

get the facts

Menopausal Symptoms and Complementary Health Practices



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Menopause is the permanent end of a woman's menstrual periods. Menopause occurs naturally, or it can be caused by surgery, chemotherapy, or radiation. Natural products or mind and body practices are sometimes used in an effort to relieve menopausal symptoms such as hot flashes and night sweats. This fact sheet provides basic information about menopause, summarizes research on the efficacy and safety of complementary health practices for menopausal symptoms, and suggests sources for additional information. It builds on findings from a 2005 National Institutes of Health (NIH) State-of-the-Science conference on the management of menopause-related symptoms, with updates to reflect new developments. Information from the conference is available from NIH at www.consensus.nih.gov/2005/menopause.htm.

Key Points

- Mind and body practices such as yoga, tai chi, qi gong, and acupuncture may help reduce the severity of menopausal symptoms.
- Researchers are studying herbal supplements sometimes used for menopausal symptoms in an effort to identify their different compounds and active ingredients and to understand their effects in the body. Some of these supplements can have serious side effects.
- “Bioidentical hormone replacement therapy” or “BHRT” is a marketing term used to describe medications that are prepared in specialized pharmacies and may contain any variation of hormones including, estrone, estradiol, progesterone, and testosterone. They are **not** approved by the U.S. Food and Drug Administration.
- Tell all your health care providers about any complementary health practices you use. Give them a full picture of what you do to manage your health. This will help ensure coordinated and safe care.

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About Menopause

“Menopausal transition” refers to the time leading up to menopause, involving hormonal changes that can span several years. A woman is said to have completed natural menopause when she has not had a period for 12 consecutive months and for American women, this typically happens at around age 51 or 52. Menopause occurs immediately if both ovaries are surgically removed,¹ or if the ovaries are severely damaged in cancer treatment with radiation therapy or chemotherapy. For menopause-related information from NIH, visit www.health.nih.gov/topic/menopause/womenshealth.

Common Symptoms During the Menopausal Transition

Some symptoms that women experience as they age are related to menopause and decreased activity of the ovaries. Other symptoms may be related to aging in general. Scientific evidence of a link to menopause is strongest for the following symptoms:

- Hot flashes and night sweats (also called vasomotor symptoms, because they involve the expansion of the blood vessels)
- Vaginal dryness, which can lead to painful intercourse.

Some women also may experience problems with reasoning or remembering things. This may be related, in part, to changes in estrogen during the menopausal transition.

It is not certain whether the following symptoms are due to menopause, other factors that can come with aging, or a combination of menopause and age-related factors:

- Urinary incontinence
- Physical complaints, such as tiredness and stiff or painful joints
- Changes in mood, such as depression, anxiety, and/or irritability. These symptoms are similar to premenstrual syndrome.

The expert panel assembled for the NIH State-of-the-Science conference noted that menopause is a normal part of women’s aging and advised that menopause should not be “medicalized” (or viewed as a disease).

Menopausal Hormone Therapy

For decades, hormone therapy was a widely used treatment for menopausal symptoms. **Estrogen** has been used alone as a menopausal hormone therapy in women who have had their uterus removed. **Progestin**, the synthetic form of an estrogen-related hormone called progesterone, is combined with estrogen as a menopausal hormone therapy in women who still have their uterus. Progestin stops the growth of cells in the lining of the uterus. Continued growth of these cells can lead to uterine cancer.

¹ In performing a hysterectomy, which refers to the surgical removal of the uterus, a surgeon may or may not also remove the ovaries. Either way, periods stop immediately. If one or both ovaries remain, some hormone production may continue.

The Women's Health Initiative (WHI), a 15-year research program launched in 1991, was designed to address the most common causes of death, disability, and poor quality of life in postmenopausal women. The research program examined the effectiveness of hormone replacement therapy in women, which at the time was considered to be a promising intervention. Findings from two WHI clinical trials examined:

- The use of estrogen plus progestin in women with a uterus
- The use of estrogen only in women without a uterus.

In both studies, women were randomly assigned to receive either the hormone medication or placebo. The findings of the studies raised serious concerns about the long-term safety of menopausal hormone therapy. For example, in both studies, when compared with placebo, the hormone medication (whether estrogen plus progestin or estrogen only) resulted in an increased risk of stroke and blood clots. In addition, the estrogen plus progestin medication resulted in an increased risk of heart attack and breast cancer. Through this long-term, well-designed series of studies, the WHI showed how rigorous research can lead to answers of difficult and important questions affecting health and health care. These concerns are one reason that many women are turning to mind and body practices and natural products to help with menopausal symptoms.

For menopausal hormone therapy-related information from NIH, visit www.nih.gov/PHTindex.htm.

Common Elements of Clinical Trials

As shown by the WHI, clinical trials are an important part of medical research. A clinical trial is a research study in which a treatment or therapy is tested in people to see whether it is safe and effective.

- **Trials can be randomized.** In a randomized trial, each participant is assigned by chance to either an investigational group or a control group. Randomization helps ensure that the study results are attributable to the treatment and not to unrelated factors that might bias the outcome or the interpretation of the results.

Each participant has an equal chance of being assigned to any group. Some complex trials include several groups.

- **Trials are often double blind.** This means that neither the researchers nor the participants know who has been assigned to which group. Blinding is another way to help minimize the chance of bias influencing the trial results.
- **Researchers design clinical trials to have one or more endpoints.** An endpoint is a measure that determines whether the treatment under study has an important effect.

To learn more or to find trials that are recruiting participants, visit NIH Clinical Research Trials and You. If you do not have access to the Internet, contact the NCCAM Clearinghouse for information.

What the Science Says About Complementary Health Practices for Menopausal Symptoms

The NIH State-of-the-Science conference panel noted the overall shortage of well-designed research on complementary health practices for menopausal symptoms. Many studies have had limitations (such as the way the research was done or treatment periods that may not have been long enough). As a result, the findings from these studies have not been strong enough for scientists to draw any conclusions. Also, many studies of botanicals have not used a standardized product (i.e., one that is chemically consistent).

Since the 2005 NIH panel's findings, scientists are continuing to build an evidence base on complementary therapies for menopausal symptoms. Although questions remain, research is progressing. For example, NCCAM is sponsoring studies on mind and body approaches that have shown promise for reducing menopausal symptoms, and on botanical products that are both well characterized (i.e., their ingredients have been carefully studied) and well standardized.

Mind and Body Therapies for Menopausal Symptoms

A growing body of evidence suggests that mind and body practices such as yoga, tai chi, qi gong, and acupuncture may benefit women during menopause. Research is under way to explore these preliminary findings.

- A 2010 review of 21 papers assessed mind and body therapies for menopausal symptoms. The researchers found that yoga, tai chi, and meditation-based programs may be helpful in reducing common menopausal symptoms including the frequency and intensity of hot flashes, sleep and mood disturbances, stress, and muscle and joint pain.
- Another 2010 review assessed studies that examined the use of acupuncture for hot flashes related to natural or induced menopause. The studies that the researchers included in their review were limited to acupuncture studies performed using needles stimulated by hand or electrically. The researchers found that acupuncture may reduce the frequency and severity of hot flashes; they also concluded that the effect may occur regardless of where the acupuncture needle is placed on the body. However, some studies did not provide sufficient evidence to support the use of acupuncture for hot flashes due to their small size and poor quality. Further research is needed in order to provide more conclusive results.

Symptoms Matter

In thinking about quality of life and what it means to be well, it is important to recognize that symptoms matter. The National Health Interview Survey showed that the primary health conditions that lead Americans to turn to complementary practices are some very common and troublesome symptoms. Therefore, research that explores the role of promising mind and body therapies for alleviating symptoms remains an important focus for future studies.

Natural Products and Menopausal Symptoms

Because natural products used for menopausal symptoms can have side effects and can interact with other botanicals or supplements or with medications, research in this area is addressing safety as well as efficacy. Some findings from this research are highlighted below.

Botanicals

- **Black cohosh** (*Actaea racemosa*, *Cimicifuga racemosa*). This herb has received more scientific attention for its possible effects on menopausal symptoms than have other botanicals. Studies of its effectiveness in reducing hot flashes and other symptoms have had mixed results. A study funded by NCCAM and the National Institute on Aging (NIA) found that black cohosh, whether used alone or with other botanicals, did not relieve hot flashes and night sweats in postmenopausal women or those approaching menopause. In the same study, black cohosh also had no effect on gynecological problems such as vaginal dryness and abnormal bleeding. Other research suggests that black cohosh does not act like estrogen, as once was thought. Recent reviews of the clinical research literature on black cohosh for menopausal symptoms conclude that its efficacy has yet to be demonstrated.

United States Pharmacopeia experts suggest that **women should discontinue use of black cohosh and consult a health care practitioner if they have a liver disorder or develop symptoms of liver trouble**, such as abdominal pain, dark urine, or jaundice. There have been several case reports of hepatitis (inflammation of the liver), as well as liver failure, in women who were taking black cohosh. It is not known if black cohosh was responsible for these problems. Although these cases are very rare and the evidence is not definitive, scientists are concerned about the possible effects of black cohosh on the liver.

Study Says Black Cohosh and Red Clover Are No Better Than Placebo

A year-long study of 89 women experiencing at least 35 episodes of hot flashes and night sweats each week compared two botanicals (black cohosh and red clover) with menopausal hormone therapy and placebo to evaluate symptom relief and safety. The researchers concluded that although neither botanical helped to relieve symptoms when compared to placebo, no safety concerns emerged during the trial.

Symptoms declined 63 percent in the placebo group—much more than the researchers expected. For red clover, the decline in symptoms (57 percent) was similar to placebo; for black cohosh, the decline (34 percent) was less than placebo. Symptoms declined 94 percent with menopausal hormone therapy.

The study was conducted by the University of Illinois at Chicago/NIH Center for Botanical Dietary Supplements Research, funded in part by NCCAM. More information about the study is available at nccam.nih.gov/research/results/spotlight/042610.htm.

- **Dong quai** (*Angelica sinensis*). Only one randomized clinical study of dong quai has been done. The researchers did not find it to be useful in reducing hot flashes. Dong quai is known to interact with, and increase the activity in the body of, the blood-thinning medicine warfarin. This can lead to bleeding complications in women who take dong quai.

- **Ginseng** (*Panax ginseng* or *Panax quinquefolius*). The 2005 NIH panel concluded that ginseng may help with some menopausal symptoms, such as mood symptoms and sleep disturbances, and with one's overall sense of well-being. However, ginseng has not been found helpful for hot flashes.
- **Kava** (*Piper methysticum*). According to the 2005 NIH panel, there is no evidence that kava decreases hot flashes, although it may decrease anxiety. Furthermore, **it is important to note that kava has been associated with liver disease**. The U.S. Food and Drug Administration (FDA) has issued a warning to patients and providers about kava because of its potential to damage the liver.
- **Red clover** (*Trifolium pratense*). The 2005 NIH panel found no consistent or conclusive evidence that red clover leaf extract reduces hot flashes. A large clinical trial and several reviews of the research literature concluded that red clover had no significant beneficial effects on menopausal symptoms. A review of the research literature also found no apparent evidence of adverse events from short-term use (up to 16 weeks). However, the same review noted the lack of data on the safety of long-term use. There are some concerns that red clover, which contains phytoestrogens, might have harmful effects on hormone-sensitive tissue (for example, in the breast and uterus). (See box below for more information on phytoestrogens.)
- **Soy**. The scientific literature includes mixed results on soy extracts for hot flashes. Some studies find benefits, but others do not. Although information on adverse effects is limited, soy extracts appear to be generally safe when taken for short periods of time. However, long-term use of soy extracts (which also contain phytoestrogens) has been associated with thickening of the lining of the uterus.

About Phytoestrogens

Phytoestrogens occur naturally in plants and act like estrogens in some tissues, including bone and cardiovascular tissue. Some botanical products, such as soy and red clover, contain phytoestrogens. Plants rich in phytoestrogens have been studied for treating menopause symptoms. However, much remains to be learned about these plant products, including their effects in the human body. Doctors caution that certain women need to be particularly careful about using phytoestrogens, especially:

- Women who have had or are at increased risk for diseases or conditions that are affected by hormones, such as breast, uterine, or ovarian cancer
- Women who are taking medications that increase estrogen levels in the body, such as birth control pills; menopausal hormone therapy; or a type of cancer drug called selective estrogen receptor modulators (SERMs), such as tamoxifen.

DHEA

DHEA is a naturally occurring substance that is changed in the body to the hormones estrogen and testosterone. DHEA is manufactured and sold as a dietary supplement. A few small studies have suggested that DHEA might possibly have some benefit for hot flashes and decreased sexual arousal, although small randomized controlled trials have shown no benefit. Because

levels of natural DHEA in the body decline with age, some people believe that taking a DHEA supplement can help treat or prevent conditions related to aging; however, there is no scientific evidence to support this notion.

Concerns have been raised about whether DHEA is safe and effective. Its long-term effects, risks, and benefits have not been well studied, and it remains unclear whether it might increase the risk for breast or prostate cancer. There is the possibility that even short-term use of DHEA supplements might have detrimental effects on the body. Before using DHEA for any purpose, people should talk to their health care provider about potential benefits and risks.

Bioidentical Hormone Replacement Therapy

“Bioidentical hormone replacement therapy,” or BHRT, is a marketing term that is not recognized by the FDA. It is a term used to describe medications that are prepared in specialized pharmacies. BHRT may contain any variation of hormones including estrone, estradiol, estriol, progesterone, and testosterone.

Compounded bioidentical hormones are often marketed as natural and safe alternatives to conventional hormone therapy prescription medications. However, compounded formulas are often inconsistent and can vary depending on the batch or the pharmacist. While FDA-approved hormone preparations have been tested for efficacy, purity, safety, and potency, there is a lack of scientific evidence surrounding BHRT and the safety and efficacy of these compounds. **As a result, compounded bioidentical hormones are not approved by the FDA.** For additional information, see the FDA publication *Bio-Identicals: Sorting Myths from Facts*, at www.fda.gov/ForConsumers/ConsumerUpdates/ucm049311.htm.

NCCAM Research on Complementary Health Practices for Menopausal Symptoms

NCCAM supports a number of studies on complementary health practices (such as natural products and mind and body practices) for menopausal symptoms, as do some of the other institutes and centers at NIH. Examples of NCCAM-funded projects include:

- A trans-NIH initiative to improve scientific measures of hot flashes, which will lead to more productive clinical studies and a better understanding of hot flashes
- Research to identify natural plant-based compounds as promising alternatives to traditional menopausal hormone therapy
- Investigations of the safety and efficacy of black cohosh, red clover, soy supplements, and other botanicals for menopausal symptoms, as well as the mechanisms of action involved
- Studies of mind and body therapies—e.g., yoga, mindfulness-based stress reduction (a form of meditation), hypnotherapy, and acupuncture—for reducing hot flashes.

In addition, an NIH initiative led by NIA in collaboration with NCCAM, the Eunice Kennedy Shriver National Institute of Child Health and Human Development, and the Office of Research on Women’s Health is looking at potential new treatments for menopausal symptoms.

If You Are Considering a Complementary Health Practice for Menopausal Symptoms

Although there is little scientific evidence to support the effectiveness of complementary health practices for menopausal symptoms, it is possible that some approaches may provide relief to women during the menopausal transition. Here are a few important points to remember if you are considering these practices:

- Keep in mind that although many dietary supplements (and some prescription drugs) come from natural sources, “natural” does not always mean “safe.” For example, the herb kava may cause serious harm to the liver. Also, a manufacturer’s use of the term “standardized” (or “verified” or “certified”) does not necessarily guarantee product quality or consistency.
- Be aware that an herbal supplement may contain several compounds and that its active ingredients may not be known. Researchers are studying many of these products to identify those ingredients and understand their effects in the body. Also consider the possibility that what’s on the label may not be what’s in the bottle. Analyses of dietary supplements sometimes find differences between labeled and actual ingredients. For additional information, see the NCCAM fact sheet *Using Dietary Supplements Wisely* at nccam.nih.gov/health/supplements/wiseuse.htm.
- Tell all your health care providers about any complementary health practices you use. Give them a full picture of what you do to manage your health. This will help ensure coordinated and safe care. For tips about talking with your health care providers about complementary and alternative medicine, see NCCAM’s Time to Talk campaign at nccam.nih.gov/timetotalk/.

In addition to some of the practices mentioned in this fact sheet, the NIH State-of-the-Science conference report (see “Selected References”) also discusses a variety of other interventions commonly used for relief of menopause-related symptoms. Women should keep in mind that certain lifestyle changes can contribute to healthy aging, including during the menopausal transition. For example, quitting smoking, eating a healthy diet, and exercising regularly have been shown to reduce the risks of heart disease and osteoporosis.

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For More Information

NCCAM Clearinghouse

The NCCAM Clearinghouse provides information on NCCAM and complementary health practices, including publications and searches of Federal databases of scientific and medical literature. The Clearinghouse does not provide medical advice, treatment recommendations, or referrals to practitioners.

Toll-free in the U.S.: 1-888-644-6226
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Web site: www.ncbi.nlm.nih.gov/sites/entrez

NIH Clinical Research Trials and You

The National Institutes of Health (NIH) has created a Web site, NIH Clinical Research Trials and You, to help people learn about clinical trials, why they matter, and how to participate. The site includes questions and answers about clinical trials, guidance on how to find clinical trials through ClinicalTrials.gov and other resources, and stories about the personal experiences of clinical trial participants. Clinical trials are necessary to find better ways to prevent, diagnose, and treat diseases.

Web site: www.nih.gov/health/clinicaltrials/

National Institute on Aging (NIA)

NIA is the NIH institute that focuses on supporting and conducting high-quality research on aging processes, age-related diseases, and special problems and needs of the aged. NIA publications include *Hormones and Menopause: Tips from the National Institute on Aging* (www.nia.nih.gov/sites/default/files/TipSheet_HormonesAndMenopause_0.pdf) and *Menopause: Time for a Change* (www.nia.nih.gov/health/publication/menopause-time-change).

Web site: www.nia.nih.gov

National Women's Health Information Center (NWHIC)

NWHIC, a service of the Office on Women's Health in the U.S. Department of Health and Human Services (HHS), provides information to help advance women's health research, services, and public and health professional education. NWHIC coordinates the efforts of all HHS agencies and offices involved in women's health. NWHIC publications include *Menopause and Menopause Treatments* (www.womenshealth.gov/faq/menopause-treatment.cfm).

Web site: www.womenshealth.gov

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