CLINICAL REVIEW

Homeopathy for insomnia: A systematic review of research evidence

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SUMMARY

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Treatment by a homeopath

Introduction

Insomnia and current management

Insomnia is a disturbance of normal sleep patterns commonly characterised by difficulty in initiating or maintaining sleep.1 A systematic review reported that 16–21% of people in the UK experience insomnia symptoms often or always.2 Current management of insomnia may include psychological and behavioural therapies and/or pharmacological treatments such as benzodiazepine receptor agonists (BZRAs), melatonin receptor agonists, and other agents.3 Pharmacological treatments have been shown to improve sleep outcomes, but may be associated with a risk of adverse effects and dependence in some patients.1,4 There remains a shortage of studies assessing the risk-benefit ratio of long-term use of these treatments, although recent studies of eszopiclone and zaleplon have indicated favourable safety profiles with treatment up to 1 year.3,6 In terms of psychological and behavioural therapies for insomnia, the following have been shown to be effective: stimulus control therapy, relaxation techniques, paradoxical intention, sleep restriction, and cognitive behaviour therapy.2 Studies and reviews of cognitive behavioural therapy (CBT) for insomnia have reported improvements in sleep quality and reductions in hypnotic drug use, although studies vary in terms of the techniques used and the setting in which they are delivered.6,8–12 Access to many non-pharmacological therapies is restricted due to lack of trained providers, cost, and a poor understanding of available options.7,13–15

A number of complementary and alternative medicines (CAM) have been investigated for treatment of insomnia. These include acupuncture,16,17 as well as herbal remedies such as valerian18,19 and other herbal preparations.20 The focus of this review relates to homeopathy for the treatment of insomnia.

Homeopathy

Homeopathy is a 'system of therapeutics' that uses doses of substances (known as homeopathic medicines or remedies) prescribed according to two principles: similitude ("like cures like")21 and potentisation (serial dilution and succussion; see

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Homeopathic medicines can be obtained over the counter in pharmacies, supermarkets and health food shops or ordered directly from homeopathic pharmacies. A United Kingdom (UK) population-based survey reported that 8.6% of respondents had purchased a homeopathic medicine in the previous twelve months and 14.6% of respondents had bought an over-the-counter homeopathic medicine in their lifetime. A trial of homeopathic medicines is one which compares a homeopathic medicine to a comparator, but does not randomise patients in terms of whether or not they receive consultations with a homeopath.

Treatment by a homeopath

Treatment by a homeopath involves taking a detailed case history which aims to build up a ‘symptom picture’ of the patient which is then matched with a ‘homeopathic drug picture’ as described in the homeopathic materia medica. On this basis, the homeopath prescribes one or more individualised homeopathic medicines. Treatment by a homeopath is a complex intervention which incorporates assessment, discussion and advice regarding the patient’s overall health profile and other aspects of the patient’s life, in addition to prescription of a medicine. A UK survey showed that 1.9% of the UK population had consulted a homeopath in the previous 12 months. A trial of treatment by a homeopath is one which compares treatment by a homeopath to a comparator (e.g., usual care).

Health service perspective on homeopathy

The traditional way of understanding or modelling ‘homeopathy’ is that the homeopathic medicine provides the specific effect. However, clinical guidance is primarily based on overall clinical and cost effectiveness of an intervention. There are an estimated 120,000 visits to homeopaths annually within the UK National Health Service (NHS), with an NHS expenditure of £3.3 million. NHS spending on homeopathic medicines accounts for around 5% of this total amount, while the bulk of the cost of ‘homeopathy’ in the NHS is the cost of the treatment by a homeopath, i.e., consultation(s) with the homeopath and the infrastructure to facilitate this. Thus the evidence that is required to inform the debate regarding NHS spending on what is termed ‘homeopathy’ is largely evidence of the clinical and cost effectiveness of treatment by a homeopath.

Homeopathy for insomnia

Two recent surveys reported that 4.5–18.5% of people with insomnia symptoms had used complementary and alternative medicines (CAM) or natural products to manage their insomnia, and a recent study showed that insomnia is one of the most commonly-treated complaints within homeopathic hospitals in the UK. Three surveys of homeopathic consultations in the UK reported that 0.4%, 4% and 7% of cases related to insomnia, respectively. This review systematically assesses current research evidence for the effectiveness of homeopathic medicines and treatment by a homeopath in the management of insomnia.

Methods

Search methods for identification of studies

A comprehensive search was carried out, including searching of biomedical databases, homeopathy-specific and complementary medicine-specific databases. The following biomedical databases were searched: MEDLINE, EMBASE, CINAHL, Cochrane Central Register of Controlled Trials (CENTRAL), Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effectiveness (DARE), Science Citation Index, and BIOSIS Previews. Searches were also undertaken of the Allied and Complementary Medicine (AMED) database and homeopathy-specific databases including Hom-Inform, ReferenceWorks and a further database of trials of homeopathy. Database searches were carried out in July 2009. No date or language restrictions were applied. When searching the standard medical databases such as MEDLINE, search terms incorporated terms for homeopathy (homeopath*, homoeopath*, and homeopathy subject headings) together with terms for insomnia (insomnia*, sleep*, and insomnia subject headings). When searching the homeopathy-specific databases, only “insomnia” and “sleep” search terms were used to increase search sensitivity.

Inclusion and exclusion criteria

This review aimed to identify any clinical studies of homeopathic medicines or treatment by a homeopath. In particular,
controlled trials were sought. Observational studies and case studies were identified as far as possible. Studies addressing insomnia as the primary condition were included, while studies with insomnia as a secondary symptom of another primary condition were excluded. No language restrictions were applied. Animal studies and laboratory-based experimental studies were excluded. Identification of relevant studies was carried out by two reviewers.

Data extraction and analysis

Data was extracted using a form designed for this study. Data extracted was checked by a second reviewer. Controlled trials were assessed for study quality using a standard appraisal form based on criteria recommended by the Centre for Reviews and Dissemination.35 Observational studies were assessed for study quality based on criteria recommended by the Critical Appraisal Skills Programme (CASP).36

Results

Included studies

The literature search identified 296 citations (Fig. 1). Of these, 39 were relevant for inclusion.

(A) Studies of homeopathic medicines: the review identified 4 placebo-controlled RCTs37–40 plus one uncontrolled cohort study41 (Table 1).

(B) Studies of treatment by a homeopath: No RCTs of treatment by a homeopath were identified. However, the review identified one cohort study,42 three case series31,43,44 and over 2600 case studies (30 from the literature search and 2580 from a search of the homeopathy database ReferenceWorks) (Table 2).

Excluded studies

A crossover RCT evaluated homeopathic medicine versus placebo for circadian dysrhythmia (“shift lag”) in 28 nurses working night shifts in an intensive care unit.45 However, this study was excluded from the analysis as it did not specifically address insomnia.

Studies of homeopathic medicines

Four RCTs and one uncontrolled cohort study of homeopathic medicines were identified (Table 1).

Randomised controlled trials

The literature search identified one crossover RCT of individualised homeopathic medicines versus placebo,37 and three RCTs of formulaic homeopathic medicines versus placebo.38–40 Carlini et al.37 assessed 44 patients with severe insomnia, who had a course of seven appointments with a homeopath. Patients received either individualised homeopathic remedies for 45 days followed by placebo for 45 days or vice versa. Of the 26 patients who had full follow-up data, no consistent difference was observed between patients starting on homeopathic remedies or placebo, although analysis was complicated by the crossover design and the fact that all patients received a course of treatment by a homeopath. Both groups showed statistically significant improvements from baseline by day 15 and for the full 90-

Citations identified via literature search: N = 296 citations

Citations rejected at title or abstract stage: N = 256 citations

Citations examined as full texts: N = 40

Citations rejected at full text stage: N = 1 citation (RCT of homeopathy for effects of night shift work)

Citations included: N = 39 citations from literature search (plus 2,580 case studies from ReferenceWorks)

Studies of homeopathic medicines:
- RCTs: N = 4
- Cohort studies: N = 1

Studies of treatment by a homeopath:
- RCTs: N = 0
- Cohort studies: N = 1
- Case series: N = 3
- Case studies: N = over 2,600 (30 from main literature search plus 2,580 from ReferenceWorks)

Fig. 1. Flow chart for identification of relevant studies.
<table>
<thead>
<tr>
<th>Reference</th>
<th>Study type</th>
<th>Population</th>
<th>Intervention and N</th>
<th>Control</th>
<th>Results</th>
<th>Quality/methodology/clinical comments</th>
</tr>
</thead>
</table>
| Carlini et al.             | RCT, crossover, Brazil (article in Portuguese) | Patients with severe insomnia  
N = 44 randomised, 26 analysed  
Mean age: not reported | Individualised homeopathic medicine (agreed by 2 homeopaths) then placebo.  
N = 25 randomised, 13 analysed up to day 45,  
9 analysed up to 3 months  
Duration: 45 days homeopathy then 45 days placebo | Placebo then individualised homeopathic medicine.  
N = 19 randomised, 13 analysed up to day 45,  
9 analysed up to 3 months  
Duration: 45 days placebo then 45 days homeopathy | The following outcomes were measured every 15 days up to 3 months: sleep duration, sleep latency, sleep quality, and clinical evaluation by homeopaths.  
Both groups showed significant improvement from baseline by day 15 and at all timepoints until 3 months, on all outcomes.  
No consistent differences between patients starting on intervention or placebo, although difficult to analyse due to crossover design. | Withdrawals: 18/44 (41%) withdrew by day 45 and not included in any analysis; 26/44 (59%) withdrew by end of study and not included in 3-month analysis  
Allocation concealment: Yes  
Blinding: Double-blind  
Comparability between groups: Not reported  
Statistical power: Lack of statistical power due to accrual difficulties |
| Cialdella et al.           | RCT, France (article in French) | Patients with insomnia having received low-dose benzodiazepines for ≥3 months  
N = 96 randomised, 61 analysed  
Mean age: 54 | Formulaic homeopathic medicines: Homeogene–46 or Sedatif-PC  
N randomised per group not reported.  
N analysed: Homeogene–46: 15; Sedatif-PC: 20;  
Placebo: 26.  
Duration: 1 month | Placebo  
N randomised per group not reported.  
N analysed: 26.  
Duration: 1 month | Patients meeting primary outcome (completed study and showed improvement or no change in symptoms on Clinical Global Impression Improvement scale at 1 month): Homeogene–46: 10/15 (67%); Sedatif-PC: 12/20 (60%); placebo: 13/26 (50%); no significant difference between groups.  
Secondary outcomes at 30 days: treatment preferences (see below); patients requesting return to BZD treatment; scale scores on a range of questionnaires.  
No significant differences between 3 groups (but did not test for difference between homeopathy or placebo).  
Percentage of patients preferring (at 1 month) (i) study treatment, (ii) prior benzodiazepine therapy, or (iii) no treatment/other treatment/no preference were as follows: homeopathy groups: 33%, 30%, 37%; placebo group: 19%, 38%, 43% respectively. | Withdrawals: 35/96 (36%) not included in analysis (due to violation of entry criteria or absence of data). Of patients analysed, 19/61 (31%) withdrew from treatment but still analysed.  
Allocation concealment: Yes  
Blinding: Double-blind  
Comparability between groups: Yes  
Statistical power: Lack of statistical power due to accrual difficulties |
### Wolf 39 RCT, Germany

Patients with difficulties falling asleep or staying asleep (both groups sleeping for average of 8 h per night at baseline).

<table>
<thead>
<tr>
<th>Formulaic homeopathic medicine</th>
<th>N randomised</th>
<th>N analysed</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requiesan</td>
<td>15</td>
<td>14</td>
<td>1 month</td>
</tr>
</tbody>
</table>

Placebo

<table>
<thead>
<tr>
<th>N randomised</th>
<th>N analysed</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>14</td>
<td>14</td>
<td>1 month</td>
</tr>
</tbody>
</table>

At 1 month: Proportion of patients reporting improvement was 8/14 (57%) in homeopathy group and 4/14 (29%) in placebo group (difference between groups not significant).

- Sleep time increased by 30 min in homeopathy group (non-significant change from baseline); unchanged in placebo group.
- Sleep latency decreased significantly from baseline in both groups (from 1 h to 30 min in homeopathy group and from 30 min to 20 min in placebo group).
- Night waking decreased significantly in both groups.

### People with insomnia lasting >1 year, with difficulty in falling asleep due to nervous excitability and flow of ideas (excluded people taking medication for insomnia)

<table>
<thead>
<tr>
<th>Formulaic homeopathic medicine</th>
<th>N randomised</th>
<th>N analysed</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coffea cruda 200C</td>
<td>not reported</td>
<td></td>
<td>1 month</td>
</tr>
</tbody>
</table>

Placebo

<table>
<thead>
<tr>
<th>N randomised</th>
<th>N analysed</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>not reported</td>
<td></td>
<td>1 month</td>
</tr>
</tbody>
</table>

Increase in sleep duration in both groups (38 min in homeopathy group, *p* = 0.003 from baseline; 35 min in placebo group; *p* = 0.007 from baseline), no significant difference between groups.

- Improvement in sleep pattern in both groups: *p* = 0.002 in homeopathy group; not reported in placebo group.
- Not reported whether significant difference between groups.

### Observational studies


#### Waldschutz and Klein

Prospective cohort study (non-randomised), Germany, 89 centres.

Patients with mild-to-moderate insomnia

<table>
<thead>
<tr>
<th>Formulaic homeopathictreatment with Neurexan</th>
<th>N enrolled</th>
<th>N analysed</th>
</tr>
</thead>
<tbody>
<tr>
<td>N = 197</td>
<td>156</td>
<td></td>
</tr>
</tbody>
</table>

Oral herbal medicine: valerian

<table>
<thead>
<tr>
<th>N enrolled</th>
<th>N analysed</th>
</tr>
</thead>
<tbody>
<tr>
<td>not reported</td>
<td>164</td>
</tr>
</tbody>
</table>

Duration: 1 month

None. Significant improvements from baseline in homeopathy group and valerian group on the following outcomes:

- Sleep duration at 2 weeks (increase of 2.2 h for homeopathy; 2.0 h for valerian).
- Sleep latency at 2 weeks (reduced by 37 min for homeopathy; 38 min for valerian).
- Sleep quality at 4 weeks.
- Daytime fatigue at 4 weeks (majority in both groups reported improvement; 49% for homeopathy and 32% for valerian reported no daytime fatigue).

Design: Not randomised or blinded.

Withdrawals: 89/409 (22%) excluded from analysis due to protocol violation.
### Table 2
Treatment by homeopath: characteristics and results of included studies.

<table>
<thead>
<tr>
<th>References</th>
<th>Study type</th>
<th>Population</th>
<th>Intervention and N</th>
<th>Control</th>
<th>Results</th>
<th>Quality/methodology/clinical comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Observational studies</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Witt et al.42</td>
<td>Cohort study (patients chose own treatment), Germany</td>
<td>493 patients with chronic conditions, including 35 with insomnia (homeopathy), 49 (conventional treatment)</td>
<td>Mean age: 42</td>
<td>Homeopathy (no further details)</td>
<td>Conventional treatment</td>
<td>No data available relating to 35 patients with insomnia. For all 493 patients with a range of chronic conditions, patient assessments of symptom severity over 12 months showed greater improvement in homeopathy group, while physician assessments of symptom severity improved significantly in both groups with no difference between groups. Overall cost per patient was similar in each group.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>N = 12 (insomnia), 253 (other conditions)</td>
<td>N = 23 (insomnia), 205 (other conditions)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Duration: 1 year follow-up (treatment duration not reported)</td>
<td>Number of consultations: Not reported.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Design: Not randomised or blinded. Patients made their own choice of treatment. Withdrawals: None reported.</td>
</tr>
<tr>
<td>Rogers43</td>
<td>Case series</td>
<td>5 patients with sleep disorders related to alcohol dependency</td>
<td>Individualised homeopathy treatment. N = 5 (completed and analysed)</td>
<td>None</td>
<td>5 patients completing study showed improvements on all measures of sleep quality (sleep diaries, Pittsburgh Sleep Quality Index, interviews) and measures of alcohol dependence. 2 patients had marked improvements, 2 slight improvements and 1 no change.</td>
<td>Design: Not randomised or blinded. Withdrawals: 0/5 (0%) Other: A controlled clinical trial was attempted, but not feasible due to issues of blinding, recruitment of adequate numbers, and clients not wishing to receive placebo.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Duration: 3 months</td>
<td>Number of consultations: Not reported.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crump31</td>
<td>Case series</td>
<td>234 consecutive cases consulting a homeopath, 17 with insomnia</td>
<td>Individualised homeopathy treatment. Duration: 3 months</td>
<td>None</td>
<td>Of 17 patients: - 6 (35%) no follow-up data - 2 (12%) no change - 7 (41%) reported as “better” - 2 (12%) reported as “much better”</td>
<td>Design: Not randomised or blinded. Withdrawals: 6/17 (35%) no follow-up data</td>
</tr>
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<td></td>
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</tr>
<tr>
<td>Treuherz44</td>
<td>Case series</td>
<td>500 consecutive cases referred via general practice in UK, at least 5 with insomnia</td>
<td>One or more consultations with homeopath</td>
<td>None</td>
<td>Of 5 insomnia cases described, 4 showed improvement; however, the total number of insomnia cases within the series was not reported.</td>
<td>Design: Not randomised or blinded. Withdrawals: Not reported</td>
</tr>
<tr>
<td>Various43,47–51</td>
<td>Case studies</td>
<td>Patients with insomnia</td>
<td>One or more consultations with homeopath</td>
<td>None</td>
<td>Of six described here, all reported benefit, but no validated outcome measures used.</td>
<td>Potential drawbacks of case studies: - Lack of validated outcome measures - Reporting bias</td>
</tr>
</tbody>
</table>

day follow-up on the following outcomes: sleep duration, sleep latency, sleep quality, and clinical evaluation by a homeopath.

Three further RCTs assessed formulaic/complex homeopathic remedies versus placebo. Cialdella et al. describe the outcomes of 61 patients with insomnia previously receiving low-dose benzodiazepines whose treatment was substituted for 1 month with one of two complex homeopathic remedies or placebo. There was a trend towards more patients in the homeopathic remedy groups meeting the primary outcome (completing the study and showing improvement or no change in symptoms at 1 month), but the difference between the groups was not significant for this outcome or the secondary outcomes. This study lacked statistical power due to accrual difficulties.

Kolia-Adam et al. reported an RCT comparing the formulaic homeopathic medicine Coffea cruda or placebo, given for 1 month to 30 patients with insomnia. There were statistically significant improvements from baseline in both groups in terms of sleep duration (increase of approximately 40 min) and sleep pattern, but no significant difference was reported between the groups.

Kigns et al. undertook a prospective cohort study (non-randomised) of 409 individuals with mild-to-moderate insomnia receiving either a combination homeopathic medicine or the herbal medicine valerian, for 1 month. Significant improvements from baseline were observed in both groups for the following outcomes: sleep duration at 2 weeks (increased by approximately 2 h in both groups); sleep latency at 2 weeks (reduced by approximately 40 min in both groups); sleep quality at 1 month; and daytime fatigue at 1 month.

Cohort studies
Waldschutz and Klein undertook a prospective cohort study (non-randomised) of 409 individuals with mild-to-moderate insomnia receiving either a combination homeopathic medicine or the herbal medicine valerian, for 1 month. Significant improvements from baseline were observed in both groups for the following outcomes: sleep duration at 2 weeks (increased by approximately 2 h in both groups); sleep latency at 2 weeks (reduced by approximately 40 min in both groups); sleep quality at 1 month; and daytime fatigue at 1 month.

Studies of treatment by a homeopath
No RCTs, one cohort study, three case series, and over 2600 case studies were identified which assessed treatment by a homeopath (Table 2).

Randomised controlled trials
There were no RCTs assessing treatment by a homeopath.

Cohort studies
Witt et al. undertook a comparative cohort study (non-randomised) of treatment by homeopaths or conventional medicine practitioners for 493 patients with chronic conditions. This study included 35 patients with insomnia, but no data was available relating specifically to this subgroup. Overall, for all 493 patients, patient assessments of symptom severity over 12 months showed greater improvement in the homeopathy group than the conventional treatment group, while physician assessments of symptom severity improved significantly in both groups with no difference between the groups. Overall cost per patient was similar in each group.
a generally safe intervention when administered by trained professionals.42

Discussion

Summary of review findings

Homeopathic medicines

Four RCTs compared homeopathic medicines to placebo; one assessing individually-prescribed medicines37 and three assessing formulaic medicines.38–40 None demonstrated a statistically significant difference in outcomes between groups, although two showed a trend towards better outcomes in the homeopathy treatment groups.38,39 Three of the RCTs demonstrated significant improvements from baseline in measures of sleep quality in both the homeopathy and placebo groups37,39,40 All four RCTs involved small patient numbers and were underpowered, and were poorly reported with high patient withdrawal rates. The use of a crossover design in one study made the results difficult to interpret.37 An uncontrolled cohort study was also identified; this reported statistically significant improvements from baseline for the group receiving formulaic homeopathic medicine.41

Treatment by a homeopath

There were no RCTs assessing treatment by a homeopath. A single cohort study reported greater improvement with treatment by a homeopath than with conventional treatment for a range of chronic conditions including insomnia, although no data was available for the insomnia subgroup specifically.42 Three case series of treatment by a homeopath reported improvement in some patients.31,43,44 However, lack of a randomised control group necessitates caution in interpreting results of these studies. A large number of case studies of treatment by a homeopath for insomnia were also identified. 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 definitively ascribe the reported improvements to the treatment.

Conclusions

Homeopaths often treat insomnia. However, there is currently a lack of high-quality studies assessing the effectiveness of homeopathy in treating this condition. The limited evidence available does not demonstrate a statistically significant effect of homeopathic medicines for the treatment of insomnia. Existing RCTs were of poor quality and were likely to have been underpowered. Well-conducted studies of homeopathic medicines and treatment by a homeopath are required to fully examine the clinical and cost effectiveness of homeopathy for insomnia.

Research agenda

1) Adequately-powered well-designed and well-reported trials of homeopathy for insomnia are required.
2) Pragmatic RCTs of treatment by a homeopath compared to usual care would inform clinical decision-making and health service commissioning.

Acknowledgements

Many thanks to Francis Treuherz who undertook the search of ReferenceWorks to provide an estimate of the number of insomnia case studies.

References


* The most important references are denoted by an asterisk.
35. NHS Centre for reviews and dissemination. Report 4: undertaking systematic reviews on effectiveness; CRD’s guidance for those carrying out or commissioning reviews; 2001 [Report].