

# Effective

# Health Care

Bulletin on the effectiveness  
of health service interventions  
for decision makers

This bulletin summarises  
the research evidence  
on the effectiveness of  
homeopathy.



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## Homeopathy

- Homeopathy is a system of treating patients using very low dose preparations according to the principle 'like should be cured with like'.
- Increasing numbers of patients are seeking information on complementary medicines from NHS health professionals. It has been estimated that there are around 470,000 users of homeopathic remedies in England every year.
- Given the large number of users, and the availability of homeopathy within the NHS, it is important to establish the effectiveness of homeopathy as a treatment.
- The evidence base for homeopathy needs to be interpreted with caution. Many of the areas that have been researched are not representative of the conditions that homeopathic practitioners usually treat. Additionally, all conclusions about effectiveness should be considered together with the methodological problems of the research.
- There is currently insufficient evidence of effectiveness either to recommend homeopathy as a treatment for any specific condition, or to warrant significant changes in the current provision of homeopathy.

## A. Introduction

Complementary medicine refers to a diverse group of health-related therapies and disciplines which are outside of mainstream medical care. In the UK, the most established complementary therapies are osteopathy, chiropractic, homeopathy, acupuncture and herbalism.

Increasing numbers of patients are seeking information on complementary medicines from NHS health professionals.<sup>1</sup> In order to advise about complementary medicine, health professionals need to understand its potential benefits and limitations.<sup>1</sup> The Department of Health, in collaboration with the Foundation for Integrated Medicine, NHS Alliance and National Association of Primary Care have produced an information pack designed to provide primary care groups (PCGs) with a basic source of reference on the complementary and alternative therapies most commonly provided by PCGs.<sup>2</sup>

This issue of *Effective Health Care* summarises the research evidence on the effectiveness of one of the most established complementary disciplines – homeopathy.

### **Use of homeopathy**

A recent (1999) BBC telephone survey reported that 17% of 1204 randomly selected British adults had used homeopathy within the past year.<sup>3</sup> Results of a 1998 survey of use and expenditure on complementary medicine in England suggested that 28% of respondents had either visited a complementary therapist or had purchased an over-the-counter herbal or homeopathic remedy in the past year. Eight percent of respondents reported that they had bought an over-the-counter homeopathic remedy in the past year. It was estimated from this that there could be over 470,000 recent users of homeopathic remedies in England.<sup>4</sup>

### **Box 1. Methods of homeopathic prescribing<sup>5,6</sup>**

Classical	Use of a single remedy prescribed according to the individual's presentation and history
Complex	More than one remedy used concurrently
Fixed	Same single agent used for a group of patients (often used in research)
Isopathy	Preparation based on causal agent
Phytotherapy	The administration of herbs or low potencies of herbs

### **What is homeopathy?**

Homeopathy was introduced during the late 18th and early 19th centuries and is a system of treating patients using very low dose preparations according to the similia principle: 'like should be cured with like'. It is based on the hypothesis that a substance which can cause certain symptoms may also be able to resolve similar symptoms. Homeopathic dilutions are often known as potencies and are prepared by a process of serial dilution with succussion (vigorous shaking).<sup>5,7</sup> There are two main series of dilutions: decimal (tenfold dilutions, denoted x in the UK) and centesimal (hundred fold, denoted c in the UK). Such dilutions are known as ultramolecular in that they are diluted to such a degree that not even a single molecule of the starting substance is likely to remain. The claim that these dilutions have a specific activity is the source of most of the scientific controversy surrounding homeopathy.

### **Homeopathic treatment**

Most of the conditions that homeopaths treat are chronic or recurrent. Homeopaths also treat a large number of patients with ill-defined illnesses that have not been given a conventional diagnosis.<sup>5</sup>

Initially, a very detailed history is taken from the patient, a clinical examination is performed, and all signs and symptoms are recorded. Attention is paid to alternating or unusual symptoms and information is sought on the impact of modalities (conditions providing relief or aggravation of

symptoms, e.g., weather or activity). The symptoms are then matched to remedies using either a repertory (an index in the homeopathic *Materia Medica*) or 'pattern recognition'. In private practice, a consultation may last for an hour or more, although some NHS GPs may provide a basic homeopathic assessment and treatment within 10-15 minutes.<sup>5</sup>

Methods of prescribing vary among homeopathic practitioners (see Box 1). Following administration of a remedy, the homeopathic practitioner follows the patient's progress, and pays attention to the development of symptoms, and will repeat or adjust the prescription depending on what is observed.<sup>7</sup>

## B. Homeopathy and the NHS

Whilst the majority of complementary medicine is provided outside the NHS, it is also available within the NHS. A 1995 survey of general practices in England reported that an estimated 39% of practices provided access to some form of complementary therapy for their NHS patients.<sup>8</sup> Around 21% of general practices offered access via a member of the primary health care team, 6% employed an 'independent' complementary therapist, and an estimated 24% of partnerships had made NHS referrals for complementary therapies. Homeopathy accounted for half the NHS referrals for complementary therapies reported.<sup>8</sup>

Homeopathy has been part of the NHS since its inception.<sup>9</sup> There are currently five homeopathic hospitals, of which the two largest in Glasgow and London have inpatient units. The hospitals provide a range of conventional and complementary treatments in addition to homeopathy. As with other complementary medicines, homeopathic services are currently accessed either through GP referral or through referral by another primary or secondary care health professional.<sup>10</sup> Referrals are subject to the service agreements between PCG/Ts or Health Authorities and providers of NHS homeopathy.

## C. Nature of the evidence

Around 200 randomised controlled trials (RCTs) evaluating homeopathy have been conducted, and there are also several systematic reviews of these trials. This bulletin is based mainly on an overview of existing systematic reviews of RCTs. Individual RCTs published subsequent to the included reviews with a specific scope are also included (see appendix for further details of methods).

There are a number of problems and controversies surrounding the existing evidence base for homeopathy.

Firstly, there is much debate over whether homeopathy shows any effect over and above placebo (a dummy medication or treatment given to participants in trials). Sceptics have argued that homeopathy cannot work because of the use of remedies that are diluted to such a degree that not even a single molecule of the starting substance remains. Given the absence of a plausible mechanism of action, it has been argued that the existing evidence base represents little more than a series of placebo versus placebo trials.<sup>11, 12</sup>

Others have argued that much of the research conducted into the

effectiveness of homeopathy is not representative of routine homeopathic practice, as homeopathic treatment is highly individualised, in that two patients showing similar symptoms may receive different treatments.<sup>13</sup> Whilst it is possible to carry out RCTs evaluating the efficacy of homeopathy, researchers have tended to focus on conducting placebo controlled RCTs either to test the effects of a single remedy on a particular condition and/or to explore the placebo issue. As such, conditions like delayed-onset muscle soreness have been studied whereas skin conditions like eczema, which homeopaths commonly treat, have been overlooked.<sup>13</sup>

Most RCTs of homeopathy have involved small numbers of patients and have suffered from low statistical power. Given the controversy surrounding the plausible mechanism of action for homeopathy, there have been calls for stronger levels of evidence for the effectiveness of homeopathy than would normally be required for other conventional interventions.<sup>6, 14</sup>

## D. Effectiveness

### Reviews with a general scope (Table 1)

Four systematic reviews were identified.<sup>6, 15-17</sup> The purpose of these reviews was to determine whether there is any evidence for the effectiveness of homeopathic treatment generally. Patients with any disease were included, as opposed to investigating effects within a specific group, e.g. people with asthma. Due to the general nature of all four reviews, participant characteristics and outcomes were not specified in the selection criteria for primary studies and both participants and interventions varied greatly. All four reviews included RCTs and one also included controlled clinical trials.<sup>6</sup> Each review covered several different types of homeopathy including classical, fixed, complex, and isopathy. All reviews identified methodological problems with the primary studies,

and as such, were unable to draw firm conclusions about the general effectiveness of homeopathy. It should be noted that the analyses undertaken in two of the reviews involved the statistical pooling of clinically heterogeneous data, and therefore the estimates shown should be viewed with caution.<sup>16, 17</sup>

### Reviews of individualised (classical) homeopathy (Table 2)

In classical or individualised homeopathy, practitioners aim to identify a single homeopathic preparation that matches a patient's general 'constitution'. Constitution refers to a 'picture' composed of different information such as personal and medical history, the medical history of family members, and the patient's personality, behaviour, and preferences (e.g. for certain types of food). Due to differences in elements of patients' constitutions, two patients with identical conventional diagnoses may receive different homeopathic prescriptions.

Two reviews were identified.<sup>18, 19</sup> Again, the scope of these reviews was general and selection criteria relating to participant characteristics and outcome measurements were unspecified. Methodological problems with the primary studies were reported in both reviews.<sup>18, 19</sup>

One review assessed the effectiveness of individualised homeopathy compared with placebo, no treatment, or another therapy, and included randomised, quasi-randomised, or double-blind trials (32 trials included).<sup>18</sup> The results from a pooled analysis of 19 trials indicated a statistically significant result in favour of homeopathy. However, when the analysis was limited to six trials of higher methodological quality, the difference between homeopathy and control treatments was no longer statistically significant. It should be noted that clinically heterogeneous data were combined in the analyses, and assessments of statistical heterogeneity were not reported. Therefore, results should be interpreted with caution.<sup>18</sup>

**Legend for Tables 1–3**

Abbreviations for assessment of methodological quality: 1 – selection criteria, 2 – search strategy, 3 – validity assessment of primary studies, 4 – presentation of details of primary studies, 5 – data synthesis. RCT = randomised controlled trial, OR = odds ratio, RR = relative risk, OA = osteoarthritis, NSAID = non-steroidal anti-inflammatory drug.

**Table 1** Reviews with a general scope

Author, year	Results	Authors' conclusions & reviewer's notes	Quality assessment
Hill <sup>15</sup> 1990	40 RCTs included. (period: 1966-89)  Half of the trials concluded that homeopathy was effective, seven concluded that results were promising but that the studies were underpowered. Of the three largest trials, one concluded that homeopathy was effective whilst the other two found no statistically significant difference between homeopathy and control.	Author's conclusions: The therapeutic value of homeopathy cannot be considered to have been demonstrated.  Reviewer's notes: The earliest general review of homeopathy. Few details were provided relating to the search strategy used, and it is possible that this may have been more rigorous than is apparent from the paper.	1. Fair/Poor 2. Fair 3. Fair 4. Fair 5. Fair
Kleijnen <sup>6, 45</sup> 1991	107 trials met inclusion criteria; 68 were RCTs (period: 1943-90)  Of 105 trials with interpretable results, 81 had positive results in favour of homeopathy, and in 24 no positive effects of homeopathy were found. Positive results were more likely to be found in trials with lower methodological quality.	Authors' conclusions: Evidence of clinical trials is positive but not sufficient to draw definitive conclusions because of low methodological quality and the unknown role of publication bias.  Reviewer's notes: Most of the trials from an earlier review <sup>15</sup> are also included in this review.	1. Fair 2. Good 3. Good 4. Fair 5. Fair
Linde <sup>16</sup> 1997	119 RCTs met the inclusion criteria (period: 1966-95). Of these, 30 had inadequate information to allow statistical pooling, leaving 89 RCTs that met all inclusion criteria.  The overall OR (all trials) was 2.45 (95% CI: 2.05, 2.93) in favour of homeopathy.  Further analyses showed that trials with better methodological quality were less likely to show positive results in favour of homeopathy. <sup>46</sup>	Author's conclusions: Results of meta-analysis not compatible with the hypothesis that the clinical effects of homeopathy are completely due to placebo. Insufficient evidence was found that homeopathy is clearly efficacious for any single clinical condition.  Reviewer's notes: Clinically heterogeneous data were combined, and the results of the test of heterogeneity were not reported, even though this was carried out. Therefore the estimates shown should be interpreted with caution.	1. Fair 2. Good 3. Good 4. Fair 5. Poor
Cucherat <sup>17</sup> 2000	17 comparisons in 16 RCTs met the inclusion criteria (period: 1967-98)  11 of the 17 comparisons (65%) showed statistically significant results in favour of homeopathy. Overall pooled p-value (17 comparisons) was 0.000036.  Sensitivity analyses: Double-blind RCTs only (n=16) p=0.000068  Double-blind RCTs of highest methodological quality (n=5) p=0.082.  Analysis of the likelihood of publication bias indicated that it was unlikely.	Author's conclusions: There is some evidence that homeopathic treatments are more effective than placebo; however, the strength of this evidence is low because of the low methodological quality of the trials. Studies of high methodological quality were more likely to be negative than the lower quality studies.  Reviewer's notes: The pooled p-values are based on clinically heterogeneous data. This method should be used and interpreted with caution, since it may mask some fundamental differences between studies.	1. Fair 2. Fair 3. Fair 4. Fair 5. Poor

The second review assessed the effectiveness of individualised homeopathy compared with allopathic (conventional) medications, and included RCTs and non-randomised controlled trials.<sup>19</sup> Six studies were included,

each involving a different disease. Results suggested that homeopathic remedies may be superior to conventional drug therapy for rheumatoid arthritis and otitis media in children. However, conventional drug

therapy may be better than homeopathy for proctocolitis (inflammation of the rectum and colon) and tonsillitis in children. No between-group differences were found for trials of irritable bowel syndrome and malaria. This

**Table 2** Reviews of individualised (classical) homeopathy

Author, year	Results	Authors' conclusions & reviewer's notes	Quality assessment
Linde (1998) <sup>18</sup>	<p>32 randomised, quasi-randomised, or double-blind design trials met inclusion criteria (Period: 1966-1998).</p> <p>The methodological quality of trials was variable. 19 placebo-controlled trials presented the results in sufficient detail to be included in the meta-analysis.</p> <p>Overall rate ratio (n=19) 1.62 (95% CI 1.17, 2.23) in favour of homeopathy</p> <p>Sensitivity analysis: Methodologically best trials (n=6): rate ratio 1.12 (95% CI 0.87, 1.44)</p>	<p>Authors' conclusions: Results suggest that individualised homeopathy has an effect over placebo. However, the evidence is not convincing because of methodological shortcomings of, and inconsistencies between, the trials.</p> <p>Reviewer's notes: The authors have pooled clinically heterogeneous data both for the overall pooling, and for the sensitivity analysis according to methodological quality. Statistical assessments of heterogeneity are not reported. Therefore results should be viewed with caution. There is some overlap between this review and the previous, more general paper.<sup>16</sup> There is a slight discrepancy between the abstract/main text and tables for the overall rate ratio figures.</p>	<p>1. Fair 2. Good 3. Good 4. Fair 5. Poor</p>
Ernst 1999 <sup>19</sup>	<p>Two double-blind RCTs, one unblinded RCT, three non-randomised trials met the inclusion criteria (Period: 1978-1998)</p> <p>Two trials suggested that homeopathic remedies may be superior to conventional drug therapy. Two other trials suggested that conventional drug therapy may be superior to homeopathy. Results of the last two trials suggested no between group differences.</p>	<p>Authors' conclusions: All of the included trials had serious methodological flaws. Thus the value of individualised homeopathy relative to allopathic treatments is unknown.</p> <p>Reviewer's notes: This is the only identified review to address the comparison between homeopathy and conventional treatments. Assessments of tests of statistical significance for between-group comparisons within trials were not presented.</p>	<p>1. Fair 2. Fair 3. Fair / Poor 4. Fair / Poor 5. Fair</p>

review did not present sufficient details of individual studies, and therefore it was difficult to judge the validity of the review's findings.

Four further RCTs of classical homeopathy, all of reasonable methodological quality, were identified.<sup>20-23</sup> Although two of these trials were included in one of the above reviews,<sup>18</sup> they are discussed here as they were previously reported only in abstract form.<sup>20,21</sup>

In the earliest trial, patients with mild traumatic brain injury were recruited.<sup>20</sup> After four months, statistically significant effects in favour of homeopathy were observed for changes in some scores of physical, cognitive, and affective symptoms, and functional disability.

A small trial (n=23) assessed the effectiveness of homeopathy versus placebo in relieving symptoms associated with the premenstrual syndrome (PMS).<sup>21</sup> Results were seen in favour of homeopathy for improvement in menstrual symptoms at three months (p=0.057), mean symptom improvement rate (p=0.048), and

the proportion of women experiencing more than 30% improvement (38% versus 90%, p=0.037). There were no statistically significant differences between groups for consumption of medications such as tranquilisers and painkillers during the seven days prior to menstruation.

Another trial assessed the effects of classical homeopathy in treating children with a recent history of diarrhoea.<sup>22</sup> Results suggested that homeopathy was significantly more effective than placebo in reducing the frequency of diarrhoea and the duration of illness. The same research group conducted another trial on children with acute otitis media.<sup>23</sup> No statistically significant between-group differences were seen for treatment failure or middle ear effusion. This was a small pilot study (n=75) and may not have been large enough to detect the true treatment effects.

In addition to the above, a follow-up study relating to a trial of classical homeopathy included in a review on homeopathic prophylaxis of headaches and

migraine was identified,<sup>24</sup> and will be discussed later.<sup>25</sup>

Since all of the reviews discussed so far have aimed to assess whether homeopathy as a general system shows any effect over and above placebo, there are no specific implications for clinical practice that can be derived. The following sections provide details of reviews with a more specific focus in terms of patient or intervention characteristics.

#### Reviews with a more specific scope (Table 3)

Eight reviews were identified with a specific focus in terms of the homeopathic agent being evaluated or the type of participants recruited.<sup>24,26-32</sup> One review focused on the effectiveness of homeopathic arnica.<sup>27</sup> Six reviews were concerned with specific conditions: post-operative ileus,<sup>26</sup> delayed-onset muscle soreness (DOMS),<sup>30</sup> arthritis and other musculoskeletal disorders,<sup>31,32</sup> headaches and migraine,<sup>24</sup> and asthma.<sup>29</sup> The last review focused on the use of homeopathic *oscillococcinum* in influenza.<sup>28</sup>

**Table 3** Reviews with a specific scope

Author, year	Results	Authors' conclusions & reviewer's notes	Quality assessment
Ernst (1998) <sup>27</sup>  Arnica	<p>Eight controlled clinical trials met inclusion criteria (n=338) (period 1966-1997)</p> <p>Potencies of arnica differed across the trials. Two trials showed a statistically significant result in favour of arnica (one delayed-onset muscle soreness and one prevention of post-operative complications). The remaining six trials did not demonstrate statistically significant between group differences.</p> <p>Most of the trials had methodological problems, and the higher quality studies tended to have negative findings.</p>	<p>Author's conclusions: The claim that homeopathic arnica is efficacious beyond a placebo effect is not supported by rigorous clinical trials.</p> <p>Reviewer's notes: more information on individual study details would have been welcome, particularly relating to results in terms of actual numbers and p-values. Two of the included studies were of experimentally induced trauma; possible problems of generalisation to usual clinical practice. There is some overlap with two of the more general reviews.<sup>6,16</sup></p>	<p>1. Fair 2. Fair 3. Good 4. Fair 5. Fair</p>
Barnes (1997) <sup>26</sup>  Post-operative ileus	<p>Six controlled clinical trials met inclusion criteria (n=1,076) (period ?-1996)</p> <p>The pooled weighted mean difference (n=6) showed a reduction in the delay in restoration of intestinal peristalsis, as measured by time to first flatus, with homeopathic treatment compared with placebo (-7.4 hours, 95% CI -4.0, -10.8 hours, p&lt;0.05).</p> <p>Sensitivity analysis of higher quality trials (n=4): WMD -6.11 hours (95% CI -2.31, -9.91 hours, p&lt;0.05)</p> <p>The largest and most rigorous study showed no statistically significant differences between groups.</p>	<p>Author's conclusions: Homeopathic treatment administered immediately after abdominal surgery may reduce the time to first flatus when compared with placebo. Analyses do not provide evidence for the use of a particular homeopathic remedy or for a combination of remedies for postoperative ileus. Several drawbacks inherent in primary studies and in the methodology of meta-analysis preclude a firm conclusion.</p> <p>Reviewer's notes: overlap with some of the more general reviews.<sup>6,16,17</sup> More details on participants (age and surgery type) would have been useful. Test for heterogeneity not reported.</p>	<p>1. Fair 2. Fair 3. Fair 4. Fair 5. Fair</p>
Ernst (1998) <sup>30</sup>  Delayed onset muscle soreness (DOMS)	<p>Eight trials met inclusion criteria (three randomised) (n=311) (period 1966-1997)</p> <p>There was a high level of heterogeneity between included studies, with regard to the type of homeopathic remedy used, and the type of exercise used to induce DOMS.</p> <p>Three RCTs all reported non-significant differences between groups for all outcome measures. Results from the non-randomised studies were inconsistent. The three RCTs were rated as being of higher methodological quality than the other studies</p>	<p>Author's conclusions: The published evidence does not support the hypothesis that homeopathic remedies are more effective than placebo in alleviating the symptoms of DOMS.</p> <p>Reviewer's notes: There is some overlap with the more general reviews.<sup>6,16</sup> Since few details of the primary studies are presented, it is difficult to determine whether the authors' conclusions follow from the evidence.</p>	<p>1. Fair 2. Fair 3. Fair 4. Poor 5. Fair</p>
Jonas (2000) <sup>31</sup>  Rheumatic disease	<p>Six RCTs met inclusion criteria (n=392) (period 1966-1995)</p> <p>Three RCTs on RA were included (n=226), and one each on OA (n=36), fibromyalgia (n=30), and myalgia (n=60).</p> <p>The pooled OR (6 RCTs) was 2.19 (95% CI: 1.55, 3.11). Pooled OR for five high quality trials was 2.11 (95% CI: 1.32, 3.35).</p>	<p>Author's conclusions: All studies were statistically but not clinically homogenous with regard to patient selection, treatment strategies, and outcomes.</p> <p>Reviewer's notes: This review is a subset of a larger review.<sup>16</sup> Some of this summary and assessment has been based on information provided in the larger review. This paper provided few details of the individual trials, and the outcome measurements used were not mentioned. Since clinically heterogeneous data have been pooled, the results should be interpreted with great caution.</p>	<p>1. Fair 2. Good 3. Good 4. Fair 5. Poor</p>

**Table 3 (continued)** Reviews with a specific scope

Author, year	Results	Authors' conclusions & reviewer's notes	Quality assessment
Long (2001) <sup>32</sup> OA	Four RCTs met inclusion criteria (n=406) (period: up to 2000)  All RCTs were judged as being of high methodological quality, but none were free of flaws. All recruited people with knee OA and assessed improvement in pain (duration range 2-5 weeks). One RCT found a statistically significant difference in favour of a homeopathic gel compared with an NSAID gel. Another RCT, which also recruited people with hip OA, showed a statistically significant difference in favour of fenoprofen when compared with homeopathy or placebo, with no difference observed between homeopathy and placebo. The other two trials did not show any statistically significant differences between homeopathy and control.	Author's conclusions: The small number of RCTs conducted to date preclude firm conclusions as to the effectiveness of combination homeopathic remedies for OA. The standardised treatments used in the trials are unlikely to represent common homeopathic practice, where treatment tends to be individualised.  Reviewer's notes: The results of the review also preclude firm conclusions as findings were inconsistent across trials.	1. Fair 2. Good 3. Fair 4. Fair 5. Fair
Ernst (1999) <sup>24</sup> Headaches and migraine	Four double-blind RCTs met inclusion criteria (n=284) (period 1966-1998)  One RCT was of poor methodological quality, two were intermediate, and one good. One RCT found statistically significant improvement in all outcomes in favour of homeopathy. A second found no significant between-group differences in terms of frequency, intensity, or duration of attacks, nor analgesic consumption, although the neurologist's assessment of attack frequency suggested a statistically significant difference in favour of homeopathy. Two trials did not find any statistically significant differences between groups.	Author's conclusions: These data do not suggest that homeopathy is effective in the prophylaxis of migraine or headache beyond a placebo effect.  Reviewer's notes: Overlap with two of the more general reviews. <sup>16, 18</sup> The author's conclusions follow on from the results but should be viewed with caution because of the small number of studies available and limited methodological quality of three out of the four studies.	1. Fair 2. Fair 3. Fair 4. Fair 5. Fair
Linde (2001) <sup>29</sup> Asthma	Three placebo-controlled, double-blind RCTs met inclusion criteria (n=154) (period 1966?-1997).  RCTs used different homeopathic treatments which precluded quantitative pooling of results.  Treatments in the RCTs were unrepresentative of common homeopathic practice.  In one trial, severity of symptoms significantly lessened in the homeopathy group compared with placebo. In another, lung function measures and medication use showed improvement in the homeopathy group compared to placebo (this trial was of lowest methodological quality). The third trial found improvement in both groups, but no statistically significant difference between groups.	Author's conclusions: There is not enough evidence to reliably assess the possible role of homeopathy in asthma. As well as RCTs, there is a need for observational data to document the different methods of homeopathic prescribing and how patients respond.  Reviewer's notes: Cochrane review. Dates for search strategy unclear. There is some overlap with one of the general reviews. <sup>16</sup>	1. Good 2. Fair 3. Good 4. Fair 5. Fair
Vickers (2001) <sup>28</sup> Influenza	Seven RCTs met inclusion criteria; three prevention (n=2,265) and four treatment (n=1,194) (period 1966-1999).  Problems with methodological quality and quality of reporting were found with the trials.  Prevention: heterogeneity was found between trials (chi squared=6.5, p=0.01) for the occurrence of influenza. There was no evidence that homeopathic treatment can prevent influenza-like syndrome (RR 0.64, 95% CI 0.28, 1.43).  Treatment: oscillococcinum reduced length of influenza illness by 0.26 days (95% CI 0.47, 0.05) and increased the chance of a patient considering treatment effective (RR 1.08, 95% CI 1.17, 1.00).	Author's conclusions: Oscillococcinum probably reduces the duration of illness in patients presenting with influenza symptoms. Though promising, the data are not strong enough to make a general recommendation to use oscillococcinum for first-line treatment of influenza. Current evidence does not support a preventive effect of homeopathy in influenza.  Reviewer's notes: Cochrane review	1. Good 2. Fair 3. Good 4. Fair 5. Fair

## **Arnica**

One review focused on the effectiveness of homeopathic arnica.<sup>27</sup> Findings did not indicate that homeopathic arnica is any more effective than placebo. Some study details were lacking, particularly with regard to results and methodological quality, and therefore it is difficult to assess the reliability of the evidence.

Eight placebo-controlled trials (including four RCTs) were included. The conditions represented included: DOMS, post-operative care, trauma, stroke, and experimental bruising (bruising deliberately induced in healthy volunteers under laboratory conditions). Two trials showed a statistically significant result in favour of arnica when used to treat DOMS and to prevent post-operative complications. However, the remaining six trials did not demonstrate statistically significant between-group differences.<sup>27</sup>

A further five RCTs concerning the use of homeopathic arnica were identified.<sup>33-37</sup> Three were concerned with DOMS,<sup>33-35</sup> and two with surgical patients.<sup>36,37</sup>

In the trials of DOMS, homeopathic arnica was compared with placebo in reducing muscle soreness after long-distance running<sup>34,35</sup> and bench-stepping.<sup>33</sup>

For the studies of long-distance running, one trial was large (n=519) and of good methodological quality.<sup>34</sup> The other was smaller (n=71 at start of trial - 25 withdrawals) and did not conduct analysis on an intention-to-treat basis (i.e. all participants are analysed according to the intervention to which they were assigned, whether or not they completed the trial).<sup>35</sup> The smaller trial found a statistically significant difference in favour of arnica in terms of reduced muscle soreness immediately after the run, but not during the subsequent three-day follow-up. No adverse events were reported.<sup>35</sup> The larger trial did not find statistically significant between-group differences for severity and duration of soreness,

and reported that adverse events were equally distributed between treatment groups.<sup>34</sup>

A small and probably underpowered trial (n=23) of bench-stepping provided no information on study withdrawals, and reported no statistically significant between-group differences for severity and duration of soreness.<sup>33</sup>

The surgical trials focused on recovery after total abdominal hysterectomy<sup>36</sup> and saphenous stripping (stripping of varicose veins).<sup>37</sup>

Patients booked for total abdominal hysterectomy received either arnica or identical placebo pre-operatively and up to five days post-operatively.<sup>36</sup> This trial had a large proportion of withdrawals (20/73 patients), and analyses were not conducted on an intention-to-treat basis. No statistically significant differences were found between groups in terms of post-operative pain and other aspects of post-operative recovery. This trial may have been too small to detect the true treatment effect. Further evidence is required before drawing conclusions about the role of homeopathic arnica in patients undergoing total abdominal hysterectomy.

In the other trial, 130 patients undergoing saphenous stripping received pre- and post-operative doses of either arnica or identical placebo.<sup>37</sup> No statistically significant differences were found between groups for the incidence of post-operative haematomae (swelling/bruising).

### **Post-operative ileus (bowel muscle paralysis)**

Post-operative ileus refers to cessation of peristalsis (alternate waves of contraction and relaxation of the gut, necessary for digestion) due to paralysis of the bowel muscle following surgery or trauma to the bowel. Normal bowel action is usually restored within the first few post-operative days, but during this time the patient cannot eat or drink. Once bowel sounds are observed (or first

flatus occurs), the patient can begin a small intake of clear fluids, and can gradually build up to the usual dietary and fluid intake.

One review assessed the effectiveness of homeopathic treatment versus placebo in resolving post-operative ileus, and included six trials (four were RCTs) of patients undergoing abdominal or gynaecological surgery.<sup>26</sup> All trials used fixed homeopathic preparations (as opposed to individualised prescription). Findings indicated that homeopathic treatment administered immediately after abdominal surgery may reduce the time to first flatus when compared with placebo. However, the possibility of bias and inappropriate pooling of data means that these findings should be treated with caution. In addition, the largest and most well-conducted study, as rated by the authors of the review, showed no difference between homeopathy and placebo. No further RCTs were identified.

### **Delayed-onset muscle soreness (DOMS)**

The effectiveness of homeopathy in reducing DOMS was assessed in a review of eight trials, including three RCTs.<sup>30</sup> The results suggested that homeopathic remedies were no more effective than placebo in alleviating DOMS.

Participants were healthy volunteers who had undergone some form of exercise in order to induce DOMS. There was a high level of heterogeneity between included studies, in terms of the homeopathic remedies, and the type of exercise used to induce DOMS. The three RCTs all reported non-significant differences between treatment groups, whilst results from the non-randomised studies were inconsistent.<sup>30</sup>

A further three RCTs concerning the homeopathic management of DOMS were identified and have been discussed above in the section on homeopathic arnica.<sup>33-35</sup>



### **Arthritis and other musculoskeletal disorders**

Two reviews were identified.<sup>31,32</sup> One examined the effectiveness of homeopathy in people with rheumatoid arthritis, osteoarthritis, and other types of musculoskeletal disorders.<sup>31</sup> The review included six placebo-controlled RCTs. Three recruited patients with rheumatoid arthritis, and one trial each covered osteoarthritis, myalgia (muscle pain), and fibrositis (pain, muscular stiffness and inflammation affecting the soft tissues of the arms, legs, and trunk). Most of the trials were rated by the review's authors as being of high methodological quality. Although the overall pooled estimate indicated that homeopathy was superior to placebo, the data were clinically heterogeneous. In addition, the outcome measurements used in the pooling were not defined, but, when referring to a related publication, it seems likely that these were highly heterogeneous.<sup>16</sup> Therefore, the findings of this review should be treated with caution.

The second review focused more specifically on osteoarthritis and included four RCTs.<sup>32</sup> Fixed, rather than individualised, treatments were used in all trials. Results between trials were inconsistent and the authors noted methodological problems in all trials. This meant that firm conclusions could not be drawn.

One additional RCT was identified.<sup>38</sup> Patients with gonarthrosis (joint disease) received either Zeel compound tablets (a preparation containing several homeopathic remedies) or diclofenac (a non-steroidal anti-inflammatory drug). No statistically significant between-group differences were observed in pain, stiffness, functional ability, or global symptoms.

### **Headaches/migraine**

One systematic review focused on the effectiveness of homeopathy as a prophylactic agent for headaches and migraine.<sup>24</sup> Results suggested that homeopathy was

not effective. Four trials of classical homeopathy versus placebo were included. One trial of poor methodological quality found a statistically significant improvement in all outcomes in favour of homeopathy, whereas the trials of better quality all reported no statistically significant differences between groups.<sup>24</sup>

No new RCTs were identified. However, follow-up data were identified for one trial rated in the review as having good methodological quality.<sup>39</sup> At one year, between-group differences for headache frequency, duration and intensity remained statistically non-significant.<sup>25</sup>

### **Asthma**

A well-conducted review assessed the effectiveness of homeopathy in treating stable chronic asthma or asthma-like symptoms.<sup>29</sup> The three included RCTs were of variable methodological quality. Two showed results in favour of homeopathy (symptom improvement, lung function improvement, and less use of corticosteroids) and one found no statistically significant differences between groups.

Two additional RCTs were identified.<sup>40,41</sup> Both trials recruited patients with chronic asthma treated with corticosteroids for at least five years prior to study entry and assessed changes in respiratory function and corticosteroid use. Neither study detected statistically significant between-group differences for change in respiratory function. However, one study showed results in favour of homeopathy for a reduction in the daily dose of corticosteroids and number of infections.<sup>41</sup> Results from both studies should be interpreted with caution due to lack of details on patient and intervention characteristics, and methodological problems.

### **Influenza**

A good quality systematic review assessed the use of homeopathic *oscillococcinum* in preventing and treating influenza.<sup>28</sup> Three

prevention and four treatment RCTs were included. Findings indicated that *oscillococcinum* may reduce the duration of influenza by 0.26 days (95% CI 0.47, 0.05), but there was insufficient evidence to suggest a preventive effect. One trial reported a higher rate of adverse events in the homeopathy group (most frequent symptoms were aching muscles and fever). Problems with methodological quality and reporting were noted in all the trials. No further RCTs were identified concerning the use of homeopathic *oscillococcinum*, or any other homeopathic preparation, in preventing or treating influenza.

### **Induction of labour**

One systematic review assessing the role of homeopathy for the induction of labour was identified.<sup>42</sup> Only one RCT (n=40) was identified, which compared homeopathic *caulophyllum* with placebo. Although statistically significant differences were found between treatment groups, this trial may have been too small to detect the true treatment effect. This review has not been shown in Table 3 as only one trial was involved. No further RCTs were identified.

### **Excluded meta-analyses and systematic reviews**

Two meta-analyses were identified which did not employ full systematic review methods, and for this reason were not included in the above review of systematic reviews.<sup>43,44</sup>

Details of reviews that failed to meet the inclusion criteria (see appendix) are available on request.

### **Overlap between reviews**

Varying degrees of overlap have been noted in terms of the primary studies included in the different systematic reviews on homeopathy. In particular, both reviews on classical homeopathy<sup>18,19</sup> and most of the reviews with a more specific focus have some degree of overlap with the two larger general reviews.<sup>6,16</sup>

## E. Implications

- The evidence base for homeopathy needs to be interpreted with caution. Many of the areas that have been researched are not representative of the conditions that homeopathic practitioners usually treat. Additionally, all conclusions about effectiveness should be considered together with the methodological inadequacies of the primary studies and some of the systematic reviews.
- Common problems with the methodological quality of the primary studies included under-powered studies, failure to analyse by intention-to-treat, and failure to use allocation concealment (process used to prevent investigators having prior knowledge of group assignment in an RCT). The main problem with some of the systematic reviews was the pooling of clinically heterogeneous data.
- There are currently insufficient data either to recommend homeopathy as a treatment for any specific condition, or to warrant significant changes in the provision of homeopathy.
- Many of the systematic reviews recommended further primary research to clarify or confirm conclusions relating to the effectiveness of homeopathy. Any future research evaluating homeopathy should address the methodological inadequacies of the existing evidence base.

## Appendix: Methods

### Search strategy

For this bulletin, literature searches were initially undertaken to identify systematic reviews of homeopathy. The Cochrane Library (Issue 1, 2001) and the DARE database (contains records of systematic reviews identified

from Current Contents Clinical Medicine, MEDLINE, CINAHL, PsycINFO, ERIC, BIOSIS Previews and AMED) were searched. This was supplemented by searches of EMBASE (1980 onwards), AMED (1999 and 2000) and MANTIS (1880 onwards). In order to update evidence in areas covered by systematic reviews with a specific clinical focus, further literature searches were undertaken to identify recent primary studies. The databases searched were: Cochrane Controlled Trials Register (Cochrane Library 2001 issue 1); MEDLINE (1995 to December 2000); EMBASE (1995 to Feb 2001); AMED (1995 to Dec 2000); MANTIS (1995 to April 2000); CISCOM (1995 to April 2001) and HOM-INFORM (The British Homeopathic Library's database) (1911 onwards). In addition, several researchers were contacted and asked to provide their up-to-date lists of RCTs of homeopathy, the SIGLE database was searched and the bibliographies of retrieved reviews and trials were examined. No language restrictions were applied to the search strategy.

### Criteria for study selection

Only systematic reviews eligible for inclusion on the DARE database were included in the review of reviews. Reviews were assessed according to the following criteria: selection criteria for primary studies; literature search; validity assessment of primary studies; presentation of details of individual primary studies; and data summary (full details available from <http://www.york.ac.uk/inst/crd/>). In terms of updating the systematic reviews with a specific scope, RCTs published during or after 1995 were considered for inclusion, as it was likely that trials published before 1995 would be covered by existing systematic reviews.<sup>6,16</sup> For trials published in abstract form only, and papers where methodological details were unclear (i.e. random allocation not specified), authors were contacted and requested to provide further details. RCTs were excluded if they did not report patient-related

outcomes (e.g. if they reported results of laboratory tests only), if they were ultimately available only as an abstract, or if they had already been included in one of the systematic reviews.

### Methods

Titles and abstracts were examined for relevance by two independent reviewers. Full papers were examined by two reviewers. Data extraction and assessment of methodological quality were undertaken by one reviewer and checked by a second reviewer. All disagreements were resolved by discussion. Data were synthesised narratively.

Data extraction and methodological assessment of systematic reviews is shown in Tables 1-3. Details of data extraction and methodological assessment for trials is available from <http://www.york.ac.uk/inst/crd/>.

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# Effective Health Care

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