



**Welcome to the third newsletter of the Homeopathy Research Institute, a newsletter for everyone who wants to understand and support scientific research into homeopathy.**

## **Homeopathy for women with menopausal symptoms: a review of the evidence**

### **Introduction**

Many women consult homeopaths for problems associated with the menopause e.g. hot flushes, night sweats, fatigue, anxiety, depression, mood swings, lack of confidence, vaginal dryness, and joint pain. A recent audit of patients receiving treatment from medically qualified homeopaths at five NHS homeopathic hospitals reported that the menopause was the third most common reason for patients to be referred for treatment (Thompson et al., 2008) and a study of professional homeopaths reported that 12.3 % of patients requested treatment for female complaints (Relton et al., 2006). This edition of the HRI newsletter summarises the existing evidence for the effectiveness of homeopathy in the treatment of menopausal symptoms. Two main types of evidence are reported, evidence from observational studies and case studies of treatment by homeopaths, and the more complex ‘experimental’ evidence from randomised controlled trials (RCTs) of ‘homeopathy’.

### **Observational evidence of treatment by homeopaths**

There is a significant amount of published observational evidence which reports the results of patients suffering from menopausal symptoms treated by homeopaths using individualised (classical) homeopathy. Individualised homeopathy consists of a series of in depth interviews with a strong focus on the patient’s subjective experience to match the homeopathic medicine to the totality of symptoms (including any psychological symptoms) that emerge during a consultation and is regarded as the gold standard of homeopathic care.

Two observational studies report the outcomes of patients treated by homeopaths at NHS homeopathic hospitals (Clover & Ratsey, 2002; Thompson & Reilly, 2003) and an audit (Relton & Weatherley-Jones, 2005) reports the outcomes of patients in an NHS community menopause clinic.

All patients sought homeopathic treatment for one or more of the following menopausal symptoms: hot flushes, vaginal dryness, mood disturbance, fatigue. Many women receiving treatment for breast cancer suffer from menopausal symptoms such as hot flushes. One study reports the results of 45 patients who have had a diagnosis of breast cancer 35 of whom were suffering from hot flushes (Thompson & Reilly, 2003). Clover & Ratsey, describe the outcomes of 31 patients with hot flushes, the majority of whom have had a diagnosis of past or current breast cancer (20/31) and who also reported taking a wide range of medication (tamoxifen, HRT, antidepressants, clonidine, and chemotherapy). These two studies used patient self-assessment as their primary outcome. Clinically significant improvements were reported by Clover & Ratsey for hot flush frequency and severity. while Thompson & Reilly reported clinically significant improvements in effect of symptoms on daily living, mood, and quality of life. Finally, an audit of 102 women attending an NHS community menopause clinic demonstrated significant improvements in headaches, vasomotor symptoms, emotional and psychological symptoms, tiredness and fatigue (Relton & Weatherley-Jones, 2004).

### **Randomised controlled trials of homeopathic remedies**

There have been four RCTs of homeopathic remedies conducted. Two small (i.e. 5 patients in total) randomised studies evaluated the use of homeopathy for menopausal symptoms in the climacteric (Bekkering, 1993; Gautier, 1983) but neither study was large enough to make the detection of a statistically significant difference between the groups possible.

Two full sized double blind placebo-controlled trials were conducted in hospital settings, one in the UK (Thompson et al, 2005) and the other in the USA (Jacobs et al., 2005).

The duration of the intervention varied between 16 weeks (Thompson et al., 2005) and 6 – 12 months (Jacobs et al., 2005). The patient sample sizes were 83 (Jacobs et al., 2005) and 53 (Thompson et al., 2005). Both RCTs used repeated consultations with a homeopath with either an individualised homeopathic remedy or placebo, however, Jacobs et al., (2005) had an additional treatment arm of a formulaic complex homeopathic remedy. Inclusion criteria for both trials were: three or more hot flushes a day and a history of breast cancer.

The patient mean age was 52 (Thompson et al., 2005) and 55 (Jacobs et al., 2005) and use of Tamoxifen was high (80% Thompson et al., 60% Jacobs et al.). Jacobs et al. reported a high dropout rate (28/83) perhaps due to the greater length and older age group. There was evidence that women taking the formulaic complex homeopathic remedy, containing homeopathic preparations of Sanguinaria, Amyl nitrate and Lachesis, experienced side effects with the development of new or proving symptoms including a significant increase in headaches.

Neither RCT found a statistically significant improvement in the primary outcome measures for 'homeopathy' over placebo. The study by Jacobs in 2005 did however show a positive trend for homeopathy in the reduction of hot flashes during the first three months ( $p=0.1$ ) and a reduction in the Kupperman Menopausal Index ( $p=0.1$ ) at one year. It is impossible to conclude whether these negative results are due to insufficient sample sizes, faulty trial designs or the ineffectiveness of the interventions.

## Conclusions

None of the randomised controlled trials (RCTs) performed to date have reported a statistically significant effect for the use of homeopathic remedies in the treatment of menopausal symptoms. On the other hand, the observational evidence for the effectiveness of the treatment by a homeopath is overwhelmingly positive; suggesting it is a clinically relevant option in this clinical setting. In this instance, we must remember that the lack of evidence of effect reported by RCTs does not constitute evidence that there is no effect. Further well conducted trials of sufficient size are required to evaluate the clinical and cost effectiveness of treatment by a homeopath.

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