

Homeopathy for Insomnia: A review of research evidence

Insomnia affects 16-21% of the UK (Ohayon, 2002). Current management includes psychological and behavioural treatment and benzodiazepine receptor agonists. Pharmacological treatments have been shown to improve sleep outcomes, but may be associated with a risk of adverse effects and dependence in some patients. Patients also use homeopathy for insomnia, purchasing homeopathic medicines over the counter or consulting homeopaths (private or NHS). Within NHS homeopathic hospitals in the UK, insomnia is one of the most commonly-treated complaints (Thompson, 2008). Three surveys of homeopathic consultations in the UK reported that, respectively, 0.4%, 4% and 7% of cases related to insomnia (Swayne, 1989; Relton, 2007; Crump, 1996).

This summary describes the key findings of a recent review of clinical studies of homeopathic medicines or consultations/treatment by a homeopath (Cooper, 2010). The review sought to identify controlled trials, observational and case studies. Studies with insomnia as a secondary symptom of another primary condition were excluded. For example, a crossover RCT which evaluated homeopathic medicine versus placebo for circadian dysrhythmia ("shift lag") in 28 nurses working night shifts in an intensive care unit (La Pine, 2006) was excluded as it did not specifically address insomnia. An additional RCT (Naudé, 2010) of 30 patients with chronic primary insomnia in South Africa published since the systematic review by Cooper (2010) is included in this summary.

It is important to understand the distinction between: (A) evidence relating to homeopathic medicines and (B) evidence relating to consultations/treatment by homeopaths (Relton, 2008). To understand what a trial is 'of' and thus the type of evidence it produces, one must identify what has been randomised - medicines, placebos, homeopaths, etc. If the trial is 'of' homeopathic medicines, then patients have been randomised to either a homeopathic medicine or a comparator, (e.g. no medicine, a placebo, or another type of intervention). If the trial is 'of' treatment by a homeopath then patients are

randomised to either treatment by a homeopath or a comparator. As 4% of NHS 'homeopathy' is spent on homeopathic medicine and 96% on providing consultations with homeopaths, then the evidence required to inform debate regarding NHS 'Homeopathy' must include (B), evidence relating to the clinical and cost effectiveness of treatment by a homeopath.

A: Homeopathic medicines

In total, five randomised controlled trials (RCTs) comparing homeopathic medicines to placebo were identified. Two RCTs had homeopaths prescribing individually-prescribed medicines according to the symptom picture of the patient to all trial patients some of whom were randomly allocated to homeopathic medicine and others to placebo (Carlini, 1987; Naudé, 2010), and three assessed the formulaic medicines Homeogene-46 or Sedatif-PC, in comparison to placebo: (Cialdella, 2001), Requesan, (Wolf, 1992), Coffea cruda 200c (Kolia-Adam, 2008). All five RCTs involved small patient numbers and were likely to have been underpowered; the number of analysed patients ranged from 26 to 61, with the largest study (Cialdella, 2001) reporting a lack of statistical power due to accrual difficulties.

Most of the RCTs were of low methodological quality and several reported high patient dropout rates. The most recent RCT (Naudé, 2010) randomised 30 patients to receive either individualised homeopathic medicines or placebos. All patients received three consultations at two week intervals. At 6 weeks, there was a statistically significant difference in favour of the homeopathic medicine group with regards to both the quantity and quality of sleep. This RCT was of higher quality, with clear reporting of methodological details. Two RCTs showed a trend towards better outcomes in the homeopathic medicine treatment groups (Cialdella, 2001; Wolf, 1992). Naudé (2010) was the only RCT to demonstrate a statistically significant difference in outcomes between the homeopathic medicine and placebo groups in addition to improvements from baseline.

A non-controlled cohort study was also identified

(Waldschutz & Klein, 2008) which reported significant improvements from baseline for the group receiving the formulaic homeopathic medicine Neurexan (n=197).

B: Treatment by a homeopath

There were no RCTs assessing treatment by a homeopath (patients randomised to either treatment by a homeopath or a comparator (e.g. no medicine, a placebo, or another type of intervention). A single cohort study (Witt, 2005) reported greater improvement with treatment by a homeopath than with conventional treatment for a range of chronic conditions, including insomnia, although no data were available for the insomnia subgroup specifically (n=35).

Three small case series of treatment by a homeopath (n=27) reported improvement in some patients (Crump, 1996; Rogers, 1997; Treuherz, 1998). A large number (2,600) of case studies of treatment by a homeopath for insomnia with positive outcomes were also identified from a search of the homeopathy database (ReferenceWorks). However, the lack of control groups, lack of consistent outcome measures, and tendency to report only positive results (reporting bias) means that it is not possible to ascribe reported improvements to the homeopathic treatment specifically.

Conclusion

Homeopaths often treat insomnia, however, there is currently a lack of high-quality sufficiently powered studies assessing the effectiveness of either homeopathic medicines or treatment by a homeopath for this condition. There is a need for further well-conducted clinical trials of treatment by a homeopath in order to examine fully the clinical and cost effectiveness of the therapeutic system of homeopathy in the management of insomnia. This evidence will enable patients, clinicians and healthcare commissioners/insurers to make informed decisions regarding the homeopathic treatment of insomnia.

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References

Campbell M, Fitzpatrick R, Haines A, Kinmonth AL, Sandercock P, Spiegelhalter D et al. Framework for design and evaluation of complex interventions to improve health. *BMJ* 2000; 321(7262):694-696.

Carlini EA, Braz S, Troncione LRP, Tufik S, Romanach AK, Pustiglione M et al. [Hypnotic effect of homeopathic medication and placebo. Evaluation by "double-blind" and "crossing" techniques]. [Portuguese]. *Revista Da Associacao Medica Brasileira*, 1987; 33(5-6):83-88.

Cialdella P, Boissel JP, Belon P. [Homeopathic specialties as substitutes for benzodiazepines: double-blind vs. placebo

study]. *Therapie*, 2001; 56(4):397-402.

Cooper K, Relton C: Homeopathy for insomnia: a systematic review of research evidence. *Sleep Med Rev*, 2010; doi.org/10.1016/j.smr.2009.11.005. [E-publication ahead of print]

Crump S, The Society of Homeopaths Research Group. Report on the pilot audit. *The Homeopath*, 1996; 60:507-509.

Kolia-Adam N, Solomon E, Bond J, Deroukakis M. The efficacy of *Coffea cruda* on insomnia: a double blind trial. *Simillimum*, 2008; 21: 91-99.

La Pine MP, Malcomson FN, Torrance JM, Marsh NV. Night shift: can a homeopathic remedy alleviate shift lag? *DCCN - Dimensions of Critical Care Nursing*, 2006; 25(3):130-136.

Linde, K., Melchart, D. (1998), 'Randomized controlled Trials of Individualized Homeopathy: A state of the art review', *Journal of Alternative & Complementary Medicine*, 4, 4, 371-388.

Naudé DF, Couchman IMS, Maharaj A. Chronic primary insomnia: efficacy of homeopathic simillimum. *Homeopathy*, 2010; 99:63-68.

Ohayon MM. Epidemiology of insomnia: what we know and what we still need to learn. *Sleep Med Rev*, 2002; 6(2):97-111.

Relton C, Chatfield K, Partington H, Foulkes L. Patients treated by homeopaths registered with the Society of Homeopaths: a pilot study. *Homeopathy*, 2007; 96(2):87-89.

Relton C, O'Cathain A, Thomas KJ. 'Homeopathy': untangling the debate. *Homeopathy* 2008; 97(3):152-155.

Rogers J. Homeopathy and the treatment of alcohol-related problems. *Complement Ther in Nursing and Midwifery*, 1997; 3(1):21-28.

Souter K. Insomnia. *Health & Homeopathy*, 2007; Spring: 8-10.

Swayne JM. Survey of the use of homeopathic medicine in the UK health system. *J R Coll Gen Pract*, 1989; 39(329):503-506.

Thompson EA, Mathie RT, Baitson ES, Barron SJ, Berkovitz SR, Brands M et al. Towards standard setting for patient-reported outcomes in the NHS homeopathic hospitals. *Homeopathy*, 2008; 97(3):114-121.

Treuherz F, Bounds Green Group Practice. An audit of 500 consecutive patients referred in general practice 1993-1998. Report published by the Society of Homeopaths, London, 1998.

Waldschutz R, Klein P. The homeopathic preparation Neurexan vs. valerian for the treatment of insomnia: an observational study. *TheScientificWorldJournal*, 2008; 8:411-420.

Witt C, Keil T, Selim D, Roll S, Vance W, Wegscheider K et al. Outcome and costs of homeopathic and conventional treatment strategies: A comparative cohort study in patients with chronic disorders. *Complement Ther Med*, 2005; 13(2):79-86.

Wolf J. Schlafstorungen ohne Hang-over behandeln. *Natura Med*, 1992; 7(9):586-589.

Zollman C, Vickers A, Richardson J. ABC of complementary medicine. 2nd edition ed. *BMJ Books*; 2008

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