M., Music, E., & Burke LE. (2008). Changes in self-efficacy and dietary adherence: The impact of weight loss in the Prefer Study. *Journal of Behavioral Medicine*, 31, 81-92.
- Webel, A., Moore, S., Hanson, J., & Salata, R. (2013). The rationale, design, and initial efficacy of SystemCHANGE™ -HIV: A systems-based intervention to improve physical activity in people living with HIV. *Journal of AIDS & Clinical Research*, 4, 200.
doi:10.4172/2155-6113.1000200.
- Welch, M. (2003). Care of Blacks and African Americans. In J. Bigby (Ed.). *Cross-Cultural Medicine*, (pp. 29-60). Philadelphia: American College of Physicians.
- Willett, W. (Ed.). (1998). *Nutritional Epidemiology*, (2nd ed). Oxford University Press: New York, NY

- Williams, R. (2009). Cardiovascular disease in African American women: A health care disparities issue. *Journal of National Medical Association*, 101(6), 536-40.
- Wing, R., Lang, W., Wadden, T., Safford, M., Knowler, W., Bertoni, A., ... Wagenknecht, L. (2011). Benefits of modest weight loss in improving cardiovascular risk factors in overweight and obese individuals with type 2 diabetes. *Diabetes Care*, 34(7), 1481-1486. doi: 10.2337/dc10-2415.
- World Health Organization (2008). Waist circumference and waist-hip ration: Report of WHO expert consultation. Retrieved from:
http://whqlibdoc.who.int/publications/2011/9789241501491_eng.pdf
- Zakzanis, K. (2001). Statistics to tell the truth, the whole truth, and nothing but the truth: Formulae, illustrative numerical examples, and heuristic interpretation of effect size analyses for neuropsychological researchers. *Archives of Clinical Neuropsychology*, 16(7), 653-667.

Chapter 4: Manuscript Three

Chapter 4 explores Aim 5 of the dissertation that identifies subjectively perceived satisfaction, obstacles and facilitators participants encountered during the program; and meeting goals of the behavioral weight-loss intervention study among this African-American community. It outlines and presents “lessons learned” by the investigators that may be beneficial to other investigators who might undertake similar research.

**A Community-Based Behavioral Weight-Loss Study for African-American Women:
Satisfaction, Challenges and Lessons Learned**

Naira Zargarian, PhD Candidate, MSN, FNP, RN; Ruth Lindquist, PhD, RN, FAAN, Professor;
Cynthia R. Gross, PhD, Professor; Erica Schorr, PhD, RN, Assistant Professor; Diane Treat-
Jacobson, PhD, RN, FAAN, Associate Professor; & Kay Savik, MS, Senior Statistician

University of Minnesota School of Nursing, Minneapolis, MN

Corresponding author:

Naira Zargarian, MSN, RN, FNP, PhD Candidate

University of Minnesota School of Nursing

5-140 WDH

308, Harvard Street SE

Minneapolis, MN

zarg0002@umn.edu

Summary

Obesity is associated with elevated risks of cancers, as well as coronary heart disease, type 2 diabetes, hypertension, stroke, and other chronic illnesses. Strategies targeting obesity and weight management, including diet, physical activity and behavioral modifications have been the focus of intensive research over the past few decades, but obesity epidemics continue to spread. This paper analyzes participants' satisfaction with a behavioral weight-loss program, explores challenges investigators faced during the study and describes lessons learned to facilitate the conduct of larger-scale behavioral studies in the future. Satisfaction with the program was unanimous among participants. The greatest challenge reported was changing eating habits, whereas education and having available resources and tools were stated as the greatest facilitators of weight loss among this group of AA women 35-75 years of age. Key lessons learned for the design of future studies include the recruitment of persons "ready to change," structuring sessions to ensure adequate time for discussion of content application, and incorporating strategies of accountability to improve adherence and attendance. Effective programs are urgently needed, and studies of strategies may help to build the knowledgebase, and lay the foundation upon which to base these programs.

Keywords: obesity, weight-loss interventions, challenges, lessons learned, satisfaction

A Community-Based Behavioral Weight-Loss Study for African-American Women: Satisfaction, Challenges and Lessons Learned

Obesity, a condition of an excessively high proportion of body fat, is associated with elevated risks of cancers, as well as coronary heart disease, type 2 diabetes, hypertension, stroke, and other chronic illnesses (Guovanucchi et al., 2010). The prevalence of obesity has increased rapidly over the last decades (Sturm & An, 2014). The McKinsey Global Institute recently released a report noting that obesity is responsible for about 5% of all deaths each year worldwide, and its global economic impact amounts to roughly \$2 trillion annually, "nearly equivalent to the global impact of smoking or of armed violence, war, and terrorism" (Dobbs et al., 2014, p. 1).

In the United States, health disparities in obesity and obesity-related illnesses have been the subject of growing concern (Lovasi, Hutson, Guerra, & Neckerman, 2009). Members of specific ethnic/racial groups, including African-Americans (AA), are at an increased risk of CVD. There is also a strong socioeconomic gradient in overweight and obesity (Mujahid, Diez Roux, Borrell, & Nieto, 2005), and socioeconomic characteristics might, in part, explain racial and ethnic differences in adiposity and health (Wang & Zang, 2006; McLauren, 2007). A vast majority of AA women (80.5%) are either overweight or obese (National Center for Health Statistics, 2009). Concomitantly, marked health disparities exist in the prevalence, morbidity, and mortality associated with CVD and its major risk factors. These disparities appear to play a key role in the differences reflected in lower overall life expectancy and quality of life of AA women (Williams, 2009; Jemal, 2007; Mensah, Mokdad, Ford, Greenlund, & Croft, 2005). Data indicate that AA women have greater mortality from cardiovascular diseases relative to Caucasian women (Keller et al., 2010; Mosca, Mochari-Greenberger, Dolor, Newby & Robb, 2010; Williams, 2009; Jemal, 2007; Department of Health and Human Services (DHHS), 2010a).

Despite increased awareness of the role of obesity in CVD and the growth of behavioral and lifestyle change programs, weight reduction among AA women remains a problem (Welch, 2003; Tussing-Humphreys, Fitzgibbon, Kong, & Odoms-Young, 2013). Findings suggest that the inclusion of cultural adaptations (e.g., group or family-oriented approaches to making changes in eating habits, cooking healthier versions of traditional and staple foods, and well-selected culturally acceptable exercise behavior) may result in more favorable weight loss and maintenance outcomes for AA women (Fitzgibbon et al., 2005).

Based on the existing information about difficulties AA women encounter in their attempts to lose weight, an effort was made to take on the challenge of promoting weight loss in a program among community-dwelling AA women in the context of a faith-based organization.

Study Context

A feasibility study was designed and conducted with added environmental approach to determine whether it will augment weight loss and weight management of AA women ages 35-75 years participating in a behavioral weight loss program. The theory employed was “System Change” theory (Moore & Charvat, 2002). According to the theory, weight loss efforts are more effective when behavioral changes are made with a series of mini-experiments (small changes in daily routine and behavior that are trialed discussed and modified as needed). If successfully applied, the behavior changes and routines are incorporated into one’s daily routine. Then a person moves on with the process making other small changes until desired goals are reached.

The study is described elsewhere in greater detail (Zargarian, Lindquist, Gross, Treat-Jacobson, & Savik, 2014). This paper describes participant satisfaction with the study protocol and processes. Lessons learned through the analysis of the study conduct are also presented, including a reflection on potential challenges encountered while conducting the study and possible reasons that participants may not have achieved their weight loss goals. Obstacles as

well as facilitators of weight loss that may have been encountered by participants while participating in the study are identified, and potential solutions to address those challenges are proposed.

Weight-loss study description

Twenty-three obese or overweight AA females were recruited through a health initiative at a meeting of the women's fellowship program at a metropolitan Twin Cities-area church. Investigators were invited to deliver a weight-loss program as a part of a church health initiative targeting the creation of a healthy community. This church setting was selected because the church is a promising setting to address health disparities (Wilcox et al., 2010). The participants ranged in age from 35 to 75 years, with an average body mass index of 33.96 (SD=5.27). Almost half (45.0%) were married; 91.0% of participants had college and graduate degrees, and 17 out of 22 (73%) were employed full-time or part-time.

The goal of the study was a modest, consistent loss by participants of 10 pounds in 10 weeks in 10 steps. Measures of systolic blood pressure (SBP), diastolic blood pressure (DBP), fasting blood sugar (FBS), hip circumference (HC), waist circumference (WC), waist-to-hip ratio (WHR), weight, and body mass index (BMI) were taken at baseline and at program completion. A one-page satisfaction survey was also administered at the program completion. Out of 23 women, 22 completed the study. Based on the responses, participants found the study very helpful and informative; however, they did not consistently participate in weekly meetings. Analysis of change in some primary outcome measures yielded statistically significant results: DBP (6.45 ± 9.71 mm/Hg, $p = 0.005$), HC (0.7 ± 1.4 in., $p < 0.001$), and WC (1.3 ± 1.6 in., $p = 0.001$), whereas no statistically significant changes were observed in the other study outcome measures. The study itself was feasible, and standard behavioral strategies were well accepted. However, the experimental intervention did not attain desired weight loss. There were many challenges

identified that have potentially influenced the program outcomes. Even though the study fell short of expected goals for weight loss, many things were learned in the process that could benefit future studies. Participants' satisfaction and perceived obstacles and facilitators for weight loss were assessed at program completion. Investigator-perceived challenges and lessons learned from the experience of protocol implementation are identified and discussed. Participants' perceptions and the investigators' accounts of challenges and lessons learned are presented below.

Participants' Perceptions

Participant Satisfaction. Monitoring of participants' satisfaction with weight-loss programs by measuring and assessing the level of satisfaction, as a function of quality, is essential to engage and retain participants (Zlatković, 2013). Customers' satisfaction is very important not only to customers themselves, but even more so to feasibility and viability of any weight-loss program. The reason why customer satisfaction directly affects feasibility of the study is simple: feasibility depends on attendance, and it is much easier to retain a happy customer than to return an unhappy one (Zlatković, 2013). Based on the results of this study, it was evident that participants with higher attendance lost more weight than their counterparts, who adhered less to attendance that was expected at the weekly meetings.

Upon completion of the program, participants were given a satisfaction questionnaire consisting of seven "yes" or "no" questions (Table 1). In their responses, participants found the program easy to understand and follow, and very informative; they reported that they learned a significant amount of new information helpful to their weight-loss efforts. However, despite unanimous satisfaction, there were three participants that reported fitting meetings into their schedule (one participant in the structured group [10%] and two in the unstructured group [20%]) was weight-loss hindering factor.

Table 1

Satisfaction Questionnaire

Statements	Experimental Group N=10 n*(%)	Control Group N=11 n(%)
I have learned what I expected from this program	10(100)	11(100)
I have learned skills that helped me change my lifestyle	10(100)	11(100)
Lectures and presentations were useful to keep me motivated to change my behavior	10(100)	11(100)
I had difficulties fitting the meetings into my schedule	1(10)	2(20)
The program instructors were knowledgeable	10(100)	11(100)
I know now what to do to continue using my skills that I acquired during this program	10(100)	10(90)
I would recommend programs like this to friends and family	10(100)	11(100)

*Note: n reflects the number of participants who positively endorsed the item.

Participant-Perceived Obstacles to Weight Loss. Difficulty of weight loss among AA may result from a combination of behavioral, socio-cultural, biological, and genetic factors (Lovasi et al., 2009). This discussion outlines potential challenges participants have encountered during the 10-week study. Overcoming these challenges might help to understand measures to take to help AA women succeed with weight loss in future studies.

The second half of the satisfaction questionnaire given to participants consisted of one open-ended question about the three most frequently encountered obstacles to reaching their weight-loss goals during the program. Qualitative content analysis was performed by the principal investigator.

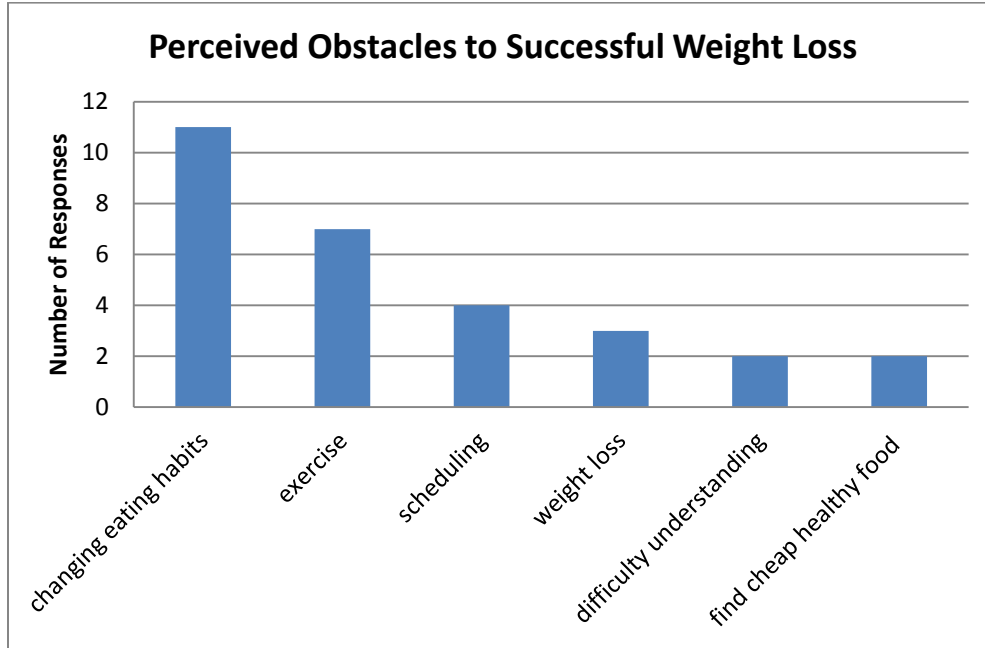


Figure 1. Perceived obstacles to successful weight loss. Perceived obstacles to weight loss are presented by the frequency with which they were identified.

Based on participants' responses, the most frequently encountered perceived obstacle was changing eating habits (n=11), including staying away from sugar and salt. One woman reported that she was trying to cut her usual 3 candy bars a day out of her diet. Some of them found it difficult to cook separate meals for themselves only, since the rest of the family eats more familiar and not necessarily healthy food. Seven out of 22 subjects found 'squeezing' exercise into daily schedule difficult, even though they were encouraged to exercise as little as 10 minutes at a time. Several women were on a limited budget and found the cost of healthy foods a big obstacle. Scheduling meetings into their weekly routine (n=4) was a problem for few women in a summertime. Some of them were taking care of children and grandchildren who were out of school; others were on vacations; several had to work on Saturdays, which affected attendance and weight-loss outcomes.

Participant-Perceived Facilitators of Weight Loss. Another open-ended question of the satisfaction questionnaire was to identify three perceived facilitators to their weight-loss efforts.



Figure 2. Perceived facilitators of successful weight loss.

The most frequently reported perceived facilitator was education about the process (n=12), including having resources and tools available. Several women (n=4) identified the help of facilitators and support group (n=3) as important factors in their understanding of the information and determination to succeed in their weight-loss goals. Having a friend, colleague, or a family member is invaluable during weight-loss efforts (Parks, Housemann, & Brownson, 2003). Cultural adaptations that include a spiritual dimension and group support involving primarily AA can be an additional stimulus to continue weight-loss efforts.

One participant indicated that motivation helped her to keep going towards her weight-loss goal. Even though motivation has been found to be of a short-lasting nature in one study (Moore et al., 2011), other studies have indicated that motivation provides good opportunity for intervention (Hardcastle et al., 2013), which, if successful, can result in reduction of obesity and

cardiovascular morbidity (Welch, 2003). Encouraging regular attendance of meetings and personalized approach can keep participants' motivation alive.

Investigators' Challenges, Lessons Learned and Recommendations

Challenges

There were several challenges experienced by investigators during the program. They were in the areas of recruitment, attendance, dietary intervention, physical activity adherence, and demonstrated commitment. There are several possible explanations for difficulty implementing the weight-loss protocol and non-significant weight reduction during the study. The lessons learned in each area are described, and recommendations for future investigations are made.

Recruitment. Participants were recruited from a church in Twin Cities Metropolitan area. There were no measurements or interventions done during the first week, leaving only nine weeks for implementation of the study interventions. Due to low enrollment at the start of the program, some participants were recruited during 2nd and even 3rd week into the study, which reduced the benefits of participation and the opportunity for weight loss. With only 7-8 weeks remaining, there might have not been enough time for participants to lose weight. Thus, the overall weight loss should be considered in light of the shortened timeframe.

Attendance. Attendance at weekly meetings was variable, ranging from 77.3% at week 1 to 59.1% at week 10. The overall range of attendance was 31.8% (week 8), to 81.8% (week 4). The lowest attendance was in the mid-summer (end of June – beginning of July), when many participants were on vacation. During the summer, participants' children and grandchildren were home from school, which may have prevented them from attending weekly meetings due to caregiving responsibilities. There were also family celebrations, birthday parties, sporting events and travel that interfered with regular participation. Among other reasons was a once a month 'food shelf' event held by the church that many participants regularly assisted in. Occasional

unanticipated unavailability of the room for meetings might have been another contributing factor; participants left before alternative arrangements were made. The highest attendance (81.8%) was noted after monthly women's fellowship at the church.

Because of low attendance and unwillingness or inability of participants to stay for the second part of the meeting when structured and unstructured individualized weight-loss strategies were to be conducted, separation of participants into 2 groups was possible 2 times only. Thus, the originally intended 2-group randomized controlled experimental design with participants of each group to receive different treatment was not completed more than twice. Participants in both groups stayed for the first hour dedicated to delivering shared information, and left afterwards, therefore the experimental aspect of the intervention was diminished and not delivered as intended.

Based on attendance and the results of weight loss, it was determined that five out of 22 participants who attended at least 8 out of 10 sessions, lost more weight (6.3 lbs. on average, $p=0.024$) than their counterparts attended fewer than 8 sessions and who gained 0.2 lbs. ($p=0.024$). These results resonate with the findings of Fitzgibbon et al. (2012) and Orth et al. (2008), who concluded that attendance was an important factor contributing to successful weight loss.

Dietary interventions. It is well-known that the most common approach to obesity treatment includes lifestyle interventions that target both diet and physical activity and some form of behavioral self-management (Svetkey et al., 2012; Akers, Estabrooks, & Davy, 2010; Bronner & Boyington, 2002). During the first two weeks, all participants were given tools to help them achieve their weight-loss goal, including HealthCheques Daily Log® (a paper check-book size tool for calculating calories and recording intake that also provides nutritional information for the most commonly consumed foods). Dietary goals for both groups were to reduce weekly caloric intake by 500 to 3500 kcal/week, depending on weight loss desired, with an ultimate goal of 10

pounds weight loss in 10 weeks. Participants who admitted that they were not going to record dietary intake or desired an alternative way of recording food intake, an online tool “MyFitness-Pal” was suggested. However, most of participants did not adhere to the proposed plan, and after 1-2 weeks, the food recording was largely abandoned by participants despite encouragement and instructions from investigators.

Actual reported dietary behaviors of participants indicated a lack of basic knowledge among many women. For example, many of them were unaware of the high sodium content of many foods eaten on a daily basis; did not know how to properly read nutritional labels and select portion sizes; how to distinguish ‘good fats’ from ‘bad fats’; and did not know the recommended distribution of nutrients such as fat, carbohydrates and protein. Many women had a difficult time and little confidence that they could control their eating in certain situations, such as during holidays, birthday parties, or restaurants. Based on participants’ limited weight-loss knowledge, and apparent low self-efficacy among many women, it is not surprising that many did not reach their weight-loss goals.

Physical activity. A primary method of physical activity suggested was walking with a goal of 10,000 steps a day, as is common in many health and weight-loss programs (Choi, Pak, Choi, & Choi, 2007). Participants were instructed on how to exercise safely, including how to recognize signs and symptoms of adverse effects of excessive exercising. Pedometers were given to them with instruction on how to use it and record taken steps. Some women participated in 30-minute weekly group exercise sessions led by a church member who was a fitness instructor. Any amount of time spent exercising was encouraged. After few weeks, it became clear that pedometers had not been used consistently, or had been lost, misplaced, or abandoned by most of participants. Not every participant was able to walk 10,000 steps a day due to joint pain, shortness of breath, or other breathing problems. Others found themselves being too tired or lacking the

time or initiative. A potential lack of focus on steps and physical activity may have been another reason for only very modest weight loss among the women.

Commitment. At the beginning of the program, participants signed a “commitment letter to myself” contract. In the contract, they recorded their current and ideal weight, as well as the reasons for participation in the program. Women committed themselves to making permanent changes in diet and exercise habits in order to live a healthier lifestyle. However, many participants admitted that other priorities such as taking care of a sick family member, or grandchildren, as well as having a stressful event, not having time, or inability to take a lunch break got in the way of their weight-loss efforts. These observations are consistent with the existing literature that challenging lifestyle or environmental factors, including stress, contribute to a failure to consistently follow a healthy diet and engage in regular exercise (Blackburn & Walker, 2005).

Lessons Learned and Recommendations

Recruitment: The first recommendation would be to assess potential participants’ preparedness and motivation by using the Prochaska’s Stages of Change model. A sustainable weight-loss program for AA must account for realistic goal setting and expectations, particularly among those with initially high self-esteem (Murphy & Williams, 2013). People should be able to commit themselves to weight loss, and sign a “commitment letter to myself” form before enrollment. Recruitment and initial data collection were extended by 2 more weeks into intervention because few people, who expressed interest initially, showed up for enrollment 2 weeks later. Other weight-loss studies concluded that high self-efficacy for weight loss before treatment may be detrimental to success, but the treatments that improve participants’ self-efficacy may result in greater weight loss (Martin, Dutton, & Brantley, 2004). Setting realistic

goals and expectations and reviewing it during the study are important to maintain and increase self-efficacy of participants. In future research, this could be measured and tracked to confirm.

Lesson Learned: Assessing participants' preparedness for change (action) and recruiting those who will make an explicit commitment to the intervention schedule could change the weight-loss outcomes. If possible, a "run-in" period in which women attend and perform study activities could be implemented to exclude women who do not adhere to minimal protocol requirements. This may ensure that women are recruited who are truly ready to change their lifestyle and behavior, and who may utilize study resources more fruitfully.

Attendance: To increase consistency of attendance, additional strategies could have been implemented. Other than door prizes and healthy food choices provided to participants at each meeting, strategies to improve recruitment, mentioned above would also likely improve attendance consistency. A refundable monetary deposit or guaranteed monetary reward contingent upon regular attendance and weight loss could have been helpful to increase attendance (Bhattacharya & Neeraj, 2011; Finkelstein, Linnan, Tate, & Birken, 2007). For those participants unable to attend, make-up sessions and alternative delivery methods to present information (e.g., email, posting information on designated web sites, texts messages, and Web-based virtual-based technology, customized in such a way as to enhance motivation of participants in their home settings) might encourage them to adhere to the regimen originally developed and agreed upon through a commitment letter and may improve participation and accommodate disparate schedules (Gerber et al., 2009). Mid-week phone follow-up and more peer-to-peer interaction can also be helpful in increasing attendance.

Lesson Learned: Sound alternative strategies for ensuring delivery of weekly content to all participants such as make-up sessions, telephone or website delivery of content and face-to-face peer-to-peer interactions should be set and agreed upon at the time of study recruitment.

During the summer months, women were busy with social activities, vacations, and taking care of children and grandchildren who were out of school. In the fall, people are ready to return to more structured routine. Even though January is a traditional month to make New Year resolutions, fall is the preferred time to launch a weight-loss program to prepare participants for challenges of upcoming holidays. It is commonly asserted that the average American gains 5 pounds or more over the holiday period between Thanksgiving and New Year's Day, and since this gain is not reversed during the spring or summer months, it contributes to the increase in body weight (Yanovski et al., 2000). In fact, in a survey of 1,500 moms, participants said fall is the ideal season to jump-start healthy eating and exercise programs (National Dairy Council, 2015).

Lesson Learned: Summer is not an optimal time to start the implementation of a weekly weight loss program. Fall would be a more suitable season.

Changing the program start date to fall might significantly increase attendance and retention of participants, because inability of people to fit meetings into their busy summer schedule was one of the reported obstacles. Based on attendance and the results of weight loss, it was determined that low weight loss was especially noted among participants with lower attendance, which resonates with Fitzgibbon et al. (2012), who concluded that session attendance is important factors to successful weight loss.

Women, who participated in the program but did not stay for the structured intervention, did not have a chance to receive the important content from the intervention sessions. This resulted in the women not being able to develop new behavioral strategies and make important lifestyle changes.

Lesson Learned: Increasing the length of the weight loss program beyond 10 weeks, keeping the duration of each session at less than 1.0 hour would increase the opportunity for

women to stay for the entire duration of sessions, acquire helpful weight-loss information and allow time to incorporate and apply the information with the potential to make more enduring lifestyle changes.

It would be beneficial suggestion to conduct a study with a longer duration since longer duration was associated with greater weight loss (Bronner & Boyington, 2002). This would potentially increase the number of weeks of attendance to receive the intervention and thus the potential impact of the intervention.

Another useful approach to conducting a weight-loss study would be researchers partnering with the target participants before the study in planning the next phase intervention. That would be an effective way to assess participants' preparedness and commitment, as well as engaging them into planning of the intervention.

Dietary Interventions: Warm, summer months make seasonal affective disorder (SAD) when people crave for carbohydrates and gain weight, much milder, and easier to control (Cizza, Requena, Galli, & De Jonge, 2011). On the other hand, depending on a geographical location, people, especially elderly, spend most of their time comfortably in air-conditioned indoors during summer, and in heated homes during winter, and tend to consume more food, and exercise less (Kobayashi & Kobayashi, 2006). Thus, it can be challenging to maintain healthy eating and control weight.

Lesson Learned: People need to be taught to monitor their energy intake and expenditure. During the summer months, exercise outdoors early in the morning and after sunset should be encouraged. Exercise indoors should be taught during cold season. Additional measures such as consistent reminders such as mid-week follow-up calls and text messages, and scheduled "in-person" record reviews by research staff might have been necessary to increase

monitoring and food record-keeping compliance, which has been shown to be a significant and effective strategy to achieve weight loss.

Studies have shown that greater use of the weight tracker tools was associated with greater weight loss (Brindal, Freyne, Saunders, Berkovsky, & Noakes. 2012). Patrick et al. (2009) found that participants who received text messages had a higher average weight loss than their counterparts receiving paper materials. As an incentive, rewards for each food record returned could be offered to participants. Another way to assess nutrient/caloric intake could be scheduling 24-hour food recall over the phone. For participants with a smart phone, detailed explanations about online trackers being able to automatically calculate calories and nutrients, and determine portion sizes for them, can be motivating. Or, using a smart phone or camera, participants could record their food intake. Improved recognition of subjects less likely to self-monitor may be helpful in promoting these behaviors in future interventions.

Lesson Learned: Offering weight-loss programs that are more individualized and utilize tools such as text messaging, and online trackers, in addition or instead of paper materials, might help to overcome that obstacle. Incentives for data collection and the use of online trackers might also be helpful.

The most frequently mentioned obstacle to weight-loss efforts was changing eating habits. Communal participation in eating and discussing and sharing good foods and food preparation is important and would allow participants to interact and share ideas and recipes for healthier versions of their favorite, traditional foods. More emphasis could be focused on assessing participants' eating behavior by inquiring about unresolved stress and other issues. It might be helpful to encourage realistic expectations and milestones; reinforce that behavioral changes are a life-long process, and that maintaining weight is maybe even more important than losing weight. As previously mentioned, lengthening the program to sixteen weeks to six months

or more would likely aid in the development of new habits and incorporation of new lifestyle behaviors. Offering cooking classes to increase peer interaction and improve skills might also add value to their efforts of changing eating habits.

Physical Activity: To overcome non-compliance with physical activity, an alternative plan could have been useful. For those participants who were unable to walk or have low back and joint problems, sitting exercises could have been suggested and taught. Beladev and Masharawi (2011) stated that group-exercising conducted in a sitting position, improved pain and range of motion of women suffering from chronic low back pain. Progressive increase in walking or short exercise periods throughout the day could be encouraged. Lara et al. (2008) concluded that integrating brief periods of physical activity could lead to substantive health benefits. Alternative mode of self-monitoring of physical activity (i.e., use of smart phones and text messages) could be more effective than regular paper diary. In their study, Shapiro et al. (2008) examined self-monitoring of physical activity and concluded that participants receiving text messages via smart phones with reminders and encouragement about physical activity completed self-monitoring by almost 25% more than participants with paper diary.

Lesson Learned: It would be helpful for the research staff to help participants set mutual goals in context of a formal “workable,” sustainable, individualized plan for increasing activity for each woman.

Conclusion

The purpose of this paper was to describe satisfaction, and facilitators and obstacles participants encountered during the study. It described how these may have contributed to the achievement of their weight-loss goals. It also explored challenges investigators faced while working with obese and overweight AA women 35-75 years of age, as well as lessons learned for future studies. Evidence exists that weight loss can be achieved and, for the most part, sustained

via behavioral management of diet and physical activity. However, weight loss and weight management have been a major challenge for AA women.

Based on the results of this study having modest weight loss, inconsistent attendance and perceived obstacles and facilitators, it is apparent that even though education was found to be the greatest facilitator, even more vigorous education might be needed. It can be achieved by conducting longer studies, mid-week follow-up phone calls, more personalized approach, and utilization of other educational tools such as specifically designed Web sites, e-mails, and text messaging. More education on healthy recipes, portion control/serving sizes, calorie recommendations, stress-management techniques, information on how to increase self-esteem might be helpful tools for better weight management.

It is important to recognize that perceptions of obesity may be different in the AA community. In future programs, information could be provided about serious health conditions associated with being overweight and obese instead of focusing on being thin (which might be interpreted by AA as a sign of illness or a “white person” value). One of the facilitators listed by participants was empowerment. People seldom make changes in their lives unless they feel a strong need to change. If the change process is to be successful, a person should have strong feeling about current situation; then the likelihood of sustained behavioral change and empowerment will increase. Promoting weight control as a means of achieving increased self-esteem and empowerment might motivate participants to adhere to the proposed plan. Further, even though the study produced modest significant results across the outcome variables, it was an important study because it identified perceived obstacles and facilitators of women’s weight loss, which might provide support for the need to address individual and environment-based weight-loss strategies. Otherwise, although women want to lose weight and understand the benefits of weight loss, they might return to familiar, cultural/comfort food and overall lifestyle.

Even though the effect size for changes in weight was small, a key to remember is that this was a short and small study and that any appropriate changes may be significant in the participant's life and health.

Future studies might benefit from lessons learned from this feasibility study, and avoid frustration, waste of time and resources, and most importantly, have increased chances of significant weight-loss results that might greatly affect cardiovascular morbidity and mortality among AA women.

References

- Akers, J., Estabrooks, P., & Davy, B. (2010). Translational research: Bridging the gap between long-term weight-loss maintenance research and practice. *Journal of the American Dietetic Association, 110*(10), 1511-1522.
- Anderson, R. & Funnell, R. (2002). Using the empowerment approach to help patients change behavior. In B. Anderson & R. Rubin (Eds.), *Practice psychology for diabetes clinicians* (p.5). Alexandria, VA: American Diabetes Association.
- Bandura, A. (1986). *Social foundations of thought and action: A social cognitive theory*. Englewood Cliffs, NJ: Prentice Hall.
- Beladev, N. & Masharawi, Y. (2011). The effect of group-exercising on females with non-specific chronic low back pain in a sitting position: A pilot study. *Journal of Back & Musculoskeletal Rehabilitation, 24*(3), 181-188.
- Bhattacharya, J. & Neeraj, S. (2011). "Who pays for obesity?" *Journal of Economic Perspectives, 25*(1), 139-158.
- Blackburn, C. & Walker, W. (2005). Science-based solutions to obesity: What are the roles of academia, government, industry, and health care? *American Journal of Clinical Nutrition, 82*(Suppl.), 207S-210S.
- Brindal, E., Freyne, J., Saunders, I., Berkovsky, S., Smith, G., & Noakes, M. (2012). Features predicting weight loss in overweight or obese participants in a web-based intervention: randomized trial. *Journal of Medical Internet Research, 14*(6), e173.
- Bronner, Y. & Boyington, J. (2002). Developing weight-loss interventions for African American women: Elements of successful models. *Journal of the National Medical Association, 94*, 224-235.

- Cizza, G., Requena, M., Galli, G., & De Jonge, L. (2011). Chronic sleep deprivation and seasonality: Implications for the obesity epidemic. *Journal of Endocrinological Investigation, 34*, 793-800. doi: 10.3275/7808.
- DeLany, J., Kelley, D., Hames, K. Jakicic, J., & Goodpaster, B. (2014). Effect of physical activity on weight loss, energy expenditure, and energy intake during diet induced weight loss. *Obesity, 22*(2), 363-370.
- Department of Health and Human Services (2010a). Healthy people 2020: The road ahead. Available at: <http://www.health.gov/healthypeople/url> (accessed on February 1, 2015).
- Dobbs, R., Sawers, C., Thompson, F., Manyika, J., Woetzel, J., Child, P., ... Spatharou, A. (2014). Overcoming obesity: An initial economic analysis. McKinsey Global Institute. Retrieved from <https://dementianews.wordpress.com/2014/11/21/more-on-the-obesity-risk-factor-bbc-news-mckinsey-global-institute/>.
- Finkelstein, E., Linnan, L., Tate, D., & Birken, B. (2007). A pilot study testing the effect of different levels of financial incentives on weight loss among overweight employees. *Journal of Occupational and Environmental Medicine, 49*(9), 981-989.
- Fitzgibbon, M., Tussing-Humphreys, L., Porter, J., Martin, I., Odoms-Young, A., & Sharp, L. (2012). Weight loss and African-American women: A systematic review of the behavioral weight loss intervention literature. *Obesity Reviews, 13*(3), 193-213.
- Gerber, B., Stolley, M., Thompson, A., Sharp, L., & Fitzgibbon, M. (2009). Mobile phone text messaging to promote healthy behaviors and weight loss maintenance: A feasibility study. *Health Informatics Journal, 15*(1), 17-25. doi: 10.1177/1460458208099865.
- Giovannucci, E., Harlan, D., Archer, M., Bergenstal, R., Gapstur, S., Habel, L., ... Yee, D. (2010). Diabetes and cancer: A consensus report. *CA: A Cancer Journal for Clinicians, 60*(4), 207-221.

- Hardcastle, S., Taylor, A., Bailey, M., Harley, R. & Hagger, M. (2013). Effectiveness of a motivational interviewing intervention on weight loss, physical activity and cardiovascular disease risk factors: A randomized controlled trial with a 12-month post-intervention follow-up. *International Journal of Behavioral Nutrition & Physical Activity*, *10*, 1-16.
- James, D. (2013) Weight-loss strategies used by African-American women: Possible implications for tailored messages. *Journal of Human Nutrition and Dietetics*, *26*, 71-77.
doi:10.1111/j.1365-277X.2012.01268.
- Jemal, A., Siegel, R., Ward, E., Murray, T., Xu, J., & Thun, M. (2007). Cancer Statistics. *CA- A Cancer Journal for Clinicians*, *57*, 43-66.
- Keller, C., Larkey, L., Distefano, J., Boehm-Smith, E., Records, K., Robillard, A., ...O'Brian, A. (2010). Perimenopausal Obesity. *Journal of Women's Health*, *19*(5), 987-997.
- Kobayashi, M. & Kobayashi, M. (2006). The relationship between obesity and seasonal variation in body weight among elementary school children in Tokyo. *Economics and Human Biology*, *4*(2), 253-261.
- Lara, A., Yancey, A., Tapia-Conye, R., Flores, Y., Kuri-Morales, P., Mistry, R. ... McCarthy, W. (2008). Pausa para tu Salud: Reduction of weight and waistlines by integrating exercise breaks into workplace organizational routine. *Preventing Chronic Disease*, *5*(1), A12.
- Lovasi, G., Hutson, M., Guerra, M., & Neckerman, K. (2009). Built environments and obesity in disadvantaged populations. *Epidemiologic Reviews*, *31*(1), 7-20.
- Liu, J., Hay, J., & Faight, B. (2013). The association of sleep disorder, obesity status, and diabetes mellitus among US adults-The NHANES 2009-2010 survey results. Retrieved from <http://dx.doi.org/10.1155/2013/234129>.

- Martin, P., Dutton, G., & Brantley, P. (2004). Self-efficacy as a predictor of weight change in African-American women. *Obesity Research, 12*(4), 646-651. doi: <http://dx.doi.org/10.1038/oby.2004.74>.
- McLaren, L. (2007). Socioeconomic status and obesity. *Epidemiological Review, 29*(1), 29-48.
- Mensah, J., Mokdad, A., Ford, E., Greenlund, K., & Croft, J. (2005). State of disparities in cardiovascular health in the United States. *Circulation, 111*, 1233-1241.
- Moore, S., Charvat, J., Alemi, F., Gordon, N., Ribisl, P., & Rocco, M. (2011). Improving lifestyle exercise in cardiac patients: Results of the SystemCHANGE Trial. *Circulation, 124*, A13341.
- Mosca, L., Mochari-Greenberger, H., Dolor, R., Newby, L., & Robb, K. (2010). Twelve-year follow-up of American women's awareness of cardiovascular disease risk. Retrieved from: <http://circoutcomes.ahajournals.org/> on December 29, 2013.
- Mujahid, M., Diez Roux, A., Borrell, L., & Nieto, F. (2005). Cross-sectional and longitudinal associations of BMI with socioeconomic characteristics. *Obesity Research, 13*(8), 1412-1421.
- Murphy, P. & Williams, R. (2013). Weight-loss study in African-American women: Lessons learned from project Take HEED and future, technologically enhanced directions. *Permanente Journal, 17*(2), 55-59.
- National Dairy Council (2015). "3-a-day of dairy" program. Retrieved from <http://www.nationaldairycouncil.org/nationaldairycouncil/health/ThreeADay>
- National Center for Health Statistics. (2009). Health, United States, 2009: With special feature on medical technology (Table 72: Overweight, obesity, and healthy weight among persons 20 years of age and over, by selected characteristics—United States, 1960-1962 through

- 2003-2006). Hyattsville, MD: Author. Retrieved from <http://www.cdc.gov/nchs/data/hus/hus09.pdf#listfigures>
- Noar, S. M., Benac, C. N., & Harris, M. S. (2007). Does tailoring matter? Meta-analytic review of tailored print health behavior change interventions. *Psychological Bulletin*, *133*(4), 673-693. doi: <http://dx.doi.org/10.1037/0033-2909.133.4.673>.
- Orth, W., Madan, A., Taddeucci, R., Coday, M., & Tichansky, D. (2008). Support group meeting attendance is associated with better weight loss. *Obesity Surgery*, *18*(4), 391-394.
- Parks, S., Housemann, R., & Brownson, R. (2003). Differential correlates of physical activity in urban and rural adults of various socioeconomic backgrounds in the United States. *Journal of Epidemiology and Community Health*, *57*, 29-35.
- Patrick, K., Raab, F., Adams, M., Dillon, L., Zabinski, M., Rock, ... G. Norman (2009). A text message-based intervention for weight loss: Randomized controlled trial. *Journal of Medical Internet Research*, *11*(1), el.
- Perri, M. (2014). Effects of behavioral treatment on long-term weight loss: Lessons learned From the Look AHEAD Trial. *Obesity*, *22*(1), 3-4.
- Shin, H., Shin, J., Liu, P., Dutton, G., Abood, D., & Ilich, J. (2011). Self-efficacy improves weight loss in overweight/obese postmenopausal women during a 6-month weight loss intervention. *Nutrition Research*, *31*(11), 822-828. doi: 10.1016/j.nutres.2011.09.022.
- Sturm, R. & An, R. (2014). Obesity and economic environments. *CA: A Cancer Journal for Clinicians*, *64*, 337-350.
- Svetkey, L., Ard, J., Stevens, V., Loria, C., Young, D., Hollis, J., ... Vollmer, W. (2012). Predictors of long-term weight loss in adults with modest initial weight loss, by sex and race. *Obesity*, *20*(9), 1820-1828.

- Tussing-Humphreys, L., Fitzgibbon, M., Kong, A., & Odoms-Young, A. (2013). Weight loss maintenance in African American women: A systematic review of the behavioral lifestyle intervention literature. *Journal of Obesity*, 2013, Article ID 437369, 31 pages, doi:10.1155/2013/437369.2003).
- Wang, Y. & Zhang, Q. (2006). Are American children and adolescents of low socioeconomic status at increased risk of obesity? Changes in the association between overweight and family income between 1971 and 2002. *American Journal of Clinical Nutrition*, 84(4), 707-716.
- Welch, M. (2003). Care of Blacks and African Americans. In J. Bigby (Ed.). *Cross-Cultural Medicine*, 29-60. Philadelphia, PA: American College of Physicians.
- Wilcox, S., Laken, M., Parrott, A., Condrasky, M., Saunders, R., Addy, C., ... Samuel, M. (2010). The Faith, Activity, and Nutrition (FAN) Program: Design of a participatory research intervention to increase physical activity and improve dietary habits in African American churches. *Contemporary Clinical Trials*, 31(4), 323-335. doi: 10.1016/j.cct.2010.03.011
- Williams, R. (2009). Cardiovascular disease in African-American women: A health care disparities issue. *Journal of National Medical Association*, 101(6), 536-40.
- Yanovski, J., Yanovski, S., Sovik, K., Nguyen, T., O'Neil, P., & Sebring, N. (2000). A prospective study of holiday weight gain. *The New England Journal of Medicine*, 342(12), 861-867.
- Zargarian, N., Lindquist, R., Gross, C., & Treat-Jacobson, D. (2014). Outcomes measures of behavioral weight-loss programs in perimenopause. *Southern Medical Journal*, 17(8), 486-496.

Zlatković, M. (November 28-30, 2013). Survey of customer satisfaction: The example of freight distribution center. 1st Logistics International Conference. Belgrade, Serbia. Retrieved from: <http://logic.sf.bg.ac.rs/wp-content/uploads/Papers/ID-39.pdf>.

Chapter 5: Discussion

This chapter discusses the major findings from each manuscript in this dissertation. The first manuscript provided an overview of the problem of obesity in perimenopause, and examined recent published studies of behavioral weight-loss programs for perimenopausal women to determine the range of potential outcome measures useful to practice. Recommendations for future research were offered.

The second manuscript described the findings of the 10-week feasibility study conducted among AA women aged 35-75 years, specifically examining the feasibility of implementation and exploring the hypothesis that individuals in a structured group discussion would exhibit improved clinical outcomes and a reduction in risk factors of CVD compared to those receiving the standard weight-loss information. A secondary purpose of this study was to determine the effect size to test this intervention in a larger future clinical trial. The study limitations were also presented.

The third manuscript examined satisfaction, challenges and facilitators identified by participants, as well as challenges faced by investigators during the study conducted with AA women ages 35-75 years. It concludes with a section of “lessons learned” and recommendations to facilitate conducting larger-scale behavioral studies in the future.

Chapter 2 (Manuscript One) Results

The findings of this review showed that exercise alone and dietary modifications alone were not as effective in CVD risk factors reduction as those interventions combined, however, weight loss as a result of these interventions was beneficial in improvement clinical outcome measures such as BP, cholesterol, CRP, insulin resistance, and HgbA1C. It was also found to be very helpful in improving quality of life, and reducing morbidity and mortality of perimenopausal women.

Chapter 3 (Manuscript Two) Results

Statistical analysis showed no statistically significant weight changes ($p=0.49$) between the experimental and active, control groups (2.16 ± 5.2 lbs. vs. 0.40 ± 6.4 lbs.) due to high variability and a small sample size. There were twenty-three obese or overweight AA females ranged in age from 35 to 75 years, with an average body mass index of 33.96 ($SD=5.27$). When groups were combined, the average weight loss for the 22 women was also not statistically significant ($p=0.31$). However, participants in the combined analysis were found to have statistically significant DBP improvement (a 6.45 ± 9.71 mm/Hg decrease, $p= 0.005$). Analyses also showed statistically significant decrease in HC (0.7 ± 1.4 in., $p=0.03$), and WC reduction (pre to post) for all women in the combined analysis (1.34 ± 1.6 in., $p< 0.001$).

The estimated effect size for change in weight was 0.3; DBP 0.5; and SBP 0.2, suggesting that the addition of a structured discussion group component could potentially produce a clinically significant additional effect on weight loss and other variables.

It was noted that participants' attendance of meetings was associated with weight change. Based on attendance and the results of weight loss, it was determined that low weight loss was especially noted among participants with low attendance.

Chapter 4 (Manuscript Three) Results

Satisfaction with the program was very high among participants; however, attendance was still low. Low attendance could have been one of the reasons participants did not achieve significant weight loss. The greatest obstacle in achieving weight loss reported by participants was changing eating habits. The greatest reported facilitator of weight loss was education about nutrition, meal preparations, portion sizes, label reading; weight-loss strategies, tools and other information.

Synthesis

Numerous behavioral strategies have been shown to be effective in weight loss as reviewed in Manuscript 1. The literature provides additional evidence that stress management, peer support or support groups, communal participation, and continued education can be great facilitators of weight loss. Setting realistic expectations and milestones, reinforcing that behavioral changes are a life-long process, and that maintaining weight is maybe even more important than losing weight, will minimize participants' disappointment when a weight-loss is not as rapid as desired.

Writing a contract and goal setting regarding weight loss are behavioral strategies that have been documented to be effective. Understanding the “drivers” or reasons that individuals are motivated to lose weight is also important to investigators to help to support and remind participants to sustain their efforts. Perceptions of obesity may be different in the AA community and among individuals within it, and thus, it is important to focus on health conditions associated with excess weight rather than on simple “numbers” (weight) or appearance of being thin which can be a sign of illness in the interpretation of AA women, or it may be perceived as an unattainable or unreasonable goal, or one that is not appealing to AA participants.

Manuscript 2 describes a feasibility study adding peer group discussion and was designed to determine if a focus on application of content in small incremental steps would be additive to the more well-documented behavioral weight loss strategies. The moderate effect sizes for change in DBP (0.5) and weight (0.3) suggest that the addition of a structured discussion group component could potentially produce a clinically significant additional effect on weight loss and DBP.

The study described in Manuscript 2 had limitations, including a small sample, which increased variability, and made effect size calculations less precise. Another limitation was the

convenience sample, which affected the generalizability of the study findings since the sample was not representative of all AA women.

Despite those limitations, this study is important because it adds to the existing literature on obesity management among AA women. The strengths and limitations of the intervention study are discussed in greater detail in Manuscript 3, and “lessons learned” for consideration in future studies are offered. The structured versus unstructured discussion approach as implemented in this study is a novel approach. If further developed and tested, and the design of future studies improved by insights learned in the feasibility study described in Manuscript 2, this type of program has the potential to be a valuable non-pharmacological approach to facilitate weight loss and weight management. Efforts to implement the protocol successfully could lead to better patient outcomes and improved quality of their life as well as to reduce the dramatic and devastating consequences of diabetes, HTN, heart disease and other comorbid conditions.

Conclusions

The results from this dissertation provide evidence that behavioral weight-loss feasibility study can be feasible, and behavioral strategies can be applied successfully with considerations of obstacles and facilitators to weight-loss efforts. Diet and physical activity combined are instrumental in weight loss, however, without permanent behavioral weight management long-term weight loss cannot be expected, and people will go back to their old eating and exercise habits. Recognizing weight-loss challenges and overcoming them might empower participants to continue their weight-loss efforts.

Recommendations for Future Research

AA women suffer the highest prevalence of obesity in our society. Effective weight loss and weight maintenance programs (or preventive programs) for AA women are urgently needed.

Based on the results of this study, several recommendations are made for future behavioral weight-loss studies designed for AA women.

The first recommendation would be assessing potential participants' preparedness and readiness to change prior to enrollment. Commitment to the study should be strongly reinforced. Setting realistic goals and expectations and reviewing it during the study are important to maintain self-efficacy of participants. In future research, this could help investigators to distribute resources fairly, minimize waste of time, and most importantly, have increased chances of significant weight-loss results that might greatly affect cardiovascular morbidity and mortality among AA women.

Another recommendation for a more successful weight-loss study will be to conduct it in the fall when people are ready to return to more structured routine after summer activities and fun. It might significantly increase attendance and retention of participants, because inability of people to fit meetings into their busy summer schedule was one of the reported obstacles.

Based on attendance and the results of weight loss, it was determined that low weight loss was especially noted among participants with low attendance. In future studies, it is recommended that make-up sessions be planned or other forms of content delivery (e.g., email, text messaging, posting information on designated websites) be offered. Mid-week phone follow-up, more peer-to-peer interaction could also be helpful in increasing attendance. Recruitment of participants who will make an explicit commitment to the intervention schedule could improve attendance. If possible, a "run-in" period in which women attend and perform study activities could be implemented to exclude women who do not adhere to minimal protocol requirements. This may ensure that women are recruited who are truly ready to change their lifestyle and behavior, and who may utilize study resources more fruitfully.

Since the most frequently mentioned obstacle to weight-loss efforts was changing eating habits, offering weight-loss programs that are more individualized and sensitive to AA food preferences might help to make it more successful. Communal participation is important. This would allow participants to interact and share ideas and recipes for healthier versions of their favorite, traditional foods. More emphasis could be focused on assessing participants' eating behavior by inquiring about unresolved stress and other issues. It might be helpful to encourage and reinforce that behavioral changes are a life-long process, and that maintaining weight is maybe even more important than losing weight.

References

- Akers, J., Estabrooks, P. A., & Davy, B. M. (2010). Translational research: Bridging the gap between long-term weight-loss maintenance research and practice. *Journal of the American Dietetic Association, 110*(10), 1511-1522.
- American Diabetic Association (2014). Retrieved from <http://www.diabetes.org/living-with-diab>
- Anthropometry Procedure Manual (Revised 2004). Center for Disease Control and Prevention. Retrieved from http://www.cdc.gov/nchs/data/nhanes/nhanes_03_04/BM.pdf
- American Diabetic Association (2013). Blood Glucose Meters 2013. Obtained from: <http://www.diabetesforecast.org/2013/jan/blood-glucose-meters-2013.html>. Accessed February 22, 2014.
- American Heart Association (2013). Statistical fact sheet: 2013 Update. Retrieved from: http://www.heart.org/idc/groups/heart-public/@wcm/@sop/@smd/documents/downloadable/ucm_319568.pdf. Accessed December 29, 2013.
- American Heart Association (2009). Cardiovascular disease: Women's No.1 health threat. [http://www.americanheart.org/downloadable/heart/1267456190628TD edited FINAL women and CVD 02.15.10.pdf](http://www.americanheart.org/downloadable/heart/1267456190628TD%20edited%20FINAL%20women%20and%20CVD%2002.15.10.pdf). Accessed August 11, 2013.
- Anderson, R. & Funnell, R. (2002). Using the empowerment approach to help patients change behavior. In B. Anderson & R. Rubin (Eds.), *Practice Psychology for Diabetes Clinicians* (p.5). American Diabetic Association.
- Anderson, D., Mizzari, K., Kain, V., & Webster, J. (2010). The effects of a multimodal intervention trial to promote lifestyle factors associated with the prevention of cardiovascular disease in menopausal and postmenopausal Australian women. *Health Care Women International, 27*(3), 238-253.

- Azadbakht, L., Kimiagar, M., Mehrabi, Y., Esmailzadeh, A., Padyab, M., Hu, F., & Willett, W. (2007). Soy inclusion in the diet improves features of the metabolic syndrome: A randomized crossover study in postmenopausal women. *American Journal of Clinical Nutrition*, 8,735-741.
- Bandura, A. (1986). *Social foundations of thought and action: A social cognitive theory*. Englewood Cliffs, NJ: Prentice Hall.
- Bas, M. & Donmez, S. (2009). Self-efficacy and restrained eating in relation to weight loss among overweight men and women in Turkey. *Appetite*, 52, 209-216
- Bassuk, S. & Manson, J. (2008). Lifestyle and risk of cardiovascular disease and type 2 diabetes in women: A review of the epidemiologic evidence. *American Journal of Lifestyle Medicine*, 2(3), 191-213.
- Beladev, N. & Masharawi, Y. (2011). The effect of group-exercising on females with non-specific chronic low back pain in a sitting position: A pilot study. *Journal of Back & Musculoskeletal Rehabilitation*, 24(3), 181-188.
- Bhattacharya, J. & Neeraj, S. (2011). "Who pays for obesity?" *Journal of Economic Perspectives*, 25(1), 139-158.
- Binks, M. & O'Neil, M. (2002). Referral sources to a weight management program: Relation to outcome. *Journal of General Internal Medicine*, 17, 596-603.
- Blackburn, C. & Walker, W. (2005). Science-based solutions to obesity: What are the roles of academia, government, industry, and health care? *American Journal of Clinical Nutrition*, 82(Suppl.), 207S-210S.
- Blaakman, S., Cohen, A., Fagnano, M., & Halterman, J. (2014). Asthma medication adherence among urban teens: A qualitative analysis of barriers, facilitators and experiences with

- school-based care. *Journal of Asthma*, 51(5), 522-529. doi: 10.3109/02770903.2014.885041.
- Bray, G. (2004). Medical consequences of obesity. *Journal of Clinical Endocrinology and Metabolism*, 89(6), 2583-2589.
- Brindal, E., Freyne, J., Saunders, I., Berkovsky, S., Smith, G., & Noakes, M. (2012). Features predicting weight loss in overweight or obese participants in a web-based intervention: randomized trial. *Journal of Medical Internet Research* 14(6), e173.
- Bronner, Y. & Boyington, J. (2002). Developing weight-loss interventions for African American women: Elements of successful models. *Journal of the National Medical Association*, 94, 224-235.
- Byrne, S., Barry, D., & Petry, N. (2012). Predictors of weight loss success: Exercise vs. dietary self-efficacy and treatment attendance. *Appetite*, 58(2), 695-698.
- Carroll, S. & Dudfield, M. (2004). What is the relationship between exercise and metabolic abnormalities? A review of the metabolic syndrome. *Sports Medicine*, 34(6), 371-418.
- Catenacci, V. & Wyatt, H. (2007). The role of physical activity in producing and maintaining weight loss. *Nature Clinical Practice Endocrinology & Metabolism*, 3, 518-529.
- Choi, B., Pak, A., Choi, J., & Choi, E. (2007). Daily step goal of 10,000 steps; A literature review. *Clinical Investigative Medicine*, 30(3), E146-151.
- Cizza, G., Requena, M., Galli, G., & De Jonge, L. (2011). Chronic sleep deprivation and seasonality: Implications for the obesity epidemic. *Journal of Endocrinological Investigation*, 34, 793-800. doi: 10.3275/7808.
- Collins, P., Rosano, P., Casey, C., Daly, M., Gambacciani, P., Hadji, R., ... Stramba-Badiale, M. (2007). Management of cardiovascular risk in the perimenopausal women: A consensus statement of European cardiologists and gynecologists. *Climacteric*, 10, 508-526.

- Crothers, M., Hughes, L., & Morine, K. (2008). *Theory and cases in school-based consultation: A resource for school psychologists, school counselors, special educators, and other mental health professionals*. New York: Routledge Taylor & Francis Group.
<http://books.google.com/books?id=vKsXLZkKiyIC>. Accessed August 11, 2013.
- dabl@Educational Trust (2013). Retrieved from <http://www.dableducational.org/disclaimer.html>
- Deci, E. & Ryan, R. (2008). Self-Determination Theory: A macrotheory of human motivation, development, and health. *Canadian Journal of Psychology*, 49(3), 182-185.
- DeLany, J., Kelley, D., Hames, K. Jakicic, J., & Goodpaster, B. (2014). Effect of physical activity on weight loss, energy expenditure, and energy intake during diet induced weight loss. *Obesity*, 22(2), 363-370.
- Department of Health and Human Services (2010a). Healthy people 2020: The road ahead.
Available at: <http://www.health.gov/healthypeople/url> (accessed on February 1, 2015).
- Dobbs, R., Sawers, C., Thompson, F., Manyika, J., Woetzel, J., Child, P., ... Spatharou, A. (2014). Overcoming obesity: an initial economic analysis. McKinsey Global Institute.
Retrieved from <https://dementianews.wordpress.com/2014/11/21/more-on-the-obesity-risk-factor-bbc-news-mckinsey-global-institute>.
- Eriksson, M., Westborg, C., & Eliasson, M. (2006). A randomized trial of lifestyle intervention in primary healthcare for the modification of cardiovascular risk factors: The Bjorkna's Study. *Scandinavian Journal of Public Health*, 34, 453-461.
- Finkelstein, E., Linnan, L., Tate, D., & Birken, B. (2007). A pilot study testing the effect of different levels of financial incentives on weight loss among overweight employees. *Journal of Occupational and Environmental Medicine*, 49(9), 981-989.

- Fitzgibbon, M., Tussing-Humphreys, L., Porter, J., Martin, I., Odoms-Young, A., & Sharp, L. (2012). Weight loss and African-American women: A systematic review of the behavioral weight loss intervention literature. *Obesity Reviews*, *13*(3), 193-213.
- Foster-Schubert, K., Alfano, C., Duggan, C., Xiao, L., Campbell, K., Kong, A., & McTiernan, A. (2012). Effect of diet and exercise, alone or combined, on weight and body composition in overweight-to-obese postmenopausal women. *Obesity*, *20*, 1628-1638.
- Frank, L., Sorensen, B., Yasui, Y., Lewis Frank, L., Sorensen, B., Yasui, Y., ... McTiernan, A. (2005). Effects of exercise on metabolic risk variables in overweight postmenopausal women: A randomized clinical trial. *Obesity Research*, *13*(3), 615-625.
- Fujioka, K. & Bakhru, N. (2010). Office-based management of obesity. *Mount Sinai Journal of Medicine*, *77*, 466-471.
- Gerber, B., Stolley, M., Thompson, A., Sharp, L., & Fitzgibbon, M. (2009). Mobile phone text messaging to promote healthy behaviors and weight loss maintenance: A feasibility study. *Health Informatics Journal*, *15*(1), 17-25. doi: 10.1177/1460458208099865.
- Giovannucci, E., Harlan, D., Archer, M., Bergenstal, R., Gapstur, S., Habel, L., ... Yee, D. (2010). Diabetes and cancer: A consensus report. *CA: A Cancer Journal for Clinicians*, *60*(4), 207-221.
- Go, A., Mozaffarian, D., Roger, V., Benjamin, E., Berry, J., Borden, W., ... Turner, M. (2013). Heart disease and stroke statistics—2013 Update. *Circulation*, *127*: e6-e245. doi: 10.1161/CIR.0b013e31828124ad.
- Gohlke-Barwolf, C. (2009). Coronary artery disease - Is menopause a risk factor? *Basic Research in Cardiology*, *95* (Suppl 1), I77-83.
- Hardcastle, S., Taylor, A., Bailey, M., Harley, R. & Hagger, M. (2013). Effectiveness of a motivational interviewing intervention on weight loss, physical activity and

- cardiovascular disease risk factors: A randomized controlled trial with a 12-month post-intervention follow-up. *International Journal of Behavioral Nutrition & Physical Activity*, *10*, 1-16.
- Hedley, A., Ogden, C., Johnson, C., Carroll, M., Curtin, L., & Flegal, K. (2004). Prevalence of overweight and obesity among US children, adolescents, and adults, 1999-2002. *JAMA*, *291*, 2847-2850.
- Herrera, B., Keildson, S., & Lindgren, C. (2011). Genetics and epigenetics of obesity. *Maturitas*, *69*(1), 41-49.
- Hertzog, M. (2008). Considerations in determining sample size for pilot studies. *Research in Nursing and Health*, *31*(2), 180-191.
- Howard, B., Van Horn, L., Hsia, J., Manson, J., Stefanick, M., Wassertheil-Smoller, S., ... Morley-Kotchen, J. (2006). Low-fat dietary pattern and risk of cardiovascular disease: The Women's Health Initiative randomized controlled dietary modification trial. *Journal of American Medical Association*, *295*(6), 655-666.
- Imayama, I., Ulrich, C., Alfano, C., Wang, C., Xiao, L., Wener, M., ... McTiernan, A. (2008). Effects of a caloric restriction weight-loss diet and exercise on inflammatory biomarkers in overweight/obese postmenopausal women: A randomized controlled trial. *Cancer Research*, *72*, 2314-2326.
- James, D. (2013) Weight-loss strategies used by African-American women: Possible implications for tailored messages. *Journal of Human Nutrition and Dietetics*, *26*, 71-77. doi:10.1111/j.1365-277X.2012.01268.
- James P., Oparil, S., & Carter, B. (2014). Evidence-based guideline for the management of high blood pressure in adults: Report from the panel members appointed to the Eighth Joint National Committee (JNC 8). *JAMA*, *311*(5), 507-520. doi:10.1001/jama.2013.284427.

- Jemal, A., Siegel, R., Ward, E., Murray, T., Xu, J., & Thun, M. (2007). Cancer statistics. *CA- A Cancer Journal for Clinicians*, *57*, 43-66.
- Kadam, P. & Bhaller, S., (2010). Sample size calculation. *International Journal of Ayurveda Research*, *1*(1), 55-57.
- Kaplan, M., Huguet, N., Newsom, J., & McFarland, B. (2004). The association between length of residence and obesity among Hispanic immigrants. *American Journal of Preventative Medicine*, *27*, 323-326.
- Keller, C., Larkey, L., Distefano, J., Boehm-Smith, E., Records, K., Robillard, A., ...O'Brian, A. (2010). Perimenopausal obesity. *Journal of Women's Health*, *19*(5), 987-997.
- Kim, J., Park, S., & Lim, Y. (2007). Analysis of the factors affecting the success of weight reduction programs. *Yonsei Medical Journal*, *48*(1), 24-29.
- Kobayashi, M. & Kobayashi, M. (2006). The relationship between obesity and seasonal variation in body weight among elementary school children in Tokyo. *Economics and Human Biology*, *4*(2), 253-261.
- Lara, A., Yancey, A., Tapia-Conye, R., Flores, Y., Kuri-Morales, P., Mistry, R. ... McCarthy, W. (2008). Pausa para tu Salud: Reduction of weight and waistlines by integrating exercise breaks into workplace organizational routine. *Preventing Chronic Disease*, *5*(1), A12.
- Liu, J., Hay, J., & Faught, B. (2013). The association of sleep disorder, obesity status, and diabetes mellitus among US adults-The NHANES 2009-2010 survey results. Retrieved from <http://dx.doi.org/10.1155/2013/234129>.
- Lovasi, G., Hutson, M., Guerra, M., & Neckerman, K. (2009). Built environments and obesity in disadvantaged populations. *Epidemiologic Reviews*, *31*(1), 7-20.

- Lovejoy, J., Champagne, C., de Jonge, L., Xie, H., & Smith, S. (2008). Increased visceral fat and decreased energy expenditure during the menopausal transition. *International Journal of Obesity*, 32(6), 949-958.
- Luz, L., Neto, G., & Farinatti, P. (2007). Validity of the Physical Activity Readiness Questionnaire (PAR-Q) in elder subjects. *Brazilian Journal of Kinanthropometry and Human Performance*, 9(4), 367-371
- Ma, J., & Xiao, L., & Stafford, R. (2008). Adult obesity and office-based quality of care in the United States. *Obesity*, 17, 1077-1085. doi: 10.1038/oby.2008.653.
- Martin, P., Dutton, G., & Brantley, P. (2004). Self-efficacy as a predictor of weight change in African-American women. *Obesity Research*, 12(4), 646-651. doi: <http://dx.doi.org/10.1038/oby.2004.74>.
- Martinez-Hernandez, A., Enriquez, L., Moreno-Moreno, M., & Mart, A. (2007). Genetics of obesity. *Public Health Nutrition*, 10(10A), 1138-1144.
- McLaren, L. (2007). Socioeconomic status and obesity. *Epidemiological Review*, 29(1), 29-48.
- Mensah, J., Mokdad, A., Ford, E., Greenlund, K., & Croft, J. (2005). State of disparities in cardiovascular health in the United States. *Circulation*, 111, 1233-1241.
- Moore, S., Charvat, J., Alemi, F., Gordon, N., Ribisl, P., & Rocco, M. (2011). Improving lifestyle exercise in cardiac patients: Results of the SystemCHANGE Trial. *Circulation*, 124, A13341.
- Moore, S. & Charvat, J. (2002). Using the CHANGE Intervention to enhance long-term exercise. *Nursing Clinics of North America*, 37(2), 272-283.
- Mosca, L., Benjamin, E., Berra, K., Bezanson, J., Dolor, R., Lloyd-Jones, D., ... Wenger, N. (2011). Effectiveness-based guidelines for the prevention of cardiovascular disease in women-2011 update (2011). *Circulation*, 123(11), 1243-1262.

- Mosca, L., Mochari-Greenberger, H., Dolor, R., Newby, L., & Robb, K. (2010). Twelve-year follow-up of American women's awareness of cardiovascular disease risk and barriers to heart health. *Circulation: Cardiovascular Quality and Outcomes*, 3, 120-127.
- Mujahid, M., Diez Roux, A., Borrell, L., & Nieto, F. (2005). Cross-sectional and longitudinal associations of BMI with socioeconomic characteristics. *Obesity Research*, 13(8), 1412-1421.
- Murphy, P. & Williams, R. (2013). Weight-loss study in African-American women: Lessons learned from project Take HEED and future, technologically enhanced directions. *Permanente Journal*, 17(2), 55-59.
- National Center for Health Statistics. (2009). Health, United States, 2009: With special feature on medical technology (Table 72: Overweight, obesity, and healthy weight among persons 20 years of age and over, by selected characteristics—United States, 1960-1962 through 2003-2006). Hyattsville, MD: Author. Retrieved from <http://www.cdc.gov/nchs/data/hus/hus09.pdf#listfigures>
- National Dairy Council's "3-A-Day of Dairy" program. Retrieved from <http://www.nationaldairycouncil.org/nationaldairycouncil/health/ThreeADay>
- Noar, S., Benac, C., & Harris, M. (2007). Does tailoring matter? Meta-analytic review of tailored print health behavior change interventions. *Psychological Bulletin*, 133(4), 673-693. doi: <http://dx.doi.org/10.1037/0033-2909.133.4.673>.
- Nicklas, B., Wang, X., You, T., Lyles, M., Demons, J., Easter, L., ... Carr, J. (2005). Effect of exercise intensity on abdominal fat loss during calorie restriction in overweight and obese postmenopausal women: A randomized controlled trial. *American Journal of Clinical Nutrition*, 89, 1043-1052.

- Noakes, M., Keogh, J., Foster, P., & Clifton, P. (2005). Effect of an energy-restricted, high-protein, low-fat diet relative to a conventional high-carbohydrate, low-fat diet on weight loss, body composition, nutritional status, and markers of cardiovascular health in obese women. *American Journal of Clinical Nutrition*, *81*(6), 1298-1306.
- Oh, E., Chu, H., Bang, S., Lee, M., Kim, S., Hyun, S., ... Lee, J. (2011). Effects of a therapeutic lifestyle modification program on inflammatory chemokines and insulin resistance in subjects with metabolic syndrome. *Biological Research for Nursing*, *13*(2), 182-188.
- Okada, S., Hiude, A., Makino, H., Nagumo, A., Takaki, H., Konishi, ... Miyamoto, Y. (2010). Effect of exercise intervention on endothelial function and incidence of cardiovascular disease in patients with type 2 diabetes. *Journal of Atherosclerosis and Thrombosis*, *17*(8), 828-833.
- O'Rahilly, S. & Farooq, S. (2006). Genetics of obesity. *Philosophical Transactions of the Royal Society B: Biological Sciences (or Philosophical Transactions B)*, *361*, 1095-1105. doi:10.1098/rstb.2006.1850.
- Orth, W., Madan, A., Taddeucci, R., Coday, M., & Tichansky, D. (2008). Support group meeting attendance is associated with better weight loss. *Obesity Surgery*, *18*(4), 391-394.
- Pampel, F., Krueger, P., & Denney, J. (2010). Socioeconomic disparities in health behaviors. *Annual Review of Sociology*, *36*, 349-370. doi: 10.1146/annurev.soc.012809.102529
- Parker, K. & Parikh, S. (2001). Applying Prochaska's model of change to needs assessment, program planning and outcome measurement. *Journal of Evaluation in Clinical Practice*, *7*(4), 365-371.
- Parks, S., Housemann, R., & Brownson, R. (2003). Differential correlates of physical activity in urban and rural adults of various socioeconomic backgrounds in the United States. *Journal of Epidemiology and Community Health*, *57*, 29-35.

- Patrick, K., Raab, F., Adams, M., Dillon, L., Zabinski, M., Rock, ... G. Norman (2009). A text message-based intervention for weight loss: Randomized controlled trial. *Journal of Medical Internet Research*, *11*(1), e1.
- Perri, M. (2014). Effects of behavioral treatment on long-term weight loss: Lessons learned from the Look AHEAD Trial. *Obesity*, *22*(1), 3-4.
- Roger, V., Go, A., Lloyd-Jones, D., Adams, R., Berry, J., Brown, T., ... Wylie-Rosett, J. (2011). Heart disease and stroke statistics: 2011 update: A report from the American Heart Association. *Circulation*, *123*, e18-e209. doi: 10.1161/CIR.0b013e3182009701.
- Sandelowski, M. (2000). Whatever happened to qualitative description? *Research in Nursing Health*, *23*, 334-340.
- Sanderson, S., Diefenbach, M., Streicher, S., Jabs, E., Smirnoff, M., Horowitz, C., ... Richardson, L. (2013). Genetic and lifestyle causal beliefs about obesity and associated diseases among ethnically diverse patients: A structured interview study. *Public Health Genomics*, *16*(3), 83-93.
- SAS Institute Inc. (2011). *Base SAS® 9.3 Procedures guide: statistical procedures*. Cary, NC: SAS Institute Inc.
- Shai, I., Schwarzfuchs, D., Henkin, Y., Shahar, D., Witkow, S., Greenberg, I., ... Stampfer, M. (2008). Weight loss with a low-carbohydrate, Mediterranean, or low-fat diet. *New England Journal of Medicine*, *359*(3), 229-241.
- Shin, H., Shin, J., Liu, P., Dutton, G., Abood, D., & Ilich, J. (2011). Self-efficacy improves weight loss in overweight/obese postmenopausal women during a 6-month weight loss intervention. *Nutrition Research*, *31*(11), 822-828. doi: 10.1016/j.nutres.2011.09.022.
- Slentz, C., Duscha, B., Johnson, J., Ketchum, K., Aiken, L., Samsa, G., ... Kraus, W. (2004). Effects of the amount of exercise on body weight, body composition, and measures of

- central obesity STRRIDE—A randomized controlled study. *Archives of Internal Medicine*, 164(1), 31-39.
- Smith, L. (2005). New AHA recommendations for blood pressure measurement. *American Family Physician*, 72(7), 1391-1398.
- Sturm, R. & An, R. (2014). Obesity and economic environments. *CA: A Cancer Journal for Clinicians*, 64, 337-350.
- Svetkey, L., Ard, J., Stevens, V., Loria, C., Young, D., Hollis, J., ... Vollmer, W. (2012). Predictors of long-term weight loss in adults with modest initial weight loss, by sex and race. *Obesity*, 20(9), 1820-1828.
- Tsai, A. & Wadden, T. (2005). Systematic review: An evaluation of major commercial weight loss programs in the United States. *Annals of Internal Medicine*, 142(1), 56-66.
- Tussing-Humphreys, L., Fitzgibbon, M., Kong, A., & Odoms-Young, A. (2013). Weight loss maintenance in African American women: A systematic review of the behavioral lifestyle intervention literature. *Journal of Obesity*, vol. 2013, Article ID 437369, 31 pages, 2013. doi:10.1155/2013/4373692013.
- U.S. Preventive Services Task Force. Screening for and management of obesity in adults. <http://www.uspreventiveservicestaskforce.org/uspstf11/obeseadult/obesers.htm>. Released July 2012. Accessed October 24, 2013.
- Van Gaal, L., Mertens, I., & Ballaux, D. (2005, 7 Suppl. L). What is the relationship between risk factor reduction and degree of weight loss? *European Heart Journal*, L21-L26.
- Velicer, W., Prochaska, J., Fava, J., Norman, G., & Redding, C. (1998). Smoking cessation and stress management: Applications of the Transtheoretical Model of Behavior Change. *Homeostasis*, 38, 216-233.

- Villareal, D., Miller, B., Banks, M., Fontana, L., Sinacore, D., & Klein, S. Effect of lifestyle intervention on metabolic coronary heart disease risk factors in obese older adults. *American Journal of Clinical Nutrition*, 84, 1117-1123.
- Wadden, T., Butryn, M., & Byrne, K. (2004). Efficacy of lifestyle modification for long-term weight control. *Obesity Research*, 12, 151S-162S.
- Wadden, T. & Butryn, M. (2003). Behavioral treatment of obesity. *Endocrinology and Metabolism Clinics of North America*, 32, 981-1003.
- Wang, Y. & Zhang, Q. (2006). Are American children and adolescents of low socioeconomic status at increased risk of obesity? Changes in the association between overweight and family income between 1971 and 2002. *American Journal of Clinical Nutrition*, 84(4), 707-716.
- Warburton, D., Gledhill, N., Jamnik, V., Bredin, S., McKenzie, D., Stone, J., Charlesworth, S. ... Shephard, R. (2011). Evidence-based risk assessment and recommendations for physical activity clearance: Consensus Document. Retrieved from <http://www.nrcresearchpress.com.ezp1.lib.umn.edu/doi/pdf/10.1139/h11-062>
- Warziski, M., Sereika, S., Styn, M., Music, E., & Burke LE. (2008). Changes in self-efficacy and dietary adherence: The impact of weight loss in the Prefer Study. *Journal of Behavioral Medicine*, 31, 81-92.
- Webel, A., Moore, S., Hanson, J., & Salata, R. (2013). The rationale, design, and initial efficacy of SystemCHANGE™ -HIV: A systems-based intervention to improve physical activity in people living with HIV. *Journal of AIDS & Clinical Research*, 4, 200. doi:10.4172/2155-6113.1000200.
- Welch, M. (2003). Care of Blacks and African Americans. In J. Bigby (Ed.). *Cross-Cultural Medicine*, 29-60. Philadelphia: American College of Physicians.

- Wilcox, S., Laken, M., Parrott, A., Condrasky, M., Saunders, R., Addy, C., ... Samuel, M. (2010). The Faith, Activity, and Nutrition (FAN) Program: Design of a participatory research intervention to increase physical activity and improve dietary habits in African American churches. *Contemporary Clinical Trials*, *31*(4), 323-335. doi: 10.1016/j.cct.2010.03.011.
- Willett, W. (1998). *Nutritional Epidemiology*, 2nd ed. Oxford University Press: New York, NY.
- Williams, R. (2009). Cardiovascular disease in African American women: A health care disparities issue. *Journal of National Medical Association*, *101*(6), 536-40.
- Wing, R., Lang, W., Wadden, T., Safford, M., Knowler, W., Bertoni, A., ... Wagenknecht, L. (2011). Benefits of modest weight loss in improving cardiovascular risk factors in overweight and obese individuals with type 2 diabetes. *Diabetes Care*, *34*(7), 1481-1486. doi: 10.2337/dc10-2415.
- World Health Organization (2008). Waist circumference and waist-hip ration: Report of WHO expert consultation. Accessed at: http://whqlibdoc.who.int/publications/2011/9789241501491_eng.pdf
- Yanovski, J., Yanovski, S., Sovik, K., Nguyen, T., O'Neil, P., & Sebring, N. (2000). A prospective study of holiday weight gain. *The New England Journal of Medicine*, *342*(12), 861-867.
- Zakzanis, K. (2001). Statistics to tell the truth, the whole truth, and nothing but the truth: Formulae, illustrative numerical examples, and heuristic interpretation of effect size analyses for neuropsychological researchers. *Archives of Clinical Neuropsychology*, *16*(7), 653-667.

Zargarian, N., Lindquist, R., Gross, C., & Treat-Jacobson, D. (2014). Outcomes measures of behavioral weight-loss programs in perimenopause. *Southern Medical Journal*, 17(8), 486-496.

Zlatković, M. (November 28-30, 2013). Survey of customer satisfaction: The example of freight distribution center. 1st Logistics International Conference. Belgrade, Serbia.

Appendix A

Southern Medical Journal Release

Permission from the Southern Medical Journal

Inbox x



jprice@sma.org

Aug 5 (4
days
ago)

to me

Dear Dr. Zargarian:

This email serves to grant you permission to use the article, "Outcome Measures of Behavioral Weight Loss Programs in Perimenopause" with limited copyright release in your dissertation.

Thank you and please do not hesitate to contact me with any questions or if I may be of further assistance.

Sincerely,

Jennifer Price, M.A.

Managing Editor, *Southern Medical Journal*

Southern Medical Association

35 W. Lakeshore Drive

Suite 201

Birmingham, AL 35209

Telephone: [\(205\) 945-1840, Ext. 185](tel:(205)945-1840)

Direct: [\(205\) 421-4185](tel:(205)421-4185)

Toll Free: [\(800\) 423-4992, Ext. 185](tel:(800)423-4992)

Fax: [\(205\) 945-1548](tel:(205)945-1548)

E-mail: jprice@sma.org

Appendix B

Topical Outline of Weekly Shared Behavioral Weight-Loss Sessions

Week 1	Introduction to the program; benefits of weight loss; commitment to goals and setting realistic goals; defining success; behavioral strategies and tools for weight loss; why to lose weight (assess motivators and knowledge); how to benefit from group support. Share stories; what worked, what did not work?
Week 2	Week Combat 10-10-10: Can we do it? 10 steps to success: Acknowledge the problem; take responsibility for finding a solution; evaluate where you are; make a commitment; set SMART goals: Specific, Measurable, Attainable, Relevant, Timed; Believe you can do it; monitor your progress; do not give up!; get support from friends and family; enjoy your good health!
Week 3	Terms we need to know: BMI (body mass index), BMR (basal metabolic rate); TEE (total energy expenditure). Change the color of your food. 10 weight-loss tips. Share stories and suggestions.
Week 4	LEPTIN – a fat hormone. Its role in hunger management. Weight-loss success by proper diet, exercise, stress management, and restful sleep. Five food groups that are the building blocks for a healthy diet: fruits, vegetables, grains, dairy, protein. Recommended Daily Allowance.
Week 5	American Dietary Guidelines. Reading labels. Serving sizes. Nutrients to limit. Nutrients to get enough of. Daily values vs. % daily value. Trans fat. Added sugars. Salt and supplements. FDA-proposed changes to food labeling.
Week 6	Control your home and work environment to stay away from “forbidden foods”; shopping; meal planning and food preparations; eating out and social eating; eating at restaurant and entertaining at home; eating during holidays; importance of exercise; have a healthy attitude;
Week 7	Meeting with a dietitian: healthy recipes; learn to substitute ingredients to make it healthier; share suggestions and recipes; hidden salt and sugar; “everything in moderation”.
Week 8	Why physical activity? How to get started, how to exercise safely and effectively; adjust your goals; exercise tips: make it a habit. Build exercise into your lifestyle; tips to increasing physical activity. Share suggestions and ideas. Terms to know: Resting Heart Rate (RHR), Maximum Heart Rate (MHR), Target Rate (THR); myth about exercise-quiz.
Week 9	Meeting with a fitness instructor; exercise for different muscle groups; how to exercise safely; nutrition after exercise; how to increase exercise at home, at work, and outside.
Week 10	Weight loss vs. weight maintenance; 13 ways to maintain weight loss; lapse vs. relapse; stages of relapse; relapse prevention; relapse prevention quiz.

Appendix C

Topical Outline of Weekly Optimized Environmental Changes Each Session 1 Hour

- Week 1 Experimenting: Using mini-experiments to change your routine and develop habits for better health. **Planning ahead for meals** (mealtimes, volume and nutrition content; lunch on the go; “quick prep” strategies). Mini-experiments of the week.
- Week 2 Experimenting: Using mini-experiments to change your routine and develop habits for better health. Making adjustments to the plan—discussion of success and revisions. **Planning ahead for snacks and “quick grabs”** (eliminating junk and having appealing snacks prominent and available). Mini-experiments of the week.
- Week 3 Experimenting: Using mini-experiments to change your routine and develop habits for better health. Making adjustments to the plan—discussion of success and revisions. **MyPlate: CDC recommendations for your intake of fruits and vegetables (working them in!):**
<http://www.choosemyplate.gov/myplate/index.aspx> Buying, preparing, eating, and tracking fruits and vegetables. Mini-experiments of the week.
- Week 4 Experimenting: Using mini-experiments to change your routine and develop habits for better health. Making adjustments to the plan—discussion of success and revisions. **Zeroing in on problem eating: charting eating patterns and identifying the source.** Mini-experiments of the week.
- Week 5 Experimenting: Using mini-experiments to change your routine and develop habits for better health. Making adjustments to the plan—discussion of success and revisions. Targeting a higher level of nutritional intake. What food, super food or nutrient is missing or could be added for better health? Mini-experiments of the week.
- Week 6 Experimenting: Using mini-experiments to change your routine and develop habits for better health. Discussion of success and revisions. Using a calendar to schedule walking (plan time of day, distance, length of time). Mini-experiments of the week.
- Week 7 Experimenting: Using mini-experiments to change your routine and develop habits for better health. Making adjustments to the plan—discussion of success and revisions. **“Routinizing” success: Tweaking, “templating” (applying blueprint of success of one behavior change to another behavior or circumstance), and making positive changes stick.** Mini-experiments of the week.

- Week 8 Experimenting: Using mini-experiments to change your routine and develop habits for better health. Making adjustments to the plan—discussion of success and revisions. Super-sizing benefits of your work-out: Targeting a higher yet level or intensity of activity—How is it possible?!. Mini-experiments of the week.
- Week 9 Experimenting: Using mini-experiments to change your routine and develop habits for better health. Making adjustments to the plan—discussion of success and revisions.
- Week 10 Experimenting: Using mini-experiments to change your routine and develop habits for better health. Making adjustments to the plan—discussion of success and revisions. ***Making your new behaviors the template for your natural life. Relapse and resolve, and techniques to start again.*** Mini-experiments of the week.

Appendix D

UNIVERSITY OF MINNESOTA

Twin Cities Campus

Human Research Protection Program
Office of the Vice President for Research

*D528 Mayo Memorial Building
420 Delaware Street S.E.
MMC 820
Minneapolis, MN 55455
Office: 612-626-5654
Fax: 612-626-6061
E-mail: irb@umn.edu or ibc@umn.edu
Website: <http://research.umn.edu/subjects/>*

April 25, 2014

Naira Zargarian
10924 Oxborough Ave S
Bloomington, MN 55437

RE: "Feasibility Study of System Change Behavioral Weight Loss Program for African American Women 45-75 Years Old"
IRB Code Number: 1403M48781

Dear Dr. Zargarian,

The Institutional Review Board (IRB) received your response to its stipulations. Since this information satisfies the federal criteria for approval at 45CFR46.111 and the requirements set by the IRB, final approval for the project version date February 22, 2014 is noted in our files. Upon receipt of this letter, you may begin your research.

IRB approval of this study also includes:

- Consent form received on April 21, 2014
- PAR-Q – the physical activity readiness questionnaire received on March 11, 2014
- Physical activity safety questionnaire received on March 11, 2014
- "Optimized health Environment" satisfaction scale received on March 11, 2014
- "Optimized health Environment" satisfaction questionnaire received on March 11, 2014
- "10-10-10" recruitment letter received on March 11, 2014

NOTE: Due to evolving guidelines, the following items are now required to be included in the footer of each page of the consent form: *study code number*, correct pagination (page x of y), and consent form *version date*. Please add the study code number and consent form version date to the footer of each page of the consent form.

The IRB would like to stress that subjects who go through the consent process are considered enrolled participants and are counted toward the total number of subjects, even if they have no further participation in the study. Please keep this in mind when calculating the number of subjects you request. This study is currently approved for 30 subjects. If you desire an increase in the number of approved subjects, you will need to make a formal request to the IRB.

For your records and for grant certification purposes, the approval date for the referenced project is April 2, 2014 and the Assurance of Compliance number is FWA00000312 (Fairview Health Systems Research FWA00000325, Gillette Children's Specialty Healthcare FWA00004003). Research projects are subject to continuing review and renewal; approval will expire one year from that date. You will receive a report form two months before the expiration date. If you would like us to send certification of approval to a funding agency, please tell us the name and address of your contact person at the agency.

Driven to DiscoverSM

As Principal Investigator of this project, you are required by federal regulations to:

- *Inform the IRB of any proposed changes in your research that will affect human subjects, changes should not be initiated until written IRB approval is received.
- *Report to the IRB subject complaints and unanticipated problems involving risks to subjects or others as they occur.
- *Inform the IRB immediately of results of inspections by any external regulatory agency (i.e. FDA).
- *Respond to notices for continuing review prior to the study's expiration date.
- *Cooperate with post-approval monitoring activities.

Information on the IRB process is available in the form of a guide for researchers entitled, What Every Researcher Needs to Know, found at <http://www.research.umn.edu/irb/WERNK/index.cfm>.

The IRB wishes you success with this research. If you have questions, please call the IRB office at 612-626-5654.

Sincerely,



Christina Dobrovolny, CIP
Research Compliance Supervisor
CD/do

CC: Ruth Lindquist, Diane Treat-Jacobson

UNIVERSITY OF MINNESOTA

Twin Cities Campus

*Human Research Protection Program
Office of the Vice President for Research*

*D528 Mayo Memorial Building
420 Delaware Street S.E.
MMC 820
Minneapolis, MN 55455*

*Office: 612-626-5654
Fax: 612-626-6061
E-mail: irb@umn.edu or ibc@umn.edu
Website: <http://research.umn.edu/subjects/>*

May 23, 2014
Naira Zargarian
10924 Oxborough Ave S
Bloomington, MN 55437

RE: "Feasibility Study of System Change Behavioral Weight Loss Program for African American Women 45-75 Years Old"

**IRB Code Number:
1403M48781**

Dear Dr. Zargarian:

The Institutional Review Board (IRB) has received your response to its stipulations of May 23, 2014. Since this information satisfies the requirement set by the IRB, final approval for the change in protocol request, dated April 30, 2014 is noted in our files. The committee would like to point out that although the title of the project states that the age range of women participants is 45-75, approval for this study is for subjects aged 35-85.

The recruitment flyer received April 30, 2014 is also approved.

For your records and for grant certification purposes, the approval date for the referenced project is April 2, 2014 and the Assurance of Compliance number is FWA00000312 (Fairview Health Systems Research FWA00000325, Gillette Children's Specialty Healthcare FWA00004003).

As Principal Investigator for this study, you are required by federal regulations to inform the IRB of any proposed changes to your research that will affect human subjects. Changes should be reviewed and approved before they are initiated. Unanticipated problems and adverse events should be reported to the IRB as they occur. Research projects are subject to continuing review and approval.

Upon receipt of this letter you may institute the changes. If you have any questions, please call the IRB office at 612-626-5654.

Sincerely,



Andrew Allen, CIP

Research Compliance

Supervisor AA/ca

CC: Ruth Lindquist, Diane Treat-Jacobson

