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[Intervention Review]

Homeopathy for treatment of irritable bowel syndrome

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ABSTRACT

Background

Irritable bowel syndrome (IBS) is a common, chronic disorder that leads to decreased health-related quality of life and work productivity. Evidence-based treatment guidelines have not been able to give guidance on the effects of homeopathic treatment for IBS because no systematic reviews have been carried out to assess the effectiveness of homeopathic treatment for IBS. Two types of homeopathic treatment were evaluated in this systematic review. In clinical homeopathy a specific remedy is prescribed for a specific condition. This differs from individualised homeopathic treatment, where a homeopathic remedy based on a person's individual symptoms is prescribed after a detailed consultation.

Objectives

To assess the effectiveness and safety of homeopathic treatment for treating IBS.

Search methods

We searched MEDLINE, the Cochrane Central Register of Controlled Trials, EMBASE, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), the Allied and Complementary Medicine Database (AMED), Cochrane IBD/FBD Group Specialised Register, Cochrane Complementary Medicine Field Specialised Register and the database of the Homeopathic Library (Hom-inform) from inception to February 2013.

Selection criteria

Randomised controlled trials (RCTs), cohort and case-control studies that compared homeopathic treatment with placebo, other control treatments, or usual care, in adults with IBS were considered for inclusion.

Data collection and analysis

Two authors independently assessed the risk of bias and extracted data. The primary outcome was global improvement in IBS. The overall quality of the evidence supporting this outcome was assessed using the GRADE criteria. We calculated the mean difference (MD) and 95% confidence interval (CI) for continuous outcomes and the risk ratio (RR) and 95% CI for dichotomous outcomes.

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Main results

Three RCTs (213 participants) were included. No cohort or case-control studies were identified. Two studies published in 1976 and 1979 compared clinical homeopathy (homeopathic remedy) to placebo for constipation-predominant IBS. One study published in 1990 compared individualised homeopathic treatment (consultation plus remedy) to usual care (defined as high doses of dicyclomine hydrochloride, faecal bulking agents and diet sheets asking the patient to take a high fibre diet) for the treatment of IBS in female patients. Due to the low quality of reporting in the included studies the risk of bias in all three studies was unclear on most criteria and high for some criteria. A meta-analysis of two small studies (129 participants with constipation-predominant IBS) found a statistically significant difference in global improvement between the homeopathic remedy asafoetida and placebo at a short-term follow-up of two weeks. Seventy-three per cent of patients in the homeopathy group improved compared to 45% of placebo patients (RR 1.61, 95% CI 1.18 to 2.18). There was no statistically significant difference in global improvement between the homeopathic remedies asafoetida plus nux vomica and placebo. Sixty-eight per cent of patients in the homeopathy group improved compared to 52% of placebo patients (1 study, N = 42, RR 1.31, 95% CI 0.80 to 2.15). GRADE analyses rated the overall quality of the evidence for the outcome global improvement as very low due to high or unknown risk of bias, short-term follow-up and sparse data. There was no statistically significant difference found between individualised homeopathic treatment and usual care (1 RCT, N = 20) for the outcome "feeling unwell", where the participant scored how "unwell" they felt before, and after treatment (MD 0.03; 95% CI -3.16 to 3.22). None of the included studies reported on adverse events.

Authors' conclusions

A pooled analysis of two small studies suggests a possible benefit for clinical homeopathy, using the remedy asafoetida, over placebo for people with constipation-predominant IBS. These results should be interpreted with caution due to the low quality of reporting in these trials, high or unknown risk of bias, short-term follow-up, and sparse data. One small study found no statistically difference between individualised homeopathy and usual care (defined as high doses of dicyclomine hydrochloride, faecal bulking agents and diet sheets advising a high fibre diet). No conclusions can be drawn from this study due to the low number of participants and the high risk of bias in this trial. In addition, it is likely that usual care has changed since this trial was conducted. Further high quality, adequately powered RCTs are required to assess the efficacy and safety of clinical and individualised homeopathy compared to placebo or usual care.

PLAIN LANGUAGE SUMMARY

Homeopathy for treatment of irritable bowel syndrome

Irritable bowel syndrome (IBS) is a common chronic disorder characterised by altered bowel habits and abdominal pain, discomfort, bloating, constipation or diarrhoea or both. It is difficult to treat because no single cause has been identified. IBS impairs health-related quality of life and work productivity. Currently there is no agreement on the best form of treatment for IBS. Therefore it is important to evaluate the effectiveness and safety of treatments, including homeopathic treatment, which some IBS sufferers use. Clinical homeopathy matches a 'remedy' to a specific condition (such as arnica for bruising), whereas individualised homeopathy involves a series of in-depth consultations to assess symptoms, the effects of remedies and other issues that may affect the patient, in order to select appropriate 'remedies'. Individualised homeopathy includes both a consultation and a remedy, whereas clinical homeopathy consists of a remedy without the in-depth consultation.

This review identified three randomised controlled trials (RCTs) including a total of 213 participants. Two RCTs (129 participants) compared a homeopathic remedy to a placebo remedy for the treatment of constipation-predominant IBS. The other study (23 participants) compared individualised homeopathic treatment (consultation plus remedy) to usual care in female patients diagnosed with IBS. Usual care consisted of high doses of dicyclomine hydrochloride (an antispasmodic drug) and faecal bulking agents (e.g. foods high in fibre). Patients in the usual care group received diet sheets asking them to take a high fibre diet. The three trials tested the effects of homeopathic treatment on the severity of IBS symptoms. None of the included studies reported on side effects. The RCT comparing individualised homeopathic treatment to usual care found no statistically significant difference between homeopathic treatment and usual care. No conclusions can be drawn from this study due to the small number of participants and the low quality of reporting in this trial. In addition, this study was carried out in 1990 and usual care for IBS may have changed since then. Therefore it is not known how individualized homeopathic treatment performs when compared with current usual care. A pooled analysis of two small studies (129 participants) suggests a possible benefit for clinical homeopathy, using the remedy asafoetida, over placebo for people with constipation-predominant IBS at a short-term follow-up of two weeks. However both of the studies were carried out in

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the 1970s when the reporting of trials was not as comprehensive as it is now. These studies were subject to bias which makes it difficult to determine whether the benefit found in these studies are a true reflection of the effectiveness of homeopathic treatment. Further high quality RCTs enrolling larger numbers of patients are required to assess the effectiveness and safety of clinical and individualised homeopathy compared to placebo or usual care.

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SUMMARY OF FINDINGS FOR THE MAIN COMPARISON [Explanation]

Homeopathy compared to usual care or placebo for treatment of irritable bowel syndrome

Patient or population: patients with treatment of irritable bowel syndrome
Settings:
Intervention: Homeopathy compared to usual care or placebo

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Homeopathy compared to usual care or placebo				
Global improvement - patients who improved - Asafoetida only	Study population		RR 1.61 (1.18 to 2.18)	129 (2 studies)	⊕○○○ very low[2,3,4]	
	455 per 1000[1]	732 per 1000 (536 to 991)				
Global improvement - patients who improved - Asafoetida + nux vom	Study population		RR 1.31 (0.8 to 2.15)	42 (1 study)	⊕○○○ very low[5,6,7]	
	522 per 1000	683 per 1000 (417 to 1000)				

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: Confidence interval; **RR:** Risk ratio;

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] Control group risk estimates come from the control arm of the meta-analysis based on included trials.

[2] The quality of reporting in these studies does not meet current accepted standards making it difficult to assess the overall risk of bias. However there is a high risk of bias due to selective reporting in Rahlfs 1979 and most bias items were rated as unknown for both studies.

[3] Rahlfs 1976 and Rahlfs 1979 reported outcomes at two weeks. Given the long term nature of IBS it is not clear how useful a two week outcome is for patients' and clinicians' decision making.

[4] The sample size is less than the optimal sample size. Sparse data (76 events).

[5] The quality of reporting in this study does not meet current accepted standards making it difficult to assess the overall risk of bias. Downgraded due to unknown risk of bias.

[6] This study is reporting outcomes at two weeks. Given the long term nature of IBS it is not clear how useful a two week outcome is for patients' and clinicians' decision making.

[7] The sample size is less than the optimal sample size. Sparse data (25 events).

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BACKGROUND

Description of the condition

Irritable bowel syndrome (IBS) is a common, chronic disorder that affects 10 to 22% of the population in the UK (Williams 2007). There are an estimated 240,000 primary care consultations for new cases of IBS per year in the UK (Ehlin 2003). The economic costs of IBS in primary care in the UK are estimated to be over GBP 200 million per year (Akehurst 2002). It is difficult to treat because no single cause has been identified. Treatment is directed at controlling symptoms, using pharmacological and non-pharmacological approaches (Spiller 2007; Zijdenbos 2009; Ruepert 2011).

IBS is characterised by recurrent symptoms (i.e. abdominal pain or discomfort, bloating, constipation, or diarrhoea) that indicate a dysfunctional gastrointestinal tract rather than an organic change or specific diagnosis. It has an uncertain prognosis for recovery (Mearin 2006). Such patients have a plethora of non-colonic symptoms such as back pain, urinary frequency, and chronic fatigue which can lead to the patient being referred to the wrong speciality and having inappropriate investigations and even surgery. This can lower quality of life (Agrawal 2006; Longstreth 2007). In addition, sleep disturbance and depressed mood are common in IBS patients.

Diagnosis of IBS can be made using the Rome III criteria (Drossman 2006; Longstreth 2006), although this is largely a research tool used to allow common reporting standards of symptoms in trials and other research populations. In clinical practice the diagnosis of IBS is largely based on symptoms and should be positive rather than by exclusion, although the presence of alarm symptoms (e.g. blood in stool, fever or weight loss) should prompt further investigations (Spiller 2007). IBS can be characterised into the following subtypes: IBS with constipation, IBS with diarrhoea, IBS with mixed bowel habits and unspecified.

Usual care for IBS commonly includes advice on lifestyle, including diet and stress reduction, possibly combined with medication. There are a number of different medications used to help treat IBS: antispasmodic medicines, which help to reduce abdominal pain and cramping; laxatives, which help to treat the symptoms of constipation; anti-motility medicines, which help to treat the symptoms of diarrhoea, and tricyclic antidepressants, which were originally designed to treat depression, but also help to reduce the feeling of abdominal pain and cramping. Alternative treatments such as hypnotherapy, psychotherapy and acupuncture have been tried and have a place in selected patients (Agrawal 2006). However these treatments have limited availability and are expensive and labour intensive. Despite much research into both psychological and pharmacological treatments for irritable bowel syndrome no consensus exists on its optimal treatment (Zijdenbos 2009; Ruepert 2011).

Description of the intervention

Homeopathy is a popular, albeit controversial form of complementary and alternative medicine. A UK survey has shown that 1.9% of the population consulted a homeopath in the 12 months prior to the survey and 8.6% had bought an over-the-counter homeopathic remedy (Thomas 2001). Homeopathy is based on treating patients with remedies prepared from substances that have been highly diluted and succussed (shaken). It was first developed by Samuel Hahnemann in the 18^{th} century in Germany and works on the principle of "like cures like" whereby a substance that would cause symptoms in a healthy person cures those same symptoms in illness.

Homeopathic treatment varies among different practitioners and four main types can be identified (Linde 1997):

- Individualised (or classical) homeopathy, the type most commonly practised in the UK, involves a consultation followed by the prescription of a homeopathic medicine individualised to the patient;
- Clinical homeopathy, where the same homeopathic medicine is used for a group of patients all presenting with the same clinical condition (e.g. lycopodium for IBS, arnica for bruising);
- Complex homeopathy, where a number of different homeopathic medicines are given either in a fixed combination or concurrently; and
- Isopathy, where the homeopathic medicine is based on the substance which has led to the problem (e.g. grass pollen for hay fever).

Homeopathic medicines when prescribed by trained professionals are generally regarded as safe (Dantas 2000).

How the intervention might work

Homeopathy is based on the '*law of similars*' i.e. a substance which causes symptoms in a healthy individual can be used to treat similar symptoms in a diseased person (Vithoulkas 1980).There is significant debate regarding the scientific basis for homeopathy amongst healthcare practitioners, scientists, politicians and policy makers and the mechanism by which homeopathic remedies may work is not completely understood.

The manufacture of homeopathic medicines involves serial dilution alternating with violent agitation (i.e. 'succussion'). The combination of these two processes is referred to as 'potentisation' or 'sequential kinetic activation' (Gariboldi 2009). Many homeopathic medicines are diluted beyond Avogadro's number and therefore fall under the classification of ultra-high dilutions (UHDs). Avogadro's number is the number of molecules in a mole of a substance, approximately 6.0225×10^{23}, which means that a sample diluted beyond 10^{24} would have reached a stage where it is very unlikely that there is even a single molecule of the original substance present. The biological efficacy of UHDs may be depen-

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dent on sequential kinetic activation (Gariboldi 2009), but the mechanism by which sequential kinetic activation enables a UHD to be biologically active is unknown. A common theory is that it involves stable water structures, created by interactions between molecules of the biological material and the water it is dissolved in, allowing the water to retain information about the biological material (Montagnier 2009).

Why it is important to do this review

Lower gastrointestinal tract disorders account for one in 20 of all general practice consultations in the UK (Thompson 2000). In addition, gastroenterology problems are the fourth most common referral to National Health Service (NHS) homeopathic hospitals (Spence 2005) and one of the eight most common conditions treated by NHS homeopaths in general practice (Mathie 2006). People with IBS are also more likely to use alternative medicine than people with upper gastrointestinal disorders or Crohn's disease (Smart 1986).The frequency with which people with IBS consult homeopaths may be some indication of the value which they place on the homeopathic approach. Homeopathic treatment may offer a treatment strategy for patients with IBS, but at present it is not clear if it offers any benefit.

OBJECTIVES

The objective of this systematic review is to assess the effectiveness and safety of homeopathic treatment for IBS.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) comparing homeopathic treatment with placebo or active comparators were considered for inclusion regardless of blinding method, publication status and language of publication. Quasi randomised studies were also considered for inclusion, where allocation was achieved by 'quasi-random' methods such as alternation between treatment arms, year of birth, month entered into study. Cohort and case-control studies were also considered for inclusion.

Types of participants

All trials of patients with a diagnosis of IBS were eligible for inclusion in this review regardless of age, gender, race, educational status or duration of IBS. Trials which included IBS patients in whom 10% or more had unstable psychiatric disorders, ulcerative colitis, Crohn's disease, bowel cancer and pregnant and breastfeeding women were excluded from this review.

Types of interventions

Trials were included if one of the groups in the trial received any type of homeopathic treatment involving the delivery of a homeopathic remedy (either by a homeopath following a consultation or studies where a homeopathic remedy was delivered without a consultation) and the other received placebo, an active comparator treatment, or no treatment.

Types of outcome measures

All trials that included any one of the following outcome measures were included in the review.

Primary outcomes

The primary outcome was global improvement of symptoms (patient-reported or clinician-evaluated or both) as measured by a global IBS symptom score (e.g. IBS Severity Scoring System, Adequate Relief Measure, GI Symptom Rating Scale, Functional Bowel Disorder Severity Index or IBS Symptom Questionnaire).

Secondary outcomes

Secondary outcomes included:

- Quality of life as measured by validated quality of life measure e.g. EQ5D, SF36, IBS Quality of Life Measure, IBS Quality of Life Questionnaire, Functional Digestive Disorder Quality of Life Questionnaire, IBS Health Related Quality of Life Questionnaire;
- Abdominal pain, discomfort and distension;
- Stool frequency, bowel transit time;
- Stool consistency; and
- Adverse events.

Search methods for identification of studies

Electronic searches

The following electronic databases were searched from inception to February 2013:
The Cochrane Central Register of Controlled Trials (CENTRAL) on the Cochrane Library, Ovid MEDLINE, EMBASE classic +

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EMBASE, the Cumulative Index to Nursing and Allied Health Literature (CINAHL) and the Allied and Complementary Medicine Database (AMED). The Cochrane IBD/FBD Group Specialised Register and the Cochrane Complementary Medicine Field Specialised Register were also searched.

MEDLINE was searched with the following terms which can be applied to other databases:

#1 colonic diseases/ OR irritable bowel syndrome/ OR colonic diseases, functional/ OR irritable bowel[tw] OR irritable colon[tw] OR spastic colon[tw] OR functional bowel disease*[tw] OR functional colonic disease*[tw]

#2 homeopathy/ OR homeopath*[tw] OR homoeopath*[tw]

#3 #1 AND #2

Searching other resources

1. Reference searching

The reference lists for all identified studies were inspected for additional studies.

2. Conference abstracts

Conference abstracts from Digestive Disease Week (DDW) 2009-2010 were searched.

3. Personal contact

The first author of each included study was contacted for information regarding unpublished trials.

4. Handsearching

The Homeopath and Homeopathic Links journals were handsearched between 2008 - 2011 to determine the likely yield of these journals.

Data collection and analysis

Selection of studies

Two authors (EJP and ERR) independently reviewed the titles and abstracts of the studies identified by the literature search. Included studies were assessed against the predefined inclusion criteria.

Data extraction and management

Two authors (EJP and ERR) independently extracted data from the included studies. Authors were contacted to clarify any unclear data.

Assessment of risk of bias in included studies

Two authors (EJP and ERR) independently assessed the methodological quality of included randomised trials using the Cochrane risk of bias tool (Higgins 2011). The following items were assessed:

- sequence generation (i.e. was allocation sequence adequately generated?);
- allocation sequence concealment (i.e. was allocation adequately concealed?);
- blinding (i.e. was knowledge of the allocated interventions adequately prevented during the study?);
- incomplete outcome data (i.e. were incomplete outcome data adequately addressed?);
- selective outcome reporting (i.e. are reports of the study free of suggestion of selective outcome reporting?); and
- other potential sources of bias (i.e. was the study apparently free of other problems that could lead to a high risk of bias e.g. baseline imbalances, evidence of carry-over in cross-over trials, comparability of groups in cluster trials).

It was intended that, based on these criteria the studies would be subdivided into three categories:

1. Low risk of bias i.e. all quality criteria met;
2. Medium risk of bias i.e. one or more of the quality criteria partly met; and
3. High risk of bias i.e. one or more of the quality criteria not met.

It was intended that the quality of quasi-randomised trials, non-randomised trials, cohort and case control studies would be assessed using a quality instrument designed for assessing the quality of non-randomised studies (Downs 1998).

Measures of treatment effect

Review Manager (RevMan 5.2) was used to analyse the data. For continuous outcomes the mean difference (MD) with 95% confidence interval (95% CI) was calculated. For each dichotomous outcome the risk ratio (RR) with 95% CI was calculated.

Unit of analysis issues

We did not anticipate any unit of analysis issues arising from cluster randomisation. In the case of multiple intervention groups each intervention group was analysed separately against the control group and the sample size for the control group was divided proportionately across each intervention group. We noted that if the results were reported at multiple time points in the studies, each outcome would be analysed at pre-defined periods of follow-up in separate meta-analyses. Time points would be grouped as follows: less than three months, three months to one year, longer than one year. These time points were chosen as representing time frames in which a difference in the likelihood of responding could be expected.

Dealing with missing data

We intended to analyse data using the intention to treat (ITT) principle and sensitivity analyses were to be undertaken as appropriate (e.g. ITT versus available case, and study quality). However, data were analysed on an available case basis as the included studies did not provide enough detail to allow for an ITT analysis.

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Assessment of heterogeneity

Statistical heterogeneity was assessed using the Chi^2 test and the I^2 statistic. The Chi^2 test was considered statistically significant if $P \leq 0.10$. If heterogeneity existed between studies ($I^2 \geq 50\%$) for the primary outcome, reasons for the heterogeneity would be explored. Clinical heterogeneity would be assessed through the description of the setting and homeopathic approach used in each study.

Assessment of reporting biases

In the protocol we noted that if more than 10 studies were identified for inclusion in this review, funnel plots would be used to assess publication biases.

Data synthesis

Data from individual trials were combined by meta-analysis if the interventions, outcomes and patient groups were sufficiently similar (determined by consensus). For continuous data the mean difference with 95% CI was calculated where the same scales have been used. Where studies were deemed sufficiently similar but different scales have been used the standardised mean difference would be used to combine data. For dichotomous outcomes the pooled risk ratio and 95% CI were calculated.
In the protocol we specified that data would not be pooled for meta-analysis if a high degree of heterogeneity ($I^2 > 75\%$) was detected. A fixed-effect model would be used to pool data in the absence of heterogeneity. An $I^2 \geq 50\%$ is considered to represent moderate heterogeneity and in such cases (I^2 50 to 75%) a random-effects model would be used for pooling the data.

Subgroup analysis and investigation of heterogeneity

Subgroup analysis was planned between studies that prospectively identified IBS patients using ROME III criteria versus studies that did not use ROME III criteria to prospectively identify IBS patients. In the protocol we also noted that if data were reported separately for the different forms of IBS then a subgroup analysis comparing the different forms would be carried out. A subgroup analysis was also planned for quasi and true randomisation, different comparators (e.g. no treatment, usual care, placebo, or other active treatment) and different homeopathy interventions (e.g. individualised or clinical homeopathy).

Sensitivity analysis

In the protocol we noted that if a sufficient number of trials were identified a sensitivity analysis would be carried out by study quality to determine if the results of the primary analysis change according to which trials are incorporated into the analysis.

RESULTS

Description of studies

See Characteristics of included studies and Characteristics of excluded studies and Characteristics of ongoing studies.

Results of the search

Figure 1 shows details of the search and selection process. From 269 citations initially identified, 29 full text sources were examined (after removal of duplicates and assessment of abstract), 25 studies were excluded for various reasons (listed in the excluded studies table) and 3 studies plus one secondary publication from an included study were included in the review (Rahlfs 1976; Rahlfs 1979; Owen 1990) . Two studies were included in quantitative synthesis (Rahlfs 1976; Rahlfs 1979). One ongoing study was also identified (Peckham 2012). No cohort or case-control studies were identified.

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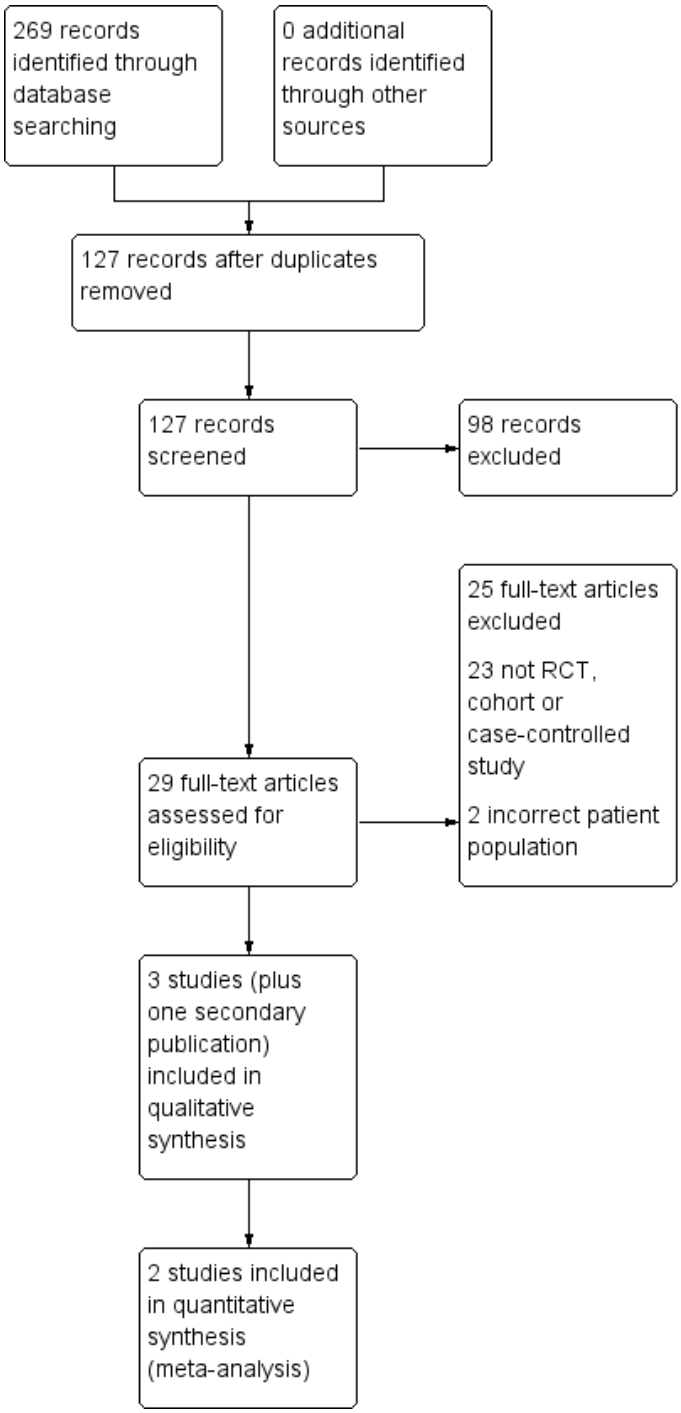
Figure 1. Study flow diagram.



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Included studies

Three studies with a total of 213 participants were included (Rahlfs 1976; Rahlfs 1979; Owen 1990). See Characteristics of included studies. Owen 1990 was conducted in the UK and published in English. Rahlfs 1976 and Rahlfs 1979 were conducted in the former Federal Republic of Germany and published in German and were translated from German into English. Rahlfs 1976, was a three arm trial comparing asafoetida against asafoetida + nux vomica, against placebo, whereas Rahlfs 1979 compared asafoetida versus placebo (the participants in the two trials are independent). The authors noted that Rahlfs 1976 failed to recruit its target number of participants, hence the (simplified) trial being re-run. There were 23 participants in Owen 1990, 72 participants in Rahlfs 1976 and 119 participants in Rahlfs 1979. All included studies were published as full articles.

Owen 1990 compared individualised homeopathic treatment which involved a homeopathic consultation and an individualised homeopathic remedy to usual care which consisted of high doses of dicyclomine hydrochloride, faecal bulking agents and diet sheets asking the patient to take a high fibre diet. This study differs from other pragmatic trials of individualised homeopathic treatment, where the more common approach has been to compare individualised homeopathic treatment plus usual care to usual care alone. In Owen 1990 participants were asked to rate how unwell they felt before and after treatment, exact details of how this was scored are not given. Although Owen 1990 did not include a global measurement of IBS as one of the outcomes, we considered the rating of how unwell patients felt to provide a global measurement of the patients' health. The other outcome measures in Owen 1990 involved the patients choosing their own top four worst symptoms and grading these on a visual analogue scale, it was not specified that these symptoms had to be related to IBS, and details of the symptoms patients chose were not reported are not given, hence this outcome measure was not included in this review.

Excluded studies

The Characteristics of excluded studies table, describes the characteristics of the 25 excluded studies along with the reason for their exclusion.

Ongoing studies

The Characteristics of ongoing studies describes the characteristics of the ongoing study on individualised homeopathy for the treatment of IBS.

Risk of bias in included studies

The risk of bias in the included studies for each domain are discussed below. See results of the risk of bias analysis are summarized in Figure 2.

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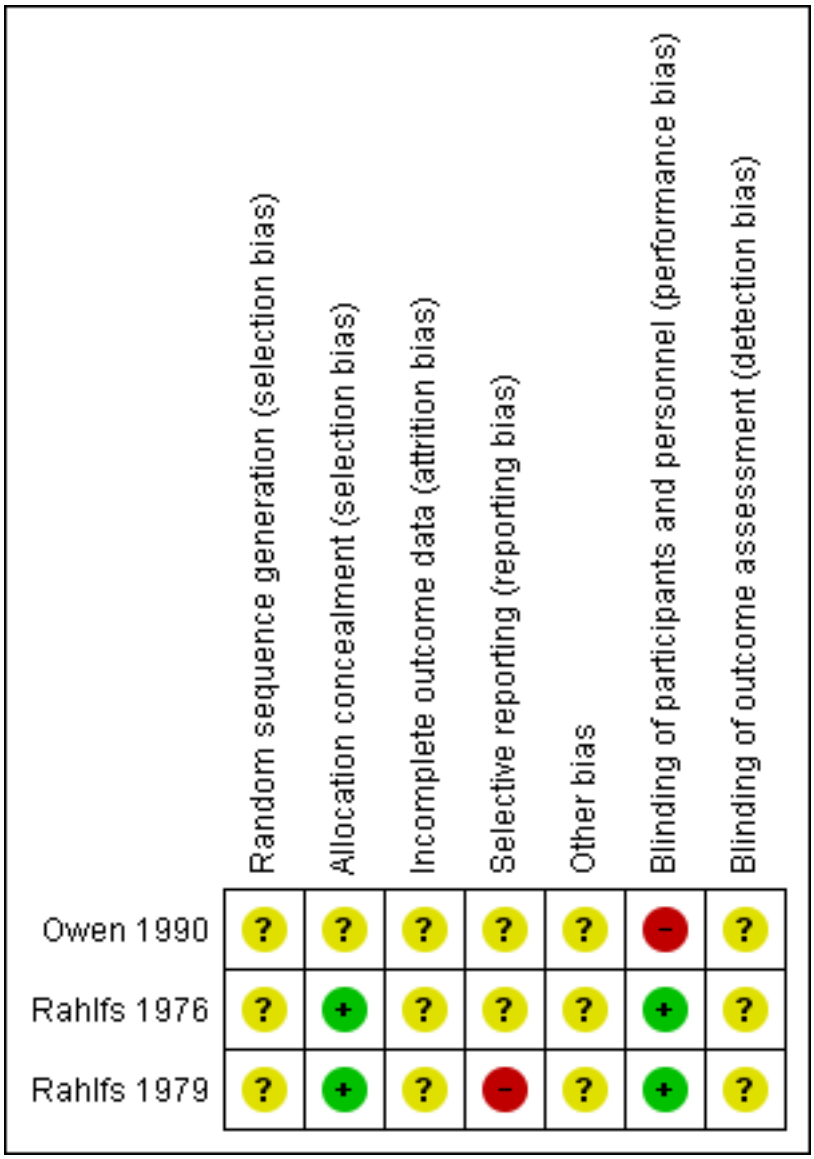
Figure 2. Methodological quality summary: review authors' judgments about each methodological quality item for each included study.



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Allocation

Owen 1990, Rahlfs 1976 and Rahlfs 1979 were described as RCTs. Owen 1990 reported that the participants were stratified and randomised into one of two treatment groups. However, no details were given about the stratification or how randomisation sequence was generated. Rahlfs 1976 reported that a chance code was used for randomisation, although what this entailed and how it was implemented was not described. Rahlfs 1979 did not report any information regarding the method of generation of the randomisation code. Rahlfs 1976 and Rahlfs 1979 provided medication in sequentially numbered drug containers and were rated as low risk for allocation concealment. Owen 1990 did not describe the procedure used for allocation concealment and was rated as unclear for this item.

Blinding

Participants and physicians were not blinded to treatment allocation in the Owen 1990 study as it was not possible to design a study where patients were not aware of their receiving an individualised homeopathic consultation or usual care. Owen 1990 did not report whether other key study personnel were blinded, or whether outcome assessment was carried out blind. In Rahlfs 1976 and Rahlfs 1979 the study participants and the doctors who recruited the participants were blinded to allocation by the use of an identical placebo. In Rahlfs 1979, the participant blinding was well described. Rahlfs 1976 and Rahlfs 1979 did not report whether other key study personnel were blinded, or if outcome assessment was carried out blind.

Incomplete outcome data

The number of patient withdrawals was reported for Owen 1990, Rahlfs 1976 and Rahlfs 1979. Although Owen 1990 reported the number of withdrawals and the arm from which the patients withdrew, the reasons for withdrawal were not reported. Rahlfs 1976 did not report which arms that patients withdrew from and therefore it was not clear whether there may be attrition bias in this trial. Rahlfs 1979 reported the number of withdrawals from each treatment group and the reasons for withdrawal. Whilst dropouts appear to be comparable in terms of number and reason for withdrawal across both arms of this study (Rahlfs 1979), it should be remembered that any dropout threatens group comparability at baseline as random allocation seeks to distribute both known and unknown characteristics across groups, and dropouts may differ for unknown characteristics that cannot be measured.

Selective reporting

Due to insufficient reporting in Owen 1990 and Rahlfs 1976 both studies were rated as unclear for the item on selective reporting. Rahlfs 1979 was deemed to be at a high risk of bias due to selective reporting because of evidence of selective choice of data for an outcome. Some participants were excluded from the outcome analyses for not meeting the inclusion criteria while other participants who did not meet the inclusion criteria in terms of age were included in the analyses.

Other potential sources of bias

Due to the low quality of reporting in Owen 1990, Rahlfs 1976 and Rahlfs 1979, the potential for other sources of bias in these studies could not be assessed.

Effects of interventions

See: **Summary of findings for the main comparison** Homeopathy compared to usual care or placebo for treatment of irritable bowel syndrome

Clinical homeopathic remedy versus placebo remedy

Rahlfs 1976 and Rahlfs 1979 assessed global improvement in IBS at two weeks as an outcome measure. For this outcome patients were asked to measure their improvement on a three-point scale (Rahlfs 1976) and a four-point scale (Rahlfs 1979). For the Rahlfs 1976 study participants were asked to rate whether they were not or negligibly improved, more than half improved or free of symptoms. Participants in the Rahlfs 1979 study were asked to rate whether they were worse, not or negligibly improved, more than half improved or free of symptoms. For the purposes of this review, we dichotomised these scales into two categories: those who had improved (more than half improved or free of symptoms) versus those who had not improved (those who were worse, or not or negligibly improved).

Rahlfs 1976 found no statistically significant difference between the homeopathic remedy asafoetida and placebo (RR 1.28, 95% CI 0.78 to 2.10), and no statistically significant difference between asafoetida plus nux vom and placebo (RR 1.31, 95% CI 0.80 to 2.15). A RR greater than one favours the homeopathic group. Rahlfs 1979 reported a statistically significant difference between the homeopathic remedy asafoetida and placebo (RR 1.82, 95% CI 1.23 to 2.96). A pooled analysis (129 participants) found a statistically significant difference between the homeopathic treatment asafoetida and placebo. Seventy-three per cent of patients in the homeopathy group improved at two weeks compared to 45% of placebo patients (RR 1.61, 95% CI 1.18 to 2.18; See Figure 3). No heterogeneity was detected for this comparison (P = 0.27; I^2 = 18%).

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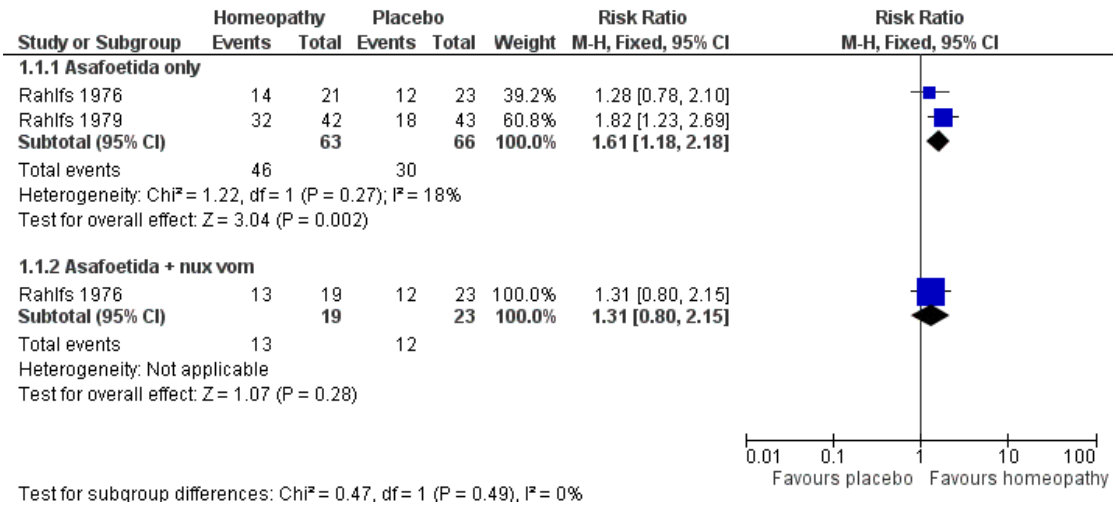
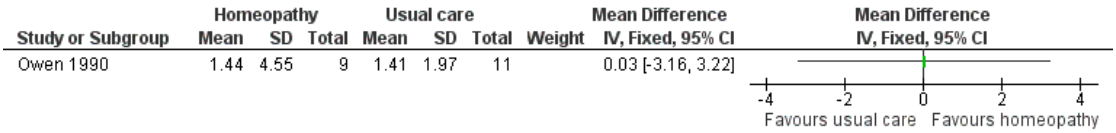
Figure 3. Forest plot of comparison: 1 Homeopathy compared to usual care or placebo, outcome: 1.1 Global improvement - patients who improved.



Homeopathic treatment versus usual care

In Owen 1990 participants were asked to rate how unwell they felt before and after treatment. No statistically significant difference was found between homeopathic treatment and usual care (MD 0.03, 95% CI -3.16 to 3.22; See Figure 4).

Figure 4. Forest plot of comparison: 1 Homeopathy compared to usual care or placebo, outcome: 1.2 Feeling unwell.



Outcome data from the Owen 1990 study was not pooled with the data from Rahlfs 1976 and Rahlfs 1979 because of heterogeneity between the studies. The three studies investigated two different types of homeopathy. Owen 1990 investigated the effectiveness of individualised (classical) homeopathic treatment, whilst Rahlfs 1976 and Rahlfs 1979 investigated clinical homeopathy. The type of IBS investigated was also potentially different. In the Owen 1990 study participants were diagnosed with IBS and no further information on type was given, whilst the participants in Rahlfs 1976 and Rahlfs 1979 had constipation-predominant IBS. In addition, the studies measured outcomes at different time points. Owen 1990 measured outcomes at 12 weeks, whilst Rahlfs 1976 and Rahlfs 1979 measured outcomes at 2 weeks. The primary outcome for the Owen 1990 study was not a global improvement measure and was not comparable with the other two studies. Although it may be tempting to combine studies in a meta-analysis when it is likely to yield a statistically significant result, it is important not to combine studies where there is significant clinical heterogeneity, because these results would not be meaningful due to the large degree of differences between the studies. For these reasons the outcomes from Owen 1990, Rahlfs 1976 and Rahlfs 1979 were not combined.

The secondary outcomes quality of life, abdominal pain, stool frequency, stool consistency and adverse events were not reported on in the included studies and therefore it was not possible to

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include them in this review.

DISCUSSION

Summary of main results

Two RCTs compared a clinical homeopathic remedy with placebo for treating constipation-predominant IBS (Rahlfs 1976; Rahlfs 1979). In a meta-analysis of these studies, the homeopathic remedy was found to be significantly more effective than placebo for improvement in global IBS symptoms at a short-term follow-up of two weeks. However, this result should be interpreted with caution due to the low quality of the reporting in these studies, a high or unknown risk of bias associated with the trials in this pooled analysis, short-term follow-up, and sparse data.

One RCT (Owen 1990) compared individualised homeopathic treatment with usual care for treating women with IBS. No significant difference was found between individualised homeopathic treatment and usual care (dicyclomine hydrochloride, faecal bulking agents, and diet sheets advising a high fibre diet) as measured by how unwell the participants felt before and after treatment. No conclusions can be drawn from this study due to the small number of participants, the low quality of reporting in this trial and a high risk of bias.

Overall completeness and applicability of evidence

Rahlfs 1976 and Rahlfs 1979 assessed the effectiveness of clinical homeopathy for the treatment of constipation-predominant IBS. Therefore this review does not provide information on the effectiveness of clinical homeopathy for the treatment of IBS in general, or diarrhoea-predominant, or mixed typology IBS. Both Rahlfs 1976 and Rahlfs 1979 reported outcomes at two weeks. Given the long term nature of IBS it is not clear how useful a two-week outcome is for patients', clinicians' and policy makers' decision making. As people live with IBS for years, an evaluation of impact at two weeks fails to take into account possible rebound effects or longer term benefits or adverse events that would be important for patients and practitioners to know about when they consider the potential benefits and harms associated with this intervention.

Only one study assessing the effectiveness of individualised homeopathic treatment was identified in this review (Owen 1990). The number of participants in this study was small (23) and the study was conducted over 20 years ago. It is likely that there have been changes in usual care for IBS since this time, therefore Owen 1990 may not provide a full picture of the effectiveness of individualised homeopathic treatment compared to usual care. Therefore this review is unable to conclude anything about the use of individualised homeopathic treatment for IBS.

Quality of the evidence

The results from the pooled analysis indicate a possible benefit for homeopathic treatment using clinical homeopathy (non-individualised homeopathic remedies) over placebo for constipation-predominant IBS. However, this result needs to be interpreted with caution. The two studies included in the pooled analysis (Rahlfs 1976 and Rahlfs 1979) were carried out in the 1970s before the introduction of the CONSORT statement (Begg 1996), and the quality of reporting in these studies does not meet currently expected standards (Schultz 2010). The low quality of the reporting means that it is not possible to determine whether or not these studies were carried out in a rigorous manner and thus how likely it is that these results are a true reflection of the treatment effect. Both studies were determined to have an unknown risk of bias for most assessed items and Rahlfs 1979 was at a high risk of reporting bias. The quality of the evidence supporting the primary outcome (i.e. global improvement) was very low due to the low quality of reporting in the included studies, high or unknown risk of bias, sparse data and short-term follow-up.

Participants in the Rahlfs 1976 and Rahlfs 1979 studies were recruited through general practice as having suspected IBS. It is not clear whether diseases such as Crohn's disease or ulcerative colitis were ruled out in these participants and it is possible that some participants had diseases such as Crohn's or ulcerative colitis rather than IBS.

The quality of the reporting in the Owen 1990 study was low, and this study does not meet the current expected standards (Schultz 2010). No conclusions can be drawn from this study due to the small number of participants and risk of bias. Owen 1990 was rated as high risk of bias for blinding of participants and personnel. The study was rated as unknown risk of bias for the other assessed items. The exact details of the medication prescribed in the usual care arm, in terms of dosage and frequency was not reported.

Potential biases in the review process

To avoid potential biases in the review process data extraction was carried out independently by two assessors. In addition, efforts were made to identify all studies that were potentially eligible for this review (see Search methods for identification of studies). However, It is possible that not all potentially eligible studies were identified. This could be because potentially eligible studies have been carried out and then have not been published, or that studies have been published but not in places where they could be accessed, possibly because they were published in little known non-indexed journals or they could have been published in places where they should have been found, but were not found. Cohort and case-control studies were considered for inclusion but none were identified by the literature search. In retrospect the inclusion of case-control studies was not appropriate given that the main reason for including case-control studies in a review is when an event is very rare and thus it is unlikely that any RCTs have been carried out

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(Reeves 2011).

Agreements and disagreements with other studies or reviews

No other systematic reviews of homeopathic treatment for IBS were identified. However non-condition specific systematic reviews of homeopathic treatment that included the Rahlfs 1976 and Rahlfs 1979 studies have been published (Linde 1997; Shang 2005). Neither of these systematic reviews carried out any analyses on homeopathy for the treatment of IBS or specifically commented on homeopathy for IBS.

AUTHORS' CONCLUSIONS

Implications for practice

In this review of homeopathic treatment for IBS, two of the included studies used clinical (non-individualised) homeopathic remedies to treat patients with constipation-predominant IBS (Rahlfs 1976; Rahlfs 1979). A meta-analysis of these two studies found a statistically significant benefit favouring the homeopathic remedy over placebo. However, these results should be interpreted with caution due to the low quality of reporting in these studies, a high or unknown risk of bias and sparse data. Thus it is not possible to be certain whether or not the trials were able to distinguish between true treatment effects, chance or bias. Furthermore, the low quality of reporting practice means that it is difficult to assess whether the results would be replicated in everyday practice, that is, whether the results are externally valid or generalisable.

It is of note that Rahlfs 1976 and Rahlfs 1979 reported outcomes at two weeks. Given the long term nature of IBS, it is not clear how useful a two-week outcome is for decision making. It is essential that trials have a follow-up period that is clinically meaningful. As people live with IBS for years, an evaluation of impact at two weeks fails to take into account any possible rebound effects, or longer term benefits or adverse events that would be important for patients and practitioners to know about when they consider the potential benefits and harms associated with this intervention.

One of the included studies (Owen 1990), found no statistically significant difference between individualised homeopathic treatment and usual care consisting of dicyclomine hydrochloride and faecal bulking agents. Individualised homeopathy is the most common form of homeopathy practised in the UK. However due to the poor quality of reporting in this study and the small number of participants in this trial, no conclusions can be made regarding the usefulness of individualised homeopathic treatment for the treatment of IBS.

Implications for research

Rahlfs 1976 and Rahlfs 1979 evaluated clinical homeopathy involving pre-specified homeopathic remedies for the treatment of constipation-predominant IBS and were therefore designed to assess the effectiveness of non-individualised homeopathic remedies. However due to the high risk of reporting bias in one of these studies and unclear reporting in both of these studies it is recommended that these trials are repeated using current reporting guidelines (Schultz 2010), to determine whether or not there is any benefit associated with homeopathy for IBS. Future high quality studies should enrol larger numbers of patients and assess longer term efficacy and safety outcomes.

Owen 1990 assessed the effectiveness of individualised homeopathic treatment compared to usual care. Due to the low quality reporting in this study and the likelihood that usual care for IBS has changed since this study was conducted, it is recommended that the effectiveness and safety of individualised homeopathic treatment be evaluated in a well-designed, adequately powered trial.

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* *Indicates the major publication for the study*

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CHARACTERISTICS OF STUDIES

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

Owen 1990

Methods	RCT, unblinded, parallel study, 12 weeks duration
Participants	Setting; county hospital, UK Number of participants; 23 patients were allocated into one of the treatment groups, 20 patients included in analysis Recruitment methods; female patients attending the out-patient department at a county hospital in whom a diagnosis of IBS was made Diagnosis of IBS; clinical diagnosis by a consultant gastroenterologist and consultant gynaecologist Age range of patients; 20-69 years Gender (of treated patients); 100% female Duration of symptoms > 3 months
Interventions	1. Individualised homeopathic treatment 2. High doses of Dicyclomine hydrocholoride (exact dose not stated), faecal bulking agents and diet sheets advising a high fibre diet
Outcomes	Patients were asked to grade: their four worst symptoms on a visual analogue scale, dysmenorrhoea, dyspareunia, and feeling unwell at baseline, 2, 6 and 12 weeks
Notes	Detailed information is given on the homeopathic treatment the participants received in terms of; remedy chosen, potency and dosage, whilst no information is given on the strength and dosage of the dicyclomine hydrocholoride and faecal bulking agents prescribed in the usual care arm

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Although it is stated that this is a randomised trial no details were given as to how randomisation was achieved
Allocation concealment (selection bias)	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient reporting of attrition, whilst possible reasons for attrition were discussed for one patient, the reasons for the other two patients leaving the study were not reported
Selective reporting (reporting bias)	Unclear risk	Insufficient information is provided to be able to judge whether the study is at risk from selective reporting

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Owen 1990 (*Continued*)

Other bias	Unclear risk	Due to the low quality of the reporting in this study it is unclear whether the study is at risk from any other forms of bias
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and doctors were not blinded to allocation, however it is not stated whether other key study personnel were blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It is not reported whether or not the outcome assessment was carried out blind

Rahlfs 1976

Methods	RCT, double blind, parallel study, 2 weeks duration
Participants	Setting; general practice, Germany Number of participants; 71 patients treated (number of patients randomised not clearly stated), 63 patients included in analysis Recruitment methods; patients presenting in general practice with suspected IBS Diagnosis of IBS; Clinical diagnosis plus completion of detailed questionnaire Mean age (of treated patients); 43.8 years Gender (of treated patients); 50.8% female Duration of symptoms > 14 days
Interventions	1. 0.1% asafoetida alcohol solution, 6 x 5 drops daily 2. 0.1% asafoetida alcohol solution + 0.01% nux vomica alcohol solution, 6 x 5 drops daily 3. placebo, 45% alcohol solution, 6 x 5 drops daily
Outcomes	Self assessment on a 3 point scale; no or negligible improvement, more than half improved, free of symptoms measured on day 8 and day 15 of the study Time to recovery assessed by the patient reporting the day they felt considerable improvement Freiburg Personality Inventory
Notes	Analysed participant data were fairly well described, but a lot of pre-randomisation and pre-analysis data were missing

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	A chance code was used for the randomisation, the exact nature of which was not reported Therefore the risk of bias cannot be deter-

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Rahlfs 1976 (*Continued*)

		mined
Allocation concealment (selection bias)	Low risk	Medication was provided in sequentially numbered drug containers
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient reporting of attrition, some reasons for attrition are given, details of allocation are not always given
Selective reporting (reporting bias)	Unclear risk	Insufficient information was provided to be able to judge whether the study was at risk from selective reporting
Other bias	Unclear risk	Insufficient information was provided to assess whether the study was at risk from any other bias
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Study participants and recruiting doctors were blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It was not reported whether outcome assessment was carried out blind

Rahlfs 1979

Methods	RCT, double blind, parallel study, 2 weeks duration
Participants	Setting; general practice, Germany Number of participants; 119 patients treated (number of participants randomised not clearly stated), 89 patients included in analysis Recruitment methods; patients presenting in general practice with suspected IBS Diagnosis of IBS; Clinical diagnosis plus completion of detailed questionnaire Mean age (of patients included in analysis, ages of those not included not stated); 42.5 years Gender (of those included in analysis, gender of those not included not stated); 68.5% female Duration of symptoms > 14 days
Interventions	1. 0.1% asafoetida alcohol solution, 6 x 5 drops daily 2. placebo, 45% alcohol solution, 6 x 5 drops daily
Outcomes	Self assessment on a 4 point scale; worsening of symptoms, no or negligible improvement, more than half improved, free of symptoms, measured on day 8 and day 15 of the study Time to recovery assessed by the patient reporting the day they felt considerable improvement

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Rahlfs 1979 (*Continued*)

Notes	Analysed participant data were fairly well described, but a lot of pre-randomisation and pre-analysis data were missing	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Although it was reported that this was a randomised trial no details were given as to how randomisation was achieved
Allocation concealment (selection bias)	Low risk	Medication was provided in sequentially numbered drug containers
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Incomplete outcome data, reasons for missing data, and how incomplete outcome data were addressed was not clearly described
Selective reporting (reporting bias)	High risk	The inclusion and exclusion criteria were applied in a variable manner, some people that were subsequently found not to meet the exclusion and inclusion criteria were removed from the analysis However people who did not meet the inclusion criteria for age, being too old were still included in the analysis This leaves the study at risk of bias due to selective reporting
Other bias	Unclear risk	Due to the low quality of the reporting it was unclear whether the study was at risk from any other forms of bias
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants and doctors were blinded to allocation
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It was not reported whether outcome assessment was carried out blind to treatment allocation

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

Study	Reason for exclusion
Aleem 2000	Discussion piece and not a randomised controlled trial, cohort or case-control study
Anonymous 2005	An initial reading of this Italian article revealed it to be discussing a meta analysis by Shang 2005 Therefore a full translation was not conducted
Anonymous 2009	Discussion piece and not a randomised controlled trial, cohort or case-control study
Bhagat 2010	Case report (n = 1) of homeopathic treatment for IBS
Bhattacharjee 2010	The article was a discussion on the different homeopathic remedies used for the treatment of IBS
Chimthanawala 2004	Case report (n = 2) of homeopathic treatment for IBS
Diamond 2005	A discussion on the use of complementary therapies for the treatment of gastroenterological problems
Feldhaus 2000	This was a discussion piece on the treatment of IBS
Gamble 2007	Discussion of a potentially new way of assessing and treating IBS, from a homeopathic perspective, using two cases as an example
Gebhardt	Discussion on homeopathic treatment for IBS, not a randomised controlled trial, cohort or case-control study
Gray 1998	This study was a case series of 25 patients with no comparator group
Greeson 2008	Non-randomised observational study of outcomes for patients attending a integrative medical centre where homeopathy was only one of the treatments offered
Innes 2000	This study was a case series (n = 20) with no comparator group
Jagose A	Case report (n = 1) of homeopathic treatment for IBS
Jones 1996	A discussion of the homeopathic treatment of IBS, illustrated by three cases
Jones 1997	Discussion piece on homeopathic treatment of IBS
Jones 1999	Case report study of a woman with IBS treated with homeopathy
Krishendu 2010	A discussion of the different homeopathic remedies used for the treatment of IBS
Lobo 2000	Case report (n = 1) on homeopathic treatment of IBS
Master 2008	Discussion piece on homeopathy for IBS

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(*Continued*)

Mohan 2006	Case report (n = 2) of IBS treated with homeopathy
Pinto 1999	A selection of case reports on homeopathic treatment for a variety of conditions
Slade 2003	Case report (n = 1) of homeopathic treatment of ulcerative colitis
Turner 2008	Discussion of homeopathic treatment of IBS, illustrated by eight case histories
White 1999	Discussion of homeopathic treatment for IBS, not a randomised controlled trial, cohort or case-control study

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

Peckham 2012

Trial name or title	Homeopathy for irritable bowel syndrome (HIBS)
Methods	Three arm, parallel group non-blinded randomised controlled trial Those randomised to the active treatment arms will be offered up to five one hour consultations, with a consultation every five weeks Outcomes will be collected at baseline, 26 weeks and 52 weeks
Participants	Setting: Hospital outpatient, UK Recruitment methods: GP database recruitment, consultant gastroenterologist in secondary care Diagnosis of IBS: diagnosed according to the Rome III criteria, potentially eligible participants were asked to complete a questionnaire which included the Rome III criteria for IBS Participants had to score a minimum of 100 on the IBS-SSS to be eligible to take part in the trial Minmium duration of IBS: 3 months
Interventions	1. Individualised homeopathic treatment plus usual care 2. Supportive listening plus usual care 3. Usual care alone
Outcomes	IBS-SSS, EQ-5D, HADS
Starting date	January 2011
Contact information	
Notes	

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DATA AND ANALYSES

Comparison 1. Homeopathy compared to usual care or placebo

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Global improvement - patients who improved	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.1 Asafoetida only	2	129	Risk Ratio (M-H, Fixed, 95% CI)	1.61 [1.18, 2.18]
1.2 Asafoetida + nux vom	1	42	Risk Ratio (M-H, Fixed, 95% CI)	1.31 [0.80, 2.15]
2 Feeling unwell	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only

Analysis 1.1. Comparison 1 Homeopathy compared to usual care or placebo, Outcome 1 Global improvement - patients who improved.

Review: Homeopathy for treatment of irritable bowel syndrome

Comparison: 1 Homeopathy compared to usual care or placebo

Outcome: 1 Global improvement - patients who improved

Study or subgroup	Homeopathy n/N	Placebo n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 Asafoetida only					
Rahlfs 1976	14/21	12/23		39.2 %	1.28 [0.78, 2.10]
Rahlfs 1979	32/42	18/43		60.8 %	1.82 [1.23, 2.69]
Subtotal (95% CI)	**63**	**66**		**100.0 %**	**1.61 [1.18, 2.18]**
Total events: 46 (Homeopathy), 30 (Placebo)					
Heterogeneity: Chi^2 = 1.22, df = 1 (P = 0.27); I^2 =18%					
Test for overall effect: Z = 3.04 (P = 0.0024)					
2 Asafoetida + nux vom					
Rahlfs 1976	13/19	12/23		100.0 %	1.31 [0.80, 2.15]
Subtotal (95% CI)	**19**	**23**		**100.0 %**	**1.31 [0.80, 2.15]**
Total events: 13 (Homeopathy), 12 (Placebo)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.07 (P = 0.28)					
Test for subgroup differences: Chi^2 = 0.47, df = 1 (P = 0.49), I^2 =0.0%					

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Analysis 1.2. Comparison 1 Homeopathy compared to usual care or placebo, Outcome 2 Feeling unwell.

Review: Homeopathy for treatment of irritable bowel syndrome

Comparison: 1 Homeopathy compared to usual care or placebo

Outcome: 2 Feeling unwell

Study or subgroup	Homeopathy N	Mean(SD)	Usual care N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Owen 1990	9	1.44 (4.55)	11	1.41 (1.97)			0.03 [-3.16, 3.22]
Subtotal (95% CI)	**0**		**0**				**0.0 [0.0, 0.0]**
Heterogeneity: not applicable							
Test for overall effect: Z = 0.0 (P < 0.00001)							

CONTRIBUTIONS OF AUTHORS

EJP initiated, designed the study and drafted the protocol. EP and RR, extracted the data and conducted the quality assessment. AN, KC and JG arbitrated. KC provided advice on search strategies. KC, AN, JG AA and ERR all commented on the review.

DECLARATIONS OF INTEREST

EJP has contributed to the design and management of an RCT of homeopathic treatment for irritable bowel syndrome which may be eligible for inclusion in future updates of this review. She is a homeopath.

EAN: None known

JG: None known

KC: None known

ERR is a homeopath

AA: None known

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INDEX TERMS

Medical Subject Headings (MeSH)

*Ferula; Constipation [therapy]; Dicyclomine [therapeutic use]; Dietary Fiber [therapeutic use]; Homeopathy [*methods]; Irritable Bowel Syndrome [*therapy]; Phytotherapy [methods]; Randomized Controlled Trials as Topic

MeSH check words

Adult; Female; Humans; Male

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