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**Evaluation of a Natural Health Product Patient Decision Aid:
A Tool for Middle Aged Women Considering Menopausal Symptom Relief**

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**Evaluation of a Natural Health Product Patient Decision Aid:
A Tool for Middle Aged Women Considering Menopausal Symptom Relief**

Prudy Menard RN, MSNH, MScN

Thesis submitted to the Faculty of Graduate and Postdoctoral Studies
In partial fulfilment of the requirements for the MSc degree in Nursing

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Faculty of Health Science
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Abstract

Objective: To evaluate the effectiveness of a patient decision aid (PtDA) for menopausal women facing decisions about natural health products (NHPs).

Background: Women experience difficulty making decisions about NHPs for the management of menopausal symptoms. Factors influencing the decision include lack of information, and inadequate communication, and support from health care providers. Decision support interventions that have been demonstrated to be successful in addressing women's decisional needs are decision aids. Although a new decision aid is available, its English version has not been evaluated in a community-based/clinical setting to determine its effect on decision quality or the process of decision making.

Design: A pre-/post-test quasi-experimental study.

Setting: The Women's Health Center at The Ottawa Hospital, Ottawa Canada.

Participants: Peri- or post-menopausal women aged 45 to 64 considering the use of NHPs for management of menopausal symptoms.

Intervention: Self-administered NHP PtDA.

Main Outcome measures: The primary outcome measure was the level of decisional conflict as measured by the Decisional Conflict Scale. Secondary outcomes included knowledge, strength of values, and choice/preference.

Results: Of 24 women, the typical participant was 50 to 59 years of age, Caucasian, married, and well educated. Compared to baseline, after using the decision aid, women's total decisional conflict was reduced from 63% to 23% ($p < 0.001$) and knowledge improved from 76% to 87% ($p = 0.001$). The values clarification exercise revealed that women who preferred NHPs were more likely to rate the non-chemical aspect as important and the cost of the NHP as less important. Of the 24 women, 10 were unsure of their choice at baseline and 3 post use of the decision aid ($p = 0.015$). Overall, women rated the decision aid as acceptable, clear, and balanced.

Conclusion: The NHP PtDA improved decision quality and supported menopausal women who were facing health decisions around using NHPs for menopausal symptoms.

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The journey of doing a Masters degree can be very tumultuous. The one thing that kept me on track was the support I received from various people. I wish to take this opportunity to acknowledge them and express my gratitude.

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Abbreviations

APN= Advanced Practice Nurse

CAM= Complementary and Alternative Medicine

CI= Confidence Interval

CNA= Canadian Nurses Association

CNO= College of Nurses of Ontario

HRT= Hormone Replacement Therapy

ODSF= Ottawa Decision Support Framework

NCCAM= National Center for Complementary and Alternative Medicine

NHP= Natural Health Product

PtDA= Patient Decision Aid

RCT= Randomized Controlled Trial

Chapter One - Introduction

1.1 Research Problem

Menopause is a natural life process that can entail mild to very severe symptoms for women (Sherman, 2005; Woods & Mitchell, 2005). These symptoms include psychological distress, depression, hot flashes, night sweats, and difficulty sleeping (Keenan et al., 2003; Matthews & Bromberger, 2005; Schmidt, 2005; Sherman, 2005). Options for these women to manage menopausal symptoms include self-care, lifestyle changes, hormone replacement therapy (HRT), other prescription medications, and natural health products (NHPs) (Woods & Mitchell, 2005).

In the past, women were encouraged to use HRT for menopausal symptoms (Goolsby, 2001). In 2002, however, the Women's Health Initiative reported an increase of coronary artery disease and breast cancer for women taking HRT (Writing Group for Women's Health Initiative, 2002). Since the release of the Women's Health Initiative findings, more women are reaching out to NHPs for management of menopausal symptoms (Gingrich & Fogel, 2003; Keenan et al., 2003; Mahady, Parrot, Lee, Yun, & Dan, 2003). About 71% of Canadians use NHPs (Health Canada Survey, 2005). The highest use of NHPs is among those with a higher education and women.

Since January 2004, NHPs have been monitored under the Natural Health Products Regulations in Canada (Health Canada, 2005). According to Health Canada, NHPs are defined as vitamins, minerals, herbal remedies, homeopathic medicines, traditional medicines (e.g., traditional Chinese medicines), probiotics, and other products (e.g., amino acids, essential fatty acids). Other common terms, often used interchangeably with NHPs, are complementary and/or alternative medicine (CAM). CAMs are defined as "a group of diverse medical and healthcare systems, practices, and products that are not presently considered to

be part of conventional medicine”; its subcategory “Biologically Based Therapies” includes “substances found in nature, such as herbs, foods, and vitamins” (National Center for Complementary and Alternative Medicine [NCCAM], 2007, p. 1).

The use of NHPs and the number of products available have increased over the past 10 years (Tindle, Davis, Phillips & Eisenberg, 2005). The use of NHPs among North American women ranges from 46% to 78% (Eisenberg et al., 1998; Health Canada, 2005, Tindle et al., 2005; Troppmann, Johns & Gray-Donald, 2002). More specifically, the proportion of women using NHPs for menopausal symptoms ranges from 46% to 82.5% (Gollschewski, Anderson, Skerman & Lyons-Wall, 2003; Keenan et al., 2003; Mahady et al., 2003). In a study of 40 peri-menopausal women, 42% reported that the main reason for using NHPs was to avoid the use of hormone replacement therapy (Gingrich & Fogel, 2003). Furthermore, the American market has capitalized on this trend with over 100 new products for menopausal women introduced from 1998 to 2000 and women have been reported to have purchased over 600 million dollars worth of NHPs (Kass-Annese, 2000). Given the myriad of NHP options and questionable quality of accessible information, these women are likely to experience decisional conflict.

Decisional conflict is defined as uncertainty about the course of action to take when there are multiple options that can result in risk, loss, or regret (North American Nursing Diagnosis Association, 2003). A national survey of 635 Canadians found that, of the 59% of Canadians who reported decisional conflict, women were more likely to feel uninformed about options, pressured to select one particular option, or unskilled in decision making (O'Connor, Drake et al., 2003). Women's knowledge about and choices of NHPs are often influenced by word of mouth, media, and the Internet (Gingrich & Fogel, 2003; Health Canada, 2005; Pettigrew, King, McGee, & Rudolph, 2004; Will & Fowles, 2003).

According to a Health Canada survey (2005), although 84% of 2,004 Canadians see a need for more information about the safe use of NHPs, 52% believe that NHPs are safe. Quality decisions, however, depend on having access to information that is balanced, unbiased, and based on the best available scientific evidence (Elwyn et al., 2006). Therefore, it is necessary to understand the decision support needs of women facing decisions about using NHPs for menopausal symptoms and determine ways they can best be supported.

Decision support can be provided through counselling and/or patient decision aids (PtDAs). A Cochrane review of 55 randomized controlled trials found that PtDAs facilitate the decision making process by increasing patients' knowledge of options and decreasing decisional conflict (O'Connor, Bennett, et al., 2007). According to the International Patient Decision Aid Standards document, a higher quality PtDA needs to be developed using a systematic and replicable process and it should be field-tested (Elwyn et al. 2006).

A NHP PtDA was developed by a Canadian-based consortium (Légaré et al. 2007). The NHP PtDA was based on a needs assessment to support women's decisional needs when considering using NHPs for menopausal symptoms. The needs assessment and decision aid were guided by the Ottawa Decision Support Framework [ODSF]. Given that the PtDA was developed concomitantly in both English and French, there was a need to evaluate it in both languages. At the time this study was planned, the French version was being pilot tested in Quebec (F. Légaré, personal communication, March 26, 2008).

1.2 Objective of the Study

Overall, the aim of this study was to evaluate the effectiveness of a NHP PtDA on the quality of decisions made by peri- and post-menopausal women facing decisions about NHPs. Specifically, the PtDA is hypothesized to reduce decisional conflict and increase decision quality. Decision quality was defined as having; a) knowledge of NHPs options,

benefits, and risks; b) clear values associated with outcomes of options; and c) concordance between the option chosen and patients' values (O'Connor, Bennett, et al., 2007).

Chapter Two – Literature Review

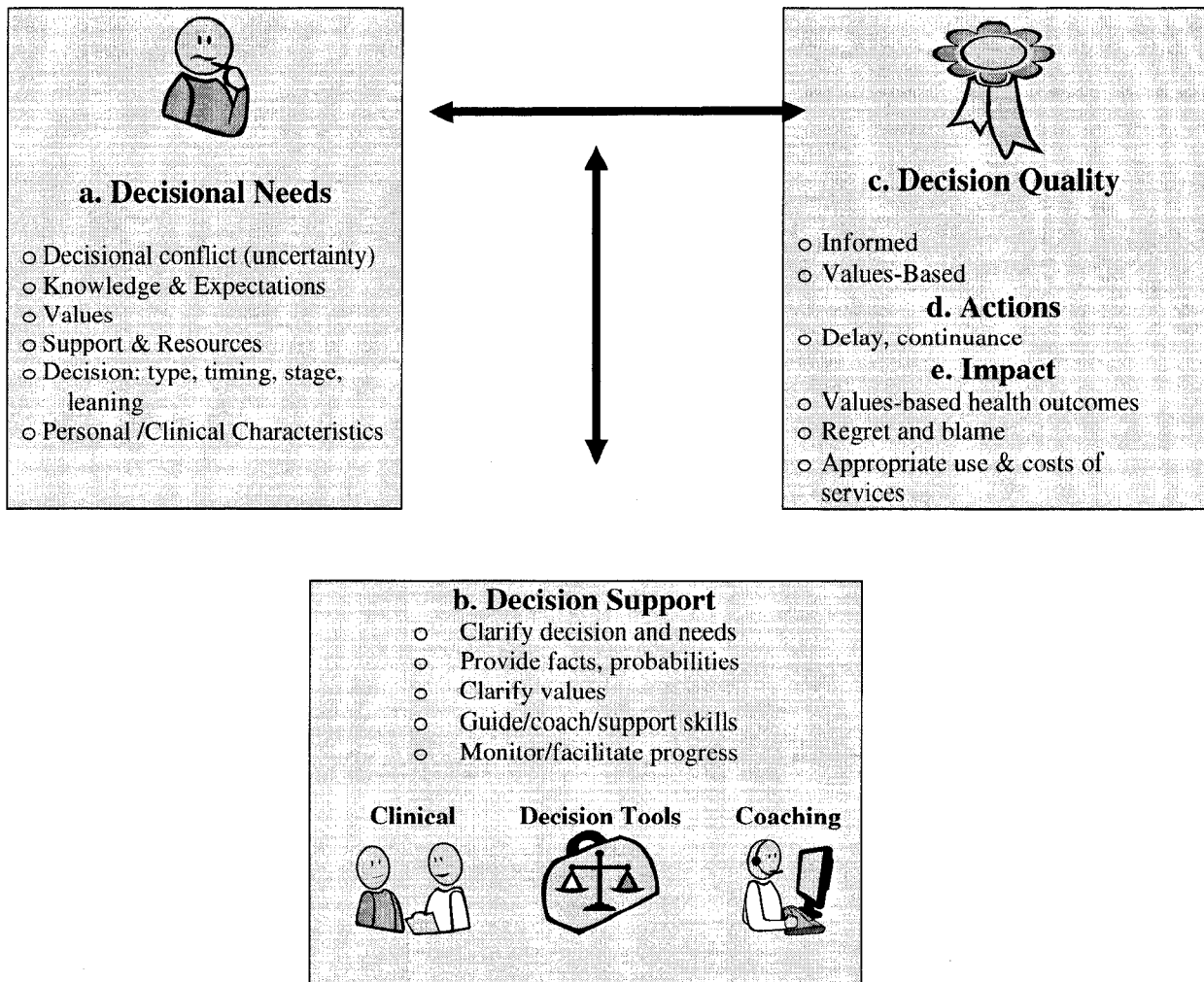
This chapter reviews the existing literature to understand the decision support needs of women facing decisions about managing menopausal symptoms and ways they can best be supported. The objective is to utilize the ODSF to examine the literature addressing:

- a) Decisional needs of menopausal women considering using NHPs for symptom management
- b) Evidence, regarding NHPs and menopause to support informed decision making
- c) Decision support interventions to support women making decisions about NHPs

2.1 Conceptual Framework

The ODSF is a middle-range theory that can guide the construction of interventions to facilitate the preparation of individuals for decision making in health care, particularly in circumstances where there is scientific uncertainty (O'Connor et al., 1998a). The ODSF consists of three steps: assessment, intervention, and evaluation (O'Connor, 1998a). See Figure 2.1 for the illustration of the ODSF and Table 2.1 for the definition of terms identified in the framework. First, decisional needs are assessed by exploring contributing factors. For example, potential decisional needs for women considering NHPs for managing menopausal symptoms include uncertainty about which option to choose, knowledge and expectations regarding NHP options, personal importance of these options, and available support systems and resources.

Figure 2.1: The Ottawa Decision Support Framework



O'Connor et al., 2007 (Reprinted with permission of the author)

Table 2.1: Glossary of Terms for the ODSF

DECISIONAL NEEDS
DECISION Type: class or characteristic of the choice that needs to be made [e.g. developmental transition or clinical options (screen, test, treat, palliate); number of options, degree of risk/uncertainty, seriousness of outcomes, whether it is irrevocable] Timing: time frame or urgency with which a decision needs to be made Stage: phase of decision making: not thinking about options; considering options; close to selecting an option; taking steps towards implementing option; have already carried out choice. Categories are similar to Prochaska's Stages of Change (1), with one important difference. Deciding <u>not</u> to change is a viable option because often there is no recommended course of action, e.g. amniocentesis. Leaning: inclination to choose one option over the other
DECISIONAL CONFLICT uncertainty about course of action to take when choice among options involves risk, loss, regret, challenge to personal life values
KNOWLEDGE & EXPECTATIONS Knowledge: cognizance of the health problem or situation, options, and outcomes Expectation: perceived likelihood or probability of outcomes of each option
VALUES desirability or personal importance of outcomes of options
SUPPORT & RESOURCES Others' opinions/ practices: perceptions of what others decide or what others think is the appropriate choice. This may include a person's spouse, family, peers, and practitioner(s). For practitioners: the patient, professional peers, and personal network Pressure: perception of persuasion, influence, coercion from important others to select one option Role in decision making: the way a participant is or wants to be involved in decision making; do they prefer to: make the choice themselves after considering opinions; share decision making with another; have others decide after considering their opinion Experience: past exposure to the situation, options, outcomes, decision making process Self-efficacy: confidence or belief in one's abilities in decision making, including shared decision making Motivation: readiness and interest in decision making, including shared decision making Skill: abilities in making and implementing a decision External support: Available, accessible assets from others that are required to make and implement the decision. Types include: information, advice, emotional support, instrumental help, financial assistance, health & social services. Sources include: social networks, professional networks, support groups, voluntary agencies, and the formal health care, education, and social sectors
PERSONAL & CLINICAL CHARACTERISTICS Patient: Age, gender, education, marital status, ethnicity, occupation, locale, diagnosis & duration of condition, health status (physical, emotional, cognitive, social) Practitioner: age, gender, ethnicity, clinical education, specialty, practice locale, experience, counseling style
DECISION SUPPORT
PATIENT DECISION AIDS Evidence-based tools to prepare people to participate in making specific and deliberated choices among healthcare options in ways they prefer. They supplement (not replace) clinician's counseling and aid decision making by: a) providing evidence-based information about a health condition, the options, associated benefits, harms, probabilities, and scientific uncertainties; b) helping people to recognize the values-sensitive nature of the decision and to clarify the value they place on the benefits, harms, and scientific uncertainties. Strategies include: describing the options in enough detail that clients can imagine what it is like to experience the physical, emotional, and social effects; and guiding clients to consider which benefits and harms are most important to them; and c) providing structured guidance in the steps of decision making and communication of their informed values with others involved in the decision (e.g. clinician, family, friends).
DECISION COACHING Support provided to people facing a decision by a trained facilitator who is supportive but neutral in the decision. Coaching can be provided face to face (individual, group) or using communication technologies (telephone, Internet). Decision coaching is used alone or in combination with patient decision aids. The strategies may include: a) clarifying decision and monitoring needs; b) facilitating access to evidence-based information, verifying understanding, clarifying values, building skills in deliberation, communication, and accessing support; and c) monitoring and facilitating progress in decision making and decision quality.
DECISION QUALITY
QUALITY OF THE DECISION The extent to which the chosen option best matches informed clients' values for benefits, harms, and scientific uncertainties
QUALITY OF THE PROCESS OF DECISION MAKING The extent to which a person is helped to: a) recognize that a decision needs to be made; b) know about the available options and associated procedures, benefits, harms, probabilities, and scientific uncertainties; c) understand that values affect the decision; d) be clear about which features of the options matter most to them (e.g. benefits, harms, and scientific uncertainties); e) discuss values with their clinician(s); and f) become involved in decision making in ways they prefer.

O'Connor et al., 2007 (Reprinted with permission of the author)

Second, once needs are identified, decision support interventions can be implemented. Decision support is defined as the preparation of the client and practitioner for decision-making and structured follow up counselling where the goals are to improve decision making by tailoring the support according to the participants' decisional needs (O'Connor, Jacobsen, & Stacey, 2002). The health care provider can offer support that includes patient decision aids and/or decision coaching. Decision aids are "interventions designed to help people make specific deliberative choices among options by providing (at the minimum) information on options and outcomes relevant to the person's health status" (O'Connor, Fiset et al., 1999, p. 67). Decision coaching is defined as health professionals effectively guiding the informed patient through the decisional process (Stacey et al., 2008).

Step three in the framework is the evaluation of the decision process and decision quality. Decision quality is defined by being informed by the best available evidence and a choice that matches what the informed patient values (O'Connor, Bennett, et al., 2007).

2.2 Rationale for Use of the Conceptual Framework

The success of this model in addressing decisional needs and developing intervention strategies has been shown in several clinical situations in women's health, especially in the area of middle-aged women's health (Clark, O'Connor, Graham, & Wells, 2003; Cranney et al., 2002; Dodin, Légaré, Daudelin, Tetroe & O'Connor, 2001; Légaré, O'Connor et al., 2003; Légaré, Tremblay et al., 2003; O'Connor et al., 1998a; O'Connor, Rostom et al., 1999). The ODSF fits well for NHP decisions about managing menopausal symptoms because women are exposed to an abundance of information of varying quality on NHPs and face multiple options for which there is no one best option for all women. Therefore, using this framework will enable a more structured approach for reviewing the literature to address the needs of women considering NHPs for menopausal symptoms, the available evidence about

products to support informed decision making, and intervention strategies to facilitate a high quality decision.

2.3 Search Strategy

A search of the literature from January 1995 to August 2007 was performed using the following electronic databases: Cochrane database, PUBMED, CINHALL, Allied and Complementary Medicine Database, Agency for Healthcare Research and Quality, SCOPUS, EMBASE and the Natural Standard website. Created by clinicians and researchers, the Natural Standard website is a database of information about Natural health products (Natural Standard, 2007). Other searches were performed on the Health Canada website and National Center for Complementary and Alternative Medicine, which are Canadian and American governing bodies targeting NHPs. The search terms included the key words: decision making (decision support, patient decision aid), natural health products (alternative therapies, complementary and alternative medicine/therapies, herbal medicine, herbal plants, medicinal plants) and menopause (peri-, post-menopause). These key words were input one at a time and then combined using “and/or”.

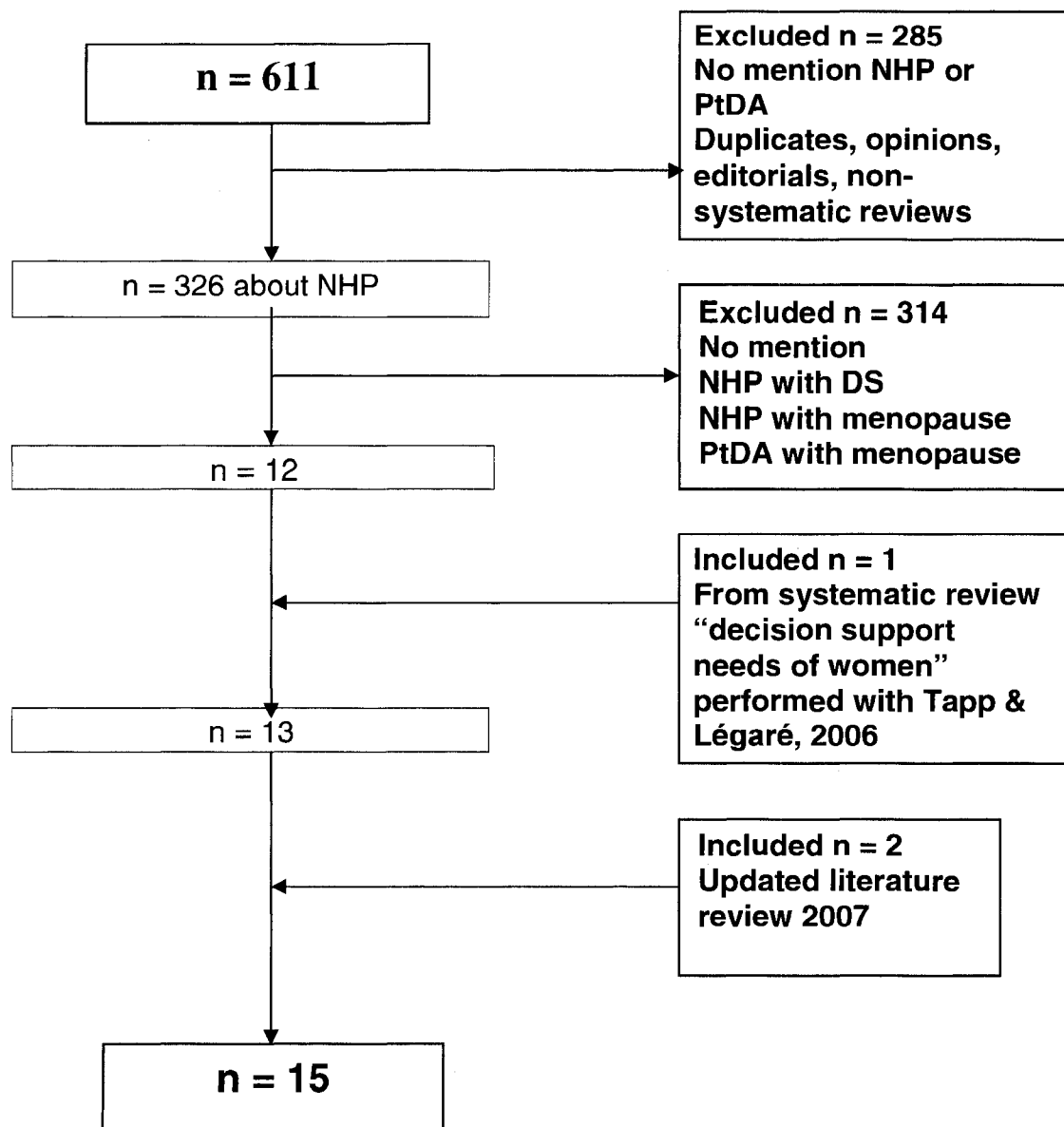
Citations included in the review were systematic reviews and any study reporting original data, available in either English or French. Exclusion criteria were opinions, editorials and non-systematic reviews, any article not including NHPs and decision support, NHPs and menopause, and PtDAs and menopause. All article abstracts were then screened based on the inclusion/exclusion criteria. Data extraction was guided by a standardized tool based on the ODSF (O'Connor et al., 1998a).

2.4 Findings

Of the 611 citations screened in 2005, 12 studies were retrieved for inclusion in this review (see Figure 2.2). Of the 12 studies, 4 described the decision support needs of women

making NHP decisions, 7 focused on the evidence to support use of NHPs for managing menopausal symptoms, and 1 study evaluated an intervention to support decision making. Subsequently, a systematic review in 2006 of “factors influencing women’s decision making regarding NHPs for menopausal symptom relief” involving 625 citations resulted in the same 4 decision support needs studies plus one additional study (Tapp, Légaré, Brouillette, Menard & Stacey, 2006). Following this, an update of the literature review in 2007 produced two additional studies focusing on decision support needs of women, resulting in 15 studies.

Figure 2.2: Search Results



2.5 Decision Support Needs of Menopausal Women

The first key element of the Ottawa Decision Support Framework is assessing decisional needs. Table 2.2 summarizes the characteristics of seven studies describing the decision support needs of menopausal women and table 2.3 describes the decisional needs of these women including knowledge, clarity of values, support from others, resources for making decisions, and preferred interventions (Gingrich & Fogel 2003; Légaré et al., 2007; Ma, Drieling & Stafford, 2006; Richter, Corwin, Rheaume & McKeown, 2001; Seidl & Stewart, 1998; Suter et al., 2007; Will & Fowles, 2003). All studies used descriptive study designs with qualitative and/or survey data (see Table 2.2). In 7 of 15 studies, women's perception of the decision was believed to be influenced by decisional conflict, lack of knowledge in 7, and unclear values in 2. Inadequate support from others, that interfered with decision making, included a lack of confidence in health care providers opinions (n=7), need to exercise desired role (n=7), lack of advice from others (n=6), and undue pressure from others (n=3) (see Table 2.2). Common resource issues included the lack of credible information or overwhelming information (n=7), the costs of NHPs (n=4) and lack of qualified healthcare providers trained in NHPs (n=2). Finally, decision support interventions that were suggested included offering information (n=7) and having health care providers communicate openly with women (n=6). Only two studies reported tailoring treatments to women's needs and one proposed a PtDA (Légaré et al., 2007).

Table 2.2: Characteristics of Decision Support Needs Studies

Author/Year/Location	Design	Participants	Principal Aim
Légaré et al., 2007 Canada	Descriptive Needs Assessment	Focus groups with 41 menopausal women (aged 44-67 year), interviews with 15 key informants (pharmacists, physicians, nurses, health food store owners, policy makers)	-To identify decision support needs for women using NHP for menopausal symptoms and develop an intervention to support decision making
Suter et al. 2007 Canada	Descriptive	22 women (aged 42-58)	-To determine how information is obtained and evaluated using alternative therapy (AT) for menopausal symptoms and barriers to making an informed decision
Ma et al., 2006 US	Descriptive Survey	781 Perimenopause or menopausal women (aged 40-60)	-To examine women's perception of AT and hormone replacement therapy in menopausal symptoms
Gingrich et al., 2004 US	Descriptive	40 Perimenopausal women ages 40 to 65 years in Southeastern	-To explore the prevalence of herbal use in women and disclosure of use to their physicians
Will et al., 2003 Canada	Descriptive	19 Caucasian women (41-62 years)	-To explore reasons why women use complementary therapy for menopausal symptoms
Richter et al., 2001 US	Descriptive	17 Focus group of 82 women (35-64 years)	-To examine women's perception on the available AT for menopausal symptoms
Seidl et al., 1998 Canada	Descriptive	13 Perimenopausal women (average age 52.6)	-To examine understanding of AT for menopausal symptoms

Table 2.3: Decision Making Needs Literature Results

Factors Influencing Decisional Needs	Légaré 2007	Suter 2007	Ma 2006	Gingrich 2004	Will 2003	Richter 2001	Seidl 1998
<u>Perception of the Decision</u>							
Decisional conflict	✓	✓	✓	✓	✓	✓	✓
Lack of knowledge	✓	✓	✓	✓	✓	✓	✓
Unclear values	✓	--	--	--	✓	--	--
<u>Perception of Others</u>							
Lack of confidence in HCP opinions	✓	✓	✓	✓	✓	✓	✓
Lack of support from others	✓	✓	✓	✓	✓	--	✓
Undue pressure from others	✓	--	--	--	✓	--	✓
Desired role in decision making	✓	✓	✓	✓	✓	✓	✓
<u>Perception of Resources to Make Decision</u>							
Lack of credible or overwhelming information on options	✓	✓	✓	✓	✓	✓	✓
Lack of other resources (qualified HCPs, computer knowledge)	✓	✓	✓	✓	✓	--	--
Cost factor	✓	✓	--	✓	--	--	✓
<u>Proposed Interventions to Support Decision Making</u>							
Offer information to make informed choice	✓	✓	✓	✓	✓	✓	✓
HCP keep open communication with women	✓	✓	✓	✓	--	✓	✓
Tailor treatment to patient needs	✓	--	--	✓	--	--	--
Patient decision aid	✓	--	--	--	--	--	--

✓ = study indicated the need; -- = need was not identified; HCP = health care provider

2.6 Natural Health Product Evidence to Inform Menopausal Women

Another important element of decision making is being informed about the most current evidence on options. Table 2.4 summarizes the seven studies which focused on the use of NHPs during menopause. The five systematic reviews included randomized controlled trials of NHPs (Huntley & Edzard, 2003, 2004; Kessel & Kronenberg, 2004; Kronenberg & Fugh-Berman, 2002; Low Dog, 2005). These systematic reviews summarized the evidence on soy extract (n=4 systematic reviews), black cohosh (n=4), red clover (n=4), dong quai (n=4), evening primrose seed oil (n=4), ginseng (n=4), vitamin E (n=2), kava (n=2), and combination products (n=3). Recently published double-blinded randomized controlled trials (RCTs) evaluated the effect of black cohosh plus St John's wort in peri- and post-menopausal women (n=2 RCTs).

Black cohosh is a perennial herb that is used as a popular alternative in relieving menopausal symptoms; the exact mechanism of action is unknown (Natural Standard, 2007). Consistently, these systematic reviews and more recent RCTs have found that black cohosh reduces hot flashes and sweating (Huntley & Edzard, 2003; Kessel & Kronenberg, 2004; Kronenberg & Fugh-Berman, 2002; Low Dog, 2005). Although no serious adverse events were reported in the RCTs, several case reports indicate that black cohosh may be linked to liver damage (Health Canada, 2006; Low Dog, 2005). Low Dog questioned the validity of the four case reports involving 5 patients highlighting that "2 of the 5 [patient] cases involved combination herbal products, 3 cases failed to analyze suspected products for purity and identification, and 1 case did not report the brand or dose of black cohosh consumed" (Low Dog, 2005, p.101).

Table 2.4: Evidence of Natural Health Product Use and Menopause

First author/year/location	Design	Target population	Results
Low Dog/2005/US	Systemic review of 19 RCTs (1966-2004) herbal therapies	Peri-, menopausal and postmenopausal women	Of 6 herbs, black cohosh most promising in relieving menopausal symptoms (various scales).
Huntley/2003/US	Systematic review of 18 RCTs (1966 to 2002) herbal products	Women (40 -70 years) in various countries	Of 7 herbal products, black cohosh most promising in relieving menopausal symptoms
Huntley/2004/US	Systematic review of 10 RCTs (1966 to 2003) of soy products	Women (30 -70 years)	Some evidence to support soy use in perimenopausal symptoms
Kessel/2004/US	Systematic review of 29 RCTs(2002-2004) CAM therapies	Peri- and postmenopausal women	Mixed findings (mostly negative) vit E, soy, red clover & black cohosh on menopausal symptoms
Kronenberg/2002/US	Systematic review of 29 RCT of CAM therapies	Peri-, menopausal and postmenopausal women	Black cohosh & soy show promising result for hot flashes & other menopausal symptoms
Chung/2007/Korea	Double-blind RCT combination of black cohosh & St John's wort	Peri- and postmenopausal women/42 treatment & 35 placebo	Black cohosh and St John's wort significantly improved menopausal symptoms and depression compared to placebo ($p = .04$)
Uebelhack/2006/ Germany	Double-blind RCT combination of black cohosh & St John's wort	Women between 45 and 60 years/151 treatment & 150 placebo	Black cohosh and St John's wort significantly improved menopausal symptoms and associated psychological complaints compared to placebo ($p < .001$)

Compared to placebo, two double blind RCTs found that women who took black cohosh with St. John wort had significant reduction in hot flashes, sleep disturbances, anxiety and depression (Chung et al., 2007; Uebelhack et al., 2006). Both groups reported similar frequencies of gastrointestinal complaints (e.g., bloating, diarrhoea).

Soy is an Asian plant that produces beans containing a substance called Isoflavones (Phytoestrogens) which are believed to produce estrogenic-like effects in the body and may be used as a dietary supplement to reduce menopausal hot flashes. The exact action is not clear (Natural Standard, 2007). Of six RCTs evaluating the use of dietary soy supplements, four found a significant reduction in hot flashes (Low Dog, 2005). Another systematic review reported on 10 RCTs of soy in dietary supplements as well as in foods such as flour and beverages; it only included studies of higher methodological quality based on Jadad score of 3 or greater (Huntley & Edzard, 2004). Of the 10 included RCTs, 4 found soy decreased hot flashes (Huntley & Edzard, 2004). Although five RCTs reported adverse effects in those who took soy, such as bloating, constipation, nausea, unpalatable taste, weight gain, and allergies, four RCTs reported the same adverse events in the control groups. Soy appears to decrease hot flashes; however, determining specific guidelines for using soy is difficult given that studies varied in their inclusion criteria, dosage, type and quality of soy used, and how they measured the outcome (i.e., the number of hot flushes) (Huntley & Edzard, 2004; Low Dog, 2005).

Red clover is a legume that is also rich in phytoestrogens, possessing an estrogenic-like action that is used to reduce hot flashes (Natural Standard, 2007). Red clover was found to reduce hot flashes significantly in two smaller studies of 30 women each but results were equal to placebo in three larger studies (Low Dog, 2005). Low Dog concluded that the results are contradictory, with lack of data, small sample size, and unclear description of

methodologies. The systematic review by Huntley and Edzard (2003), however, reported that results for red clover are promising, particularly in women with more severe symptoms. A major issue noted by both authors (Low Dog and Huntley) is that most of the studies', demonstrated inconsistencies in controlling confounding variables such as isoflavone in women's diet, leading to some women ingesting other forms of isoflavonoids. Therefore, it may prove more difficult to compare these studies considering the confounding variables.

RCTs to evaluate dong quai, evening primrose seed oil, ginseng, vitamin E and other mixed combinations have not shown them to be successful in treating menopausal symptoms (Huntley & Edzard, 2003; Kessel & Kronenberg, 2004; Kronenberg & Fugh-Berman, 2002; Low Dog, 2005). Kava has been banned in Canada and is not considered an option because it has been linked to serious liver dysfunction (Health Canada, 2002).

2.7 Literature Review Evidence Limitations

In light of the above findings, several limitations were noted in the NHP RCTs. Of concern were the lack of studies on commonly used products and methodological issues of the RCT studies such as differing inclusion/exclusion criteria, differing outcome measures as studies used different scales to measure hot flashes, no clear definition of the sample used (i.e., menopausal, postmenopausal), and differing product usage (Huntley & Edzard, 2003, 2004; Kronenberg & Fugh-Berman, 2002; Low Dog, 2005). For example, even though red clover blossoms have been commonly used as a traditional medicine in treatment of menopausal symptoms for centuries, the clinical trials performed on red clover were of its semipurified isoflavone state, which may not be representative of red clover's pure form (Low Dog, 2005).

Limitations in generalizability were also noted in the black cohosh/St John's wort combination studies. The participants in the German RCT were all Caucasian in origin and

the participants in the Korean study, were all Korean (Chung et al., 2007; Uebelhack et al., 2006). This may not be representative of a North American population. It is also difficult to know which NHP, black cohosh or St John's wort, was responsible for the symptom relief or if it was a combination of both. Although studies have been performed on black cohosh and St John's wort separately, more studies need to be performed. Given the multiple options and minimal evidence, women are likely to need help in considering their options.

2.8 Interventions to Support Decision Making

Effective decision support strategies for transfer of scientific evidence to women making health decisions can include PtDAs and/or decision coaching. A Cochrane systematic review of 55 RCTs verified that patient decision aids can help facilitate the decision making process, to produce a high quality decision, by decreasing decisional conflict, increasing knowledge, creating realistic expectations, and improving value congruence with the chosen option (O'Connor, Bennett et al., 2007). Furthermore, when nurses coached women to clarify their values associated with their options for benign uterine bleeding, in addition to the PtDA, the intervention was more cost-effective compared to the PtDA alone or usual care (Kennedy et al., 2002). Of these 55 RCTs, 9 evaluated the effect of 5 different PtDAs comparing a simple PtDA or usual care for women considering hormone replacement therapy and none evaluated the effect of PtDAs on decisions to use NHPs for menopausal symptoms.

Of the five hormone replacement PtDAs, one briefly mentioned herbal remedies as an option for dealing with hot flashes and discussed the placebo effect of herbal medicines (Foundation for Informed Medical Decision Making as cited in Murray 2001). Hormone replacement PtDA's were studied in 9 RCT's: in four RCTs, knowledge increased (Dodin et al., 2001; O'Connor et al., 1998b; Rostom, O'Connor, Tugwell, & Wells, 2002; Rothert et al., 1997), in three, expectations were more realistic (Dodin, 2001; Mc Bride et al., 2002;

O'Connor et al., 1998b), in two, value concordance with the options chosen improved (Dodin, 2001; Holmes Rovner, 1999), and in one study, participants had an increased perception of feeling informed and clear about their values (Murray et al., 2001). In addition, Bastian et al. (2002) suggested that a tailored PtDA would be more effective if provided along with telephone counselling.

A Cochrane inventory of more than 500 decision aids included 10 PtDAs focused on hormone replacement therapy (Cochrane Inventory, 2004). One of the easily accessible hormone replacement therapy PtDAs contained a small amount of information on the option of taking black cohosh to reduce hot flashes (Healthwise, 2006). Out of the 500 PtDAs only 1 PtDA focused solely on NHPs (Légaré et al. 2007).

2.8.1 Natural Health Product Patient Decision Aid Intervention Pamphlet

This patient decision aid entitled “A decision aid for women considering natural health products for menopause symptoms” (see Appendix A) is a 13 page pamphlet that includes evidence-based information on menopause (see Figure 2.3), NHP options and resources (e.g. websites, books, associations and scientific papers). Using the balance scale technique, women are asked to identify their options, list the outcome of these options, and clarify their values by rating the level of importance using a 5 point scale (see Figure 2.4).

Figure 2.3: Evidence-based Information on NHPs

Step 2. Getting the facts

When learning about the benefits and risks of natural health products that have been used by women during menopause,¹¹ it is important to know that the quality of the information varies. This quality depends on the number and types of research studies that have been done.

A: Very good level of evidence that there are benefits related to menopause (No product in this class)

B: Good quality evidence showing that there are benefits related to menopause

Common name (latin)

Black cohosh (*cimicifuga racemosa*, *Actaea racemosa*)

Active chemical

27-deoxyactein

Dose

1 to 2 mg of 27-deoxyactein

per day taken by mouth

Tablets

1 or 2 tablet

(20 mg tablet=1 mg

27-deoxyactein)

Liquid

20 to 40 drops of a 60%

ethanol tincture daily (1:10)

(20 drops=1 mg 27-deoxyactein)

Dried root powder

40 to 200 mg of dried rhizome

divided in several doses

(40 mg=1 mg 27-deoxyactein)

Dried root infusion

1 to 2 g boiled in 150 ml of water,

filtered and cooled

(doses recommend by The British

Herbal Compendium)¹²

Possible benefits

Decreases general menopause

symptoms such as migraine

headaches, sleep

disturbances, hot flashes,

mood problems, perspiration,

heart palpitations, and vaginal

dryness for up to 6 months

Possible risks

No study has reported risks and

benefits when taken longer than 6

months

If an overdose is taken, it may

cause nausea, vomiting,

bradycardia (low heart rate),

headache, fainting, sweating and

vision problems

Restrictions or warning

Consult your physician before use if you:

- have or have had breast or uterine cancer

- have an allergy to aspirin or to the ranunculaceae family

- suffer from endometriosis

- are using a hormone replacement therapy for menopause (hormones)

- suffer from epilepsy

- are taking medication for hypertension

- have heart or liver problems

It may be confused with blue cohosh (*Caulophyllum thalictroides*) that

can have harmful effects on the heart

* Please check with Health Canada Advisory regarding possible link between black cohosh

and liver damage http://www.hc-sc.gc.ca/htp-mpp/advisories-avis/index_e.html

Soya (*Soja hispida*, *Glycine max*)

Dose

50 to 75 mg of isoflavones per day taken by mouth

Isolated protein (powder)

60 g (25 g=60 mg of isoflavones)

Soy flour

45 g (50 g=60 mg of isoflavones)

Possible benefits

Decreases hot

flashes due to

menopause

Possible risks

Soya does not have any

known long-term toxic

effects

Side-effects may include

nausea, constipation, and

bloating

Restrictions or warning

Some people can have or develop an allergy to soya.

Consult your physician if you:

- have or have had breast, ovarian or uterine cancer

- are taking estrogen

- are taking medication for the treatment of cancer

- are taking a blood thinner such as warfarin (Coumadin®)

Figure 2.4: Values Clarification Worksheet

Step 3. Identify the available options

A. Take the decision you identified in step 1 and, list the options that you are considering.

B. For each of these options, list all of the benefits and risks.

C. Underline the benefits and risks that are most likely to occur.

For example, if the option is to take soya for hot flashes

Option (example)	Benefits (reasons for choosing) (examples)	Risks (reasons for avoiding) (examples)
To take soya	- decreases hot flashes - does not need a prescription from physician	- there might be side-effects such as nausea, constipation, bloating - there is a cost
Options	Benefits (reasons for choosing)	Risks (reasons for avoiding)
#1		
#2		
#3		

2.9 Overall Summary of Literature Review

Women considering the use of NHPs to manage menopausal symptoms are facing numerous barriers that interfere with making quality decisions. These barriers include lack of knowledge and information regarding product options, lack of confidence in their health care provider's ability to provide these options, and many NHPs being marketed with variable evidence to support use (Gingrich & Fogel, 2003; Huntley & Edzard, 2003; Huntley & Edzard, 2004; Kronenberg & Fugh-Berman, 2002; Légaré et al., 2007; Low Dog, 2005; Richter et al., 2001; Ma et al., 2006; Seidl & Stewart, 1998; Suter et al., 2007; Will & Fowles, 2003). NHPs that appear to reduce hot flashes are soy and black cohosh with or without St John's wort; however, there is concern that black cohosh may be linked to liver disease (Chung et al., 2007; Huntley & Edzard, 2003, 2004; Kronenberg & Fugh-Berman, 2002; Low Dog, 2005; Uebelhack et al., 2006). The evidence to support use of these NHPs is consistent with surveys of NHP use that indicate these are the NHPs most commonly used (Gollschewski et al, 2004; Mahady et al., 2003). With the numerous barriers to choosing NHPs, it is not surprising that the decision about whether or not to use NHPs causes decisional conflict among women. Although PtDAs are effective in improving decision quality and reducing decisional conflict, there is only one decision aid available for NHPs for menopause and it requires further evaluation.

Chapter Three – Methods

In this chapter, the sections used to report the methods followed the guidelines in Cone and Foster (2003). These sections include the research design, subjects, setting, independent variable, measures (dependent variables), procedure, ethics, and data analysis.

3.1 Research Design

A quasi-experimental one-group pre-/post-test design was used to evaluate a PtDA for women considering NHPs for menopausal symptoms. In this study, this type of design was chosen to be able to examine changes in the dependant variables before and after exposure to an intervention (the independent variable) (Polit & Beck, 2004). Therefore, the independent variable was the NHP PtDA and the dependent variables were decisional conflict, knowledge, choice/preference, and values clarity.

3.2 Subjects

A convenience sample of peri and postmenopausal women, who were considering the use of NHPs for symptom management, was recruited. As discussed in Chapter 2, peri and postmenopausal women are the highest users of NHPs and often seek NHPs to control menopausal symptoms (Gingrich & Fogel 2003; Gollschewski et al., 2003; Keenan et al., 2003; Légaré et al., 2007; Ma, Drieling & Stafford, 2006; Mahady et al., 2003; Richter et al., 2001; Seidl & Stewart, 1998; Suter et al., 2007; Will & Fowles, 2003).

3.2.1 Sample Size

The estimated sample size was calculated based on the paired t-test for comparing the means of the outcome ‘decisional conflict’ measured pre and post decision support. For a significance level of $\alpha = 0.05$, power $(1 - \beta) = 0.80$, a standard deviation of 0.6, and a correlation between pre/post scores of 0.25, the sample size was estimated at 23 to detect a difference of 0.4 in the decisional conflict score, out of a possible score of zero to four. This

would be considered a medium effect size and one that would be apparent to an intelligent observer (Cohen, 1988). A clinically important effect size has been observed to be between 0.43 to 0.82 for individuals who make or delay decisions (O'Connor et al., 1998a). The sample size was increased to 26 for this study to account for possible attrition rates.

3.2.2 Eligibility Criteria

Participants eligible to participate in the study were: a) female; b) aged 45 to 64; c) bothered by menopausal symptoms; d) considering NHPs to relieve menopausal symptoms; and e) unsure about what choice to make. The rationale for these criteria included that the PtDA was designed for peri- and post-menopausal women and more specifically, for women who are unsure about the best option for their situation (Légaré et al., 2007). Given that the English version of the NHP PtDA was being evaluated, participants also had to be able to read and speak English.

Women excluded from participating were those who were unsure of the diagnosis for symptoms they were experiencing. The NHP PtDA focused on symptoms caused by menopause and some menopausal symptoms such as night sweats, fatigue, and heart palpitations can be indicative of other underlying issues such as heart disease (Society of Obstetricians and Gynaecologists of Canada, 2006). Also, to avoid potential conflicts of interest, the participant could not be an owner or manager of a natural health food store, pharmaceutical company, or medical clinic.

3.3 Setting

Recruitment of participants occurred through the menopausal information sessions provided at The Ottawa Hospital, at the Women's Health Centre, and through word of mouth. The Women's Health Centre is part of the Riverside campus of The Ottawa Hospital in Ottawa, Ontario, Canada. This site was selected because the Women's Health Centre has a

menopausal clinic and offers bi-monthly menopause information sessions to the public (The Ottawa Hospital, 2008). At their menopause information nights, the researcher distributed invitational posters and presented a five-minute power point presentation about the study. The health care team within the menopause clinic also distributed the flyers (see Appendix B). After the presentation, interested participants were screened by the researcher for eligibility using a standard form (see Appendix C). Once participants agreed to be contacted by the researcher, the individual meetings were conducted at a location convenient to the participants (e.g. their home, coffee shop, office) and on the telephone.

3.4 Independent Variable (the NHP PtDA Intervention)

The independent variable was the NHP PtDA intervention, entitled “A decision aid for women considering natural health products for menopause symptoms” (see Appendix A). The NHP PtDA includes interactive pages that guide women, who are considering NHPs for menopausal symptom management, through a six step decision making process. The steps for decision making help women to: a) be clear about the decision they are trying to make; b) explore their knowledge by getting the facts; c) identify available options; d) clarify their values with the option to use/not use NHPs; e) consider their role preference in decision making and identify their support system; and f) develop an action plan for taking the next steps in the decision making process. This PtDA was developed by a Canadian-based consortium using the ODSF and is congruent with the criteria set by the International Patient Decision Aid Standards (Légaré et al. 2007). The consortium conducted a pilot test of this PtDA on 11 francophone women, and concluded that 9 women found the presentation and the usefulness of the decision aid to be good to excellent (Légaré et al. 2007).

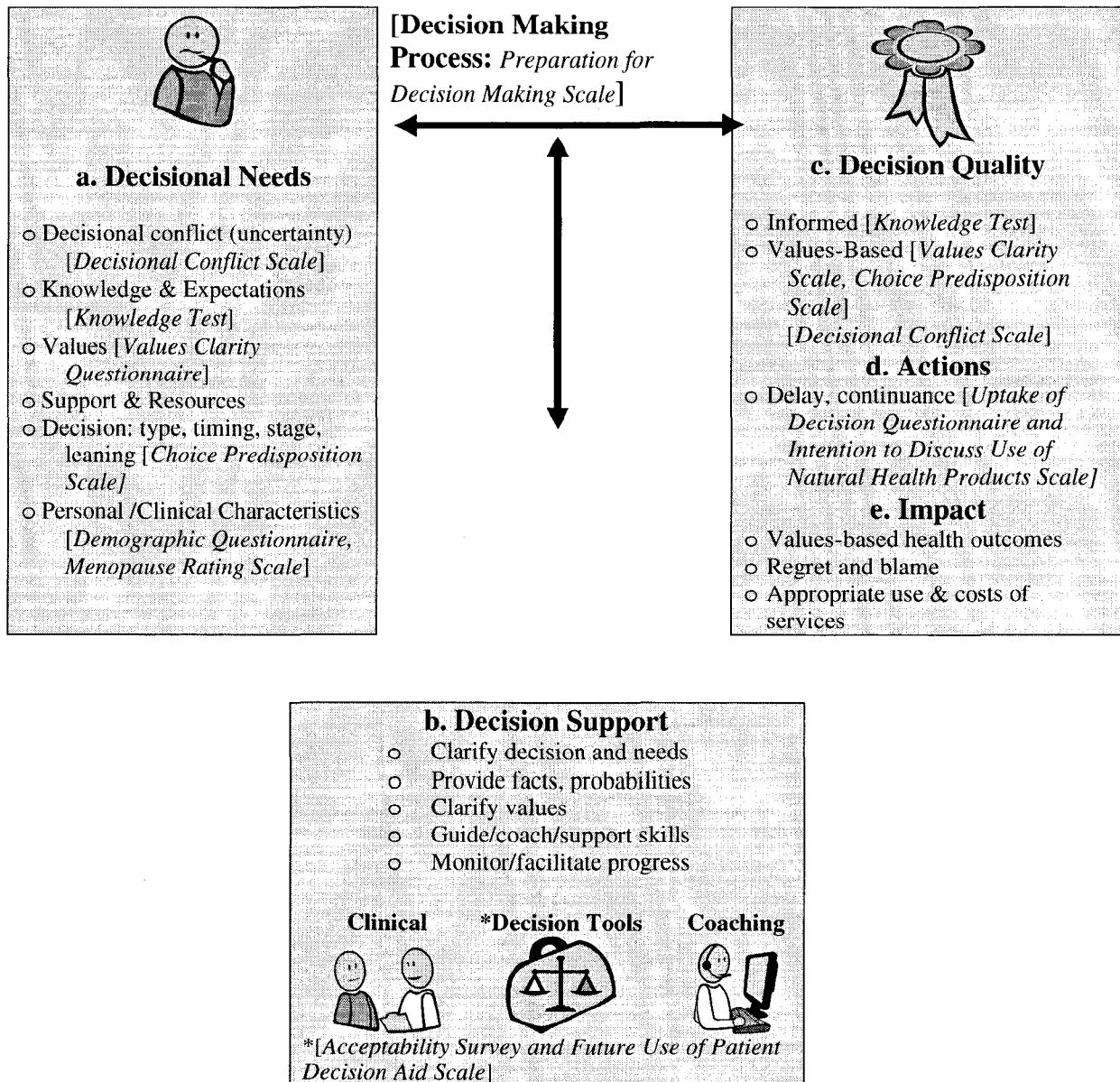
3.5 Measures (Variables)

3.5.1 Measurement Tools/Instruments

The primary dependent variable was decisional conflict which was measured using the Decisional Conflict Scale. Secondary variables included knowledge, strength of values, and choice preference, decision uptake, intention to discuss NHPs with health care providers, acceptability of the decision aid, satisfaction with the preparation for decision making, and intention to use the decision aid in the future. The participant's knowledge (i.e., awareness of NHP options, and outcomes) was measured using a knowledge test. Strength of values (i.e., personal importance of option outcomes) was measured using a values clarity questionnaire. Choice preference (i.e., inclination to choose one NHP option versus another) was measured using the Choice Predisposition Scale. The remaining variables were measured using the uptake of the decision questionnaire, Intention to Discuss Use of NHPs Scale, acceptability survey, Preparation for Decision Making Scale, and Future Use of Patient Decision Aid Scale. These dependent variables were chosen based on the ODSF, the international patient decision aid standards (Elwyn), and common outcomes used in previous studies of decision aids (O'Connor, Bennett et al., 2007). For example, according to the ODSF, decisional conflict is hypothesized to improve after participants are exposed to counselling, decision support tools such as decision aids, and/or decision coaching (O'Connor, 2000; O'Connor, Bennett et al., 2007). Furthermore, the ODSF and the international standards define decision quality as being informed and values-based. Therefore to determine the impact of the intervention on decision quality, knowledge, clarity of values, and choice are examined. Instruments for these outcomes were chosen based on their previous psychometric testing. To be able to enhance generalizability of the findings, socio-demographic characteristics of participants were collected along with the severity of their menopausal symptoms using a

Menopausal Rating Scale. Figure 3.1 indicates the outcome measures used at different points within the ODSF.

Figure 3.1: The Ottawa Decision Support Framework with Study Outcome Measures



O'Connor et al., 2007 (Reprinted with permission of the author)

Note: Information in square brackets indicates measures used within this study

3.5.2 Decisional Conflict

Decisional conflict was measured using the Decisional Conflict Scale; a 16-item scale with five subscales: uncertainty of choosing the best option, informed about the options, values clarity, support, and effective decision making (O'Connor, 1995), (see Appendix D). It uses a five point Likert scale rating from 1 (strongly agree = low decisional conflict) to 5 (strongly disagree = high decisional conflict). Total decisional conflict score was calculated by summing up 16 items and then dividing the scores by 16 then subtracting 1. Scores were subsequently standardized to produce scores out 100 by multiplying by 25, where zero indicates no decisional conflict (i.e. in other words, high certainty about the best choice) and 100 extreme decisional conflict, high uncertainty about the best choice. The test-retest and alpha coefficients for this measure exceed 0.78 (O'Connor, 1995). The measure is sensitive to change in pre-/post-test studies of decision support interventions (Drake, O'Connor, Surh, Hunter, & Engler-Todd, 1999; Fiset et al., 2000; O'Connor et al., 1998a) and is able to discriminate between different decision support interventions (Man-Son-Hing et al., 1999; O'Connor et al., 1998b).

3.5.3 Knowledge of Natural Health Products

The participant's knowledge was assessed using a 10-item questionnaire about menopause, NHPs and the benefits and risks of using NHPs for menopausal symptoms (see Appendix E). The responses to the statements were true, false, or unsure. Questions answered falsely or unsure were marked as incorrect. The total possible scores range from zero to 10 and each correct answer was multiplied by 10 and then summed to produce a score out of 100. The content validity of the questions was assessed by an expert panel that included physicians specializing in women's health, experts in decision aids and a credentialed menopause educator employed as an advanced practice nurse (APN). The knowledge test

was in line with what experts thought a woman needed to know to make an informed choice. Knowledge tests of similar format used in other decision aid studies, were sensitive to change in knowledge, had good internal consistency and were able to discriminate between interventions (Cranney et al., 2002; Drake et al., 1999; Fiset et al., 2000; O'Connor et al., 1998a; Stacey, O'Connor, DeGrasse & Verma, 2003).

3.5.4 Values Clarity

Values clarity was assessed by a five-item questionnaire that elicits how important it is to the participant to make the decision to choose NHPs (See Appendix F). The numbers on the scale range from “0”, not at all important to “10” extremely important. Test-retest coefficients using this type of questionnaire ranged from 0.79 to 0.91 and when measuring the strength of values associated with the outcomes of options, the measures explain and discriminate between those making different decisions (O'Connor et. al., 1994; O'Connor et al., 1998b). This 5- item questionnaire has been used in several different clinical applications including women's issues surrounding HRT (Dodin et al., 2001; O'Connor, 1999; O'Connor et. al., 1994; O'Connor et al., 1998a; O'Connor et al., 1998b).

3.5.5 Choice/Preference

Choice/preference was measured using the predisposition scale which is a 15-point scale anchored by not taking any NHPs on one end and taking NHPs on the other, with unsure in the middle (See Appendix G). The scale was then converted to yes, leaning towards NHPs (1-5), unsure (6-10) and no (11-15). The scale is sensitive to change and discriminates between the undecided category and those who have made a decision, exceeding a test-retest reliability coefficient of 0.90 (O'Connor et al., 1994).

3.5.6 Natural Health Product Patient Decision Aid Acceptability

Given that this was the first evaluation of the English version of the PtDA, it was deemed important to obtain feedback from participants on its acceptability and suggestions for improvement. Acceptability was measured using six closed and three open-ended questions (see Appendix H). The open-ended questions asked the participant what they liked or did not like about the decision aid, and elicited further comments. Feedback on the amount, length, clarity, helpfulness, balanced presentation of information, and whether or not they would recommend it to others was obtained from the closed-ended questions. These questions were based on a questionnaire evaluating the acceptability of the decision support programs produced by the Foundation for Informed Medical Decision Making (Barry, Fowler, Mulley, Henderson & Wennberg, 1995).

3.5.7 Satisfaction with the Decision Making Process

Satisfaction with the decision making process was measured using the Preparation for Decision Making scale (see Appendix I). This scale assesses an individual's perception of how useful a decision aid was in helping individuals to make a health decision and preparing them to discuss it with their health care provider. This scale consists of ten questions rated on a five-point scale with a total score ranging from zero to 100. A "1" on the scale is not at all and a "5" is a great deal. This scale has a high internal consistency, alpha coefficients range from .92 to .94. This scale has been shown to discriminate significantly between different decision support interventions (O'Connor, 2000 & Stacey et al., 2003).

3.5.8 Intention to Discuss Use of Natural Health Products with Health Care Providers & Future Use of Patient Decision Aid

The intention to discuss the use of NHPs and future use of the NHP PtDA was measured using six items with response categories on a 7-point response scale from "-3" not

very useful to “+3” very useful (see Appendix J). This tool measures the participant’s behavioural intention to disclose use of NHPs to their physicians or pharmacist and use the PtDA for future decision making. This tool is based on the theory of planned behaviour that is well known through its previous application to the study of health professionals’ behaviours (Ajzen, 1988; Gagnon, 2003; Godin, 1996; Légaré et al. 2003; Liabsuetrakul, 2003; Millstein, 1996). This theory postulates that when the individual has some control over a situation, intention is the immediate determinant of behaviour (Ajzen, 1988).

3.5.9 Demographic Questionnaire

The demographic questionnaire consisted mostly of closed ended questions. Data was collected on participant’s personal characteristics and relevant medical history (see Appendix K).

3.5.10 Menopause Symptom Distress

The Menopause rating scale is an 11-item scale with a five-point rating score (see Appendix L). It describes the perceived severity of symptoms ranging from “0” none to “4” very severe. The total score of all items are grouped as no or few symptoms (0-4), slight symptoms (5-8), moderate symptoms (9-16) and severe symptoms (17-44) (Schneider et al., 2000a). Each symptom item is categorized under one of three subscales. These are psychological symptoms, somato-vegetative symptoms and urogenital symptoms (Heinemann et al., 2004). The scale is internally consistent as measured by Cronbach's Alpha, where the coefficients varied between 0.6 and 0.9 across countries for the total score as well as the three subscales (Schneider et al., 2000b).

3.5.11 Uptake of the Decision

A single question was used to elicit uptake of the decision. Although intention is a predictor of behaviour change, a more rigorous measure is to access the actual behaviour

(Ajzen, 2001). The question asked “What are you currently doing to control your menopausal symptoms?” (see Appendix M).

3.6 Procedure

3.6.1 Data Collection

Data was collected by the researcher primarily using self-administered questionnaires during in-person meetings and one telephone interview 2 months after using the decision aid. In person meetings allowed the researcher to establish a rapport, obtain consent, and be available to answer any questions that the participant might have had about the study (Polit & Beck, 2004). The personal approach of presenting questionnaires can also have a positive effect on the proportion of items completed. Self-administered questionnaires were used because there were numerous questionnaires to complete; completing questionnaires themselves required less time from the participants' schedule, as compared to being asked each question by the researcher (Polit & Beck, 2004). A telephone interview was performed for the final contact with the participant because it was the most convenient and only one question was asked (Polit & Beck, 2004).

3.6.2 Data Collection Procedure

The data collection procedure occurred at three points during the study. The measures were taken: 1) at baseline; 2) 2 weeks after receiving the decision aid; and 3) 2 months later. Table 3.1 explicitly details the measures, measurement tools used to assess the dependent variables, and the timing of the data collection.

Table 3.1: Data Collection Procedure

Measures (Dependent Variables)	Measurement Tools	Baseline	2 Weeks	2 Months
Decisional Conflict	-Decisional Conflict Scale	X	X	-
Decision Quality				
• Knowledge	-Knowledge Test	X	X	-
• Values	-Values Clarity Questionnaire	X	X	-
• Choice/Preference	-Choice Predisposition Scale	X	X	-
Decision Process				
• Acceptability	-Acceptability Survey	-	X	-
• Satisfaction	-Preparation for Decision Making Scale	-	X	-
• Intention	-Intention to Discuss Use of Natural Health Products & Future Use of Patient Decision Aid scale	-	X	-
Decision Uptake	- Single Question	-	-	X
Participant Characteristics	-Demographic Questionnaire	X	-	-
	-Menopause Rating Scale	X	-	-

After eligibility was confirmed using the standardized form (Appendix C), the researcher set up an appointment to conduct the baseline in-person meeting. At this visit, the researcher explained the study in more detail and obtained written informed consent using the consent approved by The Ottawa Hospital and the University of Ottawa Research Ethics Board, Ontario, Canada (see Appendix N). Baseline data was collected using self-administered questionnaires. The researcher was available to answer questions as needed. At the end of the session, the researcher collected all the questionnaires and did not provide any answers or comments on their response to the knowledge questions. The researcher provided an over-view of each page of the PtDA; highlighting the six-step process, available resources, and instructions for completing the values clarification exercise. This was done to introduce

the participant to the PtDA and to answer any questions. The participant was given a copy of the NHP PtDA, asked to read through it more thoroughly, consider their options, and complete the values clarifications exercise contained within the PtDA, prior to their second visit. The second visit was arranged at this time.

At the in-person visit scheduled two-weeks later, the researcher asked the participant if she had read through the PtDA and if she had any additional questions. Participants subsequently completed the self-administered questionnaires (see Table 3.1). All questionnaires were collected by the researcher and incorrect answers to the knowledge test questions were discussed at this time (without making changes to the participants' responses). The two week time period was chosen to allow the participant time to read and complete the PtDA. Furthermore, given that several of the measures used at baseline were being repeated, a two-week interval has been found to provide temporal stability of similar measures (Cone & Foster, 2003).

In a telephone call by the researcher 2 months later, participants were assessed to determine whether they had implemented their choice (uptake of the decision) (see Appendix L). Given that intention to change is not always consistent with actual behaviour change (Ajzen, 2001), calls at 2 months were planned to determine if the decision had been implemented.

During this study, Health Canada published an advisory linking black cohosh to liver damage. The researcher contacted all participants who had received the decision aid and informed them of the advisory and they were instructed to check the Health Canada website for more details. The developers of the NHP PtDA were also notified and an insert was made in the PtDA stating, "Please check with Health Canada Advisory regarding the possible link

between black cohosh and liver damage, http://www.hc-sc.gc.ca/dhp-mps/advisories-avis/index_e.html” (see Appendix A, p. 84).

3.7 Ethics

In accordance with the University of Ottawa research ethics guidelines, ethical approval for the study was obtained by both The Ottawa Hospital (protocol # - 2006462-01H) and the University of Ottawa Research Ethics board (protocol # H08-06-12) (Faculty of Graduate & Postdoctoral Studies, 2006).

To protect confidentiality of participant’s data, all data is stored in a locked cabinet, in a secured office at the Ottawa Health Research Institute, and is accessible only to members of the research team. To maintain confidentiality, participants were assigned identifying numbers, and questionnaires/ documents were identified with these numbers. As per the ethics protocol, data will be destroyed 15 years after completion of the study.

3.8 Data Analysis

The Statistical Package for the Social Sciences (SPSS 14.0) was used for data analysis. Quantitative data was numerically coded and entered into Excel and then transferred into SPSS by the researcher. All of the data entered into Excel was compared to the questionnaires for inconsistencies. In addition, data transferred into the SPSS file was audited by randomly selecting questions and verifying accuracy of data entry. Interval level data was tested for distribution using the Kolmogorov-Smirnov test and found to be normally distributed thus the mean was chosen as the measure of central tendency. A paired t-test was used to test for change in the interval scales (decisional conflict scores, knowledge scores), and Wilcoxon Matched-Pairs Signed Ranks test for change in discrete measures (choice/preference) from baseline to post intervention. Descriptive analysis was used for the values clarity questionnaire to explore participants’ values surrounding NHPs. Descriptive

analysis was also used for the acceptability survey, satisfaction questionnaires and intention to use the PtDA, to explore the influence of the PtDA and whether it helped the participant in making a decision. Finally, to report the characteristics of the participants, descriptive analysis was used for the menopause rating scale and demographic questionnaire.

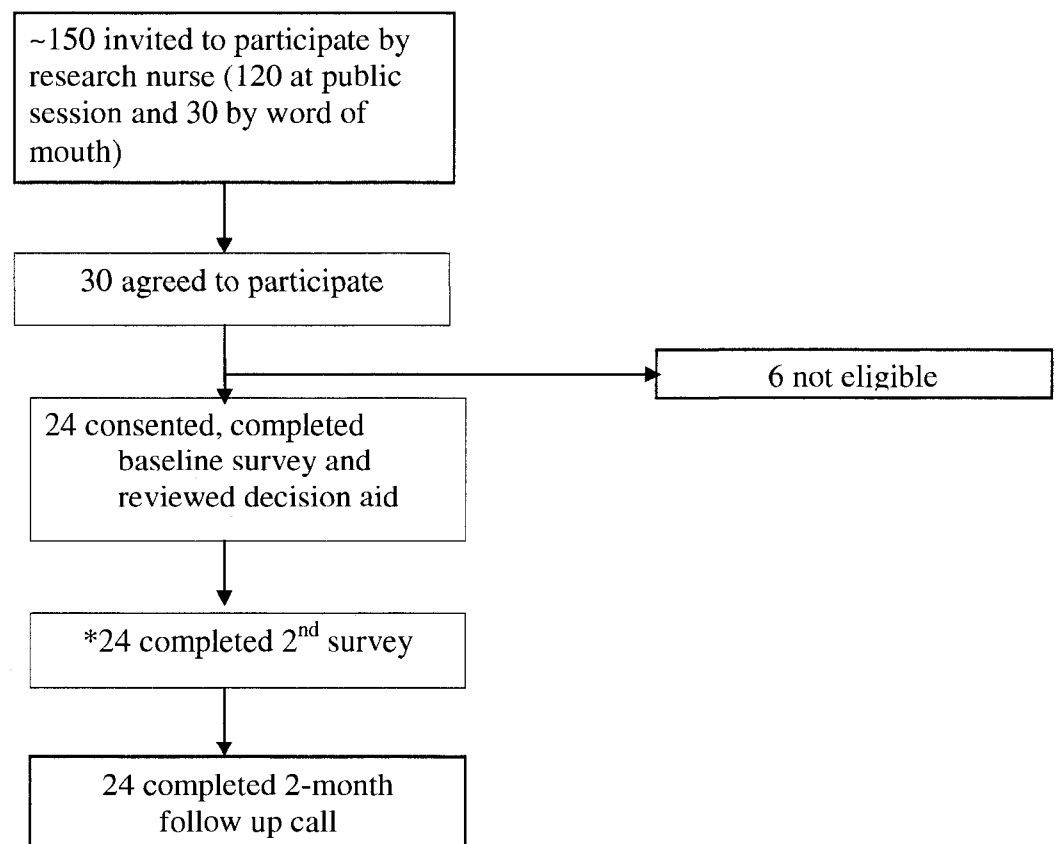
Chapter Four – Results

Chapter four reports the findings of the evaluation of a NHP patient decision aid.

4.1 Characteristics of Sample

From September 2006 to February 2007, 30 participants volunteered for the study and 24 were eligible. Three did not meet the age criteria, two were on hormone replacement therapy, and one had symptoms but was unsure of the diagnosis. From all of the surveys, one post Choice/Preference questionnaire was not completed and one Preparation for Decision Making questionnaire was illegible and therefore could not be included (see Figure 4.1).

Figure 4.1: Recruitment and Completion Rates



*missing data on 2 questionnaires

On average, participants were 50-59 years of age, Caucasian, married and well-educated (see Table 4.1). Of the 10 postmenopausal women, 8 had their onset of menopause occur naturally between 50 to 55 years of age and in 2, menopause was surgically induced. The participants scored an average of 15.7 on the Menopause Rating Scale indicating moderate symptoms. The most commonly reported mild to severe symptoms were; sleep problems (n=23), hot flushes (n=22), irritability (n=22), anxiety (n=22) and mental and physical exhaustion (n=21) (see Table 4.2).

Table 4.1: Demographic Characteristic of Participants (N=24)

Demographic characteristics	Frequency (%)
Age (in years)	
45-49	10 (41.6)
50-59	13 (54.2)
60-64	1 (4.2)
Marital Status:	
Married, common law	19 (79.2)
Divorced, separated	4 (16.7)
Single	1 (4.1)
Primary Language Spoken:	
English	19 (79.2)
French	4 (16.7)
Both	1 (4.1)
Primary Language Read:	
English	21(87.5)
French	1 (4.2)
Both	2 (8.3)
Highest level of Education:	
Some High school or less	0
High school diploma	2 (8.3)
Trade certificate/diploma	8 (33.3)
University	14 (58.4)
Relevant History:	
Hysterectomy	4 (16.7)
HRT (ever taken)	7 (29.3)
Menopausal Symptoms	
0-4 no or few symptoms	0
5-8 slight symptoms	3 (12.5)
9-16 moderate symptoms	12 (50.0)
17-44 severe symptoms	9 (37.5)

Table 4.2: Menopause Rating Scale Results (N=24)

Symptoms	Frequency Symptom present (%)
Sleep problems (difficulty in falling asleep, difficulty in sleeping through, waking up early)	23 (96)
Hot flushes, sweating (episodes of sweating)	22 (92)
Irritability (feeling nervous, inner tension, feeling aggressive)	22 (92)
Anxiety (inner restlessness, feeling panicky)	22 (92)
Physical and mental exhaustion (general decrease in performance, impaired memory, decrease in concentration, forgetfulness)	21 (88)
Depressive mood (feeling down, sad, on the verge of tears, lack of drive, mood swings)	20 (83)
Sexual problems (change in sexual desire, in sexual activity and satisfaction)	19 (79)
Joint and muscular discomfort (pain in the joints, rheumatoid complaints)	17 (71)
Bladder problems (difficulty in urinating, increased need to urinate, bladder incontinence)	15 (63)
Heart discomfort (unusual awareness of heartbeat, heart skipping, heart racing, tightness)	13 (54)
Dryness of vagina or, difficulty with sexual intercourse	10 (42)

4.2 Changes in Decisional Conflict and Modifiable Factors

After using the NHP PtDA, participants' decisional conflict scores declined from a mean total decisional conflict score of 63% (95% CI 57, 68) pre to 24% (95% CI 17, 31) post ($p < 0.001$). All subscale scores (uncertainty, informed, values, support, effective decision making) decreased post decision aid (see Table 4.3). The informed subscale showed the greatest reduction in score from 78% (95% CI 71, 86) to 21% (95% CI 15, 28) with item 3 "I know the risks and side effects of each option" causing the highest decisional conflict, of 84% of participants at baseline.

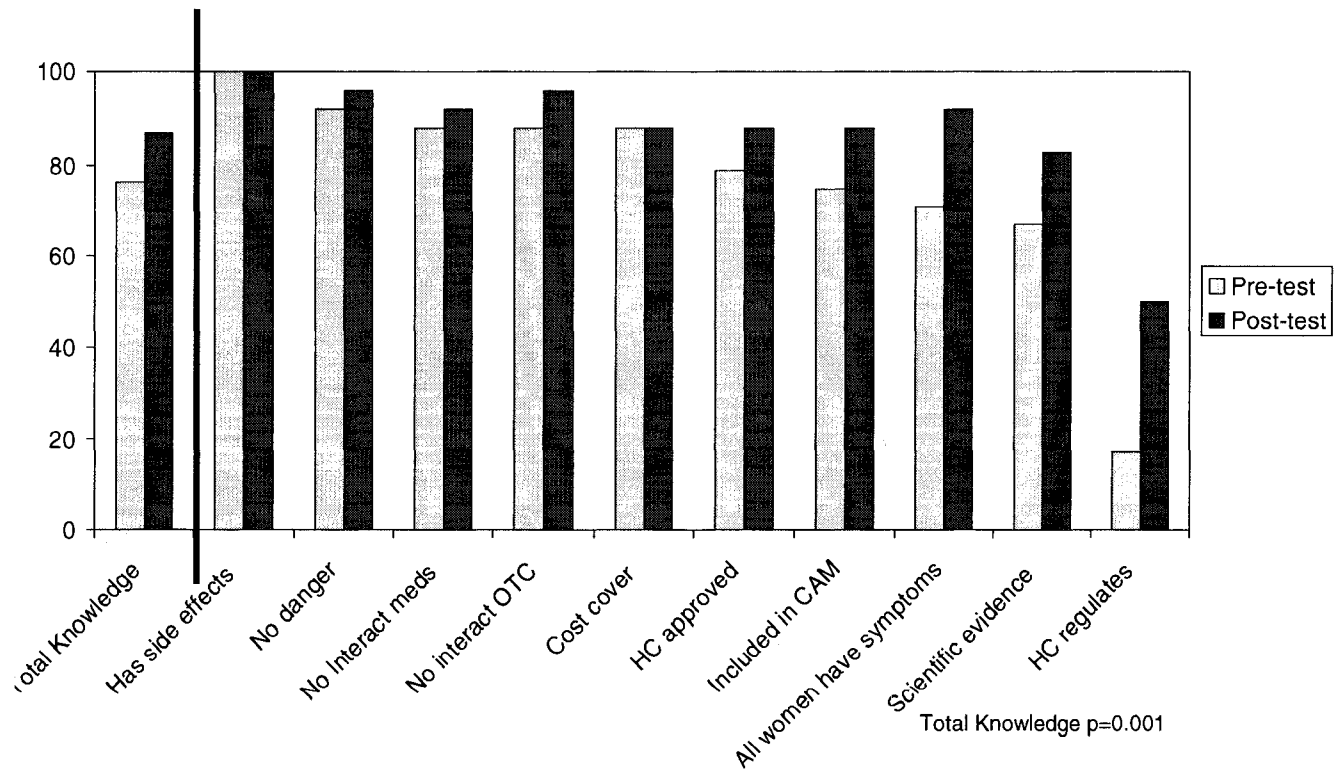
Table 4.3: Decisional Conflict and Modifiable Factors Contributing to Difficulty with Decision Making (N=24)

Subscales	Items	Pre-test		Post-test		p-value
		Item mean; (95% CI)	Sub-scale mean %; (95% CI)	Item mean; (95% CI)	Sub-scale mean %; (95% CI)	
Uncertainty	I am clear about the best choice for me	73.96 (65.44, 82.47)		34.38 (23.68, 45.07)		
	I feel sure about what to choose	75.00 (67.37, 82.63)	71.88 (63.65, 80.10)	38.33 (22.70, 43.97)	35.07 (24.54, 45.60)	=0.001
	This decision is easy for me to make	66.67 (54.74, 78.59)		37.50 (25.85, 49.15)		
	I know which Natural health product options are available to me	69.79 (57.74, 81.84)		12.50 (7.11, 17.89)		
Uninformed	I know the benefits of each option	81.25 (74.83, 87.67)	78.47 (71.29, 85.66)	22.92 (14.16, 31.68)	21.53 (15.40, 27.66)	=0.001
	I know the risks and side effects of each option	84.38 (78.30, 90.45)		29.17 (19, 39.33)		
	I am clear about which benefits matter most to me	65.63 (53.64, 77.61)		17.71 (11.12, 24.30)		
	I am clear about which risks and side effects matter most	65.63 (52.12, 79.13)	63.19 (51.41, 75)	15.63 (9.55, 21.70)	18.40 (11.84, 24.96)	=0.001
Unclear values	I am clear about which is more important to me (the benefits or the risks and side effects).	62.50 (49.29, 75.71)		20.83 (11.15, 30.51)		
Unsupported	I have enough support from others to make a choice	61.46 (49.01, 73.90)		27.08 (18.32, 35.84)		
	I am choosing without pressure from others	22.92 (11.30, 34.53)	52.00 (44.37, 59.80)	11.46 (6.09, 16.83)	22.57 (16.65, 28.48)	=0.001
	I have enough advice to make a choice	71.88 (63.46, 80.29)		29.17 (19, 39.33)		
	I feel I have made an informed choice	65.63 (57.50, 73.75)		23.96 (12.53, 35.39)		
Ineffective decision	My decision shows what is important to me	45.83 (38.42, 53.24)	50.78 (44.84, 56.72)	18.75 (9.81, 27.69)	25.00 (15.73, 34.27)	=0.001
	I expect to stick with my decision	41.67 (33.05, 50.29)		27.08 (17.79, 36.38)		
	I am satisfied with my decision	51.04 (43.75, 58.33)		26.04 (16.46, 35.63)		
			62.82 (57.34, 68.3)		23.63 (16.72, 30.54)	<0.001
Total Decisional conflict score						
CI = confidence intervals						

4.3 Knowledge

Knowledge scores increased from 76.25% (95% CI 69.45, 83.05) at baseline to 87.02%, (95% CI 83.05, 91.11) post decision aid intervention ($p=0.001$). Pre and post, the response to the question “Health Canada regulates natural health products” received the fewest correct responses. For the question about side effects of NHPs, all respondents answered correctly (see Figure 4.2).

Figure 4.2: Change in Knowledge Scores after Decision Aid Intervention (N=24)



OTC=Over the Counter

HC=Health Canada

CAM=Complementary and Alternative Medicine

4.4 Preference

Of 24 participants, 10 (42%) were unsure of their preference at baseline compared to 3 (12.5%) post decision aid (see Table 4.4). At the 2-month follow-up, all of the women had made the decision whether or not to use NHPs (see Table 4.5 & 4.6). Of these 24 women at the 2-month follow-up, 9 were using NHPs to control menopause symptoms, 8 chose to use nothing to control symptoms, 5 stated that symptoms had decreased and felt no need to use anything. Two had started using hormone replacement therapy and both participants indicated that they were still looking into using NHPs in the future after being weaned off their hormone replacement therapy.

Table 4.4: Preference Before and After Decision Aid Intervention

Before Decision aid (n=24)	After Decision aid		
	Yes NHP (n=15)	Unsure (n=3)	No NHP (n=5)
Yes NHP (n=10)	7 (47%)	1 (33%)	1 (20%)
Unsure (n=10)	5 (33%)	2 (67%)	3 (60%)
No NHP (n=4)	3 (20%)	0	1 (20%)

Wilcoxon Signed ranks test $z = -2.422$ ($p=0.015$)

Table 4.5: Preference Before and 2 Months Post Decision Aid

Before Decision aid (n=24)	Two-months after Decision aid		
	Yes NHP (n=9)	Unsure (n=0)	No NHP (n=15)
Yes NHP (n=10)	6 (67%)	0	4 (27%)
Unsure (n=10)	2 (22%)	0	8 (53%)
No NHP (n=4)	1 (11%)	0	3 (20%)

Wilcoxon Signed ranks test $z = -2.209$ 2months post decision aid ($p=0.027$)

Table 4.6: Preference

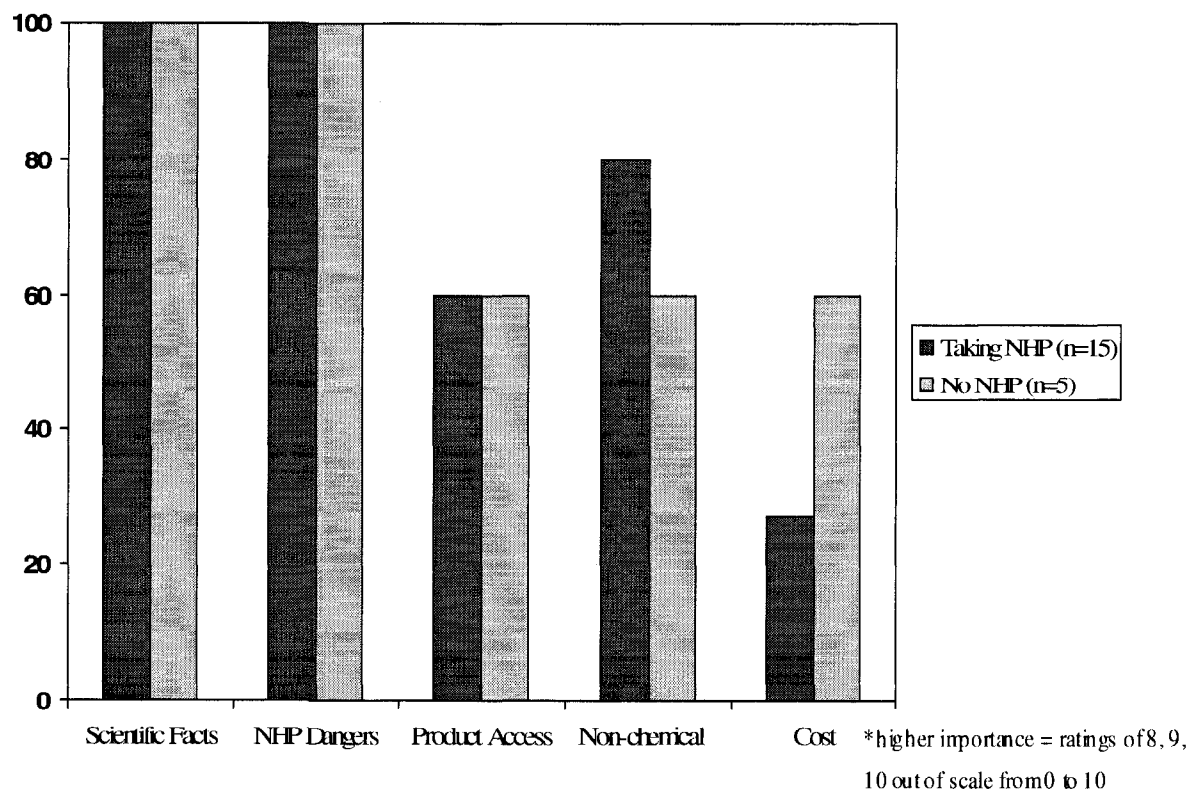
Before Decision aid (n=24)	Two-months after Decision aid	
	Decided (n=24)	Undecided (n=0)
Decided (n=14)	14 (58%)	0
Undecided (n=10)	10 (42%)	0

Wilcoxon Signed ranks test $z = -3.317$ ($p=0.001$)

4.5 Values Concordance

Post decision aid, a trend was noted as 12 of the 15 women that chose a NHP (80%) rated the importance of the non-chemical aspect highly compared to 3 of 5 women (60%) who chose not to use a NHP ($p=.766$) (see Figure 4.3). Of 15 women that chose a NHP 4 (27%) placed importance on the cost of the products compared to 3 of 5 women (60%) that chose not to use a NHP ($p=.417$). All women found scientific facts and dangers associated with NHPs to be of importance.

Figure 4.3: Value Concordance with Option Chosen



4.6 Acceptability of the Natural Health Product Patient Decision Aid

All 24 women rated the decision aid as clear and helpful in making a decision, and would recommend it to others (see Table 4.7). Eighteen (75%) rated it as a balanced presentation of options and 6 rated it as slanted toward taking a NHP. For those women who found the PtDA too slanted, one requested hormone replacement therapy be included and another stated that soy was favoured and other therapies such as counselling should be explored.

Table 4.7: Acceptability of the Decision Aid

Participants Rating Of Decision Aid	Frequency (N=24)
Clarity of the information in the workbook	
Everything was clear	15
Most things were clear	9
Some things were clear	0
Many things were unclear	0
Helpfulness of workbook in helping to make a decision	
Very helpful	11
Somewhat helpful	10
A little helpful	3
Not helpful	0
Recommendation of workbook to others	
definitely recommend it	10
probably recommend it	14
probably not recommend it	0
definitely not recommend it	0
Length of workbook	
Much too long	0
A little too long	2
Just about right	18
Should have been a little longer	4
Should of have been much longer	0
Balance and fairness of the workbook	
Clearly slanted to taking a Natural health product	2
A little slanted to taking a Natural health product	4
Completely balanced	18
A little slanted to taking no Natural health product	0
Clearly slanted to taking no Natural health product	0
Amount of information	
Much less than I needed	1
Little less than I needed	7
About the right amount of information	12
A little more information than I needed	2
A lot more information than I needed	2

Of the 24 women, 8 indicated that the amount of information was less than needed and 4 rated it as more than needed. For those who wanted more information, suggestions included adding a detailed list on the specific side effects and possible interactions of NHPs with other medications and another woman suggested adding contact information for credible, experienced professionals to whom one could address further questions. When asked what they liked most about the PtDA, participants stated the “flow of the decision making process, internet sites and references [improved knowledge of resources], awareness that family doctor & pharmacist should get involved in your decision” and “clear and concise”. In addition, 4 of the 24 women stated that they shared the NHP PtDA with their physicians prior to the second visit with the researcher.

4.7 Usefulness of the Decision Aid

Of the 23 participants, 17 (74%) indicated that the PtDA prepared them for decision making by helping them to organize their thoughts, think about the pros and cons of each option, and consider which ones were most important (see Table 4.8). The 3 items that ranked lowest were, helping to recognize that a decision needs to be made, identifying questions to ask the doctor, and preparation for the doctor’s visit. The total mean score for the intention to use the PtDA was 1.58 (SD 1.44) and for the intention to discuss use of NHPs with healthcare providers was 1.73 (SD 1.70). A score of one or more refers to a positive intention (see Table 4.9).

Table 4.8: Preparation for Decision Making Scale (N=23)

Use of Natural Health Product Patient Decision Aid:	Not at all	A little	Some what	Quite a bit	A great deal
Helped you recognize that a decision needs to be made	3	2	3	12	3
Prepared you to make a better decision	0	2	5	10	6
Helped you think about the pros and cons of each option	0	3	3	10	7
Helped you think about which pros and cons are most important	2	1	3	11	6
Helped you know that the decision depends on what matters most	1	1	5	6	9
Helped you organize thoughts about the decision	1	1	4	11	6
Helped you think about how involved you want to be in this decision	4	0	3	11	5
Helped you identify questions you want to ask the doctor	3	2	2	10	6
Prepared you to talk to the doctor about what matters most to you	4	0	4	7	8
Prepared you for a follow-up visit with the doctor	4	2	4	8	5

Table 4.9: Summary of Intention to Use Decision Aid and Discuss NHP Use

Intention to Use Decision Aid & Discuss Options with Health Care Provider:	Item Mean
Usefulness of the information booklet	1.71
Estimate the chances of using the intervention booklet in making a decision about using natural health products	1.75
Intention to use the information booklet again for future decision making	1.29
Total Intention to use Mean (SD)	1.58 (1.44)
Usefulness of discussing natural health products use with the doctor or pharmacist	1.79
Estimate the chances of discussing natural health products use with the doctor or pharmacist	1.63
Intention to discuss use of natural health with the doctor or pharmacist	1.79
Total Intention to discuss Mean (SD)	1.73 (1.70)

Scale scored from -3(negative intention) to +3 (positive intention)

4.8 Summary of Results

In summary, using the PtDA decreased menopausal women's decisional conflict and improved decision quality by increasing their knowledge, and helping those who were uncertain make a decision. The PtDA was found to be an acceptable and useful tool for helping women prepare for discussion with their health care providers. As well, suggestions for improvements to the PtDA were noted. Women wanted more information included on other therapies, detailed side effects, interactions with other medications and a contact list of credible health care providers. Nevertheless, most women would refer to it for future decision making.

Chapter Five - Discussion

The purpose of this chapter is to integrate the findings from the literature review and the results of the quasi-experimental study to evaluate a NHP PtDA. Implications for nursing practice, education and research will also be discussed.

This is the first known study to evaluate an English PtDA focused on the NHPs for menopausal symptoms. Consistent with other studies of PtDAs, this study found that women who used the PtDA had decreased decisional conflict, increased knowledge of NHPs and it assisted the undecided to make a decision (Dodin 2001; Murray et al., 2001; O'Connor et al., 1998b; Rothert et al., 1997; Rostom, O'Connor et al., 2002). Women also found the PtDA to be balanced in its presentation of the NHP options and wanted to consult their physician in making a decision.

5.1 Decisional Conflict

The magnitude of the reduction in total decisional conflict of 39 points observed in this study (from 63% to 24%) is clinically significant. According to O'Connor (1998a), at a score of 25% or lower, participants are more likely to make a choice. Furthermore, women with lower levels of decisional conflict are more likely to be satisfied with their decision and not likely to feel regret (Sun, 2004). Compared to RCTs of PtDAs, this pre-/post-test study found larger decreases in decisional conflict (O'Connor, Bennette et al., 2007). The larger reduction may be a result of the PtDA helping women address factors influencing their decisional conflict such as feeling more informed and clearer about their values or there may be other reasons for the reduction. For example, the PtDA may have sensitized women to the NHP decision and as a result, women may have explored other information sources (e.g., websites provided within the PtDA; spoken to others). A decisional needs assessment of women making decisions about using NHPs found that their most common source of

information was other women (Légaré et al., 2007). In addition, the larger difference may be related to the study design, as there were no control groups for comparison.

5.2 Knowledge

Although women's knowledge scores at baseline were high (76%), there was an 11 point improvement in their knowledge score after using the PtDA (87%). This improvement is consistent with that observed in the Cochrane review of PtDAs that found improvements ranging from 4.6 to 15.2 (O'Connor, Bennett et al., 2007). The effects on knowledge were also evidenced by women's improved perception of their knowledge on the uninformed subscale of the Decisional Conflict Scale and qualitative feedback indicating that the NHP PtDA improved their knowledge of resources for accessing evidence-based information on NHPs. Aside from websites, other resources such as journal articles, books and associations were listed in the PtDA for the women to access additional information on NHPs. Other studies have found that common information resource issues included the lack of credible information or overwhelming information (Gingrich & Fogel 2003; Légaré et al., 2007; Richter et al., 2001; Ma et al., 2006; Seidl & Stewart, 1998; Suter et al., 2007; Will & Fowles, 2003).

One reason for the high baseline knowledge test scores could have been the high education levels of the women who participated (92% had postsecondary education); however, only about half of the women who used the PtDA were aware that Health Canada regulates NHPs. This raises the question about whether Health Canada and/or the NHP PtDA adequately informed the women on NHP regulations and/or whether or not this is an important issue for women to be aware of. In a needs assessment of 40 menopausal women, it was found that women wanted Health Canada to be involved in regulating NHPs (Légaré et

al., 2007). Thus it is important to investigate further why the message is not clear regarding NHP regulations.

Another common measure of 'informed' decision making is realistic expectations of outcomes of options (O'Connor, Bennett et al., 2007), however, this PtDA did not include probabilities for outcomes of NHP options only a narrative discussion of potential benefits and risks of two different NHP options (e.g., soy, black cohosh). Current literature on use of NHPs for menopausal symptoms is limited and as a result, it is difficult to obtain adequate evidence to be able to include these probabilities.

5.3 Values-Choice Concordance

In addition to being informed, decision quality requires concordance between the option chosen and patients' values (Elwyn et al., 2006, Ratcliff et al., 1999). Of the five values statements, two appeared to indicate differences by group. Compared to women who chose not to take NHPs in this study, women choosing NHPs appeared to be more likely to value the non-chemical aspect and less likely to rate cost as important. An RCT in Quebec also found that women valuing the non-chemical aspect of NHPs chose NHPs as an option (Légaré, Dodin, Stacey, LeBlanc & Tapp, 2008). In the literature, four studies reported that women considered the cost of NHPs when making their decision (Gingrich & Fogel, 2004; Légaré et al., 2007; Seidl & Stewart, 1998; Suter et al., 2007). NHPs are not covered by most insurance plans and can be costly (Gingrich & Fogel 2004; Légaré et al., 2007). Women in our study who chose not to take NHPs for symptom relief were more likely to rate cost as important in their decision.

Another consideration for the similarities and differences between groups on the values statements is the responsiveness of the statements to different preferences. For example, women in both groups valued the need for scientific evidence on NHPs, were

concerned about potential dangers of NHPs, and rated product accessibility as important. A previous needs assessment also indicated that women were concerned about the lack of evidence and potential dangers of NHPs (Légaré et al., 2007). However, these value statements may have been too broad or general such that all women would be likely to rate them as important. In the future, the measure of values could be modified to include values statements that are more specific to a set of options and their outcomes rather than broader statements about NHP use. For example, specific value statements related to soy could ask women to rate the importance of easy access, decreased hot flashes or side effects such as constipation.

The ability to determine values-choice concordance depends on the clarity of women's values and the types of values statements being measured. The NHP PtDA, used in this study, included a balance scale approach to explicitly clarify women's values for the outcomes of the available options. Previous trials that measured values concordance found that PtDAs with explicit values clarification were superior to those in which values clarification was implicit (Dodin et al., 2001; Holmes-Rovner et al., 1999). Unlike these PtDAs, the balance scale in this decision aid required that women identify the specific decision they were considering, list the benefits and harms, and then rate the importance of each of these potential outcomes. Although, the decision aid was not collected from the women to determine completeness of the values clarification exercise, most women said they completed it and their perception of values clarity measured using the Decisional Conflict Scale indicated improved values clarity from baseline to post PtDA.

5.4 Patient Decision Aid Elements

Higher quality PtDAs are those that have been pilot tested with users, found to have balanced presentation of options, and include a range of options (Elwyn et al., 2006). The

majority of women in our study (75%) found the NHP PtDA to be completely balanced although some thought it was slanted towards taking a NHP. These findings are comparable to other trials that found 74% to 79% of patients rated PtDAs as having a balanced presentation of information (O'Connor, Llewellyn-Thomas & Stacey, 2005). Of the six women who thought the PtDA was slanted toward taking NHP, three were leaning towards NHPs at baseline and three were unsure. Barry (1995) found that men with benign prostatic hyperplasia who thought the PtDA was slanted were also leaning in the same direction as the slant post PtDA. Another reason the women may have felt it was slanted toward taking NHPs was that the PtDA only focused on the decision to use NHPs.

Although the decision that was at the center of this PtDA was “to use NHPs for menopausal symptoms or not” a different decision, focused on specific options to manage symptoms, could have been considered. A more inclusive PtDA could have also presented other options for managing menopausal symptoms such as hormone replacement therapy and lifestyle changes (e.g. exercise, nutrition, and behaviour modification). After publication of the results of the Women’s Health Initiative in 2002, most PtDAs on hormone replacement therapy were not updated and were pulled from circulation (O'Connor, Wenneberg et al., 2007).

5.5 Support with Decision Making

After using the NHP PtDA, women felt more supported in their decision making as evidenced on the support subscale of the Decisional Conflict scale (77%). Most women (88%) intended to discuss their choice with either a pharmacist or their physician. Although no direct question was asked regarding perception of support from health care providers in this study, some women did say they shared the PtDA with their physician prior to their second visit. PtDAs are intended to be used as adjuncts to practitioner counselling and

previous studies indicated that women want support from health care providers (Gingrich & Fogel, 2004; Légaré et al., 2007; Richter et al., 2001; Ma et al., 2006; Seidl & Stewart, 1998; Suter et al., 2007; Will & Fowles, 2003). Women also identified communication barriers that interfered with discussing NHP decisions with their health care professionals.

In a study to identify women's decision making needs related to NHPs, women identified that practitioners were not open to discussing NHPs (Légaré et al., 2007). Other studies measuring the quality of practitioners' counselling have found that they focus primarily on information giving without adequately exploring patients' values/concerns (Elwyn et al., 1999; Guimond et al 2003; Stacey et al., 2005). Without support from health care providers, women are more likely to rely on family, friends, media, and the Internet for information. Relying on these sources can increase the possibility that these women are receiving information that may be biased and not evidence-based (Gingrich & Fogel, 2003; Health Canada, 2005; Pettigrew et al., 2004; Will & Fowles, 2003). Interestingly, women consider physicians and other healthcare providers to be a reliable source of information but ironically perceive them to be unknowledgeable and biased against NHPs (Ma et al., 2006; Suter et al., 2007). Consequently, these women do not necessarily discuss their use of NHPs with their health care providers. When women are not open about using NHPs, physicians can unknowingly prescribe medications that interact with NHPs (Ma et al., 2006; Suter et al., 2007).

In summary, given that women are not comfortable speaking with their physicians, other approaches are needed for using NHP PtDAs as adjuncts to practitioner counselling. It is necessary to explore the nurse's role in supporting women considering NHPs for menopausal symptom management.

5.6 Implications for Nursing Practice

Nurses are well positioned on health care teams to support women facing decisions about NHPs as they can be found in places such as family practice units, in women's health centres, and menopause clinics. Areas such as women's health centres serve women experiencing health issues involving gynaecology (benign, oncology, urology), breast health (benign, oncology), and menopause. While performing admission histories and ongoing assessments, nurses could also elicit information on the use of NHPs.

It is crucial to consistently screen for NHP use or intention to use these products as it has been reported that only 36% of people who use NHPs completely agreed that it is important to consult your health care provider when taking NHPs (Health Canada, 2005). Screening also allows for discussion about interactions and adverse events as some NHPs can have herb-drug interactions (Hu et al., 2005). With a shared-decision making approach, nurses need to monitor clients for decisional conflict, and assess options with them, as well as provide initial decision support by offering resources and decision tools such as decision aids and nurse coaching (Stacey et al., 2008). This approach will also engage clients to identify and communicate their needs and preferences, as Canadian women have revealed that they want to be involved in health decisions (O'Connor, Drake et al., 2003).

5.6.1 Advanced Practice Nurse

An advanced practice nurse (APN), who focuses on menopausal women, could also be a beneficial option for a busy clinical setting such as a Women's health centre. According to the Canadian Nurses Association (CNA) framework, an APN has expertise in a specific field of nursing, through experience and graduate education, which includes theoretical, empirical and experiential knowledge (CNA, 2002). The APN works with clients and other health care providers to provide holistic, client-centred care through the understanding of

clients' lived experience and determinants of health and use of multiple assessment strategies and interventions, such as coaching and counselling (CNA, 2002). The domains of their practice include clinical practice, consultation, research, education and leadership (CNA 2003).

Women seeking treatment options to control menopausal symptoms could visit their general practitioner, however, with the shortage of family physicians, primary care settings are overwhelmed and these women are often referred to menopause clinics (The College of Family Physicians of Canada, 2006). In turn, the wait times in menopause clinics range from 6 to 12 months for non-urgent cases, and women who are bothered by their symptoms are often left frustrated at the lack of support from the healthcare system (E. Contestabile, personal communication, Sept 12, 2006). In the role of clinical practitioner, an APN specializing in gynaecology and menopause (e.g., North American Menopause Society credential) could perform the initial assessment, triage urgent cases for gynaecologist consultation, and explore treatment options for non-urgent cases (CNA, 2002).

Another role of the APN is to identify, initiate, and disseminate research that is relevant to clinical practice (CNA 2002). There are many opportunities for APNs to initiate research on decision support in a women's health centre. These could include implementing and evaluating a framework such as the Decision Coach-Mediated Shared Decision Making model in this setting, as this model has not been evaluated in a setting for managing menopausal symptoms using NHPs. Also, previous research has indicated that APNs and nurse coaching have positive effects on quality of life and reduce cost to the healthcare system (Dawes et. al., 2007; Kennedy et. al., 2002; O'Connor, Bennett et al., 2007; Oliverio & Fraulo, 1998; Stacey et al., 2008; Wirrmann & Askham, 2006).

In an RCT (n=9,105) regarding decision support for end-of-life care, it was found that APNs had a big impact on the outcomes of distressed families and patients by addressing issues, eliciting patient preferences, facilitating interdisciplinary discussions, and improving comfort (Oliverio & Fraulo, 1998). Another RCT (n=106) examined the effects of a specialist gynaecology nurse supporting women going through major abdominal/pelvic surgery pre- and post-surgery versus usual care. It concluded that, with the tailored information provided by the nurse specialist, women's satisfaction improved and length of hospital stay decreased significantly ($p=0.0001$), therefore being very cost effective (Dawes et al., 2007). Nurse coaching, provided together with a PtDA, for women considering hysterectomy for benign uterine bleeding, has also proved to be cost effective and to increase patient satisfaction (Kennedy et al., 2002).

Another important role for the APN could be monitoring and implementing research on NHPs within the clinical practice setting. Since another part of achieving a higher quality decision is being informed with the most reliable, up-to-date information, it is important to identify available literature on NHPs as research studies are escalating and new evidence is constantly emerging, (Elwyn et al., 2006; Ratliff et al., 1999). This emphasizes the need for APNs to keep up with the latest studies and the available resources in addressing menopausal women's needs. In using clinical decision making skills (e.g. application to practice, reflective practice, and research skills), APNs can interpret, disseminate research into practice, and transfer knowledge to other nurses through education, as well to clients (CNA, 2002). APNs as leaders could be change agents and role models in the integration of decision support as a standard procedure that is used by all nurses (CNA 2002).

Decision support is a concept that nurses and health care providers need to learn in order to support menopausal women considering NHPs for symptom management. Stacey et

al. (2008) reported that once nurse coaching was employed, an improvement was noted in modifiable, influencing factors affecting decision making in simulated patients (informed, values clarity, support).

5.7 Implications for Education

Nursing guidelines support the need for nurses to be knowledgeable and skilled in NHPs and decision support (College of Nurses of Ontario (CNO), 2005: Registered Nurses of Ontario (RNAO), 2006). The CNO practice guideline titled “Complementary therapies” notes that complementary and alternative medicine (CAM) is an adjunct to conventional client care (CNO, 2005). As more patients are opting for NHPs to manage various symptoms, nurses need to be aware of the evolving evidence and basic pharmacological properties of these substances as they can interfere with other medications and pose risks and benefits to their users (Hu et al., 2005). Since “nurses are partners in the decision-making process and are responsible for ensuring that clients have the appropriate information to make an informed choice...they must have sufficient knowledge of the action and effects of the therapy to assess the risks and benefits” (CNO, 2005, p.3). This guideline for nursing practice is congruent with the RNAO best practice guideline on Client Centred Care that indicates that nurses need to coach and support clients in making quality decisions based on their values (RNAO, 2006). The extent to which theoretical or empirical knowledge of CAM therapies such as NHPs is discussed within nursing curriculum or available through continuing nursing education is unclear.

A national initiative is underway to integrate CAM into the curriculum of 17 Canadian medical schools (Sierpina, Kreitzer, Burke, Verhoef, & Brundin-Mather 2007). A two-part framework was developed to assist in integrating CAM into already existing courses. One aspect of this framework offers peer-reviewed topics such as holistic medicine,

CAM regulations, and physician communication of CAM to patients. Secondly, teachers can access a database of teaching/learning resources that includes course outlines, assignments and case studies (www.caminume.ca); however, no such initiatives were noted in nursing programs associated with these Universities.

A needs assessment of faculty at two Ontario Schools of Nursing found that faculty had limited awareness of decision support resources and lacked teaching/learning activities to integrate into their courses (Stacey, Menard, Higuchi, Davies & O'Connor 2006). Current initiatives to integrate decision support across the four year curriculum include lectures that build knowledge from year to year, problem-based case studies for small group learning, and course assignments. For example, the first year focuses on introducing the nurse's role and client's values in the decision making process (see Appendix O). In the second year, the nurse's role in supporting families using various decision support tools is introduced, and in the third year, students explore the ODSF and its relevance to clinical practice, using the Ottawa Decision Support Tutorial (www.ohri.ca/decisionaid). Proposed learning activities for year four include developing students' decision coaching skills using role playing and tools to audit their performance. There is also a need to enhance the decision support knowledge and skills of nurses in practice (Stacey, O'Connor, Graham & Pomey, 2005). Effective interventions include an online decision support tutorial, decision coaching protocol, and skill building workshop using role play (Stacey, Graham, O'Connor & Pomey, 2006). By developing structured education activities, nurses can maintain continuity and consistency in their approach to supporting menopausal women facing NHP decisions.

5.8 Implications for Future Research

This pre-/post-test study included predominantly Caucasian, middle aged, married, and highly educated women experiencing symptoms such as sleep problems, hot flushes,

irritability, anxiety and mental and physical exhaustion. Findings in this study are consistent with the previous studies on NHPs and menopausal symptom management (Gingrich & Fogel 2004; Keenan et al., 2003; Matthews & Bromberger, 2005; Schmidt, 2005; Seidl & Stewart, 1998; Sherman, 2005; Suter et al., 2007). Future research needs to take into account cultural factors influencing decisions about use of NHPs for managing menopausal symptoms and the effectiveness of PtDAs used with women from different cultures. Subsequent evaluation of women's decision making needs could use purposeful sampling to invite women from different cultures, ethnicity, educational background, and socioeconomic groups. For example, it would be important to include women from Aboriginal and Oriental groups for which use of traditional therapies, such as NHPs, is more common (Gold et al., 2007; Hunter, Logan, Barton & Goulet, 2004; Wade, Chao & Kronenberg, 2007). Since menopause is a life process experienced by all women, it would be helpful to ensure a broader representation of women with different perspectives on menopause and use of NHPs.

A qualitative approach (e.g. grounded theory), could capture more of the holistic perspective of NHPs that would include the patient's experience and the healing process from menopausal symptoms (Verhoef, Dryden, Mallory & Ware, 2006). Women's decisional conflict, knowledge, and values could be elicited from an interview as the researcher does a walk-about at a drug store or health food store with the women as they are searching for NHPs to manage menopausal symptoms.

There are also opportunities for further research on interactions between patients and their health care providers about use of NHPs. First, there is a need to explore the NHP knowledge and attitudes of health care providers and the effect of the patient-health care provider relationship on options chosen. Examining health care providers' influence on alternative practices and integrated practices of western and eastern medicine could add more

depth and understanding to CAM therapy research. Finally, one could further explore the impact of PtDAs on the behavioural intention to disclose use of NHPs to health care providers. This is an important issue because women are not inclined to do so and some NHPs may have interactions or adverse events when combined with other medications (Health Canada, 2005; Hu et al., 2005).

Although the literature has demonstrated that soy and black cohosh with or without St John's wort appear to have a positive effect on hot flashes, inconsistencies in dose, product, and frequency make it difficult to know exactly how much is required and therefore, more research is needed (Chung et al., 2007; Huntley & Edzard, 2003, 2004; Kessel & Kronenberg, 2004; Kronenberg & Fugh-Berman, 2002; Low Dog, 2005; Uebelhack et al., 2006). More research is also required on the other products such as red clover, dong quai, evening primrose seed oil, and ginseng and there needs to be a system to monitor and report emerging findings for use in PtDAs (Elwyn et al., 2006; Low Dog, 2005).

Another important issue for the ongoing use of PtDAs is the need for monitoring and updating of evidence in the PtDAs (Elwyn et al. 2006). The International Patient Decision Aid Standards Collaboration (Elwyn et al., 2006) stated that PtDAs are meant to improve patients' knowledge and prepare them in making informed, values based decisions about their health care. More specifically, a quality criterion to producing effective PtDAs is about using up to date evidence (Elwyn et al., 2006). However, with the abundance of studies currently underway and emerging evidence related to the efficacy and safety of NHPs, there is a need for ongoing surveillance for evidence and updating of this NHP PtDA (NCCAM, 2007).

This leaves in question who should be responsible for the updating and disseminating of decision support resources. Should governing agencies of NHPs such as Health Canada's

Natural Health Product Directorates or NCCAM be responsible? Should these agencies include NHP PtDAs on their websites to support consumer decision making? For example, Health Canada identified a link between black cohosh and liver toxicity in 2006, and posted a warning and a brief summary on their website, but did not provide resources (e.g. access to studies) to support the consumer in exploring the evidence before making a decision. Health Canada regularly updates information on NHPs, so they are well position to update the ongoing evidence in a NHP PtDA. As more research on NHPs is performed, effective and efficient strategies are needed to translate the evidence for health care consumer decision making (O'Connor, Stacey & Légaré, 2003).

5.9 Limitations

Interpretation of these findings should be considered in view of the limitations of using a pre-/post-test quasi-experimental design. First, internal validity of the findings could have been threatened by the potential for maturation effect, history threat, response bias, and regression to the mean.

Maturation occurs when a participant changes because of time passing (Polit & Beck, 2004). In this study, participants may have been sensitized to their information needs by having written the baseline knowledge test. As a result, they may have improved their knowledge over time by exposure to information on NHPs in their environment. In an attempt to minimize a maturation effect, three strategies were employed. The participants were not initially given answers to the first knowledge test, nor a copy of the test, and they were re-assessed within two weeks of the baseline measure.

External influences because of history may have also posed a threat to the study's internal validity and increased knowledge and/or influenced values associated with the options (Polit & Beck, 2004). Events such as revisions and reviews to policies regarding

NHP use in Canada are occurring on a daily basis, leaving the opportunity for discontinuation of some products and new warnings for others. As discussed above, during the evaluation of the PtDA in this study, a new warning regarding black cohosh was announced (Health Canada, 2006). Therefore, necessitating an insertion in the decision aid stating, “Check with Health Canada advisory regarding possible link between black cohosh and liver damage”. All study participants who had not received this version were notified of the advisory.

Another potential threat to internal validity in this study was the potential for response bias, particularly with response on the ‘acceptability of the decision aid’ questionnaire that was more subjective compared to the more objective questions in the knowledge questionnaire. Response bias occurs when participants present favourable images of themselves thus distorting responses to questions in order to improve their scores (Polit & Beck, 2004). To protect against response bias, participants’ anonymity was assured by using a coding system and they were given the choice to leave questions unanswered. However, it is unlikely that response bias occurred, given that few items were blank and of 2496 items in the results database, 15 were left blank (<0.1%). Also, participants provided suggestions for improving the decision aid and given the genuine nature of these suggestions, it was likely that they were fairly ‘honest’ in their responses.

Finally, using a pre-/post-test design may result in regression to the mean (Yudkin & Statton, 1996). This occurs “whenever a non-random sample is selected from a population and two variables that are imperfectly correlated are measured” (Morton & Torgerson, 2004, p. 59). Future research to limit this effect could include using a control group, randomization of participants, and taking two measurements pre intervention.

Another limitation was the lack of power to be able to determine statistical significance of value-choice concordance with a sample size of 24. Statistical analysis

(regression analysis and correlations) used in previous studies to measure values-choice concordance suggests the need to have over 100 participants with a balanced distribution between those who choose NHP and those who do not (Dodin et al., 2001; Holmes-Rovner et al., 1999; Kearing et al., 2007; O'Connor et al., 1999).

Finally, the results of this study are likely to have limited generalizability given the small sample size and participants being primarily Caucasian, well-educated, and married and experiencing moderate menopausal symptoms (Polit & Beck, 2004). Further research should aim to determine the effect of the NHP decision aid on decision quality for women who are of more diverse ethnic and socio-economic backgrounds as mentioned previously.

5.10 Conclusion

Women struggle with making decisions about choosing NHPs for the management of menopausal symptoms. The NHP PtDA evaluated in this study provided an intervention strategy that was not previously in existence for women considering NHPs for menopausal symptoms and it is available in both French and English (Légaré et al., 2005). Not only did the NHP PtDA provide information on NHP options, it allowed the participant to work through the decision process based on using the well established Ottawa Decision Support Framework and International Patient Decision Aids Standard Collaboration (Elwyn et al., 2006; O'Connor 1998). The NHP PtDA may contribute to the further development of other decision aids focused on specific NHP products as the North American market is inundated with more choices.

The NHP PtDA supported quality decision making by informing menopausal women and helping them clarify their values associated with the outcome of options. Although this PtDA also reduced women's decisional conflict and they felt more certain about the best choice for them, subsequent research should be powered to determine the effect of the

decision aid on informed values-choice concordance. Furthermore, women reported having shared the NHP PtDA with others and they used the resource section in the PtDA to explore the websites provided. This study was limited in focusing only on women's use of the decision aid and not how the information was used with their healthcare providers. Further research should examine its influence on shared-decision making approach involving others such as nurses, pharmacists, and physicians in the decision process. It is unclear whether this subject (i.e., use of natural health products) interests certain groups of women, particularly those whose tradition or lifestyle are rooted in NHPs such as aboriginals or Orientals, as menopause is a natural life process occurring in all women. Future research should be evaluated with a more diverse group of women including women from aboriginal or oriental cultural groups.

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A decision aid for women considering natural health products for menopause symptoms

Making a decision...

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Appendices
Appendix A: A Natural Health Product Patient Decision Aid Pamphlet

This decision aid is for you if :

-  You are a woman between 45 and 64 years old
-  You are having menopausal symptoms
-  You are considering using natural health products to relieve these symptoms
-  You are not sure which choice you should make

If you are not sure that your symptoms are linked to menopause, you should consult your physician.



What is menopause?

 Menopause is defined by the permanent end of menstruation. A woman is said to be in menopause when she has not had a menstrual period for 12 months. Menopause is natural and occurs when the ovaries gradually stop producing eggs and the feminine hormones estrogen and progesterone.¹

 Natural menopause is not the same as the end of menstruation that occurs when the uterus is removed by surgery (hysterectomy) when, although there is no uterus, the ovaries continue to function. When these women enter menopause, they may have menopause symptoms such as hot flashes. Hence, only a blood test to measure the amount of hormones in the blood can confirm menopause.

 For some women, menopause is not marked by any symptom.^{2,3} However, for many women,^{2,6} some menopause symptoms (e.g., hot flashes, mood swings) can lead them to consider using one or more natural health products.

What is meant by « natural health products » ?

« Natural health products » refers to a group of products⁷ including :

-  Vitamins and minerals
-  Medicinal plants
-  Homeopathic remedies
-  Traditional remedies (e.g., traditional Chinese medicine)
-  Other products such as amino acids and essential fatty acids
-  Probiotics (group of bacteria, yeasts or seaweeds added to certain food products and which could have healthy benefits)



Step 1. Be clear about the decision

What is the decision you face? _____

What is your reason for making this decision? _____

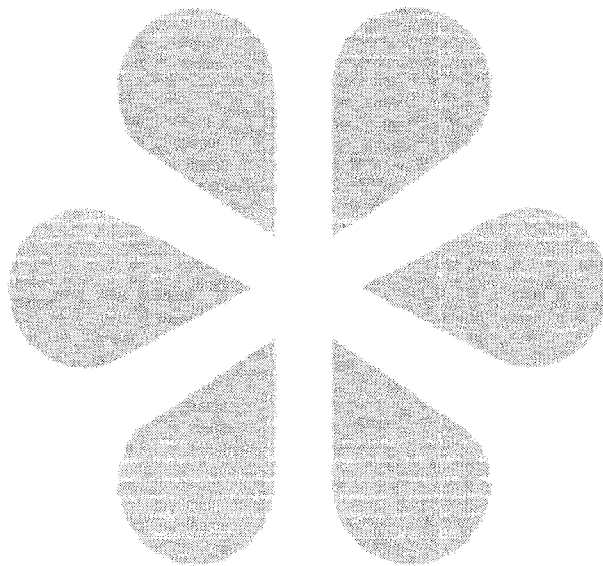
When does this decision have to be made? _____

How far along are you with your decision?

- ☐ I have not yet thought about options
- ☐ I am considering the options
- ☐ I am close to choosing an option
- ☐ I have already made a choice

Are you leaning toward a specific option?

- ☐ No, I'm unsure
- ☐ Yes, the choice is _____



Evaluate the severity of the symptoms for which you are considering using natural health products

Which of the following symptoms apply to you at this time? Please, mark the appropriate box for each symptom.

For symptoms that do not apply, please mark 'none'.

Symptoms:	none Score = 0	mild 1	moderate 2	severe 3	very severe 4
1. Hot flashes, sweating (episodes of sweating)	☐	☐	☐	☐	☐
2. Heart discomfort (unusual awareness of heart beat, heart skipping, heart racing, tightness)	☐	☐	☐	☐	☐
3. Sleep problems (difficulty in falling asleep, difficulty in sleeping through, waking up early)	☐	☐	☐	☐	☐
4. Depressive mood (feeling down, sad, on the verge of tears, lack of drive, mood swings)	☐	☐	☐	☐	☐
5. Irritability (feeling nervous, inner tension, feeling aggressive)	☐	☐	☐	☐	☐
6. Anxiety (inner restlessness, feeling panicky)	☐	☐	☐	☐	☐
7. Physical and mental exhaustion (general decrease in performance, impaired memory, decrease in concentration, forgetfulness)	☐	☐	☐	☐	☐
8. Sexual problems (change in sexual desire, in sexual activity and satisfaction)	☐	☐	☐	☐	☐
9. Bladder problems (difficulty in urinating, increased need to urinate, bladder incontinence)	☐	☐	☐	☐	☐
10. Dryness of vagina or difficulty with sexual intercourse)	☐	☐	☐	☐	☐
11. Joint and muscular discomfort (pain in the joints, rheumatoid complaints)	☐	☐	☐	☐	☐

Menopause Rating Scale (MRS) 89

Add your scores for all items. The total score ranges from 0 to 44.

0 - 4 : no or few symptoms 5 - 8 : slight symptoms 9 - 16 : moderate symptoms 17 and above : severe symptoms

This checklist may be used to discuss the severity of your symptoms with other people or to monitor changes in the severity of your symptoms over time.

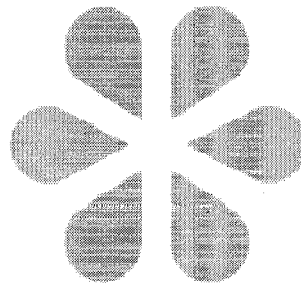
Interaction between natural health products and medications

Do you have other health conditions for which you are taking medication (a physician's prescription or an over-the-counter product)?

☐ Yes ☐ No

If yes, what prescription and/or over the counter medication are you currently taking?

Medications can cause unwanted side-effects when combined with natural health products, so discuss with your physician or pharmacist.



Step 2. Getting the facts

When learning about the benefits and risks of natural health products that have been used by women during menopause,¹¹ it is important to know that the quality of the information varies. This quality depends on the number and types of research studies that have been done.

A : Very good level of evidence that there are benefits related to menopause (No product in this class)

B : Good quality evidence showing that there are benefits related to menopause

Common name (latin)

Black cohosh (*cimicifuga racemosa*, *Actaea racemosa*)

Active chemical

27-deoxyactein

Dose

1 to 2 mg of 27-deoxyactein per day taken by mouth

Tablets

1 or 2 tablet

(20 mg tablet=1 mg

27-deoxyactein)

Liquid

20 to 40 drops of a 60%

ethanol tincture daily (1:10)

(20 drops=1 mg 27-deoxyactein)

Dried root powder

40 to 200 mg of dried rhizome

divided in several doses

(40 mg=1 mg 27-deoxyactein)

Dried root infusion

1 to 2 g boiled in 150 ml of water,

filtered and cooled

(doses recommend by The British

Herbal Compendium)¹²

Possible benefits

Decreases general menopause symptoms such as migraine headaches, sleep disturbances, hot flashes, mood problems, perspiration, heart palpitations, and vaginal dryness for up to 6 months.

Possible risks

No study has reported risks and benefits when taken longer than 6 months. If an overdose is taken, it may cause nausea, vomiting, bradycardia (low heart rate), headache, fainting, sweating and vision problems.

Restrictions or warning

Consult your physician before use if you :

- have or have had breast or uterine cancer
- have an allergy to aspirin or to the ranunculaceae family
- suffer from endometriosis
- are using a hormone replacement therapy for menopause (hormones)
- suffer from epilepsy
- are taking medication for hypertension
- have heart or liver problems

It may be confused with blue cohosh (*caulophyllum thalictroides*) that can have harmful effects on the heart.

* Please check with Health Canada Advisory regarding possible link between black cohosh and liver damage http://www.hc-sc.gc.ca/dhp-mps/advisories-notifications_a.html

Soya (*Soja hispida*, *Glycine max*)

Dose

50 to 75 mg of isoflavones per day taken by mouth

Isolated protein (powder)

60 g (25 g=60 mg of isoflavones)

Soy flour

45 g (50 g=60 mg of isoflavones)

Possible benefits

Decreases hot flashes due to menopause

Possible risks

Soya does not have any known long-term toxic effects.

Side-effects may include nausea, constipation, and bloating.

Restrictions or warning

Some people can have or develop an allergy to soya.

Consult your physician if you :

- have or have had breast, ovarian or uterine cancer
- are taking estrogen
- are taking medication for the treatment of cancer
- are taking a blood thinner such as warfarin (Coumadin®)

C : Uncertain or contradictory evidence related to menopause		
Common name (latin)		
Ginseng (<i>Panax ginseng</i>)	Red clover (<i>Trifolium pratense</i>)	It is not possible to identify the benefits or risks associated with the use of these products. Research studies are needed.
Wild yam (<i>Dioscoreaceae villosa</i>)	St Johns wort (<i>Hypericum perforatum</i>)	
Green tea (<i>Camellia sinensis</i>)	Vitamin E or alpha-tocopherol	
D : Good level of evidence showing that there are NO benefits related to menopause		
Common name (latin)		
Evening primrose oil (<i>Oenothera biennis</i>)		Studies show that evening primrose oil does not decrease hot flashes.
E : Very good level of evidence showing that there are NO benefits related to menopause (No product in this class)		
F : No available scientific evidence related to menopause		
Common name (latin)		
Garlic (<i>Allium sativum</i>)		The benefits and the risks related to these products are not known. Research studies are needed.
Chamomille (<i>Matricaria recutita</i> , <i>Anthemis nobilis</i>)		
Dong quai (<i>Angelica sinensis</i>)		
Echinacea (<i>Echinacea</i>)		
Ginkgo (<i>Ginkgo biloba</i>)		
Common valerian (<i>Valeriana officinalis</i>)		
Withdrawn from the market by Health Canada		
Common name (latin)		
Kava (<i>Piper methysticum</i>)	Health Canada and similar agencies in other countries have reports that kava may cause serious liver dysfunction and as a result have withdrawn it from the market. ¹²	
These tables are based on the information available on: http://www.naturalstandard.com , ¹⁴		
Given that NHPs may have adverse events and interactions, please discuss with your healthcare provider if you are considering taking any natural health product.		

Step 3. Identify the available options

- Take the decision you identified in step 1 and, list the options that you are considering.
- For each of these options, list all of the benefits and risks.
- Underline, the benefits and risks that are most likely to occur.

For example, if the option is to take soya for hot flashes

Option (example)	Benefits (reasons for choosing) (examples)	Risks (reasons for avoiding) (examples)
To take soya	- decreases hot flashes - does not need a prescription from physician	- there might be side-effects such as nausea, constipation, bloating - there is a cost
Options	Benefits (reasons for choosing)	Risks (reasons for avoiding)
#1	**** **** **** ****	**** **** **** ****
#2	**** **** **** ****	**** **** **** ****
#3	**** **** **** ****	**** **** **** ****

Step 4. Clarify what is important for you

D. In the table above, circle the number of stars (1 star means not very important and 5 stars means very important) to show what is most important to you about each of your options.

☐ Done

Step 5. Select the role you want to play in making the decision

Who do you prefer makes this decision?

- ☐ I prefer to make my decision with _____
- ☐ I prefer to make the decision myself after talking to _____
- ☐ I prefer that _____ make the decision for me.

Do you have enough support and advice about your decision from others?
Are you choosing without pressure from others?

☐ yes ☐ no
☐ yes ☐ no

Who else is involved in your decision?				
Which option does this person prefer?				
Is this person pressuring you?	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no
How can this person support you?				

Step 6.

ACTION PLAN

At this stage, do you feel sure about the best choice for you?

- ☐ yes, my choice is _____
☐ no

If you answered "no", check the actions below that may help you with making your decision.

Knowledge (if you feel you do not have enough facts)

- ☐ List your questions
- ☐ Note where to find answers (for example, library, counsellor, health professional, etc.)
- ☐ Ask for help from people trained in this field
- ☐ Consult the resources from the following page

Values (if you are not sure what matters most to you)

- ☐ Review the « stars » in the table earlier to see what matters to you
- ☐ Talk to others who have made the decision
- ☐ Read stories of what mattered most to others
- ☐ Share with others what matters most to you

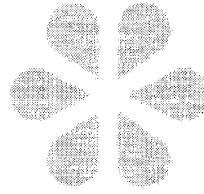
Support

If you feel you do not have enough support;

- ☐ Choose someone you trust to help you
- ☐ Find out what help is on hand to support your choice (for example, discussion groups, community organizations)

If you feel pressure from others;

- ☐ Focus on opinions of others who matter most
- ☐ Share this decision aid with others
- ☐ Ask others to complete the steps in this guide to find areas of agreement
- ☐ Find a neutral person to help you and others involved



Suggested Sources of Information :

❖ Natural Health Products Directorate at Health Canada has a website with information on new regulations and legislation governing natural health products at http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index_e.html. This site is updated on a regular basis.

❖ The following table presents websites that offer information on natural health products based on research studies. These sites have been appraised for their quality and relevance using a set of standard question that can be found at http://machaon.fmed.ulaval.ca/medecine/repertoire/PDF/evaluation_tool.pdf

Site	Country	URL	Free	Bilingual	Quality Score obtained (%)
Passeportsanté.net La santé sans frontière	CAN	www.passeportsante.net	yes	French only	80.5
Natural Standard The Authority in Integrative Medicine	US	http://naturalstandard.com	no	English only	82.5
National Centre for Complementary and Alternative Medicine	US	http://nccam.nih.gov/health/	yes	English and Spanish	86.0

Average of scores obtained by the set of 108 sites evaluated by the « Pratique professionnelle en santé fondée sur les évidences scientifiques » group at the Department of Family Medicine site at Université Laval

80.1

* Scores range from 0% (poor quality with no scientific value or relevance) to 100% (high quality with scientific value and very relevant)

More information is becoming known everyday on natural health products. Therefore, it is helpful to visit these websites regularly to learn about new scientific evidence.

Suggestions for reading

1- Just the facts, ma'am... A women's guide for understanding evidence about health and health care. The national coordinating group on health care reform and women, 2005.

You can download this guide from http://www.cwhn-cesf.ca/PDF/health_reform/evidenceEN.pdf or obtain it free of charge* from:

Canadian Women's Health Network
203-419 Graham Ave.
Winnipeg, MB R3C 0M3
cwhn@cwhn.ca
www.cwhn.ca

*The document itself is free of charge but shipping charges may be added

2- A Friend Indeed... A menopause and midlife publication.

You can download a free sample from http://www.afriendindeed.ca/free_issue.htm or subscribe from <http://www.afriendindeed.ca/subscriptions.htm>

"Not free to subscribe"

A Friend Indeed
Main Floor - 419 Graham Ave.
Winnipeg, MB R3C 0M3
afi@afriendindeed.ca
www.afriendindeed.ca



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Appendix B: Invitational Poster

Menopause and natural health products

Making a decision...



The Use of Natural Health Products during Menopause:

We are looking for women, aged 45 to 64, who are bothered by menopausal symptoms, are considering using a Natural health product to relieve symptoms and are unsure about what choice to make. Your participation in this research study would involve using a decision support tool aimed to guide women who are thinking about using a natural health product during menopause. The overall purpose of the study is to learn ways that we can better help women who are facing this decision.

For more information and/or to volunteer to participate in this study, please contact the study coordinator at 613-799-6922

Or send an email to

Please forward this phone number and email address to your friends who may also be interested.

Thank you in advance

This research study has been approved by the Ottawa Hospital Research Ethics Board.

Appendix C: Eligibility Screening Criteria

Date: _____ (day/month/year)

Study # _____

- | | | |
|---|------------|-----------|
| 1. Are you between the ages 45 and 64? | Yes | No |
| 2. Are you able to read and speak English? | Yes | No |
| 3. Are you bothered by any menopausal symptoms? | Yes | No |
| 4. Are you thinking about using a natural health product for menopausal symptoms? | | |
| | Yes | No |
| 5. Do you have symptoms for which you are unsure of the diagnosis? | Yes | No |
| 6. Are you a manager or owner of a natural health food store, pharmaceutical company or medical clinic? | Yes | No |

Set up home visit # 1 at this time if meets criteria's:

Please give me a contact number where I can reach you.

Name _____

Contact number _____

Appendix D: Decisional Conflict Scale

Date: _____ (day/month/year)

Study # _____

My difficulty in making this choice

Now think about your choice of taking or not taking a natural health product. Please show how strongly you agree or disagree with these statements by circling the number from 1 (strongly agree) to 5 (strongly disagree) that best shows how you feel about your decision.

	Strongly Agree [1]	Agree [2]	Neither Agree Or Disagree [3]	Disagree [4]	Strongly Disagree [5]
1. I know which Natural health product options are available to me.					
2. I know the benefits of each option.					
3. I know the risks and side effects of each option.					
4. I am clear about which benefits matter most to me.					
5. I am clear about which risks and side effects matter most.					
6. I am clear about which is more important to me (the benefits or the risks and side effects).					
7. I have enough support from others to make a choice.					
8. I am choosing without pressure from others.					

	Strongly Agree [1]	Agree [2]	Neither Agree Or Disagree [3]	Disagree [4]	Strongly Disagree [5]
9. I have enough advice to make a choice.					
10. I am clear about the best choice from me.					
11. I feel sure about what to choose.					
12. This decision is easy for me to make.					
13. I feel I have made an informed choice.					
14. My decision shows what is important to me.					
15. I expect to stick with my decision.					
16. I am satisfied with my decision.					

Appendix E: Knowledge Test

Date: _____ (day/month/year)

Study # _____

What I know about natural health products?

The statements below relate to natural health products (NHP).

Please answer "true", "false" or "unsure" for each of the following questions by circling the desired answer.

1. All natural health products (NHP) are without danger to health
true false unsure
2. There are no possible interactions between natural health products and over the counter medications (purchase free)
true false unsure
3. There are no possible interactions between NHP's and prescribed medications (drugs prescribed by a doctor)
true false unsure
4. Health Canada regulates natural health products.
true false unsure
5. There are scientific data showing the effectiveness of all natural health products that are available
true false unsure
6. All natural health products which are sold were approved by Health Canada
true false unsure
7. All women have symptoms related to the menopause
true false unsure
8. Natural health products can also have side effects
true false unsure
9. Natural health products are a category of products included in complementary and alternative medicine
true false unsure
10. All drug insurance companies cover the costs of the NHP's
true false unsure

Appendix F: Values Clarity Questionnaire

Date: _____ (day/month/year)

Study # _____

The factors which are important for me with regards to the use of natural health products to relieve my symptoms associated with menopause:

People making decisions about Natural Health Products consider several factors. Please show how important these factors are to you by circling the number from **0** (not at all important to me) to **10** (extremely important to me).

1. How important is the "nonchemical" aspect to you when making the decision to use Natural Health Products?

0	1	2	3	4	5	6	7	8	9	10
not at all										extremely
important										important

2. How important is it to you to have scientifically recognized facts when you make a decision on the subject of Natural Health Products?

0	1	2	3	4	5	6	7	8	9	10
not at all										extremely
important										important

3. How important is it to you the potential health dangers (interaction with drugs, unknown side effects, possible allergic reactions, etc) when you make a decision about Natural Health Products?

0	1	2	3	4	5	6	7	8	9	10
not at all										extremely
important										important

4. How important is it to you to have accessibility to the product (available without regulation, accessible close to home, etc) when you make a decision about the Natural Health Products?

0	1	2	3	4	5	6	7	8	9	10
not at all										extremely
important										important

5. How important is it to you the cost related to the products when you do make a decision about Natural Health Products?

0	1	2	3	4	5	6	7	8	9	10
not at all										extremely
important										important

Appendix G: Choice Predisposition Scale

My Opinion about Natural Health products for menopausal symptom management.

We want to know what your opinion is of taking a natural health product (NHP) for menopausal symptoms.

1. If you were asked right now to make a choice about taking a natural health product, please show where you would be on the scale below, by placing a check in the box ☐.

If you want to take a natural health product for menopausal symptoms, you would

Check ☐ far to the left.

If you do not want to take a natural health product, you would check ☐ far to the far to the right.

If you are not sure, you would check ☐ in the middle

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------

Yes

Unsure

No

NHP

NHP

1. If you were asked whether or not you wanted to take a NHP, with what you know now, check ☐ which choice looks the best for you:

☐ Taking a NHP,

Reason for this choice

☐ Not taking a NHP,

Reason for this choice

☐ I'm not sure, reason for this choice

Appendix H: Acceptability Survey

Date: _____(day/month/year)

Study # _____

Evaluation of a natural health product decision aid for women considering options for
menopausal symptom management

My thoughts on the decision aid

1. How would you rate the **amount** of information in the workbook? Please check one.

- ☐ Much less than I needed
- ☐ Little less than I needed
- ☐ About the right amount of information
- ☐ A little more information than I needed
- ☐ A lot more information than I needed

2. How would you rate the **length** of the workbook?

- ☐ Much too long
- ☐ A little too long
- ☐ Just about right
- ☐ Should have been a little longer
- ☐ Should of have been much longer

3. How **clear** was the information in the workbook?

- ☐ Everything was clear
- ☐ Most things were clear
- ☐ Some things were clear
- ☐ Many things were unclear

4. How **balanced and fair** did you find the workbook?

- ☐ Clearly slanted to taking a Natural health product
- ☐ A little slanted to taking a Natural health product

- ☐ Completely balanced
- ☐ A little slanted to taking no Natural health product
- ☐ Clearly slanted to taking no Natural health product

5. How **helpful** is the workbook in helping you make a decision about taking a NHP?

- ☐ Very helpful
- ☐ Somewhat helpful
- ☐ A little helpful
- ☐ Not helpful

6. Would you **recommend** this workbook to other people who are facing the choices for taking a NHP for menopausal symptom management?

- ☐ I would definitely recommend it
- ☐ I would probably recommend it
- ☐ I would probably not recommend it
- ☐ I would definitely not recommend it

7. What did you like **most** about the decision aid workbook?

8. What did you **not** like about the decision aid workbook?

9. Do you have any **other comments** about the workbook?

Appendix I: Preparation for Decision Making Scale

Date: _____(day/month/year)

Study # _____

Preparation for Decision Making Scale

Please show your opinion of the Natural health product decision aid by circling the number to show how much you agree with each statement.

Did this educational material.....	Not at all	A little	Some what	Quite a bit	A great deal
1. Help you recognize that a decision needs to be made?	1	2	3	4	5
2. Prepare you to make a better decision?	1	2	3	4	5
3. Help you think about the pros and cons of each option?	1	2	3	4	5
4. Help you think about which pros and cons are most important?	1	2	3	4	5
5. Help you know that the decision depends on what matters most to you?	1	2	3	4	5
6. Help you organize your own thoughts about the decision?	1	2	3	4	5
7. Help you think about how involved you want to be in this decision?	1	2	3	4	5
8. Help you identify questions you want to ask your doctor?	1	2	3	4	5
9. Prepare you to talk to your doctor about what matters most to you?	1	2	3	4	5
10. Prepare you for a follow-up visit with your doctor?	1	2	3	4	5

Appendix J: Intention to Discuss Use of Natural Health Products & Future Use of Patient Decision Aid Scale

1. The following questions relate to the intention to use the intervention that was assigned to you for your future need. The questions can seem repetitive to you but aim to get your opinion as correct as possible. Please indicate, on the scale, -3(very useless) to +3 (very useful) the importance to you of each one following statements:

1 According to you, in a situation where making a decision about natural health products, the use of the information booklet which was assigned to you appears to be:

Very useless							Very useful
-3	-2	-1	0	+1	+2	+3	

2 According to you, in a situation where making a decision with regards to natural health products, you estimate that your chances of using the intervention booklet which was assigned to you are:

Very weak							Very strong
-3	-2	-1	0	+1	+2	+3	

3 In a future situation when making a decision about natural health products, I intend to use the information booklet again which was assigned to me for this study:

Highly disagree							Highly agree
-3	-2	-1	0	+1	+2	+3	

2. The following questions relate to the intention to discuss with your pharmacist your use of natural health products of or your intention to use natural health products for the relief of your menopausal symptoms. Indicate, on an scale of -3(very useless) to +3 (very useful) the importance to you of each of the following statement:

1 According to you, the fact of discussing with your doctor or your pharmacist your use of natural health products appears:

Very useless							Very useful
-3	-2	-1	0	+1	+2	+3	

2 According to you, you estimate that your chances of discussing with your doctor or your pharmacist your use of natural health products are:

Very weak							Very strong
-3	-2	-1	0	+1	+2	+3	

3 I intend to discuss with my doctor or my pharmacist my use of natural health products

Highly disagree							Highly agree
-3	-2	-1	0	+1	+2	+3	

Appendix K: Demographic Questionnaire

Date: _____ (day/month/year)

Study # _____

Evaluation of a natural health product decision aid for women considering options for
menopausal symptom management

Clinical and Demographic Questionnaire

Personal Characteristics

1. Marital Status:

☐ married

☐ single

☐ widowed

☐ divorced/separated

2. Language most frequently spoken:

☐ English

☐ French

☐ Other: _____

3. Language most frequently read:

☐ English

☐ French

☐ Other: _____

☐ French

4. Highest grade or level of education completed:

☐ Less than grade 9

☐ some high school

☐ university

☐ High school diploma

☐ trade certificate/diploma

Relevant Medical History

History of:

☐ Hysterectomy

☐ Hormone replacement therapy

☐ Age of onset of menopause _____

☐ Other: _____

Appendix L: Menopausal Rating Scale

Date: _____ (day/month/year)

Study # _____

Which of the following symptoms apply to you at this time? Please, mark the appropriate box for each symptom. For symptoms that do not apply, please mark 'none'.

Symptoms:

	none 0	mild 1	moderate 2	severe 3	very severe 4
1. Hot flushes, sweating (episodes of sweating)	☐	☐	☐	☐	☐
2. Heart discomfort (unusual awareness of heartbeat, heart skipping, heart racing, tightness)	☐	☐	☐	☐	☐
3. Sleep problems (difficulty in falling asleep, difficulty in sleeping through, waking up early)	☐	☐	☐	☐	☐
4. Depressive mood (feeling down, sad, on the verge of tears, lack of drive, mood swings)	☐	☐	☐	☐	☐
5. Irritability (feeling nervous, inner tension, feeling aggressive)	☐	☐	☐	☐	☐
6. Anxiety (inner restlessness, feeling panicky)	☐	☐	☐	☐	☐
7. Physical and mental exhaustion (general decrease in performance, impaired memory, decrease in concentration, forgetfulness)	☐	☐	☐	☐	☐
8. Sexual problems (change in sexual desire, in sexual activity and satisfaction)	☐	☐	☐	☐	☐
9. Bladder problems (difficulty in urinating, increased need to urinate, bladder incontinence)	☐	☐	☐	☐	☐

none	mild	moderate	severe	very severe
	0	1	2	3
				4

10. Dryness of vagina or, difficulty with sexual intercourse

☐	☐	☐	☐	☐
--------------------------	--------------------------	--------------------------	--------------------------	--------------------------

11. Joint and muscular discomfort (pain in the joints, rheumatoid complaints)

☐	☐	☐	☐	☐
--------------------------	--------------------------	--------------------------	--------------------------	--------------------------

Add your scores for all items. The total score ranges from 0 to 44.

0 – 4: no or few symptoms	5 – 8: slight symptoms	9 -16: moderate symptoms	17 and above: severe symptoms
---------------------------	------------------------	--------------------------	-------------------------------

Appendix N: Consent Form

Consent Form

**Evaluating the Effectiveness of a Decision Aid for Peri and Menopausal Women
Considering the use of a Natural Health Product for Symptom Management**

Research Team:

Prudy Menard, RN, BScN, MSNH, MScN student

Dawn Stacey, RN, PhD, Professor, Faculty of Nursing, University of Ottawa

France Légaré, MD, PhD, Professor, Faculty of Medicine, University of Laval

Kirsten Woodend, RN, PhD, Professor, Faculty of Nursing, University of Ottawa

Purpose and Design – The purpose of this study is to create and test information for women making decisions about using natural health products to manage menopausal symptoms. What we learn from this study can help doctors and nurses provide better support to women making this decision in the future. There will be approximately 26 women in this study. You are being invited to take part in this study.

Study Procedures– The following are the steps in the procedure:

1. At your first home visit, you will be asked to complete a survey telling us a bit about yourself, what you know about natural health products for menopausal symptoms, and how hard the decision is for you. You may skip any questions that you do not feel comfortable answering. This survey will take about 20 minutes to complete.
2. You will then be given the natural health product decision aid and workbook to complete in the next two weeks. You may share your decision aid and workbook with others.
3. Two weeks after the first visit you will be given a survey. The other two additional surveys that you will need to fill out will be your thoughts on the decision aid and your satisfaction with your decision. Again, you may skip any questions that you do not feel comfortable answering. This should take about 25 minutes. You will be given your answers at this time.
4. About 2 months later, the research nurse will telephone you to find out if you have any additional questions and if and what you are doing to help control your menopausal symptoms.

Length of Study – The study is expected to last 3 months for each participant.

This research study was approved by The Ottawa Hospital Research Ethics Board & the University of Ottawa Research Ethics Board

Possible Side Effects and/or Risks –

- There are no known risks

Possible Benefits –

- **Benefits of the Study – The decision aid may help you make a decision about whether or not to use a natural health product for menopausal symptoms.**
- **What we learn from this study may help other women who will be making decisions regarding the option of using a natural health product for menopausal symptoms**

Withdrawal from the Study - You may withdraw from the study at any time without any impact to your care. You may also ask that your data be withdrawn from the study completely.

Study Expenses- **There will be no money paid to participants.**

Confidentiality- All results of the study will be kept confidential. Representatives of the research team as well as by representatives of the Ottawa Hospital Research Ethics Board may review my records, under the supervision of Ms. P Menard's staff for audit purposes.

You will not be identifiable in any publications or presentations resulting from this study. All information which leaves the hospital will be coded with a number and you will not be identifiable by name. No records bearing my name will leave the Ottawa Hospital.

Voluntary Participation – Joining this study is your choice. You are under no obligation to take part in the study, and you may withdraw from the study at any time. Whether or not you decide to participate will have no effect on the care you would normally receive at the Women's Health Centre.

New Information About the Study- **If any new information about the study becomes available that might affect your wanting to participate in the study, you will be informed as soon as possible.**

Questions about the Study- If you have any questions about the study please call:

Prudy Menard, RN, Master of Science in Nursing Student, University of Ottawa, telephone number: 613-799-6922 OR

Dawn Stacey, RN, PhD, Professor, Faculty of Nursing, University of Ottawa, telephone number: 613-562-5800 ext. 8419

If you have any questions about your rights as a research subject, you should contact the Chairperson of the Ottawa Hospital Research Ethics Board at 613-798-5555, extension 14902 or the Protocol Officer for Ethics in Research, University of Ottawa, Tabaret Hall, 550 Cumberland Street, Room 159, Ottawa, ON K1N 6N5, (613) 562-5841 or ethics@uottawa.ca.

Consent

I have read this Information and Consent Form and have had an opportunity to ask my research nurse any questions I had about the study.

My questions and/or concerns have been answered to my satisfaction and I agree to participate in this study. If I decide at a later stage in the study that I would like to withdraw my consent, I may do so at any time.

A copy of the Information Sheet and/or Consent Form will be provided to me should I want to review the information at a later date, if I need to contact someone about the study or my participation in the study, or simply for my records.

Signatures:

Name _____

Signature _____

Date _____

Investigator's Name _____

Investigator's Signature _____

Date _____

Appendix O: Overview of Teaching/Learning Strategies to Enhance Nurses' Knowledge and Skills in Evidence-Based Patient Decision Support

Modules	Overall Objective	Lectures	Problem-based Scenarios	Assignments
I (clinical focus: individuals as children, adults, seniors)	To introduce patient decision making and influence of values on clinical decisions	Understanding the influence of values on nursing practice* Supporting clients to be effective consumers and decision makers for lifestyle choices* Healthwise Handbook and Knowledgebase workshop*	1.1c- Stress in adults* 1.2c- Childhood healthy body weight* 1.3c- Falls in seniors*	1.1a Exploring the influence of values on health decisions
II (clinical focus : obstetrics, seniors)	To identify the nurse's role in supporting families making decisions by using patient decision support tools	Health decision making and the family for triage and values-sensitive decisions (English & French)*	2.1c- Circumcision; infant feeding 2.2c- Postpartum depression	2.1a-Utilization of patient decision aids: obstetrics focus(English & French)* 2.1b – Utilization of patient decision aids: birth control or tube feeding (English) 2.2a- Evidence-based clinical guideline (English & French)*
III (clinical focus: community health,surgery, medicine, mental health)	To explore the Ottawa Decision Support Framework and its relevance for clinical practice	The Ottawa Decision Support Framework as a mid-range nursing theory* Breast cancer patient decision making within 3-hr cancer nursing lecture*	3.1c- Lung cancer end of life care 3.2c- Adolescent suicide	3.1a-Autotutorial with knowledge test* 3.2a-Applying the Ottawa Decision Support Framework*
IV (clinical focus: complex care, consolidating knowledge & skills)	To build and appraise decision coaching skills for supporting patients facing decisions in a complex care environment	Decision support skill building workshop* Addressing oncology patient information and decision support needs*	4.1c- Medication error 4.2c- Stroke rehabilitation	4.1a-Critical appraisal of Patient Decision Coaching 4.2a- Clinical practice guideline evidence-practice gap

*pilot tested with students Additional Resources

- Guidelines for Creating Problem Based Learning case scenarios
- Summary of Evidence-based patient decision support Resources for posting on the University of Ottawa Library Website
- Conducting a Curriculum Needs Assessment: A workbook for assessing opportunities for integrating patient decision support within curriculum for health practitioners (Stacey & Menard, 2006)

Appendix P: Result Article for Submission

Manuscript Cover Letter

To Whom It May Concern:

The following article has not been published and is not being considered for publication elsewhere, and all authors meet the journal's criteria for authorship. No financial or conflict of interest noted. The authors are as follows:

1. Prudy Menard RN, MSNH, MScN(c)
2. Dawn Stacey RN, MScN, PhD
3. France Légaré MD, PhD
4. Kirsten Woodend, RN, MSc, PhD

**Evaluation of a Natural Health Product Patient Decision Aid:
A Tool for Middle Aged Women Considering Menopausal Symptom Relief**

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Abstract

Objective: To evaluate the effectiveness of a decision aid for menopausal women facing decisions about natural health products.

Background: Women experience difficulty with making decisions about natural health products for management of menopausal symptoms. Although a new decision aid is available, its English version has not been evaluated in a community-based/clinical setting to determine its effect on decision quality or the process of decision making.

Design: A pre-/post-test study.

Setting: The Women's Health Center at The Ottawa Hospital, Ottawa Canada

Participants: Peri- to postmenopausal women aged 45 to 64 considering the use of a natural health product for management of menopausal symptoms.

Intervention: Self-administered natural health product patient decision aid

Main Outcome measures: The primary outcome measure was decisional conflict. Secondary outcomes included decision quality using, knowledge, strength of values, and choice/preference.

Results: 24 women primarily between 50-59 years of age, Caucasian, married, and well educated participated. Compared to baseline, after using the decision aid, women's total decisional conflict was reduced from 62.82% to 23.63% ($p < 0.001$) and improved knowledge from 76% to 87% ($p = 0.001$). The value clarification exercise revealed that women who preferred natural health products were more likely to rate the non-chemical aspect as important and the cost of the product not as important. Of the 24 women, 10 were unsure of their choice at baseline and 3 post use of the decision aid ($p = 0.015$). Overall, women rated the decision aid as acceptable, clear, and balanced.

Conclusion: The natural health product patient decision aid improved decision quality and supported menopausal women who were facing health decisions around using natural health products for menopausal symptoms.

Word count: 253

Key words: decision support interventions, decisional conflict, patient decision aid, natural health product, menopause

Background

Menopause is a natural life process that can entail mild to very severe symptoms for women.^{1,2} In the past, women were encouraged to use hormone replacement therapy (HRT) for menopausal symptoms.³ In 2002, however, the Women's Health Initiative reported an increase of coronary artery disease and breast cancer for women taking HRT.⁴ Since the Women's Health Initiative findings, more women are reaching out to natural health products (NHPs) for management of menopausal symptoms.⁵⁻⁷ In Canada, about 71% of Canadians use NHPs.⁸ The highest uses of NHPs were in those with a higher education and women. However, little is known about the quality of decisions to take NHPs. Of concern is the limited evidence available regarding these products, and the large marketing strategies directed towards these women as the greatest users of NHPs.^{9,10}

The lack of evidence, vast number of choices and undue marketing pressures to use a NHP can lead to decisional conflict. According to the North American Nursing Diagnoses Association, decisional conflict is a state of "uncertainty about course of action to be taken when choice among competing actions involves risk, loss, or challenge to personal life values" (p. 36).¹¹ Although decisional conflict occurs because of the need to balance benefits versus harms across options, it can be exacerbated by inadequate knowledge, unrealistic expectations, unclear personal values, and inadequate support and resources for decision making.¹² Unresolved decisional conflict leads to decisional delay or reversal, dissatisfaction, regret, and blaming the provider for poor outcomes.^{13,14} Thus, many of these women making decisions about NHP are likely going to need decision support given the nature of the decision.

Decision support can be provided with counselling and/or patient decision aids (PtDAs). A Cochrane review of 55 randomized controlled trials found that patient decision

aids can help facilitate the decision making process by increasing patients knowledge of options and decreasing decisional conflict.¹⁵ Of these 55 trials, 9 were focused on hormone replacement therapy and none on NHPs. The International Patient Decision Aid Standards Collaboration stated that patient decision aids are meant to improve patient's knowledge and prepare them in making informed; values based decisions about their health care. This aim is consistent with how decision quality has been defined.^{16,17} According to the International Patient Decision Aid Standards document, a higher quality PtDA needs to be developed using a systematic and replicable process and that it should be evaluated in the field.¹⁶

The Cochrane inventory of more than 500 decision aids includes one decision aid for NHP developed by a Canadian-based consortium group which was based on a needs assessment and the Ottawa Decision Support Framework (ODSF).¹⁸ The needs assessment that was conducted in order to produce this decision aid was performed with 15 key informants (consisting of nurses, physicians, pharmacists, NHP storeowners and policy makers) and 6 discussion groups of 41 menopausal women aged 44 to 67 years was conducted in French and English.¹⁹ This study and previous research to evaluate women's needs regarding NHP use found that menopausal women were: a) experiencing difficulty deciding whether or not to take NHP; b) experiencing difficulty deciding which NHP to choose; whether to take anything at all for menopausal symptoms; feeling a lack of confidence regarding NHP; c) inadequately informed and ; d) concerned regarding cost and closed-mindedness of physicians towards NHP.^{5,20-24} To address women's needs, a patient decision aid was developed and at the time this study was planned, the French version was being pilot tested in Quebec.²⁵ Given that the PtDA was developed concomitantly in both English and French, there was a need to evaluate it in both languages.

Objective

Overall, the aim of this study was to evaluate the effectiveness of a NHP PtDA on the quality of decisions made by peri- and postmenopausal women facing decisions about natural health products. Specifically, the PtDA is hypothesized to reduce decisional conflict, and increase decision quality. Decision quality was defined as having; a) knowledge of NHPs options, benefits and risks; b) clear values associated with outcomes of options; and c) concordance between the option chosen and patients' values.

Methodology

The decision aid was evaluated in a one-group pre-/post-test study design guided by the Ottawa Decision Support Framework (ODSF) (See Figure 1). The ODSF is a middle-range theory that can guide the construction of interventions to facilitate the preparation of individuals for decision making in health care, particularly in circumstances manifested by scientific uncertainty.²⁶ The decisional process allows individuals' to become better informed by the best probative data that is congruent with their own personal values allowing for an increase in overall satisfaction with the decision making process.²⁶ The framework consists of three categories: 1) identification of decisional needs and determinants of the decision; 2) decision support intervention strategies and; 3) evaluation of the decision process and outcomes. Interventions such as decision support tools are intended to improve the quality of the decisional process through the modifiable determinants of decision making. Thus, the intervention of decision support can be utilized to reduce decisional conflict and improve the decisional process. The success of this model in addressing determinants of decisions and developing intervention strategies has been shown in several clinical situations in women's health, especially in the area of middle-aged women's health.^{27- 31,26, 32,33}

Participants & Setting

A non-randomized convenience sampling method was used. Recruitment occurred through the menopausal information sessions provided at The Ottawa Hospital at the Women's health centre in Ottawa Ontario and through word of mouth.

Peri- and postmenopausal women who were considering the use of a NHP for symptom management were recruited. Participants inclusion criteria were: a) female; b) aged 45-64; c) considering a NHP to relieve menopausal symptoms; d) not currently using prescription or NHPs for menopausal symptom control; e) unsure about what choice to make, and; f) able to read and speak English. Exclusion criteria were: a) symptoms that were not yet diagnosed by a physician or; b) being an owner or manager of a natural health food store, pharmaceutical company or medical clinic.

Intervention

The patient decision aid entitled "A decision aid for women considering natural health products for menopause symptoms" is a 13 page pamphlet that includes evidence-based information on menopause (see Figure 2), NHP options and resources (e.g. websites, books, associations and scientific papers). The decision aid includes interactive pages that guide women to explore their knowledge and values associated with the options as to whether or not to use NHPs for menopausal symptoms. Values are clarified using the balance scale technique and women are asked to identify their options and the outcome of these options and rate the level of importance using a 5 point scale (see Figure 3). As well, women are asked to identify their support system, consider their role preference in decision making and establish an action plan for taking the next steps in the decision making process. This PtDA was developed using the ODSF and is congruent with the standards set by the International Patient Decision Aid standards.¹⁹

Procedure

The data collection occurred at three points during the study. The measures were taken: 1) at baseline pre-test; and 2) 2 weeks after receiving the decision aid and 3) a follow-up telephone call 2 months later. After eligibility was confirmed, the study was explained in more detail and an informed consent was obtained using the protocol approved by the Ottawa Hospital and the University of Ottawa Research Ethics Board, Ontario, Canada. At baseline, data collection included a self-administered demographic questionnaire, decisional conflict, knowledge test, values clarity, choice/preference and severity of menopausal symptoms. The participant was subsequently given the self-administered NHP PtDA and asked to read through it, consider the options and complete the values clarifications exercise.

Approximately two weeks after receiving the decision aid, decisional conflict, knowledge test, values clarity, and choice predisposition were re-assessed. As well, acceptability of the PtDA, satisfaction with preparation for decision making and intention to use the decision aid were evaluated. Two months later, participants had the actual decision assessed during a telephone call which included a discussion with the participants regarding decision uptake.

Outcome Measures

The primary outcome was decisional conflict. Secondary outcomes included decision quality (knowledge, strength of values, choice preference), decision uptake, and decision process measures (acceptability of the decision aid and satisfaction with the preparation for decision making, intention to discuss use with health care providers to and use the decision aid in the future).

Instruments

Decisional conflict was measured using the Decisional Conflict Scale; a 16-item scale with five subscales: uncertainty of choosing the best option, informed about the options,

values clarity, support and effective decision making (O'Connor, 1995).¹² It uses a five point likert scale rating from 1 (strongly agree; low decisional conflict) to 5 (strongly disagree; high decisional conflict). Total decisional conflict score was calculated by summing up 16 items and then dividing the scores by 16 then subtracting 1. Scores were subsequently standardized for score out 100 by multiplying by 25, where zero indicates no decisional conflict (i.e. in other words, high certainty) about the best choice and 100 extreme decisional conflict, high uncertainty about the best choice. The test-retest and alpha coefficients for this measure exceed 0.78. The measure is sensitive to change^{34,35,26} and is able to discriminate between different decision support interventions.^{36,37}

The participant's knowledge was assessed using a 10-item questionnaire about menopause, NHPs and the benefits and risks of using a NHP for menopausal symptoms. The responses to the statements were true, false, or unsure and marked as correct or incorrect. The total possible scores range from zero to 10 and converted to a score out of 100. The content validity was assessed with an expert panel that included two physicians specializing in women's health, two experts in decision aids and one credentialed menopause educator who is an advance practice nurse. Similar format for knowledge tests used in other decision aid studies were sensitive to change, had good internal consistency and were able to discriminate between interventions.^{28,34,35,26,38}

Values were assessed by a five-item questionnaire that elicits how important it is to the participant in making the decision to choose NHPs. The numbers on the scale range from '0', not at all important to '10' extremely important. Test-retest coefficients range from 0.79 to 0.91 and measures explain and discriminate between those making different decisions when measuring strength of values associated with outcomes of options.^{39,26} It has been

utilized in several different clinical applications including women's issues surrounding HRT.^{29,33,39,26,37}

Choice/preference was measured using a 15-point scale anchored by not taking any NHPs on one end and taking a NHP on the other, with unsure in the middle. The scale was then converted to yes, leaning to NHP (1-5), unsure (6-10) and no (11-15). It is sensitive to change and discriminates between the undecided category, exceeding the test-retest reliability coefficients of 0.90.³⁹

The acceptability survey included six open and three closed ended questions to determine acceptability of the decision aid. The open-ended questions asked the participant what they liked or did not like about the decision aid, and elicited further comments. From the close-ended questions, feedback on the amount, length, clarity, helpfulness, balanced presentation of information, and whether or not they would recommend it to others was obtained. These questions were based on a questionnaire evaluating the acceptability of the decision support programs produced by the Foundation for Informed Medical Decision Making.⁴⁰

Satisfaction was measured using the Preparation for Decision Making scale. The 'Preparation for Decision Making' scale assesses an individual's perception of how useful a decision aid was in making a health decision and preparing them for discussion with their health care provider.⁴¹ This scale consists of ten questions rated on a five-point scale where '1' on the scale is 'not at all' and a '5' is a great deal. The total score ranging from zero to 100. This scale has a high internal consistency, alpha coefficient ranges from .92 to .94. The scale discriminates significantly between different decision support interventions.^{41,38}

The intention to discuss the use of NHPs and future use of the NHP PtDA was measured using six items with response categories on a 7-point response scale from '-3' not

very useful to '+3' very useful. This tool measures the participant's behavioural intention to disclose use of NHPs to their physicians or pharmacist and using the PtDA for future decision making. It is based on the theory of planned behaviour that is well known through its previous application to the study of health professionals' behaviours.^{42-44,30,45,46} This theory postulates that when the individual has some control over a situation, intention is the immediate determinant of behaviour.⁴²

The Menopause rating scale is an 11-item scale with a five-point rating score. It describes the perceived severity of symptoms ranging from '0' none to '4' very severe. The total score of all items can range from '0' (asymptomatic) to '44' (highest degree of severity). Rating from 0-4 (no or few symptoms), 5-8 (slight symptoms), 9-16 (moderate symptoms) and 17-44 indicate severe symptoms.⁴⁷ Each symptom item is categorized under three subscales. These are psychological symptoms, somato-vegetative symptoms and urogenital symptoms.⁴⁸ The scale is internally consistent as measured by Cronbach's Alpha, where the coefficients varied between 0.6 and 0.9 across countries for the total score as well as the three subscales.⁴⁹

Data Analysis

Sample Size

The estimated sample size was calculated based on the paired t-test for comparing the means of the outcome 'decisional conflict' measured pre and post decision support. For a significance level of $\alpha = 0.05$, power $(1 - \beta) = 0.80$, a standard deviation of 0.6, and a correlation between pre/post scores of 0.25, the sample size was estimated at 23 to detect a difference of 0.4 in the decisional conflict score, out of a possible score of zero to four. This would be considered a medium effect size and one that would be apparent to an intelligent

observer.⁵⁰ The effect size is judged clinically important, as it has been observed that the usual cut point is 0.43 to 0.82 between individuals who make or delay decisions.²⁶

The Statistical Package for the Social Sciences (SPSS 14.0) was utilized for data analysis. Quantitative data was numerically coded and entered into a data file. All of the data was compared to the questionnaires for inconsistencies. Interval level data was tested for distribution using the Kolmogorov-Smirnov test and found to be normally distributed thus, the mean was chosen as the measure of central tendency. A paired t-test was used to test for change in the interval scale (decisional conflict scores, knowledge scores), and Wilcoxon Matched-Pairs Signed Ranks test for change in discrete measures (choice predisposition) from baseline to post intervention. Descriptive statistics were used to report the responses on the values scale, acceptability survey, satisfaction questionnaires, intention to use the PtDA, menopause rating scale and demographics.

Results

From September 2006 to February 2007, 30 participants volunteered and 24 were eligible. Three did not meet the age criteria, two were on hormone replacement therapy, and one had symptoms that were not diagnosed by a physician. From all of the surveys, one post Predisposition questionnaire was not completed and one Preparation for Decision Making was illegible and therefore could not be included.

On average participants were 50-59 years of age, Caucasian, married and well educated (see Table 1). Of 10 postmenopausal women, 8 had their onset of menopause occurred naturally between 50 to 55 years of age and in 2, menopause was surgically induced. The participants scored an average of 15.7 on the Menopause Rating Scale indicating moderate symptoms. The most commonly reported mild to severe symptoms were;

sleep problems (n=23), (n=22), irritability (n=22), anxiety (n=21) and mental and physical exhaustion (n=21).

Change in decisional conflict and modifiable factors

After using the NHP decision aid, participants' decisional conflict scores declined from mean total DC Score of 63% (95% CI 57, 68) pre to 24% (95% CI 17, 31) post ($p<0.001$). All subscale scores (uncertainty, informed, values, support, effective DM) decreased post decision aid (see Table 2). The informed subscale showed the greatest reduction in score from 78% (95% CI 71, 86) to 21% (95% CI 15, 28) with item 3 'I know the risks and side effects of each option' causing the highest decisional conflict.

Knowledge scores increased from 76.25%, (95% CI 69.45, 83.05) at baseline to 87.02%, (95% CI 83.05, 91.11) post decision aid intervention ($p=0.001$). Pre and post, the response to the question 'Health Canada regulates natural health products' received the fewest of correct responses and for the question about side effects of NHPs all respondents answered correctly (see Table 3).

Choice/Preference

Of 24 participants, 10 (42%) were unsure of their choice at baseline compared to 3 (12.5%) post decision aid. At the 2-month follow-up, all of the women had made a decision whether or not to use NHPs. Of the 24 women, 9 were using NHP to control menopause symptoms, 8 chose to use nothing to control symptoms, 5 stated that symptoms had decreased and felt no need to use anything. Two had started using hormone replacement therapy and both participants indicated that they were still looking into using a NHP in the future after being weaned off their hormone replacement therapy.

Values Concordance

Post decision aid, a trend was noted as 12 of 15 women that chose a NHP (80%) rated the importance of the non-chemical aspect highly compared to 3 of 5 women (60%) who chose not to use a NHP ($p=.766$). Of 15 women that chose a NHP 4 (27%) placed importance on the cost of the products compared to 3 of 5 women (60%) that chose not to use a NHP ($p=.417$). All women found scientific facts and dangers associated with NHPs to be of importance.

Acceptability of the patient decision aid

All of the 24 women rated the decision aid as clear and helpful in making a decision, and would recommend it to others. Eighteen (75%) rated it as balanced presentation of options and 6 rated it as slanted to taking a NHP. For those women who found the DA too slanted, one requested hormone replacement therapy be included and another stated that soy was favoured and other therapies such as counselling should be explored. Of 24 women, 8 indicated the amount of information was less than needed and 4 rated it as more than needed. For those that wanted more information, suggestions included adding a detailed list on the specific side effects and possible interactions of NHPs with other medications and another woman suggested adding contact information for credible, experienced professionals to address further questions. When asked what they liked most about the DA, participants stated the “flow of the decision making process, internet sites and references, awareness that family doctor & pharmacist should get involved in your decision” and “clear and concise”.

Usefulness of the Decision Aid

Of the 23 participants, 17 (74%) indicated that the PtDA prepared them for decision making by helping them to organize their thoughts, think about the pros and cons of each option, and consider which ones were most important. The 3 items that ranked lowest were, helping to

recognize that a decision needs to be made, identifying questions to ask the doctor and preparation for the doctor's visit. The total mean score for the intention to use the PtDA was 1.58 (SD 1.44) and for the intention to discuss use of NHPs with healthcare providers was 1.73 (SD 1.70). A score of one or more refers to a positive intention.

Discussion

This is the first known study to evaluate an English natural health product patient decision aid. The patient decision aid improved decision quality by decreasing menopausal women's decisional conflict, increasing their knowledge, and helped those who were uncertain make a decision. It was found to be an acceptable and useful tool for helping women prepare for discussion with their health care provider and women indicated their intention to use it for future decision making.

The magnitude of reduction in total decisional conflict of 39 points observed in this study (from 63% to 24%) is clinically significant. According to O'Connor,²⁶ at a score of 25% or lower participants are more likely to make a choice. Furthermore, women with lower levels of decisional conflict are more likely to be satisfied with their decision and not likely to feel regret.¹⁴ Compared to randomized controlled trials of patient decision aids, this pre-/post-test study found larger decreases in decisional conflict.¹⁵ The larger reduction may be a result of the decision aid helping women address factors influencing their decisional conflict such as feeling more informed and clearer about their values or there may be other influential factors. For example, the decision aid may have sensitized women to the decision of NHP and as such, women may have investigated other information sources including those provided within the decision aid and/or more actively sought others' opinions. A common source of information for women making decisions about NHP use is other women.¹⁹

Although women's knowledge scores at baseline were high (76%), there was an 11 point improvement in their knowledge score after using the decision aid. This improvement is consistent with that observed in the Cochrane review of PtDAs that found a range of 4.6 to 15.2 point improvement.¹⁵ The effects on knowledge were also evidenced by women's improved perceived knowledge on the uninformed subscale of the Decisional Conflict Scale and qualitative feedback indicating that the NHPDA improved their knowledge of resources to accessing evidence-based information on NHPs. Aside from websites, other resources such as journal articles, books and associations were listed for the women to access additional information on NHPs. One reason for the high baseline knowledge test score could have been due to the highly educated group of women who participated (92% had postsecondary education). Of concern was that even after using the decision aid, only about half the women were aware that Health Canada regulates natural health products. This raises the question of whether Health Canada and/or the NHP PtDA adequately informed the women on NHP regulations and/or whether or not this is an important issue for women to be aware of.

Another common measure of 'informed' decision making is realistic expectations of outcomes of options.¹⁵ However, this PtDA did not include probabilities for outcomes of NHP options; only a narrative discussion of potential benefits and risks of two different NHP options (e.g., soy, black cohosh). Current literature on use of NHPs for menopausal symptoms is limited and as a result, it is difficult to obtain adequate findings to be able to include these probabilities.

In addition to being informed, decision quality requires concordance between the option chosen and patients' values.^{16,17} Of the five values statements, two appeared to indicate differences by group. Compared to women who choose not to take NHPs in this study, women choosing NHPs appeared to be more likely to value the non-chemical aspect and less likely to

rate cost as important. In the literature, four studies reported that women considered the cost of NHPs when making their decision.^{5,19,22,23} NHPs are not covered by most insurance plans and can be costly.^{5,19} Women in our study choosing not to take NHPs for symptom relief were more likely to rate cost as important in their decision.

Another consideration when measuring values is the statements that are included. In this study, women in both groups valued the need for scientific evidence on NHPs, were concerned about potential dangers of NHP, and rated product accessibility as important. One consideration may be that these value questions were too broad and that all women would rate as important. Further evaluation using this measure of values could have values statements that are more specific to a set of options and their outcome rather than broader statements about NHP use. For example, specific value statements related to soy could include ease of access, decreased hot flashes or constipation.

The ability to determine values-choice concordance depends on clarity of women's values and the types of values statements being measured. The NHP PtDA used in this study included a balance scale approach to explicitly clarify women's values for outcomes of options. Previous trials that measured values concordance found that PtDA with explicit values clarification were superior to those in which values clarification was implicit.^{29,51} However, unlike these PtDAs, the balance scale in this decision aid required that women identify the specific decision they were considering, list of benefits and harms, and then rate the importance of each of these potential outcomes. Although, the decision aid was not collected from the women to determine completeness of the values clarification exercise, most women verbalized having completed it and their perception of values clarity measured using the Decisional Conflict Scale indicated improved values clarity from baseline to post PtDA.

Important criteria for developing higher quality PtDAs are those that have been pilot tested with users, found to have balanced presentation of options, and include a range of options.¹⁶ The majority of women in our study (75%) found the NHP PtDA to be completely balanced and the others thought it was slanted towards taking a NHP. These findings are comparable to other trials that reported patients' perception of balance presentation of information ranged from 74% to 79%.⁵² Sub-analysis of the six women who thought the PtDA was slanted toward taking NHP revealed that three were leaning towards NHPs at baseline and three were unsure. Barry and colleagues⁴⁰ found that men with benign prostatic hyperplasia who thought the DA was slanted were also leaning in the same direction as the slant post DA. Another reason for women indicating it was slanted toward taking NHPs was the fact that the PtDA was only focused on the decision to use NHPs.

Although the decision that was at the center of this PtDA was “to use NHP for menopausal symptoms or not” a different decision focused on specific options to manage symptoms could have been considered. A more inclusive PtDA could have also presented other options for managing menopausal symptoms such as hormone replacement therapy and lifestyle changes (e.g. exercise, nutrition and behaviour modification).

After using the NHP PtDA, women felt more supported in their decision making as evidenced on the support subscale of the Decisional Conflict scale and most women (88%) intended to discuss their choice with either a pharmacist or their physician. Although no direct question was asked regarding perception of support from health care providers in this study, some women did say they shared the PtDA with their physician prior to their second visit. PtDAs are intended to be used as adjuncts to practitioner counselling and previous studies indicated have

that women want support from health care providers.^{5,19-24} Women also identified communication barriers that interfered with discussing NHP decision with their health care professionals.

In a study to identify women's decision making needs related to NHPs, women identified that practitioners were not open to discuss NHPs.¹⁹ Other studies measuring the quality of practitioners' counselling have found that they focus primarily on information giving without adequately exploring patients' values/concerns.⁵³⁻⁵⁵ Without support from health care providers, women are more likely to rely on family, friends, media and the Internet for information. Relying on these sources can increase the possibility that these women are receiving information that may be biased and not evidence-based.^{5,8,56,24} Interestingly, women consider physicians and other healthcare providers to be a reliable source of information but ironically perceive them to be unknowledgeable and biased against NHPs.^{20,23} Consequently, these women do not necessarily discuss their use of NHPs with their health care providers. When women are not open about using NHPs, physicians can unknowingly prescribe medications that interact with NHPs.^{20,23}

Limitations

Interpretation of these findings should be considered in view of limitations using a pre/post-test quasi-experimental design. First, internal validity of the findings could have been threatened by the potential for maturation effect. Maturation occurs when a participant changes because of time passing.⁵⁷ In this study, participants may have been sensitized to their information needs by having written the baseline knowledge test and as a result become more informed overtime by exposure to information on NHPs in their environment. In an attempt to minimize a maturation effect, the participant's knowledge was re-assessed within two weeks of the baseline measure and participants were not given a copy of the knowledge test.

Another limitation was not being able to determine statistical significance of value-choice concordance with a sample size of 24. Statistical analysis used in previous studies to measure values-choice concordance such as regression analysis and correlations indicates the need to have over 100 participants with a balanced distribution between those who choose NHP and those who do not.^{29,51,58,33}

Finally, this study is likely to have limited generalizability of the findings given the small sample size and participants being primarily Caucasian, well educated, and married.⁵⁷ Further research should aim to determine the effect of the NHP decision aid on decision quality for women who are of more diverse ethnic and socio-economic backgrounds as mentioned previously.

Conclusion & Future Plans

Women struggle with making decisions about choosing NHPs for the management of menopausal symptoms. The NHP PtDA evaluated in this study provided an intervention strategy that was not previously in existence for women considering NHPs for menopausal symptoms and it is available in both French and English.¹⁹ Not only did the NHP PtDA provide information on NHP options, it allowed the participant to work through the decision process based on using the well established Ottawa Decision Support Framework and International Patient Decision Aids Standard Collaboration.^{16,26} The NHP PtDA may contribute to the further development of other decision aids focused on specific NHP products as the North American market is inundated with more choices.

The NHP PtDA supported quality decision making by informing menopausal women and helping them clarify their values associated with the outcome of options. Although this PtDA also reduced women's decisional conflict and they felt more certain about the best choice for

them, subsequent research should be powered to determine the effect of the decision aid on informed values-choice concordance. Furthermore, women reported having shared the NHP PtDA with others and used the resource section in the PtDA to explore the websites provided. This study was limited in focusing only on women's use of the decision aid and not how the information was used with their healthcare providers. Further research should examine its influence on shared-decision making approach involving others such as nurses, pharmacists, and physicians in the decision process. Also, given that women are not comfortable speaking with their physicians, other approaches are needed for using NHP PtDAs as adjuncts to practitioner counselling. Further research should explore the nurse's role in supporting women considering NHPs for menopausal symptom management.

It is unclear whether this subject (i.e., use of natural health products) interests certain groups of women, particularly those whose tradition or lifestyle are rooted in NHPs such as aboriginal or Orientals, as menopause is a natural life process occurring in all women. Future research should be evaluated with a more diverse group of women including women from aboriginal or oriental cultural groups.

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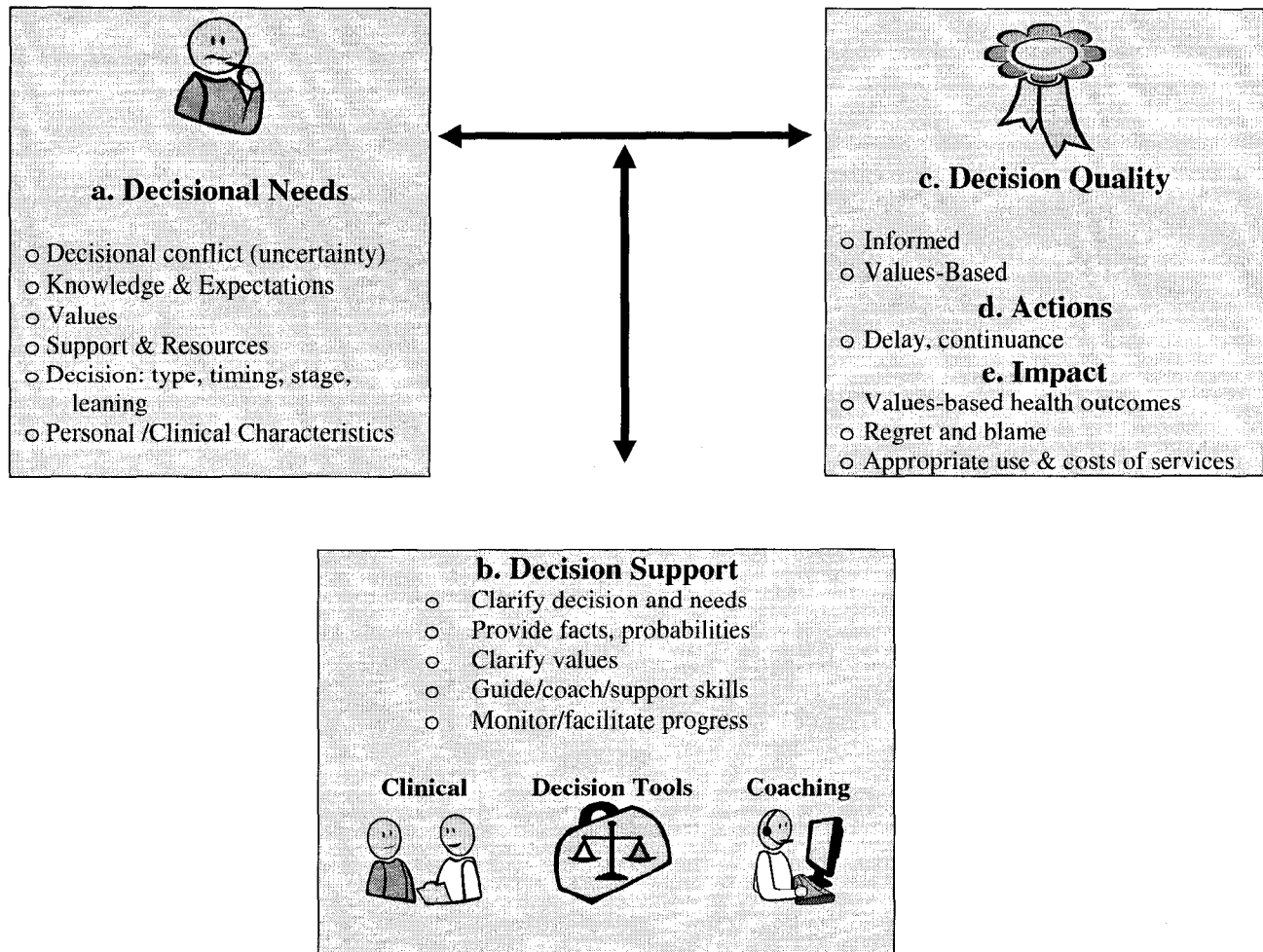
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Fig. 1 The Ottawa Decision Support Framework



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Fig. 2 Evidence-based information worksheet

Step 2. Getting the facts

When learning about the benefits and risks of natural health products that have been used by women during menopause,¹¹ it is important to know that the quality of the information varies. This quality depends on the number and types of research studies that have been done.

A: Very good level of evidence that there are benefits related to menopause (No product in this class)

B: Good quality evidence showing that there are benefits related to menopause

Common name (latin)

Black cohosh (*cimicifuga racemosa*, *Actaea racemosa*)

Active chemical

27-deoxyactein

Dose

1 to 2 mg of 27-deoxyactein
per day taken by mouth

Tablets

1 or 2 tablet

(20 mg tablet=1 mg

27-deoxyactein)

Liquid

20 to 40 drops of a 60%

ethanol tincture daily (1-10)

(20 drops=1 mg 27-deoxyactein)

Dried root powder

40 to 200 mg of dried rhizome

divided in several doses

(40 mg=1 mg 27-deoxyactein)

Dried root infusion

1 to 2 g boiled in 150 ml of water,

filtered and cooled

(doses recommend by The British

Herbal Compendium)¹²

Possible benefits

Decreases general menopause
symptoms such as migraine,
headaches, sleep
disturbances, hot flashes,
mood problems, perspiration,
heart palpitations, and vaginal
dryness for up to 6 months.

Possible risks

No study has reported risks and
benefits when taken longer than 6
months.
If an overdose is taken, it may
cause nausea, vomiting,
bradycardia (low heart rate),
headache, fainting, sweating and
vision problems.

Restrictions or warning

Consult your physician before use if you:

- have or have had breast or uterine cancer
- have an allergy to aspirin or to the ranunculus family
- suffer from arrhythmias
- are taking a hormone replacement therapy for menopause (hormones)
- suffer from epilepsy
- are taking medication for hypertension
- have heart or liver problems

It may be confused with blue cohosh (*Scutellaria*), which is noted that
can have harmful effects on the heart.

* Please check with Health Canada Advisory regarding possible link between black cohosh
and liver damage http://www.hc-sc.gc.ca/health-np/act/rac/rac_e.html

Soya (*Soja hispida*, *Glycine max*)

Dose

50 to 75 mg of isoflavones per day taken by mouth

Isolated protein (powder)

60 g (25 g=60 mg of isoflavones)

Soy flour

45 g (50 g=60 mg of isoflavones)

Possible benefits

Decreases hot
flashes due to
menopause

Possible risks

Soya does not have any
known long-term toxic
effects.

Side-effects may include
nausea, constipation, and
bloating.

Restrictions or warning

Some people can have or develop an allergy to soya.

Consult your physician if you:

- have or have had breast, ovarian or uterine cancer
- are taking estrogen
- are taking medication for the treatment of cancer
- are taking a blood thinner such as warfarin (Coumadin®)

Fig. 3 Values clarification worksheet

Step 3. Identify the available options

- A. Take the decision you identified in step 1 and, list the options that you are considering.
 B. For each of these options, list all of the benefits and risks.
 C. Underline the benefits and risks that are most likely to occur.

For example, if the option is to take soya for hot flashes

Option (example)	Benefits (reasons for choosing) (examples)	Risks (reasons for avoiding) (examples)
To take soya	- decreases hot flashes ***** - does not need a prescription from physician *****	- there might be side-effects such as nausea, constipation, bloating ***** - there is a cost *****
Options	Benefits (reasons for choosing)	Risks (reasons for avoiding)
#1	***** ***** *****	***** ***** *****
#2	***** ***** *****	***** ***** *****
#3	***** ***** *****	***** ***** *****

Table 1 Demographic characteristic of participants (N=24)

Demographic characteristics	Frequency (%)
Age (in years)	
45-49	10 (41.6)
50-59	13 (54.2)
60-64	1 (4.2)
Marital Status:	
Married, common law	19 (79.2)
Divorced, separated	4 (16.7)
Single	1 (4.1)
Primary Language Spoken:	
English	19 (79.2)
French	4 (16.7)
Both	1 (4.1)
Primary Language Read:	
English	21 (87.5)
French	1 (4.2)
Both	2 (8.3)
Highest level of Education:	
Some High school or less	0
High school diploma	2 (8.3)
Trade certificate/diploma	8 (33.3)
University	14 (58.4)
Relevant History:	
Hysterectomy	4 (16.7)
HRT (ever taken)	7 (29.3)
Menopausal Symptoms	
0-4 no or few symptoms	0
5-8 slight symptoms	3 (12.5)
9-16 moderate symptoms	12 (50)
17-44 severe symptoms	9 (37.5)

Table 2: Modifiable factors contributing to difficulty with decision making (N=24)

Subscales	Items	Pre-test		Post-test		p-value
		Item mean; (95% CI)	Sub-scale mean %; (95% CI)	Item mean;(95% CI)	Sub-scale mean %; (95% CI)	
Uncertainty	I am clear about the best choice for me	73.96; (65.44, 82.47)		34.38; (23.68, 45.07)		
	I feel sure about what to choose	75; (67.37, 82.63)	71.88; (63.65, 80.10)	38.33; (22.70, 43.97)	35.07; (24.54, 45.60)	
	This decision is easy for me to make	66.67; (54.74, 78.59)		37.50; (25.85, 49.15)		
	I know which Natural health product options are available to me	69.79; (57.74, 81.84)		12.50; (7.11, 17.89)		
Uninformed	I know the benefits of each option	81.25; (74.83, 87.67)	78.47; (71.29, 85.66)	22.92; (14.16, 31.68)	21.53; (15.40, 27.66)	
	I know the risks and side effects of each option	84.38; (78.30, 90.45)		29.17; (19, 39.33)		
	I am clear about which benefits matter most to me	65.63; (53.64, 77.61)		17.71; (11.12, 24.30)		
	I am clear about which risks and side effects matter most	65.63; (52.12, 79.13)	63.19; (51.41, 75)	15.63; (9.55, 21.70)	18.40; (11.84, 24.96)	
Unclear values	I am clear about which is more important to me (the benefits or the risks and side effects).	62.50; (49.29, 75.71)		20.83; (11.15, 30.51)		
	I have enough support from others to make a choice	61.46; (49.01, 73.90)		27.08; (18.32, 35.84)		
	I am choosing without pressure from others	22.92; (11.30, 34.53)	52; (44.37, 59.80)	11.46; (6.09, 16.83)	22.57; (16.65, 28.48)	
	I have enough advice to make a choice	71.88; (63.46, 80.29)		29.17; (19, 39.33)		
Ineffective decision	I feel I have made an informed choice	65.63; (57.50, 73.75)		23.96; (12.53, 35.39)		
	My decision shows what is important to me	45.83; (38.42, 53.24)	50.78; (44.84, 56.72)	18.75; (9.81, 27.69)	25; (15.73, 34.27)	
	I expect to stick with my decision	41.67; (33.05, 50.29)		27.08; (17.79, 36.38)		
	I am satisfied with my decision	51.04; (43.75, 58.33)		26.04; (16.46, 35.63)		
Total Decisional			62.82; (57.34, 68.3)		23.63; (16.72, 30.54)	<0.001

conflict score

CI = confidence intervals

Table 3: Change in Knowledge scores after decision aid intervention (N=24)

Knowledge question	Pre NHP DA Number of respondents answering correctly (%)	Post NHP DA Number of respondents answering correctly (%)
Natural health products of can also have side effects	24(100)	24(100)
All natural health products (NHPs) are without danger to health	22(92)	23(96)
There are no possible interactions between NHPs and prescribed medications (drugs prescribed by a doctor)	21(88)	22(92)
There are no possible interactions between natural health products and over the counter medications (purchase free)	21(88)	23(96)
All drug insurance companies cover the costs of the NHPs.	21(88)	21(88)
All natural health products which are sold were approved by Health Canada	19(79)	21(88)
Natural health products are a category of products included in complementary and alternative medicine	18(75)	21(88)
All women have symptoms related to the menopause	17(71)	22(92)
There are scientific data showing the effectiveness of all natural health products that are available	16(67)	20(83)
Health Canada regulates natural health products.	4(17)	12(50)