Project Title: Mature women's motivation for using and perception of the risks and benefits of natural health products (NHPs)

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Summary:

Natural health products (NHPs) are gaining in popularity, becoming widely used by perimenopausal and postmenopausal women without professional guidance. Although roughly '71% of Canadians use some form of NHP' (22), physicians are often unaware of their patients' supplement use. The safety and efficacy of self-prescribed herbal products are not well understood and individuals may be unaware of potential risks associated with them. This study investigated perimenopausal and postmenopausal women's motivating factors to use or refrain from using NHPs for the improvement of their menopausal symptoms or overall well being. This study indicates specific educational points about NHPs that physicians should be sharing with patients, specifically menopausal women. First, there are safe NHP treatments for vasomotor symptoms, for example black cohosh and red clover. These treatments have not been shown to have serious adverse safety effects when taken for 12 months and when taken properly (correct dose and in patients with no contraindications). However, these non- hormonal treatments are less efficacious than estrogen therapy and have not been shown to be more effective than placebo (3, 11, 14, 16, 23, 26). Physicians should also ensure that it is clear to patients that the long term side effects of these products have not been well studied.

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Introduction

Natural health products (NHPs) are gaining in popularity, becoming widely used by perimenopausal and postmenopausal women without professional guidance; physicians are often unaware of their patients' supplement use. Roughly '71% of Canadians use some form of NHP' (22). The safety and efficacy of self-prescribed herbal products are not well understood and individuals may be unaware of potential risks associated with them.

This study aims to investigate mature women's motivating factors to use or refrain from using NHPs for the improvement of their menopausal symptoms or overall well being. In the context of this paper, mature women refer to women who are perimenopausal or postmenopausal. Unawareness of motivating factors for NHP usage is particularly concerning because current literature suggests that over the counter NHPs do not have conclusive beneficial data to support their use (12). This research also investigates women's willingness to communicate NHP use with their physicians and information sources sought out in the decision making process to use or refrain from using NHPs.

The Women's Health Initiative and Decline in use of Hormone Therapy

In July 2002, results from the Women's Health Initiative (WHI) demonstrated an increased risk of breast cancer, stroke, and coronary heart disease associated with estrogen plus progestin therapy for an average of five years. Subsequent results also demonstrated an increased risk of stroke with progestin therapy alone for an average of seven years (14). Though 'estrogen therapy remains the most effective treatment for relieving menopausal hot flashes' (16), use of hormone therapy (HT) decreased significantly after these results were released, and many menopausal and post-menopausal women remain apprehensive of HT use today (3). Decline in HT use has increased interest in effective and safe complementary and alternative therapies to treat menopausal symptoms (3, 14). Natural health products have been becoming more widely used among many Canadian populations. Among menopausal and postmenopausal women it is thought that NHPs are used to relieve specific menopause symptoms and or improve general well being (21). Such NHPs are perceived as effective alternatives to conventional medication, but with fewer side effects (21).

Definition of Natural Health Products

In Canada, NHPs refers to a group of health products that include: vitamin and mineral supplements, herbal and other plant based health products, traditional medicines (such as traditional Chinese medicines), homeopathic medicines, probiotics and enzymes, and some personal care products, that contain natural ingredients (8). NHPs are intended to produce a pharmacological effect for the purpose of correcting or changing a physiological state (8).

NHPs are regulated by Health Canada, according to the *Natural Health Products Directorate*. In order to be sold and marketed in Canada as a NHP, each NHP needs a product license. This entails that "specific labeling and packaging requirements must be met, good manufacturing practices must be followed, and proper safety and efficacy evidence must be provided" (9). Once a NHP has been fully assessed and reviewed by Health Canada, that product is issued a Natural Product Number (NPN).

Despite this regulation process, many products available to consumers as supplements have not been approved or submitted to Health Canada for approval. Products that are in the process of being reviewed, but have not yet been approved, are assigned exemption numbers rather than a NHN.

Many consumers rely on a NHP's label for information when deciding whether to purchase that product. The Natural Product Number or exemption number must appear on a product's label. Additionally, a NHP label must include a complete list of medicinal and non-medicinal ingredients, product purpose or health claim, dose, route of administration, any cautionary statements, warnings, contraindications, and possible adverse reactions.

Evidence of safety and efficacy must be submitted for NHP approval. Evidence of efficacy is sought from a literature search. Applicants are expected to submit "the highest quality of evidence available that is relevant to support the safety and efficacy of the NHP according to the recommended conditions of use" (8). Safety overview and risk information and risk mitigation must also be submitted. A safety overview summarizes known adverse reactions, toxicology, previous marketing experience, and known interactions. Risk information and mitigation includes contraindications and warnings about the product (8).

Proposed Mechanism of Action of Black Cohosh and Phytoestrogens

Popular NHPs that are used to treat menopausal symptoms and many general health conditions include black cohosh and phytoestrogens.

The mechanism of action black cohosh is largely unknown. The mechanism of action is not estrogenic, but may involve serotonergic activity (3).

Phytoestrogens, plant-derived substances structurally related to estrogens, have been shown to bind to estrogen receptors. The three main classes of phytoestrogens are isoflavones, ligans, and coumestands. Legumes, red clover, and Isoflavones, which found in soybeans, are the most studied phytoestrogens (14).

Other plant-derived products marketed for vasomotor symptoms have unknown mechanisms of action or are not proven to be estrogenic (14).

Efficacy and Safety of NHPs in the Treatment of Menopausal Symptoms, and the Role of Physicians as Educators

Recent research on the efficacy and effectiveness of NHPs shows that NHPs such has black cohosh, dietary soy, soy extracts, red clover extracts, and other phytoestrogens are no more effective than placebo at managing menopause symptoms (3, 11, 14, 23, 26). This indicates a wide gap between patient perception and true efficacy (18). Although these NHPs have not been shown to be more effective than placebo at controlling menopausal symptoms, a significant placebo effect has been documented. Placebo has been shown to substantially decrease menopausal symptoms. A 2009 randomized, four-arm, double blind randomized control trial demonstrated that placebo decreased the average number of vasomotor symptoms by 63% (3). In the same study, black cohosh reduced menopausal symptoms by 34% and red clover reduced symptoms by 57%.

There is currently a lack of published data from human trials about long term safety of many NHPs (15). However, shorter-term studies indicated that chemically and biologically standardized extracts of black cohosh and red clover were safe during daily administration for twelve months (3). In a 2009 randomized, four-arm, double blind clinical trial of standardized black cohosh, red clover, placebo, and 0.625mg conjugated equine estrogen plus 2.5 mg medroxyprogesteorone acetate (CEE/MPA), there were no significant differences between the NHP treatments and placebo for any of the safety parameters, which included: breast tissue changes, endometrial thickness, liver safety, complete blood count, and lipid profiles.

Although black cohosh and red clover NHPs have not been shown to affect these safety parameters in isolation, they may have significant interactions with other medication. Black cohosh may interact with anesthetics, antihypertensives, and sedatives, causing hypotensive reactions. Red clover may interact with anticoagulants and antiplatelets, increasing the risk of bleeding. Both NHPs should be discontinued two weeks prior to surgery (11).

While there are many misconceptions about the safety and efficacy of NHPs, many individuals express interest in receiving education about proper and effective NHP use (18). This suggests that there is an opportunity for physicians and other health care professionals to council patients on true benefits and risks of NHP use. This is important because current literature suggests that many individuals who report NHP use do not disclose this fact to their physicians (1, 24). When physicians are unaware of their patients' supplement use there may be a missed opportunity for patient education on NHPs. For patients using NHPs to manage menopause symptoms, such patient-physician interactions may also offer an opportunity for physicians to reeducate about C/E CHC and address possible misconceptions about C/E CHC use (28).

The Public's Knowledge of NHPs

Although research regarding NHP has increased to reflect rising consumer NHP use, there is little research that analyzes consumer's perspectives of the benefits and risks of NPH use.

Additionally, there is little evidence to show whether individual NHP consumers thoroughly investigate the safety and efficacy of the products they use. Also largely unknown are the specific information sources that women access that influence their decisions to use NHPs. In North America although 'the highest users of NHPs were in those with a higher education and women, little is known about the quality of decisions to take NHPs' (22). This is concerning due to 'limited evidence available regarding these products, and the large marketing strategies directed towards these women as the greatest users of NHPs' (22).

Research on this topic warrants increased awareness due to potentially harmful pharmacological effects that may be associated with unsystematic use of NHPs. This issue is particularly relevant for individuals who are at risk for interactions between NHPs and prescription medications, particularly if such prescription medications are used to manage numerous health conditions (13).

Furthermore, NHPs are not covered by insurance providers, but are paid for personally by individuals. Individuals do not need a prescription for NHPs, believe that such products are beneficial, and perceive them to be safer than prescription medication. For example, women receiving HT require an interaction with a physician to obtain a prescription and receive extensive 'black box' warnings and handouts with their HT. Increased consumer knowledge on

the proven lack of efficacy of NHP at reducing menopausal symptoms may cause NHP cessation, reducing NHP expenses for many women.

Ultimately understanding the role of women's perceived benefit and risk as motivation in consuming these supplements may help physicians guide women in the safe use of NHP or cessation of NHP.

Materials and Methods

Thirty-eight female patients of the Mature Women's Centre at Victoria General Hospital (Winnipeg, Manitoba) participated in this study. To participate in the study, women were required to be perimenopausal or postmenopausal and patients of the Mature Women's Centre. Participants were not required to be NHP users. These women were recruited during their visits to the Mature Women's Centre. Ethical approval was obtained from the University of Manitoba Research Ethics Board and the institutional review committee, and Victoria General Hospital Research and Evaluation Department. Written informed consent to participate in the study was obtained from each woman from either the medical student involved in the study or a clinical nurse at the Mature Women's Centre. These individuals also administered the surveys.

Each participant completed an administered questionnaire that was developed by the medical student involved in the study (Figures 1-2). All survey questions were closed answer; participants were asked to check or circle the answer that was most applicable to them. For some questions there was an opportunity to select more than one answer. For some questions there was an opportunity for patients to select 'other' and write in an answer that was more appropriate for them. All surveys were identical and participation consisted of a one-time commitment from each woman. Participants completed their surveys between July 2011 and June 2012.

The questionnaire consisted of four sections: demographic information, personal NHP use, motivations for taking NHP, and perceptions of NHP, which included perceptions of safety and efficacy.

The study has three important limitations. First, the low number of participants (thirty-eight) decreased study power. Second, some of the participants felt that certain survey questions did not apply to them and subsequently failed to respond to these questions. As a result, for some questions there were few data, making it unfeasible to do a Chi-squared test on those questions. Third, the questionnaire was developed by the medical student involved in the study and had therefore never been previously administered or validated.

Results

The data from the questionnaires were analyzed using descriptive statistics. Due to the data limitations, results were primarily summarized via frequency and percentage distribution. Data from distribution tables or data sets were used to create bar graphs to represent the data (Figures 3-7). For questions where participants had the choice of selecting as many items as applicable, frequency distribution was utilized.

Demographics: Demographically, the average survey participant is between age ages of 50-55, married, and had completed vocational or technical school education. The majority of women live in an urban setting. Due to many cells with no response, it was not possible to do the Chi-squared test for demographic data. However, we were able to run correlations and conclude there are significant differences in income and educational levels among urban versus rural participants.

NHP Use: We found that women with menopausal symptoms that were/are worse than normal are no more likely to use NHPs than women without menopausal symptoms that were/are worse than normal. The questionnaire asked women how often they used NHP (if applicable); 47.37% of participants in the study use a NHP everyday and 34.21% of participants have been taking a NHP for longer than five years. Women were asked about people in their lives who also use NHPs. The most common participant acquaintances using NHPs are spouse/partner and friends; these groups each had ten responses. Out of the women surveyed, the most commonly used NHP are: black cohosh, evening primrose, St. John's Wort. 15.79% of women are spending between $100-250 per month on NHPs, 18.42% are spending $50-100 per month, and 31.58% are spending $1-50 per month.

Motivations for Taking NHPs: Among the women surveyed, the most common motivator for using NHPs is to improve general well being. Overall, these women indicated that NHPs helped them (Figure 4). The most common sources from which women acquire information that influence their decisions to use NHPs are: 1) friend, 2) Internet, 3) health food store (Figure 5). Of the sources provided, women perceived the most reliable sources of NHP information to be: 1) tie between pharmacist, physician, naturopathic doctor, 2) nurse, 3) compounding pharmacist. Conversely, the three least reliable sources of NHP information were thought to be: 1) in-store display, 2) tie between television, newspaper, and magazine, 3) tie between blog and talk show.

Perceptions of NHPs – Efficacy and Safety: In this section women were asked to indicate their opinions as either: strongly disagree, disagree, neutral, agree, strongly agree, or 'I don't know'. It is presumed that women may need more education about question topics that were highly answered with 'I don't know'. Specifically, women most frequently answered 'I don't know' when asked whether NHPs are bio-identical, synthetically made, and are an effective alternative to HT to alleviate menopausal symptoms. Only 5.26% of respondents disagreed or strongly disagreed with the statement: 'I think NHP are an effective alternative to Hormone Replacement Therapy to alleviate menopausal symptoms', while 13.16% agreed, 31.58% were neutral, and 44.74% did not know. For the statement 'I think NHP are more effective at relieving menopause symptoms than are lifestyle modifications (for example, balanced diet, quitting smoking, weight loss), 44.73% either disagreed or strongly disagreed, while 7.89% agreed, 21.05% were neutral, and 21.05% did not know. Only 10.52% of women disagreed or strongly disagreed with the statement 'I think that NHP have a proven benefit over placebos at relieving menopause symptoms'. 28.95% agreed or strongly agreed with this statement, 28.95% were neutral, and 26.32 did not know. Just 7.98% of participants agreed that the long term safety of NHPs have been well studied. However, 23.68% agreed that their short term safety has been well studied. This suggests that there is not considerable agreement regarding long and short term safety approval of NHPs among survey participants. 63.16% of participants thought that NHPs could have either mild or serious side effects, though the same percentage indicated that they did now know which specific side effects could arise from NHP use (Figure 6).

Perceptions of NHPs – Physician Influence and Attitude: The results indicate that women are willing to take physician recommendations to stop or start NHPs, with 84.21% and 73.68% agreeing or strongly agreeing that they would start or stop a NHP respectively under the direction of a physician. Furthermore, 65.79% of participants felt that their physicians are open-minded to the discussion and use of NHPs and 57.89% of participants discuss NHPs with their physicians. 23 of the 38 participants indicated that they feel comfortable discussion NHPs with their physician, while 8 participants indicated that their physician inquires about their NHP use (Figure 7).

Discussion

Observations from this study are consistent with previously conducted research. First, this study demonstrates that women generally receive information about NHPs from members of the general public (friends, Internet, health food store) rather than a healthcare professional(s). In 2000 the Berger Population Health Monitor found that 3 percent of respondents used a NHP based on the suggestion of an "alternative health provider", 43 percent did so at the suggestion of friends or family, 28 percent at the suggestion of a physician, 25 percent at the suggestion of media articles, and 19 percent at the suggestion of a pharmacist (7).

The implication behind receiving information from sources such as friends, the Internet, or health food stores is that such education may be informal and anecdotal, rather than evidence based. Women in this study also indicated that physicians were among the most reliable sources of NHP information. As it has been shown that many women express interest in receiving education about proper and effective NHP use (18), these results suggest that there is a significant opportunity for physicians to educate patients about NHPs.

Additionally, this study demonstrates that 'decision making about the use of NHP to manage menopausal symptoms is rife with uncertainty' (16). Indeed, 13.16% of women in this study agreed that NHPs are an effective alternative to HT to alleviate menopause symptoms, while 32.58% were neutral and 44.74% indicated that they did not know. Similarly, overall women were unsure whether NHPs had a proven benefit over placebos at relieving menopausal symptoms. Women also indicated uncertainty about possible NHP side effects, including direct effects and interactions with other medications. These findings also correlate with Theroux, who found that 'the major problems women encountered in the health care system were a lack of information and poor communication. They reported a lack of organized resources and information that was conflicting or slanted toward hormone therapy. All of the investigators found that communication between women and their physicians was less than ideal' (25).

Also consistent with current literature, some women in this study, 13 out of 38, do not discuss NHPs with their physician, and only nine women indicated that their physicians asks them about NHP use. Presumably, uncertainty about NHP, busy practices, and unawareness of patient's menopause symptoms are factors that may contribute to physicians not asking women about NHP use. When questioned, 'the high percentage of physicians responding, no advice either way, in reference to use of these therapies for menopausal symptoms suggests that they are not clear on the advantages or disadvantages of these approaches; this is supported by previous studies' (5).

When educating patients about NHPs physicians should inform women of possible side effects, interactions, and contraindications. In this study, the three most common NHPs reported by women were black cohosh, evening primrose, and St. John's Wort, respectively.

Black cohosh may interact with anesthetics, antihypertensives, and sedatives. These interactions may increase the risk of a hypotensive effect. It is contraindicated in women with a history of thromboembolic disorder or estrogen-dependent tumors.

St. John's Wort may interact with alcohol, MAO inhibitors, SSRIs, narcotics, and drugs metabolized by CYP3A (a protein family that is important in hepatic drug metabolism). It is contraindicated in patients who use MAO inhibitors or SSRIs, and is not recommended in patients who use drugs that are metabolized by CYP3A in the liver.

Evening primrose may interact with phenothiazines, increasing the risk of seizures. The SOGC clinical practice guidelines do not list any contraindications to evening primrose. (11)

In this study we hypothesized that the severity of menopausal symptoms is not associated with a propensity to use NHP. We asked women whether their menopausal symptoms were/are 'worse than normal'. Using a chi-squared test (p-value = 0.53, CI=95%), we concluded that there is not a statistically significant difference in the severity of menopausal symptoms and the decision to use NHP(s). This suggests that women may not be using NHPs to control menopausal symptoms and it is important for physicians to inquire about NHP use whether patient report significant symptoms or not. This also correlates with our finding that of the women surveyed, the most common motivator for using NHPs is to improve general well being (Figure 7).

The results of this study indicate that many women lack basic information about NHP and may not discuss NHPs with their physicians, either because patients do not disclose NHP use, do not inquire about NHPs, or are not asked about NHP use by their physicians. Whether women are using or considering NHPs for menopausal symptoms or other reasons, it is beneficial for physicians to discuss NHPs with their patients. Better care can be provided when an appropriate quality and quantity of NHP information is given (25). Ultimately the indication for NHP use is for patients to make to use such products based on their personal beliefs (25) and physicians can aid by providing information as a valuable decision making tool.

In summary, the results of this study indicate some specific educational points that healthcare professionals should be sharing with patients, specifically in women going through the menopausal transition. First, there are safe NHP treatments for vasomotor symptoms, for example black cohosh and red clover. These treatments have not been shown to have serious adverse safety effects when taken for 12 months and when taken properly (correct dose and in patients with no contraindications). Second, healthcare professionals should ensure that it is clear to patients that the long term side effects of these products has not been well studied. They should also inform patients of possible drug interactions with the NHPs. Third, these non- hormonal treatments are less efficacious than estrogen therapy and have not been shown to be more effective than placebo (3, 11, 14, 16, 23, 26). However, it has been demonstrated that placebo and NHPs may still have a significant impact on reducing menopausal symptoms (3). Although they may not be as effective as HT, for some women NHPs may be truly beneficial for relieving menopausal symptoms and improvising quality of life. Therefore, physicians and other healthcare

professionals should ask about NHP use as it pertains to menopausal symptoms or other health concerns. As this study shows, 60.53% of the participants (22/38 participants) (Figure 7) already discuss NHPs use with their physicians.

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Figure 1: Questions from the Administered Survey for 'Mature women's motivation for using and perception of the risks and benefits of natural health products (NHPs)'

- What is your age?
- What is the highest level of education that you have completed?
- What is your current marital status?
- What is your current household income?
- Which best describes where you live (rural or urban)?
- What are (were) your expectations of 'normal' menopause symptoms?
- Do you think your menopause symptoms are (were) worst than 'normal'?
- How often do you take NHP?
- How long have you been taking NHP?
- If you have stopped taking NHP, why did you stop? Please check all that apply.
- Approximately how much money do (did) you spend on NHP each month?
- Do any of the following people in your life use NHO? Please check all that apply.
- NHP Use: Please check any NHP you have used to treat the listed symptoms.
- Why did you begin taking NHP? Please check all that apply. Please circle your number one reason for taking NHP. Of the reasons indicated, do you believe that NHP have been effective? If yes, please place a checkmark in the space provided. If no, please place a checkmark in the spaces provided.
- From what sources did you receive information that influenced your decision to use NHP? Please check all that apply.
- Do you find the following are reliable sources of NHP information? Please ensure that you have made a selection for each line.
- For the following questions, circle the response that is most applicable: (1=strongly disagree, 2=disagree, 3= neutral, 4= agree, 5=strongly agree, 6=don't know):
- I think NHP are an effective alternative to Hormone Replacement Therapy to alleviate menopausal symptoms.
- I think that NHP are more effective at relieving menopause symptoms than lifestyle modifications (for example, balanced diet, quitting smoking, weight loss).
- I think that NHP have a proven benefit over placebo (sugar pills) at relieving menopause symptoms.
- I would take NHP if a physician recommended taking them.
- I would stop taking NHP if a physician recommended stopping them.
- I think all NHP are safe to use.
- I think most NHP are safe to use.
- I think some NHP are safe to use.
- I think no NHP are safe to use.
- I think that the ingredients of NHP are standardized among different brands of NHP. For example, I think that all brands of Black Cohosh have the same amount of 'active' ingredients.
- I think that the effectiveness of NHP has been scientifically proven.
- I think that the short term safety of NHP has been well studied.
- I think that the long term safety of NHP has been well studied.
- I think that Health Canada regulates the contents of NHP.
- I think that all ingredients in NHP come directly from plants.
- I do not think that NHP contain chemicals.
- I do not think that NHP are synthetically made.
- I think that NHP are bio-identical (use of hormones that are synthetically made, but molecularly identical to hormones that originate from human or animal tissue used in HT).
- I think that NHP can interfere with the safety and usefulness of prescribed medication.
- Do you discuss NHP with your physician?
- Do you tell your physician that you use NHP?
- Do you feel that your physician is open minded to the discussion and use of NHP?
- Do you feel comfortable discussing NHP with your physician? Please check all of the statements that apply to you.
- Do you think NHP can have unwanted side effects?
- Do you think that NHP can cause any of the following side effects? Please check all that apply.

Figure 2: NHP Use Worksheet Questions from the Administered Survey for 'Mature women's motivation for using and perception of the risks and benefits of natural health products (NHP)'

Symptom	Black Cohosh	Dong Quai	Evening Primrose	Ginseng	Red Clover	Valerian	Wild Yam	Aloe	Chamomile	Echinacea	St. John's Wort	Lecithinin	Soy Diet	Other 1	Other 2
Hot Flashes															
Night Sweats															
Vaginal Dryness															
Difficulty Sleeping															
Unexpected Leakage of Urine															
Frequent Urination															
Heart Beating Quickly or Strongly															
Headache															
Muscle or Joint Pain															
Breast Tenderness															
Irritability															
Crying Spells															
Panic Attacks															
Lack of Energy															
Fatigue															
Mood Swings															
Depressed															
Difficulty Concentrating															
Memory Changes															
Loss of Interest in Sex															
Painful Intercourse															
Other 1															
Other 2															

Symptoms:

Other 1 _____

Other 2 _____

NHP:

Other 1 _____

Other 2 _____

NHP USE

Please check any NHP you have used to treat the listed symptoms. If you have used a product that is not listed, please write the name of the product under 'Other'

If you have used the listed NHP to treat a symptom that is not listed, please write the name of the symptom under 'Other'

Figure 3: Commonly Used NHP. Note: 41 'other' NHPs were used by a number of participants.

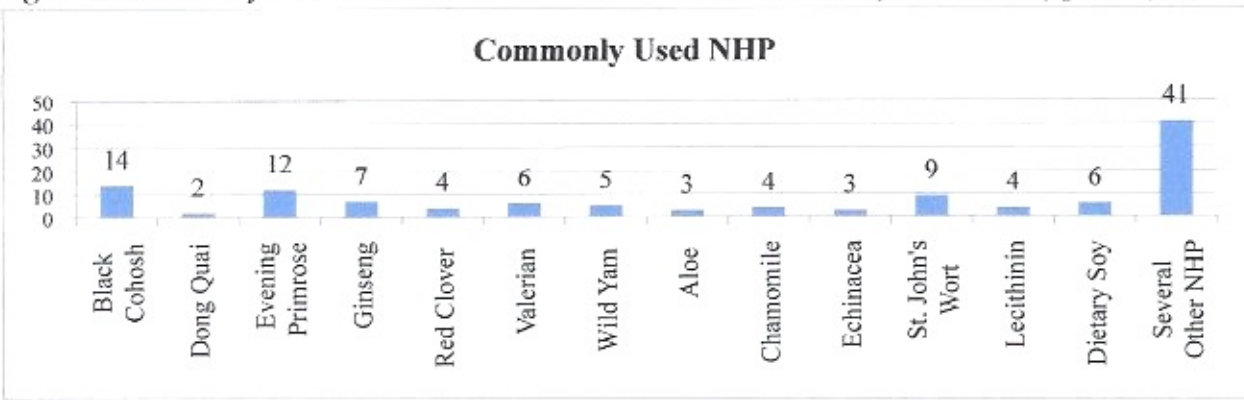

Figure 4: Common Motivators for Using NHP, and Whether NHP Helped Participants. Note: Graph depicts absolute values from 38 women surveyed.

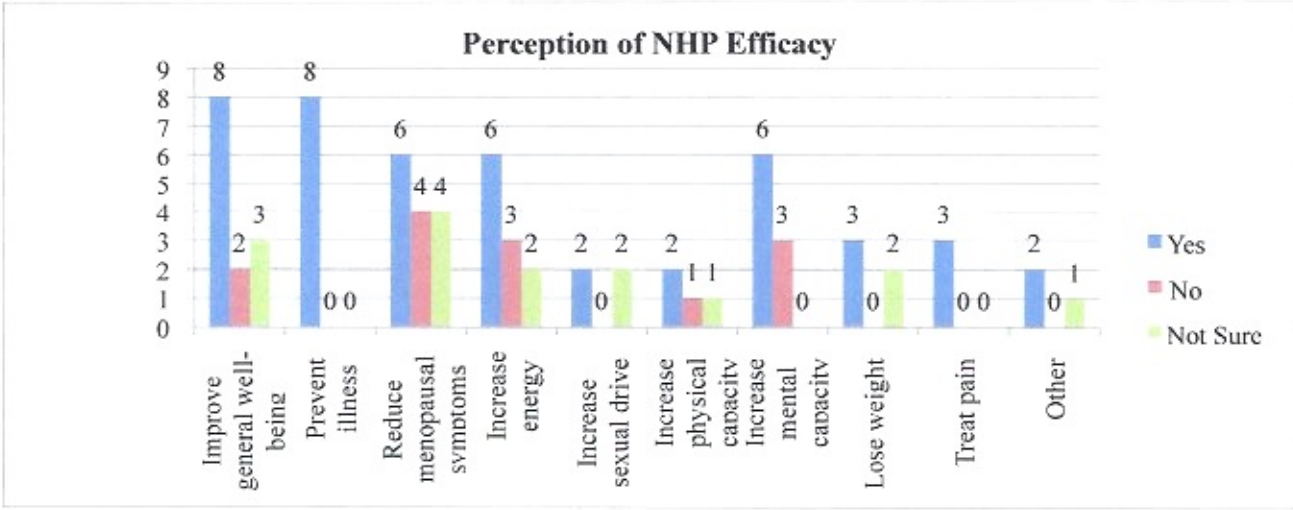

Figure 5 (Next Page): Sources From Which Women Acquire Information to Influence Decision to Use NHPs. Note: Graph depicts absolute values from 38 women surveyed.

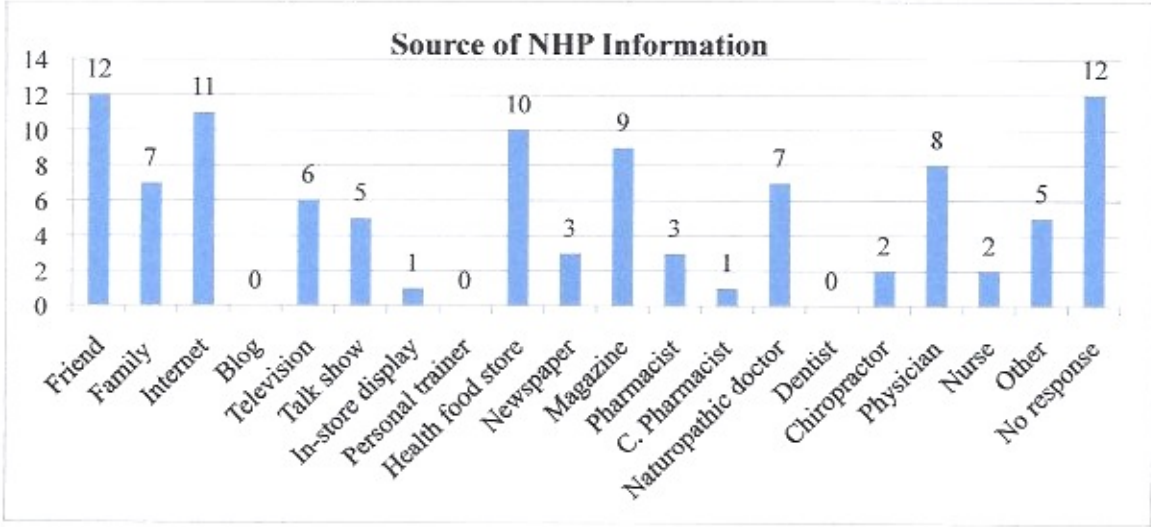

Figure 6: Specific Side Effects Participants Think Can Arise From NHP Use. Note: Graph depicts absolute values from 38 women surveyed.

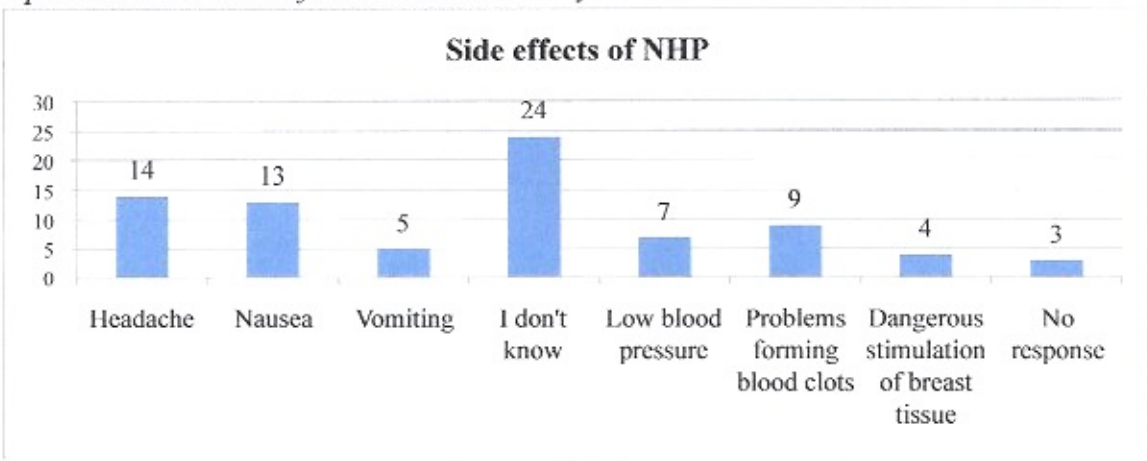

Figure 7: Participant Comfort With Discussion of NHPs With Her Physician: Note: Graph depicts absolute values from 38 women surveyed.