

IMPACT OF A WALKING INTERVENTION ON PERIMENOPAUSAL SYMPTOMS

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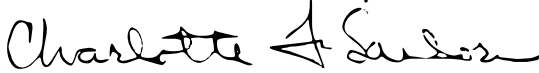
To the Associate Vice President for Research and Dean of the Graduate School:

I am submitting herewith a dissertation written by Terrilyn Pensabene entitled "Impact of a Walking Intervention on Perimenopausal Symptoms." I have examined this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy, with a major in Nursing.

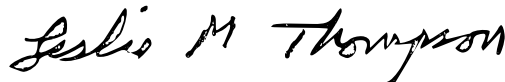


Patricia Hamilton, Major Professor

We have read this dissertation
and recommend its acceptance:



Accepted



Associate Vice President for Research
and Dean of the Graduate School

DEDICATION

This dissertation effort is dedicated to my son Cody Thomas Pensabene, for his patience, kindness, and his belief in my ability to succeed. He has taught me much about life and about trying my best at what I do.

ACKNOWLEDGMENTS

My son Cody, and my mother, Doris, have encouraged me and have made many sacrifices during the completion of this dissertation. Dr. Peggy Drapo, my original committee chair, encouraged me and offered much wisdom. Dr. Patti Hamilton, my current committee chair, believed in my ability, and provided direction and valuable information. Dr. Maisie Kashka demonstrated enthusiasm and encouragement throughout the process. Dr. Charlotte Sanborn provided much needed technical support and encouragement. These four women worked well together toward our common goal. The work of my research subjects is also greatly appreciated.

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THE IMPACT OF A WALKING INTERVENTION ON
PERIMENOPAUSAL SYMPTOMS

BY

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AUGUST 1997

The purpose of this study was to investigate physical activity as an alternative or adjunct intervention to hormone replacement therapy for sedentary, midlife women experiencing symptoms of perimenopause. The sample consisted of four subjects between the ages of 45 and 54 from Ft. Worth and Weatherford, Texas. A researcher-developed symptom checklist, a daily log and a demographic data questionnaire were developed for the study. A field test of a mile and one-half walk run was also utilized to estimate VO_2max pre- and post-intervention.

Time series analysis was used to model the patterns of perimenopausal symptoms. An eight week individualized walking intervention was examined for its effectiveness in decreasing perimenopausal symptoms and increasing cardiovascular endurance. It was hypothesized that as cardiovascular function improved, perimenopausal symptoms would decrease. Findings indicated that the intervention had a significant impact on the pattern of daily perimenopausal symptoms for participants two and four. All participants showed cardiorespiratory improvement, as indicated by the increase in Vo_2max for each participant. The walking intervention had a significant impact on the pattern of daily stress scores for participant four.

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CHAPTER I

INTRODUCTION

The impact of physical activity on sedentary, perimenopausal women is the phenomenon of interest in this study. As women's health issues have become a focus of holistic health care, particular attention is being given to how nursing can influence the health care practices of women. Investigation of suggested perimenopausal symptom relief mechanisms is one way that nursing researchers can improve women's health care practices. One nursing role is the acquisition of the most current knowledge on treatment options for their patients.

Women experience menopause and, subsequently, perimenopause as a result of decreased estrogen production associated with biological aging, or in some cases, surgical intervention. Menopause is often defined as the final menstrual period, and is experienced by most women between 50 and 59 years of age, with 52 years of age being the average age (Moore & Noonan; 1996 Shangold, 1996). Since the diagnosis is made after the woman has ceased menstruation, the diagnosis is made retrospectively (Topo & Hemminki, 1995). The period of time surrounding the cessation of menstruation, or menopause, is referred to as the climacteric or perimenopause. The discomforts of perimenopause affect the individual physically and psychologically (LeBoeuf & Carter, 1996). The array of symptoms women experience in conjunction with perimenopause include changes in thermoregulation (such as hot flushes, hot flashes or night sweats),

mucosal changes in the vagina, urinary system, and skin (decreased elasticity); changes in sexuality (decreased, or uncontrollably increased libido); affective symptoms (irritability and depression); and loss of short-term memory (Lichtman, 1996).

Hormone replacement therapy (HRT) is often used to mitigate the vasomotor symptoms and urogenital problems associated with perimenopause. HRT is also believed to provide protection against osteoporosis and cardiovascular disease often associated with the postmenopausal years (Samsioe, 1996). Compliance is often a problem with HRT due to continued menstrual bleeding and the fear of uterine or breast cancer (Samsioe, 1996).

Physical activity, recognized for its positive effect on physical health, has also been proposed to lessen the severity of perimenopausal symptoms (American College of Sports Medicine, 1991; Wallace, Lovell, Talano, Webb, & Hodgson, 1982; Wilbur, Holm, & Dan, 1992). Exercise serves to improve the adaptability and plasticity of biological cells (Astrand, 1992). Astrand posited that physical activity was necessary in order to promote optimal biologic function. Physical benefits of proper exercise include greater lean body mass and less body fat; improved cardiovascular fitness; improved flexibility and improved strength and muscular endurance (Baranowski, Bouchard, Bar-Or, Bricker, Heath, Kimm, Malina, Obarzanek, Pate, Strong, Truman, & Washington (1992); Corbin & Lindsey, 1990). Psychological benefits of exercise, independent of estrogen plasma levels, include relief of

depression, improved sleep habits, improved quality of life and improved sense of well-being (Corbin & Lindsey, 1990).

Problem of the Study

The problem of this research was to determine the effects of a walking intervention on perimenopausal symptoms among sedentary, midlife women in the absence of hormone replacement therapy (HRT), or as an adjunct intervention to hormone replacement therapy. Perimenopausal symptoms were monitored to discover pattern over time and to determine if the pattern of symptoms changed after a program of physical activity was initiated. Four subjects were recruited for the study, three subjects were residents of Ft. Worth, and the fourth subject resided in Weatherford, Texas. Participants in the study were all between the ages of 45 and 60; and reported being sedentary for the proceeding six months. All subjects recorded their perimenopausal symptoms daily on a checklist in addition to completing a log which documented any significant changes in dietary, health or lifestyle practices. During the initial eight weeks of the study the logs and checklists were completed to gain baseline information while the women continued their sedentary lifestyles. During the second eight weeks, in addition to completion of the daily checklist and log, the women took part in a moderate and progressive walking program. Participants were provided an individualized walking program by the nurse researcher. The program consisted of a stretching routine before and after walking and walking a minimum of three times per week. Initially the participants walked twenty minutes, but the duration and intensity were increased over time in order to

facilitate cardiovascular improvement. By week three of the intervention, the participants were walking a minimum of 45 minutes, three times per week. They were also instructed not to walk longer than one hour at each session. Two, mile and one-half walk-run field tests, conducted during week eight and week sixteen, were used as pre- and post-intervention evaluation. The test at sixteen weeks was used to estimate changes in VO_2max as a result of the eight-week walking program. VO_2max , also referred to as maximal oxygen uptake, is a measurement of how much oxygen an individual can utilize during a minute of maximal exercise, or the point in time when additional increase in work does not result in additional increase in oxygen consumption (Corbin & Lindsey, 1990; Wingate, 1991). Higher levels of VO_2max are associated with higher levels of fitness.

Purpose of the Study

The purpose of this study was to examine the impact of a walking intervention on the pattern of perimenopausal symptoms in the absence of hormone replacement therapy (HRT), or as an adjunct intervention to hormone replacement therapy for sedentary, midlife women.

Rationale for the Study

As life expectancies for women continue to increase a greater percentage of a woman's life is spent in the peri- and post-menopausal years (Philosophe & Seibel, 1991). It was predicted by the World Health Organization that by the year 2000 the average life expectancy for women would be 75 to 80 years in developed countries (Kruskemper, 1975). Possible therapeutic interventions warrant investigation as women search for symptom relief.

Logothetis reported the importance of research pertaining to the menopause experience (1991). Logothetis reported that in 1991, 50% of the female population was 50 years of age or older. Due to the increased predicted lifespan of women, approximately one-third of a woman's life is post-menopausal.

This study contributes to improved nursing care in its ability to provide guidance related to relief of perimenopausal symptoms. Physical activity is a health care practice women themselves can initiate and monitor. It does not require expensive equipment, and it can be individualized to match a person's likes, limitations, and resources. The nurse's role in this study was to develop and monitor the supervised walking program. In clinical practice, the nurse's role is to provide accurate information about perimenopausal symptom relief to individuals, and in some situations, develop and implement exercise routines.

Theoretical Framework

Symptoms of perimenopause develop in response to the decrease of estrogen production by the ovaries. The perception of perimenopausal symptoms depends on “the age of the woman, the rapidity with which her estradiol levels decrease, her body adiposity, and her interpretation of the symptoms,” (Scharbo-DeHann & Brucker, 1991, p. 11). Although the experience is unique, the types of symptoms are predictable: hot flashes/flushes, vaginal and urinary tract changes, and mood changes (Health and Human Services Department, 1992).

Theoretically, the participants were expected to experience, as a result of exercise, both increased cardiovascular endurance (as indicated by improved $VO_2\text{max}$), and a decrease in perimenopausal symptoms (as indicated by a change in the pattern of symptoms ascertained over time by the daily symptom checklist). The ability of physical activity to provide social camaraderie, influence the release of endorphins, or increase plasma levels of estradiol, progesterone, and follicle stimulating hormone were not directly measured. It was believed that the participants would experience decreased perimenopausal symptoms because of the ability of physical activity to improve cardiovascular functioning, particularly adaptability of the vascular system; to improve mood, by decreasing depression and anxiety; to increase plasma levels of estradiol, progesterone, and follicle stimulating hormone; to serve as a diversion; to increase relaxation, sense of self-efficacy and well being; and through the increased release of catecholamines and endorphins

(Astrand, 1991; Doyne, Ossip-Klein, Bowman, Osborn, McDougall-Wison, & Neimeyer, 1987; Wallace, Lovell, Talano, Webb, & Hodgson, 1982; Wingate, 1991). Refer to Table 1 for the mechanisms by which exercise is believed to decrease perimenopausal symptoms by body system.

Table 1

System Symptoms and Corresponding Mitigating Mechanisms

Perimenopausal Symptoms by System	Mechanism of Action of the Exercise Intervention
Cardiovascular Dizziness Fatigue Rapid Heart Beat	Increasing adaptability of vascular system aerobic capacity peripheral blood flow plasticity of blood vessels Decreasing serum cholesterol and triglycerides
Cognitive Difficulty Concentrating Forgetfulness	Increasing plasma levels of: estradiol, progesterone, and follicle stimulating hormone Decreasing metabolic clearance rate of estradiol.
Gastrointestinal Diarrhea	Not hypothesized.
Genitourinary Heavy Menstruation	Increasing plasma levels of: estradiol, progesterone, and follicle stimulating hormone Decreasing metabolic clearance rate of estradiol

Table 1 (Continues)

Symptoms by System	Mechanism of Action
Musculoskeletal	
Aches and Pains in Joints	Increasing
Backaches	flexibility
	abdominal strength
Neurological	
Headaches	Increasing
Pins and Needles in	adaptability of the nervous system
Hands and Feet	plasticity of blood vessels
	vasodilatory capacity
Psychological	
Depression	Increasing
Fatigue	diversional activity
Feelings of "Losing	endogenous opiates
My Mind"	endorphins
Irritability	plasma catecholamines
Nervous Tension	relaxation
Trouble Sleeping	self-efficacy
	sense of well-being
	social camaraderie
	Decreasing
	stress
Vasomotor	
Hot Flashes/Flushes	Increasing
Night Sweats	ability to thermoregulate
	cellular adaptability
	peripheral blood flow
	plasticity of blood vessels
	vasodilatory capacity

For Hargarten (1994) the specific mechanism by which physical activity was thought to mitigate perimenopausal symptoms was by its effect on cardiovascular function, such as hemodynamic changes; its impact on the sympathetic nervous system; baroreceptor function changes; and release of endorphins. Physical exercise promotes optimal functioning of the cardiovascular-respiratory, gastrointestinal, hematologic, hormonal-immunologic, musculoskeletal, and neurosensory systems (Astrand & Rodahl, 1986). According to Wingate (1991) the body responds to exercise with improved local blood flow, increased oxygen uptake, sympathetic stimulation, and maintenance of body temperature. Figures 1, and 2 depict the etiology of perimenopausal symptoms, and the proposed physiologic mechanisms of exercise on perimenopausal symptoms.

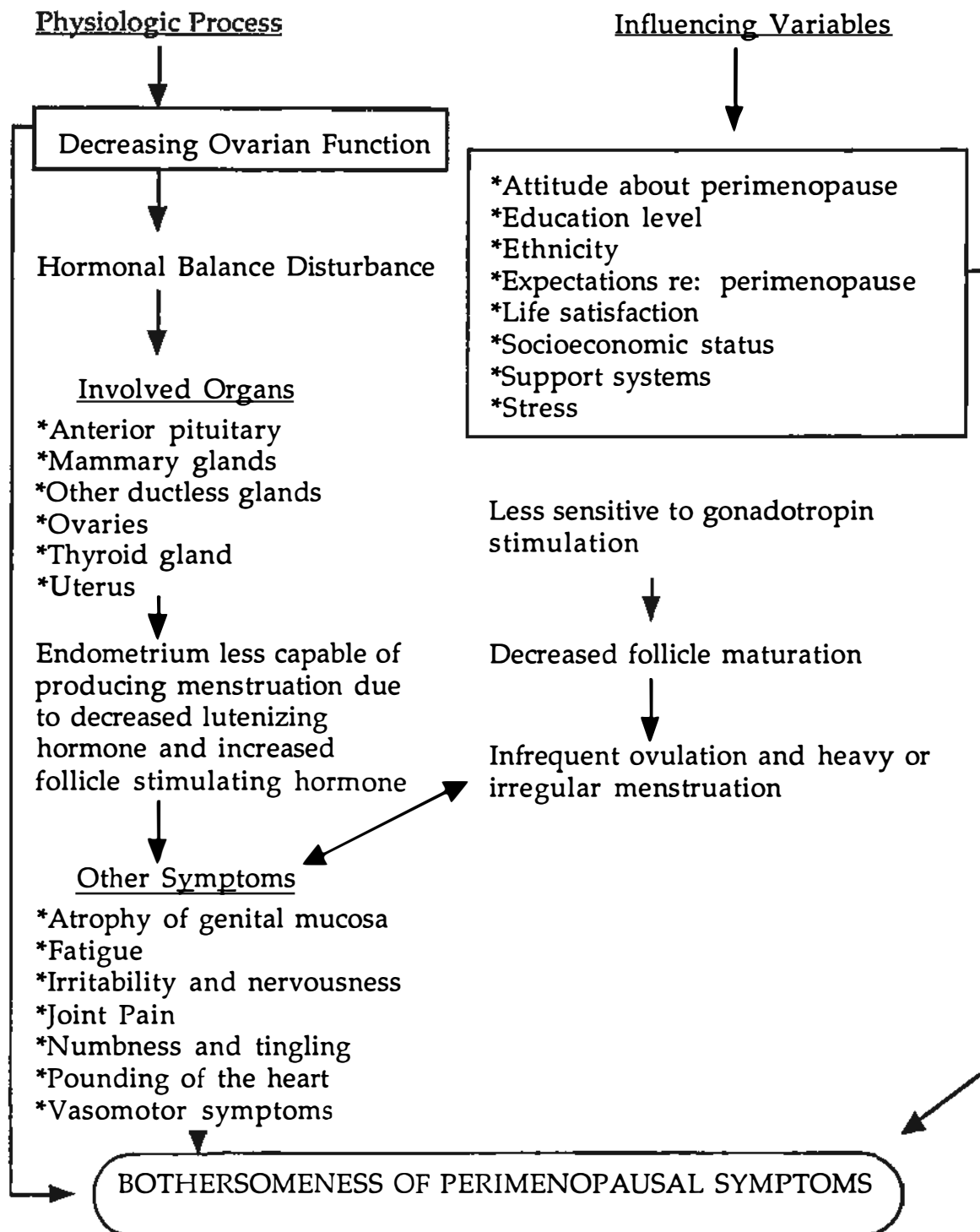
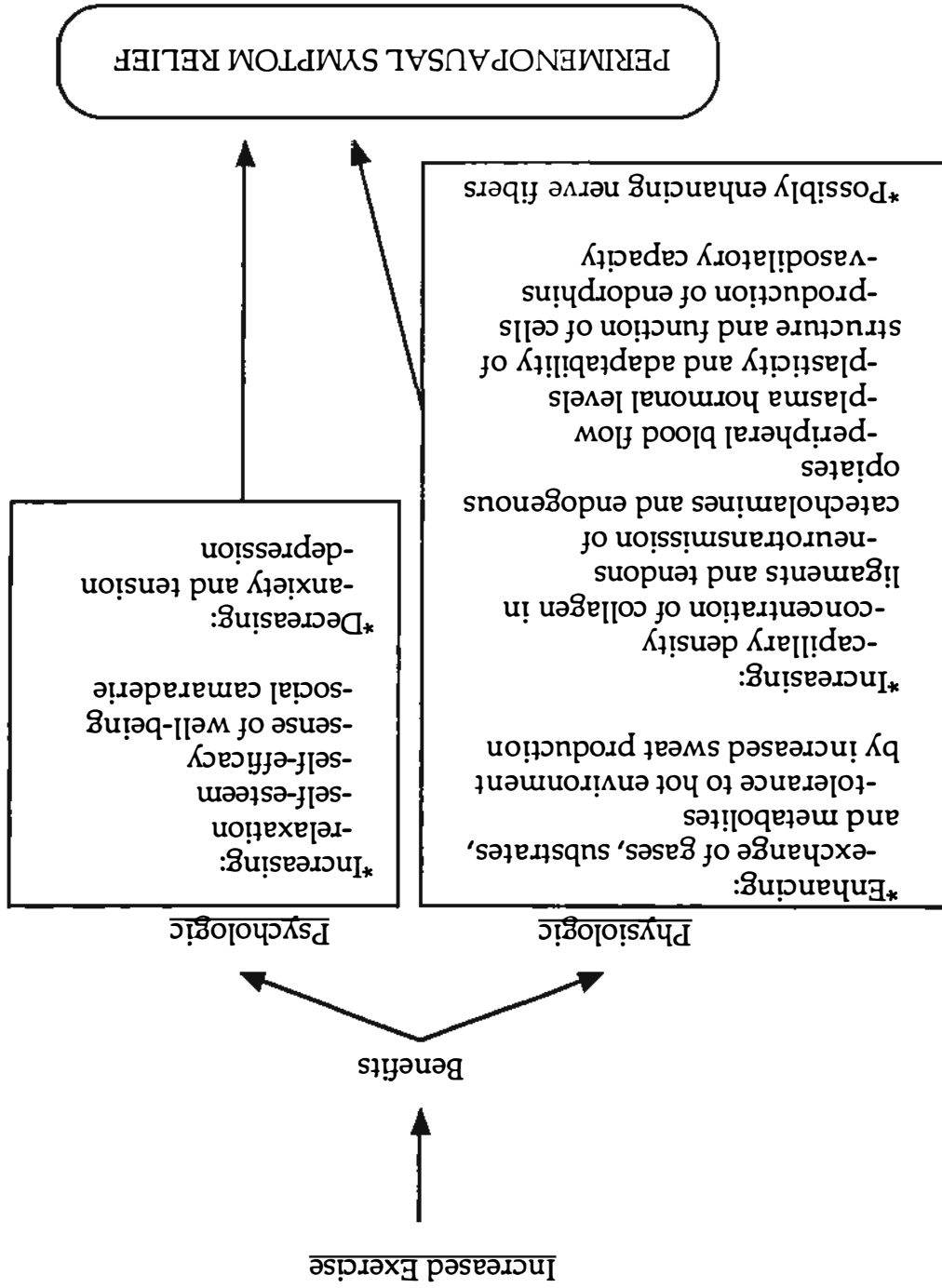


Figure 1. Etiology of Perimenopausal Symptoms

Figure 2. Effect of Physical Activity on Bothersomeness of Perimenopausal Symptoms



Based on the theoretical framework for this study sedentary, symptomatic, mid-life women should benefit from a moderate and progressive, eight-week walking program because of cardiovascular and other physiologic and psychologic benefits that occur as a result of the physical activity intervention. Bothersomeness of perimenopausal symptoms was thought to be the result of both physiologic and psychologic variables; consequently, the exercise intervention was hypothesized to be effective for physiologic and psychologic reasons.

Assumptions

1. Participants acted as their own controls therefore the findings cannot be generalized beyond the sample.
2. Participants gave valid and reliable information about their symptom reporting.
3. The 1.5 mile walk-run field test was a valid and reliable instrument for measuring cardiovascular endurance for sedentary women between the ages of 45 and 60.
4. A moderate and progressive eight-week walking program was sufficient in length and intensity to improve cardiorespiratory endurance.
5. A moderate and progressive eight-week walking program was sufficient in length and intensity to provide relief from perimenopausal symptoms among sedentary, midlife women.
6. The symptom checklist was representative of perimenopausal symptoms amenable to influence by physical activity.

Hypotheses

The following hypotheses were derived from the theoretical model.

1. Sedentary perimenopausal women who participate in an eight week moderate and progressive walking program will exhibit improved cardiorespiratory endurance.
2. Sedentary perimenopausal women who participate in an eight week moderate and progressive walking program will exhibit a decrease of perimenopausal symptoms.

Definition of Terms

For the intention of clarification, the following definitions or explanations were established for use throughout the study.

Cardiorespiratory Endurance

Conceptual Definition. Cardiorespiratory endurance is “the ability to participate in physical exercise for long periods of time without undue fatigue,” (Corbin & Lindsey, 1990, p. 52). Both the circulatory and respiratory systems are involved.

Operational Definition. Cardiorespiratory endurance was estimated utilizing the calculated VO_2max . The time on the mile and one-half, walk-run field test was utilized to calculate VO_2max . Refer to page 17 for the definition and calculation for VO_2max .

Perimenopausal Symptoms

Conceptual Definition. For the purpose of this study, identified perimenopausal symptoms were aches and pains in the joints, backaches,

depression, diarrhea, difficulty concentrating, dizziness, fatigue, feelings of “losing my mind,” forgetfulness, headaches, heavy menstruation, hot flashes (flushes) or sweats, irritability, nervous tension, night sweats, pins and needles in hands and feet, rapid heart beat, shortness of breath, and trouble sleeping.

Operational Definition. Perimenopausal symptoms were recorded daily on a researcher-developed symptom checklist. This instrument was used to assess bothersomeness of the identified perimenopausal symptoms.

Additional causes of the symptoms, other than the decreased estradiol associated with perimenopause, were identified by the participants on the daily log. For example, if a backache was experienced as a result of fatigue and strain, as opposed to being a perimenopausal symptom, this was documented on the participant’s daily log.

Perimenopausal Women

Conceptual Definition. The target population was women between the ages of 45 and 60 who self-reported experiencing perimenopausal symptoms.

Operational Definition. Perimenopausality was determined by the subject’s response to select questions on the demographic questionnaire pertaining to age and history of menstruation.

Physical Activity

Conceptual Definition. Physical activity was defined as the amount of activity that a person engaged in, on a regular basis, requiring physical participation. Prior to the moderate, progressive walking intervention, participants’ self-reported level of physical activity was sedentary.

Operational Definition. It was operationalized as a supervised walking program lasting for eight weeks; beginning with five-seven minutes of warm-up; followed by 20 minutes of walking; and completed with a five-seven minute cool-down period, three times per week. By week three, the participants walked a minimum of 45 minutes. Rating of Perceived Exertion and target heart rates were used to guide intensity and length of exercise.

Sedentary

Conceptual Definition. Sedentary was defined as lack of regular physical activity, or less than 20 minutes of exercise, three times per week, for the six months preceding study participation. The sedentary individual did not participate in exercise or physical activity to the extent that it improved their health or level of fitness. The sedentary individual may have participated in activities such as gardening, golf, or housework.

Operational Definition. Sedentariness was determined by the response to select questions on the Demographic Questionnaire pertaining to physical activity over the proceeding six month period.

Additional Definitions

Although not incorporated in the study's hypotheses, the following definitions or explanations were also established for use throughout the study.

Perceived Exertion

Conceptual Definition. Perceived exertion was a method used "to quantify subjective exercise intensity," (American College of Sports Medicine,

1991, p. 69). How hard persons perceive they were working, including “total amount of exertion and fatigue, combining all sensations and feelings of physical stress, effort, and fatigue,” (American College of Sports Medicine, 1991, p. 70).

Operational Definition. Borg’s Rating of Perceived Exertion, (American College of Sports Medicine, 1991, p. 69) was utilized to monitor how hard the individual perceived she was exercising. This rating was marked on the daily log, and was documented as shown in Table 2. Participants were instructed to exercise at a perceived rating of exertion of 13 at each session, following proper warm-up.

Table 2

Borg’s Rating of Perceived Exertion

Numerical Rating	Level of Perceived Exertion
6	
7	Very, Very Light
8	
9	Very Light
10	
11	Fairly Light
12	
13	Somewhat Hard
14	
15	Hard
16	
17	Very Hard
18	
19	Very, Very Hard
20	

Target Heart Rate

Conceptual Definition. The target heart rate was the range of heart rate an individual was expected to experience during exercise, for example, 160 to 200 beats per minute. Target heart rate was an acceptable method utilized to regulate intensity of exercise. (American College of Sports Medicine, 1991). It was important to exercise with a heart rate above the minimum and below the maximum target heart rate in order to obtain the maximum benefits of physical activity (Corbin & Lindsey, 1990). One acceptable method to determine an individual's target heart rate was to "take a percent of the difference between the maximal and the resting heart rates," (American College of Sports Medicine, 1991, p. 99). Target heart rate was used in conjunction with Rating of Perceived Exertion in order to determine that the participant was walking at a level of intensity sufficient enough to improve cardiorespiratory endurance.

Operational Definition. Target heart rate range was calculated for each participant. In order to identify the target heart rate, the resting and maximal heart rates were determined. The resting heart rate was measured by each participant in the following manner. The pulse was counted for one minute, early in the morning, before rising out of bed. The maximal heart rate was estimated by subtracting the participant's age from 220. The working heart rate range was determined by subtracting the resting heart rate from the maximal heart rate. The threshold of training was determined by calculating 60 percent and 80 percent of the working heart rate (the lower and higher limits respectively, of the target heart rate). For example, a 45 year old woman

with a resting heart rate of 68 would be as follows.

$220 - 45 = 175$ beats per minute	Maximal Heart Rate
$175 - 68 = 169$	Working Heart Rate
$169 * 60\% = 101.4 + 68 = 169$	Threshold of Training Heart Rate
$169 * 80\% = 135.2 + 68 = 203$	Upper Limit of Target Heart Rate

The target zone for this 45 year old was 169 to 203 beats per minute.

VO₂max

Conceptual Definition. VO₂max, also referred to as maximal oxygen uptake, was defined as “how much oxygen an individual can use over one minute of maximal exercise,” (Corbin & Lindsey, 1990, p, 58). VO₂max, or maximal O₂ uptake was defined as the point at which additional increase in workload does not result in additional increase in oxygen consumption (Wingate, 1991). Higher levels of VO₂max are associated with better cardiorespiratory endurance and physical fitness.

Operational Definition. VO₂max was estimated using the formula provided by Brooks, Fahey, & White (1996). VO₂max is measured in ml·kg⁻¹·min⁻¹.

$$\text{VO}_2\text{max} = 482.94 \text{ ml}\cdot\text{kg}^{-1} / \text{time in minutes} + 3.5 \text{ ml}\cdot\text{kg}^{-1}\cdot\text{min}^{-1}$$

The number 482.94 was derived as a result of research calculating VO₂max among joggers and walkers. The number 3.5 represents the resting component, or the amount of oxygen utilized at rest--3.5 ml·kg⁻¹·min⁻¹.

For example, a woman with a time of 30 minutes on the mile and one-half walk-run is calculated

$$482.94 \text{ ml}\cdot\text{kg}^{-1}/30 \text{ minutes} + 3.5 \text{ ml}\cdot\text{kg}^{-1}\cdot\text{min}^{-1}$$

$$= 16.1 + 3.5 = 19.6 \text{ ml}\cdot\text{kg}^{-1}\cdot\text{min}^{-1}$$

Limitations

The limitations of this study were as follows

1. The sample was a non random sample and is not representative of the population.
2. Responses were valid only to the extent that subjects reported accurately.
3. The variables studied were cardiorespiratory endurance, physical activity, perimenopausal symptoms. Social support and other potential risk factors for perimenopausal symptoms were not considered.

Delimitations

This study was limited to the selected women in Ft. Worth and Weatherford, Texas; women between the ages of 45 and 60 who reported being perimenopausal and sedentary, were able to read and write English, and reported the ability to be physically active.

Summary

This chapter describes the theoretical framework from which the study evolved, the problem statement and purpose of the study. It was proposed that sedentary, midlife women would benefit by an eight-week progressive, walking program as indicated by decreased daily perimenopausal symptoms and improved VO₂max.

As a consequence of the aging process, or due to surgical intervention, ovarian function decreases and results in reduced amounts of estrogen in the body. Declining levels of estrogen are associated with a number of physical and psychological symptoms such as hot flashes and short term memory loss.

Perimenopause refers to the years proceeding and extending beyond the menopause, or last menstrual period. During perimenopause, a woman may experience symptoms related to estrogen deficiency. Although each woman experiences perimenopause as a unique phenomena, the majority of American women experience some symptomatology.

CHAPTER II

REVIEW OF THE LITERATURE

Literature representative of theory and research pertaining to physical activity and perimenopausal symptoms was explored. Definitions of the variables, topics related directly to the variables, and literature supporting the relationships between variables were examined. Selected studies and theoretical discussions were reviewed in this chapter.

Perimenopause

Definitions

Menopause has occurred when the menses have ceased for 12 months. The word "menopause" was derived from two Greek words meaning "month" and "to stop," (Scharbo-DeHaan & Brucker, 1991). For many writers menopause was defined as a single event (Budoff, 1983; Neugarten & Kraines, 1965, World Health Organization, 1981). The term menopause became a part of English literature around the last quarter of the nineteenth century (Pederson & Pendleton, 1978; Voda & George, 1980). Pratt and Thomas used the term menopause to delineate the time in a woman's life from the reproductive period until senility, including the physiological cessation of menstruation (1937). For Kaufert and Syrotuik, menopause pertained to the final menses; the climacteric referred to the period in life marked by decreased ovarian function; and perimenopause was not defined (1981). Menopause was defined by many writers as the cessation of menstrual periods for one year (Notman, 1979; Sloane, 1985; Woods, 1982).

Perimenopause refers to the larger time period surrounding menopause, including both the time before and after the last menstrual period. The perimenopausal period begins at the time that a woman begins to experience the symptoms associated with menopause. the “climacteric” and “post-menopausal period” are two additional terms used in reference to perimenopause, (Scharbo-DeHaan & Brucker, 1991). The former term comes from the Greek word for “rung of the ladder,” and the latter term refers to the time period immediately following menopause. Sloane (1985) used the term climacteric to describe the time of decreasing ovarian function, terminating with menopause. McCraw provided related definitions for the terms menopause, climacteric, and perimenopause (1991) . Menopause was defined as the permanent cessation of menses; the climacteric referred to the transition period from being reproductive to losing reproductive function; perimenopause “is defined arbitrarily as the period including the last few years of the climacteric and the first year after menopause,” (McCraw, 1991, p. 17).

As early as the turn of the twentieth century, Conger and Crane documented that most women experience their last menstrual period from ages 45 to 50 (1900). Sloane wrote that one-half of women experience menopause between the ages of 45 and 50 (1985).

Etiology of Symptoms

Neugarten and Kraines provided an endocrine factor theory and an emotional factor theory guiding the etiology of menopausal symptoms (1965). According to the endocrine factor theory, symptoms appeared in response to a

disturbance in hormonal balance. The emotional factor theory took into account the woman's personality prior to menopause when evaluating menopausal symptomatology. Sawyer (1936), drawing from the work of Milliken in 1901 and Timme in 1929, identified the anterior pituitary, the ovaries with the corpus luteum and graafian follicles, the uterus, the mammary glands, the thyroid, and other ductless glands as the organs and glands involved in the menopausal experience.

Woods concluded that multiple bio-physical, socio-cultural, and intrapersonal correlates associated with perimenopausal distress (1982). Woods found hormonal fluctuations, atmospheric temperature, menopausal status, endogenous estrogen production, menstrual history, parity, and age included in bio-physical correlates. Expectations about menopause, life satisfaction, attitudes toward femininity, and attitudes toward childbearing and fertility were intrapersonal correlates influencing perimenopausal distress. The socio-cultural variables included ethnicity, marital status, social class, income, education, culture, life changes, and support systems. Woods found marital status and social class to be unrelated, negatively or positively related to severity of perimenopausal symptoms. Income was found to be negatively related with symptoms; education, beyond high school, was negatively associated with symptoms; life changes and role discontinuity had a positive correlation with symptoms for white women, but not for black women; and social support had a negative correlation with symptoms. Black women tended to have fewer symptoms than white women, Jewish women were more likely to experience depression, and middle class women were

more likely to experience depression than those in the lower socioeconomic group. For the Lepcha, the perimenopausal experience was barely recognized; in Tepoztlan, Mexico, the perimenopause was viewed as a positive event because it was associated with freedom from child bearing; and the rural Irish were found to believe that perimenopause induced insanity, with many women retiring in their mid-forties. In summary, Woods found "multiple determinants of perimenopausal distress, and these problems probably interact with one another," (1982, p. 235).

Kase related that ovaries become less sensitive to gonadotropin stimulation, thereby decreasing follicle maturation. A decrease in cycle intervals corresponds with the limited follicle maturation associated with infrequent ovulation and decreased menstrual flow (1983). A progressive increase in follicle stimulating hormone (FSH) is shown in the time just prior to menopause, with a corresponding decrease in estrogen. The uterine lining, or endometrium, is no longer capable of producing menstruation due to the higher levels of FSH and decreasing levels of lutenizing hormone.

Sloane attributed perimenopause to the decrease of ovarian follicles which lead to insufficient amounts of ovarian hormone secretion to inhibit the pituitary gonadotrophins, leading to an increase in follicle stimulating hormone and leutinizing hormone. The hypothalamic-pituitary-ovarian feedback system is altered and the menstrual cycle ceases after the ovarian hormones decreased to a certain point. Sloane added that the symptoms of perimenopause may be "psychologically or sociologically induced rather than physiological in origin," (1985, p. 91).

Scharbo-DeHann and Brucker provided a discussion of the changes in hormonal level in regard to peri- or post-menopausal changes (1991). Estrone, estradiol, and estriol are the three major estrogens that a woman produces. Estriol is only present during pregnancy. The remaining estrogens perform in the following manner. Estradiol, the most potent estrogen, is primarily produced in the ovulatory follicle. Atresia, the process of ovarian aging, leads to diminished amounts of estradiol in the body. Ovulation becomes irregular, or decreases, as a result of decreased estrogen production. Estrone, the primary estrogen of menopause, is produced either from metabolism of estradiol and also from aromatization of androstenedione in adipose tissue. The production site in fat cells is important, particularly as the amount of estradiol decreases. FSH levels increase throughout perimenopause. Hormonal concentrations before and after menopause as reported by Scharbo-DeHann and Brucker are provided in Table 3.

Table 3

Plasma Hormonal Concentrations Before and After Menopause

Hormone	Pre-menopausal		Post-menopausal
	Minimum	Maximum	
Estradiol (pg/mL)	50-60	300-500	5-25
Estron (pg/mL)	30-40	150-300	20-60
FSH (mIU/mL)	1.2	10	26-100

The symptoms of the perimenopausal period develop in response to the decrease of estrogen production by the ovaries (Scharbo-DeHann & Brucker, 1991). The experience of menopause is an individual experience. A woman's perceptions of perimenopausal symptoms depends on "the age of the woman, the rapidity with which her estradiol levels decrease, her body adiposity, and her interpretation of the symptoms," (Scharbo-DeHann & Brucker, 1991, p. 11). Individuals with less body adiposity experience increased symptoms of perimenopause.

Women are born with approximately 500,000 egg cells (Health and Human Services Department, 1992). These eggs are held in the follicles in the ovaries. One egg is released each month during the reproductive years. The uterine lining is influenced by estrogen and progesterone which thicken the

lining each month in preparation of receiving a fertilized egg. As a woman approaches perimenopause, the ovaries decline in hormone production leading to irregular menstrual cycles and heavy bleeding. A small amount of estrogen continues to be produced, and some estrogen production in the fat cells is facilitated by the adrenal glands. Ovarian hormone levels are erratic during perimenopause, this fluctuation has an effect on several body systems: bones, vagina, blood vessels, gastrointestinal tract, and skin.

Some investigators believed that there was a socio-cultural influence pertaining to women experiencing menopausal symptoms (Beyene, 1986; Hyde, 1985). How the perimenopause is experienced by the individual woman is influenced by several factors (Martin, Block, Sanchez, Arnaud and Beyene, 1993). Age at menopause, cultural beliefs and values and life experiences can all influence the experience.

According to Avis, Kaufert, Lock, McKinlay, and Vass, the menopausal experience is greatly influenced by cultural and socioeconomic factors (1993). In their study, they investigated the menopausal experience for women in Massachusetts, Manitoba, Canada, and in Japan as documented in three surveys conducted at different times. Avis, Kaufert, Lock, McKinlay and Vass found that symptom reporting was not consistent across populations (1993). In their study of 1,225 Japanese women, 1,307 Canadian women, and 7,802 women from the USA, symptom reporting was generally low among Japanese women when compared to Canadian and US women.

The hypothesis of a universal menopausal experience was rejected based on a statistically significant chi-square statistic indicating significant differences across countries, (Avis et al, 1993, p. 22). The most common reported symptoms for the Japanese women were diarrhea, and, or constipation, backaches, and headaches. Constipation was attributed to the high consumption of rice in this country. The report of symptoms for the Canadian women was similar for that of the American women. The most frequently reported symptom for these two groups was hot flashes or flushes, although the Japanese women also reported this symptom. The top three symptoms for the Canadian women were lack of energy, hot flashes or flushes, and headaches; whereas for the American women the top three symptoms were aches or stiffness in joints, lack of energy and hot flashes or flushes. Also rejected was the idea that all women experience the symptomatology of menopause, as discussed earlier. A strong cultural bias was believed to influence the perimenopausal experience. They believed that the symptoms of menopause provided by researchers are a collection of stereotypical responses rather than being representative of the actual experience.

Perimenopausal Symptoms

“Nervous disturbances such as irritability of temper, despondency, forgetfulness, sleepiness, anxiety, mental unrest, and perversion of taste” were general symptoms identified by Culbertson (1916, p. 667). Other symptoms which he attributed to vasomotor disturbances included “fainting, vertigo, numbness, sweating, congestions, headache, dizziness, cardiac

palpitations, cold hands and feet, and a tendency of the arms and legs to go to sleep readily" (p. 667). Sawyer presented the menopause syndrome as a concurrent group of symptoms appearing at or about the time of the cessation of the menstrual periods (1936).

Blatt, Wiesbader, and Kuuperman, identified hot flushes, cold sweats and rheumatic pains, numbness and tingling, sensations of skin crawling, tired feelings, pounding of the heart, dizzy spells, irritability, and nervousness, feeling blue and depressed, trouble sleeping and headaches as the symptoms of perimenopause (1953). These identified symptoms were included in the Blatt Menopausal Index, a weighted numerical symptom checklist. Polit and LaRocco added forgetfulness as a symptom (1980). Atrophy of genital tissue, shrinking of breasts, or vaginal dryness leading to painful intercourse were included by Friedrich (1982); Sloane (1985); Voda, & Eliasson (1983); Weiss (1984); and Witkin-Lanoil (1984).

Sloan added nausea, backache, bloating, decreased or uncontrollably increased libido, poor memory and breast problems to the already identified symptoms (1985). Sloane found a wide range of symptoms during perimenopause, ranging from only the cessation of the menses to incapacitating physical complaints and psychological disturbances (1985).

Nearly every organ in the female body was affected by the decrease in estrogen production (Witkin-Lanoil, 1984). The severity of symptoms was related to the degree of depletion of estrogen production. Hot flashes, dyspareunia, and diminished vaginal lubrication were symptoms associated with menopause. Hyde listed hot flashes, cold hands and feet, osteoporosis,

sweating, and vaginal discharges as symptoms experienced during perimenopause which would respond favorably to estrogen replacement therapy (1985).

Bohler and Greenblatt believed hot flushes and sweats were the result of a disturbance of the main autonomic nervous system ganglia which is centered in the hypothalamus (1974). Hot flashes occur in 43-93% of women experiencing perimenopause (Woods, 1983). Judd believed hot flushes were caused by an imbalance of the autonomic nervous system (1986). The hot flush was preceded by an aura, which coincided with a surge of LH and was accompanied by increased measurable heat over the entire body surface, with a fall in core body temperature (Kase, 1983).

Scharbo-DeHann and Brucker report the most commonly reported perimenopausal symptoms as vasomotor instability, genitourinary alteration, alterations of the skin, hair, and bones, and psychogenic complaints (1991). Scharbo-DeHann and Brucker explained that hot flashes coincide with an LH surge (1991). One theory is that the gonadotropin-releasing hormone neurons of the hypothalamus interact with an altered feedback mechanism in the menstrual cycle, thus initiating the flash.

Logothetis wrote that of all the symptoms associated with perimenopause, only hot flashes and vaginal atrophy are directly attributed to the decrease in estrogen (1991). In her study of 252 climacteric women, which investigated the decision making process for women in regard to estrogen replacement therapy, 42% of the women reported hot flashes (lower than the usually reported norm), 7% reported vaginal dryness; 17% reported

emotional lability; additional symptoms frequently reported included flooding and heavy periods, insomnia and fatigue, musculoskeletal pain, weight gain, decreased libido, heart palpitations, dizziness and poor memory. Urogenital changes occur as a result of fluctuating hormonal levels. The decreasing levels of estradiol lead to atrophy of both vaginal and urethral mucosa (McCraw, 1991).

According to Quinn, women have different perimenopausal experiences because they occur in different contextual settings, producing different meanings of the experience (1991). Although a biological process, menopause is interpreted by women within their cultural context. Most commonly reported sexual dysfunctions by perimenopausal women are “the inability to adequately lubricate with sexual arousal, a need for more time and more sexual stimulation to achieve vaginal moisturization, insertional dyspareunia from the lack of adequate vaginal lubrication, and a lessening of sexual interest and desire,” (Bachmann, 1993). The vagina also shrinks in length and width in addition to an elevated pH, the latter leading to an increased risk of vaginal infection (Hargarten, 1994). Stress incontinence can occur in addition to atrophic cystitis or urethritis.

A 1992 report by the Health and Human Services Department stated that more than 60% of American women experience hot flashes. A hot flash is experienced as sudden, intense heat in the upper body. Red blotches may appear, and the woman’s face will flush. Profuse sweating is experienced and then cold shivering. Hot flashes are often one of the first indications that a woman is becoming perimenopausal. Starting before menopause, hot

flashes occur sporadically for several years and then begin to decrease in frequency and intensity. Physiologically, the hot flashes are a result of decreased estrogen. Decreasing amounts of estrogen cause the body to secrete additional hormones which dilate blood vessels and destabilize body temperature.

Hot flashes are a common experience during perimenopause. It is estimated that 65% to 75% of perimenopausal women experience hot flashes (Martin et al., 1993). Hot flashes are thought to be the result of vasomotor instability due to changes in the circulatory system (Hargarten, 1994).

Avis, Kaufert, Lock, McKinlay, and Vass reported the common assumption that menopause is generally accompanied by “hot flushes, sweats, prolonged menstrual irregularities, vaginal dryness and a host of other ‘symptoms’ including depression, irritability, weight gain, insomnia and dizziness” (1993, p. 17). They purport, however, that “with the exception of hot flushes and accompanying sweats,” all other symptoms generally associated with menopause are not the direct result of physiologic changes.

Decreasing amounts of estrogen lead to changes in sexual function because of decreased vaginal blood flow, decreased vaginal secretions and changes in vaginal pH to a more alkaline value (Bachmann, 1993). Complaints of inadequate lubrication with a longer period of sexual stimulation required for adequate lubrication for penetration are reported. Sensory changes such as peripheral neuropathy and skin sensitivity changes have also been noted to have an impact on sexual function.

Treatments

Hormone replacement therapy is the most recognized treatment for the symptoms of the perimenopausal period, such as hot flashes or flushes, vaginal and urinary atrophy and related sexual problems, and for affective symptoms (Lichtman, 1991). Estrogen, or hormone, replacement therapy have been used to slow down osteoporosis and to decrease the incidence of cardiovascular disease.

Physical Activity

Definition and Prevalence

Fisher and Conlee (1979) offered that a person should be fit enough to be able to participate in vigorous activities without undue stress, and to be able to enjoy life more fully. In an article in Public Health Reports (Casperson, Powel, & Christenson, 1985), physical activity included work-related, recreational, and leisure-time activity; involving bodily movement produced by movement of skeletal muscles resulting in energy expenditure. Increasing physical activity among Americans was clearly a goal in Healthy People 2000; however, in 1991, Tanner reported only an estimated 25% of Americans engaged in light to moderate activity, defined as exercise 3 or more times per week. Kane (1991) examined gender as a barrier to leisure time physical activity. Gender-role conformity, that is conforming to activities that are gender related and the overwhelming responsibilities of women were two reasons provided as barriers to leisure physical activity for women.

Modern technology has had a negative influence on the amount of daily physical activity required to conduct one's business (Heyward, 1994). The physical labor involved in washing clothes, traveling to work, and washing dishes, has been greatly reduced due to the use of modern machinery. Many people have taken up leisure activities that are sedentary in nature, leading to a rise in hypokinetic diseases, such as heart disease, low back pain, adult-onset diabetes, and obesity (Heyward, 1994).

Physical Health Benefits

Wilmore stated that exercise was necessary to establish and maintain an optimal level of health, function and appearance (1982). Exercise has been shown to increase the individual's working capacity thereby improving functional performance of the heart, lungs, and blood vessels; increasing joint flexibility, muscular strength and endurance. Physical activity also offered an outlet for stress and mental fatigue and aids in weight reduction. Physical activity is also known for its role in maintaining bone density, thereby decreasing the risk of osteoporosis and subsequent fractures (Cummings, Kelsey, Nevitt, & O'Dowd, 1985). Walking, and other weight bearing physical activities, can increase bone mass, subsequently decreasing the risk of osteoporosis (Urrows, Freston, & Pryor, 1991).

Paffenbarger, Hyde, Wing, and Hsieh, (1986) in a longitudinal study of Harvard alumni, found that men who burned at least 2,000 calories a week beyond their daily activities had significantly lower mortality rates and a substantially lower risk of coronary heart disease than less active men. These findings lead to the American College of Sports Medicine's recommendation

that adults exercise three to five times a week at an intensity that raises the heart rate to between 60 and 90 percent of its maximum for 15 to 60 minutes (Olsen, 1988).

Rippe, a cardiologist and leading physiology researcher, supported the idea that immediate benefits were experienced from mild exercise, such as walking (Higdon, 1988). He claimed that as little as 12 minutes of stationary cycling three times a week could produce a significant improvement in maximum oxygen consumption. Additionally, he believed that tension and anxiety reduction, and improvements in blood pressure were evident from the first day of exercise. In one study by Rippe, (Higdon, 1988) 23 women were tested for 12 weeks using a stationary bike that simulated riding up and down hills. $VO_2\text{max}$ improved 10 to 15 percent after cycling 12 minutes a day, three days a week for 12 weeks.

Lack of physical activity, is a risk factor for cardiac heart disease, obesity, non-insulin dependent diabetes mellitus, hypertension, colon cancer, and depression (Powell, Caspersen, Koplan, & Ford, 1989). Cardiovascular disease, hypertension, osteoporosis, diabetes, major causes of morbidity and mortality in the United States, are positively affected by physical activity (McHenry, & Ellestad, 1990). Among the lifestyle habits that can be changed, physical activity is one activity that may decrease the risk of chronic disease and premature death (Paffenbarger, Hyde, Wing, Lee, Jung, & Kampert, (1993).

According to Morris and Froelicher, there is overwhelming evidence that regular physical activity plays an important role in the prevention of cardiovascular disease (1993). Consistent exercise has been shown to lessen the impact of atherosclerotic plaque through increasing coronary artery diameter. Routine exercise can also decrease the likelihood of a myocardial event. Thirty minutes, four to five times per week, was the minimum amount of exercise required by Morris and Froelicher in order to reduce the risk of coronary artery disease.

Psychological Health Benefits

Both clinical and nonclinical populations experience positive mental health effects from physical activity and exercise (Taylor, Sallis, & Needle, 1985). Research has shown that physical activity has the greatest impact for the individual experiencing mild to moderate depression. Researchers have found it more difficult to determine changes in mood in individuals who experienced low initial levels of depression. The decrease in depression has been attributed to social reasons, such as diversion, social reinforcement; psychological reasons - improved self-efficacy; and biological reasons - increased neurotransmission of catecholamines or endogenous opiates or both. Physical activity is associated with increased relaxation, sense of well-being, and a sense of camaraderie (Dunn, 1987).

Forty women diagnosed as having major or minor depressive disorder were randomly assigned to an eight-week running program, a weight lifting program, or a wait-list control condition (Doyne, Ossip-Klein, Bowman, Osborn, McDougall-Wison, & Neimeyer, 1987). The Beck Depression

Inventory, Lubin's Depression Adjective Check List, and the Hamilton Rating Scale for Depression were utilized. Subjects were assessed at mid- and post-treatment, and at one, seven, and 12-month follow-ups. Both exercise groups demonstrated a significant reduction in depression compared with the wait-list control condition.

Cardiovascular Benefits of Physical Activity

There is a reduced incidence of myocardial infarction and complications from coronary heart disease among active individuals than among sedentary individuals (Heyward, 1991). Higher levels of physical fitness are negatively correlated with coronary artery disease (Powell, Thompson, Caspersen, & Kendrick, 1987). According to Wingate (1991), there are three major acute responses to dynamic exercise: oxygenation of working musculature, stimulation of the sympathetic nervous system, and maintenance of body temperature. During exercise there is a shift in distribution of blood flow, most significantly are the decrease in blood flow to the internal organs and inactive muscle and the increase in flow to the heart and active muscle. The blood vessels in the muscles are able to dilate almost immediately in response to exercise thereby allowing increased blood flow. Muscle capillaries also fill with blood during exercise. Vasodilation of selective vessels in the skin account for the bodies ability to cool itself, even under the conditions of increased heat during exercise (Wingate, 1991). These mechanisms could account for a decrease in frequency and intensity of the hot flashes associated with perimenopause. As the vascular system improves in response to

exercise, these benefits may also have an impact on the bodies ability to adjust to temperature changes associated with the hot flash.

During exercise, the cardiovascular system is faced with the unique challenge of increasing the blood supply to the skeletal muscles while providing sufficient blood supply to the brain and the internal organs (Mitchell & Raven, 1994). Heart rate and stroke volume increase in order to meet the increased oxygen consumption needs during exercise.

Vasodilatation occurs in order to increase the blood supply to the muscles, with a corresponding vasoconstriction of the non-exercising muscles and visceral organs.

One study (Martin, Ogawa, Kohrt, Malley, Korte, Peter, Kieffer, & Schechtman, 1991) found that there was a decrease in the vasodilatory capacity in the calf muscle in women as they age. In their study of 110 healthy subjects, individuals were grouped according to age, physical activity, and gender. Two maximal treadmill tests were utilized in order to evaluate maximal oxygen uptake, blood pressure during exercise, and distal lower extremity (calf) blood flow and conductance. They concluded that the "age-related increase in blood pressure during exercise is greater in women than in men and that calf vasodilatory capacity is reduced with aging only in women," (Martin et al., p. 661). Irrespective of age or gender, calf vasodilatory capacity increased with exercise. Post-menopausal women on estrogen therapy were found to have increased vasodilatory capacity, in addition to lower resting blood pressure and lower lower blood pressure during exercise.

Link Between Physical Activity and Menopause

Wallace, Lovell, Talano, Webb, and Hodgson (1982) determined that women experienced an increase in plasma estrogen levels, and a subsequent decrease in vasomotor symptoms after an aerobic conditioning program. Two studies by Wilbur, Holm and Dan examined the relationships between physical activity, physical and psychologic symptoms and menopausal status. The first study, reported in Family Community Health (1990), examined and described the relationships between menopausal status, menopausal symptoms, energy expenditure, and aerobic fitness of 386 healthy women, ages 34 to 62 years. The women were participating in the first wave of a longitudinal study investigating bone density. Four questionnaires were utilized in order to obtain information regarding demographics, health, 12-month dietary calcium intake and physical activity. Additionally, aerobic fitness was estimated from a standard submaximal cycle ergometer test. The study was completed by 375 women, ages ranging from 34 to 62 years. Less than 30% of the women reported experiencing hot flashes or night sweats. In their study they found a weak positive correlation between occupational energy expenditure and general health symptoms ($r = 0.14$, $p = 0.01$); weak negative correlations between leisure energy expenditure and nervous symptoms ($r = -0.15$, $p = 0.004$) and leisure energy expenditure to general health symptoms ($r = -0.17$, $p = 0.001$). "Energy expenditure did not ameliorate the effects of menopausal status on vasomotor symptoms" (Wilbur, Dan, Hedricks, & Holm, 1990, p. 77). These researchers did not evaluate if an increase in energy expenditure had an impact of

perimenopausal symptoms. Instead they determined that women classified as perimenopausal had the most significant incidence of vasomotor symptoms (such as hot flashes, or night sweats) associated with perimenopause. They concluded that physical activity was not a viable alternative to HRT for vasomotor symptoms, but that nervous and general health symptoms were less among women with higher energy expenditures. Wilbur, Holm and Dan (1992) proposed physical activity as an alternative to estrogen replacement therapy in order to decrease physical and psychologic perimenopausal symptoms in midlife women. Identified symptoms included, but were not limited to vasomotor symptoms (hot flashes and night sweats). In their study they sought to identify relationships between menopausal status, physical and psychologic symptoms, and energy expenditure. The latter represented physical activity. They used a modified version of the Tecumseh Occupational Activity Questionnaire for the occupational and leisure dimensions in addition to the Minnesota Leisure Time Questionnaire. Their participants, 561 women, ages 36 to 60, were part of a second wave of a longitudinal study of health, physical activity, bone density and general health among midlife women. Negative correlations (actual Pearson product-moment correlations not provided) were found between leisure time activity and all symptom measures (measured with the Kaufert and Syrotuik Index). These authors identified low levels of psychological or physical symptoms, making it difficult to detect any significant differences in the symptom experience between women with high levels of energy expenditure versus low levels. Another weak aspect of this

study, identified by the researchers, was that physical activity was estimated based on the calculated energy expenditure.

Hargarten (1994) proposed that physical activity had a positive influence on many of the symptoms associated with being perimenopausal.

Hargarten's guidelines for exercise are summarized in Table 4.

Table 4

Hargarten's Guidelines for Physical Activity to Mitigate Perimenopausal Symptoms

Symptoms	Exercise Guidelines
Cardiovascular (fitness and protection)	Continuous aerobic activity Twenty minutes, three times per week Heart rate of 70% to 85% maximal heart rate
Reproductive Changes (genital mucosal changes)	25 Kegel exercises twice daily
Skeletal Integrity	Aerobic and strength-training Weight-bearing exercises (walking, jogging,) three times per week Resistance exercises, every other day for >30 minutes
Symptom Relief	Regular aerobic exercise

The American College of Sports Medicine (1991) recommends 15 to 60 minutes of exercise, three to five days per week, within 55 to 90% of maximal heart rate. Astrand recommends a minimum of 60 minutes of physical activity daily, and more strenuous, continuous exercise three times per week for 30 to 45 minutes in order to maintain functional health (1992).

Pronk, Jawad, Crouse, and Rohack evaluated the effect of a single session of aerobic exercise on mood, calculated to expend 350 kcal of energy in 11 pre-menopausal women and 11 post-menopausal women (1994). The mean age of pre-menopausal women was 35.1 plus/minus 1.4 years; and the mean age of the post-menopausal women was 54.9 plus/minus 2.2 years. Both groups of women walked on treadmills on two separate occasions for sessions designed to expend 350 kcal of energy. The women performed at 50 to 70 percent of VO_2max . An abbreviated version of the Profile of Mood States questionnaire was utilized before and after the exercise sessions. Both groups were found to have increases in mood following the exercise sessions. Additionally, the post-menopausal women increased self-esteem and pre-menopausal women showed a decrease in confusion following the exercise. These authors concluded that a single session of aerobic exercise calculated to expend 350 kcal of energy had the potential to evoke significant changes in the mood profile of both pre- and post-menopausal women.

Based on the finding that “women who exercise regularly tend to report fewer menopausal symptoms and problems than sedentary women,” Shangold reported that exercise was an excellent way to lessen the symptoms of menopause in addition to decreasing the long-term risk of cardiovascular

disease, osteoporosis, and obesity (1996, p. 32). Shangold suggested an exercise prescription that was individualized and included aerobic exercise, resistance training, with a stretching component could improve mood, thought processes, and patterns of sleep. She added that although sedentary women tend to report a greater incidence of hot flashes, that increased physical activity has not been shown to decrease this symptom.

Physical Activity As An Intervention

In a study of eight female clerks, Epps, Washburn, and Casali, found an eight-week aerobic exercise program to be sufficient to produce cardiovascular training effects, although having little impact on body weight and percent of body fat (1983). Pollock, Foster, Salisbury, and Smith conducted a study investigating the effects of a YMCA starter fitness program (1982). Fitness changes in 892 men and 470 women who participated in the eight-week starter fitness program from 1973 until 1980 were monitored. The exercise consisted of one hour, three times per week. Fitness improvement was related to attendance in the program. After eight weeks, there was a significant reduction in body weight, body fat, and resting heart rate, and significant increases in $VO_2\text{max}$, flexibility, and muscle strength and endurance.

Cowan and Gregory examined pre- and post-menopausal females for their response to aerobic conditioning (1985). Sedentary pre-menopausal women, between the ages of 35 and 49, experiencing normal monthly menstrual cycles ($N=16$) and post-menopausal women, between the ages of 47 and 66 ($N=14$) were assigned to a walking intervention and compared to a

pre-menopausal women control group ($N=4$) and a post-menopausal women control group ($N=4$) in regard to cardiorespiratory endurance and body composition. The exercise groups took part in a nine week walking program four days per week. The duration of the training program was increased by three minutes per week, thereby increasing the distance walked. Participants were instructed to walk at 80% of their age-adjusted heart rate maximum. Both exercise groups experienced significant improvements in submaximal cardiorespiratory endurance; the pre-menopausal women showed an improvement of 12.1% for $VO_2\text{max}$ and the post-menopausal women showed an improvement of 19% for $VO_2\text{max}$; no significant changes were noted for the control groups.

Percent of body fat and lean body weight were improved for the pre-menopausal exercise group; while the post-menopausal exercise group showed an improvement of total body weight and percent body fat but not in lean body weight. A panel of six researchers agreed that walking was an ideal activity to improve aerobic capacity ("Walking for Fitness," 1986). They found walking to be relatively easy and inexpensive, with few injuries and helpful in preventing osteoporosis. They suggested that walking was an excellent way to adapt a lifelong pattern of exercise. Walking is a physical activity that can be adopted by most people of all ages. Regular walking has both physical and psychologic benefits (Pender, 1987).

Nieman, Haig, DeGuia, Dizon, and Register demonstrated an improved VO_2max of 20.9 percent (plus or minus 3.2 percent) in a study of mildly obese women (1988). Twenty-one subjects were randomly assigned to either an exercise or a non-exercise group. The exercise program consisted of five 45 minute walking/jogging sessions at 60% of VO_2max per week, for five weeks. Body weight, fat weight, and lean body weight did not differ significantly after five weeks for the two groups.

In a study by Jett, Sidney, and Campbell it was determined that an exercise prescription based on an appropriate walking pace was an effective, safe and simple procedure to enhance cardiorespiratory fitness of sedentary middle-aged men and women (1988). Volunteers aged 35 to 53 (14 male and 12 female) were randomly assigned either to an experimental or to a control group. The subjects in the exercise group walked at a pace that elicited 60% of VO_2max for 30 minutes, three times weekly for 12 weeks. Females gained 17.3 percent of VO_2max and males 9.7 percent of VO_2max as a result of the 12 week training program.

Sedentary adult volunteers ($N=109$) were assigned to four groups: high intensity aerobic training, moderate intensity aerobic training, attention-placebo, and a waiting list group (Moses, Steptoe, Mathews, & Edwards, 1989). After a 10 week training period, positive aerobic fitness changes were noted in all three physically active groups; and psychological benefits, such as increased mood, were associated with the moderate exercise condition, but not in the high intensity exercise or attention-placebo groups.

Nieman, Henson, Gusewitch, Warren, Dotson, Butterworth and Nehlsen-Cannarella found in their study of physical activity and immune function in elderly women that a 12 week walking program improved the VO₂max of sedentary women 12.6 percent (1993). However there was no improvement in their immune system function as demonstrated by a lack of increase in T cell function. Their study involved 32 sedentary, elderly, Caucasian women, 67 to 85 years of age. In a related study, Nieman, Warren, Dotson, Butterworth, and Henson found a 12.6 percent improvement in VO₂max among 32 sedentary, elderly, Caucasian women, 67 to 85 years of age after a 12 week walking program (1993) . No improvement in psychological well-being or mood state was demonstrated.

Thirty sedentary elderly women (mean age = 73.6 plus/minus 0.7 years) participated in a 12 week moderate exercise program examining cardiorespiratory responses to exercise (Warren, Nieman, Dotson, Adkins, O'Donnell, Haddock, & Butterworth, 1993). Sedentary subjects were assigned to a walking group or a calisthenics control group. The walking group exercised at 60 percent of maximum heart rate, five days per week, for 30 to 40 minutes for 12 weeks. The calisthenics control group took part in mild musculoskeletal exercise for 12 weeks. The walking group demonstrated an improvement in VO₂max of 12.6 percent compared to an increase of 2.2 percent for the control group.

Emery, Hauck, MacIntyre and Leatherman found significant gains in cardiopulmonary endurance, and fewer symptoms of depression and anxiety

in their study of 27 adults, after a 30 day rehabilitation program including exercise, education and stress management (1994). Ten men and 17 women, ages ranging from 27 to 83 with a mean sample age of 55.5, underwent the 30 day treatment program.

In a study of 86 sedentary women ranging in age from 20 to 50, Larkin randomly assigned 30 women to a walking group, 29 to an ever-striding group and 27 to the control group (1994). The walkers and ever-striders exercised for 30 to 45 minutes per day, four days per week for 12 weeks at 70-85 percent of maximum heart rate. $VO_2\text{max}$ increased by 7.6 percent for the walkers and 7.7 percent for the ever-striders.

Twenty-seven sedentary, eumenorrheic women, ages 22 to 40, with high baseline levels of plasma high-density lipoprotein cholesterol, were randomly assigned to a walking ($N=16$) or control group ($N=11$), (Santiago, Leon, & Serfass, 1995). The walking group exercised on treadmills for 40 weeks at a mean intensity of 72 percent maximal heart rate. $VO_2\text{max}$ was improved by 22 percent. Most of the improvement in $VO_2\text{max}$ was demonstrated in the first 20 weeks. No training effect was demonstrated in the blood lipid/lipoprotein levels. Brown, Wang, Ward, Ebbeling, Fortlage, Puleo, Benson, and Rippe, studied the chronic psychological effects of exercise and exercise plus cognitive strategies among healthy, sedentary adults (1995). Sixty nine women (mean age = 54.8 plus/minus 8.3 years) and 66 men (mean age = 50.6 plus/minus 8.0 years) were randomly assigned to a control group, moderate intensity walking group, low intensity walking group, low intensity

walking plus relaxation response group, or mindful exercise group (a Tai Chi type program), in order to examine the effect of exercise and exercise plus cognitive strategies on personality, self-esteem, life-satisfaction, cognition and mental health. The exercise program lasted 16 weeks. The exercise plus cognitive strategy training program was more effective than exercise alone in promoting psychological benefits. Women in the mindful exercise group experienced reductions in mood disturbance and improvement in general mood. Women in the moderate intensity walking group noted greater satisfaction with physical attributes (body cathexis) and men in the moderate intensity walking group reported increased positive affect. Measures of mood, self-esteem, personality, or life satisfaction demonstrated no differences between groups.

Moul, Goldman, and Warren studied the impact of physical activity on cognitive performance in the older population (1995). Thirty sedentary men and women, ages 65-72, were randomly assigned to a walking group, a weight training group, or a placebo control group. Participants in the intervention groups exercised 30 to 60 minutes, five days per week for 16 weeks. The walking group trained at 60 percent heart rate reserve. The placebo control group engaged in mild range-of-motion and flexibility movements without raising their heart rates above resting levels. The subjects were tested using the Ross Information Processing Assessment (RIPA), a maximal graded treadmill test, and a strength assessment of the knee extensors and elbow flexors, at baseline and at the end of the 16 week training period. VO_{2max} improved 15.8 percent for the walking group, but did not significantly

improve in the other two groups. The RIPA scores for the walkers increased 7.5 percent, whereas the RIPA scores for the other two groups did not change appreciably.

Summary

In summary, the literature has encompassed definitions, prevalence rates, theoretical notions, and research related to the concepts of perimenopausal symptoms and physical activity. While the review of literature did reveal some research on factors which influence the experience of perimenopausal symptoms, few studies focused on the impact of an individualized walking program on the symptom experience. In addition, the review of the literature did support the physical and psychological benefits of physical activity. The experience of perimenopause was described, although there was a great deal of confusion over what symptoms actually define the experience. Studies, involving walking as an intervention and assessment of changes in cardiorespiratory endurance, were examined for method and findings.

CHAPTER III

PROCEDURE FOR COLLECTION AND TREATMENT OF DATA

The purpose of this study was to examine the impact of physical activity on perimenopausal symptoms in the absence of hormone replacement therapy (HRT), or as an adjunct intervention to hormone replacement therapy for sedentary, midlife, women. During the intervention phase, the researcher attempted to walk with the participants three times per week. In the event that the participant walked without the researcher, their progress was monitored through the use of telephone supervision.

Two participants were not receiving HRT; the two participants who were receiving HRT continued to be symptomatic, had similar symptoms as the women without HRT, and expressed the desire for additional symptom relief. The procedures followed for the study are presented in this chapter under the following headings (a) time-series research design, (b) setting, (c) population and sample, (d) protection of human subjects, (e) instruments, (f) data collection, (g) treatment of data.

Time-Series Research Design

A time-series design was utilized to examine the pattern or underlying process of each participant's bothersomeness of daily symptoms as well as daily stress scores, and to determine if the patterns during an eight-week moderate, progressive walking program were significantly different from the

baseline patterns. "A time-series is a set of ordered observations

$$Y_1, Y_2, Y_3, \dots, Y_{t-1}, Y_t, Y_{t+1} \dots "$$

(McCleary & Hay, 1980, p. 30). The purpose of time-series analysis is to (a) forecast in order to develop models to predict future values of a variable, (b) test models in order to explain phenomena, (c) discover systematic patterns in a series that can be mathematically modeled in order to explain the behavior of the series, and (d) evaluate the effect of some event or intervention.

Time-series analysis was developed by economists and econometricians in the 1930's in order to predict trends in the economy (H. Clarke, personal communication, September, 1995). The Box-Jenkins-Tiao techniques were developed in the early 1970's in a reaction to the perceived failure of conventional approaches, and national economic models, to forecast the economy (H. Clarke, personal communication, September, 1995). The early 1970's was a time of profound crisis for economic theory and economists hoped to develop accurate, cheaper methods to forecast. In its simplest form, the Box-Jenkins-Tiao method predicts Y from its own history

$$Y_t = \text{fn}(Y_{t-1})$$

where Y is the variable, t is the point in time, fn is translated as a function of, and Y_{t-1} is the preceding value of Y . Certain conditions or criteria must be met in order to utilize time-series analysis:

1. Data must be collected at equal intervals of time. The intervals of time may be minutes, hours, days, or any other equal interval of time. The interval is determined by the variable of interest. For example, in

determining the effect of global warming on monthly rainfall amounts in southern Florida, the data would be compiled on a monthly basis; whereas in a study examining the impact of pain medication administration on blood pressure in a patient who is 12 hours post-open heart surgery, the data collection interval may be at 60 second intervals. In the current study, examining the impact of physical activity on perimenopausal symptoms, the data were collected daily at bedtime.

2. In order to have confidence in the data analysis, a minimum of 50 data points is necessary to “estimate the structure of the correlated error in the series” (Cook & Campbell, 1979, p. 228). For monthly data, that would be the equivalent of 50 months; in yearly data, 50 years of data would be required. For the current study data were collected for 112 days (56 days pre-intervention, and 56 days during the intervention).

3. Missing data in time-series are difficult to accommodate because any error in estimation of the missing value will impact the analysis of the entire series. Missing data are often the result of one observation not being available, if at the beginning or end of the series, the series can be shortened and hence accommodated. However, when the missing observation is embedded in the series this presents a more serious problem. Generally the time-series statistical package will provide a mechanism for estimating the missing value. For example, in SPSS-X Trends a command can be given to estimate the missing value by use of linear interpolation, the mean of surrounding values, the median of surrounding values, the series mean, or

the linear trend at the point of the missing value (1988, p. C-70). The current study did not experience any missing data for daily symptoms or daily stress scores.

4. There is a qualitative aspect of time-series analysis involving “eye-ball” analysis of the series. One of the first steps in the interpretation is to inspect a plot of the series examining it for any upward or downward trends, or cyclic patterns. In the current study more than eight time-series plots were examined; observations from each participant were used to generate a plot of the daily symptom scores and the daily stress scores; additionally individual symptoms, such as the frequency of hot flashes, were plotted for individual participants in order to ascertain if the pattern of a particular symptom changed in relation to the intervention.

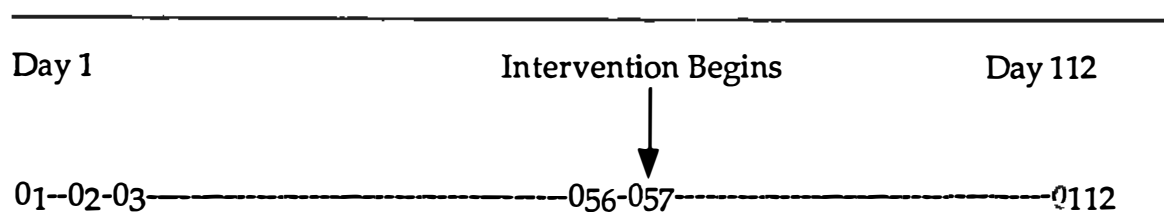
5. Time-series analysis requires an active interaction with the data. In this type of analysis decisions in the modeling process are made in response to how well the series is modeled by tentative identification attempts. In essence, a tentative model is identified; the model is tested and changes in the model are made based on the diagnostic results of the testing process.

The time-series design was chosen because it allowed examination of data over time rather than examining pre-test and post-test scores on a variable. Consider the following series of data.

5, 6, 4, 7, 6, 4, 2, 1, 7, 9, 10

If the data were collected on the first day (score equal to 5) and the last day (score equal to 10), the researcher may draw the incorrect conclusion that the

series steadily increased over time. A pre-test score of five and a post-test score of 10 would indicate a change in the series as a result of the intervention. Some of the information is lost, however, by taking only two scores, the middle scores of four, two, and one are not taken into consideration in the pretest post-test design. Figure 3 shows the research design.



Key: 0 = Observation (checklist and daily log)

Note: The $\text{VO}_{2\text{max}}$ was calculated on day 56 and day 112.

The walking intervention took place from day 57 until day 112.

The Symptom Checklist and Daily Log were completed daily from day 1 until day 112.

Figure 3. The Time-Series Research Design

VO₂max was calculated based on the performance time of a mile and one-half walk-run field test in order to determine changes in cardiorespiratory endurance as a result of the walking intervention.

Setting

The study was conducted in Ft. Worth and Weatherford, Texas. The setting for the study included the participants' homes, area walking tracks, or other acceptable walking areas such as local neighborhoods. The Symptom Checklist and Daily Log were completed by the participant each day at bedtime. The log included a daily score for stress in addition to any changes in lifestyle practices or significant life events.

Population and Sample

The population of study were women between the ages of 45 and 60, experiencing perimenopausal symptoms, and sedentary for six months prior to participation in the study. Recruitment of subjects was accomplished via friends and acquaintances, through advertisements in local newspapers, and advertisements posted in area businesses, with word of mouth being most successful in the recruitment of subjects. There were 20 inquiries as a result of eight weeks of newspaper advertisements; however only one participant joined the study after inquiring about the advertisement. Three participants joined the study after hearing about it via friends or acquaintances. Twenty information packets were distributed to telephone inquiries.

The sampling technique was criterion, although the participants self-selected themselves for the study. Subjects were included if they met the criteria for acceptance and expressed a willingness to participate in the study. Criteria for acceptance in the sample were female, between the ages 45 and 60, experiencing perimenopausal symptoms by self report, sedentary for six

months prior to the study, and physically able to participate in the mile and one half walk-run and the eight-week walking program. The subjects ($N = 4$) lived in Ft. Worth (3) and Weatherford (1) Texas. All participants completed the 16-week study.

Sample size had been limited to five, in order to be able to fully analyze the data, however, only four participants agreed to participate in the study. Each participant served as her own control, and the data were examined case by case. Time-series analysis requires a minimum of fifty data points to provide confidence in the model parameters of the findings. Perimenopausal symptom data were collected daily for each participant yielding a total of 56 data points for each woman prior to the intervention, and an additional 56 data points after initiation of the intervention; giving each participant a total of 112 data points. Scores were recorded for each woman, on a daily basis, for both bothersomeness of perimenopausal symptoms and level of stress. The symptom checklist included 19 symptoms typical of the perimenopausal experience. Participants rated the presence of each of the symptoms as “none” (zero points), “moderate” (one point), or “extreme” (two points). The points were summed for each day, providing the daily score of bothersomeness of perimenopausal symptoms. Level of stress was ranked by each subject on a daily basis on a scale from 1 (the lowest possible amount of stress possible) to 7 (the most possible amount of stress possible). The study met the criterion for using time-series analysis, primarily the necessity of obtaining at least 50 data points.

Protection of Human Subjects

The study followed the Human Subjects Guidelines of the Texas Woman's University. Permission to conduct the study was obtained from the Human Subjects Review Committee (see Appendix A). Assurances were provided regarding confidentiality of the information obtained. A written informed consent form was obtained from each subject prior to beginning the study (Appendix B). Due to the large amount of data collected for each participant, the questionnaires were marked with the participant's number, and a week and day number. Participant numbers were known only to the researcher.

Instruments

A Checklist for Perimenopausal Symptoms was utilized to measure daily symptoms (see Appendix C). A daily log was utilized to document events in the participant's life and to provide a self-report of the amount of perceived stress for each day (see Appendix D). The mile and one-half walk-run field test was utilized to calculate an estimated VO_{2max} in order to compare pre- and post-intervention cardiorespiratory endurance. An investigator-developed questionnaire surveyed demographic variables (see Appendix E).

Checklist for Perimenopausal Symptoms

The Checklist for Perimenopausal Symptoms was developed by the author for this study. Existing instruments were rejected because of the period of time that they encompassed. The Neugarten and Kraines'

Index (1981), and Miller and Wilbur's Symptom Measurement Scale for Midlife Women (1994) were utilized as resources in developing the checklist for the study. Neugarten and Kraines' (1965) Menopausal Symptoms Check List included 28 symptoms considered by menopausal women and specialists in the field to be typical complaints. Essentially, somatic symptoms (such as hot flushes or breast pains) were 12 in number; 11 were psychologic in nature (such as irritability and nervousness); and five were categorized as psychosomatic (such as pounding of the heart, and headaches).

The Kaufert and Syrotuik Symptom Index was developed to assess vasomotor, nervous, and general health symptoms. Eight menopausal symptoms were embedded in an 18-item general symptom checklist. Six nervous symptoms (tiredness, irritability, nervous tension, depression, headaches, and trouble sleeping), two vasomotor symptoms (night sweats and hot flashes) were included with 10 general health symptoms (dizziness, diarrhea, cough, backaches, aches and pains, upset stomach, rapid heartbeat, shortness of breath, sore throat, and pins and needles) to make up the checklist. Respondents reported the frequency of experiencing the symptoms over the past few months, as "never," "sometimes," or "often."

Miller and Wilbur's Symptom Measurement Scale for Midlife Women was developed based on earlier symptom indexes (1994). This instrument was unique in that frequency, severity and bothersomeness were all considered in a four point likert scale ("never," "occasionally," "sometimes," and "often"). A total of 34 symptoms were included. The symptoms were

those associated with perimenopause in addition to symptoms common to midlife in women.

The instrument for this study was developed for administration on a daily basis. The original Symptom Checklist was administered in a pilot study in three forms (see Appendices F, G, and H), with the symptoms being the same for all three lists. The lists differed only in regard to what term was used to describe the symptoms. That is, one form asked how severe the symptoms were, another how frequent, and the third how frequent and bothersome. Symptoms were ranked on a three point likert scale (“none,” “moderate,” or “extreme”). The three forms of the checklist were tested in a pilot study. The final form of the Symptom Checklist had 19 symptoms on a three point likert scale, asking the participants how bothersome the symptoms were for the day (none, moderate, or extreme). The final checklist had three cardiovascular symptoms (dizziness, fatigue and rapid heart beat), two cognitive symptoms (difficulty concentrating and forgetfulness), one gastrointestinal (diarrhea), one genitourinary (heavy menstruation), two musculoskeletal (aches and pains in joints and backaches), two neurological (headaches and pins and needles in hands and feet), six psychological (depression, fatigue, feelings of “losing my mind,” irritability, nervous tension and trouble sleeping), and two vasomotor (hot flashes/flushes and night sweats). Cough, sore throat, and upset stomach were deleted from the

instrument because they were not chosen by any of the participants in the three week pilot study, nor discussed in the post-pilot interviews, nor with interviews with perspective participants.

The Daily Log.

A daily log was developed to document changes in the participant's lifestyle, or other events that could impact the pattern of perimenopausal symptoms other than the planned intervention (Appendix D). For example a situational crisis, such as loss of employment, change in medications, or changes in nutritional intake could all have an impact on the bothersomeness of perimenopausal symptoms. This information was later examined in conjunction with the time series data. This information helped the researcher to increase confidence that any significant change in the pattern of post-intervention symptoms was related to the intervention and not the result of extraneous variables. The log was used to document the amount of time spent walking, perceived exertion while walking, and the level of perceived stress for the day. A space was provided for the participant to comment on any other events in their life, such as loss of a loved one or change in employment.

The Mile And One-Half Walk-Run.

This field test was utilized to estimate $VO_2\text{max}$ for each participant, pre- and post-intervention. During the week prior to the walking intervention and at the end of the walking intervention, each participant walked-ran for 1.5 miles on a track, after stretching and warming up. In order

to obtain an accurate estimation of VO_2max , the participants were instructed to complete the mile and one-half as quickly as possible and were encouraged to do so throughout the test. The time, to the closest minute was recorded and used to estimate VO_2max .

Pilot Study

Data Collection

One pilot study was conducted. The purpose of the pilot study was to investigate the feasibility of having participants complete a symptom checklist every day for three weeks. The formal study, however, involved participation over 16 weeks. The second purpose of the pilot was to decide which one of three forms of the checklist (see Appendices F, G, and H) would be most valid and acceptable. The symptoms were the same for all three lists; however, the descriptive term was changed for each form. One form asked how severe the symptoms were; another asked for how bothersome the symptoms were; and the third asked how frequent and bothersome the symptoms were.

Six women were recruited via friends and acquaintances to participate in the three week long pilot study. Six individuals were recruited so that the three forms of the checklist could be given in random sequence in order to eliminate the chance of participants favoring the first or last form that they completed. In other words, Participant One completed the questionnaires in such a way that "severity" of symptoms was administered during week one, "bothersomeness" in week two and "bothersomeness and frequency" in week

three. Participant Two was administered the bothersomeness form in week one, bothersomeness and frequency in week two and severity in week three, and so forth. In order to participate, the women had to be experiencing symptoms of perimenopause and report a willingness to participate in the study. The study was explained and a written consent form was obtained (Appendix I). Each woman completed symptom checklists for three weeks. At the end of the three weeks, each woman was interviewed individually. At this time three questions were asked: 1) "Which form of the checklist best describes your symptoms?" 2) "Tell me about the experience of completing the forms daily for three weeks;" and 3) "Are you having any symptoms that are not listed on the checklists; if so what are they?"

Treatment of Pilot Study Data

The points for each woman were tallied for each day in order to provide a daily score. The scores recorded for the participants are presented in Table 5.

Table 5

Participants' Scores for the Three-week Pilot Study

	Week 1	Week 2	Week 3
Participant #1	Severity	Bothersomeness	Bothersomeness and Frequency
Day 1	2	4	4+4
Day 2	2	4	2+3
Day 3	4	2	5+7
Day 4	2	7	3+3
Day 5	0	5	8+7
Day 6	2	4	7+7
Day 7	0	5	7+7
	Week 1	Week 2	Week 3
Participant #2	Bothersomeness	Bothersomeness and Frequency	Severity
Day 1	12	8+12	12
Day 2	13	6+6	12
Day 3	2	7+6	16
Day 4	5	7+7	17
Day 5	7	11+8	14
Day 6	1	10+9	15
Day 7	5	8+6	17

Table 5 (Continues)

	Week 1	Week 2	Week 3
Participant #3	Bothersomeness and Frequency	Severity	Bothersomeness
Day 1	17+22	17	17
Day 2	14+18	17	6
Day 3	9+11	10	9
Day 4	12+12	9	16
Day 5	19+19	11	10
Day 6	17+17	15	13
Day 7	9+9	16	16
	Week 1	Week 2	Week 3
Participant #4	Severity	Bothersomeness and Frequency	Bothersomeness
Day 1	8	6+11	3
Day 2	15	5+5	3
Day 3	8	4+5	3
Day 4	8	5+3	4
Day 5	10	5+4	3
Day 6	11	2+3	8
Day 7	9	2+1	6

Table 5 (Continues)

	Week 1	Week 2	Week 3
Participant #5	Bothersomeness	Severity	Bothersomeness and Frequency
Day 1	4	4	3+M
Day 2	2	4	3+M
Day 3	4	4	3+M
Day 4	1	2	2+M
Day 5	1	2	1+M
Day 6	3	5	3+M
Day 7	1	2	2+M

M = missing data

	Week 1	Week 2	Week
Participant #6	Bothersomeness and Frequency	Bothersomeness	Severity
Day 1	16+4	17	17
Day 2	16+M	16	15
Day 3	13+M	18	19
Day 4	M+20	16	18
Day 5	M+16	17	15
Day 6	M+18	17	19
Day 7	M+16	17	15

M=missing data

The following comments represent the responses elicited to the three questions asked at the interviews:

Question #1: Which form of the checklist best described your symptoms?

- *Frequent and bothersome are two different things, harder to do
- *Bothersome was the best description
- *Bothersome best described my symptoms

Question #2: Tell me about the experience of completing the forms daily for three weeks.

- *Not bad at all
- *It was OK, no problem. It only took five minutes each night

Question #3: Are you having any symptoms that are not listed on the checklists, if so what are they?

- *Some of the symptoms I already had before perimenopause, such as depression
- *Memory problems
- *Feelings of “losing my mind” or going crazy

Based on the data obtained from the checklists, the corresponding interviews, and conversations with prospective participants for the 16 week study, the following changes were made to the checklist. Forgetfulness, difficulty concentrating, feelings of “losing my mind,” and heavy menstruation were added to the symptom checklist. Cough, sore throat and upset stomach were deleted from the symptom checklist. Bothersome was the term chosen as the descriptor; the use of bothersomeness and frequency was confusing and time consuming, the majority of participants indicated bothersome alone as the term that best described their experience.

The 16-Week Study

Data Collection

Volunteer participants were recruited via friends and acquaintances and advertisements in the local newspaper and fliers posted in area businesses. After receiving the initial information regarding the study, interested individuals telephoned notifying the researcher of their desire to participate. The study was explained on the telephone or in person and a packet including an introductory letter (Appendix J), demographic questionnaire, consent form, Physical Activity Readiness Questionnaire (PARQ, Appendix K), and enough checklists and the daily log for one week were given to the individual. Each individual was contacted within three days to answer any questions regarding the study. Interested participants signed their consent forms and began completing the daily checklists and the daily log immediately. The checklists and logs were collected weekly by the researcher, at which time additional forms were given to the individual for the following week. This process continued for the 16 weeks. During week eight and at the end of week 16, the mile and one-half walk-run was conducted. The participants' resting heart rates were also obtained during week eight and at the end of week 16. The initial resting heart rate was used to calculate the participant's target heart rate for their workout. The second heart rate was also compared with the first.

Weeks nine through 16 comprised the walking intervention.

Individuals walked either alone or with the researcher three times per week. Participants were instructed on stretching exercises and on the importance of warming up and cooling down (see Appendix L). Initially participants walked for 20 minutes after stretching and warming up. Participants worked at Borg's perceived level of exertion of "somewhat hard" (American College of Sports Medicine, 1991). They were instructed to increase the length of their walking to 45 minutes by week three, to continue increasing their duration but not to exceed 60 minutes. Over the eight weeks they were instructed to walk longer and with greater intensity, in order to maintain the level of work at the perceived level of exertion of "somewhat hard". Compliance of the walking program was documented on the daily log in the form of frequency, duration, and perceived exertion during exercise. On the days that the participant chose to walk without the researcher, the participant was contacted by telephone to monitor progress and to answer any questions.

Treatment of Data

This study was designed to determine the effects of physical activity on bothersomeness of perimenopausal symptoms and cardiorespiratory endurance in sedentary, midlife women. The effects of an eight-week training program were evaluated by comparing the pattern of symptoms over the initial eight weeks with the pattern of symptoms over the second eight weeks during which time the moderate, progressive walking program was conducted.

Demographic data were presented both in a compiled form and case by case. For example, ages, household income, and number of children were summarized for the sample ($N = 4$). Individual profiles were developed for each participant. The individual profiles were viewed in relation to the participant's pattern of symptoms and response to the exercise intervention. Time series analysis, specifically autoregressive, integrative, moving average (ARIMA) modeling, was used to analyze the data case by case. Time series analysis was chosen because multiple observations over time were obtained (Cook & Campbell, 1979). Initially, a plot of the data for each participant was graphed in order to look for any obvious changes in the series over time. After inspecting the plot of the series, the initial step in ARIMA modeling was to plot the autocorrelation function (ACF) for each case. The ACF correlates the series with itself at various time lags, up to K lags. This is done in order to determine stationarity of the data (McDowall, McCleary, Meidinger, & Hay, 1980). Stationary data has a stable mean and variance. The ACF in conjunction with the Partial Autocorrelation Function (PACF), are the primary diagnostic tools of ARIMA modeling. Nonstationary data are depicted in the ACF as starting with an initially high number which declines slowly. In order to make the time series stationary, when the variance is nonstationary, the series is differenced. If determined nonstationary in variance the series is transformed using natural logarithms.

Once stationarity was either established or the data were transformed to be made stationary, step two was undertaken. Tentative model identification is the second step in the process. ARIMA (autoregressive integrated moving average) modeling techniques were utilized (Cook & Campbell, 1979). Once the model was identified, step three was to estimate model parameters; followed by the use of diagnostic checks to determine if the model was satisfactory or problematic (step four). If satisfactory, the model was accepted, if problematic the model was re-identified and re-estimated. Step five incorporated the intervention as a dichotomous “dummy” variable in order to determine if the series was modeled more accurately with or without the intervention.

The Box Tiao Intervention Model was utilized to determine the type of impact the intervention had on the time series, whether it was abrupt permanent, gradual permanent, abrupt temporary, or gradual temporary. It was hypothesized that physical activity would have a gradual, permanent effect on the variable perimenopausal symptoms. In general the steps are 1) develop the univariate ARIMA model; 2) specify the intervention model; 3) construct the intervention variables in light of the intervention model; and 4) test the intervention model to look at all parameter estimates and their corresponding t-ratios, to determine if the intervention was statistically significant.

Once the time-series analysis was completed, the time on the mile and one-half walk-run field test was utilized to compute the estimated VO_2max for each participant prior to and at the completion of the walking intervention. Demographic data were analyzed for any trends or themes. The daily logs were examined for events that correlated with the time series in addition to the planned intervention. The level of stress was plotted against the time series of symptoms for each case.

Summary

Six participants were recruited for the pilot study in order to finalize the symptom checklist and to identify problems involved in collecting data on a daily basis. The feedback was analyzed and the checklist was revised to a 19 symptom instrument asking the daily bothersomeness of perimenopausal symptoms. Four sedentary participants were recruited for the 16 week study. During the initial eight weeks participants remained sedentary, completing the checklist and daily log each day at bedtime. On day 56 the pre-intervention, mile and one-half walk-run field test was administered; and on day 112, the post-intervention field test was completed. The resting heart rate was also recorded on days 56 and 112. The initial resting heart rate was used to calculate the target heart rate for exercise, while the post-intervention resting heart rate was compared to the pre-intervention resting heart rate.

During the second eight weeks, the participants continued completing the symptom checklist and daily log in addition to walking three times per week. Initially they walked for 20 minutes, after warming up, and worked up

to 45 minutes by week three. They were instructed not to walk more than 60 minutes at a session. The daily symptom scores and stress scores were analyzed using time-series analysis.

CHAPTER IV

ANALYSIS OF DATA

The purpose of this study was to investigate physical activity as an alternative and/or adjunct intervention to hormone replacement therapy for women experiencing symptoms of perimenopause. Data for the analysis were derived from responses by four women to self-administered symptom checklists, daily logs, and a demographic questionnaire designed to measure the variables under study. Time-series analysis provided the design of the study and the means by which the hypotheses were tested.

Description of Sample

The four women in this study ranged in age from 45 to 54 with a mean age of 48.3 years. All participants were Caucasian and married. Three of the women listed "some college courses" as the highest educational level, with the fourth listing a graduate degree. Three of the women were employed full-time outside of the home, and the fourth was a homemaker. Of the three women working outside of the home, one was employed as a medical transcriptionist, one as a licensed practical nurse and one a registered nurse. Two of the women listed two children; one woman, three children and the fourth had five children. Ages of the children ranged from 12 to 34, with an average age of 19.7 years. Combined household incomes were described as one in the \$40,001 to 60,000 range; one in the \$60,001 to 80,000 range; one in the over \$100,001 range, and one refused to answer this question.

Obstetrical history was obtained for number of pregnancies, number of miscarriages, and number of live births (Table 6).

Table 6

All Participants: Description of the Sample - Obstetrical History

Obstetrical Classification	<u>N</u>
Number of pregnancies	12
Number of miscarriages	02
Number of live births	10

Three participants listed menopausal status as “irregular or infrequent menses over the past 12 months,” and the fourth listed this status as “no menses over the past 12 months.” Two listed no hormone replacement therapy (HRT), and two listed Estrogen and Progestin as HRT.

All four participants listed “none” as their pattern of exercise over the last six months. Three of the women listed medications taken regularly, in addition to hormone replacement therapy. Participant One listed Ziac (an antihypertensive), Ultram (an analgesic), Propulsid (used to treat heartburn, as a result of gastroesophageal reflux disease) as scheduled medications and Benadryl (antihistamine) as an “as needed” medication for hives. Participant Two listed Maxide (a diuretic/antihypertensive) and Prozac (an antidepressant) as daily medications. Participant Number Four listed Prozac

(antidepressant) and Lisinol (an antihypertensive) as daily medications. Results of the health history are listed in Table 7. Other health conditions, specified by Participant One, were chronic lower right groin spasms, spastic colon and chronic low back pain. Length of time associated with perimenopausal symptoms was two to three years for Participant Number Two, ten years for Participant Number Three, and Participants One and Four did not provide this information.

Table 7

All Participants: Description of the Sample - Health History

Health History	<u>N</u>
1. High Blood Pressure	1
2. Diabetes Mellitus	0
3. Family History of Coronary Disease Before Age 55	1
4. Pain or Discomfort In Chest During Activity	0
5. Shortness Of Breath With Mild Activity	1
6. Dizziness	1
7. Swelling Of The Ankles	1
8. Heart Murmur	0

Findings

The data were analyzed in a case by case method presenting the results by individual. In some areas the data were combined, comparing participants; for example, the comparison of all participants' symptom scores over the 112 days. Demographic data, significant information obtained via the use of the daily log, frequency of individual symptoms per participant and the time-series analyses of bothersomeness of perimenopausal symptoms and daily level of stress for each participant were analyzed.

Exploratory Data Analysis

The data were initially examined using ClarisWorks Spreadsheet on a Macintosh computer. Table 8 provides the mean, median, mode, standard deviation (SD), and coefficient of variation (CV) for the pre- and post-intervention symptom scores, by participant. Coefficient of variation was determined with the formula-- $100(\text{standard deviation}/\text{mean})$. This calculation provides a relative measure of dispersion. Larger coefficient variations indicate larger dispersion relative to the mean. The coefficient of variation serves as a way to compare standard deviations provided in different units of measure (Tabachnick & Fidell, 1989). Table 9 provides the range in scores.

Table 8

All Participants: Exploratory Data Analysis of Daily Symptom Scores

	<u>Pre-Intervention</u>					<u>Post-Intervention</u>				
	<u>Mean</u>	<u>Median</u>	<u>Mode</u>	<u>SD</u>	<u>CV</u>	<u>Mean</u>	<u>Median</u>	<u>Mode</u>	<u>SD</u>	<u>CV</u>
1	5.59	5.0	2 & 6	9.11	162	5.17	5.0	2	2.50	48
2	7.40	7.0	6	4.56	61	7.2	6.0	6	5.56	77
3	4.90	3.0	2	3.30	67	2.9	2.0	2	7.07	243
4	3.71	5.0	0	3.54	95	3.75	3.5	0	2.12	57

The mean for Participant One decreased by 0.42 while the median remained the same for pre- and post-intervention data. The mode changed from being bimodal (two and six) to a single mode of two. As indicated by the standard deviation and coefficient of variance, there was less variance in the post-intervention data.

Participant Two's mode remained the same, the median decreased by one and there was more variation in the post-intervention data as demonstrated by the increase in the standard deviation and the coefficient of variance.

Participant Three demonstrated the most significant changes from pre- to post-intervention data. The mode, two, remained the same, with a

decrease in the mean and median; the increases in the standard deviation and coefficient of variance indicate a greater fluctuation of daily symptom scores in the post-intervention data.

Participant Four demonstrated an increase in the mean of symptom scores, a decrease of the median. The mode remained constant at zero, and the standard deviation and coefficient of variance indicated less fluctuation during the post-intervention phase.

Table 9

All Participants: Range of Daily Symptom Scores

	Range	
	Pre-Intervention	Post-intervention
Participant		
1	2 to 11	2 to 11
2	2 to 14	0 to 15
3	1 to 15	0 to 11
4	0 to 10	0 to 12

A total daily symptom score of zero to 38 was possible (19 symptoms were marked as either none, or zero points; moderate, or one point; and extreme, or two points). The highest participant score was 15 on the 38 point scale, with the range for the participants being zero to 15.

Neugarten and Kraines, in their study of 460 married women, defined the symptoms most indicative of menopausal status as hot flashes, numbness and tingling, sensations of skin crawling, irritability and nervousness, and feeling blue and depressed (1965). With the exception of sensations of skin crawling, all other symptoms identified by Neugarten and Kraines were included on the symptom checklist. All participants experienced these symptoms, to varying degrees. Table 10 compares the pre- and post-intervention frequencies for the five symptoms.

Table 10

All Participants: Pre- and Post-Intervention Frequencies of the Symptoms "Hot Flashes; Numbness, or Pins and Needles; Irritability; Nervousness; and Depression"

Hot Flashes

	Pre-Intervention	Post-Intervention
1	8	10
2	37	43
3	2	2
4	2	0

Table 10 (Continues)

Pins and Needles

	Pre-Intervention	Post-Intervention
1	1	0
2	38	41
3	0	1
4	0	0

Irritability

	Pre-Intervention	Post-Intervention
1	10	11
2	5	1
3	16	12
4	14	20

Nervousness

	Pre-Intervention	Post-Intervention
1	4	3
2	26	15
3	25	11
4	16	14

Table 10 (Continues)

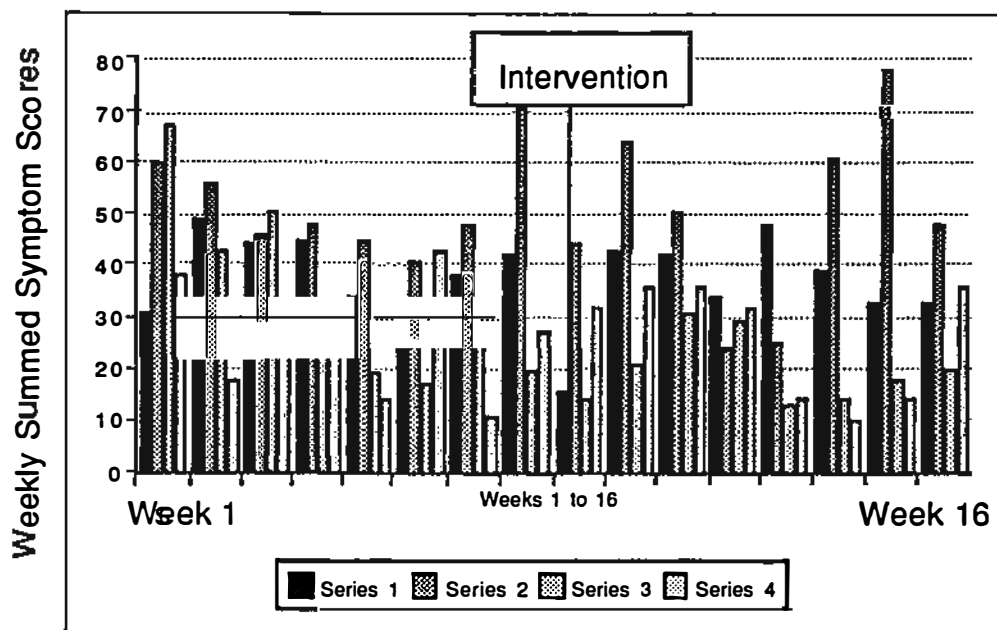
Depression

	Pre-Intervention	Post-Intervention
1	14	12
2	4	1
3	24	6
4	9	11

As seen in this table, the incidence of the identified symptoms varied by participant. The incidence of hot flashes increased for two participants, decreased for one participant and remained the same for one participant during the intervention phase. Pins and needles, changed by a frequency of only one to three for three participants. The frequency of irritability increased or decreased for a frequency of one to six. Nervousness decreased in frequency for all participants, by 1 to 14. Depression decreased for all but one participant, by 2 to 18, and increased by a frequency of two for participant four. The symptom nervousness demonstrated the most consistent changes as a result of the walking intervention.

The participants' daily symptom scores were summed by week and plotted across time, this was done in order to identify any patterns in the data that were not obvious in the day by day examination of the data. The comparison of the four participants' weekly summed symptom scores is

provided in Figure 4.



Series 1 = Participant 1
 Series 2 = Participant 2
 Series 3 = Participant 3
 Series 4 = Participant 4

Figure 4. All Participants: Comparison of Weekly Summed Symptom Scores Over 16 Weeks

As seen from this figure, the primary variation was the way in which Participant Two's summed scores differed from the other three participants in weeks eight, ten, fourteen and fifteen.

Table 11 provides the mean, median, mode, standard deviation (SD), and coefficient of variation (CV) for the pre- and post-intervention daily stress scores, by participant.

Table 11

All Participants: Exploratory Data Analysis of Daily Stress Scores

	Pre-Intervention					Post-Intervention				
	Mean	Median	Mode	SD	CV	Mean	Median	Mode	SD	CV
1	1.60	1.0	1	1.05	66	1.70	1.0	1	1.33	78
2	4.10	4.0	3 & 7	4.56	111	3.96	4.0	7	5.56	140
3	3.32	4.0	7	5.44	163	3.23	3.0	2	2.76	85
4	3.34	3.0	2	1.55	46	3.34	3.5	2	2.41	72

Participant One demonstrated a slight increase in daily mean stress scores, while the median and mode remain unchanged. There was an increase in the fluctuation of day to day scores as indicated by the increase in mean, standard deviation and coefficient of variance.

Participant Two showed a small decrease in mean score, no change in median and a change from being bimodal (three and seven) to having a single mode of seven. The increase in standard deviation and coefficient of variance indicate an increase in day to day variation during the second phase.

Participant Three's mean remained unchanged in the post-intervention phase, however the median and mode decreased. The decrease in standard deviation and the coefficient of variance indicate less day to day fluctuation in the second phase.

Participant Four's mean daily stress score also remained the same for both phases, with the median increasing, the mode remaining unchanged and an increase in standard deviation and coefficient of variance indicating more day to day fluctuation in the second phase.

Table 12 presents the range of stress scores by participant pre- and post-intervention.

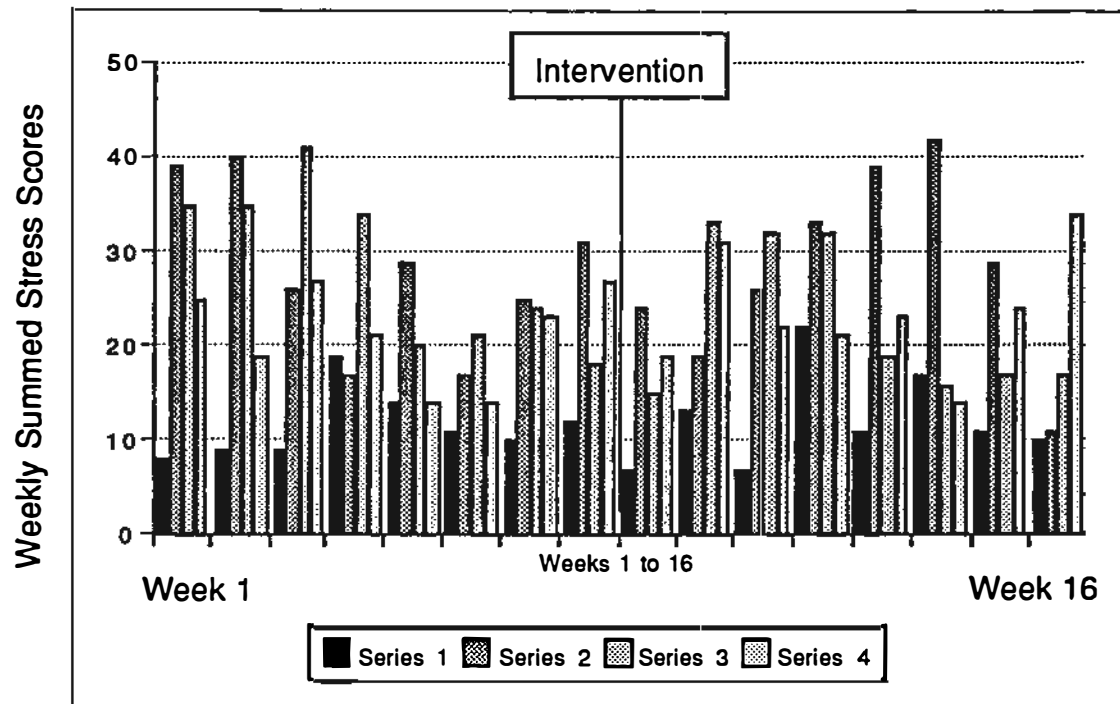
Table 12

All Participants: Range of Daily Stress Scores

Subject	Range	
	Pre-Intervention	Post-Intervention
1	0 to 7	1 to 7
2	0 to 7	0 to 7+
3	2 to 7	1 to 7
4	2 to 7	0 to 7

Participants were instructed to rate their daily stress on a scale of one to seven each evening when completing their symptom checklists. As seen in

Table 12, three of the participants ranked their stress as low as zero, which was outside of the prescribed range. Additionally, participant number two ranked her stress as more than seven, on more than one occasion, ratings greater than seven, were reduced to seven. Participant One's stress increased in range in the post-intervention phase, Participant Number Two demonstrated no change in range and Participants Three and Four had a decrease in range of scores in the second phase. Figure 5 provides a comparison of the summed weekly stress scores for the four participants.



Series 1 = Participant 1
 Series 2 = Participant 2
 Series 3 = Participant 3
 Series 4 = Participant 4

Figure 5. All Participants: Comparison of Weekly Summed Stress Scores Over 16 Weeks

Participant Number One

This participant was a 45 year old married woman, employed outside of the home, full-time, as a medical transcriptionist, listing “some college courses” as her highest educational level. She had been pregnant twice and had two children, ages 12 and 16. Combined household income per year was not provided. She listed irregular or infrequent menses over the past 12 months and was on hormone replacement therapy. She reported having taken Premarin (a conjugated estrogen used to treat moderate to severe vasomotor disorders of menopause) and Provera (a synthetic Progestin, used with estrogen to treat menopausal symptoms) for 14 months and was currently taking Prempro (a combination of estrogen and a synthetic Progestin) for three months. Significant health history included high blood pressure, a family history of coronary or other atherosclerotic disease before age 55, chronic lower right groin spasms, colon spasms, and chronic low back pain. This participant was overweight by observation, but her actual weight was not included. Analysis of the daily logs revealed the following information. During week one she reported taking pain medication before bedtime on day one. In week two, she complained of having difficulty breathing and increased backache; she took Zantac on day one and Seldane on days six and seven. Daily stress for the first two weeks was reported as a score of one or two. This participant took antibiotics for an upper respiratory infection during week three. During week four, she ran out of hormone medication on day five, but resumed taking them on day on day seven. A

decreased appetite on days four through six was reported. During this week she recorded her highest level of stress (seven) on day six. She began taking ginseng and fiber on day six and reported a decrease in appetite all week. She didn't provide an explanation for the addition of the ginseng, although it is mentioned in the literature as a homeopathic supplement used to lessen hot flashes. This participant reported eight days (14% of the days) of being bothered by hot flashes in the initial eight weeks. Week seven, she reported a decrease in the amount of pain medication she was taking; and complained of exhaustion, going to bed by eight o'clock the night of day seven. In week eight she reported taking no hormone medication from day one through day six, but resuming on day seven. Her mean daily symptom score for the eight week was 6, compared with an overall mean for the first eight weeks of 5.59.

Exercise began in week nine. She was instructed to walk at a perceived rate of exertion of 13 (moderately hard) and within her target heart rate (135 to 155 beats per minute), at least 20 minutes, three times per week and to increase the duration of walking to be at least 45 minutes, three times per week by week three. During week nine nothing was recorded in the daily log as being unusual, she did report feeling better overall. The average symptom score for this week was 2.3, below both the mean for the initial eight weeks (5.59) and the mean for the second eight weeks (5.17). In week ten, there was a dramatic increase in the symptom scores with a mean of 6.1. Symptoms noted during this week were aches and pains, backache, depression, diarrhea, fatigue, forgetfulness, headaches, heavy menstruation, hot flashes, and

irritability. She documented in her log about difficulties at work, including a yearly evaluation with her employer. Her daily mean increased slightly during week eleven to 6.7. Continued problems at work were documented in addition to taking Seldane for a “stuffy head.” The mean for week 12 decreased to 4.9, during this week she reported feeling better and did not comment on anything in regard to her employment.

In week 13 she complained of being more tired than usual which she attributed to an increase in headaches during the week. She reported taking Tylenol (an analgesic) for headaches on days 1 through 7 without much relief. In week 14 she reported headaches only on day seven, which continued into days 1 and 2 of week 15. She documented in her log about being particularly tired and about having a great deal of activities to attend outside of her home that week. During week 15 her mean daily symptom score was 4.7 and during week 16 her mean score was also 4.7.

As documented in the daily log, this participant walked three times per week during the second eight weeks. Initially participant one walked for a duration of 20 minutes at each session, beginning week three she began walking 45 minutes each time, and by week five she was walking 60 minutes at each session. She recorded ratings of perceived exertion from 11 (fairly light) to 15 (hard). Greater than 75% of the time she recorded a perceived exertion of 13 (somewhat hard). This individual walked with the researcher 80% of the time, the remaining 20% of the time she walked alone, with friends or family.

Prescribed medications taken were Prempro (for the vasomotor symptoms of perimenopause), Zantac (for gastroesophageal reflux), and Seldane (for respiratory congestion). Zantac is generally taken daily, for several weeks at a time, as opposed to the one-time dose that this participant took (week two, day one). Seldane was only taken on days six and seven of week two. Both of these medications can cause dizziness, however, neither of the medications were taken more than two days the entire study. Compliance regarding the administration of Pempro was not ascertained. As noted in the daily log, she did not take her hormone medication during week four, days five and six, and in week eight, days one through six; however, the incidence of hot flashes was higher in during the intervention phase than in the initial eight weeks (10 and 8 respectively).

The symptom by symptom raw data for Participant Number One is provided in Table 13 including the frequency and percent of time experienced for each symptom. During the entire 112 days this participant indicated both aches and pains and backache daily. During the first eight weeks she indicated the presence of depression 14 times, or 25% of the time. The largest period of time without an indication of depression was 14 days. Diarrhea was marked in clusters of two to four days, with no more than nine days between episodes. Difficulty concentrating seemed to coincide with the frequency of headaches. There was only one time when she marked headaches but did not also mark difficulty concentrating. All five times that she marked dizzy she also marked headaches.

Table 13

Participant One: Comparison of Symptom Frequency, Pre- and
Post-Intervention

Symptoms	Pre-Intervention		Post-Intervention	
	Frequency	% of Time	Frequency	% of Time
Aches and Pains	56	100%	56	100%
Backache	56	100%	56	100%
Depression	14	25%	12	21%
Diarrhea	15	27%	12	21%
Difficulty Concentrating	13	23%	15	27%
Dizziness	5	9%	4	7%
Fatigue	37	66%	32	57%
Feelings of "Losing My Mind"	6	11%	9	16%
Forgetfulness	10	18%	12	21%
Headaches	24	43%	20	36%
Heavy Menstruation	14	25%	12	21%
Hot Flashes	8	14%	10	18%
Irritability	10	18%	11	20%
Nervous Tension	4	7%	3	5%
Night Sweats	0	0%	0	0%
Pins and Needles	1	2%	0	0%
Rapid Heart Rate	0	0%	0	0%
Shortness of Breath	14	25%	10	18%
Trouble Sleeping	3	5%	3	5%

Next to “aches and pains” and backaches, fatigue was the most frequently marked symptom (37 times, or 66%). The patterns for feelings of “losing my mind” and forgetfulness coincided with difficulty concentrating. Heavy menstruation was marked 14 times (25% of the time), which is high when considering the impact this symptom can have on one’s day to day routine. Irritability was only mentioned 10 times, and it was accompanied by fatigue on every occasion. With the exception of one time (day 37), nervous tension also occurred in the presence of fatigue. “Pins and needles” was only marked on day nine. She indicated a fair amount of shortness of breath, on days 11 to 15, 33, 35, 40, 41, 43, 46, 48 and 50. However she documented in her log during the same time periods having problems breathing, taking Seldane (an antihistamine), Robitussin-CF (an expectorant and decongestant), and an unnamed antibiotic. She also indicated being “out of Chromion,” (an antiasthmatic, antiallergic medication) during the week of days 33 and 35. The presence of the symptoms was validated by the daily log entries; however, a casual relationship between being perimenopausal, and the symptoms can not be ascertained. She had relatively little incidence of trouble sleeping which coincided with the fact that she did not report any night sweats, often the reason for difficulty sleeping in perimenopausal women.

For the second eight weeks, this participant had five symptoms which remained the same in frequency (“aches and pains”, backache, night sweats, rapid heart rate, and trouble sleeping); nine symptoms decreased, and five

symptoms increased in frequency. The greatest decrease in frequency was seen in the symptom fatigue, which decreased in frequency by five. The increases in frequency ranged from one to three, for "difficulty concentrating," feelings of losing my mind," forgetfulness, hot flashes, and irritability. There was relatively little change in the symptoms from the pre- to post-intervention phases. The incidence of depression decreased from 14 to 12, or 21%, with the greatest period without this symptom being the last 20 days of the study. Diarrhea also decreased from 15 to 12, with the greatest period of time without this symptom being nine days, and with the symptom occurring primarily in episodes of two days at a time. She continued to indicate a moderate amount of aches and pains and backache daily. Shortness of breath was indicated on days 71, 72, 73, 74, 85, 86, 90, 92, 93, and 99, and was supported by documentation in her log of taking Seldane during these days. Figure 6 portrays the weekly summed symptom scores for participant number one. The post-intervention series does not differ significantly from the pre-intervention series, with the exception of the low summed score noted for week nine.

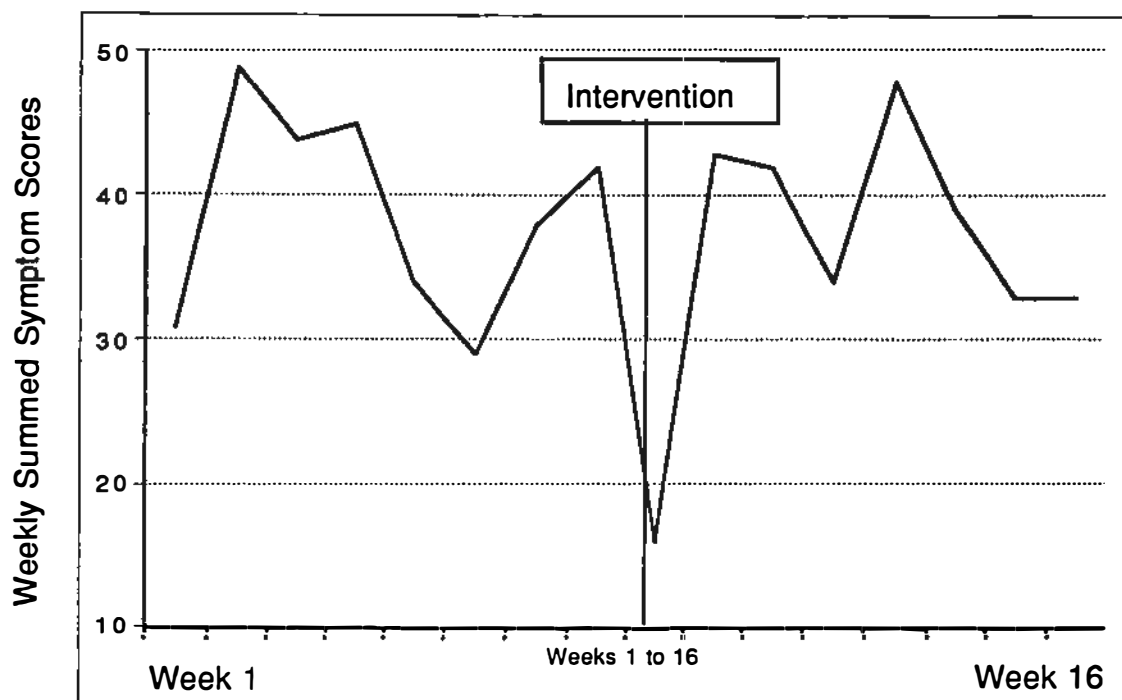
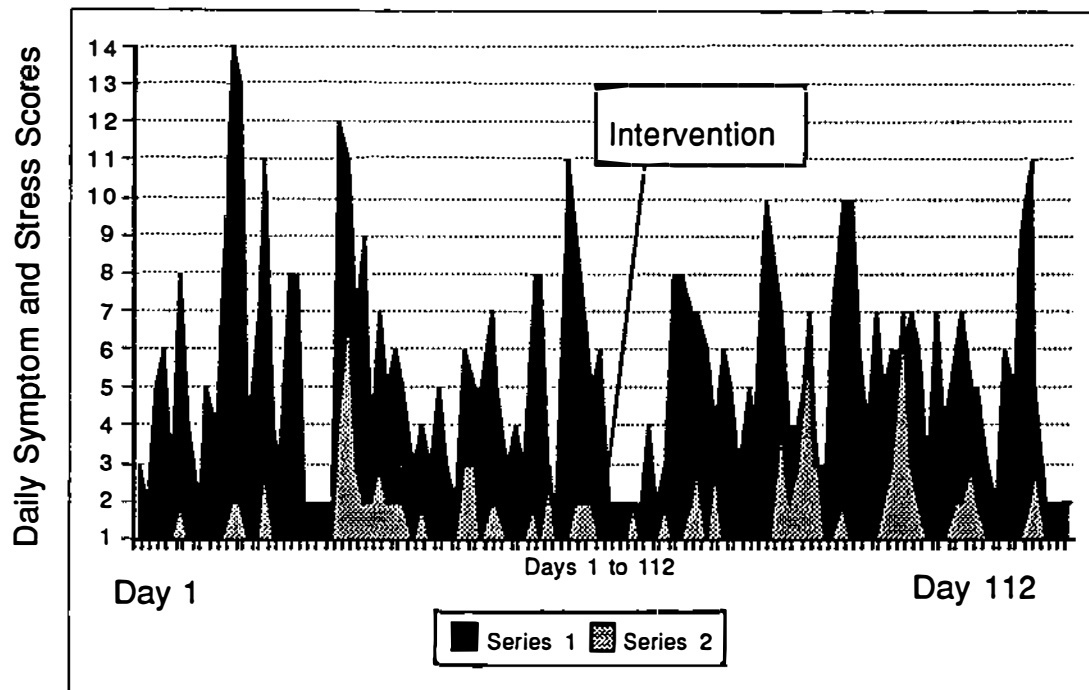


Figure 6. Participant One: Weekly Summed Symptom Scores Over 16 Weeks

Figure 7 compares the patterns of the daily symptom and stress scores.



Series 1 = Daily Symptom Scores
 Series 2 = Daily Stress Scores

Figure 7. Participant One: Comparison of Daily Symptom and Daily Stress Scores Over 112 Days

This participant consistently scored low on the daily stress scores, with a mean stress score of 1.6 for the initial eight weeks and 1.7 for the second eight weeks. This visualization must be interpreted with care however, because the total possible score for stress was only seven and the highest symptom score documented was 14, meaning that the two scores were not documented on the same scale. It appears that the two scores mimic each other; spikes in the stress score correlate with spikes in the symptom score. Overall she

indicated her daily level of stress as relatively low on the seven point scale. Her scores ranged from one to seven, with a frequency of 33 (59%) for a score of one and a frequency of one for a score of seven over the initial 56 days. The daily stress score of seven was accompanied by a symptom score of 11 (above her average of 5.59).

The time-series data were analyzed using the BMDP Time-Series statistical software. The plot for participant one's perimenopausal symptoms time-series is provided in Figure 8.

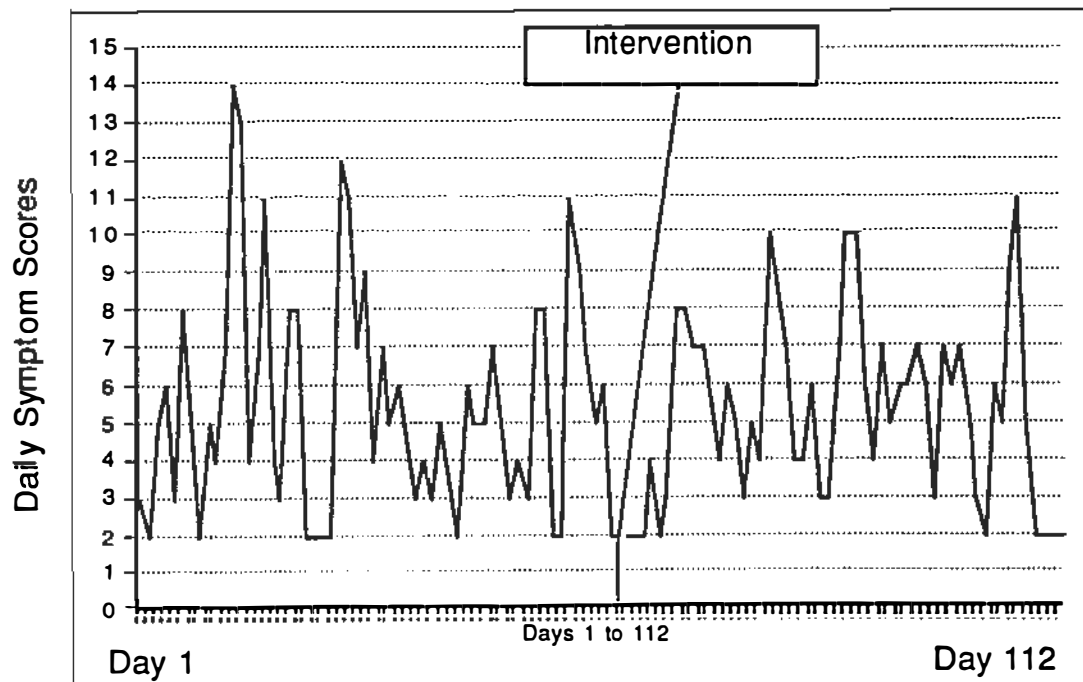


Figure 8. Participant One: Daily Symptom Scores Over 112 Days

As seen in this figure, the higher peaks of daily symptoms occurred during the initial eight weeks, particularly days 12, 13, and 25. During the first week of the intervention, the symptom scores were two every day except for day six, which was four, this was the longest period of time of having consecutive scores of two. The mean score for this week was 2.29, with the mean score for the first eight weeks being 5.59 and for the second eight weeks being 5.17. Other than this finding, the series for the second half does not appear remarkably different than the series for the first half. Summing the scores by week revealed similar patterns, showing little variation for the series from the first to the second eight weeks (Figure 6, page 93).

After examining the series for obvious patterns, the next step in modeling data with time-series analysis is to determine the stationarity of the series (Cook & Campbell, 1979). This is generally accomplished through examination of the autocorrelation function (ACF). The ACF provides a correlation of the series with it's own prior values at various lags. Correlation in a stationary series dies out exponentially. Correlation in a non-stationary series deteriorates slowly, generally having significant correlations for greater than six lags, which in this study would be the equivalent of five days. In a non-stationary series, what happened long ago is more important than what happened yesterday in predicting the value of the variable at any given time. The plot of the ACF typically provides the lags at which the series is being compared with itself, the correlation between the two values, and a graph indicating which lags have significant

autocorrelations. Significant autocorrelations are determined by visually inspecting the graph in order to identify any lags which lie outside of the significance parameters, or two standard deviations. The software package identifies the correlations which are significant. For participant one, the ACF revealed one significant spike at lag one with no other significant spikes. The correlation between the value at time t and the previous value was 0.42 (Table 14); the correlation between the value at time t and the value at $t - 2$ was 0.06. This information indicated that the correlations died out quickly, meaning that the value at time t was most highly correlated with the previous value and that the correlations with all other values deteriorated quickly.

Table 14

Participant One: Autocorrelation Function of Daily Symptom Scores Over 112 Days, For 6 Lags

Lag	Correlation
1	0.42*
2	0.06
3	0.03
4	-0.02
5	0.03
6	0.02

Note. * indicates significant correlations.

The second step in the modeling process is to determine the tentative ARIMA model. The acronym ARIMA stands for autoregressive (AR), integrative (I), moving average (MA). In an AR model the value at time t is the coefficient ϕ times the value at time $t - 1$ plus the error, or disturbance, at time t .

$$\text{Value}_t = \phi(\text{Value}_{t-1}) + E_t$$

The coefficient ϕ gives an indication of how strongly each value depends on the preceding value. In integrative models, there is a cumulative effect of a process. In the long term the “average level of an integrated series might not change, but in the short term values can wander quite far from the average level purely by chance (SPSS-X Trends, 1988, p. B-32). An ARIMA (0,1,0) model is also called a random walk, where each value has a perfect recall of the previous value, but only of the previous value.

$$\text{Value}_t = \text{Value}_{t-1} + \text{disturbance}_t$$

A random walk leaves only white noise in the autocorrelation after differencing. In moving average models, each observation is determined by the average of the current disturbance with one or more previous disturbances.

$$\text{Value}_t = E_t + \phi(E_{t-1})$$

Conceptually, one would hypothesize that the process influencing the bothersomeness of perimenopausal symptoms may be autoregressive. In an autoregressive model, any value in the series “is a linear function of the preceding value or values” (SPSS-X Trends, 1988, p. B-31). That is, one would

believe that the level of bothersomeness of symptoms experienced on any given day would be related to the level of symptoms experienced on the previous one or two days. In a first-order autoregressive process only the value immediately preceding the identified value is utilized, or considered the most important factor in predicting the value at time t . In a second-order autoregressive process, the two preceding values are used. The autoregressive model makes sense conceptually because it is accepted that the symptoms of perimenopause are in part a result of declining levels of estrogen. The serum level of estrogen at time t would be a function of the serum level of estrogen at time $t-1$. Additionally, women using a self-rating symptom checklist, retain a memory of the symptoms of the previous day ($t-1$) thus influencing the score at time t (Taylor, 1990). In other words, there is a cumulative response of memory from the previous days responses. The estimated parameters coefficient indicate how strongly the value at time t is depends on the preceding value.

The ACF and PACF of the entire series (data points 1 through 112) were examined in order to develop a tentative ARIMA model. The autocorrelation function and the partial autocorrelation function are utilized as a starting place to determine the ARIMA model. Generally, for an autoregressive model the ACF dies out exponentially, and the PACF has one or few spikes.

For the moving average model the ACF has a spike or spikes and the PACF dies out exponentially. In a mixed model, one in which there is an AR and a MA component, both the ACF and the PACF die out exponentially. Initially the model was identified as an ARIMA (1,0,1) because both the ACF and PACF declined rapidly, with the PACF having a significant spike at lag 1. Using the ARIMA command, the statistical package estimated the parameters of the model, the third step of the modeling process. The parameters were estimated as 0.73 for the moving average (MA) component and 0.99 for the autoregressive component (AR), with significant t-ratios for both parameter estimations (11.25 and 409.99 respectively). The residual mean square, defined by Dr. H. Clarke (personal communication, October, 1995) as the average size of the residuals, was 7.64. The Box-Ljung Q statistic was also utilized during the diagnostic phase. The SPSS-X Trends manual (1988) recommends examination of the Box-Ljung Q statistic (LBQ) at about one quarter of the sample size (or at lag 28 in a sample of 112 data points); according to Dr. H. Clarke (personal communication, October, 1995), the general rule to follow is to have an LBQ of less than 30 at 20 lags. The LBQ is an estimate of how much information is left unexplained; it is a form of chi square goodness of fit. This number should not be significant. The LBQ statistic was 35 at lag 20. The autocorrelation of the error series was examined in order to determine the accuracy of the model. The error series had one significant spike at lag one, indicating that it was significantly different from zero. After the modeling process, it is preferred to have the ACF of all the

residuals be insignificant, or in other words, not statistically different than white noise. The spike on the ACF of the residuals, the LBQ of 35 at lag 20 and the MA parameter (0.99) indicated the need to reject this model and attempt another model. According to Dr. McCleary (personal communication, March, 1997) the MA high parameter estimate (0.99) may indicate the need to difference the series even though the original ACF of the series appeared stationary.

An ARIMA (1,1,0) model, or an autoregressive, integrative model, was next attempted with the series. This model serves to difference the data, thus making an unstationary series, stationary. The results however were unsatisfactory. The AR parameter estimate was 0.40, with a t-ratio of 4.57; the LBQ was 41 at 20 lags and the ACF of the residuals showed a significant spike at lag two. The rise in the LBQ indicated that less of the series was explained than in the original model, the spike on the ACF of the residuals was also larger than the original model. The third model attempted was an AR1, or (1,0,0) model. The diagnostics for this model revealed an AR estimate of 0.26 with a t-ratio of 2.76; an RMS of 7.14 and an LBQ of 26 at 20 lags. The ACF of the residuals had a marginal spike at lag two and the (1,0,0) model was accepted with an AR parameter of 0.26.

Next the series was examined utilizing the intervention as a dichotomous "dummy" variable. For days 1 through 56 the variable was coded zero, for values greater or equal to 57 the variable was coded one. The AR parameter was estimated as 0.71 with a t-ratio of 0.73, and the

intervention parameter was estimated as 0.83 with a t-ratio of 1.66. The RMS was 7.27, and the LBQ was 22 at 20 lags. The ACF of the residuals indicated no significant findings. Table 15 provides the comparison of the pre- and post-intervention model analysis. The model with the intervention component was rejected based on the insignificant t-ratios on the parameter estimates. According to Dr. McCleary (personal communication, March, 1997), the intervention model is accepted if all of the estimate parameters have a significant t-ratios, or a t-ratio of greater than 1.96.

Table 15

Participant One: Comparison of Pre- and Post-Intervention ARIMA (1,0,0) Models for Daily Symptom Scores

	Pre-Intervention	Post-Intervention
RMS	7.14	7.27
LBQ @ 20	26.00	22.00
AR Parameter Estimate	0.26	0.70
t-ratio	2.76	0.73
Intervention Estimate	Not Applicable	0.83
t-ratio	Not Applicable	1.66

The plot for Participant One's daily stress time-series is provided in Figure 9. There was one incidence of the score of seven in the first eight weeks, with two scores of seven during the intervention phase. This participant indicated a score of one a total of 68 times (33 times in the pre-intervention phase, and 35 times in the post-intervention phase). No apparent trends or drifts appear in this series.

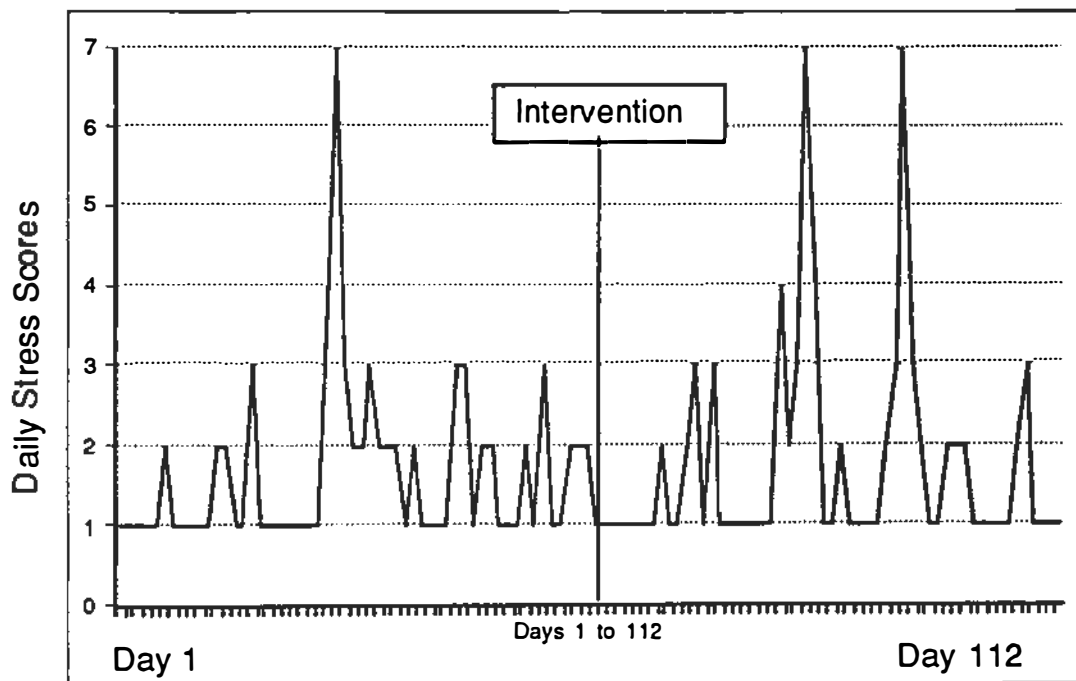


Figure 9. Participant One: Time-Series of Daily Stress Scores Over 112 Days

As with the symptoms time-series, this series was determined stationary because the ACF deteriorated within six lags (see Table 16). The autocorrelation was 0.38 at lag one and 0.06 at lag two.

Table 16

Participant One: Autocorrelation Function of Daily Stress Scores Over 112 Days, For 6 Lags

Lag	Correlation
1	0.38*
2	0.06
3	0.03
4	-0.05
5	-0.15
6	-0.10

Note. * indicates significant correlations.

An ARIMA(1,0,0), an ARIMA (1,0,1), with a spike at lag one, and ARIMA (1,1,0) models were attempted with the stress series. The ARIMA (1,0,0) model provided an estimated AR parameter of 0.80 with a t-ratio of 13.90, an RMS of 1.68, and an LBQ statistic 30 at lag 20. The ACF of the residuals indicated two marginal spikes at lags 1 and 2. This model was not accepted because of the two marginal spikes on the ACF of the residuals.

Next the ARIMA (1,0,1) model was attempted. The RMS was 1.59, the LBQ statistic was 43 at lag 20, and the estimated MA parameter was 0.8 with a corresponding estimated AR parameter of 0.99, indicating the possible need to difference the series. The ARIMA (1,1,0) model provided an AR estimated parameter of 0.24 with a t-ratio of 2.56, an RMS of 1.78 and an LBQ of 31 at 20

lags. The ACF of the residuals indicated one spike at lag 2. The ARIMA (1,1,0) model was accepted with an AR parameter of 0.24. This particular model provides the necessary differencing, indicated by the high MA and AR parameters, in addition to inferring that the value at time t is a linear function of its previous value.

After the model was accepted, the series was examined using the intervention as a dichotomous "dummy" variable. The results of the diagnostics for this model were an AR parameter estimate of 0.16 with a t -ratio of 1.60, and an intervention parameter estimate of 0.87 with a t -ratio of 3.39, the RMS was 2.03 and the LBQ was 25 at lag 20. There was a marginal spike at lag 2 on the ACF of the residuals. Table 17 shows the comparison of the diagnostics of the pre- and post-intervention models. The intervention model was not accepted because of the insignificant t -ratio for the AR parameter. Rejection of the intervention model was supported by the time-series for the daily stress scores depicted in Figure 9.

Table 17

Participant One: Comparison of Pre- and Post-Intervention ARIMA (1,1,0) Models For Daily Stress Scores

	Pre-Intervention	Post-Intervention
RMS	1.78	2.03
LBQ @ 20	30.00	25.00
AR Parameter Estimate	0.24	0.16
t-ratio	2.56	1.60
Intervention Parameter Estimate	not applicable	0.87
t-ratio	not applicable	3.39

This participant's pre-intervention time for the mile and one-half walk-run was 30 minutes. Using a formula provided by Brooks, Fahey, and White (1996) her estimated $\text{Vo}_{2\text{max}}$ was $19.6 \text{ ml}\cdot\text{kg}^{-1}\cdot\text{min}^{-1}$. The time on her post-intervention mile and one-half walk-run was 25 minutes, or $22.8 \text{ ml}\cdot\text{kg}^{-1}\cdot\text{min}^{-1}$ estimated $\text{Vo}_{2\text{max}}$. An improvement of 16.4% was demonstrated. Resting heart rate (beats/minute) pre-intervention was 80, and post-intervention was 74, showing a decrease of 7%.

Participant Number Two

This participant was a 45 year old married woman, employed outside of the home, full-time, as an licensed practical nurse in an intensive care unit, listing “some college courses” as highest educational level. She had been pregnant twice and had two children, ages 16 and 20. Combined household income per year was identified in the range of \$60,001-\$80,000. She listed irregular or infrequent menses over the past 12 months and was not on hormone replacement therapy. Significant health history included shortness of breath with mild activity, dizziness, and swelling of the ankles. She reported having symptoms associated with perimenopause for two to three years.

During week one of the study this participant reported losing her job on day seven, and only took scheduled Prozac (an antidepressant) on day two, at which time she took two doses. During week two, she reported day three as her last night of work. She also had two examinations at school on days five and seven. She resumed taking Prozac on a daily basis. In week three she had an examination at school on day one, with no other changes. No changes were reported in week four. Week five she reported that friends were commenting on how much happier she seemed since she had been laid off from the hospital. She also reported two “marathon shopping sprees” next to “feelings of losing my mind” in the symptom checklist and reported taking no Prozac all week. In week six she discontinued her Prozac; no other changes were noted. In week seven, day two, she reported eating seafood

with cajun spices, and she remained off of Prozac. During this week, she spent nine hours in the emergency room with on neighbor on day three, reporting a stress level of six on that day. During week eight, her father underwent surgery after being newly diagnosed with prostate cancer. The surgery revealed an inoperable condition. She reported missing her Maxide (to treat hypertension or edema) on days two and three and continued without the Prozac. Her husband's birthday was also this week, and she spent several days at her parents home taking care of her father, reporting sleep deprivation for 36 hours. She also inhaled more second-hand smoke than usual. During week eight she performed her mile and one-half walk-run, with a time of 36 minutes.

Exercise began in week nine. She was instructed to walk at a perceived rate of exertion of 13 (moderately hard) and within her target heart rate (135 to 155 beats per minute), at least 20 minutes, three times per week and to increase the duration of walking to be at least 45 minutes, three times per week by week three. In week ten, she reported feeling better and having more energy. In week 11, day two, she and her daughter adopted a wounded baby dove. She reported getting up at night to feed the bird, and arising earlier than usual for school. No changes were reported in week 12. Week 13 was quite eventful. On day two, she spent several hours in her physician's office waiting for an appointment. On day three she was NPO (receiving nothing by mouth) for a barium swallow. She gained seven pounds in two days because she didn't take her diuretic (Maxide) on days three and four. The baby bird got

sick on day seven. In week 14, the baby bird died on day one, and she reported feeling responsible. On day two of week 14, she was tearful all day because of the bird. Day three her brother, whom she hadn't seen in one year, was visiting. The whole time she was with him she reported being worried because she had school work to do. On day one of week 15 she started back on Prozac, 20 mg every other day. She also reported "losing it" at school. No changes were reported in week 16.

As documented in the daily log, this participant walked three times per week during the second eight weeks. Initially Participant Two walked for a duration of 20 minutes at each session, beginning week three she began walking 45 minutes each time, and by week five she was walking 60 minutes at each session. She recorded ratings of perceived exertion from 13 (somewhat hard) to 15 (hard). Greater than 75% of the time she recorded a perceived exertion of 13 (somewhat hard). This individual walked with the researcher 83% of the time, the remaining 17% of the time she walked alone, with friends or family.

The raw data revealed that in the initial eight weeks, one of the symptoms (night sweats) was not chosen at all. During the second eight weeks, she did not report any dizziness or night sweats, but did report the remaining 17 symptoms. As seen in Table 18, the most common symptom in the pre-intervention data was headaches, with a frequency of 48 (86% of the time). Five other symptoms were reported more than 50% of the time; pins and needles in hands and feet, with a frequency of 38 (68% of the time),

hot flashes with a frequency of 37 (66% of the time), fatigue, with a frequency of 35 (63% of the time), backache, with a frequency of 33 (59% of the time), and aches and pains in the joints, with a frequency of 32 (57% of the time). Three additional symptoms were identified between 25% and 49% of the time (sleep and rapid heart rate, both at a frequency of 16 or 25 % of the time, and difficulty concentrating at a frequency of 12, or 29%). In total, there was a frequency of 327 symptoms over the initial eight weeks. The average score for daily symptoms for the initial eight weeks was 7.4, with 33 days scoring less than the average, and the remaining 23 days scoring greater than the average daily score, with no days scoring zero for the daily checklist, and the range being two to fourteen.

Table 18

Participant Two: Comparison of Symptom Frequencies, Pre- and Post-Intervention

Symptoms	Pre-Intervention		Post-Intervention	
	Frequency	% of Time	Frequency	% of Time
Aches and Pains	32	57%	45	80%
Backache	33	59%	45	80%
Depression	4	7%	1	2%
Diarrhea	2	4%	1	2%
Difficulty Concentrating	12	21%	14	25%
Dizziness	5	9%	0	0%
Fatigue	35	63%	27	48%
Feelings of "Losing My Mind"	1	2%	12	21%
Forgetfulness	10	18%	3	5%
Headaches	48	86%	41	73%
Heavy Menstruation	0	0%	0	0%
Hot Flashes	37	66%	43	77%
Irritability	5	9%	1	2%
Nervous Tension	26	46%	15	27%
Night Sweats	0	0%	0	0%
Pins and Needles	38	68%	41	73%
Rapid Heart Rate	16	29%	10	18%
Shortness of Breath	7	13%	11	20%
Trouble Sleeping	16	29%	14	25%

During the intervention phase, the most frequently reported symptom was also headaches, with a frequency of 25 (45% of the time). Overall, 10 symptoms decreased during the intervention phase (refer to Table 18); seven symptoms increased in frequency (aches and pains in joints, backache, difficulty concentrating, feeling of losing my mind, hot flashes, pins and needles in hands and feet, and shortness of breath). Two symptoms, heavy menstruation, and night sweats remained the same (both at zero frequency). Although a decrease in frequency of depression was noted, the participant reported resuming the medication Prozac (an antidepressant) during the 15th week of the intervention. Overall frequency of symptoms during the second eight weeks was 327, an overall decrease of only three points (9%) during the intervention phase of the study. Average daily frequency of symptoms during this phase was 7.2% with 34 days scoring under this average, and the remaining 22 days scoring over the average daily score, not a significant change from the pre-intervention symptom frequencies. The range of symptoms for this phase was two to 15, not significantly different from the pre-intervention phase. Two days in this phase were scored as having zero symptoms.

The most frequently marked symptom for Participant Number Two during the initial eight weeks was headaches, (frequency equal to 48 times, or 86% of the time). One interesting finding was an increased incidence of aches and pains in the joints and backache beginning at day 26. Nothing recorded in the daily log suggested a reason for this finding. Difficulty concentrating,

dizziness and forgetfulness primarily occurred prior to day 35. This participant consistently reported hot flashes (37 times in the first eight weeks), although there was a 13 day period (day 34 to day 46) without any hot flashes. Irritability and nervous tension appeared several days in a row, as opposed to a scattered incidence in these two symptoms. In other words, nervous tension occurred from five to 18 days in a row, with a the longest period of time without this symptom being 14 days. At the beginning of the study, she reported several days of having trouble sleeping (13 times in the first 22 days); she then had a period of 27 days without this symptom. During the last week of the pre-intervention phase she had six days with symptom scores above the average daily symptom score of 7.4. Scores for this week were 12, 12, 11, 14, 5, 8 and 9, producing an average of 10.14 for this week. During this particular week the participant's father had surgery for cancer, during which time she stayed with him at the hospital. She then went with him to his house, leaving her family at home, in order to provide additional care for him. Her husband's birthday was also during this week. Figure 10 demonstrates the pattern of incidence for the symptom nervous tension. This symptom was present 26 times in the first eight weeks and 15 times in the second eight weeks, a decrease of 19%. As seen in this figure, the longest period of time without this symptom in the first eight weeks was 14 days; during the second eight weeks she was without this symptom for the initial 36 days, she marked this symptom 15 times in the remaining 21 days of the intervention phase.

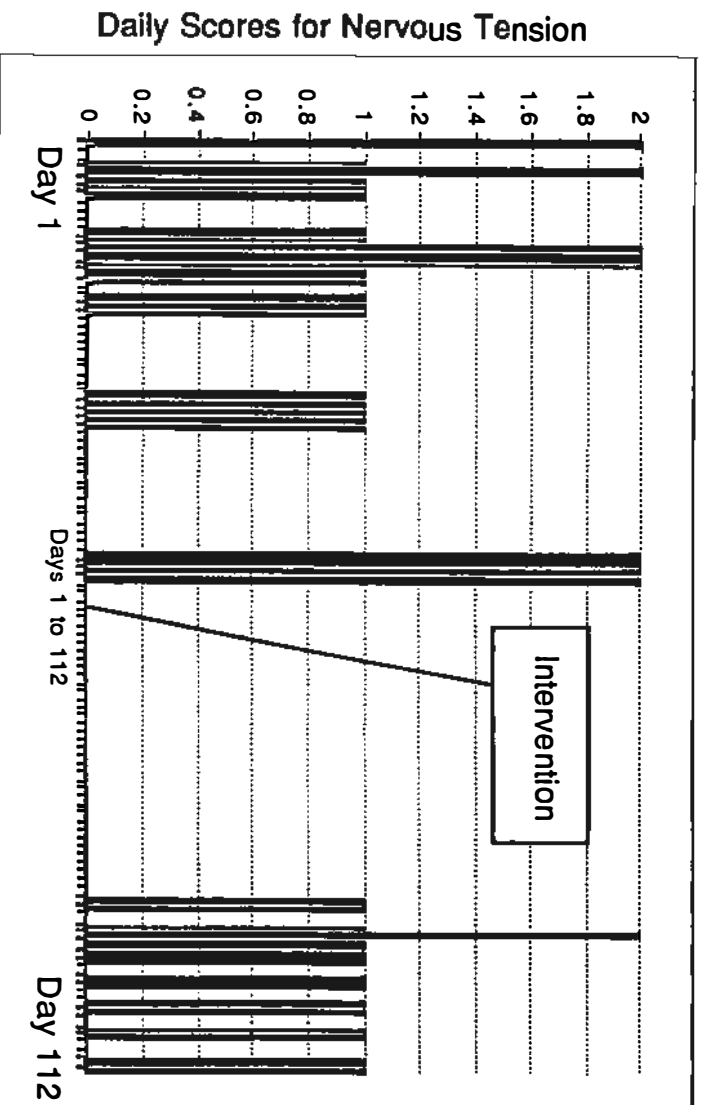


Figure 10. Participant Two: Bar Graph of the Symptom "Nervous Tension"
Over 112 Days

On day 92 (week 14) when she began marking the “nervous tension” symptom, she recorded in her daily log that their baby bird that they had been taking care of had died, she documented a great deal of concern regarding the bird, writing that she felt it was her fault that it died. She also voiced concerns about a visit from her brother, and her school responsibilities. Her stress score for this week ranged from three to seven, with an average of six for the daily score. She reported staying up late every night working on

reports for school. During week 15 she reported “losing it” at school; also at this time she resumed taking Prozac, 20 mg. every other day per recommendation of her physician. During the 16th week she did not report anything unusual. This participant had a similar pattern with the symptom “difficulty concentrating.” Noting a frequency of 12 in the initial eight weeks, and 14 times during the intervention phase. In the first half she only reported this symptom during the first 29 days; during the second half, she did not report the symptom until day 93, which closely corresponds with the symptom nervous tension.

A third, related, symptom which coincided with these two symptoms were the “feeling of losing my mind.” In the initial eight weeks she recorded this symptom only one time; during the intervention phase the incidence increased to 12 times, all noted in the last 16 days of the series. Fatigue showed a decrease of 15% in the post-intervention phase. As seen in Figure 11, the pattern of this symptom did not improve dramatically.

In summary, Participant Two had an increase of seven symptoms (37%) during the intervention phase of the study. Difficulty concentrating, feelings of losing my mind and irritability coincided in frequency and pattern of incidence. “Aches and pains in the joints” and backache increased from 57% and 59% in the first eight weeks to 80% for both symptoms during the intervention phase. This may indicate that the physical activity was irritating some preexisting condition. In terms of percent of time, fatigue decreased from 63% of the time in weeks one through eight to 48% of the time in weeks

nine to sixteen. The incidence of depression decreased from a frequency of four to one; however, she resumed taking Prozac during the 15th week of the study. She also had two days with a symptom score of zero, which did not occur at all during the first eight weeks.

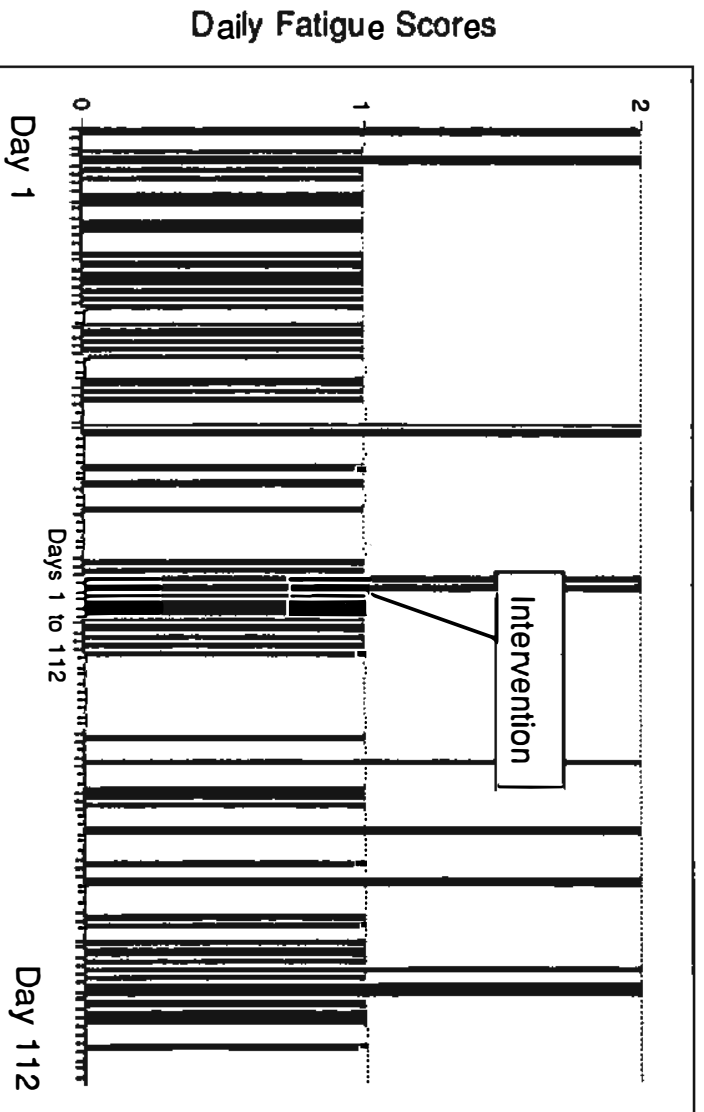
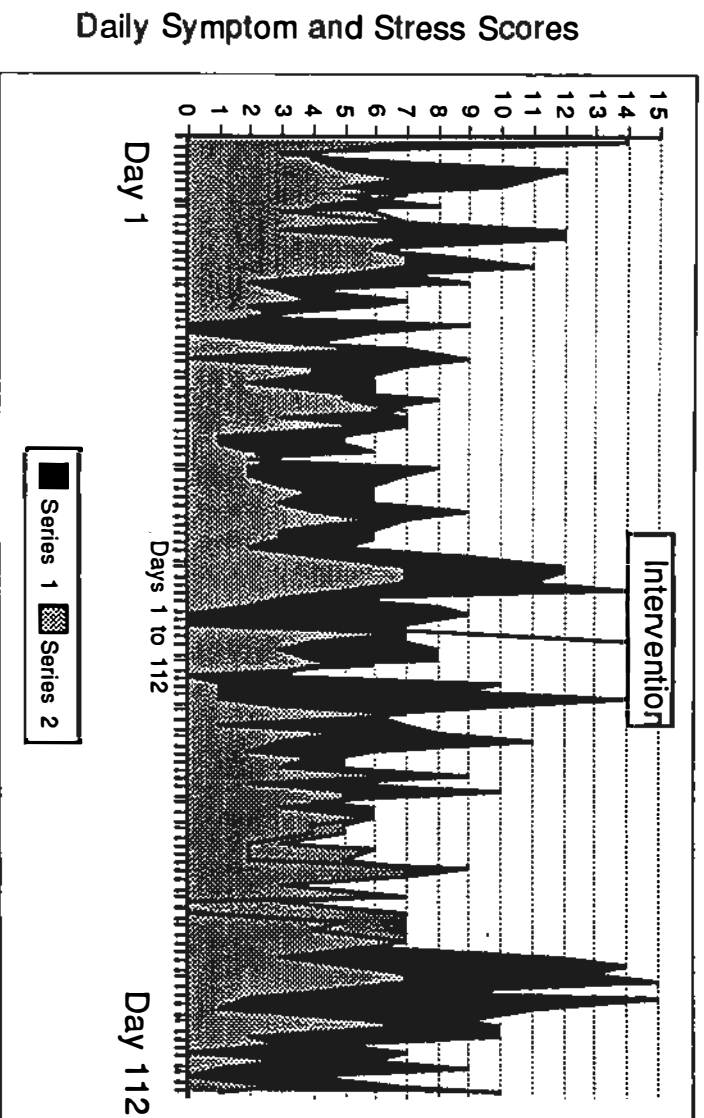


Figure 11. Participant Two: Bar Graph of the Symptom “Fatigue” Over 112 Days

Participant Two indicated a consistently higher daily level of stress than Participant One. Her range for the daily stress score was zero to seven, although the scale was one to seven. She also indicated several days with a level of stress of seven “plus” or as high as 10. Scores recorded higher than

seven were reduced to seven. Her pre-intervention and post-intervention scores were: mean of 4.0 and 3.98 respectively; median of 4.0 for both pre- and post-intervention scores; and the mode was bimodal for the initial eight weeks, at three and seven and at seven for the second eight weeks. The standard deviation for the first eight weeks was 4.56, and the coefficient of variation was 111; the standard deviation for the second eight weeks was 5.56, with the coefficient of variation equal to 160, indicating a great deal of fluctuation from score to score. Figure 12 depicts the relationship between the daily stress score and the daily symptom score for participant two.

During the second eight weeks, the series for daily symptom scores appears to be overshadowed by the series on daily stress scores, which indicates an increased daily stress score and a decrease in the daily symptom scores. Figure 13 provides the summed weekly time-series for Participant Two's symptom scores.



Series 1 = Symptoms

Series 2 = Stress

Figure 12. Participant Two: Comparison of Daily Symptom and Daily Stress Scores Over 112 Days

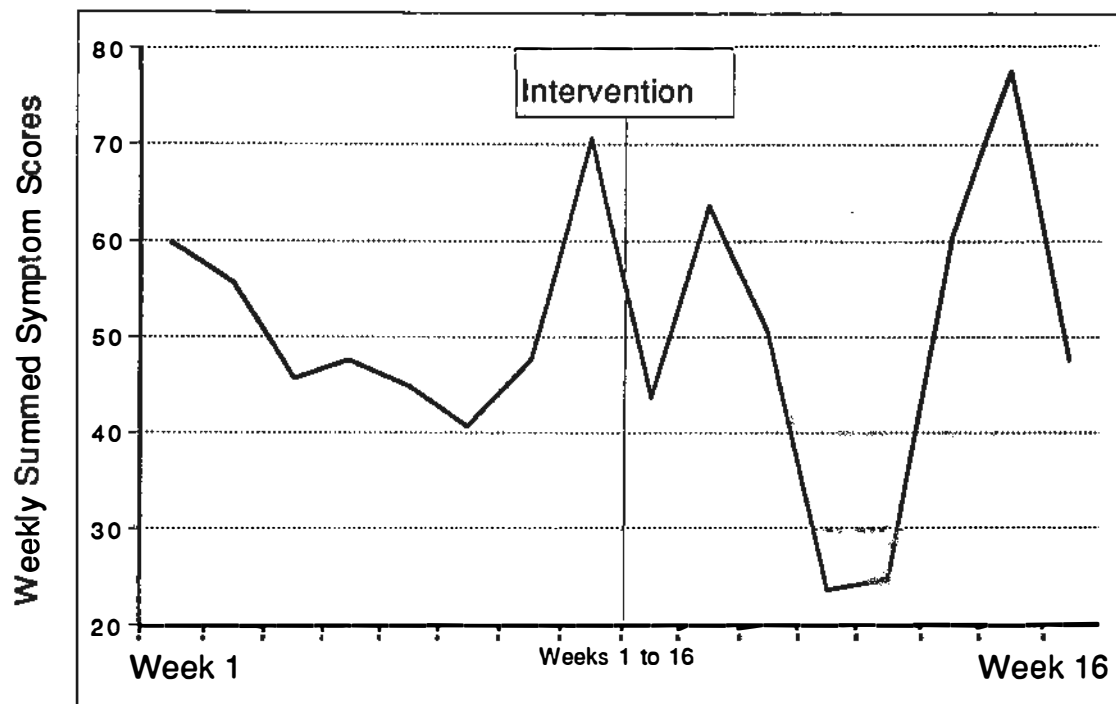


Figure 13. Participant Two: Weekly Summed Symptom Scores Over 16 Weeks

As seen in this figure, the weekly summed scores indicate a significant decrease over weeks 12 and 13, followed by a sharp increase in week 15. The first week of the intervention, demonstrated a decline from the previous week.

The plot for the time-series for Participant Two's perimenopausal symptoms is provided in Figure 14. It is not as easy to identify the decrease in symptoms in the daily time-series, but during the second eight weeks, she had

her only documented scores of zero, however, she also had her highest scores during this period of time.

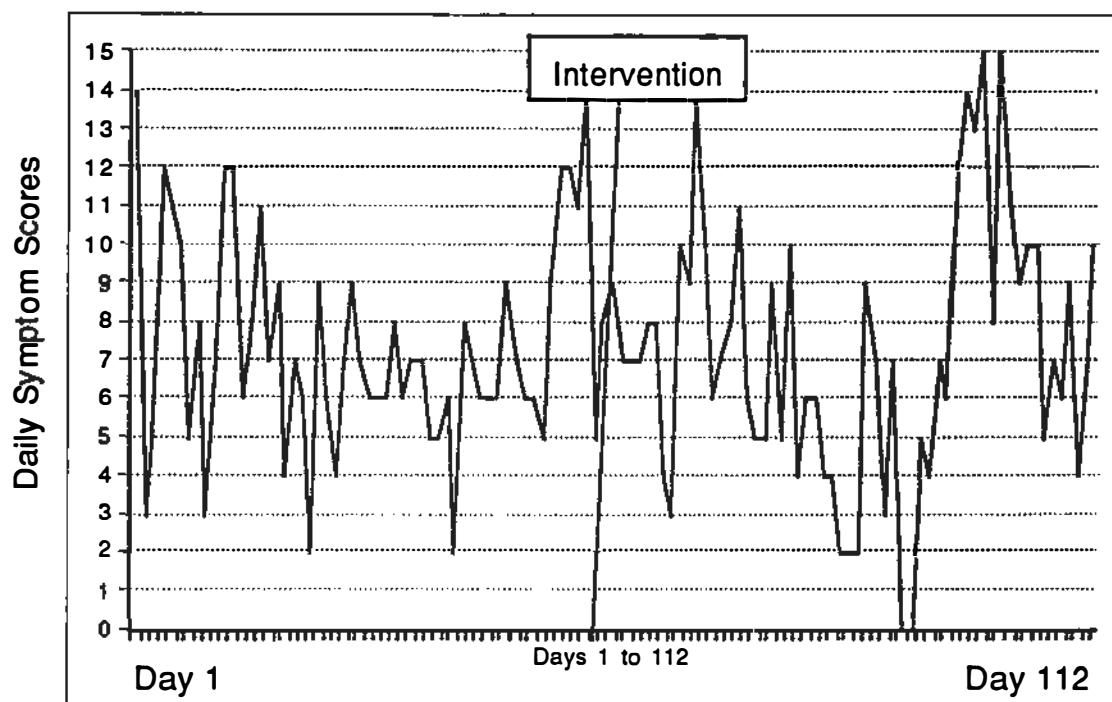


Figure 14. Participant Two: Daily Symptom Scores Over 112 Days

No trends or drift appear in the data. The second half of the series has the only scores of zero (recorded on days 89 and 90), but then is followed by an upward trend and a smaller downward trend. Stationarity was determined by examining the ACF of the entire series. The autocorrelation function died out within six lags, indicating stationarity. The correlation was 0.378 at lag one, 0.221 at lag two, 0.155 at lag three and -0.002 at lag four (see Table 19).

Table 19

Participant Two: Autocorrelation Function of Daily Symptom Scores Over 112 Days, For 6 Lags

Lag	Correlation
1	0.38*
2	0.22
3	0.15
4	-0.00
5	0.03
6	-0.05

Note. * Indicates significant correlations.

The ACF and PACF of the series were examined in order to develop a tentative ARIMA model. Initially the model was identified as an ARIMA (1,0,1) because both the ACF and PACF declined rapidly, with the PACF having a significant spike at lag 1. Using the ARIMA command, the statistical package estimated the parameters of the model. The parameters were estimated as 0.63 for the moving average (MA) component and 0.99 for the autoregressive component (AR), with significant t-ratios for both parameter estimations. The residual mean square was 9.42. The LBQ statistic was 18 at lag 20. The ACF of the error series was examined in order to determine the accuracy of the model. The error series was not significantly different from zero. The residuals were without pattern, meaning the residuals were white

noise. However, the high AR parameter was not reassuring. An AR parameter of 0.99 in a mixed model indicates the need to difference the series (McCleary, 1997). Next the ARIMA (1,1,0) model was attempted. Results of this model were a RMS of 10.07 an estimated AR parameter of 0.37 with a significant t-ratio LBQ statistic 17 at lag 20 with no significant spikes on the ACF of the residuals. The ARIMA (1,1,0) model was accepted with the AR (1) parameter equal to 0.37 because of the improved LBQ statistic, and because it was a more parsimonious model.

Next the data were reanalyzed utilizing a dichotomous "dummy" variable in order to determine the effectiveness of the intervention. Using the accepted ARIMA (1,1,0) model, the results were an RMS of 10.50; with the AR parameter estimated at 0.35 and an intervention parameter of 0.96, LBQ statistics of 16 at lag 20; and no significant spikes on the ACF of the residuals. Table 20 compares the pre- and post-intervention model analysis. The post-intervention model was found to be a better model than the pre-intervention model as evidenced by the significant t-ratios for both the AR and intervention parameters.

Table 20

Participant Two: Comparison of Pre- and Post-Intervention ARIMA (1,1,0) Model for Daily Symptom Scores

	<u>Pre-Intervention</u>	<u>Post-Intervention</u>
RMS	10.07	10.50
LBQ @ 20	17.00	16.00
AR Estimate	0.37	0.96
t-ratio	4.56	4.27
Intervention Estimate	Not Applicable	0.96
t-ratio	Not Applicable	7.38

The t-plot for Participant Two's daily stress time-series is provided in Figure 15. The overall pattern of the series including the intervention looks different, although not better than the initial eight weeks. There is an upward trend from approximately day 63 to day 104 with the series having lower scores for the final week.

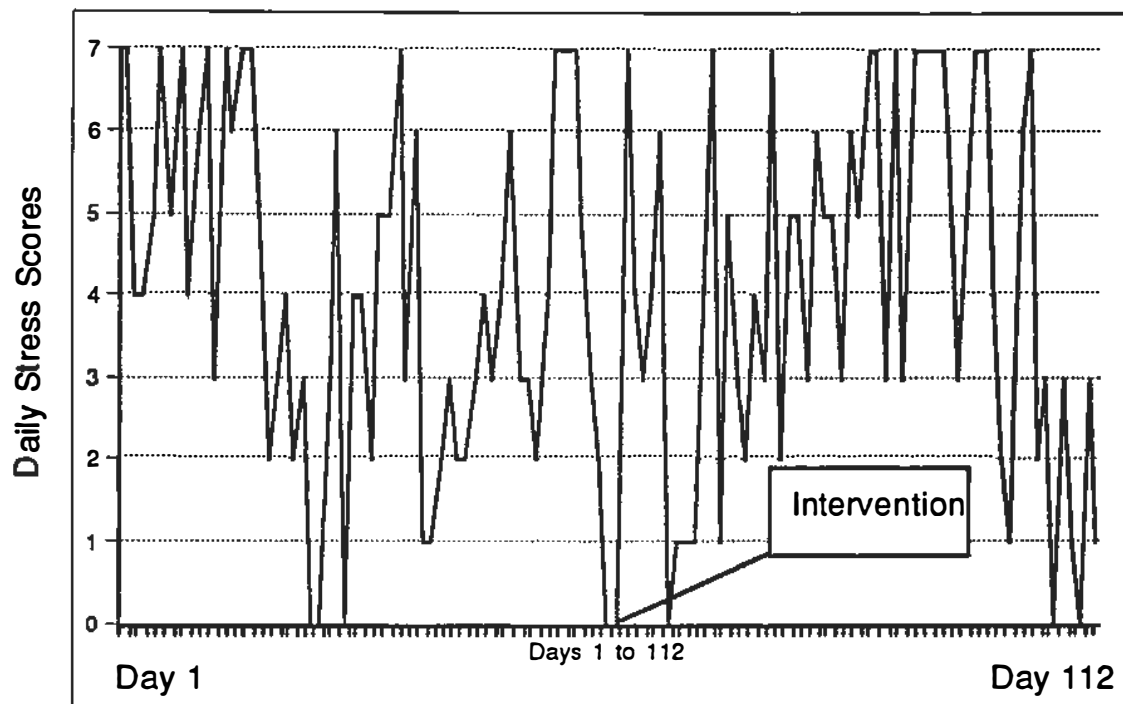


Figure 15. Participant Two: Time-Series of Daily Stress Scores Over 112 Days

As with the symptoms time-series, this series was determined stationary (see Table 21).

Table 21

Participant Two: Autocorrelation Function of Daily Stress Scores Over 112 Days, For 6 Lags

Lag	Correlation
1	0.31*
2	0.25
3	0.15
4	0.08
5	0.13
6	0.14

Note. * Indicates significant correlations.

This series was initially modeled with an ARIMA (1,0,1) model, with the spike at lag 1. This model was rejected because of a high AR estimated parameter. The MA parameter was estimated at 0.72, the AR parameter at 0.99, both with significant t-ratios, an RMS of 4.61 and an LBQ statistic of 18 at 20 lags. Next the ARIMA (1,1,0) model was attempted since the high AR parameter suggested the need to difference the series. The AR parameter was 0.46 with a t-ratio of 5.43, an RMS of 5.4 and an LBQ of 24 at 20 lags. The autocorrelation of the residuals revealed a significant spike at lag two. This model was accepted with an AR parameter of 0.46. Next the intervention was incorporated as a dichotomous "dummy" variable providing an AR parameter estimate of 0.44 and an intervention parameter estimate of 1.01,

both with significant t-ratios. The intervention model was rejected based on the intervention parameter being greater than the absolute value of one.

This participants pre-intervention time for the mile and one-half walk-run was 36 minutes. Her estimated $\text{VO}_{2\text{max}}$ was $16.9 \text{ ml}\cdot\text{kg}^{-1}\cdot\text{min}^{-1}$ (Brooks, Fahey, & White, 1996). The time on her post-intervention mile and one-half walk-run was 27 minutes, producing $21.4 \text{ ml}\cdot\text{kg}^{-1}\cdot\text{min}^{-1}$ as the estimated $\text{VO}_{2\text{max}}$. An improvement of 26% was demonstrated. Resting heart rate (beats/minute) pre-intervention was 76, and post-intervention was 57, showing a decrease of 25%.

Participant Number Three

This participant was a 54 year old married woman, employed outside of the home, full-time, as a registered nurse, listing “graduate degree” as her highest educational level. She had been pregnant four times and had five children, ages 16, 16, 18, 31, and 34. Combined household income per year was identified in the range of \$40,001-\$60,000. She listed no menses over the past 12 months and was on Progestin and Estraderm Patch as hormone replacement therapy. There was no significant health history and no routine medications (other than HRT). She reported having had symptoms associated with perimenopause for 10 years.

For the first week this participant reported a decreased appetite on days one, three and seven. She also recorded a score of seven for stress for every day. She commented on extreme stress due to “intrapersonal” problems.

Nothing was recorded as change in week two; however, she recorded her level of stress again as seven for every day. No changes in week three were noted. Only two days were scored as seven on daily stress, the rest ranged from four to six. No other changes were listed for weeks four through eight. During week nine she began the walking intervention. She was instructed to walk at a perceived rate of exertion of 13 (moderately hard) and within her target heart rate (130 to 148 beats per minute), at least 20 minutes, three times per week and to increase the duration of walking to be at least 45 minutes, three times per week by week three.

There were no recorded changes until week 11 when she reported taking an antihistamine and decongestant for sinus and allergies, beginning on day seven. During weeks 12 through 14 she continued taking the antihistamine and decongestant daily. No changes were recorded in weeks fifteen or sixteen.

As documented in the daily log, this participant walked three times per week during the second eight weeks. Initially participant three walked for a duration of 20 minutes at each session, beginning week three she began walking 45 minutes each time, and by week five she was walking 60 minutes at each session. She recorded ratings of perceived exertion of 13 (somewhat hard) 100% of the time. This individual walked with the researcher 78% of the time, the remaining 22% of the time she walked alone, with friends or family.

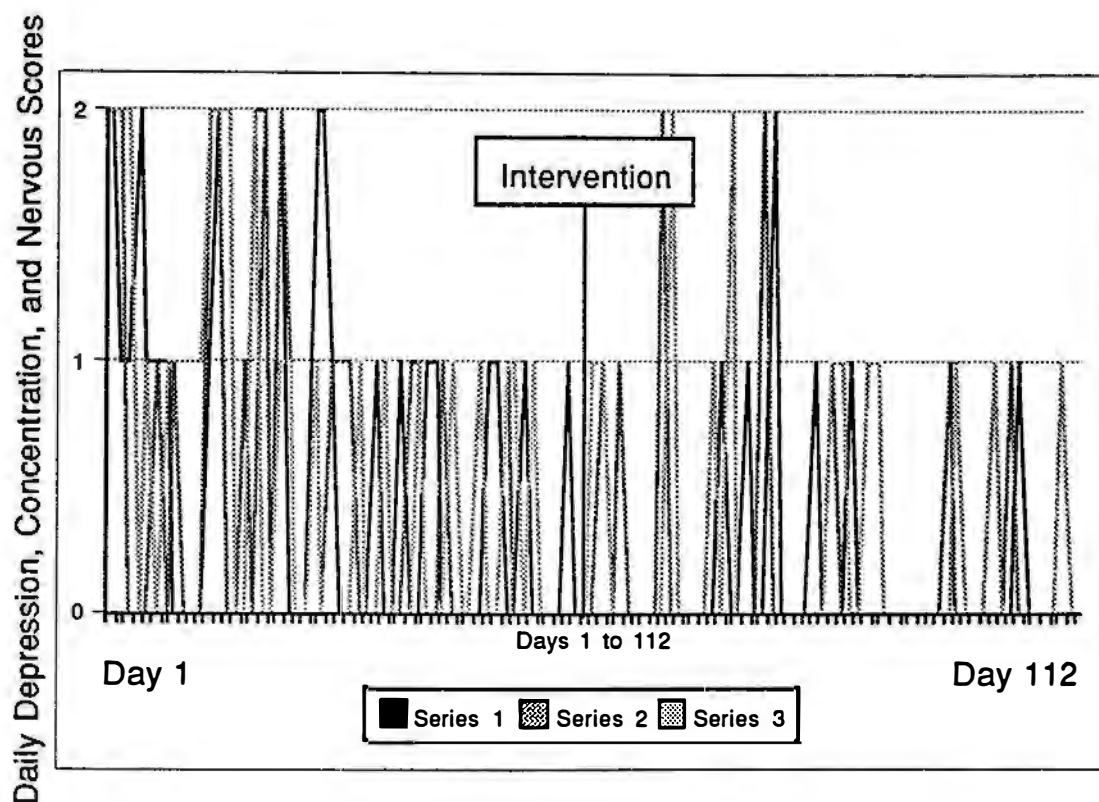
The raw data revealed that in the initial eight weeks, this participant did not choose two of the nineteen symptoms on the daily checklist (“pins and needles” in hands or feet and shortness of breath). During the second eight weeks, she did not report any heavy menstruation or rapid heart rate, but did report the remaining 17 symptoms. As seen in Table 18, the most common symptom in the pre-intervention data was headaches, with a frequency of 35 (63% of the time). This was the only symptom reported more than 50% of the time. Symptoms noted between 25% and 49% of the time were aches and pains (frequency of 14, 25%), depression (frequency of 24, 43%), diarrhea (frequency of 13, 23 %), irritability (frequency of 16, 29%), nervous tension (frequency of 25, 45 %), and trouble sleeping (frequency of 25, 45%). The range of scores were one to 15, with no days receiving a score of zero, and only two days receiving a score of 1. Average daily symptom score was 4.9, with 34 days under 4.9 and 26 days over 4.9. Total summed points for this phase were 276.

Table 22

Participant Three: Comparison of Symptom Frequency, Pre- and Post-Intervention

Symptoms	Pre-Intervention		Post-Intervention	
	Frequency	% of Time	Frequency	% of Time
Aches and Pains	14	25%	7	12.5%
Backache	11	20%	5	9%
Depression	24	43%	6	11%
Diarrhea	13	23%	6	11%
Difficulty Concentrating	19	34%	7	12.5%
Dizziness	1	2%	1	2%
Fatigue	11	20%	12	21%
Feelings of "Losing My Mind"	4	7%	2	4%
Forgetfulness	5	9%	9	16%
Headaches	35	63%	25	45%
Heavy Menstruation	2	4%	0	0%
Hot Flashes	2	4%	2	4%
Irritability	16	29%	12	21%
Nervous Tension	25	45%	11	20%
Night Sweats	5	9%	4	7%
Pins and Needles	0	0%	1	2%
Rapid Heart Rate	5	9%	0	0%
Shortness of Breath	0	0%	6	11%
Trouble Sleeping	25	45%	21	38%

During the intervention phase, the most frequently reported symptom was also headaches, with a frequency of 25 (45% of the time). Overall, 13 symptoms decreased during the intervention phase (refer to Table 18); three symptoms increased in frequency (fatigue, forgetfulness, pins and needles of hands and feet, and shortness of breath). The participant did report being bothered by allergies for several weeks during the second eight weeks, which could account for the increase in shortness of breath. Two symptoms, dizziness, and hot flashes remained the same (one time, and two times respectively). The range of scores was 0 to 11, with the number of days with a score of zero being one, and the number of days scoring 1 as 13. The average daily symptom score for the intervention phase was 2.9 (decreased from 4.9 in the pre-intervention phase), with 30 days scoring less than 2.9 and the remaining 26 scoring greater than 2.9. Total summed points for this phase were 154, compared to the initial sum of 276 points (a decrease of 44%). Symptoms that decreased by more than 50% were depression, decreased by 75%; difficulty concentrating, decreased by 63%; and nervous tension, decreased by 56%. In terms of percent of decrease, headaches was listed next with a decrease of 29%. Figure 16 provides the time-series for the three symptoms that demonstrated the greatest decreases during the intervention phase. These three symptoms had less frequency of the score two, and overall appeared to be less frequent during the intervention phase. Of the symptoms that increased in frequency, none of them increased by more than a frequency of six (shortness of breath).



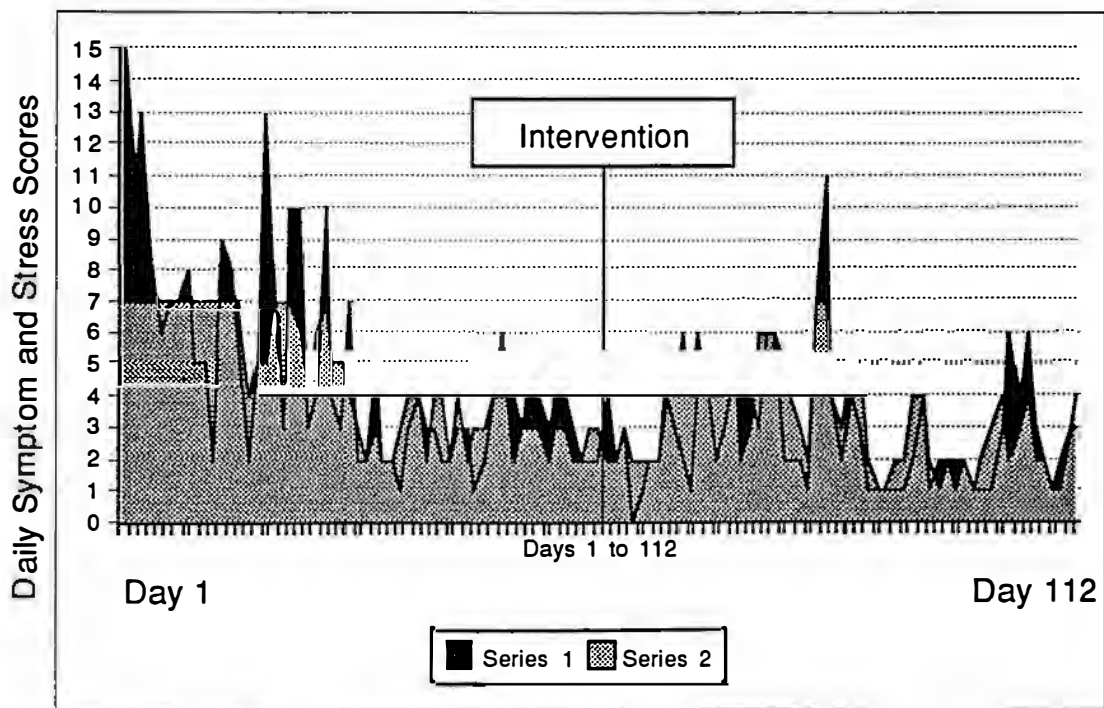
Series 1 = Depression
 Series 2 = Difficulty Concentrating
 Series 3 = Nervous Tension

Figure 16. Participant Three: Time-Series for the Symptoms “Depression, Difficulty Concentrating, and Nervous Tension” Over 112 Days

Participant Number Three scored the maximum amount (seven) on the stress score for the initial 14 days, her symptom scores during this week were also higher than later in the series. Week one presented with an average of 9.6 (the mean for the series was 4.9), and week two had a mean of 6.14. Additionally, this participant scored her highest symptom score (15) on day

one of the first week. This was the only time a score that high was documented. "Headaches" was the most frequent symptom for the series (35 times, or 63% of the time); unfortunately, there was no information regarding the frequency of symptoms prior to perimenopausal status.

Figure 17 depicts the relationship between the daily stress score and the daily symptom score for Participant Three. The first two weeks of high stress are obvious on this series. The daily symptom and the stress scores appear lower in frequency following the initiation of the intervention.



Series One = Daily Symptom Scores
Series Two = Daily Stress Scores

Figure 17. Participant Three: Comparison of Daily Symptom and Daily Stress Scores Over 112 Days

The plot for the summed weekly symptom scores is presented in Figure 18. The series after the initiation of the intervention looks remarkably decreased from the initial series. The plot for Participant Three's perimenopausal symptoms time-series is provided in Figure 19.

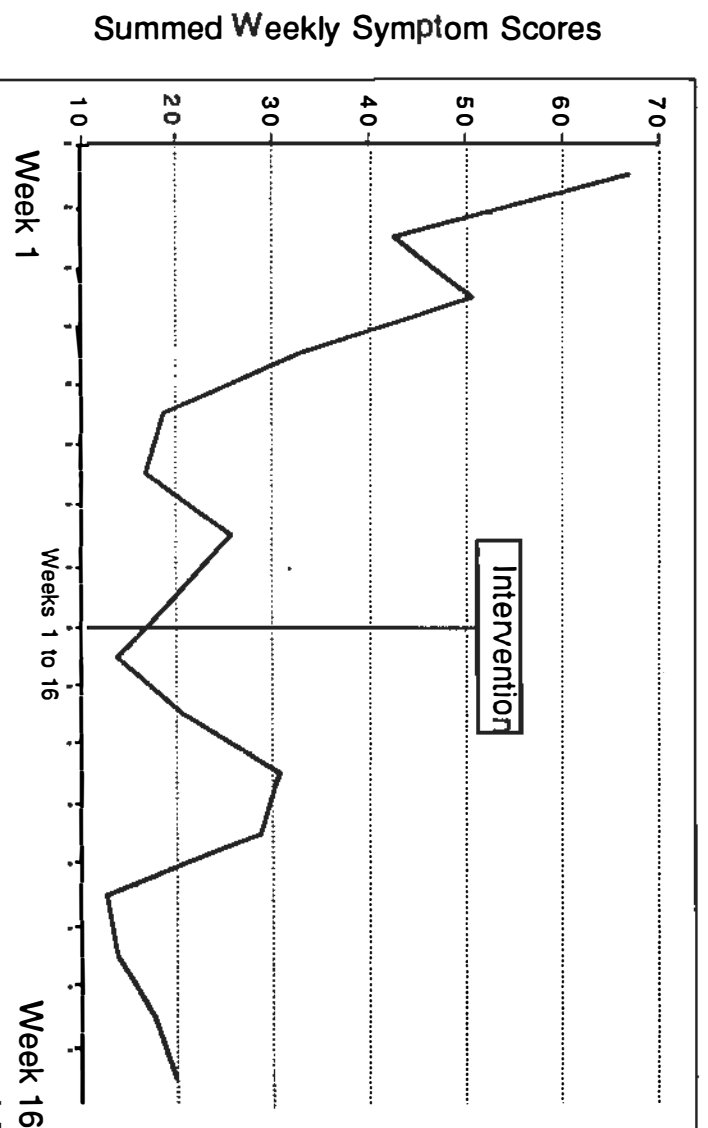


Figure 18. Participant Three: Weekly Summed Symptom Scores Over 16 Weeks

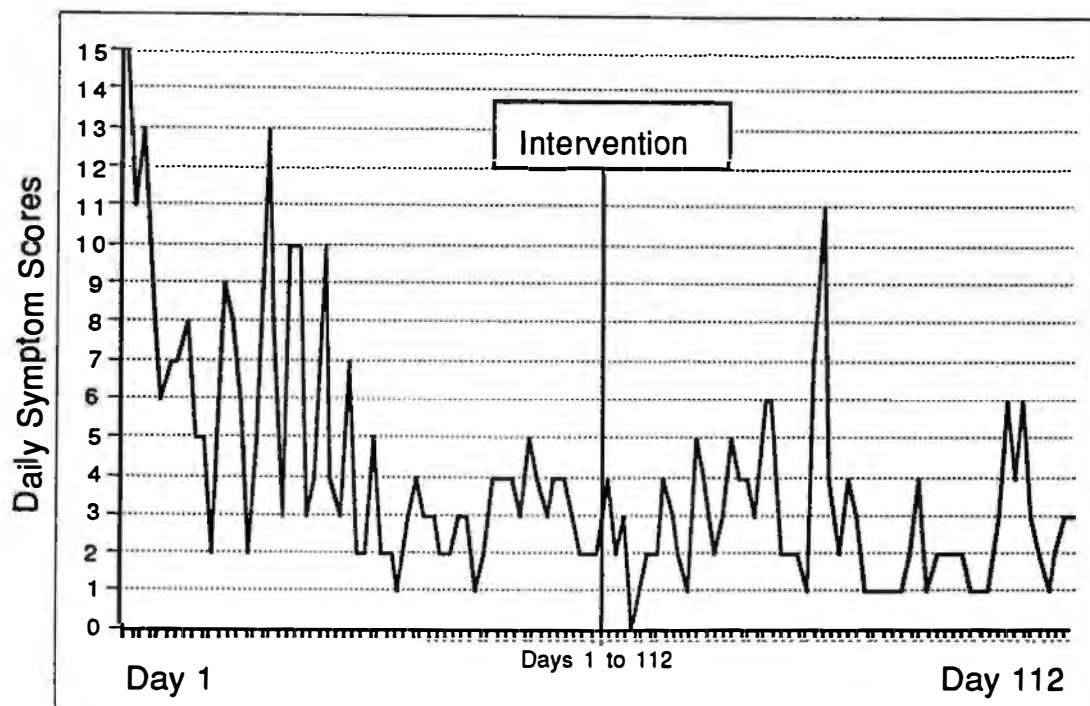


Figure 19. Participant Three: Daily Symptom Scores Over 112 Days

The change in the series mean from pre-intervention (mean = 4.9) to post-intervention (mean = 2.9) is apparent in this figure. It appears, however, there may have already been a downward trend prior to the initiation of the intervention. The highest scores appeared in the first half, and the lowest scores in the second half.

The series was determined nonstationary by examining the ACF of the entire series (see Table 22). Initially the series was differenced rendering stationarity, as evidenced by the undifferenced series having only two significant correlations.

Table 23

Participant Three: Comparison of Autocorrelations for Undifferenced and Differenced Series for Daily Symptom Scores Through Lag Seven

Correlations		
Lag	Undifferenced Series	Differenced Series
1	0.50*	0.25*
2	0.24*	0.43*
3	0.34*	0.21
4	0.33*	0.12
5	0.22	0.16
6	0.25	0.00
7	0.12*	

Note. * Indicates significant correlations.

The ACF and PACF of the entire series were examined in order to develop a tentative ARIMA model. Initially the model was identified as an ARIMA (1,1,0) because the PACF had a significant spike at lag 1. Using the ARIMA command, the statistical package estimated the parameters of the model. The parameters were estimated as 0.24 for the autoregressive component (AR);

with significant t-ratio for the parameter estimation. The residual mean square was 6.8. The LBQ statistic was 63 at lag 20. The ACF and PACF of the error series was examined in order to determine the accuracy of the model, and exhibited one spike on lag 2. The error series was not significantly different from zero. The residuals were without pattern, meaning the residuals were white noise. The ARIMA (1,1,0) model was accepted with an AR parameter of 0.24.

Next the data were re-analyzed utilizing a dichotomous "dummy" variable in order to determine the effectiveness of the intervention. Using the accepted ARIMA (1,1,0) model, the results were a RMS of 13.88, with the AR parameter estimated at 0.31, an intervention parameter of 0.93, the LBQ statistic 80 at lag 20, indicating a large amount of information remained in the residuals; and three significant spikes on the ACF of the residuals. The t-ratio for the estimated intervention parameter were not found to be significant (1.91). Table 23 compares the pre- and post-intervention model analysis. The post-intervention model was rejected.

Table 24

Participant Three: Comparison of Pre- and Post-Intervention ARIMA (1,1,0)
Model for Daily Symptom Scores

	<u>Pre-Intervention</u>	<u>Post-Intervention</u>
RMS	6.8	13.88
LBQ @ 20	63.00	80.00
AR Estimate	0.24	0.31
t-ratio	2.64	3.41
Intervention Estimate	Not Applicable	0.93
t-ratio	Not Applicable	1.91

The t-plot for Participant Three's daily stress time-series is provided in Figure 20. The series begins with two weeks of the score seven, the initial eight weeks then trends downward. The mean daily stress score for this series was 3.32 for the first half, and 3.23 for the second half, with the second half having less variability from the mean. These findings are supported by the plot of the series.

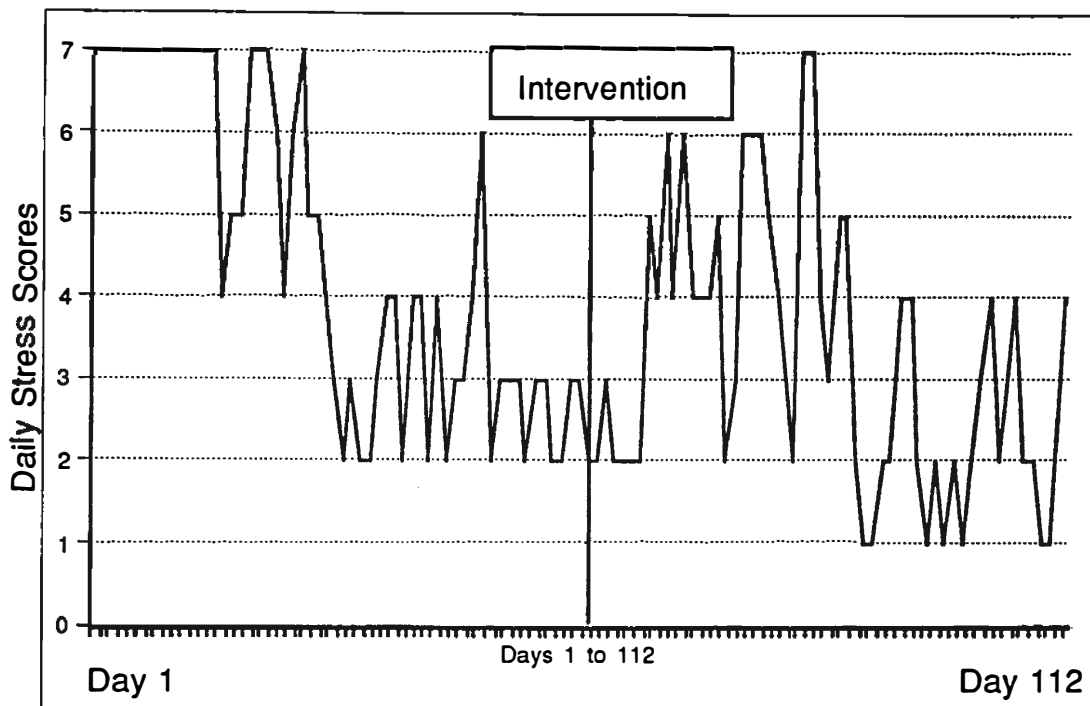


Figure 20. Participant Three: Time-Series of Daily Stress Scores Over 112 Days

As with the symptoms time-series, this series was determined nonstationary, see Table 24 for comparison of the autocorrelation for the undifferenced and differenced series. The necessity to difference the series was not unanticipated since this participant indicated a daily stress level of seven for the first two weeks. The data were determined nonstationary because the ACF of the series deteriorated very slowly. After differencing the data one time, the series was made stationary.

Table 25

Participant Three: Comparison of Autocorrelations for Undifferenced and Differenced Series for Daily Stress Scores Through Lag Six

Lag	Correlations	
	Undifferenced Series	Differenced Series
1	0.73*	-0.24*
2	0.59*	-0.17
3	0.52*	-0.09
4	0.51*	0.08
5	0.46*	-0.04
6	0.42*	-0.13

Note. * Indicates significant correlations.

This series was modeled successfully with an ARIMA (1,1,0) model. The parameters were estimated as 0.24 for the AR, with a significant t-ratio for the parameter estimation. The residual mean square was 1.88. The LBQ statistic was 43 at lag 20. The ACF of the error series was examined in order to determine the accuracy of the model. The error series was not significantly different from zero. The residuals were without pattern, meaning the residuals were white noise. The ARIMA (1,1,0) model was accepted with an

estimated AR parameter of 0.24. Next the intervention was added as a dichotomous "dummy" variable in order to attempt the ARIMA (1,1,0) model with the intervention. The parameter for the AR was estimated at 0.24, and the estimated parameter for the intervention was 0.56, with t-ratios of 2.55 and 0.76 respectively. The intervention was rejected based on the insignificant t-ratio for the intervention. The RMS was 1.9 and the LBQ at 20 lags was 43, with one spike on lag two of the autocorrelation of the residuals. Table 26 compares the pre- and post-intervention model analysis.

Table 26

Participant Three: Comparison of Pre- and Post-Intervention ARIMA(1,1,0) Models for Daily Stress Scores

	<u>Pre-Intervention</u>	<u>Post-Intervention</u>
RMS	1.88	1.92
LBQ @ 20	43.00	43.00
AR Estimate	0.24	0.24
t-ratio	2.58	2.55
Intervention Estimate	Not Applicable	0.56
t-ratio	Not Applicable	0.76

This participant's pre-intervention time for the mile and one-half walk-run was 20 minutes. Her estimated $\text{Vo}_{2\text{max}}$ was $27.7 \text{ ml}\cdot\text{kg}^{-1}\cdot\text{min}^{-1}$

(Brooks, Fahey, & White, 1996). The time on her post-intervention mile and one-half walk-run was 14 minutes, or $38.0 \text{ ml}\cdot\text{kg}^{-1}\cdot\text{min}^{-1}$ estimated $\text{VO}_{2\text{max}}$. An improvement of 37% was demonstrated. Resting heart rate (beats/minute) pre-intervention was 75, and post-intervention was 68, showing a decrease of 9%.

Participant Number Four

This participant was a 49 year old married homemaker, listing “some college courses” as highest educational level. She had been pregnant five times and had three children, ages 12, 21 and 24. Combined household income per year was identified in the range of over \$100,001. She listed irregular or infrequent menses over the past 12 months and was not on hormone replacement therapy. There was no significant health history, no routine medications, and she did not report how long she had been having perimenopausal symptoms.

No changes or significant events were recorded on the daily log until week five when she reported taking aspirin (an analgesia) and Dimetapp (a decongestant) for days two through five. No further events until week seven, when she reported taking Anaprox (a nonsteroidal anti-inflammatory drug) on days one through five. No events were listed in week eight. No anecdotal notes were made during the intervention phase. Total number of points marked during the intervention phase was 210 compared with a pre-intervention total of 210 points. In the second eight weeks, her daily stress score ranged from zero to seven, with an average score of 3.32.

As documented in the daily log, this participant walked three times per week during the second eight weeks. Initially participant one walked for a duration of 20 minutes at each session, beginning week three she began walking 45 minutes each time, and by week five she was walking 60 minutes at each session. She recorded ratings of perceived exertion from 11 (fairly light) to 15 (hard). Greater than 75% of the time she recorded a perceived exertion of 13 (somewhat hard). This individual walked with the researcher 75% of the time, the remaining 25% of the time she walked alone, with friends or family.

The raw data revealed that in the initial eight weeks, this participant chose all but one of the nineteen symptoms on the daily checklist (pins and needles in hands or feet). The symptom with the highest frequency was fatigue with a frequency of 31 (55% of the time), a decrease of 23%. As seen in Table 27.

Table 27

Participant Four: Comparison of Symptom Frequency, Pre- and Post-Intervention

Symptoms	Pre-Intervention		Post-Intervention	
	Frequency	% of Time	Frequency	% of Time
Aches and Pains	17	30%	25	45%
Backache	20	36%	25	45%
Depression	9	16%	11	20%
Diarrhea	4	7%	3	5%
Difficulty Concentrating	16	29%	19	34%
Dizziness	3	5%	1	2%
Fatigue	31	55%	24	43%
Feelings of "Losing My Mind"	14	25%	4	7%
Forgetfulness	17	30%	12	21%
Headaches	10	18%	11	20%
Heavy Menstruation	14	25%	2	4%
Hot Flashes	2	4%	0	0%
Irritability	14	25%	20	36%
Nervous Tension	16	29%	14	25%
Night Sweats	3	5%	2	4%
Pins and Needles	0	0%	0	0%
Rapid Heart Rate	1	2%	1	2%
Shortness of Breath	2	4%	0	0%
Trouble Sleeping	2	4%	8	14%

The plot for Participant Four's perimenopausal symptoms time-series is provided in Figure 21. This visualization demonstrates the similarity of the total daily scores for phase one and phase two (195 and 180, respectively). The symptom which demonstrated the largest improvement during the intervention phase was heavy menstruation which decreased from 14 to 2, a decrease of 86%. The direct causal relationship between the intervention and the symptom decrease can not be drawn because it is not known if the menstrual flow was decreased by increased levels of estrogen which occurred naturally, or if there were increased levels of estrogen as a result of the walking intervention. Feelings of "losing my mind" demonstrated the next best improvement going from an incidence of 14 (25%) to an incidence of 4 (7%), a decrease of 71%. Aches and pains in the joints and backache increased by 47% and 20% respectively during the intervention phase. As in the case with Participant Number Two, the physical activity may have aggravated a pre-existing condition.

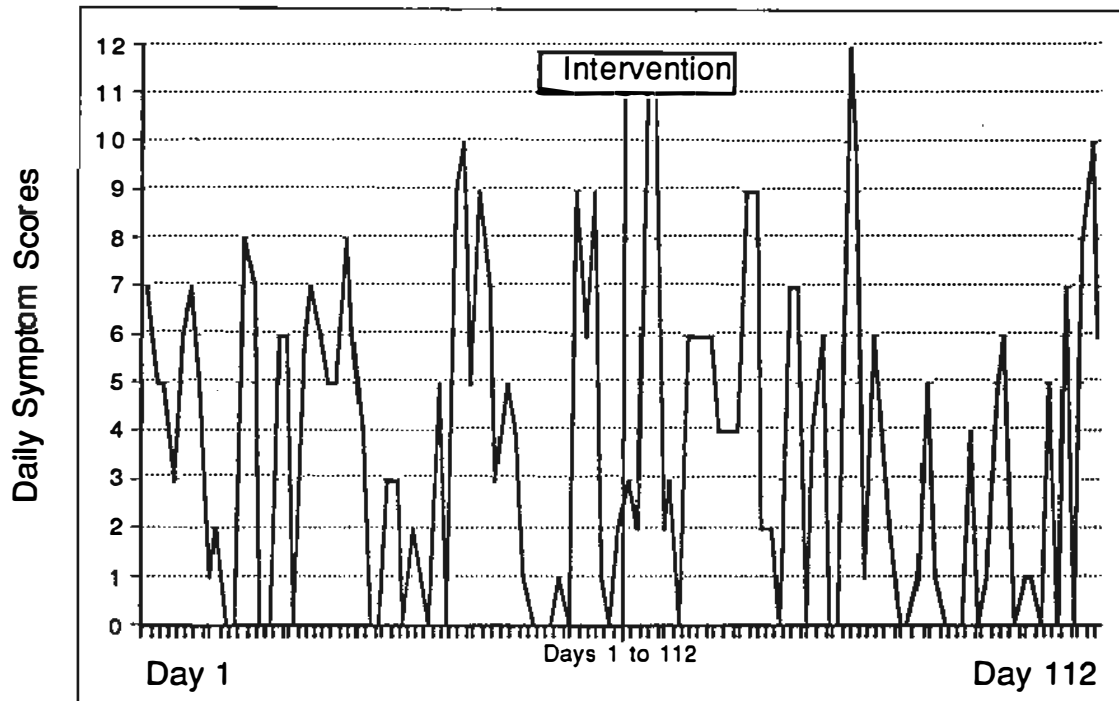
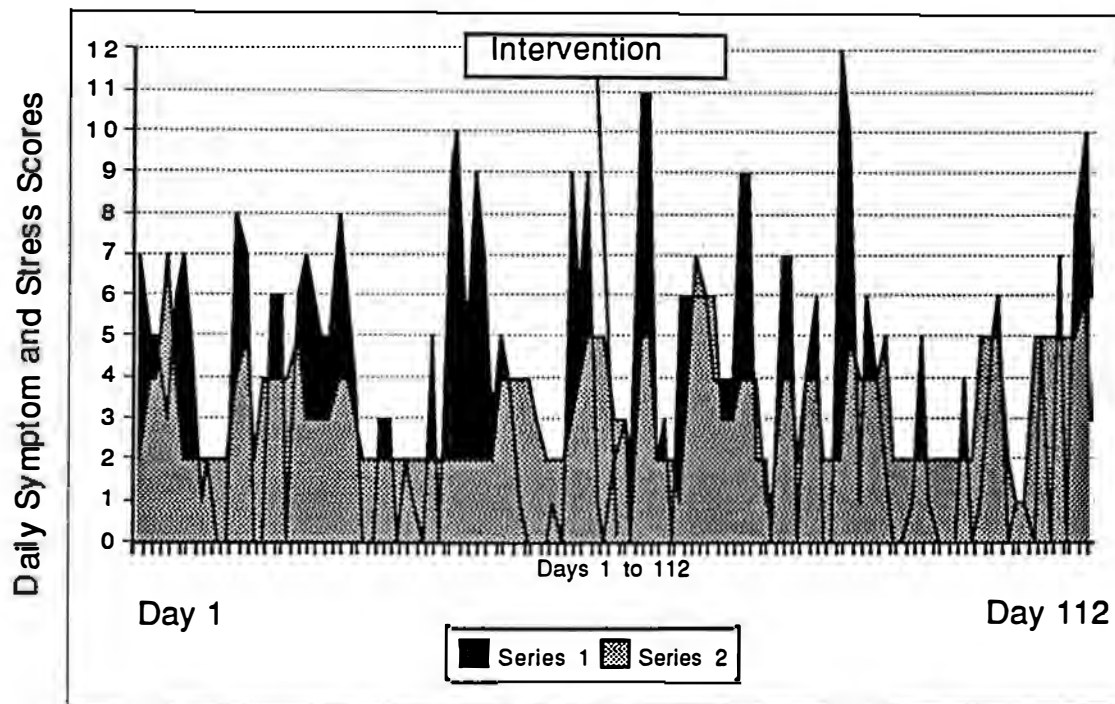


Figure 21. Participant Four: Daily Symptom Scores Over 112 Days

Figure 22 provides the comparison of daily symptom scores and daily stress scores for participant four. As seen in this figure, peaks on the stress scores are accompanied by peaks on the symptom scores.



Series 1 = Symptoms Scores
 Series 2 = Stress Scores

Figure 22. Participant Four: Comparison of Daily Symptom and Stress Scores Over 112 Days

Figure 23 depicts the weekly summed symptom scores for this participant. The pre- and post-intervention series' have very different patterns, although the participant did not necessarily feel better during that time.

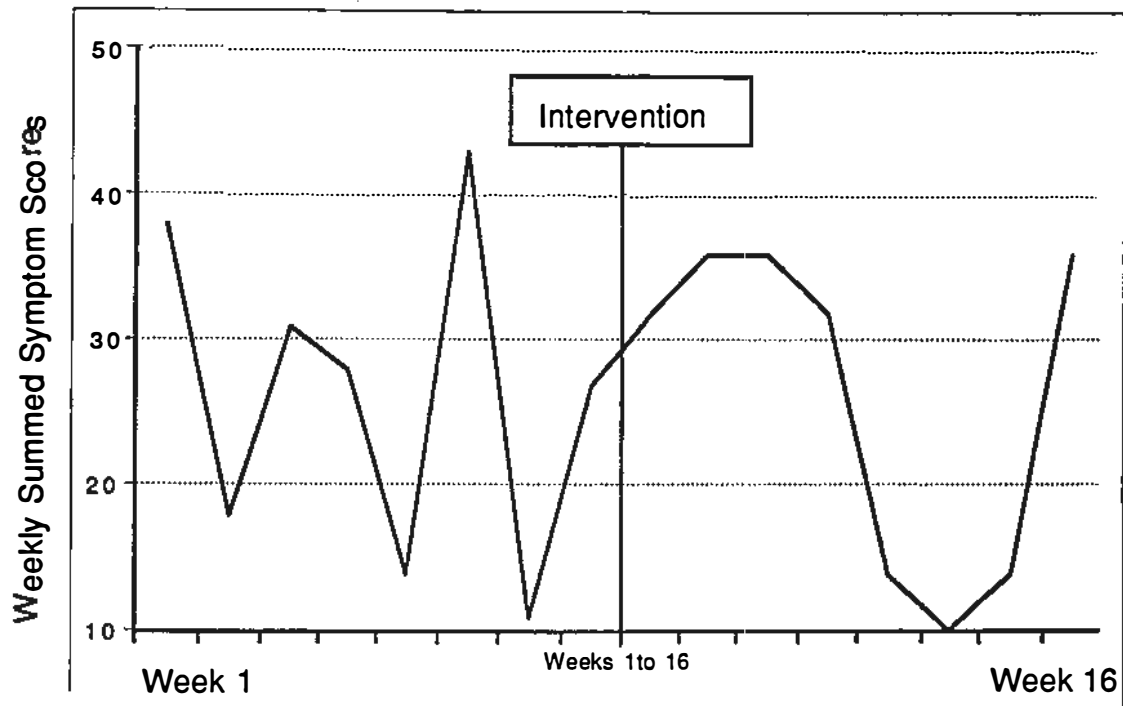


Figure 23. Participant Four: Weekly Summed Symptom Scores Over 16 Weeks

The autocorrelation (ACF) revealed stationary data (Table 28), with only one significant spike on the autocorrelation. There was one significant spike on the partial autocorrelation.

Table 28

Participant Four: Autocorrelation Function of Daily Symptom Scores Over 112 Days, For 6 Lags

Lag	Correlation
1	0.25*
2	-0.07
3	0.00
4	-0.02
5	-0.05
6	-0.02

Note. * indicates significant correlations.

The series for daily symptom scores was modeled initially with an ARIMA (1,0,1) model with the spike on the PACF at lag one, because both the ACF and PACF deteriorated quickly, indicating a mixed process. The MA parameter estimate was 0.89 and the AR estimated parameter was 0.99, both with significant t-ratios. The RMS was 11.67, the Box-Ljung Q statistic was 17 at 20 lags, the ACF of the error series had one marginal spike at lag one. The model was rejected because of the high AR parameter, which was not significantly different from 1.0, indicating the need to difference the series. The integrative ARIMA (0,1,1) model was then used to estimate the parameter coefficients. This model resulted in an RMS of 11.18, an AR parameter of 0.98 with a significant t-ratio, and LBQ of 16 at 20 lags. The autocorrelation function of the residuals exhibited a spike on lag two. The ARIMA (0,1,1) model was accepted with an estimated MA parameter

coefficient of 0.98.

Next the series was modeled with the ARIMA (0,1,1) model incorporating the intervention as a dichotomous "dummy" variable. The diagnostics for this model provided an MA estimate parameter of 0.63 with a t-ratio of 8.21 and an intervention estimated parameter of 0.96 with a t-ratio of 3.42. The intervention model was accepted as the better model because of the significant t-ratios on the model parameters. The RMS for this model was 13.35 and the LBQ was 20 at lag 20. The ACF of the residuals had one significant spike on lag two. Table 29 compares the pre- and post-intervention model analysis.

Table 29

Participant Four: Comparison of Pre- and Post-Intervention ARIMA (1,1,0) Model for Daily Symptom Scores

	<u>Pre-Intervention</u>	<u>Post-Intervention</u>
RMS	11.18	13.35
LBQ @ 20	16.00	20.00
MA Estimate	0.98	0.63
t-ratio	63.78	8.21
Intervention Estimate	Not Applicable	0.96
t-ratio	Not Applicable	3.42

The plot for participant four's daily stress time-series is provided in Figure 24.

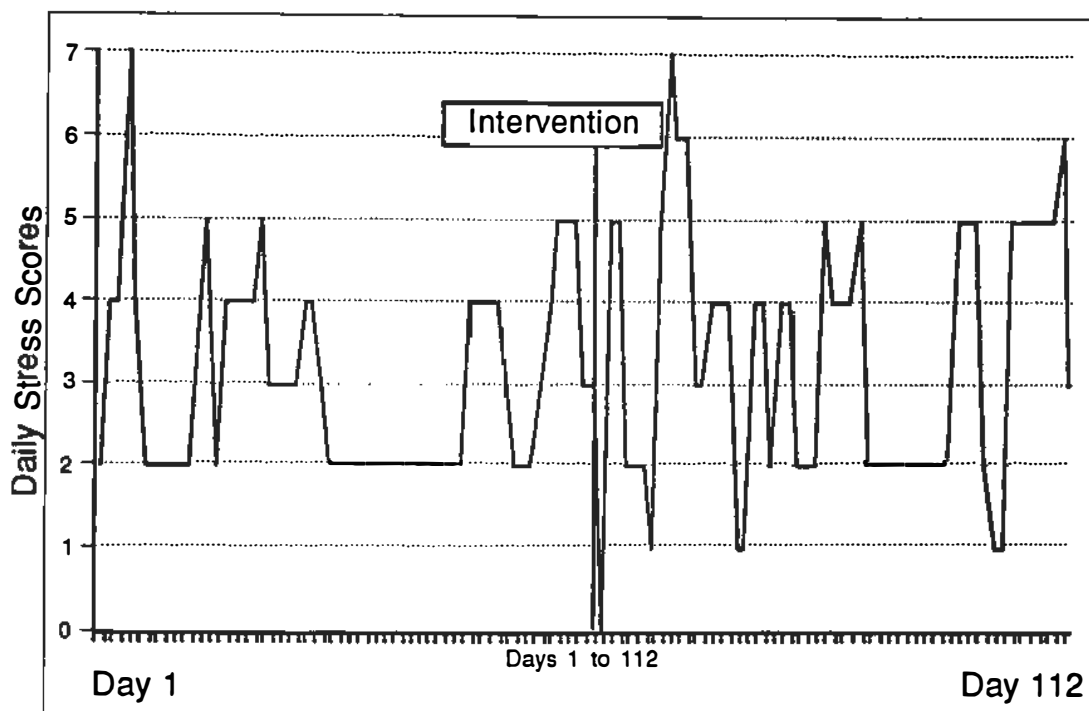


Figure 24. Participant Four: Time-Series of Daily Stress Scores Over 112 Days

The second half of this series, has the only scores of one, with a frequency of five times. The mean for both the first half and second half of this series was 3.34, with the coefficient of variance being 46 and 72 respectively, indicating more variance in the second half of the series; probably because of the scores of one which were present in this half.

As with the symptom time-series, this series was determined stationary, with only one significant spike at lag one (see Table 30). The partial autocorrelation also had one significant spike indicating a mixed process.

Table 30

Participant Four: Autocorrelation Function of Daily Stress Scores Over 112 Days, For 6 Lags

Lag	Correlation
1	0.49*
2	0.12
3	-0.07
4	-0.11
5	-0.05
6	0.06

Note. * indicates significant correlations.

This series was modeled initially with an ARIMA (1,0,1) model, with the spike at lag 1. The residuals of the error series had a marginal spike at lag one. The MA estimate was 0.28 and the AR estimate was 0.99, both with significant t-ratios. The Box-Ljung Q statistic was 35 at lag 20; the RMS was 2.07 This model was rejected based on the high AR parameter indicating the need to difference the series. The ARIMA (1,0,0) model yielded an RMS of 2.05, an AR parameter of 0.92 with a significant t-ratio, and an LBQ of 34. The ACF of the residuals had no significant spikes. The ARIMA (1,0,0) model with an AR parameter of 0.92 was accepted.

Next the data were reanalyzed utilizing a dichotomous "dummy" variable in order to determine the effectiveness of the intervention. Using the accepted ARIMA (1,0,0) model, the results were a RMS of 1.97 with the AR parameter estimated at 0.91, the intervention parameter at 0.81 both with significant t-ratios, an LBQ statistic of 34 at lag 20, with one significant spike on lag two of the ACF of the residuals. Table 31 compares the pre- and post-intervention model analysis. The post-intervention model was accepted.

Table 31

Participant Four: Comparison of Pre- and Post-Intervention ARIMA (1,0,0) Model for Daily Stress Scores

	Pre-Intervention	Post-Intervention
RMS	2.05	1.97
LBQ @ 20	34.00	34.00
AR Estimate	0.92	0.91
t-ratio	24.14	22.70
Intervention Estimate	Not Applicable	0.81
t-ratio	Not Applicable	4.25

This participants pre-intervention time for the mile and one-half walk-run was 16 minutes, yielding an estimated $\text{Vo}_{2\text{max}}$ was $34.68 \text{ ml}\cdot\text{kg}^{-1}\cdot\text{min}^{-1}$ (Brooks, Fahey, & White, 1996). The time on her post-intervention mile and one-half walk-run was 14 minutes, or $38.0 \text{ ml}\cdot\text{kg}^{-1}\cdot\text{min}^{-1}$ estimated $\text{Vo}_{2\text{max}}$. An improvement of 10% was demonstrated. Resting heart rate (beats/minute) pre-intervention was 72, and post-intervention was 68, showing a decrease of 6%.

Summary

Four women were recruited via word of mouth and through the use of newspaper advertisements. Each of the women were between the ages of 45 and 60, had been sedentary for at least six months, capable of participating in a moderate, progressive walking program, symptomatic with perimenopausal symptoms and willing to participate in the 16 week study. After explanation of the study, consent forms were signed and the individuals began completing their symptom checklists and logs on a daily basis. Two of the women were not taking hormone replacement (HRT) therapy; two of the women were taking hormone replacement therapy, but reported similar symptoms as the women without HRT, and they stated the desire for additional symptom relief.

The initial eight weeks the participants remained sedentary, and during the second eight weeks the walking intervention was implemented. The data were analyzed using the BMDP statistical package for time-series analysis.

Exploratory data analysis included examination of individual symptoms for each participant.

Time-series analysis was utilized to examine each participant's daily and summed weekly symptom scores, and daily and summed weekly stress scores with and without the exercise intervention. Table 32 provides the ARIMA model for each participant for daily symptoms and daily stress scores, and whether the intervention model was accepted or rejected. The intervention had a significant impact for Participants Two and Four, on the daily symptom scores time-series, and on Participant Four's daily stress score time-series. No other intervention models were accepted.

Table 32

All Participants: Comparison of ARIMA Model and Acceptance or Rejection of Intervention Model for Daily Symptom, Use of Hormone Replacement Therapy, and Daily Stress Scores

Daily Symptom Scores			Daily Stress Scores	
Model	Intervention	HRT	Model	Intervention
1. (1,0,0)	Rejected	Yes	(1,1,0)	Rejected
2. (1,1,0)	Accepted	No	(1,1,0)	Rejected
3. (1,1,0)	Rejected	Yes	(1,1,0)	Rejected
4. (0,1,1)	Accepted	No	(1,0,0)	Accepted

All participants demonstrated an improvement in estimated $\text{Vo}_{2\text{max}}$.

Table 33 provides the pre- and post-intervention $\text{Vo}_{2\text{max}}$ measurements.

The participant who had the best pre-intervention $\text{Vo}_{2\text{max}}$ (Participant Number Four) demonstrated the least amount of improvement in cardiorespiratory endurance as a result of the walking intervention.

Table 33

All Participants: Comparison of Pre- and Post-Intervention $\text{Vo}_{2\text{max}}$ Measurements

Estimated $\text{Vo}_{2\text{max}}$			
	Pre-Intervention	Post-Intervention	Improvement
1.	19.6	22.8	16.4%
2.	16.9	21.4	26.0%
3.	27.7	38.0	37.0%
4.	34.7	38.0	10.0%

Note. $\text{Vo}_{2\text{max}}$ is measured in $\text{ml}\cdot\text{kg}^{-1}\cdot\text{min}^{-1}$.

According to Cooper's women's aerobic fitness classification (1977), all of the participants demonstrated improvement as a result of the eight-week walking program (see Table 34).

Table 34

All Participants: Aerobic Fitness Classifications

Participant	Pre-Intervention	Post-Intervention
1	very poor	poor
2	very poor	poor
3	good	superior
4	excellent	superior

CHAPTER V

SUMMARY OF THE STUDY

This study was undertaken to determine the effects of an eight week walking intervention on the bothersomeness of perimenopausal symptoms and cardiorespiratory endurance among sedentary, mid-life, women. Recruitment of participants was conducted via friends and acquaintances and through newspaper advertisements in Ft. Worth and Weatherford, Texas. Four women met the screening criteria and were accepted as subjects. A time-series design was employed in order to analyze the impact of the walking program on perimenopausal symptoms. Each woman completed a 19 symptom checklist and kept a log every day at bedtime. The daily log documented level of stress for the day and any lifestyle changes or unusual life events during the 16 weeks. In the eighth week, a 1.5 mile walk-run was conducted on a walking track. The time on this field test was utilized to calculate the pre-intervention estimated VO₂max for each participant. During the second eight weeks the women continued the prescribed documentation in addition to participating in a moderate, progressive walking program. Post-intervention VO₂max was calculated based on the 1.5 mile field test.

Two hypotheses were proposed. Data were analyzed using frequency statistics, time-series analysis and examination of the daily log entries. The first research hypothesis predicted a positive relationship between participation in an eight-week, moderate, progressive walking program and

cardiovascular endurance, and it was supported. The second research hypothesis predicted a negative relationship between participation in an eight-week, progressive walking program and perimenopausal symptoms. This hypothesis was partially supported.

This chapter provides a summary and discussion of the findings in relation to each hypothesis. Additional findings, conclusions, implications, and recommendations for further study are also presented.

Descriptive statistics were used to test the relationships predicted in the first hypothesis. A time-series analysis was used to test the relationships predicted in the second hypotheses. The theoretical framework for the study included a physiological explanation of the symptoms of perimenopause, while taking into consideration variables which influence the experience. The physiologic process was defined as the result of decreasing ovarian function leading to hormonal balance disturbance and the resulting symptoms of atrophy of genital mucosa, fatigue, irritability and nervousness, vasomotor symptoms, and others. Influencing variables included attitudes regarding perimenopause, education level, support systems, and amount of stress experienced.

A review of the literature was presented and concentrated on areas related to the population of the study and the study variables. The literature revealed a paucity of empirical findings about the effectiveness of non-hormonal interventions for the reduction of perimenopausal symptoms.

Data collection was conducted over 16 weeks using a symptom checklist and a daily log. This non-randomized sample from Ft. Worth and Weatherford Texas was comprised of four women between the ages of 45 and 54 years. All of the participants listed themselves as Caucasian and married. Three of the women were employed full-time outside of the home, and the fourth was a homemaker. All of the subjects had children. Combined household incomes ranged from \$40,000 to over \$100,000 with one participant not providing this information. All participants had been sedentary for at least six months prior to the study. Three participants reported an irregular or infrequent menses over the past 112 months, and the fourth listed no menses over the past 12 months. Two participants were taking hormone replacement therapy (Participants One and Three), although they reported a desire for additional symptom relief.

Daily symptom checklist scores, summed by participant, decreased for three participants (see Table 35), the fourth subject's summed score increased from 208 to 209.

Table 35

All Participants: Pre- and Post-Intervention Summed Daily Symptom Scores

Participant	Pre-Intervention	Post-Intervention
1	313	290
2	414	402
3	277	161
4	208	209

All participants demonstrated improvement in VO₂max (refer to Table 33, page 156). According to Cooper's women's aerobic fitness classification (1977), all of the participants demonstrated improvement as a result of the eight-week walking program (see Table 34, page 157). Data revealed the following results about the sample. Through descriptive statistics, Hypothesis One was supported. Through time-series analysis, Hypothesis Two was partially supported.

Discussion of Findings

Findings are discussed for each hypothesis under study. Two hypotheses were tested in this study:

Hypothesis One

1. Sedentary perimenopausal women who participate in an eight week moderate and progressive walking program will exhibit improved cardiorespiratory endurance.

This hypothesis was supported by the data which indicated improvement of VO_2max for each participant. The four participants maintained their sedentary status for the initial eight weeks of the study. During the intervention phase they participated in a moderate, progressive walking program. Compliance to the walking program was documented through the use of the daily log. Participants were instructed to walk within their calculated target heart rate, and at a level of perceived exertion of 13 "somewhat hard". Documented levels of perceived exertion deviated from the level of 13, to as low as 11 "fairly light," to as high as 15 "hard," with the majority of the exercise being conducted at the level of 13 "somewhat hard." All participants walked the desired duration and frequency for the eight week period. Initial calculations of VO_2max ranged from 16.9 to 34.7 (measured in $\text{ml}\cdot\text{kg}^{-1}\cdot\text{min}^{-1}$). Post-intervention calculations of VO_2max ranged from 21.4 to 38, indicating improvements of 10% to 37%.

Participant One demonstrated a 16.4% improvement in VO_2max (refer to Table 33, page 156). Additionally, her resting heart rate decreased from 80 beats per minute to 74, indicating a decrease of 7%. The lower resting heart rate indicates the ability of the heart to work more effectively as a result of the walking intervention. This participant had a great deal of anxiety about completing the 1.5 mile walk-run, stating that she wasn't sure if she could complete the pre-intervention test.

Participant Two had the poorest pre-intervention VO_2max (16.9), and improved 26% after the eight week walking intervention. Her resting heart rate decreased from 76 beats per minute to 57, indicating a decrease of 25%.

Participant Three demonstrated the greatest amount of improvement in VO_2max (from 27.7 pre-intervention, to 38.0 post-intervention, an improvement of 37%). She decreased her 1.5 mile walk-run time from 20 minutes pre-intervention to 14 minutes post-intervention. Her heart rate decreased from 75 beats per minute to 68, a decrease of 9%.

Participant Four demonstrated the least amount of improvement in VO_2max , however, this individual was categorized as having excellent aerobic capacity based on the time of her pre-intervention 1.5 mile walk-run. Subsequently, there was not much room for improvement for this participant. Based on these findings for participant four, the actual pre-intervention level of physical activity (sedentary for six months prior to the study) is questioned.

These results are supported in similar results by Cowan, and Gregory (1985); Epps, Washburn; and Casali (1983), Jett, Sidney, and Campbell (1988); and Warren, Nieman, Dotson, Adkins, O'Donnell, Haddock, and Butterworth (1993). Who found improvement of VO_2max from 12.1% to 19% in sedentary women, ages 35 and above, as the result of exercise programs lasting from 8 to 12 weeks in duration. The literature supported the relationship of physical activity and improved VO_2max .

Hypothesis Two

2. Sedentary perimenopausal women who participate in an eight week moderate and progressive walking program will exhibit a decrease of perimenopausal symptoms.

Four sedentary, midlife perimenopausal women participated in the 16 week study. Time-series analysis of the participants' daily symptom scores revealed two participants had significantly different patterns of symptoms during the intervention phase, and two participants did not have significantly different patterns during the intervention phase. The intervention was accepted for the two women who were not taking hormone replacement therapy. There appeared to be a relationship between the use of hormone replacement therapy and the effectiveness of the eight week walking intervention. It was not asked however, if the participants felt better, or were less bothered, by their symptoms during the intervention phase. For example, the summed daily symptom scores for participant one decreased by 23 (313 in the pre-intervention phase and 290 in the post-intervention phase), however, the intervention model was rejected for this individual. Conversely, the intervention model was accepted for participant number four, although her summed daily symptom scores increased by one from pre- to post-intervention (208 and 209 respectively). In summary, the pattern of the bothersomeness of perimenopausal symptoms was changed for participants two and four (those not receiving hormone replacement therapy) and the pattern of bothersomeness of perimenopausal symptoms did not

change for Participants One and Three (those receiving hormone replacement therapy).

Additional Findings

The daily stress scores were analyzed in regard to how the pattern of scores correlated to the pattern of daily symptom scores. Each participant showed a slightly different relationship between the graphs of two scores (see pages 95, 119, 133 and 147). The majority of the time, peaks in the stress score were accompanied by peaks in the symptom score. Participant Two did not have as many corresponding peaks in the second half of the study as she did in the first half.

Time-series analysis of the daily stress scores for each participant was conducted. The intervention model was rejected for Participants One, Two, and Three and was accepted for Participant Four, indicating that the pattern of stress did not differ pre- and post-intervention for Participants One, Two, and Three. It is conceivable that there was more stress for these individuals as a result of worrying about compliance with the walking intervention.

Conclusions

Examination of summed daily symptom scores by participant for pre- and post-intervention, indicated an decrease in scores for three participants (One, Two, and Three). However, the ARIMA models which incorporated the intervention as a dichotomous “dummy” variable were accepted for only Participants Two and Four. Review of the weekly summed symptom scores and time-series of daily symptom scores for Participant One

intervention model. For Participant Two, the model was accepted, and referring back to the summed weekly scores and the time-series of the daily scores (Figure 13, page 120, and Figure 14, page 121), acceptance of the intervention model is supported. This participant experienced a decrease in symptoms, particularly for weeks 12 and 13. Participant Three's series was not modeled more effectively with the intervention component, although from Figures 18 and 19 (pages 134 and 135) it appears that the series is different in the post-intervention phase. The intervention model for the fourth participant was accepted, based on Figures 21 and 23 (pages 146 and 148), there was a smoothing of the pattern of symptoms in the post-intervention phase.

Participant One was receiving Prempro (hormone replacement therapy), was 45, married, and employed outside the home full-time. She reported a number of health problems, including a family history of coronary or other atherosclerotic disease before age 55, chronic lower right groin spasms, colon spasms, and chronic low back pain. During the study she received pain medications for her back, Zantac (for epigastric reflux), Seldane (a decongestant), and an unnamed antibiotic for an upper respiratory infection. She consistently scored her daily stress as low on a scale of one to seven. There were two days during her pre-intervention phase when she did not take her hormone medication therapy.

Initially, during the intervention phase, her pattern of symptoms decreased drastically, returning to baseline by the second week of the intervention (pages 94 and 96). During the initial eight weeks she had higher

daily symptom scores, however the pattern of symptoms post-intervention was not significantly different from pre-intervention as determined by using time-series analysis. During the intervention phase this participant recorded difficulties at work, including a yearly evaluation, she also recorded having a great deal of activities outside of the home during week 15. It is possible that the additional stressors at work and in her personal life outweighed the impact of the walking program on her daily symptoms.

Participant Two was a 45 year old married woman, employed outside of the home, full-time. She was not receiving hormone replacement therapy, although she was receiving Maxide (a diuretic/antihypertensive) and Prozac (an antidepressant) as daily medications. During the initial eight weeks of the study she stopped taking her scheduled Prozac, lost her full-time job, her father was diagnosed with inoperable prostate cancer, and she reported being very busy with her school schedule. During the intervention phase, she complied with the walking program, and immediately reported feeling better as a result of the program. During this phase, she had a barium swallow, adopted a baby bird (which later died), continued to be busy with her work at school and reported reinitiating her daily Prozac during week 15, after the baby bird died. This individual had seven symptoms that increased and ten symptoms that decreased in frequency during the intervention phase. The intervention model was accepted for her daily symptom scores. The graph of the weekly data, indicates a different pattern of symptoms during the post-intervention phase (page 120), however, information is lost by summing

the data. The change in the pattern of daily symptoms appears to be a greater amount of variance. The question remains, had she not had the encounter with the baby bird that died, would the intervention had been more successful? A second issue remains unresolved, did she feel better during the intervention phase? The intervention did not appear robust enough to counteract the impact of negative life events.

Participant Three, a 54 year old, married woman, working full-time outside of the home reported being on hormone replacement therapy, and having had the symptoms associated with perimenopause for 10 years. She reported her menses as non over the past 12 months, which would put her in a classification of menopause rather than perimenopause. This participant recorded a daily stress level of seven for the initial two weeks of the study, during which time she indicated a great deal of personal problems. She was taking no prescribed medications other than the hormone replacement therapy. There was very little documentation in her daily log other than the incidence of personal problems during the initial two weeks. During the intervention phase she reported having difficulty with allergies, and taking an antihistamine and a decongestant for several days. The mean daily symptom score for the intervention phase was 2.9 (decreased from a mean of 4.9 in the pre-intervention phase). The daily symptom score series was not modeled better by incorporating the intervention parameter. The 16 week series was determined to be nonstationary and was differenced prior to modeling. Although the plots of both the daily and the summed weekly

series (pages 134 and 135) appear to have a different pattern in the post-intervention phase, there appears to be a pre-existing downward trend in the pre-intervention phase. Once the series was de-trended, by differencing, the post-intervention pattern was not significantly different than the pre-intervention pattern.

Participant Four was a 49 year old, married homemaker. She had no significant health history, no routine medications, and no hormone replacement therapy. This participant provided very little documentation in her daily log regarding significant life events. During the initial eight weeks she did report taking Aspirin (an analgesia), Dimetapp (a decongestant), and Anaprox (an anti-inflammatory). It appears that these medications were not taken during the intervention phase. Her total symptom score increased from 208 in the pre-intervention phase to 209 in the post-intervention phase. The intervention model was accepted for this individual. However, it is not known if she felt better during the second eight weeks. As shown in the graph of her daily symptom scores (page 146) she had several incidences of a score of zero in both the pre- and post-intervention phases. The summed weekly data graph (page 148) indicates a change in the pattern of symptoms from pre- to post-intervention, with the second eight weeks having a pattern resembling a sinus wave, perhaps indicating a difference in the way plasma hormonal levels were varying.

In summary, the two participants who were not receiving hormone replacement therapy exhibited a significantly different pattern of daily

symptoms post-intervention as determined by the use of ARIMA time-series analysis. Life events, such as loss of employment, or personal losses appeared to have an impact on the bothersomeness of perimenopausal symptoms. Influencing variables, other than physiological processes, did not appear to have a significant impact on the results of this study. Influencing variables identified in the conceptual framework were attitudes, education, ethnicity, expectations regarding menopause, life satisfaction, nutritional status, overall health, socioeconomic status, stress and support systems. With the exception of attitudes, expectations, and life satisfaction, these variables were addressed either in the demographic questionnaire or in the daily logs. All of the participants were married and Caucasian. Three listed “some college” as the highest level of education, and participant three listed a graduate degree. Overall, the participants were educated, Caucasian, and not in the lower socioeconomic status. Participant One had some pre-existing health problems, as did Participant Two.

The following conclusions were reached based on the quantitative and qualitative results of the study.

1. Daily symptom scores showed a great deal of day to day variability. The ways in which women experience the daily symptoms of perimenopause has rarely been the subject of research interest. To date, research studies have focused on the experience of symptoms over the last “two weeks” or some

other specified period of time. New knowledge has been gained that describes individual patterns of perimenopausal symptoms.

2. This study confirmed that significant improvement in $VO_2\text{max}$ can occur as the result of an eight-week, moderate, progressive walking program among sedentary, mid-age women.

3. The findings from the daily log indicated that participants in this sample were taking a number of prescription medications, such as Prozac, hormone replacement therapy, and anti-hypertensive medications.

4. The findings from the daily symptom checklist indicated that individuals tended to experience "cluster" of symptoms, such as the occurrence of "difficulty concentrating" with headaches, dizziness with headaches, and fatigue with irritability.

5. No single symptom was experienced by all participants; Night sweats, "pins and needles," rapid heart rate and shortness of breath are examples of symptoms not experienced by all individuals.

6. Increased levels of daily stress was positively correlated with times of great interpersonal struggle.

7. The theoretical model performed well with this sample. Because the components of the study are similar to the elements contained in the model, the results of the study support the tested relationships proposed by the model.

8. Physical activity may be effective in reduction of perimenopausal symptoms in sedentary women who are not receiving hormone replacement therapy.

9. Physical activity may have little effect on sedentary, perimenopausal women who are receiving hormone replacement therapy.

Implications for Nursing

The critical implication of this study is that symptomatic women who are receiving hormone replacement therapy may not receive additional, significant symptom relief as the result of incorporating a walking program into their lifestyles. The walking intervention may not be robust enough to impact the many variables influencing the perimenopausal experience. Intervention strategies for symptomatic women on hormone replacement therapy can be broadened to address the psychological influencing factors such as attitudes towards menopause, support systems, and stress.

The nursing profession needs to know more about the perimenopausal experiences of women. It is important to note the the symptoms present a great deal of day to day variability. Future research done by nursing scholars could help explore the reasons why the symptom experience varies so greatly from day to day. Qualitative as well as quantitative research is necessary to expose the entire phenomena. Research must try to understand the differences and discover the similarities between perimenopausal women.

Recommendations for Further Studies

Several recommendations for further study are identified based on the conclusions of this study.

1. Measure plasma levels of estrogen in order to determine the relationship of daily symptoms to actual estrogen levels..
2. Utilize a longer walking intervention.
3. Incorporate a qualitative aspect which explores the meaning of the symptoms.
4. Recruit subjects with a higher severity of symptoms.
5. Gather data for a longer period of time prior to the intervention, or gather data pertaining to the individual in regard to the symptoms prior to perimenopause: for example--did the woman always have headaches, or did these begin with perimenopause?
6. Use of a 12 minute walk-run instead of the 1.5 mile test.
7. Investigate the common medications used in this age group and explore their potential effect on perimenopausal symptoms.
8. Incorporate compliance as a co-variate.
9. Ascertain whether the subjects report feeling better as a result of the increased physical activity.
10. Control for prescription medication compliance with the treatment regimen.

In summary, recommendations for further study are suggestions that would increase confidence in the findings or make interpretation of the findings more useful.

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Appendix A

Human Subjects Review Approval

████████████████████

TEXAS WOMAN'S UNIVERSITY

DENTON DALLAS HOUSTON

HUMAN SUBJECTS
REVIEW COMMITTEE
P.O. BOX 22939
Denton, TX 76204-0939
Phone: 817/898-3377

March 8, 1995

Terrilyn Pensabene
2715 Gardner Rd.
Weatherford, Tx 76086

Dear Terrilyn Pensabene:

Social Security #:

Your study entitled "Impact of Physical Activity on Perimenopausal Symptoms, Depression, and General Well-Being" has been reviewed by a committee of the Human Subjects Review Committee and appears to meet our requirements in regard to protection of individuals' rights.

Be reminded that both the University and the Department of Health and Human Services (HHS) regulations typically require that agency approval letters and signatures indicating informed consent be obtained from all human subjects in your study. These are to be filed with the Human Subjects Review Committee. Any exception to this requirement is noted below. This approval is valid one year from the date of this letter. Furthermore, according to HHS regulations, another review by the Committee is required if your project changes.

Special provisions pertaining to your study are noted below:

- ☐ The filing of signatures of subjects with the Human Subjects Review Committee is not required.
- ☐ Other:
- ☒ No special provisions apply.

Sincerely



Chair

Human Subjects Review Committee - Denton

cc: Graduate School
Dr. Peggy Drapo, Nursing
Dr. Carolyn Gunning, Nursing

Appendix B
Written Consent Form

TEXAS WOMAN'S UNIVERSITY
SUBJECT CONSENT TO PARTICIPATE IN RESEARCH

Title of Study: Impact of Physical Activity on Perimenopausal Symptoms

Investigator's Name: Terrilyn Pensabene
Investigator's Phone: Weatherford: 817-596-3960
Office: 817-531-4576
Beeper: 817-827-9939

Description of the study: The purpose of this study is to examine the impact of walking on perimenopausal symptoms, such as hot flashes/flushes. Participants will complete the perimenopausal symptom index and daily log each evening at bedtime for the first 8 weeks. For the second 8 weeks, participants will continue to complete the symptom checklist and daily log every evening in addition to participating in a brisk walking program. Participants will meet with the investigator three times per week, for approximately 45 minutes, in order to conduct the walking program (5-7 minutes of warm-up, 20 minutes of walking, and 5-7 minutes of cool-down). Estimated time to complete the questionnaire each evening is 5 minutes. A personal data form and the Physical Activity Readiness Questionnaire will be completed prior to beginning the study. Estimated time to complete these forms is 10 minutes. A mile and one half walk run will be conducted in week 8 and again in week 16. This should be accomplished in less than one hour.

Description of risk or discomfort: The risks all participants will be exposed to are: loss of time to complete the questionnaires, monetary costs for local transportation; the associated risks of initiating and maintaining a walking program: soreness, fatigue, injury, and possibly public embarrassment. The investigator will be assisted by an individual who works as a personal fitness trainer. This woman will design the nature of the walking program, warm-up and cool-down sessions. You will complete the Physical Activity Readiness Questionnaire prior to beginning in order to ascertain your ability to participate. The questionnaires will be stored for five years in a locked file cabinet and will be shredded at the end of that time.

Description of possible benefits: As a participant in this study you may experience the following benefits: an increased awareness about yourself and perimenopausal symptoms; as a result of the walking program, you will have the benefits associated with such a program, for example, feeling better physically and mentally, group camaraderie, and contact with the nurse investigator for the duration of the study. Physical and mental benefits associated with sustained, regular physical activity include: improved physical fitness; improved circulation, reducing fatigue, increasing energy, and increasing the ability to deal with stress; decreased depression and an increase in general well-being; increased self-esteem; improved digestion and increased absorption of nutrients; better sleep; weight loss, due to increased metabolism, decreased appetite, increased muscle mass and expenditure of calories. After completion of the study, all participants will be provided a packet of information pertaining to menopause and will be offered a summary of the results of the study.

We will try to prevent any problem that could happen because of this research. Please let us know at once if there is a problem and we will help you. You should understand, however, that TWU does not provide medical services or financial assistance for injuries that might happen because you are taking part in this research.

If you have any questions about the research or about your rights as a subject, I want you to ask me. My phone numbers are at the top of this form. If you have questions later, or if you wish to report a problem, please call me or the Office of Research & Grants Administration at 817-898-3375.

Participation in this study is voluntary, you may withdraw at any time. You may refuse to participate without penalty and will still be offered the packet of information.

This is to certify that I have fully informed and explained to the above named person a description of the study. An offer has been made to answer all of the subjects questions and concerns. The subject will be given a signed consent form to keep.

Investigator

Date

Consent to Act as a Subject for Research and Investigation:

I have received an oral description of this pilot study, including a fair explanation of the procedures and their purpose, any associated discomforts or risks, and a description of the possible benefits. An offer has been made to me to answer all questions about the study. I understand that my name will not be used in any release of the data and that I am free to withdraw at any time. I further understand that no medical service or compensation is provided to subjects by the university as a result of injury from participation in research.

Participant Name (Print)

Signature

Date

Appendix C

Checklist for Perimenopausal Symptoms

SYMPTOM CHECKLIST

DIRECTIONS: For each symptom, circle the number that corresponds to how bothersome the symptom is today.

Symptom	None	Moderate	Severe
<hr/>			
aches and pains in the joints	0.....	1.....	2.....
backaches	0.....	1.....	2.....
depression	0.....	1.....	2.....
diarrhea	0.....	1.....	2.....
difficulty concentrating	0.....	1.....	2.....
dizziness	0.....	1.....	2.....
fatigue	0.....	1.....	2.....
feeling of "losing my mind"			
forgetfulness	0.....	1.....	2.....
headaches	0.....	1.....	2.....
heavy menstruation	0.....	1.....	2.....
hot flashes (flushes) or sweats	0.....	1.....	2.....
irritability	0.....	1.....	2.....
nervous tension	0.....	1.....	2.....
night sweats	0.....	1.....	2.....
pins and needles in hands and feet	0.....	1.....	2.....
rapid heart beat	0.....	1.....	2.....
shortness of breath	0.....	1.....	2.....
trouble sleeping	0.....	1.....	2.....

Appendix D

Daily Log

DAILY LOG

Date	Time Spent Walking	Perceived Exertion	Dietary Changes	Medication Changes	Stress

STRESS: RANK ON A SCALE OF 1 TO 7, WITH 1 BEING THE LOWEST POSSIBLE AMOUNT AND 7 BEING THE HIGHEST POSSIBLE AMOUNT OF STRESS.

COMMENTS: NOTE ANY DIETARY OR MEDICATION CHANGES, OR OTHER COMMENTS.

Appendix E
Demographic Questionnaire

PERSONAL DATA FORM

DIRECTIONS: Please answer the following questions by circling the number in front of your answer or filling in the blank where appropriate.

1. Age: _____
2. Race/Ethnic Group:
 - 1 Caucasian/White
 - 2 African-American/Black
 - 3 Spanish-American/Hispanic
 - 4 Asian-American
 - 5 Native American/American Indian
 - 6 Other (Specify) _____
3. Marital Status:
 - 1 Single
 - 2 Single living with significant other
 - 3 Married
 - 4 Married, separated
 - 5 Divorced
 - 6 Widowed
4. Educational Level:
 - 1 Grammar school
 - 2 High school or GED
 - 3 Some college courses
 - 4 Vocational school
 - 5 College degree
 - 6 Graduate degree
 - 7 Other (Specify) _____
5. Employment:
 - 1 Unemployed
 - 2 Homemaker
 - 3 Employed outside the home, part-time
 - 4 Employed outside the home, full-time
 - 5 Retired
 - 6 Other (Specify) _____
6. Occupation: _____
7. Number of children and ages: _____
8. Household (combined) income per year:
 - 1 less than \$20,000
 - 2 20,001 - 40,000
 - 3 40,001 - 60,000
 - 4 60,001 - 80,000
 - 5 80,001 - 100,000
 - 6 Over 100,001

9. Menopausal Status:

Menstrual pattern over the past 12 months:

- 1 Normal menses (monthly periods) over the past 12 months
- 2 Irregular or infrequent menses over the past 12 months
- 3 No menses over the past 12 months
(Specify number of years since last menses) _____
- 4 Uterus removed but at least one ovary intact (Hysterectomy) (Specify when) _____
- 5 Other (Specify) _____

10. Hormone Replacement Therapy:

- 1 None
- 2 Estrogen only
- 3 Estrogen and Progestin
(Specify name and amount of medication) _____

11. Activity Level:

Over the past 3 months, which best describes your pattern of exercise

- 1 None
- 2 Some
- 3 Regular

Specify _____

12. Medications Taken Regularly (In addition to hormone replacement therapy):

Name of Medication	Amount Taken	Number of Years Taken
--------------------	--------------	-----------------------

_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

13. Health History: For the following health conditions, indicate with a yes if you have it, and write in the word no if you don't.

High blood pressure

Diabetes mellitus

Family history of coronary or other atherosclerotic disease before age 55

Pain or discomfort in chest during activity

Shortness of breath with mild activity

Dizziness

Swelling of the ankles

Heart murmur

Other health conditions. Specify:

Appendix F

Pilot Study: Daily Symptom Checklist, Form A

SYMPTOM CHECKLIST

DIRECTIONS: For each symptom, circle the number that corresponds to how severe the symptom is today.

Symptom	None	Moderate	Extreme
aches and pains in the joints	0.....	1.....	2.....
backaches	0.....	1.....	2.....
cough	0.....	1.....	2.....
depression	0.....	1.....	2.....
diarrhea	0.....	1.....	2.....
dizziness	0.....	1.....	2.....
fatigue	0.....	1.....	2.....
headaches	0.....	1.....	2.....
hot flashes (flushes) or sweats	0.....	1.....	2.....
irritability	0.....	1.....	2.....
nervous tension	0.....	1.....	2.....
night sweats	0.....	1.....	2.....
pins and needles in hands and feet	0.....	1.....	2.....
rapid heart beat	0.....	1.....	2.....
short of breath	0.....	1.....	2.....
sore throat	0.....	1.....	2.....
trouble sleeping	0.....	1.....	2.....
upset stomach	0.....	1.....	2.....

Appendix G

Pilot Study: Daily Symptom Checklist, Form B

SYMPTOM CHECKLIST

DIRECTIONS: For each symptom, circle the number that corresponds to how bothersome the symptom is today.

Symptom	None	Moderate	Severe
aches and pains in the joints	0.....	1.....	2.....
backaches	0.....	1.....	2.....
cough	0.....	1.....	2.....
depression	0.....	1.....	2.....
diarrhea	0.....	1.....	2.....
dizziness	0.....	1.....	2.....
fatigue	0.....	1.....	2.....
headaches	0.....	1.....	2.....
hot flashes (flushes) or sweats	0.....	1.....	2.....
irritability	0.....	1.....	2.....
nervous tension	0.....	1.....	2.....
night sweats	0.....	1.....	2.....
pins and needles in hands and feet	0.....	1.....	2.....
rapid heart beat	0.....	1.....	2.....
short of breath	0.....	1.....	2.....
sore throat	0.....	1.....	2.....
trouble sleeping	0.....	1.....	2.....
upset stomach	0.....	1.....	2.....

Appendix H

Pilot Study: Daily Symptom Checklist, Form C

SYMPTOM CHECKLIST

DIRECTIONS: For each symptom, circle the number that corresponds to how frequent and bothersome the symptom is today.

Symptom	None	Moderate	Severe	None	Occasional	Often
aches and pains in the joints	0.....	1.....	2.....	0.....	1.....	2.....
backaches	0.....	1.....	2.....	0.....	1.....	2.....
cough	0.....	1.....	2.....	0.....	1.....	2.....
depression	0.....	1.....	2.....	0.....	1.....	2.....
diarrhea	0.....	1.....	2.....	0.....	1.....	2.....
dizziness	0.....	1.....	2.....	0.....	1.....	2.....
fatigue	0.....	1.....	2.....	0.....	1.....	2.....
headaches	0.....	1.....	2.....	0.....	1.....	2.....
hot flashes (flushes) or sweats	0.....	1.....	2.....	0.....	1.....	2.....
irritability	0.....	1.....	2.....	0.....	1.....	2.....
nervous tension	0.....	1.....	2.....	0.....	1.....	2.....
night sweats	0.....	1.....	2.....	0.....	1.....	2.....
pins and needles in hands						
and feet	0.....	1.....	2.....	0.....	1.....	2.....
rapid heart beat	0.....	1.....	2.....	0.....	1.....	2.....
short of breath	0.....	1.....	2.....	0.....	1.....	2.....
sore throat	0.....	1.....	2.....	0.....	1.....	2.....
trouble sleeping	0.....	1.....	2.....	0.....	1.....	2.....
upset stomach	0.....	1.....	2.....	0.....	1.....	2.....

Appendix I
Written Consent Form for Pilot Study

TEXAS WOMAN'S UNIVERSITY
SUBJECT CONSENT TO PARTICIPATE IN RESEARCH

Title of Study: Impact of Physical Activity on Perimenopausal Symptoms

Investigator's Name: Terrilyn Pensabene

Investigator's Phone:

Description of the study: The purpose of this pilot study is to evaluate the effectiveness of three variations of a perimenopausal symptom checklist. Participants will meet with the investigator at the beginning of the pilot study in order to receive instructions. Participants will complete three different forms of a symptom checklist over three weeks. Each form will be completed for one week only. For example, form "A" may be completed week one, form "B" during week two, and form "C" during week three. Estimated time to complete the checklist is 15 minutes. At the end of the three weeks, each participant will meet individually with the investigator. At this time the investigator will ask questions regarding the three different forms of the checklist. These sessions will be audio-tape recorded. The interview will take approximately 15 minutes. The participants will not be identified by name on the checklists nor during the interviews. The purpose of taping the interviews is to allow the investigator to review the conversations prior to making final decisions about which form to use for the formal study. The primary investigator and one research assistant will be the only individuals with access to the tape recordings. The tapes will be kept locked in a file cabinet for one year, and will be erased at the end of that time.

Description of risk or discomfort: The risks involved are: loss of time to complete the questionnaires, monetary costs for local transportation to the interview and any possible feelings of discomfort associated with having the interview audiotape recorded. The symptoms checklist will be stored for five years in a locked file cabinet and will be shredded at the end of that time.

Description of possible benefits: As a participant in this study you may experience an increased awareness about yourself and your perimenopausal symptoms. All participants will be offered a summary of the results of the study.

We will try to prevent any problem that could happen because of this research. Please let us know at once if there is a problem and we will help you. You should understand, however, that TWU does not provide medical services or financial assistance for injuries that might happen because you are taking part in this research.

If you have any questions about the research or about your rights as a subject, I want you to ask me. My phone number is at the top of this form. If you have questions later, or if you wish to report a problem, please call us or the Office of Research & Grants Administration at 817-898-3375.

Participation in this pilot study is voluntary, you may withdraw at any time. You may refuse to participate without penalty.

This is to certify that I have fully informed and explained to the participant a description of the study. An offer has been made to answer all of the subjects questions and concerns. The subject will be given a signed consent form to keep.

Investigator

Date

Consent to Act as a Subject for Research and Investigation:

I have received an oral description of this pilot study, including a fair explanation of the procedures and their purpose, any associated discomforts or risks, and a description of the possible benefits. An offer has been made to me to answer all questions about the study. I understand that my name will not be used in any release of the data and that I am free to withdraw at any time. I further understand that no medical service or compensation is provided to subjects by the university as a result of injury from participation in research.

Participant Name (Print)

Signature

Date

Appendix J
Introductory Letter to Participants

Dear Prospective Participant:

My name is Terri Pensabene and I am a doctoral student in nursing at Texas Woman's University. Thank you for inquiring about my study. My dissertation is entitled "The Impact of Physical Activity on Perimenopausal Symptoms."

In order to qualify for the study you have to be a woman between the ages of 40 and 60, experiencing symptoms of perimenopause, such as hot flashes, night sweats, forgetfulness, or heavy irregular periods, have been sedentary for at least six months and willing to participate in the study. Participation in my study involves completing a symptom checklist and daily log for eight weeks; and continuing the checklist and log for a second eight weeks while participating in a walking program.

To get started you need to read and sign the consent form (a Xerox copy will be returned to you); complete the form entitled PAR-Q, and the demographic questionnaire. Any information obtained will be held in confidence. Now you're ready to begin.

Complete the daily log and symptom checklist every evening. On the log, document any changes in diet or medication, and level of stress for the day. Ignore "time spent walking" and "perceived exertion" for the first eight weeks. Note any other pertinent information on the log. For the symptom checklist, circle how **bothersome** each of the listed symptoms were for that day. I'll be in touch with you each week in order to give you new checklists and to collect the completed forms.

During week eight, I'll meet with you in order to calculate your target heart rate and to complete a mile and one-half walk-run. Beginning in week nine we'll start walking. We'll meet to walk three times per week. I plan to start with 20 minute walks but we'll have to increase in time and distance in order to show any cardiovascular improvement in the eight weeks. After the eight weeks of walking, I'll conduct the mile and one-half walk-run again.

I appreciate your interest in my study. You can reach me at home (596-3960) or by beeper (817-827-9939). Call me any time you have any questions.

Sincerely,

Terri Pensabene

Appendix K
Physical Activity Readiness Questionnaire

PHYSICAL ACTIVITY READINESS QUESTIONNAIRE

YES NO

- | | | | |
|-----|-----|----|---|
| --- | --- | 1. | Has your doctor ever said you have heart trouble? |
| --- | --- | 2. | Do you frequently have pains in your heart and chest? |
| --- | --- | 3. | Do you often feel faint or have spells of severe dizziness? |
| --- | --- | 4. | Has a doctor ever said your blood pressure was too high? |
| --- | --- | 5. | Has your doctor ever told you that you have a bone or joint problem such as arthritis that has been aggravated by exercise, or might be made worse with exercise? |
| --- | --- | 6. | Is there a good physical reason not mentioned here why you should not follow an activity program even if you wanted to? |
| --- | --- | 7. | Are you over age 65 and not accustomed to vigorous exercise? |
| --- | --- | 8. | Are you pregnant or do you think you could be pregnant? |

Developed by the British Columbia Ministry of Health

Appendix L

Exercise Instruction to Participants

INSTRUCTIONS TO PARTICIPANTS

Now that the initial eight weeks of data collection is completed we will begin the walking phase of the study. The following guidelines will be followed during the exercise phase.

Frequency of walking: 3 times per week

Duration of walking: Begin with 20 minutes, but increase over time. The goal is to increase to 45 minutes by the third week of walking. Do not walk over 60 minutes.

Intensity of walking: After warming up it is important to walk within your target heart rate, or at a perceived exertion rate of 13. Rating of Perceived Exertion is scored as follows:

7	very, very light
9	very light
11	fairly light
13	somewhat hard
15	hard
17	very hard
19	very, very hard

As you continue walking, you will have to increase the intensity of the activity in order to achieve a "somewhat hard" Level of Perceived Exertion.

Warm up?Cool down: It is important to warm up and cool down every time you walk. This prevents soreness and injuries.

Duration of Walking Phase: The walking phase of the study will last eight weeks. At the end of this time a second mile and one-half walk-run will be completed.

If at any time during the walking activity you feel sick, dizzy or feel you have injured yourself, stop immediately and seek medical attention.

WARM UP

HALF NECK ROLLS --four of each. Stretches neck rotators.
 --down and up
 --left to right

CURL DOWN--standing with feet slightly apart, curl down until hands are touching feet. Curl up. Repeat 3 times.

LATERAL TRUNK--stretch right hand over head to the left. Bend to the left with arm slightly in front of head. Do 2 in each direction. Stretches trunk muscles.

LUNGES--lunge to the left with right foot forward. Keep back foot flat. Hold 5 seconds. Bring right foot towards left foot, with head down, hold 5 seconds. Pull up toe of right foot, hold 5 seconds. Repeat each side 2 times.

LUNGES--lunge forward with right foot. Lift left arm and reach behind head. Push elbow with right hand. Hold 5 seconds. Repeat each side 2 times.

SITTING STRETCH--sit with bottom of feet together. Using hands press down on knees while at the same time provide resistance against hands. Stretches inside of thighs.

STRIDE-SIT--sit with legs apart. Bend over with hands forward, head towards knees. Hold for 5 seconds. Left, right, center. Repeat 2 times.

Never bounce while stretching.

After completing the stretching exercises, walk slowly for two minutes before beginning to walk at you working level.

COOL DOWN

First walk slowly for two minutes before stretching.

Repeat warm-up exercises.