



Evaluation of a natural health product decision aid: A tool for middle aged women considering menopausal symptom relief

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ABSTRACT

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

Study design: This pre-/post-test study included peri- or post-menopausal women, aged 45–64 considering the use of a natural health product for management of menopausal symptoms. They were recruited from a Women's Health Center.

Outcome measures: The primary outcome was decisional conflict and secondary outcomes included knowledge, strength of values, and decision preference.

Results: Of 24 women, the typical participant was 50–64 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 24% ($p < 0.001$) and knowledge improved from 76% to 87% ($p = 0.001$). Of the 24 women, 10 were unsure of their choice at baseline and 3-post use of the decision aid ($p = 0.015$). There was a trend for women preferring natural health products ($n = 12$) to be more likely to rate the non-chemical aspect as important and the cost of the natural health product as less important; women who preferred not to take natural health products ($n = 3$) rated the non-chemical aspect as less important and the costs as more important.

Conclusions: The natural health product decision aid improved the quality of decisions by enhancing knowledge and reducing decisional conflict. As well, women were more likely to make a choice that was consistent with their values.

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1. Introduction

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].

Currently, menopausal women are challenged with many decisions and those about to decide whether or not to use NHPs can be even more difficult [11]. Several studies of menopausal women describe women's decision making about using NHPs for menopausal symptoms as being strongly influenced by their lack of confidence in the effectiveness of NHPs; being inadequately informed; worrying about costs; and feeling unsupported by health care professionals [5,12–15]. Therefore, lack of evidence, vast number of choices, undue marketing pressures to use a NHP, and women's personal decision needs lead to decisional conflict.

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” [16]. Although decisional conflict occurs because of the need to balance benefits versus harms across options, it can be exacerbated by inadequate

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knowledge, unrealistic expectations, unclear personal values, and inadequate support and resources for decision making [17]. Unresolved decisional conflict leads to decisional delay or reversal, dissatisfaction, regret, and blaming the provider for poor outcomes [18,19]. Thus, given the nature of the decision, many of these women making decisions about NHP are likely going to need decision support.

Decision making can be facilitated by interventions such as decision aids. Decision aids are defined as interventions “designed to help people understand the options, consider the personal importance of possible benefits and harms, and participate in decision making” [20]. A Cochrane review of 55 randomized control trials found that decision aids facilitate shared-decision making by increasing patients’ knowledge of options, improving expectations of option outcomes, and decreasing decisional conflict [20]. These findings are consistent with the International Patient Decision aid Standards that define higher quality decision aids as having been evaluated to determine that they improve decision quality and the process of decision making [21]. Of these 55 trials, 9 were focused on HRT for menopausal women and no trials evaluated decision aids about NHPs.

The Cochrane inventory of over 500 decision aids has one decision aid focused on NHP for menopause which was available in French [22]. At the time this study was planned, the French version of the decision aid had just been compared to a pamphlet on menopause in a randomized controlled trial (RCT) with 84 women [23]. Women in both groups improved their knowledge and reduced their decisional conflict but there was no significant difference between groups. Of interest was that about half the women in both groups were undecided and/or were already taking NHPs, and few were experiencing distressing symptoms from menopause. However, it was unclear if French speaking women from Quebec were representative of the Canadian population given differences in cultural factors, including language [23,24]. A previous study of a patient decision aid for hormone replacement therapy found to be effective in English Canada needed to be adapted to fit the needs of French speaking women in Canada [25,26]. Therefore, the aim of this study was to evaluate the effectiveness of the English version of a NHP decision aid on decisional conflict and the quality of decisions made by

menopausal women about whether or not to use natural health products.

2. Methods

2.1. Design

The NHP decision aid was evaluated in a pre-/post-test study guided by the Ottawa Decision Support Framework. This framework describes that the quality of decision making can be adversely affected by decisional needs such as decisional conflict, insufficient knowledge, unrealistic expectations, unclear values, and inadequate support or resources [25].

2.2. Participants and setting

A convenience sample of peri- and post-menopausal women, who were considering the use of a NHP for symptom management, were recruited. Participants were eligible if female, aged 45–64, English speaking, considering a NHP to relieve menopausal symptoms, but not currently using prescription or NHPs for menopausal symptoms. As well, women needed to be feeling unsure about what choice to make. Women were excluded if their symptoms were not yet diagnosed by a physician or there was a perceived conflict of interest (e.g. owner of a natural health food store, pharmaceutical company or medical clinic).

2.3. Intervention

The 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 NHP options and resources (e.g. websites, books, associations and scientific papers). Fig. 1 shows the evidence-based information women can read in the decision aid. As well, it guides women through a six step decision making process: (a) be clear about the decision to be made; (b) explore their knowledge by getting the facts; (c) identify available options; (d) clarify what is important; (e) consider their role in decision making; and (f) develop an action plan. This decision aid was designed based on the Ottawa Decision

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 (<i> Cimicifuga racemosa, Actaea racemosa</i>) 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 orally (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 <i>(doses recommend by The British Herbal Compendium)¹²</i>	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 true cohosh (<i>Aulophyllum thalictroides</i>) that can have harmful effects on the heart. <small>¹¹ Please check with Health Canada Advisory regarding possible link between black cohosh and liver damage: http://www.hc-sc.gc.ca/nr/rdmt/lvls/articles/nhp/actaea_racemosa.html</small>
Soya (<i> Soja hispida, Glycine max</i>) Dose 50 to 75 mg of isoflavones per day taken by mouth isolated protein (granules) 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. 1. Natural health product decision aid.

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