5-8-2024

Improving Quality of Life in Menopausal Women Through a Best Practice Protocol: the Use of Hormone Therapy, Mindfulness-Based Module and Exercise

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IMPROVING QUALITY OF LIFE IN MENOPAUSAL WOMEN THROUGH A BEST PRACTICE PROTOCOL:

THE USE OF HORMONE THERAPY, MINDFULNESS-BASED MODULE AND EXERCISE

by

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Submitted to the College of Nursing and Health Professions

of Valparaiso University,

Valparaiso, Indiana

in partial fulfillment of the requirements

For the degree of

DOCTOR OF NURSING PRACTICE

2024

Student 05/05/2024 Date

Advisor 5/8/2024 Date

ACKNOWLEDGMENTS

I would like to thank my project advisor, Dr. Jamie Bump. I am very grateful for the guidance and expertise she has provided to make this project successful. I would also like to thank Dr. Christina Cavinder and Dr. Theresa Kessler for their support and wisdom throughout my program and project completion. I would like to thank the providers and staff at the clinical site where this project was implemented for making this project possible.

Most importantly I would like to thank my parents, Tracie and Christian, and my sister, Olivia for their continued support to continue in my doctoral education. I want to lastly thank my fiancé, Trey for unwavering love and support through all of the ups and downs I have experienced these past few years. Thank you all for believing in me.

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ABSTRACT

Menopause is a normal process of aging, but many of the symptoms negatively impact women's day-to-day quality of life (QOL), as well as activities of daily living, physical and mental health (ACOG, 2014). Generally, systemic estrogen hormone therapy is indicated for menopause-related vasomotor symptoms, but there is no research further addressing QOL issues or lifestyle management in addition to hormone therapy. The purpose of this evidence-base practice (EBP) project was to implement a menopause protocol to address QOL issues in menopausal women with the use of hormone replacement therapy, education through an online mindfulness module, and the use of exercise. Participants were recruited through convenience sampling from eligible patients at scheduled appointments. Ten women aged 46-58 years old from an outpatient private women's health clinic in Wisconsin participated in this project. Once recruited, participants completed a demographic form, a menopause-specific quality of life (MENQOL) survey and were given educational handouts (Appendix A). The intervention included the application of UCLA Mindful creation of an individual exercise program for the patient, and hormone replacement therapy (HRT). HRT was prescribed by the providers, based on patient eligibility and preference. Participants were monitored for a total of ten weeks, which included a check-in at five weeks. Post intervention, participants were readministered the MENQOL to determine effectiveness of the intervention. Pre and post intervention scores were evaluated using a paired sample *t* test. Overall, results of the MENQOL scores showed a significant large difference between pre intervention scores (M= 4.5, SD = 1) and post intervention scores (M= 3.8, SD = 0.8), t (9) = 2.9, p = 0.17. Findings from this project can inform future development of guidelines for provider use in the management of menopausal women and their symptoms.

Keywords: Menopause, quality of life, hormone replacement therapy, exercise, mindfulness

CHAPTER 1

INTRODUCTION

Background

Menopause is defined as the permanent cessation of menstruation that occurs after the loss of ovarian activity (ACOG, 2014). Menopause cannot be determined to have occurred until 1 year after the last menstrual period (ACOG, 2014). Most women will reach menopause between the ages of 45-64, with a mean age of 51 (ACOG, 2014). While menopause is a normal process of aging, it negatively impacts many women's day-to-day quality of life, and may negatively impact their activities of daily living, physical and mental health (Song et al., 2020). Menopause symptoms are a leading cause of why women seek medical treatment (Song et al., 2020). Symptoms associated with menopause have a wide range and can include prominently vasomotor symptoms such as hot flashes, anxiety, chills, and flushing. Other symptoms include insomnia, headaches, brain fog, aches and pains, lack of energy, vaginal dryness, dyspareunia, urinary frequency and urgency. (ACOG, 2014). Symptoms during menopause occur in up to 85% of women, while 20% of women report significant symptoms (O'Neil & Eden, 2017). Sleep duration and quality are important contributors to health quality and wellness.

Reproductive aging and menopause occur with loss of follicular activity (O'Neill & Eden, 2017). The endocrinology of the menopausal transition is very complex and varies between each woman (O'Neill & Eden, 2017). As a woman ages, her numbers of ovarian follicles will decrease. Due to the lack of inhibition from estrogen and inhibin on gonadotropins, follicle-stimulating hormone (FSH) and luteinizing hormone (LH) production will increase (National Library of Medicine, n.d.). FSH generally is higher in the blood than LH because LH is cleared from the blood faster. This decline in estrogen levels leads to a disruption in the hypothalamic-pituitary-ovarian axis, causing a failure of endometrial development. As a result, this will cause irregular menstrual cycles until the stop altogether (National Library of Medicine, n.d.). The pathophyslogy

of vasomotor symptoms, which are some of the most troubling for those during menopause, is still unknown (O'Neill & Eden, 2017, ACOG, 2014). It is thought that changes in reproductive hormones play a role in the hot flash, due to evidence showing that estrogen improvs these symptoms (ACOG, 2014). Menopausal age is the main health indicator, early menopause can increase the risk of osteoporosis, cardiovascular disease, and mental disorders, whereas late menopause is associated with a higher risk of mortality, acute cardiac ischemia and breast cancer (Khandehroo et al., 2022). The American College of Obstetrics and Gynecology (ACOG) practice guideline recommends that systemic estrogen hormone therapy (HT), with or without progestin should be used for menopause-related vasomotor symptoms (2014). However, ACOG does not further address QOL issues or lifestyle management in addition to HT. A multi-modal individualized protocol is needed to address these symptoms in menopause is recommended so women can improve their quality of life.

Data Supporting Need for the Project

Global, National, Regional Data

The mean global age that women will experience menopause is 51.7 years (Khandehroo et al., 2020). At the moment, there are around 850 million women aged 40-60, and 88% of this group will experience menopause (Zhang et al., 2021). The world population of menopausal and postmenopausal women is projected to increase to 1.2 billion by 2030, with 47 million new women beginning menopause each year (Khandehroo et al., 2020). Further, it is expected that menopausal and postmenopausal women will account for almost 60% of the population by 2060 (Zou et al., 2022). In the United States, around 6,000 women will reach menopause every day, roughly two million women each year (ACOG, 2014). In addition, 31 million women experience menopause related symptoms daily, which translates to nearly 20 percent of the American workforce (ACOG, 2014). It typically begins between the ages of 51 and 52 (National Library of Medicine, n.d.). The prevalence of menopausal symptoms in North America ranges from 36-50%, and the most common symptoms experienced are hot flushes, night sweats, insomnia,

vaginal dryness, mood disorders, and weight gain (ACOG, 2014). Among Caucasian women, self-reported QOL was higher in HRT-only users than in those who had to interventions (P = 0.30, d= 0.11, 95% confidence interval, 0.01-0.21). On the other hand, Black or African American women using HT only had lower self-reported QOL compared with those using no interventions (P=0.027, d=0.-.21, 95% confidence interval, -.040 to -0.02) (Christmas et al., 2022).

Clinical Agency Data

This EBP project was implemented in an outpatient women's health clinic, which is a private organization, located in Kenosha, Wisconsin. As of July 2023, the population is estimated to be 98,484 residents (United States Census Bureau 2023) with 51% estimated to be female (United States Census Bureau 2023). The adult population of this city is 69.4% (United States Census Bureau 2023). Kenosha primarily consists of Caucasians (73.2%), while African Americans make up 10.6%, and those identifying as Hispanic/Latino make up 18.4% (United States Census Bureau 2023). 89.8% have a high school diploma or higher and 27.4% have a bachelor's degree or higher (United States Census Bureau 2023). 8.9% report not having health insurance (United States Census Bureau 2023). This clinic serves primarily menopausal aged women, and there are around 30 patients seen by the two providers within this office per day (J. Garson, July 18, 2023). Approximately half of these women are seeking advice for menopausal treatment, and more than half are either in menopause or have completed menopause.

To determine priority level, the EBP project was discussed with the healthcare providers within the clinical agency. The two providers at the agency included a physician and nurse practitioner (NP), who were all supportive of the project idea and agreed that there was a need to better manage symptoms and quality of life in those women who are experiencing menopause. In communications with both providers, they believe that the interventions and approach would be feasible to conduct at the site and would result in benefit for women who are experiencing menopause, and improvement in their quality of life. The NP and MD, who are the sole providers at this clinic report that patients frequently seek advice on treatments that may improve their

menopausal symptoms, as well as on what may improve their quality of life through lifestyle management, not simply hormone replacement therapy (J. Arnold, personal communication, May 18, 2023).

Purpose of the Evidence-Based Practice Project

Purpose Statement and PICOT Question

The clinical question that led to the development of this project was, “What are the most effective interventions for managing menopausal symptoms, and therefore improving menopausal women’s quality of life? The purpose of this EBP project was to implement a menopause protocol to address QOL issues in menopausal women with the use of HRT, education through a mindfulness online module, and exercise. The PICOT question for this project was: In menopausal women aged 40-65 does a multi-modal intervention of pharmacotherapy, an online mindfulness course, and exercise improve patient’s quality of life scores over an 8-week period in the primary care setting?

EBP Project Description

The EBP project focused on implementing a multimodal intervention to improve quality of life in menopausal women. The intervention was a combination of pharmacotherapy, a mindfulness application on meditation, and implementation of an exercise program to improve quality of life in menopausal women. Mindfulness, which is a major component of cognitive behavior therapy and stress reduction has shown to have positive benefits in improving overall well-being and quality of life (Huberty et al., 2019). The mindfulness mediation aspect was delivered through an application entitled UCLA Mindful. Developed by UCLA Health, this application was designed to encourage mindfulness and meditation with guidance of the UCLA Mindfulness Awareness Research Center (MARC) (UCLA, 2023). This app was chosen because it was no cost to the participant and easy to use. Begin et al. (2022) noted that UCLA Mindful is an effective modality to delivery mindfulness mediation, focused on on stress reduction and mindfulness improvement. UCLA Mindful offers informative videos exploring how to begin a

practice of mindfulness, supportive meditations postures, and the science of mindfulness as well as wellness meditations for those suffering from health conditions. The app also has a built in timer for users to mediate on their own. Education was also provided to patients, through a FAQ from the International Menopause Society. The providers within the clinic prescribed HRT, specifically estrogen, based on patient eligibility and preference. Gaining in popularity, patients also requested to trial bioidentical hormone therapy, though there is evidence lacking to support the efficacy of this treatment over menopausal hormone therapy (ACOG, 2014). Participants were recruited in the office during their scheduled well-woman or menopause specific visits. Chart review was done around a week prior to determine which patients may be eligible, and patients were recruited the day of their visit. The MENQOL was the measurement tool used to determine pre- and post- intervention quality of life (QOL). When a patient came to the office with symptoms of menopause or was in the age range of menopause and eligible, the project leader asked the patients if they would like to participate in the project. Description of the project, timeframe, interventions, and education were provided to the patients at this time, as well as implementation of the pre-intervention MENQOL survey (See Appendix A), which was similar to the survey already implemented in office for menopausal women. Patients were then given the menopause FAQ and given instructions on how to download the UCLA Mindful mobile app. Participants began in the tab labeled “getting started” where they were able to view introductory mindfulness videos. Participants were free to use the basic mediations or wellness meditation to fit to their specific goals. Participants were asked to mediate or use the app for at least 10 minutes each day due to previous research showing improvements in mental health with this timeframe (Hubery et al., 2019). Participants were also informed about exercise benefits in the menopause period and encouraged to participate in regular exercise. The goal for participants was to be exercising at least 30 minutes every other day by the end of the intervention period. The project leader followed the patients over the course of ten weeks. At the halfway mark, the project leader contacted the participants by phone or text to follow up with how the intervention

was progressing and answer any questions. The MENQOL was then re-administered at the end of the intervention period. The pre- and post-scores were examined following the end of the implementation phase.

CHAPTER 2

EBP MODEL AND REVIEW OF LITERATURE

Evidence-based Practice Model

Overview of EBP Model

The model chosen for this EBP project was the Iowa EBP model. This Iowa Model was developed to serve as a guide for nurses to use research findings to help improve patient care (Duff et al., 2020). The model was developed 25 years ago by nurses at the University Iowa Hospital and faculty from the University of Iowa College of Nursing. The model underwent a significant review and revision in 2017 (Duff et al., 2020). The model is rooted in the Diffusion of Innovations Theory and the Quality Assurance Model Using Research, with the intent to promote quality care through research utilization (Duff et al., 2020; Hanrahan et al., 2019). The Iowa Model is a systemic process consisting of seven steps: identify triggers or a clinical issue; state the purpose or ask a question; form a team for the project; find and appraise the evidence on the topic; design and test the practice change; incorporate change long term; and share the results (Melnyk & Fineout-Overholt, 2019).

In step one, a problem or knowledge focused trigger is identified that initiates a need for change. Problem-focused triggers may be clinical problems whereas knowledge triggers may involve practice guidelines or new findings in research (Haxton et al., 2012). After this, a team is formed, and relevant literature is identified and reviewed. An important process in these steps is the critiquing process. It is at this stage that the team determines if there is a sufficient research base that warrants the implementation of an intervention (Haxton et al., 2012). If there is sufficient evidence, the team then takes steps to implement that practice change on a pilot basis. After the pilot, it is determined through the team if the change should be permanently adopted into practice (Haxton et al., 2012). Through this feedback loop, if it is chosen for the change to result in permanent practice, education is implemented, as well as data monitoring over a long-

term basis (Haxton et al., 2012). This last step is the most important to the promotion of long-term change through evidence-based practice throughout the healthcare system (Melynk & Fineout-Overholt, 2019).

The Iowa Model has been successfully used to improve nursing practice in many different care settings across the world (Haxton et al., 2012). This means that the model is able to adapt to many different settings and clinics. Due to the small size of the clinic where the EBP project was conducted, the Iowa Model is appropriate for the implementation. The Iowa Model also provides clear directions and steps to follow, making it a useful tool for this project. Menopause and menopause-related symptoms are very evident in women 40-65 years old, and interventions to help manage these symptoms while improving quality of life was heavily supported by key stakeholders at the clinical site, as in accordance with the Iowa Model.

Literature Search

Sources Examined for Relevant Evidence

An exhaustive initial search of library databases, including Joanna Briggs Institute (JBI), Cochrane Library, CINAHL, MEDLINE with Full Text (via EBSCO), and Turning Research into Practice (TRIP), was conducted to identify interventions for improving menopausal quality of life as shown in Table 2.1 This search was completed after trialing many different keywords within each database, and with the assistance of the Research Services Librarian at Valparaiso University. The search terms were eventually narrowed down and searches were finalized across all databases. Each database was searched using the date range limiter 2018-2023. Following the initial searches for best practice interventions, each article within the search was evaluated for relevance to the project and was compared against inclusion and exclusion data. Inclusion data also consisted of articles published in English, with scholarly, peer-reviewed publications, and interventions that focused on improving quality of life, interventions included lifestyle and pharmacological modification. Exclusion criteria consisted of studies that focused solely on medically induced menopause, patients with cancer, or patients pre- or -post

menopausal. To further select articles for inclusion, full articles were reviewed for the use of multi-modal interventions or guidelines for more than one treatment, due to the nature of the project and proposed intervention.

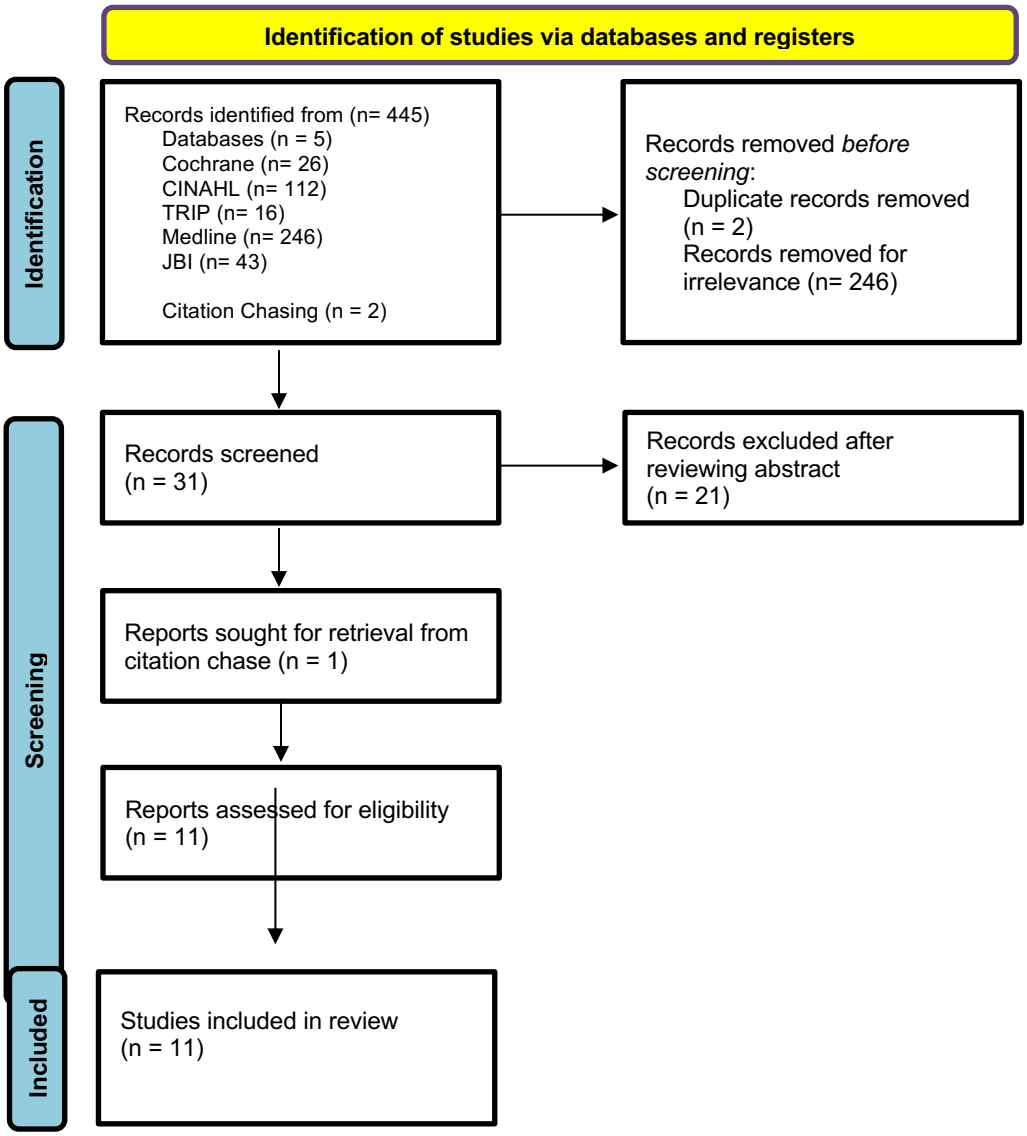
Database Searches and Key Words

The JBI search was simple, the keyword was menopausal. This search yielded 43 results. Four articles were selected after review of their abstracts. After application of inclusion and exclusion criteria, one article was chosen for the review (Ombech, 2022). The search was similar in Cochrane, with the keyword used being menopause. Both of these databases required simple searches due to quality of life in menopausal women not being a frequently studied topic, and both journals requiring a broader search strategy. In Cochrane, 26 articles were identified, but no articles were deemed relevant for use due to lower quality and irrelevance to the topic of interest. Within TRIP, a title search included: menopause AND (manage* OR treat* OR intervent*) and this search yielded 16 guidelines (11 UK, 4 USA, and 1 other). Three guidelines were selected for potential inclusion. After further analysis of the selected articles, two CPGs were selected for final inclusion in this review (NAMS, 2022; RCM, 2020). Lastly, the databases of CINAHL and MEDLINE with full text via EBSCO were searched. Due to the high number of results in both databases, the major headings were included in the search, and MM “quality of life” was added to the search terms. The final search of CINAHL used the keywords, (MM “quality of life”) AND menopaus* AND treat* OR intervent* OR manage* OR therap*, with additional limiters being scholarly (peer reviewed journals, English language and research article. This final search resulted in 112 results. Of these results,15 were selected for their relevance to the topic. After going through each article and further examining the results, two articles were selected for inclusion (Beni et al., 2022; Zou et al., 2022). The MEDLINE search mirrored the search in CINAHL, using the subject heading and keywords: (MM: “quality of life”) AND menopaus* AND treat* OR intervent* OR manage* OR therap* with additional limiters of English language and scholarly (peer reviewed) journals. This resulted in 246 results. Of the 246 results,

11 articles were handpicked for further analysis. After examining and appraising these individual articles, four were selected for inclusion in this review (Shorey et al., 2019; Li et al., 2023; Diem et al., 2020; Ye et al., 2022). To further the original searches conducted in the databases, both citation chasing, and an examination of a common journal (*Menopause)* published between 2019-2023 were conducted to discover additional relevant evidence. Two articles from multiple citation chases were chosen (Taebi et al., 2018; NICE, 2019). The search of each database was performed and documented, with assistance from the Research Services Librarian. In total, 11 articles were chosen for the final EBP project literature review. Figure 2.1 demonstrates the identification and screening of studies that are included in this review.

Figure 2.1

PRISMA Diagram of Literature Search



Levels of Evidence

To determine the levels of evidence for use in the literature review, the Melnyk and Fineout-Overholt (2019) hierarchy of evidence tool was used. This tool was chosen due to the hierarchy portraying evidence that is able to be generalized to the broader population with low risk of bias (Melnyk Fineout-Overholt 2019). Each piece of evidence was assigned a level I-VII according to the study design (Melnyk Fineout-Overholt 2019). Of the 11 pieces of evidence

selected, seven fell into Level I, which is the highest level of evidence. This includes systematic reviews and meta-analysis of randomized controlled trials (RCT), or clinical practice guidelines. The levels of evidence included for this review consisted of one evidence summary (Ombech 2022), three CPGs (NAMS, 2022; RCN, 2020; NICE, 2019 and three systematic reviews (Shorey et al., 2019; Zou et al., 2021; Taebi et al., 2018). Level II evidence is evidence from one or more well-designed RCTs. Three pieces of evidence fell into this category (Ye et al., 2022; Diem et al., 2020; Beni et al., 2022) Level III evidence consists of controlled trials without use of randomization. One article was chosen for its strong quality and relevance to the interventions (Li et al., 2023). Level IV evidence is most often case-control or cohort studies. Level V evidence is systematic reviews of descriptive and qualitative studies. Level VI evidence is a single descriptive or qualitative study. Lastly, Level VII evidence is an expert opinion. No level IV, V, VI, or VII evidence was chosen for inclusion. As identified in Table 2.1, only level I-III evidence was chosen for this project.

Analysis and Appraisal of Relevant Evidence

After rating selected articles by level of evidence, each article was appraised. Two different tools were used to critically appraise and determine the quality of evidence selected from the extensive literature search. The Appraisal of Guidelines for Research and Evaluation (AGREE II) was used to assess the quality of the level I practice guidelines that were published by the North American Menopause Society (2022), Royal College of Nursing (2020), and the National Institute for Health and Care guidelines (NICE) (2019). AGREE II was chosen for these guidelines because of the purpose to assess the quality of guidelines, provide a methodological strategy for the development of guidelines, and inform what information and how information should be reported in guidelines (Brouwers et al., 2017). The other tool that was used in article appraisal was the Johns Hopkins tool. This tool was chosen because of the familiarity and ease of use. This tool was used to appraise was used to appraise the rest of the evidence included in this project. The Johns Hopkins tool ensures that all important factors are taken into account and

provides a framework that increases consistency in decision making, focusing on validity, reliability, and applicability. Both of these tools were also chosen because of their accessibility and helped to identify quality evidence for inclusion in this review, as well as facilitating in identification of strengths and limitations of each article. The evidence selected was graded as high or good quality. See Table 2.1 for the summary of evidence level, quality, as well as the appraisal tools used.

Table 2.1

Summary of Evidence

Author/yr	Database(s)	Level of Evidence/Type	Quality/Tool
Beni et al. (2022)	CINAHL	II/ RCT	High/ John Hopkins
Diem et al. (2020)	MEDLINE	II/RCT	High/John Hopkins
Li et al. (2023)	MEDLINE	III/NRC	High/John Hopkins
NAMS (2022)	TRIP	I/Guideline	High/AGREE II
Ombech (2022)	JBI	I/Summary	High/John Hopkins
NICE (2019)	CC	I/Guideline	High/AGREE II
RCN (2020)	TRIP	I/Guideline	High/AGREE II
Shorey et al. (2019)	MEDLINE	I/SR	High/ John Hopkins
Taebi et al. (2018)	CC	I/SR	Good/ John Hopkins
Ye et al. (2022)	MEDLINE	II/RCT	Good/ John Hopkins
Zou et al. (2022)	CINAHL	I/SR	High/ John Hopkins

Note: NRC= non-randomized control; CC= citation chased; CS= cohort study

Construction of Evidence-based Practice

Synthesis of Critically Appraised Literature

The North American Menopause Society, Royal College of Nursing, and National Institute for Health Care recommend that hormone replacement therapy as a pharmacologic intervention is beneficial for relieving menopausal symptoms, and in turn may increase quality of life. However, it is also noted that individual approaches to symptom management should be incorporated, while evaluating both the risks and benefits of hormone replacement therapy. Various pharmacologic and non-pharmacologic interventions were identified throughout the literature. A notable amount of research has been conducted on both pharmacologic and non-pharmacologic therapies, but there is still a gap in research done on the quality of life in menopausal women. In addition, many women cannot, or will refuse hormone replacement therapy (HRT), so non-pharmacologic therapies are a necessary component of menopausal management. Women also often will opt for therapies such as bioidentical hormone therapy or pellets. After critically appraising the evidence, the following themes were selected for synthesis: hormone replacement therapy, mindfulness or CBT practices, and exercise.

Hormone Replacement Therapy

Research shows that HRT, most specifically low dose estrogen plus progesterone formulations, have been shown to be the most effective treatment for vasomotor symptoms (VMS) caused by menopause, including hot flashes and night sweats. (NAMS, 2022; Ombrech, 2022; RCN, 2020, NICE, 2019; Taebi et al., 2018, Ye et al., 2022; Diem et al., 2021). Typically, these VMS or physical symptoms are the most bothersome quality of life concern (Diem et al., 2021, NAMS, 2022). HRT has been shown to prevent bone loss and fracture and improve genitourinary syndrome of menopause (NAMS, 2022). In addition, sleep disturbances are strongly associated with these VMS and a decreased quality of life (NAMS, 2022). Multiple double-blind RCTs have shown that HRT relieves VMS, and is FDA approved as a first-line

treatment of VMS due to menopause (NAMS, 2022). Several algorithms are available for facilitation of safe selection of HRT for VMS (Ye et al., 2022; RCN, 2020).

Benefits and Risks

Hormone replacement therapy should be used with a clear understanding of the risks versus benefits (NICE, 2019). For women who are younger than 60 years old within 10 years of menopause onset, with no contradictions, the benefit-risk ratio is favorable for the use of HRT (NAMS, 2022). Benefits of HRT include relief of VMS, relief of some psychological symptoms, reduced urogenital atrophy, reduction in osteoporotic fracture and reduced incidence of colorectal cancer (RCN, 2020; NICE, 2019). On the other hand, HRT does come with risks, including venous thrombosis, stroke, an increased risk of breast cancer and cardiovascular events (RCN, 2020; Li et al., 2022). Monitoring of women on HRT should take place every three months until they are stable, then yearly after this (RCN, 2020). It is crucial to provide women with information on the benefits and risks of HRT, so they are able to make an informed choice about what treatment to use for menopausal symptoms (NICE, 2019).

Education

Education has many benefits for menopausal women, including improved menopausal symptoms and quality of life, as well as increase in awareness and attitude (Taebi et al., 2018; Li et al., 2022). Much of the literature assessed revolves around educational interventions including seminars, cognitive behavior therapy (CBT), and individualized lifestyle education (Tabei et al.,2018; Li et al., 2022; RCN, 2022; Zou et al., 2022). Lifestyle education can also play a key component on women's health and quality of life during menopause (RCN, 2020).

Li et al. (2022) assessed the effect of multidisciplinary health education on menopausal symptoms and lifestyle behaviors of menopausal women over a two month period. One intervention included multidisciplinary health education to enhance the awareness of the women, while improving positive attitudes towards menopause and further treatment options. The menopausal syndrome of participants was significantly improved in the intervention group (Li et

al., 2022). Tabei et al. (2018) conducted a systematic review with studies on educational programs and quality of life. Improvement of quality of life was noted after 8-12 weeks of education. Education included speech and educational films, support groups, group discussions, relaxation and coping techniques (Tabei et al., 2018). The results indicated the effectiveness of education on menopausal women (Tabei et al., 2018). Beni et al. (2022) conducted an RCT that noted self-care education significantly improves menopausal women's quality of life and health-related outcomes.

Mindfulness

Mindfulness practices, such as cognitive behavior therapy and meditation have shown efficacy in reducing VMS, as well as improving sleep and mood disturbances (Ye et al., 2022, RCN, 2020). CBT is often used to address many different problems in menopause to help patient translate their experience into a positive action or action plan (RCN, 2020). CBT also may help women deal with events that may be contributing to anxiety (RCN, 2020). Telephone and Internet-based CBT is recommended due to accessibility and affordability of treatment (Ye et al., 2022). Zou et al. (2022) conducted a systematic review on the effects of virtual interventions for menopause management. Of the 16 articles reviewed, three focused on internet-based CBT (iCBT) with findings showing high adherence rates and decreased menopausal symptoms, including VMS (Zou et al., 2022). Each study intervention lasted approximately 10-12 weeks (Zou et al., 2022).

Lifestyle Education

Reviewing individualized lifestyle plans with women while explaining normal menopausal changes can help women feel more comfortable in the transition to menopause (RCN, 2020). Examples of areas to cover include smoking status, alcohol consumption, and reduction in the impact of symptoms (RCN, 2020). Nutrition is important, and the diet of menopausal women should be low in fat, low in salt, and rich in calcium (RCN, 2020). A balanced diet will also ensure an adequate intake of essential minerals and vitamins (RCN, 2020). Symptoms can be caused

by diet, such as hot flushes triggered by eating spicy foods or drinking alcohol and caffeine (RCN, 2020). Diet education can help women control an aspect of what may be causing troubling menopausal symptoms (RCN, 2020).

Exercise

Literature has shown that healthy lifestyle has improved quality of life in menopausal patients (Li et al., 2022, Zou et al., 2022). Lifestyle modification in the literature revolves around the main component of exercise (Shorey et al., 2020, RCN, 2020). Physical activity, especially aerobic exercise, can improve the quality of life in menopausal women by decreasing the symptoms of menopause (Taebi et al., 2018). RCN (2020) notes that regular exercise is critical to for menopausal women to remain active, healthy and independent, with the recommendation that exercise should be practiced at least 30 minutes 5 days a week for maximum benefit. Examples of excersie that are recommended include walking, dancing, aerobics, tennis, yoga, cycling, and swimming (RCN, 2020; Shorey et al., 2020). Yoga has been associated with improvements in menopause-related quality of life (Diem et al., 2020). Exercise can improve quality of life, general wellbeing, mood, stamina and fitness (RCN, 2020). To add, exercise was shown in a study to improve on the MENQOL scale physical function compared to control (Diem et al., 2020).

In the systematic review conducted by Shorey et al. (2020), most studies used an exercise-based intervention. The durations of the interventions ranged from 1 week to 24 weeks (Shorey et a., 2020). Interventions included walking-based interventions, Pilates or yoga, high-impact and strengthening exercises, dance, and full exercise programs. Of the five studies and six interventions that examined quality of life as an outcome, a significant effect was found for exercise-based intervention (Shorey et al., 2020). Results from these reviews also showed a large intervention on exercise based interventions on reducing menopausal symptoms (Shorey et al., 2020). Taebi et al. (2018) conducted a systematic review as well, with results showing that aerobic and walking exercises are effective in the improvement of not only the general quality of

life in menopausal women, but vasomotor, mental, social, physical, and sexual symptoms of menopause as well. Most trials were 8-12 weeks long and focused on aerobic exercise at least three times a week (Taebi et al., 2018).

Recommendation for Best Practice

According to the synthesis of evidence, hormone replacement therapy, mindfulness modules and practices, and exercise are the interventions that are best supported by the research to be effective at treating menopausal symptoms, and therefore improving quality of life in these patients. The EBP project aimed to utilize the protocol combining these interventions to provide best practice care to each patient. Hormone therapy is recommended by numerous organizations, including the American College of Obstetricians and Gynecologists, as the gold standard treatment for menopause and bothersome symptoms, but not every patient wants pharmacological therapy or is a candidate, or patients opt for other forms of pharmacologic treatment. Due to this, a multimodal approach to menopausal treatment was conducted. For the mindfulness/CBT therapy intervention portion, online apps were shown to be most cost and time efficient for usage and were recommended for use by the participants throughout the 10-week period of intervention. Patients were encouraged to complete at least a 10-minute mindfulness session using the UCLA Mindful app daily. Patients were given an educational handout from the International Menopause Society. Patients were informed about the benefits of exercise in the menopausal period. Exercise is recommended 3-5 times per week, specifically aerobic activity. The first two to three weeks patients were informed to start with 20 minutes of exercise two to three times weekly. If stable, patients were able to progress to 30 minutes three to four times weekly, with an increase in duration and intensity. Other activities such as yoga and Pilates were encouraged. A baseline assessment of menopausal quality of life was obtained before and after implementation of interventions through the use of the Menopause-Specific Quality of Life Questionnaire (MENQOL) (See Appendix A). This tool assesses four different domains; vasomotor, psychosocial, physical, and sexual, and is also considered a valid scale for

evaluating the quality of life in menopausal women that has been used in numerous studies (Diem et al., 2021; Ye et al., 2022; Taebi et al., 2018).

CHAPTER 3

IMPLEMENTATION OF PRACTICE CHANGE

During the planning phase, the project manager met with key stakeholders, mainly both providers at the clinic, in person and by telephone, to discuss potential issues and topics to address in the project. DNPs are able to recognize a need for change, so they are able to improve patient outcomes. Based on the supporting recommendations within the literature, the DNP student developed a multimodal intervention involving pharmacotherapy, an online mindfulness application, and an exercise program to manage menopausal QOL as measured by improved MENQOL scores. When the identified issue was agreed on as a high priority for the clinic and location, the project manager prepared to plan for the implementation of the project. After input from stakeholders, it was decided that the intervention will include counseling on lifestyle management and modification, including exercise, HRT, if eligible and agreed upon, and use of a mindfulness-based program. A Powerpoint and binder was used to organize information and educate stakeholders about the project. Throughout the planning process and future intervention process, feedback from key stakeholders was considered and revisions were made to the planned implementation protocol.

Participants and Setting

This EBP project took place in Kenosha, Wisconsin at a women's health primary care office that serves adult, female patients. The key stakeholders at this clinical agency included a physician with over 25 years of experience, and a NP with 15 years of experience. The current practice had a menopausal questionnaire that is administered to women of menopausal age that is similar to the MENQOL, but less specific. There was no set protocol for how to treat the patient based on menopausal symptoms, each patient was treated on an individual basis. Other key stakeholders included two medical assistants (MA) and the office manager. The physician at the site was agreeable to be the project facilitator.

Pre-Intervention Group Characteristics

The population of interest for this project is women aged 45-64 who are in menopause and experiencing menopausal symptoms, with compete cessation of menstruation in the last 12 months. Patients who were not in natural menopause were deemed ineligible for this study (hysterectomy or oophorectomy). Patients also had to be literate, with access to a smart phone. Patients who fit this criterion completed a cost/benefit analysis for HRT through a shared decision-making process with the providers. There were no restrictions regarding ethnicity or current medication usage. Exclusion criteria included inability to participate in data collection activities, disclosure of illicit drug use, pregnancy, and/or a medically restricted diet and excersie program. A convivence sample of patients was identified and patients were agreeable to participate in the project during well-woman or menopause-specific visits. Demographic data was heavily based upon those collected in the literature (Hilditch et al., 1996) (Appendix B).

Intervention

The intervention to address menopausal quality of life was a combination of treatments based on a systemic and through synthesis of evidence (Beni et al., 2022; Diem et al., 2020; Li et al., 2023, NAMS, 2022; NICE, 2019; Ombech, 2022; RCN, 2020; Shorey et al., 2020; Taebi et al., 2018; Ye et al., 2022; Zou et al., 2022). This intervention consisted of a three-part series including hormone therapy if deemed eligible, a mindfulness module application, and an exercise recommendation. Throughout the planning process, the project manager retrieved information regarding different tools useful for the interventions. From the project leader's clinical experience and research at this site, patients did not have a set exercise program or mindfulness education recommendation. This was identified to most likely due to time constraints, availability of providers, and lack of resources. For this reason, the project implementation had to be one that was not time consuming or hard to fit into the day to day office routine.

The project manager met with the project site key stakeholders to further discuss how patients will be screened and recruited for the project. Female patients in active menopause

were identified as possible participants. Before furthering the project intervention, the providers did have final say in the patients who were included in the intervention. When approved, the patients were asked by staff or the project leader to complete the MENQOL assessment tool. Licensure to use the assessment tool was obtained through ePROVIDE (Mapi Research Trust) on July 15, 2023 (See Appendix D).

Interventions were conducted by the DNP project leader. Education about the menopause process was combined with lifestyle education changes to improve knowledge, self-efficacy, and symptom management skills. An educational handout was also provided to participants discussing common questions about menopause. In addition, the participant was asked to complete 10-minute sessions on the mindfulness application and follow the exercise program as indicated. The participant was reminded that routine follow up will be conducted, and the project leader will be available as needed to answer any questions. Lastly, participants were told that at the end of the intervention portion the participants would be asked again to complete the MENQOL questionnaire.

The providers at the clinic prescribed pharmacotherapy to those that agree to participate in the project and have met criteria for starting medication. Education on hormone replacement therapy was provided by both the providers and the project leader to describe how HRT works, side effects, and dosage. The participants will take the prescription as prescribed. If there are any concerns about the pharmacotherapy portion, the participants were instructed to contact their provider.

Comparison

During conversations with the NP and MD at the clinic, it was clear that there was no protocol put in place in regard to menopausal women that related to their quality of life prior to project implementation. Per a conversation with the NP, education and treatment focused on targeted symptomatic treatment, and was not multi-modal. The NP and MD have voiced their opinion on a need for a protocol to examine what can improve quality of life in menopausal

women, and both reported a lack of emphasis on menopausal women and understanding their symptoms in general (J. Arnold & J. Thompson, personal communication, May 17, 2023). After this opinion was shared and a review of literature was conducted, an area for practice improvement among menopausal women was identified. Pre-intervention comparison data, the MENQOL, was obtained during the initial in-office visit. This score was then compared with the post-intervention MENQOL at the conclusion of the intervention.

Outcomes

The primary outcome of the EBP project is increased quality of life as shown on the MENQOL scores before and after intervention. These MENQOL scores will be recorded pre and post-intervention in office on paper. The MENQOL was established in 1996 as a tool to assess health-related quality of life and is widely used in practice. The MENQOL itself consists of 29 total items in a Likert-scale format (Radtke et al., 2012). Each item assesses the impact of one of four different domains of menopausal symptoms, as experienced by the patient over the last month. These domains include; vasomotor, psychosocial, physical, and sexual (Radtke et al., 2012). It has been shown that if vasomotor symptoms are controlled, quality of life often improves as well (Diem et al., 2021; Ye et al., 2022; Taebi et al., 2018). The majority of the evidence used for this project used this measurement tool and it has been validated as effective and reliable among women experiencing naturally occurring menopause. The secondary outcome assessed was decrease in vasomotor menopausal symptoms. Data was collected and managed on an Excel spreadsheet. Pre- and post-intervention data was analyzed using an paired sample t test. Demographics collected from the patients who agreed to participate in the project was also be managed on an Excel spreadsheet and was reviewed for trends relating to demographics.

Time

The project manager began recruitment in late August 2023, coinciding with the beginning of Valparaiso University's fall semester. Prior to the implementation phase, the DNP

student developed the project over summer 2023, prepared educational handout folders, and a PowerPoint for the staff and will end by beginning of September 2023. A goal of around 15 participants was set at the beginning of the intervention phase. The project was implemented during October and November of 2023, and the timeline was set at 10 weeks to complete the implementation phase of the project to avoid interference with the holidays in November and December. The implementation phase of the project finished prior to the spring 2023 semester at Valparaiso University. See Appendix C for the implementation timeline.

Protection of Human Subjects

A major priority during this project was the protection of human subjects. The project leader completed IRB training about the protection of human subjects through the Collaborative Institute Training initiative before any project implementation or developing the intervention. IRB exemption was obtained because this is an evidence-based practice project, and original research is not being implemented. This exemption was obtained through the Valparaiso University Institutional Review Board. The participants were made aware that their participation was voluntary and that they were able to withdraw from participation at any time. All participation and data that was collected was done so confidentially. This was upheld through a laptop that was, and still is, double password protected. Each password was only known by the project leader. Hard copies were kept and locked in an office at the clinical site. Any information collected was only accessible to the project manager and clinicians on site. Furthermore, outcome data was only reported in aggregate form, and no identifiable information regarding any patient was or will be released or disclosed.

CHAPTER 4

FINDINGS

The purpose of this EBP project was to improve quality of life in menopausal women, through research and implementation of the most effective best practice protocol. The intervention included the screening of menopausal women who were experiencing bothersome menopausal quality of life symptoms. Each participant also partook in a cost-benefit analysis if they were eligible and willing to participate in HRT. If participants were a fit for the project, they were invited to participate in the 10-week multimodal best practice protocol including mindfulness, exercise, and optional HRT, if indicated. Participants were assessed both before and after the intervention with the MENQOL survey. The PICOT question for this project was: In menopausal women aged 40-65 does a multi-modal intervention of pharmacotherapy, an online mindfulness course, and exercise improve patient's quality of life scores over an 8-week period in the primary care setting? The primary outcome of this project was to assess for increase in quality of life through the use of the MENQOL assessment tool. The secondary outcome measured was a reduction in vasomotor symptoms. This data was also collected though use of the MENQOL. This chapter provides the results of the data analysis conducted on participant demographics, and well as the pre-intervention and post-intervention MENQOL questionnaire scores, and correlation between statistically significant variables.

Participants

A total of 15 participants were identified as eligible to participate in the project; all were agreeable. The post-intervention group consisted of 10 female, white, menopausal women who completed the intervention of the project. Five participants were started on HRT at the initial meeting per EBP and HRT guidelines adhered to at the project site, but only three completed HRT throughout the intervention period. Three patients were lost to a different form of hormone therapy, bioidentical hormone replacement therapy.

Participants filled out a demographic questionnaire to collect demographics on age, race, smoking status, education, marital status, exercise weekly, and menopausal state. The age of the pre-intervention comparison group was between 46 and 58 (M = 53.1 SD = 5.08). The post-intervention group included women between the ages of 46 and 58 (M= 53.9, SD= 4.04).

The pre-intervention comparison group consisted of 15 Caucasian women and the post-intervention group consisted of ten Caucasian women. The race was the same in the pre-intervention and post-intervention group. The education level of the post-intervention participants included 1(10%) high school education, 2 (20%) some college, 6 (60%) college degree, and 1 (10%) doctorate degree. The smoking status of the post intervention group included 2 (20%) smokers and 8 (80%) non-smokers. The martial status of the post-intervention group included 1 (10%) single, 7 (70%) married, and 2 (20%) divorced. 5 (50%) of the post-intervention participants reported that they exercised less than twice a week, 3 (30%) reported exercise two or three times weekly, and 2 (20%) reported exercise three to four times weekly. 4 (40%) of post-intervention participants began menopause less than five years ago, whereas 6 (60%) began menopause in the last five years.

Two providers were employed at the clinic, both who participated in patient recruitment and project implementation. Refer to Table 4.1 for pre-intervention and post-intervention demographic data. See Appendix B for the patient demographic form.

Table 4.1

Demographic characteristics

Characteristic	Baseline *n* = 15	10 weeks *n* = 10
Age (*M*)	53.1	53.9
Age (*SD)*	5.08	4.04
Gender		
Female	15 (100%)	10 (100%)
Race		
Caucasian	15 (100%)	10 (100%)
Black or African American	0	0
Hispanic/Latino or Spanish Origin	0	0
Native American or Pacific Islander	0	0
Asian	0	0
Smoker		
Yes	4 (26.6%)	2 (20%)
No	11 (73.3%)	8 (80%)
Education		
Highschool diploma	2 (13.3%)	1 (10%)
Some College	2 (13.3%)	2 (20%)
College Degree	10 (66.7%)	6 (60%)
Doctorate	1 (6.7%)	1 (10%)
Martial Status		
Single	2 (13.3%)	1 (10%)
Married	10 (66.7%)	7 (70%)
Divorced	3 (20%)	2 (20%)
Exercise per week		
<2 times weekly	8 (53.3%)	5 (50%)
2-3 times weekly	4 (26.6%)	3 (30%)
3-4 times weekly	3 (20%)	2 (20%)
Postmenopausal state		
Less than 5 years ago	8 (53.3%)	4 (40%)
Over 5 years ago	7 (46.7%)	6 (60%)

Changes in Outcomes

Both the primary and secondary outcomes were measured using the MENQOL survey (see Appendix A). The 29-questionnare assessment assessed menopausal symptoms divided into four domains, vasomotor (3 items), psychosocial (7 items), physical (16 items), and sexual (3 items). For each item of MENQOL, scoring was done according to the guidelines, from 1 to 8. The scores were then added, and the mean score was calculated. Interpretation of level of QOL was made based on the mean score, 1-2 (no effect on QOL), 2-4 (mild decline in QOL), 4-6 (moderate decline in QOL), and 6-8 (severe decline in QOL). A paired sample t-test was used to examine the results of pre-intervention and post-intervention score for statistical significance.

Statistical Testing and Significance

All data was entered into the Statistical Package for the Social Sciences, also known as SPSS, for analysis. The project leader used the SPSS step-by-step guide by Cronk (2020) to perform analysis and interpret the results. Data was analyzed using a paired sample t-test to best address the PICOT question. The paired sample t-test was an appropriate test to assess the difference in mean score, interval, or ratio data, between two related samples (Cronk, 2020). Descriptive statistics of both the primary and secondary outcomes served to determine statistical significance. The participants operated as their own comparison for the primary and secondary outcomes. A Chi squared test was conducted to assess the relationship for statistical significance between pharmacotherapy (HRT) and MENQOL scores.

Analysis of the Instrument

A Cronbach's alpha is a measure of internal consistency and determines if homogeneity exists between all items on a questionnaire measuring the same concepts (Cronk, 2020). Therefore, the Cronbach's alpha was performed to determine the internal consistency of the MENQOL survey tool used at baseline and week ten. The Cronbach's alpha score determined that the MENQOL had excellent internal consistency (α – 0.94).

Findings

Primary Outcome

Mean MENQOL Scores from Baseline to Ten Weeks. A paired sample t test examined the MENQOL pre-intervention and post-intervention scores (Table 4.2). The primary outcome of this project demonstrated a statistically significant decrease in MENQOL scores of women with bothersome menopausal quality of life symptoms who had participated in a 10-week multimodal best-practice model ($t(9) = 2.9$, $p = .017$) (see Table 4.3). The mean score on the pre-intervention screening was 4.5 (SD = 1) and the mean score at the 10-week post-intervention follow up was 3.8 (SD = 0.8).

Table 4.2

Participant Mean MENQOL Scores

	Pre-intervention (Baseline)	Post-intervention (10-weeks)
1	4.7	4.2
2	5.3	4.5
3	4.5	3.1
4	5.4	4.4
5	5.4	4.4
6	4.2	4.9
7	2.9	2.7
8	5.4	3.5
9	3.5	3.0
10	3.2	3.1

Table 4.3

Paired t tests comparing baseline MENQOL scores to 10-week MENQOL scores

	Mean (*SD*)	*t*	*df*	*p*
MENQOL Survey		9	2.9	0.017
Pre-Intervention	4.5 (1)			
Vasomotor	4.2 (1.7)			
Psychosocial	4.2 (0.9)			
Physical	5.1 (0.8)			
Sexual	4.2 (1.9)			
Post-intervention	3.8 (0.8)			
Vasomotor	3.7 (1.4)	9	1.5	.171
Psychosocial	3.8 (1.1)	9	2	.76
Physical	3.8 (1.1)	9	3.8	.004
Sexual	3.5 (2)	9	1.5	.162

Secondary Outcome

Mean Categorical Scores from Baseline to Ten Weeks. A paired sample t test was also conducted to examine the pre- and post- intervention scores on each category on the MENQOL assessment tool. The categories included vasomotor, psychosocial, physical, and sexual. The most impactful domain pre-intervention were physical symptoms, while post-intervention psychosocial and physical were tied for most impactful. The mean pre-intervention and post-intervention vasomotor scores were 4.2 (SD = 1.7) and 3.7 (1.4), respectively. The reduction in vasomotor scores was not statistically significant (t (9) = 1.5, p = .171). The mean psychosocial pre-intervention score was mean 4.2 (SD = 0.9), while post-intervention score mean was 3.8 (SD = 1.1). The reduction in psychosocial score was not statistically significant (t (9) = 9 = 2, p =.76). The mean physical pre-intervention score was 5.1 (SD = 0.8) while the mean post-intervention score was 3.8 (1.1). The reduction in the physical domain was statistically significant (t (9) = 3.8, p <0.05). Lastly, the mean sexual pre-intervention score was 4.2 (SD = 1.9), while the mean post-intervention scores as 3.5 (SD = 2). This reduction was not statistically significant (t (9) = 1.5, p = .162). (see Table 4.3).

Effect of Pharmacotherapy. The Chi square test was used to compare MENQOL scores and subsequent pharmacotherapy use, which was not statistically significant. Three participants in this project took part in the pharmacotherapy portion of the intervention. This outcome demonstrated no significant association between pharmacotherapy use and a decrease in MENQOL scores (X^2 (7, N = 10) = 7.619, p = 0.367). Furthermore, due to only having three participants complete pharmacotherapy, the analysis is not valid due to the lack of participants.

CHAPTER 5

DISCUSSION

This EBP project was implemented to determine the effects of a multi-modal intervention including a mindfulness module, exercise, and HRT on improving quality of life in women who are experiencing bothersome menopausal symptoms. Demographics were collected on project participants and an analysis was conducted to determine if age, educational status, smoking status, and marital status had a statistically significant impact on the outcome of the intervention as well. This chapter serves to discuss the primary and secondary outcomes of the EBP project while also addressing both strengths and limitations of this project. The EBP model and its relevance will also be discussed as it guided the implementation of this project. Practice change, sustainability, and recommendations for future research and education will also be addressed.

Explanation of Findings

Primary Outcome

The primary outcome of this EBP project demonstrated a statistically significant ($p = 0.017$ decrease in MENQOL scores from pre-intervention ($M = 4.5$) to post-intervention ($M = 3.8$). This means that the MENQOL scores decreased after implementation of the multimodal intervention of education, a mindfulness module, exercise, and, in some cases, hormone replacement therapy, which is consistent with evidence found in the literature (NAMS, 2022; Ombrech, 2022; RCN, 2020, NICE, 2019; Taebi et al., 2018, Ye et al., 2022; Diem et al., 2021). The average baseline MENQOL score of 10 participants was 4.5. This score is considered moderate decline in QOL. It is important to note that many participants were already doing some sort of lifestyle modification upon beginning the interventions. Because of this, the average severity of symptoms may be lower than when each participant began menopause and experiencing the bothersome QOL symptoms. In addition, only three of the ten participants fit the guidelines, and agreed to hormone replacement therapy, and all had significant decline in the

MENQOL survey, so it is likely that the combination of lifestyle modifications and HRT was influential on decreasing MENQOL scores. Following the ten-week intervention, the average MENQOL score for the ten participants was 3.8. This average score is considered a mild decline in QOL. The literature does suggest that interventions to manage MENQOL, ranging from 10-14 weeks, and sometimes over a 24-week period (Shorey et al., 2020., Taebi et al., 2018). Upon the last meeting with project participants, they were encouraged to continue these interventions even after project conclusion. To conclude, results suggest that use of more than one intervention, such as simply pharmacotherapy, leads to a decrease in MENQOL scores, and therefore improved quality of life.

Secondary Outcomes

Statistical analyses were conducted to look at each of the domains of the MENQOL and determine the statistical significance of the decrease in any of the domains. The only domain that had a statistically significant decrease in pre-intervention and post-intervention scores was the physical domain. The mean physical pre-intervention score was 5.1 (SD = 0.8) while the mean post-intervention score was 3.8 (1.1). The reduction in the physical domain was statistically significant ($t(9) = 3.8$, $p < 0.05$). The results are consistent with current literature stating that the physical domain is often most effected, and physical symptoms are often the most bothersome to menopausal women. In addition, the results are consistent with current literature that using multiple interventions collectively improves symptoms. However, there is very limited research on what these interventions would consist of. The age of participants ranged from 46 to 58 and mean post-intervention scores ranged from 3 to 4.9. There was not a pattern of either increasing or decreasing scores with age (See Table 5.1)

A Chi square test was used to compare MENQOL scores and pharmacotherapy use, which was not statistically significant (X^2 (7, N = 10) = 7.619, p = 0.367). Only three of the participants were on HRT, so this analysis is limited. For these three women, treatment was clinically significant as they all saw a reduction in mean MENQOL scores. The mean pre-

intervention score for participants participating in the pharmacological intervention was 4.9 (SD = 0.47), while the mean post-intervention score was 3.6 (SD = 0.55). These findings of the mean reduction, although not statistically significant, are consistent with current literature (NAMS, 2022; Ombrech, 2022; RCN, 2020, NICE, 2019; Taebi et al., 2018, Ye et al., 2022; Diem et al., 2021).). Current guidelines according to ACOG (2014) suggest that HRT, specifically estrogen should be the first choice in medication to manage menopausal symptoms. Research shows that HRT, most specifically low dose estrogen plus progesterone formulations, have been shown to be the most effective treatment for vasomotor symptoms (VMS) caused by menopause, including hot flashes and night sweats. (NAMS, 2022; Ombrech, 2022; RCN, 2020, NICE, 2019; Taebi et al., 2018, Ye et al., 2022; Diem et al., 2021).

The medications prescribed for participants at the project site was solely estrogen-based products and formulations. Three participants were lost, and countless others were unable to be recruited due to the use of bioidentical hormone replacement therapy. Of the 10 participants that completed the 10-week intervention, only three completed the pharmacological portion of the intervention. Best practice suggests that estrogen should be the first-line medication and choice in women who are experiencing menopausal symptoms, and the results from this project helped to reinforce those recommendations (NAMS, 2022; Ombrech, 2022; RCN, 2020, NICE, 2019; Taebi et al., 2018, Ye et al., 2022; Diem et al., 2021). However, due to the very small sample size, it is likely that this contributed to the lack of statistical significance. Research does show that this is the gold standard of care and in larger population samples, HRT has shown to significantly decrease menopausal symptoms (NAMS, 2022; Ombrech, 2022; RCN, 2020, NICE, 2019; Taebi et al., 2018, Ye et al., 2022; Diem et al., 2021).

Table 5.1

Participant MENQOL Scores by Age

Age	Pre-intervention (Baseline)	Post-intervention (10-weeks)
46	5.4	4.4
50	3.2	3.1
52	4.7	3.7
52	5.3	4.5
53	5.4	4.4
55	5.4	3.5
57	3.5	3
58	2.9	2.7
58	4.2	4.9
58	4.5	3.1

Strengths and Limitations of the DNP Project

Strengths

A major strength of this EBP project was the support of the staff and site stakeholders. The NP helped to brainstorm project ideas, so it was mutually beneficial for both the project manager and the site. The NP and MD both allowed the project leader to meet with the participants outside of appointment time, which was a very helpful when initiating this project. This allowed the project leader to create a space of trust between the project leader and the participants. Additional time following their office appointment was essential for smooth project implementation.

Another strength was the ease of use of the MENQOL questionnaire tool, which was both free of charge and user-friendly for assessing menopausal quality of life. Patients were easily able to complete the questionnaire in the clinic which led to an easy process of onboarding. The

free application, UCLA Mindful, was also a strength of this project. UCLA Mindful was used for mindfulness practice and had aspects of CBT that patients were able to select to use. Patients reported positive feedback regarding the application, and that it was very user-friendly. Participants liked that mindfulness modules could be accessed anywhere through the use of their smartphone.

Lifestyle modifications can improve MENQOL symptoms and also leads to promotion of overall well-being in adults. Daily exercise is one of many health-promoting behaviors that is needed, especially in the aging adult population. This EBP project demonstrated statistical significance on a small scale, and individual participants experienced improvements in their symptomology, thereby demonstrating clinical significance as well. Lastly, the knowledge and leadership that the project leader gained from development and implementation of this project will be essential to future practice as a doctorly-prepared advanced practice registered nurse.

Limitations

The largest limitation to the project was the number of barriers encountered during patient recruitment. It proved to be difficult to recruit eligible participants that were willing to participate in the study. Many participants were already ineligible due to current HRT treatment, or bioidentical hormone replacement therapy, which was a major selling point of the clinic where the project was implemented. Patients also were very hesitant to start on HRT. A goal of this project was to have all eligible participants on HRT, due to it being the gold standard for relieving bothersome menopausal quality of life symptoms, but only 30% of participants completed the pharmacological portion of this intervention. Patient recruitment could only take place when the project leader was in the office, due to the additional time requirements of onboarding participants, including administering the MENQOL, collecting demographic data, onboarding the participants, and orienting them to UCLA Mindful Application. This time also was key to the project leader establishing a relationship with the participants. The process was time-consuming and could take upwards of 30 minutes per participant. If the MENQOL was standardly

implemented at the beginning of each visit, this could have reduced the time spent during the onboarding process.

Another limitation is the possibility of confounding influences on MENQOL scores. These may include mental health, religion, stress, work status, relationship status, and many other variables. These other variables may have impacted change or lack of change in MENQOL scores.

It should also be addressed that small sample size was a significant limitation to this project. A goal of 15 participants was set for this project, and only 10 were able to follow through with the intervention. There was a 33.3% attrition rate. If the intervention period was longer, perhaps even over a year, as in some studies, more participants could have been identified, and longer conversations and decision periods about HRT could have taken place. To add, there was not much variability in the sample group, with all women the same race, and had similar answers on their demographic surveys. Further research should be done, particularly in lower-socioeconomic areas where women are unable to receive some of the same care and have access to less resources.

Sustainability

Although statistically significant findings were found as a result of the EBP project, due to the sample size being so small, future implementation of managing quality of life will be an uphill battle. The multimodal treatment plan as it stands would not be sustainable at the clinic site. The onboarding time to administer the MENQOL, educate the patient, establish an exercise plan, download, and explain the application, review HRT guidelines with the patient, and answer any questions was notably time consuming. The providers already used a personalized menopausal symptom survey at this site, not the MENQOL, so due to many different reasons, and despite clinically significant results, this new practice will not be adopted. This was a common discussion between providers, that it would be too time consuming to continue to implement. Although the intervention cannot be adopted at the clinical site, the providers at the clinical site should

continue to provide patients with educational handouts and individualized education to improve quality of life though interventions aimed at reducing menopausal symptoms.

The providers at the clinical site were already adhering to best practice regarding pharmacotherapy and HRT treatment. Estrogen was the mainstay of treatment for vasomotor menopausal symptoms and will continue to be following the conclusion of the project. However, the clinical site is also adopting bioidentical hormone replacement therapy, which is starting to take precedent over regular HRT at the site. One aspect that would have improved the project's overall sustainability would be increase in provider participation. This would include providers taking more initiative through the recruiting process and project implementation. Had providers played a bigger part of the recruitment process, the intervention could have been more sustainable and perhaps had a greater impact on the patient population.

Relevance for EBP Model

The IOWA Model (2017) was used for the planning, guiding, and implementation of this EBP project. When forming the project steps and guidelines, the model was essential for a backbone to lead the project through development. The model is clear with pathways easy to follow, and most importantly has been used in the past to implement evidence-based changes. The model suggests that inquiry about a practice should lead project development. Both the project leader and key stakeholders agreed that the project should focus on one of the most impactful processes to happen to women throughout their lives. By identifying this need, key stakeholders were in on the project and therefore project implementation and practice change became feasible. The first feedback loop confirmed that menopausal symptoms were a priority problem that was not addressed in this population and clinical setting. A pilot was not implemented as recommended by the Iowa Model due to lack of time and resources. If given the opportunity to redesign this project, the project leader would reassess the time limitation and identify interventions that can be performed to fit best into the clinic lifestyle. A thorough literature search and synthesis of evidence was conducted and discovered best practice

recommendations, including the best way to screen for menopausal-related quality of life symptoms, and management including exercise, education, CBT through a mindfulness module, and HRT. Using the Iowa Model, it was confirmed that there was substantial evidence available to support the multimodal intervention proposed to manage bothersome menopausal related quality of life symptoms. The change was considered appropriate at the clinical site and the model promotes continuous evaluation of both the implementation process and outcomes of the EBP project at both the project site and two other research conferences. An email was sent to the providers that included project findings. The project leader was invited to present an oral and poster presentation in Northwest Indiana, as well as another poster presentation in Southern Indiana to promote the practice change to the advanced practice nursing profession.

The project leader found that the Iowa Model (2017) was an excellent to guide and implement the EBP project. The intervention was clearly supported by key stakeholders, and the evidence was overwhelmingly supporting of the implementation of this practice change at the clinical site. The model should be continually recommended for future EBP projects because the model widely focuses on patient care and is very user friendly. The model was essential to ensure feasibility and success of the project. To add, uses of this model on smaller scales, such as the small population have been found to be successful. In short, this model should continue to serve as a guide for APRNs as they seek to implement practice changes and improve patient outcomes in the clinical setting.

Recommendations for the Future

This EBP project demonstrates that implementing a multimodal intervention plan for women who are experiencing bothersome quality of life symptoms can lead to improved MENQOL scores in the outpatient setting. Most all women experience menopause, but do not receive the proper treatment or education on how to improve symptoms, and therefore quality of life. This project combined lifestyle modifications, education, CBT therapy through a mindfulness application, and pharmacotherapy to improve MENQOL scores in participants over a ten-week

period. Providers should consider using a mindfulness application and using educational handouts in their own practice to improve menopausal-related quality of life. Therefore, the need for further research, revise menopausal treatment guidelines, including pharmacotherapy, and both student and healthcare provider education is essential to improve quality of life in women of menopausal age.

Research

Future research is needed about management of menopause in the primary care setting. As menopause is a normal process of aging, symptoms are generally swept under the rug and not properly treated. Therefore, evidence-based treatment approaches to managing these troublesome symptoms is essential. Further research should aim to determine the efficiency of lifestyle and pharmacotherapy, as well as efficiency of applications for menopause related symptoms. Having EBP accessible on the phone could be a major resource for providers, as they educate women on the menopause cycle, what to expect, and how to go about receiving the best treatment needed. Although HRT is recommended is a first-line treatment option for menopausal symptoms, due to the guidelines and preferences, not everyone will choose pharmacotherapy. Research should be conducted to identify barriers to implementing pharmacotherapy interventions and evaluate its effectiveness in comparison to nonpharmacological interventions. Therefore, provider must do their due diligence and make sure that nonpharmacological therapies are provided to the patient to help them best manage their symptoms. Research should also be conducted on a fairly new therapy that has taken off, bioidentical hormone therapy, and on its safety and efficacy as well as its role in menopause and menopausal quality of life.

Education

Education played a major role in this project implementation. A huge part of the intervention was patient education. During the recruitment phase of this EBP project, a lot of time was spent education patients on menopause, HRT, and proper exercise. In addition, a great

portion of this time was dedicated to how to download and operate UCLA Mindful. Participants were given educational handouts on menopause, as well as education on lifestyle modifications. If participants were interested, participants were educated on HRT by both the project leader and providers at the site, to determine if HRT was the best fit for them. Both undergraduate and graduate nursing students should understand that menopause is a process that significantly impacts quality of life of women. Students should have a strong foundation of menopause, what nonpharmacological and pharmacological interventions to use, and how to best communicate and educate patients on the best treatment path. Healthcare professionals should be encouraged to talk and ask patients about menopausal symptoms so patients can best receive treatment and discuss the impact symptoms may be having on their quality of life. This project demonstrates that there are many different ways to improve menopausal related quality of life symptoms. Although pharmacologic treatment is the gold standard for treatment, non-pharmacologic interventions can support and offer a more holistic approach to patient care. Both students and healthcare professionals should be aware of the importance of management strategies to address women who are experiencing menopausal symptoms. All levels of nursing education should incorporate both pharmacologic and nonpharmacologic strategies into their curriculum.

Conclusion

A multi-modal intervention approach is essential to improving quality of life in menopausal women. While menopause is a normal process of aging, it negatively impacts many women's day-to-day quality of life, and may negatively impact their activities of daily living, physical and mental health (Song et al., 2020). Menopause symptoms are affecting millions of women daily, and women are not satisfied with the level of care they are receiving. The project leader determined that improved practice was necessary to manage women experiencing bothersome menopausal symptoms at the clinical site as a doctoral FNP student. Identifying the need for improvement instigated the project leader to do research on and further investigate the need for

an evidence-based treatment practice to address menopausal symptoms and their impact on women's quality of life in the primary care setting. After a thorough review of literature and an appraisal process, the project leader determined that a multimodal intervention treatment plan would be implemented over ten weeks.

The MENQOL assessment tool is a valid and reliable tool that is used to screen menopausal patients on their quality of life. This tool is available for no fee online. Once bothersome MENQOL symptoms are detected, patients should be offered effective strategies, including a multimodal approach to therapy to best fit their needs ((Beni et al., 2022; Diem et al., 2020; Li et al., 2023, NAMS, 2022; NICE, 2019; Ombech, 2022; RCN, 2020; Shorey et al., 2020; Taebi et al., 2018; Ye et al., 2022; Zou et al., 2022).

The purpose of this EBP project was to assess the efficacy of a multi-modal intervention including exercise, CBT and mindfulness practice through an application, and use of pharmacotherapy if indicated. The results from the project showed that this combination in patients who completed both the nonpharmacologic and pharmacologic intervention has statistically significant result on MENQOL scores after ten-weeks of implementation. A decrease in MENQOL scores from the time of screening to week 10 was demonstrated in 90% of participants. This project should serve as a framework for implementing a holistic approach of both pharmacologic and non-pharmacologic treatments to manage bothersome menopausal symptoms. The project should also highlight a need for pharmacologic treatments for menopause to be more widely addressed and the inclusion of further research on bioidentical hormone replacement therapy. Future EBP projects should also focus on having a larger participant group and longer length of intervention. Different applications for CBT and mindfulness therapies can also be explored to promote adherence to the program. Therefore, research should further aim to identify barriers to implementing multi-modal menopausal treatment protocols, and to improve quality of life in menopausal women.

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BIOGRAPHICAL MATERIAL

Ms. Czerwonka began her education at Valparaiso University, graduating Cum Laude with her Bachelor of Science in Nursing in 2021. During this time, Ms. Czerwonka played Division 1 tennis for the university, earning numerous academic and athletic accolades along the way, while serving as a three-time captain. The two accolades that Ms. Czerwonka is most proud of include breaking the record for career doubles wins in Valparaiso University history and receiving the Missouri Valley Conference (MVC) Scholar Athlete of the Year Award in 2021. Throughout her undergraduate program she was also a member of the Sigma Theta Tau International Society and recipient of the Rebecca D. Carter Memorial Award, which is given to an athlete who best demonstrates what it means to be a champion in the community, by way of selflessly giving of their time/talents to the betterment of the campus and to society as a whole. Mrs. Czerwonka is also an avid volunteer in the community, and member of an undergraduate research group.

After spending five years on the tennis court herself, Ms. Czerwonka was asked to step into a new role as assistant coach for the Valpo women's tennis program. Ms. Czerwonka took this opportunity to further her education and enrolled in the Doctor of Nursing Practice (DNP) program at Valparaiso. While in the DNP program and outside of coaching, Ms. Czerwonka worked seasonally as a nurse at a pediatric camp in her home state of Wisconsin. Currently she is working as a nurse at a behavioral health center in Kouts, Indiana caring for children and adolescents with complex mental illnesses.

Ms. Czerwonka was one of three selected to give an oral presentation of her evidence-based practice (EBP) project at the Northwest Indiana Research Consortium in November of 2023. Ms. Czerwonka is also currently a member of Coalition of Advanced Practice Registered Nurses of Indiana (CAPNI) and was invited to present her EBP project at their annual conference in February. She is set to graduate this May of 2024 and will continue her career in her home

state of Wisconsin, where she will willingly serve her community as a family nurse practitioner (FNP).

ACRONYM LIST

ANA: American Nurses Association

APRN: Advanced practice registered nurse

ACOG: American College of Obstetricians and Gynecologists

BHRT: Bioidentical hormone replacement therapy

CDC: Centers for Disease Control

CBT: Cognitive behavioral therapy

DNP: Doctoral prepared nurse practitioner

EBP: Evidence=based practice

HRT: Hormone replacement therapy

JBI: Joanna Briggs Institute

MA: Medical assistant

MENQOL: Menopause-specific quality of life

NAMS: North American Menopause Society

NICE: National Institute of Health and Care Excellence

NP: Nurse Practitioner

QOL: Quality of life

RCN: Royal College of Nursing

RCT: Randomized controlled trial

SPSS: Statistics Package for Social Sciences

TRIP: Turning research into practice

VMS: Vasomotor symptoms

APPENDIX A

Menopause Specific Quality of Life Questionnaire

Study Specifics:

Subject ID #:_____ **Date:_____ /_____ /_____**
mm dd yy

THE MENOPAUSE-SPECIFIC

QUALITY OF LIFE QUESTIONNAIRE

MENQOL™

Primary Care Research Unit
Department of Family and Community Medicine
Sunnybrook Health Sciences Centre
University of Toronto

Authors: John R. Hilditch, Jacqueline E. Lewis, Peter G. Norton, Earl V. Dunn

The development of the MENQOL™ questionnaire was funded by CIBA-GEIGY Canada Ltd., Mississauga, Canada.

The authors request citation of the 1996 and 2005 development papers whenever MENQOL or MENQOL-I is used or otherwise acknowledged.

For information or permission to use the questionnaire, please submit a request through ePROVIDE™, Mapi Research Trust, online platform.

INSTRUCTIONS

Each of the items in the questionnaire is in the form of the examples below:

		Not at all bothered → Extremely bothered 0 1 2 3 4 5 6
NIGHT SWEATS	☐ No	☐ Yes → ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

Indicate whether or not you have experienced this problem in the **PAST MONTH**.

IF YOU ***HAVE NOT*** EXPERIENCED THE PROBLEM:

Mark "No"

NIGHT SWEATS	☑ No	☐ Yes → ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

→ Go to the next item.

IF YOU ***HAVE*** EXPERIENCED THE PROBLEM:

Mark "Yes," then check off how bothered you were by the problem.

NIGHT SWEATS	☐ No	☑ Yes → ☐ 0 ☐ 1 ☑ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

→ Go to the next item.

This questionnaire is completely confidential. Your name will not be associated with your responses. However, if for any reason you do not wish to complete an item, please leave it and go on to the next one.

Date: _____/_____/_____ Subject ID #:_____
mm dd yy

For each of the following items, indicate whether you have experienced the problem in the **PAST MONTH**. If you have, rate how much you have been ***bothered*** by the problem.

			Not at all bothered → Extremely bothered						
			0	1	2	3	4	5	6
1. HOT FLUSHES OR FLASHES	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
2. NIGHT SWEATS	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
3. SWEATING	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
4. DISSATISFACTION WITH MY PERSONAL LIFE	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
5. FEELING ANXIOUS OR NERVOUS	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
6. POOR MEMORY	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
7. ACCOMPLISHING LESS THAN I USED TO	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
8. FEELING DEPRESSED, DOWN OR BLUE	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
9. BEING IMPATIENT WITH OTHER PEOPLE	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
10. FEELINGS OF WANTING TO BE ALONE	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
11. FLATULENCE (WIND) OR GAS PAINS	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
12. ACHING IN MUSCLES AND JOINTS	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
13. FEELING TIRED OR WORN OUT	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
14. DIFFICULTY SLEEPING	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
15. ACHES IN BACK OF NECK OR HEAD	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
16. DECREASE IN PHYSICAL STRENGTH	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

Date: _____/_____/_____ Subject ID #:_____
mm dd yy

			Not at all bothered → Extremely bothered						
			0	1	2	3	4	5	6
17. DECREASE IN STAMINA	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
18. LACK OF ENERGY	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
19. DRY SKIN	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
20. WEIGHT GAIN	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
21. INCREASED FACIAL HAIR	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
22. CHANGES IN APPEARANCE, TEXTURE OR TONE OF MY SKIN	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
23. FEELING BLOATED	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
24. LOW BACKACHE	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
25. FREQUENT URINATION	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
26. INVOLUNTARY URINATION WHEN LAUGHING OR COUGHING	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
27. DECREASE IN MY SEXUAL DESIRE	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
28. VAGINAL DRYNESS	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
29. AVOIDING INTIMACY	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

INSTRUCTIONS FOR USE AND SCORING OF THE MENOPAUSE-SPECIFIC QUALITY OF LIFE QUESTIONNAIRE MENQOL™

USE:

1. The title page, subject questionnaire instruction and 29 items constitute the official MENQOL™.

2. Pages i, ii, and iii inclusive contain information for the researchers only.

3. Ensure you have the correct questionnaire recall period based upon your study need.

4. The MENQOL™ questionnaire is designed to be self-administered either in person or using mail, email or both.

5. Use of electronic, verbal, Braille, sign language, or other delivery methods requires pre-testing.

6. Researchers are advised to pre-test the average time required by subjects to complete the questionnaire.

REFERENCES:

Hilditch JR, Lewis J, Peter A, van Maris B, Ross A, Franssen E, Guyatt GH, Norton PG, Dunn E. A Menopause-Specific Quality of Life Questionnaire: development and psychometric properties. Maturitas 1996;24: 161-75

Lewis JE, Hilditch JR, Wong CJ. Further psychometric property development of the Menopause-Specific Quality of Life questionnaire and development of a modified version, the MENQOL-Intervention questionnaire. Maturitas 2005; 50:209-221.

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SCORING:

1. Convert the Subject Response (the item raw data score) to a Conversion Score (a score for further analysis), in the following manner:

Subject Response	Conversion Score
No	1
Yes 0	2
1	3
2	4
3	5
4	6
5	7
6	8

2. a) The MENQOL™ contains four domains.
   - i Vasomotor - Items 1 to 3
   - ii Psychosocial - Items 4 to 10
   - iii Physical - Items 11 to 26
   - iv Sexual - Items 27 to 29

   b) Each domain is scored separately.

   c) After conversion, each domain mean ranges from 1 to 8.

3. The overall questionnaire score is the mean of the domain means.

4. Interpretation of the results:
   a) The questionnaire instructions ask the participant to check the "No" box if she does not experience the item. The Conversion Score, '1', means the individual does not experience the item.

   b) The Subject Response, "Yes" with a raw data score '0,' has an important meaning in the MENQOL™ because it permits the subject to experience the item, "Yes," BUT to be "Not at all bothered" by the item's occurrence. The Conversion Score '2' means the subject experiences the item BUT is "Not at all bothered" by the experience.

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c) Conversion score '3' means the subject experiences the item, "Yes," and is minimally bothered, raw score '1.'
Conversion score '4' is the equivalent of a bothersome raw score of '2.'
Conversion score '5' is the equivalent of a bothersome raw score of '3.'
Conversion score '6' is the equivalent of a bothersome raw score of '4.'
Conversion score '7' is the equivalent of a bothersome raw score of '5.'
Conversion score '8' means the subject experiences the item and is "Extremely bothered," reflecting a raw data score of '6.'

d) Hence, the Conversion score ranges from 1 to 8, whereas the questionnaire raw data score is No or Yes, with a bothersome score of '0,' "Not at all bothered," worsening to '6,' "Extremely bothered."

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APPENDIX B

Demographics Form

Menopausal Multi-modal Intervention to Improve Quality of Life

Valparaiso University

Please complete the following form. Information provided will be kept confidential.

Date: _____

Initials: _____

Age: _____

Smoker:

____ Y

____ N

Race:

____ White

_____ African-American

____ Asian

_____ Hispanic

_____ Other

Marital status:

_____ Married

_____ Divorced, separated

_____ Single

Education:

_____< high school

_____ high school diploma

_____ some college

_____ college degree

_____ masters or doctorate

_____ other

Income level:

_____ Less than $25,000

_____ $25,000-$50,000

_____ $50,001-$75,000

_____ > $75,000

APPENDIX C

Implementation Timeline

Pre-screening: August 25-September 4

Review charts for patients and scheduled appointments.

Week 1: If patient meets menopausal criteria for visit, offer 10-week mindfulness and exercise program. Evaluate with provider if eligible for HRT. Collect program intake form and demographic form. Administer pre-intervention MENQOL in person.

Week 5: Telephone follow up for encouragement and adherence to program

Week 10: Administer post-intervention MENQOL assessment tool via telephone.

APPENDIX D

MENQOL License Agreement

SPECIAL TERMS No86176

These User License Agreement Special Terms (Special Terms) are issued between Mapi Research Trust ("MRT") and Claire Czerwonka (User).

These Special Terms are in addition to any and all previous Special Terms under the User License Agreement General Terms.

These Special Terms include the terms and conditions of the User License Agreement General Terms, which are hereby incorporated by this reference as though the same was set forth in its entirety and shall be effective as of the Special Terms Effective Date set forth herein.

All capitalized terms which are not defined herein shall have the same meanings as set forth in the User License Agreement General Terms.

These Special Terms, including all attachments and the User License Agreement General Terms contain the entire understanding of the Parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto. If the terms and conditions of these Special Terms or any attachment conflict with the terms and conditions of the User License Agreement General Terms, the terms and conditions of the User License Agreement General Terms will control, unless these Special Terms specifically acknowledge the conflict and expressly states that the conflicting term or provision found in these Special Terms control for these Special Terms only. These Special Terms may be modified only by written agreement signed by the Parties.

1. User information

logo

Image not found or

User name	Claire Czerwonka
Category of User	Student
User address	1400 Chapel Drive, Valparaiso, 46383, Indiana, United States
User VAT number	
User email	claire.czerwonka@valpo.edu
User phone	2629456520
Billing information	1400 Chapel Drive, Valparaiso, 46383, Indiana, United States

2. General information

3. Identification of the COA

logo

Image not found or

Effective Date	Date of acceptance of these Special Terms by the User : 30 Jul 2023
Expiration Date (Term)	Upon completion of the Stated Purpose
Name of User's contact in charge of the request	Claire Czerwonka

Name of the COA	MENQOL - Menopause-specific Quality of Life Questionnaire
Author	Lewis JE, Hilditch JR
Copyright Holder	Copyright © 2005 Sunnybrook Health Sciences Centre. All rights reserved.
Copyright notice	Copyright © 2005 Sunnybrook Health Sciences Centre. All rights reserved.
Bibliographic reference	Lewis JE, Hilditch JR, Wong CJ. Further psychometric property development of the Menopause-Specific Quality of Life questionnaire and development of a modified version, MENQOL- Intervention questionnaire. Maturitas. 2005 Mar 14;50(3):209-21 (PubMed Abstract) Hilditch JR, Lewis J, Peter A, van Maris B, Ross A, Franssen E, Guyatt GH, Norton PG, Dunn E. A menopause-specific quality of life questionnaire: development and psychometric properties. Maturitas. 1996 Jul;24(3):161-75 (PubMed Abstract)
Module(s)/version(s) needed	MENQOL_1-month

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4. Context of use of the COA

The User undertakes to use the COA solely in the context of the Stated Purpose as defined hereafter. 4.1 Stated Purpose

Clinical research

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Title	IMPROVING QUALITY OF LIFE IN MENOPAUSAL WOMEN THROUGH A BEST PRACTICE PROTOCOL: THE USE OF HORMONE THERAPY, EDUCATION, AND EXERCISE
Study/protocol reference	
Sponsor	
Disease or condition	
Type of research	Other Other: EBP project
COA used as primary end point	No
Number of sites	
Number of enrolled patients/subjects	
Number of estimated failed patients/subjects	
Number of submissions of the COA for each enrolled patient/subject	
Planned Term*	Start: 08/2023 End: 12/2023
Mode of Administration*	Paper
If electronic administration, please indicate mode of data collection	

4.2 Country and languages

MRT grants the License to use the COA on the following countries and in the languages indicated in the table below:

The User understands that the countries indicated above are provided for information purposes. The User may use the COA in other countries than the ones indicated above.

5. Specific requirements for the COA

The Copyright Holder of the COA has granted ICON LS exclusive rights to translate the COA in the context of commercial studies or any project funded by for-profit entities. ICON LS is the only organization authorized to perform linguistic validation/translation work on the COA.

In case the User wants to use an e-Version of the COA, the User shall send the Screenshots of the original version of the COA to MRT or ICON LS for review and approval. The Screenshots review may incur additional fees.

In case the User wants to use an e-Version of the COA, ICON LS shall update (if needed) and populate the COA translations into the User's or IT Company's system and the User shall send the Screenshots of the translations of the COA to ICON LS for approval. The update (if needed), population of translations and the Screenshots review may incur additional fees.

By accepting these Special Terms, the User acknowledges and confirms that it has read and approves the User Agreement General Terms.

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Use of IT Company (e-vendor)	No

Version/Module	**Language**	**For use in the following country**
MENQOL_1-month	English	the USA

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