

Complementary Medicines and Therapies for Hot Flushes

KEY POINTS

- There have been many studies of complementary and herbal medicines for the relief of menopausal symptoms.
- Any product used for the treatment of menopausal symptoms should have been shown in clinical studies to be safe and effective.
- There is currently insufficient evidence to support the use of herbal therapies.
- Compounded bioidentical hormonal preparations are not recommended due to major concerns about the safety and efficacy of these products.
- No complementary therapy is as effective as oestrogen therapy for menopausal symptoms.

Many women experience hot flushes and night sweats around the time of menopause. Menopausal hormone therapy (MHT) has been proven to be effective in alleviating these symptoms. However, some women choose to explore complementary medicines and therapies (CM&T) for relief of symptoms. There have been many studies on CM&T; some have suggested benefits, and others have shown no benefit. It can be difficult for consumers and doctors to interpret this mixed information. This information sheet provides a brief overview of the current evidence for the use of CM&T.

CM&T are sometimes referred to as "natural" and may be derived from plants and other sources. Some people believe that these products are safer than prescription products. However, scientific studies of these compounds do not always support this belief.² Extracts from plants and other so-called "natural" products may actually cause harm and interact with prescribed medicines.³ They do not necessarily act like the hormones normally produced by women. Some over-the-counter treatments, including plant extracts, are not subject to the rigorous testing for content, safety and effectiveness that prescription treatments are subject to. Herbal products may contain heavy metals, illegal ingredients and toxic chemicals as well as naturally occurring organic toxins.

Any product used for the treatment of menopausal symptoms should have clinical studies showing it to be effective. This usually requires a placebo-controlled trial or a head-to-head comparison with a known effective treatment, or both. The placebo comparison is important because there is often a temporary placebo that commonly lasts around three months.¹



Unless the product is tested for more than three months, it is not possible to say it is truly effective for menopausal symptoms. This short-term placebo effect is quite different from the prolonged improvement in menopausal symptoms demonstrated by treatments such as MHT. MHT reduces hot flushes by around 90% and continues to be effective for as long as they are used.⁴ Prescription drugs cannot be licensed until they have been shown to be safe and effective. This is not the case for over-the-counter remedies for menopausal symptoms.

The AMS advocates that all therapies, whether prescription or alternative, should not be used unless there is good research evidence for their effectiveness and safety over the short and long term.

CM&T use in Australia

In a national representative sample of 10,011 Australian women aged 59-64 years:5

- 39% of menopausal women consulted CM&T practitioners.
- 75% used self-prescribed CM&T.
- 95% consulted general practitioners (GP) and 50% consulted specialists during the previous year, and 12% were current menopausal hormone therapy (MHT) users.

Similarly, a cross-sectional questionnaire-based study of 2020 Australian women aged 40-65 years living independently in the community found that the prevalence of CM&T use to manage menopausal vasomotor symptoms (VMS) was 13.22%.6

Specific herbal and botanical therapies

Black cohosh (Cimicifuga racemosa or Actaea racemosa)

Specific extracts of black cohosh (isopropanolic), and higher therapeutic doses may improve menopausal symptoms, including hot flushes, as shown in a recent systematic review and meta-analysis.⁷ It should be noted that most of the included studies were conducted over short time frames (i.e. 3-6 months) and on small numbers of patients. In addition, although many were placebo-controlled trials, no studies compared black cohosh to conventional MHT.

There were originally reports of liver toxicity from the use of black cohosh.⁸ A review of the 69 cases of suspected black cohosh-induced liver disease concluded that data does not support a direct causal relationship, with no signal of safety concern.⁹ Another meta-analysis found no evidence of black cohosh adversely affecting liver function, although studies were only up to 6 months of treatment.¹⁰



Phytoestrogens (including red clover, below)

A wide range of products containing plant or phytoestrogens, including soy products, are available as over the counter remedies for hot flushes. The active product of these is thought to be isoflavones which bind to the oestrogen receptor. Isoflavones have a greater affinity for ER- β than for ER- α and possess both oestrogen agonist and antagonist properties. There are study limitations and differences in the interventions and the findings are mixed. Some studies demonstrated efficacy of soy in reducing VMS or severity and others showing no benefit from soy compared to placebo. Efficacy of soy may be influenced by whether an individual is able to metabolize the soy isoflavone daidzein to the more potent phytoestrogen, equol. Around 20-30% of Caucasians (compared to 40-70% of Asians) are equol producers. Equol supplements are not readily available in Australia. Compared to placebo, equol supplementation was found to be superior to placebo for reducing VMS frequency in 3 of the 5 trials assessed in a 2019 systematic review and meta-analysis. The active products are not readily available in Australia.

Updated information by the Cancer Council of Australia, influenced by the World Cancer Research Fund (WCRF) state that the available evidence suggests that soy and other isoflavone-containing foods are unlikely to increase cancer risk, and recommend that people, including those who have been diagnosed with breast cancer, who consume soy foods, should continue to do so.^{14,15}

Red clover (Trifolium pratense)

Specific extracts of red clover may be useful in reducing the daily frequency of hot flushes, particularly in post-menopausal women, if taken for a period of 12 weeks and with higher doses of isoflavones (≥80 mg/day,) and when the formulations contained a higher proportion of biochanin A.¹⁶

Preliminary evidence suggests there may be some benefit from use of red clover in reducing cholesterol and low-density lipoprotein (LDL).¹⁷

Siberian rhubarb (*Rheum rhaponticum*)

A systematic review and meta-analysis of the standardised extract of *Rheum rhaponticum* root, ERr 731® significantly reduced the Menopause Rating Scale score compared with control.¹⁸ Ffurther research is needed to establish long-term efficacy and safety.¹¹



St John's wort (Hypericum perforatum)

Combined with black cohosh, St John's Wort can be effective for menopausal mood symptoms. A small, randomised control-trial (n=301) compared isopropanolic black cohosh extract and ethanolic St John's wort against a placebo. Scores on the Menopause Rating Scale decreased by 50% in the treatment group compared to 19% in the placebo group. Depression also significantly decreased compared with placebo.¹⁹

It is important to note that this therapy may interact with many prescription medicines. A lack of long-term safety data limits recommendations for its use.¹¹

Evening primrose oil

Very few studies have addressed whether evening primrose oil improves hot flushes. Existing data shows no benefit in one study,²⁰ and another small study showed a reduced frequency and severity of night sweats, but not hot flushes, compared to placebo at a dose of 1000 mg twice a day for 8 weeks (n=170).²¹ Evening primrose oil lowers the seizure threshold in people with epilepsy and interferes with the actions of anti-epileptic medication.³

Flaxseed

Two small recent studies have shown flaxseed (also known as linseed) may be beneficial in improving hot flushes, night sweats and vaginal dryness in perimenopausal women, with the longest study conducted over 8 months.^{22,23} More evidence is needed before flaxseed can be recommended for use.

Ashwaganda (Withania somnifera)

Ashwaganda is an herbal product used in Ayurvedic medicine for its supposed adaptogenic and anti-stress properties. Only one small study, undertaken in 100 women over only 8 weeks, looked at its use for management of perimenopausal symptoms, with significant reductions in menopause symptom scores noted.²⁴

Importantly, the Therapeutic Goods Association (TGA) issued a safety advisory for Withania somnifera in 2024 due to reports of severe gastrointestinal symptoms and liver damage in patients taking the herb, several of whom required hospitalisation.²⁵ Use of medicines or herbal supplements containing Withania somnifera should be avoided in patients with existing or previous liver pathologies.²⁵



Non-herbal medicines and therapies

Vitamin E

Two very small and short-term studies have shown that Vitamin E (800 iu per day for 4 weeks) decreased the number of hot flushes by 1 per day when used by women who have had breast cancer (n=120),²⁶ and reduced the number of hot flushes by 2 per day in other women (400 iu vitamin E daily, n=51).²⁷

Omega-3

Use of Omega-3 showed no difference in the frequency and severity of hot flushes, insomnia severity, sleep quality compared to placebo in a systematic review and meta-analysis (n=183).²⁸

Supplementation with omega-3 can improve the lipid profile of postmenopausal women,²⁹ and the Heart Foundation of Australia recommend fish oils as part of an adult diet to help lower the risk of coronary heart disease.³⁰

Cognitive behavioural therapy, hypnosis, yoga and non-prescription medicines

The AMS information sheet 'Nonhormonal treatments for menopausal symptoms' covers this.

Compounded bioidentical menopausal hormone therapy (including progesterone cream)

There is no evidence to support the efficacy or safety claims of compounded "bioidentical" hormones, or the superiority claims of these over conventional MHT. These products also pose the additional risks of variable purity and potency. All major national and international menopause societies have raised concerns about the safety and efficacy of these products and recommend that patients be counselled to avoid their use.³¹ The AMS information sheet <u>Bioidentical hormones for menopausal symptoms</u> has more information.

Other CM&T with <u>little or no evidence of benefit</u> in treating menopausal symptoms

- Wild yam cream
- Ginseng (Panax ginseng or Panax quinquefolius)
- Maca (Lepidium Meyennii Walp or Lepidium peruvianum Chacon)
- Pine bark (Pyncogenol)
- Pollen extract
- Magnesium
- Combination botanical therapies
- Homeopathy
- Acupuncture



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Additional Reading

- Management of menopausal symptoms in women with a history of breast cancer |
 Cancer Australia
- The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society Advisory Panel: https://pubmed.ncbi.nlm.nih.gov/37252752/
- Memorial Sloan Kettering Cancer Center information on Integrative medicine including
 the "About Herbs" database. Note this is a USA website and not all of the products
 mentioned will be available in Australia: https://www.mskcc.org/cancer-care/diagnosis-treatment/symptom-management/integrative-medicine/herbs/search

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