Non-hormonal treatments for menopausal symptoms

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What you need to know

Menopause is a normal event, but around 25% of women have problematic vasomotor symptoms (hot flushes and night sweats) that impair quality of life and might require treatment.

Systemic hormone replacement therapy (HRT) is currently the most effective treatment for vasomotor symptoms and may also improve vaginal dryness, sleep, and quality of life.

For those wishing to avoid HRT, there are non-pharmacological and non-hormonal pharmacological treatments for vasomotor symptoms.

Most non-hormonal treatments act quickly, so if there is no improvement after 2–4 weeks consider a different approach.

Management of menopausal symptoms should be individualised and address patient aims and preferences for treatment. Therapies should target the symptoms that most affect function and quality of life.

Menopause is a normal event, and most women do not seek medical intervention. Of those who do, some will require only information and advice, but around 25% have problematic symptoms that may need treatment. Vasomotor symptoms are the main reason that women seek treatment. Hormone replacement therapy is effective for vasomotor symptoms, but for some it is unsuitable (due to preference or contraindications) and non-hormonal treatments can be considered.

This update provides an overview of the evidence supporting non-hormonal treatments for vasomotor and...
vaginal symptoms, and translates this into practical guidance on managing these symptoms in clinical practice.

What are menopausal symptoms?

The menopause is the final menstrual period. The “perimenopause” or “menopause transition” is the time from the onset of menstrual cycle changes until one year after the final menstrual period.1 Changes in vaginal bleeding patterns and vasomotor symptoms characterise the menopause transition, but the overall experience is highly variable and may be influenced by psychological, social, and cultural factors.2 Common symptoms include hot flushes and night sweats (vasomotor symptoms) and genital symptoms (vaginal dryness, dyspareunia), which may be accompanied by mood and sleep disturbance.3 Physical and psychological symptoms are often related. For example, night sweats may disturb sleep, leading to low mood and reduced ability to cope with vasomotor symptoms. Beliefs about menopause may affect symptom experience; negative expectations and beliefs and low self esteem are associated with more problematic symptoms.45

Definitions of terms

Hormone replacement therapy—Administration of exogenous oestrogen to treat menopausal symptoms. Oestrogen should be combined with a progestogen in women who retain their uterus

Non-hormonal therapies—Treatments for menopausal symptoms that do not contain sex steroid hormones

Menopause—The permanent cessation of menstruation due to loss of ovarian follicular activity. Menopause is a retrospective diagnosis after 12 consecutive months of amenorrhea with no other obvious pathological or physiological cause

Perimenopause or menopause transition—The time from the onset of menstrual cycle variability or the onset of menopausal symptoms until one year after the final menstrual period

Vasomotor symptoms—Hot flushes and/or night sweats

Who is affected?

Vasomotor symptoms affect about 80% of women, with around 25% reporting problematic symptoms that affect quality of life.678 Vasomotor symptoms usually occur daily and may continue for 4-10 years9 with a peak in the year around the final menstrual period.1011 Vaginal symptoms (dryness and/or dyspareunia) affect around a third of women and tend to persist until older age (age 80 years) or may appear some years after the menopause.12 Around a third of women experience sleep disturbance during the menopause transition,13 and an estimated 10% have depressive symptoms, which tend to resolve in the postmenopause and may be associated with psychosocial factors.14 Ethnicity may affect the nature and severity of symptoms, and menopausal symptoms may differ for premature or early menopause or following chemotherapy, oophorectomy, or anti-oestrogen treatments.

Measures of vasomotor symptoms include frequency (measured subjectively and objectively), frequency×severity scores, and measures of how much vasomotor symptoms are problematic and interfere with daily life.81516
Why are non-hormonal treatments needed?

Sources and selection criteria
Evidence informing this clinical guidance was derived from the best available recent data, including national and international guidelines17184661 and adequately powered randomised controlled trials.

We searched PubMed between April and September 2017 for full-text English language papers using the key search terms “menopause”, “vasomotor”, and “hot flushes”. We also searched for “menopause” AND “vaginal dryness”, “non-hormonal”, “pharmacological”, “non-pharmacological”, “complementary”, “alternative”, “CBT”, “mindfulness”, “hypnosis”, “acupuncture”, “diet”, “exercise”, or “yoga” from 1990 to 2017. We also considered review articles from 2010 to 2016.

Hormone replacement therapy (HRT or HT) is the most effective treatment for menopausal symptoms but is contraindicated for some women (see box 1) and avoided by others. Vasomotor symptoms are common in breast cancer patients and may be more severe and persistent than in the general population.19 Systemic HRT is avoided after breast cancer, and non-hormonal treatments may be needed. Most women experience a resurgence of vasomotor symptoms when HRT is discontinued,20 which may require treatment with non-hormonal approaches. Many women turn to the internet or friends and family for advice about menopause management and are confused by the vast array of options. Differences in study populations, variations in outcome measures, a paucity of head-to-head comparisons between non-hormonal and hormonal treatments and conflicting advice in guidelines about the efficacy of non-hormonal treatments has complicated clinical management. Figure 1 offers a suggested approach to using non-hormonal treatments for a patient with problematic menopausal symptoms.

Box 1: Contraindications to hormone therapy1718

- History of breast cancer
- Coronary heart disease
- Previous venous thromboembolic event
- Transient ischaemic attack or previous stroke
- Unexplained vaginal bleeding
- High risk endometrial cancer
- Active liver disease
Non-pharmacological treatments for vasomotor symptoms

Cognitive behavioural therapy
Cognitive behavioural therapy (CBT) effectively reduced the impact (problem rating) of vasomotor symptoms in women with and without a history of breast cancer, by an average of 50% after 8 hours of group CBT (weekly group sessions over 4-6 weeks) with benefits maintained at six months (see table 1).\[^{15}\]

Comparison of group CBT with self help CBT (booklet and audio with up to 1.5 hours of telephone guidance, with the same content as group CBT, followed over 4 weeks) suggested that both forms of CBT were equally effective in reducing how problematic vasomotor symptoms were, but group CBT resulted in more improvements to quality of life compared with self help CBT.\[^{15}\] CBT also reduced subjective frequency of night sweats by an average of 39% and reduced objectively measured vasomotor symptoms (sternal skin conductance monitoring) in well women,\[^{40}\] but not in breast cancer patients.\[^{16}\] This may reflect differences in the nature of menopausal symptoms in breast cancer patients.\[^{41}\] The North American Menopause Society (NAMS) guideline recommends CBT for the treatment of vasomotor symptoms.\[^{17}\]

Table 1
Comparative efficacy of non-hormonal treatments for vasomotor symptoms (table modified from\[^{21,22,23,24}\])

<table>
<thead>
<tr>
<th>Treatment Type</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>Non-pharmacological</td>
<td>Offer cognitive behavioural therapy, offer hypnotic if available, consider acupuncture if available, or offer if ineffective, offer psychological treatments. Both pharmacological and non-pharmacological treatments can be used together.</td>
</tr>
<tr>
<td>Pharmacological</td>
<td>Offer escitalopram 10 mg or citalopram 10 mg, increasing to 20 mg if needed. If ineffective or not tolerated, offer venlafaxine (extended release) 37.5 mg increasing to 75 mg. If ineffective or not tolerated, offer paroxetine 10-20 mg unless using tamoxifen. If ineffective or not tolerated, offer gabapentin 100-300 mg, up to 900 mg/day. Can be used at night to improve sleep. If ineffective or not tolerated try clonidine 0.1 mg. Review pharmacological treatments after 4 weeks if possible. Treatment should be re-evaluated every 6-12 months. Consider specialist referral if symptoms are persistent.</td>
</tr>
<tr>
<td>Vaginal symptoms</td>
<td>Consider use of vaginal estrogens with informed consent and, for breast cancer patients, in consultation with the treating oncologist. For discomfort during sexual activity, offer silicone-based lubricants or water-based lubricants. Consider topical anaesthetic to the vulva as 4% aqueous lignocaine.</td>
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Hypnosis
The NAMS guideline recommends hypnosis for the treatment of vasomotor symptoms, based on randomised controlled trials including women with and without a history of breast cancer demonstrating a statistically significant reduction in the frequency of subjective and objective vasomotor symptoms (measured by sternal skin conductance monitoring) and subjective severity after five weekly sessions (each an hour long) of hypnosis plus practice at home (see table 1). Subjective hot flush frequency from baseline to week 12 showed a mean reduction of 55.82 (74.16%) hot flushes for the clinical hypnosis intervention versus a mean reduction of 12.89 (17.13%) hot flushes for controls (P<0.001; 95% confidence interval 36.15 to 49.67). The mean reduction in hot flush score was 18.83 (80.32%) for the clinical hypnosis intervention compared with 3.53 (15.38%) for controls (P<0.001; 95% CI 12.60 to 17.54).

Mindfulness and relaxation
Current evidence does not support the efficacy of mindfulness based stress reduction (MBSR) or relaxation for vasomotor symptoms. One randomised controlled trial of 110 women found no statistically significant improvement in vasomotor symptoms (compared with a wait list control) after 20 hours of MBSR (P=0.116), and a systematic review of four randomised controlled trials (including 261 women) of relaxation techniques for vasomotor symptoms concluded that the quality of published studies was generally poor and that there was insufficient evidence to recommend these treatments.

Lifestyle changes
Some women can identify specific triggers for their vasomotor symptoms. Avoiding these and facilitating cooling down (such as by dressing in layers) may help some women, but there is no high quality evidence supporting this. Paced breathing was previously recommended but has been found to be ineffective (compared with a control of rapid shallow breathing). The efficacy of cooling devices, such as pads, gels, and collars has not yet been adequately evaluated but studies are in progress (clinicaltrials.gov. NCT02795741).

Diet and supplements
A systematic review of randomised controlled trials of plant based therapies concluded that dietary or supplementary phytoestrogens modestly improve hot flushes (average reduction in the number of hot flushes of 1.3 per day) and vaginal dryness but do not improve night sweats. While the overall quality of evidence for these therapies is poor, current evidence from randomised controlled trials does not support specific diet regimens such as plant based diets or diets rich in fish for the management of vasomotor symptoms.

There is limited evidence from randomised controlled trials that isoflavones (soy) or black cohosh may relieve vasomotor symptoms. However, a 2016 systematic review and a meta-analysis concluded that there is currently insufficient evidence to support the use of black cohosh for vasomotor symptoms. Another systematic review of black cohosh for vasomotor symptoms reached a similar conclusion. More recently, a parallel, double blind, randomised controlled trial of 63 women showed that a combination of probiotic and red clover isoflavone was superior to placebo and reduced the frequency of vasomotor symptoms by 4.3 hot flushes per day on average compared with <1 per day with placebo (P<0.01, 95% CI −6.8 to −2.3). NICE guidelines on management of early breast cancer recommend avoiding black cohosh and isoflavones in breast cancer patients.

Vitamins
One randomised, placebo controlled trial of vitamin E (800IU/day) in 105 breast cancer survivors produced a
A small reduction in frequency in vasomotor symptoms of less than one hot flush per day.

A trial of gabapentin versus vitamin E in 115 breast cancer survivors found that vitamin E was less effective than gabapentin for vasomotor symptoms (57% reduction in hot flush frequency with gabapentin versus 10% with vitamin E).

**Exercise**

A systematic review of five randomised controlled trials including 733 women concluded that exercise does not improve vasomotor symptoms or sleep, although it is likely to confer other health benefits.

Comparing exercise with usual activity (three studies, 454 women), there was no difference between groups in the frequency or intensity of vasomotor symptoms (standardised mean difference −0.10, 95% CI −0.33 to 0.13, I²=30%), but the quality of evidence was considered to be low.

**Yoga**

Current evidence does not support the efficacy of yoga for improving vasomotor symptoms. A randomised trial of yoga, 12 weekly 90-minute classes with daily home practice, (n=107) versus aerobic exercise training three times a week for 12 weeks (n=106) or usual activity (n=142) in women with vasomotor symptoms reported that neither yoga or exercise reduced vasomotor symptoms, but both yoga and exercise improved sleep quality, and exercise also improved mood.

**Weight loss**

Longitudinal studies show that higher body mass index is a risk factor for vasomotor symptoms (odds ratio 1.03). The NAMS guideline advises that weight loss in overweight women may be beneficial for menopausal symptoms but this is not yet supported by high quality evidence.

**Stellate ganglion block**

Injecting local anaesthetic into the sympathetic nerve fibres of the neck (the stellate ganglion) disrupts neural temperature regulation. This is an invasive and costly procedure, and the NAMS guidelines state that more evidence is needed from ongoing trials before stellate ganglion block can be recommended for vasomotor symptoms.

**Complementary and alternative treatments for vasomotor symptoms**

Many women use complementary and alternative medicines (CAMs) for menopausal symptoms and may not discuss this with their doctor. The most popular CAMs are herbal medicine, followed by soy or phytoestrogens, evening primrose oil, relaxation, and yoga.

Current evidence does not support the use of CAMs for vasomotor symptoms. A recent systematic review of 22 randomised controlled trials (2902 women) concluded that there was insufficient evidence to determine whether Chinese herbal medicines were effective for menopausal symptoms.

NICE recommends that clinicians should explain that many CAMs are available, that their safety is uncertain, and that interactions with other medicines have been reported. If patients choose herbal treatments they should be advised to look for the MHRA “traditional herbal remedy” stamp validating strength and quality.

Acupuncture, a component of Chinese medicine where thin needles are inserted into the skin, has been extensively tested for treating vasomotor symptoms. A systematic review in 2013 of randomised controlled trials of acupuncture versus no treatment, HRT, or sham acupuncture found that acupuncture was less effective than HRT for hot flush frequency (mean difference of 3.81 flushes per day) and insufficient evidence to conclude whether acupuncture has any effect on vasomotor symptoms.

A randomised trial of 10 treatments over eight weeks comparing standardised Chinese medicine inserted needle acupuncture with sham (non-insertive) acupuncture in 327 women found no difference in hot flush scores between acupuncture...
and the sham procedure at 12 weeks (15.36 v 15.04, mean difference 0.33). A systematic review published in 2017 concluded that acupuncture was more effective than no treatment but that improvements in vasomotor symptoms with acupuncture may be a placebo effect. Acupuncture was not associated with adverse side effects.

**Non-hormonal pharmacological treatments for vasomotor symptoms**

Developing novel targeted treatments for vasomotor symptoms has been limited by poor understanding of the underlying mechanisms. Pharmacological treatments demonstrated in randomised placebo controlled trials to improve vasomotor symptoms include selected serotonin selective reuptake inhibitors (SSRIs), serotonin and noradrenaline reuptake inhibitors (SNRIs), gabapentin, and clonidine.

**Serotonin selective reuptake inhibitors and serotonin and noradrenaline reuptake inhibitors**

International guidelines and systematic reviews of randomised controlled trials recommend selected SSRI and SNRI for the non-hormonal treatment of vasomotor symptoms (see table 1). However, NICE recommends that these pharmacological treatments should not be offered as first line treatments for vasomotor symptoms alone. Breast cancer patients commonly experience vasomotor symptoms. Those taking tamoxifen as endocrine therapy or high-risk women taking tamoxifen to reduce their breast cancer risk should avoid the SSRIs fluoxetine and paroxetine since these impair conversion of tamoxifen to its active metabolite, potentially diminishing its efficacy.

A randomised trial comparing the SNRI venlafaxine (extended release, 75mg/day) with 0.5 mg/day oral oestradiol found that both treatments were associated with a statistically significant reduction in the frequency of vasomotor symptoms of around 50% after eight weeks of use. Oestradiol improved menopause-related quality of life (as measured by the MENQOL) more than venlafaxine. Neither treatment affected sexual function over an eight week treatment period and both significantly improved sleep quality compared with placebo. Oestradiol at this dose is effective for at least four years for vasomotor symptoms, but the long term efficacy of venlafaxine is not known. Desvenlafaxine 100mg/day is the active metabolite of venlafaxine and reduces vasomotor symptoms for up to 12 months. Gabapentin and pregabalin are not licensed for the treatment of vasomotor symptoms in the UK.

SSRI and SNRI side effects may include nausea, dizziness, dry mouth, nervousness, constipation, somnolence, and sexual dysfunction. Sleep disturbance is common in menopausal women and is a high patient priority for treatment. The addition of the sedative zolpidem (10mg/night) to an SSRI or SNRI in breast cancer survivors improves sleep and quality of life compared with placebo. However, long term use of zolpidem is not recommended because of concerns about tolerance and daytime somnolence.

**Gabapentin and pregabalin**

Gabapentin is an anticonvulsant also used for neuropathic pain. A systematic review of 13 randomised controlled trials including 1714 women found that gabapentin (300mg three times per day) reduced the severity and frequency of vasomotor symptoms in breast cancer survivors (table 1). Up to 900mg/day gabapentin is generally well tolerated, but side effects are dose related and may include somnolence, dizziness, and fatigue. A randomised controlled trial in 163 breast cancer survivors found that pregabalin (75mg twice daily) significantly reduced the frequency and severity of vasomotor symptoms (table 1). Gabapentin and pregabalin are not licensed for the treatment of vasomotor symptoms in the UK.
Clonidine
Clonidine is a centrally active α-2 adrenergic agonist anti-hypertensive. It is the only licensed non-hormonal medicine for the treatment of vasomotor symptoms in the UK. A double-blind, randomised, placebo controlled trial of clonidine (0.1 mg/day) versus venlafaxine (75 mg/day extended release) versus placebo in 102 breast cancer survivors over a 12 week period showed that both clonidine and venlafaxine were superior to placebo in reducing vasomotor symptoms and, although venlafaxine worked more quickly, clonidine was more effective at 12 weeks. Side effects of clonidine include dizziness, hypotension, headache, constipation, and dry mouth.

Topical treatments for vaginal symptoms of menopause

Topical oestrogen
Vaginal symptoms such as dryness and dyspareunia are common in postmenopausal women and can affect relationships and sexual function. Vaginal (topical) oestrogen is the most effective treatment for vaginal symptoms, and systemic absorption is minimal. Vaginal dryness is also common in breast cancer survivors, particularly in women taking aromatase inhibitors. In addition to their negative impact on quality of life, vaginal dryness and discomfort may lead to discontinuation of endocrine therapy for breast cancer, which in turn can reduce disease-free survival. The safety of vaginal oestrogens in breast cancer patients is not established, and there are theoretical concerns that systemic absorption of oestradiol may reduce the efficacy of anti-oestrogen treatments such as aromatase inhibitors. However, recent evidence from a randomised controlled trial assessing the efficacy and systemic absorption of vaginal oestrogen (via a ring) in 69 breast cancer survivors taking aromatase inhibitors demonstrated improvements in vaginal dryness and sexual function with no increase in systemic oestradiol at 12 weeks compared with baseline, suggesting that vaginal oestrogen may be safe to use in breast cancer survivors. Current guidelines from the American College of Obstetrics and Gynaecology recommend reserving vaginal oestrogens for intransigent vaginal dryness in breast cancer survivors, discussion with the treating oncologist, and inclusion of the patient in decision making when considering potential risks and benefits. Ospemifene is a selective oestrogen receptor modulator that is superior to placebo for vaginal dryness. Ospemifene is approved by the FDA in the US but not currently available in the UK.

Vaginal moisturisers
Non-hormonal options for vaginal dryness are limited. Moisturisers (such as Replens and RepHresh) are marketed as long term treatments but mainly contain water and there is little evidence that these products lead to clinical improvements in vaginal symptoms. Moisturisers can cause local irritation, and this may be more marked in preparations where the osmolality and pH differ from normal vaginal secretions. There is currently insufficient comparative data to recommend one vaginal moisturiser over another.

Vaginal lubricants
Vaginal lubricants can be used during sexual activity to reduce friction. Lubricants may be water based (such as K-Y Jelly or Astroglide), silicone based (such as Pjur), or plant oil based (such as olive oil). One double-blind placebo controlled trial of a pH balanced vaginal gel for vaginal dryness in 86 breast cancer survivors found that the pH balanced gel was more effective than placebo for vaginal dryness (P=0.001) and dyspareunia (P=0.04). In 38 breast cancer survivors with discomfort during sexual activity, one randomised crossover trial comparing a silicone based and a water based lubricant found that the silicone based lubricant (Pjur) was more effective in reducing pain and discomfort during intercourse compared with the water based lubricant (Astroglide) (odds ratio 5.4, 95% CI 1.3 to 22.1, P=0.02). However, most women (88%) continued to experience clinically significant sexually related distress despite use of either lubricant.
Vulvar symptoms may also contribute to sexual discomfort. One randomised, placebo controlled, double blind trial of 4% aqueous lidocaine (v saline) applied to the vulvar vestibule for 3 minutes before vaginal penetration statistically significantly reduced pain during intercourse (P=0.007) in breast cancer survivors with severe dyspareunia and no male partners reported penile numbness.

**Emerging therapies and future directions**

*Neurokinin 3 receptor antagonists*—In a phase II placebo controlled randomised controlled trial a novel neurokinin 3 receptor antagonist demonstrated a 45% (95% CI 22% to 67%) reduction in the number, severity, and bother/interference due to vasomotor symptoms at 4 weeks. Treatment was generally well tolerated. More evidence is needed, but these agents have the potential to be the first targeted non-hormonal treatments for vasomotor symptoms.

*Standardising outcomes measures for vasomotor symptoms*—Understanding how hormonal and non-hormonal treatments compare for managing vasomotor symptoms has been hampered by inconsistency in outcome measures (such as frequency or severity or bother/interference of hot vasomotor symptoms). Bother/interference is more strongly associated with quality of life than frequency of vasomotor symptoms.

As part of the COMET initiative (www.comet-initiative.org), we are developing a core outcome set for menopausal symptoms (COMMA, Core Outcomes in Menopause), which will consider the outcomes most important to women and provide a standardised approach for evaluating treatment efficacy in future studies.

*CO₂ laser for vaginal symptoms of menopause*—Vaginal CO₂ laser therapy may improve dryness and discomfort due to collagen remodelling. This treatment is expensive, and there is currently insufficient evidence to recommend vaginal laser therapies.

**Conclusions**

Many women request non-hormonal treatments for menopausal symptoms, and clinicians should be familiar with approaches that are safe and effective. Management should include offering evidence based information about self management and effective treatments, both pharmacological and non-pharmacological. Treatment should focus on symptoms that most affect quality of life and may require different approaches to manage both vasomotor and vaginal symptoms. It is likely that targeted non-hormonal therapies will be available in the future, and by standardising outcome measures it will be easier to compare treatments and pool study data and consequently to translate this into improved clinical care.

**Education into practice**

- How can you incorporate a decision support tool for non-hormonal management of vasomotor symptoms into treatment discussions with women (such as that developed by NAMS)?

- How can you better communicate the information about common menopausal symptoms and evidence based treatment options to women?

**Tips for patients**

For a downloadable factsheet for women on self management of vasomotor symptoms, see www.womens-health-concern.org/help-and-advice/factsheets/cognitive-behaviour-therapy-cbt-menopausal-symptoms

**How patients were involved in the creation of this article**

Three women affected by menopausal symptoms, one British and two Australian, reviewed and commented on the manuscript. Input from patients changed the focus and content of the manuscript.
Footnotes

- Contributors: MH led the manuscript development. All authors contributed to the content and modification of this manuscript.
- Competing interests: We have read and understood BMJ policy on declaration of interests and have no relevant interests to declare.
- Provenance and peer review: Commissioned; externally peer reviewed.

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