The “Midlife Study”
Mindfulness as an Intervention to Change Health Behaviors in Midlife Women

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“The true joy lies in the journey and not the destination.”

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daughter Molly. Research in women’s health is lacking and I hope that we can find ways to
change the trajectory of women’s midlife heart health, so she and generations of women to come
will benefit.
Dedication

This work is dedicated to nurses in my life that have inspired me. Nursing truly is the heart and soul of healthcare. It is an honorable discipline that makes an invaluable difference in the lives of others on a daily basis. Research to further the knowledge of our discipline is of critical importance and a study by nurses for nurses seems fitting indeed.

I am incredibly honored and forever in the debt of the nurses from Allina Health Systems, Abbott Northwestern for participating in this study. Your dedication to this study, through holidays and a long 16 weeks say a tremendous amount about you as individuals. It is my hope that not only will this study make a difference, but that this study made a difference for you.

I would be remiss if I did not mention that I am the nurse that I am today because of the nurses that mentored me along the way. The path I have followed has been made easier because of those that came before me.
Abstract

Heart disease is the leading cause of death of women in the US. Many of the risk factors for heart disease are not only preventable but also modifiable through the adoption of healthy eating and exercise. These risk factors include: obesity, lack of exercise, high fat diet, elevated cholesterol, smoking, elevated glucose, elevated blood pressure and chronic psychosocial stress. Unfortunately, health related behavior changes are difficult to initiate and even harder to maintain. In fact, adherence to behavior change intervention is often abysmal. Thus interventions must be aimed at both the successful intervention and maintenance of heart healthy living. Heart disease becomes problematic for many women during menopause. Therefore, aiming interventions to decrease heart disease in the years that precede menopause may be a key time to change health behaviors. Perimenopause, the time that precedes menopause, is often marked by disruptive physiologic symptoms such as weight gain, hot flashes and sleep disruption. These physiologic changes coupled with pressures of work and home –such as providing care for older generations and children at the same time, often make this a time of increased stress. Female nurses in midlife may be at particular risk for stress and its adverse effects on health because of their roles in the increasingly complex healthcare system of today, coupled with the aforementioned midlife stressors.

Mindfulness based stress reduction (MBSR) is an approach to stress reduction that may have utility for women at midlife. MBSR is an eight-week course that includes yoga, guided imagery, and meditation; it emphasizes the concept of living in the present moment. It has been effective in reducing stress and has been theorized to help promote better health choices such as healthy eating and exercise. There currently are no known studies on MBSR and its use to promote and sustain health behavior change. It is not known if combining an MBSR course with a program of diet and exercise will help middle-aged female nurses at risk for heart disease (body
mass index >23 but less < 41) with the initiation and sustaining of health related behaviors among perimenopausal nurses.

The purpose of this paper is to describe a pilot study designed to determine whether MBSR as a component of a program of research designed to change health behaviors could be an effective intervention to increase adoption of and adherence to heart health related behavior change. Forty nurses, aged 39 -57 yrs, with a BMI ≥ 23 but ≤ 41 were recruited and enrolled in the study, stratified by BMI, and randomized into the MBSR (experimental) intervention or the perimenopausal education (active control) intervention. After recruitment and randomization, the 20 women enrolled in the experimental arm of the study completed a MBSR course and then participated in an eight-week program of diet and exercise. Women (n=20) in the active control arm attended educational classes on midlife health issues followed by the same eight week program of diet and exercise in which both groups participated together. Baseline measures of weight, height, body mass index, blood pressure, pulse, waist/hip ratio, glucose, low density lipoprotein, high density lipoprotein, triglycerides, total cholesterol, highly sensitive C-reactive protein, cortisol, and instruments that measured sleep, depression, psychosocial stress and mindfulness were obtained. Immediately following eight weeks of health education classes or an MBSR course, psychosocial assessment and weight were repeated. Participants then participated together in an eight week program of a pedometer-based exercise program and lowered calorie DASH diet. Measurements of adherence to diet and exercise, changes in heart health-related physiological measures, and associated weight loss outcomes were assessed in both groups again immediately post study at 16 weeks.

There was a 95% combined completion rate for the program. Baseline measures revealed that the two groups were very similar on demographic measures such as age, education and hours worked, but the women in the control arm had on average a higher family income than the women in the intervention arm. The two groups were also very similar on baseline
anthropometric, physiologic and psychosocial measures. At baseline the women in the intervention arm weighed on average 181.39 (sd = 28.50) and the women in the control arm weighed on average 186.46 (sd = 29.03) this difference was not statistically significant. At eight-weeks, women in the control arm had lost on average 1.58 pounds, whereas women in the intervention arm gained .11 pounds. Upon completion of the program women in the control arm had lost from Baseline to Week 16, an average of 2.77 pounds. Women in the intervention arm had lost from Baseline to Week 16, an average of 2.61 pounds. This means that on average, the women in the control arm lost .16 pounds more than women in the intervention arm. A spline linear mixed model was constructed to test the hypothesis that mindfulness based stress reduction would improve adherence and result in greater changes in weight, BMI, depressive symptoms, anxiety, perceived psychosocial stress, sleep quality, and mindfulness at 16 weeks.

This program of research had a protocol that was feasible and of interest to midlife women. In terms of satisfaction, 95% completion rate reflected success. The outcome of the hypothesis testing based on spline linear mixed model for weight, BMI and psychosocial variables revealed there were not statistically significant differences between arms at 16 Weeks. However, both groups had improvement on all of the variables tested. There was a reduction from Baseline to Week 16 on weight, BMI, perceived stress, depressive symptoms, anxiety, and improvements in sleep quality and mindfulness. The main difference between the two groups was the pattern of change in these variables over time. The women in the MBSR arm experienced a linear decline which suggested an improvement in perceived stress, depressive symptoms, and symptoms of anxiety that started while enrolled in the MBSR course. Sleep quality and mindfulness improved during this time period as well. The women in the control group had a similar linear decline in all measures from Week 8 to Week 16 (not from Baseline to Week 8), during the time period in the study when a focus on healthy eating and exercise began. Women in
both arms commented that they had started changing the way they ate, how they dealt with stress
and that they paid more attention to exercise as an outcome of being enrolled in this study.

This feasibility study had strengths and weaknesses. The greatest strength of this
feasibility study was that the design made it readily apparent when changes began. It was readily
apparent when examining the growth curves, that group assignment had an impact on patterns of
change. The small group size made it difficult to determine if the intervention made a difference.
The lack of commitment by some members of the two groups was detrimental and in the future, a
readiness to change instrument should be a part of inclusion criteria. Some women were upset
over group assignment and subsequently either dropped out of the study, or believed that they
would not experience successful change based on not being a part of the mindfulness
intervention. It was difficult to conduct a research study that dealt with diet and exercise during
the holidays. Consideration in the future should be placed on time of year. Ultimately, conducting
a feasibility study and piloting the program provided the opportunity to determine what was
feasible, where weaknesses in design occurred, and how to better improve operations in the future
of further study in this area of research.

This program was shown to be feasible, but several recommendations are made for future
research. The program could be tested combining simultaneous engagement in mindfulness (or
health education) and the diet and exercise portion for an eight-week program. Follow-up could
be more intensive in the ensuing weeks after program termination. In the future, weekly
individual or small group interaction about diet and exercise that is woven into the health
education or mindfulness may have greater impact and relevance in aid of adopting healthy
lifestyle behaviors and weight management. Clearly further research is needed. The program was
safe and feasible and may be implemented in practice with diet and exercise program combined
with health education and stress management. However, until the content and protocol processes
are refined with data to support their efficacy, it is recommended that the outcomes are closely evaluated.
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CHAPTER 1

Introduction

Heart disease is the leading cause of death and disability in women and a significant public health concern (Rosamond, Flegal, & Friday, et al., 2007). Two thirds of women that have a heart attack never fully recover. Healthy People 2010 mandates a 20% reduction in heart disease (U.S. Department of Health & Human Services, 2000), therefore efforts to prevent heart disease and reduce cardiovascular deaths in women are urgent priorities. Risk factors for heart disease become problematic for many women in the decade preceding menopause, a term coined “perimenopause.” It is a time where weight gain, elevations in fasting glucose and lipids, a rise in blood pressure and changes in fat distribution may occur with attendant increases in risk for the development of cardiovascular disease and for cardiovascular events. It is also a time for many women of increased psychosocial stressors related to a multitude of issues such as caring for aging parents, raising teenagers, and becoming “empty nesters.”

Nurses have jobs that are well known to be stressful (Wieck, Dols & Northam, 2009). There are increasing time demands with a patient population that is sicker and more complex. Since the median age of a nurse in Minnesota is 47 (Minnesota Department of Health, 2005), there are an abundance of female nurses who fall in the perimenopausal/menopausal age range. Historically, nursing is predominately a female profession. Thus, it makes good sense to select nurses who practice in Minnesota as a sample for this feasibility study. This is a group where the issues addressed by this study are salient, particularly nurses who have high normal BMIs and have signs of metabolic syndrome, which places them at increased risk for heart disease.

Risk factors for heart disease are well known and include obesity, smoking, lack of exercise, elevated cholesterol, poor nutrition, diabetes, genetics, aging, depression and psychosocial stress (Rosamond, Flegal, Friday et al., 2007). There has been a renewed interest in the role of psychosocial stress and heart disease since the landmark findings of the
INTERHEART study. This 52 country case control study enrolled 11,119 cases and 13,648 controls to identify risks of cardiovascular mortality. The findings of this study ranked chronic psychosocial stress second only to lifetime smoking as a risk factor for cardiovascular death (Rosengren, Hawken, Ounpuu, Sliwa, Zubaid, Almahmeed, et al., 2004). Findings of this study underscored the importance of biobehavioral contributions to health status and disease development. It further raised the provocative question as to whether stress reduction could be a critical intervention in preventing development, progression, or death from heart disease.

Stress Response

The stress response is a key concept to the understanding of the relationship between psychosocial stress and health or illness. Hans Selye defined stress as the nonspecific response of the organism to any pressure or demand and further developed the concept of stress to include: The stress response, how the body reacts to a stressor. Stress occurs at the physiological, psychological, and social level (Kabat-Zinn, 2005). An individual’s perception and response to a potential stressor determines whether the impact of the stressor will be maladaptive or adaptive (Kabat-Zinn).

The human body has a unique and complex stress response system that responds to internal and external stressors in a multifaceted way. As neurochemicals such as epinephrine and norepinephrine and other hormones are released to engage in a “fight or flight” response, the individual experiences an increase in heart rate, and in respiration and sweating, along with a heightened sense of arousal accompanied by feelings of anxiety and other symptoms. How each woman responds is impacted by both internal and external resources that can be mobilized to handle situations or to promote health. Different people will view similar demands as more or less stressful depending on the resources available to them (McGrath & Tschau, 2004). Helping individuals find useful resources to deal with stress may be a critical step in tempering the flight or fight response.
The problem is multi-factorial, complex, and of critical importance. How can women in midlife be helped to change patterns of behavior that are potentially damaging to heart health and to make these changes become a permanent part of heart healthy living? There simply must be a better way to manage in contemporary society in the U.S. It is well known that good nutrition and regular exercise are essential building blocks to health and for aging, and yet helping women to make these behavioral health choices on a long term basis is difficult. Potential pathways of success must be explored. Perhaps adding a stress reduction component to a diet and exercise program could be a useful tool in not only making better choices in the short term but also to help people to commit to a longer term change in lifestyle behavior. A majority of nurses are female and in roles that are known to be at particularly high risk for stress; those with high BMIs may be at particularly increased risk. This population was selected as a target population for the Midlife Study.

Purpose

This pilot study was to designed to determine the feasibility and potential efficacy of a 16-week intervention to change health, and health behaviors of midlife women who were at potential increased cardiovascular risk (with relatively high BMIs), and who were employed as nurses at one very large, complex and busy medical center. The pilot study was designed to determine the whether a program of exercise and nutrition that was built on a foundation of a program of mindfulness-based stress reduction (MBSR) could be a potentially effective tool to change health behaviors. The efficacy of the program of exercise/diet that followed an MBSR program participation (experimental condition) was compared to efficacy of the exercise/diet without the foundation of the MBSR (control condition) to explore whether women participating in MBSR had the potential to achieve better health and weight loss/weight control. Another purpose of this study was to determine if the 16 week treatment intervention would have a positive impact on potential risk factors for heart disease such as psychosocial stress, depression,
anxiety, poor sleep quality, and elevated physiologic measures such as high sensitivity C-reactive protein (hs-CRP), cortisol, glucose, blood pressure and high waist-to-hip ratio (WHR). Future research will explore whether the MBSR platform has the potential to aid women “at risk” for heart disease to adhere to healthy lifestyle behaviors over time.
CHAPTER 2
Background and Review of the Literature

This chapter provides more extensive background and a review of the literature on the prevention of heart disease in perimenopausal women. It begins with an overview of the risks for heart disease for women during perimenopause and why this period of time is a prime time for intervention. It continues with a review of effective interventions to prevent heart disease in women. The chapter concludes with an overview of mindfulness based stress reduction with regard to stress reduction, heart disease and its potential use as part of an intervention to change health behaviors.

Prevalence of Heart Disease in Women

Heart disease is the leading cause of death in women in industrialized countries with more than one in two women dying from it. Each year in the United States, more than one half of a million women die of heart disease, which exceeds the next 7 most common causes of death in women combined (Mosca, et al., 2007). Nearly two thirds of women who die suddenly from heart disease have no previous symptoms, thus prevention is of paramount importance (American Heart Association, 2004). The risk factors associated with heart disease include: High cholesterol, high triglycerides, obesity, physical inactivity, smoking, hypertension, excessive alcohol intake, family history and chronic psychosocial stress.

Women often develop risk factors for heart disease during perimenopause, which is the time preceding menopause. Obesity, a significant risk factor for heart disease (American Heart Association, 2008), is not directly linked to perimenopause, but decreases in muscle mass and increases in abdominal adipose tissue may occur during perimenopause because of declines in physical activity (La Valleur, 2002). In addition, declines in estrogen may be associated with increases in: Abdominal fat stores, cortisol, LDL cholesterol, triglycerides, insulin resistance, and in C-reactive protein (Vliet, 2002), all which are risk factors for heart disease. Finally,
perimenopause is often marked with psychosocial stressors related to role change (Woods & Mitchell, 1999), and thus it is a key time for interventions to modify risk factors.

**Obesity and Heart Disease**

Obesity is linked to heart disease in both direct and indirect ways (Hubert, Feinleib, McNamara, Castelli, & Mathew, 1983). Indirect mechanisms include dyslipidemia, hypertension and glucose intolerance which are associated with metabolic syndrome (Malik, Wong, Franklin, et al. 2004). Chemical mediators and adipokines such as cholesteryl ester transport protein, estrogens, and angiotensinogen are increased in obesity and have adverse effects on the cardiovascular system causing endothelial damage, inflammation and vascular hypertrophy (Lundgren, Brown, Nordt, Sobel & Fujii, 1996). In addition, sleep apnea which is more prevalent in the obese can affect the heart in different ways (Hubert, et al.).

There are several direct pathways leading from obesity to heart disease. Obesity is strongly associated with hypertension (Zalesin, Franklin, Miller, Peterson & McCullough, 2008). Hypertension is more prevalent because cardiac output increases due to increased blood flow to adipose tissues which in turn increases blood pressure (Summers, Samra, Humphreys, Morris & Frayn, 1996). Vascular resistance may increase due to inflammation, insulin resistance, over-activity of the sympathetic nervous system, and disordered sleep (Wolk, Shamsuzzaman & Somers, 2003). These are all linked to cardiovascular disease.

**Psychosocial Stress and Heart Disease**

A growing number of studies have shown a potential relationship between psychosocial stress and heart disease, independent of other risk factors such as smoking, obesity and diabetes (Brisson, Laflamme, Moisan, Milot, Masse, Vezina, 1999; Daubenmier, Weidner, Sumner, Mendell & Merritt-Worden, 2007; Hellerstedt & Jeffrey, 1997). Findings from the INTERHEART study suggest that psychosocial factors are more important than formerly
recognized, as there may in fact be a causal relationship between stress and heart disease (Sheps, Frasure-Smith, Freedland & Carney, 2004).

Sleep Deprivation and Heart Disease

Sleep deprivation is associated with adverse health outcomes such as heart disease, Type 2 diabetes, hypertension, depression and obesity (Trupp, 2008). The relationship between lack of sleep and the potential development of heart disease is complex and multi-factorial. With lack of sleep, there appears to be an alteration in glucose metabolism, an increase in insulin resistance, a dysregulation of neurendocrine control of appetite which increases hunger, and a subsequent decrease in energy expenditure (Knutson, Spiegel, Penev & Cauter, 2007).

Stress and Eating

Stress may trigger overeating and binge eating in some individuals (Arnow, Kenardy & Agras, 1995; Lowe & Levine, 2005) that may lead to elevated body mass indexes (BMIs) and obesity, a contributing factor in heart disease. The association of stress and overeating is well documented in the literature. Not only may stress cause weight gain; but stress may lead to weight regain (Haley, 2006). Thus, including stress reduction as a component of a research program aimed at weight loss and weight loss maintenance should include stress reduction strategies. Mindfulness-Based Stress Reduction is a program that targets stress management and emphasizes “living in the present moment.” The mindful approach to living is a key component to stress management and may also contribute to the stability of lifestyle changes leading to weight loss and management.

Mindfulness Based Stress Reduction as an Intervention

There are growing numbers of studies in the literature that have focused on Mindfulness Based Stress Reduction (MBSR) as an intervention in a wide variety of patient populations such as cancer, fibromyalgia, anxiety, depression, smoking cessation, hot flashes, and eating disorders (University of Alberta, 2007). Few studies examining effects of MBSR have dealt specifically
with patient populations with heart disease or the prevention of heart disease. There were no published studies that used MBSR as an intervention to change health behaviors, but there were studies that used Mindfulness Based Cognitive Therapy (MBCT) to help with behavior change. MBCT is a method of psychotherapy that blends cognitive therapy with mindfulness. It follows that mindfulness may be a useful intervention for health behavior change.

A number of studies support the use of MBSR for stress, anxiety and depression. Tacon, McComb, & Caldera et al. (2002) investigated the use of MBSR to reduce anxiety in women with heart disease. Anxiety, emotional control, health locus of control and coping styles were compared pre and post treatment for the intervention (n = 10) and wait list control group (n=10). Significant effects for the intervention group from MBSR were seen for anxiety (p < .01), emotional control (p< .02), and reactive coping (p < .03). However there were no significant group differences on reflective or suppressive coping.

Gross, Kreitzer, Russas, Treesak and Frazier (2004) investigated the use of a MBSR program to reduce symptoms after organ transplant. This 1-group pretest-posttest intervention study enrolled 20 participants. Although this was a heterogeneous transplant population, the majority were kidney transplant recipients. In this study, 19 of the 20 participants completed the eight-week MBSR course. Baseline, post-course, and 3-month follow-up measures were obtained. Depression symptoms were significantly lower post treatment (p=.004), but the 3 month follow-up scores were not significantly different from baseline (p = .19). Anxiety symptoms were not statistically significant at post treatment, but there was a linear trend which suggested that there was a slight improvement in anxiety symptoms from baseline to post-course follow-up and a further improvement from baseline to the 3 month follow up measurement. There was an improvement in sleep symptoms over time that was highly significant (p=.007).

MBSR was used as an intervention in a study by Davis, Fleming, Bonus & Baker (2007) to determine the effects of MBSR on smoking cessation as measured by abstinence, and to
determine if there was a reduction in stress and affective distress for smokers trying to quit smoking. There were 18 research subjects recruited for this group, pretest, post-test intervention study. Meditation compliance was tested with a weekly meditation calendar. Smoking cessation to verify non-smoking compliance was measured with a carbon monoxide breath test. At the 6 week post-quit visit, 10 of the 18 subjects had achieved biologically confirmed smoking cessation. Highly compliant meditators demonstrated less stress and distress during the intervention than did moderately compliant meditators. There were 23 participants enrolled in the study, 5 were lost due to attrition. The 18 participants that remained in the study were highly or moderately compliant meditators.

Heart Disease and Perimenopause

The risk for heart disease before menopause in women is relatively low (Kannel, Hjortland, McNamara & Gordon, 1976). This is followed by a rise in the incidence of heart disease in women after menopause (Weinberger, 2006). The Framingham study found a 4-fold increase in heart disease in the 10 years following menopause (Kannel, Hjortland, McNamara & Gordon).

Perimenopause (the time period that precedes menopause by up to ten years) is associated with age-related risk factors and endocrine changes seen with decreasing estrogen levels. Although cardiovascular disease (CVD) increases with age in both men and women, there is an additional increase in women that has been attributed to the time of menopause (Rosano, Vitale, Marazzi & Volterrani, 2007). The menopausal transition, which encompasses perimenopause, is often a time of great change. There are physiological, psychological, sociological, lifestyle factors and personal perceptions of menopausal events that can be troublesome. Yet it is a natural process in the ebb and flow of life (McKinlay, Brambilla & Posner, 1992). These changes, along with concurrent aging, underscore the need for behavioral lifestyle adjustments to preserve health (Anonymous, 2006). Deleterious changes in cardiac risk factors during perimenopause, including
increased stress, point to perimenopause as an important time of health transition and a vital time for intervention.

*Physiologic Stressors*

Physiologic changes that are detrimental to cardiovascular health and associated with perimenopause include weight gain (especially central body fat tendency) as metabolism slows, a rise in fasting glucose, elevations in blood pressure (BP), and elevations in serum cholesterol (Rosano et al., 2007). There is a shift in fat distribution from gynoid to android distribution that has detrimental effects on insulin resistance and is enhanced by estrogen deficiency (Gambacciani, Ciapoini, Cappagli, et al., 2001). Metabolic syndrome, a constellation of risk factors that include insulin resistance, hypertension, dyslipidemia, and an increase in abdominal adiposity, is estimated to affect 20 – 30% of the middle-aged population and is associated with a substantially increased risk for cardiovascular disease. Since even a moderate reduction in weight loss is associated with a marked reduction in the risk of metabolic syndrome (Phelan, Wadden, Berkowitz, Sarwer, Womble, Cato & Rothman, 2007), programs that target health related behavior changes that lead to weight loss in midlife are of critical importance to prevent heart disease in women.

Symptom clusters that are common and may be problematic for women during perimenopause may include hot flashes, night sweats, sleep disruption, vaginal dryness, memory changes, decreased libido, mood fluctuations, hair loss and skin changes (Woods & Mitchell, 2005). These symptoms may contribute to the overall psycho physiological stress experienced in the perimenopausal period.

*Psychological Stressors*

Psychological changes of perimenopause may include labile mood swings, increases in depressed mood, and an increase in anxiety (Woods & Mitchell, 2005). These changes are thought to be related to fluctuating hormone levels and role changes (Woods & Mitchell, 1999).
Clinical studies and research in animals support the hypothesis that fluctuations in reproductive hormones may impact neurochemical pathways linked to depression (Soares, 2008). In addition, in both the Penn Ovarian Aging Study and the Study of Women’s Health Across the Nation (SWAN), a correlation was found between higher levels of BMI, lack of sleep, hot flashes and depression for women in midlife (Woods, Smith-DiJulio, Percival, Tao, Mariella, & Mitchell, 2008).

**Social Stressors**

Role change is common during perimenopause and although it is not a direct result of perimenopause, it often occurs at this time and may increase the stress experienced. Women are often “caught in the middle” in the family structure, and have demands to provide care for children and aging parents---even as their own biological health is in transition. The climacteric, which signals the end of childbearing, may have significant meaning in the lives of women. Clearly the changes and potential stress experienced by women during the perimenopause are significant; perimenopause is concomitantly associated with significant declines in health (Vliet, 2002).

**Targeting Perimenopause to Prevent Heart Disease**

Perimenopause, as the transitional time that precedes menopause, is a key time to implement primary prevention strategies (National Heart Lung & Blood Institute, 2001). Results from epidemiologic studies support the important role of primary prevention in the reduction of cardiovascular disease (Grundy, 1999; Stampfer, Frank, Manson, Rimm, & Willet, 2000). The average age of menopause is 51.3 years (Speroff, 2002). Perimenopause, on average, lasts 6 years and is associated with menstrual cycle changes, and other menopausal symptoms. The transitional endpoint is menopause, defined as 1 year without a menstrual cycle (North American Menopause Society, 2008). It is a natural part of the aging process in women. For reasons not clearly understood, cardiovascular disease becomes problematic during menopause and is associated
with age related risk factors and endocrine changes seen with decreasing estrogen levels. 

Although cardiovascular disease (CVD) increases with age in both men and women, there is an additional increase in women due to menopause (Stevenson, 2007).

**Exercise and Heart Disease Prevention**

The benefits to health from exercise are well known (Alevizos, Lentza, Kokkoris, Mariolis, & Koranzopoulos, 2005; Brown, 1992; Dugan, 2007; Karacabey, 2005). Unfortunately, people often find it difficult to incorporate exercise into their daily lives (Swartz, Strath, Bassett, Moore, Redwin, et al., 2003). Pedometer use has been found to motivate and promote physical activity and can be useful for researchers as a surveillance tool (Choi, Pak, Choi, & Choi, 2007; Tudor-Locke, 2002). In a study of walking programs, it was found that a 30 minute walk represented approximately 4,000 steps (Welk, Corbin & Dale, 2000). Currently, 10,000 step programs are widely accepted by the media as an appropriate health goal (Tudor-Locke, Ainsworth, Thompson & Matthews, 2002). A recent meta-analysis found that the use of a pedometer was associated with a significant increase in physical activity and decreases in body mass index (BMI) and blood pressure (Bravata, Smith-Spangler, Sundaram, Gienger, Lin, Lewis, et. al., 2007). Several research studies have found that a 10,000 steps per day walking program decreased systolic and diastolic blood pressure; improved glucose tolerance in overweight women (Swartz, et al.); was effective in weight loss (Schneider, Bassett, Thompson, Pronk, Bielak, 2006); decreased low density lipoprotein (LDL) cholesterol; decreased triglycerides; and decreased psychosocial stress (Bravata, et al.). Aim 2 of the present study was designed to build on the findings of these studies.

**Dietary Approach to Modify Heart Disease Heart Disease Risk Factors**

A heart-healthy diet, rich in a wide variety of fruits, vegetables, low fat or non fat dairy products, fish, low saturated fat protein sources, and whole grains, is the recommendation from the American Heart Association for the prevention of cardiovascular disease in women.
In addition, women who do not eat fish should consider sources of omega 3 fatty acids such as flaxseed oil, soybean oil, canola oil or walnuts (Mosca, et al., 2004). One dietary program that incorporates the recommendations of the American Heart Association for a heart healthy diet and also works to lower hypertension is the DASH diet (National Heart Lung & Blood, 2008). The Dietary Approach to Stop Hypertension (DASH), a dietary program developed by the National Heart Lung and Blood Institute, has been found to be an effective nutritional intervention to reduce blood pressure and has been extensively studied (Elmer, et al., 2006; Appel, et al., 1997; Karanja, Erlinger, Pao-Hwa, Miller, Bray, 2004). The DASH diet is approximately 2000 kcal per day. The DASH diet recommends 7-8 servings of grains; 4-5 servings of vegetables; 4-5 servings of fruit; 2-3 servings of dairy; 2 or less servings of meats, poultry and fish; 4-5 servings nuts, seeds and beans per week; 2-3 servings of fats and oils (healthy sources of fat); and 5 servings of sweets per week. The diet can be modified to be less than 2,000 calories per day and can be used effectively as a weight loss intervention. As an approach to lower blood pressure, it is recommended that this diet be used with a population that has pre-hypertension, with minimal blood pressure elevations, and for whom medication is not currently indicated (Clough, 2004).

Not only would the DASH diet be a healthy nutritional approach for women to prevent heart disease, with its recommendations for 2-3 servings of dairy and green leafy vegetables, it would also be rich in calcium an important nutrient to prevent osteoporosis (Lin, et al., 2003).

**Rationale for MBSR as an Intervention to Reduce Heart Disease**

As previously noted, there is growing evidence for psychosocial stress as a significant risk factor for heart disease. Effective programs to help with stress reduction should be included in programs that target risk factors for heart disease. Health interventions, including interventions to reduce stress and its adverse physiological and psychological effects, can aid in the physiological and social transitions that occur during menopause, and may result in reduced
cardiovascular risk. In addition, it is well documented that there is a relationship between psychosocial stress and weight gain because of the relationship between increased cortisol levels seen with stress and an increase in adipose tissue. Also there seems to be a correlation between stress and binge eating, and stress and relapses in weight loss. Therefore, stress reduction may have positive effects on the prevention of heart disease through multiple mechanisms of action.

Mindfulness Based Stress Reduction (MBSR) is a structured program that originated at the University of Massachusetts and is widely used across the country in a variety of settings. Usually, MBSR encompasses eight weeks of weekly meetings lasting 2½ hours where participants receive instruction and practice meditation, body scan meditation, mindful hatha yoga and sitting meditation. There is a 1 day meditative retreat, and 30 minutes of daily meditative practice is recommended (Kabat-Zinn, 2005). It follows that MBSR may have the potential to reduce stress, improve health and quality of life, and reduce risks of heart disease in perimenopausal women. Programs of Mindfulness Based Stress Reduction (MBSR) have shown promise to reduce stress in a wide range of populations but more evidence is needed (National Heart Lung & Blood Institute, 2007; Grossman, et al., 2004). Mindfulness, the process of living in the present moment, without judgment and the possession of an attitude of kindness, acceptance and patience may be developed and strengthened through participation in MBSR courses. Carmody, Baer, Lykins and Olendzki (2009) conducted a study with participants from 17 MBSR classes and determined there was a significant increase in mindfulness after completion of the MBSR courses. In addition, mindfulness meditation as a stress reduction intervention may in fact be a solid and feasible intervention. MBSR is a cost effective intervention that can be learned in a relatively short period of time. It can be used in a wide variety of situations and has no known risks. Since psychosocial stress has been identified as a significant and modifiable risk factor for heart disease, an intervention such as MBSR which appears to be effective in the reduction of stress and anxiety may be highly effective in reducing the morbidity and mortality
from heart disease. It follows that MBSR may have the potential to reduce stress, improve health and quality of life, and reduce risks of heart disease in perimenopausal women. It may also prove useful in health related behavioral decision making through living in the present moment and eating and living mindfully instead of mindlessly. Although the level of evidence to support MBSR as an intervention to change health behaviors is weak due to lack of research and thus limited, it does offer great promise.

The literature supports the use of MBSR to reduce symptoms of stress, depressive symptoms, and anxiety that are all common concerns for women during midlife. There appears to be a relationship between psychosocial stress and heart disease and as previously discussed, a very salient consideration since the midlife years for women are often filled with psychosocial stress. It is well documented in the literature that exercise and dietary changes may have a positive impact on risk factors for heart disease. Thus, designing an intervention that incorporates heart healthy nutrition utilizing the DASH diet, exercise that stresses 10,000 steps per day, and “mindful” stress reduction may be an effective and innovative approach to change the heart health trajectory for midlife women. It is not known if Mindfulness Based Stress Reduction as an intervention will increase the adoption of and adherence to behavioral change, but teaching women to live in the present moment and to be mindful of what they eat, how they exercise, and how they respond to stressors is a promising approach to help midlife women achieve heart healthy living as they age.

**Conceptual Framework**

The conceptual framework for this study is summarized in Figure 1. It is based on the work by Kabat-Zinn (2005). Midlife, a time in the lives of women often marked with significant physiologic and psychosocial changes may be viewed as stressful. A common response to stress is a stress reaction often coined the “flight or fight response” which elicits stress hormones such as epinephrine. Living in a chronic state of an active stress reaction may adversely impact health.
Women during this time may choose either maladaptive or adaptive coping to deal with stressors. Stress may exert a powerful influence on self destructive behaviors. Thus, teaching women better ways to deal with stress is critical. Stress in life is virtually a constant. Adaptive coping strategies to break the “stress reactivity cycle” are therefore crucial and may be instrumental in effective behavior change. Therefore, teaching women in midlife healthy ways to deal with stress through Mindfulness Based Stress Reduction which emphasizes the concept of mindfulness and living in the present moment may be an effective intervention to change behavior and encourage adaptive coping techniques. Kabat Zinn’s model proposes that mindfulness may help optimize adaptive coping strategies such as exercise and healthy nutritional choices. These healthy choices may lead to positive health outcomes such as reductions in stress, anxiety and depression; decreases in blood pressure, fasting glucose, stress hormones; may increase weight loss; increase mindfulness and, finally, improve sleep.

Specific Aims

This study was designed to determine the feasibility and potential efficacy of the use of MBSR as a platform to improve health and health behavior change among female nurses having elevated BMIs at midlife in one healthcare institution. Specifically, the purpose of this study was to explore whether a program of Mindfulness Based Stress Reduction (MBSR), followed by diet and exercise intervention, compared to an active control group of health education followed by diet and exercise intervention would result in greater changes in behavior and weight loss. This study was designed to:

Aim 1. Determine the efficacy of MBSR (eight weeks) coupled with a (eight weeks) behavioral weight loss program of diet and exercise to change patterns of diet and exercise, and resultant weight loss at 16 weeks relative to a control group having behavioral weight loss program and attention control menopausal education program (eight weeks)(without MBSR).
Aim 2. Determine the effects of MBSR coupled with the behavioral weight loss program versus the control group on changes in blood pressure, waist/hip ratio, fasting glucose, C-reactive protein, physiologic stress markers (cortisol), perceived psychosocial stress, mindfulness, and sleep.

As a feasibility study, it was premature to test hypotheses. However, comparisons between groups on the variables of interest (gathered at Baseline, Week 8, and Week 16) were planned to examine changes from baseline and the potential differences in outcomes in order to determine whether MBSR should be used in future studies of health behavior change.
Figure 1. Conceptual framework for MBSR and health behavior change for midlife women.

External Stressors
Changes with Menopause/Perimenopause

<table>
<thead>
<tr>
<th>Physiologic Changes</th>
<th>Self Image</th>
<th>Psycho-Social Situations</th>
<th>Energy</th>
</tr>
</thead>
<tbody>
<tr>
<td>↓ Sex Hormones</td>
<td>Changes in physical appearance (grey hair, wrinkles, loss of agility) in a youth oriented society</td>
<td>Aging parents, grandchildren, teenagers “Empty nest” Financial concerns about retirement</td>
<td>↓ Energy</td>
</tr>
<tr>
<td>↑ Weight, BP</td>
<td></td>
<td></td>
<td>↑ Fatigue</td>
</tr>
<tr>
<td>↑ Lipids, Glucose</td>
<td></td>
<td></td>
<td>↓ Stamina</td>
</tr>
<tr>
<td>↑ Cortisol, hs-CRP</td>
<td></td>
<td></td>
<td>(Less sleep related to hot flashes and the aging process may contribute to energy changes)</td>
</tr>
</tbody>
</table>

Stress Reduction
“Fight or Flight” – Release of stress hormones such as epinephrine

Mindfulness
MBSR: 8 week course that emphasizes living in the present moment through yoga, guided imagery, meditation and relaxation breathing.

Adaptive Coping
Utilize effective coping tools by being mindful and in the present moment – choosing to exercise, make healthy food choices and dealing with psychosocial stress effectively.

Maladaptive Coping
Overeating, lack of exercise, overuse of alcohol, smoking, overworking, too much caffeine, place time priorities around others, not sleeping.

Physical/Psychosocial Outcomes
↓ BP, Glucose, Cortisol, hs-CRP
↓ Weight
↑ Improved Sleep
↑ Mindfulness
↓ Psychosocial Stress
↓ Anxiety
↓ Depressive Symptoms
CHAPTER 3

Methods

This chapter provides an overview of the methodology used for this pilot study to evaluate the feasibility and potential efficacy of the use of MBSR as a platform for health behavior change, and to examine its potential physiological and psychosocial health benefits. The design, setting, subjects, measures, timeline and procedures are described in detail.

Design

This pilot study used a two-group design with an intervention group and an active control group. A longitudinal design with measures at Baseline, Week 8 and Week 16 was used in order to detect changes over time in the variables of interest. Women who met the inclusion criteria were invited to participate in the study. Consenting research participants were randomly assigned to receive eight weeks (Phase One) of either the treatment (MBSR) or active control (Midlife Health Education Classes) followed by an eight-week diet/exercise intervention (Phase Two). All participants met as a single group during Phase Two. The subjects were not blinded to the nature of the intervention and a single consent form was used (see Appendix A).

Subjects and Setting

Subjects. Nurses from a large metropolitan healthcare system were asked to participate in the study. Inclusion criteria included: a) Body mass index (BMI) greater than 23, but less than 41; b) females between 39 and 57 years old; c) no prior history of completing a mindfulness course; d) not exercising regularly 3 or more times per week in the past 4 months; e) no physical contraindications to exercise; f) perceived high levels of psychosocial stress; and, g) able to read English. Exclusion criteria included: a) known history of heart disease; b) systolic BP greater than 160 mmHg; c) insulin dependent diabetes mellitus; and d) chronic diseases that would preclude use of the diet or exercise components of this study.
Setting. Abbott Northwestern Hospital is a large medical center in the Midwest. This site was chosen because it offered an onsite clinic for lab draws and other measurements. The setting could provide onsite space for classes. Finally, it provided a large convenience sample of nurses in a small geographic area.

Recruitment and Consent Procedures

After receiving Institutional Review Board approval, nurses were recruited through flyers distributed at the healthcare system (see Appendix B). Potential participants were given information that explained the time commitment and the requirements of the study. If a potential research participant declined participation or was deemed ineligible based on inclusion and exclusion criteria, another subject was screened until 40 participants were obtained. Informed consent was obtained before pre-study (baseline) physiologic and psychological measures of participating subjects were obtained.

Height, weight, BMI based on height and weight, waist/hip ratio, blood pressure, and fasting labs such as glucose, cortisol, and highly sensitive C-Reactive Protein, were obtained at Baseline (Week 0) and at Week 16 (study end). High density lipoprotein, low density lipoprotein, total cholesterol and triglycerides were obtained at baseline and were to be repeated at six months (post study). Demographic information about marital status, age, total family income, education, and shift work and surveys on psychosocial stress, depressive symptoms, anxiety, mindfulness and sleep quality were obtained at Baseline, Week 8 and Week 16. Weight was measured weekly from Week 8 to Week 16.

Random Assignment

Random assignment was made with stratification using subjects’ pre-study BMI. The BMI median of the 40 member group was 30. All of the research participants with a BMI greater than 30 had their research number placed in a hat and numbers were drawn at random and assigned to either MBSR or Health Education until all were assigned to a group. The exact same
procedure was carried out for women with a BMI of 30 or less, with numbers drawn randomly from a hat until all numbers had been assigned to either MBSR or Health Education. The groups were divided evenly.

**Timing of Measurements**

Physiological and psychosocial measures were obtained at baseline prior to the start of Phase One, post Phase One (at eight weeks) and post Phase Two (at 16 weeks). Table 1 presents a timeline of physiological measurements and Table 2 presents a timeline for psychosocial measurements. A copy of each instrument is located in the Appendices. (See listing of Appendices directly following Table 2).

Table 1

**Physiological Measurement Schedule**

<table>
<thead>
<tr>
<th>Physiological Measures</th>
<th>Pre-Study</th>
<th>Post Phase One</th>
<th>Post Phase Two</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (in lbs)</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Body Mass Index</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Blood Pressure</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Pulse</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Waist/Hip Ratio</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Cholesterol</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HDL Cholesterol</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LDL Cholesterol</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Triglycerides</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C-Reactive Protein</td>
<td>X</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 2

*Psychosocial Measurement Schedule*

<table>
<thead>
<tr>
<th>Psychosocial Measures</th>
<th>Pre-Study</th>
<th>Post Phase One</th>
<th>Post Phase Two</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression/Anxiety (DASS)</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Psychosocial Stress (PSS)</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Depression (CES-D)</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Mindfulness (CAMS-R)</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Sleep Quality (PSQI)</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

DASS = Depression Anxiety Stress Scale (Appendix C); PSS = Perceived Stress Scale (Appendix D); CES-D = Center for Epidemiologic Studies Depression Scale (Appendix E); CAMS-R = Cognitive and Affective Mindfulness Scale-Revised (Appendix F); PSQI = Pittsburgh Sleep Quality Index (Appendix G).

*Measurement Procedures*

All participants had their pre-study measures performed “first thing” in the morning, at a clinic after a 12-hour fast. Blood draws were done by a trained phlebotomist. Eight cc’s of serum were drawn. All of the pretest physiological measures were performed in the privacy of a clinic exam room with a trained research assistant. Pre-study heights and weights were used to calculate BMIs. Blood pressure and waist-to-hip ratio (WHR) were also obtained at this time. The research participants completed the pre-study surveys either at the clinic visit or, if time was an issue, completed them at home and returned them the next day to one of the study’s co-investigators. Demographic information was collected; including date of birth, education, whether they worked...
shift work (and if so what shift they most commonly worked), race, and household income (see form in Appendix H).

Study Measures

Physical activity. Physical activity was also measured with the Stanford Seven Day Physical Activity Recall (Blair et al., 1985). The scale is one of the most commonly used measures of physical activity and is found to be significantly correlated ($r = 0.20$-$0.86$) with other measures of energy expenditure based on diary and questionnaire (Poudevigne & O’Connor, 2005). It is a well known instrument for surveying work and leisure time activities. It has been used extensively in epidemiologic research. This 14-question self report has respondents rate questions that range from “on average how many hours did you sleep each night last Friday and Saturday” to “how many hours did you spend during the last 5 weekdays doing these hard activities?” Each question is scored from 0 (not applicable), 1 (more), 2 (less) or 3 (about the same). The list of activities range from moderate (e.g., golf) to hard (e.g., cycling) to very hard (e.g., running) for these questions (see Appendix J).

Blood pressure. Blood pressure (BP) was monitored with a Welch Allyn manual cuff, a clinically validated mercury sphygmomanometer. This type of monitor is considered to be the “gold standard” for blood pressure measurement (United States Food and Drug Administration [FDA], 2005). BP was obtained using the appropriate sized cuff after the participant had been in a seated and relaxed position for 5 minutes. The blood pressure monitor is calibrated when manufactured and has a lifetime warranty on the calibration.

Weight. Weight was measured in pounds using SR Instruments Model 555 digital stand On Scale (Tonawanda, New York) 1) prior to the start of the research study, 2) Post Phase One, 3) weekly during Phase Two, and 4) post Phase Two. The scale is calibrated once per year by trained biomedical staff per manufacturer’s recommendation. Participants were weighed without shoes, in light clothing, on the same day of the week each week.
**Body mass index.** BMI (kg/m²) was calculated based on the weekly weight and the participants’ height recorded prior to the beginning of the study.

**Central obesity.** Central obesity was determined by waist-to-hip ratio. A tape measure was used to measure the waist at the umbilicus on bare skin during mid-respiration and hip girth was measured at the maximum circumference of the buttocks. In order to reduce measurement error, instructions were given to make sure that the waist was measured at the umbilicus on bare skin and the hip measured across the widest portion of the buttocks with only a very light layer of clothing. The same tape measure was used for all measurements during the pre-post measures to increase test-retest reliability. The waist-to-hip ratio was determined by dividing the waist measurement in centimeters by the hip measurement in centimeters (Toobert et al., 2003). A waist-to-hip ratio of .80 or greater is considered to be a marker of obesity and increases health risks such as cardiovascular disease (Donato et al., 2006).

**Physiological Measures of Heart Health**

Physiologic markers for heart health were collected at the Minneapolis Heart Clinic at 7:00 in the morning after a 12-hour fast. All lab work was serum. Per current recommendations from the American Heart Association (2008), the following labs were drawn: Fasting glucose, low density lipoprotein cholesterol, high density lipoprotein cholesterol, triglycerides, total cholesterol, high sensitivity C-Reactive Protein (hs-CRP) and serum cortisol per the measurement schedule (see Table 1). A lipid panel was drawn pre-study but was not evaluated post study since the time needed to see a change in lipid levels is usually 6 months. Changes in lipids will be evaluated in a separate follow-up study report. The labs were run by the Allina Medical Laboratories, which is a Centers for Medicare and Medicaid Services, Clinical Laboratory Improvement Amendments (CLIA) Certified Lab. CLIA ID Number 24D0401558, CLIA Certification Code 310 (see Appendix K).

*Normal Ranges for Lab Values Established at Allina Medical Laboratories:*
Glucose. The normal range for a fasting glucose is 65-100 mg/dl.

C-Reactive Protein. The normal range is < 0.5.

Cortisol. The normal reference range for cortisol is 5-25 µg/dl for a.m. draw and 3-13 µg/dl for p.m. draw.

Dietary Intake

Each research participant was provided with a diet log. The purpose of this log was to motivate health behavior change. The National Weight Control Registry (Brown University, 2008) determined that successful weight loss required tracking of daily food intake.

Healthcheques Daily Log (Appletree-Press, Mankato, MN) provided a tool for tracking caloric intake and also provided nutritional content for hundreds of common foods and fast foods as well (see Appendix L). The log tracks daily calorie counts, servings and serving sizes of fruits, vegetables, dairy, protein, fat, sugar, and whole grains. The logs were analyzed by a nutritionist (if the participants desired) to help them with nutritional advice (this was not mandatory but was encouraged). At the end of Phase Two, participants were asked to provide their average daily calorie count and servings of grains, fruits, vegetables, proteins, fats and sugars that were tracked in their logs.

Sleep. Sleep was evaluated with the Pittsburgh Sleep Quality Index (PSQI; Buysse, Reynolds, Monk, Berman & Kupfer, 1989; see Appendix C). The PSQI was developed to measure the difference between good and poor sleepers. It comprises 19 self rated questions, which are grouped into seven component scales that measure sleep quality, sleep duration, use of medication for sleep and daytime dysfunction. The items are scored on a scale of 0-3. The potential range of scores is 0 – 21. A score of 6 or higher is associated with sleep disturbances that are significant. It has demonstrated high reliability and validity in multiple research studies across a wide range of populations. Initial psychometric testing of the instrument found acceptable measures of test-retest reliability and validity. A global score of greater than 5 yielded
a specificity of 86.5% and a diagnostic sensitivity of 89.6% distinguishing between good and poor sleepers (Buysse et al., 1988). The measure has been used with menopausal women. It takes between 5-10 minutes to complete. In studies that involved women of the perimenopausal age group, the PSQI was found to be a reliable and valid instrument (Carlson & Garland, 2005; Gross, Kreitzer, Russas, Treesak, & Frazier, 2004). A study by Gross et al., 2004, determined Cronbach’s alpha ranged from .57 to .72 across time points and a study by Buysse et al., (1988) determined Cronbach’s alpha to be .83.

*Depressive symptoms.* Depressive symptoms were measured using the Center for Epidemiologic Studies Depression Scale (CES-D; Radloff, 1977), a general measure of depressive symptoms intended for the general population (see Appendix C). In the original study, the Cronbach alpha was 0.85 in the general population. In later studies, the Cronbach’s alpha was 0.87, with test-retest reliability 0.51 (Hann, Winter, Jacobsen, 1999; Radloff, 1991). It is a 20-item self-report instrument with questions like “I did not feel like eating; my appetite was poor” to “I felt sad,” asking how often during the past week the respondents felt this way. The response choices are 1 (rarely or none), 2 (some of the time), 3 (occasionally) or 4 (most of the time). The possible range of scores are 0 – 60. In a study that involved women of the perimenopausal age group, the CES-D was found to possess good validity and reliability (Gross et al., 2004).

*Psychosocial stress.* Psychosocial stress was measured with the Perceived Stress Scale (PSS; Cohen, Kamarck & Mermelstein, 1983; see Appendix D), a 14-item self-report instrument with a 5-point scale (0 = never, 1 = almost never, 2 = sometimes, 3 = fairly often, 4 = very often). This is not intended to be a diagnostic instrument but rather a comparison of perceived stress related to current events. The higher the score, the higher the degree and duration of perceived stress. The PSS is not intended to be used as a diagnostic tool, there are not cut-off scores and it recommended that it be used to compare scores within the research sample where it is used (Carnegie Mellon University, 2009). The PSS is a well known and well used instrument. The
questions are general in nature and intended to not be content specific and thus applicable across a wide range of populations. It has been shown to possess substantial reliability and validity with Cronbach alpha of .84, .85 and .86 in three samples (Cohen et al., 1983). The possible range of scores are 0 – 56. Two studies with perimenopausal women found the PSS to be a valid and reliable instrument (Chung & Tang, 2005; Davis et al., 2007).

*Depression, anxiety and stress.* Depression, anxiety and psychosocial stress were measured with the Depression Anxiety Stress Scale (DASS-21; Lovibond & Lovibond, 1995). Factor analytic studies have validated that this scale can be grouped into three scales: a) Depression (DASS-D), b) Anxiety (DASS-A), and c) Stress (DASS-S). The stress scale also includes items that measure tension, irritability and a tendency to overreact to events that are stressful (Antony, Bieling, Enns, & Swinson, 1998). Lovibond and Lovibond found reliability using Cronbach’s alpha was acceptable. Cronbach’s alpha for depression, stress and anxiety were .91, .90 and .84, respectively. A total score which is the combined score from all three scales was used for this research study. This 21-item self report scale is a shorter version of the original 42-item scale and demonstrates high internal consistency and strong reliability and validity in both clinical and non-clinical populations (University of New South Wales, 2008; Antony, Bieling, Enns, & Swinson). It is recommended that DASS 21 be used for purposes of research rather than the longer 42-item DASS. The potential range of scores are 0 – 63 for the DASS 21. These scores must be multiplied by two to compare to the original version of DASS. It is recommended that for the purposes of research, is best to use the DASS scores and not attempt to assign a classification or assign a cut off score (Psychology Foundation of Australia, 2009).

*Mindfulness.* Mindfulness was measured with the Cognitive and Affective Mindfulness Scale-Revised (CAM-S-R; Feldman, Hayes, Kumar, Greeson & Laurenceau, 2003, 2004). This 12-item self report measures mindfulness through awareness, acceptance, attention, and being
present-focused. Items are rated on a 4-point Likert-type scale (1 = not at all, 5 = almost always). Questions range from “I can tolerate emotional pain” to “I am preoccupied with the future.” Higher scores on CAMS-R are associated with higher levels of mindfulness. There currently are no reported studies that have tested the psychometric properties of the CAMS-R for test-retest reliability and validity. The potential range of scores are 12 – 60.

Attendance. Attendance was measured weekly for each participant in both groups for Phase One on a sign-in sheet. During Phase Two, attendance was measured for each participant with a sign in sheet. If a research participant could not stay for the content presentation and discussion at the weekly meeting, attendance was credited if they weighed in and picked up study materials.

Intervention Groups

Phase One Experimental Group: MBSR. In the experimental group, during Phase One (Baseline to Week 8), 20 female nurses who met the inclusion criteria were enrolled in an eight-week Mindfulness Based Stress Reduction (MBSR) program. MBSR is a structured program started by Kabat-Zinn, at the University of Massachusetts. It comprises eight weeks of 2 ½ hour weekly meetings that encompasses meditation, yoga and mindfulness. Daily practice was encouraged and there was a full day retreat of silent meditation towards the end of the program. The program fee of $375.00 was paid for through a grant for this study by the Institute for Health and Healing at Abbott Northwestern Hospital. At the conclusion of the eight-week program, measurements were obtained (see Table 1). Members of the experimental group were advised prior to the start of the first class that attendance at eight weekly Mindfulness Based Stress Reduction (MBSR) classes was expected. Books on mindfulness were distributed the first night and they were asked to read through the book in order to strengthen their understanding of mindfulness. A full day silent retreat was conducted at a center conducive to meditation. Emphasis each week was placed on living in the present moment and the concept of mindfulness.
(see Table 3). The MBSR classes were led by a trained mindfulness instructor with greater than 15 years of experience in leading courses on mindfulness based stress reduction. During the eight-week series, healthy snacks were provided but no caffeine was served, which is consistent with the underpinnings of MBSR. After eight weeks, participants of this group joined with the participants from the Health Education Classes (active control group) and participated in eight weeks of diet and exercise (Week 9 to Week 16 – Phase Two) intervention.

Table 3

*Weekly Topical Schedule of the MBSR Course*

<table>
<thead>
<tr>
<th>Week</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>One</td>
<td>Yoga, meditation, mindful eating, didactic work, homework. Focus on being in the present moment. Caffeine-free tea and healthy snack</td>
</tr>
<tr>
<td>Two</td>
<td>Yoga, meditation, mindful eating, didactic work, homework. Focus on being in the present moment. Caffeine-free tea and healthy snacks</td>
</tr>
<tr>
<td>Three</td>
<td>Yoga, meditation, mindful eating, didactic work, homework. Focus on being in the present moment. Caffeine-free tea and healthy snacks</td>
</tr>
<tr>
<td>Four</td>
<td>Yoga, meditation, mindful eating, didactic work, homework. Focus on being in the present moment. Caffeine-free tea and healthy snacks</td>
</tr>
<tr>
<td>Five</td>
<td>Yoga, meditation, mindful eating, didactic work, homework. Focus on being in the present moment. Caffeine-free tea and healthy snacks</td>
</tr>
<tr>
<td>Six</td>
<td>Yoga, meditation, mindful eating, didactic work, homework. Focus on being in the present moment. Caffeine-free tea and healthy snacks</td>
</tr>
<tr>
<td>Seven</td>
<td>Yoga, meditation, mindful eating, didactic work, homework. Focus on being in the present moment. Caffeine-free tea and healthy snacks</td>
</tr>
</tbody>
</table>
Retreat: Seven hour silent meditative retreat. Focus on being in the present moment. Caffeine-free tea and healthy snacks.

Eight: Yoga, meditation, mindful eating, didactic work, homework. Focus on being in the present moment. Caffeine-free tea and healthy snacks.

Active Control Group: Health Education

The women who were assigned to the active control group were encouraged to attend eight weekly, 1 hour health education classes on topics relevant to perimenopausal women. These classes were held on the same night each week and on the same day of the week as the MBSR classes. They were held during the exact same eight weeks, so that the Phase One for each group occurred simultaneously. If they were unable to attend a class, materials were provided to them on the topic that was discussed during their absence (see Table 4 for the class schedule). After eight weeks, they moved in to an eight-week Phase Two intervention with the women of the MBSR group.

Table 4

Health Education Topics – Phase One, Group 2 – Active Control Group

<table>
<thead>
<tr>
<th>Week</th>
<th>Topic – Each Class One Hour</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Midlife Health – An Overview of Common Issues: Hormonal fluctuations, hot flashes, urinary incontinence, skin changes, memory issues, sleep deprivation, weight gain, changes in physiologic health measures, social changes, aging parents, teenage children.</td>
</tr>
<tr>
<td>2</td>
<td>Osteoporosis: Calcium recommendations, Vitamin D, Magnesium, Exercise Recommendations, Risk Factors, Genetics, Medications to Treat, Medications that Can Cause Osteoporosis, Morbidity and Mortality of Hip Fractures, Prevention, Testing, DEXA, Bone Health</td>
</tr>
<tr>
<td>3</td>
<td>Skin Health: What Causes Skin Changes, How to Detect Skin Cancers, How to Prevent Skin Problems with Aging, Products that Help Keep Skin Moist, When to See a Dermatologist, Foods that Keep Skin Healthy, Common Skin Issues Such as Psoriasis, Dermatitis and Rosacea</td>
</tr>
</tbody>
</table>
4 An Evening with A Life Coach: What is your best life and how to achieve this type of life. Discussion on aging and how our goals change. Ways to identify what our goals are. An exercise on how to implement healthy changes in our personal or professional lives.

5 Bio-identical Hormones and Supplements for Midlife: Led by a PharmD. Discussion on common supplements such as calcium, vitamins, Evening Primrose Oil, Valerian, and SamE. Also a discussion on synthetic and bioequivalent hormones such as estradiol, progesterone and testosterone. What each hormone is used for (such as estradiol for vaginal dryness).

6 Pilates; Strengthening the Core: Demonstration and 1 hour class led by a Certified Pilates Instructor. Pilates is an exercise program that focuses on strengthening the core. Each participant was encouraged to wear comfortable clothing and practiced strengthening abdominal, back, arm and leg exercises. Focus was on strengthening of core muscle groups.

7 Bladder and Vaginal Health Issues and Sexuality at Midlife. Discussion on the following common midlife issues: stress and urge incontinence; kegels, bladder and/or uterine prolapsed; vaginal atrophy, dyspareunia, and ways to either avoid or treat these midlife problems.

8 Dressing for Midlife with a Fashion Consultant. Discussion on common midlife body issues. Topics discussed included: how to dress using color, fabric, and style to enhance appearance and boost confidence.

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Phase Two: DASH and Pedometer Based Walking

Both groups received the exact same intervention during Phase Two (Week 9 to Week 16). This approach was chosen to more clearly evaluate whether the mindfulness intervention made a difference in the adoption of healthy lifestyle behaviors, resulting in improved health outcomes relative to the active control. Since the primary purpose of this study was to determine whether mindfulness would be a useful intervention in health behavior change, having Phase Two be exactly the same for both groups made it more sound to compare the outcomes of the two groups.

Exercise Content and Monitoring

Physical activity was encouraged by providing each participant with a pedometer. New Lifestyles NL 2000 pedometer (Yamax, Tokyo) was used as a motivational tool (Tudor-Locke, Ainsworth, Thompson & Matthews, 2002). A study by Crouter, Schneider, Karabulut and Bassett
(2003) compared the effects of walking speed on the reliability and accuracy of 10 electronic pedometers. The New Lifestyles NL-2000 brand of pedometer calculated steps within 1% of the steps actually taken, with a reliability correlation coefficient of .99. The New Lifestyles NL-2000 estimates kilocalories by taking into account gender, age, weight and height, which provides an estimate of the resting metabolic rate (Crouter, et al., 2003). It stores 7 days of data and can distinguish between the kilocalories for running and walking. Pedometers measure movement in steps. It is estimated that 10,000 steps per day are equal to walking approximately 5 miles and expending approximately 400-500 kcal/day (Rowland, Eston & Ingledew, 1997; Tudor-Locke & Myers, 2001). Steps were recorded in a log book if the participants desired to do so. The pedometer was used for motivational purposes and to provide objective feedback on exercise for women who found this useful.

The research participants picked up their pedometers two weeks before Phase Two of the study began. They were given written instructions on their use (see Appendix J) and were also asked to program their age, weight, height and gender into the pedometer so that kilocalories could be tracked while wearing the pedometer. They were asked to wear the pedometers for several days in order to feel comfortable on where to wear them, how to read the data and to make sure that the pedometers were working correctly.

An exercise physiologist, Dr. Ulf Bronas, from the University of Minnesota, met in small group sessions with participants who were interested. He also provided an hour-long presentation on exercise and weight loss during Week 3 of Phase Two.

Nutritional Content and Monitoring

Dietary logs were also distributed prior to Phase Two so that each participant would have time to review the log before Phase Two began (see Appendix K). A dietician who is an expert in nutrition and weight loss presented information on the first night of Phase Two on how the diet for Phase Two worked. Copies of Dietary Approaches to Stop Hypertension (DASH) (National
Heart Lung & Blood Institute, 2008; see Table 5) were distributed and reviewed. In addition, each week they received recipes that were consistent with the DASH concepts and information on exercise and strategies to support weight loss (see Table 6). They were encouraged to follow the diet plan and keep track of their nutritional intake in a dietary log.

Table 5

*The DASH Diet Modified for 1500 K Calories*

<table>
<thead>
<tr>
<th>Food Group</th>
<th>Daily Servings*</th>
<th>Serving Sizes, Examples, and Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grains, Grain products</td>
<td>6</td>
<td>Serving Sizes: 1 slice bread, 1 oz dry cereal, ½ cup cooked rice, pasta or cereal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Examples: Whole wheat bread, English muffin, pita bread, bagel, cereals, grits, oatmeal, crackers, unsalted pretzels, popcorn</td>
</tr>
<tr>
<td>Vegetables</td>
<td>3–4</td>
<td>Serving Sizes: 1 cup raw leafy vegetable, ½ cup cooked vegetable, 6 oz vegetable juice</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Examples: Tomatoes, potatoes, carrots, green peas, squash, broccoli, turnip greens, collards, kale, spinach, artichokes, green beans, lima beans, sweet potatoes, chaya</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Significance: Rich sources of potassium, magnesium and fiber</td>
</tr>
<tr>
<td>Fruits</td>
<td>4</td>
<td>Serving Size: 6 oz fruit juice, 1 medium fruit, ¼ cup dried fruit, ½ cup fresh, frozen, or canned fruit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Examples: Apricots, bananas, dates, grapes, oranges, orange juice, grapefruit, grapefruit juice, mangoes, melons, peaches, pineapples, prunes, raisins, strawberries, tangerines</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Significance: Important sources of potassium, magnesium and fiber</td>
</tr>
<tr>
<td>Low fat or fat free dairy</td>
<td>2–3</td>
<td>Serving Sizes: 8 oz milk, 1 cup yogurt, 1 ½ oz cheese</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Examples: Fat-free (skim) or low-fat (1%) milk, fat-free or low-fat buttermilk, fat-free or low-fat regular or frozen yogurt, low-fat and fat-free cheese</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Significance: Major source of calcium and protein</td>
</tr>
<tr>
<td>Meats, poultry, and fish</td>
<td>2 or less</td>
<td>Serving Sizes: 3 oz cooked meats, poultry, or fish</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Note: Select only lean meats; trim away visible fat; broil, roast, or boil, instead of frying; remove skin from poultry</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Significance: Rich sources of protein and magnesium</td>
</tr>
<tr>
<td>Nuts, seeds and beans</td>
<td>4–5 per week</td>
<td>Serving Sizes: 1/3 cup of 1 ½ oz nuts, 2 Tbsp or ½ oz seeds, ½ cup cooked dry beans</td>
</tr>
</tbody>
</table>
Examples: Almonds, filberts, mixed nuts, peanuts, walnuts, sunflower seeds, kidney beans, lentils, peas
Significance: Rich sources of energy, magnesium, potassium, protein, and fiber

Fats and oils 2–3
Serving Sizes: 1 tsp soft margarine, 1 Tbsp low-fat mayonnaise, 2 Tbsp light salad dressing, 1 tsp vegetable oil
Examples: Soft margarine, low-fat mayonnaise, light salad dressing, vegetable oil (e.g., olive, corn, canola, safflower)

Sweets 0
Serving Size: 1 Tbsp sugar, 1 Tbsp jelly or jam, ½ oz jelly beans, 8 oz lemonade
Examples: Maple syrup, sugar, jelly, gelatin sorbet, candy

Table 6

Schedule of Topics for Phase Two – Nutrition and Exercise

<table>
<thead>
<tr>
<th>Week</th>
<th>Topic – Each Class One Hour</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Motivational Quote of the Week; Success Story that identified a story from the local newspaper on successful weight loss; Recipes that followed the DASH principles; Journals and how to use as a motivational tool in weight loss; How to calculate calories, Portion Control/Serving Size; Pedometers; Keys to Success; Realistic Weight Loss Goals; Motivation; Recipes; Group Support; Pedometers. Healthy snack served that followed DASH principle to reinforce learning.</td>
</tr>
<tr>
<td>2</td>
<td>Motivational Quote of the Week; Success Stories for the Holidays – articles from magazines and newspapers of people that had been successful during the holidays; Recipes that followed DASH principles; Food Counts of Popular Holiday Foods; Success Strategies; Motivation; National Weight Registry Control Success Stories and Tips for Success; Recipes. Healthy snack served that followed DASH principles to reinforce learning.</td>
</tr>
<tr>
<td>3</td>
<td>Motivational Quote of the Week; Success Story - time for participants to share helpful suggestions and what was working for them; Recipes that followed DASH principles; Healthy Snacks; Eating on the Run; Reading Food Labels; Grocery Shopping; Mall Walking; Handouts on Mall Walks with Mileage and Hours Available, Holiday Strategies: Smaller Portions, Food Exchanges, How to Reduce Calories in Traditional Thanksgiving Foods. Healthy snack served each week that followed DASH principles to reinforce learning.</td>
</tr>
<tr>
<td>4</td>
<td>Motivational Quote of the Week; Success Stories from Participants, Exercise- articles from magazines and newspapers that described different forms of exercise and how it helped with weight loss; Recipes that followed DASH principles; – Mixing it Up; Nordic Walking, Walk/Jog; Stair Climbing. Demonstration with Nordic Walking Poles and a video on Nordic Walking which burns 20% more calories than walking alone.</td>
</tr>
</tbody>
</table>
Motivational Quote of the Week; Success Stories from Participants; Recipes that followed DASH principles; Plateaus- often weight remains the same for a period of time, important to not become discouraged; Triggers to Overeating and how to avoid these triggers. Group walking (5-6 people in a group) for 30 minutes while playing a game that included common misperceptions about weight loss.

Motivational Quote of the Week; Success Stories from Participants; Recipes that followed DASH principles; Mindless Eating- discussion of how easy it is to eat without thinking and how quickly the calories can add up; The Hunger Scale- discussion on taking the time to rate hunger on a scale and to not become over hungry which can sabotage efforts. Strength training demonstration with exercise bands.

Motivational Quote of the Week; Success Stories from Participants; Recipes that followed DASH principles; Holidays – Calorie Counts of Traditional Foods, Keys to Success at Christmas Dinner; Visual demonstration of common Christmas foods and how to either use portion control or to substitute another food to keep calories in check. Salsa Dancing (exercise) demonstrations for 30 minutes that included participation.

Motivational Quote of the Week; Success Stories from Participants; Recipes that followed DASH principles; Maintenance; Staying on Track; Relapses with weight loss and strategies to avoid negative thinking and weight gain. Wii Fit demonstrations that included Yoga, strength training, balance exercises and a cardio workout. Participation was encouraged.

Human Subjects Considerations

Every effort was made in this study to protect the rights of the research participants. The study was reviewed and approved prior to recruitment of subjects by both the University of Minnesota and Allina Health System’s Institutional Review Boards. Permission was obtained from the healthcare system for the study to be conducted at their site. The research team followed the guidelines established by HIPPA laws and safeguarded all personal information The study’s investigators had completed training in the Protection of Human Subjects. The Principal Investigators completed the NIH’s modules of Human Participant Protection Education for Research Teams and Responsible Conduct of Research through the University of Minnesota. The purpose of the study was discussed with each participant. Potential benefits and risks were reviewed. All participants were informed that participation was voluntary; that there was no financial compensation for time; that they would be randomly assigned to either the experimental or control group; and that they could withdraw at any time from the study. They were asked to
read through the consent form to see if they had any questions before the form was signed. All of the study data were de-identified and kept in a locked file.

**Statistical Analysis**

Descriptive cross-sectional statistics consisting of means, standard deviations, and either independent samples t-tests or chi square analyses were performed on all demographic data and dependent variables that were collected at baseline. The purpose of this analysis was to determine if there were significant differences between the two groups on any of these measures at the beginning of the study.

Regression was chosen as the method to analyze Aim 1 and the psychosocial measures of Aim 2 for several reasons. First, since this is a repeated measures design there will be correlated data, since the observations are on the same individuals over 3 time points. Regression works well with correlated data. Second, a regression model describes the mean response of the dependent variable based on various covariates or predictors. These covariates can be continuous such as time or qualitative such as treatment group. Third, regression models are an excellent way to determine patterns of change over time. Since this is a longitudinal study, it is important to be able to identify and describe patterns of change. More specifically, a spline, linear mixed effects model was chosen because it can accommodate factors that are fixed and assumed to be shared by all individuals such as group assignment (MBSR or HE) and random effects that are specific to the individual (e.g., age, individual response to change, unique psychosocial factors, physiologic responses based on time of day). The term mixed effects refers to the fact that this regression model has both fixed and random effects. A linear spline model refers to a type of model (regression equation) that accommodates changes in the slope of the regression line that is not a straight line with a continuous slope, but rather is a sequence of connected linear segments. Two line segments are connected at a point generally referred to as a knot, which is a point in the regression line where the slope changes markedly. This can be either a positive or negative
change in slope (Fitzmaurice, Laird & Ware, 2004). Finally, since this is a small under powered feasibility study, the chance of finding change in the mean response at a statistically significant alpha level is small. Therefore, to have a method of statistical analysis that is descriptive and is designed to identify patterns of change and suggestive of trends is an appropriate methodology.

Mean growth curves were inspected as a part of the initial exploratory analysis. Visual examination of the mean growth curves for the dependent variables were run for the physiologic measures of weight and body mass index. Visual examination of the mean growth curves was used to determine if there were apparent differences based on group assignment on weight change and changes in body mass index. Similarly, mean growth curve analyses were conducted on the psychosocial measures of: Perceived Stress Scale (PSS), Center for Epidemiologic Studies Depression Scale (CES-D), Depression, Anxiety and Stress Scale-21 (DASS-21), Cognitive Affective Mindfulness Scale-Revised (CAMS-R) and the Pittsburg Sleep Quality Index (PSQI). A spline linear mixed model for repeated measures was used to evaluate BMI, weight loss, and psychosocial measures. The focus of linear mixed model (LMM) analysis is on modeling the marginal mean along time points of various dependent variables. LMM assumes independence between research participants (random selection) and correlated observation on repeated measures within participants and a normal distribution (Fitzmaurice et al., 2004).

The purpose of Aim 1 was to determine if a program of MBSR as an intervention would be an effective behavior change treatment and thus result in changes in weight loss and BMI over time from Baseline to Week 16. The main hypothesis was that there would be a greater decline from Baseline to Week 16 in weight and BMI in the experimental intervention group than in the control group. Since body mass index is determined by weight, a reduction in weight would result in a reduction in BMI. In order to detect changes in these two dependent variables, a linear mixed effects model, which models both random effects (individuals) and fixed effects (treatment group assignment and time) was selected to determine if there was a difference between groups.
In order to determine if there was a treatment effect on physiologic dependent variables of weight and BMI (Aim 1) and on the psychosocial dependent variables of anxiety, stress, depressive symptoms, sleep quality and mindfulness (Aim 2) based on the intervention, linear mixed effects models, were constructed and tested. A spline model was determined to be a potential good fit for data analysis for this study as there was a potential knot or inflection point at the Week 8 time point. A knot is a point in the line where the slope changes markedly due to an increase or decrease in the mean response of the dependent variable. This point was visually apparent when examining the mean growth curves of weight, BMI, and the psychosocial measures for the two groups. Therefore, the spline variable was coded as 0 for the time point prior to or equal to Week 8 and coded as 1 for a time point after Week 8.

The following baseline demographic variables were tested as possible covariates to be entered into the models: a) age, b) years of education, c) total family income, and d) marital status. In addition, attendance at classes from Baseline through Week 16 was also used as a covariate to determine if class attendance accounted for a significant amount of variance. Finally, all of the baseline physiologic markers were tested as covariates. These physiologic markers included: a) fasting glucose, b) cortisol, c) highly sensitive C-Reactive Protein, d) diastolic blood pressure, e) systolic blood pressure, and f) waist-to-hip ratio. None of the psychosocial instruments such as a) Perceived Stress Scale (PSS), b) Centers for Epidemiologic Studies Depression Scale (CES-D), c) Pittsburg Sleep Quality Index (PSQI), d) Cognitive Affective Mindfulness Scale Revised (CAM-5-R) or e) Depression Anxiety and Stress Scale (DASS-21) were used because dependent variables cannot be used as covariates in linear mixed effects modeling. In addition, weight and BMI were not used as covariates for the same reason as the psychosocial instruments since they are dependent variables in the model and cannot be used as covariates in the linear mixed effects model.
The base model (regression equation) \( Y_{ij} = \beta_0 + \beta_1 \text{Time}_{ij} + \beta_2 \text{spline}_{ij} \) used time and spline as predictors of change. The reduced model (regression equation) was built up from the base model by testing covariates separately for each dependent variable. Each covariate was introduced one by one into the base model, tested with each dependent variable to determine if it contributed a significant amount of variance and was then removed. If it was determined that a covariate accounted for a significant amount of variance in the dependent variable, it was added after all testing was completed to the base model to produce the reduced model. The full model included all of the covariates from reduced model (age, education, salary, attendance, glucose, cortisol, and hs-CRP), and added group as a predictor. The 5 predictors were: Time, spline, Group, Group*Time and Group*spline. Testing the effect of the mindfulness program (treatment) relied on the model comparison. In other words, if adding Group to the model made a significant difference, then it would suggest that Group assignment (treatment) had in fact made a significant difference in the mean change over time on the dependent variable.

The full model included all variables in the reduced model and added three predictor variables to assess the effect of the treatments. The three predictors added to form the full model were Group (0 = Control, 1 = MBSR), Group*Time and Group*spline. Testing the effect of the mindfulness program (treatment) relied on the comparison of the reduced and full models. In other words, if adding the three predictors that involved the group variable to the model accounted for a statistically significant amount of variance in the respective dependent variable, it would indicate that group assignment (treatment) had an effect on the mean change over time on the dependent variable. The difference between the two models was analyzed by the likelihood ratio test with chi square as the test statistic.

The partial regression coefficient for the Group variable represents the difference between groups (control and intervention group) at baseline, averaging over all three time points (Week 0, Week 8 and Week 16). The partial regression coefficient for the Group*Time
interaction can be used to test if the slope from Week 0 to Week 8 is the same for both treatment
groups. The partial regression coefficient for the Group*spline interaction can be used to test if
the slope for the change from Week 8 to Week 16 is the same for both treatment groups. The
effects of the Group*Time and group*spline interactions were assessed using t-statistics. If the
overall chi-square statistic was statistically significant, but neither t-statistic indicated a
significant effect for either interaction, this indicated that the main effect of the treatment was a
significant difference between the two groups that persisted from Week 0 to Week 16.

The physiologic measures of diastolic and systolic blood pressure, glucose, cortisol and
hs-CRP; pre and post tests were measured at Baseline and Week 16. The difference between the
pre-scores and post-scores was computed for each of these dependent variables and a one-way
ANOVA with Group as the independent variable was conducted.
CHAPTER 4

Results

Overview

This chapter presents the findings of this study. It begins with a description of enrollment and then baseline demographics of the study participants including age, education, total family income and body composition markers of weight, blood pressure, waist-to-hip ratio and BMI, baseline physiologic measures, and baseline psychological measures. Independent samples t-tests and a chi square analysis were conducted to evaluate whether the two groups were similar on demographic and other pertinent physiologic and psychosocial variables at baseline. To determine if the treatment accounted for significant differences in weight loss and body mass index (BMI), a spline model was fit to the data using a linear mixed effects model. A spline model was also used to determine differences between the treatment and control groups for changes in psychosocial measures for both groups using a linear mixed model. Differences between the treatment and control groups in physiologic measures for Aim 2 were analyzed using one way analysis of variance (ANOVA) with the difference score (posttest – pretest) as the dependent variable.

Recruitment, Enrollment and Retention

Recruitment began on August 8, 2008 and was completed on August 31, 2008. The primary method of recruitment was through flyers (see Appendix A). Visits were also made to various nursing stations and clinics that were a part of the Abbott Northwestern Hospital campus, by the Principal Investigators to explain the nature of the study and to answer any questions. Forty nurses that met inclusion and exclusion criteria were consented and enrolled. Thirty eight nurses completed the study, 20 in the experimental (mindfulness) group and 18 in the active control (health education) group. Two women in the active control group withdrew prior to study completion. One research subject from the control group that did not complete the study was at the higher end of the weight and BMI range, the higher end of the total family income level, the
higher end of educational level and the lower end of age range. The other research subject from
the control group that did not complete the study, was at the higher end of age range, higher end
of total family income level, higher end of education and the lower end of weight and BMI range.
The following analyses for this pilot study were conducted on the majority completing the full
protocol including pre-tests and post-tests.

Sample Characteristics

Demographics. Results of the t-tests revealed that there were no statistically significant
differences between the control and intervention groups at baseline for the demographics
variables including age, education, and numbers of hours worked. However, the distribution of
total family income levels for the women in the control group was statistically different between
treatment groups (see Table 7 & 8). All of the women in the study were Caucasian.

Anthropometric, physiologic and psychosocial measures at baseline. There were no
statistically significant differences between the control and treatment groups for weight, BMI,
other physiologic or psychosocial measures prior to the onset of the interventions (see Table 7).

Table 7

Descriptive Demographic, Physiologic and Psychosocial Measures at Baseline for MBSR and HE
Groups.

<table>
<thead>
<tr>
<th>Variable</th>
<th>MBSR n=20 (SD)</th>
<th>HE n = 20 (SD)</th>
<th>Independent t Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yrs</td>
<td>48.3 (5.0)</td>
<td>48.4 (6.2)</td>
<td>0.08 .940</td>
</tr>
<tr>
<td>Hours worked/wk</td>
<td>39.1 (6.3)</td>
<td>36.5 (11.9)</td>
<td>-0.85 .401</td>
</tr>
<tr>
<td>Variable</td>
<td>MBSR (n=20)</td>
<td>HE (n=20)</td>
<td>Chi-Square</td>
</tr>
<tr>
<td>---------------------------</td>
<td>-------------</td>
<td>-----------</td>
<td>------------</td>
</tr>
<tr>
<td>Weight, lb</td>
<td>181.4 (2.5)</td>
<td>186.5 (29.0)</td>
<td>0.36</td>
</tr>
<tr>
<td>Body Mass Index</td>
<td>29.1 (3.87)</td>
<td>32.9 (4.29)</td>
<td>0.49</td>
</tr>
<tr>
<td>Waist/Hip Ratio</td>
<td>0.85 (0.05)</td>
<td>0.86 (.07)</td>
<td>0.21</td>
</tr>
<tr>
<td>Cortisol</td>
<td>11.55 (4.8)</td>
<td>13.6 (4.7)</td>
<td>1.37</td>
</tr>
<tr>
<td>C-Reactive Protein</td>
<td>2.91 (2.8)</td>
<td>3.92 (3.92)</td>
<td>0.95</td>
</tr>
<tr>
<td>Systolic BP</td>
<td>106.9 (24.5)</td>
<td>116.7 (11.2)</td>
<td>1.64</td>
</tr>
<tr>
<td>Diastolic BP</td>
<td>72.5 (7.4)</td>
<td>75.3 (7.6)</td>
<td>1.20</td>
</tr>
<tr>
<td>PSS</td>
<td>24.3 (7.6)</td>
<td>24.5 (4.96)</td>
<td>0.06</td>
</tr>
<tr>
<td>CES-D</td>
<td>13.1 (5.93)</td>
<td>9.9 (6.16)</td>
<td>0.82</td>
</tr>
<tr>
<td>DASS</td>
<td>11.0 (8.11)</td>
<td>11.8 (6.83)</td>
<td>0.33</td>
</tr>
<tr>
<td>PSQI</td>
<td>12.6 (6.19)</td>
<td>12.4 (5.82)</td>
<td>0.09</td>
</tr>
<tr>
<td>CAMS-R</td>
<td>33.1 (5.93)</td>
<td>32.8 (6.17)</td>
<td>0.13</td>
</tr>
</tbody>
</table>

Table 8

Baseline Demographic Measures of Income and Education for MBSR and HE Groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>MBSR (n=20)</th>
<th>HE (n=20)</th>
<th>Chi-Square</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Income</td>
<td></td>
<td></td>
<td>8.42</td>
<td>.038</td>
</tr>
<tr>
<td>30-49,999</td>
<td>0%</td>
<td>5%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>50-69,999</td>
<td>5.26%</td>
<td>15%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>70-89,000</td>
<td>42.11%</td>
<td>5%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>90,000</td>
<td>52.63%</td>
<td>75%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td>1.412</td>
<td>.703</td>
</tr>
<tr>
<td>Post HS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Associate 16.67% 20%
Bachelor 77.78% 65%
Master 5.55% 10%
Doctorate 0% 5%

Attendance

The mean attendance for the MBSR (intervention group) was 12.3 sessions with a standard deviation of 1.8, and the mean attendance for the women in the control group was 10.1 sessions with a standard deviation of 2.2. The women in the intervention group attended on average two more classes (out of 16 offered) than the women in the control group. An independent groups t-test was performed and using an alpha of 0.05, this test was found to be statistically significant, t(36) = 2.39, p =0.02 indicating that attendance was better for women in the MBSR group than in the HE group.

Aim 1

The purpose of Aim 1 was to determine if a program of mindfulness (MBSR) would be an effective treatment to improve heart health in women in midlife by changes in weight reduction and reductions in BMI. A visual display of patterns of change in weight over time for each of the 38 women that completed the study is presented in Figure 2. Examining the individual trend lines suggests that overall there is a weak negative relationship between weight loss and time, although there certainly is variation between the individuals. The slope of the regression line is zero or close to zero in some of the individuals. This variation in change highlights the heterogeneity of individuals and the unique patterns of change over time.
Figure 2. Individual (ID # 1-38) weight changes for Subjects in both groups Baseline (Week 0), Week 8, and Week 16.

**Spline Model**

A spline linear effects model was used to determine if there was a significant difference between the treatment and control group for weight loss and decreases in BMI based on group assignment. As described in Chapter 3, the initial reduced model consisted of time and spline as predictors to model change in weight and BMI over time. The initial reduced model was expanded through a process of testing covariates of baseline demographics and baseline physiologic markers. Each covariate was introduced one by one into the base model, tested with
each dependent variable to determine if it contributed a significant amount of variance in the
dependent variable and was then removed (see Appendix L). The final reduced model was as
follows:

\[ Y_{ij} = \beta_0 + \beta_1 \text{Time}_{ij} + \beta_2 \text{spline}_{ij} \]
\[ + \beta_3 \text{WHratio}_i + \beta_4 \text{WHratio}_i \cdot \text{Time}_{ij} + \beta_5 \text{WHratio}_i \cdot \text{spline}_{ij} \]
\[ + \beta_6 \text{SBP}_i + \beta_7 \text{SBP}_i \cdot \text{Time}_{ij} + \beta_8 \text{SBP}_i \cdot \text{spline}_{ij} \]
\[ + \beta_9 \text{DBP}_i + \beta_{10} \text{DBP}_i \cdot \text{Time}_{ij} + \beta_{11} \text{DBP}_i \cdot \text{spline}_{ij} \]
\[ + \beta_{12} \text{COR}_i + \beta_{13} \text{COR}_i \cdot \text{Time}_{ij} + \beta_{14} \text{COR}_i \cdot \text{spline}_{ij} \]
\[ + \beta_{15} \text{GLU}_i + \beta_{16} \text{GLU}_i \cdot \text{Time}_{ij} + \beta_{17} \text{GLU}_i \cdot \text{spline}_{ij} \]
\[ + \beta_{18} \text{CRP}_i + \beta_{19} \text{CRP}_i \cdot \text{Time}_{ij} + \beta_{20} \text{CRP}_i \cdot \text{spline}_{ij} \]
\[ + \beta_{21} \text{Age}_i + \beta_{22} \text{Age}_i \cdot \text{Time}_{ij} + \beta_{23} \text{Age}_i \cdot \text{spline}_{ij} \]
\[ + \beta_{24} \text{SalLevel}_i + \beta_{25} \text{SalLevel}_i \cdot \text{Time}_{ij} + \beta_{26} \text{SalLevel}_i \cdot \text{spline}_{ij} \]
\[ + \beta_{27} \text{EduLevel}_i + \beta_{28} \text{EduLevel}_i \cdot \text{Time}_{ij} + \beta_{29} \text{EduLevel}_i \cdot \text{spline}_{ij} \]
\[ + \beta_{30} \text{Attendance}_i + \beta_{31} \text{Attendance}_i \cdot \text{Time}_{ij} + \beta_{32} \text{Attendance}_i \cdot \text{spline}_{ij} + e_{ij} \]

The full model added variables (group, group*time, and group*spline) to model the effects of the
treatments:

\[ Y_{ij}^2 = Y_{ij}^1 + \beta_{33} \text{Group}_i + \beta_{34} \text{Group}_i \cdot \text{Time}_{ij} + \beta_{35} \text{Group}_i \cdot \text{spline}_{ij} + e_{ij} \]

The full model was tested against the reduced model with the results reported in Table 9.

Table 9

Summary Table Reporting Results for Model Testing for BMI and Weight

<table>
<thead>
<tr>
<th>Dependent Variables</th>
<th>$\chi^2$ statistic</th>
<th>p</th>
<th>$\beta_{34}$ (t-value)</th>
<th>$\beta_{35}$ (t-value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight</td>
<td>73.16</td>
<td>&lt;0.001</td>
<td>1.815 (1.170)</td>
<td>-2.271 (-1.192)</td>
</tr>
<tr>
<td>BMI</td>
<td>55.68</td>
<td>0.003</td>
<td>0.304 (1.180)</td>
<td>-0.398 (-1.064)</td>
</tr>
</tbody>
</table>

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The statistically significant $\chi^2$ values for the dependent variables of weight and BMI suggest there is a difference between the two treatments. However the t-values for the interactions that involve the group variable are small and do not support a significant difference in slopes between the two groups from Baseline to Week 8 ($\beta_{34}$) or significant differences between the slopes from Week 8 to Week 16 ($\beta_{35}$).

**Weight and BMI Changes by Group**

The difference between the means for both groups on weight loss and BMI, after being adjusted for the covariates, was very small (see Table 10).

**Table 10**

*Adjusted Mean Changes in Weight and BMI for MBSR and HE Group from Baseline to Week 16*

<table>
<thead>
<tr>
<th>Measure</th>
<th>Group</th>
<th>Baseline Mean (SD)</th>
<th>Week 8 Mean (SD)</th>
<th>Week 16 Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI</td>
<td>MBSR</td>
<td>29.62 (4.35)</td>
<td>29.66 (4.25)</td>
<td>29.23 (4.3)</td>
</tr>
<tr>
<td></td>
<td>HE</td>
<td>30.24 (4.36)</td>
<td>30.15 (4.42)</td>
<td>29.86 (4.7)</td>
</tr>
<tr>
<td>WT/lbs.</td>
<td>MBSR</td>
<td>186.9 (33.45)</td>
<td>186.9 (32.50)</td>
<td>184.3 (32.8)</td>
</tr>
<tr>
<td></td>
<td>HE</td>
<td>183.3 (30.03)</td>
<td>181.7 (29.04)</td>
<td>180.5 (30.3)</td>
</tr>
</tbody>
</table>

The pattern of change however, as illustrated in the Adjusted Mean Growth Curves for weight, was different (see Figure 3). It appears that the women in the control group (HE) began losing weight during the first eight weeks of the study and continued this downward slope to Week 16. The slope for the women in the treatment group (MBSR) did not decrease in a negative direction until after Week 8. The slope was steeper from Week 8 to the Week 16 than the control
group, but both groups had similar endpoints. However, the observed difference in trends between the two treatments may not be reliable given the small t-values for the interactions (see Table 9).

Figure 3. Trends in adjusted means for weight for the MBSR and HE groups from baseline to Week 16.

The pattern of change for both groups on BMI was different. The control group had a change in slope from Baseline to Week 8. This downward slope continued to Week 16. The treatment group did not have a change in slope until after Week 8. This downward slope continued until Week 16. The BMI endpoints were similar for the two groups. As was the case for weight loss, the observed difference in trends between the two treatments may not be reliable given the small t-values for the interactions (see Table 9).
Aim 2

The purpose of Aim 2 was to determine if a program of MBSR as a treatment would increase adherence to a program of diet and exercise which would result in improvement on psychosocial measures of depressive symptoms, anxiety, psychosocial stress, sleep quality and mindfulness. These variables were measured over the 3 time points of Baseline, Week 8 and Week 16. The same linear mixed model comparison was performed as described.

The results are described in Table 11. None of the p values were statistically significant, which indicates that there was no significant effect for the treatment on the psychosocial measures. There were however large effect sizes (i.e., large t-values) for both interactions with PSQI and CAM-R as dependent variables, which indicates a trend towards significance in the change of slope between the two groups from Baseline to Week 8 (β_34) and from Baseline to
Week 16 ($\beta_{35}$). The potential interactions for both of these dependent variables are explored in later sections.

Table 11

*Summary of Psychosocial Measures for the Spline Model*

<table>
<thead>
<tr>
<th>Dependent Variable</th>
<th>$\chi^2$ statistic</th>
<th>p-value</th>
<th>$\beta_{34}$ (t-value)</th>
<th>$\beta_{35}$ (t-value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression &amp; Stress (DASS)</td>
<td>38.853</td>
<td>0.129</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Psychosocial Stress (PSS)</td>
<td>29.347</td>
<td>0.499</td>
<td>NA</td>
<td>NS</td>
</tr>
<tr>
<td>Depression (CES)</td>
<td>36.765</td>
<td>0.184</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Sleep Quality (PSQI)</td>
<td>41.623</td>
<td>0.077</td>
<td>-5.932 (-2.749)</td>
<td>11.296 (2.942)</td>
</tr>
<tr>
<td>Mindfulness (CAM)</td>
<td>40.802</td>
<td>0.090</td>
<td>3.644 (2.279)</td>
<td>-7.089 (-2.983)</td>
</tr>
</tbody>
</table>

NA = t statistic is not presented since p value for $\chi^2$ statistic not close to statistical significance at .05 level

*Psychosocial Changes between Groups*

There were changes in all psychosocial measures for both groups during the study. There were decreases in mean score on all of the measures except mindfulness, indicating improvement. The mindfulness score increased for both groups, indicating an improvement in mindfulness. The pattern of change appears to be different for all measures between the two treatments. This is visually apparent from the trends in the adjusted Mean Growth Curves for each psychosocial measure presented in Figures 5 through Figure 9. However, the apparent difference in trends may not be reliable for DASS, PSS, and CES-D given the small t-values for the interactions with the group variable (see Table 11).
Table 12

Adjusted Group Mean Scores and Standard Deviation for Psychosocial Measures for
MBSR and HE for Baseline, Week 8 and Week 16

<table>
<thead>
<tr>
<th>Dependent Variable</th>
<th>Group</th>
<th>Baseline Mean (SD)</th>
<th>Week 8 Mean (SD)</th>
<th>Week 16 Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MBSR</td>
<td>11.6 (8.3)</td>
<td>7.6 (6.3)</td>
<td>6.0 (4.7)</td>
</tr>
<tr>
<td>DASS</td>
<td>HE</td>
<td>10.3 (6.4)</td>
<td>9.6 (6.5)</td>
<td>7.2 (5.1)</td>
</tr>
<tr>
<td></td>
<td>MBSR</td>
<td>24.3 (7.9)</td>
<td>21.18 (8.5)</td>
<td>17.9 (7.5)</td>
</tr>
<tr>
<td>PSS</td>
<td>HE</td>
<td>24.1 (5.2)</td>
<td>22.9 (8.1)</td>
<td>17.8 (6.4)</td>
</tr>
<tr>
<td></td>
<td>MBSR</td>
<td>13.1 (10.3)</td>
<td>8.8 (7.5)</td>
<td>5.8 (4.9)</td>
</tr>
<tr>
<td>CES-D</td>
<td>HE</td>
<td>9.2 (5.59)</td>
<td>8.93 (6.15)</td>
<td>6.07 (4.98)</td>
</tr>
<tr>
<td></td>
<td>MBSR</td>
<td>11.81 (5.91)</td>
<td>10.88 (5.73)</td>
<td>10.19 (5.47)</td>
</tr>
<tr>
<td>PSQI</td>
<td>HE</td>
<td>12.50 (5.40)</td>
<td>13.00 (7.86)</td>
<td>11.50 (5.75)</td>
</tr>
<tr>
<td></td>
<td>MBSR</td>
<td>32.50 (6.03)</td>
<td>35.56 (5.54)</td>
<td>35.75 (6.25)</td>
</tr>
<tr>
<td>CAM</td>
<td>HE</td>
<td>33.00 (6.9)</td>
<td>33.07 (6.91)</td>
<td>35.07 (6.53)</td>
</tr>
</tbody>
</table>

Depression/Anxiety/Stress (DASS)

Both groups improved their scores on DASS-21, one self report measure of depression, anxiety and psychosocial stress from Baseline to Week 16. The MBSR group had a higher baseline score on this measure and had a larger drop in score. While the pattern of change for both groups appears to be different, as illustrated in Figure 5, the difference is not supported by the statistical results. The treatment group (MBSR) had a negative linear decline from baseline to Week 8 and a more gradual decline in slope from Week 8 to Week 16. The control group (HE), had a gradual yet consistent decline in slope from Baseline to Week 16.
Figure 5. Trends in adjusted means for DASS-21 from baseline to Week 16 for MBSR and HE groups.

*Perceived Stress Scale (PSS)*

The adjusted mean scores on the Perceived Stress Scale (PSS), a measure of psychosocial stress declined for both groups during the study (see Figure 6). The initial mean score for both groups at baseline were very similar and the final mean scores for both groups were also very close. While the pattern of change appears to differ by group assignment, the difference may be specific to the sample since the differences were not statistically significant. The women in the intervention group (MBSR) showed a gradual decline from Baseline to Week 8 that continued to Week 16. The women in the control group (HE) began with a slight decrease from Baseline to Week 8 with a steep descent of slope that began at Week 8 and ended at Week 16.
Figure 6. Trends in adjusted means for the Perceived Stress Scale (PSS) for MBSR and HE groups for Baseline, Week 8 and Week 16.

The initial adjusted mean score for the treatment group (MBSR) was higher than for the control group (HE) and the final mean score for the MBSR group was lower than for the control group (see Figure 7). The two groups appear to have different patterns of change based on group assignment, although, again, the reliability of the difference is not supported by the statistical results. The treatment group had a gradual yet steady descent in slope from Baseline to Week 16. The control group’s slope of change was rather flat from Baseline through Week 8 and then had a negative decline from Week 8 to Week 16. The slope of the two group’s lines from Week 8 to Week 16 is almost parallel.
Figure 7. Trends in the adjusted means for the Center for Epidemiologic Studies Depression Scale (CES-D) for MBSR and HE groups from baseline to Week 16.

Pittsburg Sleep Quality Index (PSQI)

The control group (HE) had a slightly higher adjusted mean Baseline score on sleep quality than the treatment group (MBSR; see Figure 8). Higher scores indicate poorer sleep quality. The final sleep quality scores between the two groups at Week 16 were fairly similar, suggesting that both groups had improvements in sleep quality over the course of 16 weeks. The HE group has an incline in slope from Baseline to Week 8, suggesting a worsening of sleep quality during this phase and a change in the direction of the slope (decline) from Week 8 to Week 16 which suggests an improvement in sleep quality. The MBSR group had a gradual yet consistent decline in slope from Baseline to Week 16. This may imply an improvement in sleep quality that began when the intervention began. These differences in trends between the two treatments may be reliable given the large t-values for the group by time and group by spline interactions (see Table 11).

Figure 8. Trends in adjusted means for Pittsburg Sleep Quality Inventory (PSQI) for MBSR and HE group from baseline to Week 16.

Cognitive and Affective Mindfulness (CAM) Scale
The adjusted mean scores on the Cognitive and Affective Mindfulness Scale increased for both groups. An increase in score is associated with increased mindfulness. The pattern of change over time between groups was different, which is supported by the large t-values for the interactions with the group variable (see Table 11). The treatment group (MBSR) increased with a steady upward slope from Baseline to Week 8 and then a more gradual increase in slope from Week 8 to Week 16. Conversely, the control group (HE) had a subtle increase in slope from Baseline to Week 8 and then had a more marked increase in slope from Week 8 to Week 16, with a similar endpoint as the control group.
Figure 9. Trends in adjusted means for Cognitive Affective and Mindfulness Scale (CAM) for MBSR and HE groups from baseline to Week 16.

Aim 2, Physiologic Markers

In order to evaluate the effect of treatment on physiologic markers, a difference score was computed for each physiological marker by subtracting the Baseline score from the Week 16 score and then conducting one-way ANOVAs for each of the eight physiological difference scores with treatment as a factor. The dependent variables included cortisol, fasting glucose, hs-CRP, diastolic and systolic blood pressure and waist-to-hip ratio. There was no statistical difference (p = .05) post study based on group assignment on any of the physiologic markers, and all of the effect sizes were small, suggesting that there were no treatment effects (see Table 13).
### Table 13

**ANOVA Summary Table for Physiologic Measures**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group</th>
<th>Baseline Mean (SD)</th>
<th>Week 16 Mean (SD)</th>
<th>F</th>
<th>p</th>
<th>Eta Squared</th>
</tr>
</thead>
<tbody>
<tr>
<td>Waist/Hip Ratio</td>
<td>MBSR</td>
<td>.86 (.06)</td>
<td>.87 (.06)</td>
<td>.19</td>
<td>.67</td>
<td>.01</td>
</tr>
<tr>
<td></td>
<td>HE</td>
<td>.86 (.07)</td>
<td>.86 (.06)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glucose</td>
<td>MBSR</td>
<td>95.9 (10.1)</td>
<td>93.8 (8.7)</td>
<td>.24</td>
<td>.63</td>
<td>.01</td>
</tr>
<tr>
<td></td>
<td>HE</td>
<td>100.7 (11.3)</td>
<td>96.9 (10.1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cortisol</td>
<td>MBSR</td>
<td>11.6 (4.8)</td>
<td>13.8 (6.2)</td>
<td>.01</td>
<td>.92</td>
<td>.00</td>
</tr>
<tr>
<td></td>
<td>HE</td>
<td>13.6 (4.7)</td>
<td>15.7 (6.5)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C-Reactive Protein</td>
<td>MBSR</td>
<td>2.9 (2.7)</td>
<td>2.7 (3.0)</td>
<td>1.19</td>
<td>.28</td>
<td>.03</td>
</tr>
<tr>
<td></td>
<td>HE</td>
<td>3.9 (3.9)</td>
<td>4.6 (5.8)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diastolic BP</td>
<td>MBSR</td>
<td>72.5 (7.2)</td>
<td>72.9 (9.0)</td>
<td>1.09</td>
<td>.30</td>
<td>.03</td>
</tr>
<tr>
<td></td>
<td>HE</td>
<td>75.3 (7.6)</td>
<td>78.4 (8.6)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic BP</td>
<td>MBSR</td>
<td>106.9 (24.4)</td>
<td>114.0 (10.3)</td>
<td>.57</td>
<td>.46</td>
<td>.02</td>
</tr>
<tr>
<td></td>
<td>HE</td>
<td>116.7 (11.2)</td>
<td>116.4 (10.9)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Eta squared = estimate of effect size. Small effect size = .01, medium effect size = .06, large effect size = .14.

**Diet and Exercise**

As previously described, the women in both the treatment and control group were given a pedometer that would track the actual daily steps taken and log this information for a week. In addition, they were given a log book to track daily intake of protein, fruits, vegetables, dairy
products, and calories. There also was a place on the daily log to record exercise and thus steps
taken. Approximately ten of the thirty eight women enrolled in the study consistently used the
Healthcheques log book as a tracking tool, so it was difficult to collect accurate data on steps
taken, daily caloric intake or servings of food consistent with the DASH diet plan.

Summary

Forty subjects were enrolled in this study at Baseline and thirty eight were still enrolled at
Week 16. At Baseline, there were no statistically significant differences between the MBSR and
HE groups on any of the demographic, physiologic or psychosocial measures except for total
family income. The HE group had on average, a higher total family income. Attendance was
better for the MBSR group than HE. The mean group difference for attendance was statistically
significant.

The purpose of Aim 1 was to determine if a program of MBSR would increase weight
loss and thus reduce BMI. These changes would occur through a program of exercise and dietary
changes with increased commitment to the program through being “mindful.” In order to
determine if there was a treatment effect based on group assignment, a spline linear mixed effects
model was tested. The results of this testing found no statistically significant interactions between
treatment and time on weight loss or reductions in BMI from Baseline to Week 8 and from Week
8 to Week 16.

The purpose of Aim 2 was to determine if a program of MBSR would improve sympotms
of psychosocial stress, depression, anxiety, poor sleep quality and increase mindfulness. Another
purpose of Aim 2 was to determine if a program of MBSR would lower cortisol, fasting glucose,
hs-CRP, hip-to-waist ratio, diastolic and systolic BP. A spline linear mixed model was tested to
determine if there was a treatment effect based on group assignment on any of the psychosocial
measures. There were no statistically significant differences between the two groups on any of the
psychosocial measures from Baseline to Week 8 or from Week 8 to Week 16. There were
however large t values for sleep quality and mindfulness from Baseline to Week 8 and from Week 8 to Week 16, which suggests there may be a trend towards significance based on MBSR group membership.
The purpose of this chapter is to discuss the impact of study interventions on health behavior change. It was anticipated that utilizing Mindfulness Based Stress Reduction (MBSR) as an intervention preceding a diet and exercise intervention would result in a significant change in heart health-related risk factors (weight and BMI; and physiologic and psychosocial variables). These findings, relative to the findings of the active control group are discussed. In addition, recommendations for future research and potential implications for clinical practice are discussed. Finally, limitations of this study and recommendations based on this pilot study for future studies and practice are presented.

Aim 1: Mindfulness Based Stress Reduction as a Foundation for a Program of Diet and Exercise to Change Weight and Body Mass Index.

The findings of this study do not support that there is a treatment effect from MBSR on weight loss and BMI. There is a dearth in the literature on studies using MBSR as an intervention in health behavior change and its effect on weight loss and/or BMI. A randomized controlled trial explored the effect of a mindfulness based weight loss intervention for women (Tapper, et al., 2009). Data were collected at baseline, four and six months and the results showed no significant differences in weight loss or mental health. However, this study did not utilize the traditional MBSR approach, but rather utilized four, two-hour workshops and the content of the workshops was significantly different than the Kabat-Zinn approach.

A telephone survey from the National Physical Activity and Weight Loss Survey on the use of complementary and alternative medicine for weight control found that 8% of the 372 surveyed used meditation as tool for weight loss. Meditation is an integral component of MBSR, but the survey did not identify the kind of meditation used or whether it was learned through a
MBSR course. There currently are no studies in the literature that utilized MBSR as a health behavior change strategy, thus findings from this pilot are difficult to confirm or refute based on current research. Since finding effective mechanisms to potentiate health behavior change with weight loss and changes in BMI is of critical importance to heart health, this study has broken new ground in an effort to increase knowledge in this area. This has importance not only from a research perspective, but to enable clinicians in clinical practice to find effective interventions to aid in weight loss and changes in BMI. Further, it is the belief of this investigator that the foundation of MBSR laid before health behavior change intervention may result in continuing and enduring health behavior changes.

Both groups in this study lost weight. However, the amount of weight lost for both the intervention and control group was less than expected. In a study by Miller, et al. (2002) that utilized the Dietary Approaches to Stop Hypertension (DASH) as a weight loss intervention, the mean weight loss after nine weeks was 4.9 kilograms (10.7 lbs). It is difficult to determine why the women in this study did not achieve a greater weight loss, but one potential issue was the timing of this study. The diet and exercise component of this study occurred during the Thanksgiving and Christmas holidays, a challenging time for a weight loss program when the norm is to gain not lose weight. In a prospective study of holiday weight gain, in a convenience sample of 195 adults who were blinded to the true nature of the study, it found the mean weight increased significantly during the holiday period of mid-November to New Years on average 0.37 ± 1.52 kg (.82 lbs to 3.35 lbs) (Yanovski, et al. 2000). In addition, 15% of the adults in that study attempted to lose weight during the holiday period but their weight change was similar to those not attempting to lose weight.

Although the findings of this study did not support that there was a treatment effect on weight and BMI, it is interesting to examine the patterns of weight change and changes in BMI for the two groups. It appears that the women in the HE group began to lose weight (and thus
decrease BMI) during the time period of Baseline to Week 8, and this trend continued until Week 16. The women in the MBSR group did not appear to lose weight and in fact may have gained weight from Baseline to Week 8 and began to experience weight loss and changes in BMI from Week 8 to Week 16. It will be interesting to see if this trend continues at the six month post study follow up. It would be informative to replicate this study with a larger sample size to determine if in fact there is a real pattern of change and if this pattern is statistically significant but this study’s small sample size lacked the power to detect a difference between the two groups.

Aim 2: Effect of MBSR on Anthropometric, Physiologic and Psychosocial Variables

The findings of this study found no difference between the intervention (MBSR) and control (HE) groups on any of the physiologic or psychosocial variables. Both groups had improvements on all of the dependent variables for Aim 2. The differences between the two groups if there were any might be reflected rather in the patterns of change over time for psychosocial measures.

Psychosocial Variables

The women in the MBSR group demonstrated a small yet consistent improvement in adjusted mean scores for depressive symptoms, psychosocial stress, anxiety, sleep quality, and an increased awareness of being mindful from Baseline to Week 8. These improvements were not statistically significant but there was a consistent pattern to the timing of these improved scores. This timing coincides with their involvement and progression in the mindfulness course. These findings are consistent with other research studies on MBSR.

There were no known studies in the literature that studied the effect of MBSR in a non-clinical (non-patient) population of perimenopausal/menopausal women and examined its use to reduce psychosocial symptoms. There were however, a few studies that specifically investigated MBSR to reduce anxiety, depressive symptoms or psychosocial stress and included women in this
age group as a part of their sample. In addition, depressive symptoms, anxiety and psychosocial stress were often either linked as symptom clusters or the terms were used interchangeably.

Tacon, McComb, Caldera and Randolph (2003) investigated the use of MBSR to reduce anxiety in women with heart disease. Significant effects for MBSR were seen on anxiety \( (p < .01) \). In other research, a significant reduction in depressive symptoms was found in a study of 91 women with fibromyalgia, who participated in a MBSR course; there was a significant reduction \( (p < .001) \) in depressive symptoms in the MBSR intervention group versus control at the immediate post-program measurement (Sephton et al., 2007).

Anxiety and psychosocial stress were two outcome variables measured post MBSR for women with breast cancer in a 1-group pre-post intervention study conducted by Tacon, Caldera & Ronaghan (2004). The effects of the intervention were measured at baseline, and at eight weeks (at the conclusion of the eight-week MBSR intervention). There was a significant reduction in anxiety \( (p < .001) \) and psychosocial stress, \( (p < .001) \).

Sleep quality significantly improved in a study with oncology patients that completed a MBSR course (Carlson & Garland, 2005) and in a study on transplant patients by Gross, Kreitzer, Russas, Treesak and Frazier (2004). There were significant increases \( (p = .015) \) in mindfulness following a work site intervention utilizing MBSR (a shortened version) in a study on working adults (Klatt, Buckworth & Malarkey, 2009).

In the present study, women in the control group experienced unanticipated decreases in psychosocial stress, depressive symptoms, anxiety, and increases in sleep quality and mindfulness during Week 8 to Week 16 that were comparable to the improvements observed in the MBSR group. The difference between the MBSR and HE mean scores on all of the psychosocial variables was not statistically significant, and the improvement in scores was small, yet consistent. It is well documented in the literature that exercise (which increased in both groups) increases serotonin levels in the brain and can contribute to improved mood, decreased anxiety,
and decreased psychosocial stress and less depressive symptoms. In addition, improved sleep is also a potential benefit from exercise (Alevizos, Lentza, Kokkoris, Mariolis, & Koranzopoulos, 2005; Brown, 1992; Dugan, 2007; Karacabey, 2005).

It is interesting to note that there were large t values for both PSQI and CAM for the MBSR group, which may support there is a trend towards significance on these two measures. A larger sample size would be useful to determine if there may in fact be a statistically significant difference between the two groups on these two dependent variables. Poor sleep quality is a significant issue in midlife health for women and if a program of MBSR helps improve sleep quality, then further research in this area is warranted.

There were no prior studies found that have shown increased mindfulness as a result of diet and exercise intervention (Phase Two of this study). During the second phase of the study, there was a mixing of women between groups. The women that had participated in the MBSR arm of the study were potentially able to discuss mindfulness with women in the control group. In addition, since many of the nurses worked together--not only for the same healthcare system, but often on the same units of the hospital--there was a certain amount of information sharing that occurred throughout the study. Women in the active control group were aware that they were in a control group and several mentioned that they wanted to be in the MBSR group. One woman in the control group stated that she was in the group that was not supposed to lose weight and the MBSR group had an unfair advantage. This may have contributed to the increase in mindfulness scores of the active control group seen at Week 16, as they became familiar with the concepts of mindfulness though discussion with women that were in the MBSR group.

**Anthropometric and Physiologic Changes**

There were no statistically significant differences between the two groups in any of the anthropometric or physiologic measures. There was an improvement, albeit small for both groups on weight. Although an improvement was to be expected for both groups as dietary changes and
increases in exercise were initiated for both groups from Week 8 to Week 16, the lack of greater improvement for the MBSR group was unexpected. A prospective observational study by Rosenzweig, et al. (2007) found that participation in an eight-week MBSR course lowered glucose (hemoglobin A1C) levels (p = .03) and blood pressure (p=.009). A review article by Tanji (2000) found that exercise for women has many potential benefits which include a) improved blood pressure control, b) improved glycemic control, c) improvements in sleep quality, and d) decreased anxiety and depression. Women in both treatment groups of the present study apparently demonstrated the benefits of the diet and exercise program.

It is important to note that the mean diastolic blood pressure readings and systolic blood pressure readings for both groups at Baseline and Week 16 were in the normal range. It may not be realistic to expect a significant change in mean scores when the Baseline readings are within normal limits.

The fasting glucose values for the HE group improved from what is considered “pre-diabetic” to normal from Baseline to Week 16. The MBSR group has a fasting glucose level at Baseline that was within the normal range. There was a small decrease in the MBSR group mean at Week 16, but since the Baseline was within the normal range to expect a decrease in glucose values may not be realistic. It was an unexpected finding that in a group of research participants with elevated BMIs that fasting glucose levels were within the normal range.

The waist-to-hip ratio was elevated for both groups at both Baseline and Week 16. The decrease in this ratio for the HE group was nonexistent and the ratio actually increased for the MBSR group. Although, the lack of change or actual increase in this ratio in a group that lost weight (albeit small drop in weight) may be due to measurement error. The American Heart Association (2009) has changed its recommendations from using waist-to-hip ratio as a potential marker for heart disease risk to waist circumference (American Heart Association, 2009). This may eliminate some source of measurement error.
The morning (“a.m.”) mean cortisol levels for both the MBSR group and HE group at Baseline and Week 16 were within normal limits. The MBSR had a small increase in mean score from Baseline to Week 16 and the HE group had a small decrease in mean score from Baseline to Week 16. The difference between the two groups was not statistically significant. It may be unrealistic to expect improvements in score when the values are within normal range.

There were no statistically significant differences between the mean scores for hs-CRP for the MBSR and HE group. Both groups had elevated scores at Baseline and Week 16. There was a slight improvement in score for the MBSR group and a slight worsening of score for the HE group. This difference was not statistically significant. The mean scores for both groups at Week 16 were elevated and far from the normal range.

Clinical Significance

Even though there were no statistically significant differences between the two groups on any of the physiologic or psychosocial measures, both groups had decreases from Baseline to Week 16 scores on several measures.

Study Limitations

The main limitation to this study was the small sample size. The small sample size reduced statistical power and increased the risk of a Type II error, although the statistical analysis used compensated for this to a certain degree. It would be advantageous to have a larger sample size in the future based on an a priori power analysis.

The use of a convenience sample was another limitation as it limits the generalizability of the findings, as this sample may not be representative of nurses in midlife. In addition, there may be selection bias as the nurses self selected for this study.

The 16-week time commitment may have been another barrier. It was unusual that in a 16-week study, that there were only two women lost to follow-up, but it clearly became a burden to some of the participants to make a 16 week commitment, especially during the holiday season.
It might be more effective in the future, to have the MBSR and diet and exercise program occur simultaneously within an eight-week time frame. In such a program, the MBSR principles and practice would be blended to determine whether MBSR practices would augment diet and exercise (healthy lifestyle) behavior changes. In addition, it was difficult to have some women wait the eight weeks of Phase I, to start the diet and exercise component of the program. One participant in the control group joined Weight Watchers at Baseline and lost a tremendous amount of weight (21 pounds), which may have in fact skewed the data and made MBSR look relatively less effective (compared to the active control) than it really was.

The lack of commitment to utilizing the daily diet and exercise log was another limitation. Only a few of the women used the log books provided to them. It would be more effective in future studies to emphasize the importance of daily tracking of nutrition which highlighted adherence to the DASH diet and that this was an expectation of study participation. Future study will include specific motivational interventions and weekly review of diet and exercise logs along with feedback and recommendations to improve performance in the ensuing week. In addition, the tracking of exercise and nutritional intake would provide a tool to measure construct validity for adherence, which would have been useful for this study.

Another unforeseen occurrence was the lack of commitment to the utilization of the pedometer. Although some of the women used their pedometer on a daily basis, it became apparent that not all women in the study did. Pedometers were left inadvertently in destinations that precluded use, (one participant left her pedometer at a family cabin that was hours away) were broken, or lost or were used incorrectly even though very clear instructions on their use were given and the pedometers were distributed several weeks in advance in order to allow time for practice.

Scheduling of future studies should take into consideration time of year. Even though, in theory, a study on behavior change should not be influenced by naturally occurring seasons, it
was in fact an issue. It is a normative value in American culture to overeat during the holiday season and to fill time with social commitments rather than exercise commitments. It might be more fruitful in future studies to start a study of this nature in the New Year when thoughts of change are ripe or in the spring when weather causes inhabitants of the northern tundra to exercise.

The administration of instruments should be performed as a part of the scheduled clinic visits. The original intent was to have the women answer instruments during the scheduled clinic visits, but some had time constraints and returned them at a later date. It became a challenge to have all of the surveys completed and the end result were some missing data. In addition, a trained research assistant should administer the Stanford 7 Day Physical Activity Scale via interview. It was treated as a self-report instrument and this caused confusion and lack of clarity for the research participants, with the end result being questionable validity of the data obtained. This oversight was discovered by the Principal Investigator when a literature search after the study had began, uncovered the error of administration. The literature suggests that the Stanford Seven Day Daily Activity Scale should be administered by a trained research assistant and not by self-report.

**Recommendations for Future Research**

There is a critical need in clinical research to identify treatment options based on the unique needs of the individual rather than on the mean of the group, where the individual becomes lost. Unfortunately, individuals that do in fact respond to various treatments have often been lost to the “tails” of the research findings and their positive response to treatment effect not reported and thus not available to practitioners in clinical practice. Often, it is the individuals that do not respond to therapies described as “evidence based” (which are based on the mean of the group rather than on outliers) that will respond to other types of therapies. These patients present a challenge for practitioners and speak to the need for different ways to both design and analyze
these studies. Therefore, future studies that are both longitudinal in nature and utilize different types of statistical analysis plans designed to look at the individuality of the person in the study are needed. Since linear mixed effects models can predict the magnitude and direction of the response to treatment for patients with specific covariate values (Fitzmaurice, Laird & Ware, 2004, pg. 228), further studies utilizing this approach would be useful. Linear mixed effects models can be used to identify patients in clinical practice that do not respond to specific therapies (Fitzmaurice, Laird & Ware, 2004). There currently are no known studies where this approach with MBSR is being utilized. Thus, future longitudinal studies that utilize MBSR as a treatment and that utilize statistical analysis plans that are designed to analyze both the pattern of change and response to treatment over time for both the group and the individual are needed.

Further, qualitative studies (or mixed method studies) to study MBSR are needed. There are few studies in the literature that have utilized a qualitative research approach to MBSR. Since the experience of being “mindful” is unique to the individual, utilizing a method of inquiry that views mindfulness through the perspective of the individual is needed. For example, several women in this study discussed with the Principal Investigators that the MBSR course had been very helpful in reducing stress or improving sleep for example, but this response is lost in data that centers on the mean response of the participants as a whole.

Future studies should include a readiness to change questionnaire and evaluation. Only women who clearly want to change health behaviors should be included in the study and utilize precious, costly study resources. For example, there was one participant who had excellent attendance and was a delightful addition to the group, but clearly had no desire to change her eating or exercise habits. Every week healthy snacks consistent with the DASH diet were provided, but she chose to bring her own snacks during group meeting times that were high in saturated fat and calories (e.g., root beer float) and not what was recommended by the nutritionist.
that counseled the women on several occasions about heart healthy foods and foods to choose to lose weight.

Since the women in the MBSR group did not begin to lose weight until the MBSR program was complete, it might be useful to conduct qualitative interviews with the women from this group to determine what caused this behavior. Participants may be asked how they perceived that the mindfulness that was learned might have contributed to their health behavior change. Information from interviews might help guide future studies that involve MBSR as a health behavior change strategy.

Another potential issue was an unforeseen issue that pertained to joining other diet programs while in the study. One participant in the control group was bothered by her weight at Baseline. It was a revelation to her that she needed to lose weight. The thought of waiting eight weeks to begin an exercise and diet program were unsettling and she joined Weight Watchers to begin losing weight. Since it was not clearly stipulated prior to consenting for the study, it was not possible to advise her to not change her diet or exercise habits. She lost 21 lbs (and is continuing to lose weight) through this nationally acclaimed diet program and she began exercising in earnest. Unfortunately, in a small pilot study, this type of weight loss can skew the data and so it is difficult to determine the relative effects of the MBSR intervention on weight loss due to this statistical outlier.

Another limitation was that this study pertained to nurses from one healthcare system in one small geographic area. The findings of this study cannot be generalized to other populations. Much has been learned by this small pilot investigation. Future studies, incorporating recommendations to improve efficacy of intervention that have been delineated, could be done with other or similar populations—both locally or other geographically distinct locations. Also, it would be helpful to blind the study participants to the nature of the MBSR intervention group.

There was some discontent from some of the research participants in the active control group
because they had wanted to be in the MBSR. Perhaps a wait-list control group study would have circumvented some discontent. Also, an unfortunate labeling of the health education group as “a control condition” rather than active control intervention, seemed to cause some participants in the health education group to feel that there was no merit in attending the weekly meetings of this group. This was despite the investigators’ efforts to design the active control intervention to have other (not directly weight-loss related) benefits including wardrobing, skin care, bone care, relaxation, etc.).

The results from this study provide promising though limited evidence for the use of Mindfulness-Based Stress Reduction as a foundation for successful lifestyle and health behavior change interventions. Since cardiovascular disease in women is so prevalent, finding effective intervention strategies is of critical importance. MBSR programs have the potential to serve as an effective foundational platform and foundation for health behavior change, but more research in this area is needed. Future studies should include a) increased sample sizes to increase the ability to detect a significant difference between treatment groups; b) administering the Stanford Seven Day Physical Activity Scale in-person by a trained research assistant; c) including 1 on 1 weekly visits to review diet and exercise logs to help identify problem areas, provide brief motivational interventions, and to reward positive progress and effort; d) add a mandatory use measurement tool for pedometer use and food choices to provide construct validation for health behavior change; e) consider tailoring the MBSR course more specifically to utilize mindfulness techniques to change health behaviors—perhaps combining content on health behavior change simultaneously and synergistically with the MBSR program content; f) provide a MBSR refresher course midway through the second phase of the study; g) perform a power analysis to determine the size needed to more accurately assess treatment effect; and g) replicate this study in other geographic areas and with other patient populations.
REFERENCES


http://www.americanheart.org/presenter.jhtml?identifier=4489


http://www.goredforwomen.org/know_your_numbers.aspx


http://www.americanheart.org/downloadable/heart/1103835297279FS27SDCA5.pdf


Hubert, H. B., Feinleib, M., McNamara, P. M., & Castelli, W. P. (1983). Obesity as an independent risk factor for cardiovascular disease: A 26-year follow-up of participants in


of Obesity, 31*, 1442-1448.

12/5/09 from http://www.2.psy.unsw.edu.au/group/dass/

Radloff, L. S. (1977). The CES-D scale: A self-report depression scale for research in the general

Radloff, L. S. (1991). The use of the center for epidemiologic studies depression scale in
adolescents and young adults. *Journal of Youth and Adolescence, 20*(2), 149-166.

update: A report from the American Heart Association committee and stroke statistics


Rosengren, A., Hawken, S., Ounpuu, S., Sliwa, K, Zubaid, M., Almahmeed, W. A., Blackett, K.
factors with risk of acute myocardial infarction in 11 119 cases and 13 648 controls from
52 countries (the INTERHEART Study): Case-control study. *The Lancet, 364*(9438),
953-962.


Retrieved 1/3/08 from


http://www2.psy.unsw.edu.an/groups/dass


APPENDIX A

CONSENT FORM
[Midlife Women’s Health Study]

You are invited to participate in a research study. You were selected as a possible participant in this study because you are a nurse at Abbott Northwestern hospital, between the ages of 40-55 and are over your ideal weight. You volunteered either because you read a flyer about this study or heard about it through discussions at nursing staff meetings at Abbott Northwestern Hospital. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

BACKGROUND AND PURPOSE
Heart disease is the leading cause of death in women. Heart disease becomes problematic for many women after menopause but subtle changes in the risk factors for heart disease may develop in the years that precede menopause. Risk factors for heart disease that can be changed may include being overweight, psychosocial stress, changes in cholesterol, elevations in blood glucose, lack of exercise and a high fat diet. Research has shown that heart disease may be preventable with lifestyle modification to reduce these risk factors. These modifications include changes in diet and patterns of exercise and programs of stress reduction to help control weight, blood pressure, cholesterol, blood glucose, stress hormones and blood pressure.

This study is being conducted by Ruth Lindquist, PhD, University of Minnesota, School of Nursing; Melissa Frisvold, PhD Candidate, University of Minnesota, School of Nursing; Ulf Bronas, PhD, University of Minnesota, School of Nursing; Dr. Betty Gray, MD, Abbott Northwestern Hospital; Sue Sendelbach, PhD, Abbott Northwestern Hospital; Denise Windenburg, BA, Minneapolis Heart Institute; Jackie, Boucher, RD, MS, Minneapolis Heart Institute Foundation. It is funded by the Minneapolis Heart Institute, Abbott Northwestern Hospital, and the Institute for Health and Healing.

Study Purpose
The purpose of this study is to evaluate two programs of interest designed to aid in weight loss, stress reduction, improve cholesterol, improve blood glucose, and possibly help with sleep (Groups A & B below). One purpose of this feasibility study is to determine whether participation in Mindfulness Based Stress Reduction (MBSR) is more effective in helping midlife women change dietary and exercise patterns, reduce stress, and reduce weight—and maintain weight loss—in response to participation in a program of health behavior change compared to midlife women who participate in a comparable program of health behavior change without MBSR. We also hope to determine if women who follow specific programs that are designed to help prevent heart disease by modifying risk factors will improve participants’ risk factors as reflected in survey responses, weight, blood pressure, and several blood measures. If you are selected to participate in Study Group A, you also may be interviewed to help determine if a program of mindfulness meditation helps change health behaviors related to heart disease. This study is designed to evaluate the potential use of either a stress reduction program or midlife health education program coupled with a program of diet and exercise will help change and maintain health behaviors. This study is designed to evaluate the potential use of certain questionnaires, blood tests and also to evaluate the potential feasibility and effectiveness of the group interventions.
Study Procedures

STUDY GROUPS
Your participation in this study will be for a period of twelve months. If you participate in this study, you will be assigned to one of two groups. There will be a total of 36 participants. Each group has a 16-week period of participation and follow up at 6 months and one year. The content and techniques utilized are not experimental since the material and processes have been used for long and commonly used. This research is focused on the feasibility of conducting the study procedures, on whether participation in these groups helped with health behavior change and the maintenance of these changes and on potentially detecting any physical, emotional, or stress-related changes from participation in either Group A or Group B.

Please read this form and ask any questions you may have before agreeing to be in the study. It is important that you read and understand the following explanations, which describes the research subjects’ rights. Also below, we describe the procedures, benefits, risks, discomforts and precautions associated with this study. We also describe the alternative procedures that are available to you and your right to withdraw from the study at any time. The investigators do not have any financial interest in this study and this study does not have any outside funding to report.

Research Subject’s Bill or Rights

People who volunteer to participate in an experiment (also called a research study or clinical trial) need to understand what is expected of them and why the research is being done. As you think about whether or not to volunteer, it is important that you know you have rights in place to help protect you. These rights, listed below, will be further explained as you read this informed consent document.

If you are asked to participate in a research study, you have the right to:

- be told the purpose and details of the research study,
- have the drugs or devices (tools or pieces of equipment) used in the research study described,
- have the procedures of the research study and what is expected of you explained,
- have the risks, dangers and discomforts of the research study described,
- have the benefits and advantages of the research study described,
- be told of other drugs, devices or procedures (and their risks and benefits) that may be helpful to you,
- be told of medical treatment available to you should you be injured because of the research study,
- have a chance to ask questions about the research study,
- quit the research study at any time without it affecting your future treatment,
- have enough time to decide whether or not to take part in this research study and to make that decision without feeling forced or required to participate, and be given a copy of this signed and dated informed consent form.

STUDY PROCEDURES
Once the research team has determined that you are qualified to participate in the study, participants will be randomly assigned to either Group A or Group B until the groups are filled.
Prior to participation you will have your height and weight taken, and blood pressure checked. You will be asked to complete short surveys and to have your blood taken for lab tests.

Group A Phase One: Participants in this group will attend an eight week course on Mindfulness Based Stress Reduction at the Institute of Health and Healing. This eight week class consists of a weekly class for eight weeks concluding with a 7-hour day of mindfulness. This introductory course is based on Jon Kabat-Zinn’s model in his book, Full Catastrophe Living. Mindfulness-based stress reduction (MBSR) is ideal for anxiety, depression, chronic pain and illness, cardiac disease, the demands of care-giving, life-threatening illness, grief, spiritual emptiness and balancing everyday stress. Participants learn and practice the basic skills and begin to experience their impact on everyday life, health and well-being. Each session involves walking, eating, sitting and/or yoga meditation, instruction and group discussion. The instructor for this course has trained professionally with Jon Kabat-Zinn and has years of experience with MBSR training.

Some participants from Group A, Phase One may be asked to be interviewed about their experiences after taking a MBSR course. Semi-structured interviews will be conducted and audio-recorded at a location determined by the participant. Each participant will be briefed on the nature of the project, and asked to describe their experiences with mindfulness. The general purpose of the interviews is to understand the overall meaning of mindfulness and if it impacted your choices about health related issues. You may be asked questions such as “have you changed the way you eat and exercise since participating in a mindfulness course”. You may be asked to clarify information, so additional questions may be used. The interviews will last approximately 30 minutes. A follow up phone call will last approximately 15 minutes.

Group A, Phase Two
Phase Two begins immediately after Phase One. This phase is for 8 weeks and involves a pedometer based walking program where you will be encouraged to exercise 5-6 times per week. Initially you will be asked to walk for 30 minutes and gradually increase this time to 60 minutes over the course of 8 weeks. You will be asked to exercise at your own pace. In addition, you will be given verbal and written instruction on the Dietary Approaches to Stop Hypertension (DASH) diet. This is a diet designed to help lower blood pressure but may also be used for weight management through healthy food choices and portion control. You will be asked to complete daily food logs and exercise logs. There will be weekly meetings lasting approximately one hour where your weight will be taken, your blood pressure checked, weekly logs collected and classes on strategies to help with diet and exercise will be conducted.

Group B, Phase One
This group on health education in midlife meets weekly for 8 weeks one time per week. Each class will last approximately 2 ½ hours. The topic each week will differ and have various speakers that are experts in their respective fields. The topics will include physiological and psychological issues common in midlife women’s health, Pilates (and exercise program that teaches how to strengthen the body’s core muscles - abdominal muscles), life coaching which involves analyzing one’s personal goals for life, osteoporosis prevention, skin care, and clothing and how to dress for midlife.

Group B, Phase Two
Phase Two begins immediately after Phase One. This phase is for 8 weeks and involves a pedometer based walking program where you will be encouraged to exercise 5-6 times per week. Initially you will be asked to walk for 30 minutes and gradually increase this time to 60 minutes over the course of 8 weeks. You will be asked to exercise at your own pace. In addition, you will
be given verbal and written instruction on the Dietary Approaches to Stop Hypertension (DASH) diet. This is a diet designed to help lower blood pressure but may also be used for weight management through healthy food choices and portion control. You will be asked to complete daily food logs and exercise logs. There will be weekly meetings lasting approximately one hour where your weight will be taken, your blood pressure checked, weekly logs collected and classes on strategies to help with diet and exercise will be conducted.

Participants in both groups will complete a set of questionnaires combined in one survey. The survey items assess such things as demographic information, perceptions of stress, mindfulness (if participating in Group A) anxiety and depression and sleep. The survey will take approximately 30 minutes to complete. These questionnaires will be completed at the beginning of the study, after the Phase One, eight week period, after the Phase Two, 8 week period, at 6 months (from program start) and at 1 year from beginning the program. In addition, you consent to having 30 cc’s (or approximately 6 teaspoons) of your blood drawn to look at markers that may reflect cardiovascular health and those that may be affected by stress hormones in your body. This will be done at the beginning of the study, the end of Phase Two, at the 6 month mark and at 1 year. Between the time of the end of the 16-week program and the 6-month and 1 year follow-up, we would send you monthly reminders and encouragements by mail or email to continue your practice of the exercises, and dietary changes that you learned in the program.

We will ask all participants for basic information about medications used, medical conditions, and demographic information (like education, age, marital status).

If you participate in Group A and are asked and to be interviewed, this interview will be tape recorded. These recorded transcripts will have all identifying information removed such as names and location. Data will be kept in a locked cabinet. Only personnel directly involved in the research will access to the data. Interview tapes will be destroyed once transcribed and reviewed for accuracy. Transcribed interviews will be identified by number and not by name. Research records and transcribed interviews will be stored separately. All personnel involved in this study will complete and adhere to HIPPA training and procedures. Any quotes used in publications will be done in such a way as to protect the identity of the source. Data may be used for education purposes for 20 years after the study is completed.

**RISKS AND DISCOMFORTS**

There are no additional risks identified that you will incur as a study participant. Drawing blood may cause bruising and discomfort at the site and sometimes it causes people to feel lightheaded, or even faint. On rare occasions, the site might become infected. You may feel uneasy participating in the speech tests. Normally, speaking under these conditions raises blood pressure and heart rate. These will be monitored by a nurse. Participation in the Mindfulness-Based Stress Reduction program (Group A) may make you feel awkward because you do light stretching or assume positions of relaxation in the company of others in your group. Participation in any specific exercise is always optional. This presents a possible risk of privacy and every measure will be implemented to keep the information private, secure and confidential. Also, all participants will be asked to complete fairly lengthy questionnaires to report information about themselves that you may consider private or personal. You do not have to answer all questions.

**BENEFITS**

As no benefit is guaranteed, you may or may not benefit directly from participation in this study. Your participation will provide information that may in the future benefit others and will help us refine the procedures and conduct of our future studies in this area.
ALTERNATIVES
You may choose not to participate in this study.

COSTS
What charges will be paid by the study?
All testing and services performed for your participation in this study will be provided at no cost.
The materials and classes for this study will be paid for in addition to any parking fees associated
with the classes.

BILLING ERROR INFORMATION
If you believe at any time during the research study that you have received a bill in error,
contact the study coordinator, Denise Windenburg at 612-863-3816.

COMPENSATION
You will not be paid for participating in this study.

COMPENSATION FOR A RESEARCH-RELATED INJURY
If you are injured as part of your participation in this research study, treatment will be available,
including first aid, emergency treatment and follow-up care, as needed. Care for such injuries will
be billed in the ordinary manner to you or your insurance company.

CONFIDENTIALITY
Every reasonable effort will be made to keep your records of this study confidential. Your
identity, clinic and hospital records, and other information that is obtained in this trial are
confidential, except as required by law. This information will not be revealed to any person,
except personnel involved with the study at the Minneapolis Heart Institute/Foundation, the
Food and Drug Administration (FDA), other applicable regulatory authorities, or the Abbot
Northwestern Hospital Institutional Review Board, without your consent. If the results of the trial
are published, your identity will remain confidential.

VOLUNTARY PARTICIPATION/withdrawal
Your participation in this research study is voluntary. Your decision whether or not to participate
in this study will not affect your current or future relations with the University of Minnesota,
Abbott Northwestern Hospital, Minneapolis Heart Institute or the Institute for Health and
Healing. If you decide to participate, you are free to withdraw at any time without affecting those
relationships.

You can refuse to participate or you can withdraw from this study at any time for any reason.

Confidentiality

The records of this study will be kept private. In any publications or presentations, we will not
include any information that will make it possible to identify you as a subject. To these extents,
confidentiality is not absolute.

Protected Health Information (PHI)

Your PHI created or received for the purposes of this study is protected under the federal
regulation known as HIPAA. Refer to the attached HIPAA authorization for details concerning the use of this information.

Contacts and Questions

The researchers conducting this study are Dr. Ruth Lindquist at 612-624-5646 or Melissa Frisvold, PhD Candidate, 612-963-2738 or the study coordinator, Denise Windenburg at 612-863-3816. You may also contact the Abbott Northwestern Hospital Institutional Review Board at 612-262-4920. You may ask any questions you have now, or if you have questions later, you are encouraged to contact them at the numbers listed above.

If you have any questions or concerns regarding the study and would like to talk to someone other than the researcher(s), you are encouraged to contact the Fairview Research Helpline at telephone number 612-672-7692 or toll free at 866-508-6961. You may also contact this office in writing or in person at University of Minnesota Medical Center, Fairview-Riverside Campus, 2200 Riverside Avenue, Minneapolis, MN 55454.

STATEMENT OF CONSENT
This research study and related procedures have been explained to me to my satisfaction. I understand that my participation in this study is voluntary and that I may withdraw my consent at any time without penalty, prejudice or loss of benefits to which I am entitled. I have been given the opportunity to ask questions and all of my questions have been answered. I will be given a signed copy of this consent form for my records.

You will be given a copy of this form to keep for your records.

I have read the consent form.

Signature of Subject___________________________________ Date______________________
Signature of Investigator________________________________ Date______________________
NURSES WANTED
For Midlife Women’s Health Study

Women between the ages of 40 and 55 are invited to enroll in a research study.

The study will explore the effects of a stress reduction program on weight loss.

Participants will take part in an 8-week stress reduction group or Midlife education group. Both groups will also participate in an additional 8-week walking and dietary program.

For further information, please contact:

Denise Windenburg, Co-Investigator

Research conducted by:

Women’s Heart Health Program
920 E. 28th Street, Suit 210
Minneapolis, MN 55407
&
University of Minnesota
School of Nursing
APPENDIX C
Depression Anxiety Stress Scale

<table>
<thead>
<tr>
<th>DASS21</th>
<th>Name:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please read each statement and circle a number 0, 1, 2 or 3 that indicates how much the statement applied to you over the past week. There are no right or wrong answers. Do not spend too much time on any statement.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*The rating scale is as follows:*
0 Did not apply to me at all
1 Applied to me to some degree, or some of the time
2 Applied to me to a considerable degree, or a good part of time
3 Applied to me very much, or most of the time

1. I found it hard to wind down
2. I was aware of dryness of my mouth
3. I couldn't seem to experience any positive feeling at all
4. I experienced breathing difficulty (eg, excessively rapid breathing, breathlessness in the absence of physical exertion)
5. I found it difficult to work up the initiative to do things
6. I tended to over-react to situations
7. I experienced trembling (e.g., in the hands)
8. I felt that I was using a lot of nervous energy
9. I was worried about situations in which I might panic and make a fool of myself
10. I felt that I had nothing to look forward to
11. I found myself getting agitated
12. I found it difficult to relax
13. I felt down-hearted and blue
14. I was intolerant of anything that kept me from getting on with what I was doing
15. I felt I was close to panic
16. I was unable to become enthusiastic about anything
17. I felt I wasn't worth much as a person
18. I felt that I was rather touchy
19. I was aware of the action of my heart in the absence of physical exertion (eg, sense of heart rate increase, heart missing a beat)
20. I felt scared without any good reason
21. I felt that life was meaningless

The DASS 21 Appendix is Public Domain:
APPENDIX D

INSTRUCTIONS:

The questions in this scale ask you about your feelings and thoughts during THE LAST MONTH. In each case, you will be asked to indicate your response by placing an “X” over the circle representing HOW OFTEN you felt or thought a certain way. Although some of the questions are similar, there are differences between them and you should treat each one as a separate question. The best approach is to answer fairly quickly. That is, don’t try to count up the number of times you felt a particular way, but rather indicate the alternative that seems like a reasonable estimate.

<table>
<thead>
<tr>
<th></th>
<th>Never 1</th>
<th>Almost Never 2</th>
<th>Sometimes 3</th>
<th>Fairly Often 4</th>
<th>Very Often 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>In the last month, how often have you been upset because of something that happened unexpectedly?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>2.</td>
<td>In the last month, how often have you felt that you were unable to control the important things in your life?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>3.</td>
<td>In the last month, how often have you felt nervous and “stressed”?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>4.</td>
<td>In the last month, how often have you dealt successfully with day to day problems and annoyances?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>5.</td>
<td>In the last month, how often have you felt that you were effectively coping with important changes that were occurring in your life?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>6.</td>
<td>In the last month, how often have you felt confident about your ability to handle your personal problems?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>7.</td>
<td>In the last month, how often have you felt that things were going your way?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>8.</td>
<td>In the last month, how often have you found that you could not cope with all the things that you had to do?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>9.</td>
<td>In the last month, how often have you been able to control irritations in your life?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>10.</td>
<td>In the last month, how often have you felt that you were on top of things?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>11.</td>
<td>In the last month, how often have you been angered because of things that happened that were outside of your control?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>12.</td>
<td>In the last month, how often have you found yourself thinking about things that you have to accomplish?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>13.</td>
<td>In the last month, how often have you been able to control the way you spend your time?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>14.</td>
<td>In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>

The PSS Appendix—Permission to use is Pending:

APPENDIX E

Center for Epidemiologic Studies Depression Scale

Center for Epidemiologic Studies Depression Scale (CES-D), NIMN

Below is a list of the ways you might have felt or behaved. Please tell me how often you have felt this way during the past week.

<table>
<thead>
<tr>
<th></th>
<th>During the Past Week</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Rarely or more of the time (less than 1 day)</td>
<td>Some or a little of the time (1-2 days)</td>
<td>Occasionally or a moderate amount of time (3-4 days)</td>
</tr>
<tr>
<td>1.</td>
<td>I was bothered by things that usually don’t bother me.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>2.</td>
<td>I did not feel like eating: my appetite was poor.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>3.</td>
<td>I felt that I could not shake off the blues even with help from my family or friends.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>4.</td>
<td>I felt I was just as good as other people.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>5.</td>
<td>I had trouble keeping my mind on what I was doing.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>6.</td>
<td>I felt depressed.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>7.</td>
<td>I felt that everything I did was an effort.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>8.</td>
<td>I felt hopeful about the future.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>9.</td>
<td>I thought my life had been a failure.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>10.</td>
<td>I felt fearful.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>11.</td>
<td>My sleep was restless.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>12.</td>
<td>I was happy.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>13.</td>
<td>I talked less than usual.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>15.</td>
<td>People were unfriendly.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>16.</td>
<td>I enjoyed life.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>17.</td>
<td>I had crying spells.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>18.</td>
<td>I felt sad.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>19.</td>
<td>I felt that people dislike me.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>20.</td>
<td>I could not get “going.”</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

SCORING: Zero for answers in the first column. 1 for answers in the second column, 2 for answers in the third column, 3 for answers in the fourth column. The scoring of positive items is reversed. Possible range of scores is zero to 60, with the higher scores indicating the presence of more symptomatology.

The CES-D Appendix is Public Domain:

APPENDIX F

Cognitive and Affective Mindfulness Scale – Revised

Cognitive and Affective Mindfulness Scale – Revised (CAMS-R)

People have a variety of ways of relating to their thoughts and feelings. For each of the items below, rate how much each of these ways applies to you.

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rarely/Not at all</td>
<td>Sometimes</td>
<td>Often</td>
<td>Almost Always</td>
</tr>
</tbody>
</table>

_____ 1. It is easy for me to concentrate on what I am doing.
_____ 2. I am preoccupied by the future.
_____ 3. I can tolerate emotional pain.
_____ 4. I can accept things I cannot change.
_____ 5. I can usually describe how I feel at the moment in considerable detail.
_____ 6. I am easily distracted.
_____ 7. I am preoccupied by the past.
_____ 8. It’s easy for me to keep track of my thoughts and feelings.
_____ 9. I try to notice my thoughts without judging them.
_____ 10. I am able to accept the thoughts and feelings I have.
_____ 11. I am able to focus on the present moment.
_____ 12. I am able to pay close attention to one thing for a long period of time.

The CAMS-R Appendix—Permission to use is Pending:
APPENDIX G

Pittsburg Sleep Quality Index

Subject’s Initials ______________ ID# ______________ Date ______________ Time ______ PM

PITTSBURGH SLEEP QUALITY INDEX

INSTRUCTIONS:
The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

1. During the past month, what time have you usually gone to bed at night?
   BED TIME __________

2. During the past month, how long (in minutes) has it usually taken you to fall asleep each night?
   NUMBER OF MINUTES __________

3. During the past month, what time have you usually gotten up in the morning?
   GETTING UP TIME __________

4. During the past month, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spent in bed.)
   HOURS OF SLEEP PER NIGHT __________

For each of the remaining questions, check the one best response. Please answer all questions.

5. During the past month, how often have you had trouble sleeping because you . . .
   a) Cannot get to sleep within 30 minutes
      Not during the past month _____ Less than once a week _____ Once or twice a week _____ Three or more times a week _____
   b) Wake up in the middle of the night or early morning
      Not during the past month _____ Less than once a week _____ Once or twice a week _____ Three or more times a week _____
   c) Have to get up to use the bathroom
      Not during the past month _____ Less than once a week _____ Once or twice a week _____ Three or more times a week _____
d) Cannot breathe comfortably

Not during the past month _____
Less than once a week _____
Once or twice a week _____
Three or more times a week _____

e) Cough or snore loudly

Not during the past month _____
Less than once a week _____
Once or twice a week _____
Three or more times a week _____

f) Feel too cold

Not during the past month _____
Less than once a week _____
Once or twice a week _____
Three or more times a week _____

g) Feel too hot

Not during the past month _____
Less than once a week _____
Once or twice a week _____
Three or more times a week _____

h) Had bad dreams

Not during the past month _____
Less than once a week _____
Once or twice a week _____
Three or more times a week _____

i) Have pain

Not during the past month _____
Less than once a week _____
Once or twice a week _____
Three or more times a week _____

j) Other reason(s), please describe ____________________________________________
____________________________________________________________________________
____________________________________________________________________________

How often during the past month have you had trouble sleeping because of this?

Not during the past month _____
Less than once a week _____
Once or twice a week _____
Three or more times a week _____

6. During the past month, how would you rate your sleep quality overall?

Very good ______________
Fairly good ______________
Fairly bad ______________
Very bad ________________

7. During the past month, how often have you taken medicine to help you sleep (prescribed or "over the counter")?

Not during the past month _____
Less than once a week _____
Once or twice a week _____
Three or more times a week _____
8. During the past month, how often have you had trouble staying awake while driving, eating
meals, or engaging in social activity?

<table>
<thead>
<tr>
<th>Not during the past</th>
<th>Less than once a week</th>
<th>Once or twice a week</th>
<th>Three or more times a week</th>
</tr>
</thead>
</table>

9. During the past month, how much of a problem has it been for you to keep up enough
enthusiasm to get things done?

<table>
<thead>
<tr>
<th>No problem at all</th>
<th>Only a very slight problem</th>
<th>Somewhat of a problem</th>
<th>A very big problem</th>
</tr>
</thead>
</table>

10. Do you have a bed partner or room mate?

<table>
<thead>
<tr>
<th>No bed partner or room mate</th>
<th>Partner/room mate in other room</th>
<th>Partner in same room, but not same bed</th>
<th>Partner in same bed</th>
</tr>
</thead>
</table>

If you have a room mate or bed partner, ask him/her how often in the past month you have
had . . .

a) Loud snoring

<table>
<thead>
<tr>
<th>Not during the past month</th>
<th>Less than once a week</th>
<th>Once or twice a week</th>
<th>Three or more times a week</th>
</tr>
</thead>
</table>

b) Long pauses between breaths while asleep

<table>
<thead>
<tr>
<th>Not during the past month</th>
<th>Less than once a week</th>
<th>Once or twice a week</th>
<th>Three or more times a week</th>
</tr>
</thead>
</table>

c) Legs twitching or jerking while you sleep

<table>
<thead>
<tr>
<th>Not during the past month</th>
<th>Less than once a week</th>
<th>Once or twice a week</th>
<th>Three or more times a week</th>
</tr>
</thead>
</table>

d) Episodes of disorientation or confusion during sleep

<table>
<thead>
<tr>
<th>Not during the past month</th>
<th>Less than once a week</th>
<th>Once or twice a week</th>
<th>Three or more times a week</th>
</tr>
</thead>
</table>

e) Other restlessness while you sleep; please describe ____________________________

<table>
<thead>
<tr>
<th>Not during the past month</th>
<th>Less than once a week</th>
<th>Once or twice a week</th>
<th>Three or more times a week</th>
</tr>
</thead>
</table>

The PSQI Appendix—Permission to use is Pending:

APPENDIX H

Midlife Women’s Health Study
Demographic Information

Subject: _______     Date: _____________

Please fill out the following information:

1. Age ______
2. Date of Birth _____________
3. Marital Status  Married ____ Single ____  Divorced ____
   Widowed ____  Living with Someone _____
4. Race/Ethnic Origin (please check one)
   African American  _______
   Caucasian _______
   Hispanic _______
   Asian American _______
   Multiracial/Biracial _______
   Pacific Islander or Native Hawaiian _______
   American Indian/Alaska Native _______
   Other (please specify) _______
5. Current total annual household income (check one):
   Less than $5,000  _______
   $5,000 - $9,999 _______
   $10,000 - $19,999 _______
   $20,000 - $29,999 _______
   $30,000 - $49,999 _______
   $50,000 - $69,000 _______
   $70,000 - $89,999 _______
   More than $89,999 _______
APPENDIX I

Stanford Seven Day Physical Activity Recall

ID #: ________________               Date: __________

Seven-Day Physical Activity Recall

Instructions:
This questionnaire is called the Seven-Day Physical Activity Recall. The information from it will be used to estimate the number of calories you burn up through physical activity.

# 1:
On the average, how many hours did you sleep each night during the last five weekday nights, Sunday through Thursday?
Enter a numeric value (0 if not applicable) ___ ___ . ___

# 2:
On the average, how many hours did you sleep each night last Friday and Saturday nights?
Enter a numeric value (0 if not applicable) ___ ___ . ___

# 3:
How many hours did you spend during the last five weekdays doing these moderate activities or others like them?
Enter a numeric value (0 if not applicable) ___ ___ . ___

# 4:
How many hours did you spend last Saturday and Sunday doing these moderate activities?
Enter a numeric value (0 if not applicable) ___ ___ . ___

# 5:
How many hours did you spend during the last five weekdays doing these hard activities, or others like them?
Enter a numeric value (0 if not applicable) ___ ___ . ___

# 6:
How many hours did you spend last Saturday and Sunday doing these hard activities?
Enter a numeric value (0 if not applicable) ___ ___ . ___

# 7:
How many hours did you spend the last five weekdays doing these very hard activities, or others like them?
Enter a numeric value (0 if not applicable) ___ ___ . ___

# 8:
How many hours did you spend last Saturday and Sunday doing these very hard activities?
Enter a numeric value (0 if not applicable) ___ ___ . ___
# 9:
Were you employed outside the home during the last seven days? If no, put zeros for questions 9-13. If yes, how many days?
Enter a numeric value (0 if not applicable) ___ ___ . ___

# 10:
How many hours per day?
Enter a numeric value (0 if not applicable) ___ ___ . ___

# 11:
How many of these hours per day were spent doing moderate activities?
Enter a numeric value (0 if not applicable) ___ ___ . ___

# 12:
How many of these hours per day were spent doing hard activities?
Enter a numeric value (0 if not applicable) ___ ___ . ___

# 13:
How many of these hours per day were spent doing very hard activities?
Enter a numeric value (0 if not applicable) ___ ___ . ___

# 14:
Compared to your physical activity over the past three months, was last week’s physical activity more, less, or about the same?

1–More 2–Less 3–About the same
### Moderate Activities (3–5 METs)
These activities involve modest increases in heart rate & breathing—e.g., many household & home repair tasks.

- Calisthenics without weights
- Carpentry
- Cleaning, heavy (such as vacuuming, sweeping)
- Croquet
- Cycling—leisure, 5.5 mph mild
- Electrical work
- Feeding farm animals, manual milking
- Fending
- Forestry—slow ax chopping, power sawing, stacking firewood, weeding
- Frisbee playing
- Gardening—hedging, raking, planting, mowing
- Golf—no power cart
- Gymnastics
- Horseback riding
- Locksmith
- Machine tooling—lath, punch press, tapping & drilling, welding
- Mopping floor
- Motor-cross
- Mowing lawn—push & power mower
- Music—playing drums
- Painting—outside
- Planting seedlings
- Plastering
- Sailing & board sailing
- Scraping Paint
- Stock clerking
- Surfing
- Sweeping
- Swimming—mild
- Grocery shopping
- Table tennis
- Laundry—heavy
- Childcare
- Window cleaning
- Walking on firm level surface, 3–4 mph – Average to fairly brisk
- Yoga
- Tai-chi
- Bowling
- Horse shoes
- Grocery shopping
- Heavy cooking

### Hard Activities (5.1–6.9 METs)
Most people will have noticeable increases in breathing and will likely perspire—e.g., vigorous household, home repair and gardening tasks, heavy industrial work and some construction and vigorous sports.

- Aerobic Dance
- Badminton
- Climbing hills with no load
- Coal shoveling
- Cycling—leisure, 9.4 mph (moderate)
- Farming—shoveling grain
- Fast Walking
- Folk Dancing
- Forestry—hoeing, planting by hand
- Karate or Judo
- Roller skating
- Scrubbing floors
- Skiing, water or downhill
- Tennis, doubles
- Walking on level Brisk or striding, firm surface @ 4.5 mph
- Weight lifting or training (count only lifting time)
- Swimming—moderate

### Very Hard Activities (>7.0 METs)
These include strenuous sports involving a lot of movement and running. Very few household or occupational tasks are included, except carrying heavy loads, digging or chopping with heavy tools, or other similar hard physical labor.

- Boxing—in ring, sparring
- Circuit training
- Climbing hills with 5–20 kg load
- Cycling, racing (intensive)
- Digging ditches
- Farming—barn cleaning
- Field hockey
- Football
- Forestry—fast ax chopping, barking trees, carrying logs, sawing by hand
- Gardening, digging
- Marching, rapid
- Racquetball
- Rope jumping
- Running, jogging—cross country, 6–10 min/mile
- Skiing, cross country
- Skindiving as frogman, moderate motion
- Soccer
- Squash
- Swimming, continuous—intensive
- Tennis, singles
APPENDIX K

NEW-LIFESTYLES NL-2000


APPENDIX L

HealthCheques Daily Food & Activity Log

<table>
<thead>
<tr>
<th>GRAINS</th>
<th>DAILY FOOD &amp; ACTIVITY LOG</th>
<th>DATE:</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>TIME</td>
<td>FOODS</td>
</tr>
<tr>
<td></td>
<td>6-11 SERVINGS</td>
<td></td>
</tr>
<tr>
<td>FRUIT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2-4 SERVINGS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VEGETABLE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3-5 SERVINGS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DAIRY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2-3 SERVINGS</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

PROTEIN

|        | 2-3 SERVINGS |      |        |          |     |

FAT

SPARINGLY

EATING PATTERN GOAL:

SWEETS

SPARINGLY

PHYSICAL ACTIVITY GOAL:

<table>
<thead>
<tr>
<th>TYPE OF ACTIVITY</th>
<th>TOTALS</th>
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</thead>
<tbody>
<tr>
<td>PHYSICAL ACTIVITY (Minutes)</td>
<td></td>
</tr>
<tr>
<td>Pedometer (Steps)</td>
<td></td>
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</tbody>
</table>

FLUIDS

| 8 OZ. |  |  |

COMMENTS:

APPENDIX M

Demographic and Physiologic Variables Tested as Covariates for Spline Model

<table>
<thead>
<tr>
<th>Covariate Variables</th>
<th>p value</th>
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<tbody>
<tr>
<td>Waist/hip Ratio</td>
<td>p &lt; .001</td>
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<tr>
<td>Systolic Blood Pressure</td>
<td>p &lt; .001</td>
</tr>
<tr>
<td>Diastolic Blood Pressure</td>
<td>p &lt; .001</td>
</tr>
<tr>
<td>Cortisol</td>
<td>p &lt; .001</td>
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<tr>
<td>Glucose</td>
<td>p &lt; .001</td>
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<tr>
<td>C-Reactive Protein</td>
<td>p &lt; .001</td>
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<tr>
<td>Age</td>
<td>p &lt; .001</td>
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<tr>
<td>Salary Level</td>
<td>p &lt; .001</td>
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<tr>
<td>Education Level</td>
<td>p &lt; .001</td>
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<tr>
<td>Attendance</td>
<td>p &lt; .001</td>
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<tr>
<td>Marital Status</td>
<td>p = .31</td>
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