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Author(s): S O'Meara, P Wilson, C Bridle, K Wright, J Kleijnen

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The research evidence on the effectiveness of homoeopathy presented in a recent issue of Effective Health Care is reviewed.

Homoeopathy is a system of treating patients using very low dose preparations according to the principle: “like should be cured with like”. This paper summarises the research evidence presented in a recent issue of Effective Health Care on the effectiveness of homoeopathy.¹

Increasing numbers of patients are seeking information on complementary medicines from NHS health professionals.² 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 homoeopathic remedy in the past year.³ From this survey it was estimated that there could be over 470 000 recent users of homoeopathic remedies in England.³

Homoeopathy has been part of the NHS since its inception.⁴ There are currently five homoeopathic hospitals, of which the two largest in Glasgow and London have inpatient units. These hospitals provide a range of conventional and complementary treatments in addition to homoeopathy.

Most of the conditions treated by homoeopathic practitioners are chronic or recurrent. They also treat a large number of patients with ill defined illnesses that have not been given a conventional diagnosis.⁵ 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 such as weather or activity). The symptoms are then matched to remedies using either a homoeopathic repertory or “pattern recognition”.

Homoeopathic remedies are often known as potencies and are prepared by a process of serial dilution with succussion (vigorous shaking).⁶ 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 an active mechanism is the source of most of the scientific controversy surrounding homoeopathy. The symptom and information is sought on the impact of modalities (conditions providing relief or aggravation of symptoms such as weather or activity). The symptoms are then matched to remedies using either a homoeopathic repertory or “pattern recognition”.

Methods of prescribing vary among homoeopathic practitioners (see box 1).⁷ Following administration of a remedy, the homoeopathic 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.⁸

Box 1 Methods of homoeopathic prescribing⁹

- Classical: single remedy prescribed based on patient’s presentation and history
- Complex: more than one remedy used concurrently
- Fixed: some single agent used for a group of patients
- Isopathy: preparation based on causal agent
- Phytotherapy: administration of herbs or low potencies of herbs

NATURE OF THE EVIDENCE

Around 200 randomised controlled trials (RCTs) evaluating homoeopathy have been conducted, and there are also several systematic reviews of these trials. This paper is based mainly on an overview of existing systematic reviews of RCTs. Some reviews are general overviews, some focus on individualised (classical) homoeopathy, while the remainder have a more specific focus. Individual RCTs published subsequent to the included reviews of individualised homoeopathy and those with a specific scope are also included (more detail on the included RCTs is available at www.york.ac.uk/inst/crd/ehcb.htm). Details of the review methods are available elsewhere.¹

There are a number of problems and controversies surrounding the existing evidence base for homoeopathy. Firstly, there is much debate over whether homoeopathy shows any effect over and above placebo (a dummy medication or treatment given to participants in trials). Sceptics have argued that homoeopathy 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 is likely to remain. Given the presence 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 RCTs.¹

Others have argued that much of the research conducted on the effectiveness of homoeopathy is not representative of routine homoeopathic practice as homoeopathic treatment is highly individualised—that is, two patients with similar symptoms may receive different treatments.¹⁰ While it is possible to carry out RCTs evaluating the efficacy of homoeopathy, 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 such as delayed onset muscle soreness (DOMS) have been subject to study whereas skin conditions such as eczema, which are commonly treated by homoeopathy, have been overlooked.¹¹
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 its effectiveness than would normally be required for more conventional interventions. 1-7

**REVIEWS WITH A GENERAL SCOPE**

Four systematic reviews were identified (table 1). 1-2,7-12 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 rather than investigating effects within a specific group such as those with asthma. Because of the general nature of all four reviews, characteristics of the participants 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 non-randomised studies. 7 Each review covered several different types of homeopathy including classical, fixed, complex, and isopathy. All reviews identified methodological problems within 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 (table 1). 13,14

<table>
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<tr>
<th>Table 1 Systematic reviews of homeopathy with a general scope and of individualised (classical) homeopathy</th>
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<td>Hill 7-11</td>
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<td>Kleijnen 5-7</td>
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<td>Linde 7-13</td>
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<td>Cucherat 14-16</td>
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<td>Linde 15-17</td>
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<td>Ernst 18-20</td>
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*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.
REVIEWS OF INDIVIDUALISED (CLASSICAL) HOMEOOPATHY

Two reviews were identified (table 1).11–14 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.15–16

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 (n=32).15 The results from a pooled analysis of 19 trials indicated a statistically significant result in favour of homoeopathy. 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 (table 1). It should be noted that clinically heterogeneous data were combined in the analyses, and assessments of statistical heterogeneity were not reported. The results should therefore be interpreted with caution.

The second review assessed the effectiveness of individualised homeopathy compared with allopathic (conventional) medications and included RCTs and non-randomised controlled trials.16 Six studies were included, each involving a different disease. The 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 tonsillectis in children. No between group differences were found for trials of irritable bowel syndrome and malaria. This review did not present details of individual studies, including aspects of methodological quality, and therefore it was difficult to judge the validity of the findings of the review.

Four further RCTs of classical homeopathy, all of reasonable methodological quality, were identified,17–20 two of which were included in one of the above reviews16 but had been reported only in abstract form.17,18 In addition, a follow up study relating to a trial of classical homeopathy included in a review on homeopathic prophylaxis of headaches and migraine was identified19 and will be described later.20

In the earliest trial patients with mild traumatic brain injury were included.21 After 4 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) compared homeopathy with placebo in relieving symptoms associated with the premenstrual syndrome (PMS).22 The results were in favour of homeopathy for improvement in menstrual symptoms at 3 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).

Another trial assessed the effects of classical homeopathy in treating children with a recent history of diarrhoea.23 The 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 (n=75) on children with acute otitis media.24 No statistically significant between group differences were seen for treatment failure or middle ear effusion.

REVIEWS WITH A MORE SPECIFIC FOCUS

Since all of the reviews described so far have aimed to assess whether homeopathy as a general system shows any effect over and above placebo, no specific implications can be derived for clinical practice. The following sections provide details of nine reviews with a more specific focus in terms of the homoeopathic agent being evaluated or the type of participants recruited (table 2).21–26

Arnica

One review focused on the effectiveness of homeopathic arnica.24 The 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, postoperative 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 postoperative complications. However, the remaining six trials did not show statistically significant between group differences.25

A further five RCTs of the use of homeopathic arnica were identified.26–30 Three were concerned with DOMS26–28 and two with surgical patients.13,14 In the trials of DOMS, two of the three studies did not show statistically significant between group differences.13,14 The surgical trials focused on recovery after total abdominal hysterectomy31 and saphenous stripping (stripping of varicose veins).26 Neither trial found statistically significant differences between groups.

Postoperative ileus (bowel muscle paralysis)

Postoperative ileus refers to cessation of peristalsis due to paralysis of the bowel muscle following surgery or trauma to the bowel. One review assessed the effectiveness of homeopathic treatment versus placebo in resolving postoperative ileus and included six trials (four RCTs) of patients undergoing abdominal or gynaecological surgery.32 All trials used fixed homoeopathic preparations (as opposed to individualised prescription). The findings indicated that homeopathic treatment administered immediately after abdominal surgery may reduce the time to first flatus 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.27 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 homoeopathic remedies and the type of exercise used to induce DOMS. The three RCTs all reported non-significant differences between treatment groups, while results from the non-randomised studies were inconsistent.27

A further three RCTs of the homeopathic management of DOMS were identified and have been discussed in the section on homeopathic arnica.31–33

Arthrits and other musculoskeletal disorders

Two reviews were identified.28–30 One examined the effectiveness of homeopathic remedies in people with rheumatoid arthritis, osteoarthritis, and other types of musculoskeletal disorders.28 Most of the trials were rated by the authors of the review 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 more specific publication, it seems likely that these were highly heterogeneous.31 The findings of this review should therefore be treated with a great deal of caution.

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Table 2  Systematic reviews of homeopathy with a more specific focus

<table>
<thead>
<tr>
<th>Author</th>
<th>Results</th>
<th>Authors’ conclusions and reviewer’s notes</th>
<th>Quality assessment*</th>
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<tr>
<td>Ernst24 (Arnica)</td>
<td>8 controlled clinical trials met inclusion criteria (n=338) (1966–97). Potencies of arnica differed across the trials. Two trials showed a statistically significant result in favour of arnica (1 delayed onset muscle soreness and 1 prevention of postoperative complications). The remaining six trials did not demonstrate statistically significant between group differences. Most of the trials had methodological problems and the higher quality studies tended to have negative findings.</td>
<td>Authors’ conclusions: the claim that homeopathic arnica is efficacious beyond a placebo effect is not supported by rigorous clinical trials. 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.</td>
<td>1=fair 2=fair 3=good 4=fair 5=fair</td>
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<td>Barnes23 (postoperative ileus)</td>
<td>6 controlled clinical trials met inclusion criteria (n=1076) (1996). 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 to –10.8 hours, p&lt;0.05). Sensitivity analysis of higher quality trials (n=4): WMD = −6 11 hours (95% CI −2 31 to −9 91 hours, p&lt;0.05). The largest and most rigorous study showed no statistically significant differences between groups.</td>
<td>Authors’ conclusions: homeopathic treatment administered immediately after abdominal surgery may reduce the time to first flatus 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. Reviewer’s notes: overlap with some of the more general reviews. More details on participants (age and surgery type) would have been useful. Test for heterogeneity not reported.</td>
<td>1=fair 2=fair 3=good 4=fair 5=fair</td>
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<tr>
<td>Ernst27 (delayed onset muscle soreness; DOMS)</td>
<td>8 trials met inclusion criteria (3 randomised) (n=311) (1966–97). 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. 3 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.</td>
<td>Authors’ conclusions: the published evidence does not support the hypothesis that homeopathic remedies are more effective than placebo in alleviating the symptoms of DOMS. Reviewer’s notes: there is some overlap with the more general reviews. Since few details of the primary studies are presented, it is difficult to determine whether the authors’ conclusions follow from the evidence.</td>
<td>1=fair 2=fair 3=fair 4=fair 5=fair</td>
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<tr>
<td>Jonas28 (rheumatic disease)</td>
<td>Six RCTs met inclusion criteria (n=392) (1966–95). Three RCTs on RA were included (n=226) and one each on OA (n=36), fibromyalgia (n=30), and myalgia (n=60). The pooled OR (6 RCTs) was 2.19 (95% CI 1.55 to 3.11). Pooled OR for five high quality trials was 2.11 (95% CI 1.32 to 3.35).</td>
<td>Authors’ conclusions: all studies were statistically but not clinically homogenous with regard to patient selection, treatment strategies, and outcomes. Reviewer’s notes: this review is a subset of a larger review. 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.</td>
<td>1=fair 2=good 3=good 4=fair 5=fair</td>
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<td>Long29 (OA)</td>
<td>Four RCTs met inclusion criteria (n=406) (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 fenesprofen when compared with homeopathic 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.</td>
<td>Authors’ conclusions: all studies were statistically but not clinically homogenous with regard to patient selection, treatment strategies, and outcomes. Reviewer’s notes: this review is a subset of a larger review. 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.</td>
<td>1=fair 2=good 3=good 4=fair 5=fair</td>
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<td>Ernst30 (headaches and migraine)</td>
<td>4 double blind RCTs met inclusion criteria (n=284) (1966–98). 1 RCT was of poor methodological quality, 2 were intermediate, and 1 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 homeopathy and control.</td>
<td>Authors’ 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. The authors’ 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.</td>
<td>1=fair 2=fair 3=fair 4=fair 5=fair</td>
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<td>Linde31 (asthma)</td>
<td>3 placebo controlled, double blind RCTs met inclusion criteria (n=154) (1966–97). 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 homeopathic group compared with placebo. In another, lung function measures and medication use showed improvement in the homeopathy group compared with placebo (this trial was of lowest methodological quality). The third trial found improvement in both groups, but no statistically significant difference between groups.</td>
<td>Authors’ 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.</td>
<td>1=good 2=fair 3=good 4=fair 5=fair</td>
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The second review focused more specifically on osteoarthritis and included four RCTs. Fixed rather than individualised treatments were used in all trials. Results between trials were inconsistent and the authors noted methodological problems in all cases. This meant that firm conclusions could not be drawn. The methodological quality of the review was fair to good.

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

**Headaches/migraine**

A systematic review of fair methodological quality focused on the effectiveness of homoeopathy as a prophylactic agent for headaches and migraine. The results suggested that homoeopathy was not effective. Four trials of classical homoeopathy versus placebo were included. One trial of poor methodological quality found a statistically significant improvement in all outcomes in favour of homoeopathy, whereas the trials of better quality all reported no statistically significant differences between groups.

No new RCTs were identified. However, follow up data were identified for one trial rated in the review as having good methodological quality. At 1 year, between group differences for headache frequency, duration, and intensity were still not statistically significant.

**Asthma**

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

Two additional RCTs recruited patients with chronic asthma treated with corticosteroids for at least 5 years before 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 homoeopathy for a reduction in the daily dose of corticosteroids and number of infections. The results from both studies should be interpreted with caution due to lack of details on patient and intervention characteristics, and methodological problems such as failure to analyse by intention to treat.

### Table 2 continued

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<th>Author</th>
<th>Results</th>
<th>Authors’ conclusions and reviewer’s notes</th>
<th>Quality assessment*</th>
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<tr>
<td>Vickers25 [influenza]</td>
<td>7 RCTs met inclusion criteria; three prevention (n=2265) and four treatment (n=1194) (1966–99). Problems with methodological quality and quality of reporting were found with the trials. Prevention: heterogeneity was found between trials (χ²=4.5, p=0.01) for the occurrence of influenza. There was no evidence that homoeopathic treatment can prevent influenza-like syndrome (RR 0.64, 95% CI 0.28 to 1.43). Treatment: oscillococcinum reduced length of influenza illness by 0.26 days (95% CI 0.47 to 0.05) and increased the chance of a patient considering treatment effective (RR 1.08, 95% CI 1.17 to 1.00).</td>
<td>Authors’ 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 homoeopathy in influenza. Reviewer’s notes: Cochrane review</td>
<td>1=good 2=fair 3=good 4=fair 5=fair</td>
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*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.

**Influenza**

A good quality systematic review assessed the use of homoeopathic oscillococcinum in preventing and treating influenza. 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 to 0.05) but there was insufficient evidence to suggest a preventive effect. One trial reported a higher rate of adverse events in the homoeopathy group (most frequent symptoms were aching muscles and fever). Problems with methodological quality and reporting were noted in all the trials. No further RCTs concerning the use of homoeopathic oscillococcinum or any other homoeopathic preparation in the prevention or treatment of influenza were identified.

**Induction of labour**

One systematic review assessing the role of homoeopathy in the induction of labour was identified. Only one RCT (n=40) was identified which found no statistically significant differences between homoeopathic caudal hypnum and placebo. However, this trial may have been too small to detect the true treatment effect. This trial has not been shown in table 2 as only one trial was involved. No further RCTs were identified.

**IMPLICATIONS**

The evidence base for homoeopathy needs to be interpreted with caution. Many of the areas researched are not representative of the conditions that homoeopathic practitioners usually treat. In addition, 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 underpowered 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 to either recommend homoeopathy as a treatment for any specific condition or to warrant significant changes in the provision of homoeopathy. The authors of many of the systematic reviews recommended further primary research to clarify or confirm conclusions relating to the effectiveness of homoeopathy. Any future research evaluating homoeopathy should address the methodological inadequacies of the existing evidence base.

**Authors’ affiliations**

S O’Meara, P Wilson, C Bridle, K Wright, J Kleijnen, NHS Centre for Reviews and Dissemination, University of York, York YO10 5DD, UK
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Homoeopathy
S O'Meara, P Wilson, C Bridle, et al.

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