

# HRT: Benefits and risks

**Although there have been concerns raised about HRT and the potential risks to various aspects of women's health, more recently published findings show that although not entirely risk free, it remains the most effective solution for the relief of menopausal symptoms and is also effective for the prevention of osteoporosis. It may in certain age groups provide protection against heart disease.**

This leaflet sets out the known facts about HRT. It summarises the results of studies regarding its safety and addresses the controversy that still surrounds it, together with current thinking about its suitability. It is written specifically for women wishing to know about HRT. Our medical advisory panel strongly recommends that you should discuss with your doctor both the benefits and the risks of HRT on an individual basis. The types of HRT available are listed below.

## Concerns over the safety of HRT – a history

HRT was first available in the 1940s but became more widely used in the 1960s, creating a revolution in the management of the menopause. HRT was prescribed commonly to menopausal women for the relief of their symptoms such as hot flushes, night sweats, sleep disturbances, psychological and genito-urinary problems – urinary frequency and vaginal dryness – and for the prevention of osteoporosis.

In the 1990s two of the largest studies of HRT users were undertaken, one clinical randomised trial in the USA [Women's Health Initiative (WHI)] and one observational questionnaire study in the UK [the Million Women Study (MWS)]. The published results of these two studies during 2002 and 2003 raised concerns regarding the safety of HRT. These safety concerns revolved around two main issues: 1) that the extended use of HRT may increase the risk of breast cancer and 2) that the use of HRT may increase the risk of heart disease.

The results of the studies received wide publicity, creating panic amongst some users and new guidance for doctors on prescribing.

After the results were published, the UK regulatory authorities issued an urgent safety restriction about HRT, recommending that doctors should prescribe the lowest effective dose for symptom relief, should use it only as a second line treatment for the prevention of osteoporosis, and advised against its use in asymptomatic postmenopausal women.

There remains widespread confusion and uncertainty amongst both doctors and HRT users. Many doctors stopped prescribing HRT and many women abandoned HRT immediately, with a return of their menopausal symptoms. The number of women taking HRT fell by 66%, which has not changed so that now after more than 10 years, there has been almost a generation of women who have mostly been denied the opportunity of improved quality of life during their menopausal years. The women studied in the WHI were North American women in their mid-sixties, often overweight and thus totally unrepresentative of women in the UK for whom HRT might be considered suitable. These would usually be around the age of the menopause, namely 45-55 years.

It should also be appreciated that, in a surprising turnabout, subsequent publication of the full WHI results showed the apparent increased risk for breast cancer was only found in those who had taken HRT before entering the study.

The WHI long-term randomised clinical trials published in 2020 showed a significant reduction in breast cancer diagnosis and mortality in women using estrogen only HRT. Like the NICE guideline conclusions, they found that women on combined estrogen and progestogen containing HRT had an increased risk of breast cancer diagnosis but no significant increase in mortality. The Collaborative Group on Hormonal Factors in breast cancer 2019 reported that obesity attenuated the absolute and the relative excess breast cancer risk associated with both estrogen only and combined HRT. Large observational trial data suggest that micronized progesterone and dydrogesterone are likely to be associated with a lower risk of breast cancer compared to that seen with other progestogens.

With regard to cardiovascular risk and HRT, recent data has been reassuring. A large controlled trial from Denmark reported in 2012 has demonstrated that healthy women taking combined HRT for 10 years immediately after the menopause had a reduced risk of heart disease and of dying from heart disease. The Cochrane data-analysis have shown a reduction in cardiovascular events and deaths in women taking either estrogen only or combined HRT within 10 years of menopause or under 60 years of age. In addition to this the Cochrane group and the follow up data from WHI found that there doesn't appear to be an increased risk in cardiovascular events or mortality in women initiating HRT more than 10 years after the menopause.

Recent evidence from the Collaborative Group on Hormonal Factors demonstrated that there may be a slight increased risk of some types of ovarian cancer associated with HRT use but this is small and equates to around 1 extra case of ovarian cancer per 1000 HRT users .

Hormonal status can affect cognitive function and over the years there has been conflicting evidence regarding the risk of dementia and HRT use. Based on the current evidence, women can be reassured that HRT is unlikely to increase the risk of dementia or be detrimental to cognitive function in women initiating HRT under the age of 60 years.

### HRT today; key points

The balance of benefit to harm always needs to be assessed but appears to have shifted favourably for HRT. Users can be reassured provided:

- HRT is taken for the correct reasons, i.e. to alleviate the symptoms of the menopause. It has a role in the prevention of osteoporosis but long term use is often required
- The dose and duration of HRT use should be made on an individual basis after discussing the risks and benefits. No arbitrary limit should be set on duration of use
- HRT users are assessed by their GP at least once a year.

If women start HRT around the time of menopause the risk is very small and there appear to be cardiovascular and bone protective benefits. It is not usually appropriate for women over 60 to be starting HRT but as the WHI study shows, women initiating it over 60 years do not seem to be at increased risk of cardiovascular events or mortality.

Many women seek advice on the effects of HRT on sexual activity and desire. Whilst there is no definitive answer, case studies indicate that the estrogen in HRT can help maintain or return sex drive. It will also help other menopausal symptoms such as vaginal dryness and pain with intercourse. If vaginal symptoms are the only problem, then the use of local vaginal estrogen or dehydroepiandrosterone (DHEA) may be preferable. Separate factsheets on Sexual Health are available for download from the Women's Health Concern website.

Bio-identical hormones are hormone preparations which are identical molecules to those produced by the body. However, in practice the term is used for preparations made by compounding chemists which are claimed to be safer than "traditional" hormones used in hormone replacement therapy (HRT). In fact, some traditional HRT preparations are actually "bio-identical", using oestradiol 17-beta which is the natural human estrogen, or using micronised progesterone capsules which is the natural human progesterone.

It should be obvious that any product which is a “bio-identical” hormone will carry the same benefits and risks as the HRT products produced by pharmaceutical companies and properly licensed for use, and there is absolutely no evidence that the bio-identical hormones are any safer than those used in traditional HRT. Indeed, they may be less safe – their production is not monitored by government drug regulatory authorities and thus their dosage may be inaccurate or inconsistent, their purity is certainly not guaranteed, and their safety is not tested as it is with approved HRT formulations.

The bio-identical hormones are often compounded following salivary hormone measurements and are therefore claimed to be “customised”. The accuracy and usefulness of such tests are highly questionable. We would not recommend the use of bio-identical hormones that have not been licensed by the UK regulatory authorities, and indeed would strongly caution women against obtaining such products.

### Types of HRT available

There are more than 50 types of HRT available: HRT can be given orally (tablets), transdermally (through the skin); subcutaneously (a long-lasting implant); or vaginally.

- Cyclical HRT mimics the normal menstrual cycle. Estrogen is taken every day and progestogen for 12 to 14 days. At the end of each course of progestogen there is some bleeding as the body “withdraws” from the hormone and the womb lining (endometrium) is shed. Progestogen regulates bleeding and protects the endometrium from harmful pre-cancerous changes
- Estrogen-alone HRT is normally prescribed to women who have had their womb removed (hysterectomy). The benefits of all HRTs are derived from estrogen; progestogen is only necessary to protect the womb lining
- In continuous combined therapy HRT (CCT) combinations of an estrogen and progestogen are prescribed continuously to achieve period-free HRT. Usually, women start on cyclical HRT and change to CCT later
- Tibolone is a synthetic form of period-free HRT which may have similar benefits to CCT. It is taken continuously in tablet form
- Long cycle HRT uses a formulation which causes withdrawal bleeds every three months instead of every month, and is most suited to women who suffer side effects when taking a progestogen. Its safety in long-term use with regard to the lining of the womb is questionable
- Local estrogen, such as vaginal tablets, creams, or rings, is used for treating local uro-genital problems, such as dry vagina, irritations, bladder problems or infections
- Testosterone, in the form of a gel or subcutaneous implant is indicated for women with decreased libido. It is unlicensed for use in women in the UK but the dose for males can be titrated for female use. It should be used in conjunction with conventional oestrogen containing HRT and women with a uterus require progestogens to protect the endometrium.

### In summary

Women wishing to start HRT should carefully discuss the benefits and risks of treatment with their doctor to see what is right for them, taking into account their age, medical history, risk factors and personal preferences.

For the majority of women who use HRT for the short-term treatment of symptoms of the menopause, the benefits of treatment are considered to outweigh the risks.

The lowest effective HRT dose should be taken, with duration of use depending on the clinical reasons for use.

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This fact sheet has been prepared by Women's Health Concern and reviewed by the medical advisory council of the British Menopause Society. It is for your information and advice and should be used in consultation with your own medical practitioner.

HRT remains licensed for osteoporosis prevention and can be considered the treatment of choice for women starting treatment below age 60 years, and especially for those with a premature menopause.

Women on HRT should be re-assessed by their doctor at least annually. For some women, long-term use of HRT may be necessary for continued symptom relief and quality of life.

Many health centres and practices have a doctor with a special interest in postmenopausal health. These specialist GPs will know the up-to-date recommendations for prescribing HRT. They may also be members of the British Menopause Society, the professional partner to Women's Health Concern, and therefore have access to its latest literature, studies and training. However, if your family doctor does not have sufficient knowledge of the current situation concerning the benefits and risks of HRT and many have lost confidence in prescribing because of the recent scares, then it is your right to request advice from a local Menopause clinic or a specialist with known expertise in menopausal health.

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