Homeopathy for chronic asthma (Review)

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[Intervention Review]

Homeopathy for chronic asthma

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ABSTRACT

Background

Homeopathy involves the use, in dilution, of substances which cause symptoms in their undiluted form. It is one of the most widespread forms of complementary medicines and is also used to treat asthma.

Objectives

The objective of this review was to assess the effects of homeopathy in people with chronic stable asthma.

Search methods

We searched the Cochrane Airways Group Specialised Register of trials. Searches were current as of August 2007.

Selection criteria

Randomised trials of homeopathy for the treatment of stable chronic asthma, with observation periods of at least one week were included.

Data collection and analysis

Data extraction was undertaken by two reviewers. Trial quality was assessed by the reviewers.

Main results

Six trials with a total of 556 people were included. These trials were all placebo-controlled and double-blind, but of variable quality. They used different homeopathic treatments which precluded quantitative pooling of results for the primary outcome. Standardised treatments in these trials are unlikely to represent common homeopathic practice, where treatment tends to be individualised. No trial reported a significant difference on validated symptom scales. There were conflicting results in terms of lung function between the studies. There has been only a limited attempt to measure a 'package of care' effect (i.e., the effect of the medication as well as the consultation, which is considered a vital part of individualised homeopathic practice). An update search in August 2005 did not identify any new studies.

Authors' conclusions

There is not enough evidence to reliably assess the possible role of homeopathy in asthma. As well as randomised trials, there is a need for observational data to document the different methods of homeopathic prescribing and how patients respond. This will help to establish to what extent people respond to a 'package of care' rather than the homeopathic intervention alone.

PLAIN LANGUAGE SUMMARY

Homeopathy for chronic asthma

Homeopathy is a complementary healing system based on "curing like with like". It involves greatly diluting substances (potentising) which ordinarily may or may not cause symptoms, in order to strengthen the body's own healing response to a problem. Homeopathic remedies (potencies) aim to minimise the risk of adverse effects. There are different types that may be used for asthma, such as classical homeopathy (tailored to an individual's symptoms) or isopathy (for example using a dilution of an agent that causes an allergy, such as pollen). The review of trials found that the type of homeopathy varied between the studies, that the study designs used in the trials were varied and that no strong evidence existed that usual forms of homeopathy for asthma are effective. There has been only a limited attempt to measure a 'package of care' effect (i.e., the effect of the medication as well as the consultation, which is considered a vital part of individualised homeopathic practice). Until stronger evidence exists for the use of homeopathy in the treatment of asthma, we are unable to make recommendations about homeopathic treatment.

BACKGROUND

Homeopathy is one of the most widespread and most controversial forms of complementary or alternative medicine. Although exact data on the frequency of use of homeopathy in asthma patients is not available, surveys among general practitioners, (for example Knipschild 1990), and chest physicians (Querfurt 1995) indicate that a significant proportion might seek additional advice from homeopaths.

The fundamental concept of homeopathy is that a substance which gives rise to specific symptoms, when given in pharmacological doses to healthy individuals, can be used to treat patients presenting with these same symptoms ('simile principle'). In general, the homeopathic 'remedies' are applied as 'potencies' which are prepared by several consecutive dilutions with vigorous shaking (succussion) in between each dilution step. The resulting potency is labelled on the basis of the of the ratio of diluent and diluted agent (D = decimal dilution = 1/10 diluted agent/diluent; C = centesimal dilution = 1/100 diluted agent/diluent) and the number of dilution steps (e.g. C6 indicates 6 dilution steps 1/100). It is believed that this preparation process both minimizes the risk of side effects and retains the therapeutic potency of the remedy.

Consequently, many of the preparations in homeopathy would contain either very few or even no molecules of the original agents since they are diluted beyond Avogadro's number. Therefore, according to current pharmacological theory it would appear impossible that homeopathic therapy could have any effect over placebo (Vandenbroucke 1997). The available hypotheses for a possible mechanism of action, however, do not claim that homeopathic remedies act through pharmacological but through biophysical pathways and all include the idea of some form of information transfer from the diluted substance to the diluting agent (e.g. Berezin 1990; Anagnostatos 1994; del Giudice 1994; Lo 1996).

Although homeopathy seems highly implausible from the current bio molecular point of view, two recent meta-analyses of placebo-controlled clinical trials have found an effect greater than placebo (Boissel 1996; Linde 1997). No systematic review has yet been done to evaluate the evidence regarding homeopathic treatment strategies in asthma.

Any review of homeopathic treatment strategies should take into account that homeopathy is not used uniformly. At least four basic types of homeopathy should be differentiated: classical homeopathy, clinical homeopathy, isopathy, and complex homeopathy.

For chronic diseases such as asthma the "classical" homeopathic approach is probably most widespread. In classical homeopathy the choice of the remedy is determined by the individual and subjective symptoms of each patient. As a consequence, different asthma patients might receive very different remedies, fitting their individual symptom patterns. Classical homeopathy involves detailed and intense history taking, which might give rise to significant non-specific effects. "Clinical" homeopathy by contrast, uses

the same remedy in patients presenting with a relatively homogeneous pathology or constellation of symptoms.

In some conditions (e.g. allergy) the diluted causative agent (e.g. potentised pollen) may be used. This is called "isopathy". The use of fixed combinations of several homeopathic remedies (so called "complex" remedies - "complex homeopathy") for one or a limited number of conditions is popular among general practitioners or "beginners" of homeopathy and is particularly widespread in Europe, especially Germany and France.

OBJECTIVES

The objective of this review was to evaluate the evidence for the efficacy of homeopathic interventions for the treatment of patients with stable chronic asthma.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised or possibly randomised trials with observation periods of at least 1 week.

Types of participants

Patients with stable chronic asthma or asthma-like symptoms.

Types of interventions

All interventions in which homeopathically prepared remedies were applied.

Types of outcome measures

Primary outcomes

Symptoms

Secondary outcomes

1. Lung function (peak expiratory flow rates = PEFR, forced expiratory volume in one second = FEV1, forced vital capacity = FVC)
2. Change in medication use
3. Quality of life
4. Well-being
5. Global assessment.

Search methods for identification of studies

Electronic searches

Trials were identified using the Cochrane Airways Group Specialised Register of trials, which is derived from systematic searches of bibliographic databases including the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE and CINAHL, and handsearching of respiratory journals and meeting abstracts. All records in the Specialised Register coded as 'asthma' were searched using the following terms:
homoeop* OR homeop*
This search is updated on an annual basis (see Table 1 for search history). The most recent search was carried out in August 2007.

Searching other resources

Additionally, the trial database of the initiative for a Cochrane Complementary Medicine Field and the reference lists of published reviews and papers were checked.

Data collection and analysis

Selection of studies

Titles, abstracts and, in any case where there was any doubt, a full copy of all papers identified by the literature search were screened by the reviewers (KL, RM and TJL).

Data extraction and management

Extraction of descriptive data and study results, and assessment of methodological quality was done using a standard extraction form. Extraction was done by the reviewers (KL, TJL and RM).

Assessment of risk of bias in included studies

Quality of reporting was assessed using the scale developed and validated by Jadad 1996. This involves 3 items giving a maximum score of 5 points: two points each for random allocation and blinding, one point for description of drop-outs and withdrawals. In addition, the adequacy of randomisation concealment was assessed (central randomisation = adequate, sealed envelope = partly adequate, alternation etc. = inadequate).
We tried to collect additional information from trialists which was successful for three studies (Reilly 1994; Matusiewicz 1999; Lewith 2002).
Matusiewicz 1999 supplied an English translation of his article published in German. This was verified by one of the reviewers (TL).

Data synthesis

For continuous variables reported as means and standard deviations (SDs), data were extracted and entered in order to calculate either a weighted mean difference (WMD) or standardised mean difference (SMD), depending upon whether studies measured outcome on the same or different metrics. Where the difference between the means for treatment and control groups was reported, a treatment effect estimate was calculated based upon the generic inverse variance (GIV). For dichotomous variables, data were extracted and entered in order to calculate a Relative Risk (RR).

Fixed Effect modelling was used in the calculation of the pooled treatment effect estimates unless significant heterogeneity was observed (P =<0.1), in which case a Random Effects model was also used to calculate the effect estimate.

Differences in the interventions used in the trials raised many questions as to how to analyse the findings of the studies. Two reviewers (RM and TL) discussed the alternatives for combining the data and established three key characteristics:

1. Individualised and formula. It was felt that the approach to treatment differed sufficiently between these two to merit separation. One important scientific question asked of homeopathy is whether an observed effect would be non-local in origin: this division gets closer to addressing this question as the package of care associated with individualised differs greatly from that provided with formula homeopathy, which by its very nature is generic.
2. Adults and children. This formed the basis for the subgroup analysis.
3. Homeopathy and isopathy. As there does seem to be a slightly different rationale with isopathy it was decided that a sensitivity analysis would be performed on the basis of standard homeopathic or isopathic treatment.

Some concern was expressed over pooling oral and subcutaneous administration as they were considered different types of treatment. With subcutaneous administration there is potentially a greater placebo effect and also an increased possibility of (a different type of) adverse event occurring. However the amount of data did not justify such a division: making this division will be considered in updates of the review, if possible.

Although within homoeopathic practice treatment can be categorised as either complex or clinical, we did not feel that such a distinction was based on scientific rationale as both seem to rely on formula prescription. The amount of data in the review simply did not enable us to explore the effects of separate remedies and potencies but if possible in updates this would be considered (and of course complex and clinical homeopathy would be treated in this manner).

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of ongoing studies.

This review includes six trials (Reilly 1994; Freitas 1995; Matusiewicz 1995; Matusiewicz 1999; Lewith 2002). For full details on each study please refer to 'Characteristics of Included Studies'. An update search in August 2007 identified two references, neither of which were relevant to the review.

Study design

All studies were described as randomised, double-blind, placebo-controlled, parallel group trials.

Participants

Diagnosis was defined in terms of respiratory function by Reilly 1994, symptoms by Freitas 1995 , clinical history and spirometry by Matusiewicz 1995, clinical history, spirometry and medication usage by Matusiewicz 1999, lung function, symptoms and medication usage by Lewith 2002, and GP diagnosis and medication prescription by White 2003.

Two studies recruited children only (Freitas 1995: 1-12 years; White 2003: 4-16 years). Four studies recruited adults only (Reilly 1994: >16 years; Matusiewicz 1995: 24-48 years; Matusiewicz 1999: 36-70 years; Lewith 2002: 18-55 years).

Participants suffered from mild to moderate asthma in White 2003; mixed severity (mild to severe) in Freitas 1995 and Lewith 2002. No attempt was made to grade severity in Reilly 1994; Matusiewicz 1995 or Matusiewicz 1999. See Characteristics of Included Studies for baseline lung functions and symptom scores.

Reilly 1994 detailed the prescribed allergen used as a basis of homeopathy: House dust mite: active/control, 11/12; Cat: 0/1; Dog: 0/1; Feathers: 1/1; Mixed moulds: 1/0. Lewith 2002 only recruited participants with a positive skin test reaction to house dust mite allergen. Both studies used allergen-based homeopathic treatments (isopathy).

No details were given in Freitas 1995 as to concomitant therapy. The majority of participants in all the remaining studies were described as taking medication to control their asthma. Corticosteroids were taken by 10 participants in each group from Reilly 1994, and were not taken by three and five participants in the active and placebo treated groups respectively. Lewith 2002 reported that 95 and 101 participants were taking inhaled steroids in the active and placebo groups respectively. Bronchodilator usage at baseline was measured in Lewith 2002. Matusiewicz 1999 reported that participants were treated with triamcinolone (2-8mg), short acting ß$_2$-agonists, methylxanthines, expectorants and antibiotics in case of infections. Matusiewicz 1995 recruited steroid-treated asthma patients. White 2003 reported that 72% and 77% participants in the treatment and control groups were prescribed steroids for their asthma.

Interventions

Active treatment was compared with placebo as adjunctive treatment to usual care in all the studies. Four studies employed homeopathic dilutions, either single remedies (Freitas 1995: Blatta officinalis C6); individualised remedies (classical homeopathy: White 2003); or a standardised combination (Matusiewicz 1995: Engystol N containing Vincetoxin D6/D10/D30 and sulfur D4/D10; and Matusiewicz 1999: Asthma H containing 14 different potencies of either D3, D4, D5 or D6). Two studies used isopathy, a form of homeopathy where the allergen is serially diluted to form the remedy (Reilly 1994 and Lewith 2002, both to 30C). For the purposes of this review, isopathy is considered as formula homeopathy. This is because although the prescription is based on an *individual's* positive response to a weal test, it is standardised (for example the same potency is always used), only based on this one presenting response, rather than from a holistic realisation of the person and (if appropriate) would be unaltered for the duration of the study. By contrast the prescription in trials of individualised homeopathy (as defined by this review) is based on a holistic interpretation and may well vary throughout the course of treatment. Duration of treatment in the studies ranged from 1 day (Lewith 2002 - plus 16 week follow-up) to 1 year (White 2003 - up to 6 consultations over 1 year).

Outcomes

Five studies assessed lung function: Reilly 1994 (FVC, FEV1, PEF); Matusiewicz 1995 (FVC, FEV1, PEF); Matusiewicz 1999 (FVC; FEV_1, FEV_1 / FVC); Lewith 2002 (FEV1; PEF); White 2003 (improvement in PEF). Four studies measured symptoms: Reilly 1994 (visual analogue and digital symptom scales); Freitas 1995 (intensity and duration of exacerbations); Lewith 2002 (visual analogue scale; mood and asthma-free days); White 2003 (days absent from school). Medication usage was reported by Matusiewicz 1995 (required daily dose of oral corticosteroid); Matusiewicz 1999 (required daily dose of corticosteroid); Lewith 2002 (bronchodilator usage); White 2003 (use of 'inhaler' - categorised as increase/no change or reduced). One study measured the frequency of exacerbations of asthma: Freitas 1995. No other studies attempted to measure the effects of homeopathy on exacerbations. One study measured quality of life: White 2003 (Childhood Asthma Questionnaire - CAQ). One study measured subjective perception of global change: White 2003 (participants and parent/guardian - short ordinal scale 0-5). Although Matusiewicz 1995; Matusiewicz 1999 measured the effects of homeopathy on biochemical markers, this was not deemed of clinical relevance and not used in the review.

Risk of bias in included studies

Overall study quality was deemed as mixed. Randomisation concealment and blinding was adequately described in Reilly 1994; Freitas 1995 and White 2003. All studies were double-blind. Loss to follow up was described by Reilly 1994; Freitas 1995; Lewith 2002; White 2003. Entry criteria, additional conventional treatment and outcome measurements were inadequately described by Freitas 1995; furthermore outcome measurements were unusual and methodologically weak (the frequency, duration and intensity of bronchospastic episodes). Matusiewicz 1995 was considered to have been inadequately reported; as a consequence, the assessment of the quality of this study, reported below, is problematic.

The high Jadad ratings for the studies represent adequate reporting of trial methodology. The low scores attributed to Matusiewicz 1995 and Matusiewicz 1999 indicate poor reporting of methods. Whilst the aim of the review was to establish the efficacy of homeopathy compared with placebo, all the studies administered homeopathic treatment in addition to usual care. In most instances this was in addition to steroids or $ß_2$ -agonists. The effects of these medications may have confounded potential benefits of homeopathy. It should be noted that the patients participating in White 2003seemed relatively healthy: the mean PEFR (% predicated) in the homeopathy and placebo groups were 100.4 and 96.9 respectively. The reviewers felt that the asthma severity across the other studies was largely mild to moderate. The generalisability of the evidence assembled in this review is undermined by these factors.

Effects of interventions

Due to the heterogeneity of trials (regarding patients, interventions, and outcome assessment) quantitative meta-analysis of the studies was limited. We have only been able to assess homeopathic treatments in addition to usual care.

Formula homeopathy versus placebo (in addition to usual care)

Symptoms (Reilly 1994*;* Lewith 2002*)*

Due to disparate reporting of outcomes no meta-analysis was possible.

Reilly 1994 found that the severity of symptoms quantified by a daily 100 mm visual analogue scale improved by 7.2 (standard deviation 10.6) mm in the treatment group while there was a deterioration by 7.8 (10.8) mm in the placebo group. The difference between the groups is highly significant (p = 0.003). No significant difference was observed for PEFR.

Lewith 2002 reported no significant difference between treatment and control neither after treatment nor at 15 weeks follow-up.

Lung function (Reilly 1994; Matusiewicz 1995; Matusiewicz 1999; Lewith 2002)

PEF (morning) (Matusiewicz 1995; Lewith 2002)

No data could be pooled due to disparate outcome assessment.

Matusiewicz 1995 reported a significant difference between homeopathy and control in favour of homeopathy (no p value reported). PEF increased from 200 ml to 330 in the treatment group while it decreased from 210 ml to 190 ml in the placebo group.

Lewith 2002 reported no significant difference after treatment and at 15 week follow-up.

FEV_1 (Reilly 1994; Matusiewicz 1995; Matusiewicz 1999; Lewith 2002)

Data could be pooled for Matusiewicz 1999 and Lewith 2002. No significant difference was observed (-0.06 litres; 95% CI -0.17 to 0.04).

Reilly 1994 assessed the difference between the medians with 95% confidence intervals (CI). No significant difference was detected (8.5% predicted; 95% CI -3 to 18).

Matusiewicz 1995 reported that there was a 'clear difference' between treatment and control: FEV_1 litres improved from 1.7 at baseline to 2.4 after treatment in the homeopathy group versus a change from 1.9 to 1.8 litres in the placebo group. No SDs were reported.

FVC (Reilly 1994; Matusiewicz 1995; Matusiewicz 1999)

No data could be pooled due to disparate outcome assessment.

Reilly 1994 reported a significant difference between the medians of the groups (0.36 litres; 95% CI 0.03 to 0.73. p value 0.03).

Matusiewicz 1995 reported a 'clear difference' between treatment and control (treatment group: +1.3 litres versus control group: 0 litres. No p values reported).

Matusiewicz 1999 reported no significant differences (2.7 litres (SD 0.91) in the treatment group versus 2.74 (SD 0.7) in the control group). Also reported was FEV_1 as a percentage of FVC (treatment group: 69.01 (SD 12) versus placebo group: 65.10 (SD 8.8)).

Medication usage (Matusiewicz 1995; Matusiewicz 1999; Lewith 2002)

Matusiewicz 1995 and Matusiewicz 1999 reported steroid usage. Matusiewicz 1995 showed a 'clear difference' between treatment and control in terms of oral steroid use (3mg per day in the treatment group versus 7mg in the control group with no SD or p value reported). Matusiewicz 1999 reported inhaled triamcinolone usage with treatment leading to a significant reduction (baseline 4.73mg versus 2.3mg in the treatment group ($p<0.01$) and 4.38mg versus 4.51mg in the control group ($p>0.01$)).

Lewith 2002 reported no significant difference in bronchodilator usage after treatment or at 15 week follow-up.

Exacerbations (Freitas 1995)

Freitas 1995 only measured intensity, frequency and duration of exacerbations in 86 children, some of whom did not exacerbate. We have not extracted and entered data as not all participants entered into the study contributed to the outcomes. No significant difference was reported between the groups in terms of intensity, frequency and duration of exacerbations.

Individualised homeopathy versus placebo (in addition to usual care)

One study measures individualised homeopathy (White 2003).

Symptoms

White 2003 measured days-off school in the previous month; categorised as either increased, no change or reduced. Out of 43 participants in the homeopathy group, the number who increased, had no change and reduced days absent from school were 2, 32 and 9 and 4, 32 and 10 in the placebo group. No statistically significant difference was reported.

Lung function

White 2003 reported no difference in terms of improvement in PEF, expressed as <15% change or ≥15% change, was reported. In the homeopathy group 31 and 12 participants had <15% and ≥15% change respectively. In the placebo group the numbers of participants with <15% and ≥15% change were 29 and 17 respectively.

Quality of life

White 2003 reported a 95% CI of -3.98 to 6.62 for overall scores on the CAQ for the mean difference between treatment and control (not significant).

Medication usage

White 2003 reported no significant difference in terms of use of inhaler. Numbers with increased, no change and reduced inhaler usage were 1, 24 and 18 in the homeopathy group and 1, 27 and 18 in the placebo group respectively (not significant).

Global assessment of change

White 2003 did not report a significant difference between groups (no data was presented).

Adverse events

(Please see Table 2) White 2003 did not report significant differences between the two groups.

DISCUSSION

This review identified six randomised trials comparing homeopathic remedies with placebo in the treatment of asthma in adults and children. There are several key limitations to the current evidence which should be discussed.

Firstly, the focus of the trials was limited to assessing homeopathy as an *additional* treatment to allopathic medications. This in itself is a crucial characteristic of the evidence available and raises questions as to whether homeopathy can ever be accepted by trialists as a treatment worthy of assessment without recourse to steroids and bronchodilators. In Freitas 1995 all allopathic treatments were maintained on ethical grounds. Whilst two studies did determine an effect in terms of steroid usage (Matusiewicz 1995; Matusiewicz 1999), the findings of the studies were inadequately reported and so could not be assessed in terms of clinical relevance. This does not mean that there is no potential for homeopathy as a *complementary* treatment, but such an additional effect as an adjunct to allopathic medicine is hard to assess other than in the context of 'global assessment'. One study did not detect a difference in 'global assessment' of well-being (White 2003).

The package of care on offer in the studies is also worthy of discussion. In the absence of a scientific rationale for homeopathy, some would argue that any observed effect cannot be seen outside the context of the entire treatment package, which consists of one-on-one, in depth, 'holistic' consultation, administration of homeopathic treatment and follow-up. For example in White 2003 there was extensive telephone contact in addition to six consultations and as many changes of remedy as were deemed appropriate. It is difficult to see how this can be assessed alongside some of the less extensive 'one off' treatments offered in Reilly 1994 and Lewith 2002. Careful, systematic observational studies documenting what homeopaths do, and how asthma patients respond to homeopathic therapy are needed before practice and treatment can be evaluated, or meaningful and clinically relevant randomised trials of representative treatment strategies can be justified. If the view is maintained that all homeopathy is placebo and this continues to dominate discussions of the topic, it is questionable whether observational studies will ever be performed. However, the probability that substantial numbers of asthma sufferers will continue to seek homeopathic treatment remains high. In 1998 there were estimated to be over 470,000 regular users of homeopathy in the UK alone, with 8.6% of the population purchasing homeopathic medicines in that year, sales of homeopathic medicines are growing at around 12% annually (Thomas 2001). This considered, it is therefore imperative that more regulation is introduced into the profession to ensure quality of care is of the highest possible standard and potential users should always seek care from registered practitioners.

The quality of the studies varied considerably. Many reviews of homeopathy have reported that trial findings are rarely applicable (Ernst 1999; Cucherat 2000). In this review, the applicability of the findings are hampered by varying quality between the studies. The recent studies by Lewith 2002 and White 2003 were both well reported and adequately powered trials. The methods of randomisation, concealment and blinding were appropriate and hopefully indicate a trend in improved reporting of study methods for homeopathy trials. Conversely, Matusiewicz 1995 and Matusiewicz 1999 were inadequately reported and subsequent outcome reporting was also incomplete. White 2003 reported a trial which assessed homeopathic treatment administered by certified homeopaths. There were also attempts to standardise a complex treatment in this study through regular case conferences amongst the homeopaths involved. This attempt to create a uniform approach to treatment is recommended for future research.

AUTHORS' CONCLUSIONS

Implications for practice

The currently available evidence is insufficient to assess reliably the possible role of homeopathy in the treatment of asthma. Whilst the scientific rationale behind homeopathy remains unproven, non-specific benefits associated with a 'holistic' package of care may exist. The effect of homeopathy on asthma has yet to be proven in a randomised study. However, the varied quality of the studies precludes us from extrapolating any effects observed to the general population level.

Implications for research

As it is likely that a proportion of asthma sufferers will continue to seek advice and additional treatment from homeopaths further research is desirable.

Although replications of the existing trials might be useful to further investigate the remedies tested, studies of more widely applicable and widespread treatment strategies would be more relevant, such as those used in White 2003.

Currently the major obstacle to clinically relevant research is a paucity of information, systematically acquired, on a) what homeopaths actually do, and the range of remedies used in their routine treatment of patients with asthma and b) how patients respond to homeopathic treatment.

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Vandenbroucke JP. Homoeopathy trials: going nowhere. *Lancet* 1997;**350**:824.

* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Freitas 1995

Methods	Design: parallel group Allocation concealment: by numbered pharmacy Blinding: patients and evaluators Drop-outs/withdrawals: 7/10 in Blatta and placebo groups respectively Jadad score: 1-2-1 Study schedule: six months.
Participants	N = 69 (34 male, 35 female). Age range: 1-12 years. Diagnosis: Asthma (?). Inclusion criteria: "at least 3 bronchospastic episodes with intervals of 3 months or less, or continuous wheeze for at least 3 months". Setting: Homeopathic (?) outpatient clinic in Sao Paulo, Brasil
Interventions	Blatta officinalis C6 or indistinguishable placebo, 2 globules 3 times per day for 6 months
Outcomes	Frequency, duration and intensity of bronchospastic episodes and a score combining these 3 measures. Lung function or medication used does not seem to have been documented
Notes	Characterization of the patient sample insufficient: is it really asthma?

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	Pharmacy generated randomisation schedule

Lewith 2002

Methods	Design: parallel group Allocation concealment: central, independent pharmacy. Blinding: patients and evaluators Drop-outs/withdrawals: 21 in treatment 19 in control. Jadad score: 2-2-1 Study schedule: 4 weeks run-in, 1 day treatment, 16 weeks follow-up
Participants	N = 242 (153 female, 89 male). Mean age: 38.2 treatment group, 37.9 placebo. Diagnosis: Mild to severe asthma. 15% improvement in lung function after bronchodilator, plus at least two of the following: asthma symptom diary score>1; variation in PEF>15% on at least 7/14 baseline days; inhaled salbutamol on at least 7/14 baseline days. Inclusion criteria: positive skin prick test to house dust mite with response greater than aeroallergens tested. Exclusion criteria: no impairment in QoL during 14 day run-in period; non-completion of study diary>4/14 days; recent participation in another drug trial (<30 days)); any previous homeopathic prescribing; pregnancy/ lactating; RTI <3 weeks; suspicion of poor compliance; change in concurrent medication<2 weeks. Setting: primary care.

Lewith 2002 (*Continued*)

	Baseline characteristics: No of patients in treatment/placebo groups with mild asthma were 44/40; moderate 61/58; and severe 17/23. % predicted FEV1 in treatment group was 80.9 (+-19.9); placebo group 79.9(+-18.4). Asthma VAS in treatment group was 3.02(+-2.19); placebo group 2.85(+-2.07). Inhaled bronchodilator use per week in treatment was 3.2(0-10); placebo group was 3.4(0-14)
Interventions	Isopathy (30C house dust mite) or indistinguishable placebo (same without house dust mite). 3 doses orally in 24 hours
Outcomes	Lung function, medication use, subjective symptoms.
Notes	No difference in effect found. Significant interactions reported between treatment group and week of assessment. No adverse events reported

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Yes	Pharmacy generated randomisation schedule

Matusiewicz 1995

Methods	Design: parallel group Allocation concealment: not stated. Blinding: patients and evaluators Drop-outs/withdrawals: not reported. Jadad score: 0-1-0 Study duration: 6 months.
Participants	N = 40 (unclear if this number refers to number of patients randomized, analysed or completing the study). Diagnosis: corticosteroid-dependent bronchial asthma. Inclusion criteria: Diagnosis confirmed by history and spirometry. Treatment with Triamcinolone, 4 to 8 mg daily for at least 5 years. Setting: Polish hospital
Interventions	1 ampoule Engystol N (a complex remedy consisting of the homeopathic remedies Vincetoxin D6/D10/D30, Sulfur D4/D10) or placebo injected subcutaneously at intervals of 5 to 7 days. In addition patients received methylxanthines for mucolysis and tetracycline in case of exacerbations
Outcomes	Lung function, medication use, granulocyte function.
Notes	Insufficient reporting.

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	Information not available

Matusiewicz 1999

Methods	Design: parallel group Allocation concealment: not stated. Blinding: patients and evaluators. Drop-outs/withdrawals: not reported. Jadad score: 1-1-0 Study duration: 9 months.
Participants	N = 84 (unclear if this number refers to number of patients randomized, analysed or completing the study) . Diagnosis: chronic bronchial asthma based on history, spirometry physical examination and medication use. Severity unclear. Triamcinolone use for last 5 years. Exclusion criteria not stated. Setting: outpatient department in Polish hospital
Interventions	1 ampoule of Asthma H (a complex remedy consisting of 14 homeopathic potencies of D3, D4, D5 and D6) or placebo injected subcutaneously at intervals of 5 to 7 days
Outcomes	Lung function, medication use, immune system functioning.
Notes	Insufficient reporting. Sgnificant effect reported in terms of medication use, immune functioning, global rating and number of infections

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	Information not available

Reilly 1994

Methods	Design: parallel group Allocation concealment: independent pharmacy . Blinding: patients and evaluators. Drop-outs/withdrawals: 2 in each group. Jadad score: 1-2-1 Study duration: 4 weeks placebo run in and pre-randomization qualification period - 4 weeks treatment phase - 4 weeks optional follow-up
Participants	N = 28 (randomized), N = 24 (analysed). Diagnosis: Allergic asthma, mostly sensitivity to house-dust mite. Inclusion criteria: >15% improvement of FEV1 with bronchodilators, >1 year history, atopy (reactive to inhaled allergens and positive skin tests), age >16 years. Setting: Asthma specialist outpatient clinic in Scotland
Interventions	Homeopathic preparation of the individual allergens in potency C30 (30 dilution steps 1:100) prepared in a water-alcohol solution and impregnated on lactose/sucrose globules (placebo impregnated with diluent only). Treatment consisted of 3 doses of globules within 24 hours (once). Random samples of the preparation were independently analysed for contamination
Outcomes	Predefined main outcome measure was the change of subjective symptoms measured on a 100mm visual analogue scale. Additional outcome were lung function and digital symptom scale

Reilly 1994 (*Continued*)

Notes	Small but rigorous study.	
Risk of bias		
Item	**Authors' judgement**	**Description**
Allocation concealment?	Yes	Independent pharmacy

White 2003

Methods	Design: parallel group. Allocation concealment: independent pharmacy . Blinding: patients, practitioners and evaluators. Drop-outs/withdrawals: 7 in each group. Jadad score: 2-2-1 Study duration: 52 weeks of treatment, followed-up at end of this period	
Participants	N = 93. Aged 5-15 years. 46% female. Baseline characteristics in treatment/ control: exercise induced 6/5; hay fever 26/21; smoker 18/16; eczema 15/17; prescribed inhaled steroids 33/36; mean PEF (% predicted) 100.4/96.9; mean duration of asthma in years 4.2/4.8; median number of prescriptions in previous 3 months 2/2; median asthma events in previous year 0/1. Diagnosis: GPs diagnosis and prescription for either beta-agonist or corticosteroid inhaler in previous 3 months. Exclusion criteria: oral corticosteroids in last 12 months, previous consultation with homeopath, suspicion of poor compliance. Setting: primary care (3 non-medically qualified homeopaths' practices)	
Interventions	Any number of individualised homeopathy or placebo prescriptions. Up to 6 consultations (plus telephone consultations if required) throughout the year. Use of adjunctive therapies allowed by practitioner	
Outcomes	Lung function at 4, 8 and 52 weeks (only reported at 52 weeks); quality of life	
Notes	Starting lung function not much different to healthy individuals (PEF 100.4 and 96.9 % predicted) so unclear as to whether much change could occur and doubt over whether the quality of life measure was sensitive enough to change. 13 adverse events reported in the homeopathy group and 10 in the placebo (no serious)	
Risk of bias		
Item	**Authors' judgement**	**Description**
Allocation concealment?	Yes	Independent pharmacy

FEV1: Forced expiratory volume in 1 second; PEF: Peak expiratory flow; QoL: Quality of Life; VAS: Visual analogue score (symptoms) Jadad scores reflect the points awarded for the three component domains in the order of: randomisation (0,1 or 2), blinding (0, 1 or 2) and withdrawals (0 or 1).

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Boucinhas 1990	Design: non-randomized controlled trial Patients: 135 children with a history of a least 3 asthmatic crises. Intervention: 109 children received Lung histamine C5, 26 children no treatment Results: Decrease of the number of asthmatic crises in the homeopathic group Subjective assessment of trial quality: low Reason for exclusion: allocation to treatment groups not randomized
Matusiewicz 1996	The report of this study - which is described as double-blind - does not define the method of allocation to the treatment group. As the number of patients in treatment and control groups (71 vs 32) raised additional doubts, the study was excluded. If contact with the authors should reveal that treatment allocation was randomized, the trial will be included in the next update of this review Patients: 103 patients with corticosteroid-dependent asthma Intervention: Weekly s.c. injection of Traumeel S (a combination of 14 homoeopathic remedies) or placebo for 20 weeks. Results: No difference between groups for lung function but lower use of corticosteroids in the treatment group. Subjective assessment of trial quality: probably low (difficult assessment due to insufficient reporting)

Characteristics of ongoing studies *[ordered by study ID]*

Koster 1994

Trial name or title	
Methods	
Participants	
Interventions	
Outcomes	
Starting date	
Contact information	
Notes	

Thompson 2005

Trial name or title	Can homeopathy in addition to standard care, increase symptom free days and improve asthma control and quality of life in children with poorly controlled asthma?
Methods	

Thompson 2005 (*Continued*)

Participants	
Interventions	
Outcomes	
Starting date	
Contact information	Avon Primary Care Research Collaborative Bristol Homeopathic Hospital, Cotham Hill, Bristol, BS6 6JU, United Kingdom
Notes	

Warner 1994

Trial name or title	
Methods	
Participants	
Interventions	
Outcomes	
Starting date	
Contact information	
Notes	

DATA AND ANALYSES

Comparison 1. Individualised homeopathy versus placebo

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Reduction in the number of days absent from school	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
2 Improvement by >/=15% PEF	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
3 Use of inhalers (reduced)	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected

Comparison 2. Formula homeopathy versus placebo

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Symptoms	1		Std. Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.1 Adults	1		Std. Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.2 Children	0		Std. Mean Difference (IV, Fixed, 95% CI)	Not estimable
2 Symptoms (change scores)	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
2.1 Adults	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
2.2 Children	0		Mean Difference (IV, Fixed, 95% CI)	Not estimable
3 PEF (morning)	2		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
3.1 Adults	2		Mean Difference (IV, Fixed, 95% CI)	Not estimable
3.2 Children	0		Mean Difference (IV, Fixed, 95% CI)	Not estimable
4 FEV1	3	366	Mean Difference (IV, Fixed, 95% CI)	-0.06 [-0.17, 0.04]
4.1 Adults	3	366	Mean Difference (IV, Fixed, 95% CI)	-0.06 [-0.17, 0.04]
4.2 Children	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
5 FVC	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
5.1 Adults	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
5.2 Children	0		Mean Difference (IV, Fixed, 95% CI)	Not estimable
6 Steroid usage	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
6.1 Adults	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
6.2 Children	0		Mean Difference (IV, Fixed, 95% CI)	Not estimable
7 Bronchodilator usage	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
7.1 Adults	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
7.2 Children	0		Mean Difference (IV, Fixed, 95% CI)	Not estimable

Analysis 1.1. Comparison 1 Individualised homeopathy versus placebo, Outcome 1 Reduction in the number of days absent from school.

Review: Homeopathy for chronic asthma

Comparison: 1 Individualised homeopathy versus placebo

Outcome: 1 Reduction in the number of days absent from school

Study or subgroup	Treatment n/N	Control n/N	Odds Ratio M-H,Fixed,95% CI	Odds Ratio M-H,Fixed,95% CI
White 2003	2/43	4/46		0.51 [0.09, 2.95]

Analysis 1.2. Comparison 1 Individualised homeopathy versus placebo, Outcome 2 Improvement by >/=15% PEF.

Review: Homeopathy for chronic asthma

Comparison: 1 Individualised homeopathy versus placebo

Outcome: 2 Improvement by >/=15% PEF

Study or subgroup	Treatment n/N	Control n/N	Odds Ratio M-H,Fixed,95% CI	Odds Ratio M-H,Fixed,95% CI
White 2003	12/43	17/46		0.66 [0.27, 1.62]

Analysis 1.3. Comparison 1 Individualised homeopathy versus placebo, Outcome 3 Use of inhalers (reduced).

Review: Homeopathy for chronic asthma

Comparison: 1 Individualised homeopathy versus placebo

Outcome: 3 Use of inhalers (reduced)

Study or subgroup	Treatment n/N	Control n/N	Odds Ratio M-H,Fixed,95% CI	Odds Ratio M-H,Fixed,95% CI
White 2003	18/43	18/46		1.12 [0.48, 2.61]

Analysis 2.1. Comparison 2 Formula homeopathy versus placebo, Outcome 1 Symptoms.

Review: Homeopathy for chronic asthma

Comparison: 2 Formula homeopathy versus placebo

Outcome: 1 Symptoms

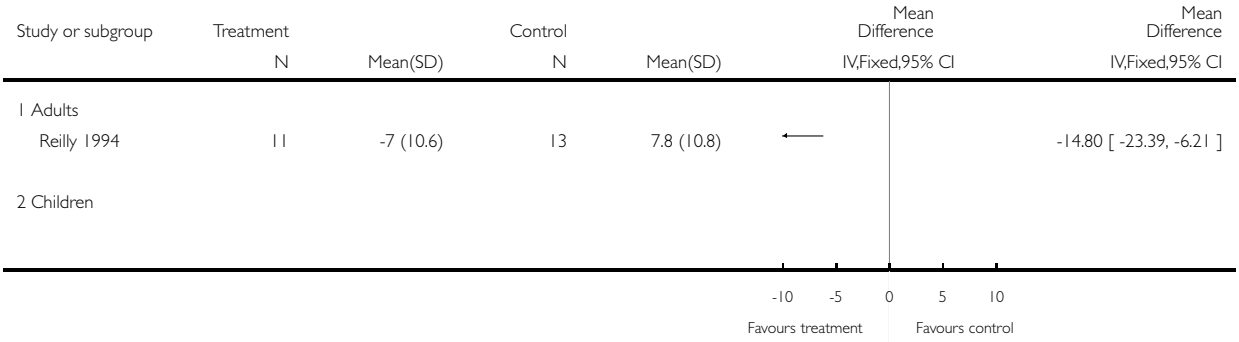
Study or subgroup	Treatment N	Mean(SD)	Control N	Mean(SD)	Std. Mean Difference IV,Fixed,95% CI	Std. Mean Difference IV,Fixed,95% CI
1 Adults						
Lewith 2002	122	2.73 (1.88)	120	2.68 (1.97)		0.03 [-0.23, 0.28]
2 Children						

Analysis 2.2. Comparison 2 Formula homeopathy versus placebo, Outcome 2 Symptoms (change scores).

Review: Homeopathy for chronic asthma

Comparison: 2 Formula homeopathy versus placebo

Outcome: 2 Symptoms (change scores)

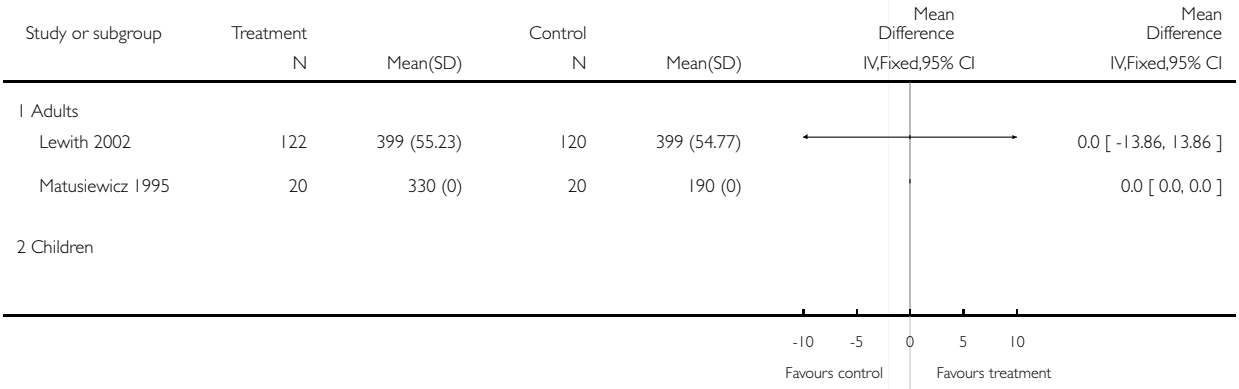


Analysis 2.3. Comparison 2 Formula homeopathy versus placebo, Outcome 3 PEF (morning).

Review: Homeopathy for chronic asthma

Comparison: 2 Formula homeopathy versus placebo

Outcome: 3 PEF (morning)



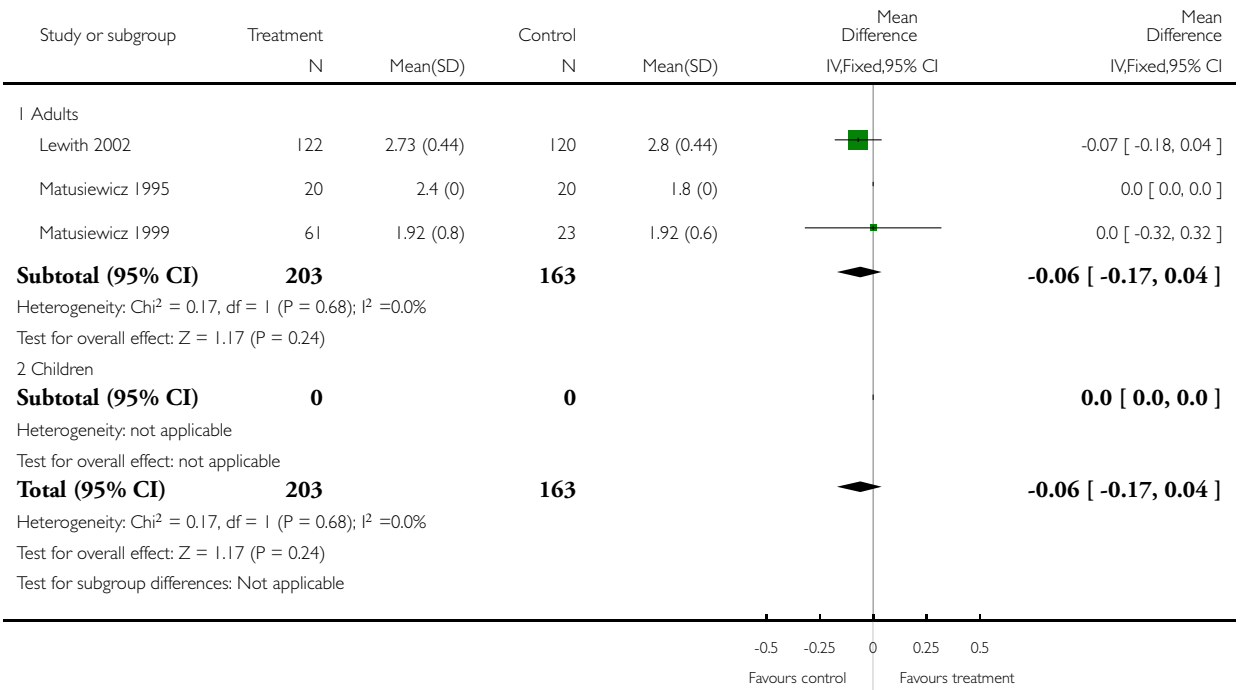
Analysis 2.4. Comparison 2 Formula homeopathy versus placebo, Outcome 4 FEV1.

Review: Homeopathy for chronic asthma

Comparison: 2 Formula homeopathy versus placebo

Outcome: 4 FEV1

Study or subgroup	Treatment N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 Adults						
Lewith 2002	122	2.73 (0.44)	120	2.8 (0.44)		-0.07 [-0.18, 0.04]
Matusiewicz 1995	20	2.4 (0)	20	1.8 (0)		0.0 [0.0, 0.0]
Matusiewicz 1999	61	1.92 (0.8)	23	1.92 (0.6)		0.0 [-0.32, 0.32]
Subtotal (95% CI)	**203**		**163**			**-0.06 [-0.17, 0.04]**
Heterogeneity: Chi^2 = 0.17, df = 1 (P = 0.68); I^2 =0.0%						
Test for overall effect: Z = 1.17 (P = 0.24)						
2 Children						
Subtotal (95% CI)	**0**		**0**			**0.0 [0.0, 0.0]**
Heterogeneity: not applicable						
Test for overall effect: not applicable						
Total (95% CI)	**203**		**163**			**-0.06 [-0.17, 0.04]**
Heterogeneity: Chi^2 = 0.17, df = 1 (P = 0.68); I^2 =0.0%						
Test for overall effect: Z = 1.17 (P = 0.24)						
Test for subgroup differences: Not applicable						



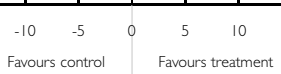
Analysis 2.5. Comparison 2 Formula homeopathy versus placebo, Outcome 5 FVC.

Review: Homeopathy for chronic asthma

Comparison: 2 Formula homeopathy versus placebo

Outcome: 5 FVC

Study or subgroup	Treatment N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 Adults						
Matusiewicz 1999	61	2.7 (0.91)	23	2.74 (0.7)		-0.04 [-0.41, 0.33]
2 Children						



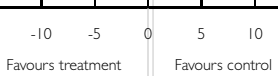
Analysis 2.6. Comparison 2 Formula homeopathy versus placebo, Outcome 6 Steroid usage.

Review: Homeopathy for chronic asthma

Comparison: 2 Formula homeopathy versus placebo

Outcome: 6 Steroid usage

Study or subgroup	Treatment N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 Adults						
Matusiewicz 1999	61	2.3 (2.71)	23	4.51 (1.9)		-2.21 [-3.24, -1.18]
2 Children						

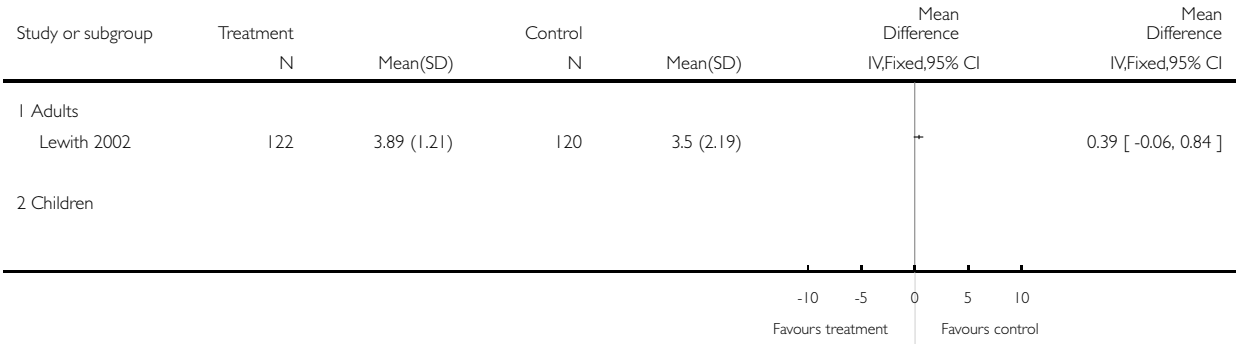


Analysis 2.7. Comparison 2 Formula homeopathy versus placebo, Outcome 7 Bronchodilator usage.

Review: Homeopathy for chronic asthma

Comparison: 2 Formula homeopathy versus placebo

Outcome: 7 Bronchodilator usage



ADDITIONAL TABLES

Table 1. Search history

Date	Detail
1997	One trial (Boucinhas 1990) was excluded as it was not randomised. Another trial (Matusiewicz 1996) was excluded as it made no statement about the method of allocation, and the number of patients in the groups (71 versus 32) suggested that allocation had not been randomised (although there is still some doubt; see characteristics of excluded studies). In the proceedings of homeopathic research meetings, abstracts of draft protocols of two planned additional trials investigating classical homeopathy were identified (Koster 1994, Warner 1994). These studies have yet to published
August 2003	Six additional references were identified from electronic searches conducted up to August 2003. After excluding duplicate references, two papers were retrieved and included (Matusiewicz 1999; Lewith 2002). A further study was identified from an automated alert system (White 2003)
August 2005	No new studies.
August 2005-2007	Two new references. Neither were relevant to the review

Table 2. Adverse events (White 2003)

Adverse event	Homeopathy group (n)	Placebo group (n)
Eczema	4	2
Asthma exacerbation	3	2
Headache	3	0
Fever	1	0
Sickness	1	0
Rash	0	1
Depression or irritability	0	3
Sleeping difficulties	0	2
No details	1	0
TOTAL	13	10

WHAT'S NEW

Last assessed as up-to-date: 31 July 2007.

Date	Event	Description
28 July 2008	Amended	Converted to new review format.

HISTORY

Protocol first published: Issue 2, 1997

Review first published: Issue 2, 1998

Date	Event	Description
23 September 2003	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

Klaus Linde - initial version of the review (including protocol development, data analysis)

Rob McCarney - first author on update of the review. Data extraction, quality assessment, analysis and interpretation. Author of Results, revised discussion section and conclusions.

Toby Lasserson - co-author on update of the review. Data extraction, analysis and interpretation. Co-author of Results, Discussion and Conclusions.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- NHS Research and Development, UK.
- Blackie Foundation Trust, UK.

External sources

- Homoeopathic Trust, UK.
- Karl und Veronica Carstens-Stiftung, Germany.
- NIAMS Grant No 5 U24-AR-43346-02, USA.
- British Homoeopathic Association, UK.

INDEX TERMS

Medical Subject Headings (MeSH)

*Homeopathy; Asthma [drug therapy; *therapy]; Chronic Disease; Randomized Controlled Trials as Topic

MeSH check words

Humans