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HORMONAL REPLACEMENT THERAPY

presented by

Ann W. Fowler

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# THE RELATIONSHIP OF LEVEL OF WOMEN'S KNOWLEDGE OF MENOPAUSE TO LEVEL OF ADHERENCE TO PLAN FOR EXERCISE, CALCIUM SUPPLEMENTATION, AND HORMONAL REPLACEMENT THERAPY

By

Ann W. Fowler

# A THESIS

Submitted to
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#### ABSTRACT

THE RELATIONSHIP OF LEVEL OF WOMEN'S KNOWLEDGE OF MENOPAUSE TO LEVEL OF ADHERENCE TO PLAN FOR EXERCISE, CALCIUM SUPPLEMENTATION, AND HORMONAL REPLACEMENT THERAPY

By

#### Ann W. Fowler

Women desire information about menopause. Failure to obtain this information may affect their capability for self-care. This study utilized a convenience sample of 201 women age primarily between 40 to 55 years of age to examine the relationship between knowledge of menopause and adherence to plans for exercise, calcium supplementation, and hormonal replacement therapy (HRT). A self-care framework was used. The women scored 88% on the knowledge instrument. Those who planned to exercise did so 59% of the time, those who planned to take calcium supplements did so 77% of the time, and those who planned to take HRT did so 95% of the time. There was no relationship between knowledge and level of adherence to plan for exercise, calcium supplementation, or HRT. Implications include continued client education about menopause and further research to determine what influences adherence to self-care measures.

To Bob, Rob, and Dan for their loving support.

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#### INTRODUCTION

As women enter midlife they begin to experience menopausal symptoms. This normal phase of the life cycle is unique for each woman. Menopause has been viewed negatively by society which places high value on the reproductive ability of women (Frey, 1981). Rather than look at themselves in a negative fashion women are seeking information regarding menopause, its symptoms, and indications for self-care. With roughly half of their lives before them, women want quality of life in the postmenopausal period. Menopause is an integral part of women's health.

The advanced practice nurse (APN), with experience as an educator, has the ability to fill in the educational gaps that exist for the majority of middle-aged and younger women concerning menopause. By sharing scientific knowledge and providing access to primary care, the APN can collaborate with female clients to meet their identified needs.

According to Pender (1987), client education for health promotion emphasizes higher levels of wellness, fulfillment, and life satisfaction. The health of women can be actualized at any phase of the life cycle when these outcomes are reached: "physical fitness, good nutritional

status, creative relaxation, self-awareness, enhanced self-esteem, expanded social support systems, and attainment of important life goals" (Pender, 1987, p.209).

Primary care is the setting in which the APN can collaborate with women to see that these outcomes do occur. All women deserve access to healthcare. As healthcare is changing, women's health programs are being developed to meet the specific needs of women throughout the lifecycle. Research funds are increasingly being allocated for women's health issues (Hickey, Ouimette, & Venegoni, 1996).

In determining client teaching priorities, Futrell et al. (1980) have identified two goals for improving self-care: to determine what issue is most important to the client and what area of knowledge will contribute the most to improving the client's health. The APN tailors health education to focus on the topic that is currently most relevant to the client. The maintenance or enhancement of the health of the client can be achieved as the APN provides the client with the knowledge base that is necessary to meet the client's needs. Continual assessment of the client's knowledge level and ability to incorporate what has been learned into daily self-care measures is necessary to individualize education for the client.

In an educational intervention study conducted by Rothert (1990) women who volunteered for the study made the topic of menopause a priority through their self-selection for the study. These women decided what was on their minds

by answering the media advertisement to participate in the study. In the year that followed, the women kept track of their self-care measures for exercise, calcium supplementation, and hormonal replacement therapy (HRT). They decided on a daily basis what self-care measures they would implement.

The purpose of this study is to determine the relationship between the level of women's knowledge of menopause and their adherence to their plan for exercise, calcium supplementation, and HRT. As an educator, the APN needs to understand what impact knowledge of menopause has on women's self-care strategies.

#### Research Ouestions

The research questions for this study are: Is level of knowledge of menopause associated with adherence to exercise? Is level of knowledge of menopause associated with adherence to calcium supplementation? Is level of knowledge of menopause associated with adherence to HRT? Study Relevance

The results of this study have the potential to provide the APN with a stronger understanding of the impact of education on the menopausal woman. This study will yield information showing whether providing appropriate knowledge required for self-care measures has the potential to improve adherence to self-care. The APN works in partnership with

the menopausal woman to maximize her health for the perimenopausal and postmenopausal period of the life cycle.

#### THEORETICAL FRAMEWORK

The self-care deficit theory of nursing (S-CDTN) developed by Dorothea Orem (1980) will serve as the theoretical framework for this study. Orem's theory consists of three interrelated theories: self-care, self-care deficit, and nursing systems. Self-care is defined as behavior that has been learned through interaction and communication in larger social groups. Self-care is considered to be deliberate and is performed in response to a known need. It is not instinctive or reflexive.

According to Orem, individuals possess the ability and motivation to provide care for themselves and dependents. Unfortunately, not all individuals will seek knowledge or act (Orem, 1980).

Self-care deficit acknowledges the fact that individuals may periodically experience limitations that prevent them from meeting their self-care needs. These limitations may arise from internal or external factors. If a legitimate need exists, then the nurse may address the self-care deficit of the individual (Orem, 1980).

The purpose of the nursing system is to increase the client's capabilities to meet a need or to decrease the demand. The nursing system is composed of the nurse and the patient. If a family member is involved in the care of the client, then this person is also part of the nursing system.

Together the actions of the nurse, client, and family caregiver make up the nursing system (Orem, 1980).

orem (1991) views self-care as deliberate, learned behavior. She sees self-care as goal-directed behavior with a specific purpose. Self-care occurs in phases. Prior to performing a specific self-care action, knowledge of the action and its relationship to continued life, health, and well-being are required. The phases of seeking knowledge and decision-making must take place prior to self-care action. As new life events such as pregnancy and menopause occur, individuals seek out information. One way that individuals learn to understand about their individual needs and the self-care actions necessary to meet these identified needs is through interaction with healthcare professionals. Such an interaction allows the intermingling of scientific knowledge from the healthcare professional with the personal knowledge of the individual (NDCG, 1979).

In the educational intervention study conducted by Rothert (1990), the research team functioned in a supportive-educative capacity as the women performed all the self-care activities (Orem, 1991) over the twelve month intervention period. By volunteering for the study the women sought knowledge about menopause and received education in the form of the study's intervention. As they continued to participate in the study, these women continually made decisions about their self-care activities. They documented whether or not they performed the self-care

measures of exercise, calcium supplementation, and/or HRT.

According to Orem (1990) these women had the right and
capability to be knowledgeable participants in their own
health care. The researchers supported and facilitated the
self-care measures of these menopausal women through the
educational intervention (Orem, 1990).

For the purpose of this study only the concept of selfcare as it pertains to menopausal women will be considered (Figure 1). The model presents a bidirectional relationship between the menopausal woman and the APN. With each interaction, there is an opportunity for an exchange of information between the APN and the woman.

Women's self-care deficits with regards to menopause are not being studied at this time. In this research setting, the women possessed primary responsibility for their personal health. The researchers functioned in a consultative capacity (Orem, 1985).

# CONCEPTUAL DEFINITIONS

### Knowledge of Menopause

According to Webster's Ninth New Collegiate Dictionary (1986), knowledge is the fact or condition of knowing something with familiarity gained through experience or association; the acquaintance with or understanding of a science, art, or technique; and the sum of what is known: the body of truth, information, and principles acquired by mankind (p. 665).

Menopausal Woman

Advanced Practice Nurse

(Personal Knowledge) 
Supportive/Educative (Scientific Knowledge)

Figure 1. A Conceptual Framework for Self-Care of the Menopausal Woman

Performs Self-care

Menopause is the cessation of menstruation due to the loss of ovarian function as a result of surgery or natural process. The menses must be absent for at least twelve months. The perimenopausal period, also called the climacteric, is the period of diminishing ovarian activity before menopause and the first few years of amenorrhea. Postmenopause is the span of life after actual menopause. A normal developmental phase, menopause takes place between 50 to 51 years of age for women who have not undergone surgical removal of their ovaries. Menopause occurs roughly at the same time for each woman regardless of menses, childbearing, socioeconomic factors, weight, or race. Each woman can plan on spending about one-third of her life in the postmenopausal period (McCance & Huether, 1994).

This author defines knowledge of menopause as the understanding of the physiology, symptomatology, and treatment measures/options/risks related to menopause. Failure to have adequate information about menopause

threatens the control a woman has over her own body (McElmurray & Huddleston, 1991). Unfortunately, women's knowledge of menopause seems to be defined by what they do not know. Women have been tested to ascertain their understanding of this natural event. Even when a woman feels well-informed about menopause, this is not always the case when tested (LaRocco & Polit, 1980). According to Cook (1993) some of the problems associated with perimenopause can be lessened and potentially disabling problems avoided through education concerning aging, menopause, osteoporosis, sexuality, self-esteem, and treatment alternatives.

#### Adherence

Webster's Ninth New Collegiate Dictionary (1986) defines adherence as a steady or faithful attachment, an act, action, or quality of adhering (to bind oneself to observance) (p. 56). The medical literature frequently interchanges compliance with adherence. Sackett and Haynes (1976) define compliance as the extent to which a person's behavior coincides with medical advice. In the spirit of developing a partnership with clients rather than a paternalistic relationship, this author would prefer to refer to client behavior as adherent.

These two variables have been chosen as a means to understand what may influence how a menopausal woman performs self-care. Each woman brings personal knowledge to her own experience of menopause. The APN provides scientific knowledge that the woman may or may not possess.

Women require both personal and scientific knowledge to make decisions about menopause (Rothert, Padonu, Holmes-Rovner, Kroll, Talarczyk, Rovner, Schmitt, & Breer, 1994). By looking at level of knowledge of menopause and adherence to plans for self-care after the women have undergone an educational intervention, this study hopes to find that the supportive-educative interaction that the research team had with study participants made a difference in the women's adherence to plans of self-care.

### REVIEW OF LITERATURE

# Knowledge of Menopause

Within the healthcare literature the dissatisfaction of women with their knowledge of menopause is documented (Andrews, 1995). A recent Gallup poll of North American women in the 40 to 60 age bracket showed that only 44% were satisfied with the knowledge that they received from their physicians regarding menopause (Utian & Stiff, 1994). This sends a clear message that the information regarding menopause is not reaching the people to whom it is most relevant: women.

LaRocco and Polit (1980) studied the relationship between a woman's level of knowledge and her background characteristics. Using a mailed questionnaire, data were collected from 167 women from 40 to 60 years of age, in an urban setting. The results indicated that younger women, women who were employed, and women with higher levels of education were more knowledgeable about menopause than

older, unemployed, and less well-educated women. The authors noted that what the women feared most about menopause was not knowing what to expect. LaRocco and Polit concluded that this gave nurses the opportunity to play a supportive and educative role in helping women cope with menopause and any potential problems (1980).

Johnson and Snow (1979) compared the concerns, attitudes, and beliefs about menopause and menstruation of 31 patients in a prenatal clinic serving low-income clientele with 24 students from a nearby university. The data were gathered as part of a larger study about the knowledge and beliefs of women regarding reproductive life. The results demonstrated that young women of the same age group living in the same geographic area can possess very different knowledge about menopause and menstruation. No assumptions could be made on the level of knowledge of menopause simply on the basis of amount of education a woman possessed. Anxiety and a deficiency of knowledge of menopause exist for many women.

Millette (1981) surveyed the attitudes and knowledge of menopause among 130 professional and blue collar employees of a community hospital and local school system. A difference was noted in the relationship between income level and knowledge for the two groups of women. The women from the upper income level demonstrated higher knowledge scores.

Frey (1981) studied women's perceptions of menopause and their relationship to physical symptoms, psychological, and sociocultural variables. The survey of 78 women, aged 40 to 60 years, investigated attitudes, symptoms, demographic characteristics, mother's experiences with menopause, age of menarche, number of children, and socioeconomic status. The relationship among the demographic variables, physical symptoms, and attitudes toward menopause was explored. The results demonstrated that in general the women did not possess an illness orientation toward menopause. Rather than devising a treatment program focused on drug therapy or surgical intervention, Frey recommended using support techniques, teaching coping skills, and providing health-oriented information to meet the needs of menopausal women.

The body of the literature pertaining to women's knowledge of menopause is clearly lacking. More literature regarding symptoms and symptom management can be found than information about what women actually know about menopause. In McElmurray and Huddleston's (1991) meta-analysis of self-care and menopause, it was found that women have little access to usable information regarding the menopausal experience. Much of the literature at the time the meta-analysis was conducted was written in technical language or biased by either a disease-oriented or hormone-deficiency perspective. McElmurray and Huddleston concluded that

without sufficient information, women are thwarted in their attempts to control their own bodies.

The limited published research concerning women and their knowledge of menopause underscores the important role of the APN as an educator and researcher. Further studies are necessary to determine what women currently know about menopause. Then interventions can be devised to promote, maintain, and enhance women's health (McElmurray & Huddleston, 1991).

#### Adherence to Exercise

The following is a review of the literature related to adherence to exercise. This author did not find studies related specifically to knowledge of menopause and adherence to exercise. Exercise has been discussed as a form of symptom management in menopause. The exercise literature discusses adherence to plans for exercise. Within the osteoporosis literature, many articles recommend that women in midlife should exercise to decrease the risk of osteoporosis (Bond, 1991; Gregory, 1982; MacPherson, 1985; & Wark, 1993). Appropriate exercise contributes to good health and decreases the risk of disease (Bouchard, Shephard, Stephens, Sutton, & McPherson, 1990).

Robertson and Keller (1992) developed a model to identify the relationships between variables that explained adherence to an exercise regimen for clients who had undergone coronary artery bypass graft surgery (CABG) or percutaneous transluminal angioplasty (PTCA). Thirty-one

percent of the variance in exercise adherence was explained by perceived barriers, benefits, severity, self-efficacy, and type of surgery. Perceived barriers contributed the largest amount of variance, followed by self-efficacy and type of surgery. The study findings suggested the importance of self-efficacy and health beliefs in describing exercise adherence in this particular cardiac population. It should be noted that 75% of the 51 subjects were male.

Jensen and Lorish (1994) surveyed physical therapists and patients to create a database regarding barriers experienced in the implementation of exercise programs in clinical practice. The questionnaires from 568 physical therapists and 305 rheumatic disease patients were analyzed. Patient survey results indicated that the difference between patients who continued an exercise program from those who did not were: patient beliefs about consequences, judgments of consequences as positive or negative, and the importance of the consequences. To enhance patient cooperation with exercise programs, inquiry into the patient's belief system, problem solving, and negotiation between patient and therapist were recommended. The authors did not specifically state whether the survey measured the patients' knowledge of their rheumatic disease as it looked at their belief systems.

Wilbur, Holm, and Dan (1992) identified the relationship between menopausal status, physical and psychologic symptoms, and energy expenditure. Two hundred

and seventy-nine women, age 37 to 64, were included in this second wave of a longitudinal study of midlife women's health. Physical activity was explored as a means of menopausal symptom management. Leisure activity energy expenditure appeared to have a positive effect on decreasing menopausal symptoms. Occupational activity energy expenditure had a negative effect on menopausal symptoms.

Dzewaltowski, Noble, and Shaw (1990) compared the theory of reasoned action, theory of planned action, and social cognitive theory in the prediction of physical activity participation. Two hundred and fifty-four undergraduates self-administered a 7-day recall questionnaire about the previous week's physical activity participation. Then for each of the next four weeks, the participants again completed the 7-day recall questionnaire. The results demonstrated that self-efficacy was the better predictor of exercise behavior than intention.

Lee (1993) conducted a telephone survey of attitudes and behavior related to the adoption of exercise by 286 Australian women, age 50 to 64 years. The study identified psychological variables that distinguished stages of change related to exercise. The purpose of the study was to identify possible targets for intervention. A multivariate analysis of variance was performed for the three change categories: precontemplators, contemplators, and action/maintenance. Forty percent of the subjects reported regular exercise. Precontemplators of change were

distinguished from the action group by exercise knowledge, perceived family support, and perceived psychological barriers. The precontemplators were older, possessed lower levels of exercise knowledge, viewed their families as less supportive of their exercise activity, expected less psychological benefits from exercise, and rated avoidance of smoking as more important than exercise. Contemplators and the action group were distinguished from each other by perceived barriers. One third of all respondents expressed a reluctance to go out alone to exercise and a reluctance to use public changing facilities. More than half the women in the sample viewed gyms and fitness centers as the domain of younger people. The study found that there was a need for basic information about safe and effective levels of exercise activity for women in this age group. Finally the study identified attitudes and knowledge as potential areas for future interventions with middle-aged women.

Bernhard and Sheppard (1992) conducted a crosssectional survey of 101 menopausal women who were over 40
years of age, menopausal, had not used hormones during the
last six months, and had an intact uterus. The study tried
to determine the relationship among menopausal symptoms,
perceived health, and self-care responses in perimenopausal
and postmenopausal women. The authors concluded that health
was related to self-care and menopausal symptoms.

The health-promoting behaviors of African-American women were surveyed by Ahijevych and Bernhard (1994). The

187 women ranged from 19 to 69 years. The Health-Promoting Lifestyle Profile (HPLP) instrument was used to assess the health promotion activities of these women. Self-actualization and interpersonal support subscales had the highest means. The exercise scale had the lowest mean. Dulberg (1992) also found that black women practiced exercise less than white women.

Hartweg (1993) studied 153 black and white women ranging from age 40 to 59. The study attempted to describe specific health actions performed by middle-aged women for health promotion. The relationship between self-care actions to age, sociocultural orientation, work patterns, and family system factors was explored. The activity category identified walking as the most frequent physical activity used to promote physical well-being. Higher levels of formal education were related to more self-care actions of social interaction, normalcy, activity, solitude and hazards. The women with higher education also undertook more activities associated with developmental change and self-care demands related to alterations in health status.

Further study is necessary to determine what relationship exists between knowledge of menopause and adherence to exercise. Little research was found in this area. Lee's (1993) study emphasized the need to provide middle-aged women with more information about exercise. Hartweg (1993) found that more educated women engage in more self-care activities. Perceived barriers to exercise cannot

be ignored when examining the exercise behavior of individuals. The APN can help the menopausal woman to make appropriate decisions related to menopause as the woman learns about of the effects of exercise. Every woman has the right to individualized care that addresses needs and risk factors.

# Adherence to Calcium Supplementation

The review of the literature did not reveal data related to knowledge of menopause and women's use of calcium supplements. Instead the data focus on the role of calcium in the prevention of osteoporosis with or without HRT (Bond, 1991; Christiansen, 1994; Larson & Shannon, 1984; Ravnikar, 1993; & Wark, 1993). Larson and Shannon (1984) developed an osteoporosis health risk assessment form designed to solicit information from the client population regarding exercise, calcium in the diet, calcium supplementation, family risk for osteoporosis, and knowledge of osteoporosis. No data collection using this tool was found in the literature search conducted by this author.

The Women's Health Initiative (WHI) was developed to determine whether or not long-term preventive measures would decrease the incidence of certain cancers, cardiovascular disease, and fractures. The WHI was also designed to find better predictors of future disease and health in older women. Part of the clinical trial and observational study will include a component related to the prevention of osteoporotic fractures. Forty-five thousand women will be

involved in the trial to determine the effect of calcium and vitamin D supplementation on the prevention of colorectal cancer and osteoporotic fractures. It is predicted that the information from the WHI will be available by 2007 (Rossouw, Finnegan, Harlan, Pinn, Clifford, & McGowan, 1995). This data will have the opportunity to increase the body of knowledge regarding women's health.

As little information is available concerning the way that adherence to calcium use relates to knowledge of menopause, further research is warranted. Women may be taking calcium supplements for various reasons. If the goal of the menopausal woman is to promote her health through self-care activities, then she needs to be well-informed as to what type of calcium supplement she should take, the correct amounts, reasons for, and the possible adverse side effects of the specific supplement.

# Adherence to HRT

As previously noted, the majority of the literature relating to women's continued HRT use is referred to in terms of compliance, not adherence. Perhaps this comes from the paternalistic medical frame of reference regarding prescriptions and the client's reaction to this form of a medical command. In any case, the manner in which women have chosen to take or not take HRT will be discussed.

Ryan et al. (1992) assessed the compliance of 400 postmenopausal women in taking HRT after they were screened for osteoporosis. This screening lead to increased use of

HRT for women who were identified as being at greatest risk of osteoporosis. After 8 months, 40% of the women with low bone density stopped taking HRT. The two main reasons for cessation of HRT were weight gain and withdrawal bleeding.

Coope and Marsh (1992) used education and screening to determine if these two factors could improve HRT compliance. A clinic was designed to provide education and screening of British women aged 40 to 60. Of the 1322 women who were identified by the medical practice's age-sex register and sent a postal invitation to attend the screening, 681 women responded and attended the health education clinic. weekly clinic was run by a doctor and a nurse. education process included information about calcium dietary intake, HRT for eligible individuals, sunlight for vitamin D synthesis, smoking cessation, and exercise. Advice about health, cardiac diet, aerobic exercise, smoking cessation, and the advantages of HRT for osteoporosis and cardiovascular disease were given. Compliance with HRT was measured by repeat prescriptions for the medication. data was collected by an audit of the patient's records and a computerized list of repeat prescriptions for HRT. Compliance for HRT over a one to five year period ranged from 84% to 92%. Reasons given for stopping HRT were: fear of breast cancer, dislike of bleeding, anxiety over possible thrombosis, and side-effects such as painful breasts.

Groeneveld et al. (1995) tried to determine the cumulative incidence of first HRT prescription and what

predicts its prescription. The study also looked at the influence of women's well-being, attitude toward menopause, menopausal status, and other variables on first HRT prescription in the sample during the nine month follow up period. The sample consisted of 1689 Dutch women from age The researchers found that within 21 months, the 45 to 60. majority of the women who had been prescribed HRT had discontinued the medication. For women who did not have typical menopausal complaints, physicians prescribed HRT five times more frequently to those women who demonstrated lower levels of well-being. For women who had typical menopausal complaints, the HRT prescription was mainly related to the women's attitude toward the medical treatment of menopause. Thus it appeared that most HRT prescriptions were given to the women for therapeutic rather than preventive reasons.

Cano (1995) followed 331 postmenopausal women for 1 to 5 years. Compliance was defined as taking the medication for 1 year. Nine percent never filled the prescription, 15% interrupted treatment, and 14% demonstrated sporadic compliance. The variables of progestins and oral route of administration of HRT determined lower levels of compliance. Source of referral and severity of menopausal symptoms did not influence compliance in the study. Cano concluded that women who understood why HRT was prescribed were more compliant in taking the medication.

Wren and Brown (1991) reviewed HRT use in 101
postmenopausal women 1 year after the initiation of
treatment. Sixty-one percent continued therapy. Twentyseven percent ceased to take HRT. No data were available on
12% of the subjects. The main reason for cessation of HRT
was the return of bleeding. Fear of adverse reaction to HRT
was also common in compliant and non-compliant groups. The
researchers strongly recommended followup visits, monitoring
of the client's response to HRT, and the individualization
of HRT for each client. Stumpf and Trolice (1994) also
stressed the importance of education and individualization
in HRT to enhance compliance.

This literature review demonstrates the need for further research regarding women's knowledge of menopause and their adherence patterns to methods of self-care. Though not the focus of this study, the areas of self-efficacy and perceived barriers to action warrant further research with regards to menopausal women. As the research is compiled, the APN will be in a position to provide women with the access to the knowledge that they desire. When uncertainty about menopause is replaced with usable knowledge, women will be better prepared to make sound decisions (Andrews, 1995) and implement individualized self-care measures.

#### **METHOD**

# Design

This study is a secondary analysis of the data from the "Decision Making in Menopause" study conducted by principal investigator Rothert (1990) (Appendix A) and funded by the National Center for Nursing Research (NR01245). The purpose of the original study was to design an educational intervention to aid women to become more effective decision—makers regarding menopause and HRT.

Description of Parent Study. In the original study, the convenience sample of 379 women age 40 and over was recruited through the media of radio, television, and newspaper requests. Women were not excluded from the study because of menopausal status, current medication taking behavior, or hysterectomy. Sociodemographic data about the participants was collected in the following areas: age, race, education, employment, household income, religion, and time since last menstrual period. The subjects ranged from 40 to 65 years of age. Forty-six percent of the sample fell between the ages of 46 to 50. Ninety-four percent of the sample was Caucasian, more than half were married and employed full-time. Almost half of the sample had a household income between \$50,000 to \$99,999. Forty-nine percent had earned a bachelor's degree or more. More than half the sample still reported having menstrual periods, 14.3% had had a hysterectomy, and one-tenth had had one or both ovaries removed. Half the women reported that they

were currently experiencing menopausal symptoms, while 24% were not sure if they were having symptoms. More than half the women were not sure if they would take HRT (Rothert, 1990).

Following recruitment, the women were randomly assigned to one of three groups. Group A received a written brochure about menopause. Group B received the brochure and participated in a lecture/discussion group. Group C received the brochure and was given interactive decision support (Rothert, 1990).

Data was collected at pre-intervention (Time 1), three weeks later/post intervention (Time 2), six months post-intervention (Time 3), and 12 months post-intervention (Time 4). Data collection took place in a classroom setting on a large Midwestern university campus. At the three different classroom sites, two members of the research team were present to offer consistent instruction to the participants. Instruments used in the study included sociodemographic, perceptions of menopause, menopausal symptoms, symptom management and self-care, knowledge of menopause, satisfaction with interaction with health professional, and self-care efficacy. Adherence to a plan for self-care was measured using a calendar format (Rothert, 1990).

The researchers found no differences in the level of adherence between the three groups. A small, but statistically significant difference was noted in the level of knowledge between the three groups post-intervention.

Although the women were assigned to three different treatment groups, the data for the three groups was pooled for this study.

In terms of attrition, of the 379 women who registered for the study, 300 (79%) women participated in Session 1.

Two hundred and fifty-two women participated in the additional sessions. Two hundred and one (80%) women completed the entire twelve month study.

Description of Present Study. This study used a descriptive correlational design to determine if a relationship existed among the identified variables. These variables were: level of knowledge of menopause and adherence to plan for exercise, calcium supplementation, and HRT.

The sociodemographic characteristics for the 201 women who participated in the study at time 4 are given in Table

1. These women were primarily 40 to 55 years of age,
married, employed full-time, earned a household income of
\$50,000 or greater, college-educated, Protestant, Caucasian,
and more than half still had natural menstrual periods.

Operational Definitions of Variables and Instrumentation

For the purpose of this study the knowledge of menopause scale and the calendar self-report measure were utilized from the research developed by Rothert (1990). Only the data collected at month 12 (Time 4) was used. As with all the instruments, these two instruments were developed and reviewed by a multidisciplinary team of

Table 1

Sociodemographic Characteristics of Sample (Time 4)
(N = 201)

Characteristic	n	*
Age (years)		
40-45	62	(24.6)
46-50	84	(33.3)
51-55	48	(19.0)
56-60	5	(2.0)
61-65	2	(0.8)
Race		
African-American	3	(1.2)
Hispanic	1	(0.4)
American Indian	1	(0.4)
White	194	
Other	2	(0.8)
Marital Status		
Married	137	(54.4)
Divorced	47	(18.7)
Single	15	(6.0)
Widowed	2	(0.8)
Employment Status		
Full-time	126	(50.0)
Part-time	40	(15.9)
Retired	12	(4.8)
Not employed	19	(7.5)
Other	4	(1.6)
Income		
< \$14,999	9	(3.60)
\$15,000-\$29,999	21	(8.3)
\$30,000-\$49,999	54	(21.4)
\$50,000-\$99,999	92	(36.5)
\$100,000-\$200,000	18	(7.5)
>\$200,000	4	(1.6)
Education Wight Cohool Products		_
High school graduate	16	(6.3)
> 12 years	53	•
Technical trade/community college	25	•
Bachelors degree	52	•
Masters degree	37	•
PhD/Professional degree Other	16	` '
Other	2	(0.8)

Table 1 (continued)

Characteristic	n	8
Religion		
None	27	(10.7)
Jewish	3	(1.2)
Protestant	110	(43.7)
Catholic	49	(19.4)
Other	12	(4.8)
When last period?		
Still have natural period	111	(44.0)
Less than three months ago	5	(2.0)
3 to 12 months ago	20	(7.9)
More than 12 months ago	65	(25.8)

nurses, physicians, menopause researchers, psychologists, and lay representatives. This group assessed the instruments for validity, conceptual definition, and clinical relevance (Rothert, 1990).

# Sample

Knowledge. Level of knowledge of menopause was measured using a 24 item scale which assessed the subjects' knowledge regarding risk factors associated with HRT, menopausal symptoms, and self-care strategies related to menopause. The questions were comprised of 11 multiple choice and 13 true-false items. Items were coded "1" or "0" for correct or incorrect/missing and are summed. A higher level of knowledge of menopause was reflected in a higher number of correctly answered items. A lower level of

knowledge of menopause was demonstrated by a lower number of correctly answered items (Appendix B: Knowledge Scale).

The internal consistency of the knowledge scale was measured by computation of an alpha coefficient. In the original pilot study of 120 women recruited from faculty and staff of a large Midwestern university, an alpha coefficient of 0.77 was produced. During a process of modification to improve the clarity of the scale, several items were either deleted or rewritten. Following the administration of the scale to 251 women, the knowledge scale produced a coefficient alpha of 0.85. Factor analysis of the knowledge scale revealed a unidimensional scale (Rothert, 1990). No test-retest reliability has been done.

Adherence Measurement. This study looked at the calendar data for month 12. To measure adherence to plan for exercise, calcium supplementation, and HRT use, the subjects agreed to keep a record of their activities on a calendar (Appendix C: Calendar). The calendar data was returned monthly for 12 months. Each woman devised a personal plan for intended exercise, calcium supplementation, and HRT. At the end of each month, the planned activity frequency (i.e., exercise three times per week) was divided by the actual frequency (i.e., exercised two times per week). Only the mean adherence scores for exercise, calcium supplementation, and HRT for month 12 were used in this study.

# Data Collection Procedure

This study considered data that was collected at month

12. The knowledge scale was administered in the classroom

setting of a large Midwestern university. Participants

mailed the calendar data for month 12 to the research office

as they had done for the previous 11 months.

# Data Analysis

Data analysis was conducted using the SPSS computer software. Pearson's correlation coefficient was used to analyze the relationship between level of knowledge and exercise adherence, the relationship between level of knowledge and adherence to HRT, and the relationship between level of knowledge and adherence to calcium supplementation.

# Protection of Human Subjects

Individual rights of subjects were protected according to the University Committee on Research Involving Human Subjects (UCRIHS) guidelines. Application for approval to conduct this secondary analysis was made prior to data analysis. Confidentiality was protected by giving an identification code number to each participant in the study. Each person signed a consent form prior to participation in the study. All responses throughout the study remained confidential. Data results were collectively reported.

# RESULTS

# Analysis by Research Ouestion

Ouestion 1. The purpose of this research was to answer three questions about menopausal women. The first was: What

is the relationship between level of knowledge of menopause and adherence to plan for exercise?

The mean knowledge score from the 24 item scale is 20.8 with a standard deviation of 2.7 and a range from 11 to 24 (Figure 2). A mean score of 21 indicates that the women on average correctly answered 87.5 percent of the questions.

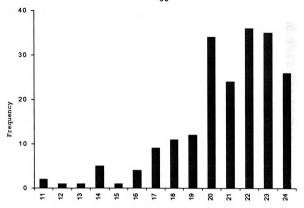
The mean adherence to plan for exercise score for month 12 is .59 with a standard deviation of .39 and a range of .00 to 1.00 (Figure 3). A mean score of .59 indicates that women adhered to a plan for exercise 59 percent of the time.

Pearson's correlation coefficient indicates that there is a very weak relationship between level of knowledge and adherence to exercise in this sample, r=.06. The results are not generalizable to the population as the probability is .25.

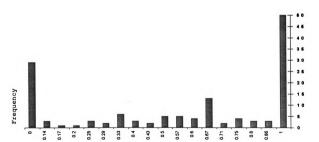
Question 2. The second question was: Is there a relationship between level of knowledge of menopause and adherence to plan for calcium supplementation?

The mean adherence to plan for calcium supplementation is .77 with a standard deviation of .38 and a range of .00 to 1.00 (Figure 4). A mean score of .77 indicates that the women adhered to a plan for calcium supplementation 77% of the time.

Pearson's correlation coefficient indicates that there is weak negative relationship between level of knowledge of menopause and calcium supplementation, r=-.09. This result

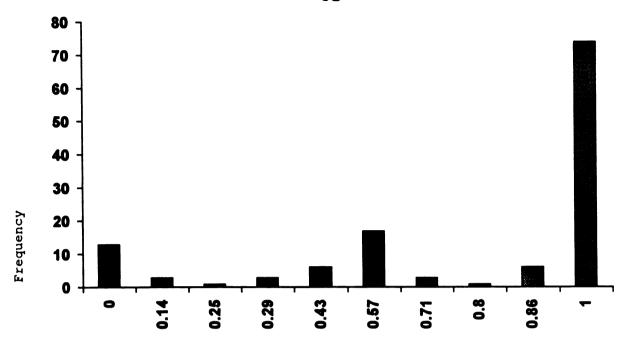


Knowledge=4; Mean=20.8; Standard Deviation=2.7; №201
Figure 2. Frequency Distribution of Knowledge Scores



Adherence to Exercise, Month 12
Mean=.59; Standard Deviation=.39; N=139

Figure 3. Frequency Distribution of Adherence to Exercise



Adherence to Calcium, Month 12 Mean=.77; Standard Deviation=.38; N=117

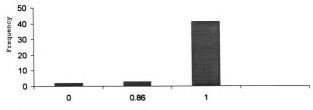
Figure 4. Frequency Distribution of Adherence to Calcium

is not generalizable to the population as the probability is .18.

Ouestion 3. The third question was: Is there a relationship between level of knowledge of menopause and adherence to plan for HRT?

The mean adherence to plan for HRT is .95 with a standard deviation of .21 and a range of .00 to 1.00 (Figure 5). The variance for this group is very low at .043. A mean score of .95 indicates that women adhered to a plan for HRT 95 percent of the time.

Pearson's correlation coefficient indicates that there is a weak negative relationship between level of knowledge of menopause and adherence to plan for HRT, r=-.08. The



Adherence to HRT, Month 12 Mean=.95; Standar Deviation=.21; N=46

Figure 5. Frequency Distribution of Adherence to HRT

results are not generalizable to the population as the probability is .30.

#### DISCUSSION

Study findings are reviewed in this section. First, an overview of findings is given, second the three research questions are discussed, and third, implications of study findings in terms of self-care and the APN as a primary care provider are reviewed. Finally the limitations of the study are presented with suggestions for future research.

The women who participated in this study were recruited through convenience sampling methods. The sociodemographic characteristics indicated that this was a fairly homogeneous group. The majority of the women were Caucasian (77%), married (54.4%), employed full-time (50.0%), and over half of the sample reported an income of \$50,000 or more. Almost

half of the women had earned a degree at a bachelor's level or greater.

In comparing the characteristics of the women who chose to take follow plans for exercise, calcium supplementation, and/or HRT versus the entire sample of 201 women at time 4, differences are noted in the subsample that took HRT.

Analysis of variance for each subsample and each of the sociodemographic variables demonstrates that the women who took HRT were older (F-ratio 5.37, F-probability .0215), less educated (F-ratio 4.41, F-probability .037), and had a greater lapse of time since last period (F-ratio 50.0, F-probability .0000) than those women in the sample who chose not to take HRT.

The findings of this study will serve as a starting point in looking at a menopausal woman, her knowledge of menopause, and how she adheres to plans for self-care. Future inclusion of more diverse populations and cultures of women would provide more information to increase the body of knowledge regarding the menopausal woman.

# Research Ouestions

Knowledge and Adherence to Exercise. The weak relationship found between level of knowledge of menopause and adherence to plan for exercise in month 12 of this study raises new questions. What other factors affect the daily adherence to exercise? A look at the reviewed literature may provide direction for issues to be pursued.

After reviewing the results of the study by Jensen and Lorish (1994), one would ask what perceived barriers to exercise existed for the women in this study. Health beliefs and self-efficacy are also factors to consider to determine how these women viewed exercise. Did those who followed a plan for exercise have differences in their beliefs regarding the consequences of exercise? If so, did they see these consequences as positive or negative? Were the consequences of exercise important to them?

Dzewaltowski et al. (1990) concluded that self-efficacy was a better predictor of exercise than intention. If this study had looked at self-efficacy related to the subjects and their exercise plans would a strong relationship been found? What about intention?

Lee (1993) concluded that women who were classified as precontemplators of exercise were older, possessed less exercise knowledge, and perceived less family support for exercise. This study found no age difference between those women who followed a plan for exercise and those who did not. Exercise knowledge and family support were not measured. In future studies exercise knowledge of menopausal women could be measured along with general knowledge of menopause. Researchers might ask menopausal women whether they viewed their families as supportive of exercise and if they perceived any barriers to exercise.

Dulberg (1992) noted that black women exercise less than white women. This study was too homogeneous in terms

of its ethnic makeup to look at this issue. A more diverse sample would be necessary to compare exercise characteristics of menopausal women. Sociodemographic characteristics, exercise knowledge, self-efficacy, and perceived barriers are areas that could provide information about the menopausal woman and her exercise profile. Choice of exercise type, environment, and ease of exercise are also factors to consider.

Knowledge and Adherence to Calcium Supplementation.

The weak relationship found between level of knowledge of menopause and adherence to plan for calcium supplementation in month 12 of the study illustrates the lack of information about menopausal women and calcium use. What other factors affect the daily ingestion of a calcium supplement? Cost, choice of supplement type, sense of risk of osteoporosis may influence the decision. The information from the WHI study may yield information about women and calcium use (Rossouw et al., 1995).

Knowledge and Adherence to HRT. The weak relationship between level of knowledge of menopause and adherence to plan for HRT at month 12 suggests that other factors affect adherence besides knowledge. Previous research has shown that side effects such as bleeding and breast tenderness along with fear of cancer are reasons women give for ceasing to take HRT (Cano, 1995; Coope et al., 1992; Natchingall, 1990). Cano (1995) concluded that women who understand why they take HRT are more compliant than those who do not.

This study looked at only the last month of the entire 12 month plan. To examine knowledge and adherence to HRT over the entire 12 month period might demonstrate a more significant relationship. The sample size in this study for the HRT group consisted of only 46 women.

Groenewald et al. (1995) noted that most HRT prescriptions were written for therapeutic rather than preventative reasons. Did this mean that women wanted to take HRT for symptom management rather than for the longterm benefits? Would these women be planning only short term use of HRT? In parent study (Rothert, 1990), the brochure that the women were given addressed the long-term benefits of HRT. Did these women who followed a plan for HRT do so for symptom management, long-term benefits, or both? A longitudinal study of greater than one year might yield more information about a long-term adherence to plan and how women dealt with the side effects and fears that so often influence women to stop taking HRT. Do women who take HRT for preventative reasons view coping with HRT side effects in the same way as women who choose HRT for preventive reasons? Are side effects a greater predictor of non-compliance in one group more than another? Implications for Advanced Practice Nursing and Primary Care

Though this study did not show a relationship between the selected variables, there is still much to consider in terms of primary care issues for menopausal women and women in general. As Pender (1996) notes, physical fitness,

adequate nutrition, effective relaxation methods, selfawareness, increased self-esteem, expanded social systems,
and fulfillment of life goals are all important issues for
women. All women have a right to good health. Knowledge
about their bodies is part of self-care for women.

Menopausal women need health-oriented information to meet
their own needs not just information about drug therapy and
surgical interventions (Frey, 1981). Healthcare
professionals who value self-care can assist women by
teaching them self-care measures and relevant information
and assisting them to explore choices (McElmurray et al.,
1991).

Hartweg (1993) found that women with higher levels of education undertook more self-care actions as they experienced developmental changes and self-care demands. This study did not find any difference between the women who followed plans for self-care versus those who did not. The women who followed a plan for HRT were actually slightly less educated than the women who did not. However the small sample size and homogeneity of this group must be considered as there was little variance among the 46 women who chose to follow a plan for HRT.

Millete (1981) supported the need to look at the differences in levels of knowledge of menopause for women with lower economic means. This underscores the importance of including women of diverse educational and economic levels in research studies to obtain a better understanding

of menopausal women. Economic means and access to healthcare are important issues to take into account when trying to provide comprehensive healthcare to menopausal women. Not all menopausal women are aware of the appropriate screening measures they should be receiving or what options exist for menopausal symptoms. Even if women do possess the understanding of these pertinent healthcare issues, they may not possess the resources to obtain adequate care. The APN can serve as an advocate for such women by providing access to primary healthcare.

The APN should never assume that clients who are articulate and well-educated are knowledgeable about the basic facts regarding basic physiological function of menstruation or its cessation at menopause (Johnson & Snow, 1979). A higher economic status and educational level do not guarantee a fuller understanding of menopause.

Assessment of every client's knowledge level is necessary.

The APN has the opportunity to assess the client's understanding of her body during visits to the primary care setting. When the adolescent comes to the APN for healthcare, this is when a holistic approach to self-care can be initiated: the need for exercise on a lifelong basis and its implications throughout the life cycle, the importance of calcium in dietary and supplemental forms for bone growth, a knowledge of the crucial periods of bone formation and loss, osteoporosis risk factors, hormonal replacement therapy, cardiac health, etc. Health promotion

and prevention are ongoing. Having established a working collaborative relationship with individuals, the APN is in a position to take advantage of every encounter to reinforce health teaching to promote the health and self-care of clients.

Though this study did not support the model for self-care for the menopausal woman that was proposed (Figure 1), it does not mean that knowledge of menopause does not play a role in self-care activities of middle-aged women. The schematic drawing is perhaps too simplistic. Further research is needed to look at what other factors influence a menopausal woman to carry out a plans for self-care.

The model depicts a bidirectional relationship between the menopausal woman and the APN. The menopausal woman provides the APN with new information with each interaction. The APN, in a supportive/educative role, has the potential to influence the health outcomes of the woman. As the menopausal woman seeks to meet her self-care demands by performing self-care measures, it is at this point that the APN can serve as a resource to maximize the responsible health-seeking behaviors of her client.

Pender (1996) states "Adequate attention to self-care during the young and middle-aged years promotes optimal productivity and life satisfaction and lays the groundwork for a healthy and productive retirement and old age rather than one fraught with discomfort, disability, and compromised quality of life" (p. 102). There is no better

health legacy that an APN could encourage a menopausal woman to invest in. Health promotion for the menopausal woman is a plan that focuses on health and will save the individual and society healthcare dollars as well. This long-term plan for health needs to begin in adolescence, not with the first hot flash.

A knowledge assessment tool is a starting point. By determining what women know and do not know the APN has some sense of how to assist the client to meet her self-care needs. A menopause questionnaire would provide the woman with an opportunity to focus on herself to assess her own health needs. Such a knowledge assessment would stimulate new questions and heighten self-awareness (Gendler, 1979). The exchange of information about menopause should be formalized in the manner similar to the preconception visit with specific guidelines and recording keeping tools (Andrews, 1995).

According to Orem (1971), the first step in self-care is for the client to come to understand her health status, capabilities, and level of functioning. Once a knowledge questionnaire has been completed, the APN and menopausal client have the opportunity to assess and review together what the client does and does not know. This is also a time to identify what strengths and weaknesses may affect the self-care actions of the client (Gendler, 1979). Together the APN and client can collaborate to set goals for self-care. Assessment of clinical outcomes for the

individualized self-care plan of the client must be incorporated into the mutually-defined plan of care.

Through assessment of outcomes, both the client and the APN are given feedback about the success of the plan.

The APN can use the following self-care education components (Carporael-Katz, 1983): allow time for expression of feelings, reinforce client self-esteem, provide open access to healthcare, foster immediate practice of self-care skills, present alternative health care views, and critically evaluate traditional and alternative therapies. The APN can help the woman to systematically plan to incorporate health promotion activities into her busy home and work routines. Not only will this enhance the client's health in a busy lifestyle, but it will also model a healthy lifestyle for other family members and co-workers (Pender, 1996).

As a primary care provider the APN is in a position to act as a counselor and educator of women. Andrews(1995) recommends that an in-depth counseling session be offered to women at age 45 or sooner. At this time a personal risk assessment should be performed, including family history. Any myths or fears the woman has about menopause should be replaced with factual knowledge about signs and symptoms of menopause, immediate and long-term effects of estrogen decline, and treatment options with associated benefits and risks. At this and future visits, the APN can teach the woman about health promotion and prevention practices that

are appropriate for her lifestyle and personal needs. As a primary healthcare provider, the APN is responsible for insuring that the client is given the opportunity to have the recommended screening tests such as Papanicolaou smear, pelvic exam, breast exam, and mammogram according to the current practice guidelines (Andrews, 1995).

With each transitional period in a woman's life an opportunity arises for that woman to pause and assess where she has been and where she is going in terms of her health and lifestyle. At the time of the menopause transition she presents with a bone mass that is a consequence of her lifestyle before menopause. After documentation of the client's lifestyle habits, nutrition, and any alternative medical methods, the APN can present options for a multifaceted approach for optimum bone mass: HRT, exercise, and calcium (dietary and supplemental). Estrogen is important for maintenance of bone mass postmenopausally and for prevention of decreasing bone mass that leaves postmenopausal women prone to fractures. HRT should be offered to all women for whom it is not contraindicated. The adverse effects of smoking, alcohol, lactose malabsorption, a vegetarian diet, and caffeine on bone loss should also be presented (Ravnikar, 1993).

For those women who chose to take HRT, Natchigall (1990) suggests the following strategies to enhance compliance: education with clear discussion, booklets, and books; communication of need for continued surveillance of

client even after HRT has been started; provision of printed prescriptions and handouts; emphasis on the ease of taking medication; utilization of appropriate measures to decrease nuisance factors such as breast tenderness, breakthrough bleeding, vaginal irritation or local skin irritation; endometrial biopsy when warranted; and demonstration of results/benefits through cholesterol levels, vaginal exam, and bone density measurement. The last strategy is a means of positive reinforcement for taking HRT.

Measurement of self-care and clinical outcomes is important for determination of the quality and success of the menopausal woman's self-care plan. For the women who choose to take HRT, the following self-care behaviors can be measured: type, frequency, and duration of weight-bearing exercise; frequency and type of dietary and/or supplemental calcium intake; monthly self-breast exams; yearly mammograms, scheduling and completion of annual history and physical exam appointments; actual HRT use; side effects of HRT experienced; and effectiveness of interventions in relieving side effects (Uphold & Graham, 1994). The APN and client can work on ways to individualize the HRT for the client. The goal is for the client to feel that she has ownership of this plan and is responsible for carrying it to fruition.

The same can be said for a plan of self-care developed for the woman who decides not to take HRT. Her self-care performance will be evaluated for exercise, calcium intake,

interventions for menopausal symptoms, monthly self-breast exams, annual mammograms, annual physical with emphasis on menopausal, osteoporotic, and cardiac changes, and risk behaviors such as smoking, heavy caffeine use, and alcohol intake (Uphold et al., 1994).

The APN assists the menopausal woman to decide whether or not to take HRT by providing the necessary scientific knowledge. The woman is empowered to perform self-care. She determines whether or not she will adhere to the plan of self-care individualized to meet her needs. She has ownership of her self-care plan and determines on a daily basis whether she will alter, adhere to, or abandon her personal plan.

# Recommendations for Future Research

According to McElmurray et al. (1991), the goal of research in women's health is to develop knowledge that helps to prevent illness, prolong life, and promote and enhance well-being. Through such research, interventions are created and discovered that promote, maintain, and enhance health. These interventions are to be based on an understanding of the ways in which women take care of themselves and with an appreciation for cultural context in which these self-care measures are to be carried out (McElmurray et al., 1991).

This study hoped to increase the understanding about the relationship between women's level of knowledge of menopause and their adherence to plan for exercise, calcium

supplementation, and exercise. The results did not provide the information expected. Therefore it would appear that adherence to these particular plans for self-care were influenced by factors other than knowledge. The lack of significant results in this study does not mean that knowledge does not bear a relationship to adherence to plan for self-care. Rather the flaw in the study may be the fact that it looked at these variables only in the twelfth month of the study.

Future research may ask if a significant level of exercise adherence is more likely for women who have exercised at a similar rate prior to menopause? What about women who have been sedentary? Can their behavior pattern for exercise change if they come to view exercise as a self-care activity that has meaning for them?

In terms of calcium supplementation, further dietary information is needed to determine why some women chose to take supplements and why others did not. How many women in the study chose to increase dietary intake of calcium alone or in conjunction with other supplements? Are women who feel that they are at greater risk for osteoporosis more likely to take supplements? Had any of the women in the study had bone density studies performed? According to the data, only one woman in the study had experienced fractures. What influences what supplements women chose to take? Pharmaceutical advertising, women's magazines, and provider information are sources to consider.

HRT adherence is a complex issue. Why did 90% of the women who had chosen a plan for HRT follow through and adhere to it? Considering the poor levels of compliance to HRT that are found in the literature (Hammond, 1994; Natchingall, 1990), it is worthwhile to determine why these 46 women had a 90 percent success rate for adherence? What were the characteristics of these 46 women? How many of them were hysterectomized? Of those with an intact uterus, were they afraid of cancer? Had any of them taken birth control pills in the past? Did they experience side effects from HRT?

Future research will continue to ask questions to increase understanding of menopausal women and their healthcare needs. Such studies must include more diverse populations to determine how different women perceive the menopausal experience, their symptoms, and self-care practices related to menopause. What self-care measures do they employ? What place does diet, exercise, and HRT have in their lives?

Menopausal women of lower educational and income levels warrant further study. Do women with lower educational levels require more information about menopause than the well-educated women in this study? What other types of educational interventions might be necessary for these adult learners? Are women with lower income levels as concerned about menopause as much as women with greater financial resources for healthcare and intervention measures?

# Limitations of Secondary Analysis

In doing the secondary analysis certain limitations existed. First, the questions posed in this study were limited by the questions and data gathered by the parent study. Second, no information was given as to what influenced the women to adhere to their plans for exercise, calcium, and HRT. Third, this study looked at knowledge level and adherence post-intervention. Would a relationship between level of knowledge of menopause and adherence to exercise, calcium, and HRT been found if examined over the entire 12 month course of the parent study?

#### SUMMARY

This study did not demonstrate that a relationship exists between level of women's knowledge of menopause and adherence to plan for exercise, calcium supplementation, and HRT. The study showed menopausal education and did not impact adherence to plans for self-care. The study was unable to conclude whether provision of appropriate knowledge for the menopausal woman had the potential to improve adherence to the three self-care measures. This does not mean that knowledge of menopause is not important for women to perform self-care activities. Rather further research is necessary to determine why some women adhere to particular plans for self-care and others do not. Also, women may use other aspects of their personal knowledge to come to decisions to adhere to self-care. As a primary care provider, the APN is obligated to assist women to become as

knowledgeable as possible about their bodies and how to care for them. The APN must use clinical skills, current practice standards, and research to provide high quality care to all menopausal women.



# LIST OF REFERENCES

- Andrews, W.C. (1995). The transitional years and beyond. Obstetrics & Gynecology, 85(1), 1-5.
- Ahijevych, K. & Bernhard, L. (1994). Health-promoting behaviors of African-American women. <u>Nursing Research</u>, 43(2), 86-89.
- Bernhard, L.A. & Sheppard, L. (1992). Health, symptoms, self-care, and dyadic adjustment in menopausal women. <u>Journal of Obstetrics</u>, <u>Gynecology</u>, and <u>Neonatal Nursing</u>, 22(5), 456-460.
- Bond, K. (1991). Osteoporosis. <u>NAACOG'S Clinical</u> <u>Issues, 2(4), 498-507.</u>
- Bouchard, C.J., Shephard, R.J., Stephens, T., Sutton, J.R., & McPherson, B.D. (Eds.) (1990). Exercise, fitness, and health: A consensus of current knowledge. Champaign, IL: Human Kinetics.
- Cano, A. (1995). Compliance to hormone replacement therapy in menopausal women controlled in a third level academic center. <u>Maturitas</u>, 20, 91-99.
- Carporael-Katz, B. (1983). Health, self-care, and power: Shifting the balance. <u>Topics in Clinical Nursing</u>, 5, 31-41.
- Christiansen, C. (1994). The different routes of administration and the effect of hormone replacement therapy on osteoporosis. Fertility and Sterility, 62 (suppl. 2), 6, 152S-155S.
- Cook, M. J. (1993). Perimenopause: An opportunity for health promotion. <u>Journal of Obstetrics, Gynecology, and Neonatal Nursing</u>, 22(3), 223-228.
- Coope, J. & Marsh, J. (1992). Can we improve compliance with long-term HRT? <u>Maturitas, 15</u>, 151-158.
- Duelberg, S. (1992). Preventive health behavior among black and white women in urban and rural areas. <u>Social</u> <u>Science and Medicine</u>, 34, 191-198.

- Dzewaltowski, D.A., Noble, J.M., & Shaw, J.M. (1990). Physical activity participation: Social cognitive theory versus the theories of reasoned action and planned behavior. Journal of Sport & Exercise Psychology, 12, 388-405.
- Frey, K.A. (1981). Middle-age women's experience and perceptions of menopause. Women & Health. 6, (1-2), 26-35.
- Gendler, P.A. (1979). The relationship between the symptoms a woman attributes to her menopause and her perception of their effect on her performance of selected life activities. Unpublished master's thesis, Michigan State University, East Lansing, MI.
- Gregory, C.A. (1982). Possible influence of physical activity on musculoskeletal symptoms of menopausal and postmenopausal women. <u>Journal of Obstetrics</u>, <u>Gynecology</u>, and <u>Neonatal Nursing</u>, March-April, 103-107.
- Groeneveld, F.P.M.J., Bareman, F.P., Barensten, R., Dobter, H.J., Drogenijk, A.C., & Hoes, A.W. (1995). Determinants of first prescription of hormone replacement therapy. A follow-up study among 1689 women aged 45-60 years. Maturitas, 20, 81-89.
- Hammond, C.B. (1994). Women's concerns with hormone replacement therapy-compliance issues. <u>Fertility and Sterility</u>, 62(6), 1575-160S.
- Hartweg, D.L. (1993). Self-care actions of healthy middle-aged women to promote well-being. <u>Nursing Research</u>. 42(4), 221-227.
- Hickey, J.V., Ouimette, R.M., & Venegoni, S.L. (1996). Advanced Practice Nursing: Changing roles and clinical applications. Philadelphia: Lippincott.
- Jensen, G.M. & Lorish, C.D. (1994). Promoting patient cooperation with exercise program. <u>Arthritis Care Research</u>, 7(4), 181-189.
- Johnson, S.M. & Snow, L.F. (1979). What women do not know about the menopause. The Osteopathic Physician, 2, 28-37.
- LaRocco, S.A. & Polit, D.F. (1980). Women's knowledge about the menopause. Nursing Research, 29(1), 10-13.
- Larson, K.A. & Shannon, S.C. (1984). Decreasing the incidence of osteoporosis-related injuries through diet and exercise. Public Health Reports. 99(6), 609-613.

- Lee, C. (1993). Attitudes, knowledge, and stages of change: A survey of exercise patterns in older Australian women. Health Psychology, 12(6), 476-480.
- McCance, K.I. & Huether, S.E. (1994). <u>Pathophysiology:</u> The biologic basis for disease in adults and children (2nd ed.). St. Louis, MO: Mosby.
- McElmurray, B.J. & Huddleston, D.S. (1991). Self-care and menopause: Critical review of research. Health Care for Women International, 12, 15-26.
- MacPherson, K.I. (1985). Osteoporosis and menopause: A feminist analysis of the social construction of a syndrome. Advances in Nursing Science, 7(4), 11-22.
- Millette, B.M. (1981). Menopause: A survey of attitudes and knowledge. <u>Issues in Health Care of Women. 3</u>, 263-276.
- Natchingall, L.E. (1990). Enhancing patient compliance with hormone replacement therapy at menopause. Obstetrics & Gynecology, 75(4), 775-80S.
- Nursing Development Conference Group (1979). Concept formalization in nursing: Process and product (2nd ed.), D.E. Orem (ed.). Boston: Little, Brown.
- Orem, D.E. (1980). <u>Nursing: Concepts in practice</u> (2nd ed.). New York: McGraw-Hill.
- Orem, D.E. (1985). <u>Nursing: Concepts of practice</u> (3rd ed.). New York: McGraw-Hill.
- Orem, D.E. (1991). <u>Nursing: Concepts of practice</u> (4th ed.). St. Louis: Mosby-Year Book, Inc.
- Pender, N.J. (1996). <u>Health promotion in nursing practice</u> (3rd ed.). Norwalk, CT: Appleton & Lange.
- Pender, N.J. (1987). <u>Health promotion in nursing practice</u> (2nd ed.). Norwalk, CT: Appleton & Lange.
- Ravnikar, V.A. (1993). Diet, exercise, lifestyle in preparation for menopause. Obstetrics & Gynecology Clinics of North America, 20(2), 365-376.
- Robertson, D. & Keller, C. (1992). Relationship among health beliefs, self-efficacy, and exercise adherence in patients with coronary artery disease. Heart & Lung. 21(1), 56-63.

- Rothert, M. (1990). Women's judgements of estrogen replacement therapy. (Research Grant No. NR1245-04A2). Washington, D.C.: U.S. Department of Health and Human Services, National Center for Nursing Research.
- Rothert, M. Kroll, J., Breer, L., Rovner, D., Holmes-Rovner, M., Schmitt, N., Talarczyk, G., & Padonu, G. (1994). Communicating risks and benefits to mid-life women.

  Communicating Risks to Patients. United States Pharmacopeial Convention, Reston, VA.
- Rossouw, J.E., Finnegan, L.P., Harlan, W.R., Pinn, V.W., Clifford, C., & McGowan, J.A. (1995). The evolution of the Women's Health Initiative: Perspectives from the NIH. Journal of the American Medical Women's Association, 50(2), 50-5.
- Ryan, P.J., Harrison, R., Blake, G.M., & Fogelman, I. (1992). Compliance with hormone replacement therapy (HRT) after screening for post menopausal osteoporosis. British Journal of Obstetrics and Gynecology, 99, 325-328.
- Sackett, D.L. & Haynes, B. (1976). <u>Compliance with therapeutic regimens</u>. Baltimore, MD: Johns Hopkins University Press.
- Stumpf, P.G. & Trolice, M.P. (1994). Compliance problems with hormone replacement therapy. Obstetrics and Gynecology Clinics of North America, 21(20), 219-229.
- Uphold, C.R. & Graham, M.V. (1994). <u>Clinical</u> <u>Guidelines in Family Practice</u> (2nd ed.) Gainesville, FL: Barmarrae Books.
- Utian, W.H. & Stiff, I. (1994). North American Menopause Society-Gallup survey of women's knowledge, information sources and attitudes to menopause and hormone replacement therapy. Menopause: Journal of North American Menopause Society, 1, 39-48.
- Wark, J.D. (1993). Osteoporosis: Pathogenesis, diagnosis, prevention, and management. <u>Bailliere's Clinical</u> <u>Endocrinology and Metabolism, 7(1), 151-181.</u>
- Webster's Ninth New Collegiate Dictionary. (1986). Springfield, MA: Merriam-Webster.
- Wilbur, J., Holm, K., & Dan, A. (1992). The relationship of energy expenditure to physical and psychologic symptoms in women at midlife. Nursing Outlook, 40(6), 269-276.

Wren, B.G. & Brown, L. (1991). Compliance with hormonal replacement therapy. <u>Maturitas, 13</u>, 17-21.



APPENDIX A

Research Team

# APPENDIX A

# Research Team

Marilyn Rothert, RN, PhD, FAAN Principal Investigator College of Nursing Geri Talarczyk, RN, EdD Co-investigator College of Nursing Georgia Padonu, RN, DrPH Co-investigator College of Nursing David Rovner, MD Co-investigator College of Human Medicine Margaret Holmes-Rovner, PhD Co-investigator College of Medicine Neal Schmitt, PhD Co-investigator College of Social Science Jill Kroll, PhD Co-investigator Research Associate

# APPENDIX B Knowledge Instrument

# DECISION MAKING IN MENOPAUSE STUDY Menopause Information

The following questionnaire contains questions about menopause, (the change of life) a time which signifies the end of the menstrual cycle. In this section we are interested in your knowledge about the process of menopause. Answers to some of the questions will depend on whether or not a woman has a uterus. Please answer all questions assuming the woman has a uterus.

- 68. What can be said about birth control after menstruation stops?
  - 1 = Birth control should be used for 1 year
  - 2 = Birth control should be used up to 5 years
  - 3 = Birth control should be used as long as sexually active
  - 4 = Birth control is not necessary
  - 5 = Don't know
- 69. What causes the symptoms of menopause?
  - 1 = The pituitary gland stops functioning
  - 2 = The uterus will not allow egg implantation
  - 3 = The fallopian tube becomes blocked
  - 4 = The ovaries produce less estrogen (female hormone)
  - 5 = All of the above
  - 6 = Don't know
- 70. Menopause increases the risk for which of the following?
  - 1 = Liver disease
  - 2 = Eye disease
  - 3 = Kidney disease
  - 4 = Lung disease
  - 5 = Osteoporosis
  - 6 = All of the above
  - 7 = None of the above
  - 8 = Don't know

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# Check your answer sheet. You should now be filling in row number 71

- 71. What physical changes can occur in the vagina due to menopause?
  - 1 = It becomes dryer, shorter and less elastic
  - 2 = It becomes less easily injured
  - 3 = The vagina remains the same following menopause
  - 4 = Don't know
- 72. Risk of osteoporosis (brittle bones) can be reduced by:
  - 1 = Vitamin C
  - 2 = Estrogen pills
  - 3 = Relaxation exercises
  - 4 = Don't know
- 73. To help reduce the uncomfortable feelings associated with hot flashes, a person can...
  - 1 = Increase caffeine intake
  - 2 = Take vitamins above recommended daily allowance
  - 3 = Wear several light wraps so one can be removed
  - 4 = Increase spices and seasoning in food
  - 5 = Don't know
- 74. Vaginal dryness caused by menopause may lead to...
  - 1 = Increased chance of vaginal infection
  - 2 = Decreased chance of vaginal infection
  - 3 = No change in chance of vaginal infection
  - 4 = Don't know
- 75. Vaginal dryness can best be relieved by...
  - 1 = Using a petroleum jelly lubricant (Vaseline®)
  - 2 = Estrogen replacement therapy
  - 3 = Using cold cream
  - 4 = Don't know

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# Check your answer sheet. You should now be filling row number 76

- 76. After menopause, a woman's risk of heart disease:
  - 1 = Decreases
  - 2 = Increases
  - 3 = Is the same as before menopause
  - 4 = Don't know
- 77. Estrogen replacement therapy:
  - 1 = Increases a woman's risk of heart disease
  - 2 = Decreases a woman's risk of heart disease
  - 3 = Has no effect on a woman's risk of heart disease
  - 4 = Don't know

Please answer questions 78-90 using the following scale:

- 1 = True
- 2 = False
- 3 = Don't Know
- 78. Although many women have menopausal symptoms, approximately 20% seek medical relief.
- 79. Hormone therapy (estrogen) after menopause increases the risk of osteoporosis.
- 80. Hormonal therapy (estrogen) can be used to help relieve the symptoms of menopause.
- 81. Estrogen therapy without progestogen increases the risk of cancer of the uterus.
- 82. If a menopausal woman unexpectedly bleeds or spots a year after she completely stops menstruating she should report this to her physician.
- 83. Symptoms most often reported during menopause are hot flashes and night sweats.
- 84. Once a woman is through menopause she no longer has to be concerned with breast cancer or other female cancers.
- 85. As long as a woman is ovulating she can still become pregnant.
- 86. Ovulation may occur without menstrual bleeding occurring.

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# Check your answer sheet. You should now be filling in row 87

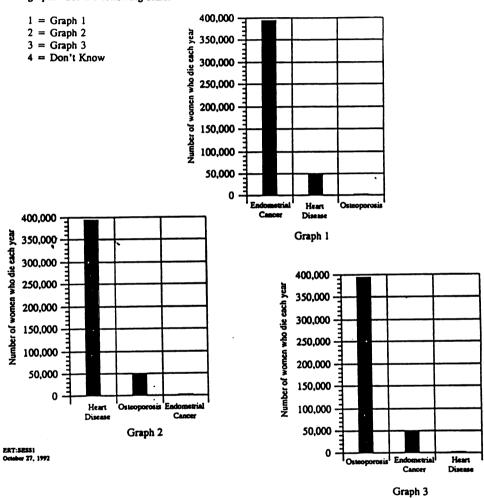
- 87. The addition of a progestational agent (Provera®) to estrogen replacement therapy frequently results in monthly menstrual flow.
- 88. The addition of a progestational agent (Provera®) to estrogen replacement therapy increases the risk of cancer to the uterus.
- 89. The most common cause of death among women is breast cancer.
- A woman's chance of dying from cancer of the uterus is greater than her chance of experiencing osteoporosis fractures.

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58

# Check your answer sheet. You should now be filling in row 91

91. Choose the graph below which correctly shows the number of women who die each year from these medical problems. Darken the circle on your answer sheet corresponding to the correct graph. Use the following scale:



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# APPENDIX C Calendar Instrument

# ACTIVITY RECORD CALENDAR

January 1993

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
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# Instructions

Activity	Symbol
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Premarin / Proverce  Aerobic Exercise Video	<u> Ha</u>
<u></u>	

- Use this calendar to record the activities you planned on your personal plan form. If you chose activities under the categories exercise, calcium intake or HRT, the symbol for the activity is listed already.
- 2. If your Personal Plan lists an activity not on the key to the left, write the activity planned and assign a symbol for it (do not use E, C or H).
- Each day of the month that you perform an activity as planned, place the appropriate symbol in the box for that day.
- 4. If you change your planned activity during the month, indicate the change on you plan form and write in the new activity on one of the blank lines at the left. If the new activity replaces another activity in the same category, assign the same letter but use a different subscript number. For example, if you changed from aerobic walking [E1] to swimming, you would assign the symbol E2 for swimming.

REMEMBER: RECORD YOUR ACTIVITIES EVERY DAY!

# **ACTIVITY RECORD CALENDAR**

		Ŀ	January 1993		Month 0 1 2 3 4 5 6 7 8 9 10 11 12		
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# Activity Symbol Exercise E1 Calcium C1 Hormone Replacement Therapy H1

Use this calendar to record the activities you planned on your personal plan form. If you chose activities under the categories exercise, calcium intake or HRT, the symbol for the activity is listed already.

Instructions

ID#\_\_\_

- 2. If your Personal Plan lists an activity not on the key to the left, write the activity planned and assign a symbol for it (do not use E, C or H).
- 3. Each day of the month that you perform an activity as planned, place the appropriate symbol in the box for that day.
- 4. If you change your planned activity during the month, indicate the change on you plan form and write in the new activity on one of the blank lines at the left. If the new activity replaces another activity in the same category, assign the same letter but use a different subscript number. For example, if you changed from aerobic walking [E1] to swimming, you would assign the symbol E2 for swimming.

REMEMBER: RECORD YOUR ACTIVITIES EVERY DAY!

# PERSONAL PLAN INSTRUCTIONS

Using the information you have gained about risks and benefits at menopause, identify a plan of action for maintaining you health during and following menopause. Write each planned activity on the attached page. Include how often you are to engage in the activity, the purpose of the activity and the date. Do this for up to three activities.

We would like you to focus on exercise, calcium intake and hormone replacement therapy. You are free to choose other behaviors or to continue behaviors you are already doing, if you wish. For each behavior you list, check the box which indicates the category (exercise, calcium intake, HRT or Other).

If you find in necessary to modify any one of you planned activities once you implement it, be sure to write down your new activity (i.e. the change), how often you plan to carry it out, the reason for the change and the date you made the change.

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APPENDIX D

UCRIHS Approval

# **MICHIGAN STATE** UNIVERSITY

June 3, 1996

Ann W. Fowler 10849 Wildon Way Grand Ledge, MI 48837 TO:

IRB#: TITLE: DR.

96-334
THE RELATIONSHIP OF THE LEVEL OF WOMEN'S
KNOWLEGGE OF MENOPAUSE TO LEVEL OF ADHERANCE TO
PLAN FOR EXERCISE, USE OF CALCIUM AND VITAMIN
SUPPLEMENTS AND HORMONAL THERAPY

REVISION REQUESTED: CATEGORY: APPROVAL DATE: N/A 1-E 05/31/96

The University Committee on Research Involving Human Subjects' (UCRIHS) review of this project is complete. I am pleased to advise that the rights and welfare of the human subjects appear to be adequately protected and methods to obtain informed consent are appropriate. Therefore, the UCRIHS approved this project and any revisions listed

REMEMAL:

UCRIHS approval is valid for one calendar year, beginning with the approval date shown above. Investigators planning to continue a project beyond one year must use the green renewal form (enclosed with the original approval letter or when a project is renewed) to seek updated certification. There is a maximum of four such expedited renewals possible. Investigators wishing to continue a project beyond that time need to submit it again for complete review.

REVISIONS: UCRIHS must review any changes in procedures involving human subjects, prior to initiation of the change. If this is done at the time of renewal, please use the green renewal form. To revise an approved protocol at any other time during the year, send your written request to the UCRIHS Chair, requesting revised approval and referencing the project's IRB # and title. Include in your request a description of the change and any revised instruments, consent forms or advertisements that are applicable.

OFFICE OF RESEARCH AND **GRADUATE STUDIES**  PROBLEMS/ CHANGES:

Sincerely,

Should either of the following arise during the course of the work, investigators must notify UCRIHS promptly: (1) problems (unexpected side effects, complaints, etc.) involving human subjects or (2) changes in the research environment or new information indicating greater risk to the human subjects than existed when the protocol was previously reviewed and approved.

**University Cor** rsearch involving Human Subjects (UCRIHS)

If we can be of any future help, please do not hesitate to contact us at (517)355-2180 or FAX (517)432-1171.

Michigan State University 232 Administration Building East Lansing, Michig

48624-1046 David B. Wright, Ph.D. UCRIHS Chair 517/355-218

FAX: 517/432-1171 DEW: bed

cc: Marilyn Rothert

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MSU is an affirmative

