Managing Perimenopausal and Menopausal Symptoms Naturally: The Development of an Evidence-Based Information Booklet for Perimenopausal and Menopausal Women

By

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A Practicum Project

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Abstract

The negative results of the Women's Health Initiative study related to risks of hormone replacement therapy have increased the demand for alternative treatments of menopausal symptoms. Obtaining comprehensive and accurate information on these alternative therapies continues to present a challenge for both health care providers and women. While there is a great deal of information available, not all information is based on scientific evidence.

In response to this growing need, the development of an evidence-based information booklet for women who may be interested in alternative therapies to treat menopausal symptoms is the focus of this practicum project. The scientific evidence related to the use of 7 commonly used herbs, 3 foods, and 1 vitamin to treat symptoms of menopause was examined. Based on findings in the literature, the information booklet is organized into these subheadings: menopausal symptoms, herbal, food and vitamin alternatives, recommended dosages, cautions, drug interactions, recommended length of use, and potential side effects. A conscious effort was made to develop an information booklet that maximized the interaction and participation of women who may choose to use this booklet. This was achieved by including written exercises and follow-up charts that were tailored to each woman's use of these alternative therapies.

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CHAPTER 1: INTRODUCTION TO THE PROJECT

Introduction

"Menopause is mystery. Menopause is power."
Whisper the women.
(The Wise Woman Tradition, Weed, 1999, p. 267).

Menopause is a complex transition in a woman's life involving biological, psychological, social and cultural factors (Bain, Lumsden, Sattar & Greer, 2003). The term menopause is derived from the Greek *meno* (month) and *pausis* (pause). The period immediately prior to menopause is known as the perimenopause. It is a time when the biological/endocrine, and clinical features of approaching menopause commence. Some define this period as "being in" or "going through" menopause (North American Menopause Society [NAMS], 2000, p. 15). On average perimenopause usually begins around age 38 and lasts anywhere from 4 to 13 years (NAMS, 2000; Northrup, 1997). In the Western world menopause occurs at a median age of 51.4 years, with a range from 40 to 58 years (NAMS, 2000). While there are other causes of menopause, for example, surgical menopause, premature ovarian failure, chemotherapy, and or radiation-induced menopause, this practicum project focuses on the treatment of menopause as a natural biological event.

As a natural biological event, menopause is a time in a woman's life when menstruation has ceased for 12 consecutive months for no pathological reason (NAMS, 2000). Menopause is characterized by a decline in ovarian follicular activity particularly in the production of estrogen. As a result of this decline, some women may experience

vasomotor symptoms such as hot flushes, flashes or night sweats. Other symptoms including insomnia, headaches, irritability, depression, memory loss, declining libido and genitourinary changes have been described (NAMS, 2000). At a psychological level, a wide range of emotions has been associated with menopause although their direct connection to declining hormones is uncertain. These emotions extend from a sense of freedom from worrying about contraception and menstrual periods to a feeling of loss over one's fertility (Busch, Barth-Olofsson, Rosenhagen, & Collins, 2003). While many women pass through this stage of their lives with few physical or emotional complaints others become debilitated by them (Dog, Riley & Carter, 2001).

For many years the most conventional treatment for menopausal symptoms in the Western world has been the use of combined estrogen and progesterone hormone replacement therapy (HRT). However, in July 2002, the National Institute of Health (NIH) prematurely ended the estrogen and progesterone arm of the Women Health Initiative's (WHI) randomized control trial because of the discovery of significant risks associated with HRT. These risks included increased risk of breast cancer, coronary heart disease, stroke, and venous thromboembolism (Hersh, Stefanick & Stafford, 2004). As a result, more women are turning to the use of complementary and alternative therapies in the hope of relieving their menopausal symptoms (Huntley & Ernst, 2003; Mahaffee-Gingrich & Ingram-Fogel, 2003). According to Weed (1999), women today are demanding a more natural approach to menopause. Citing Begley, Weed (1999) affirmed that "the wonder" is not that estrogen is the most widely prescribed drug in the United

States, but that 85 percent of the 37 million postmenopausal women want nothing to do with the stuff" (Begley, as cited in Weed, 1999, p. 267).

Statement of Purpose

Given the increasing demand for a natural approach to menopause (Weed, 1999), the purpose of this practicum project is to develop an information booklet for women who may be interested in herbal, food, and vitamin therapies to treat their menopausal symptoms. This will be achieved through an examination of 7 herbs, 3 foods, and 1 vitamin that are commonly used for treating symptoms of menopause. The efficacy of these products will be investigated by consulting current clinical evidence as reflected in the literature. Obtaining comprehensive and accurate information on alternative therapies presents a challenge for both health care providers and consumers because (a) there are many sources of information available, and (b) not all information is based on clinical evidence. Based on findings in the current literature, this information booklet will contain a brief description of each product, its purported use, side effects, contraindications, and recommendations.

Epidemiology

Life expectancy for North American women continues to increase. Today, many women in Canada can expect to live until the age of 85 (Statistics Canada, 2003). According to Lindsay (1999) by the year 2015, half of all U.S women will be menopausal; this is similar to the situation in Canada (Statistics Canada, 2003). According to NAMS, 15 % of the Canadian population was age 50 and older in 2000. As a consequence, health care professionals are increasingly being called upon to answer

questions and assist menopausal women to make as smooth a transition as possible through this period of their lives.

Brief History of Herbal Remedies

Prior to the 19th century the use of whole plants, leaves, and other parts of plants was practically the only type of medical treatment available (Sierpina & Blessing, 2000). The isolation of morphine from the opium poppy in 1805 heralded the modern era of pharmacology (Sierpina & Blessing, 2000). Subsequently, other medicinal ingredients were extracted from the leaves, roots and flowers of plants. With the dawn of the science of pharmacology, the use of whole or parts of plants and other forms of herbal treatments were "abandoned...and regarded as primitive and without scientific merit" (p. 26).

Today, the general use of herbal therapies is one of the more rapidly expanding alternative therapies in the modern world. Compared to North America, many countries in Asia and Europe are further ahead in integrating herbal therapies into the mainstream of health care. For example, in Asia, the Chinese have used traditional Chinese medicine for at least 20 centuries. Evidence of the use of herbal medicine has been documented in Lei Gong's *Treatise on Preparation of Materia Medica* as early as AD 588 (Dog et al., 2001). The government of Germany has established Commission E, a review panel, whose mandate is to examine and assess the safety and efficacy of more than 1400 herbal agents used in that country (German Commission E, 1978). This review panel is composed of physicians, pharmacists, toxicologists, pharmaceutical representatives, and people from outside the medical profession and industry. The commission publishes its

recommendations in the form of monographs and bases them on clinical trials, field studies, and expert opinion.

Why the Shift to Alternative Health Care?

The findings of Astin (1998) and Seidl and Stewart (1998) provide some reasons for why consumers choose alternative health care. Astin (1998) hypothesized that people seek alternative treatments because they are dissatisfied with conventional treatment. His findings, however, did not support his hypotheses. He found that negative attitudes towards health care providers or experience with conventional medicine were not predictors for choosing alternative therapies. What he found, instead, was that the main predictor for the use of alternative medicine was the level of education. Individuals with post-secondary education were twice as likely as high-school graduates to use alternative forms of health care. Further research in this area led him to conclude that herbal therapy users chose alternative treatments to gain greater personal autonomy and control over their health care decisions.

Seidl and Stewart (1998), on the other hand, discovered that negative attitudes towards conventional treatments **were** a predictor for consideration and use of alternative therapies. In their interviews with Canadian women/clients, they cited reasons such as (a) lack of confidence in advice received from health care professionals, (b) will of women to gain personal control over their own health care practices, (c) resistance by physicians to consider and provide alternative treatments, and (d) lack of choices, as predictors for the consideration and use of alternative therapies.

Regardless of individual motivations or level of education, it may be fair to suggest that more women could be looking for alternative forms of therapy because of the recent publication of the results of the Women's Health Initiative Heart and Estrogen/progestin Replacement Study (HERS), (JAMA, August, 2002). As stated earlier, this publication affirmed the positive correlation between the use of HRT and increased risk of developing breast cancer, heart disease, and stroke. It may be fair to suggest that this publication and the media attention it generated have increased women's motivation and desire to seek out and consider alternative treatments for menopause (Anand & Yusuf, 2002). At the same time, Nurse Practitioners are also seriously addressing this issue. One major educational objective of the National Association of Nurse Practitioners in Women's Health (NPWH) conference which is being held in Chicago, Oct. 13, 2004 for example, reads as follows: "Upon completion of this program, participants should be able to discuss the risks and benefits of hormone therapy, considering new factors from the termination of the estrogen-only arm of the WHI."

While numerous forms of alternative therapies exist, for example, diet, exercise, lifestyle changes, stress management and relaxation techniques, biofeedback, acupuncture, and nutritional supplements, this project focuses primarily on the use of 7 herbs, 3 food supplements and 1 vitamin. For many women the decision to use an alternative approach is more congruent with their own values, beliefs, and philosophical orientations towards health and life (Astin, 1998). According to Barrett et al. (2000) women/clients who used some form of alternative therapy described it as "healing and staying healthy in a proactive sense" (p.236). Others described this proactive approach as

an integrated focus on the physical, psychological, and spiritual well being of the individual (Benjamin, Benson, Gordon, & Sullivan, 1997).

Internationally, there appears to be a general shift in physicians' attitude towards the use of alternative health care. For example, "a 1994 survey of physicians from a wide array of medical specialties (in Washington, New Mexico, and Israel) revealed that more than 60% recommended alternative therapies to their patients at least once in the preceding year" [parenthesis original] (Astin, 1998, p. 1548).

Statement of the Problem

The recent publication of the studies of conventional HRT, as mentioned above, and the desire of women to take control of their own well-being present both the health care professional and consumer with a new reality. Sierpina and Blessing (2000) suggested that a "new era of patient-centered care is upon us, in the form of alternative therapies" (p. 40). In direct response to the dawning of this new era, they strongly recommended that both health care providers and consumers should strive to keep abreast of this emerging trend and learn about therapies outside the realm of standard medical care" (p. 40). The development of an information booklet for women who may be interested in alternative therapies is one response to this trend.

Significance of Practicum Project

While there are a many issues connected to the use of alternative therapies, three deserve particular mention. First, women who choose alternative therapies are faced with the question of which alternative therapy best treats their particular menopausal symptom(s) (Gilbert, 2004). Information obtained in popular magazines or the media can

sometimes be misleading and may not be based on sound scientific evidence. This can leave consumers confused as to what is best and safest to use. Second, the consciousness of individuals is such that "natural" is a term usually linked to healthy, positive behaviors and natural therapies fall into this realm of all that is wholesome and good. As a consequence, there is a tendency for individuals to believe that because they are using a "natural" product there can be no side effects, nor do they need to be concerned about drug interactions (Astin, 1998). Side effects, as well as interactions with other prescription and non-prescription medications, are usually not noted. Third, individuals might not realize that different brand names of herbal therapies contain varying amounts of an active ingredient or standardized extract. As a consequence, different herbs under different brand names may not be as effective as they could be because of varying potency and quality. Manufacturers may obtain their raw materials from a variety of sources, some of whom may use herbicides and pesticides on their plants, thus affecting overall quality and safety. These three factors suggest that health care providers could be of greater service to their clients by providing reliable and informed advice to women who choose alternative therapies for treating menopause. According to Sierpina and Blessing (2000), the acquisition of knowledge related to herbal therapies is invaluable "if for no other reason that to help interpret what your patients are doing" (p. 40).

The urgency for health care professionals to become more informed about the terminology and common usage of alternative therapies is further evidenced by new Canadian federal regulations governing 50,000 over-the-counter natural health products (Sibbald, 2003). These regulations, which took effect in January 2004, include practices

such as labeling and monitoring the use of natural health products, and the notification of adverse effects (Sibbald, 2003). In addition, each natural health product will be licensed and assigned a natural health or homeopathic product number similar to the current Drug Identification Number [DIN] used on all consumer health products (Sibbald, 2003). The Natural Health Products Directorate (NHPD) is hoping that practices such as these will (a) enable the consumer to gain valuable health related product information that is supported by evidence from clinical trials, published studies, and traditional references, and (b) not be solely reliant upon manufacturers' claims of the effects of their products (Sibbald, 2003). The NHPD is currently compiling 300 "sample" monographs for commonly used alternative health products to provide consumers with the information they need to make an informed choice based on the latest research (Sibbald, 2003).

List of 7 Commonly Used Herbs, 3 Food Products and 1 Vitamin for the Treatment of Menopausal Symptoms

This practicum project will focus on 7 most commonly used herbs as identified below, three products derived from a food source namely, flax, soy, and wild yam and Vitamin E for treating menopausal symptoms. These products are alphabetically listed below. They are by no means intended to be an exhaustive list and neither are they presented in any order of importance. For the purpose of this practicum project the following alternative remedies will be explored in greater depth.

Herbs

Black Cohosh: (*Cimicifuga racemosa*)
Purported Use: Reduces the symptoms of hot flashes, breast tenderness, depression, irregularity and dysmenorrhea.

Chasteberry: (*Vitex agnus-castus*)
Purported Use: Helps with decreased libido, vaginal dryness, dyspareunia

Dong quai: (*Angelica sinensis*)
Purported Use: Menstrual regulation, PMS, dysmenorrhea, fatigue, oligomenorrhea, uterine spasm, dry vagina and palpitations.

Ginseng: (*Panax ginseng*)
Purported Use: Increased energy levels, and metabolic rate. Recommended for hot flashes, stress and headaches.

Red clover: (*Trifolium pratense L*)
Purported Use: Vasomotor symptoms, cardiovascular disease, increase bone loss

St. John's Wort: (*Hypericum perforatum*)
Purported Use: Reduction of symptoms of depression

Valerian: (*Valerian officinalis*)
Purported Use: To alleviate insomnia

Foods

Flax seed and oil: (*Linum usitatissimum*)
Purported Use: Protects against heart disease and cancer

Soy or isoflavones:
Purported Use: Reduction of vasomotor symptoms and to prevent bone loss.

Wild yam: (*Dioscorea villosa*)
Purported Use: Used for decreased libido, vaginal dryness.

Vitamin

Vitamin E (*Alpha tocopherol*)
Purported Use: Cardiovascular support and treatment of hot flushes

Summary

Chapter 1 addressed the purpose, rationale and significance of this practicum project. This practicum project begins with the premise that women experiencing menopause should at least have the opportunity to increase their knowledge on the use of alternative therapies in order to make informed choices. It is hoped that the development of an information booklet regarding the aforementioned list will provide menopausal women with the information they require to facilitate informed decision-making.

As identified in the literature, chapter 2 focuses on the indications, contraindications, side effects, dosages, and special instructions for each of the seven identified herbs, three foods and one vitamin. Chapter 3 will focus on the theoretical and methodological context informing the development and use of an information booklet for potential users. In chapter 4, the information booklet will be presented in a manner that is mindful of the audience for which it is intended. Finally, chapter 5 focuses on conclusions and recommendations that flow from this practicum project.

CHAPTER 2: REVIEW OF THE LITERATURE

Overview

A literature search was conducted using MEDLINE, CINAHL and the Cochrane Library of systematic reviews. Keywords used in the search were menopause, herbal remedies, climacteric, alternative/complementary therapies and perimenopause.

The literature review is divided into two major sections. The first section explores the literature surrounding the treatment of menopause prior to the findings of the effects of hormone replacement therapy (HRT) in July 2002. Section two examines the evidence for the use of alternative therapies as a part of an individual's overall health care in treating their menopausal symptoms.

Section 1: Conventional Treatment for Menopause

Over the past several decades, the conventional practice for treating menopausal symptoms was to prescribe hormone replacement therapy (HRT) (Mahafee-Gingrich & Ingram-Fogel, 2003). In the United States of America, the use of HRT in women increased from 5.7% in 1989 to 10.9% in 1996 (Bain, Lumsden, Sattar & Greer, 2003). It was believed that the use of HRT would benefit perimenopausal women by providing them with an exogenous source of estrogen to help alleviate the vasomotor and urogenital symptoms, and also provide them with a reduced risk of developing heart disease and osteoporosis (NAMS, 2000). For most women with an intact uterus, the use of combined (estrogen and progesterone) HRT presented the best option, because there was a lesser chance of developing endometrial hyperplasia and cancer (Bain et al., 2003). The most widely used estrogen product in North America was conjugated equine estrogen derived from the urine of pregnant mares and marketed as Premarin (NAMS, 2000). The

progestin formulation for endometrial protection was oral medroxyprogesterone acetate or Provera (generics) (NAMS, 2000).

In 1991 the U.S. National Institute of Health (NIH) funded the Women's Health Initiative (WHI), a series of studies to evaluate the risks and benefits of two types of HRT and to see how they affected the incidence of heart disease, breast cancer, colorectal cancer, and fractures in post-menopausal women. Two particular arms of this study are of specific interest to this practicum project. One arm involved approximately 17,000 women ages 50-79 years who had not had a hysterectomy. This group of women took a combination of estrogen and progestin pills or a placebo daily. The second arm involved more than 10,000 women who had undergone a hysterectomy. They took only estrogen pills or a placebo. The WHI study hypothesized that the use of HRT in postmenopausal women should provide relief from the vasomotor and urogenital symptoms associated with menopause, as well as protection from osteoporosis and coronary artery disease (Day, 2002). The findings of the WHI, especially for women who had not had a hysterectomy, moved them to prematurely end this arm of the study in July 2002. Compared to placebo, specific study findings for the first arm included the following:

- 41 % increase in stroke;
- 29 % increase in heart attacks;
- 50% increase in the rates of venous thromboembolism ;
- 22% increase in total cardiovascular disease;
- 26% increase in breast cancer;
- 37 % reduction in colorectal cancer; and

- 24 % reduction in total fractures;

As a consequence of these findings, the estrogen and progesterone arm of the WHI study was halted in July 2002 (JAMA, August, 2002). Following the results of the WHI study, HRT use in North America declined substantially (Hersh, Stefanick, & Stafford, 2004). Due to the association of HRT with an increased risk of cardiovascular events and breast cancer, many women today are seeking more natural approaches to managing their menopausal symptoms (Penrose White, & Schilling, 2000).

Patient and Provider Characteristics Related to Complementary Alternative Medicine

The findings of Barrett et al. (2000) confirmed the importance of a provider-patient relationship and the principles needed to guide health care professionals in the modern age. In their study, they investigated the knowledge, attitudes, and practices of patients and providers of complementary and alternative therapies. Four principles of health care: holism, empowerment, access, and legitimization emerged from their research. It is important to take these patient-provider related principles into account as they could potentially decrease the risk of alienating modern day patients (Sierpina & Blessing 2000) and increase health care professionals' relevance to their clients.

According to Barrett et al. (2000) women today are demanding to be treated as a whole person rather than as "a composite of numerous bio-medical attributes" (p. 236). Barrett et al. defined this approach as holism. Today, women/clients want to be considered as whole beings rather than fragmented composites of numerous physical ailments. At the same time, there is also a desire among health care professionals to treat their clients from this perspective (Barrett et al.).

Barrett et al. (2000) also linked the shift to alternative medicine to the concept of empowerment, which is understood as the desire of women/clients to take responsibility for their own health. They suggested that many women/clients are becoming disillusioned with their conventional health care providers because, by acting in ways that are condescending, disparaging, and paternalistic, they are seen as disempowering. In contrast, complementary healers were seen as encouraging the client in the process of taking personal responsibility for their own health.

The shift by health care professionals to recommending complementary medicine is, however, not without its challenges. Both women/clients and practitioners desire accessibility to timely, holistic, and all encompassing care. However, accessibility to complementary or alternative medicine is often an "out of pocket expense" and less economically feasible from the women/clients' point of view. While conventional medicine is usually paid for by the individual's health insurance and, hence, not considered an "out of pocket expense", alternative or complementary choices are not usually covered by one's health insurance and considered an "extra" expense. The decision by some women to use alternative medicine for treating their symptoms of menopause is an indication that it may be an expense they think is worth paying for. Further, women can purchase these therapies over the counter without the need for medical appointments. As a consequence of these challenges, health care professionals need to be responsive to what modern day health care users consider valuable for their health.

Finally, legitimization of complementary or alternative therapies is an area that many conventional practitioners in North America and the United States have difficulty accepting. The relative lack of results from Randomized Control Trials (RCT's) conducted on alternative or herbal therapies may make the advocating of certain alternative therapies difficult for some practitioners to recommend (Barrett et al., 2000). However, according to the Thomas C. Chalmers Centre for Systematic Reviews in Ottawa, there are already 5,000 to 10, 000 RCT's on various herbal products worldwide. It is encouraging to note that a body of hard evidence related to the use of herbal therapy is growing (Ernst, 2003; Sibbald, 2003). It is hoped that evidence from these RCT's, will contribute to the legitimization of alternative therapies within the larger health community.

Sources of Information

Information about herbs can be obtained from a variety of sources. In Mahafee-Gingrich and Ingram-Fogel's (2003) research on the use of herbal therapy by perimenopausal women, almost three quarters of the 40 women in their convenience-sample obtained their information about herbs from books, magazines and newspapers. Two-thirds identified family and friends, and just over one third mentioned television, radio and "the helpful clerk at the health food store" (p.186) as their sources of information. At the same time, one third obtained their herbal information from complementary and alternative practitioners, such as massage therapists, herbalists, acupuncturists, chiropractors, and naturopaths. Advanced Practice Nurses provided

herbal information for one in five respondents. Registered nurses were not common sources of information about herbs (Mahafee-Gingrich & Ingram-Fogel).

While women are seeking more information about herbal therapy in general, Richter et al. (2001) discovered that most women did not, or could not articulate what specific herbs, supplements, or protocols they could use for their menopausal symptoms. Some women expressed an interest and desire in learning about alternative therapies and the options available to them. This was evidenced by comments such as " I wish there was more information...that I could make a decision on my own" (p. 35).

Information about herbal therapies for the purpose of this practicum project was gleaned from the medical and nursing literature using principles of evidence-based practice (EBP). This method of evaluating the literature relied on a careful examination of clinical research and the applications of formal rules of evidence in evaluating the legitimacy of research findings (Hamric, 2000). A key component of EBP is the notion of "levels" or strength of evidence (Hamric, 2000). Appendix A provides a guide for interpreting evidence. While acknowledging the place for qualitative research, a decision was made in this practicum project to use only the results from RCT's in order to increase the ability of herbal therapy users to make an informed decision. The information will be presented in a format that the lay-person can understand and use if they so choose.

Since the results of the WHI study (July, 2002), women are looking for alternative ways to deal with their menopausal symptoms. It is likely that herbal therapies will be examined more closely for their potential usefulness in dealing with these symptoms. In the next section the evidence for particular herbal therapies from the empirical literature

will be examined. Information regarding the type of herbal therapy, its indication for use, side effects, dosages, and special instructions will be presented. A glossary of clinical terms is presented in Appendix B.

Section 2: Evidence of Specific Alternative Therapies as Reflected in the Literature

Herbs, foods, and vitamin organize the information that follows. Presented alphabetically, they are not presented in any order of importance and neither are they meant to be an exhaustive list.

Herbs

Black Cohosh/Actaea formerly (Cimicifuga Racemosa)

Indications

Black Cohosh is a member of the buttercup family and has a long-standing history in folk medicine, especially among Native Americans who boiled the root in water and drank the resulting medicinal liquid to treat labor pain; menstrual difficulties, upset stomach, and arthritis (Seibel, 2003). Black Cohosh also has been used for other symptoms of menopause such as depression, and anxiety (Newton et al., 2002). Remifemin is the trade name of an approved standardized extract of Black Cohosh that is manufactured in Germany under the jurisdiction commission E and available in the United States for the treatment of menopausal symptoms (Weil et al., 2000). While Black Cohosh is marketed under the trade name of NUFEM in Canada, the German product Remifemin is not available in Canada (Nguyen, 2003).

In a 1987 study by Stoll, as cited by Dog et al. (2003), Black Cohosh was used in 80 patients treated for 12 weeks with Remifemin, conjugated estrogens, or placebo. The

Black Cohosh preparation was found to be more effective in reducing anxiety, hot flashes, and atrophic vaginitis (Level 1 evidence).

Two out of 3 RCT's done to examine the estrogenic effect on vaginal epithelium reported a stimulatory effect. Black Cohosh appears to have a positive effect on vaginal epithelium and may act to prevent the condition known as dyspareunia, or painful intercourse, that sometimes occurs (Level 1 evidence) (Kronenberg & Fugh-Berman, 2002). Physiologically Black Cohosh appears to mimic the effects of estriol, a weaker form of estrogen than estrone or estradiol (Meschino, 2002). Consequently, it should be safe to recommend to women with estrogen dependent neoplasms or those with estrogen related disorders, such as Deep Vein Thrombosis (DVT) (Gass & Taylor, 2001). However, other researchers are not as quick to make the same suggestion. Seibel (2003) suggested that, since Black Cohosh has weak estrogenic effects on the breast, it should be used with caution in women with breast cancer or a high risk of breast cancer.

Other research conducted by Stolze (1982) in Germany and Lieberman (1998) in the United States suggested that women who had menopausal symptoms such as hot flashes, night sweats, headaches, nervousness, and depression showed improvement with the use of Remifemin (Level 11-2 evidence). This extract is standardized to contain 20 mg of Black Cohosh extract including 1 mg triterpene glycosides 27 deoxyactein per tablet (Gass & Taylor, 2001). Jarry, Harnischfeger, and Dueker, (1985) as cited in Newton et al. (2002), examined the mechanism by which Black Cohosh appeared to exert its beneficial effects. They discovered the presence of several constituents in the roots that are capable of interacting with the estrogen receptor. One of these plant estrogens has

been identified as formononetine. This phytoestrogen appears to interact with estrogen receptors as a weak partial agonist thus exerting its estrogenic effects (Newton et al., 2002).

Perimenopausal women generally have higher levels of two hormones - Follicle Stimulating hormone (FSH) and Luteinizing hormone (LH) - and lower levels of estrogen. Their menstrual pattern becomes irregular and bleeding, when it does occur, can be heavier and more prolonged than usual (Bain et al., 2003). Three of 4 studies showed that Black Cohosh had no effect on either of these two hormones and therefore, had no effect on the erratic and prolonged bleeding that characterizes this stage (Level 11-3 Evidence). Other researchers examined the active ingredient triterpene and found it acts as a precursor or building block for the synthesis of progesterone in the body (Meschino, 2002). This may help to preserve the declining progesterone balance thus preserving bone health and maintaining libido and psychological well-being (Level 11-3 Evidence) (Meschino, 2002).

Side effects and contraindications

Side effects of Black Cohosh include gastrointestinal discomfort, headache, dizziness, weight gain, heaviness in the legs, and cramping. Large doses have also been associated with bradycardia and miscarriage (Level 111 evidence) (Weil et al., 2000).

Menopausal women may be taking a variety of other herbal therapies along with Black Cohosh to alleviate their symptoms. This is generally not recommended as some products can cause negative interactions. For example, the use of Black Cohosh with chasteberry and evening primrose oil can cause nocturnal seizures (Nguyen, 2003). In

addition, the use of Black Cohosh with Tamoxifen and or any antihypertensive medication may potentiate the drugs effects leading to an increase in side effects such as light-headedness and nausea. Black Cohosh may decrease the absorption of iron containing drugs leading to a less than therapeutic effect. Therefore, women who are taking iron supplements for anemia may have to increase their dosage of iron in order to achieve the desired effect (Nguyen, 2003).

Dosages and special instructions

Some Black Cohosh products have a Drug Identification Number (DIN) and are subject to regulations by Health Canada, similar to other pharmaceutical products. This indicates that these products have been subject to more stringent production protocols and contain a standardized dose of the active ingredient for that particular brand. This gives the consumer a greater level of confidence in the quality of products they are purchasing. The recommended dosage of Black Cohosh is 20 mg by mouth two times per day (20 mg tablet = 1 mg triterpene glycoside) and is found in the standardized product Nufem, that is available in Canada. Other authors suggest the use of up to one teaspoon of dry powdered Black Cohosh in a tea or tincture helps alleviate the vasomotor symptoms of menopause (Lindsay, 1999). The German commission E recommends the dose of Black Cohosh to be between 40 to 80 mg per day of the product Remifemin, and the length of use should not exceed six months (Weil et al., 2000). The reason for this duration of use is that no clinical trials of Black Cohosh have lasted more than 6 months. As a consequence, women who use this product as a form of "natural" hormone replacement therapy are cautioned against the use of this herb for more than 6 months. Counseling

women/clients on the recommended length of use of Black Cohosh is important from a safety perspective. Information of this nature will be included in the booklet on alternative therapies being developed as part of this practicum project.

There appears to be a lack of consensus in the literature regarding the use of Black Cohosh for menopausal symptoms. Weil et al. (2000) suggested that initial studies of Black Cohosh indicated a reduction in symptoms of hot flashes in menopausal women. Although preliminary evidence is encouraging, currently available data are not sufficient to support a recommendation on the use of Black Cohosh for menopausal symptoms (National Institutes of Health (2003). Further long-term RCT's are needed to confirm its effectiveness prior to the clinician recommending its standard use for menopausal symptoms.

Chasteberry/Chaste Tree Berry/Vitex Agnus-Castus

Indications

Chasteberry has been widely used in Europe for treatment of hot flashes, breast tenderness, and dysmenorrhea and is recommended by the German commission E for these symptoms of perimenopause and menopause (Weil et al., 2000). There are data supporting the use of chasteberry in reducing breast tenderness for perimenopausal women because it decreases the release of prolactin (Level 11-3 evidence) (Weil et al., 2000). Another author suggested its use for decreased libido, vaginal dryness, and dyspareunia (Level lll evidence) (Nguyen, 2003). However, there is a lack of controlled studies documenting any effects in menopausal women and there are no documented beneficial effects in the treatment of hot flashes (Level lll evidence) (Weil et al., 2000).

Side effects and contraindications

Chasteberry has been used in many African countries for thousands of years and is reputedly free of most side effects (Lindsay, 1999). However, it is known that continuous use of this product for more than eighteen months may cause itching, gastrointestinal complaints, and intermenstrual bleeding (Nguyen, 2003). The consumption of chasteberry with Black Cohosh and evening primrose oil can cause nocturnal seizures (Level 1 evidence) (Nguyen, 2003). Other potential drug interactions could also occur between the consumption of chasteberry and anti-psychotics, anti-Parkinsonian agents, or bromocriptine (Level 11-2 evidence) (Weil et al., 2000). While Nguyen (2003) documented the potential negative effects with neuroleptics, oral contraceptives, Hormone Replacement Therapy (HRT), and metoclopramide, his documentations were not substantiated by evidence (Level lll evidence).

Dosages and special instructions

Chasteberry is generally well tolerated and used safely in trials up to 1.5 years in length (Nguyen, 2003). It may be recommended for premenstrual women who have mastalgia as it has been shown to be effective in decreasing prolactin levels (Tesch, 2003). The German commission E has endorsed Chasteberry for the treatment of premenstrual syndrome mastalgia and menopausal symptoms (Dog et al., 2001). However, there is no clear evidence supporting a recommendation of chasteberry for the treatment of vasomotor symptoms of menopause (Weil et al., 2000).

Despite the lack of scientific evidence for the use of chasteberry, some women may still choose to use it for their menopausal symptoms. Menopausal women who want

quick and immediate results may be disappointed, as the effects may not be seen for up to 3 months. The recommended daily dosage of this herb is three capsules of freshly powdered berries or 1 cup of tea of powdered berries taken for several months before results are seen (Lindsay, 1999).

Dong Quai (Angelica Sinesis)

Indications

Dong Quai herb originated in China and is commonly used for treating a variety of premenstrual and menopausal symptoms (Kronenberg & Fugh-Berman, 2002). While it is most often used as part of a mixture of herbs in China, it is sold as a single entity in the West (Seibel, 2003). Dong Quai is thought to act as a phytoestrogen and exert estrogenic action on the vagina and uterus aiding in the regulation of menstrual irregularities, PMS, dysmenorrhea, and oligomenorrhea (Level 1 evidence) (Lindsay, 1999). However, these claims of its estrogenic activity are probably inaccurate, as clinical studies done using monopreparations of Dong Quai have not demonstrated this effect (Level 1 evidence) (Dog et al., 2001). For example, in their study, Hirata et al. (1997) randomly prescribed 71 women to receive either three capsules of Dong Quai powder or placebo for 24 weeks. There were no statistically significant differences between the two groups in terms of hot flashes, night sweats, or vaginal dryness. In addition, no signs of estrogen-like stimulation of the uterine lining were discovered (Level 1 evidence). Other authors, such as Chang (1987) and Hudson et al. (1997) stated that Dong Quai formulas may help decrease the severity and frequency of hot flushes (Level 1 evidence).

The aqueous extract of Dong Quai has shown a decrease in whole blood viscosity, improved circulation, and an inhibitory effect on thromboses (Level 1 evidence) (Chandler, 2000). This effect could potentially assist menopausal women who, due to the decline in circulating estrogen, are at increased risk of cardiovascular disease and its related complications.

Side effects and contraindications

Dong Quai can cause photodermatitis and phototoxicity if applied externally and there is a concern that one of its active components is a carcinogen (Weil et al., 2000).

Other concerns over its safety arise over its anticoagulation effects and the potential risk of uncontrolled bleeding due to the presence of a coumarin derivative, such as psoralen (Lindsay, 1999; Weil et al., 2000). The use of Dong Quai with Warfarin potentiates its anticoagulative effects (Level 11-2 Evidence) (Nguyen, 2003) Therefore women who may be on anticoagulant therapy for other medical conditions such as deep vein thrombosis, should be made aware of the potential of the additive effect of using Dong Quai. It would be interesting to know whether there are any studies on the use of Dong Quai as a substitute for traditional anticoagulation therapy. None were found in the literature reviewed.

Dosages and special instructions

For those who take Dong Quai for fatigue, menstrual irregularities, and dysmenorrhea, the dose is generally 3.5 to 4.0 gms per day of the dried root. This is equivalent to 200 mg three times daily of a standardized extract containing the active

ingredient called ligustilide. For the tincture where an aqueous – alcoholic solution exists in a (1:1) formulation, the dose is .5 to 2.0 mls, three times daily (Chandler, 2000).

There is no clear evidence supporting the use of Dong Quai **alone** for treatment of the vasomotor symptoms of menopause (Level 1 evidence) (Weil et al., 2000). There are some peer reviewed human data to indicate that its use as a combination formula with other herbs is of some benefit for menopausal symptoms (Level 1 evidence) (Chandler, 2000). However, the precise nature of those menopausal symptoms was not identified. Therefore, according to Weil et al. (2000) the use of Dong Quai in combination with other herbal agents has not been evaluated sufficiently to support recommending its use for the vasomotor symptoms of menopause.

Ginseng (Panax Ginseng)

Indications

Ginseng is one of the more popular herbal products sold in the United States and has been used in Asia for over 2,000 years (Tesch, 2003). Its active ingredients are the saponins or ginsenosides which contain a chemical similarity to estrogen, albeit in a mild form (Lindsay, 1999; Seidl & Stewart, 1998). In addition, the ginsenosides act as scavengers of free radicals which are a precursor to some cancers. The name Panax ginseng alludes to its purported panacea –like quality (Tesch, 2003). In Chinese medicine, ginseng is used as an adaptogen, acting by increasing the body's resistance to physical, chemical and biological stress (Tesch, 2003). Some human, animal and in vitro studies have supported its use for symptoms of anxiety, weakness, fatigue, forgetfulness, and decreased libido (Level 11 evidence) (Chandler, 2000; Lindsay, 1999; Tesch, 2003).

Ginseng is reputed to encourage natural estrogen production in women and is thus used by many women in menopause (Lindsay, 1999). Ginseng is often recommended as a method to try and reduce the vasomotor symptoms of menopause such as hot flashes and night sweats (Gass & Taylor, 2001). However, the evidence for its use in this regard is still lacking.

A16-week placebo-controlled study of almost 400 menopausal women using ginseng found that vasomotor symptoms were not reduced. However, improvements were noted on scales used to rate depression, general health and well-being (level 11-2 evidence) (Gass & Taylor, 2001). This finding was supported by another study by Wiklund et al. as cited in Tesch (2003). This study consisted of a multicenter, double-blind, parallel group study with 284 perimenopausal women. The authors found that women taking ginseng reported less depression and improved well-being but there was no effect on their hormonal parameters (Level 1 evidence).

Commercial preparations of ginseng vary widely in quality due to the lack of stringent guidelines by government and manufacturers. In its purest form, panax ginseng is expensive and consequently many products contain little, if any of the active ingredient and are often contaminated with other substances that may do more harm than good (Tesch, 2003). The importance of standardized dosing for herbal therapies cannot be overemphasized. This is especially important with ginseng. Due to its expense, it is often sold in an adulterated form. The consumer may be caught unawares and believe they are receiving the therapeutic dosage of the herb when in reality they are not (Chandler, 2000).

From the literature reviewed, there is no definitive recommendation that can be made on the use of panax ginseng for menopausal symptoms. Practitioners may recommend it with extreme caution for symptoms of fatigue, decreased energy, and mild depression (Tesch, 2003). Further independent studies are needed to more fully determine whether ginseng offers any true benefit to menopausal women (Gass & Taylor, 2001).

Side effects and contraindications

Women taking ginseng have reported vaginal bleeding and mastalgia (Tesch, 2003). Ginseng interacts with the anticoagulant warfarin, and has shown to reduce the International Normalized Ratio (INR) in patients on warfarin therapy (Kronenberg & Fugh-Berman, 2002; Tesch, 2003). The significance of this is that individuals taking warfarin are obviously in need of anticoagulation for one reason or another. An increase in their clotting mechanism places them at greater risk of strokes and blood clots. Individuals taking ginseng may be totally unaware of this risk placing them in even greater jeopardy.

Seidl and Stewart (1998) and Tesch (2003) strongly recommended that women experiencing hypertension, headaches, heart palpitations, insomnia, asthma, fever, and schizophrenia avoid the consumption of ginseng. Other negative effects associated with ginseng are that it has been associated with falsely elevated digoxin levels because of interference with the assay (Tesch, 2003).

Dosages and special instructions

Ginseng is marketed in many forms such as slices, tonics, powders, tablets, teas, extracts, and mineral drinks. The quality of the product purchased varies widely

depending on the producer. However, a rule of thumb is that the product should contain 1% to 6% of selected ginsenosides, (the active ingredient) (Chandler, 2000).

The dose is 100 to 300 mg of liquid ginseng extract three times a day or 0.5-1.0 grams of the dried processed root twice a day for 15 to 20 days .The woman/client should then be evaluated for any potential adverse effects. Long-term safety data on the use of ginseng is lacking, therefore ginseng should not be used for periods of longer than one month duration (Tesch, 2003).

Red clover/Trifolium Pretense

Indications

Red clover is a herb that contains the phytoestrogens formononetin, biochanin A, diadsein, and genistein as well as coumestrol (Fugh-Berman & Kronenberg, 2002; Newton et al., 2002). It is sold in North America under the trade name Promensil (Fugh-Berman & Kronenberg, 2001). Its use has been investigated for decreasing the vasomotor symptoms of menopause, decreasing serum cholesterol levels, increasing arterial compliance, and increasing bone mineral density (Newton et al., 2002). Its original use was by the Native Americans to treat whooping cough, gout, and cancer (Seibel, 2003).

Two double-blind placebo controlled trials did not find red clover extract to be significantly more beneficial than placebo for the vasomotor symptoms of menopause (Level 1 evidence) (Fugh-Berman& Kronenberg, 2001; Newton et al., 2003). A RCT of 252 menopausal women aged 45-60 who were experiencing 35 hot flashes per week compared the dosages of Promensil (82 mg/day of total isoflavones) and Rimostil (57 mg/day of total isoflavones) with placebo. At the end of twelve weeks the hot flash count

was similar for the Promensil, Rimostil, and placebo group. However, in comparison with the placebo group the Promensil group had a more rapid reduction in frequency of hot flashes (Level 1 evidence) (Tice et al., 2003). Given that the overall reduction in hot flashes was no different between the three treatment groups, and the effect of the isoflavone supplementation on rate of reduction was seen only for the Promensil group, it could be argued that the results were due to chance alone and not due to the biological effects of the isoflavones (Tice et al., 2003). On the other hand, the results may indicate that the isoflavones found in the Promensil formulation were more effective for hot flash reduction than the active ingredients found in the Rimostil.

More recently, results from two unpublished trials were presented at the International Menopause Society World Congress in Tokyo. The results of the first trial suggested that 40 mg of Promensil versus placebo in 30 postmenopausal women over 4 months resulted in a 75% reduction in hot flashes in the Promensil group versus the placebo group (Fugh-Berman & Kronenberg, 2001). The second trial used 40 mg of Promensil in postmenopausal women over a 2 month period, resulting in a decrease in hot flashes and night sweat severity of 43-52% (Level 1 evidence) (Fugh-Berman & Kronenberg, 2001). The results of these studies suggest that the use of Promensil taken over a longer period of time such as four months versus two months may be of greater benefit to menopausal women with symptoms of hot flashes and night sweats (Fugh-Berman & Kronenberg, 2001).

Red clover has also been investigated for its cardiovascular effects in menopausal women (Newton et al., 2002). Overall, the investigators found that arterial compliance

was significantly improved with the use of Promensil, but the downward trend in LDL cholesterol and the upward trend in HDL cholesterol did not result in a statistically significant change in plasma lipid levels (Level 1 evidence) (Newton et al., 2002).

Fugh-Berman & Kronenberg in 2001 and Newton et al. have studied the effects of red clover on bone mineral density in menopausal and postmenopausal women. In 2002, Atkinson, Compston, Robins and Bingham (2000) as cited in Newton et al. discovered perimenopausal women taking red clover isoflavones at a dose of 40 mg/day, had a significantly reduced loss of spinal bone mineral density and bone mineral content over a period of one year than women not taking this herb. However, this benefit does not apply equally to menopausal or postmenopausal women. The reasons for this are unclear.

Clinical studies do not support the use of standardized red clover extract for the treatment of menopausal hot flashes or hypercholesterolemia (Fugh-Berman & Kronenberg, 2001). Ongoing studies with different manufacturers of red clover products are needed to test the effects on bone mineral density, cholesterol levels, arterial compliance and endometrial thickness particularly in menopausal women (Fugh-Berman & Kronenberg, 2001)

Side effects and contraindications

Through an in-vitro study, Dog et al. (2001) concluded that red clover stimulated proliferation of estrogen positive breast cancer cells. This led these authors and Newton et al. (2002) to recommend against the use of red clover therapy in women who have had an estrogen-receptor positive cancer. However, its use in other menopausal women remains inconclusive at best. In addition, the possibility of endometrial hyperplasia due to

the estrogenic effects of red clover has not been ruled out (Fugh-Berman & Kronenberg, 2001). Red clover has also been identified as containing coumarin like substances, which cause the blood to thin (Seibel, 2003). As a consequence, patients on anticoagulants such as coumadin, heparin, aspirin, clopidrogel or pentoxifylline may be at increased risk of bleeding (Siebel, 2003).

Dosages and special instructions

The recommended dosage of Red clover is 40 mg per day when used for the treatment of hot flashes. Due to its potential for significant adverse effects on blood clotting, it may be beneficial to include prothrombin time, partial thromboplastin time, and International Normalized Ratio as a test for coagulation (Fugh-Berman & Kronenberg, 2001).

St. John's Wort (Hypericum Perforatum)

Indications

St. John's Wort has been widely sold in Europe for the treatment of depression (Ahlgrimm et al., 1998). In Germany it is prescribed 20 times more often than the antidepressant Fluoxetine (Chervenak, 2003). Variable hormonal levels during the perimenopausal and menopausal years can lead to fluctuations in emotional wellbeing (Ahlgrimm et al, 1998). Many women do not want to take antidepressants for fear of becoming "addicted" and are looking for "natural" methods of enhancing feelings of well-being. St. John's Wort is purported to exert its mechanism of action in two ways: (a) a Monoamine oxidase inhibitor (MAOI) effect, and (b) as a selective seretonin reuptake inhibitor (SSRI) mechanism (Weil et al., 2000). More recent evidence suggests that it

may actually involve several different neurochemicals including gamma-aminobutyric acid (GABA), dopamine, and norepinephrine to varying degrees (Bonakdar, 2003; Tesch, 2003).

A 1996 meta-analysis of 23 randomized clinical trials involving almost 2000 patients with depression found St. John's Wort to be superior to placebo and as effective as prescription medication for the treatment of mild to moderate depression. However, no trial lasted longer than 8 weeks (Tesch, 2003). Other randomized multi-center, double-blind parallel group trials done in 40 out-patient clinics in Germany compared patients taking St. John's Wort to the antidepressant imipramine. The results indicated that patient's taking St. John's Wort scored better on the Hamilton Depression Rating Scale and Patients Global Impression Scale than those taking the conventional antidepressant (Level 1 evidence) (Tesch, 2003).

Although the German commission E monograph for St. John's Wort does not specifically list menopausal symptoms as one of its uses, many practitioners and patients use it to ameliorate symptoms of mild depression during the perimenopausal and menopausal years (Weil et al., 2000). Glisson, Crawford, & Street (1999) suggested that St. John's Wort may be particularly helpful for individuals with somatic symptoms, such as fatigue and seasonal affective disorder.

According to some researchers, the evidence for the use of St. John's Wort is turning out to be quite favorable for its efficacy in treating some of the negative symptoms of menopause (Chandler, 2000). However, while some practitioners are recommending the use of St. John's Wort (Chervenak, 2003) for the treatment of mood

disorders, others are suggesting that more double-blind, placebo controlled studies be conducted (Tesch, 2003).

Side effects and contraindications:

According to a recent report, St. John's Wort is the most common herb involved in drug interactions due to its utilization of the cytochrome P- 450 system by which more than 50% of all medications are metabolized (Bonakdar, 2003). Side effects, as reported in the Cochrane meta-analysis of 2,291 patients, include gastrointestinal symptoms, dizziness and confusion, sedation, and dry mouth (Tesch, 2003). Other documented interactions include those with cyclosporine, amitriptyline, digoxin, Indinavir, warfarin, theophylline, oral contraceptives, selective seretonin re-uptake inhibitors, and loperamide (Bonakdar). In addition, anesthetists have reported sporadic cases of either inhibition or potentiation of anesthetics in patients taking St. Johns Wort (Gass & Taylor, 2001). Current recommendations call for a 3-week washout period before any operative-procedure, requiring anesthesia (Gas & Taylor, 2001). Users of St. John's Wort should avoid prolonged exposure to the sun and artificial tanning salons due to the risk of photosensitivity (Chandler, 2000).

Individuals taking St. John's Wort and either digoxin or indinavir should be given a special warning due to increasingly severe interactions between these two drugs and the herb (Bonakdar, 2003). In response, several countries including Japan, the United Kingdom, and Canada have restricted sales and regulated labeling. The French government banned the sale of all food products and health supplements containing St. John's Wort (Tesch, 2003).

Dosages and special instructions

For mild to moderate depression the initial dose is 300 mg three times a day of the standardized hypericum extract (McCutcheon, 2000). The dose may be increased to 1800 mg per day if it seems insufficient, and then tapered to a maintenance dose of 300-600 mg per day (Chandler, 2000). A therapeutic effect usually occurs within 10 to 14 days and a significant response should be apparent after 4 to 6 weeks (Chandler, 2000). The increased consumer interest in herbal therapies for treatment of depression has prompted a great deal of research in this area.

Valerian/Valeriana Officinalis

Indications

The use of the Valerian root as a sedative and hypnotic agent goes back thousands of years (Ahlgrimm et al., 1998). Consumption of valerian root promotes the release of gamma aminobutyric acid and binds the same receptors as benzodiazepenes (Weil et al., 2000). The German commission E monographs recommends valerian root as a safe and effective treatment for restlessness and sleep disorders, as well as the vasomotor symptoms of menopause. However, no published data exist to support the use of valerian in the treatment of hot flashes (Weil et al., 2000).

Peer -reviewed human data have indicated that Valerian is useful in treating short-term insomnia without the residual morning sedation seen with many pharmaceutical drugs (level 1 evidence) (Chandler, 2000). Valerian root has been used safely in clinical trials up to 28 days duration (Level 1 evidence) (Nguyen, 2003). Other uses of Valerian described in recognized folklore references, but without clinical or scientific support,

include treatment of anxiety, tension, muscle cramping and indigestion, stress related palpitations, and uterine cramps (Level lll evidence) (Chandler, 2000).

Side effects and contraindications

Clients taking anxiolytics, sedatives, benzodiazepines, and alcohol should be cautioned about concomittant use of valerian as it could potentiate the effects of these drugs and increase central nervous system effects (Nguyen, 2003; Tesch, 2003; Weil et al., 2000). As a consequence, consumers are cautioned against driving or operating machinery after taking valerian due to its sedative effects (Tesch, 2003). Side effects of valerian root include headache, hangover, restlessness, and cardiac disturbances (Tesch, 2003).). Documented withdrawal symptoms include cardiac failure, delirium, ataxia, hallucinations, increased muscle relaxation, dystonic reactions, hypothermia, restlessness, and palpitations (Nguyen, 2003; Lindsay, 1999).

Dosage and special instructions

The usual dose of a standardized extract of valerian (0.8% valerenic acid) is 400-800 mg orally at bedtime for the relief of insomnia (Chandler, 2000; Nguyen, 2003). Two randomized blind, placebo-controlled crossover trials compared the use of 450 mg of valerian with a higher dose of 900 mg. The results indicated that the higher dose offered no advantage in terms of improved sleep quality, decreased sleep latency, and residual morning sedation (Level 1 evidence) (Tesch, 2003). According to Weil et al. (2000) there is no scientific evidence to support a recommendation of valerian root as a treatment for menopausal symptoms due to the lack of long-term safety data. However, given the results of the studies on the use of valerian for insomnia, it seems reasonable to suggest

that valerian could be recommended to menopausal women who often suffer from this debilitating symptom. There was no mention in the literature of a maximum duration for valerian use (Chandler, 2000).

Foods

Flax /Linum Usitatissimum

Indications

The seed of the flax plant contain the estrogenic precursor secoisolariciresinol diglycoside. This precursor is converted by bacteria in the colon into the estrogenic lignans enterodiol and enterolactone (Newton, Combest, Kosier & Davis, 2002). Lignans are phytoestrogens, compounds that have been shown to interact with the estrogen receptor as partial agonists, similar to the isoflavone phytoestrogen found in soy (Newton et al., 2002). Other known benefits of lignans include (a) protecting the body against cancer of the breast and colon, and (b) providing the body with two essential fatty acids namely, alpha linolenic acid or Omega-3 fatty acid and linoleic, or Omega-6, fatty acid (Kosier & Davis, 2002). Since the body does not manufacture these acids naturally, they must be obtained through the diet (Newton et al., 2002).

Several small studies done on animals have indicated that the ingestion of flaxseed may be useful for the prevention or treatment of cardiovascular disease (Chandler, 2000). Flaxseed can lower total and low-density lipoprotein cholesterol (TC & LDL cholesterol) but does not increase high-density lipoprotein cholesterol (HDL cholesterol) (Newton et al., 2002). Traditionally, flax has been used to treat a variety of gastrointestinal problems including constipation, irritable bowel syndrome and

diverticular disease (Chandler, 2000). In relation to perimenopausal and menopausal symptoms, clinical trials involving the concomitant use of soy and flaxseed have shown a decrease in the number of hot flashes (level of evidence not cited) (Newton et al., 2002).

Side effects and contraindications

Flax appears free of major adverse effects, however ingestion of large amounts of flaxseed, (greater than 32g of flaxseed oil daily for several months) may increase bleeding times and therefore should be used with caution in patients with a bleeding disorder and those taking anticoagulants (Chandler, 2000). The concomitant use of flax with other drugs may reduce the absorption of the other medication and therefore clients should be cautioned to wait at least two hours before taking any other drugs (Chandler, 2000). Diabetic clients have to be especially cautious as the ingestion of flaxseed reportedly decreased postprandial hyperglycemia due to the dietary fiber causing a delay in gastric emptying time (level 1 evidence) (Chandler, 2000). Flax should not be used in clients with acute abdominal pain or a suspected intestinal obstruction due to its bulk forming effect on the stool (Newton et al., 2002).

One animal study indicated that flaxseed oil taken with indomethacin, a non-steroidal anti-inflammatory drug (NSAID) led to a greater prevalence of stomach ulcers than ingestion of indomethacin alone (Chandler, 2000). Based on this report, caution is recommended with the use of flax with all NSAIDs (Chandler, 2000).

Dosages and special instructions

Flaxseed (whole or crushed) should be soaked in water before ingestion and should be taken with at least 150 ml of fluid per dose to avoid gastrointestinal obstruction

(Chandler, 2000). The usual dose of flaxseed oil is 20 g daily and up to 50 g of ground flaxseed daily. Ground or milled flaxseed should be stored in the refrigerator for no longer than 30 days duration for optimum freshness and nutritional quality. Whole flaxseeds can be stored in the a clean, dry container at room temperature for up to one year (Flax Council of Canada, 2000)

Soy or Isoflavones

Indications

Over the past few years the phytoestrogens have received much interest for their potential role in reducing the symptoms of menopause. The reason for this interest is that phytoestrogen, a plant based compound, is known to have a chemical structure similar to estrogen, but with less potency (Brewer, 2000). Sources of phytoestrogens include alfalfa, garlic, licorice, parsley, rice and soybeans (Brewer, 2000). The three main classes of phytoestrogens are isoflavones, lignans, and coumestins (Sidani & Campbell, 2002). Isoflavones are the most highly researched type of plant phytoestrogen. These are chemical compounds found in legume type plants, such as soy, flax and the leaves of red clover. Researchers became interested in these compounds when it was observed that cardiovascular disease and hormone dependent neoplasms were lowest in Asian countries where individuals consumed diets rich in these compounds (Level lll evidence) (Weil, Cirigliano, & Battistini, 2000).

In general, the average amount of isoflavones consumed in a typical Asian diet is approximately 50 mg/day. One gm of soy protein contains approximately 1 mg of soy isoflavones (Seibel, 2003). When ingested these compounds have an estrogenic or

antiestrogenic effect depending on their concentration, the concentration of endogenous sex hormones, and the specific end organ involved (NAMS, 2000). Isoflavones have a chemical structure similar to estrogen which enables them to bind to estrogen receptors. However, they are 100 to 1000 times weaker than estradiol, the most potent naturally occurring estrogen formed by the ovary, placenta, and possibly the adrenal cortex (Sidani & Campbell, 2002). Isoflavones act as a selective estrogen receptor modulator (SERM), exerting antiestrogenic effects in the high–estrogen environment of **peri**menopause and estrogenic effects in the low estrogenic environment of menopause (Seibel, 2003).

Kronenberg and Fugh- Berman (2002) reviewed 29 randomized controlled clinical trials of Complementary and Alternative medicine (CAM) for hot flashes and other menopausal symptoms (Level 1 evidence). Of these clinical trials, 12 dealt with soy or soy extracts. Unfortunately varying preparations of soy confounded the clinical trial data. For example, soy flour, soy protein isolates powder, and soy-containing foods such as tofu all contain varying concentrations of isoflavones. However, the preliminary results indicated that soy seems to have modest benefit for hot flashes although results are not entirely conclusive. In another double blind, parallel, randomized and placebo controlled trial to assess the effect of daily dietary supplementation of soy protein isolate powder on hot flushes in postmenopausal women, Albertazzi et al. as quoted in Sidani and Campbell (2002), discovered that women taking an isoflavone soy supplement of 40 gm per day in two divided doses had a 45% reduction in their daily hot flash frequency and severity, versus a 30% reduction obtained with the placebo ($P < .01$) (Level 1 evidence). This finding strongly suggested that the use of soy isoflavone supplements

could benefit the vasomotor symptoms of menopause (Level 1 evidence). Merritt (2001) investigated the demographic characteristics of climacteric events within Asian populations, especially the Japanese, due to their greater consumption of soy compared to Western populations. His findings suggested that dietary consumption of soy- based foods is protective against many early signs of menopause, especially hot flushes, mood swings, and night sweats (Level lll evidence).

More recently Alekel, St. Germain, and Peterson (2000) investigated the use of soy for its estrogen-like activity on bone metabolism in perimenopausal women. They discovered that participants who consumed up to 80 mg of soy protein per day had a significant, positive effect on their bone mineral density and bone mineral content [using dual energy x-ray absorptiometry (DEXA)] as compared to the other two groups who only consumed 4.4 mg of soy protein per day and the control. (Level 1 evidence). Hence their conclusion was that the use of isoflavones from soy protein might be useful as an adjunctive therapy for treating osteoporosis in menopausal women. However, whether these results can be extrapolated for use in postmenopausal women remains to be seen.

The use of soy has also been investigated for its cardio-protective and lipid lowering effects (Merritt, 2001). A recent meta-analysis of 38 published controlled clinical trials of soy protein consumption (47g/day on average) showed that the consumption of soy protein decreased total serum cholesterol levels, low-density lipoprotein cholesterol (LDL) and triglycerides (Level 1 evidence). (NAMS, 2000, Sidani & Campbell, 2002). The United States Food and Drug Administration (FDA) in October 1999 officially recognized the use of soy and soy products as a benefit for patients with

cardiovascular disease (Merritt, 2001). Menopausal women have a declining amount of circulating estrogen, which is though to put them at increased risk of cardiovascular disease. It may be that the use of soy may help decrease the risk of cardiovascular disease in this group (NAMS, 2000).

Side effects and contraindications

One of the risks of using soy or other compounds that contain phytoestrogens is their potential effect on the growth of estrogen dependent tumors. Because isoflavones and other phytoestrogens bind to estrogen receptors, they may promote the growth of estrogen dependent tumors, such as some types of breast cancer (Anderson, Anthony, Cline, Washburn, & Garner, 1999). McMichael-Phillips et al. (1998) raised a similar concern after their investigation of women taking a daily dose of 60 mg of dietary soy protein per day. Their findings suggested that even short-term use of soy protein isolates might increase the proliferation of breast epithelial cells in women. In addition, women with estrogen dependent breast tumors, taking the estrogen modulating drugs Tamoxifen or Raloxifene should avoid the use of soy or other phytoestrogens as it is not yet clear whether the soy compounds interfere with the effects of the chemotherapeutic drugs (Newton, Combest, Kosier & Davis, 2002).

On the other hand, postmenopausal women with breast cancer in Japan were found to have a more positive prognosis than those with breast cancer in the U.S. or Great Britain (Lindsay & Claywell, 1998). The speculation by researchers is that the increased amounts of phytoestrogens in the Japanese diet inhibits cell cancer growth and may even promote cell death or apotosis (Knight & Eden, 1996).

Side effects of soy include bloating and flatulence (Seibel, 2003). Interactions between soy and other drugs also can occur, such as a decreased absorption of calcium, iron, and zinc. The use of soy is not recommended for patients being treated for hypothyroidism as the soy may bind to the thyroid medication thus lowering absorption (Seibel, 2003). In addition, soy may increase theophylline levels in patients taking this drug predisposing them to serious consequences (Nguyen, 2003).

Dosage and special instructions

Optimal dosing remains a concern with most authors recommending between 20 to 60 gms of dietary soy protein per day. One cup of soy-milk contains 6-9 gms of soy protein and 100gms of tofu contains 8-14 gms soy protein. Therefore, the consumption of adequate amounts of soy protein through dietary sources may be difficult for most individuals to achieve on a regular basis. Anderson et al. (1999) infer that the bioavailability of isoflavones in isolated soy protein preparations may be better than that found in whole foods. His recommendation is that a combination of both isolated soy isoflavones and soy containing whole foods achieves the greatest benefit especially in promoting heart health. This premise is supported by Weil et al. (2000) who also recommend increasing the amount of dietary isoflavone by adding foods, such as Tofu, Tempeh, Miso, and soybeans to one's diet. Including these foods in one's diet appears to be a relatively safe and beneficial strategy that may improve, not only the vasomotor symptoms, of menopause but contribute positively to cardiovascular health (Level 1 Evidence) (Weil et al., 2000).

Some conclusions that can be made from studies done on soy and isoflavone are that the dosages of isoflavone needs to be quite high, in the 60-100mg /day range, in order to exert their beneficial effects on cells (Anderson et al., 1999). What are the implications of the use of soy for menopausal women? Based on the findings from the literature, it seems that the greatest benefits of soy are its cardiovascular protective effects (Level 1 evidence) (Anderson et al., 1999). These effects are best seen when the purified isoflavone supplements are added to the soy protein obtained from a dietary source (Level 1 evidence) (Anderson et al., 1999). Health care providers can suggest that menopausal and postmenopausal women use a variety of soy products in their diet, as well as a soy protein supplement to achieve the most desirable cardiovascular effects. Recommendations of this nature will be made in the section on soy in the booklet on alternative therapies.

Wild Yam /Dioscorea Villosa

Indications

Topical wild yam root has been recently touted as a more "natural" means of obtaining progesterone during menopause as a treatment for hot flashes, decreased libido, vaginal dryness, improved bone density, and prevention of breast and endometrial cancer (Chervenak, 2003; Kronenberg & Fugh-Berman, 2002). The active ingredient in wild yam preparation is diosegnin, a constituent also found in ginseng (Chandler, 2000). Proponents of wild yam cream claim it is a "natural" source of dehydroepiandrosterone (DHEA) a precursor to the synthesis of the hormones estradiol and progesterone in the

body (Berne & Levy, 2000). However, the conversion to progesterone has been shown to occur in the lab but *not* in the human body (Kronenberg & Fugh-Berman, 2002).

A double-blind placebo controlled crossover trial tested wild yam cream against placebo for 3 months in 23 symptomatic women. The two groups did not differ in the frequency and severity of hot flashes or night sweats. The confounding results however, were that both groups improved slightly in both the frequency and severity of hot flashes and night sweats possibly indicating a strong placebo effect (Level 1 evidence) (Kronenberg & Fugh-Berman, 2002).

Few clinical trials have been performed to date to determine whether the over-the counter progesterone creams have enough progestin in them to alter blood hormone levels (Chervenak, 2003). In one well-designed study, the use of pharmacologically active progesterone cream on hot flashes and bone density was examined. While the authors found that the treatment did not affect bone density, the frequency of hot flashes decreased significantly (Level 1 evidence) (Kronenberg & Fugh-Berman, 2002).

Side effects and contraindications

The use of wild yam is generally well tolerated; however, in large doses, vomiting is known to occur (Nguyen, 2003). Vaginal spotting, endometrial proliferation, early menopause, masculinization, and postmenopausal bleeding are several known adverse side effects that need to be explored further (Kronenberg & Fugh-Berman, 2002).

Dosages and special instructions

The dosage for wild yam ranges from 300mg to 4 g for the powdered form and from 60 to 180 ml of decoction made from one ounce or approxiamtely 30 g of the dried

root in 600 mls of water (Chandler, 2000). It is difficult to recommend the use of wild yam for the treatment of hot flashes, decreased libido and vaginal dryness, since from a physiological perspective the body is unable to convert the dehydroepiandrosterone in wild yam to the biologically active form of progesterone (Chervenak, 2003).

Vitamin

Vitamin E (Tocopherol)

Indications

Based on reports in the medical and popular literature, Gass and Taylor (2001) suggested that the use of 800 IU of Vit E/day reduces the effects of hot flashes in menopausal women (Level 11-3 evidence). However, there are conflicting results in scientific research. Results of placebo controlled randomized controlled trials's of Vit E in breast cancer survivors who experienced two to three hot flashes per day, found marginal clinical benefit (Level 1 evidence) (Gass &Taylor, 2001). However, it is not known whether these results can be extrapolated to the population of perimenopausal and menopausal women. While not statistically significant, it is interesting to note that another study that examined the use of Vit E for hot flashes, found a 28 % decrease in severity in women who took Vit E compared to 20 % in the placebo group, thus reminding us of the importance of the placebo effect (Dog et al., 2001). Ahlgrimm, Battistini, Ravnikar, Reed, and Schiff (1998) suggested applying Vit E oil to vaginal membranes to help with the dryness that sometimes accompanies menopause (Level 111 evidence). Other RCT's have demonstrated that the benefits of Vit E treatment lie in its

protective effects against ischemic heart disease and fatal myocardial infarction (Level 1 evidence) (NAMS, 2000).

Side effects and contraindications

Reported side effects of Vit E treatment are dermatitis, vaginal bleeding, and hemorrhagic luteal cyst (Seidl & Stewart, 1998). Other reported side effects include minor gastrointestinal complaints, mild skin rash, increased acne, headaches, and increased menstrual flow (Tesch, 2003).

Dosage and special instructions

The recommended dosage of Vit E varies from 100 to 800 IU per day (Soffa, 1996). When used in suppository form, Vit E is suggested to alleviate hot flashes and night sweats and improving vaginal dryness (level of evidence not cited) (Soffa (1996).

Menopausal women may choose to use Vit E for its cardioprotective effects and in so doing discover other potential hidden benefits in the way of reduced hot flashes and night sweats. Nurse Practitioners can also counsel their patients on food sources of Vit E, such as asparagus, cucumber, green peas, kale,mangos, almonds, peanuts, fish, liver, brown rice, corn, and seed oils (Soffa, 1996). Many of these foods are rich in other vitamins and minerals and constitute part of a healthy diet.

The information that follows summarizes the conclusions for each of the herb, food, and vitamin as reflected in the literature review. Gleaned from the results of clinical studies, the information that follows is aligned with the levels of clinical evidence for treating women with particular perimenopausal and menopausal symptoms. A guide to interpreting levels of clinical evidence can be found in Appendix A.

Summary of Herbs

Black Cohosh

- Black Cohosh was found to be effective in reducing anxiety, hot flashes/flushes and atrophic vaginitis. (Level 1 Evidence).
- Two out of three randomized controlled trials reported a stimulatory effect on vaginal epithelium. Recommended use of this herb for the treatment of vaginal epithelium is inconclusive. (Level l Evidence).
- Three of four studies indicated that Black Cohosh had no effect on hormones that caused prolonged bleeding in perimenopausal and menopausal women. (Level ll-3 Evidence).
- Two studies suggested that women who had menopausal symptoms such as hot flashes, night sweats, headaches, nervousness, and depression showed improvement with the use of Black Cohosh. (Level ll-2 Evidence).

Chasteberry

- There is data supporting the use of Chasteberry for treating breast tenderness because it decreases the release of prolactin. (Level ll-3 Evidence).
- There are no documented beneficial effects in the treatment of hot flashes/flushes.
- Some respected authorities have suggested the use of Chasteberry for decreased libido, vaginal dryness, and dyspareunia. (Level lll Evidence).
- The German Commission E recommended Chasteberry for hot flashes, breast tenderness, and dysmenorrhea.

Dong Quai

- Clinical studies that used Dong Quai showed conflicting effects on menstrual irregularities, PMS, dysmennorhea, and oligomenorrhea. (Level l Evidence).
- Conflicting evidence for the use of Dong Quai to treat symptoms such as hot flashes/flushes, night sweats, or vaginal dryness. (Level l Evidence).
- Dong Quai has been shown to improve circulation and improve blood clots. (Level l Evidence).

Ginseng

- Level ll Evidence supporting the use of Ginseng for treating symptoms of anxiety, decreased libido, fatigue, forgetfulness, and weakness.
- Lack of evidence to support its use for the treatment of hot flashes/flushes and night sweats.
- Useful for treating depression, general health, and well-being. (Level ll-2 Evidence).

Red Clover

- Conflicting evidence of the use of Red Clover for the treatment of hot flashes/flushes and night sweats. (Level l Evidence).
- Contributes to reducing the loss of spinal bone mineral density and bone mineral content for perimenopausal women. (Level ll Evidence).

St. John's Wort

- Effective in treating mild to moderate depression. (Level l Evidence).

Valerian

- Useful for treating short term insomnia without the residual morning sedation. (Level l Evidence).
- German Commission E recommends Valerian for hot flashes and night sweats.

Summary of Foods

Flax

- Flaxseed can lower total and low-density lipoprotein cholesterol (TC & LDL cholesterol) but does not increase high-density lipoprotein cholesterol (HDL cholesterol). (Level ll Evidence).
- Inconclusive evidence for the use of flax in treating hot flashes/flushes.

Soy

- Modest benefits for hot flashes/flushes but results are inconclusive. (Level l Evidence).
- Positive effect on bone mineral density and bone mineral content. (Level l Evidence).
- Beneficial for cardio-protective and lipid lowering effects. (Level l Evidence).
- Dietary consumption of soy-based foods is protective against early signs of menopause, especially hot flashes, mood swings, and night sweats. (Level lll Evidence).

Wild Yam

- Difficult to recommend the use of wild yam for the treatment of hot flashes, decreased libido, and vaginal dryness.

Summary of Vitamin

Vitamin E

- Marginal benefit for hot flashes/flushes and vaginal dryness. (Level lll Evidence).
- Protects against ischemic heart disease and fatal myocardial infarction. (Level l Evidence).

Summary

Chapter 2 reviewed seven of the most commonly used herbs, 3 food products and 1 vitamin used to treat symptoms of menopause. Each of these products was examined in relation to its chemical composition, potential side effects, contraindications, dosages and special instructions. Chapter 3 focuses on the theoretical and methodological context that will inform the development of an information booklet for menopausal women who choose to use alternative therapies to alleviate some of their menopausal symptoms.

CHAPTER 3: METHODOLOGY

Overview

The purpose of this practicum project was to develop an information booklet to increase women's knowledge and understanding of the more popular herbal therapies available to treat menopausal symptoms. Chapter 3 focuses on the theoretical and methodological context that will inform the development and use of this booklet. The remainder of this chapter will be subdivided into two sections. The first will focus on the theoretical context underpinning the development of the information booklet. The second section will address the methodological implications of producing this information booklet.

Section 1: Theoretical Context

Conventionally, one of the goals of client teaching in the field of health care, is to provide adequate information to help clients and their families deal with different aspects and implications of their disease (Serxner, 2000). In relation to the **natural** biological event of menopause, a wide range of anecdotal and scientific information is available through popular magazines, books, and articles. However, there is a lack of a comprehensive and concise booklet on complementary and alternative therapies that women with menopause can choose to access and utilize. The development of this information booklet, as a learning tool, is a direct response to this situation.

The development of an information booklet as a learning tool for adults needs to take into account an understanding of how adults learn. According to Mayer (1996) adult learners are information processors in that they "are active seekers and processors of

information, they select and attend to features of the environment… relate new information to previously acquired knowledge, and organize knowledge to make it meaningful" (p.154). While there are many theories that describe how adults learn, the detailed discussion of each learning theory is beyond the scope of this practicum project. Instead, the development of this information booklet will focus on information processing, as it appears to be the most relevant theory for this project. Information processing is not the name of a single theory but a name that is used when discussing the sequence and execution of cognitive events (Schunk, 2000). The main components of the information-processing model are: attention, perception, working (short-term) memory, long-term memory (storage, retrieval, forgetting) (Schunk).

The development of this information booklet focused primarily on two personal factors, namely cognition and memory to assist in the decision making process. As stated earlier, Mayer (1996) claimed that, "learners are active seekers and processors of information. They select and attend to features of the environment, transform and rehearse information, relate new information to previously acquired knowledge, and organize knowledge to make it meaningful" (p.154). Accordingly, the development of print material such as this information booklet is aligned with adult learning styles. At the levels of cognition and memory, Figure 1, which is a variation of Atkinson and Shiffrin's (1968, 1971) information processing model, graphically displays the different stages of information processing.

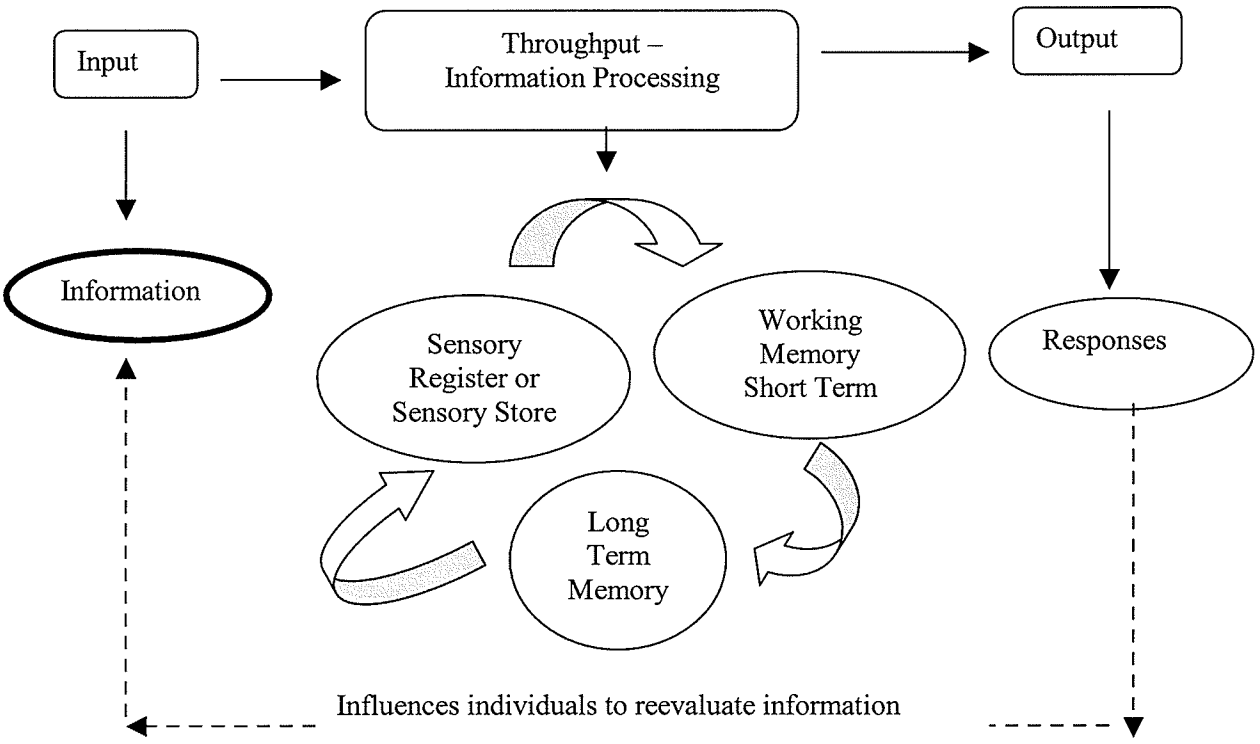

Figure 1: Information Processing Model

What is the significance of adult learning principles in developing the information booklet? Given (a) the results of the WHI study, (b) the transitional stage of women's lives as they experience menopause, and (c) the negative experience of some women with conventional treatments (Seidl & Stewart, 1998), it is likely that women would be interested in learning about alternative therapies. Consequently, their utilization of this information booklet could be viewed as a natural extension of their "developmental changes and life tasks" (Smith, as quoted in Brookfield, 1986, p. 31). This practicum project assumes that menopausal women will use this information booklet because they perceive it to be meaningful to them in relation to their past experiences and their

possible knowledge of the results of the WHI study gleaned from talking to their physicians and/or, more likely, from the media.

Within the context of this practicum project, menopausal women may have previously read about or received information about the results of the WHI study from various sources. In addition, they may have received information about alternative therapies from their friends and colleagues and observed the behavior of other women who have chosen alternative therapies. They may also have had difficulty accessing allopathic medical care. All these pieces of information are processed through the appropriate sensory dimensions, their knowledge of what they know in the here and now (working memory), and what they have come to know in the past (long term memory). A decision is made as a consequence of this processing (response). Their decision and responses move them to evaluate previous information and seek new and more detailed information. Consequently, the production of this information booklet is intended to be one place where menopausal women can gain more detailed information about herbal and food based alternative therapies.

The production of this information booklet included the following principles of information processing: memory, encoding, and multiple intelligences. These 3 principles are further elaborated below.

Memory

Memory is one way through which adult learners receive and process information (Schunk, 2000). This concept suggests that "how information is learned, determines how it is stored in and retrieved from memory" (Schunk, p.13). The development of this information booklet is intended to be a product of this critical element of learning. In

other words, it is intended to be a place where information about alternative remedies is encoded, stored, and easily retrieved by menopausal women who choose to gain a better understanding of the uses and contraindications of various alternative therapies.

The production of the information booklet as a storage tool is intended to be a concrete outcome of the workings of memory. As displayed in Figure 1, Short Term Memory (STM), which is a part of an individual's working memory, is primarily concerned with the acquisition of knowledge and awareness at any given moment (Schunk, 2000). The working memory of an individual assists in relating "information activated in LTM" (long term memory) {parenthesis mine] (Schunk, p. 139).). Long Term Memory (LTM) is also known as permanent memory and information stored within remains there for a long period of time (Schunk). When a stimulus (new information) is received, the incoming information is transferred to working, short-term memory or immediate consciousness, and stored there for approximately 12-30 seconds (Schunk). It is at this point that the information is processed (Schunk). LTM stores knowledge in symbolic forms or intelligences. Schunk defined this as dual-coded knowledge. The purpose of using dual-coded knowledge is because visual and linguistic intelligences aid long-term memory (Clark & Paivio, 1991).

Encoding

The development of the information booklet is also intended to be a tangible demonstration of the process of encoding. According to Schunk (2000) "encoding is the process through which adult learners (put) new … information into the information processing system and (prepares) it for storage in LTM" (p.143). Relating this process to the results of the WHI, for example, menopausal women could be viewed as processing

new information they may have learnt (i.e. results of the WHI study, unacceptable risks associated with medical therapies, increasing acceptance of alternative therapies, difficulty accessing primary care medical services) against what has been stored in their long-term memories (discomforts of menopausal symptoms and rejection of aging symptoms). Their long-term memory has been encoded to suggest that the use of HRT is a beneficial treatment of their menopausal symptoms. It is conceivable to suggest that the results of WHI have raised doubts in the information stored in their long-term memory. As a consequence, the development of this information booklet is *one* response to new learning and to the encoding and processing of new information.

Factors that influence encoding are: organization, elaboration, and schema (Schunk, 2000). These factors are elaborated below.

Organization

According to Miller (1988) grouping bits of information into well-organized chunks facilitates learning and recall. Organized material improves memory because items are linked to each other systematically. Recall of one item prompts the recall of other closely linked items (Schunk, 2000). To this end, the development of this information booklet will be mindful of how it is organized.

Elaboration

When disseminating new information, Schunk (2000) suggested that it is important to expand upon, add to, and link it to what one already knows This facilitates the encoding and retrieval of new information because a link is forged between the new information and the pre-existing knowledge (Schunk). Elaborations are often recalled

even when the new information may be forgotten (Schunk). It is hoped that the elaborations offered through the question and answer approach in this information booklet, namely the intelligence of logic, will reinforce linkages with previous experiences and knowledge.

Schema

Like organization, a schema is a "method of organizing large amounts of information into a meaningful system" (Schunk, 2000, p.145) and into a coherent whole (Anderson, 1990). This information booklet is intended to be a meaningful and coherent system for women who choose to gain a better understanding of the use of complementary and alternative therapies. It is intended to assist potential users through the process of encoding, as new material is elaborated into a meaningful structure and important information is highlighted.

Multiple Intelligences

From the standpoint of the presentation of materials (information booklet, input), it is incumbent upon writers of information materials to take into account how individuals receive information (sensory registers). Gardner's (1983) seven learning styles or intelligences and their corresponding interactions or plays could also be understood as how individuals process information. These multiple intelligences include,

- linguistic (play or use of words),
- logic (play with questions),
- visual/spatial (play with pictures/graphs/figures),
- music (play with rhythm),
- kinesthetic (play with movement),

- interpersonal (play with others), and
- intrapersonal (plays alone).

In the development of this information booklet linguistic, logic, and visual intelligences were used. As seen earlier, whereas Clark and Paivio (1991) identified visual and linguistic intelligences as aiding long-term memory, this information booklet also used the intelligence of logic. As Gardner (1983) noted, the intelligence of logic, through the play of questions, is also a critical way through which individuals learn. The information booklet was written in a manner that provides for a comprehensive description of various herbal, food, and vitamin based therapies for different menopausal symptoms. In addition, it was written in an interactive manner in order to engage readers through the intelligence of logic. It is hoped that potential users would use these multiple intelligences to make informed decisions.

Section 2: Methodological Implications in the Development of the Information Booklet

The development of a complementary/alternative information booklet for menopausal women was conducted as a project component of a clinical practicum in the Nurse Practitioner program. This practicum occurred over a three-month period at the Family Medical Center, 400 Tache Avenue. The goal of the project was to provide menopausal women with an information booklet to facilitate their decision-making regarding the use of complementary and alternative therapies. This information booklet was based on the most recent evidence available in the literature.

Ideally, prior to the development of this information booklet, a formal assessment of the learning needs of menopausal women would have been conducted. However, due

to the time constraints of the practicum project, this was not feasible. The need for more information about the use of herbal therapies for menopausal women was drawn instead from informal conversations with co-workers, patients, and fellow students within the practicum setting.

A review of the literature was performed in order to obtain a better idea of existing information. While there were many magazine articles, popular books, and various lists of herbs, foods, and vitamins, recommendations for relief of menopausal symptoms rarely were based on clinically sound data.

Format

The development of the information booklet was structured in terms of the information contained in the review of the literature. Concepts related to information processing, and factors that affect content, literacy demand, graphics or visuals layout, logic (play of questions), and cultural appropriateness, were incorporated in the information booklet. The most current scientific information as gleaned from the literature was utilized to inform the content. The information booklet aligned the use of specific alternative therapies with specific menopausal symptoms.

Content

In the preparation of print materials, such as this information booklet, Serxner (2000) identified four key points in relation to the content of the material. First, it "must address the purpose of the information" (p. 99) in order that readers understand the importance of the information to them. Second, in alignment with the principles of adult learning, the content must relate to the person's concern. Third, the writer should be careful not to overwhelm the reader with too much detail. Finally, in alignment with

information processing, a "clear summary and review of key points should be included so the reader can reinforce the important lessons" (p. 99). The development of this information booklet will be organized accordingly.

Literacy Demand

While literacy demand is one component of readability, it is used often as the only criterion (Serxner, 2000). The Fry formula (Fry, 1968), the SMOG index (McLaughlin, 1996) and the FOG index (Meade & Wittbrot, 1988) have been also used to assess levels of reading. The SMOG Readability Formula, for example, suggests that if a person reads at or above a grade level, they will understand 90-100% of the information. McLaughlin (1969) suggested that writers of written materials aim for a reading level of sixth grade or less. All three methods, which are further elaborated in Appendices C, D, and E, identified a combination of counting the number of words per sentence, number of sentences per paragraph, and number of syllables per word to determine the levels of readability (Serxner, 2000). For this project, the use of the SMOG readability formula will be utilized as it is a quick and simple method for grading the readability of written materials and is of particular value for shorter materials like a booklet or pamphlet.

Writing style is another aspect of readability and it is considered to be most effective when utilized in an active voice and an easy to understand conversational manner (Serxner, 2000). The use of simple and explicit words will give the context before new information will be presented. Headings will be used to encourage readability (Serxner, 2000). While the use of simple descriptors for the symptoms of menopause will be used in this information booklet, it may be impossible not to use larger more complex language to convey the information. For example, it may be impossible to find another

simplified word for "phytoestrogen," or "isoflavone" as doing so may render the information inaccurate and incomplete. Consequently a "glossary of terms" at the back of the booklet will be provided for the purpose of clarifying the meanings of the words used.

Given the audience who may choose to use this information booklet, the material will be organized to "fit" a Grade 11-12 literacy level. It is anticipated that health care providers would also use this information as a teaching tool.

Graphics

Depending on how they are used, the use of illustrations, lists, tables, and charts are commonly understood as reducing or increasing the suitability of reading (Serxner, 2000). This information booklet will include the use of tables in a special way. Rather than being used only to provide information, tables will be used to actively engage readers in their own learning. The interactive nature of tables is captured in the discussion below.

The Intelligence of Logic

In alignment with the principles of adult learning, Serxner (2000) suggested that written materials "should appropriately *stimulate and motivate the reader to learn*" [italics original] (p. 99). The logic of asking questions is one way of engaging readers in the written materials. One of the strategies used in this information booklet will include asking readers to list some of their symptoms of menopause that they may have experienced, what they have done about these, and the corresponding results. It will also allow them to compare their experiences and corresponding results with the recommended herbal therapies. This information will include a table as follows.

Conventional Treatment		Alternative Remedies	
Drugs Taken	Results/Experience	Herbs Taken	Results/Experience

Another interactive component of this information booklet will include leaving a blank section beneath each of the herbs for the purpose of inviting readers to write down any questions or health related information that they may have. For example, beneath the herbal therapy "St. John's Wort," readers could note whether they used this herb, for what particular symptom, and whether or not they found it to be effective. Measures of effectiveness could include variables such as having a good night sleep, reduced anxiety, increased feelings of well being, and higher levels of energy. In addition, the client could note if there had been any side effects.

The booklet could become a tool for ongoing discussion and review that readers could use either individually or, if they choose, with appropriate health care providers. The booklet could serve as a reminder for health care providers to review the patient's current herbal therapy use, as well as any other current medication use, contraindications, and side effects.

Layout

Serxner (2000) identified two key points in relation to the layout of the information booklet. First, the layout and sequence of information needs to be consistent. Second, subheadings or "chunking" (p. 99), namely grouping information into pieces that belong together (Schunk, 2000), help readers more easily understand and remember the

information. This approach will be applied to assist in the elaboration of the written material as previously discussed for the sake of long-term memory.

Cultural Appropriateness

The test of cultural appropriateness, as it is used in the context of written materials, is whether or not readers identify with the material (Serxner, 2000). In this practicum project, an assumption is made that menopausal women will identify with the alternatives provided in this information booklet for reasons already discussed. Accordingly, every effort will be made to match or align the logic, language, and experience with menopausal women since they are the audience for this information booklet. Other factors that will be taken into account will be the use of positive language when discussing menopause and its symptoms. As mentioned in Chapter 1 menopause is a "natural biological event" not a process of decay. Women who seek out information should be commended for taking responsibility for their health.

Evaluation of Information Booklet

To validate the content of the information booklet, it would have been ideal to have had the opportunity to share this booklet with colleagues and support staff who are themselves experiencing menopausal symptoms. While this was outside the scope of this practicum project, this information booklet was shared with a purposive sample of 2 women who shared their menopausal symptoms with this writer. Their comments and feedback were integrated and reflected in chapter 5.

The suitability of assessment materials (SAM) measures the 6 categories identified above, namely, content, literacy demand, graphics, layout and typography, learning stimulation (intelligence of logic), and cultural appropriateness (Doak, Doak, &

Root, 1996). The SAM is constructed in a manner that yields a final percentage score. This score falls into one of three categories: superior, adequate, or not suitable. The SAM can be used to identify specific shortcomings that reduce the suitability of materials, either in the development stages or with existing materials. A full description of the SAM is presented in Appendix F. The suitability assessment of materials was used as a method to evaluate the content, literacy demand, learning simulations and motivation, graphics, layout, and cultural appropriateness of this information booklet.

Summary

Chapter 3 focused on the theoretical and methodological implications of developing an information booklet for menopausal women. It highlighted the critical elements in providing quality health learning for menopausal women. The development of this information booklet is one step in the process of developing materials for information and learning.

In Chapter 4, the information booklet is introduced. In this practicum project, the information booklet is presented in Appendix G. It is hoped that this booklet will be meaningful and relevant to menopausal women.

CHAPTER 4: INFORMATION BOOKLET

Overview

Chapter 4 is a presentation of a 26-page information booklet on alternative therapies for menopausal women. As reflected in chapter 3, since adult learners "are active seekers and processors of information" and that "they select and attend to features of the environment" (Mayer, 1996, p. 154), this information booklet was organized according to the most common menopausal symptoms. It was organized from the assumption that adult learners will use the information booklet in an attempt to address their particular menopausal symptoms.

Detailed in the form of a chart, seven herbs, three food supplements and one vitamin were aligned with various menopausal symptoms. The information about each herb, food supplement, and vitamin was based on the most recent scientific information available.

Organization of Booklet

Interactive Dimension

To enhance the interest, interaction, and participation of potential users, three particular multiple intelligences, as identified by Gardner (1983) were utilized. These included, visual, logic, and linguistic. Two interactive components were included in this information booklet. The first encouraged women to identify their unique menopausal symptoms prior to using the booklet. As seen in chapter 3, this was done because adults "use experience as a resource in learning" (Smith, as cited in Brookfield, 1986, p. 31). Accordingly, the interactive process was intended (a) to engage potential users in

integrating their past experiences, as stored in their long-term memory (Schunk, 2000), and (b) to enable potential users to relate to their particular "developmental changes and life tasks" (Smith, as cited in Brookfield, p. 31). The second interactive component included a "How am I doing?" section. As outlined in chapter 3, this second interactive component was included for the purpose of enabling potential users to encode their knowledge and experiences for the purpose of processing information. The organization of the booklet also took into account grouping bits of information into well-organized chunks to facilitate learning and recall (Miller, 1998). Items related to menopausal symptoms were grouped together, in order to facilitate clients' recall of their personal menopausal symptoms.

Elaboration

The process of elaboration was important in the development of this booklet. As seen in chapter 3, Schunk (2000), for example, suggested that individuals respond well to new information when it is linked to what they already know. Accordingly, the process of elaboration was utilized by using a chart approach for each of the alternative therapies by including a section on "How am I doing?" and a comparison chart to conventional medicine to reinforce linkages to both current and previous knowledge and experiences.

Schema

To facilitate the organization of large amounts of information into a meaningful system (Schunk, 2000, p.145), the schema of this booklet was formatted as a chart. Three key points as outlined by Serxner (2000) were incorporated into the content of the booklet. First, the information contained in the booklet was aligned with menopausal

symptoms. Second, the content was outlined so as not to overwhelm the reader with too much detail and information. Finally, the reader was presented with a blank chart to record their own personal experiences with taking various herbs, foods, or vitamin supplements in the hopes that this would reinforce the important lessons learnt from the booklet.

Literacy Demand

The SMOG readability formula was used a quick and simple method of grading the readability of the booklet. Using this formula as outlined in Appendix D, the readability of the booklet was found to be at a grade level of Grade 10. This is not unusual in a booklet of this nature as many of the terms and words used are medical in nature and are consequently at a higher reading level. Every attempt was made to use the most simplified terminology without losing the essence of the information provided. Unfortunately, this was not always possible. In order to make it easier for the reader to understand the more complex medical terminology, a glossary of terms was provided.

Introduction to the Information Booklet

The information booklet is presented in Appendix G. The information in this booklet was organized as follows:

- General information about managing perimenopausal and menopausal symptoms naturally,

- Seven different herbs, three food supplements, and one vitamin are included in the booklet,
- A definition of herbs and information on herbs are provided as part of the informational context,
- The information on herbs, food supplements and vitamin are aligned with specific menopausal symptoms,
- Interactive charts are included to engage the participation of potential users, and
- In light of one of the elements identified in SAM, a conscious effort was made to sustain a conversational style.
- Vis-à-vis conflicting scientific evidence for the use of herbs, foods and vitamin in treating specific menopausal symptoms, a decision was made to include all relevant symptoms in this booklet for the purpose of allowing women to tailor the use of these alternative therapies to their particular symptoms.

CHAPTER 5: DISCUSSION AND RECOMMENDATIONS

Overview

The goal of this practicum project was to develop an information booklet for women who may be interested in complementary therapies to manage their perimenopausal and menopausal symptoms. Seven herbs, three foods and one vitamin were examined for their efficacy, safety, interactions with other drugs and side effects. Information in the booklet was taken from the current scientific literature on the subject. Every attempt was made to include only information from well designed randomized controlled trials as a means of providing the reader with results based on the highest levels of evidence as outlined by the scientific community.

Limitations

An assessment conducted with the identified targeted audience could have helped to more clearly identify their specific information needs prior to the development of the booklet. Ideally, the information booklet should have been shared initially with the target audience, namely perimenopausal and menopausal women, to elicit their feedback in terms of usefulness, content, clarity and readability. In addition, feedback from health professionals who work with perimenopausal and menopausal women could also have been useful, as it would have helped validate the content for ease of use and clarity. Unfortunately due to time constraints this was not done.

While recognizing the importance of complementary lifestyle issues such as attitude, diet, and exercise such as swimming, yoga, and deep paced breathing as a means of relieving menopausal symptoms, these were not included in detail because they are

outside the scope of this practicum project. In addition, for purposes of this information booklet, this writer is of the opinion that the inclusion of other complementary lifestyle issues in greater detail would be too cumbersome.

Feedback from a Purposive Sample of 2

Information Booklet

Since this information booklet was designed for perimenopausal and menopausal women, they need to be included in assessing the usefulness of this booklet. While this was not formally done, this information booklet was shared with a purposive sample of 2 female acquaintances. One is the Director of a day care centre and the other an engineer. Both women are between 40-45 years of age and they had informally discussed their perimenopausal and menopausal symptoms with this writer. They were asked to (a) read and evaluate the information booklet by utilizing the Suitability of Reading Materials (SAM) scoring sheet as outlined in Appendix F, and (b) include any other comments. Their feedback was intended to assess whether the information booklet was of a suitable quality for meeting the informational needs of perimenopausal and menopausal women. Based on their written and conversational feedback, 11 changes were made under the respective categories as reflected in the SAM scoring sheet.

Content

(i) A section to more clearly define the purpose of this information booklet was developed. This was done in response to one comment that the purpose of the information booklet was "a bit fuzzy." In relation to the information contained in the

booklet and general flow of the content, the other individual commented that the content was "very useful" and required a "short read time."

(ii) A paragraph identifying the organization of the booklet rather than providing a table of contents was constructed. This was in response to a comment: "could there be some instruction as to what I should be doing here, perhaps at the beginning of the booklet." As reflected on page 100 of this practicum project (see Appendix G), the booklet was reorganized in order to prepare the reader in terms of both the informational and interactional components of the booklet and to preserve the conversational style of the booklet. Four additional text boxes were used on pages, 102, 104, 117, and 120 to lead the reader to the next section. While the information of pages 102 and 104 managed the readers' anticipated questions, the text boxes on pages 117 and 120 preserved the conversational style of this booklet. In addition, the text box on page 120 invited the reader to actively engage the advice and services of their health care providers.

(iii) Information on other methods of dealing with perimenopausal and menopausal symptoms, such as attitude, diet, and exercise, and relaxation techniques were briefly incorporated into this booklet.

Literacy Demand

(iv) The language used was simplified. For example, "smoking cessation" was changed to "stop smoking", "insomnia" was changed to "trouble sleeping." One individual wrote: "The material in the booklet is easy to read and easy to understand."

(v) The headings and subheadings were reconstructed to reflect a conversational style. In Gardner's (1983) language the intelligence of logic, namely the use of questions,

was included in the headings and subheadings. For example, rather than using "Glossary of Terms" as a heading, the alternative chosen was "What do the terms mean?"

Layout

(vi) The glossary of terms was placed before the informational charts on herbs, foods and vitamin rather than at the end of the booklet as is conventionally done. One individual suggested that this would better prepare the reader to understand the terms prior to reading the charts that followed. In relation to aiding the reader, one individual commented that the layout assisted her as follows: "Information was easy to find after first read through."

(vii) Subheadings were created to chunk text to facilitate learning and recall. For example, the purpose and the organization of the information booklet were more clearly outlined.

Learning Simulation, Motivation

(viii) While no changes were recommended in this category, the following written comment is heartening. "The topic encourages you by comics and language to read on. I was hooked…The positive approach made me feel I could get through menopause and there was (sic) alternative remedies."

Graphics

(ix) As above, while no changes were recommended in this category, the following written comment is also encouraging. "The charts are great…I love all the pictures…I always love having something to track progress."

(x) In relation to the information contained in the charts, one individual wrote: "Could there be some instructions as to what I should be doing here, perhaps at the beginning, sort of feels it comes out of the blue." As a consequence two specific changes were made. First, the organization of the booklet was made more explicit in that the reader was prepared in terms of both the informational and interactive nature of this booklet (see page 100). Second, "what next?", "how am I dong?", and "where do we go from here?," captions were added to preserve the continuity and conversational style of this booklet (see pages 104, 117, 120).

SAM Scoring of Information Booklet

(xi) As mentioned in chapter 3 and in Appendix F, the SAM scoring sheet yielded a final percentage score that fell into one of three categories, namely superior, adequate or not suitable. The percentage score by the purposive sample of 2 women who evaluated the information booklet was 82% and 89% respectively. According to Doak, Doak, and Root (1996), a score of 70 – 90% can be interpreted as "superior material".

Comparison with other Informational Materials

This information booklet was compared with similar materials for assisting women in the management of their menopausal symptoms. These materials included information from the public library and pamphlets that were available from local hospitals and community centers.

Public Library

Michele Moore's (2000) book, titled *The Only Menopause Guide You'll Ever Need* caught the attention of this writer because it implies that this is the only book that

menopausal women need to read. While Dr. Moore offered a balanced account of options that ranged from traditional medical practice to holistic and alternative approaches for the management of menopause, four key differences between her approach and the approach in this practicum project must be noted.

(i) In relation to information on herbal therapeutic options, Moore (2000) merely listed the various herbs for the management of different menopausal symptoms. She did not, for example, provide the detailed information regarding, dosages, interaction with other drugs, cautions, recommended length of use, and other effects as reflected in this information booklet.

(ii) Moore included ibuprofen as a complementary therapeutic option (p. 46) rather than as a medical option.

(iii) Moore collapsed flax and wild yam as herbal therapeutic options rather than as food supplementary options. This information booklet attempted to distinguish between herbal, food, and vitamin as different forms of complementary therapies.

(iv) Moore also included "cucumber slices on eyes" and "tea bags on eyes" as herbal therapeutic options. While these may be cultural practices, Moore did not link these options to any clinical studies. At the same time, by chunking these types of practices under the category of herbs, she inadvertently trivializes the use of herbs as appropriate or legitimate alternatives for the management of menopausal symptoms.

(v) A similar feature utilized by Moore included the use of a table format to present the symptoms of perimenopause and menopause. Her table on therapeutic options for perimenopause, menopause, and postmenopause included five informational categories,

namely problems, medical, complementary, herbal, and homeopathic. Her use of the word "problems" rather than "symptoms", however, presented a negative picture of a natural biologic event. On a more positive note, her recommendation for women to "make every effort to educate themselves and inform their health care providers about all the medications they are taking, regardless of whether they are prescription medications or not" (Moore, 2000, p. 42) is to be commended. It is important to recognize that "when self-treating with herbals...anything that is potent enough to have significant beneficial effect may also have potent side effects" (p. 42). As mentioned earlier, it is precisely for reasons like these, that it is desirable to include optimal dosages, drug interactions, and other effects. The information booklet designed for this practicum project differs from Moore's (2000) table in this respect.

Community Health Centers and Hospital Based Clinics

Upon reviewing the information via the Internet, two major clinics, namely Women's Health Clinic (Community Based) and Mature Women's Health Program (Hospital Based), were identified as sources where women could learn more about the management of their menopausal symptoms in Manitoba. Accordingly, this writer approached both clinics to obtain their information. Unlike the Mature Women's Health Program, the Women's Health Clinic provided this writer with a standardized pre-packaged envelope of information. Through a telephone conversation with a health care provider from the Mature Women's Health Program, it was learned that information to their clients was provided on a case-by-case basis. Health care providers in this program obtained their herbal information through a subscribed website, namely

www.naturaldatabase.com. Being a non-subscriber to this website, this writer was unable to get further information on the types of herbs, food, or vitamins that are available to health care providers through their website. According to this health care provider, part of the reason why hard copies of information were not made available to women is captured in the following comment: "The information on herbs is constantly changing...some of the effects are inconclusive. We would have to change our pamphlets constantly."

The Women's Health Clinic has a pamphlet that provides helpful hints for menopausal women. The pamphlet, entitled, *Help Yourself Through Menopause,* contains some useful, practical, and holistic ways through which menopausal women can manage their symptoms of menopause. Several differences between this pamphlet and the information booklet developed in chapter 4 must be noted.

(i) All the information in the pamphlet is contained on a two-sided 8 x 11 sized paper. While being solely informational, it does not provide the reader with any interactive opportunities.

(ii) Unlike the information booklet that was developed for this practicum project, the pamphlet provided information on more than one vitamin. It contained some useful information on Vitamins B-Complex, D, and E. Their pamphlet also contained recommended dosages for the aforementioned vitamins.

(iii) The pamphlet included only one herb, namely Ginseng. The only information on Ginseng is as follows: "Ginseng is an herbal root and appears to be effective in controlling some of the menopausal symptoms, especially 'hot flashes'."

One particularly appealing feature of this pamphlet is its positive and empowering tone. In chapter 1, for example, it was noted that Barrett et al. (2000) linked the shift to alternative medicine to the concept of empowerment, which is understood as the desire of women to take responsibility for their own health. This pamphlet exemplifies this shift through their subheading: *What You Can Do.* As a reader of this pamphlet, this writer was encouraged by the notion that she was not a victim of menopause.

It must be noted that the pamphlet is not the only source of information that is provided by the Women's Health Clinic. Other information and services for menopausal women include (a) Menopause Information Series, (b) Menopause Clinics, (c) Women's Health Clinic Resource Centre, (d) Health practitioner Services, (e) nutritional counseling, and (f) mental health counseling.

Similarly the Mature Women's Health Program offers a comprehensive range of services for women over 35 who are looking ahead with an interest in improving their health. Their team of health care providers provides a wide range of services aimed at addressing individual concerns and therapeutic choices. These services include (a) personalized therapy, (b) osteoporosis prevention, (c) smoking cessation, (d) exercise program, (e) psychological counseling, (f) heart disease and cancer prevention, (g) nutrition counseling, (h) breast health, (i) hormone replacement therapy, (j) family history risk factors, (k) herbal therapy, and (l) vitamin therapy. In addition, written information derived from pharmaceutical journals is provided to each woman on a case-by-case basis. The information is obtained from the Internet and tailored to the particular needs of each individual.

Given the wide range of services available at both the Women's Health Clinic and the Mature Women's Health Program, it must be noted that the information booklet as developed in this practicum project is a part of a larger process of healthy living. At the same time, it could be a complementary feature to existing pieces of information.

Recommendations

As a consequence of feedback received from a small purposive sample of 2, it is strongly recommended that this information booklet be shared with a larger group of perimenopausal and menopausal women in a clinical or community setting. This setting could be a hospital gynecological outpatient department, community health clinic, mature women's health centre, church groups, or a primary care clinic. This could be done prior to the final printing and use of this booklet in the clinical setting. The SAM scoring sheet could be used as a tool for assessing the suitability of the information booklet for content, literacy demand, graphics, layout and typography, learning stimulation and appropriateness.

Second, health care providers who are testing the booklet could be asked for their feedback on the usefulness and ease of use of the booklet. Issues related to clarity of information provided, areas of concern and lack of certain information provided would help to improve the efficacy of the final product. It would be important for health care providers to familiarize themselves with the organization and layout of the booklet prior to sharing this informational booklet with women, as it would enable them to more easily explain the information contained in the booklet. Clarification of the content of the

booklet between this writer and health care professionals could be discussed at a meeting prior to its actual use.

Third, it is also recommended that information booklets such as the one developed in this practicum project, make a concerted effort to include and update their guidelines based on more recent scientific evidence. For example, information from more RCTs, as they are completed, could be used to update information. The information contained in this booklet sought to exemplify a step in that direction. This could aid women to make a more informed choice about managing their symptoms of menopause.

Fourth, it is recommended that every effort be made not to trivialize the use of herbs, food supplements, or vitamins with cultural practices. For this reason, practices such as "cucumber slices on eyes" or "tea bags on eyes" were excluded in this information booklet. Instead, the development of this booklet was focused on information, as it was available through RCTs.

Fifth, it is recommended that the information booklet also include drug interactions as a key component. Both women in the purposive sample acknowledged that this piece of evidence was "critical" to their decision making process.

Finally, it is also recommended that the information in this booklet be integrated into a larger and more comprehensive program for menopausal women and not be used as a stand-alone. The expertise of health care providers, including dieticians, could be solicited to enhance the content and validity of information contained in this booklet.

Summary

The challenges in putting the information together for this booklet was compounded by (a) conflicting scientific evidence, (b) lack of clinical trials and research for alternative remedies as identified in this project, (c) the difficulty in condensing and distinguishing "nice to know" information from "need to know information", and (d) simplifying the information for the general public while attempting to maintain the accuracy and integrity of the efficacy of each herb, food, and vitamin supplement. It is hoped that with the increasing shift to alternative remedies, especially as it relates to perimenopausal and menopausal women, health care providers will be able to conduct further research and provide improved information on the efficacy of the herbs, food, and vitamin reflected in this practicum project.

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Appendix A

Guide to Interpreting Evidence

The Canadian Guide to Clinical Preventive Health Care (1998) subdivided the interpretation of evidence into two categories, namely quality of evidence and classification of evidence. In this practicum project, quality of evidence will be used because it is more appropriate and relevant. Many articles are now using notations of the levels of research evidence to signify the reliability of findings. The five levels evaluating the quality of evidence are identified in the table below. Level l is the highest and Level lll is the lowest level of research evidence.

Quality of Evidence	
Levels of Research Evidence	Interpretation of Levels of Research Evidence
l	Evidence is obtained from at least one correctly designed randomized control trial.
ll	Evidence is obtained from well-designed controlled trials without randomization.
ll-2	Evidence obtained from well-designed cohort or case controlled investigative studies, preferably from more than one research group or centre.
ll-3	Evidence obtained from cross-sectional study or studies with external control groups. Significant results in uncontrolled experiments could also be in this evaluation.
lll	Opinions of respected authorities, based on clinical expertise, and experience, descriptive studies or reports of expert committees.

Table 1. Adapted from *The Canadian guide to clinical preventive health care* (1998). Health Canada.

Appendix B

Glossary of Terms

Anticoagulant: A drug, such as Warfarin, that is taken to prevent formation of blood clots.

Anti-Parkinsonian: Drugs used to help in the treatment of Parkinson's disease or other similar diseases of the nervous system.

Anti-psychotics: Drugs that are used to help patients with mental illness such as schizophrenia.

Biofeedback: A training technique that helps individuals to control their automatic body functions such as heart rate.

Bromocriptine: A drug that is often used with Parkinson's disease.

Hot Flashes: A menopausal symptom that is experienced as an intense warmth and redness particularly of the head, neck, and upper body.

Isoflavone: Plant based mixture that is found in rich supply in soybean, soy products and red clover.

Libido: the desire for and /or enjoyment of sexual activity.

Menopause: A natural biologic event that marks the end of menstruation.

Night Sweats: Excessive sweating that sometimes accompanies a hot flash. This occurs mainly while sleeping.

NSAIDS: Non Steroidal Anti-Inflammatory Drugs used for mild to moderate pain. It includes drugs like Advil, Aspirin, and Naprosen.

Osteoporosis: A progressive loss of bone with increased risk of fractures to the hip, wrist, and verterbrae.

Paced deep breathing: Slow, rhythmic, and deliberate breathing to slow down more rapid rate of breathing. This is thought to help with hot flashes.

Palpitations: Feeling of the heart pounding in the chest.

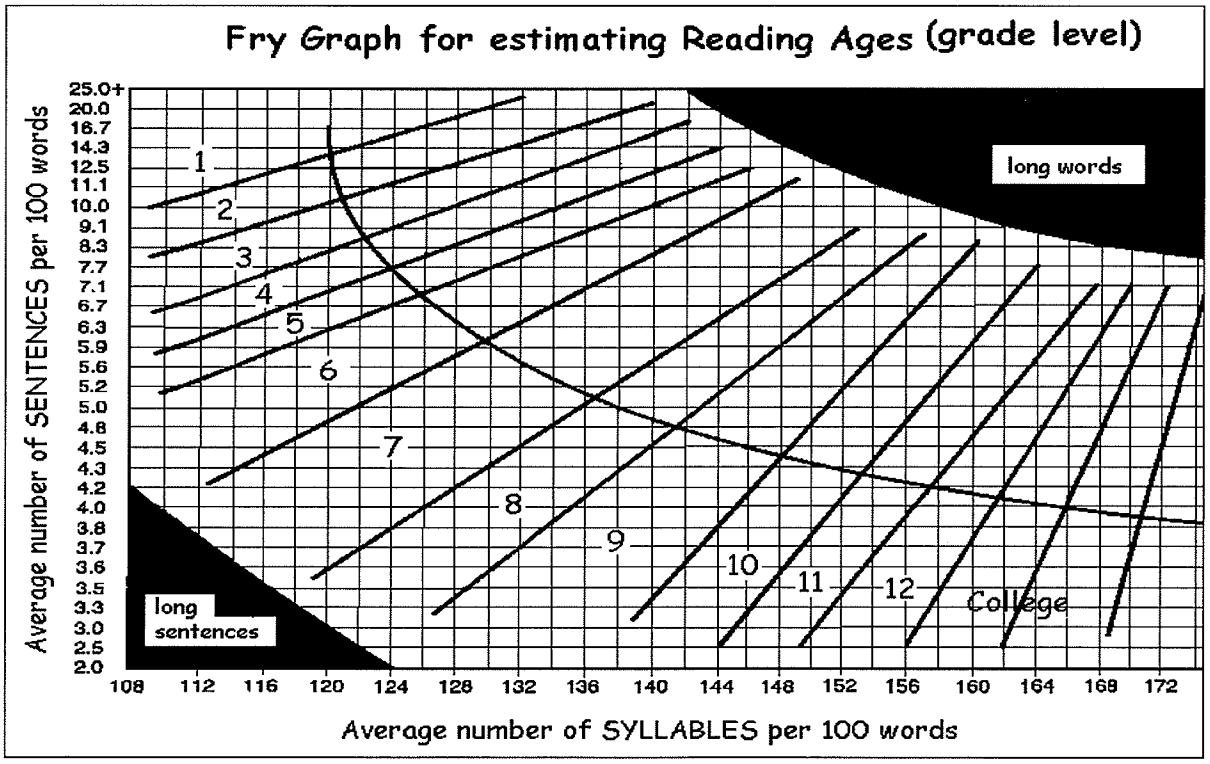
Raloxifene: Sold under the brand name EVISTA, this drug is used for the prevention and treatment of osteoporosis.

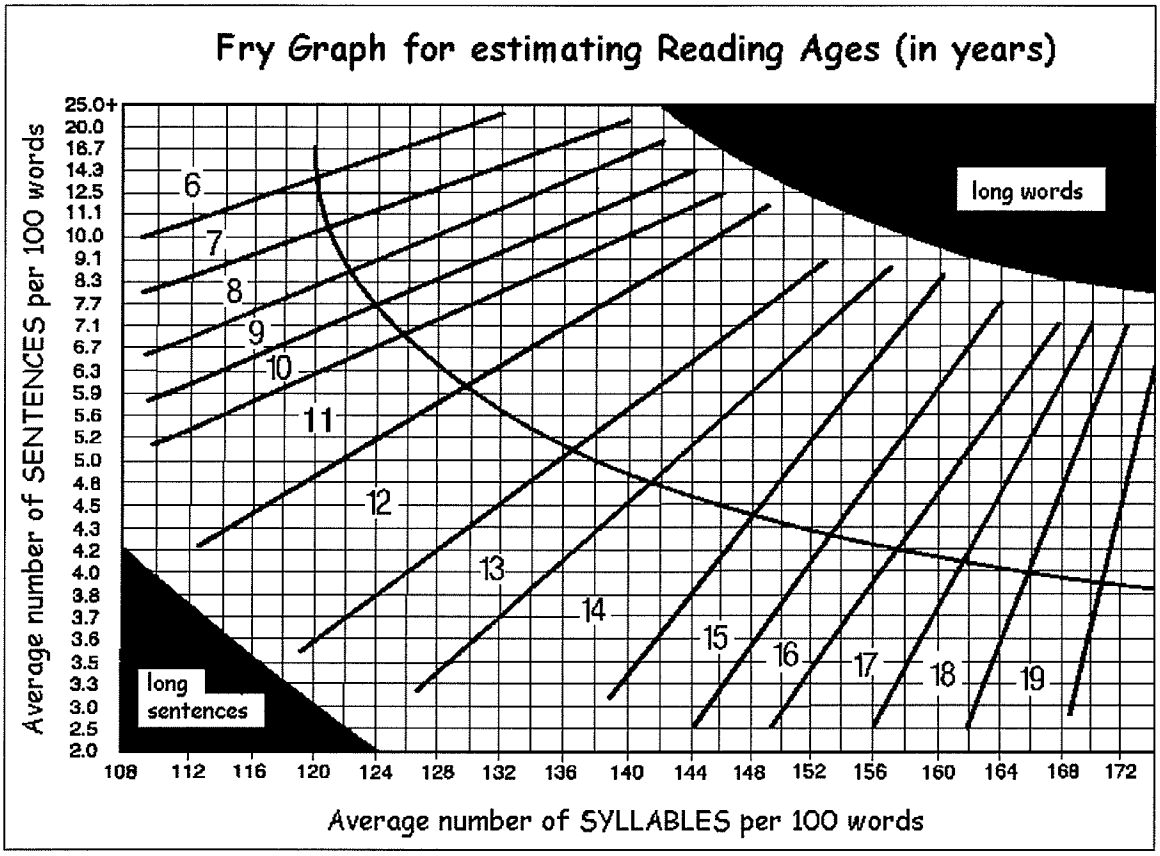
Tamoxifen: A drug used in the treatment of breast cancer

Appendix C

The Fry Formula

Edward Fry (1997 developed The Fry Formula. It is widely used by educators to aid them in understanding levels of readability by age and grade level. Pfizer, a major pharmaceutical company, has selected this formula as its model for Principles of Clear Health Communication, The graphics below further elaborate the estimation of reading levels by grade and age. Interpretation of how to read the Fry readability graphs will follow.





Direction for how to Read the Fry Readability Graph

1. Randomly select three 100-word passages from a book or an article.
2. Plot the average number of syllables and the average number of sentences per 100 words to estimate the grade level of the material.
3. Plot the average number of syllables and the average number of sentences per 100 words to estimating the reading ages in years.

Source: http://school.discovery.com/schrockguide/fry/fry2.html (Retrieved May 20 2004)

Appendix D

The SMOG Readability Formula

The SMOG formula is a quick and simple to use method for grading the readability of written materials. It is particularly useful for shorter materials like the design of this information booklet. The SMOG conversion table below allows one to calculate the grade level of reading.

Total Polysyllabic Word Count	Approximate Grade Level (+1.5 Grades)
1-6	5
7-12	6
13-20	7
21-30	8
31-42	9
43-56	10
57-72	11
73-90	12
91-110	13
111-132	14
133-156	15
157-182	16
183-210	17
211-240	18

Directions for Use

- Count off 10 consecutive sentences near the beginning, in the middle, and near the end of the text. If the text has fewer than 30 sentences, use as many as are provided.
- Count the number or words containing 3 or more syllables (polysyllabic), including repetitions of the same word.
- Look up the approximate grade level on the SMOG conversion table as above.

Appendix E

The Fog Index

The Fog Index is acclaimed as being the easiest to use and probably the most popular readability index. It is popular because it (a) reduces to simple formulas the complex work of writing, (b) provides a convenient check and measure of the level of one's writing, (c) possesses the sizzle of mathematical exactness, and (d) can be calculated by word processing software like Microsoft Word. There are 4 essential steps to the calculation of readership level.

- Select a sample
- Determine the average number of words per sentence
- Determine the percentage of hard words ((Hard words exclude definite and indefinite articles like 'a' and 'the', prepositions like 'of' etc.)
- Add the 2 factors and multiply by 0.4

Computation: The numbers in the formula below are hypothetical

130 words in 10 sentences	= average sentence length of 13 words per sentence
30 hard words out of 130	= 23%
Average sentence length	= 13
Percentage of hard words	= 23
Total (13+23)	= 36
Multiply by	= 0.4
Grade readership level	= 14.4

Appendix F

The Suitability of Reading Materials (SAM) Scoring Sheet

(2 points for Yes, 1 point for Needs Improvement (NI), 0 points for No)

The SAM scores materials in 6 categories: content, literacy demand, graphics, layout and typography, learning stimulation and cultural appropriateness. The SAM yields final percentage score. This score falls into one of three categories: superior, adequate or not suitable. The SAM can be used to identify specific shortcomings that reduce the suitability of materials- either in the development stages or with existing materials. Adapted from Doak, Doak, and Root (1996) the SAM scoring could be presented as per the Table below.

Assessing the Suitability of the Propose Information Booklet				
Categories		Yes	No	NI
Content	Topic is within content areas of menopause			
	Information is research-based			
	Information is accurate			
	Purpose is explicit			
	Purpose is relevant			
	Scope is limited to fit the purpose			
	Scope is limited to what can be learned			
	Title of display explains content			
	Behavioral outcomes are emphasized			
Literacy Demand	Common words are used			
	Conversational style is used			
	Text is interesting			
	Heading/subheading explain the text			
	Context is provided first			
	Reading level is 6^{th} grade or below			
	Short sentences are used			

Learning Simulation, Motivation	Reader is encouraged to interact with content of material			
	Small doable behavior changes are suggested			
	Information increases self-efficacy			
Cultural Appropriateness	Content/graphics reflect audience in logic, language, experience, gender, age, and culture			
	Ethnic subgroups are presented in positive and non-stereotypical ways			
Graphics	Graphics or illustrations are attractive			
	Graphics or illustrations are simple			
	Charts are well explained			
	Captions are used for graphics			
Layout	Layout aids the reader			
	Typographic cues are used to emphasize key points (example, bullets, bolding, font size, etc.)			
	Subheadings are used to chunk text			

Doak, Doak, and Root (1996) suggested the following interpretation for scoring the information booklet.

70 - 90% = Superior material

40 – 69 % = Adequate material

0 – 39% = Not suitable material

(Total SAM score divided by total possible score) multiplied by (100%) = score interpretation.

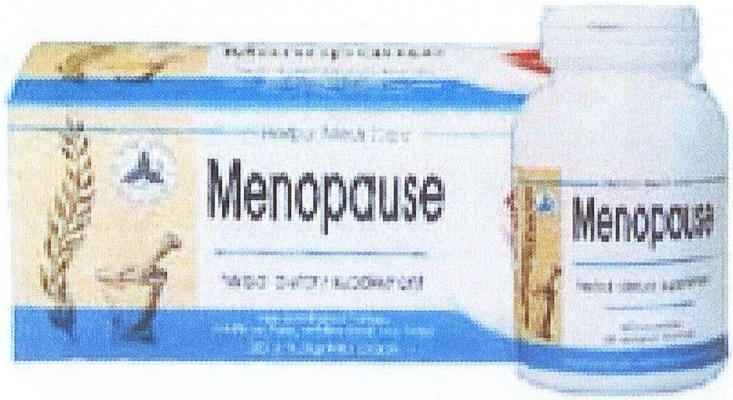
Appendix G

The Information Booklet

Menopause is mystery. Menopause is Power. Whisper the Women

The Wise Woman Tradition

An Information Booklet



Managing Perimenopausal & Menopausal Symptoms Naturally

Managing Perimenopausal & Menopausal Symptoms Naturally

Menopause is a natural part of a woman's life. As your hormones begin to change through perimenopause and menopause - you may feel a variety of emotions that may make this period in your life very difficult. Some women find that perimenopause and menopause affects their sex life, triggers mood swings, causes debilitating hot flashes, or even takes them down the road to bone and heart problems. Others welcome the end to monthly bleeding and inconvenience. Some have even gone so far as to redefine hot flashes as a "power surge."

You can do many things to help ease your way through perimenopause and menopause. Lifestyle modifications such as diet, exercise, stopping smoking, and attitude may be just as important and effective as medications in helping you feel better and live longer.

Attitude: This information booklet encourages you to view perimenopause and menopause as a normal process of aging. As a woman, you are moving to yet another stage of your life. You have the power to honor and respect your changing body. Susun Weed asks this provocative question: "Your wise blood and your wise hormones are shifting in their courses. Are you ready for the ride of your life?"

Diet: Caffeine, alcohol, and spicy foods have been known to trigger hot flashes and night sweats. Hence, avoid these triggers if possible.

Exercise: Walking, jogging, aerobics, swimming, biofeedback, yoga, meditation, paced deep breathing, and other relaxation techniques are also effective in managing hot flashes, restlessness, and difficulty sleeping.

Menopause: An opportunity for renewal...

Purpose

This information booklet is intended particularly for women who are interested in or who are using natural remedies for treating symptoms of menopause.

How is this Information Booklet Organized?

This booklet is both informational and interactive.

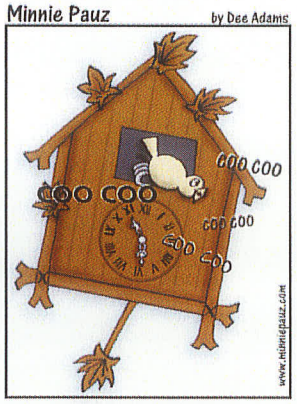
Informational: Organized by three groups, namely, **herbs, foods**, and **vitamin**, this booklet contains information on 11 commonly used natural remedies.

Herbs: Black Cohosh, Chasteberry, Dong Quai, Ginseng, Red Clover, St. John's Wort, and Valerian

Food: Flax, Soy, and Wild Yam

Vitamin: Vitamin E

Interactive: You are invited to complete the written exercises as they are found in this booklet. The written exercises begin with where you are now and end with follow-up charts. These charts are meant to help you keep track of how you feel after you have used the various remedies as outlined in this booklet. You are also encouraged to share your experiences with your health care provider and consider any recommended courses of action.



The midlife woman's biological clock

Is the information in this booklet foolproof?

Although this information booklet is based on the most recent scientific data, it must be noted that there have been a limited number of clinical studies to test the effectiveness of herbs, food supplements, and vitamin that are included in this booklet. Not all women react the same way to each herb, food, or vitamin. Some women may have a favorable response, while others may not. It is hoped that you use the information provided wisely.

This information booklet is not intended as medical advice. It is solely informational and educational. The information is not a substitute for talking with your licensed health care professional.

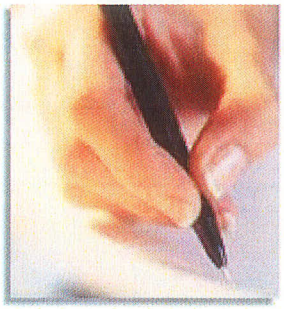
This informational booklet is organized by the most common menopausal **symptoms**. How to proceed?

(i) From the list below, identify the symptoms that closely resemble your experience, and
(ii) Complete Exercise A

Common symptoms associated with perimenopause and menopause. Which of the following symptoms have you experienced?

Anxiety	Irregular bleeding
Breast tenderness	Irritability
Decreased interest in sex	Mild depression
Difficulty sleeping	Mood swings
Fatigue	Night sweats
Forgetfulness	Painful intercourse
Hot flashes	Painful periods
Indigestion	Vaginal dryness

Exercise A: Write down any other symptoms you may have experienced or add details if you wish.



What do I do with my identified symptoms?

- Pages 106 – 116 of this information booklet identifies the herbs, foods, or vitamin that might help you manage your symptoms.
- In addition, you will find more information on recommended dosages and length of use, cautionary notes, the effects of these complementary therapies on other drugs, and other effects.

There are only two ways to live your life. One is as though nothing is a miracle. The other is as though everything is a miracle.

-- Albert Einstein

What are Herbs?

Herbs are plants or parts of plants valued for medicinal, savory, or aromatic qualities. They contain a variety of substances that act upon the body. Herbs have been applied to virtually every disease and condition of humankind. They include plant material such as leaves, flowers, fruit, seed, stems, wood, bark, roots, rhizomes or other plant parts, which may be entire, fragmented or powdered.

General Information about Herbs

- Unlike traditional medicine, herbs act more slowly in the body. While you may not see any substantial effect for up to 4 months, the information that follows provides you with recommended length of use for specific herbs.

- The potency of herbs is dependent upon the quality of herbs purchased. When in doubt, ask your licensed health care provider, pharmacist, or naturopath.

- Just because we think of herbs as "natural" does not mean that they are harmless. It is important to read labels carefully and take only the recommended dosages. More is not necessarily better.

- It is strongly recommended that you introduce only one herb, food supplement or vitamin at a time. This will give you an opportunity to isolate the effects of each herb, food, or vitamin.

What Alternative Remedies am I Taking?

I have tried the following alternative remedies.	This alternative remedy has helped me with the following symptoms
1.	
2.	
3.	
4.	
5.	
6.	

What's Next?

- Terms used in this information booklet will first be defined.
- This will be followed by specific information on 7 herbs, 3 food supplements and 1 vitamin.
- Finally you will be provided with charts to track your progress. Hang on to your pen or pencil!

What do the terms mean?

Anticoagulant: A drug, such as Warfarin, that is taken to prevent formation of blood clots.

Anti-Parkinsonian: Drugs used to help in the treatment of Parkinson's disease or other similar diseases of the nervous system.

Anti-psychotics: Drugs that are used to help patients with mental illness such as schizophrenia.

Biofeedback: A training technique that helps individuals to control their automatic body functions such as heart rate.

Bromocriptine: A drug that is used with Parkinson's disease.

Cyclsoporin: A steroid used skin infections.

Hot Flashes: A menopausal symptom that is experienced as an intense warmth and redness particularly of the head, neck, and upper body.

Indinavir: An anti-viral drug used to slow the progression of HIV infection.

Isoflavone: Plant based mixture that is found in rich supply in soybean, soy products and red clover.

Libido: the desire for sexual activity.

Menopause: A natural biologic event that marks the end of menstruation.

Night Sweats: Excessive sweating that sometimes accompanies a hot flash. This occurs while sleeping.

NSAIDS: Non Steroidal Anti-Inflammatory Drugs used for mild to moderate pain. It includes drugs such as Advil, Aspirin, and Naproxen.

Osteoporosis: A progressive loss of bone with increased risk of fractures to the hip, wrist, and verterbrae.

Paced deep breathing: Slow, rhythmic, and deliberate breathing to slow down more rapid rate of breathing. This is thought to help with hot flashes.

Palpitations: Feeling of the heart pounding in the chest.

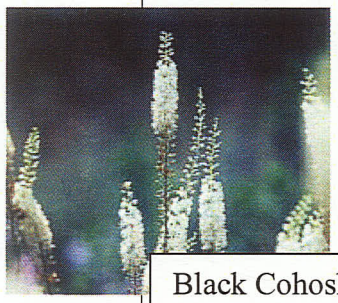
Raloxifene: Sold under the brand name Evista, this drug is used for the prevention and treatment of osteoporosis.

Tamoxifen: A drug used in the treatment of breast cancer.

Theophylline: Drug used in the treatment of chronic asthma.

Managing Perimenopausal & Menopausal Symptoms Naturally

Symptoms	Herb	Dosage	Caution	Drug Interactions	Recommended Length of Use	Other Effects
Anxiety, Depression Dry Vagina Headaches Hot Flashes Nervousness Night Sweats	**Black Cohosh**  	20 mg. by mouth, twice a day	Not recommended for women with breast cancer or at high risk of breast cancer due to family history	If Black Cohosh is taken with: (i) Evening Primrose and Chasteberry – may cause seizures. (ii) With Blood Pressure medications and Tamoxifen - may cause nausea and light headedness If Black Cohosh is taken with iron supplements less iron is absorbed by the body.	Use for more than 6 months has not been studied..	Dizziness Headaches. Heaviness & cramping in legs. Lower heart rate. Stomach pain and discomfort. Weight Gain.



Black Cohosh

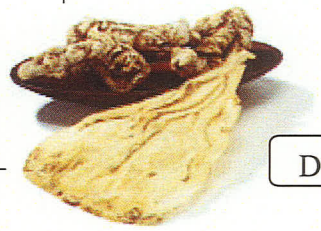
Managing Perimenopausal & Menopausal Symptoms Naturally

Symptoms	Herb	Dosage	Caution	Drug Interactions	Recommended Length of Use	Other Effects
Breast Tenderness Decreased Libido Dry Vagina Painful Intercourse Painful Periods	**Chasteberry** 	3 capsules per day or 1 cup of berry tea per day		If Chasteberry is taken with Black Cohosh and Evening primrose – can cause seizures Negative effects when taken with anti-psychotics, anti-parkinsonian drugs and bromocriptine (which is a drug used for Parkinsons disease)	No more than 18 months. If taken for more than 18 months, may develop side effects such as itching, stomach pains and discomfort, and vaginal bleeding.	Bleeding between periods. Diarrhea. Menstrual Cramping. Rash.

Chasteberry

Managing Perimenopausal & Menopausal Symptoms Naturally

Symptoms	Herb	Dosage	Caution	Drug Interactions	Recommended Length of Use	Other Effects
Fatigue Irregular Bleeding Menstrual Clots Painful Periods Poor Circulation	**Donq Quai** 	3.5 – 4.0 g per day of dry root or 200mg 3 times per day of a standardized extract Liquid Extract 0.5-2.0 mls 3 times per a day	Some parts of this herb have been shown to increase risk of certain types of cancer	In combination with Warfarin, - may cause excessive bleeding	No recommendations made in the literature.	Diarrhea. Fever. Improves circulation and decreases potential for blood clots. Rash caused by exposure to sunlight after taking Dong Quai.



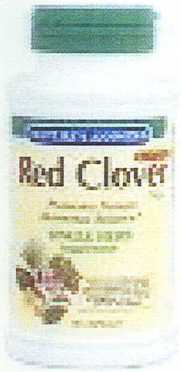
Dong Quai

Managing Perimenopausal & Menopausal Symptoms Naturally

Symptoms	Herb	Dosage	Caution	Drug Interactions	Recommended Length of Use	Other Effects
Anxiety Decreased Libido Fatigue Forgetfulness Mild Depression Weakness	**Ginseng**	Liquid Ginseng: 100-300 mg 3 times per day --- 0.5-1.0 grams of Dry Processed Root 2 times per day for 15-20 days Product should contain 1-6% of the active ingredient – *ginsenoside*	If you have asthma, diabetes, fever, headaches, heart palpitations, hypertension, and schizophrenia, consult your health care provider before use.	In combination with Warfarin it may increase the risk of strokes and blood clots. May falsely increase digoxin levels by interfering with the blood tests.	Not studied for longer than 30 days.	Chest pain. Diarrhea. Improves feelings of general health and well-being. Increases Blood Pressure. Increases Breast Tenderness and Vaginal Bleeding. Insomnia. May decrease blood sugars in diabetics and non-diabetics. Rapid Heart Beat

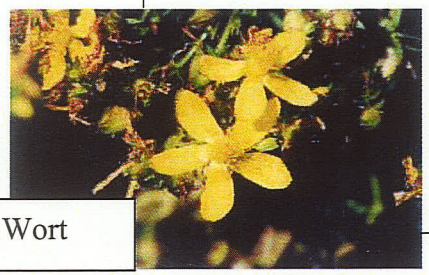
Ginseng

Managing Perimenopausal & Menopausal Symptoms Naturally

Symptoms	Herb	Dosage	Caution	Drug Interactions	Recommended Length of Use	Other Effects
Hot Flashes Night Sweats	**Red Clover**  Also sold as **Promensil**	40 mg per day	Not recommended for women with breast cancer  Red Clover	In combination with Warfarin, Heparin, Aspirin, or Plavix – may increase risk of bleeding	Has been shown to be effective after 4 months of use.	Causes thinning of blood. Causes a build up of tissues that line the uterus. Decreases loss of bone in perimenopausal women. Decreases LDL (bad) cholesterol Increases HDL (good) cholesterol.

Managing Perimenopausal & Menopausal Symptoms Naturally

Symptoms	Herb	Dosage	Caution	Drug Interactions	Recommended Length of Use	Other Effects
Depression Fatigue Seasonal Affective Disorder	**St. John's Wort** 	300 mg 3 times per day of the standardized extract Maintenance Dosage: 300 – 600 mg per day	Stop taking St. John's Wort 3 weeks prior to any procedure(s) requiring anesthesia. Avoid prolonged exposure to sunlight and avoid tanning salons.	Not recommended if you are taking the following drugs: Amitriptyline Anti-Depressants, Cyclosporine Indinavir, Oral Contraceptives, Theophylline, Warfarin, St. John's Wort effects the break down of many drugs in the body	Therapeutic effects usually felt after 10 – 14 days. Significant response in 4 to 6 weeks. Not studied for longer than 8 weeks.	Confusion. Dizziness. Dry Mouth. Rash if exposed to sunlight or tanning salons. Sleepiness. Stomach pain and discomfort.



St. John's Wort

Managing Perimenopausal & Menopausal Symptoms Naturally

Symptoms	Herb	Dosage	Caution	Drug Interactions	Recommended Length of Use	Other Effects
Hot Flashes Night Sweats Trouble sleeping	**Valerian** 	400 – 800mg orally at bedtime	Withdrawal effects may be noted to include hallucinations, restlessness, heart palpitations, delirium, and cardiac failure	If Valerian is taken with sedatives, anti-anxiety pills or alcohol - may increase the concentration of these drugs resulting in toxicity.	Safely used for 28 days. No maximum is noted in the literature.	Drowsiness – driving or operation of machinery is not recommended Feeling of pounding in the chest Feeling sleepy and lethargic Headache Restlessness,

Valerian

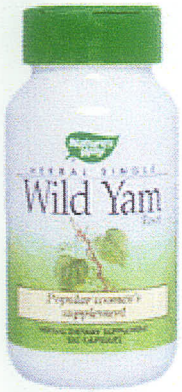
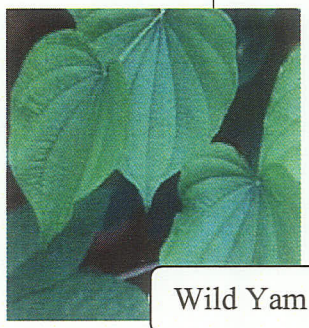
Managing Perimenopausal & Menopausal Symptoms Naturally

Symptoms	Food	Dosage	Caution	Drug Interactions	Recommended Length of Use	Other Effects
Constipation Hot Flashes	**Flax Seeds** 	20 grams of flax seed oil or up to 50 grams of flax seed daily.	Known to increase bleeding if used for longer than 2 months Use with caution if taking NSAIDS, for example, Advil, Ibuprofen, Naprosyn, Aspirin	Avoid use if you are taking the anticoagulant Coumadin or if you have a bleeding disorder. If flax is take with Indomethacin - may cause an increase in stomach ulcers.	Can be used in moderation for prolonged periods of time. It is recommended that you wait 2 hrs before taking any other drug.	Decreases blood sugars. May reduce the absorption of other drugs. May reduce cardiovascular disease by lowering cholesterol. Protects against breast and colon cancer

Managing Perimenopausal & Menopausal Symptoms Naturally

Symptoms	Food	Dosage	Caution	Drug Interactions	Recommended Length of Use	Other Effects
Hot Flashes Mood Swings Night Sweats	**Soy** 	20 – 60 g of dietary soy protein per day 60 - 100 mgs of soy isoflavone supplements per day	Not recommended if you have a history of breast cancer	Decreases effect of Tamoxifen and Raloxifene Decreases levels of thyroxine Increase levels of theophylline Decrease absorption of calcium, iron, & zinc.	Safely used in trials for up to 2 months	Bloating Constipation Flatulence May protect bones May protect the heart and blood vessels by decreasing cholesterol levels in the blood.

Managing Perimenopausal & Menopausal Symptoms Naturally

Symptoms	Food	Dosage	Caution	Drug Interactions	Recommended Length of Use	Other Effects
See NOTE in Caution column	**Wild Yam** 	300mg to 4g for the powdered form	Taken in large doses, it may cause nausea, vomiting, and diarrhea. **The body lacks the enzyme to convert wild yam into progesterone.** **NOTE:** Inconclusive evidence to recommend wild yam for the treatment of hot flashes, decreased desire for sex, and vaginal dryness.	None noted to date.  Wild Yam	No recommendations made	It must be noted that there has been little difference in menopausal symptoms with wild yam versus a sugar pill. Increases growth of uterine lining May also cause excessive facial hair growth, postmenopausal bleeding, and vaginal spotting.

Managing Perimenopausal & Menopausal Symptoms Naturally

Symptoms	Vitamin	Dosage	Caution	Drug Interactions	Recommended Length of Use	Other Effects
Dryness of Vaginal Tissue Hot Flashes	**Vitamin E** 	800 IU of natural Vitamin E orally per day 100IU used as a suppository for vaginal dryness	Exercise caution if you have diabetes, high blood pressure, rheumatic heart disease, or an over active thyroid	If you are on blood thinners or anticoagulants, be extra careful as it can result in increased risk of bleeding.	None noted in the literature. However, be careful if you are on blood thinners and using vitamin E daily.	Headaches Increased Acne Increased Menstrual Flow. Mild Skin Rash Protects against heart disease and fatal heart attacks Upset Stomach Vaginal Bleeding

How am I doing?

Time to use your pen or pencil again.

My Symptoms	Natural Remedies			Effects	
	Herb(s) Taken	Food(s) Taken	Vitamin	*After 2 Months*	Notes to Myself

How am I doing?

My Symptoms	Natural Remedies			Effects	
	Herb(s) Taken	Food(s) Taken	Vitamin	*After 4 Months*	Notes to Myself

How am I doing?

My Symptoms	Natural Remedies			Effects	
	Herb(s) Taken	Food(s) Taken	Vitamin	*After 6 Months*	Notes to Myself

Compared with Conventional Treatment

Conventional Treatments for Menopausal Symptoms		Alternative Remedies	
Drugs Taken	Results/Experiences	Herbs, Food, or Vitamin	Results/Experiences

Where to go from here? You are invited to share your results and experiences with your health care provider to further discuss your questions and concerns.

Concluding Comments

The Wisdom of Today

By: E. Jordan

We often wish for more, without realizing that life's most precious treasures, are often within the palms of our hands.

It is not success, but rather the journey there, that often makes our lives complete.

We are most at peace with the world, when we accept the wonderful and amazing creature. . .that is. . .ourselves.

When we give our all TODAY; and look forward to giving tomorrow the same, then there is no reason for regretting our yesterdays.

Despise not the past, for in it lies the wisdom of today, and the hope of tomorrow.

Source: www.inspiredliving.com/inspire/inspire.htm

Are you ready for "the ride of our life?" It is hoped that this information booklet will enable you to experience perimenopause and menopause in healthy and inspiring ways.