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EXPERIENCE AND EXPERIENCES,
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presented by

Jill (Walther) Kroll

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**PERCEIVED CONTROL OVER THE MENOPAUSE EXPERIENCE AND
EXPERIENCES, EXPECTATIONS AND BEHAVIORS REGARDING
MENOPAUSE**

By

Jill (Walther) Kroll

A THESIS

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ABSTRACT

PERCEIVED CONTROL OVER THE MENOPAUSE EXPERIENCE AND EXPERIENCES, EXPECTATIONS AND BEHAVIORS REGARDING MENOPAUSE

By

Jill (Walther) Kroll

The purpose of this research was to determine the correlates of perceived control relating to menopause for use in developing an educational intervention to aid women in active involvement in their menopausal health care.

Two hundred sixty nine women age 45 to 55 responded to written questionnaires relating to menopause. High internal perceived control was found to correlate $-.24$, ($p < .05$), with experienced symptoms, and $-.35$, ($p < .05$), with symptoms expected by those not yet experiencing menopause. Women whose periods were still regular perceived more internal control relating to menopause than women whose last period was 3 to 12 months ago, ($F(3, 263) = 4.92$; $p < .05$). Women who scored higher in knowledge of menopause perceived more internal control related to menopause than did women who scored lower. It was concluded that an intervention addressing women's needs during menopause should be sensitive to the variation in perceived control among women as it relates to differing knowledge and symptoms experienced.

**Dedicated to John
and
our sons, David and Thomas**

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Chapter 1

Problem Definition: Menopause and the Hormone

Replacement Therapy Controversy

Because of an increased life span, 95% of women today will live beyond menopause (Hamilton & Clements, 1982) making menopause a nearly universal experience for American women. Up to 88% of women experience symptoms such as hot flashes (Feldman, Voda & Gronseth, 1985). Following menopause, women may be more prone to debilitating fractures of the spine, hip or wrist, due to accelerated loss of bone mass, (National Institutes of Health Consensus Development Panel on Osteoporosis [NIH], 1984). Symptom management and prevention of osteoporosis are therefore important issues for middle years women (Kirkpatrick & Edwards, 1985; Hallal, 1985) but women have been found to lack information regarding menopause (LaRocco & Polit, 1980). Since many of the issues surrounding management of symptoms and prevention of osteoporosis are complex, support and information groups addressing the concerns of menopausal women have emerged in the United States and Europe (Schmid-Heinisch, 1985; Caldwell, 1982; Drennan & McGeeney, 1985; Staff, 1986), but no controlled studies of the effectiveness of such groups have been reported in the literature to date. Preparation for the development of an educational intervention addressing the needs of menopausal women involves an understanding of current perceptions and concerns regarding the issues related to menopause today. One issue which may add to our understanding of how women view menopause is perceived control.

Perceived control has been found to be related to a variety of health related behaviors (Strickland, 1978) and may be an important variable to understand relating to the experience of menopause for women. Duffy (1988) found that health locus of control accounted for 16% of the variance observed in health promotion lifestyle among a convenience sample of 262 middle years women. Additionally, it has been found that individuals may differ in the level of control they desire to have in regard to their health care (Wallston, Smith, Wallston, King, Rye & Heim, 1987). In a review of locus of control and health Wallston, Smith, Wallston, King, Rye and Heim (1987) concluded that health education programs which tailor the orientation of the program to internally or externally-oriented individuals were more effective in changing targeted health behaviors.

In our youth-oriented society (Rosenthal, 1979) the period of midlife has often been overlooked in the study of the human life cycle (Uphold & Susman, 1981). Today, at the time of menopause a woman still has one third of her life left to live (Schmid-Heinisch, 1985). Included in the period between the birth of a woman's last child and old age, is the transition from the reproductive phase of the woman's life to the nonreproductive phase (Rosenthal, 1979). This life stage, which includes the menopause, is a time of physical and psychosocial change which may be accompanied by uncomfortable physical or psychological symptoms for some women (Uphold & Susman, 1980). To fully understand the context in which the issues related to menopause and the middle years are experienced it is necessary to understand the physical, psychological and social changes occurring during this time.

Menopause

"Menopause" means the cessation of menses (Rosenthal, 1979; Feldman et al, 1985). The "climacteric" has been described as "that phase in the aging process of women making the transition from the reproductive stage of life to the nonreproductive stage" (Rosenthal, 1970, p. 358), "a natural life phase, occurring in all women as the ovaries cease production and the estrogen level decreases permanently" (Dosey & Dosey, 1980, p. 14). "Climacteric symptoms" were defined by Uphold & Susman (1981) as "the common physiological and psychological identifiable complaints associated with the gradual regression of the ovarian hormonal function," p. 85. A related term, "menopause transition," has been described as "a period of time marked by a progressive change in the pattern of menstrual cyclicity indicated by unusually long or short menstrual cycles, diminished menstrual flow, or intermittent menstrual cycles that terminate in menopause" (Feldman et al, 1985, p.262). "Perimenopausal" has been defined as, "a period of time surrounding the actual experience of menopause" (Feldman et al, 1985, p. 262). Although some studies have included definitions of menopause, many have not and a woman's status in regard to menopause is often unclear leading to confusion in the menopause literature (Alexander & Roberts, 1987). There are difficulties in determining a woman's menopausal status since menopause can only be diagnosed retrospectively (after menstrual periods have ceased) without measurement of hormone levels (World Health Organization [WHO], 1981).

The physical changes which occur at menopause have been postulated to be due to ovarian aging. By the time a human female is born she has all of the

oocytes that she will have in her lifetime. These oocytes degenerate at various stages of follicular development, beginning prenatally and continuing throughout the woman's lifetime, (less than .01% of oocytes in women are ovulated). When all of the oocytes have either degenerated or been ovulated ovarian failure occurs (Gosden, 1985). Since the somatic cells which surround an oocyte and make up the follicle are the source of follicular oestradiol, when the store of oocytes and follicles is depleted, the ovary ceases to produce estrogen and menopause occurs (Gosden, 1985). The mean age at natural menopause is about 49.5 years, but 30 percent of women cease menstruating due to surgery (Krailo & Pike, 1983). Estimates of the mean age of menopause vary from 46.7 to 50.1 (Batrinos, Panitsa-Fafila, Pitoulis, Pavlou, Piaditis, Alexandridis, & Liappi, 1979; Van Keep, Brand, & Leher, 1979; Feldman et al, 1985).

Menopausal symptoms vary greatly among women. For slightly less than half of women, menses cease abruptly, while for others, cessation of menses follows a period of menstrual irregularity (Batrinos et al, 1979). For women who experience menstrual irregularity, the period of irregularity lasts less than 1 year for almost 90% of the women, but continues for up to 2 years for about 10% of the women, (Batrinos et al, 1979). Accompanying the changes in the menstrual cycle are a variety of symptoms including but not limited to hot flashes, vaginal dryness, headaches, weight gain, aches in the back of the neck and skull, trouble sleeping, depression, forgetfulness, irritability and tiredness, tingling in limbs, joint aches, night sweats, shortness of breath, dizziness, palpitations, loss of appetite, aching breasts, backache, bladder difficulties, and sexual problems (Babuna, Aksu, & Erez, 1982; Feldman, Voda, & Gronseth, 1985;

Jaszmann, van Lith, & Zaat, 1969; Bungay, Vessey, & McPherson,, 1980, Dosey & Dosey, 1980).

The withdrawal of estrogen which was being produced by the ovaries prior to menopause results in changes to estrogen-sensitive tissues like the vagina. The vagina is gradually shortened and has reduced compliance to applied force following the withdrawal of estrogen (Gosden, 1985). The uterus, cervix and vulva also show estrogen withdrawal related changes (Gosden, 1985). Among the symptoms reported by women during the menopause, hot flashes has been the most frequently reported complaint (Polit & LaRocco, 1980). The incidence of hot flashes has been estimated to be between 40% and 90% (Batrinos et al, 1979; Jaszmann, van Lith & Zaat, 1969; Feldman et al, 1985). Hot flashes were defined by Feldman et al (1985) as an experience associated with the menopause transition, characterized as vasomotor instability, resulting in a sudden sensation of heat or a feeling as perceived and determined through the self-report of women. Nonthermal body sensations may also be described including sensations of tingling, throbbing, rush of blood, lightheadedness, chills, and suffocation (Feldman et al, 1985).

Finally, in addition to experiencing physical and psychological symptoms during menopause, many women are faced with social changes as well, such as a changing family and marital role due to children achieving adulthood (Bungay et al, 1980), financial difficulties, employment changes, and body changes due to aging (Lien, 1981).

Which of the symptoms experienced by a woman are directly attributable to menopause remains unclear (Greene, 1976). There is evidence that vasomo-

tor symptoms and symptoms associated with changes in estrogen sensitive tissues may be directly attributable to the decline in estrogen associated with menopause (Jaszmann et al, 1969; Bungay, et al, 1980). Other symptoms may be related to psychosocial changes which occur at midlife or may have other origins and are not unique to menopause (Bungay, et al, 1980; Ballinger, 1985).

The Hormone Replacement Therapy (HRT) Controversy

One of the most popular treatments for menopausal symptoms today is hormone replacement therapy (HRT), also called estrogen replacement therapy or ERT (National Center for Health Statistics, 1983; American Medical Association Council on Scientific Affairs [AMA Council], 1983). Estrogen was first prescribed for menopause-related symptoms in the United States in 1929 (Furuhjelm, 1977) and has usually been prescribed as one of two regimens: estrogen alone, or estrogen/progestin combined (Upton, 1980).

Controversy exists regarding whether estrogen is an appropriate treatment for the problems of menopause. It has been put forth that an alternative causal explanation for osteoporosis in older women is poverty-induced low-calcium diets and fear of walking alone in a violent society (MacPherson, 1985, 1987).

Estrogen has been seen by some as contributing to the perception of menopause as a deficiency disease, rather than an adaptive life event (Alington-MacKinnon & Troll, 1981). Estrogen has also been seen as a beneficial treatment for problems experienced by some women during menopause. Estrogen replacement therapy has been found to be highly effective in reducing the frequency of hot flashes (by 91%) when compared with a placebo (Judd, 1987) and was concluded to be the single most effective modality for the

prevention of osteoporosis in women by the National Institutes of Health Consensus Development Panel on Osteoporosis (1984). The issue is of concern because of the severity of the problem of osteoporosis. Osteoporosis is an age-related disorder characterized by decreased bone mass and increased susceptibility to fractures in the absence of other recognizable causes of bone loss (NIH, 1984). Osteoporosis has been estimated to affect as many as 20 million individuals in the United States and about 1.3 million fractures per year in people age 45 and older have been attributed to osteoporosis (NIH, 1984). The cost of osteoporosis in the United States was estimated to be \$3.8 billion per year, in 1984 (NIH, 1984). A significant number of those who experience fractures die from complications directly associated with the fracture (NIH, 1982). No laboratory tests for defining individuals at risk or those with mild osteoporosis are available (NIH, 1984) so a decision regarding whether to take estrogen replacement therapy must be made based on risk factors. It has been clearly documented that unopposed postmenopausal estrogen use increases the risk for endometrial cancer from 1 case per 1,000 women to between 3 and 7 cases per 1,000 women (Persson, et al, 1989; Gastel, Cornoni-Huntley & Brody, 1980; Hulka, Kaufman, Fowler, Grimson & Greenberg, 1980). The addition of the hormone progesterone to the estrogen treatment regimen has been found to reduce the risk of endometrial cancer to the rate for non-estrogen users (Gambrell, 1987; Persson, et al, 1989; Gambrell, 1978) but when administered cyclically in the dose believed to be required to provide protection from endometrial cancer may promote a resumption of monthly bleeding or spotting (Luciano, Turksoy, Carleo & Hendrix, 1988; Jones, Francis & Nordin, 1982).

Estrogen replacement therapy may also provide protection from coronary heart disease in women, by reducing serum levels of low density lipoprotein (LDL) cholesterol (Wolfe & Huff, 1989; Henderson, Paganini-Hill & Ross, 1988) and increasing levels of high density lipoprotein cholesterol (Fahraeus, 1988). The addition of progestins to the therapy may have the opposite effect however, and may actually increase the risk for coronary heart disease (La Rosa, 1989). Finally, evidence regarding the relationship between HRT and breast cancer remains unclear and may be dose related (Dupont, Page, Rogers & Parl, 1989). Studies of death from all causes have suggested that women who used estrogen replacement therapy may be at less risk of death than women who did not (Bush et al, 1983). In summary, the issues facing women today at the menopause are complex, with risks as well as benefits inherent in the decision regarding HRT. All of the factors discussed above, discomfort from hot flashes, risk of fractures due to osteoporosis, risk of endometrial cancer, heart disease risks and all-cause mortality risks combine to create a dilemma for the woman as she approaches menopause. Should she rely entirely on the expert opinion of her health care provider as to decisions regarding her menopausal health care, or should she take an active role in the decision making? If she chooses to take an active role, how will she weigh the various risks and benefits? Many women will want to take an active role in the decision making and will wish to be informed regarding the risks and benefits associated with estrogen replacement therapy. Other women will desire a lesser degree of involvement in the decision making. Wallston, et al (1987) found that not all individuals desired the same degree of involvement in or "control" regarding their health care.

Control relating to menopause may therefore be an important variable to understand as it relates to the woman's participation in her menopausal health care.

Perceived control, also called locus of control was first described by Rotter (1966). Locus of control was said to refer to an individual's generalized expectations about how reinforcement is controlled (Rotter, 1966). Individuals who perceived events as occurring as the result of luck or powerful others, or as unpredictable, were said to maintain an external locus of control (Rotter, 1966). Those who believed that an event was contingent upon their own behavior or characteristics maintained a generalized internal locus of control (Rotter, 1966).

Control has been studied extensively in many different spheres or situations and a variety of situation-specific scales to measure control have been developed, including several particularly addressing health-related issues (Wallston, Wallston, Kaplan & Maides, 1976; Long & Haney, 1986; Labs & Wurtele, 1986). Situation-specific measures of control have been found to provide enhanced prediction of behavior in specific situations (Wallston, Wallston, Kaplan & Maides, 1976). Although many studies have addressed control as it related to health care issues, few previous studies have examined the relationship between control and experiences, expectations or behavior relating to menopause. Of the studies reported, many were found to have significant limitations or failed to address important issues relating to menopause such as knowledge of menopause, menopausal status or symptom management behavior.

Review and Critique of the Literature

This section reviews previous studies of control as it relates to menopause. The conclusions of previous literature reviews will be described, along with criteria for future research. Following this, the literature search methodology will be described, and the studies will be discussed.

Criteria for Evaluation of Research

Several critiques of the general menopause literature have discussed the limitations of past research and delineated criteria for future research (Barnett & Baruch, 1978; Koesk, 1982; Perlmutter & Bart, 1982).

Some research has been based on the assumption that menopause was a psychosocial stresser which stirred up previous psychosexual adjustments and produced turmoil and regression (the premorbid personality model). Research based on this model has been criticized because it has drawn study subjects from patient populations and used psychological testing, retrospective report and clinical observation to study menopause (Koeske, 1982).

Research which could challenge such assumptions would draw study participants from non-patient populations and employ means other than clinical observation to gather data. Other research has been based on the assumption that stresses on women during their middle years has predisposed them to psychological difficulties (the coincidental stress model). Research based on this model was primarily anecdotal and based on case reports (Koeske, 1982).

A general recommendation for future research indicated that research should involve aggregated data from multiple individuals. Additional

difficulties with past research were discussed by Koeske (1982). Koeske (1982) saw research which was based on the Behavioral Science models of menopause as deficient because like the biomedical models, the research was usually seeking to explain non-normative phenomena and posit a simple 1 to 1 relationship between hormone deficiency and behavior, social environment (past or present) or social structure and experience. The recommendation to break out of this pattern was that future research should look for multiple and interacting variables as explanations for experience (Koeske, 1982).

Also ignored by most behavioral science research on menopause has been the complex influence and interaction of biological factors (Woods, 1982; Koeske, 1982) and the way in which social-environmental factors (past or present) can affect biology (Koeske, 1982).

Perlmutter and Bart (1982) suggested that future research should look at the ways in which women understand and make sense of their experiences in order to go beyond models of menopause which see women as passively victimized by their hormones, psyches and society.

In summary, future research dealing with menopause should draw study participants from non-patient populations, use other than clinical observations as a means of data collection, report aggregated data collected from large samples of women, look for multiple and interacting variables as explanations for observed variation, consider ways in which social-environmental factors can influence biology and examine the ways women themselves understand and make sense of their experiences.

There have also been recommendations for future research addressing locus of control. Rotter (1975) and Lowery (1981) suggested development of locus of control scales specific to various situations. It was believed that a measure of generalized expectancy would be less useful for making predictions in specific situations than a control scale designed to measure expectancies in that situation or a situation of the same subclass (Rotter, 1975) particularly if one is seeking a practical application of the information (Rotter, 1975).

Search Method

A computer search in August, 1987 of five databases resulted in 6 documents including 1 duplication. The key words used were "menopause" combined with one of the following: "internal-external-control," or "locus with control." Of the 5 non-duplicates, 2 were dissertations. The databases searched were: Medline, (Index Medicus) (1), Dissertation Abstracts International (2), Psychological Abstracts (3-1 repeat), Social Science Citation Index (0), and Research in Nursing and Allied Health (0). The number in parentheses represents the number of documents from the preceding source. Of the 5 non-duplicated citations, one was irrelevant to the topic and 1 was a general review of research on women in the middle years and reported no research findings.

Three relevant articles found through the search and an additional article found since the computer search were reviewed. They were critiqued with regard to the relationship between menopause and perceived control.

Locus of Control and Menopause

Collins, Hanson and Eneroth (1983) examined the relationship between climacteric symptoms, response to hormonal replacement therapy, personality

characteristics and masculine and feminine self-concept. Masculine and feminine self-concept were measured by an instrument developed by the researchers. Study participants were 17 post-menopausal women selected by an unspecified means from among the patients attending an outpatient gynecology clinic. The women's post-menopausal state was verified by measurement of FSH (follicle stimulating hormone) levels.

Self-reports of vasomotor, psychosomatic, psychological and sleep-related symptoms were obtained using a graphic scaling technique with items adapted from the Blatt Menopausal Index and the Neugarten and Kraines check list and personality characteristics were measured by the Karolinska Scales of Personality questionnaire. Internal-external locus of control was measured by a questionnaire adapted from Rotter. The study sample scored higher on somatic anxiety ($p < .05$) and muscular tension ($p < .05$) than a non-patient sample of the same age did, but scores on masculinity/femininity were similar to those obtained by the researchers from female university students. Internal-external locus of control scores were higher than those obtained from female university students, indicating high perceived external control. The magnitude and statistical significance of the difference was not reported. After the instruments were administered, study participants were placed on a regimen of estrogen/progestin on a 28 day cycle, and the same measures were administered again at 4-6 weeks after the start of the hormone treatment.

Psychological symptoms before treatment were found to correlated significantly with external locus of control ($r = .48, p < .05$), but psychosomatic, vasomotor and sleep-related symptoms were not. None of the symptoms

correlated significantly with control after treatment.

The authors warned that the results had to be interpreted with caution because some of the symptoms and the personality variables could have been measuring the same underlying dimension. Interpretation of these results was also limited by the small sample size, lack of a comparable comparison group and use of a patient sample with little descriptive information in regard to relevant characteristics in relation to the general population of women in this age group. Additionally, no explanation was given for the lack of findings post treatment, increasing suspicion that the single significant finding before treatment could have been due to chance.

Lind (1984) examined the relationship between menopausal symptoms, use of estrogen replacement therapy and locus of control as measured by the Rotter internal-external locus of control scale. [One hundred volunteers between the ages of 36 and 80 who were postmenopausal (reported that there had been no spontaneous menses for 12 months or more) completed a symptom checklist, the Rotter I-E scale and a sociodemographic questionnaire.] Sixty one percent had not had a hysterectomy, 25% had undergone a partial hysterectomy (only the uterus, not the ovaries had been removed) and 14% had undergone a complete hysterectomy involving removal of uterus and ovaries.

[Fifty percent of the participants were employed part or full-time and 80% had at least some college. Forty percent of the participants had annual incomes of \$25,000 or more.]

Women were categorized as "High Internal Locus of Control" or "High External Locus of Control" by splitting the scores on the I-E scale at the median

point and placing women who scored below the mean into the "High Internal" group and those who scored above the mean in the "High External" group. Women were also categorized according to whether they used estrogen or not, producing 4 groups: High Internal Users of Estrogen, High Internal Non-users of Estrogen, High External Users of Estrogen and High External Non-users of Estrogen.

[There was a significant difference ($p < .05$) between the four groups (Internal Non-users, Internal Users, External Non-Users and External Users) on number of symptoms reported. External Non-users of Estrogen reported the most symptoms and Internal Non-users of Estrogen reported the fewest symptoms. Lind (1984) found that while there were no differences in symptoms reported between estrogen users and non-users, there was a significant difference in symptoms reported between high external locus of control subjects and high internal locus of control subjects.]

Lind (1984) found no relationship between locus of control and the use of estrogen, ($\chi^2 = .002, p > .05$). There was also no significant relationship between locus of control and age or income.

* The conclusion in this study was that the results supported the premorbid personality model of menopause-that menopausal symptomatology was psychological in origin, rather than being an estrogen deficiency disease. It was also concluded that locus of control strongly influenced a woman's reaction to menopause.

While the Lind study used an adequate sample size, used a non-patient sample, and reported adequate reliability of the control instrument, the

measure of control was not situation-specific and so had limited practical application for drawing conclusions about women's perceived control over their menopause experience.

Lien (1981) studied the needs of middle aged adults in the Lutheran Church in Texas. Seven hundred seventy five men and women, aged 35 to 64, from 31 Lutheran congregations in Texas were randomly chosen to participate in the study. Of these, 218 agreed to participate. Data was collected by a written questionnaire and a group interview, held during a workshop at the participants' church. Thirty four percent of the participants were aged 35 to 44, 43% were between the ages of 45 and 54, and 22% were between 55 and 64 years old. Sixty three percent (139) of the participants were women, and 91% of the participants were married.

"Locus of Control" was measured by 21 items on the questionnaire instrument. The origin of the items was unspecified. The internal consistency of the scale was not reported, but the "validity" of the instrument was verified through pilot testing with middle aged adults and a panel of experts over age 35. The experts included a Ph.D. in Science Education, clergymen and lay people and "members of the Christian community."

The items comprising the "Locus of Control" scale are shown in Table 1.

Lien (1981) used a non-patient sample of adequate size and developed a control scale specifically for the purpose of the study, but no measure of scale internal consistency was reported. Additionally, the construct validity of the control scale could be challenged. While it was reported that the instrument validity was addressed by having a panel of experts review the items, this

appeared to address the relevance of the items to middle aged adults rather than to the construct of control.

Table 1
Locus of Control items in Lien (1981) study

Items
<p>There has been a change in my social activities. I have experienced the death of a close friend. I have experienced difficulties in demonstrating academic ability. I feel out of place in church activities. I have worried about whether a decision I made was the right one. I need someone to talk to. I am alone more than I like to be. I feel more at ease with people after I have an alcoholic drink. I have considered suicide. I have attempted suicide. I seem to dwell on the past. I do not feel free to do things I want to do. I feel free to do things I want to do. I feel that I am a useful person. I feel useless. I feel effective. I am not respected as an individual. I feel depressed. My life seems to have lost its meaning. I am satisfied with life.</p>

Duffy (1988) studied 262 women (for a response rate of 44%) who responded to a mailed questionnaire relating to midlife health. The women ranged in age between 35 and 65, were predominantly white and 80% had college or graduate degrees. Twenty five percent of the variance observed in a

total health promotion score (from the Health-promoting Lifestyle Profile) was explained by chance health locus of control, internal health locus of control (both from the Multidimensional Health Locus of Control Scale), self-esteem (from the Rosenberg Self-esteem Scale), current health, health worry / concern, and post-high-school education. It was concluded that the findings supported Pender's health promotion model which posited that individual perceptions of health locus of control, self-esteem, and health status influence health promotion behavior. It was concluded that highly educated midlife women would not want to leave their health to chance.

The major short-coming of this study was the low response rate and homogeneity of the sample. Since the sample was self-selected the results could not be generalized to the population at large or to other women with similar sociodemographic characteristics. It did indicate however, that for at least some women, control was an important variable in relation to midlife health concerns.

In summary, the literature to date suggested that there may be a relationship between locus of control and symptoms during menopause, with those experiencing more symptoms having an external locus of control. No relationship between control and estrogen use has been detected. Nor was a relationship found between control and any demographics studied. Some findings indicated that there may be a relationship between control and health-promoting behavior among some subgroups of women.

An examination of selected studies of health locus of control and control research relating to women provided information partially applicable to the

issue of control as it related to menopause.

Health Locus of Control Scales

In a study of control which used the Health Locus of Control [HLC] scale, Wallston et al, (1976) found that high-value internals selected more pamphlets relating to a health condition about which they knew nothing than did other groups of individuals which suggested that health locus of control could be used to predict health related behavior such as information seeking. ("High-value" individuals ranked health as one of their top 4 terminal values).

✱ In a second study, Wallston et al (1976) found that overweight women who attended an 8 week weight loss program consistent with their expectancies as measured by the HLC were significantly more likely to be satisfied with the program than were women attending programs inconsistent with their expectancies. This finding indicated that control may be an issue in health related interventions such as a program addressing health care during menopause.

The HLC has been one of the most frequently used scales for application to health-related situations. The HLC Scale consisted of 11 face-valid items in a 6 point Likert-type format with half of the items worded internally and half worded externally. The alpha coefficient of reliability has ranged from .40 to .72, depending on the sample and the test-retest reliability (8 week interval) was .71. The scale correlated -.01 with the Marlowe-Crowne Social Desirability Scale and .25 to .46 with Rotter's I-E scale. Wallston et al (1976) found no significant differences between males and females on the HLC scale. The HLC scale has been found to be more predictive of health related behavior than the Rotter I-E scale (Wallston et al, 1976).

In a review of research examining control and health Strickland (1978) indicated that measures specific to health such as the Wallston et al HLC scale were better predictors of health-related behaviors than were non-specific measures but concluded that the I-E variable (Internal-External) was only one of a number of complex factors that may converge to predict health attitudes and behaviors and that the variance that I-E accounted for was fairly small in many situations. Strickland concluded that although results were not unanimous, the bulk of the research suggested that internal individuals appeared to engage in more adaptive responses when faced with health problems than did externals and that development of an internal orientation could lead to improved health practices. Wallston and Wallston (1978) in a review of locus of control and health, also concluded that health education programs should be tailored to locus of control beliefs since some education programs had been found to be differentially effective for internals and externals. They also concluded that since internals appeared more likely to engage in positive health behaviors health educators should train patients to hold more internal beliefs and that internal locus of control could be used in conjunction with behavioral measures to evaluate health education programs. This conclusion conflicted with the findings of Wallston et al (1987) who studied patients scheduled for a barium enema examination and found that low desire for control patients experienced less distress in an information only condition as compared to choice or predictability conditions. Contrary to prediction, high desire for control patients experienced less distress in the predictability condition compared to the choice or information only conditions. It was hypothesized that this was due to reac-

tance. The choice condition failed to provide a true choice and instead was perceived to be a travesty, providing a choice “between poisons” (Wallston et al, 1987). These results indicated that individuals differed in their desire for control and suggested that interventions should be tailored to the needs of individuals in regard to control.

While there was disagreement as to whether an internal orientation relating to health should be encouraged or whether attempts should be made to accommodate the individual’s internal or external orientation (Strickland, 1978; Wallston & Wallston, 1978; Wallston et al, 1987) there was general agreement that control was an important variable in health related issues and for application to health interventions.

Control Research Relating to Women

While Wallston et al (1976) reported no differences between men and women on the HLC scale, research relating health locus of control to situations specific to women’s health may be especially useful when considering control in relation to an issue such as menopause because of potential greater similarity between the situations.

A study of women’s choice of prenatal health provider supported the finding described above regarding differing desire for control. Women who had selected a nurse midwife scored significantly higher on the internal locus of control subscale of the Multidimensional Health Locus of Control [MHLC] scale than did women who had chosen an obstetrician. Women who chose an obstetrician scored more highly on the powerful other subscale. The two groups of women (N = 244) did not differ significantly on other variables such

as demographic characteristics, how long they had been pregnant, when they first sought prenatal care or rankings of life values (Aaronson, 1987). This supported experimental data which suggested that women differed in the amount of control they desired over their health care.

Also supporting this concept was a study by Littlefield and Adams (1987) which found that women who chose a conventional birthing method (versus an alternative birthing center) scored significantly higher ($p < .01$) on the powerful others subscale of the MHLC than did women who chose to birth at the alternative birthing center. Littlefield and Adams (1987) also found that women did not score differently on the internal control subscale after delivery compared to prior to delivery, which suggested that internal control was a stable personality characteristic. Women in both birthing conditions did increase significantly in powerful others scores post delivery, which suggested that experience may influence women's perceptions regarding control relating to health. Since the findings found change on one control dimension (powerful others) after delivery but not on another dimension (internal control) it was unclear whether control was a personality characteristic or a situation specific variable. Since control may be situation specific or may change with experience, studies of control as it related specifically to menopause may be needed for practical application of the information. While this research may generalize to women and health during menopause, there are some differences to consider. First, while this research specifically examined control in relation to a health issue for women, the data may not generalize from prenatal care to menopausal care because the women belong to different age cohorts and some studies indicated

that some control dimensions were influenced by situation or experience. Menopause is not only a different situation, but is experienced by women at a different age than the women who were studied regarding childbirth. Both the general research conducted using the HLC scale, which used college students as subjects (Wallston et al, 1976) and the studies related to childbirth health providers (Aaronson, 1987; Littlefield & Adams, 1987) studied women under the age at which menopause occurs. The Littlefield and Adams (1987) study described above showed that score on the powerful others subscale can change as a result of experience which also indicated that studies examining women at one age may not generalize to women at a different age. Secondly, the measure used (the MHLC) was a general measure of health locus of control. The more situation-specific a measure is the better it is expected to predict behavior (Rotter, 1975) suggesting that a measure developed specifically to measure control relating to menopause may be more appropriate for applied use. Labs and Wurtele (1987) found that a measure developed specifically to assess control relating to fetal health significantly predicted maternal behavior, while the MHLC scale did not.

For this reason it is important to examine locus of control as it relates specifically to menopause. Additional research is needed to verify the relationship between symptoms and control using a situation-specific measure and to look at the relationship between control and management of symptoms with estrogen therapy and other strategies. Additionally, sociodemographics should be examined using a situation-specific measure of control to determine whether women of different backgrounds differ significantly on control

relating specifically to menopause. Another topic which has not been addressed in the literature to date is whether a relationship exists between control and knowledge regarding menopause. Do those who are more knowledgeable about menopause perceive more or less control relating to menopause? Ferguson, Hoegh and Johnson (1989) found that knowledge regarding menopause issues was significantly related to likelihood of taking ERT and that women who were more likely to take ERT were more likely to view menopause as a medical condition and less likely to favor natural approaches to menopause. Is the perception of control relating to menopause dependent on a woman's menopausal status as measured by last menstrual period? Do women perceive more or less control relating to menopause while they are actually experiencing the change in their menstrual pattern?

Addressing these questions requires an instrument designed to measure perceived control which is situation-specific to menopause and has adequate internal consistency. It requires a non-patient sample of adequate size and a data collection measure other than clinical observation. Aggregate data should be the basis of any conclusions drawn.

The study described on the following pages aimed to describe one of the key variables in the experience of menopause-perceived control-and to correct some of the methodological flaws of past research on the menopause. The instrument developed for the study was designed for use with a non-patient sample and was designed to be situation-specific to the issue of control relating to menopause. The data collection method was self-report rather than clinical observation and a sufficiently large sample size was used to ensure adequate

statistical power in the analysis of the aggregate data. The methods, procedures and hypotheses for the study follow.

Chapter 2

Method

The purpose of this research was to determine the correlates of perceived control relating to menopause for use in developing an educational intervention to aid women in active involvement in their menopausal health care. Perceived control was examined in relation to demographic variables, symptoms, knowledge about menopause, symptom management behavior, and likelihood of taking hormone therapy.

Hypotheses

1. Marital status, employment, household income, and education will differentiate between individuals who are high in perceived control and those who are low in perceived control.
2. Religious preference will differentiate between individuals who are high in perceived control and those who are low in perceived control.
3. Menopausal status (as measured by time since last menstrual period-item 13 on Sociodemographic instrument) will differentiate between individuals who are high in perceived control and those who are low in perceived control.
4. Women who indicate experiencing or expecting more symptoms on the symptoms instrument will differ in perceived control from women who indicate fewer symptoms.

5. Women who indicate experiencing or expecting more severe symptoms on the symptoms instrument will differ in perceived control from women who indicate less severe symptoms.
6. Women who indicate a higher mean number of symptom management strategies on the management instrument will differ in perceived control from women who indicate a lower mean number.
7. Symptom management strategy category will differentiate between individuals who are high in perceived control and those who are low in perceived control.
8. Overall knowledge regarding menopause as measured by the Menopause Information Instrument will differentiate between individuals who are high in perceived control and those who are low in perceived control.
9. Mean likelihood of taking estrogen replacement therapy will differentiate between individuals who are high in perceived control and those who are low in perceived control.

Subjects

Two hundred eighty three women between the ages 45 and 55 (inclusive) completed instruments, of which 271 met the criteria for participation and had usable data. To meet the criteria for inclusion in the study, women were required to be between 45 and 55 years old, not presently taking estrogens and

not have had a hysterectomy. Twelve women were eliminated from data analysis because either they did not meet these criteria, or they failed to complete one or more entire instruments. The demographic characteristics of the sample are shown in Table 2. Participants were volunteers recruited through Lansing area churches, synagogues and women's organizations and through newspaper and newsletter articles requesting participants and a television interview describing the study. Participants were also recruited through an article in the Detroit Free Press which reached women in the Detroit area and in other Michigan cities. Seventy of the participants attended a data collection session in the Detroit metropolitan area, and 201 participants attended sessions in the Lansing area. All of the participants were English-speaking and able to respond to written material.

The sample consisted of women who volunteered to participate in this study and were told that they would receive information about estrogen replacement therapy and menopause. The sample was not necessarily representative of the population of women in this age range, but was descriptive of a subsample who were interested in the topic and might be likely to attend an informational program on ERT and menopause.

Table 2

Description of the Participant Sample

Variable	N	%
Last Menstrual Period		
Still Regular Periods	142	52.4%
Less than 3 Months Ago	34	12.6%
3 -12 Months Ago	35	12.9%
12 or More Months Ago	58	21.4%
Missing	2	.7%
Marital Status		
Married	210	77.5%
Divorced	38	14.0%
Single	11	4.0%
Widowed	10	3.7%
Separated	1	.4%
Missing	1	.4%
Employment Status		
Employed Full Time	136	50.2%
Employed Part Time	71	26.2%
Not Employed, Retired or Other	64	23.6%
Yearly Family Income		
\$50,000/yr or More	105	38.7%
\$35,000 - \$49,999	55	20.3%
\$30,000 - \$34,999	33	12.2%
Less than \$30,000	65	24.0%
Missing	13	4.8%
Education		
Less than 12 years	4	1.5%
High School Graduate	61	22.5%
More than 12 yrs. but no degree	67	24.7%
Tech. School or Community College Degree or Other	21	7.8%
Bachelors Degree	68	25.0%
Masters Degree	42	15.5%
Ph.D or Professional Degree	8	3.0%
Race		
White	254	93.7%
Black	7	2.6%
Hispanic	7	2.6%
Other	3	1.1%

Setting

The questionnaires were completed during a meeting scheduled for the purpose. The meetings were held at a location and time convenient to the women, usually in the evenings, and took approximately 1 1/2 to 2 1/2 hours. Meetings were held at churches, community centers, schools and at Michigan State University. Usually the room used for the completion of the questionnaires contained a table and chairs, though occasionally the women simply sat in a circle in chairs. Five to 70 women, usually from several different organizations, attended each session. Name tags and coffee were provided for the discussion session with the nurses after completion of the questionnaires. Sessions began with a brief description of the purposes of the study and instructions regarding completion of the questionnaires. See appendix A for instructions to participants. Following this, the women worked through the questionnaires individually and then participated in the group question and answer period with the nurse afterward, if they desired. Frequently the question and answer period was held in another room and women joined the discussion after they had finished with the questionnaires. Other times, it was held in the same room and did not begin until all women in the group were finished with the questionnaires.

Design

This study was a descriptive correlational study, with total on the perceived control scale as the dependent variable. The independent variables were marital status, employment status, yearly household income, educational level, religious preference, and menopausal status all measured by self-report to

items on the Sociodemographic Instrument (see appendix B). Additional dependent variables were total symptom score, measured using the Menopausal Symptoms Instrument (see appendix C), type of symptom management strategies employed and mean number of strategies used, measured with the Symptom Management Instrument (see appendix D), knowledge of menopause, measured by the Menopause Information Instrument (see appendix E), and likelihood of taking estrogen replacement therapy, measured using the Judgment Cases Instrument (see appendix F). The correlation between perceived control and the independent variables (described for more fully under the instruments section) were examined using the Pearson Correlation Coefficient and one-way Analysis of Variance.

Instruments

Perceptions of Menopause. The items forming the Perceived Control scale were drawn from the Perceptions of Menopause Instrument (see appendix G) developed by Rothert, et al (1986). The instrument consisted of 32 statements reflecting subjective assessment of the experience or expectations of menopause. One half of the items reflected positive and half reflected negative perceptions. The response choices which formed a Likert-type scale were "strongly agree," "agree," "neither agree nor disagree," "disagree," and "strongly disagree." Responses were coded 1 through 5, with 5 indicating a more positive perception or greater internal perceived control and 1 indicating a negative perception or less internal perceived control. The Perceptions of Menopause Instrument was constructed to have 5 scales, including Feelings, Control, Attitudes Toward Hormone

Table 3

Perceptions Instrument Items

Item #	Content
<u>Menopause As Problem Scale</u>	
1	Menopause has been/will be an unpleasant experience for me.
2	The thought of menopause is disturbing to me.
10	I expect to (do) experience physical trouble during menopause.
11	I expect to (do) experience emotional trouble during the menopause.
12	Menopause will bring/has brought many changes to my life.
16	I have been/will be able to experience menopause without problems.
18	Menopause will/did cause me to be sick a lot.
19	Menopause probably will not/did not have a negative effect on me.
23	Women are more tired than usual during menopause.
25	Menopause is associated with mood changes.
<u>Control Scale</u>	
6	Menopause symptoms that I might have can be helped.
9	There are things I can do to feel good during the menopause other than going to a health care provider.
15	There is little that an individual can do to control the symptoms of menopause.
17	Menopause causes problems no matter what you do.
20	I believe that I can control menopausal symptoms.
22	Special diets & foods may help control some of the symptoms of menopause.
24	Menopause is something I just have to put up with.
<u>Hormones Help Scale</u>	
8	Hormones are necessary for the management of menopausal symptoms.
21	Taking hormones for menopausal symptoms can make me feel better.
<u>Positive Expectations Scale</u>	
4	On the whole, I expect to feel better after the menopause than I did before the menopause.
5	I welcome the menopause.

Therapy, Attitudes Toward Health Care Providers, and Activities of Daily Living. Ten items formed the a priori Control scale: *6, 7, 8, *9, 13, *14, *20, 21, *22, and 24. The items preceded by an asterisk were reflected (1=5, 2=4, 5=1, 4=2) so that a 5 on all of the items represented more internal perceived control. Each scale was scored by adding up the code (1-5) for each item in the scale.

Cronbach's alpha coefficient of internal consistency was .4531 for the a priori scale. The corrected item-total correlations ranged from .0207 to .3014. Based on item content the scale was revised. Items 7, 8, 13, and 21 were eliminated from the scale and items 15 and 17 were added. Cronbach's alpha for the new scale was .6498. The corrected item-total correlations ranged from .1697 to .5327 and the scale variance increased from 9.59 for the a priori scale to 10.53 for the new scale. Item 14 correlated least well with the scale ($r = .1697$) and was eliminated to form the final scale which consisted of the following 7 items: *6, *9, 15, 17, *20, *22 and 24. Cronbach's alpha for the final Control scale was .6580. The item content of the final scale is shown in Table 3. The Perceptions of Menopause instrument yielded four internally consistent scales in their final forms: Menopause As Problem, Control, Hormones Help, and Positive Expectations. The content of each of these scales is shown in Table 3. Only the Control scale was utilized in this study. The corrected item-total correlations for each of the 7 items in the Control scale are shown in Table 4, along with the item-scale correlations for the Control scale items with the other final Perceptions instrument scales and the inter-scale correlations. Item 17 correlated highly with the Menopause As Problem scale as well as the Control scale but was included in the Control scale based on content and because it

increased the reliability of the Control scale slightly by increasing the length of the scale. The minimum score possible on the scale was 7 and the maximum score possible was 35. The mean score on the scale was 24.31 and the standard deviation was 3.06. The distribution of the scores on the scale is shown in Figure 1.

Table 4

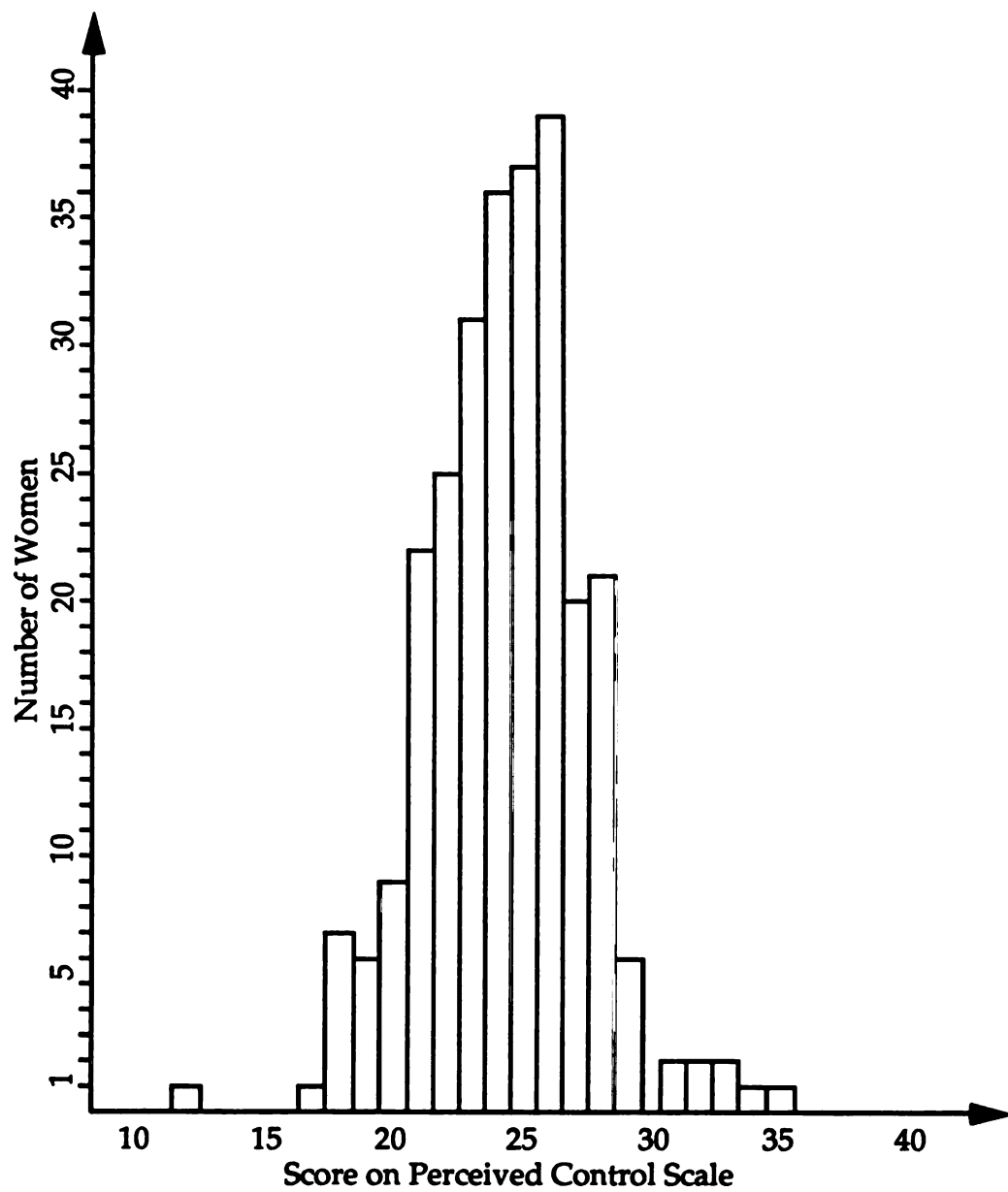
Interscale Correlations for Perceptions Instrument

	Control	Men. As Prob.	Horm. Help	Pos. Expec.
Control	1.00	0.4838 ($p < .001$)	-.1107 (N.S.)	.0968 (N.S.)
Men/Prob.		1.00	.0956 (N.S.)	.1046 (N.S.)
Hor. Help			1.00	.1043 (N.S.)
Pos. Exp.				1.00

Item-Total and Item-Scale Correlations for Control Scale Items

Item	Corrected Item-Total Correlation	Item-Scale Correlations		
		Men/Prob	Hor. Help	Pos. Exp.
6	.3545	.1758	-.1775	.1387
9	.2387	.1221	.0380	.0245
15	.5350	.3636	-.0711	.0731
17	.4019	.5274	-.0219	-.0122
20	.4289	.3434	-.0548	.0609
22	.2066	.0650	-.0585	.0247
24	.4106	.2755	-.1148	.0713

Figure 1
Distribution of Scores on Control Scale



Sociodemographic. The sociodemographic instrument was a 28 item questionnaire which asked not only for sociodemographic information such as age, race and income, but also included items relating to the health history of the respondent, particularly menstrual history. See appendix B.

Menopausal Symptoms. The Menopausal Symptoms instrument was divided into 2 sections, color coded green and yellow. See appendix C. Respondents read the 56 symptoms listed and for those symptoms they had experienced, indicated whether they were, "Not Bothered," "Bothered a Little," "Bothered Somewhat," or "Bothered a Lot" by the symptom. Women who answered "yes" to the question: "Are you currently experiencing or have you experienced symptoms in the past which you believe are or were caused by menopause?" read the symptom list on the green pages. Women who answered "no" read the same list of symptoms on the yellow pages but their responses choices were "Will Not Bother Me," "Will Bother Me a Little," "Will Bother Me Somewhat," and "Will Bother Me a Lot." The instructions to the women who answered on the yellow sheets were to answer only for those symptoms they expected to experience due to menopause. After the women checked how much each symptom they had experienced or expected to experience bothered them, the instructions asked them to rank the 5 symptoms which bothered them the most. The total symptom scale for each woman was computed by totaling her bothersomeness ratings for all symptoms she indicated. Cronbach's alpha coefficient of internal consistency was .9475 for the scale.

Management of Symptoms. This instrument was completed only by women who answered “yes” to question A on the Menopausal Symptoms instrument . It had space for the respondent to list the five symptoms ranked as most bothersome to her and four categories of symptom management strategies. The four categories were Medications, Diet, Vitamin and Mineral Supplements, and Other. The instructions directed the respondent to indicate what strategies, if any, she used to manage each symptom she listed.

The instrument consisted of four a priori scales made up of the strategies in each of the management categories: Medications, Diet, Vitamin and Mineral Supplements and Other. The rationally derived scales were developed by Rothert, et al (1986). The Management instrument scales were coded by scoring each strategy indicated by the respondent with a “1” for each symptom checked and scoring a “0” for each symptom under each strategy which was not checked by the respondent. For example, if the respondent indicated that she took sleeping pills for symptoms 1 and 2 and tranquilizers for symptom 3 under medication and she had 4 symptoms listed, she received a “1” for sleeping pills for symptom 1 and a “1” for sleeping pills for symptom 2, and a “0” for sleeping pills for symptoms 3 and 4. She would also receive a “1” for tranquilizers for symptom 3, and “0’s” for tranquilizers for symptoms 1, 2, and 4. Each strategy checked for each symptom was counted as a “1.” To obtain a scale score for symptom management for each category, the number of ones was added up for all of the items in each category, and divided by the number of strategies listed in that category. This total was then divided by the number of symptoms that were listed to obtain a mean number of strategies per

symptom score. The purpose was to make the measure equivalent across strategy scales and subjects. See appendix H for equation and example. Cronbach's alpha coefficient of internal consistency for the Medications scale was .4244. For the Diet scale, alpha = .8155. The alpha coefficient for the Vitamin/Minerals scale was .9185. The alpha coefficient for the Other scale was .8429.

Menopause Information. This instrument was a 21 item questionnaire designed to assess the respondent's knowledge about the physiology of menopause and related issues. Its general intent was to assess knowledge of factual information. Each item answered correctly was counted as a one and the total score was tabulated as a measure of overall knowledge. One item for which the correct answer was not clear-cut was excluded from the analysis resulting in 20 possible points. Cronbach's alpha coefficient of internal consistency was .7721. See appendix I for answer key.

Judgment Cases. The Judgment Cases instrument was a series of 32 (16 replicated) systematically designed cases which presented three factors related to the decision to take ERT. The factors represented in one of two levels were: hot flashes (severe or minimal); risk of endometrial cancer (standard or high); and risk of osteoporosis (standard or high). The factors were selected based on the literature and interviews with nurses, physicians and women. All possible combinations of the factors were included which resulted in eight cases. The eight cases were randomly ordered and then replicated for a total of 16 cases in each of two separately ordered sets. In the first set of cases the women were asked how likely they would be to take estrogen replacement therapy

unopposed by progestogen and in the second set the women were asked to indicate how likely they would be to take estrogen combined with progestin. Each set of cases was preceded by an information sheet describing major risks and benefits of the treatment and by two practice cases to help control for any practice effect. The cases were orthogonally designed creating statistical independence of the factors. The respondent was instructed to indicate likelihood of taking hormone therapy on a scale of 1 to 5, from very certain she would NOT take hormone therapy in that situation (1) to very certain that she WOULD take hormone therapy (5), with (3) indicating may or may not take hormone therapy. Probably would NOT and Probably WOULD take hormone therapy are coded (2) and (4), respectively. Likelihood of taking estrogen was computed by adding up the numbers (1-5) indicated by the respondent, as to likelihood of taking hormone therapy. Cronbach's alpha coefficient of internal consistency was .9641 for the Average Likelihood of Taking Hormone Therapy scale.

Procedure

Subject recruitment

Subjects were recruited from churches, synagogues, local women's organizations, and through media requests for study participants (See appendix J). When requesting participants through organizations, a contact letter (see appendix K) was sent to the individual responsible for the group, such as the clergyperson of a church or the president of an organization. The letter described the study and requested an opportunity to come to a group meeting and ask for volunteers to complete the questionnaires. The letter

indicated that a follow-up telephone call would be made to learn whether any women from the organization would be interested in participating in the study or whether the organization would be interested in hosting a session to complete questionnaires and participate in the question and answer period about menopause. During the telephone contact the study was described further, and any questions answered. If there were women in the organization who were interested in participating in the study but too few to schedule a separate session for the organization, the women were contacted individually and scheduled for a session already scheduled elsewhere. If the organization was interested in the study, the contact person was provided with participant sign-up sheets to distribute (see appendix L) and examples for newsletter and bulletin board announcements (see appendix M). If the organization was interested in hosting a session, a time and date were set and a letter confirming the appointment was sent to the contact person. Organizations were told that if they hosted a session to complete questionnaires, all women in the group were welcome to participate in the question and answer discussion with the nurse following the questionnaire period, even if they did not meet the criteria for participation in the study. Women who were scheduled individually for sessions were sent letters confirming their appointment. If additional information regarding the study was requested, a packet of informational materials (see appendix N) was sent to the contact person or individual.

Data Collection

Data was collected by having the women complete the written questionnaires at data collection sessions conducted by the researcher. Each

data collection session began with an introduction to the study and a description of its purpose (see appendix A). Verbal instructions for completing the questionnaires briefly reviewed the written instructions included with each instrument. Participants were informed that participation in the study was completely voluntary and that they could terminate participation at any time. The participants were encouraged to ask questions regarding the instructions if needed while completing the instruments. They were also encouraged to answer all questions and to indicate if they chose not to answer a particular question so that it was clear that they had not inadvertently missed the item.

The women then signed the informed consent form (see appendix O) and completed the questionnaires. The instruments were completed in the following order for most of the participants: Consent form (appendix O), Introduction sheet/Results Request Form (appendix P), Sociodemographic instrument (appendix B), Perceptions of Menopause instrument (appendix G), Menopausal Symptoms instrument (appendix C), Symptoms Management instrument (appendix D), Menopause Information instrument (appendix E), Judgment Cases instrument (appendix F). Forty-nine participants completed the Judgment Cases instrument following the Introduction sheet/Results Request Form and before the Sociodemographic instrument. The order of the other instruments remained the same. The purpose in completing the Judgment Cases before the other instruments was to determine whether there were any instrument order effects on the Cases instrument. The importance rank of hot flashes, osteoporosis risk and cancer risk was found to be the same for those who completed the cases first as for those who completed them last.

No order effects were detected. Completion of the instruments took 45 minutes to 1 1/2 hours for most women. Further instructions regarding specific instruments were clarified to the group at intervals during the questionnaire period.

After the women had completed all of the instruments they were invited to join a question and answer discussion group lead by a member of the faculty of the College of Nursing. The nurse answered questions raised by the questionnaires and other concerns expressed by the women. The question and answer group served as a debriefing period and attendance was voluntary but almost all women participated in the discussions.

Following the data collection, each participant was sent a thank you letter. Contact persons and organization leaders were also sent thank you letters where appropriate. See appendix Q for example letters.

Chapter 3

Results

The purpose of this study was to determine the correlates of level of perceived control over the menopause experience. The data collected from the six questionnaires described in the methods section was used to explore nine hypotheses regarding the relationship of sociodemographics such as marital status, employment status, and household income, and reported behavioral and experiential characteristics such as symptomatology, knowledge about menopause and symptom management behaviors, to level of perceived control.

Evaluation of Hypotheses

Hypothesis 1. Null hypothesis 1 predicted that the sociodemographics marital status, employment status, household income, and educational level would not differentiate between individuals who were higher in perceived control and those who were lower.

A one-way analysis of variance was performed to determine whether there was a significant difference in marital status between those who were higher in perceived control and those who were lower. There were no significant differences in perceived control over the menopause experience between women who were married, divorced, single, widowed, or separated, $p > .05$.

An Analysis of Variance was performed to determine the relationship between employment status and perceived control over the menopause experience. There were no significant differences in perceived control over the menopause experience between women who were employed full-time, employed part-time, retired, or not employed, $p > .05$.

The Pearson Correlation Coefficient was computed to determine whether yearly household income correlated significantly with perceived control over the menopause experience. A 2-tailed significance test showed that the correlation between income and perceived control, was not significant at the .05 significance level.

The Pearson Correlation Coefficient was computed to determine whether there was a relationship between educational level and perceived control over the menopause experience. The correlation between educational level and perceived control was found to be $r = .1267$, ($p < .05$, 2-tailed). The positive correlation found indicated that more highly educated women perceived greater control over the experience of menopause. The relationship was no longer significant at below the .05 level however, when the group "Other" (N = 5) was excluded. "Other" included "beauty school," "registered med. tech.," "Associate degree in business and legal assistant," and "certified graphoanalyst." The hypothesis regarding educational level and control could not be rejected at the .05 significance level. The means for each group are shown in Table 5.

Table 5
Education and Mean Score on Perceived Control

Educational Level	N	Mean	S.D.
Less than 12 Years	4	24.00	2.45
High School Graduate	61	23.69	3.04
More than 12 Years/No Degree	67	24.34	3.40
Technical/Community College Degree	16	23.70	2.71
Bachelor's Degree	67	24.51	3.06
Master's Degree	41	24.85	2.82
Ph.D. or Professional Degree	8	24.75	2.82
Other	5	25.60	2.07
Total	269	24.31	3.06

Since no significant correlations were found for demographic variables , Null Hypothesis 1 could not be rejected.

Hypothesis 2 . Null hypothesis 2 predicted that individuals who indicated a religious preference would not differ in perceived control from individuals who did not.

An Analysis of Variance was performed to determine whether there was a significant relationship between religion and perceived control over the menopause experience. There was no significant difference in perceived control between those who indicated no religion, Jewish, Protestant, Catholic, or Other, $p > .05$. Null hypothesis 2 was not rejected.

Hypothesis 3. Null hypothesis 3 predicted that individuals categorized as menopausal according to question 13 on the sociodemographic instrument (last menstrual period) would not differ in perceived control from individuals

categorized as premenopausal according to the same question. Table 6 shows the means and standard deviations on the perceived control scale by last period. A higher mean on the Control scale indicated greater or more internal perceived control.

A one-way Analysis of Variance was performed to determine whether menopausal women differed in perceived control over the menopause experience from premenopausal women. As Table 6 shows, the omnibus F-test for perceived control by menopausal status was statistically significant, $F(3, 263) = 4.9242, p < .05$.

The Scheffe multiple range test indicated that the pair "Still have regular periods" and "Last period 3 to 12 months ago" were significantly different at beyond the .05 level. Women whose periods were still regular scored higher (more internal) on perceived control over menopause than women whose last period was 3-12 months ago. Figure 2 shows the mean and one standard deviation for each of the four groups compared. An estimate of treatment effect size (ω^2) was calculated (see appendix R) and found to be .042 which indicated that Last Menstrual Period accounted for approximately 4.2% of the variance in Perceived Control. Since the omnibus F-test as well as the Scheffe multiple range test indicated that 2 groups differed significantly from each other, null hypothesis 3 was rejected.

Table 6

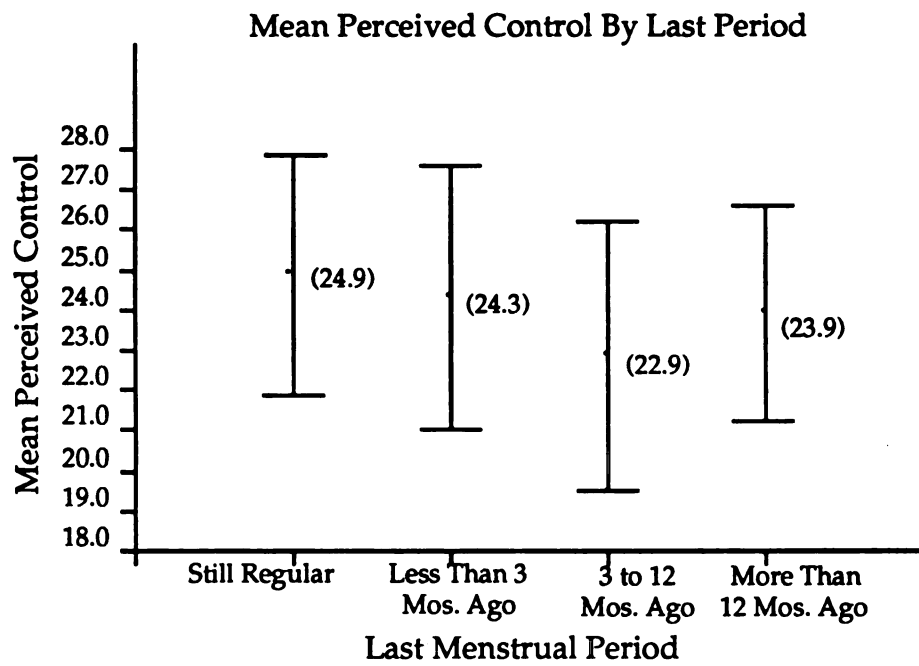
Summary Statistics for Perceived Control and Last Menstrual Period

<u>Last Menstrual Period</u>	<u>N</u>	<u>Mean</u>	<u>S.D.</u>
Still Regular	140	24.91	2.93
Less than 3 mos. ago	34	24.29	3.22
3 to 12 mos. ago	35	22.89	3.34
12 or more mos. ago	58	23.90	2.67
Total	267	24.35	3.04

Analysis of Variance

<u>Source</u>	<u>D.F.</u>	<u>Sum of Squares</u>	<u>Mean Square</u>	<u>F-Ratio</u>	<u>F-Prob.</u>	<u>ω^2</u>
Between Groups	3	130.5258	43.5086	4.924	.0024	.042
Within Groups	263	2323.7738	8.8356			
Total	266	2454.2996				

Figure 2



Hypotheses 4 & 5. Null hypothesis 4 predicted that individuals who indicated experiencing or expecting more symptoms on the symptoms instrument would not differ in perceived control over the menopause experience from women who indicated fewer symptoms. Null hypothesis 5 predicted that women who indicated experiencing or expecting more severe symptoms on the symptoms instrument would not differ in perceived control from those who indicated less severe symptoms. The total symptom score, tabulated for each individual by summing the severity scores for all of the symptoms, reflected both severity and number of symptoms reported. Severity and number of symptoms were combined to provide a more complete picture of the women's responses. Simply counting the number of symptoms would not have described the severity of the symptoms experienced by the woman, and dividing the total symptom severity score by number of symptoms to obtain a measure of severity per symptom was also thought to be a less useful measure of symptomatology. The Pearson Correlation Coefficient was computed to determine whether women who had a higher total symptoms expected score were lower in perceived control over the menopause experience than women who had a lower total symptoms expected score. Perceived control was found to correlate $-.3530$ with the total symptoms expected score, $p < .05$, 2-tailed. Correcting the correlation for unreliability in the measures (see Appendix S) increased the correlation to $-.4471$. This indicated that women who reported expecting fewer symptoms perceived greater (more internal) control relating to menopause than women who reported expecting more symptoms. Null hypothesis 4 was rejected.

The Pearson Correlation Coefficient was also computed for women who reported experiencing symptoms due to menopause ($N = 207$) to determine whether women who had a higher total symptoms experienced score were lower in perceived control over the menopause experience than women who had a higher total symptoms experienced score. Perceived control was found to correlate $-.2353$ with the total symptom score, $p < .05$, 2-tailed. The correlation corrected for unreliability (see Appendix S) was $-.2980$. This indicated that women who reported experiencing fewer symptoms due to menopause perceived greater (more internal) perceived control relating to menopause than women who reported experiencing more symptoms. Null hypothesis 5 was rejected.

Hypothesis 6. Null hypothesis 6 predicted that women who had a higher mean for symptom management behaviors on the symptom management instrument would not differ in perceived control over the menopause experience from women who had a lower mean. The Pearson Correlation Coefficient was computed for Control with Total Management Strategies. There was no significant relationship between total management strategies reported and perceived control ($p > .05$, 2-tailed). Null hypothesis 6 could not be rejected.

Hypothesis 7. Null hypothesis 7 predicted that women who were higher in perceived control would not differ in the symptom management strategies used from women who were lower in perceived control. The means and standard deviations on the perceived control scale for each management strategy category are shown in Table 7.

Table 7
Summary Statistics for Symptom Management and Perceived Control

Management Strategy Category	N	Mean*	S.D.	Pearson r	P
Medications	205	.02	.02	-.0982	N.S.
Diet	204	.06	.08	.0673	N.S.
Vitamins	205	.04	.10	-.0440	N.S.
Other	205	.11	.12	.1930	.006

*Mean # of strategies per symptom per category

Pearson Correlation Coefficients were computed for each management category with perceived control. Table 7 shows the correlations and 2-tailed significance level for each category.

For the Medications category (see Table 8 for items), the Pearson Correlation Coefficient shown in Table 7 indicated that there was no significant difference in perceived control relating to menopause between women who utilized more versus fewer medications to manage menopausal symptoms.

Table 8 shows each item listed under the symptom management category Medications and the frequency (f) with which the item was checked. The frequency indicates the total number of times the strategy was indicated. As described previously, the Management instrument asked women to indicate which strategies they used to manage their 5 most bothersome menopausal symptoms. The women wrote each of their 5 symptoms in spaces on the instrument. Each participant could check each strategy from zero to five times.

If she did not use a given strategy for any of her top five most bothersome symptoms, she would not check the item at all. If she reported that she used the strategy for all 5 of her most bothersome symptoms, then she would have

Table 8
Medication Strategies and Frequencies

<u>Strategy</u>	<u>f</u>
Sleeping Pills	4
Tranquilizers	7
Blood Pressure Pills	6
Estrogen Alone	-
Progestin Alone	4
Estrogen and Progestin Combined	-
Pain Relievers	90
Sodium Fluoride Pills	2
Vaginal Lubricant	35
Estrogen Creams-Vaginal	-
Other	52
Total	200

checked the item 5 times. In Table 8 above, if a strategy has a frequency of '5', the number listed under 'f' could indicate that 5 women each used the strategy for 1 symptom each, or that one woman used the strategy for all five of her listed symptoms. The range possible for 'f' for each strategy was therefore 0 (if not one woman used the strategy for any of her symptoms) up to $N(\sum S_T)$ where N was the number of women (205) and $\sum S_T$ was the total number of symptoms listed on the Management Instrument by all of the women (between 0 and 5 for each woman). For clarification of how the scale was scored see

appendix H. The estrogen and estrogen/progestin items were used only to screen participants, since only women who were not presently taking ERT were included in the study. The "Other Medications" category included strategies written in by participants such as Bellergal, Norpramin, Tagamet, and P.M.S Tabs.

The Pearson Correlation Coefficient shown in Table 7 indicated that there was no significant difference on perceived control between women utilizing more versus fewer Diet strategies. Table 9 shows the strategy items listed under the category Diet, and the total number of times each strategy was checked. See discussion for Table 8 for explanation of frequency information.

Table 9
Diet Strategies and Frequencies

Strategy	f
Low Calorie	68
Low Fat	55
Low Salt	113
Low Cholesterol	42
High Calcium	46
Avoid Caffeine Products	144
Avoid Spicy Foods	17
Other	26
Total	511

The Pearson Correlation Coefficient shown in Table 7 indicated that women who utilized more versus fewer strategies listed under the Vitamins and

Minerals category did not differ from each other in perceived control relating to menopause. Table 10 shows the strategy items listed under the category Vitamins and Minerals, and the total number of times each strategy was checked. See discussion for Table 8 for explanation of frequency (f) information.

The Pearson Correlation Coefficient shown in Table 7 was significant and indicated that women who utilized more strategies listed under the "Other" category perceived greater (more internal) control relating to menopause than did women who utilized fewer "Other" strategies. The significant correlation increased to .2592 when corrected for unreliability in the measures (see Appendix S). Table 11 shows the strategy items listed under the category "Other" and the total number of times each strategy was checked. See discussion for Table 8 for explanation of frequency (f) information.

Table 10
Vitamins and Minerals Strategies and Frequencies

<u>Strategy</u>	<u>f</u>
Calcium Supplements	61
Vitamin E	45
Vitamin C	28
Vitamin D	13
Multivitamin	86
Iron	32
Other	37
Total	302

Table 11
"Other" Strategies and Frequencies

<u>Strategy</u>	<u>f</u>
Walking	237
Exercising	210
Relaxation Techniques	135
Douche	7
Skin Creams	12
Keep Diary	32
Talk With Others	175
See Health Professional	167
Other	34
Total	1009

Hypothesis 8. Null hypothesis 8 predicted that women who were higher in perceived control would not differ in score on overall knowledge regarding menopause from women who were lower in perceived control. A Pearson Correlation Coefficient was computed to determine whether the relationship between knowledge and perceived control was significant. The correlation between perceived control and total score on the Knowledge instrument was $r = .2365$, ($p < .05$, 2-tailed). The correlation corrected for unreliability (see Appendix S) was .3318. The null hypothesis was rejected. Women who scored higher on the Knowledge instrument perceived greater (more internal) control relating to menopause than women who scored lower.

Hypothesis 9. Null hypothesis 9 predicted that mean likelihood of taking estrogen replacement therapy would not differentiate between individuals who were high in perceived control and those who were low in perceived control. The Pearson Correlation Coefficient was computed to determine whether there was a relationship between likelihood of taking estrogen replacement therapy and perceived control. Control was correlated .1271, ($p < .05$), with likelihood of taking hormone replacement therapy. Corrected for unreliability (see Appendix S), the correlation was .1596. Null hypothesis 9 was rejected. Women who perceived greater (more internal) control relating to menopause were more likely to take hormone therapy than women who perceived less control.

Additional Analyses

In order to more completely examine the relationship of the variables discussed above to perceived control, a stepwise regression analysis was

performed. The independent variables included in the analysis were Total Symptom Severity Score, Average Likelihood of Taking Hormones, Knowledge Score, Income, Education, Employment, Marital Status, and Last Menstrual Period. The four symptom management strategy categories were not included in the regression analysis because there was data only for women who reported experiencing symptoms. Three variables entered the regression equation at or below the .05 significance level. Total Symptom Severity Score entered the equation first ($R = .2548$; R^2 change = .0649; F change = 17.14, $p < .0001$). Last Menstrual Period entered the equation second ($R = .3012$; R^2 change = .0258; F change = 6.98, $p = .0088$) and Knowledge Score entered third ($R = .3424$; R^2 change = .0265; F change = 7.36, $p = .0071$). To understand why only three variables out of eight entered the regression equation the intercorrelations between the variables were studied. Table 12 shows the Pearson Correlation Coefficients and significance levels for the variables included in the regression equation.

Table 12

Pearson Correlation Coefficient Matrix

	Cntrol	Sym.	ERT	Know.	Income	Educ.	Empl.	Marital	Period
Cntrol	1.00	-.2699*	.1271*	.2365*	-.0442	.1267*	-.0879	-.0334	-.1820*
Sym.		1.00	-.0752	-.0984	-.1171	-.1302*	-.0055	-.0314	-.0359
ERT			1.00	.2246*	.0572*	.1366*	-.0656	.0316	-.1685*
Know.				1.00	.1235*	.2783*	.0069	-.0248	.0304
Income					1.00	.2293*	-.0249	-.3502*	-.0096
Educ.						1.00	-.0782	.1039	-.1533*
Empl.							1.00	-.1851*	.1547*
Marital								1.00	-.0617
Period									1.00

* $p < .05$

Although most of the correlations were small in magnitude, some of them were statistically significant. Education, for example was significantly correlated with each of the other variables and highly significantly correlated ($p < .001$) with the variable Knowledge, which had already entered the regression equation. Likelihood of Taking Hormone Therapy was also highly significantly correlated with the variable Knowledge and with the variable Last Menstrual Period, both of which were already in the regression equation. The 3 variables which entered the regression equation, Symptoms, Last Period and Knowledge accounted for 12% of the variance in Perceived Control relating to menopause.

The variables relating to the Symptom Management instrument were not included in the regression analysis nor in the correlation matrix because there was data for these variables only for women who indicated that they were experiencing symptoms due to menopause (N=207).

Other Management Strategies ("Other") was significantly correlated with Knowledge score ($r = .25, p < .05$), Education ($r = .18, p < .05$) and Last Menstrual Period ($r = -.24, p < .05$). A first order partial correlation controlling for Total Symptom score increased the correlation between "Other" and Control to $r = .29$ ($p < .05$). First order partial correlations controlling for Knowledge, Education, and Last Period each decreased the correlation between "Other" and Control slightly but the correlation remained statistically significant at below the .05 level in each case. A partial correlation which simultaneously controlled for Likelihood of Taking ERT, Knowledge score, Education, Total Symptom score and Last Period increased the correlation between "Other" and Control to $r = .23$ (N=193, $p < .05$).

First order partial correlations indicated that the correlation between control and education was due to the correlation between education and the variables Total Symptom Score, Likelihood of Taking Estrogen Therapy, Knowledge score and Income. In order to examine the effect of Total Symptom Score, Likelihood of Taking ERT, Knowledge score or Income on the correlation between education and control, first order partial correlation analyses were conducted. When first order partial correlations were computed which controlled for Total Symptom Score, Likelihood of Taking ERT, Knowledge score or Income the correlation between education and control

dropped to below .05 in each case and did not attain statistical significance.

When a first order partial correlation was computed which controlled for Knowledge score the correlation between Control and Likelihood of Taking ERT no longer attained statistical significance. First order partial correlations which controlled for Education or Last Menstrual Period, resulted in correlations of $r = .12$ ($p < .05$) and $r = .11$ ($p < .05$), respectively. When Last Period, Knowledge score and Education were all partialled out (in that order) the correlation between control and Likelihood of Taking ERT was no longer statistically significant.

Partialling out the influence of Education (N=266) on the correlation between Control and Knowledge score decreased the correlation observed only slightly (from $r = .24$ to $r = .21$). The correlation was still significant at below the .05 level. First order partial correlations controlling for Likelihood of Taking Estrogen (N=249), and for Income (N=249) resulted in correlations of $r = .16$ ($p < .05$) and $r = .20$ ($p < .05$), respectively. Partialling out Likelihood of Taking, Income and Education (in that order) resulted in a correlation of $r = .16$ (N=247; $p < .05$). The number of cases included in the third order partial correlation analysis was 247, down from 266 when only Control, Knowledge and Education were included in the analysis. Any case for which data was missing for any one of the five variables in the third order analysis was eliminated.

Partialling out the influence of the variables Likelihood of Taking ERT, Employment and Education decreased the correlation between Control and Last Menstrual period from $r = -.18$ (N = 261; $p < .05$) to $r = -.14$ (N = 258; $p = .05$).

A first order partial correlation controlling for Education only decreased the correlation between Control and Total Symptom Score from $r = -.27$ ($N = 267$; $p < .05$) to $r = -.26$ ($N=266$; $p < .05$).

Summary

Of the 9 null hypotheses, 6 were rejected. Null hypotheses 1 and 2 could not be rejected. The sociodemographic variables marital status, employment status, income, education and religion were not significantly correlated with perceived control relating to menopause. Sociodemographics did not predict degree of perceived control relating to menopause.

Null hypothesis 3, which stated that there would be no relationship between control relating to menopause and menopausal status as measured by time since last menstrual period was rejected. The pair Still Regular Periods and 3-12 Months Ago were significantly different at below the .05 level of significance. Women whose periods were still regular perceived more internal control relating to menopause than did women whose last period had been 3-12 months ago.

Null hypotheses 4 and 5, that there would be no relationship between perceived control and symptoms expected (hypothesis 4) or experienced (hypothesis 5) were both rejected. Women who reported expecting or experiencing more symptoms due to menopause perceived less control relating to menopause than did those who reported fewer symptoms.

Null hypothesis 6 was not rejected. There was no significant relationship between perceived control and number of symptom management strategies reported.

Null hypothesis 7, which stated that women who differed in the category (type) of symptom management strategies utilized would not differ in perceived control relating to menopause, was rejected. Women who utilized symptom management strategies categorized under "Other" perceived significantly greater control relating to menopause than did women who did not.

Null hypothesis 8, that perceived control would not be related to Knowledge score was rejected. Women who scored higher on the Knowledge instrument perceived more control relating to menopause than did women who scored lower.

Null hypothesis 9 was also rejected. Women who indicated a greater likelihood of taking hormone therapy perceived greater control relating to menopause than did women who indicated a lower likelihood. The observed relationship between Control and Likelihood of taking ERT appeared to be primarily due to differences in Knowledge score. A partial correlation controlling for Knowledge score showed that the correlation between Control and Likelihood of Taking ERT fell to less than .10 and was no longer statistically significant at below the .05 level.

Women who expected or experienced fewer symptoms due to menopause, who were still having regular menstrual periods, who scored more highly on the Knowledge instrument and who utilized more symptom management strategies categorized as "Other" perceived more internal control relating to menopause.

Chapter 4

Discussion

The purpose of the study was to determine whether there were significant correlates of perceived control over the experience of menopause. Of particular interest was examining the correlates of perceived control in light of their application to designing an educational intervention for menopausal women to help them in their decision making regarding estrogen and menopause. The goal was to apply the knowledge to tailor the intervention to meet the needs of women with different levels of perceived control over their menopausal experience. Based on literature such as Duffy (1988) who found that health locus of control accounted for 16% of the variance observed in health promotion lifestyle among middle years women, the assumption was made that control was an important variable in health-related behavior and that an intervention tailored to the level of control a woman perceived to have over her experience would be more successful in meeting the needs of that woman.

Self-administered questionnaires were used to gather information about women's sociodemographic characteristics, perceptions of menopause, symptomatology, symptom management behaviors, knowledge of menopause and decision making regarding estrogen replacement therapy. These variables were then correlated with perceived control to form the basis of conclusions about menopause and perceived control.

The finding that Control was not related to sociodemographics supported previous research on locus of control and demographics (Lind, 1984; Lewis, Morisky, & Flynn, 1978). The finding that religion was not related to perceived

control over the experience of menopause supported the study by Berrenberg (1987) which found that God-mediated control differed from internal and external personal control. The finding that women whose last menstrual period was 3-12 months ago scored lower (more external) on perceived control relating to menopause suggested that women who were in the perimenopause perceived less internal control relating to menopause than women who were premenopausal. This supported the findings of Littlefield & Adams (1987) who found that experience influenced locus of control. Since this was a cross-sectional sample it was impossible to conclude whether women perceived less internal control relating to menopause due to their menopausal status (i.e., their locus of control changed as they began to actually experience the menstrual changes related to menopause) or whether some other variable accounted for the difference in perceived control observed between perimenopausal women and premenopausal or postmenopausal women. A longitudinal study of women as they progress from premenopause through the perimenopause to postmenopause would be needed to clarify the relationship observed.

It was unknown why the group "Less Than 3 Months Ago" did not differ significantly in perceived control from the group "Still Regular Periods" when the group "3 to 12 Months Ago" did differ. The "Less Than 3 Months Ago" group conceivably included women who were not yet in menopause, but had missed a period for other reasons (pregnancy, normal fluctuation in menstrual cycle, etc). It was less likely that the reported change in periods for women in the "3 to 12 Months Ago" group was due to factors other than menopause since

more time had elapsed since the last period so women in this group were perhaps more likely to actually be perimenopausal.

The finding that a higher symptom severity score was correlated negatively with internal perceived control over menopause must be interpreted keeping in mind that the direction of causation was unknown and that the data was obtained from a cross-sectional sample. It was conceivable that women experiencing more symptoms perceived less internal control relating to menopause. It was also possible that those who perceived less internal control reported more symptoms. The relationship observed may have been due to variation in a variable other than expected or experienced symptoms since the groups differed in other variables in addition to symptoms indicated. The results supported the findings of Lind (1984) however, who found that internal non-users of estrogen reported the fewest symptoms due to menopause and that external non-users of estrogen reported the most symptoms.

Women who engaged in the general, health-conscious preventive strategies listed under the "Other" category perceived greater control over their menopause than women who utilized fewer strategies listed under "Other." This finding coincided with Duffy (1988) who found that women who scored high on internal health locus of control and low on chance health locus of control had high scores on nutrition and exercise.

The finding that women who were higher in perceived control had a higher score on overall knowledge regarding menopause supported the findings of Wallston and Wallston (1978) who reviewed five studies of health locus of control and health knowledge or information-seeking and found that across

studies, individuals who were more internal on locus of control had more knowledge regarding their illness or sought more knowledge than more external individuals.

Again, it is important to note here that this research was correlational in nature leaving not only the direction of causality unknown, but also leaving open the possibility that the results could have been due to variation in a third factor.

The finding that perceived control and likelihood of taking ERT were correlated indicated that women who perceived greater control over menopause were more likely to take hormone therapy, possibly because the action would relieve the symptoms of menopause and prevent osteoporosis. The review of health locus of control literature by Wallston and Wallston (1978) found that individuals who were more internal in health locus of control were more likely to engage in behaviors that facilitated physical well-being.

A partial correlation controlling for Knowledge score showed that the relationship between Likelihood of Taking ERT and Control was due to the correlation between Knowledge and Likelihood of Taking ERT ($r = .23$; $p < .05$). The relationship observed between control, health knowledge and health behavior suggested a path by which Control may be related to Likelihood of Taking ERT. As before however, it should be noted that the correlational nature of this study and the results of the partial correlation analysis prevented conclusions regarding the presence of a direct causal relationship between control and taking ERT.

Finally, the low to moderate correlations found and the fact that only three of the variables which were significantly correlated with perceived control entered the regression equation must be addressed. In previous studies of the relationship between control and health-related behaviors, control consistently emerged as a useful but weak predictor of health behavior (Lau, 1982; Strickland, 1978). The findings of this study supported this general conclusion. The relationship between control and the variables studied was small to moderate, with the strongest relationship observed between control and symptoms experienced or expected. It should be noted that several items on the perceived control scale directly related to the symptoms of menopause, which may have accounted for the strong correlation between the scale and reported symptoms. In defense of including such items however, the data indicated that women perceived menopause as defined by symptoms, not necessarily by a change in their menstrual periods. Women who had not experienced a change in their menstrual periods indicated that they were experiencing symptoms they attributed to menopause. These findings suggested that some women defined menopause according to the experience of symptoms rather than change in periods.

While the relationship between last menstrual period and report of experiencing symptoms due to menopause was correlated $-.34$ ($p < .05$), 33% of those women whose periods were still regular reported that they were experiencing symptoms which they attributed to menopause, and 38% indicated that they did not know if they were experiencing symptoms due to menopause. Only about one third of the women indicated that they were not

experiencing symptoms they attributed to menopause.

In conclusion, several significant predictors of perceived control over the experience of menopause were identified. The magnitude of the relationships varied from $r = .13$ to $r = -.27$. The relationships identified have implications for developing an educational program for women about menopause but caution must be exercised in applying these findings due to their small magnitude and correlational nature. The finding that perceived control relating to menopause was a significant, though small aspect of the women's experience of and response to menopause indicated that an intervention addressing women's needs during menopause should be designed to be sensitive to the variation in perceived control among women. Women with different levels of perceived control may be experiencing or expressing different degrees of symptomatology, may present with differing levels of knowledge and may be using different strategies to manage symptoms. Most importantly they may approach their menopausal health care differently and desire greater or lesser degrees of participation in their menopausal health care decisions. It will be important to measure perceived control preintervention and postintervention but the small magnitude of the relationships observed in this study indicated that it should not be expected that perceived control will be a major influencing factor in an intervention addressing the needs of menopausal women.

Limitations

The major limitations of this study included that the participants were self-selected, that the data were cross-sectional rather than longitudinal and that the correlational nature of the research prevented conclusions regarding causation.

Since the participants were self-selected, it was not known to what extent the results could be generalized to another sample with similar sociodemographic characteristics, or to the population of women as a whole. Since the study was cross-sectional in nature, it could not be determined whether the results obtained were due to developmental factors. Finally since none of the variables was manipulated experimentally, the direction and nature of causality was unknown. An additional limitation was that the variables studied were all measured through self-report. No concrete behavioral data was gathered limiting the accuracy of the study to the accuracy of the self-reports. The reliability of the control scale ($r = .65$) was weak, which attenuated the treatment effects, contributing to the low correlations observed.

Future Directions

A longitudinal study examining women's perceptions relating to menopause within women and across menopausal status would clarify the role of experience in perceptions of menopause. In addition, an experimental study which manipulated knowledge relating to menopause would illuminate the relationship between knowledge and perceived control relating to menopause. Finally, applying the findings of this study to an educational intervention for perimenopausal women in which perceived control was monitored across time would clarify whether perceived control relating to menopause was useful in understanding women's concerns regarding menopause and how they may be best addressed. As described earlier, the low correlations between control and the independent variables indicated that control was not a major influencing factor for the women in regard to their menopausal experience. The correlation

between control and symptoms expected or experienced indicated that perceived control may influence the experience or expression of symptoms (or expectations regarding symptoms) or that those who experience or expect more symptoms perceived less internal control relating to menopause. This finding, combined with the finding that women whose periods were still regular perceived more control relating to menopause than did women experiencing a change in their periods, may have indicated that some women might desire an intervention which provided information on issues relating to menopause as a means of returning to a sense of internal control over their menopausal experience. As pointed out earlier however, the findings of this study indicated that variables other than control influenced the women's experience of menopause and that it should not be expected that perceived control relating to menopause would be influenced in any significant way by such an intervention. An understanding of what factors influenced women's experience of menopause must be pursued through examining factors other than control. Factors such as symptomatology experienced premenopausally and perimenopausally and knowledge and attitudes about menopause may provide more useful insights that further study of perceived control and menopause.

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APPENDICES

APPENDIX A

APPENDIX A

Instructions to Participants
(Paraphrased)

Hello and welcome to the estrogen replacement therapy study. The purpose of this study is to learn about what is important to women in making the decision whether or not to take estrogen replacement therapy. We are asking women who are between 45 and 55 years old, not presently taking estrogen, and who have not had a hysterectomy to participate in the study. Even if you don't qualify to participate in the study you are welcome to look over the questionnaires if you wish, and attend the question and answer period with the nurse after the questionnaire session.

It will take approximately an hour to an hour and a half to complete the questionnaires. When you are finished we will begin the question and answer period.

Please complete the consent form on top of the packet. If you have any questions please feel free to ask me at any time. Sometimes our instructions aren't as clear as they seem to us so please feel free to ask me to clarify them. If you do not wish to answer a particular question, just indicate that you saw the question but do not wish to answer it, by putting a mark or something by the question. That way we will know that you did not just accidentally miss the

question. You do not have to answer any questions you do not wish to, but of course the more questions you answer, the more information we get about what is important to you about this issue.

Please complete the questionnaires in order. I will give additional instructions later for some of the questionnaires. If you have any questions just let me know.

-Later-

I'd like to clarify the instructions for the Symptoms instrument which is the questionnaire with the green and yellow pages. If you are currently experiencing symptoms which you believe are due to menopause, or have experienced symptoms in the past, answer "yes" to question A. If you have not experienced symptoms which you believe are due to menopause, answer "no." If you answered "yes" to question A, complete the green pages, if you answered "no," complete the yellow pages. On the green or yellow pages is a list of 56 symptoms. Not all women experience all or even most of these symptoms. This is a very comprehensive list. If you are answering the green pages, indicate only those symptoms which you personally have experienced which you believe are due to menopause. If you have not experienced a symptom, leave it blank. If you have experienced a symptom but you believe it is due to something else, leave it blank. We are interested in your opinion. If you are completing the yellow pages, indicate only those symptoms which you expect to experience due to menopause. If you do not expect to experience a symptom leave the

symptom blank. If you expect to experience a symptom, but believe it will be due to something else, leave it blank. After you have checked each of the symptoms and indicated how much it does or will bother you, go back and rank the five symptoms which bother you the most, with 1 as the symptom which is most bothersome and 5 as the 5th most bothersome symptom. If you have any questions please don't hesitate to ask.

-At the End-

I want to thank you all for helping us with this study. Thank you very much. If you know of anyone who would be interested in participating in the study, please have them give me a call, or I can call them.

APPENDIX B

- 19 6. What was the highest grade or class you completed in school? (CHECK ONE)
- ☐ 1. LESS THAN 12 YEARS
☐ 2. HIGH SCHOOL GRADUATE (INCLUDES G.E.D.)
☐ 3. GREATER THAN 12 YEARS, BUT NO DEGREE
☐ 4. TECHNICAL TRADE/COMMUNITY COLLEGE DEGREE
☐ 5. BACHELOR'S DEGREE
☐ 6. MASTER'S DEGREE
☐ 7. Ph.D./PROFESSIONAL DEGREE
☐ 8. OTHER (specify _____)
- 20 7. Please indicate your religious preference. (CHECK ONE)
- ☐ 1. NONE
☐ 2. JEWISH
☐ 3. PROTESTANT (Baptist, Lutheran, Methodist, Presbyterian, etc.)
☐ 4. CATHOLIC
☐ 5. OTHER (specify _____)
- 21 8. What is your race? (CHECK ONE)
- ☐ 1. BLACK
☐ 2. HISPANIC
☐ 3. AMERICAN INDIAN
☐ 4. WHITE
☐ 5. ASIAN/PACIFIC ISLANDER
☐ 6. OTHER (specify _____)
- 22 23 9. How many pregnancies have you had? _____
(WRITE IN NUMBER)
- 24 10. How many people live in your household including yourself? (CHECK ONE)
- ☐ 1
☐ 2
☐ 3
☐ 4
☐ 5
☐ 6
☐ 7
☐ 8 OR MORE
- 25 26 27 11. How are those who live with you related to you? (Check all that apply.)
- ☐ 1. HUSBAND/SIGNIFICANT OTHER
☐ 2. PARENT(S)
☐ 3. CHILDREN
☐ 4. OTHER (specify _____)
☐ 5. NOT APPLICABLE (live alone)
- 28 29

- 30 12. A) Indicate the level of stress you are experiencing at this time.
(PLEASE CIRCLE THE NUMBER ON THE FOLLOWING LINE).

1 2 3 4 5 6 7 8 9
NO HIGH
STRESS STRESS

- 31 B) Please indicate your major source of stress. (CHECK ONE)

- ☐ 1. WORK
☐ 2. FAMILY (teenagers, caring for parents, re-marriage, etc).
☐ 3. ILLNESS (family and/or self)
☐ 4. FINANCIAL
☐ 5. COMBINATION OF _____ AND _____ (specify)
☐ 6. OTHER (specify _____)

The following questions ask about your menstrual cycle. All of your answers will be kept confidential.

- 32 13. How many months ago was your last menstrual period? (CHECK ONE)

- ☐ 1. STILL HAVE PERIODS REGULARLY
☐ 2. LESS THAN 3 MONTHS AGO
☐ 3. 3 TO 12 MONTHS AGO
☐ 4. 12 OR MORE MONTHS AGO

- 33 14. On the following line, circle the number that best shows how bad you think your menstrual problems are or were.

1 2 3 4 5 6 7 8 9
NO SEVERE
PROBLEMS PROBLEMS

15. Consider the following menstrual problems. Indicate whether you have experienced or are experiencing each problem by marking a check by YES or NO. Even if you experience(d) the problem occasionally, answer YES. For each problem that you mark YES, circle the number on the line that follows that best shows how severe you think the menstrual problems was or is for you.

- 34 35 A) CRAMPS

☐ NO
☐ YES
1 2 3 4 5 6 7 8 9
NOT EXTREMELY
SEVERE SEVERE

15. (CONTINUED) Please indicate yes or no for each symptom. For each symptom you mark YES, circle the number which best shows how severe the symptom was or is.

36 37	B) EXCESSIVE BLEEDING (HEAVY FLOW, FLOODING)	<input type="checkbox"/> NO <input type="checkbox"/> YES	<div> 1 2 3 4 5 6 7 8 9 NOT SEVERE EXTREMELY SEVERE </div>
38 39	C) SPOTTING	<input type="checkbox"/> NO <input type="checkbox"/> YES	<div> 1 2 3 4 5 6 7 8 9 NOT SEVERE EXTREMELY SEVERE </div>
40 41	D) IRREGULAR PERIODS	<input type="checkbox"/> NO <input type="checkbox"/> YES	<div> 1 2 3 4 5 6 7 8 9 NOT SEVERE EXTREMELY SEVERE </div>
42 43	E) WATER RETENTION	<input type="checkbox"/> NO <input type="checkbox"/> YES	<div> 1 2 3 4 5 6 7 8 9 NOT SEVERE EXTREMELY SEVERE </div>
44 45	F) TENSION	<input type="checkbox"/> NO <input type="checkbox"/> YES	<div> 1 2 3 4 5 6 7 8 9 NOT SEVERE EXTREMELY SEVERE </div>
46 47	G) HEADACHES	<input type="checkbox"/> NO <input type="checkbox"/> YES	<div> 1 2 3 4 5 6 7 8 9 NOT SEVERE EXTREMELY SEVERE </div>
48 49	H) OTHER	<input type="checkbox"/> NO <input type="checkbox"/> YES	<div> 1 2 3 4 5 6 7 8 9 NOT SEVERE EXTREMELY SEVERE </div>
	Specify:		

50 51 52 16. What do you do (or did you do) to relieve any discomfort you feel or felt) just before or during your period? (Check all that apply.)

53 54 55

56 57

- ☐ 1. PAIN RELIEVER (ex. Advil, aspirin, Excedrin, Tylenol)
- ☐ 2. REST
- ☐ 3. EXERCISE
- ☐ 4. HEATING PADS
- ☐ 5. DIET CHANGES (specify _____)
- ☐ 6. OTHER MEDICATION (specify _____)
- ☐ 7. OTHER (specify _____)
- ☐ 8. NOTHING NEEDED

58 17. Within the past five years have you ever sought medical help for problems with your menstrual periods or menopause?

- ☐ 1. YES ☐ 2. NO - go to question 18.

59 60 If yes, what did the health care provider recommend?
(specify) _____

61 18. Do you currently consider yourself to be experiencing menopausal symptoms? (CHECK ONE)

- ☐ 1. YES
- ☐ 2. NO
- ☐ 3. NOT SURE

62 19. Which of the following responses best describes your mother's menopausal experience? (CHECK ONE)

- ☐ 1. NO DIFFICULTIES
- ☐ 2. SOME DIFFICULTIES
- ☐ 3. SERIOUS DIFFICULTIES
- ☐ 4. DON'T KNOW

63 20. Have you had a hysterectomy (an operation where the doctor removed all or part of your uterus)? (CHECK ONE)

- ☐ 1. YES ☐ 2. NO

64 21. Have one or both of your ovaries been removed? (CHECK ONE)

- ☐ 1. NO
- ☐ 2. YES, BOTH OVARIES REMOVED
- ☐ 3. YES, ONE OVARY REMOVED
- ☐ 4. NOT SURE

65 22. A) Are you currently taking estrogens (female hormones) of any kind (including birth control pills)? If in doubt, please list the name of your medication. _____

___ 1. YES ___ 2. NO - go to question 23

___ 8. If yes, please specify the type by checking one of the following:

66 ___ estrogen pills alone
 ___ estrogen pills and progestin pills
 ___ estrogen patch
 ___ estrogen patch and progestin pills
 ___ birth control pills

67 23. What would be your source of payment for any medicines you take which are prescribed by a physician? (CHECK ONE)

___ Payment is provided completely out of your pocket.

___ Payment is provided completely by a source other than you or your family (ex, insurance, government agency).

___ Payment is provided partly out of your pocket and partly by another source (ex, insurance, government agency).

___ Don't know

The following questions are about your health history and your health care behaviors. Again, they are to help us interpret the results of the study. All answers will be kept confidential.

68 69 24. A) How often have you seen a health care professional (doctor, nurse) in the last 12 months? _____ TIMES
 (WRITE IN)

70 71 72 B) What was the purpose of your visit(s) to a health care professional?
 73 74 75 (CHECK ALL THAT APPLY)

76

___ 1. ROUTINE CHECK-UP (INCLUDES INTERNAL CHECK-UPS)
 ___ 2. CHRONIC PROBLEMS (EX. BURSITIS)
 ___ 3. MENSTRUAL PROBLEMS
 ___ 4. SICKNESS (EX. COLDS, FLU)
 ___ 5. INJURIES
 ___ 6. MENOPAUSAL SYMPTOMS
 ___ 7. OTHER (SPECIFY _____)

77 25. A) Have you ever had cancer? (CHECK ONE)

___ 1. YES ___ 2. NO

78 26. Do you take any prescribed medications regularly? (CHECK ONE)

☐ YES ☐ NO

79 27. Do you take over-the-counter medications routinely? (CHECK ONE)

☐ YES ☐ NO

80 28. Please check the birth control method you now use. (CHECK ONE)

- ☐ 1. ORAL CONTRACEPTIVE
- ☐ 2. INTRAUTERINE DEVICE (IUD)
- ☐ 3. BARRIER METHOD (DIAPHRAGM, CREAM, CONDOM, SPONGE)
- ☐ 4. STERILIZATION (YOU OR YOUR PARTNER)
- ☐ 5. PERIODIC ABSTINENCE, (RHYTHM)
- ☐ 6. NO BIRTH CONTROL METHOD USED
- ☐ 7. OTHER (SPECIFY _____)

/sc
110:2
4/15/87

APPENDIX C

89
APPENDIX C

Menopausal Symptoms Instrument

Pt. ID	---	(1-3)
CARD	--	(4-5)
DATE	-----	(6-11)

ERT STUDY

Menopausal Symptoms Instrument

A. Are you currently experiencing or have you experienced symptoms in the past which you believe are or were caused by menopause?

___ 1. YES

If you answered YES, please answer questions on green pages, indicating only those symptoms RELATED TO MENOPAUSE which YOU are experiencing or have experienced.

___ 2. NO

If you answered NO, please answer questions on yellow pages, indicating only those symptoms RELATED TO MENOPAUSE which YOU expect to experience.

___(12)

If you answered YES:

Listed on the next few pages are a number of symptoms which sometimes occur in women as they go through menopause. Please read the list and indicate which of these symptoms you have experienced or are experiencing. We are interested in knowing only about those symptoms which you feel are caused by menopause or which you feel are directly related to menopause. For each symptom you have experienced indicate how bothersome that symptom has been for you, from "Does not bother me" (or hasn't bothered me) to "Bothers(ed) me a lot."

If you have not experienced the symptom,
leave blank.

Rank

	Does not bother me	Bothers me a little	Bothers me somewhat	Bothers me a lot
1. Weight Gain (over 10 pounds)				
2. Difficulty Sleeping				
3. Crying Spells				
4. Low Work Performance				
5. Muscle Stiffness or Aches				
6. Forgetfulness				
7. Confusion				
8. Need for Naps				
9. Headaches				
10. Skin Disorders				
11. Loneliness				
12. Menstrual Cramps				
13. Dizziness or Faintness				
14. Desire to Avoid Social Activities				
15. Anxiety				
16. Backaches				
17. Cold Sweats (perspiration)				
18. Poor Judgement				
19. Fatigue - Tiredness				
20. Nausea or Vomiting				
21. Restlessness				
22. Hot Flashes or Flushes				

CONTINUE ON NEXT PAGE

If you have not experienced the symptom,
leave blank.

Rank

	Does not bother me	Bothers me a little	Bothers me somewhat	Bothers me a lot
23. Difficulty in Concentration				
24. Painful or Tender Breasts				
25. Swelling or Fluid Retention				
26. Accident prone				
27. Irritability				
28. Mood Swings				
29. Depression				
30. Decreased Mental Efficiency				
31. Decreased Motor Coordination				
32. Tension (nervousness)				
33. Tingling Sensations, Numbness				
34. Palpitations - Heart Pounding				
35. Unwanted Growth of Hair				
36. Irregular Periods, Bleeding				
37. Changes in Eating Habits				
38. Flooding (heavy menstrual flow)				
39. Less Affectionate				
40. Excitable				
41. Unusual Bursts of Energy, Activity				
42. Feeling of Suffocation				
43. Chest Pains				

CONTINUE ON NEXT PAGE

Rank	If you have not experienced the symptom, leave blank.	Does not bother me	Bothers me a little	Bothers me somewhat	Bothers me a lot
_____	44. Ringing in Ears				
_____	45. Blind Spots, Fuzzy Vision				
_____	46. Sexual Desire Increased				
_____	47. Sexual Desire Decreased				
_____	48. Lack of Energy				
_____	49. Lack of Confidence				
_____	50. Difficulty Making Decisions				
_____	51. Painful Intercourse				
_____	52. Vaginal Infections				
_____	53. Vaginal Dryness				
_____	54. Painful Urination				
_____	55. Have to Urinate More Often				
_____	56. Feeling of Crawling on Skin				

Now that you have gone through the list, go back and rank the five symptoms that are most bothersome to you.

Assign a "1" beside the symptom that has bothered you the most, a "2" beside the next symptom, and so on, up to five symptoms. If you marked fewer than five symptoms, rank only the symptoms you marked. (i.e., if you marked four symptoms, you would rank them "1" to "4".) If you marked more than 5 symptoms rank only the 5 which bother(ed) you the most. Rank the symptoms on the left of the page in the spaces provided.

_____(69) _____(70) _____(71) _____(72) _____(73)
 _____(74) _____(75) _____(76) _____(77) _____(78)

/sc
 110:5
 3/24/87

If you answered NO:

Listed on the next few pages are a number of symptoms which sometimes occur in women as they experience menopause. Think about the menopausal symptoms which you expect to experience during that time. For each symptom which you expect to experience, indicate how bothersome you believe that symptom will be for you, from "will not bother me" to "will bother me a lot."

If you do not expect to experience the symptom,
leave blank.

Rank		Will not bother me	Will bother me a little	Will bother me somewhat	Will bother me a lot
_____	1. Weight Gain (over 10 pounds)				
_____	2. Difficulty Sleeping				
_____	3. Crying Spells				
_____	4. Low Work Performance				
_____	5. Muscle Stiffness or Aches				
_____	6. Forgetfulness				
_____	7. Confusion				
_____	8. Need for Naps				
_____	9. Headaches				
_____	10. Skin Disorders				
_____	11. Loneliness				
_____	12. Menstrual Cramps				
_____	13. Dizziness or Faintness				
_____	14. Desire to Avoid Social Activities				
_____	15. Anxiety				
_____	16. Backaches				
_____	17. Cold Sweats (perspiration)				
_____	18. Poor Judgement				
_____	19. Fatigue - Tiredness				
_____	20. Nausea or Vomiting				
_____	21. Restlessness				
_____	22. Hot Flashes or Flushes				

CONTINUE ON NEXT PAGE

If you do not expect to experience the symptom,
leave blank.

Rank

	Will not bother me	Will bother me a little	Will bother me somewhat	Will bother me a lot
<u>23. Difficulty in Concentration</u>				
<u>24. Painful or Tender Breasts</u>				
<u>25. Swelling or Fluid Retention</u>				
<u>26. Accident prone</u>				
<u>27. Irritability</u>				
<u>28. Mood Swings</u>				
<u>29. Depression</u>				
<u>30. Decreased Mental Efficiency</u>				
<u>31. Decreased Motor Coordination</u>				
<u>32. Tension (nervousness)</u>				
<u>33. Tingling Sensations, Numbness</u>				
<u>34. Palpitations - Heart Pounding</u>				
<u>35. Unwanted Growth of Hair</u>				
<u>36. Irregular Periods, Bleeding</u>				
<u>37. Changes in Eating Habits</u>				
<u>38. Flooding (heavy menstrual flow)</u>				
<u>39. Less Affectionate</u>				
<u>40. Excitable</u>				
<u>41. Unusual Bursts of Energy, Activity</u>				
<u>42. Feeling of Suffocation</u>				
<u>43. Chest Pains</u>				

CONTINUE ON NEXT PAGE

If you do not expect to experience the symptom,
leave blank.

Rank

	Will not bother me	Will bother me a little	Will bother me somewhat	Will bother me a lot
44. Ringing in Ears				
45. Blind Spots, Fuzzy Vision				
46. Sexual Desire Increased				
47. Sexual Desire Decreased				
48. Lack of Energy				
49. Lack of Confidence				
50. Difficulty Making Decisions				
51. Painful Intercourse				
52. Vaginal Infections				
53. Vaginal Dryness				
54. Painful Urination				
55. Have to Urinate More Often				
56. Feeling of Crawling on Skin				

Now that you have gone through the list, go back and rank the five symptoms that you expect to be most bothersome to you.

Assign a "1" beside the symptom that will bother you the most, a "2" beside the next symptom, and so on, up to five symptoms. If you marked fewer than five symptoms, rank only the symptoms you marked. (i.e., if you marked four symptoms, you would rank them "1" to "4".) If you marked more than 5 symptoms rank only the 5 which you expect to be most bothersome to you. Rank the symptoms on the left of the page in the spaces provided.

(69) (70) (71) (72) (73)
 (74) (75) (76) (77) (78)

APPENDIX D

APPENDIX D

Management of Symptoms Instrument

Site	10	(1-2)
Pt.	10	(3-5)
CARD	10	(6-8)
DATE	10	(8-13)

ERT STUDY MANAGEMENT OF SYMPTOMS

COMPLETE THIS QUESTIONNAIRE IF YOU ANSWERED YES TO QUESTION A ON THE MENOPAUSAL SYMPTOMS QUESTIONNAIRE, "ARE YOU CURRENTLY EXPERIENCING SYMPTOMS WHICH YOU BELIEVE ARE CAUSED BY MENOPAUSE." The purpose of this questionnaire is to help us learn what women do to manage symptoms of menopause. We have grouped some things that women might do under four categories: diet, vitamin and mineral supplements, medication and other.

1. On the Menopausal Symptoms Questionnaire you ranked the five symptoms which have been the most bothersome to you. Write these on each page of this questionnaire in the blank spaces numbered one through five under the heading Menopausal Symptoms.
2. After you do this, start at the beginning of the list and indicate with a check for each item in each category if you do this for the menopausal symptoms you listed in the five columns.

Example: If you cut down on calories to relieve the menopausal symptom of weight gain, your answer should look like this.

MENOPAUSAL SYMPTOMS	
1	Weight gain
2	Hot flashes
3	
4	
5	

DIET	
	Low Calorie

MENOPAUSAL SYMPTOMS

Write in your five symptoms. →

MEDICATION	1	2	3	4	5
Sleeping Pills					
Tranquillizers					
Blood Pressure Pills					
Estrogen Alone (e.g., PREMARIN)					
Progestin Alone (e.g., PROVERA)					
Estrogen and Progestin Combined					
Pain Relievers					
Sodium Fluoride Pills					
Vaginal Lubricant					
Estrogen Creams - Vaginal					
Other (please specify):					
If in doubt, write out medication					

MENOPAUSAL SYMPTOMS

Write in your five symptoms. →

	1	2	3	4	5
DIET					
Low Calorie					
Low Fat					
Low Salt					
Low Cholesterol					
High Calcium					
Avoid Caffeine Products (coffee, tea, colas)					
Avoid Spicy Foods					
Other (please specify):					

MENOPAUSAL SYMPTOMS

Write in your five symptoms. →

	1	2	3	4	5
VITAMIN AND MINERAL SUPPLEMENTS					
Calcium Supplements					
Vitamin E					
Vitamin C					
Vitamin D					
Multivitamin					
Iron					
Other (please specify):					

MENOPAUSAL SYMPTOMS

Write in your five symptoms. →

	1	2	3	4	5
OTHER					
Walking					
Exercising					
Relaxation Techniques					
Douche					
Skin Creams					
Keep Diary					
Talk with Others					
See Health Professional					
Other (please specify):					

APPENDIX E

4/17/87

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APPENDIX E

Menopause Information Instrument

Pt. ID	---	(1-3)
DATE	-----	(4-9)

ERT STUDY

Menopause Information

The following questionnaire contains questions about menopause, (the change of life) a time which signifies the end of the menstrual cycle. We are interested in finding out what women know about menopause. Please answer the following questions to the best of your ability.

- 10 1. Between what ages does menopause usually begin (without hormone therapy)? (Check one)
- ☐ a. 35 TO 44 YEARS.
 - ☐ b. 45 TO 54 YEARS.
 - ☐ c. 55 TO 64 YEARS.
- 11 2. Ovulation frequently occurs for how many years after a women stops menstruating? (Check one)
- ☐ a. 0 YEARS (Not at all).
 - ☐ b. 1 YEAR.
 - ☐ c. 2 YEARS.
 - ☐ d. 3 YEARS.
 - ☐ e. 4 YEARS.
- 12 3. What can be said about birth control after menstruation stops? (Check one)
- ☐ a. BIRTH CONTROL SHOULD BE USED FOR 1 YEAR.
 - ☐ b. BIRTH CONTROL SHOULD BE USED UP TO 5 YEARS.
 - ☐ c. BIRTH CONTROL SHOULD BE USED AS LONG AS SEXUALLY ACTIVE.
 - ☐ d. BIRTH CONTROL IS NOT NECESSARY.
- 13 4. What causes the symptoms of menopause? (Check one)
- ☐ a. THE PITUITARY GLAND STOPS FUNCTIONING.
 - ☐ b. THE UTERUS WILL NOT ALLOW EGG IMPLANTATION.
 - ☐ c. THE FALLOPIAN TUBE BECOMES BLOCKED.
 - ☐ d. THE OVARIES PRODUCE LESS ESTROGEN.
 - ☐ e. ALL OF THE ABOVE

- 14 15 5. Menopause increases the risk for which of the following? (Check all that apply.)
- 16 17 _____ a. LIVER DISEASE.
- _____ b. HEART DISEASE.
- 18 19 _____ c. KIDNEY DISEASE.
- _____ d. LUNG DISEASE.
- 20 _____ e. OSTEOPOROSIS (BRITTLE BONE DISEASE).
- _____ f. ALL OF THE ABOVE
- _____ g. NONE OF THE ABOVE
- 21 6. What physical changes can occur in the vagina due to menopause? (Check one.)
- _____ a. IT BECOMES DRYER AND LESS ELASTIC.
- _____ b. IT BECOMES SHORTER AND MORE NARROW.
- _____ c. IT BECOMES THIN AND EASILY INJURED.
- _____ d. ALL OF THE ABOVE.
- 22 7. For how many years do menopausal symptoms without estrogen treatment usually last? (Check the best response.)
- _____ a. 1 TO 2 YEARS.
- _____ b. 3 TO 5 YEARS.
- _____ c. 6 TO 10 YEARS.
- _____ d. MORE THAN 10 YEARS.
- 23 24 8. By the end of menopause, which of the following occur? (Check all that apply.)
- 25 26 _____ a. THE OVARIES DECREASE FUNCTIONING.
- _____ b. MENSTRUAL BLEEDING WILL HAVE STOPPED.
- _____ c. OSTEOPOROSIS (BRITTLE BONES) OCCURS MORE.
- _____ d. ALL OF THE ABOVE.
- 27 28 9. Osteoporosis (brittle bones) may be treated by: (Check all that apply.)
- 29 30 _____ a. ESTROGEN PILLS.
- _____ b. SUFFICIENT CALCIUM INTAKE.
- _____ c. MODERATE PHYSICAL ACTIVITY.
- _____ d. ALL OF THE ABOVE.

Please answer the following questions with "true" or "false". (Circle True or False for each question)

- 31 10. Hormone therapy (estrogen) after menopause increases the risk of osteoporosis.

TRUE

FALSE

- 32 11. Hormonal therapy can be used to help relieve the symptoms of menopause.
TRUE FALSE
- 33 12. Estrogen therapy increases the risk of cancer of the uterus.
TRUE FALSE
- 34 13. Bleeding or spotting a year after a woman completely stops menstruating (menopausal women) should be reported to your physician.
TRUE FALSE
- 35 14. Symptoms most often reported during menopause are hot flashes and night sweats.
TRUE FALSE
- 36 15. Once a woman is through menopause she no longer has to be concerned with breast cancer or other female cancers.
TRUE FALSE
- 37 16. By the time of the last menstrual period, women can generally not become pregnant.
TRUE FALSE
- 38 17. As long as a woman is ovulating she can still become pregnant.
TRUE FALSE
- 39 18. Ovulation may occur without menstrual bleeding occurring.
TRUE FALSE

- 40 19. To help reduce the uncomfortable feelings associated with hot flashes, a person can...(Check one)
- | | |
|---|--|
| <input type="checkbox"/> a. eat a balanced diet | <input type="checkbox"/> d. exercise daily |
| <input type="checkbox"/> b. take extra vitamins | <input type="checkbox"/> e. estrogen replacement therapy |
| <input type="checkbox"/> c. wear layered clothing | <input type="checkbox"/> f. all of the above |
- 41 20. Vaginal dryness caused by menopause may lead to...(Check one)
- ☐ a. painful intercourse
- ☐ b. increased chance of infection
- ☐ c. itching
- ☐ d. all of the above
- 42 21. Vaginal dryness can best be relieved by...(Check one)
- ☐ a. using a water soluble lubricant
- ☐ b. using a vaseline lubricant
- ☐ c. douching
- ☐ d. estrogen replacement therapy

/sc
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APPENDIX F

Site	__	(1-2)
Pt. ID	__	(3-5)
Date	__	(8-13)

APPENDIX F

4/28/87

Judgment Cases Instrument
INFORMATION SHEET

We are going to give you some written situations (cases) and ask you to imagine yourself in that situation. You will be asked to read each case and indicate how likely you would be in that situation to take hormone therapy. There are two sets of 16 cases each, and it will probably take you about 30 minutes to complete all of the cases.

The purpose of asking you to tell us what you would do in these situations is to find out what information is important to women in making these decisions. We want to make sure that you have all the information you need to make those decisions. Therefore, we have written down some of the facts that we think would be helpful to you.

There are at least three important things to think about when you consider whether to take estrogen therapy. These three factors are menopausal symptoms, risk of fractures due to osteoporosis, and risk of endometrial cancer. Information about each of these factors is given below. Also, there is a paragraph about estrogen therapy and whether it would be expected to help or make worse each of the three factors.

MENOPAUSAL SYMPTOMS-Somewhere in middle age, usually around fifty years of age, women stop having monthly menstrual periods and are said to be going through menopause or, "the change of life". One of the most common problems that women mention related to menopause is hot flashes or the feeling of warmth in the upper body. These hot flashes are usually mild, and even if untreated, usually subside in a period of a few months or years. Some women may have severe hot flashes accompanied by perspiration which cause them to lose sleep or make it difficult or embarrassing to carry out their daily activities.

RISK OF FRACTURES DUE TO OSTEOPOROSIS-You may have heard people talk about having broken bones or fractures because they have brittle bones. Usually, they are referring to osteoporosis, where the bones become weaker after menopause. Thin, white women who smoke and do not exercise have the highest risk of fractures due to osteoporosis, and black women, heavier women, and those who exercise regularly have a lower risk. Assuming the usual life-span of 85 years, for women presently 60-65 years old it is estimated that 50 out of 1,000 will have a fracture of the hip, spine, wrist or pelvis due to osteoporosis each year. For many younger people fractures may not be perceived as very serious, but in the older populations complications can occur. One third of women over age 65 will have vertebral fractures. By extreme old age, one of every three women will have had a hip fracture. This catastrophic type of fracture is fatal in 12 to 20 percent of cases and it leads to long-term nursing home care for half of those who survive.

RISK OF ENDOMETRIAL CANCER-Endometrial cancer is cancer of the uterus or womb. In women not taking estrogen, approximately 1 in 1000 can be expected to develop endometrial cancer each year. In most cases, if cancer develops, it is detected early because it causes vaginal bleeding. It can be treated with a hysterectomy (surgical removal of the uterus) and removal of the ovaries with a 90% cure rate. However, if the cancer is advanced, it can cause significant pain and not only require a hysterectomy, but also some form of follow up radiation (X-Ray) therapy and perhaps anticancer drugs (chemotherapy).

ESTROGEN REPLACEMENT THERAPY-You may have heard about other hormone treatments for menopause, but this information is about estrogen alone. If you were taking estrogen therapy, one plan is that you would take a pill once a day for 25 days, then not take any pills for 5 days each month. There are other plans and your doctor would prescribe the best one for you. The pills cost approximately \$5.50 per month. The physician would want you to come in for an annual physical. Possible side effects other than those mentioned include weight gain, nausea and vomiting, breast tenderness or enlargement.

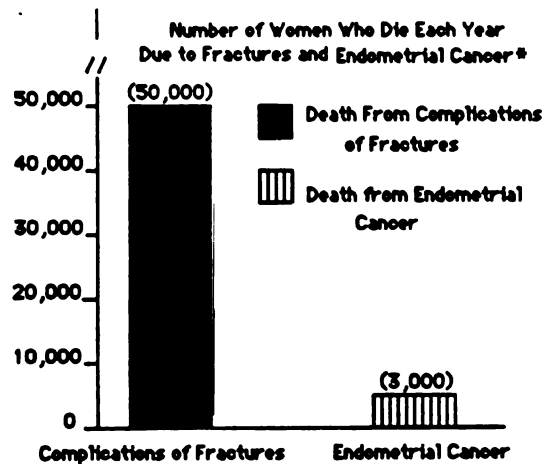
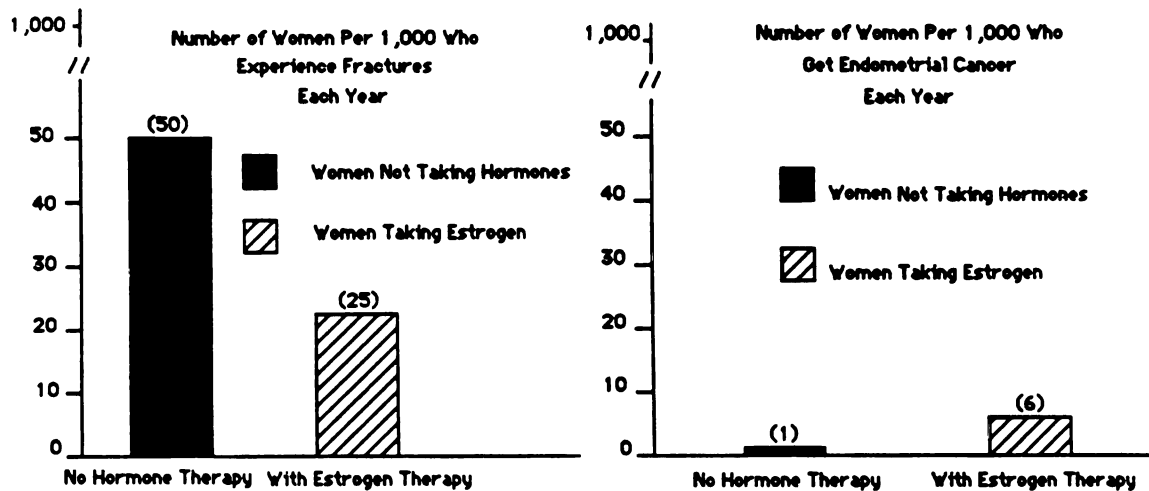
Hormone therapy with estrogen reduces or eliminates hot flashes, decreases the chance of fracture due to osteoporosis, but increases the chances of endometrial cancer. Estrogen therapy does not bring back monthly bleeding.

Fractures due to osteoporosis are much more common than endometrial cancer. In numbers, for women who are not taking estrogen and who are presently 60-65 years old (assuming the usual life span of 85 years) the occurrence of fractures and endometrial cancer is as follows. 50 out of every 1,000 women can be expected to develop fractures of the hip, spine, wrist or pelvis each year, and 1 out of every 1,000 women can be expected to develop endometrial cancer each year. Most of the deaths due to complications of fractures and most of the deaths due to endometrial cancer occur after age 75.

In women taking estrogen who are presently 60-65 years old (assuming the usual life span of 85 years) 25 out of every 1,000 women can be expected to develop fractures of the hip, spine, wrist or pelvis each year, and 6 out of every 1,000 women can be expected to develop endometrial cancer each year. The estrogen increases the risk of cancer from 1 per 1,000 to 6 per 1,000, but cuts the osteoporosis fracture risk in half, from 50 per 1,000 to 25 per 1,000.

Not only is the occurrence of osteoporosis fracture greater than cancer, but the death rate is also higher. Overall, approximately 3,000 women die of endometrial cancer each year and 50,000 die due to complications associated with fractures in the U.S. each year. Again, these deaths occur mostly after age 75.

Therefore, the woman in menopause is faced with a difficult decision: to take the hormone therapy and run a higher risk of developing uterine cancer, or not take it and run a higher risk of developing bone fractures. The following graphs may be helpful in better understanding this information.



*Most of the deaths related to both complications of fractures and endometrial cancer occur after age 75.

DEFINITIONS

Now we want you to imagine yourself in a number of real situations and think about how likely you would be to take estrogen therapy in each of those situations. You will be given three kinds of information about each situation. This information will include how bad the menopausal symptoms are, chances of getting endometrial cancer, and chances of developing osteoporosis. We ask you to think about what it would be like if you were in this situation. Listed below are the definitions of several terms you will need to know.

MENOPAUSAL SYMPTOMS-This refers to how bad your hot flashes are and whether they are interfering with your sleep, social activities, work and daily activities. We have defined two levels of menopausal symptoms.

High level means that you have very bad hot flashes which interfere with your sleep, daily activities, and social life.

Standard level means that you have a few hot flashes which really don't bother you or interrupt your daily life.

RISK OF FRACTURE DUE TO OSTEOPOROSIS-This refers to how likely it is that you will develop fractures due to osteoporosis. With osteoporosis bones become more porous and brittle and may break more easily. We have defined two levels of risk.

High level means that you have a greater than average chance of developing fractures of the hip, spine, wrist or pelvis due to osteoporosis. On the average, about 50 women out of 1,000 have such a fracture but the high level defines you as having a greater than 50 out of 1,000 chances of having a fracture.

Standard level means that you have an average chance of having a fracture due to osteoporosis. Thus, your chances are about 50 out of 1,000 per year.

RISK OF ENDOMETRIAL CANCER-This is a description of how likely it is that you will develop endometrial cancer. Endometrial cancer is cancer of the lining of the uterus, or womb. We have defined two levels:

High level means that you have a greater than average chance of developing endometrial cancer. On the average, about one woman in 1,000 develops endometrial cancer each year but the high level defines you as having a greater than 1 in 1,000 chance of having endometrial cancer.

Standard level means that you have an average chance of developing endometrial cancer. Therefore, your chances of developing endometrial cancer are about 1 in 1,000 per year.

As you read the cases please try to consider each one individually. The cases may seem very similar, but it is important to consider each one. Do not worry about how you answered earlier cases, just consider each one as you read it. The number of women who experience each problem on the average (that is, the average risk) will be written in parentheses to help you.

DIRECTIONS

PLEASE REMOVE THIS PAGE FROM THE BOOKLET AND REFER TO THE DIRECTIONS AND SCALE AS YOU READ AND MAKE JUDGMENTS ON EACH CASE.

Each of the following situations will ask you to imagine that you are experiencing hot flashes at a standard (average) or high level, that you are at a greater or standard (average) risk than most women for developing osteoporosis and endometrial cancer, and ask you how likely you would be in that situation to take hormone pills.

Please read each case and decide how likely you would be to take hormone pills in the situation described. Make your decision using the following scale:

1. VERY CERTAIN THAT YOU WOULD NOT TAKE HORMONE THERAPY
2. PROBABLY WOULD NOT TAKE HORMONE THERAPY
3. MAY OR MAY NOT TAKE HORMONE THERAPY
4. PROBABLY WOULD TAKE HORMONE THERAPY
5. VERY CERTAIN THAT YOU WOULD TAKE HORMONE THERAPY

For each case, write down the number from this scale that represents your decision as to how likely you would be to take hormone therapy in the situation described. Continue until all cases are completed. The first 2 cases are practice cases followed by 16 cases.

PRACTICE CASE 1

You have frequent and severe hot flashes which interfere with your sleep and make it difficult to carry out your daily activities.

You have been told by your physician that you have an average chance (50 out of 1,000 women) of developing a fracture of the hip, spine, wrist or pelvis due to osteoporosis.

Your chances of developing endometrial cancer are greater than most women (greater than 1 in a 1,000) according to your physician.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN HORMONE THERAPY?

ANSWER: _____

Using the descriptions given, consider the level of hot flashes described, your risk for fractures due to osteoporosis and risk for endometrial cancer as described in the case. If you need to look back at the more detailed descriptions of each, do so.

Write down your decision as to how likely you would be to take hormone therapy in each situation. Write your decision on the line following the word ANSWER. Refer to the "Directions" and choose the number on the 5 point scale that most closely represents your judgment. For example, if you feel you probably would not take hormone therapy in this situation, put a 2 on the line as your answer.

PRACTICE CASE 2

You sometimes have mild hot flashes but they do not keep you from sleeping or bother you very much during the day.

While 50 out of 1,000 women on the average will develop a fracture of the hip, spine, wrist or pelvis due to osteoporosis, you have been told by your physician that your chances are higher than average.

Your chances of developing endometrial cancer are greater than most women (greater than 1 in a 1,000) according to your physician.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN HORMONE THERAPY?

ANSWER: _____

CASE 1

You sometimes have mild hot flashes but they do not keep you from sleeping or bother you very much during the day.

You have been told by your physician that you have an average chance (50 out of 1,000 women) of developing a fracture of the hip, spine, wrist or pelvis due to osteoporosis.

Your chances of developing endometrial cancer are greater than most women (greater than 1 in a 1,000) according to your physician.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN HORMONE THERAPY?

ANSWER: _____

CASE 2

You have occasional mild hot flashes which do not interfere with your sleep or other daily activities.

While 50 women out of 1,000 on the average will develop a fracture of the hip, spine, wrist or pelvis due to osteoporosis, you have been told by your physician that your chances are higher than that average.

Your chances of developing endometrial cancer are about average, that is about 1 out of 1,000 women according to your physician.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN HORMONE THERAPY?

ANSWER: _____

CASE 3

You have many severe hot flashes that keep you from sleeping well and interfere with what you normally do during the day.

Your chances of developing a fracture of the hip, spine, wrist or pelvis due to osteoporosis are about average (50 chances out of 1,000) according to your physician.

Your chances of developing endometrial cancer are greater than most women (greater than 1 in a 1,000) according to your physician.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN HORMONE THERAPY?

ANSWER: _____

CASE 4

You have had some mild hot flashes but are able to sleep O.K. and they have not kept you from doing your usual daily activities.

You have been told by your physician that you have a greater than average chance of developing a fracture of the hip, spine, wrist or pelvis due to osteoporosis (odds greater than 50 out of 1,000).

You have been told by your physician that you have a greater than average (that is, greater than 1 in a 1,000) chance of developing endometrial cancer meaning you are at higher risk than most women.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN HORMONE THERAPY?

ANSWER: _____

CASE 5

You have occasional mild hot flashes which do not interfere with your sleep or other daily activities.

Your chances of developing a fracture of the hip, spine, wrist or pelvis due to osteoporosis are about average (50 chances out of 1,000) according to your physician.

You know that 1 out of 1,000 women on the average will develop endometrial cancer, and your physician tells you that your chances are about average.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN HORMONE THERAPY?

ANSWER: _____

CASE 6

You have many severe hot flashes which cause you to lose sleep and keep you from doing your usual daily activities.

You have been told by your physician that you have a greater than average chance of developing a fracture of the hip, spine, wrist or pelvis due to osteoporosis (odds greater than 50 out of 1,000).

Your physician tells you that you have an average chance, (1 out of 1,000 women) of developing endometrial cancer.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN HORMONE THERAPY?

ANSWER: _____

CASE 7

You have frequent and severe hot flashes which interfere with your sleep and make it difficult to carry out your daily activities.

About 50 women out of 1,000 on the average will develop a fracture of the hip, spine, wrist or pelvis due to osteoporosis, you have been told by your physician that you have the an average chance of developing the problem.

You know that 1 out of 1,000 women on the average will develop endometrial cancer, and your physician tells you that your chances are about average.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN HORMONE THERAPY?

ANSWER: _____

CASE 8

You have many severe hot flashes that keep you from sleeping well and interfere with what you normally do during the day.

Your chances of developing a fracture of the hip, spine, wrist or pelvis due to osteoporosis are greater than the average (greater than 50 out of 1,000 women) according to your physician.

While 1 in 1,000 women on the average will develop endometrial cancer, you have been told by your physician that your chances are higher than average.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN HORMONE THERAPY?

ANSWER: _____

CASE 9

You have had some mild hot flashes but are able to sleep O.K. and they have not kept you from doing your usual daily activities.

You have been told by your physician that you have a greater than average chance of developing a fracture of the hip, spine, wrist or pelvis due to osteoporosis (odds greater than 50 out of 1,000).

You have been told by your physician that you have a greater than average (that is, greater than 1 in a 1,000) chance of developing endometrial cancer meaning you are at higher risk than most women.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN HORMONE THERAPY?

ANSWER: _____

CASE 10

You have occasional mild hot flashes which do not interfere with your sleep or other daily activities.

Your chances of developing a fracture of the hip, spine, wrist or pelvis due to osteoporosis are about average (50 chances out of 1,000) according to your physician.

You know that 1 out of 1,000 women on the average will develop endometrial cancer, and your physician tells you that your chances are about average.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN HORMONE THERAPY?

ANSWER: _____

CASE 11

You have many severe hot flashes that keep you from sleeping well and interfere with what you normally do during the day.

Your chances of developing a fracture of the hip, spine, wrist or pelvis due to osteoporosis are greater than the average (greater than 50 out of 1,000 women) according to your physician.

While 1 in 1,000 women on the average will develop endometrial cancer, you have been told by your physician that your chances are higher than average.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN HORMONE THERAPY?

ANSWER: _____

CASE 12

You have frequent and severe hot flashes which interfere with your sleep and make it difficult to carry out your daily activities.

About 50 women out of 1,000 on the average will develop a fracture of the hip, spine, wrist or pelvis due to osteoporosis, you have been told by your physician that you have an average chance of developing the problem.

You know that 1 out of 1,000 women on the average will develop endometrial cancer, and your physician tells you that your chances are about average.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN HORMONE THERAPY?

ANSWER: _____

CASE 13

You have many severe hot flashes which cause you to lose sleep and keep you from doing your usual daily activities.

You have been told by your physician that you have a greater than average chance of developing a fracture of the hip, spine, wrist or pelvis due to osteoporosis (odds greater than 50 out of 1,000).

Your physician tells you that you have an average chance (1 out of 1,000 women) of developing endometrial cancer.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN HORMONE THERAPY?

ANSWER: _____

CASE 14

You have many severe hot flashes that keep you from sleeping well and interfere with what you normally do during the day.

Your chances of developing a fracture of the hip, spine, wrist or pelvis due to osteoporosis are about average (50 chances out of 1,000) according to your physician.

Your chances of developing endometrial cancer are greater than most women (greater than 1 in a 1,000) according to your physician.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN HORMONE THERAPY?

ANSWER: _____

CASE 15

You have occasional mild hot flashes which do not interfere with your sleep or other daily activities.

While 50 out of 1,000 women on the average will develop a fracture of the hip, spine, wrist or pelvis due to osteoporosis, you have been told by your physician that your chances are higher than that average.

Your chances of developing endometrial cancer are about average, that is about 1 out of 1,000 women according to your physician.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN HORMONE THERAPY?

ANSWER: _____

CASE 16

You sometimes have mild hot flashes but they do not keep you from sleeping or bother you very much during the day.

You have been told by your physician that you have an average chance (50 out of 1,000 women) of developing a fracture of the hip, spine, wrist or pelvis due to osteoporosis.

Your chances of developing endometrial cancer are greater than most women (greater than 1 in a 1,000) according to your physician.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN HORMONE THERAPY?

ANSWER: _____

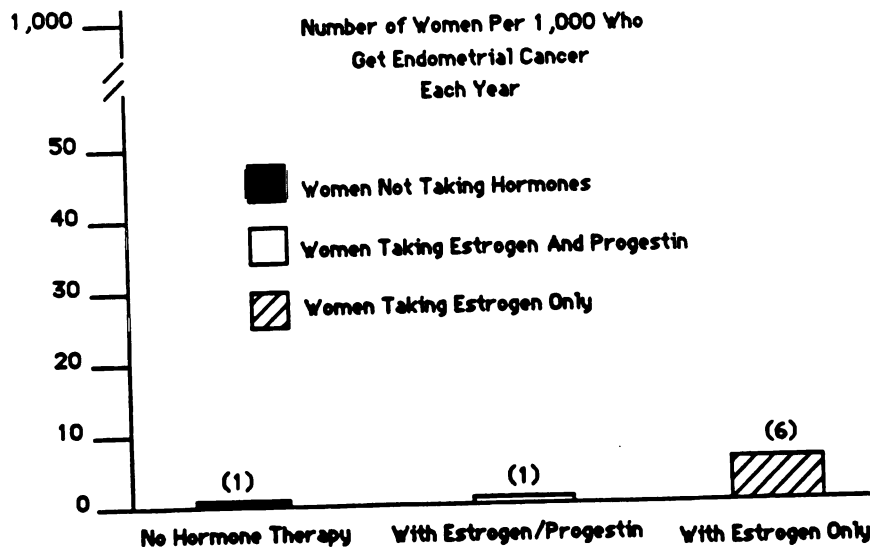
DIRECTIONS-SET 2

You will find the next set of cases very similar to the first set you just completed. The one difference is the hormone treatment. You have been thinking about whether to take estrogen, an example of which was one pill for 25 days followed by no pill for 5 days. The estrogen decreases the risk of osteoporosis, relieves hot flashes, but increases the chance of endometrial cancer.

There is another treatment program we would like you to think about now. This hormone treatment would be estrogen and progestin. One plan would be on a 30 day cycle, you would take an estrogen pill for 15 days, then take an estrogen pill and progestin pill for the next 10 days, then no pills for five days. The cost would be approximately \$12.50 per month. There are other plans and your doctor would prescribe the best one for you. As the chart below shows, adding the progestin takes away the problem of increasing the risk of endometrial cancer, that is, if you take this treatment program the risk of endometrial cancer is no greater than if you did not take the estrogen.

Taking this treatment program does have one other side effect. You will again start or continue to have vaginal bleeding or monthly periods. Thus, estrogen with progestin will relieve hot flashes, reduce osteoporosis, have no increase in risk of cancer, but will cause monthly periods.

Please turn the page and answer this set of cases by indicating how likely you would be in each case to take the combined estrogen/progestin hormone therapy. Use the page you pulled out for the first set to refer to for the response scale.



4/6/87

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CASE 1

You sometimes have mild hot flashes but they do not keep you from sleeping or bother you very much during the day.

Your chances of developing a fracture of the hip, spine, wrist or pelvis due to osteoporosis are greater than the average (greater than 50 out of 1,000 women) according to your physician.

Your physician tells you that you have an average chance, (1 out of 1,000 women) of developing endometrial cancer.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN/PROGESTIN HORMONE THERAPY?

ANSWER: _____

CASE 2

You have had some mild hot flashes but are able to sleep O.K. and they have not kept you from doing your usual daily activities.

About 50 women out of 1,000 on the average will develop a fracture of the hip, spine, wrist or pelvis due to osteoporosis, and you have been told by your physician that you have an average chance of developing the problem.

You have been told by your physician that you have a greater than average (that is, greater than 1 in 1,000) chance of developing endometrial cancer meaning you are at higher risk than most women.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN/PROGESTIN HORMONE THERAPY?

ANSWER: _____

CASE 3

You have many severe hot flashes that keep you from sleeping well and interfere with what you normally do during the day.

Your chances of developing a fracture of the hip, spine, wrist or pelvis due to osteoporosis are about average (50 chances out of 1,000) according to your physician.

Your chances of developing endometrial cancer are about the same as average, that is 1 out of 1,000 women according to your physician.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN /PROGESTIN HORMONE THERAPY?

ANSWER: _____

CASE 4

You have many severe hot flashes which cause you to lose sleep and keep you from doing your usual daily activities.

You have been told by your physician that you have a greater than average chance of developing a fracture of the hip, spine, wrist or pelvis due to osteoporosis (odds greater than 50 out of 1,000).

Your chances of developing endometrial cancer are greater than most women (greater than 1 in a 1,000) according to your physician.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN/PROGESTIN HORMONE THERAPY?

ANSWER: _____

CASE 5

You have occasional mild hot flashes which do not interfere with your sleep or other daily activities.

While 50 out of 1,000 women on the average will develop a fracture of the hip, spine, wrist or pelvis due to osteoporosis, you have been told by your physician that your chances are higher than that average.

While 1 in 1,000 women on the average will develop endometrial cancer, you have been told by your physician that your chances are higher than average.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN/PROGESTIN HORMONE THERAPY?

ANSWER: _____

CASE 6

You sometimes have mild hot flashes but they do not keep you from sleeping or bother you very much during the day.

You have been told by your physician that you have an average chance (50 out of 1,000 women) of developing a fracture of the hip, spine, wrist or pelvis due to osteoporosis.

Your chances of developing endometrial cancer are about average, that is 1 out of 1,000 women according to your physician.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN/PROGESTIN HORMONE THERAPY?

ANSWER: _____

CASE 7

You have frequent and severe hot flashes which interfere with your sleep and make it difficult to carry out your daily activities.

While 50 out of 1,000 women on the average will develop a fracture of the hip, spine, wrist or pelvis due to osteoporosis, you have been told by your physician that your chances are higher than that average.

You know that 1 out of 1,000 women on the average will develop endometrial cancer, and your physician tells you that your chances are about average.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN/PROGESTIN HORMONE THERAPY?"

ANSWER: _____

CASE 8

You have many severe hot flashes which cause you to lose sleep and keep you from doing your usual daily activities.

You have been told by your physician that you have an average chance (50 out of 1,000 women) of developing a fracture of the hip, spine, wrist or pelvis due to osteoporosis.

You have been told by your physician that you have a greater than average (that is, greater than 1 in 1,000) chance of developing endometrial cancer, meaning you are at higher risk than most women.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN/PROGESTIN HORMONE THERAPY?

ANSWER: _____

CASE 9

You have many severe hot flashes which cause you to lose sleep and keep you from doing your usual daily activities.

You have been told by your physician that you have a greater than average chance of developing a fracture of the hip, spine, wrist or pelvis due to osteoporosis (odds greater than 50 out of 1,000).

Your chances of developing endometrial cancer are greater than most women (greater than 1 in a 1,000) according to your physician.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN/PROGESTIN HORMONE THERAPY?

ANSWER: _____

CASE 10

You have occasional mild hot flashes which do not interfere with your sleep or other daily activities.

While 50 out of 1,000 women on the average will develop a fracture of the hip, spine, wrist or pelvis due to osteoporosis, you have been told by your physician that your chances are higher than that average.

While 1 in 1,000 women on the average will develop endometrial cancer, you have been told by your physician that your chances are higher than average.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN/PROGESTIN HORMONE THERAPY?

ANSWER: _____

CASE 11

You have many severe hot flashes which cause you to lose sleep and keep you from doing your usual daily activities.

You have been told by your physician that you have an average chance (50 out of 1,000 women) of developing a fracture of the hip, spine, wrist or pelvis due to osteoporosis.

You have been told by your physician that you have a greater than average (that is, greater than 1 in 1,000) chance of developing endometrial cancer, meaning you are at higher risk than most women.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN/PROGESTIN HORMONE THERAPY?

ANSWER: _____

CASE 12

You have frequent and severe hot flashes which interfere with your sleep and make it difficult to carry out your daily activities.

While 50 out of 1,000 women on the average will develop a fracture of the hip, spine, wrist or pelvis due to osteoporosis, you have been told by your physician that your chances are higher than that average.

You know that 1 out of 1,000 women on the average will develop endometrial cancer, and your physician tells you that your chances are about average.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN/PROGESTIN HORMONE THERAPY?"

ANSWER: _____

CASE 13

You sometimes have mild hot flashes but they do not keep you from sleeping or bother you very much during the day.

You have been told by your physician that you have an average chance (50 out of 1,000 women) of developing a fracture of the hip, spine, wrist or pelvis due to osteoporosis.

Your chances of developing endometrial cancer are about average, that is 1 out of 1,000 women, according to your physician.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN/PROGESTIN HORMONE THERAPY?

ANSWER: _____

CASE 14

You have many severe hot flashes that keep you from sleeping well and interfere with what you normally do during the day.

Your chances of developing a fracture of the hip, spine, wrist or pelvis due to osteoporosis are about average (50 chances out of 1,000) according to your physician.

Your chances of developing endometrial cancer are about the same as average, that is 1 out of 1,000 women, according to your physician.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN/PROGESTIN HORMONE THERAPY?

ANSWER: _____

CASE 15

You have had some mild hot flashes but are able to sleep O.K. and they have not kept you from doing your usual daily activities.

About 50 women out of 1,000 on the average will develop a fracture of the hip, spine, wrist or pelvis due to osteoporosis, and you have been told by your physician that you have an average chance of developing the problem.

You have been told by your physician that you have a greater than average (that is, greater than 1 in 1,000) chance of developing endometrial cancer meaning you are at higher risk than most women.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN/PROGESTIN HORMONE THERAPY?

ANSWER: _____

CASE 16

You sometimes have mild hot flashes but they do not keep you from sleeping or bother you very much during the day.

Your chances of developing a fracture of the hip, spine, wrist or pelvis due to osteoporosis are greater than the average (greater than 50 out of 1,000 women) according to your physician.

Your physician tells you that you have an average chance, (1 out of 1,000 women) of developing endometrial cancer.

QUESTION: IN THIS SITUATION, HOW LIKELY WOULD YOU BE TO TAKE ESTROGEN/PROGESTIN HORMONE THERAPY?

ANSWER: _____

1. Assuming equal benefits would result, how would you rate your preference for each of the following ways of taking estrogen and progestin?

- 4 = Much the preferred method
- 3 = Preferred over some other methods
- 2 = Probably not as preferred as other methods
- 1 = Definitely not a preferred method

- _____ 1. Injections taken every month
- _____ 2. Skin implants that need to be changed periodically
- _____ 3. Pills
- _____ 4. Patch

2. Besides risk of osteoporosis and endometrial cancer, relief of hot flashes, and resumption of monthly bleeding, are there any other factors or pieces of information that are important to you in deciding whether to take hormone therapy for menopausal symptoms?

_____ YES _____ NO

If YES, please explain. _____

3. Please indicate on the scale provided how important each factor was to you as you responded to the cases.

Hot Flashes

1 2 3 4 5 6 7
Not Important Extremely
At All Important

Risk of Endometrial Cancer

1 2 3 4 5 6 7
Not Important Extremely
At All Important

Risk of Osteoporosis

1 2 3 4 5 6 7
Not Important Extremely
At All Important

Resumption of Monthly Bleeding

1 2 3 4 5 6 7
Not Important Extremely
At All Important

Thank you for your help.

APPENDIX G

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APPENDIX G

Perceptions of Menopause Instrument
ERT STUDY

Pt. ID	---	(1-3)
DATE	-----	(4-9)

Perceptions of Menopause

Some of you will have not experienced menopause yet, and some of you are experiencing menopause now. We are interested in finding out what your perceptions are about menopause regardless of whether or not you are experiencing menopause. In the questions that follow, please circle the response that most represents how you feel about each statement.

- | | | | | | | |
|-----------|---|-------------------|-------|-------------------------------|----------|----------------------|
| <u>10</u> | 1. Menopause has been/will be an unpleasant experience for me. | STRONGLY
AGREE | AGREE | NEITHER AGREE
NOR DISAGREE | DISAGREE | STRONGLY
DISAGREE |
| <u>11</u> | 2. The thought of menopause is disturbing to me. | STRONGLY
AGREE | AGREE | NEITHER AGREE
NOR DISAGREE | DISAGREE | STRONGLY
DISAGREE |
| <u>12</u> | 3. My body may change during the menopause, but I will not change personally. | STRONGLY
AGREE | AGREE | NEITHER AGREE
NOR DISAGREE | DISAGREE | STRONGLY
DISAGREE |
| <u>13</u> | 4. On the whole, I expect to feel better after the menopause than I did before the menopause. | STRONGLY
AGREE | AGREE | NEITHER AGREE
NOR DISAGREE | DISAGREE | STRONGLY
DISAGREE |
| <u>14</u> | 5. I welcome the menopause. | STRONGLY
AGREE | AGREE | NEITHER AGREE
NOR DISAGREE | DISAGREE | STRONGLY
DISAGREE |
| <u>15</u> | 6. Menopausal symptoms that I might have can be helped. | STRONGLY
AGREE | AGREE | NEITHER AGREE
NOR DISAGREE | DISAGREE | STRONGLY
DISAGREE |

- 16 7. Women should be under a health provider's care during menopause.
- | | | | | |
|-------------------|-------|-------------------------------|----------|----------------------|
| STRONGLY
AGREE | AGREE | NEITHER AGREE
NOR DISAGREE | DISAGREE | STRONGLY
DISAGREE |
|-------------------|-------|-------------------------------|----------|----------------------|
- 17 8. Hormones are necessary for the management of menopausal symptoms.
- | | | | | |
|-------------------|-------|-------------------------------|----------|----------------------|
| STRONGLY
AGREE | AGREE | NEITHER AGREE
NOR DISAGREE | DISAGREE | STRONGLY
DISAGREE |
|-------------------|-------|-------------------------------|----------|----------------------|
- 18 9. There are things I can do to feel good during the menopause other than going to a health care provider.
- | | | | | |
|-------------------|-------|-------------------------------|----------|----------------------|
| STRONGLY
AGREE | AGREE | NEITHER AGREE
NOR DISAGREE | DISAGREE | STRONGLY
DISAGREE |
|-------------------|-------|-------------------------------|----------|----------------------|
- 19 10. I expect to (do) experience physical trouble during the menopause.
- | | | | | |
|-------------------|-------|-------------------------------|----------|----------------------|
| STRONGLY
AGREE | AGREE | NEITHER AGREE
NOR DISAGREE | DISAGREE | STRONGLY
DISAGREE |
|-------------------|-------|-------------------------------|----------|----------------------|
- 20 11. I expect to (do) experience emotional trouble during the menopause.
- | | | | | |
|-------------------|-------|-------------------------------|----------|----------------------|
| STRONGLY
AGREE | AGREE | NEITHER AGREE
NOR DISAGREE | DISAGREE | STRONGLY
DISAGREE |
|-------------------|-------|-------------------------------|----------|----------------------|
- 21 12. Menopause will bring/has brought many changes to my life.
- | | | | | |
|-------------------|-------|-------------------------------|----------|----------------------|
| STRONGLY
AGREE | AGREE | NEITHER AGREE
NOR DISAGREE | DISAGREE | STRONGLY
DISAGREE |
|-------------------|-------|-------------------------------|----------|----------------------|
- 22 13. I am confused about all of the controversy over hormone treatment and menopause.
- | | | | | |
|-------------------|-------|-------------------------------|----------|----------------------|
| STRONGLY
AGREE | AGREE | NEITHER AGREE
NOR DISAGREE | DISAGREE | STRONGLY
DISAGREE |
|-------------------|-------|-------------------------------|----------|----------------------|
- 23 14. Despite what health care providers say, I believe I should make the decisions about management of my menopause.
- | | | | | |
|-------------------|-------|-------------------------------|----------|----------------------|
| STRONGLY
AGREE | AGREE | NEITHER AGREE
NOR DISAGREE | DISAGREE | STRONGLY
DISAGREE |
|-------------------|-------|-------------------------------|----------|----------------------|

- 24 15. There is little that an individual can do to control the symptoms of menopause.
- | | | | | |
|-------------------|-------|-------------------------------|----------|----------------------|
| STRONGLY
AGREE | AGREE | NEITHER AGREE
NOR DISAGREE | DISAGREE | STRONGLY
DISAGREE |
|-------------------|-------|-------------------------------|----------|----------------------|
- 25 16. I have been/will be able to experience menopause without problems.
- | | | | | |
|-------------------|-------|-------------------------------|----------|----------------------|
| STRONGLY
AGREE | AGREE | NEITHER AGREE
NOR DISAGREE | DISAGREE | STRONGLY
DISAGREE |
|-------------------|-------|-------------------------------|----------|----------------------|
- 26 17. Menopause causes problems no matter what you do.
- | | | | | |
|-------------------|-------|-------------------------------|----------|----------------------|
| STRONGLY
AGREE | AGREE | NEITHER AGREE
NOR DISAGREE | DISAGREE | STRONGLY
DISAGREE |
|-------------------|-------|-------------------------------|----------|----------------------|
- 27 18. Menopause will/did cause me to be sick a lot.
- | | | | | |
|-------------------|-------|-------------------------------|----------|----------------------|
| STRONGLY
AGREE | AGREE | NEITHER AGREE
NOR DISAGREE | DISAGREE | STRONGLY
DISAGREE |
|-------------------|-------|-------------------------------|----------|----------------------|
- 28 19. Menopause probably will not/did not have a negative effect on me.
- | | | | | |
|-------------------|-------|-------------------------------|----------|----------------------|
| STRONGLY
AGREE | AGREE | NEITHER AGREE
NOR DISAGREE | DISAGREE | STRONGLY
DISAGREE |
|-------------------|-------|-------------------------------|----------|----------------------|
- 29 20. I believe that I can control menopausal symptoms.
- | | | | | |
|-------------------|-------|-------------------------------|----------|----------------------|
| STRONGLY
AGREE | AGREE | NEITHER AGREE
NOR DISAGREE | DISAGREE | STRONGLY
DISAGREE |
|-------------------|-------|-------------------------------|----------|----------------------|
- 30 21. Taking hormones for menopausal symptoms can make me feel better.
- | | | | | |
|-------------------|-------|-------------------------------|----------|----------------------|
| STRONGLY
AGREE | AGREE | NEITHER AGREE
NOR DISAGREE | DISAGREE | STRONGLY
DISAGREE |
|-------------------|-------|-------------------------------|----------|----------------------|
- 31 22. Special diets & foods may help control some of the symptoms of menopause.
- | | | | | |
|-------------------|-------|-------------------------------|----------|----------------------|
| STRONGLY
AGREE | AGREE | NEITHER AGREE
NOR DISAGREE | DISAGREE | STRONGLY
DISAGREE |
|-------------------|-------|-------------------------------|----------|----------------------|

- 32 23. Women are more tired than usual during menopause.
- | | | | | |
|-------------------|-------|-------------------------------|----------|----------------------|
| STRONGLY
AGREE | AGREE | NEITHER AGREE
NOR DISAGREE | DISAGREE | STRONGLY
DISAGREE |
|-------------------|-------|-------------------------------|----------|----------------------|
- 33 24. Menopause is something I just have to put up with.
- | | | | | |
|-------------------|-------|-------------------------------|----------|----------------------|
| STRONGLY
AGREE | AGREE | NEITHER AGREE
NOR DISAGREE | DISAGREE | STRONGLY
DISAGREE |
|-------------------|-------|-------------------------------|----------|----------------------|
- 34 25. Menopause is associated with mood changes.
- | | | | | |
|-------------------|-------|-------------------------------|----------|----------------------|
| STRONGLY
AGREE | AGREE | NEITHER AGREE
NOR DISAGREE | DISAGREE | STRONGLY
DISAGREE |
|-------------------|-------|-------------------------------|----------|----------------------|
- 35 26. Most women make too much of menopause.
- | | | | | |
|-------------------|-------|-------------------------------|----------|----------------------|
| STRONGLY
AGREE | AGREE | NEITHER AGREE
NOR DISAGREE | DISAGREE | STRONGLY
DISAGREE |
|-------------------|-------|-------------------------------|----------|----------------------|
- 36 27. Health care providers don't really understand the problems women experience with menopause.
- | | | | | |
|-------------------|-------|-------------------------------|----------|----------------------|
| STRONGLY
AGREE | AGREE | NEITHER AGREE
NOR DISAGREE | DISAGREE | STRONGLY
DISAGREE |
|-------------------|-------|-------------------------------|----------|----------------------|
- 37 28. There is a difference between male and female health care providers in how they understand the problems that women experience with menopause.
- | | | | | |
|-------------------|-------|-------------------------------|----------|----------------------|
| STRONGLY
AGREE | AGREE | NEITHER AGREE
NOR DISAGREE | DISAGREE | STRONGLY
DISAGREE |
|-------------------|-------|-------------------------------|----------|----------------------|

When I experience menopause I feel that...(PLEASE CHECK ONLY ONE ANSWER FOR EACH QUESTION)

- 38 29. ☐ A) My sex life will be/is more satisfying.
☐ B) My sex life will be/is relatively the same.
☐ C) My sex life will be/is less satisfying.
- 39 30. ☐ A) My sleep patterns will get/are better.
☐ B) My sleep patterns will remain/are relatively the same.
☐ C) My sleep patterns will get/are worse.
- 40 31. ☐ A) Participating in social activities will be/is much more enjoyable.
☐ B) Participating in social activities will be/is no more or less enjoyable.
☐ C) Participating in social activities will be/is much less enjoyable.
- 41 32. ☐ A) It will be/is much easier for me to do the things that I normally do during the day.
☐ B) There will be/is little change in how I do the things that I normally do during the day.
☐ C) It will be/is more difficult for me to do the things that I normally do during the day.

/sc
110:4
3/26/87

APPENDIX H

Equations for Management Scales

$$\text{Total Management Score} = \sum_{ij} X_{ij} \div M_T S_T$$

X_{ij} = response for management strategy i , for symptom j

(X_{ij} = 0 or 1; 0 = Does not use strategy ' i '; 1 = Does use strategy ' i ')

M_T = total no. of management strategies = 35

S_T = total no. of symptoms listed - obtained from ranked symptoms on symptoms instrument (S_T varies from 1 to 5)

$$\text{Medication Scale Score} = \sum_{i=1}^{i=m} X_{ij} \div M_m S_T$$

X_{ij} = response for management strategy i , for symptom j for all X_{ij} in category ' m '

(X_{ij} = 0 or 1; 0 = Does not use strategy ' i '; 1 = Does use strategy ' i ')

M_m = total no. of management strategies in medications category = 11

S_T = total no. of symptoms listed - obtained from ranked symptoms on symptoms instrument (S_T varies from 1 to 5)

$$\text{Diet Scale Score} = \sum_{i=1}^{I=d} X_{ij} \div M_d S_T$$

X_{ij} = response for management strategy i, for symptom j for all X_{ij} in category 'd'
 (X_{ij} = 0 or 1; 0 = Does not use strategy 'i'; 1 = Does use strategy 'i')
 M_d = total no. of management strategies in diet category = 8
 S_T = total no. of symptoms listed - obtained from ranked symptoms on
 symptoms instrument (S_T varies from 1 to 5)

$$\text{Vitamin/Mineral Scale Score} = \sum_{i=1}^{I=V} X_{ij} \div M_V S_T$$

X_{ij} = response for management strategy i , for symptom j for all X_{ij} in category ' v '
 (X_{ij} = 0 or 1; 0 = Does not use strategy ' i '; 1 = Does use strategy ' i ')
 M_V = total no. of management strategies in vitamin/mineral category = 7
 S_T = total no. of symptoms listed - obtained from ranked symptoms on
 symptoms instrument (S_T varies from 1 to 5)

$$\text{"Other" Scale Score} = \sum_{i=1}^{I=0} X_{ij} \div M_o S_T$$

X_{ij} = response for management strategy i, for symptom j for all X_{ij} in category 'o'

(X_{ij} = 0 or 1; 0 = Does not use strategy 'i'; 1 = Does use strategy 'i')

M_o = total no. of management strategies in "other" category = 9

S_T = total no. of symptoms listed - obtained from ranked symptoms on symptoms instrument (S_T varies from 1 to 5)

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Example Calculations

Calculations: $X_{34} = 1; X_{43} = 1; X_{61} = 1; X_{62} = 1; X_{63} = 1$; For all other, $X = 0$

$$\text{Vitamin/Mineral Scale Score} = \sum X_{ij} + M_{VTr} = 5 + (7 \times 4) = .625$$

APPENDIX I

APPENDIX I
Menopause Information Instrument
Answer Key

Item Number	Correct Answer
1	b
3	a
4	d
5	b & e
6	d
7	a
8	d -or- a & b & c -or- a & b & c & d
9	d -or- a & b & c -or- a & b & c & d
10	false
11	true
12	true
13	true
14	true
15	false
16	true
17	true
18	true
19	c
20	d
21	d

APPENDIX J



APPENDIX J

Press Release and Media Requests for Participants

Contact: Marilyn Rothert, Nursing
(517) 355-6525
or Tom Oswald, News Bureau
(517) 355-2281

**MSU ESTROGEN STUDY
SEEKS PARTICIPANTS**

EAST LANSING — A Michigan State University study on menopause and the use of estrogen is in need of participants.

The study, which is being conducted by the MSU College of Nursing, will survey at least 200 women, gathering their thoughts on menopause and the use of estrogen replacement therapy.

To take part in the study, a woman must be between the ages of 45 and 55, not presently taking estrogen, and not had a hysterectomy (surgical removal of the uterus). Participants will spend about an hour completing a questionnaire on their experiences. All information will be kept confidential.

An optional question-and-answer session with a nurse will follow and women who choose to attend will obtain information about the benefits and risks of estrogen replacement therapy.

Menopause is the time in a woman's life when her body reduces its production of the female hormone estrogen, said Marilyn Rothert, associate professor of nursing at MSU and principal investigator for the project. Estrogen replacement therapy is one method often used to deal with the physical discomforts which may accompany menopause.

Whether to use estrogen is one of the hardest decisions a woman will make, Rothert said. While it does offer some relief for such problems as osteoporosis (brittle bones) and hot flashes, there are some risks as well, such as the threat of cancer of the uterus.

(more)

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"Decision-making regarding estrogen use and menopause has been studied from the perspective of physicians, but little is known about what is important to women as they face this decision," said Rothert.

The information gathered in this study will be used to develop an educational program for women to help them become more informed decision-makers about estrogen and menopause.

The project is funded by the National Center for Nursing Research.

For more information, contact Rothert or Jill Kroll, MSU College of Nursing, (517) 355-6744.

#tnof

APPENDIX K

APPENDIX K

Participant Recruitment Letters

MICHIGAN STATE UNIVERSITY

COLLEGE OF NURSING • DIVISION OF LIFELONG EDUCATION • A230 Life Sciences Building • East Lansing, Michigan 48824-1317 • Area Code 517/355-6525

October 15, 1987

Ms. Jane Doe
Any Denomination Church
1122 Church Road
Lansing, MI 99999

Dear Ms. Doe:

The Michigan State University College of Nursing is conducting a study of the experiences and expectations of women regarding menopause, and what is important to them in deciding whether or not to take estrogen replacement therapy (ERT). The information will be used to develop educational materials to help women become more informed decision-makers regarding menopause and ERT. We are contacting women primarily through local churches and would like to know if any women in your church are interested in participating in the study.

Study participants should be between the ages of 45 and 55 years old and English-speaking. Additionally, we are asking that participants not have had a hysterectomy and not be taking estrogens. Women who participate will read a series of written cases describing factors related to menopause, and indicate how likely they would be to take ERT in each case. They will also answer other questions regarding their perceptions of and experience with menopause.

We plan to set up a meeting in your area to complete the questionnaires for the study. If there are any women in your church or neighboring area who would be interested in participating in the study they are welcome to come. If your church would be interested in hosting the meeting, please contact Jill Kroll at the telephone number below.

Some times and locations for completing the study questionnaires have already been scheduled and a list is enclosed. Women who wish to attend one of these meetings are welcome to do so, and should contact Jill Kroll or Sue Cousineau at (517) 355-6744, or write to MICHIGAN STATE UNIVERSITY, COLLEGE OF NURSING, DIVISION OF LIFELONG EDUCATION, 421 WEST FEE HALL, EAST LANSING, MICHIGAN, 48824-1317. Additional meetings will be scheduled in the future.

Page 2

If you would like more information about the study, or have women who would like to participate, you may contact Jill, Sue or me at the College of Nursing at Michigan State University, at (517) 355-6525.

Enclosed are some informational materials about the study. Please feel free to copy any of these materials and distribute or post them. If you would like additional copies of this material please call Jill or Sue at the number above.

Jill will be contacting you by telephone in the near future to learn whether there are any questions.

Thank you for your help.

Sincerely,

Marilyn Rothert
Associate Professor and
Director for Lifelong Education

Jill Kroll
Research Assistant

APPENDIX L

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APPENDIX L

Participant Sign-up Sheet
ESTROGEN REPLACEMENT THERAPY
MICHIGAN STATE UNIVERSITY
COLLEGE OF NURSING

The Michigan State University College of Nursing is conducting a study of the experiences and expectations of women regarding menopause, and what is important to them in deciding whether or not to take estrogen replacement therapy (ERT). The information will be used to develop educational materials to help women become more informed decision-makers regarding menopause and ERT.

Women who participate in the study come to a meeting and spend about 1 hour completing the questionnaires. After this there is an informal question and answer period with a nurse to answer your questions about menopause. Study participants should be between the ages of 45 and 55 years old and English-speaking. Additionally, we are asking that study participants not be presently taking any kind of estrogens and not have had a hysterectomy.

Women who participate in the study will read a series of written cases describing factors related to menopause, and indicate how likely they would be to take ERT in each case. They will also answer other questions regarding their perceptions of and experience with menopause. Those who choose to participate will also be asked to sign a consent form.

IF YOU WOULD LIKE TO PARTICIPATE YOU MAY CONTACT Sue AT THE COLLEGE OF NURSING AT MICHIGAN STATE UNIVERSITY AT 355-6744 OR COMPLETE THE FORM BELOW AND RETURN IT TO: ESTROGEN REPLACEMENT THERAPY, COLLEGE OF NURSING, MICHIGAN STATE UNIVERSITY, 421 WEST FEE HALL, EAST LANSING, MI 48824.

If you have any questions regarding the study you may contact Sue Cousineau or me at the College of Nursing at Michigan State University, at (517) 355-6525.

Thank you for your interest.

Marilyn Rothert, R.N., Ph.D.
Associate Professor and
Director for Lifelong Education

Please contact me about participation in the ERT study being conducted by the College of Nursing at Michigan State University.

Name: _____	Session you wish to attend:
Telephone: (Day) _____	___ Tues., Dec. 1, 7-9 p.m.
(Evening) _____	___ Wed., Dec. 9, 12-2 p.m.
Address: _____	___ Mon., Dec. 14, 7-9 p.m.
_____	___ Tues., Dec. 15, 7-9 p.m.
Where did you hear about the ERT Study? _____	___ Other: _____
_____	_____
_____	_____

Additional dates will be scheduled in the future. Please call 355-6744 for information.

APPENDIX M

APPENDIX M

Newsletter Example

ESTROGEN REPLACEMENT THERAPY STUDY
MICHIGAN STATE UNIVERSITY
COLLEGE OF NURSING

The Michigan State University College of Nursing is conducting a study of the experiences and expectations of women regarding menopause, and what is important to them in deciding whether or not to take estrogen replacement therapy (ERT). The information will be used to develop educational materials to help women become more informed decision-makers regarding menopause and Estrogen Replacement Therapy. We are looking for English-speaking women between the ages of 45 and 55 years old who have not had a hysterectomy and who are not taking estrogen, to participate in the study. Women who participate in the study will be asked to read a series of written cases describing factors related to menopause, and indicate how likely they would be to take ERT in each case. They will also be asked to answer other questions regarding their perceptions of and experience with menopause. Women interested in participating in the study would come to a meeting and spend about 1 hour completing questionnaires. After this there would be an informal question and answer period with a nurse to answer questions about menopause.

IF YOU WOULD LIKE TO PARTICIPATE PLEASE CALL SUE AT THE COLLEGE OF NURSING AT MICHIGAN STATE UNIVERSITY AT 355-6744 OR SPEAK TO _____, THE CONTACT PERSON FOR YOUR GROUP.

APPENDIX N

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APPENDIX N
Additional Information Packet

MICHIGAN STATE UNIVERSITY

COLLEGE OF NURSING • DIVISION OF LIFELONG EDUCATION • A230 Life Sciences Building • East Lansing, Michigan 48824-1317 • Area Code 517/355-6525

September 17, 1987

Dear Interested Participant:

The Michigan State University College of Nursing is conducting a study of the experiences and expectations of women regarding menopause, and what is important to them in deciding whether or not to take estrogen replacement therapy (ERT). The information will be used to develop educational materials to help women become more informed decision-makers regarding menopause and ERT. We are contacting women primarily through local women's groups. Women who think they might be interested in participating in the study would come to a meeting and spend about 1 hour completing the questionnaires. After this there would be an informal question and answer period with a nurse to answer your questions about menopause. Study participants should be between the ages of 45 and 55 years old and English-speaking. Additionally, we are asking that study participants not be presently taking any kind of estrogens and not have had a hysterectomy. Women in your group who are interested in the study but who do not fit these criteria are welcome to join the meeting and participate in the question and answer period.

Women who participate in the study will read a series of written cases describing factors related to menopause, and indicate how likely they would be to take ERT in each case. They will also answer other questions regarding their perceptions of and experience with menopause. The information sheet attached explains the study more completely. Those who choose to participate will also be asked to sign a consent form which is enclosed.

If you have any questions regarding the study you may contact Jill Kroll, one of our research assistants, or me at the College of Nursing at Michigan State University, at (517) 355-6744.

Thank you for your help.

Sincerely,

Marilyn Rothert
Associate Professor and
Director for Lifelong Education

Jill Kroll
Research Assistant

Information Sheet

This research, sponsored by Michigan State University College of Nursing, studies the judgments of women regarding estrogen replacement therapy (ERT) as they anticipate and experience menopause. The decision to take or not to take the hormone therapy is complex. For example, while the use of ERT relieves hot flashes and decreases the risk of brittle bones (osteoporosis) it may also increase the risk of endometrial cancer. As such, women need to be fully informed of the risks, benefits and implications of ERT for the relief of menopausal symptoms so that they can make informed decisions.

In this particular study, we are interested in what women feel are important factors and considerations in taking ERT and what decisions they would make given various hypothetical situations. We are also interested in the relation of various factors to decisions regarding menopause. These factors include previous health behaviors, perceptions, management and knowledge of menopause, and expectations and experience with menopause. Ultimately it is the intention of the research team to use the information in designing an educational program for nurses so that they can help women make informed decisions regarding ERT.

During the study, care will be taken to ensure confidentiality of all participants answers, and women who choose to participate will be free to discontinue their participation at any time during the study. A nurse will be on hand to answer any questions women may have about the study and about menopause. Finally, results from the study will be made available to all those who request it.

Consent Form - Phase I Survey

One option for dealing with some menopausal symptoms is taking hormones or estrogen replacement therapy. The College of Nursing at Michigan State University is conducting a study to better understand how women make decisions about whether or not to use estrogen. The results from this study will be used to design materials which can be used to help women make informed decisions about whether or not to take estrogen replacement therapy.

In this survey, you will be asked a number of questions about your perceptions, expectations and experience with menopause and what you would decide about estrogen replacement therapy given some hypothetical situations. You will also be asked to give information about such things as your marital status, age and education.

By signing this form I understand that:

1. I have freely consented to take part in this study.
2. The study has been explained to me. Furthermore, I understand the explanation that has been given to me and what my participation will involve.
3. I am free to discontinue my participation in the study at any time without penalty.
4. My responses will be treated with strict confidence and all participants will remain anonymous.
5. I will be responding to written information.
6. It will take approximately 60 minutes to complete the questionnaires.
7. I am not guaranteed any beneficial results from my participation in this study.
8. I may be contacted at a later time to participate in a later phase of the research. Based on preliminary analysis of responses from the initial study, a second study will be done with selected representatives of participants from the original study. If I am contacted at a later time, I will be under no obligation to participate further in the study.
9. Results of the study will be made available to me at my request.

Signed: _____

Date: _____

APPENDIX O

APPENDIX O

Consent Form

Consent Form - Phase I Survey

One option for dealing with some menopausal symptoms is taking hormones or estrogen replacement therapy. The College of Nursing at Michigan State University is conducting a study to better understand how women make decisions about whether or not to use estrogen. The results from this study will be used to design materials which can be used to help women make informed decisions about whether or not to take estrogen replacement therapy.

In this survey, you will be asked a number of questions about your perceptions, expectations and experience with menopause and what you would decide about estrogen replacement therapy given some hypothetical situations. You will also be asked to give information about such things as your marital status, age and education.

By signing this form I understand that:

1. I have freely consented to take part in this study.
2. The study has been explained to me. Furthermore, I understand the explanation that has been given to me and what my participation will involve.
3. I am free to discontinue my participation in the study at any time without penalty.
4. My responses will be treated with strict confidence and all participants will remain anonymous.
5. I will be responding to written information.
6. It will take approximately 60 minutes to complete the questionnaires.
7. I am not guaranteed any beneficial results from my participation in this study.
8. I may be contacted at a later time to participate in a later phase of the research. Based on preliminary analysis of responses from the initial study, a second study will be done with selected representatives of participants from the original study. If I am contacted at a later time, I will be under no obligation to participate further in the study.
9. Results of the study will be made available to me at my request.

Address: _____

Signed: _____

Phone: _____

Date: _____

APPENDIX P

Introduction Sheet and Results Request Form

The Michigan State University College of Nursing is trying to better understand what is important to women when they decide whether or not to take estrogen (hormone) replacement therapy for menopausal symptoms. We know that some women decide that they want hormonal therapy as they approach menopause, others decide that they do not, and others are undecided or don't feel they have enough information.

Our goal is to better understand how women make this decision. At the completion of this project, we will use what we have learned to develop materials to help women have the information they need to make the best decision regarding hormonal or estrogen therapy.

We are asking you to help us with the project by answering some questions and giving us your thoughts about some written situations. We are asking women who are between 45-55 years of age who have not had a hysterectomy (removal of the uterus or womb) to participate in the study. This will include women who are approaching menopause and women who are now experiencing menopause.

The information you give us will be used only for this study. All information obtained will be treated with strict confidence. People will remain anonymous, that is, the information collected will be identified only by a code number and the researchers will be the only ones who know which number is assigned to whom.

Your decision to participate or not to participate in this study has nothing to do with the health care you receive. You have the right to withdraw from the study at any time without penalty. While we appreciate you answering all of the questions, you have the right not to answer a question if you choose.

This task is estimated to take about 1 hour. First you will be asked to answer some written questions about menopause. Then you will be asked to read some situations and tell us how likely you would be to take hormone therapy in those situations.

The results of the study, while not of direct benefit to you, will help us find ways to help women have the information they need to make the best decision for themselves regarding estrogen replacement therapy. Without your help we could not do this study, and we greatly appreciate your cooperation. If you would like a report of the study when completed, please indicate it on the enclosed form.

Thank you for your help.

Please send me a copy of the results of this study.

Name _____
Street _____
City _____ Zip _____

APPENDIX Q

APPENDIX Q

Example Thank-you Letters

MICHIGAN STATE UNIVERSITY

COLLEGE OF NURSING • DIVISION OF LIFELONG EDUCATION • A230 Life Sciences Building • East Lansing, Michigan 48824-1317 • Area Code 517/355-6525

December 15, 1987

Ms. Jane Doe
1212 State Street
Lansing, MI 99999

Dear Ms. Doe:

Thank you very much for your help in coordinating the meeting for the estrogen replacement therapy study. We appreciate your help and thank you for the use of for participating. The information your group provided will be used to learn more about menopause and about what is important to women in making the decision regarding estrogen therapy. Ultimately, the information your group and other participants have provided will be used to develop educational materials for women, to provide the information they need about menopause and to help them make informed decisions about estrogen therapy and other health care issues.

If participants completed the form requesting a copy of the results of this study when it is completed, we will send them when they become available. Results may be available in 6 to 10 months.

Again, thank you very much for your help, and if in the future you hear of any individuals or groups of women who may be interested in participating in the Estrogen Replacement Therapy Study please feel free to contact Jill Kroll or myself at 355-6744, or to share this telephone number with them, and encourage them to contact us.

Sincerely,

Marilyn Rothert, R.N., Ph.D.
Associate Professor and
Director of Lifelong Education

MICHIGAN STATE UNIVERSITY

COLLEGE OF NURSING • DIVISION OF LIFELONG EDUCATION • A230 Life Sciences Building • East Lansing, Michigan 48824-1517 • Area Code 517/355-6525

January 4, 1988

Ms. Jane Doe
4444 City Road
West Bloomfield, MI 48322

Dear Ms. Doe:

Thank you very much for participating in the estrogen replacement therapy study being conducted by the College of Nursing at Michigan State University. The information you provided will be used to learn more about menopause and about what is important to women in making the decision regarding estrogen therapy. Ultimately, the information you and other participants have provided will be used to develop educational materials for women, to provide the information they need about menopause and to help them make informed decisions about estrogen therapy and other health care issues.

If you completed the form requesting a copy of the results of this study when it is completed, we will send them when they become available. Results may be available in 6 to 18 months.

Again, thank you very much for your help.

Sincerely,

Marilyn Rothert, R.N., Ph.D.
Associate Professor and
Director of Lifelong Education

MICHIGAN STATE UNIVERSITY

COLLEGE OF NURSING • DIVISION OF LIFELONG EDUCATION • A230 Life Sciences Building • East Lansing, Michigan 48824-1317 • Area Code 517/355-6525

October 9, 1987

Any Church of Lansing
3333 Church Street
Lansing, MI 99999

Dear Pastor:

Thank you very much for your church's participation in the estrogen replacement therapy study being conducted by the College of Nursing at Michigan State University. We appreciate your help in putting us in contact with your women's group and thank the group for participating. The information provided by the women in your church and other churches will be used to learn more about menopause and about what is important to women in making the decision regarding estrogen therapy. Ultimately, the information will be used to develop educational materials for women, to provide the information they need about menopause and to help them make informed decisions about estrogen therapy and other health care issues.

If the participants from your church completed the form requesting a copy of the results of this study when it is completed, we will send them the results when they become available. Results may be available in 6 to 18 months.

Again, thank you very much for your help.

Sincerely,

Marilyn Rothert, R.N., Ph.D.
Associate Professor and
Director of Lifelong Education

APPENDIX R

Appendix R

Calculation of Omega-squared (ω^2)

An Estimate of Treatment Effect Magnitude

From Kepple (1982):

$$\omega^2 = \frac{SS_{bn} - (a-1)(MS_{wi})}{SS_T + MS_{wi}}$$

where:

SS_{bn} = Sum of Squares Between Groups

SS_T = Sum of Squares Total

MS_{wi} = Mean Square Within Groups

a = Number of Groups

APPENDIX S

Appendix S

Calculation of Correction for Unreliability

$$r_{xy\text{true}} = \frac{r_{xy\text{obt}}}{\sqrt{r_{xx}} \sqrt{r_{yy}}}$$

where:

$r_{xy\text{true}}$ = True correlation

$r_{xy\text{obt}}$ = Observed correlation

$\sqrt{r_{xx}}$ = Reliability of measure x

$\sqrt{r_{yy}}$ = Reliability of measure y

From : Edwards, A. L. (1954). Statistical methods for the behavioral sciences.
New York: Holt, Rinehart and Winston.

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