#### MENOPAUSE GROUP MEDICAL VISITS LED BY NURSE PRACTITIONERS

by

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# A CULMINATING PROJECT SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF NURSING-NURSE PRACTITIONER

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#### Abstract

Women in Canada and around the world vary in their experience of menopause. Symptom severity and perception of menopause effects symptom management and accessing of Primary Care Provider (PCP) services. A mismatch exists between the holistic menopausal care that women want and what many PCPs provide in standard care. Group medical visits (GMVs) increase access to PCPs, improve health outcomes and increase satisfaction with care. Success of GMVs in chronic disease management outcomes, particularly around self-efficacy, may be transferable to menopause GMVs. Increased self-care abilities may in turn influence health behaviors, and ultimately outcomes of modifiable diseases in later life. Nurse Practitioner (NP) training and skills are well suited to the facilitation style of GMV's. The project described in this paper consists of a series of Nurse Practitioner led GMV lesson plans designed to improve patient outcomes and satisfaction with menopause-related primary care. The project will be presented to a primary care clinic management for consideration.

Key words: menopause, group medical visits, nurse practitioner

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#### **Menopause Group Medical Visits Led by Nurse Practitioners**

Canadian women are living longer than ever, with 1/3 of their life spent in the menopausal period. Average age of menopause at 51 years and an increased life span of Canadian women to 83 years has shifted menopause from an entry into older age to a midlife transition (Statistics Canada, 2015). The menopausal period is associated with decreased physical and mental health (Reid et al., 2014; Rindner et al., 2017), some researchers label this phase "the window of vulnerability" (Dennerstein & Soares, 2008; Lokuge, Frey, Foster, Soares & Steiner, 2011). Morbidity in this phase of life has significant effects on women, families and society (Baber, Panay & Fenton, 2016; Shifren & Gass, 2014).

Increased societal focus on healthy ageing is shifting perception on the menopausal period and the chronic diseases associated with later life. Canadian surveys have found that the majority of women use complementary and alternative therapies (CAMS) (Hyde, Nee, Drennan, Butler & Howlett, 2010; Peng, Adams, Hickman & Sibbritt, 2016), yet these are often not addressed within primary care (Walter et al., 2004). Research has shown that women perceive menopausal counseling by GPs as minimal, and neglectful of their individualized needs (Hvas, Reventlow & Malterud, 2004; Laborde & Foley, 2002; Walter, Rogers, & Britten, 2004). This project will aim to improve and expand primary care around menopause through application of GMVs led by NPs.

#### **Background**

#### **Definitions of Menopausal Period**

The menopausal period is subdivided into 3 main stages; *perimenopause* is characterized by declining and fluctuating hormone levels, and varies from 2-15 years. *Menopause* is a specific point in time when the cessation of menses has occurred for 12 consecutive months. The

remainder of a woman's life is spent in *post menopause*. For the purpose of this paper, the term "menopausal period" will be used to refer to perimenopause, and the first 5 years of early post menopause.

The landscape of medical care in the menopausal period has changed dramatically over the last half century. Estrogens were commonly prescribed to women up to the 1980's, based on many observational studies showing benefit in coronary disease, osteoporosis, prevention of Alzheimer's disease, decrease in all-cause mortality, and an inconsistent effect on breast cancer rates (Lobo, 2014). The Women's Health Initiative (WHI), released in 2002, was designed to test the effects of postmenopausal hormone therapy, diet modification, and calcium and vitamin D supplements on heart disease, fractures, and breast and colorectal cancer. Hormone replacement therapy (HRT) was found to increase risk of heart attack, stroke, blood clot and breast cancer (Manson et al, 2003). The WHI trials have been subsequently critiqued in terms of their generalizability, particularly among younger women. In recent years, general consensus exists among experts that HRT is a safe option for most women (Baber et al., 2016; Stuenkel et al., 2012), but confusion and concern about HRT remains in the general population (Langer, 2017; Steefel, Hyatt & Heider, 2013; Stuenkel et al., 2012).

#### PCP roles and current model of menopausal care in British Columbia (BC)

In BC, PCPs currently provide care for women about their menopausal concerns in individual appointments. A PCP can be a General Practitioner physician (GP) or a Nurse Practitioner (NP) who provides primary care. NPs are nurses who have attained postgraduate education and increased scope of practice. NP scope of practice includes diagnosing of diseases and conditions, prescription of medication, ordering and interpretation of laboratory tests and referral to specialist care. Not all women have access to a PCP, however, particularly in rural

areas. In BC, women access a Primary health provider (PCP) for 1:1 appointments for menopausal period concerns. Application of current guidelines, shifting attitudes/expectations, and the plethora of varied treatment options all challenge PCPs ability to provide satisfactory care within existing time constraints.

#### Perceptions of menopause

Prior to exploration of problems related to care of women in the menopausal period, it is important to note that significant variations exist in perception of menopause across cultures and religions. In some non-Western societies, cessation of menstruation is central to a more involved societal role (Avis, 2009; Sievert, 2014). An example of this is the increased participation experienced by some Muslin and Hindu women, as religious observation during menstruation are lifted (Sievert, 2014). Another example can be seen with Inuit Canadian women, who have described menopause as a positive transition which affords greater societal respect for their wisdom (Madden et al., 2010). Among the Mayan Q'egchi in Guatemala, discussion of menstruation and menopause are considered taboo, and many women reported being worried about unexpected menopausal symptoms (Michel, Mahady, Veliz, Suejarto & Caceras, 2006). Women from areas such as Southeast Asia and Eastern Europe may be embarrassed to be asked questions about sensitive topics such as vaginal dryness (Sievert, 2014). A fundamental perception of menopause as a natural phase of life, however, has been found across cultures (Mackey, Teo, Dramusic, Lee & Boughton, 2014). Perception of menopause is relevant in that a correlational relationship exists between how women view menopause and reporting and treatment of VMS (Sievert, 2014; Woods et al., 2008).

#### **Description of the Problem**

#### Women's Current Knowledge

The past few decades of health knowledge research have shown that women express a lack of knowledge about the menopausal transition (Hunter, 1992; Doubova, Infante-Casteneda, Martinez-Vega & Perez-Cuevas, 2012). Women also generally underappreciate their midlife health risk changes (Almeida et al., 2016; Dennerstein & Soares, 2008). Blumstein, Benyamini, Boyko & Lemer-Geva (2016) concluded that women's knowledge about cardiovascular disease in midlife is insufficient. Awareness of osteoporosis has been found to be limited (Rideiro, Blakeley, Laryea, 2000). Clark (2015) found that while individual women knew about osteoporosis, they engaged in risky behaviors such as smoking, insufficient calcium intake and exercise, and lacked perception of risk. Therefore, the menopausal period represents an opportunity for dialogue about women's health at mid-life (Reid et al., 2014).

#### Vasomotor Symptoms (VMS)

About 80% of women will experience VMS (Avis et al., 2015; Freeman & Sharif, 2009; Reid et al., 2014). Most common VMS symptoms include hot flashes and night sweats (Stute et al., 2016). Median vasomotor duration of symptoms is 7.4 years (Avis et al., 2015). VMS are of great clinical concern to women and is the primary reason women access their PCP for menopausal concerns (Carpenter et al., 2015; Melby, Anderson, Sievert & Obermeyer, 2011).

In their systematic review on prevalence of VMS across countries, Freeman & Sherif (2009) found although there was a high overall prevalence of VMS across countries, variation between countries existed; with Japanese and Chinese women reporting least prevalence, and North American and European reporting the most. Freeman & Sherif postulate that reporting of increased symptoms in North America may be related to the medicalization of menopause. The Study of Women's Health (SWAN) has provided several years of longitudinal data and studies derived from a large cohort of American multi-ethnic women between 1995-2002. Racial/ethnic

differences have been found in VMS with African American women reporting higher prevalence (Thurson & Joffe, 2011).

In addition to racial differences, women who enter perimenopause obese, who smoke, consume high levels of alcohol, and have sedentary lifestyles have higher rates of vasomotor symptoms, independent of confounding variables. Lower education, negative affect and sleep problems have also been associated with increased VMS (Anderson, Seib, McGuire & Porter-Steele, 2015; Thurston & Joffe, 2011). In summary, VMS are common, and a main reason why women access primary care. Additionally, individual variation, culture, ethnicity, perception and lifestyle all play a role in how women experience VMS.

#### Non-Vasomotor Symptoms (non-VMS)

Non-VMS of menopause are less well-known and include weight gain, sleep disturbances, joint and muscle pain, tiredness, moodiness, decreased sex drive, and dyspareunia. Weight gain, while very common in the menopausal period, has not been linked to hormonal changes (Reid et al., 2014), though abdominal distribution has (Baber et al., 2016; Bitner & Wild, 2014). Shaver & Wood's 2015 narrative review report reported poor sleep in the menopausal period beyond the expectations for age. Urogenital symptoms related to atrophy include vaginal dryness, discharge, pruritus, dyspareunia, recurrent UTI, dysuria, urgency, frequency, and voiding difficulties. Vaginal atrophy is common, as is the under-treatment of vaginal atrophy (Krychman, Graham, Bernick, Mirkin & Kinsberg, 2017; Palma, Vecchia & Cagnacci, 2016). Sexual dysfunction is also common, whether related to vaginal atrophy, androgen deficiencies, or other concurrent issues.

Psychological issues stem from hormonal changes and/or life events, and include irritability, mood swings, anxiety, and difficulty concentrating. Sleep disturbances of varying

degrees are one of the most common non-VMS, reported by 38% of women (Avis, 2009). Many women have multiple non-VMS, and the effects on quality of life are considered to be exponential rather than additive (Carpenter et al., 2015).

The prevalence of clinically significant depression increases as women go through the menopausal period (Hickey, Bryant & Judd, 2012). One in 4 women has been found to have clinically significant affective disorder during this time (Bromberger et al., 2007), with women 4 times more likely to have a major depressive episode once they enter the menopausal period (Bromberger et al., 2011). Controversy exists over the role of ovarian hormonal changes in depression during the menopausal period, as ageing and other life events occur concurrently (Dennerstein & Soares, 2008). However, many studies find no clear evidence that the menopausal transition alone increases risk of depression/anxiety in women without risk factors such as psychosocial stressors, severe VMS or previous history of affective disorder (Hickey et al., 2012; Woods et al., 2008).

Clouding the diagnosis of depression during the menopausal period is the fact that symptoms such as insomnia, fatigue, irritability and fogginess are non-specific. The recognition of the interweaving and overlapping of issues is reflected in the recommendation of multifaceted approaches around mood in guidelines from the Society of Obstetricians and Gynecologists of Canada (SOGC). Awareness of risk is also reflected in SOGC guidelines recommending screening all women in the menopausal period for depression and anxiety (Reid et al., 2014).

#### **Complimentary Alternative Medicine (CAM)**

It is perhaps not surprising that, with the prevalence and variety of VMS and non-VMS symptoms, many women take a broad view of treatment options. A Canadian survey of 423

women contacted through list serves, e-mail lists and Internet advertisements found that 91% of women reported trying CAM therapies, using an average of 5 different kinds. Other surveys have found that 50-80% of women use non-hormonal therapies for VMS (Peng et al., 2016). Primary care practitioners may not be fully aware or comfortable with counseling women on alternatives or additions to HRT, even though CAMs are commonly used (Peng et al., 2016; Walter et al., 2004).

Recent attention has been given to CAM therapies from governing bodies including North American Menopause Society (NAMS) and the European Menopause and Andropause Society's (EMAS) 2015 position statements on CAMs, as well as the International Menopause Society's (IMS) 2016 position statement on non-hormonal management. Goldstein et al.'s umbrella review on mindfulness, meditation and relaxation for VMS (2017) is another example of recent and increased attention to CAMs. While this broader focus on treatment options aligns well with women's interests, it does not reflect current practice. For example, women have reported little if any discussion of non-HRT treatment in their PCP visits (Hyde et al., 2010).

#### **Impact of Menopausal Symptoms**

Physical and mental health declines during this phase of life has significant effects on women, families and society. Reduced quality of life over the menopausal transition has been largely explained by VMS, vaginal atrophy, incontinence, insomnia, arthritis, depression and stress. (Avis et al., 2009). Somatic illness and mental illness are common causes of long-term sick leave (Rindner et al., 2017). 1 in 3 women will have an osteoporotic fracture in her lifetime, with the majority having an additional fracture within 5 years (Osteoporosis Canada, 2017). About 50% of women in the menopausal period report incontinence (Steefel, Hyatt & Heiden, 2013). Depressive symptoms and disorders are leading causes of disability worldwide (Almeida

et al., 2014). Cardiovascular disease is the number one cause of death for women in Canada and Worldwide, and sex differences in presentation can lead to delays in diagnosis and treatment (Worrall-Carter, Ski, Scruth, Campbell & Page, 2011). These health concerns are either directly related to menopause, or co-occur at this time of life; reflecting the "window of vulnerability" previously mentioned.

#### **How This Project will Alleviate the Problem**

This window creates an opportunity to enact a health care intervention at a natural juncture in women's lives. This project is an education plan for a series of GMVs facilitated by a Nurse Practitioner (NP), aimed at increasing the capacity for primary care around menopause. The GMVs will be open to anyone who identifies as a woman in the 45-55 age group. In each GMV 8-12 participants will explore trusted information about menopausal symptoms, treatments, and risk status changes, meet 1:1 with the NP, and participate in group activities.

#### **Review of the Literature**

#### **Search Strategy**

The literature review search strategy included accessing the following databases: Pub Med, Cumulative Index to Nursing and Allied Health (CINAHL), Cochrane Library, Google Scholar and Psych Info. A combination of the following terms was used: *menopause, primary care, gynecology, group medical visits, group medical care (chronic disease, diabetes, pregnancy)*, and *nurse practitioner*. Due to the volume of literature, the search was initially limited to the date range 2012-2017. Snowballing was used to locate key and seminal older publications. The Cochrane Library Database was used to search for systematic reviews, meta analysis and meta synthesis on GMVs. PsychInfo was also searched using *menopause* and *experience*. Articles were screened by reading the abstract for applicability and quality. 173

abstracts were read. Results and content from the literature were included if they pertained directly to the discussion.

#### **Recent International Menopause Guidelines**

Significant national and international literature around the menopausal period has been published in the last 4 years. Position statements and official recommendations have been published by EMAS on the management of menopausal health (2015), non-hormonal management of vasomotor symptoms (2015) (previously mentioned in the CAMs discussion), healthy ageing (2016), and conditions in the workplace for menopausal women (2016). The IMS has published a position statement updating the cardiovascular risk assessment of women (2016). In the UK, the National Institute for Health and Care Excellence (NICE) published menopause and diagnosis guidelines (2015). NAMS has published guidelines on clinical care of midlife women (2014). The SOGC published an 84-page guideline on managing menopause (2014). These new guidelines have broadened the scope of recommended menopausal care to include significant content on non-vasomotor symptoms such as sleep, mood, and sexuality.

These recent guidelines align more with the holistic way many women have been found to conceptualize menopause. For example, the 2016 EMAS position statement emphasizes a focus beyond hormonal concerns, and "healthy menopause" is described as a state of being defined by the woman as a dynamic state of satisfaction with her physical health, mental health and social functioning. The woman's interest and ability to manage disability and disease within this period is described as core component of healthy menopause. Key terms "self-perceived", "desired ability" and "self-manage" used in the EMAS statement lend clues to models of care effective in achieving these kinds of outcomes.

#### **Models of Care Which Have Shown Success**

Group education. Models of care which shift power differentials and have shown success with self-awareness and self-management include group education and GMVs. Group educational programs around menopause can have been associated with a wide variety of good outcomes, including decreased menopausal symptoms, decreased depression, increased self-management and self-care (Doubova et al., 2012; Velez Toral et al., 2014). However, women report wanting to learn about menopause with their trusted PCP (Huston, Jackowski & Kirking, 2009). Reinforcement and personalization of information on menopause by a clinician's endorsement is important for women to feel confident in deciding what was best for themselves (An, Yu, Chou, Szu & Tao, 2016; Flanagan, Serrato, Altschuler, Tallman, & Thomas, 2005), lending argument to inclusion of a PCP in the intervention.

#### Group medical visits.

Perinatal GMV's. GMVs have a clinician embedded into the model. GMVs emerged in the 1990's as a way to improve access to health care services, provide increased education content, and utilize the benefits of group support. GMVs initially started in antenatal care. A 2015 systematic review concluded that antenatal GMVs resulted in no differences in prematurity rates (Catling et al., 2015). However, antenatal GMVs care have shown positive effects on health outcomes in vulnerable groups (Ickovics et al., 2016). Several research studies have found antenatal GMVs to be associated with increased preparedness for birth and improved satisfaction with care (Herrman, Rogers, Ehrenthal & Ehrenthal, 2012). Locally, the South Community Birth Program in Vancouver was the intervention arm of a study which showed women in GMVs were less likely to have a cesarean delivery, had shorter hospital stays on average and were more likely to breastfeed exclusively than women receiving standard care, when compared to a matched control group delivered by Obstetricians and GP's (Harris et al., 2012).

Chronic disease GMVs. While there is no published literature on GMVs for the menopausal period, there is compelling evidence for GMVs affecting physiologic parameters in chronic disease. Management of complex chronic illnesses within a primary care practice has been identified as a challenge by PCPs and patients (Trento et al., 2010; Wong et al., 2015). Chronic disease GMVs over the past decades have demonstrated significant benefits in physiological, psychological and behavioral outcomes (Beck et al., 1997; Lavoie et al., 2013; Remick & Remick, 2014). GMVs for diabetes has particularly robust body of literature on positive outcomes, with multiple systematic reviews concluding positive outcomes in reduction of HgbA1C (Deakin, McShane, Code & Williams, 2005; Edelmen, Gierisch, McDuffie, Housden & Wong, 2013; Edelman, Gierisch, McDuffle, Oddone & Williams, 2015). Recent literature has found positive outcomes in self-management (Housden & Wong, 2016), quality of life and knowledge about diabetes (Eisenstat, Ulman, Siegel & Carlson, 2013; Trento et al., 2010).

Menopause GMVs. No literature was found on GMVs specific to menopause. However, it is possible that GMVs could similarly help decrease the burden of menopausal symptoms.

Menopause is a life transition, but also has many shared characteristics of chronic disease.

Positive outcomes in the original focus of antenatal care as well as chronic disease suggest applicability of the model to the menopausal period. Additionally, discussion of some aspects menopause is considered taboo by some (Doubova et al., 2012), and the peer support from GMVs may be better suited to sensitive topics such body image, incontinence, vaginal atrophy and sexuality.

*Power shifts and GMVs.* GMVs depart from the expert-driven 1:1 consult model of care by putting participants at the center of care, and takes the focus off the "expert" (Lavoie et al., 2013). GMVs have been shown to promote self-acceptance. Qualitative research has highlighted

the value of comparing experiences, attitudes and practice about a particular health condition. Participants reported these experiential learning discussions caused them to reassess and change specific aspects of their self-management (Ridsdale, Hilpott, Krooupa & Morgan, 2017). Qualitative research has also highlighted GMVs success in knowledge acquisition and disruption of power differentials between both PCP and patient as well as between PCPs (Housden, Wong, Browne & Dawes, 2017).

Logically, a shift in power from PCP to participants should lead to increased self-efficacy. A recent meta-analysis supports the causal link between self-efficacy and health behavior changes (Sheeran et al., 2016). Self-efficacy can be defined as the confidence to work toward an identified goal. Bandura's Self-Efficacy Theory in the 1970's explained the potential of behavior change. In their Meta-Analysis, Sheeran et al. (2016) reported evidence of a causal relationship between self-efficacy and behavior change, concluding that "...interventions that modify attitudes, norms, and self-efficacy are effective in promoting health behavior change" (p. 1178). Qualitative data has identified patients' value on experiential learning as enhancing self-efficacy and behavior change (Ridsdale et al., 2017).

GMVs promote self-efficacy through deliberate mechanisms including encouraging self-monitoring (Berry, Williams, Wall, Heroux, Bennett-Lewis, 2016), feedback by peers and the PCP, and social support. Stress management has also been associated with self-efficacy (Prestwich et al., 2013). Segar, Eccles & Richardson (2008) report that women in mid-life who approach lifestyle modifications from sense of well-being and stress reduction had greater ongoing participation in physical activity. Certainly, improved health behaviors in midlife have been shown to promote healthy ageing (Hartman-Stein & Potkanowicz, 2003; Stute et al., 2016).

As discussed in a previous section, decreased self-esteem is common in the menopausal period. Self-esteem may benefit from the increases in confidence and self-care management seen with GMVs. A 2012 focus group on CenteringPregnancy discovered 4 main themes: It's about respect, Knowledge is Power, I'm a better mother, and Supporting each other (Herrman et al., 2012). These themes support the concepts that GMVs shift power to the client, and increase self-confidence through knowledge acquisition and peer support. Increasing the confidence of menopausal women has been shown to be effective in terms of developing self-efficacy, the capacity for decision-making and reduction of anxiety (Woods et al., 2008). Similarly, NAMS, as one of their 3 clinical menopause guidelines states that it is through consideration of women's concerns and preferences around menopause that practitioners enhance well-being in menopause and beyond. The facilitative approach and peer support of GMVs are designed to inhabit these zones of potential transformation.

The role of facilitator can be central to helping women develop as an active partner in care. Flanagan, Serrato, Altschuler, Tallman, & Thomas (2005) found that reinforcement and personalization of information on menopause by a clinician's endorsement was important for women to feel confident in deciding what was best for themselves. Lavoie at al. (2013) describe shifts in the roles of both PCP's and peers in GMVs. The PCP in GMS shifts from an adjudicator to a facilitator who can assist the group define norms of self-care that may be a combination of medical information and lived and pragmatic experience. The peers shift from passive recipients of care suggestions to active peer supporters who promote group norms, thereby improving self-management.

GMVs include these elements-facilitation, peer support, individualized assessment, continuity; which in turn support the client's self-management. Interestingly, according to an

expert panel on chronic disease self-management, the majority of the content in most successful self-management programs emphasized generic lifestyle issues such as exercise, nutrition, and coping skills, rather than specific disease-related content (Shelkelle et al., 2007). This lends support to the idea that Menopausal GMVs may also lead to healthy behavior change through focus on lifestyle issues, rather than a narrower focus on VMS, for example.

Nurse practitioners and GMVs. NPs may be particularly suited for GMVs due to their RN training and experience which emphasizes a holistic perspective, communication skills, focus on prevention, patient self-management, team building, Motivational Interviewing (MI) and the recognition of the importance of family support (Watts et al., 2009). In BC, NPs are well-versed in the social determinants of health (Archibald & Fraser, 2013), which could increase their comfort with approaching the menopausal transition holistically through an informed, yet flexible lens keeping women at the center.

Watts et al. (2009) highlight that NP's are particularly strong in 3 of the 6 core components of the Chronic Care Model often used in chronic care GMVs; self-management support, decision support, and delivery system design. Strengths in these areas would be key to GMVs focused on the menopausal period as it is a time of complicated decisions which women would like to explore both with a trusted PCP and with other women. The content of the GMVs will include decision-making aids aimed at helping women make their own informed decisions about their health, and capitalizing on Watt's findings around NPs strengths.

GMVs may be another way for NPs to increase collaboration with other health care providers and develop leadership skills. These strengths would be relevant for NPs to take leadership in development and facilitation of GMVs, as well as leading the multi-disciplinary role needed to posit this model of care within an existing primary care program. Trotter et al.

(2013) describe the importance of the NP taking full responsibility for the care of those in the GMVs as being key to acceptance of what is perceived to be an innovative model within a busy multidisciplinary practice.

Satisfaction with care and GMVs. Satisfaction with antenatal GMVs (Andersson, Christensson & Hildingsson, 2013) and chronic care GMVs have been found to be higher than individual care (Dickman et al., 2012; Remick & Remick, 2014). Providers in GMVs also more satisfied with care (Trento et al., 2010; Craswell, Kearney & Reed, 2016; Dickman et al., 2012). Trust has been shown to increase between patients and PCP in GMVs (Lavoie et al., 2013). Specific to satisfaction around menopausal care, qualitative research has shed light on specific limitations of the current model. Qualitative research has described midlife women are getting information about their risk, without any assistance in putting recommendations into action (Smith-DiJulio, Windsor & Anderson, 2010). GMV's through their group discussions will help women see how others are translating risk into action, and the 1:1 consultation with the NP may increase women's confidence in doing so, consequently improve satisfaction with care.

#### Gaps in the Literature

While there is significant literature on both menopause and GMVs, there are no studies on GMVs specific to menopause. No studies were found reporting NP-specific primary care interventions for the menopausal period. According to Housden, Wong, Browne & Dawes (2017), there is no research on NP's in Canada leading GMVs as part of their primary care portfolio. Housden et al. (2017) summarize the main barriers as remuneration through the feefor-service model, insufficient clinical space and power differentials between NP's and other health practitioners.

The literature has little discussion of the dose of GMV intervention needed to achieve outcomes. Mallow, Theeke, Barnes & Whetsel (2014) looked at dose dependency GMVs for diabetes. They found no significant correlations, however, the majority of the clients attending less than 2 GMVs in one year the dose was likely insufficient for both outcomes and ongoing attendance. The richness of group work is something women have reported as very important when discussing menopause (Doubova et al., 2012), and there needs to enough time and space for this to occur.

There was not much literature focused on the under-treatment of non-VMS. This gap may reflect that many women are less aware of how non-VMS may be related to their menopausal status. It may reflect unconscious expectations of our society that challenges such as insomnia, depression, and decreased libido are normal, expected, or not particularly significant. It may also be reflective of subtle gender expectations, or of the challenges in treating these issues.

#### **Description of the Project**

#### **Overview and Recruitment**

The project is an educational plan for series of GMVs entitled "Menopause and Beyond: A Midlife Tune-Up for Women". The GMVs will be designed for patients of a primary care clinic, 7 sessions 2 weeks apart in the early evening. The GMVs will be facilitated by a NP working within that practice. This allows the NP to continue to develop relationship with the patients, as well as the ability to write and follow up with prescriptions, referrals and laboratory requisitions. GMV sessions will target women in perimenopause, age 45-55. By targeting this age group, the burden of menopausal symptoms is minimized and the opportunity for health behavior changes maximized. Older women will be welcome and invited to participate up until age of 65 years. The GMVs could be offered in a "referral" model to more symptomatic women

across the region rather than within a particular primary care practice. This could help PCPs refer more appropriately when a holistic approach rather than Gynecology specialty skills are needed.

Within a primary health clinic offering GMVs, women will be recruited through posters at the clinic, announcements on the clinic website, cards given out by PCPs, and announcements on the clinic's social media page. If there are insufficient numbers to run a group with these strategies, management will be asked to consider a targeted approach in which women in the age range will be contacted directly and in adherence to privacy guidelines.

#### **Main Goals and Rationale**

The main goals for the project and rationale are as follows:

- Goal: Decrease women's reporting of menopausal symptoms (VMS and Non-VMS). Rationale: VMS are the #1 reason women access care for menopausal concerns, and are common across cultures. Non-VMS vary widely in frequency but are also common, can have significant impact, and are often undertreated.
- Goal: Increase self-efficacy. Rationale: Increased self-efficacy has been linked to positive health behavior change, which may in turn affect future health outcomes.
- Goal: Improve satisfaction with care. Rationale: Many women are not currently satisfied with menopausal primary care.

#### Secondary goals include:

Goal: Improve mental health-frequency of depression and anxiety in this age
group. Rationale: High rates of mental health issues in the menopausal period
cause reduced productivity and quality of life.

**Goal:** Increased adherence to screening protocols including lipid profiles, FIT, mammograms, FRAX testing, Framingham testing. *Rationale:* Infrequent health

maintenance appointments in primary care lead to less opportunity to access screening programs for some patients.

#### **Description of GMV Sessions**

An overview of the 7 sessions is as follows. Detailed session plans are in Appendices A-G.

- 1. VMS Part 1: Overview and non-pharmacological treatments: Introductions, personal impact of menopause. *Menopausal Tour*, designed to elicit cultural perceptions around the menopausal period. Overview of menopause. Decision aids and worksheets around VMS will be used. Focus on lifestyle and non-pharmacologic treatment.
- VMS Part 2: Pharmacological treatments including HRT: Continued exploration of VMS focusing on pharmacologic treatment including local and systemic HRT.
- 3. **Non-VMS Part 1: Overview:** Joint pain, sleep issues, fatigue, moodiness and weight gain. Ranking of non-VMS impact will be done individually, then amalgamated. Group will discuss the most common non-VMS together.
- 4. **Non-VMS Part 2: Pelvic Day-Incontinence & Sexuality:** genito-urinary syndrome of menopause (often denoted as *vaginal atrophy*), and sexuality. Guest speaker- Pelvic floor physio to review pelvic floor exercises. Sexual symptom checklist.
- 5. **Mental Health in the Menopausal Period:** Guest therapist for Cognitive Behavioral Therapy (CBT) group session. Optional self-guided CBT toolkit. Small group scenarios where depression/anxiety is amplified by menopause. PHQ-9 and GAD will be used.

6. Health Risks after Menopause: Focus on related health issues including osteoporosis, heart disease, smoking and weight control. Risk tools (Framingham, FRAX) will be explored. Small group goal-setting on health behaviors worksheet. Motivational Interviewing techniques used to discuss goals in larger group.

7. **Maximize the Now and Next Steps:** Open agenda, where women will request topics to discuss. Review small group work on goal-setting building from session #6 to increase clarity on self-care. Check out. Program evaluation.

All GMVs will include 1:1 appointments with the NP where women can ask individualized questions, receive prescriptions, requisitions, and referrals. The NP will have reviewed the charts prior to the GMV. Women will be encouraged to bring relevant worksheets/goal sheets to the 1:1 appointments. The session plans at the end include a detailed breakdown of how to organize session content, 1:1 checks, and discussion.

Group discussions will use a facilitative leadership approach. Techniques of MI can be used in the group to help explore ambiguity related to behavior change as appropriate. CAMs, non-pharmaceutical treatments, pharmaceuticals and lifestyle issues will be discussed. Decision and other tools will be explored in group discussion and women will be encouraged to complete the tools. Women will be encouraged to share their experiences with each other. Each session will have an agenda but with flexibility to allow the group to determine content discussed. For this project, a multidisciplinary team will be utilized in session 4 with a Pelvic Floor Physiotherapist and in session 5 with a leader for group CBT session.

Written materials for GMV participants would include a notebook consisting of information on vasomotor and non-vasomotor symptoms, worksheets to facilitate self-management, health screening tools, and worksheets to organize women's priorities in the 1:1

check-in with the NP. Descriptions of written materials relevant to each session are included in the session plans in Appendix 1, at the end of each session plan. However, the participant notebook itself is beyond the current scope of this project.

#### **Motivational Interviewing**

The Review of the Literature outlined the reasons why GMVs could be effective. This section will discuss rationale for including MI in GMVs. As described previously, a facilitative style in GMVs takes the focus off the 'expert'. More specific to behavioral change theory, MI has been shown to be an effective intervention. It acknowledges the central role of conflicting feelings about a behavior change that is leading to behavior stasis. MI allows the client to express their ambivalence in order to guide them to a satisfactory resolution, building motivation for positive health behavior change (Stott, Rollnick, Rees & Pill, 1995). Watts, O'Day, Schaub, Lawrence, Aron & Kirsh (2009) describe use of MI in GMVs as a way to support clients in self-management. During group discussions, effective use of MI promotes participants' readiness to change. The NP, therefore, will access MI training as part of preparing for GMVs to aid the group in explore barriers to health behavior changes. This will be particularly relevant in sessions 5 and 6.

Self-Determination theory concerns itself with human motivation, that as humans we have inherent growth tendencies. Self-Determination theory can increase understanding of the efficacy of MI (Foote et al., 1999; Markland, Ryan, Tobin & Rollnick, 2005). Essentially, the innate propensity of humans toward personal growth can be supported through ambient supports for competence, autonomy and relatedness. This suggests that MI is a good fit with GMVs, as GMVs supports competence and autonomy through group exploration of content with support for the participant to individualize, and relatedness through group dynamics.

#### **Cognitive Behavioral Therapy**

CBT is a popular therapy technique which has shown consistent success in a variety of areas. As mental health issues at this time of life are common, and CBT has shown success with mood as well as vasomotor symptoms (Balabanovic, Ayers & Hunter, 2013; Norton, Chilcot & Hunter, 2014; Stefanopoulou & Hunter, 2013) and insomnia (Van Straten et al., 2017), a trained CBT psychologist will be brought in to lead a session. A self-guided CBT program will be made available in the written notebook. Self-guided, particularly with one episode of telephone support, has been shown to be effective and can increase access to CBT (Ayers, Smith, Hellier, Mann & Hunter, 2012; Stefanopoulou & Hunter, 2013). The theory behind CBT for VMS is that a range of psychological factors may be influencing physiological mechanisms and perception of VMS. By emphasizing a calm approach and acceptance of symptoms, less problematic symptoms are reported (Hunter & Man, 2010; Rendall, Simonds & Hunter, 2008). Information about local individual and CBT groups will also be made available for interested participants.

#### **Strengths and Limitations**

Strengths of this project have been discussed throughout this paper, and include: a recognized gap in care for a large amount of the population; a teachable 'moment' in menopause, under-treatment of both VMS and non-VMS, prevalence of mental health challenges, and the possibility long-term impact on healthy ageing. Limitations include the identified gaps in the literature around application of GMVs to the menopausal period. Addition of Motivational Interviewing strategies and CBT into the GMVs may muddy the waters in terms of evaluating what may be effective or not in the intervention. Lack of literature around GMVs and menopause leads to uncertainty around adequate dose of the GMV intervention. Antenatal GMVs usually consist of 10 visits, chronic illness GMVs are often ongoing with rolling participation. GMVs for

menopause is new territory, and increased or decreased frequency or timing of visits may be superior. The connection of self-efficacy to health behavior change has been discussed previously. The ability to effectively measure if self-efficacy leads to improved health outcomes is always a challenge.

Finances are always an issue, as NPs are not able to bill Medical Services Plan. Working with the practice to arrange how to bill for this intervention will take institutional support. Salary fees would include NP time and speaker's fees for the CBT and Pelvic Floor Physio. Overhead costs associated with GMV include administrative organization, room bookings, heat/cooling, laptop, materials, and snacks. Training costs would be necessary for the NP new to GMVs, and in Motivational Interviewing techniques. In addition to financial barriers, Housden et al (2017) detail power differentials between NPs and other PCPs which can challenge implementation.

Women also may have less interest or ability to participate than anticipated. Looking at other populations using GMVs, in psychiatric group care, patients had roughly equal perceptions of individual and GMV. In prenatal group care, about 50% of women self-select into GMV (Remick & Remick, 2014). Women at mid-life often have competing demands, however, which may affect their ability to commit to the GMV series. Women who have minimal symptoms may not self-select for GMVs, thereby missing out on some of the intended positive physical and mental health outcomes. Women may become more anxious if they hear about possible future health risks or hear others' struggles. Women may find that the series of GMVs is more than they need, if they are focused on VMS treatment rather than looking at a "mid-life tune up". Finally, Women with challenges related to the social determinants of health will likely experience multiple barriers to participation.

Confidentiality has been raised as a concern in GMVs as medical results and conditions are at times discussed in the group setting, and the 1:1 meeting with the HCP is usually done within the same room as other participants. Wong et al. (2015) found that confidentiality is not a major concern of patients in GMV, even in rural settings where many patients would know each other. Therefore, I do not see this as a significant barrier or weakness.

It is difficult to critique this project at this juncture, however, both patients and PCPs with a medicalized view of menopause may not see the need for such a lengthy intervention. As discussed there may be problems with uptake due to this and competing interests. Funding issues would need to be resolved, or this project would not be successful. Targeted recruitment to reach and include women with challenges related to the social determinants of health would take consideration and effort.

#### **Next Steps and Future Implications**

In terms of next steps, primary care practices may want to do a needs assessment to see if appetite exists, and decide whether they as a practice want to support this well-researched model of care. The practice would need to have an NP willing to spearhead implementation, and the funds to cover NP training and time, as well as other costs. Recruitment of participants could be started via the acceptable channels of the primary care practice and could include posters in the office, information given by PCPs, and social media outlets connected to the office. The GMVs would then start with a pilot group. A CBT therapist and Pelvic Floor physiotherapist would need to be found. Program evaluation would need to be planned as per intended outcomes.

If sufficient demand exists to run "Menopause and Beyond: A Women's Midlife Tune-Up" GMVs, and it shown to be successful in outcome goals, then this model could be expanded to other primary care practices. Training for NPs in planning and running Menopause GMVs

could be provided by experienced NPs. Additionally, NPs could spearhead future application of GMVs to other complex diagnoses where 1:1 care is the only current option.

#### Conclusion

Women are living longer lives, with one-third of that time after menopause. They report insufficient knowledge about menopause, and about the health changes related to loss of estrogen. Women commonly experience VMS, a common entrance point into primary care. Primary care appointments often fail to address VMS treatment options beyond HRT. Many women are hesitant to utilize HRT and are instead using CAMs. Non-VMS of menopause are seldom explored during primary care visits for menopausal concerns. The impact of undertreated menopausal symptoms on women, family and society is difficult to quantify, but certainly significant.

GMVs have shown to have positive outcomes in perinatal and chronic disease care. Similar successes may transferrable to GMVs through individual and group processes which increase in self-confidence and self-management. Patient satisfaction has been positive for GMVs. NP skills have been shown to be particularly well-suited to GMVs for several reasons, including familiarity with disease management, comfort with facilitative style, and recognition of the importance of patient support. In summary, there is a health care need for which a proven but underutilized model of care, GMVs, could be applied. GMVs are particularly suited to the skill set of NPs. By taking leadership roles in GMVs around menopause, NP's can not only provide the care that women deserve, but also contribute to the development of primary care in BC.

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# Appendix A

# **Session 1: VMS Part 1**

Prior to session 1, email an overview of sessions, bio on NP, and link to funny video on menopause:

https://www.youtube.com/watch?v=\_2OzLREwHtI

#### 5:00-5:15

Welcome

Description of GMV, benefits of group work. Role of NP

What sessions will look like

Ground rules on confidentiality

Give out and tour of Notebook

6:30-7:00, when not with NP, can talk to other participants, and/or do homework listed in the "While waiting" section for each session.

#### 5:15-5:30

OPENER---INTRODUCE SELF, DESCRIBE HOW MENOPAUSE HAS AFFECTED YOU (positive and negative) "loss" "relief" "freedom" "transition"

# 5:30-5:45

NP introduces self and why GMV's around menopause were started.

Review some different perceptions of menopause.

Definition of menopause and perimenopause

Perimenopause usually starts in mid 40's with:

Menstrual problems/irregularities

PMS, irritation, paranoia

Premenstrual and menstrual migraine

Insomnia, tiredness

Joint aches, poor concentration poor memory

Loss libido, sex drive

Inability to concentrate, multi-task

One newer (holistic) definition of healthy menopause, on poster board; "A dynamic state, following the permanent loss of ovarian function, characterized by self-perceived satisfactory physical, psychological and social functioning, incorporating disease and disability as well as a woman's desired ability to adapt and capacity to self-manage." Stute et al, 2016 A model of care for healthy menopause and ageing: EMAS position statement

#### 5:45-5:50

Fill out MRS to get a starting sense of current menopausal symptoms. Keep in Notebook. Will take again in last session.

#### 5:50 -5:55

Start with #1 reason women go to their doctors with menopausal concerns: VMS. WHAT IS A "HOT FLASH"?

Main theory: narrow of thermoneutral zone, so easy with hormonal fluctuations (high FSH, low estrogen) and small fluctuations of core body temp to trigger thermoregulatory mechanisms (sweating, shivering).

# 5:55-6:30

What can you do about hot flashes and night sweats? (VMS) (non-hormonal)

CAMS-what stand for? (Complementary and Alternative Medicines), or Complimentary or Alternative Therapies

Quality summary of evidence on CAMS: Pull up on overhead screen and refer to this throughout discussion.

Mind and Body practices: Have you used any of these before? Do they help with any of your "hot flash" symptoms? Other effects?

Can write down what is relevant to you on your Hot Flash Worksheet.

If you aren't having hot flashes, congratulations! They may be coming, around 80% of women get them.

Low risk of harm

*Exercise*-does not decrease vasomotor s/s (2015). Of course, beneficial for mood, sleep, bone and CVD health. QOL increased.

Wt. loss-2014 pilot study showed significant reduction of hot flashes with weight reduction program (Thurston et al., 2014). Now recommended for VMS along with many other reasons. Historically, thought adipose tissue with estrogen was protective so weight loss wouldn't helpnot so. Looks like adipose tissue instead acts as insulator-increasing hot flashes.

Meditation, relaxation, controlled breathing, CBT, mindfulness—all show promise for vasomotor (small benefit only in meta-analysis (refs 8-10 in 2016 IMS). CBT stronger results (MENOS)

CBT-MENOS -2 Ayers RCT good results. Idea that emotions and thoughts are linked to physiology, by accepting hot flash will be less

Hypnosis-helps with vasomotor and sleep with WOMEN WITH BREAST CA, Cramer et al (2015). Hypnosis in breast cancer care: a systematic review of RCT's (3 trials)-YES decrease in hot flashes (same as gabapentin). Also reported by Goldstein (2016) Hypnosis for menopause (not in breast CA) as promising, but evidence limited. Recommended in NAMS 2015 position paper.

Relaxation-NO decrease in VMS (Goldstein, 2016)

*Mindfulness*-one RCT no change VMS but better sleep quality and reduced anxiety. Insufficient evidence. Not recommended in position statements of NAMS, EAMS Some studies directly comparing interventions to each other (rather than placebo). Guthrie et al (2015) did pooled analysis of 6 pharmacologic and non-pharmacologic interventions for VMS

and found that escitalopram, venlafaxine and low dose estrogen therapy provide comparable modest reduction in VMS, while exercise, yoga and omega-3 supplements had no effect.

Stellate ganglion blockade-Nerve block done by anesthesiologist, used commonly in pain relief. Promising for hot flashes, decreases vasomotor by 50%-safe and well tolerated.

*Acupuncture*-small effect in reducing VMS and increasing QOL, though not more than sham treatment (Goldstein et al, 2016, RCT). Fine as adjunct and some studies show improved sleep. Moderate strength of evidence. **Avis** et al (2017) found that 47% of women reported reduction in frequency of VMS. 2013 Cochrane review of 16 RCT's and 1155 women found no diff between acupuncture and sham but both helped.

*Yoga*-inconsistent though some effects on reducing VMS and increasing QOL (Goldstein et al, 2016, EMAS Hunter 2015 statement). Low strength of evidence.

*Tai chi, prayer, self-help groups-*2010 review of 21 papers (Innes, Selfe & Vishnu, 2010) found yoga, tai chi and meditation based program *may* be helpful in reducing hot flashes, sleep issues, muscle and joint pain, stress.

Alternative medical systems: homeopathy

Manual therapy: reflexology

SUMMARY: For non-HRT treatment for VMS, paced respiration (mixed), CBT, mindfulness training (mixed), acupuncture, hypnosis and stellate ganglion blockade have some positive evidence (2015 NAMS statement and 2016 IMS).

# Vitamins, herbs and Supplements: (show and tell basket of these). Has anyone tried these or known anyone to use them?

Phytoestrogens: (i.e. red clover and sov).

Soy supplements: Isoflavone prep from soy and red clover-variable efficacy/insufficient evidence for VMS (IMS 2016 cites 3 studies: Lethaby, Marjoribanks, Kronenberg, Eden & Brown (2013), Shakeri, Taavoni, Goushegir, Haghai (2015), Taylor-Swanson, Thomas, Ismail, 2015). Some studies find efficacy but are critiqued as biased. High placebo effect. Inconsistent relief. *Red Clover*: Shakeri 2015 article small but very positive reduction of MRS not just for VMS but also mood (40mg daily dried red clover). "Promensil".

**Safety:** Phytoestrogens not recommended for women with personal history of hormone CA, thromboembolic events or cardiovascular events (American Academy of Endocrinologists).

Botanical therapies: probiotics, prebiotics, plant sterols and stanols, fiber, herbal products, hops, evening primrose oil

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

Product called "Remifemin" –OTC herb. Has been studied more than other botanicals. 2012 Cochrane review found insufficient evidence. Popular herbal treatment used for dysmenorrhea and menopause. Has been recommended for sleep, mood and VMS-evidence confounded by placebo effect. Mechanism unclear, but contains substances with selective estrogen receptor modulator (SERM) activity, so binds to estrogen receptors and reduces LH from the pituitary—improving s/s. DOSE: 16-127 mg qd, usual Remifemin dose one 20-mg tab BID. Long term safety profile not established, Germany recommends 6 months. Mixed results. Generally well-tolerated.

**Safety:** Adverse effects GI upset rashes, usually mild. F/u to review response to treatment 4-8 wks. Adverse effects/interactions with other meds, particularly w drugs toxic to liver or kidneys. There have been several case reports of hepatitis, as well as liver failure, in women who were taking black cohosh. While it is not known if black cohosh was responsible for these problems, there is concern about the possible effects of black cohosh on the liver.

*St. John's wort*-used extensively for depression, especially in Europe. Some studies show same result or better than anti-depressants. Interact with many meds (serotonin syndrome with SSRI's), can decrease effectiveness of meds. So not for VMS, but for mood issues related to menopause.

*DHEA*-naturally occurring substance that turns into estrogen and testosterone in body. 2015 Cochrane review showed no improved QOL, and androgenic s/e (acne, hair growth). May slightly improve sexual function. Guidelines issued by a task force from several professional societies recommend against routine use of DHEA.

*Dong quai*-traditional Chinese medicine herb, often used for women's health problems, including menopause. Very little research has been done on dong quai for menopausal symptoms, so no conclusions can be reached about its effects. May interact with the anticoagulant (blood-thinning) drug warfarin (Coumadin).

Flaxseed/flaxseed oil-studies done in 2010 and 2012 show no effect VMS. (Simbalista RL, Sauerbronn AV, Aldrighi JM, et al, 2010, Pruthi S, Qin R, Terstreip SA, et al, 2012)

*Gingko biloba*-long history in traditional Chinese medicine. Used for dementia, intermittent claudication, diabetes. No good evidence helps with cognitive decline. Thought to be safe in low/mod doses. Interacts w other drugs.

Ginseng-traditional Chinese medicine, Asian ginseng was believed to replenish energy. Now used as a dietary supplement to improve general well-being, physical stamina, concentration, stimulate immune function, slow aging process. Also used for various health problems such as respiratory disorders, cardiovascular disorders, depression, anxiety, erectile dysfunction, and menopausal hot flashes.

Evidence-no effect. Seems to be safe in small amounts. May effect BP and blood sugar. Low risk of interaction with meds but maybe warfarin.

*Glucosamine*-amino sugar the body produces and distributes in cartilage and other connective tissue. Used with chondroitin for Osteoarthritis-GAIT study (2006, 2008, 2010) all show no better than celecoxib or placebo.

Mexican yam/progesterone cream

Methylsulfonylmethane (MSMS), S-adenosyl-L-methionine (SAMe)

Evening primrose oil-women report effective, no evidence

Genistein-Cochrane (Lethaby) 2013 review found positive effects with extracts with higher levels (> 30 mg/d) of genistein for reducing hot flashes, needs more study. No info on possible estrogenic stimulation of endometrium or other adverse effects.

*Vitamin E*-small amount of research which has shown a small benefit. High doses such as those in supplements may increase bleeding (including strokes) and interact with blood-thinning meds like warfarin.

"Bioidentical" hormones-not recommended (UpToDate)-no evidence for safety/efficacy comparted to HRT. Means hormone with same molecular structure as hormone that is produced in the body. In popular culture, refers to custom-compounded, multihormone regimens with dose adjustments based upon serial hormone monitoring.

Summary: Controversial as limited evidence for efficacy (and safety as herbs not regulated by medicines agencies). Most studies and meta-analysis do not show consistent efficacy for VMS. Herbs may interact with other herbs or medications.

# 6:30-7:00

1:1 Appointments with NP

While Waiting:

Keep working on Hot Flash Worksheet

# Written material in notebook:

**MRS** 

Hot Flash Worksheet

Specific VMS symptom diary: number, severity, and bother rating (mild, moderate, severe) of VMS-divided into nighttime and daytime.

# Appendix B

# Session 2: VMS Part 2: Pharmacological treatments including HRT

#### 5:00-5:10

Questions from last time

# 5:10-5:20

HORMONE THERAPY: if you have hesitations about hormone therapy, what those are? (breast CA, CVD/stroke, blood clots)

# 5:20-5:40

GO THROUGH RESULTS OF WHI F/U REPORT as a short Power Point:

WHI reports in the 13 years since the initial report do not show increased risk of CVD in any age group, with the exception of venous thrombosis. The risk of breast cancer is marginally increased with combination estrogen/progesterone therapy, and is related to duration of use. The "timing hypothesis" has held consistently in RCT's since the initial WHI report-younger women have a coronary benefit and decrease in all-cause mortality with HT. In summary, significant concerns and changes in recommendations around HT have led to confusion, concern, and under treatment in regard to HT.

#### Hormonal:

Differentiate local from systemic HRT

Best evidence

ET: vasomotor, prevention of osteoporosis

Prostaglandins added to decrease risk of endometrial hyperplasia/carahome or when mgmt. of vasomotor where E is contraindicated

Recent large RCT 2015 (Gleason et al) KEEPS study looked at cognitive and mood with younger women with low cardiac risk profiles on HRT. No change in cognition compared to control, and small to med improvement in mood with systemic HRT, not seen with transdermal.

# HRT: Absolute contraindications (RED LIGHT): (USE STOPLIGHT POSTER WITH THESE IN RED LIGHT PART AND RELATIVE CONTRAINDICATIONS IN YELLOW LIGHT)

Active liver disease

Active breast ca

Active vascular thrombosis

History of unexplained vaginal bleeding

Pregnant

>60 years

>10 years since menopause

HRT Relative contraindications:

Gallbladder or chronic renal

History of endometriosis or fibroids

Uterine or ovarian ca

Fibrocystic breast disease

Hypertension

Hypertriglyceridemia

Migraine (with aura, patch is preferred)

TIA

Thromboembolism

History of breast ca

### SUMMARY:

E very effective in VM

Progestins also 25-85% effective but can increase risk of breast CA (consider if benefit/risk profile is acceptable to women)

Go off HRT at 4-5 years as that is when breast CA risk increases (SOGC)

Best evidence for VMS is low-dose estrogen, also SSRI (escitalopram, Cipralex) and SNRI (venlafaxine, Effexor).

Oral vs. transdermal (patch)

Oral-better for lowering LDL

Transdermal-reduced risk of clot

# Other options to HRT: mainly for VMS

Non-hormonal meds (SSRI's, SNRI's, gabapentin, others)

Clonidine 0.05 mg PO bid

Paroxetine 7.5 mg once daily

Venlafaxine 37.5-75 mg PO once daily

Gabapentin 300 mg PO TID

(Fluoxetine 20 mg PO daily)

#### 6:30-7:00

1:1 appointments with NP

# While waiting:

If interested in Hormone Replacement Therapy, fill out Decision tool for HRT, which will include following:

Detailing s/s and impact on QOL (MRS SCORE)

Woman's preference about treatment

Menstrual history including age and type of menopause and contraception

Family or personal history of breast, ovarian, endometrial and colon CA, venous

thromboembolism, migraine, risk factors for osteoporosis, DM, HTN, heart disease and stroke

Physical: weight, height, waist/hip ratio, BP

Measure waist circumference (want <88cm)

Can do Decision-aid tool app: HRT—"MENOPRO" APP FROM NAMS

Written materials in Notebook:

Decision tool for HRT

# Appendix C

# **Session 3: Non-VMS Part 1: Overview**

#### 5:00-5:10

Questions from last time

# 5:10-5:25

In Notebook, have sheet with 8 symptoms plus and "other", tick all that they have. Number 1-3 the ones they would like to alleviate. Stickies in 3 different colors (pink = #1 want to alleviate, yellow = #2 want to alleviate, green = #3 want to alleviate). They put each of the stickies on poster listing 8 symptoms-visual to see spread and commonalities of symptoms.

# 5:25-6:30

Review as a group the top 3 most common. Cover: what the research shows, what people have tried, what questions they have. Participants use worksheets in notebook for what they may try, and can use this during 1:1 apt.

# 1. Disturbed sleep

Why?

After VMS, most common complaint. Influences everything else.

Take Insomnia Severity Index in notebook and self-score

Nearly 1/3 of women score higher then 8 (moderate to severe) on ISI

Can help with sleep: layers (VMS hot flashes common at night).

HRT can help when sleep disturbances related to hot flashes.

SWAN results describe problems with VMS and sleep-falling asleep, staying asleep and early awakening.

Pittsburg Sleep Quality Index more global sleep quality, 18 items.

# 2. Feeling tired or worn out (fatigue)

Why?

Related to sleep problems

Mental health, will discuss more in session 4

# 3. Trouble remembering or concentrating (concentration)

Why?

Related to sleep problems

HRT not shown to help (UpToDate) with cognitive function or dementia SWAN studies (n=2362) shown transient decrement in cognitive performance during perimenopause-diminished ability to learn that resolves as women become postmenopausal (Greendale et al. 2009)

# 4. Mood swings

Why?

Related to sleep problems

HRT can help

VMS and mood related in numerous and complex ways. Depressive symptoms most common when VMS symptoms are most prevalent. However, many women with VMS are not depressed and many depressed women have no VMS. (Thurston & Joffe, 2011)

# 5. Feeling irritable

Why?

Related to sleep problems

# 6. Aches and pains

Most common in later perimenopause. Not often identified as major concern. Not clear if r/t estrogen deficiency or rheumatologic disorder, but HRT helps with pain and stiffness.

Sometimes HRT can help

7. **Headaches**-hormone fluctuations (like PMS). HRT may make better. Patch steadier dose.

# 8. Weight gain

Mini True-False

1. Weight gain in menopause is inevitable and related to loss of estrogen.

False

"The steady weight gain, of about 0.5 kg per year, seen in women at midlife is associated with age and environmental factors, not menopause" from 2016 IMS report.

# 2. HRT causes abdominal fat

False

Abdominal fat is ameliorated by estrogen therapy, with reduction in overall fat mass, improved insulin sensitivity and lower rate of T2DM (2016 IMS)

3. Central obesity is associated with CVD and diabetes.

True

(Bitner & Wild, 2014). These researchers found that WAIPointes worked in women 35-55 (decreased waist circumference, diastolic and improved men s/s and physical activity)

BMI, waist circumference-want <88cm to decrease risk of DM, heart dis, HTN, metabolic syndrome. Menopause associated with abdominal girth (see Baber, 2016) Women gain an average of 10 kg from 40-60 years of age (Neves-e-Castro et al, 2015) Hormonal changes are associated with increases in total body fat and abdominal fat, even in lean women (2016 IMS)

# Goal setting-homework

# 6:30-7:00

1:1 Appointments with NP

While waiting:

Measure waist circumference and calculate BMI

# Written materials in notebook:

Sheet with 12 symptoms, they circle all they have then rank top 3 bothersome symptoms Worksheet for this, possible solutions, space to write which if any they'd like to try. Can use as notes for 1:1 PRN Insomnia Severity Index

# Appendix D

# Session 4: Non-VMS Part 2, Pelvic Day- Incontinence & Sexuality

#### 5:00-5:10

Questions from last session

# 5:10-5:20

Overview by NP or Pelvic Floor physio of Pelvic changes in perimenopause.

Then focus down on incontinence and role of pelvic floor muscle training. Now being called "Genito-urinary syndrome of menopause" (instead of vaginal atrophy)

Content: (Poster with symptoms on one side of outline of woman—treatment on other side) UpToDate: estrogen deficiency leads to thinning of vaginal epithelium, which causes dryness, itching, dyspareunia and sometimes urinary s/s. Vaginal and systemic treatment effective but without VMS local treatment is recommended.

Key points: (2016 IMS)

Vaginal dryness, soreness, dyspareunia, urinary frequency, nocturia and urgency extremely common in post menopause

Incontinence prevalence increases with age

Wide variation in urogenital aging

Loss of lubrication and hormonal changes may lead to sexual dysfunction

Treatment improves QOL for women and partners

Urogenital s/s respond well to estrogens

Long-term treatment often required (s/s recur on d/c)

Systemic risks have not been identified with local low pot/low dose estrogens

HRT no better than local for urogenital atrophy or recurrent UTI

Lifestyle changes and bladder retraining recommended as 1st line therapy for OAB

Antimuscarinic drugs, combined with local estrogens=first line medical treatment for OAB Stress incontinence=benefit from pelvic floor training

suess incommence—benefit from pervic from training

Duloxetine may work synergistically with conservative treatment

Sample PT plan for UI includes: (Sran et al., 2016)

Manual digital palpation using PERFECT scheme, education on causes of incontinence, conservative treatment, management of constipation, urge control techniques, biofeedback, motor control exercises, functional PFM exercises, bladder habit retraining, dietary changes PRN, audio tapes for reminders.

Some women need surgery (retropubic and transobturator tapes most common)

#### 5:20-5:40

Pelvic floor physio speaker leads practice pelvic floor exercises

(Stress urinary incontinence benefits from pelvic floor muscle training (Moore, Dumoulin, Bradley et al (2013) Adult Conservative Management)

**Ouestions** 

Continence clinic at BC Women's

#### 5:40-5:50

Intro by NP to sexual health changes in menopausal period. WHO definition of sexual health-right of every woman

Attitudes about libido article. Sexual dissatisfaction decreased QOL.

Vaginal atrophy-Genitourinary Syndrome of Menopause

From Portman et al., (2014)

Collection of s/s associated with decreased estrogen including:

Changes to labia majora/minora, clitoris, introitus, vagina, urethra and bladder. May include dryness, burning, irritation, lack of lubrication, discomfort/pain, urinary symptoms of urgency, dysuria, frequent UTI.

#### 5:50-6:10

Small group activity. In groups of 2-3, review common sexual health concerns: What can do?

- 1. Low libido
- 2. Painful intercourse

# 6:15-6:30

Back together, talk about treatments. What did you talk about?

1. Low libido:

Hormones and decreased libido:

Cochrane review 2015 on Libido DHEA showed minimal effect. No effect in systematic review Systemic E not effective. Neither is P

Testosterone works

Oxytocin-insufficient data

Decreased androgens-normal in perimenopause-associated with low desire

International society for sexual medicine

2016 consensus: trial of transdermal test therapy considered

<6 month if no benefit

limited by availability of approved formulations

formulations used to treat male hypogonadism and compounded and formulated should not be used

# 2. Painful intercourse

Lubrication

Local estrogen therapy

# 6:30-7:00

1:1 Appointments with NP

While waiting:

SOGC Sexual symptom index

#### Written materials in notebook:

Sexual symptom index Pelvic floor exercise guide Options for vaginal atrophy treatment page Common sexual health scenarios

# Appendix E

# Session 5: Mental Health in the Menopausal Period

#### 5:00-5:10

Questions from last time

# 5:10-5:40

Volunteer reads a scenario where a women's mental health (depression/anxiety) is amplified by the effects menopause; interaction of life stresses. (partner, kids, work, no time). Ask if that resonates for anyone. Open up for discussion on thoughts on mood.

So, when discussion (or NP) brings up idea that mood issues are multi-factorial, then so is the approach to treatment. (From Almeida et al., 2014)

Education (how common, how can manifest) Anxiety, depression.

Lifestyle (diet, exercise, smoking, alcohol)

Optimizing general health and social support

Minimize and treat VMS

Problem solve around issues

If depression prominent, consider Rx and/or psychotherapy

HRT may help with mood (only use if having VMS)

#### 5:40-6:30

CBT: what is it?

CBT has been shown to help with vasomotor symptoms (Balabanovic, J et al, 2013, Norton, 2013) and insomnia (McCurrey, 2016).

Group CBT Session by therapist

Describe CBT options in community and CBT Self-led program in Notebook.

#### 6:30-7:00

1:1 Appointments with NP

While Waiting:

PHO-9

GAD-7

# Written materials in notebook:

Scenario of woman with depression (amplified by menopause)

PHQ-9

**GAD** 

CBT Self-led program description (self-paced, optional, buy booklet/CD)

Community Resources: "Reduced-Cost Counselling Options in Vancouver"

https://willowtreecounselling.ca/wp-content/themes/willowtree/reduced-cost-counselling.pdf

# Appendix F

# Session 6-Health Risks after Menopause

#### 5:00-5:10

Questions from last session

# 5:10-5:20

Group question: How do health risks change after menopause?

-CVD, CA, osteoporosis. Will focus CVD and osteoporosis today, on understanding own risk by working through steps together. Starting to come up with self-care plan, if needed.

# 5:20-5:50

# CVD:

Presentation often different for women: 10 years later, atypical symptoms Framingham Risk Score (FRS) is recommended q 3-5 years 50-79.

# DO Online calculator (more accurate than paper-based)

General screening guidelines:

Lipid profile-if >50, or postmenopausal, or at increased risk, q 5 years if normal. T2DM –Fasting plasma glucose OR hgb A1C.

(CA screening: Mammogram q 2 years 50-69 years, FIT q year > 50)

Manage other conditions if present i.e. DM, HTN, CKD

MY CVD WORKSHEET: (worksheet will include below and can be brought to 1:1 apt w NP)

My Framingham score:

My personal CVD history (heart attack, stroke, TIA, angina):

My family CVD history:

My risk factors (see chart):

Table 1. Modifiable and non-modifiable risk factors for CVD

i.	Modifiable Risk Factors	Non-modifiable Risk Factors	
0		o age - chronological and biological	al
0	low physical activity levels / sedentary lifestyle <sup>4, 7, 8</sup>	age (frailty) <sup>17</sup> ○ gender - men	
0	poor diet <sup>4, 9</sup> excessive body weight / body	<ul> <li>family history of CVD<sup>18</sup> or familiant familiant family</li> <li>hyperlipidemia</li> </ul>	al
0	mass index (BMI) / waist circumference <sup>4, 10, 11</sup>	<ul> <li>ethnicity<sup>19-21</sup> - First Nations, Sou Asians (defined as Indian,</li> </ul>	ıth
0	elevated blood pressure/hypertension <del>^</del>	Pakistani, Bangladeshi or Sri Lankan origin)	
0	$diabetes^{4, 12, 13}$	o chronic kidney disease <sup>22</sup>	

- elevated lipid levels<sup>4</sup>
- socioeconomic factors<sup>14</sup> (e.g., income, level of education, employment)
- psychosocial factors<sup>4,15,16</sup>(e.g., stress levels, depression, anxiety)
- o *certain autoimmune inflammatory diseases*<sup>23</sup> (e.g., rheumatoid arthritis, psoriatic arthritis, systemic lupus erythematosus, vasculitis (polyarteritis nodosa))

BC Guidelines-Cardiovascular Disease-Primary Prevention

- Non-modifiable:
- Modifiable:

My blood pressure here today: My usual blood pressure:

These are the tests that I know I have done: Lipids, total cholesterol, HDL/LDL, Diabetes, TG, cardiac stress test. There was an abnormality with the following test(s):

I'm wondering if these tests are appropriate for me? Lipids, total cholesterol, HDL/LDL, Diabetes, TG, cardiac stress test?

My current level of exercise:

My current diet:

Considering the above, I think this is important for me:

#### HRT and CVD:

HRT not first line for CVD-lifestyle is

Increased risk of stroke for all women with HRT, but with younger women, and with low doses of E, risk is small

"Critical window" idea where cardio protection happens and adverse events low (within 10 years of menopause)

plus recommended (and women only want to be on HRT) for 5 years, so big message is lifestyle

#### CVD T/F as group

T/F: Heart disease for women is 80% attributable to modifiable risk factors

FALSE, 94% per INTERHEART STUDY (2004). Substantial contributors: DM, HTN, abdominal obesity, current smoking, stress.

T/F: My obstetric history has no impact on my risk for CVD: FALSE, If history of PIH, HTN, GD, abrupt, idiopathic premature and IUGR-increased risk for premature CVD/death and increased need for screening

# 5:50-6:15

Osteoporosis: T/F as group

T/F I've know someone who has had a hip fracture. Group Question: How did it affect their life? T/F Vertebral fractures are uncommon. (F), cause considerable morbidity (Center, Nguyen, Schneider, Sambrook & Eisman (1999)

Skeletal disease of diminishing bone strength and increased risk of facture when falling from own body height (fragility fracture). Postmenopausal osteoporosis is from failure to attain peak bone density, accelerated bone loss in menopause, age-related bone loss. Accelerated postmenopausal bone loss from estrogen deprivation.

Show photos of healthy and osteoporotic bone

Skeletal health---can we modified? Genetic predisposition-no, Lifestyle-diet, weight bearing exercise, avoiding of bone-toxic substances (like...)

# DO FRAX TOOL TOGETHER

FRAX tool for measuring osteoporosis risk and guiding threshold for therapy

Definition of OP: T score <+-2.5 or fragility fracture

Osteopenia T score < -1 and > -2.5

e FRAX model developed by the World Health Organization, which is available online at www.sheffield.ac.uk/FRAX/.5

IMS 2016: Postmenopausal women need a dietary reference intake (DRI) of 1000–1500 mg of elemental calcium... Calcium supplementation should be restricted to bridge the shortfall between dietary intake and the DRI, and to patients being treated for high fracture risk. Routine dietary calcium supplementation is not justified in terms of safety, efficacy and cost. Excessive calcium supplementation may be associated with increased cardiovascular risk, renal calculi and constipation.

DRI of Vitamin D is 800-1000 IU in postmenopausal women.

Other meds for osteoporosis:

Biophosphonates

Inhibit bone reabsorption, proven efficacy in prevention of bone and hip fracture. Has been associated w safety issue of femur shaft fracture d/t over-suppression of bone turnover in those exposed longer than 3-5 yrs. Drug free period could be considered after 3 years provided T score is > -2.5 and no fracture. Osteonecrosis of jaw rare

SERM's ((selective estrogen receptor modulators, raloxifine and bazedoxifine) reduce vertebral fracture in postmenopausal women, and hip fracture in some women.

Parathyroid hormone (PTH) anabolic agent significantly reduces vertebral fracture by stim bone formation. For severe cases osteoporosis for pts who fracture while on other therapy. Daily SQ injection for maximum of 18 months (then go to anti-reabsorbtive agent). Cost \$. Prior treatment with Biophosphonates blunts response

Strontium ranelate-reduces vertebral and non-vertebral fracture. Concerns of cardiovascular safety-severe osteoporosis only with low cardiovascular risk.

Denosumab-human monoclonal antibody to RANKL 60mg XQ q 6 monthly sig reduces vertebral, non-vertebral + hip fracture. Safe and well tolerated.

Complete: My Osteoporosis Worksheet (worksheet will include below and can be brought to 1:1 apt with NP)

My FRAX score is:

My risk factors for osteoporosis is/are:

I have done the following testing:

I take the following medications or supplements to prevent/minimize osteoporosis:

I am considering starting the following medication or supplement to prevent/minimize osteoporosis:

# 6:15-6:30

Participants pair off 1:1 and talk to each other about: My health strengths What are my biggest barriers to health self-care for CVD and/or osteoporosis?

# 6:30-7:00

1:1 Appointments with NP Review 2 worksheets

While waiting: Keep working on 2 worksheets

# Written materials in notebook:

Framingham FRAX tool My CVD Worksheet My Osteoporosis Worksheet

# Appendix G

# **Session 7: Maximize the Now and Next Steps**

# 5:00-5:40

Open agenda (write down agenda items on board). Group discussion.

# 5:40-5:45

Retake the MRS.

Has anything you've tried helped your menopausal symptoms? Group discussion

Looking Forward: How do I see my next years? Complete individual worksheet on priorities for self-care. Share 1:1 with person next to you.

# 5:45-6:15

Check Out: share something with the group about what you are excited about.

# 6:15-6:30

Formal ending of program. Positive ideas about menopause and next phase of life. Emphasize value of group support.

# 6:30-7:00

1:1 Appointments with NP.

While waiting:

**Program Evaluation** 

# Written materials in notebook:

Program evaluation MRS "Looking Forward" worksheet Useful websites: menopausematters.co.uk https://nccih.nih.gov/