The use of complementary and alternative medicines in the treatment of menopausal symptoms by private healthcare patients in Pretoria, South Africa

Lynn Randall

M.Sc. in Pharmacy Administration and Policy Regulation

Supervisor: Dr M van Huyssteen

Co-Supervisor: Mr R Bapoo

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ABSTRACT

BACKGROUND

The use of complementary and alternative medicine (CAM) is widespread in the treatment of menopausal symptoms. While observational studies indicate that CAMs can bring some relief of symptoms, there is mixed evidence of this based on clinical trials and other studies (Thompson, 2010 and Newton *et al*., 2006), with very little available research specific to South Africa.

OBJECTIVES

The primary aim of this study was to determine the use of complementary and alternative medicines in the treatment of menopausal symptoms by private health-care patients in Pretoria, South Africa, based on findings from a single site.

Two secondary objectives were to gather information on the concurrent usage of CAMs and allopathic medicines, as well as to gather information on the sources of information utilised for CAMs.

METHOD

The study was cross-sectional and descriptive in design. The data was collected using a structured questionnaire to collect information from randomly selected participants at the study site, a private community pharmacy. The data collected included demographic details, participant's attitude towards menopause, menopausal symptoms and treatments and sources that the participant utilised for information on CAMs.

RESULTS

The response rate for the study was 38.1%, based on an initial contact list of 197 potential participants. The study found that 38.0% of all participants had used CAMs to treat their menopausal symptoms, with 48.1% of these using more than one CAM product. CAM users reported significantly more severe menopausal symptoms than non-CAM users (p-value = 0.02). Around 63.0% of CAM users found at least one of the CAM treatments they used to be effective, with 43.1% of all individual CAM treatments being perceived as effective. A small proportion of participants (18.3%) had used both CAM and HRT treatments concurrently.

Nearly two thirds (63.0%) of CAM users consulted with their medical doctor in some way before initiating CAM treatment for their menopausal symptoms. However, the single

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primary source used by participants to gather information on CAMs was the internet, with 59.3% of CAM users using the online resource as their primary information source.

CONCLUSION

The use of CAMs in the treatment of menopausal symptoms by private healthcare patients in Pretoria, South Africa is widespread, with 38.0% of participants in this study using them to treat their menopausal symptoms. Future research should attempt to understand why CAM usage is associated with more severe menopausal symptoms. Research comparing the prevalence of individual CAMs to their efficacy may also be illuminating.

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DECLARATION

I declare that this thesis that I now submit for assessment on the programme of study leading to the degree Master of Science in Pharmacy Administration and Policy Regulation has not been submitted for the purpose of a degree at this or any other higher education institution. It is entirely my own work and has not been taken from the work of others, save the extent that such work has been cited and acknowledged within the text of my work.

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Signed: L Randall Dated: 14 December 2017

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LIST OF ABBREVIATIONS

ANOVA	Analysis of Variance
ATM	African Traditional Medicine
CAM	Complementary and Alternative Medicine
EPO	Evening Primrose Oil
HRT	Hormone Replacement Therapy
ID	Identification
LSM	Living Standards Measure
MRS	Menopause Rating Scale
NCCIH	National Centre for Complementary and Integrative Health
NHS	National Health Service
QOL	Quality of life
UK	United Kingdom

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1. Introduction

1.1 Background

Menopause is the permanent end of a woman's menstrual periods, and is experienced by all women, typically between the ages of 40 and 58 years, with the average age being 51 years (The North American Menopause Society, 2017b). In most cases menopause occurs naturally, but its onset may also be triggered by medical interventions such as pelvic radiation or chemotherapy causing damage to the ovaries, or by surgery such as a bilateral oophorectomy, which is the removal of both ovaries (The North American Menopause Society, 2017b).

Many women experience symptoms with the onset of menopause, including urogenital, somato-vegetative and psychological symptoms (Berlin Centre for Epidemiology and Health Research, 2008). These symptoms may affect a woman physically or psychologically, thereby altering her behaviour or impacting day to day activities, which may lead to an altered or decreased overall quality of life (QOL) (Moustafa *et al.,* 2015). The National Health Service (NHS) in the United Kingdom (UK) reports that women typically continue to experience these symptoms after the permanent end of their menstrual periods, with most symptoms lasting on average around four years from the last period (NHS Choices, 2015). Around one in ten women continue to experience symptoms associated with menopause for up to twelve years (NHS Choices, 2015), and hot flushes can continue for up to fourteen years after menopause (Avis *et al.*, 2015).

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Menopausal symptoms are a result of fluctuating and lowered oestrogen levels (Women's Health Concern, 2015). Hormone Replacement Therapy (HRT) has been widely used for decades as the standard conventional treatment for menopausal symptoms, typically in the form of either oestrogen alone, or oestrogen combined with progestin. The 1920's saw the first development of synthetic oestrogen, and by the mid 1930's, HRT was being used to treat menopausal symptoms (Brett and Chong, 2001). While the therapy is effective in the treatment of symptoms, trials have however shown serious risks with even short-term use (Newton *et al.*, 2006).

1.2 Problem statement

The use of complementary and alternative medicines (CAMs) is globally widespread and is used to treat a broad range of conditions, including menopausal symptoms. Worldwide, many women look to CAMs as an alternative to HRT (Women's Health Concern ,2015). This can be in direct response to adverse side-effects of HRT such as bloating, headaches, water retention or nausea. Others may have a belief that the manipulation of their hormones using synthetic oestrogen is unnatural, or principally wrong. For many, the risks associated with

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HRT, such as increased risk of stroke, blood clots, heart attack and breast cancer, has encouraged the use of CAM treatments (Hill-Sakurai *et al.*, 2008).

A 2015 Women's Health survey, conducted in the UK, (Women's Health Concern, 2015) revealed that 95% of these women would try alternative therapies before HRT due either to concerns around the health risks of HRT, or to a preference for a more natural treatment. Further evidence from many studies suggest the worldwide prevalence of CAMs for the treatment of menopausal symptoms is high, although these were mostly observational studies (Posadzki *et al.*, 2013)

Many women in South Africa also look to CAMs as an alternative to HRT (South African Menopause Society, 2017). Despite some CAM-allopathic drug interactions being dangerous and potentially fatal, many South African women believe that alternative and natural remedies are safer than allopathic alternatives, and in fact may not be aware of the risks associated with these interactions at all (Van der Westhuizen, 2009). There is a need for pharmacists and other South African healthcare practitioners to inform women of possible CAM interactions with other drugs, as well as the potential side-effects of the CAM treatments themselves. Black Cohosh is one such alternative treatment that has the potential to cause side-effects, including jaundice and gastric upset, although no studies have focused on sustained usage for more than 6 months (National Center for Complementary and Integrative Health, 2017).

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1.3 Motivation for study

Many botanical therapies have been used as biologically-based treatments for menopause-related conditions (Sonnedecker, 2006). These foods and supplements are derived from plants and include a range of natural product classes (e.g. phyto-oestrogens such as the isoflavones found in soy or Red Clover) and individual natural products (e.g. Black Cohosh, St John's wort, or Ginseng). Despite their popularity, common herbal interventions such as Black Cohosh, soy and multibotanicals have been shown to have no clinically meaningful effects in the treatment of vasomotor symptom frequency or intensity, based on the results from several large, randomised, double-blind trials (Newton *et al.*, 2006).

Homeopathy as a complementary treatment has been delivered within the NHS in the UK since 1948 (Thompson, 2010). Data on many observational studies (Clover, 2000; Richardson, 2001; Spence *et al.*, 2005) around homeopathic care as a treatment for the symptoms of menopause was collected from hospitals around the UK, with patients being assessed on the frequency and severity of symptoms. Results indicated symptomatic benefits were perceived

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by a number of patients; however, two randomised controlled trials (Thompson, 2010) did not indicate effectiveness of the treatments at a statistically significant level.

Studies show that women tend to use more CAM products than men, and that within the female population, women experiencing menopausal symptoms are of the highest users of CAM products and therapies (Committee on the Use of Complementary and Alternative Medicine by the American Public, 2005). While the use of CAMs is widespread in the treatment of menopausal symptoms, there is a shortage of scientific research in this area (National Centre for Complementary and Alternative Medicine, 2012). Observational studies indicate that CAMs can bring some relief of menopausal symptoms, but these studies tend to be inconsistent in form, and there is mixed evidence of prevalence, efficacy or safety based on clinical trials and other studies (Thompson, 2010; Newton *et al*., 2006).

Published research on CAM usage has been extremely limited in South Africa, although community pharmacies in South Africa do sell a range of CAM products. Some of these products are indicated for the treatment of symptoms associated with menopause (MIMS, 2016). This study intends to measure the prevalence of the usage of these products to treat menopausal symptoms in the single pharmacy selected as the study setting, and to analyse the demographic attributes of CAM users.

1.4 Research question

How widespread is the use of complementary and alternative medicines in the treatment of menopausal symptoms by private healthcare patients in Pretoria, South Africa?

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1.5 Primary aims and objectives

The primary aim of this study was to describe the use of CAMs in the treatment of menopausal symptoms by women who access private healthcare in Pretoria, South Africa.

Two secondary objectives were to gather information on the concurrent usage of CAMs and allopathic medicines, as well as to gather information on the sources of information utilised for CAMs.

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2. Literature review

2.1 Introduction

The literature review begins with a review of treatments included in the CAM definition, followed by a review of the motivation for the usage of CAMs for menopausal symptoms and the concurrent usage of CAMs and allopathic medicines. The final sections discuss six surveys on the use of CAMs for the treatment of menopausal symptoms.

2.2 Scope of complementary and alternative medicines

The United States National Centre for Complementary and Integrative Health (NCCIH) defines CAMs as a group of diverse medical and health care systems, practices and products that are not generally considered part of conventional medicine (U.S. National Library of Medicine: National Institutes of Health, 2003). The NCCIH classifies CAMs therapies into 5 categories (U.S. National Library of Medicine: National Institutes of Health, 2003):

1. Alternative medical systems,
2. Mind-body interventions,
3. Biologically-based systems e.g. botanicals, herbalism, vitamins, minerals, amino acids
4. Manipulative and body-based methods e.g. massage, chiropractic, and,
5. Energy therapies.

While this study focused primarily on biologically-based systems (i.e. the third category classified by the NCCIH), a broader spectrum of treatments for menopausal symptoms could be considered complementary or alternative. These include traditional healers and faith healers, as well as acupuncture, aromatherapy, meditation, neural therapy, static magnets and yoga, among others (Posadzki *et al.*, 2013).

In South Africa, the Medicines and Related Substances Act 101 of 1965 defines Complementary Medicine (Medicines Control Council, 2016) as:

any substance or mixture of substances that—
(a) originates from plants, fungi, algae, seaweeds, lichens, minerals, animals or other substance as determined by Council, and
(b) is used or purporting to be suitable for use or manufactured or sold for use—

> *(i) in maintaining, complementing, or assisting the innate healing power or physical or mental state, or*
>
> *(ii) to diagnose, treat, mitigate, modify, alleviate or prevent disease or illness or the symptoms or signs thereof or abnormal physical or mental state, of a human being or animal, and*

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(c) is used—

(i) as a health supplement, or

(ii) in accordance with those disciplines as determined by Council, or

(d) is declared by the Minister, on recommendation by the Council, by notice in the Gazette to be a complementary medicine.

2.3 Motivation for usage of complementary treatments for menopausal symptoms

Many women choose complementary and alternative treatments for their menopausal symptoms as a reflection of their personal beliefs and values (Sonnendecker, 2006). Others are dissatisfied with the efficacy of allopathic hormonal medicines, or are concerned with the high risk or adverse effects of conventional treatments, primarily HRT (Sonnendecker, 2006).

While there is no single common reason for women to use CAMs for the treatment of their menopausal symptoms, there are four broad themes that emerge when describing women's decisions in this regard (Hill-Sakurai *et al.*, 2008). The first is that the approach is "natural", often referring to a perception that treatments are safer or gentler, or that the approach does not involve physicians. The second is that menopause is a life stage condition, rather than a medical one, and should therefore drive an individual prioritisation of personal health and wellness. The third is that information about menopause is generated from personal experiences of friends and family, even though such experiential information may be disregarded by medical experts. Finally, current usage of CAMs may drive patterned responses in individuals and direct future treatment choices (Hill-Sakurai *et al.*, 2008).

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There are a wide range of symptoms associated with menopause. Common menopausal symptoms include hot flushes, sleep problems, night-time sweating, heart palpitations, muscle and bone pain, vaginal dryness, depressive moods, and a lack of energy. Women may experience various combinations of these symptoms, with varying perceived severities. The Menopause Rating Scale (MRS II) (Berlin Centre for Epidemiology and Health Research, 2008), is one measurement tool that has been designed to represent the severity of menopausal symptoms. It asks women to rate the severity of their own menopausal symptoms in 11 individual categories, with each category rated on a five-point scale, ranging from "None" to "Very Severe".

A number of CAM products and treatments are associated with the relief of menopausal symptoms. For example, phyto-oestrogens, black cohosh and magnesium bring benefits associated with hot flushes (Sonnedecker, 2006; Tonick and Muneyyirci, 2016), omega 3 brings benefits associated with lubrication of body tissues thus assisting with vaginal dryness (Menopause Centre Australia, 2016), while omega 6 brings benefits associated with night

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flushes (Sonnedecker, 2006). Calcium can prevent bone loss (University of Maryland Medical Center, 2105a) and magnesium can improve insomnia, irritability, agitation and anxiety (University of Maryland, 2015d). However, usage of CAMs may also be associated with symptomatic risks including gastro-intestinal disturbances for black cohosh, omega 3 and calcium (Sonnedecker, 2006), endometrial hyperplasia from soy products (Sonnedecker, 2006) and nausea or vomiting from both omega 6 and magnesium (Sonnedecker, 2006; University of Maryland Medical Center, 2015d).

Many women use CAMs in conjunction with allopathic medicines (Peng *et al.,* 2014; Van der Sluijs *et al.*, 2007). A concern is that the tendency to use herbal products and allopathic medicines concurrently can result in herb-drug interactions (Fasinu *et al.*, 2012). The pharmacologic properties of herbal products have been observed to induce pharmacodynamic interactions, potentially including synergistic, additive or antagonistic effects. Various pharmacokinetic interactions have also been identified, such as the alteration of gastrointestinal functions, inhibition of metabolic enzymes and alteration of renal excretion of drugs (Fasinu *et al.*, 2012). These potential interactions highlight the benefit of studies on the concurrent usage of CAMs and allopathic medicines.

2.4 Review of global surveys

Several studies on the use of CAM treatments to treat menopausal symptoms have been conducted globally and the results of these reference studies are summarised in Table 1. The objectives of these studies were generally to describe the prevalence rates of CAM usage for menopausal symptoms within the target demographic, as well as to document the perceived effectiveness of these treatments. Most of these studies were performed predominantly in developed countries and recorded prevalence of CAM use ranging from 23 to 83%

In addition, several secondary factors have been included in some of these studies. These include the concurrent usage of CAMs with allopathic medicines, interaction and communication with medical practitioners regarding information and recommendations on CAMs, and prevalence of non-medicine based treatments.

While all the studies used a cross-sectional questionnaire to collect data, it is worthwhile to note that the studies did not all use the same questionnaire. Furthermore, five of the six studies used a standardised scale of some sort to measure the severity of menopausal symptoms. The study conducted in Germany by Buhling *et al.* (2014) used the MRS II, and both Cardini *et al.* (2010) and van der Sluijs *et al.* (2007), used a symptom rating scale very similar to MRS II but not identical. Both these studies used the same rating scale to measure the severity of menopausal symptoms, with a severity rating of 0 to 6 collected across 15

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symptoms. Gerber *et al.* (2014) used similar symptom groupings as the MRS II (somatic, psychological and vasomotor instead of urogential) but applied a binary scoring method rather than a scale. Gollschewki *et al*. (2004) also grouped symptoms into three categories (physical, psychological and vasomotor) with a severity rating scale of 0 to 3, however they included 21 symptoms (Greene, 1976).

While the various surveys had broadly similar objectives, the data collected as well as the inclusions and exclusions for each study were not standardised and thus are challenging to compare and aggregate directly. However, the various studies tend to utilise a common set of references and cross-citations.

2.5 South African context

The South African regulatory definition of complementary medicine mentioned in section 2.1 (Medicines Control Council, 2016) covers four broad disciplines of complementary treatments:

- Western Herbal preparations,
- Traditional Chinese, Ayurvedic and Unani Tibb substances,
- Homeopathic preparations, and,
- Aromatherapy substances.

A notable exclusion from this list is African Traditional Medicines (ATMs), which were not included as one of the CAM disciplines in the South African definition of complementary medicine, because of its complex and political disposition in post-apartheid South Africa. However, the use of traditional healers in South Africa has seen a general decline over the 13 years leading up to 2009, based on several published and unpublished research studies (Peltzer, 2009). In addition, ATMs are not routinely sold in community pharmacies in South Africa and are thus beyond the scope of this study. The exact range of complementary treatments that are offered by a particular community pharmacy in South Africa would depend largely on the demographic and socio-economic profile of the community which they serve. In their 2014 guideline on the quality, safety and efficacy of complementary medicines, the Medicines Control Council states that “In general Complementary Medicines (CMs) are used and sold by many people in RSA.” (Medicines Control Council, 2014), indicating broad usage patterns in South Africa.

Both public and private healthcare services are available in South Africa. The public sector is state-funded with aggregate healthcare expenditure accounting for 11% of the government’s total budget (Jobson, 2015). Consumers that elect to access private healthcare services such

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as community pharmacies tend to correspond to a comparatively higher Living Standards Measure (LSM) (Hospital Association of South Africa, 2008) than consumers that use only public healthcare services. While public facilities do offer some CAMs treatments, private facilities would offer a far broader range of CAMs options.

In general, CAMs are used by a substantial proportion of the general population, for a broad range of conditions and symptoms. In a 2008 study, only a third of South African women believed that soy could be used as an alternative to HRT, and less than a quarter reported that its usage would relieve menopausal symptoms, despite over 60% acknowledging its benefit for preventing cardiovascular disease and osteoporosis (Bosman *et al.*, 2008). Yet, several CAMs may have potentially fatal interactions with allopathic drugs and treatments (Van der Westhuizen, 2009). For instance, the Western herbal preparation St John's Wort (*Hypericum perforatum)* can be used by women to treat depressive moods associated with menopausal symptoms. Patients that use this concurrently with tricyclic antidepressants, selective serotonin reuptake inhibitors and monoamine oxidase inhibitor classes of anti-depressants have been observed to develop serotonin syndrome, which can be fatal if left untreated (University of Maryland Medical Centre, 2007). As such, South African pharmacists have an important role to play in informing women of possible side-effects and drug interactions (Van der Westhuizen, 2009) for women who use CAMs for menopausal symptoms.

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Table 1: Studies showing the prevalence of CAMs use and most common CAM products and approaches to treat menopausal symptoms

No	Author's name/ reference	Study Design	Target population and recruitment	Geography	Age Range	Sample Size	Rating metric used to assess menopausal symptoms	Prevalence of CAMs usage	Most Common CAMs Treatment Used
1	Buhling *et al.*, 2014	Cross-sectional study Postal questionnaire	Insurance Broker Client List	Germany	45-60	1893	MRS II (12 symptoms across 3 categories, severity scale 0 to 4)	48%	Lifestyle Alteration (29%) St John's Wort (18%)
2	Van der Sluijs *et al.*, 2007	Cross-sectional study Self-administered questionnaire	Menopause Clinics, GP Clinics and Government Health Agencies	Sydney (Australia)	45-65	1296	Similar to MRS II (15 symptoms, no grouping, severity scale 0 to 6)	54%	Soy (25%)
3	Cardini *et al.*, 2010	Cross-sectional study Self-administered questionnaire	Family Planning & Women's Health Clinic, and Menopause Centre	Bologna (Italy)	45-65	1106	Similar to MRS II (15 symptoms, no grouping, severity scale 0 to 6)	34%	Herbal (41%)

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4	Gerber *et al.*, 2014	Cross-sectional study Interview-guided questionnaire	Primary Care Centres (9)	Qatar	40-60	814	Used an adapted SWAN assessment (3 symptom groupings similar to MRS II, binary severity rating)	38%	Nutritional and Herbal
5	Gollschewki *et al.*, 2004	Cross-sectional study Postal questionnaire	Electoral Roll	Queensland (Australia)	47-67	885	Greene Climacteric Scale (21 symptoms across 3 categories, severity scale 0 to 3)	83%	Nutrition (76%) Phyto-oestrogens (56%)
6	Bosman *et al.*, 2008	Cross-sectional study Face-to-face interview	1996 Census Data across all 9 provinces	South Africa	50-59	825	n/a (no section on severity of symptoms)	n/a (study was on attitudes/beliefs not usage)	Soy

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3. Methodology

3.1 Study design

The study was cross-sectional and descriptive in design. A structured questionnaire (Appendix 1) was used to collect the information from the randomly selected participants. This design was selected to provide the best comparability to related global and South African studies while still providing the level of detail necessary to effectively meet the study aims and objectives.

3.2 Study setting

The study was a single-site study conducted at a private community pharmacy with a clinic in Pretoria, South Africa.

3.3 Recruitment of participants

The target demographic for the study was women aged 40-65 years that had experienced symptoms associated with menopause. Women with co-existing medical conditions such as diabetes, hypertension, arthritis etc. were eligible for inclusion in this study. Women whose menopause was triggered by damage to the ovaries from radiation, chemotherapy or other drugs or a bilateral oophorectomy were excluded from the study.

The sampling for the study was done using the customer database at the pharmacy and this was the primary source for the recruitment of participants. The sampling strategy used a representative sample based on the pharmacy family birthday list. From this list, the following exclusions were applied:

- Men,
- Women whose age was not between 40 and 65 years,
- Physical address not in Pretoria,
- Inactive customers, and,
- No telephonic contact details.

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This exclusion process yielded 214 potential participants who were shortlisted as eligible for inclusion and each was assigned a unique anonymous participant number by the researcher. The researcher, in her capacity as pharmacist at the study setting, used the database contact details to attempt to contact all shortlisted individuals telephonically to inform them of the study and invite them to participate. An additional two attempts were made to contact potential participants that were not immediately reachable.

Contacted individuals that agreed to participate in the study were invited to receive and read the Study Pack, which included the Study Information Sheet (Appendix 2), Informed Consent (Appendix 3), and Questionnaire (Appendix 1), which could be collected in printed form at the pharmacy, or sent via email. Those that opted out of the study were not contacted again.

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3.4 Data collection and analysis

To validate the questionnaire, two women known to the researcher were invited to complete the questionnaire in a pilot study. The researcher requested feedback regarding the time taken to complete the questionnaire as well as ease and comprehension of the questions. The final questionnaire was revised as per the feedback received.

A structured questionnaire was used to collect the data from the participants. The participants were given the option to complete the questionnaire unassisted or with the assistance of the researcher (interview guided). Those participants who selected the self-administered route were invited to contact the researcher, either at the study setting, telephonically or by email should they need clarity on any of the questions in the questionnaire.

The questionnaire was designed to capture all information required to meet the primary and secondary objectives of the study, with specific focus on those variables required to identify and describe CAM usage for the treatment of menopausal symptoms. The questionnaire consisted of 17 questions, divided into four sections:

- Section 1 (questions 1 to 5) related to the demographic details of the participant, including age, race, marital status, education level and employment status.
- Section 2 (questions 6 and 7) dealt with the participant's attitude toward menopause.
- Section 3 (questions 8 to 12) focused on menopausal symptoms and treatment.
- Section 4 (questions 13 to 17) focused on the sources that the participant utilised for information on CAMs. This section was only completed by participants who indicated CAM usage for menopausal symptoms in Question 12.

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Other than questions 11 and 12, the questionnaire consisted of simple categorical questions that could be rapidly answered, mostly in the "select one option" or "select all options that apply" pattern. This approach allowed the questionnaire to be rapidly completed by the respondent and minimised the risk that questions would be misunderstood or omitted.

Question 11 asked the participant to rate their own menopausal symptoms across 11 specifically defined symptoms, as defined in MRS II. For each symptom, the participant had to select a severity on the scale ranging from none, mild, moderate, severe and very severe. Section 3.5 describes the MRS II scale in detail, including its development and validation.

Question 12 asked the participant to detail their usage of all allopathic medicines, CAM, and supplements. For each product, the participant had to define its effectiveness on a three-point scale: effective, partially effective or ineffective.

Completed questionnaires were collected by the researcher as either a print-out at the study setting, or as a scanned attachment to an e-mail from the participant. Those questionnaires that were received

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electronically were printed out by the researcher. Each questionnaire was physically labelled with the unique participant number pre-allocated to that participant at the time of their entry into the study and used on the signed informed consent form.

The data from each questionnaire was captured by the researcher into the anonymous coding sheet, mastered in Microsoft® Excel®, and later verified to minimise capturing errors. This was used to create a single data table view with each participant representing a row in the data table, and each question or sub-question representing a column. For categorical data, standard coding was used across each participant to ensure that the data could be analysed easily.

The data table was analysed using a range of statistical methods in Microsoft® Excel®. These include descriptive techniques to describe the demographic breakdown of the participants, the prevalence of CAM usage per demographic attribute and overall sample, and analysis of variance to analyse the differences between group means. These statistics allowed some inferences to be drawn from the sample population.

The responses from Question 12 (medications used and their perceived efficacy) were recorded in a separate data table and were captured verbatim from the questionnaire. These responses were analysed individually by the researcher, who used her professional training to identify and categorise CAM treatments for menopausal symptoms, and to analyse usage of allopathic medicines, in line with the research objectives and prevailing literature. CAMs users in the context of the study findings included only participants who treated their menopausal symptoms with biologically-based systems as categorised in the NCCIH classification of CAMs therapies. These include botanicals, herbalism, vitamins, minerals and amino acids (U.S. National Library of Medicine: National Institutes of Health, 2003). The study findings and statistical analyses are presented in chapters 4 and 5.

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3.5 Menopause rating scale

One variable that the study aimed to investigate as a driver for the usage of CAMs was the severity of menopausal symptoms. To test this correlation effectively, it was necessary to formulate an objective measurement for the severity of menopausal symptoms, or at least a validated ranking within the sample. One such measurement that is supported by the literature is the MRS II, and this measurement was applied in the questionnaire and analysis.

The MRS II is a QOL scale developed in the early 1990's, and further refined to its final MRS II version in 1996. The scale was built and calibrated based on the evaluation of a questionnaire that was sent out to 689 German women aged between 40 to 60 years (Berlin Centre for Epidemiology and Health Research, 2008).

MRS II is a questionnaire-based approach that analyses menopausal symptoms in 11 categories across 3 dimensions (somato-vegetative, psychological and urogenital), with severity measured on a 5-point Likert scale, from "none" (0 points) to "very severe" (4 points). The somato-vegetative dimension includes symptoms such as hot flushes, heart or muscular discomfort and sleeping problems. The psychological dimension covers depressive moods, irritability, anxiety and exhaustion. The urogenital dimension includes

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sexual or bladder problems, as well as vaginal dryness. The score for each dimension is calculated by adding up the category scores in the respective dimension. These dimensions are ultimately combined to form an overall MRS score, ranging from 0 to 44, which is a validated measure for severity of menopausal symptoms.

Development of MRS II has validated that the questionnaire can be self-administered should the participant wish to do so, and can be completed within 10 minutes. Individual questions have a low omission rate since women do not typically feel the questions to be too private or sensitive (Heinemann, 2007).

Validation of the scale was confirmed through an open post-marketing study of 3282 women (Dinger *et al.,* 2006), which confirmed evidence for the scale to measure treatment effects on QOL. The MRS scale can be applied in women irrespective of age, and its application is not limited by ethnicity, social class, health status or geographic region.

3.6 Ethical considerations

Permission to conduct this study was granted from the University of the Western Cape's Biomedical Science Research Ethics Committee on 18 August 2017 (ref BM17/6/20) using the prescribed form and process. Permission was also granted from the community pharmacy to conduct the research at their premises, use their customer database to select participants, and contact their customers directly to request their participation in the study. Permission was granted by the owner of the pharmacy on 12 May 2017.

Participants' ethical rights and the ethical standards that this study conforms to were adhered to during the data collection process. No personal identifying information of participants was included in the questionnaire or published in this final research report.

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Potential participants were selected from the pharmacy's customer database. Once identified, each potential participant was contacted to inform them of the study and to request their participation. If the potential participant showed an interest in participating in the study a study information sheet explaining the details of the study was handed to them in person at the pharmacy at an arranged time, or via email if so requested. The informed consent, and the importance of understanding and signing it before participating in the study was explained to each participant. Each willing participant signed the informed consent before any data was obtained from them.

Each participant in the study was assigned a unique participant number that formed part of the coding of the study. The decoding document which maps any individual completed questionnaire to the personal identification of that participant was only available to the researcher. The informed consent and questionnaires were kept separately to ensure participant anonymity.

The electronic data extraction sheet and any data analysis contained only the unique participant numbers of each participant in the study and could not be mapped back to any personal participant details. Once the research is completed and all reports, publications, or other output have been complied, the electronic databases as well as all other data collection tools will be deleted and destroyed.

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This study raises no concern about patient safety or medical welfare. The researcher in this study was employed as a pharmacist at the study setting, and as a result, the researcher was also acting as the participant's health care professional. There was a possibility that the researcher might become aware of new health problems or concerns that came to light during the interview process or data coding process. In such a case, the researcher committed to advise and/or refer the participant to the relevant health care professional for further care and treatment. There was no anticipated direct benefit to the participants because of their participation in the study.

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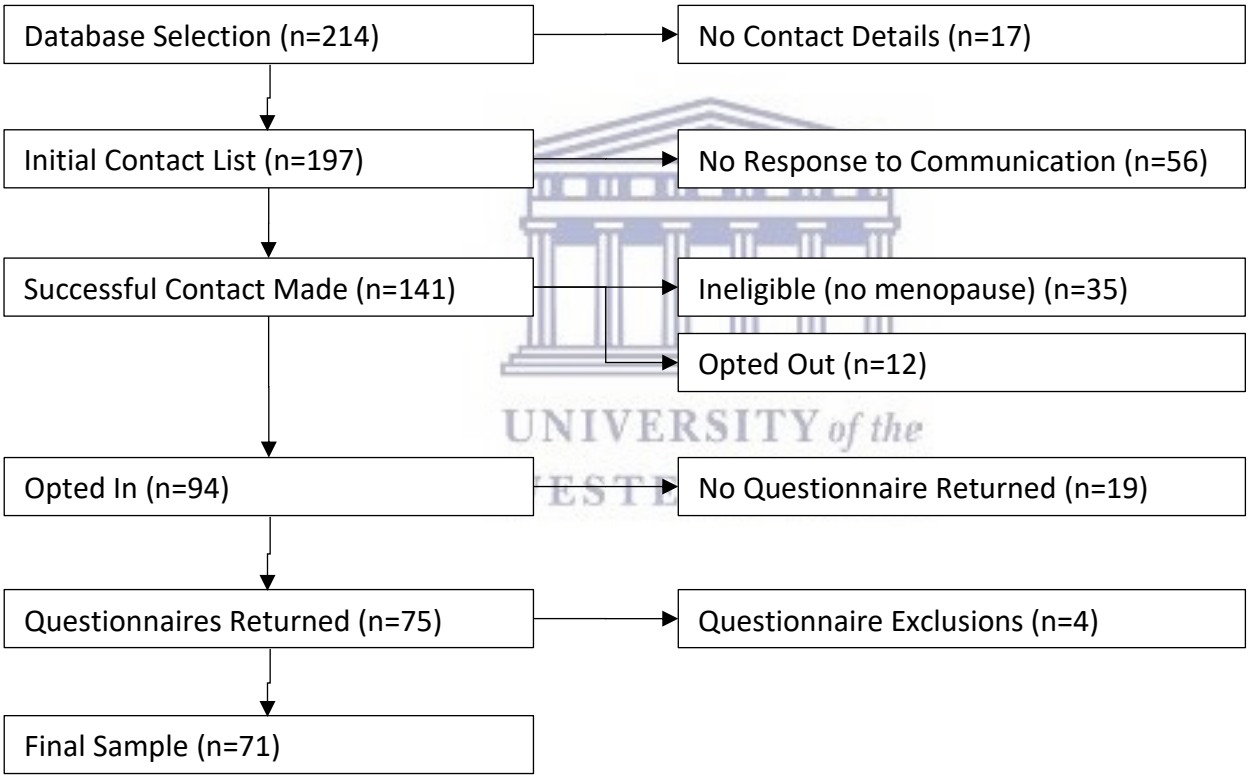
4. Findings

4.1 Responses

The database selection process yielded 214 potential participants for the study. Seventeen of these individuals did not have current contact details on the customer database and could not be contacted, resulting in an initial contact list of 197 potential participants. No response was received from 56 of these individuals despite several telephonic attempts made to reach them.

The researcher successfully contacted 141 potential participants and determined that 35 of them were not eligible for inclusion in the study, mostly because they had not yet experienced menopausal symptoms and still experienced regular periods. A further 12 individuals opted out of the study, indicating that they were either unable or unwilling to participate. Ninety-four participants agreed to partake in the study following this initial contact period. The initial contact and response process is illustrated in Figure 1 below.

Figure 1: Questionnaire distribution and responses



After being informed of the Study Pack, all the final 94 participants elected self-administration of the questionnaire rather than an interview-guided process. Of the 94 participants that opted to participate in the study, a total of 75 completed questionnaires were ultimately submitted by participants, representing a response rate of 38.1% based on the initial contact list, and 53.7% when accounting for participants that opted out or were ineligible for inclusion. Four participants had to be excluded from the 75 completed questionnaires because the onset of their menopausal symptoms was due to radiation, chemotherapy or other drugs or a bilateral oophorectomy. The final sample size was therefore 71 participants.

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4.2 Demographics of participants

The demographic analysis of participants is provided in Table 2 below. Analysis is presented for the entire sample (n=71) and split by participants who have used CAMs for the treatment of their menopausal symptoms (n=27) and those that have not (n=44).

Table 2: Demographic analysis of participants (n=71)

	Sample (n=71)		CAMs Users (n=27)		No CAMs (n=44)	
	Count	**Proportion**	**Count**	**Proportion**	**Count**	**Proportion**
AGE						
40-44	1	1.4%			1	100.0%
45-49	10	14.1%	4	40.0%	6	60.0%
50-54	32	45.1%	13	40.6%	19	59.4%
55-59	18	25.4%	6	33.3%	12	66.7%
60-64	10	14.1%	4	40.0%	6	60.0%
	71	**100.0%**	**27**	**38.0%**	**44**	**62.0%**
RACE						
Asian	1	1.4%	1	100.0%		
Black	3	4.2%	1	33.3%	2	66.7%
White	66	93.0%	25	37.9%	41	62.1%
Omitted	1	1.4%			1	100.0%
	71	**100.0%**	**27**	**38.0%**	**44**	**62.0%**
MARITAL STATUS						
Divorced	8	11.3%	6	75.0%	2	25.0%
Married	57	80.3%	21	36.8%	36	63.2%
Single	4	5.6%			4	100.0%
Widowed	2	2.8%			2	100.0%
	71	**100.0%**	**27**	**38.0%**	**44**	**62.0%**
HIGHEST LEVEL OF EDUCATION						
Matric	9	12.7%	3	33.3%	6	66.7%
Diploma	18	25.4%	10	55.6%	8	44.4%
Degree	16	22.5%	7	43.8%	9	56.3%
Post-Graduate	28	39.4%	7	25.0%	21	75.0%
	71	**100.0%**	**27**	**38.0%**	**44**	**62.0%**
EMPLOYMENT STATUS						
Full-Time	31	43.7%	10	32.3%	21	67.7%
Part-Time	5	7.0%	2	40.0%	3	60.0%
Retired	7	9.9%	2	28.6%	5	71.4%
Self-Employed	19	26.8%	8	42.1%	11	57.9%
Unemployed	9	12.7%	5	55.6%	4	44.4%
	71	**100.0%**	**27**	**38.0%**	**44**	**62.0%**

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In comparison to the study target age range of 40 to 65 years, participants' ages ranged from 44 to 64 years with a median age of 53 years. Nearly a quarter of participants were aged 53 or 54. The majority of participants in this study were white (93.0%, n=66). Most (80.3%, n=57) of the participants were married, with a relatively small proportion of divorced (11.3%, n=8), single (5.6%, n=4) and widowed (2.8%, n=2) participants. These overall proportions for race and marital status aligned with the reported demographics for CAM users across race (92.6% white) and marital status (77.8% married).

In terms of highest level of education, participants with post graduate qualifications formed 39.4% of the total sample, however only 25.9% of CAM users reported having a post graduate qualification, compared to 47.7% of participants that did not report CAM usage. This may indicate that women with higher levels of formal education are less likely to use CAMs for the treatment of their menopausal symptoms. However, using a 5% level of significance, a chi-square test provided no significant indication that there was a dependency relationship between CAM usage and educational level (p-value = 0.20).

The second observation was that the proportion of CAM users that were unemployed (18.5%) appeared more than the sample proportion (12.7%), whereas the proportion of CAM users that were retired (7.4%) appeared lower than the sample proportion (9.9%), which may indicate a correlation between employment status and CAM usage. However, using a 5% level of significance, a chi-square test provided no significant indication that there was a dependency relationship between CAM usage and employment status (p-value = 0.73). It was not appropriate to test variable independence for marital status and race due to the large number of low expected frequencies in each case.

As an extension to their basic demographic attributes, participants were asked to select the phrase that best described both their personal understanding of menopause, as well as their personal attitude toward menopause. The responses are summarised in Table 3. Most participants viewed menopause as a natural life stage for women (85.9%, n=61), with only 12.7% (n=9) viewing it as a permanent chronic medical condition. Furthermore, 47.9% (n=34) indicated that their own personal attitude to menopause was positive. A minority (15.5%, n=11) reported a negative attitude toward menopause. This proportion appeared higher among CAMs users however, where 22.2% reported a negative personal attitude to menopause. However, using a 5% level of significance, a chi-square test provided no significant indication that there was a dependency between CAMs usage and attitude to menopausal symptoms (positive, neutral or negative) (p-value = 0.27).

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Table 3: Participants' personal understanding and attitude toward menopause (n=71)

	Sample (n=71)		CAMs Users (n=27)		No CAMs (n=44)	
	Count	**Proportion**	**Count**	**Proportion**	**Count**	**Proportion**
PERSONAL UNDERSTANDING OF MENOPAUSE						
Natural Life Stage	61	85.9%	27	44.3%	34	55.7%
Temporary Medical Condition	1	1.4%			1	100.0%
Permanent Medical Condition	9	1.4%			9	100.0%
	71	**100.0%**	**27**	**38.0%**	**44**	**62.0%**
PERSONAL ATTITUDE TO MENOPAUSE						
Positive Attitude	34	47.9%	11	32.4%	23	67.6%
Neutral Attitude	26	36.6%	10	38.5%	16	61.5%
Negative (loss of youth)	2	2.8%	2	100.0%		
Negative (symptoms)	9	12.7%	4	44.4%	5	55.6%
	71	**100.0%**	**27**	**38.0%**	**44**	**62.0%**

The study is aimed at describing CAMs usage in the treatment of menopausal symptoms. Even though women are defined as having experienced menopause once they have not had a menstrual cycle for 12 months (The North American Menopause Society, 2017b), menopausal symptoms can be experienced within the peri-menopausal stage, before actually reaching menopause. More than 80% (n=58, 81.7%) of the study participants reported that their last menstrual cycle was more than 12 months in the past, and thus meet the definition for experiencing menopause. Of the remaining participants, six (8.5%) did not have a menstrual cycle in the previous 2-11 months, and seven (9.9%) did have a menstrual cycle within the last month. All 13 of these peri-menopausal participants reported symptoms associated with menopause.

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4.3 Severity of menopausal symptoms

The MRS II was the validated rating scale used to measure and compare the severity of menopausal symptoms among participants. Eleven symptoms were reported across three dimensions, namely somato-vegetative, psychological and urogenital. Each symptom had a numeric severity score of 0-4 ranging across the five severity levels: None (0), Mild (1), Moderate (2), Severe (3) and Very Severe (4). The individual severity ratings were then aggregated by dimension, and finally an overall MRS II rating was calculated on a scale of 0 to 44, with 0 indicating no symptoms and 44 indicating that all 11 symptoms were reported as very severe. The average MRS II ratings are provided in Figure 2 for all participants (11.83), as well as for non-CAM/HRT uses, HRT users, CAM users and CAMs + HRT users.

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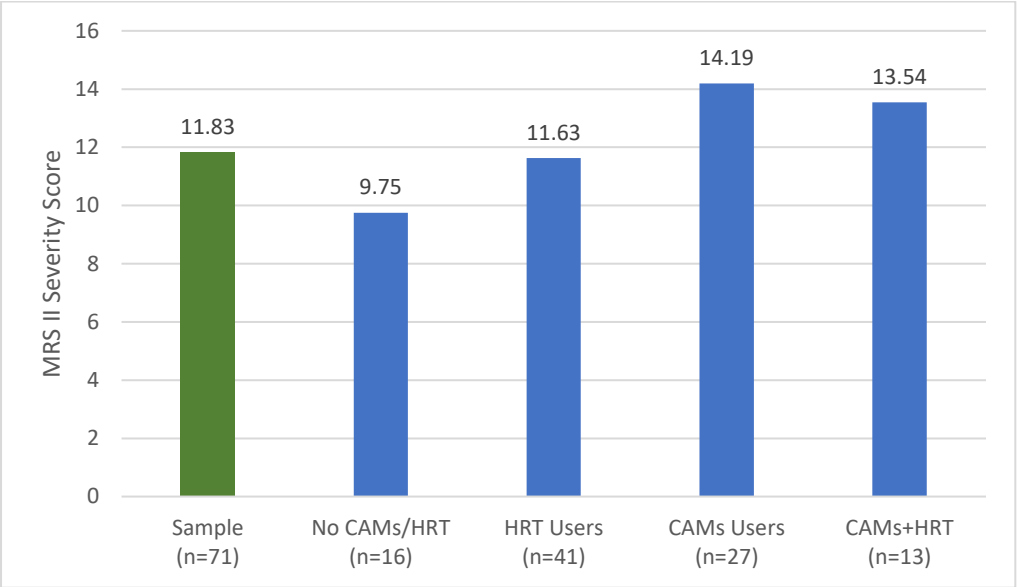
Figure 2: Average overall menopausal symptom rating scale scores (0-44) for study participants (n=71)



Given that the observed MRS II severity for CAM users (14.19) appeared materially higher than that for the entire study (11.83), a t-test was applied to test whether this relationship was statistically significant. Using a 5% level of significance, a t-test indicated that CAM users reported significantly more severe overall menopausal symptoms than participants not using CAMs (p-value = 0.02).

In contrast, the observed MRS II severity for HRT users (11.61) was lower than that for the entire study population (11.86), and a t-test was applied to test whether this relationship was statistically significantly. Using a 5% level of significance, a t-test provided no significant indication that HRT users reported significantly less severe symptom severity than non-HRT users (p-value = 0.40). Detailed results of statistical t-tests are presented in Appendix 4.

Figure 3 presents the average severity ratings for each MRS II symptom across the entire sample. The individual symptom with the most severe MRS II rating in the sample was sleep problems, which included difficulty in falling asleep, difficulty in sleeping through and waking up early. The average MRS II rating for sleep problems across the study was 1.49, compared to the overall average study symptom rating of 1.08, and the lowest of 0.69 (bladder problems including difficulty in urinating, increased need to urinate and bladder incontinence).

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Figure 3: Comparative severity of the different menopausal symptoms across the study participants (n=71)

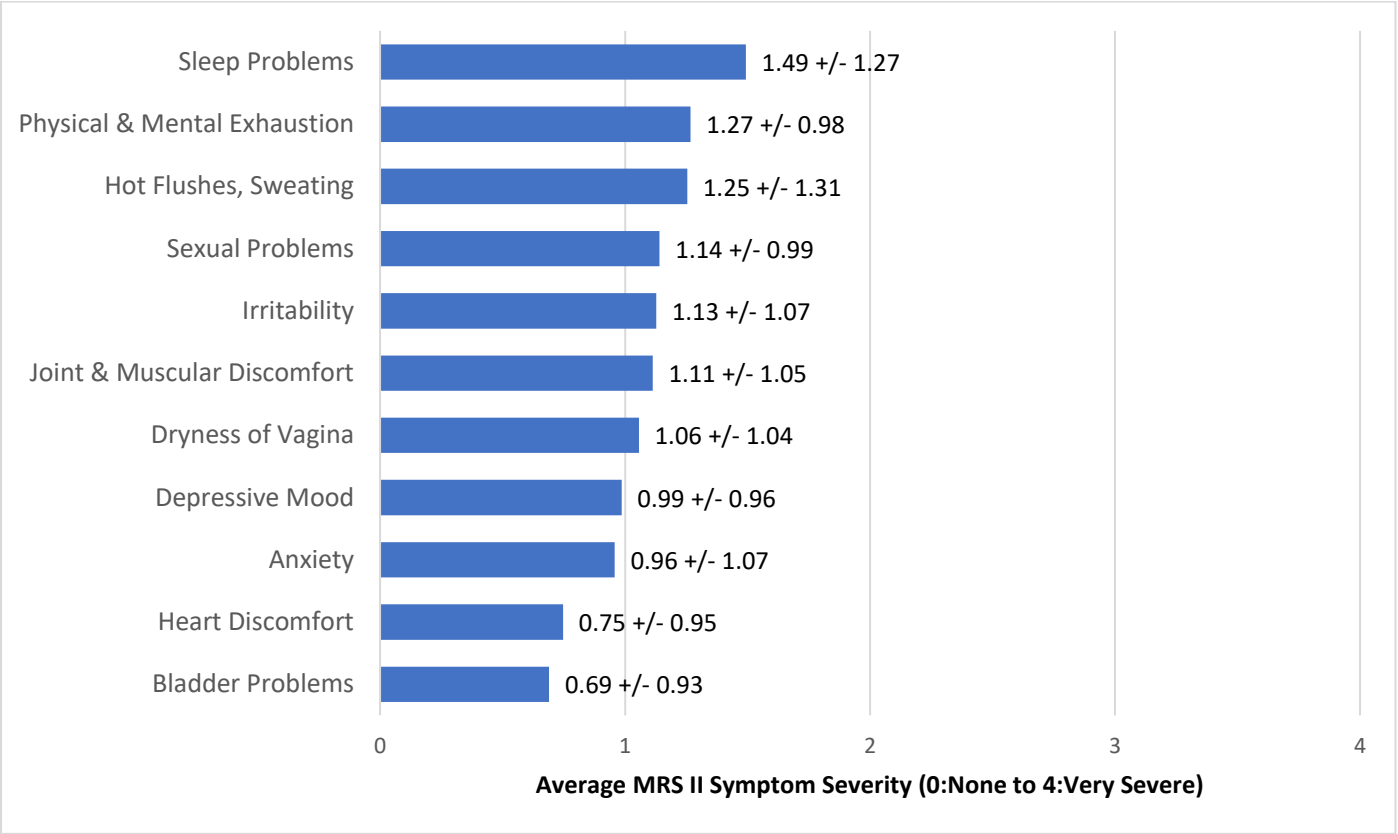

Table 4 provides the average MRS II ratings for each of the eleven symptoms divided into the three dimensions. The averages are provided separately for CAM users and HRT users in addition to the overall study result. Furthermore, averages are provided for participants that used both CAMs and HRT, as well as for participants that used neither CAMs nor HRT. CAMs users experienced more severe symptoms across every one of the eleven symptoms compared to all participants. In line with the overall study result, sleep problems were also the most severe symptom across CAM users, non-CAM users, HRT users and non-HRT users.

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Table 4: Average severity of menopausal symptoms and dimensions reported by study participants (n=71)

Symptom / Dimension	Sample (n=71)	CAMs Users (n=27)	HRT Users (n=41)	CAMs+HRT (n=13)	No CAMs/HRT (n=16)
Hot Flushes, Sweating	1.25	1.48	1.27	1.38	0.94
Heart Discomfort	0.75	0.81	0.73	0.85	0.75
Sleep Problems	1.49	1.74	1.41	1.54	1.31
Joint & Muscular Discomfort	1.11	1.30	1.12	1.54	1.13
Somato-Vegatative (average)	**1.15**	**1.33**	**1.13**	**1.33**	**1.03**
Depressive Mood	0.99	1.04	1.07	1.08	0.75
Irritability	1.13	1.19	1.17	1.15	0.94
Anxiety	0.96	1.07	1.00	1.08	0.75
Physical & Mental Exhaustion	1.27	1.59	1.22	1.54	1.06
Psychological (average)	**1.09**	**1.22**	**1.12**	**1.21**	**0.88**
Sexual Problems	1.14	1.41	1.12	1.31	0.88
Bladder Problems	0.69	1.11	0.56	0.92	0.50
Dryness of Vagina	1.06	1.44	0.95	1.15	0.75
Urogenital (average)	**0.96**	**1.32**	**0.88**	**1.13**	**0.71**

The dimension with the most severe average MRS II rating in the sample was the somato-vegetative dimension, which included symptoms such as hot flushes, heart discomfort, sleep problems, joint discomfort and muscular discomfort. The average MRS II rating for somato-vegetative symptoms across the study was 1.15, compared to 1.09 for the psychological dimension, and 0.96 for the urogenital dimension.

Similarly, the highest dimension MRS II rating for CAM users was the somato-vegetative dimension, with an average dimension MRS II rating for CAM users of 1.33. The next most severe dimension was only marginally less severe, and not significantly so (p-value = 0.95), with an average dimension MRS II rating of 1.32 for the urogenital dimension, which included symptoms such as sexual problems, bladder problems and vaginal dryness.

4.4 Complementary and alternative medicines usage

CAMs were used by 38.0% (n=27) of the participants to treat their menopausal symptoms. Just over half (51.9%) of these CAM users used a single CAM treatment, with the rest using between two and four separate treatments, although not necessarily concurrently. The number of CAM treatments used by each participant is summarised in Table 5.

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Table 5: Number of CAM products used by participants (n=27)

Number of CAMs	Frequency	Proportion
1	14	51.9%
2	9	33.3%
3	1	3.7%
4	3	11.1%
	27	**100.0%**

There were five specific CAMs that were used by multiple participants, with calcium, and phyto-oestrogens such as soy and Red Clover isoflavones, being the most frequently used, each with 9 participants reporting their usage. Table 6 lists all CAMs where there was reported usage by more than one participant.

Table 6 combines omega 3 and omega 6 usage into a single category, since three of the eight omega users either reported using a combination omega 3 and 6 treatment, or alternatively did not specify the type of omega treatment used.

Table 6: Most frequently used CAMs used by multiple participants (at least 5 reported users)

Treatment	Total Frequency	Total Proportion
Phyto-oestrogens	9	33%
Calcium	9	33%
Omega (3 and/or 6)	8	30%
Black Cohosh	6	22%
Magnesium	5	19%

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In addition to the five most frequently used CAMs treatments, there were 14 other vitamins, herbal, botanical, amino-acid and homeopathic remedies used, although none were used by more than a single participant. Table 7 lists these CAM treatments together with their active ingredient. In total, 43.1% of all individual CAM treatments were perceived as effective.

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Table 7: CAMs treatments with limited usage patterns

Treatment	Active Ingredient	Type
Vitamin B Complex	B-vitamins	Vitamins
Vital multivitamin for mature women	Multiple	Vitamins
Vitamin E	E-vitamin	Vitamins
CP Melatonin	Melatonin	Botanical
GABA	Gamma-aminobutyric acid	Amino acid
SEPIA	Sepia Succus, Sepia Officinalis	Homeopathic
KY Jelly		Lubricant
Kolorex	Horopito	Herbal
Solal Hormone Booster	3,4-divanillyltetrahydrofuran	Botanical
Heel ovarium compositum	Ovarium suis D8	Homeopathic
Premular	Vitex agnus-castus	Herbal
A Vogel Hot Flush and Night Sweat Remedy	Sage herb	Herbal
Procaps	Progesterone compound	Botanical
Testogel cream	Testosterone compound	Botanical

While the overall prevalence of CAM usage was 38.0%, this prevalence appeared to be somewhat higher for women with more severe symptoms. Women reporting a MRS II rating of more than 15 were in the 30th percentile of most severe symptoms in this study, and at this level CAM usage was 57.9%.

4.5 Complementary and alternative medicines efficacy

Participants reported on the efficacy of their CAM interventions across three categories, namely effective, partially effective and ineffective. Participants reported on the effectiveness of individual CAM treatments for their menopausal symptoms, with 63.0% (n=17) of CAM users finding at least one CAMs treatment to be effective.

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Across the five CAM treatments that were used by more than one participant, only omega (3 and/or 6) and magnesium saw more than half of users report the treatment to be effective, with 80% of magnesium users reporting effectiveness, and 62.5% of omega users. Black Cohosh had the lowest reported full effectiveness levels of 33.3%. The reported levels of effectiveness are summarised in Figure 4.

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Figure 4: Efficacy ratings of CAMs users (n=27) for the most commonly used CAMs treatments

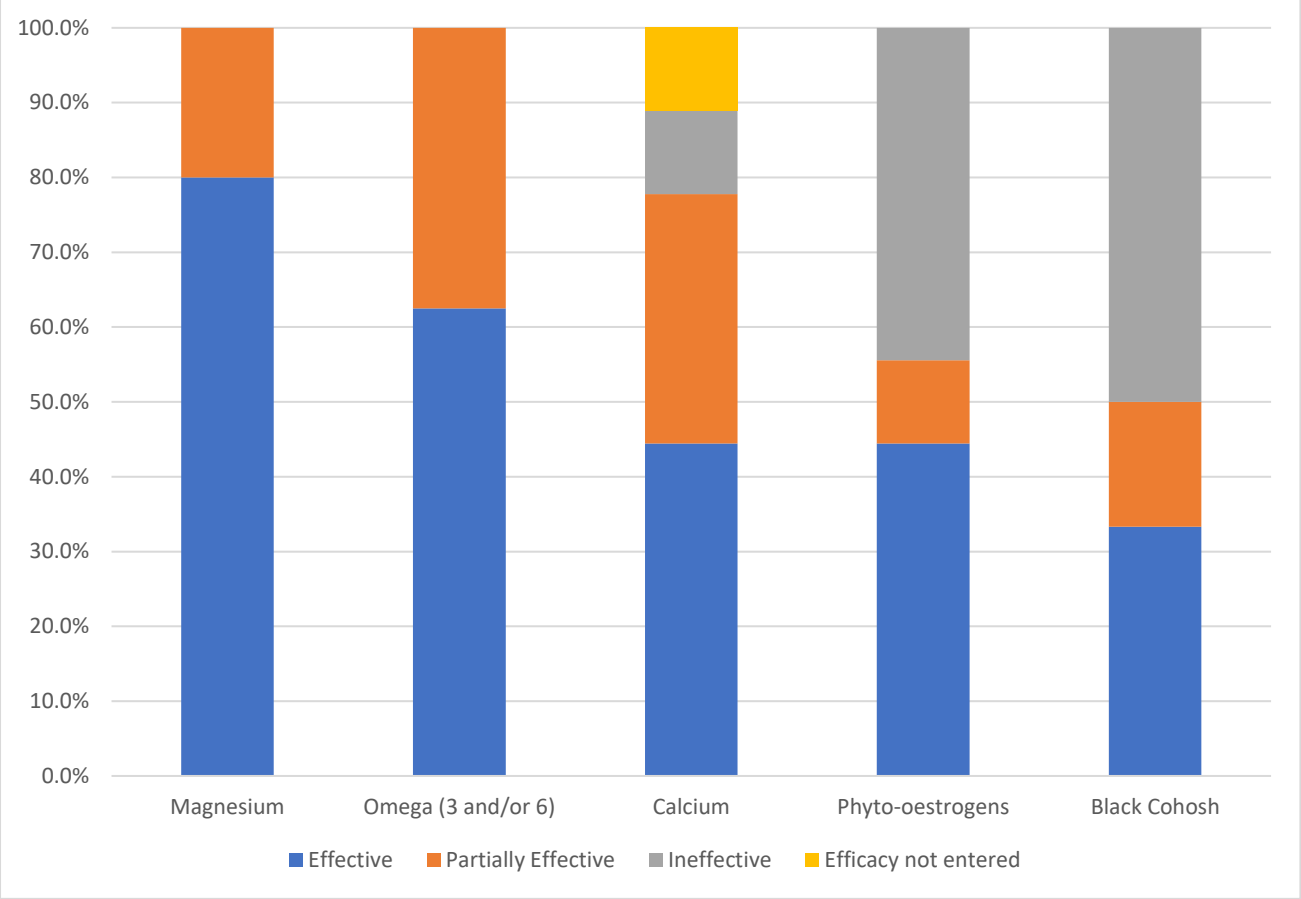

Table 8 lists the reported efficacy of CAM products that were used by a single participant. Of these, only three reported the intervention to be effective, namely Vitamin B, Vitamin E and Progesterone compound (Procaps).

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Table 8: Efficacy of CAMs treatments with limited usage patterns

Treatment	Active Ingredient	Perceived Efficacy
Vitamin B Complex	B-vitamins	Effective
Vital multivitamin for mature women	Multiple	
Vitamin E	E-vitamin	Effective
CP Melatonin	Melatonin	Partially Effective
GABA	Gamma-aminobutyric acid	Partially Effective
SEPIA	Sepia Succus, Sepia Officinalis	Partially Effective
KY Jelly		
Kolorex	Horopito	Ineffective
Solal Hormone Booster	3,4-divanillyltetrahydrofuran	Partially Effective
Heel ovarium compositum	Ovarium suis D8	Ineffective
Premular	Vitex agnus-castus	Partially Effective
A Vogel Hot Flush and Night Sweat Remedy	Sage herb	Ineffective
Procaps	Progesterone compound	Effective
Testogel cream	Testosterone compound	Partially Effective

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4.6 Comparing complementary and alternative medicine and hormone replacement therapy usage

There was a significant number of participants who used CAM and HRT treatments concurrently (18.3%), although the largest category in this study were HRT users who had not used CAMs (39.4%). Table 9 summarises the concurrent usage of CAMs and HRT, showing the four possible combinations of CAM users and HRT users. More participants that did not use HRT were non-CAM users (22.5%) rather than CAM users (19.7%).

Table 9: Concurrent CAM and HRT usage patterns of participants (n=71)

	HRT Users	Non-HRT Users	**Row Totals**
CAM Users	18.3% (n=13)	19.7% (n=14)	**38.0% (n=27)**
Non-CAM Users	39.4% (n=28)	22.5% (n=16)	**62.0% (n=44)**
Column Totals	**57.7% (n=41)**	**42.3% (n=30)**	**100.0% (n=71)**

Nearly half (48.1%, n=13) of CAM users were also using HRT at the time of the questionnaire, with 51.9% (n=14) of CAM users not using HRT to treat their menopausal symptoms. Altogether, 57.7% (n=41) of the participating women reported to be current HRT users, with the rest of participants (42.3%, n=30) not currently using HRT. Of these 30 non-HRT users, 4 participants had previously used HRT but had subsequently terminated their usage. A chi-square test applied to test whether CAM usage was independent of HRT usage did not indicate that there was a significant dependence between CAM usage and HRT usage (p-value = 0.20).

Table 10 presents the overall average MRS II score per category, using the same CAM usage vs. HRT usage categorisation applied in Table 9. Participants that were using both CAMs and HRT reported an average MRS II rating of 13.5, less than the 14.2 reported by all CAM users. However, CAM users that were not using HRT reported the most severe symptoms with a MRS II rating of 14.8. Among HRT users, it was found that the symptom severity was higher for participants who were also CAM users (13.5) compared to those who did not use CAMs (10.8).

Table 10: Average overall MRS rating for CAMs and HRT users (n=71)

	HRT	**No HRT**	**Row Averages**
CAM Users	13.5	14.8	**14.2**
Non-CAM Users	10.8	9.8	**10.4**
Column Averages	**11.6**	**12.1**	

4.7 Sources of information for complementary and alternative medicines users

The 27 participants that used CAMs in the treatment of their menopausal symptoms responded to four additional questions around their sources for CAM information and recommendations. Participants were asked to identify all the media sources that they had used to obtain information on CAMs, as well as the key individual that they identified as their primary information source. They were asked to indicate whether they had consulted with their medical doctor directly before using CAMs, as well as to identify all the

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individuals who had provided them with a specific CAM recommendation. The final question in this section of the questionnaire requested the participant's primary motivation for CAM usage.

The second section of Table 11 summarises the primary source participants used to obtain information on CAMs ("Primary source for CAMs information"), and the questionnaire limited participants to select a single choice for this question. The other three sections in the table report on questions that allowed participants to select multiple responses if applicable.

Table 11: Qualitative assessment by CAM users: information sources, recommendation sources, and motivation for CAM usage (n=27)

SOURCES OF MEDIA UTILISED FOR CAMS		
	Count	**Proportion**
Internet	16	59.3%
Magazines	9	33.3%
Books	5	18.5%
Other	4	14.8%
Television	2	7.4%
PRIMARY SOURCE FOR CAMS INFORMATION		
	Count	**Proportion**
Medical Doctor	9	33.3%
Internet	8	29.6%
Pharmacist	4	14.8%
Friend	2	7.4%
N/A	2	7.4%
CAM Practitioner	1	3.7%
Colleague	1	3.7%
	27	**100.0%**
SOURCE OF RECOMMENDATIONS FOR CAMS PRODUCT		
	Count	**Proportion**
Medical Doctor	17	63.0%
Friend	5	18.5%
Pharmacist	4	14.8%
Family Member	3	11.1%
Other	3	11.1%
Colleague	2	7.4%
CAM Practitioner	1	3.7%
PERSONAL REASONS FOR USING CAMS		
	Count	**Proportion**
Adverse HRT effects	9	33.3%
Personal Values	9	33.3%
Other	9	33.3%
Lack of efficacy of allopathic medicines	3	11.1%

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The internet was utilised to obtain information on CAMs by 59.3% of CAM users, although other sources of media were also used, including magazines (33.3%), books (18.5%) and television (7.4%). When asked to identify the single main source of information relied on to gather information on CAM treatments, 33.3% of CAM users indicated their medical doctor, although this was closely followed by 29.6% who selected the internet. Of the 16 CAM users that used the internet to obtain information on CAMs, 7 of them viewed the internet as their single main source of information on the subject, ahead of doctors and other medical professionals.

Nearly two thirds (63.0%) of CAM users consulted with their medical doctor before initiating CAM treatment for their menopausal symptoms. Of these 17 participants, 14 received a recommendation from their medical doctor for a specific CAM treatment, and medical doctors were in fact the dominant source for recommending specific CAM treatments across all CAM users (63.0%).

The reasons that participants identified to adopt CAMs as a treatment plan were varied. Nine participants responded that it was due to HRT treatments resulting in adverse side-effects (33.3% of CAM users), and 9 participants responded that it was due to their personal beliefs or values. In addition to the three choices provided, 9 participants selected the "other" option and specified their own reason for the choice to use CAMs, such as: "Needed an energy boost", "Additional relief of severe symptoms" (2), "Recommended/Prescribed" (3), "Family history of breast cancer" (2), and "Environmental concerns".

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5. Discussion

The main purpose of this study was to describe the use of CAMs in the treatment of menopausal symptoms by women who access private healthcare in Pretoria, South Africa. The study also sought to gather information on the concurrent usage of CAMs and hormonal treatments, as well as to collect data on the sources of information utilised for CAMs.

5.1 Responses

Despite opting out of a formal assisted-questionnaire process, several participants did seek clarity from the researcher on specific questions while completing the questionnaire - either at the study setting, telephonically or by email. The researcher could resolve all such interactions satisfactorily at a time convenient for the participant and was thus able to provide the assistance required. Of the five comparative studies that utilised a questionnaire (Buhling *et al.*, 2014; van der Sluijs *et al.*, 2007; Cardini *et al.*, 2010; Gerber *et al.*, 2014; Gollschewki *et al.*, 2004), all except the Gerber *et al.* (2014) study were designed on a self-administration basis, and the preferences indicated by our study validate that self-administration appears to be the preferred approach for study participants. It is however reasonable to believe that the four participants who submitted questionnaires that were subsequently excluded may have been identified earlier in a guided interview approach.

5.2 Demographics of participants

In comparison to the study target age range of 40-65 years, participants' ages ranged from 44 years to 64 years with an average age of 54 years. The average age was in line with the results of Buhling *et al.* (2014), (52.6 years), van der Sluijs *et al.* (2007), (52.5 years) and Gollschewki *et al.* (2004) (54.8 years).

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The single-site study was conducted at a private community pharmacy situated in Pretoria. In aggregate, participants indicated a high level of education and a high proportion of salary-earners, which is in line with private healthcare patients in South Africa. While South Africa is not regarded as a developed country, consumers of private medical services in South Africa do tend to correspond to a LSM of 8-10 (Hospital Association of South Africa, 2008) indicating a higher average living standard compared to the typical South African. As a result, the participants from our study setting would have some level of comparability to results of the studies situated in developed countries (Buhling *et al.*, 2014; van der Sluijs *et al.*, 2007; Cardini *et al.*, 2010; Gollschewki *et al.*, 2004).

The van der Sluijs *et al.* (2007), Cardini *et al.* (2010) and Gerber *et al.* (2014) studies were conducted out of healthcare facilities, which would be broadly comparable the setting for our study, which is a community pharmacy and clinic. It is however not clear from those two studies whether the settings were public or private facilities, whereas our study was restricted to a private healthcare facility.

Cardini *et al.* (2010) reported no significant differences between demographic groups including age, marital status and employment status. Gerber *et al.* (2014) did however find that higher levels of education were associated with CAM usage. Our study found no statistically significant dependence between CAM usage

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and either employment status or educational levels. Nonetheless, in the post-graduate educational level category specifically, there was a lower prevalence of CAM usage observed (25.0%) compared to no usage (48.8%), although this pattern was not observed across the other educational level categories.

5.3 Severity of menopausal symptoms

Comparing CAM users to the entire sample, they had a higher average MRS score (14.19 vs. 11.83) and higher median MRS score (12 vs 11), and as such a statistical test was conducted to test the hypothesis that the average MRS score for CAM users is higher than that for non-CAM users. This test was conducted at a 5% level of significance and indicated that CAM usage is associated with more severe menopausal symptoms that non-CAM usage. Furthermore, CAM users experienced more severe symptoms across every one of the eleven symptoms compared to the symptoms of non-CAM users. Although not all the comparative studies included an analysis at the symptom level, this finding does align with the van der Sluijs *et al.* (2007) study which found that CAM users considered all menopausal symptoms as more severe compared to non-CAM users.

5.4 Complementary and alternative medicine usage

The prevalence of CAM usage to treat menopausal symptoms in this study was 38.0%. Five comparative studies found CAM usage ranging from 34% to 83%, with a median study result of 48% (Buhling *et al.*, 2014; van der Sluijs *et al.*, 2007; Cardini *et al.*, 2010; Gerber *et al.*, 2014; Gollschewki *et al.*, 2004). Bosman *et al.* (2008) focused their South African based study on attitudes and beliefs around soy products, rather than actual prevalence of usage.

This study found that calcium and phyto-oestrogens were the most commonly used CAM treatments. Table 12 lists the findings from comparative studies with respect to the most common CAMs used.

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Table 12: Most commonly used complementary and alternative medicines in comparative studies

Study	Most commonly used CAMs
Buhling *et al.*, 2014	St John's wort (18%), homeopathy (15%)
Van der Sluijs *et al.*, 2007	Soy (25.4%), omega 6 (18.4%)
Cardini *et al.*, 2010	Herbal products (41%), soy (26%)
Gerber *et al.*, 2014	Nutritional remedies (18.8%), herbal remedies (16.9%)
Gollschewki *et al.*, 2004	Phyto-oestrogens (56%), omega 6 (34%), vitamin E (29%)

Phyto-oestrogens in general are identified by three of these studies as frequently used, in line with the finding that 33% of CAM users used phyto-oestrogens in our study. Gollschewski *et al.* (2004) found that 55.8% of participants used phyto-oestrogens, including 10.5 of total participants that used red clover. The Bosman *et al.* (2008) study focused exclusively on the health benefits of soy and soy products, finding that 69% of respondents agreed that soy has many health benefits.

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Table 13 lists some of the known benefits, risks and drug interactions relevant to the five common CAM treatments identified in our study. Due to the differences in risks and benefits, omega 3 and omega 6 have been listed separately, although the usage column in Table 13 reflects the combined usage for omega 3 and/or 6.

Table 13: Benefits, risks and drug interactions of the CAM treatments most commonly used by study participants (n=27)

CAM Treatment	Usage	Possible Benefit	Risks	Drug Interactions
Phyto-oestrogens	33%	Improves hot flushes[3]	Endometrial hyperplasia (Soy products)[3]	Anticoagulants (Red Clover)[3]
Black Cohosh	22%	Better then placebo for hot flushes[3]	GI Disturbances[3] Skin rashes[10] Jaundice[10]	None known[3]
Omega 3	30%*	Reduce inflammation of painful joints[1] Lubricate the body thus helping with vaginal dryness[1] Reduce the frequency of hot flushes with the right dosage[1]	GI Disturbances[6]	Anticoagulants[4,6] Some oral diabetic medicines[6]
Omega 6 (EPO)	30%*	Decreases night flushes[3]	Inflammation[3] Thrombosis[3] Nausea[3] Diarrhoea[3]	Anticoagulants[2,3] Phenothiazines[2,3]
Calcium	33%	Preventing bone loss[4]	GI Disturbances[7]	Ceftriaxone[7] Biphosphates[7] Digoxin[7] Gentamycin[7]
Magnesium	19%	Improves hot flushes[9] Improves insomnia, irritability, agitation and anxiety – potential symptoms of menopause[8]	Nausea and vomiting[8] May lower blood pressure[8]	Possible interaction with calcium channel blockers[5] Possible interaction with quinolone and tetracycline antibiotics as well as Nitrofurantoin[5]

([1]:Menopause Centre Australia, 2016; [2]:The North American Menopause Society, 2017a; [3]:Sonnedecker, 2006; [4] :University of Maryland Medical Center, 2015a; [5]:University of Maryland Medical Center, 2015b; [6]:University of Maryland Medical Center, 2015c; [7]:University of Maryland Medical Center, 2016; [8]:University of Maryland Medical Center, 2015d; [9]:Tonick and Muneyyirci-Delale, 2016; [10]:National Center for Complementary and Integrative Health, 2017)

In our study, just less than half of CAM users (48.1%) had used more than a single CAM treatment for their menopausal symptoms. Buhling *et al.* (2014) found 64.8% of CAM users had used more than one CAM intervention, although van der Sluijs *et al.* (2007) had a far lower finding of 23.7% of CAM users that had used two or more products.

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A few participants (15.4%, n=11) did not use CAMs to treat their menopausal symptoms but did use CAMs for the treatment of unrelated conditions. These participants were excluded from the definition of CAM users in our study. Van der Sluijs *et al.* (2007) found that nearly a quarter of that study's participants (25.3%) used CAMs for health conditions other than menopause.

5.5 Complementary and alternative medicines efficacy

Participants reported on the effectiveness of CAM treatments for their menopausal symptoms, with 63.0% (n=17) of CAM users finding at least one CAM treatment effective. Across the five most commonly used treatments, magnesium was reported to be effective by 80% of users, and omega (3 and/or 6) by 62.5% of users. In contrast, van der Sluijs *et al.* (2007) found that the three most effective CAM treatments were phyto-oestrogens, evening primrose oil (EPO) and black cohosh. Three out of five (60%) of the participants in the van der Sluijs *et al.* (2007) study found at least one practitioner or product to be very effective in improving menopausal symptoms, which is almost the same as the 62.5% found in our study.

None of the eight CAM users that used omega 3 and/or 6 found it ineffective. In contrast, some studies have found that EPO provides no added benefit for menopausal hot flushes or night time sweating (Chenoy *et al.*, 1994 and van der Westhuizen, 2009) while another agreed that omega 3 has no effect on vasomotor frequency or intensity (Cohen, 2009). Yet, the Menopause Centre of Australia has found that omega 3 can decrease the frequency of hot flushes by up to half, with the correct dosage (Menopause Centre Australia, 2016).

This study found that phyto-oestrogens were effective in treating symptoms in 44.4% of cases, partially effective in 11.1%, and ineffective in 44.4% of the cases. Soy and Red Clover were CAMs that were classified as phyto-oestrogens in this study. According to the Bosman *et al,* (2008) study, one third of South African women agreed that soy can be used as an alternative to HRT despite only 23% believing that it could relieve menopausal symptoms. Other studies have found phyto-oestrogens the most ineffective CAM treatment (Buhling *et al.*, 2014) whereas some evidence of soy improving hot flushes has been reported (Sonnedecker, 2006), based on a meta-analysis of randomised controlled trials.

This study found that CAM usage was associated with more severe menopausal symptoms. Even considering only HRT users in isolation, CAM users reported more severe symptoms than non-CAM users. This may indicate that CAMs do not provide high levels of effectiveness when menopausal symptoms are more severe. There have been reports that CAM interventions are rated less effective in comparison to HRT where women have more severe complaints (Buhling *et al.*, 2014).

5.6 Comparing complementary and alternative medicines and hormone replacement therapy usage

There was a meaningful number of participants who used CAMs and HRT concurrently (18.3%). Van der Sluijs *et al.* (2007) found that 37.4% of respondents were using CAM products in conjunction with some pharmaceutical product, and Cardini *et al.* (2010) found that only 6.8% of respondents used CAMs in conjunction with HRT.

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It is possible that women who experience more severe menopausal symptoms may find that their quality of life is significantly impacted and may consequently be more likely to consider a range of interventions, either allopathic, complementary, or a combination thereof. CAM users in our study reported more severe symptoms than non-CAM users. While the study found no dependence between CAM and HRT usage, participants that used CAMs alone reported more severe symptoms overall than who used both CAMs and HRT. This is different to a study which reported that menopausal symptoms are significantly higher for users of CAMs and HRT together than for CAM users alone (Buhling *et al.*, 2014).

5.7 Sources of information for complementary and alternative medicines users

When asked to identify the single main source of information relied on to gather information on CAM treatments, 33.3% of CAM users indicated their medical doctor, although this was closely followed by 29.6% who selected the internet. This data aligns with the Cardini *et al.* (2010) study, which found that medical doctors were the most popular source of information (25%), although in contrast the internet was the least popular source of information (2%).

The internet was utilised to obtain some information on CAMs by 59.3% of CAM users in our study. Of the 16 CAM users that used the internet to obtain information on CAMs, 7 of them viewed the internet as their single main source of information on the subject, ahead of doctors and other medical professionals. In a systemic review of available research, the internet has been identified as the primary source for women collecting information regarding CAMs usage for menopausal symptoms (Posadzki, 2013).

Nearly two thirds (63.0%) of CAM users consulted with their medical doctor before initiating CAM treatment for their menopausal symptoms. Of these 17 participants, 14 received a recommendation from their medical doctor for a specific CAM treatment, and medical doctors were in fact the dominant source for recommending specific CAM treatments across all CAM users (63.0%). In contrast to the 63.0% of CAM users who received specific CAM recommendations from their medical doctor in our study, only one in five women in the van der Sluijs *et al.* (2007) reference study in Australia had been referred to those treatments by medical practitioners.

Just more than one quarter (27.0%) of CAM users indicated the adverse effects of HRT as the primary motivation for CAM usage, in line with the Sonnendecker (2006), findings linking CAM usage with a concern for the high risk or adverse effects of conventional treatments. An additional 11.1% of CAM users selected CAMs due to a perceived inefficacy of allopathic medicines in the treatment of their menopausal symptoms.

5.8 Ethical considerations

One of the participants reported that she currently used both St John's Wort and a selective serotonin reuptake inhibitor. The concurrent usage of these two treatments leads to increased risk of developing serotonin syndrome, which can be fatal. The researcher contacted the participant directly to inform her of the potential risks associated with this usage pattern and recommended that she seek further advice from her medical practitioner.

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5.9 Study limitations

The data was collected on a voluntary basis, with potential participants being informed of the study purpose before deciding to opt in. As such, there may have been some selection bias from participants with more extreme menopausal symptoms, or a stronger personal support for CAM usage. This could potentially have resulted in either the severity of menopausal symptoms or the prevalence of CAM usage in the study being higher than that found the in the general population.

While the usage of a single-site study setting enables some conclusions to be made with more confidence, it also means that it is less appropriate to generalise the study findings to a broader population, such as all South African women experiencing menopausal symptoms. It also makes it more challenging to provide meaningful comparisons to other studies in the literature, although significant care has been taken to use comparative target demographics, questionnaire and approach to the rating of menopausal symptom severity.

The researcher categorised participants as CAMs users based on her identification of CAM treatments in line with the research objectives and prevailing literature. The study did not consider any complementary treatments falling outside of the NCCIH classification of biologically-based systems (U.S. National Library of Medicine: National Institutes of Health, 2003). Furthermore, some CAMs included in this definition, such as vitamins, were not identified by all participants as CAMs. It may have provided useful context for participants to include the exact detail of how a CAMs user was defined in the study information sheet. This definition could also have been included in the questionnaire itself in the introduction to Section 4.

The study did not ask participants to list the exact symptom that each CAM treatment was taken for. This information could potentially have been used to analyse the severity of individual menopausal symptoms in the context of the perceived efficacy of the particular CAM taken to treat them.

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6. Conclusion

This study described the usage of CAMs within the study setting across several dimensions, namely: demographics of study participants, severity of menopausal symptoms, prevalence of CAM usage, and individual CAM products used. Furthermore, the concurrent usage of CAMs and HRT was described, both from a prevalence perspective, and from a symptom severity perspective. Finally, information was gathered on the sources of information used by participants on CAM treatments, as well the sources for specific CAM recommendations.

6.1 Summary of findings

There were 71 women who participated in this single-site study, representing a response rate of 38.1%. Participants in the study were predominantly white (93.0%), married (80.3%), income-earning (77.5%) women between the ages of 50 and 59 (66.5%).

The study found that 38.0% of all participants had used CAMs to treat their menopausal symptoms. More than one CAM product was used by 48.1% of CAM users, and in total, 19 different CAM treatments were used by the participants to treat their menopausal symptoms. Of these 19, five CAM treatments were used by multiple participants, namely phyto-oestrogens, calcium, omega 3 and/or 6, Black Cohosh and magnesium.

The MRS II scale was used to rank the severity of participants' menopausal symptoms within the study. The average MRS II rating for all participants was 11.83; in contrast the average MRS II rating for CAM users was 14.19. CAM users reported significantly more severe symptoms than non-CAM users (p-value = 0.02). Sleep problems, such as difficulty in falling asleep, difficulty in sleeping through or waking up early were reported as the most severe of the eleven measured symptoms across both the entire study and for CAM users. Bladder problems were reported as the least severe symptoms across all participants, although heart discomfort was reported as the least severe symptom by CAM users.

Around 63.0% of CAM users found at least one of the CAM treatments that they used to be effective, with 43.1% of all individual CAM treatments being perceived as effective. Magnesium was perceived to be the most effective in treating menopausal symptoms of the five common CAM treatments, with 80% of users reporting it effective, and 20% reporting it partially effective. Black Cohosh was perceived to be the least effective of the five, with half its users perceiving it to be ineffective.

There was a meaningful proportion of participants (18.3%) who used both CAM and HRT treatments concurrently. HRT users reported less severe symptoms than CAM users (MRS II rating 11.6 vs. 14.2), although whether this is due to HRT treatments being more effective than CAM treatments, or whether women who display more severe symptoms are more likely to use CAMs, is unclear.

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Seventeen CAM users (63.0%) consulted with their medical doctor in some way before initiating CAM treatment for their menopausal symptoms. Of these 17 participants, 14 received a recommendation from their medical doctor for a specific CAM treatment, and medical doctors were in fact the dominant source for recommending specific CAM treatments across all CAM users (63.0%). Nonetheless, the single primary source used by participants to gather information on CAMs was the internet, with 59.3% of CAM users using the online resource as their primary information source.

6.2 Recommendations

Recommendations have been made to address challenges that have arisen from this study, or to highlight secondary questions that have developed from the study findings. These recommendations and questions are intended to contribute to the shaping of future research into the usage of CAMs for the treatment of menopausal symptoms.

This study has found that CAM usage is associated with significantly more severe menopausal symptoms than non-CAM usage. Future research should identify any qualitative reasons behind this relationship, and whether the association is causal in nature. It may be the case that women with the most severe menopausal symptoms are more motivated to actively seek a wider range of treatment interventions beyond the traditional HRT approach, in an attempt to counteract their decreased quality of life.

Future research should also consider using the MRS II scale to maximise comparability of results around symptom severity. More work can be done to standardise the definitions of CAM, and in particular to consider comparative analysis of traditional, complementary and alternative practitioners and medicines. Individual CAMs could be analysed in the context of the specific symptom that they are intended to treat. Research comparing the popularity of individual CAMs to their efficacy may also be illuminating.

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The study has focused on participants who have experienced menopausal symptoms. Future research should investigate whether CAMs usage is related to stages of menopause, and in particular whether CAMs usage patterns vary between the peri-menopausal phase and post-menopausal phase. This could be achieved by tracking individual participants throughout their menopause.

Finally, there is room to perform an investigation into the potential and actual occurrences of drug-herb interactions. This could potentially be aligned with the work of the National Adverse Drug Event Monitoring Centre under the South African government Department of Health (Medicines Control Council, 2017). Where there are known risks, such as the concurrent use of St John's Wort and Selective Serotonin Reuptake Inhibitor's, these could be the subject of specific research.

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7. References

Avis, NE., Crawford, SL., Greendale, G., Bromberger, JT., Everson-Rose, SA., Gold, EB., *et al*. (2015) 'Duration of Menopausal Vasomotor Symptoms Over the Menopause Transition', *JAMA Internal Medicine*, 175(4), pp. 531–539. [Online]. Available at : https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2110996 (Accessed: 30 November 2017)

Berlin Centre for Epidemiology and Health Research. (2008) *MRS – The Menopause Rating Scale*. [Online]. Available at: http://www.menopause-rating-scale.info/about.htm and http://www.menopause-rating-scale.info/documents/MRS_English.pdf (Accessed: 25 April 2015).

Bosman, M., van Wyk de Vries, A., Bouwer, S., Badham, J., van Aardt, A. and Ellis, S. (2008) 'Opinion of South African Pre- and Post-Menopausal Women on the Potential Menopause-related Health Benefits of Soy and Soy products', *Health SA Gesondheid*, 13(2), pp. 25 – 37.

Brett, K. and Chong, Y. (2001) 'Hormone Replacement Therapy: Knowledge and Use in the United States', *Hyattsville, Maryland: National Center for Health Statistics*. [Online]. Available at: https://www.cdc.gov/nchs/data/misc/hrt_booklet.pdf (Accessed: 2 December 2017)

Buhling, K., v. Daniels, B., v. Studnitz, F., Eulenburg, C. and Mueck, A. (2014) 'The use of complementary and alternative medicine by women transitioning through menopause in Germany: Results of a survey of women aged 45 – 60 years', *Complementary Therapies in Medicine*, 22, pp. 94 – 98. [Online]. Available at: https://www.ncbi.nlm.nih.gov/pubmed/24559823 (Accessed: April 2015)

Cardini, F., Lesi, G., Lombardo, F and van der Sluijs, C. (2010) 'The use of complementary and alternative medicine by women experiencing menopausal symptoms in Bologna', *BMC Women's Health,* 10 (7). [Online]. Available at: http://www.biomedicalcentral.com/1472-6874/10/7 (Accessed: 18 April 2015)

Chenoy, R., Hussain, S., Tayob, Y., O'Brien, P., Moss, M. and Morse, P. (1994) 'Effect of oral gamolenic acid from evening primrose oil in treating hot flushes and sweating associated with menopause', *British Medical Journal,* 19, 308 (6927), pp. 501 – 503. [Online]. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2542782/ (Accessed: 9 November 2017)

Clover, A. (2000) 'Patient benefit survey: Tunbridge Wells Homeopathic Hospital'. *British Homeopathic Journal,* 89, April (2), pp. 68 – 72.

Cohen, LS. (2014) 'Efficacy of omega-3 treatment for vasomotor symptoms: a randomised controlled trial', *Menopause,* 21(4), pp. 347 – 354. [Online]. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4072122/ (Accessed: 9 November 2017)

UNIVERSITY of the WESTERN CAPE

http://etd.uwc.ac.za/

Committee on the Use of Complementary and Alternative Medicine by the American Public. (2005) 'Complementary and Alternative Medicine in the United States', *Institue of Medicine (US),* Chapter 2. [Online]. Available at: https://www.ncbi.nlm.nih.gov/books/NBK83794/?log$=activity (Accessed: 10 October 2017)

Dinger, J., Zimmermann, T., Heinemann, LAJ. and Stoehr, D. (2006) 'Quality of life and hormone use: new validation results of MRS scale', *Health and Quality of Life Outcomes*, 4(32). [Online]. Available at: https://hqlo.biomedcentral.com/articles/10.1186/1477-7525-4-32 (Accessed: 21 May 2017)

Fasinu, P., Bouic, P. and Rosenkranz, B. (2012) 'An overview of the evidence and mechanisms of herb-drug interactions', *Frontiers in Pharmacology,* 3 (69), pp. 1 – 19.

Gerber, L., Mamtani, R., Chiu, Y., Murphy, M., Cheema, S. and Verjee, M. (2014) 'Use of complementary and alternative medicine among midlife Arab women living in Qatar', *Eastern Mediterranean Health Journal*, 20 (9), pp. 554 – 560. [Online]. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4364539/pdf/nihms668402.pdf (Accessed: April 2015)

Gollschewki, S., Anderson, D., Skerman, H and Lyons-Wall, P. (2004) 'The use of complementary and alternative medications by menopausal women in South East Queensland', *Women's Health Issues*, 14, pp. 165 – 171.

Greene, J. (1976) 'A factor analytic study of climacteric symptoms', *Journal of Psychosomatic Research*, 20 (5), pp. 425—430. [Online]. Available at: https://www.ncbi.nlm.nih.gov/pubmed/1003364 (Accessed: 21 November 2017)

Heinemann, LAJ. (2007) 'The Menopause Rating Scale (MRS) – Development of the Scale', pp. 1 – 10. Available at: http://www.menopause-rating-scale.info/documents/Development_of_MRS_scale_review_as_PRO.pdf (Accessed 21 May 2017)

Hill-Sakurai, L., Muller, J. and Thom, D. (2008) 'Complementary and Alternative Medicine for menopause: A Qualitative Analysis of Women's Decision Making', *Journal of General Internal Medicine,* 23 (5), pp. 619 – 622. [Online]. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2324155/pdf/11606_2008_Article_537.pdf (Accessed: April 2015)

Hospital association of South Africa. (2008) 'Presentation to National Health Portfolio Committee', pp. 54. [Online]. Available at: http://pmg-assets.s3-website-eu-west-1.amazonaws.com/docs/080610hasa.pdf (Accessed: 14 October 2017)

Jobson, M. (2015) 'Structure of the health system in South Africa', *Khulumani Support Group*, pp. 3 – 4. [Online]. Available at: https://www.khulumani.net/active-citizens/item/1164-the-health-system-in-south-africa-actions-to-secure-the-right-to-health-in-south-africa.html (Accessed: 2 December 2017)

UNIVERSITY of the WESTERN CAPE

http://etd.uwc.ac.za/

Medicines Control Council. (2014) 'Complementary medicines – Quality, Safety and Efficacy', *National Department of Health*, 7.01_CAMs_QSE_Dec13_v2_1.doc [Online]. Available at: http://www.mccza.com/documents/035a3c0c7.01_CAMs_QSE_Dec13_v2_1.pdf (Accessed: 2 December 2017)

Medicines Control Council. (2016) 'Complementary medicines - discipline-specific safety and efficacy', *National Department of Health*, 7.01_CMs_SE_DS_Jun16_v3.doc [Online]. Available at: http://www.mccza.com/documents/8b57b09c7.01_CMs_SE_DS_Jun16_v3.pdf (Accessed: 30 November 2017)

Medicines Control Council. (2017) 'Adverse drug reactions reporting form', *National Department of Health*, 6.04_ARF1_Jul16_v4. [Online]. Available at: http://www.mccza.com/documents/14ed44a46.04_ARF1_jul16_v4.pdf (Accessed: 30 November 2017)

Menopause Centre Australia. (2016) 'How omega-3 can provide relief of menopausal symptoms', *Australian Menopause Centre Articles.* [Online]. Available at: https://www.menopausecentre.com.au/information-centre/articles/how-omega-3-can-provide-relief-for-menopausal-symptoms-2/ (Accessed: 13 November 2017)

MIMS. (2016). 'Menopause', *MIMS Guide to OTC products*, 22, pp. 275 – 277.

Moustafa, MF., Ali, RR., El saied, SF. and Mohamed Taha, SA. (2015) 'Impact of menopausal symptoms on quality of life among women's in Qena City', *IOSR Journal of Nursing and Health Science*, 4(2) Ver. II, pp. 49-59. [Online]. Available at: http://www.iosrjournals.org/iosr-jnhs/papers/vol4-issue2/Version-2/H04224959.pdf (Accessed: 30 November 2017)

National Center for Complementary and Alternative Medicine. (2012) *National Center for Complementary and Integrative Health.* Available at: https://nccih.nih.gov/health/menopause/menopausesymptoms (Accessed: 18 April 2015)

National Center for Complementary and Integrative Health. (2008) 'The use of complementary and alternative medicine in the United States', *National Center for Complementary and Integrative Health.* [Online]. Available at: https://nccih.nih.gov/research/statistics/2007/camsurvey_fs1.htm (Accessed: 10 October 2017)

National Center for Complementary and Integrative Health. (2016) 'Menopausal Symptoms and Complementary Health Practices', *National Center for Complementary and Integrative Health Clinical Digest for Health Professionals.* [Online]. Available at: https://nccih.nih.gov/health/providers/digest/menopause (Accessed: 10 October 2017)

UNIVERSITY of the WESTERN CAPE

http://etd.uwc.ac.za/

National Center for Complementary and Integrative Health. (2017) 'Black Cohosh', *National Center for Complementary and Integrative Health Clinical Digest for Health Professionals.* [Online]. Available at: https://ods.od.nih.gov/factsheets/BlackCohosh-HealthProfessional/ (Accessed: 8 November 2017)

Newton, K., Reed, S., LaCroix, A., Grothaus, L., Ehrlich, K and Guiltinan, J. (2006) 'Treatment of Vasomotor Symptoms of Menopause with Black Cohosh, Multibotanicals, Soy, Hormone Therapy and Placebo', *Annals of Internal Medicine*, 145, pp. 869 – 879.

NHS Choices. (2015) 'Menopause' [Online]. Available at: https://www.nhs.uk/conditions/menopause/symptoms/ (Accessed: 1 December 2017)

Peltzer, K. (2009) 'Utilisation and practice of traditional/ complementary/ alternative medicine (TM/CAM) in South Africa', *African Journal of Traditional, Complementary and Alternative Medicines*, 6(2), pp. 175 – 185.

Peng, W., Adams, J., Sibbritt, DW. and Frawley, JE. (2014) 'Critical review of complementary and alternative medicine use in menopause: focus on prevalence, motivation, decision-making and communication', *The Journal of The North American Menopause Society,* 21(5), Abstract only. [Online]. Available at: https://www.ncbi.nlm.nih.gov/pubmed/241046044 (Accessed: 10 October 2017)

Posadzki, P., Lee, M., Moon, T., Choi, T., Park, T. and Ernst, E. (2013) 'Prevalence of complementary and alternative medicine (CAM) use by menopausal women: A systematic review of surveys', *Maturitas*, 75, pp. 34 – 43.

Richardson, WR. (2001) 'Patient benefit survey: Liverpool Regional Department of Homeopathic Medicine'. *British Homeopathic Journal,* 90(3), pp. 158 – 162.

Sonnendecker, E. (2006) 'Use of Alternative Medicine by Menopausal Women', *South African Pharmacy Journal*, 73 (4), pp. 23 – 28.

Spence, DS., Thompson, EA. And Barron, SJ. (2005) 'Homeopathic treatment of chronic disease: a 6-year, university-hospital outpatient observational study', *Journal of Altern Complement Med,* 11, pp. 793-798.

South African Menopause Society. (2017) 'The Natural Approach'. Available at: http://www.menopause.co.za/Patients/Approach (Accessed: 11 October 2017)

The North American Menopause Society. (2017a) 'Do Mother Nature's Treatments Help Hot Flashes?', Natural Remedies for Hot Flashes. [Online]. Available at: http://www.menopause.org/for-women/menopauseflashes/menopause-symptoms-and-treatments/natural-remedies-for-hot-flashes (Accessed: 5 December 2017)

UNIVERSITY of the WESTERN CAPE

http://etd.uwc.ac.za/

The North American Menopause Society. (2017b) *Menopause 101.* Available at: http://www.menopause.org/for-women/menopauseflashes/menopause-symptoms-and-treatments/menopause-101-a-primer-for-the-perimenopausal (Accessed: May 2017)

Thompson, E. (2010). 'Alternative and complementary therapies for the menopause: A homeopathic approach', *Maturitas*, 66, pp. 350 – 354.

Tonick, S. and Muneyyirci-Delale, O. (2016) 'Magnesium in Women's Health and Gynaecology', *Open Journal of Obstetrics and Gynaecology*, 6, pp. 325 – 333. [Online]. Available at: https://file.scrip.org/pdf/OJOG-2016042816190975.pdf (Accessed: 5 December 2017)

University of Maryland Medical Centre. (2007) 'Possible interactions with St Johns Wort' [Online]. Available at: http://www.umm.edu/health/medical/altmed/herb-interaction/possible-interactions-with-st-johns-wort (Accessed: 2 December 2017)

University of Maryland Medical Center. (2015a) 'Menopause'. [Online]. Available at: http://www.umm.edu/health/medical/altmed/condition/menopause (Accessed: 5 December2017)

University of Maryland Medical Center. (2015b) 'Possible interactions with: Magnesium'. [Online]. Available at: http://www.umm.edu/health/medical/altmed/supplement-interaction/possible-interactions-with-magnesium (Accessed: 5 December2017)

University of Maryland Medical Center. (2015c) 'Omega 3 fatty acids'. [Online]. Available at: http://www.umm.edu/health/medical/altmed/supplement/omega3-fatty-acids (Accessed: 5 December2017)

University of Maryland Medical Center. (2015d) 'Magnesium'. [Online]. Available at: http://www.umm.edu/health/medical/altmed/supplement/magnesium (Accessed: 5 December2017)

University of Maryland Medical Center. (2016) 'Calcium'. [Online]. Available at: http://www.umm.edu/health/medical/altmed/supplement/calcium (Accessed: 5 December2017)

U.S. National Library of Medicine: National Institutes of Health. (2003) 'Complementary and Alternative Medicine'. [Online]. Available at: https://www.nlm.nih.gov/tsd/acquisitions/cdm/subjects24.html (Accessed: 10 October 2017)

Van der Sluijs, C., Bensoussan, A., Liyanage, L. and Shah, S. (2007) 'Women's health during mid-life survey: the use of complementary and alternative medicine by symptomatic women transitioning through menopause in Sydney', *The Journal of The North American Menopause Society*, 14, pp. 397 – 403.

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http://etd.uwc.ac.za/

Van der Westhuizen, A. (2009) 'Evidence-based Pharmacy Practice (EBPP): Hot Flushes', *South African Pharmaceutical Journal*, July, pp. 12 – 17. [Online]. Available at: https://repository.up.ac.za/bitstream/handle/2263/10845/VanDerWesthuizen_Evidencebased(2009).pdf?sequence=1&isAllowed=y (Accessed: 4 September 2017)

Women's Health Concern. (2015) 'Complementary and alternative therapies and non-hormonal prescribed treatments', [Online]. Available at: https://www.womens-health-concern.org/_wpress/wp-content/uploads/2015/12/WHC-FACTSHEET-Complementary-And-Alternative-Therapies.pdf (Accessed: 20 July 2017)

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8. Appendix 1: Questionnaire

Mrs Lynn Randall Tel: 083 380 2340

Dr Mea van Huyssteen Tel: 0219592864

School of Pharmacy, University of the Western Cape, Robert Sobukwe Road, Bellville, Cape Town, 7535

The use of complementary and alternative medicines in the treatment of menopausal symptoms by private health-care patients in Pretoria, South Africa

UNIQUE IDENTIFIER (*OFFICIAL USE ONLY*): _____

SECTION 1: DEMOGRAPHIC INFORMATION

1. Current Age:

2. Race: *OPTIONAL*

Asian	Black	Coloured	Indian	White

Other (please specify): _____

3. Marital Status:

Single	Married	Divorced	Widowed

4. Highest Level of Education

Some High School	Matric	Diploma	Degree	Post Graduate

5. Employment Status

Employed Full time	Employed Part Time	Self-Employed	Unemployed	Retired

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SECTION 2: PHILOSOPHY TOWARD MENOUPAUSAL STATUS

6. Tick the one box that most closely represents your personal understanding of menopause in your life

Natural Life Stage	
Temporary medical condition	
Permanent chronic medical condition	

7. Tick the one box that most closely represents your personal attitude toward menopause

Positive Attitude	
Neutral Attitude	
Negative due to loss of youth	
Negative due to loss of fertility	
Negative due to menopausal symptoms	

SECTION 3: MENOPAUSAL SYMPTOMS AND TREATMENT

8. When did your menopause start? (when was your last menstrual cycle)?

More than 12 months ago	
2 – 11 months ago	
One month or less ago	

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9. Did the onset of your menopause coincide with a bilateral oophorectomy or damage to the ovaries caused by pelvic radiation, chemotherapy or other medicines?

Yes	No

10. Are you currently using Hormone Replacement Therapy (HRT)?

Yes	No

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11. Complete the Menopause Rating Scale (MRS) (Berlin Centre for Epidemiology and Health Research, 2008)

For each listed symptom, tick the severity of the symptoms that you have experienced within the last 4 months. Tick 'none' for symptoms that do not apply to you.

	Symptom	None	Mild	Moderate	Severe	Very Severe
1	Hot flushes, sweating					
2	Heart discomfort (unusual awareness of heartbeat, heart skipping, heart racing, tightness)					
3	Sleep problems (difficulty in falling asleep, difficulty in sleeping through, waking up early)					
11	Joint and muscular discomfort (pain in the joints, rheumatoid complaints)					
4	Depressive mood (feeling down, sad, on the verge of tears, lack of drive, mood swings)					
5	Irritability (feeling nervous, inner tension, feeling aggressive)					
6	Anxiety (inner restlessness, feeling panicky)					
7	Physical and mental exhaustion (general decrease in performance, impaired memory, decrease in concentration, forgetfulness)					
8	Sexual problems (change in sexual desire, in sexual activity and satisfaction)					
9	Bladder problems (difficulty in urinating, increased need to urinate, bladder incontinence)					
10	Dryness of vagina (sensation of dryness or burning in the vagina, difficulty with sexual intercourse)					

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12. Please list any medicines that you are currently taking, or have previously taken since the onset of your menopausal symptoms. Please include all medicines (allopathic and OTC), complementary and alternative medicines (CAMs) and supplements, both prescribed and self-medicated. *This is not restricted to medicines taken for the treatment of menopause.*

Medicine / CAM	**Dosage**	**Frequency**	**Date Started**	**Date Stopped**	**Reason for stopping**	**Effectiveness (Circle One)**
Name of medicine, CAM or supplement	*Quantity of medicine consumed at each dosage*	*Number of doses taken per day*	*Date that you started taking the medicine*	*Date that you ceased to take the medicine*	*Reason that you ceased to take the medicine, if applicable (adverse effects etc.)*	*Effective, Ineffective or Partially Effective*
						E / I / P
						E / I / P
						E / I / P
						E / I / P
						E / I / P
						E / I / P
						E / I / P
						E / I / P
						E / I / P
						E / I / P
						E / I / P

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SECTION 4: COMPLEMENTARY AND ALTERNATIVE MEDICINES

Complete this section only if you entered complementary or alternative medicines (CAMs) in Question 12

13. Did you consult with your healthcare practitioner before using CAMS treatment for menopause?

No	
Yes	

14. Did any of the following recommend a specific CAM treatment?
Tick all that apply.

Family Member	Friend	Colleague	Medical Doctor	CAM Practitioner	Pharmacist

Other (please specify): _____

15. Which sources of information you have referred to regarding your CAM usage?
Tick all that apply.

TV	Internet	Books	Magazines

Other (please specify): _____

16. What is the single main source of information that you have referred to regarding your CAM usage?

Family Member	Friend	Colleague	Medical Doctor	CAM Practitioner
TV	Internet	Books	Magazines	Pharmacist

Other (please specify): _____

17. Why did you decide to try CAMS as a treatment for your menopausal symptoms?
Tick all that apply.

Personal beliefs/ values	
Adverse effects on allopathic (regular) HRT	
Efficacy of allopathic meds	
Other (please specify)	

Thank you for taking the time to participate in my study. Your answers and feedback are valuable to me.

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9. Appendix 2: Study information sheet

Mrs Lynn Randall Tel: 083 380 2340
Dr Mea van Huyssteen Tel: 0219592864
School of Pharmacy, University of the Western Cape, Robert Sobukwe Road, Bellville, Cape Town, 7535

The use of complementary and alternative medicines in the treatment of menopausal symptoms by private health-care patients in Pretoria, South Africa

STUDY INFORMATION SHEET

INTRODUCTION:

You are being invited to take part in a clinical research study conducted by Mrs Lynn Randall, a master's student from the School of Pharmacy at the University of the Western Cape. The study is being carried out at The Medicine Shop Pharmacy in Groenkloof, Pretoria, where I work as a Pharmacist. The study is entitled: **The use of complementary and alternative medicines in the treatment of menopausal symptoms in private healthcare patients in Pretoria, South Africa.**

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Before you decide whether you wish to take part in this study, you should read the provided information sheet carefully. If you wish to discuss it with your family, friends or GP, then please take the time to do so. Take time to ask questions – do not feel rushed or under any obligation to make a hasty decision.

You are not obliged to take part in this study and failure to participate will have no effect on your future care. You may change your mind at any time (before the start of the study or even after you have commenced the study) for whatever reason without having to justify your decision and without any negative impact on the care you will receive from the pharmacy.

WHY IS THIS STUDY BEING DONE?

The purpose of my research study is to gather information about the prevalence of Complementary and Alternative Medicines (CAMs) usage for the treatment of menopausal symptoms by women in Pretoria. Many studies regarding the use of CAMS in menopause have been done in various parts of the world, but none as yet in South Africa. This study will

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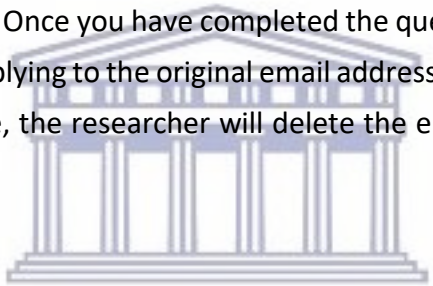
help determine whether the use of CAMS in menopausal women in South Africa is consistent with the worldwide trend of CAMS usage in the treatment of menopausal symptoms. I also intend to gather information on the simultaneous usage of CAMs with Hormone Replacement Therapy (HRT), allopathic medicines and complementary treatments, as well as the sources that people use to obtain information regarding CAMs usage.

PROCEDURE

If you agree to be a participant I will contact you to set up a convenient time for the interview. The interview/ guided questionnaire will take place at The Medicine Shop Pharmacy in Pretoria at should last no more than 20 minutes. We will work through a 17-question questionnaire, ensure that you understand the detail behind each question, and document your answers. Alternatively, should you be fluent in English you may also choose to complete the questionnaire electronically. The questionnaire will be emailed to you in a Word format and you may either complete it electronically, or else complete a paper copy and then scan the completed questionnaire. Once you have completed the questionnaire, you should email it back to the researcher by replying to the original email address. After receiving and printing your completed questionnaire, the researcher will delete the email in order to protect your personal information.

RISKS AND BENEFITS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This study raises no concern about participant safety or medical welfare, with no risks associated with participating in this study. There are no anticipated direct benefits to you as a participant. All participants enrolled in the study participate on a voluntary basis.

CONFIDENTIALITY AND ANONIMITY

All information provided by you during the study will be kept confidential. No personal or identifying information will be included in my final research, with all results presented in a combined form. On completion of the study, the sample data will be kept for a period of two years after which it will be destroyed by paper shredding.

VOLUNTARY PARTICIPATION

Participation in this study is the sole decision of the participant and your participation is completely voluntary. If you agree to partake in the study, you will need to sign a consent form before your information may be collected. You may withdraw from the study at any

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time. Withdrawal from the study will not affect the participants' relationship with the pharmacy in any way.

IF YOU REQUIRE FURTHER INFORMATION

Any further queries or information required may be directed to:

Lynn Randall
MOBILE: +27 833802340
EMAIL: lynn@therandalls.co.za
OR

Dr Mea van Huyssteen

Pharmacy building, First floor Room F6, School of Pharmacy, University of the Western Cape, Robert Sobukwe Road, Bellville, 7535, South Africa.

Tel: +2721 9592864

The committee giving ethical approval for this study is the UWC Biomedical Research Ethics Committee. The biomedical research ethics administration is available in the Research Office in the New Arts Building, C-Block, Top Floor, Room 28 at the University of the Western Cape, Robert Sobukwe Road, Bellville, South Africa. If you have any problems or questions about this study you can also contact the Ethics committee directly at telephone number 021 9593170.

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10. Appendix 3: Informed consent

Mrs Lynn Randall Tel: 083 380 2340
Dr Mea van Huyssteen Tel: 0219592864
School of Pharmacy, University of the Western Cape, Robert Sobukwe Road, Bellville, Cape Town, 7535

STUDY TITLE: The use of complementary and alternative medicines in the treatment of menopausal symptoms in private healthcare patients in Pretoria, South Africa.

UNIQUE ID *(Official Use Only)*: _____

I confirm that I have read and understood the study information sheet, and that I have had ample opportunity to ask questions all of which have been satisfactorily answered. ☐***Yes*** ☐***No***

I understand that my participation in this study is entirely ***voluntary*** *and that I may withdraw at any time, without giving reason, and without this decision affecting my future treatment or medical care.* ☐***Yes*** ☐***No***

I understand that my identity will remain confidential at all times and that all the information that I provide will be kept at a secure location and will be destroyed after 2 years of the report being written. ☐***Yes*** ☐***No***

I have been given a copy of the Patient Information Leaflet and this Consent form for my records.

☐***Yes*** ☐***No***

_____ _____

Signature and date: ***Name in block capitals:***

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To be completed by the Person Taking the Consent

I, the undersigned, have taken the time to fully explained to the above patient the nature and purpose of this study in a manner that he/she could understand. I have explained the risks involved, the experimental nature of the treatment, as well as the possible benefits and have invited him/her to ask questions on any aspect of the study that concerned them.

_____	_____	_____	_____
Signature:	***Name in Block Capitals:***	***Qualification:***	***Date:***

2 copies to be made: 1 for patient and 1 for researcher records.

The committee giving ethical approval for this study is the UWC Biomedical Research Ethics Committee. The biomedical research ethics administration is available in the Research Office in the New Arts Building, C-Block, Top Floor, Room 28 at the University of the Western Cape, Robert Sobukwe Road, Bellville, South Africa. If you have any problems or questions about this study you can also contact the Ethics committee directly at telephone number 021 9593170.

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11. Appendix 4: Results of statistical tests

11.1 Comparison of MRS II scores for CAMs users vs. non-CAMs users

H_0: There is no difference in the variance of MRS scores between CAMs users and non-CAMs users

Table 14: F-Test Two-Sample for Variances

	No CAMs	CAMs
Mean	10.38636364	14.18518519
Variance	55.73097252	41.6951567
Observations	44	27
df	43	26
F	1.336629406	
P(F<=f) one-tail	0.217738516	
F Critical one-tail	1.842924793	

The F test statistic (1.34) is less than the test critical value at 5% level of significance (1.753) and it can therefore not be said that there is a significant difference between the variances of the two groups. Assuming equal variances of MRS score, a t-test is then applied to test whether there is a significant difference in MRS scores between CAMs users and non-CAMs users.

H_0: There is no difference in the average MRS scores between CAMs users and non-CAMs users

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Table 15: t-Test Two-Sample assuming equal Variances

	No CAMs	CAMs
Mean	10.38636364	14.18518519
Variance	55.73097252	41.6951567
Observations	44	27
Pooled Variance	50.44211438	
Hypothesized Mean Difference	0	
df	69	
t Stat	-2.187919291	
P(T<=t) one-tail	0.016032565	
t Critical one-tail	1.667238549	
P(T<=t) two-tail	0.03206513	
t Critical two-tail	1.994945415	

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The t test statistic (-2.18) is less than the test critical value at 5% level of significance (-1.667) and the null hypothesis is therefore rejected. CAMs usage is therefore associated with significantly more severe menopausal symptoms than non-CAMs usage.

11.2 Comparison of MRS II scores for HRT users vs. non-HRT users

A similar approach was followed to determine whether HRT usage is associated with more severe menopausal symptoms. In this test, it was seen that the variance of MRS scores between HRT users and non-users was not significant (p-value = 0.34). Furthermore, the application of a t-test could not reject the hypothesis that mean MRS scores for HRT users (11.6) and HRT non-users (12.1) are the same (p-value = 0.40). HRT usage could not be significantly associated with less severe menopausal symptoms.

Table 16: t-Test Two-Sample assuming equal Variances

	HRT	No HRT
Mean	11.63414634	12.1
Variance	57.98780488	48.23103448
Observations	41	30
Pooled Variance	53.88713326	
Hypothesized Mean Difference	0	
df	69	
t Stat	-0.264137676	
P(T<=t) one-tail	0.396230583	
t Critical one-tail	1.667238549	
P(T<=t) two-tail	0.792461165	
t Critical two-tail	1.994945415	

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