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Review

Efficacy of homeopathic therapy in cancer treatment

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ABSTRACT

Many cancer patients use homeopathic approaches to increase their body's ability to fight cancer, improve their physical and emotional well-being, and alleviate their pain resulting from the disease or conventional treatments. Homeopathy is highly controversial as there is no plausible mode of action for these highly diluted remedies. The aim of this systematic review is to summarize and critically evaluate the efficacy of homeopathic remedies used as a sole or additional therapy in cancer care. We have searched the literature using the databases: Amed (from 1985); CINHAL (from 1982); EMBASE (from 1974); Medline (from 1951); and CAMbase (from 1998). Randomised and non-randomised controlled clinical trials including patients with cancer or past experience of cancer receiving single or combined homeopathic interventions were included. The methodological quality of the trials was assessed by Jadad score. Six studies met our inclusion criteria (five were randomised clinical trials and one was a non-randomised study); but the methodological quality was variable including some high standard studies. Our analysis of published literature on homeopathy found insufficient evidence to support clinical efficacy of homeopathic therapy in cancer care.

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1. Introduction

Cancer is the second most frequent cause of death in developed countries according to a World Health Organization (WHO) report from 2003 [1]. Even though non-surgical orthodox treatments can control or even cure cancer, many adverse effects limit their use [2]. Cancer patients therefore often turn towards complementary therapies, including homeopathy [2]. A recent European survey has shown that homeopathy is amongst the most commonly used complementary therapies for cancer in 7 out of 14 European countries [3].

As a palliative or supportive treatment, homeopathy is used mainly to strengthen the body in its fight against cancer, to improve general well-being, and to alleviate pain resulting from disease or conventional treatments [2,3]. Homeopathy is controversial as no plausible mode of action has been identified for substances that are so highly diluted that they can not be measured [4]. Homeopathic remedies are believed to be most effective when they are selected to address a total set of symptoms and characteristics [5] and in classical or individualized homeopathy, choice of remedies are based on the match of a patient's particular symptoms with a remedy picture rather than conventional diagnosis

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[6]. Prescribing homeopathic substances is based on its proposed law of similars that suggests that “like cures like” [7]. Although Hahnemann initially diluted these substances in order to reduce toxicity, he came to believe that the actual process of diluting and shaking imparted additional potency to each solution [5]. His process of testing natural substances in healthy individuals became known as “drug proving” and results continue to be collected into an encyclopaedia of homeopathic drug effects known as the *Materia Medica* [8,9]. In “classical homeopathy” single remedies are given to patients, whereas in “complex homeopathy” several homeopathic medicines are combined into one formula, where concentration tends to be below 24X and usually below 12X [10] (the numbers indicate the dilution of the homeopathic remedy; that is, remedies are obtained by “decimal dilution”, one part substance to nine parts alcohol, and then labelled by the letter X or D).

In the 1950s, Hans H. Reckeweg developed a new form of homeopathy known as homotoxicology [11], which generally uses formulations that contains measurable amounts of homeopathically prepared active ingredients, designed to work with the body’s defence mechanisms and facilitate the body’s elimination of toxic substances (homotoxins). Homo-

toxicological remedies are prepared according to the rules of homeopathy and are used in combinations as complex remedies. Some experts fail to differentiate between homeopathic and homotoxicological medicines. However, there are important differences. Homeopathy follows the “like cures like” principle, while homotoxicology does not [12]. Homotoxicology often makes use of biological material that would be atypical in homeopathy, such as material from pigs. Some reports suggest the efficacy of homotoxicology for defined conditions, but many caveats exist [12].

Isopathy is another subset of homeopathy that was developed by Johann Lux in the 1830s. It differs from homeopathy in that remedies are prepared from those substances that cause the illness (e.g., allergens or bacteria) [13] and several trials have suggested its clinical efficacy [14].

The aim of this systematic review is to summarize and critically evaluate the clinical trial evidence for the effectiveness of any type of homeopathic remedy in cancer care.

2. Methods

Electronic literature searches were conducted using the following databases: Amed (from 1985); CINHAL (from 1982);

Table 1 – Search terms to identify the studies for this systematic review

Database	Intervention(s)	Cancer patients	Types of study design	Location of studies
PubMed	1. Homeopath*.ab, de. 2. Homeopath* remed*.ab, de. 3. Homeopath* drug*.ab, de. 4. Simil*.ab, de. 5. Homotoxicology.ab, de. 6. Single remedy.ab, de. 7. Combination remedies 8. OR/1–7	9. Cancer*.ti, ab, rw, sh. 10. Neoplasm*.ti, ab, rw, sh. 11. Terminal adj.illness.ti,ab 12. Carcin*.ti, ab, rw, sh. 13. Oncol*.ti, ab, rw, sh. 14. Sarcoma.ti, ab, rw, sh. 15. Tumour.ti, ab, rw, sh. 16. Leuk*.ti, ab, rw, sh. 17. Aden*.ti, ab, rw, sh. 18. Malignant.ti, ab, rw, sh. 19. Lymphoma.ti, ab, rw, sh. 20. OR/9–19	21. Clinical trial.pt. 22. Controlled clinical trial.pt. 23. Randomised controlled trial.pt. 24. Random*.tw. 25. Double blind.tw. 26. Placebo*.tw. 27. Control*.tw. 28. Symptom*.tw. 29. Quality of life.tw. 30. Palliative treatment.tw. 31. Palliative care.tw. 32. OR/21–31	33. 8 AND 20 AND 32
NHS dialog (AMED, CINHAL, EMBASE, MEDLINE)	1. Homeopath\$2.AB.DE. 2. Homeopath\$2 adj.remed\$3.AB.DE 3. Homeopath\$2 adj.drug\$1.AB.DE 4. Simil\$4.DE. 5. Homotoxicology.DE. 6. Single adj.remedy.DE. 7. Combination adj.remедies.DE. 8. OR/1–7	9. Cancer\$6.AB. 10. Neoplasm\$4.AB. 11. Terminal adj.illness.AB.DE 12. Carcin\$6.AB. 13. Oncol\$4.AB. 14. Sarcoma.AB. 15. Tumour\$3.AB. 16. Leuk\$5.AB. 17. Aden\$6.AB. 18. Malignant.AB. 19. Lymphoma.AB. 20. OR/9–19	21. Clinical trial.AB. 22. Control\$3.AB. 23. Study.AB. 24. Random\$7.AB. 25. Double adj.Blind.AB. 26. Placebo.AB. 27. Control\$4.AB.DE 28. Sympto\$2.AB. 29. Quality adj.life.AB. 30. Palliative adj.treatment.DE. 31. Palliative adj.care.DE. 32. OR/21–31	33. 8 AND 20 AND 32
CAMbase	N/A	N/A	N/A	Homeopathy for cancer; homeopathic complex remedies for cancer; trial of homeopathy for cancer

sh, subheading; ab, abstract; tw, textword; *, truncation; ti, title word; \$, truncation; de, drug effect; pt, publication type.

EMBASE (from 1974); Medline (from 1951); and CAMbase (from 1998). AMED, CINHALL, and EMBASE were searched through the NHS Dialog portal, whereas MEDLINE was searched through NHS Dialog as well as through PubMed. CAMbase was searched by simply typing a naturally spoken sentence, as the system requires.

Randomised and non-randomised controlled clinical trials (RCTs and CCTs, respectively) were included if they investigated patients with cancer or past experience of cancer who received single or combined homeopathic interventions as sole treatment or as adjuvant to conventional treatments, and their outcomes were compared to any other intervention or no intervention. Details of the literature searches are summarised in Table 1.

The main outcome measures we considered were efficacy of homeopathic remedies for treating symptoms in cancer patients and cancer survivors. Secondary outcome measures included tumour response and quality of life. All articles were read by two independent reviewers and data from the articles were validated and extracted according to pre-defined criteria. The methodological quality of all studies was independently assessed by the two reviewers using Jadad score [26]. Discrepancies between reviewers were resolved by a third independent reviewer. Statistically significant results of each trial were documented.

3. Results

The searches identified 55 potentially relevant studies, of which six met our inclusion criteria (Fig. 1). Three were double-blinded RCTs, one was a triple-blinded study, and another one was a CCT. Key data are summarised in Tables 2 and 3.

Kulkarni [15] conducted an RCT in cancer patients to assess the effectiveness of homeopathy on the severity of radiotherapy-related side effects. Patients with different types of cancer were randomized into three parallel arms: placebo; cobaltum 30; and causticum 30 (types of dilution were not specified). These homeopathic remedies were selected because they mimic various symptoms of radiation reaction.

All the patients were evaluated once a week according to an 18-point radiation reaction profile, and the average grading was calculated at the end of the study: 0–5 for minimal reaction; 6–10 for moderate but tolerable reaction; and >11 for

severe degree of reaction. Reaction index was lower in both intervention groups compared to placebo (5 for homeopathic groups vs. 8.5 for placebo group). No significant differences in tumour reduction were observed in the study.

A study by Oberbaum [16] tested the effects of Traumeels® on chemotherapy-induced stomatitis (mouth sores) in a non-randomized CCT. This treatment for 20 children and teenagers was compared with seven randomly chosen controls from the same age group with similar stages of cancer, who received no treatments for stomatitis.

Traumeels® is an homeopathic preparation containing: arnica 2X, calendula 2X, millefolium 3X, chamomilla 3X, symphytum 6X, belladonna 2X ana 0.1 ml, aconitum 2X 0.06 ml, bellis perennis 2X 0.05 ml, hypericum 2X 0.03 ml, echinacea angustifolia 2X, echinacea purpurea 2X ana 0.025 ml, hamamelis 1X 0.01, mercurius sol. 6X 0.05 g, and hepar sulfuris 6X 0.1 g. It was administered orally using liquid doses provided in vials. The primary outcome measure was the level of pain measured according to opiate requirements. Ulcer severity was assessed according to the WHO staging of disease: 0 for no ulcer; 1 for oral pain with no ulcers; 2 for oral pain with ulcers but the ability to eat is retained; 3 for liquid diet only; and 4 for inability to eat or to drink. In all treated patients, the treatment was followed by an immediate decrease in pain. There was a non-significant trend suggesting less patients in the intervention group required opiates compared to the control group ($P = 0.09$) and some patients in this group also reported a mood improvement. Symptom duration was numerically different between the two groups favouring the treated group (6 vs. 13 days). Oberbaum [17] subsequently carried out a larger RCT to assess the effectiveness of Traumeels® for chemotherapy-induced stomatitis in cancer patients after allogeneic or autologous stem-cell transplantation. Patients (ages 3–25 years) were randomized to two groups receiving, in addition to standard mouth-washes, Traumeels® oral rinse or a placebo rinse. Traumeels® preparation contained high dilutions (10^{-1} – 10^{-9}) of different extracts (see above). The main outcomes were occurrence of stomatitis and time to worsening of symptoms. Subjective symptom scores were recorded during the first 7 days of the trial. Significant differences occurred in the reduction of severity and/or duration of stomatitis in the intervention group ($P < 0.01$) compared to the placebo group. Mean “area under the curve”

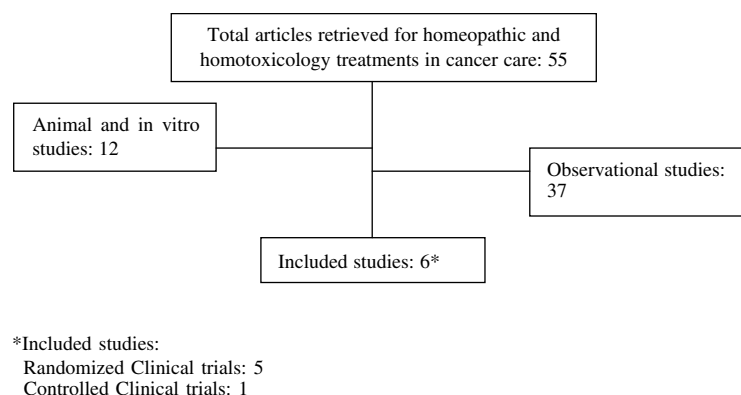


Fig. 1 – Flowchart of inclusion process.

Table 2 – List of included studies

First author (year)	Jadad score [26]	Study design ^a and follow up	Sample size	Patient condition	Intervention (n)	Control intervention (n)	Condition investigated	Outcome measures	Main results	P value	Adverse events (nP:nI)
Kulkarni 1988 [15]	1	RCT with three parallel arms Follow up: NS	82	Cancer patients undergoing radiation therapy	Cobaltum 30 (28) Causticum 30 (26)	Placebo (28)	Radiation reaction	Primary outcome: Degree of reaction (0–5; 6–10; >11)	Lower radiation reaction in intervention groups	NS	None reported
Oberbaum 1998 [16]	0	CCT Follow up: NS	27	Leukemia	Traumeel®	No treatment	Chemotherapy Induced-Stomatitis	Primary outcome: Opiate requirements for pain Secondary: Duration of symptoms; Quality of life	Lower opiate requirements in treated group Decrease in duration of symptoms in intervention group Mood improvement in intervention group	0.09 NS NS	None reported
Balzarini 2000 [18]	4	Randomised double-blind placebo-controlled clinical trial Follow up: 10 weeks	61	Breast cancer and undergoing radio-therapy	Belladonna 7cH and X-ray 15cH (29)	Placebo (32)	Radiodermatitis	Primary outcome: Skin heat; Hyperpigmentation; Erythema; Oedema Secondary: Total severity of symptoms	Skin temperature decrease at week 3, 4, 6, 8 and 10 Less frequent hyperpigmentation at week 5 and 10 Less intense colour of the skin at week 10 High frequency of oedema at week 5, 6 and 10 Decrease of total severity of symptoms during recovery	0.008, 0.016, 0.023, 0.011, 0.250 0.050, 0.060 0.280 0.025 0.025 0.890 0.05	Hot flushes, perspiration and migraine (0:1)

Report of main results in the intervention groups.

nP:nI number of patients in the placebo group:number of patients in the intervention group; NS, not specified.

a If not stated otherwise trials have two parallel arms.

Table 3 – List of included studies. Report of main results in the intervention group

First author (year)	Jadad score [26]	Study design* and follow up	Sample size	Patient condition	Intervention (n)	Control intervention (n)	Condition investigated	Outcome measure	Main results	P value	Adverse events (nP:nI)
Oberbaum 2001[17]	4	Random. double-blind placebo controlled clinical trial Follow up: 44 weeks	30	Patients affected by blood malignant cancer, who underwent BMT	TraumeelS® (15)	Placebo (15)	Chemotherapy-induced stomatitis	Primary outcome: Occurrence of stomatitis; Time to worsening of symptoms Secondary: Oral pain	Reduction of severity and duration of stomatitis in intervention group Decrease of time to worsening of symptoms in intervention group Reduction in oral pain and discomfort; dryness of mouth and tongue; difficulty to swallow; and dysphagia in the intervention group	<0.01 NS	Graft versus host disease (6:3) Sepsis (8:3) Gastrointestinal complication (5:0) Venous occlusive disease (0:4) Pneumonitis (0:4)
Jacobs 2005 [19]	5	Triple-blind RCT with three parallel arms Follow up: 1 year	83	Breast cancer survivors	Hyland's menopause (30)	Identical placebo (27)	Menopausal symptoms	Primary outcome: Hot flushes severity; Hot flushes frequency Secondary: Quality of life	Increase of hot flushes severity score in combination remedy group compared to placebo and single remedy Increase of hot flushes frequency in comb. group compared to placebo and single remedy Lower KMI score in single remedy group Improvement of quality of life in both intervention groups	0.01; <0.001 0.006; 0.002 Not signific. <0.05	Headaches in combination remedy group (NS)

	[26]		(n)	(nP:nI)
Thompson 2005 [20]	5	Random. double-blind placebo-controlled clinical trial Follow up: 16 weeks	53	NS
		Breast cancer survivor	71 different remedies. Tablets liquid or granules (28)	
			Indistinguishable placebo (25)	
			Estrogen withdrawal symptoms	
			Primary outcome: MYMOP Activity score; MYMOP Profile score	Neither positive nor significant results were observed
			Secondary: Hot flushes frequency and severity; Quality of life	

nP:nI number of patients in the placebo group:number of patients in the intervention group; NS, not specified.
* If not stated otherwise trials have 2 parallel arms.

score was 10.4 compared to 24.3. There was also a statistically significant difference between the two groups in the mean time to worsening of symptoms with an average of 6.9 days in the intervention group compared to 4.3 days in the placebo group ($P < 0.001$). However the median times were similar (4.7 compared to 4.0, respectively). In a subgroup of patients, aged less than 15 years, the lower severity score in the intervention group (11 compared to 25.9 of placebo) was also statistically significant ($P < 0.01$). Patients in the Traumeels® group showed a reduction in oral pain and discomfort; dryness of mouth and tongue; difficulty to swallow; and dysphagia (no P values of statistical significance for these symptoms were provided). Nausea was reported in two patients in each group at the beginning of the trial and they were not included in the analysis. Serious complications occurred in both treatment groups without significant differences between the two groups. Graft vs. host disease, sepsis, and gastrointestinal complications occurred mainly in the placebo group. On the other hand, more patients in the intervention group experienced venous occlusive disease and pneumonitis.

Balzarini [18] investigated the effectiveness of homeopathic treatment for skin reactions during radiotherapy for breast cancer treatment. Patients were randomised into two groups receiving homeopathic remedies or placebo. Both groups also received a topical medication containing fluocortolone. Homeopathic treatment consisted of three granules of Belladonna 7cH (twice a day) and X-ray 15cH (once a day). The main outcomes measured in this study were: erythema; skin heat; cutaneous and subcutaneous oedema; and hyperpigmentation. Patients treated with homeopathy appeared to experience transient benefits. Less hyperpigmentation (P value at 5th week = 0.050) and decrease of skin heat (P value at 8th week = 0.011) were observed although these differences were no longer significant by the end of the 10-week follow up. Total severity score was positive in favour of homeopathic treatment during radiotherapy and recovery, but statistical significance for the difference was noticed only during recovery ($P = 0.05$).

High frequency of oedema was observed in the intervention group, and statistical significance was reached at the 5th and 6th week ($P = 0.025$). Otherwise, adverse events were equally distributed between the two groups.

Jacobs and colleagues [19] evaluated the homeopathic effects on menopausal symptoms in breast cancer survivors. Patients who suffered from menopausal symptoms; had a history of carcinoma in situ or stage I-III breast cancer; had completed all surgical, chemo- or radiation therapy; and had an average of three hot flushes per day for a month before the trial were included in the trial. Following a “double-dummy” design, each patient was prescribed an individualized homeopathic medication and randomized into three treatment groups: a placebo combination and a verum single remedy; a verum combination medicine and a verum single remedy; and two placebo combinations. Single remedies consisted of 35 different homeopathic medications, mainly: sepia, calcarea carbonica, sulfur, lachesis, and kali carbonicum. The combination remedy was “Hyland’s menopause”, which contained: amyl nitrate, sanguinaria canadensis, and lachesis.

Main outcome measures were hot flush severity and number of hot flushes, measured according to the Kupperman Menopausal Index (KMI) score. Quality of life score was

measured using the Short Form 36 (SF-36), which evaluated mental and physical health status. Although the overall single remedy homeopathic group tended to experience lower severity score and fewer hot flushes, no significant differences were found among the three groups in the univariate model of all patients adjusted for baseline, time, and tamoxifen use over 1 year period. A statistically significant improvement in general health score was observed in both homeopathy groups compared to placebo (combination: $P < 0.03$; single: $P = 0.02$). A subgroup analysis was carried out for the patients taking (60%) or not taking (40%) tamoxifen. In the subgroup not receiving tamoxifen, there was a statistical significant increase in the hot flush severity score in the combination homeopathy group compared to placebo ($P = 0.01$, 95% CI, 6.2–47.1) and a highly significant difference when compared to single remedy ($P < 0.001$, 95% CI, –51.9–15.0). In the group not receiving tamoxifen, the total number of hot flushes increased statistically significantly in the combination homeopathic remedy group compared to the placebo and to the single remedy (combination $P = 0.006$; single remedy $P = 0.002$; 95% CI not provided). Statistically significant increase of headaches was also observed in the combination homeopathic group ($P = 0.03$).

Thompson and co-workers [20] conducted a double-blind RCT to evaluate the effect of homeopathy in 53 breast cancer survivors affected by oestrogen withdrawal symptoms. Selection criteria of patients included: more than three hot flushes per day; not having metastatic disease; no concurrent treatment for hot flushes; no severe concurrent illness; and not undergoing chemotherapy or about to receive any adjuvant chemotherapy. Patients were randomized to receive homeopathic remedies or placebo. Patients randomized to homeopathy were individually prescribed 71 different remedies, most commonly: sulfur, sepia, carnosin, natrum muriaticum, belladonna, and arnica. Primary outcome measures were activity score and overall profile score, measured according to the Measure Yourself Medical Outcome Profile (MYMOP). Secondary outcome measures included: hot flush frequency and hot flush severity (measured with Menopausal symptom questionnaire); and quality of life (measured according to EORTC QLQ-C30, plus Breast module). No significant differences between intervention and placebo group for both MYMOP activity and overall profile scores were noted ($P = 0.17$, 95% CI –1.0–0.2; $P = 0.13$, 95% CI –0.9–0.1, respectively). There were no differences between the groups for any other secondary outcomes measured at final follow up. Adverse events were experienced by approximately one quarter of women in both groups and no significant difference was observed between active remedy and placebo group.

4. Discussion

Five out of six trials included in this systematic review yielded positive results, which suggest the effectiveness of homeopathic remedies for cancer care. Cancer patients appear to have benefited from homeopathic interventions specifically for chemotherapy-induced stomatitis, radiodermatitis and general adverse events from radiotherapy. Breast cancer survivors, suffering from menopausal symptoms, experienced a general improvement on their quality of life.

Among the six studies we included, five were randomised [15,17–20] and only one was not randomised [16]. Statistical analysis for significance was performed in all the studies, but only four provided statistical features in their result sections. Oberbaum [16] discussed highly significant differences between the groups regarding duration of symptoms, but no statistical features for those differences were given. This was a pilot study conducted in order to test the rationale for performing a more rigorously designed trial [17]. The study by Kulkarni [15], investigating the effectiveness of some homeopathic remedies for radiation protection, concluded that the remedies reduced the degree of radiation reaction significantly, but results of their statistical analysis were not shown. This study also lacked complete information regarding patients and remedies, as well as essential methodological details, such as randomisation method.

Even trials with a Jadad score of 5 were not devoid of flaws. The small sample size in Jacobs [19] precluded definitive conclusions, and a major flaw in the study was the use of combination remedies in an ongoing daily regimen, without following over-the-counter instructions that suggested to discontinue use if adverse effects occurred. In the trial conducted by Thompson [20], the high placebo response can probably be related to a type II error in the study, since their sample size was only adequate for detecting large differences in response.

Of the 6 trials included in this systematic review, only two reported statistically significant positive results of their primary outcomes. One of these was a RCT conducted by Oberbaum [17] that showed encouraging results confirming the need to perform the trial on a larger scale. The other study was the RCT carried out by Balzarini [18], although this trial showed statistically significant differences in favour of the intervention group, these differences were not consistently observed at all time points. The rest of the studies indicated a positive trend towards homeopathic interventions for improvements in quality of life and symptom management, which seems to justify further investigations.

Homeopathic remedies are thought to trigger the body's own defence and self-regulatory response. However, their mode of action is unclear. As homeopathic remedies are often diluted beyond Avogadro's number, no pharmacological action can be expected. Sceptics therefore insist that homeopathy's clinical success is solely due to a placebo response [21]. Homeopaths counter this criticism by postulating that homeopathic remedies work through mechanisms other than pharmacological ones [22,23]. The evidence for homeopathic remedies in cancer care may not be fully conclusive but it does seem to warrant further study. Clinical trials of homeopathy should be rigorously designed to minimize bias. The existing trials have a number of limitations, e.g. sample size, which should be addressed in future research. Such research can be expensive and it is therefore a precondition that adequate research funds for homeopathy are made available. Considering that positive results have been obtained in some cases [24] using the controversial remedy "Carnosin" (a carcinogenic substance) and in some animals studies [25] investigating the possible anticancer effect of homeopathic interventions, further studies testing homeopathy for tumour response should also be undertaken.

The main limitation of our systematic review is the lack and sometimes poor quality of the primary data. The studies we evaluated were highly heterogeneous in virtually every respect. In some studies, individualized remedies were applied. Although individualization of therapy allows homeopathy to be practiced in its traditional fashion, this increases the complexity of comparing outcomes. In conclusion, the evidence emerging from this systematic review is encouraging but not convincing. Further research should attempt to answer the many open questions related to homeopathy.

Conflict of interest statement

None declared.

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