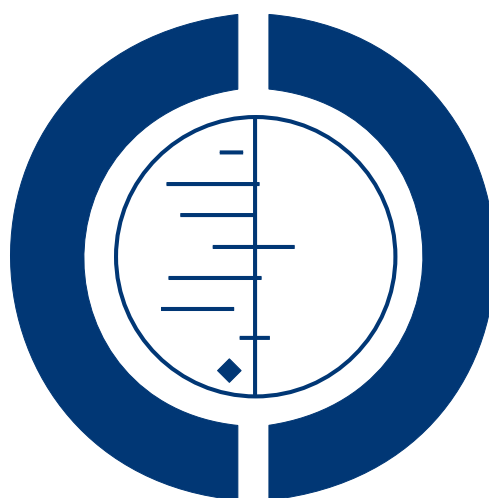


Herbal medicines for treatment of irritable bowel syndrome (Review)

Liu JP, Yang M, Liu Y, Wei ML, Grimsgaard S



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[Intervention Review]

Herbal medicines for treatment of irritable bowel syndrome

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ABSTRACT

Background

Traditional herbal therapies have been used for a long time to treat gastrointestinal disorders including irritable bowel syndrome, and their effectiveness from clinical research evidence needs to be systematically reviewed.

Objectives

To assess the effectiveness and safety of herbal medicines in patients with irritable bowel syndrome.

Search methods

We searched the following electronic databases till July 2004: The Cochrane Library (CENTRAL), MEDLINE, EMBASE, AMED, LILACS, the Chinese Biomedical Database, combined with hand searches of Chinese journals and conference proceedings till end of 2003. No language restriction was used.

Selection criteria

Randomised controlled trials of herbal medicines compared with no treatment, placebo, pharmacological interventions were included.

Data collection and analysis

Data were extracted independently by two authors. The methodological quality of trials was evaluated using the components of randomisation, allocation concealment, double blinding, and inclusion of randomised participants.

Main results

Seventy-five randomised trials, involving 7957 participants with irritable bowel syndrome, met the inclusion criteria. The methodological quality of three double-blind, placebo-controlled trials was high, but the quality of remaining trials was generally low. Seventy-one different herbal medicines were tested in the included trials, in which herbal medicines were compared with placebo or conventional pharmacologic therapy. Herbal medicines were also combined with conventional therapy and compared to conventional therapy alone.

Compared with placebo, a Standard Chinese herbal formula, individualised Chinese herbal medicine, STW 5 and STW 5-II, Tibetan herbal medicine Padma Lax, traditional Chinese formula Tongxie Yaofang, and Ayurvedic preparation showed significantly improvement of global symptoms. Compared with conventional therapy in 65 trials testing 51 different herbal medicines, 22 herbal medicines demonstrated a statistically significant benefit for symptom improvement, and 29 herbal medicines were not significantly different than conventional therapy. In nine trials that evaluated herbal medicine combined with conventional therapy, six tested herbal preparations showed additional benefit from the combination therapy compared with conventional monotherapy. No serious adverse events from the herbal medicines were reported.

Authors' conclusions

Some herbal medicines may improve the symptoms of irritable bowel syndrome. However, positive findings from less rigorous trials should be interpreted with caution due to inadequate methodology, small sample sizes, and lack of confirming data. Some herbal medicines deserve further examination in high-quality trials.

PLAIN LANGUAGE SUMMARY

Herbal medicines for treatment of irritable bowel syndrome

The use of herbal medicines for the treatment of irritable bowel syndrome is popular. Traditional Chinese herbal medicine is a common practice in the East, and some clinical trials show a benefit of herbal medicines for symptomatic treatment of this condition. This systematic review identified and included 75 randomised clinical trials evaluating the effects of various herbal preparations (including single herbs or mixtures of different herbs) for treating people with irritable bowel syndrome. The review shows that some herbal medicines improve global symptoms such as abdominal pain, diarrhoea and/or constipation. However, the methodological quality of the majority of clinical trials evaluating these herbs was generally poor. There is evidence indicating that small, poor quality trials with positive findings are more likely to be associated with exaggerated effects. Although the included trials did not report serious adverse effects from using herbal medicines more research is needed to determine the safety of herbal medicines. In conclusion, herbal medicines might be promising for the treatment of irritable bowel syndrome. However, it is premature to recommend herbal medicines for routine use in irritable bowel syndrome. Testing the herbs in larger, well-designed trials is needed in order to establish sound evidence for their use.

BACKGROUND

Irritable bowel syndrome (IBS) is a functional gastrointestinal disorder of chronic or recurrent symptoms attributed to the intestines, including abdominal pain, disturbed defecation, and/or bloating and distension unexplained by structural or biochemical abnormalities. Epidemiologic studies indicate a high prevalence in the general population, ranging from 17% to 22% depending on the diagnostic criteria used to define the condition (Fass 2001; Talley 2002). It is the most common diagnosis in gastroenterology clinics (Thompson 2001a). A higher prevalence of IBS is found in women than in men (Lee 2001). The high prevalence of IBS, related healthcare costs and workplace absenteeism cause substantial economic loss (Pittler 1998).

The pathophysiological mechanism of IBS postulates the role of abnormal intestinal motility, increased visceral sensitivity, psychosocial distress, post-infectious neuromodulation, and luminal

factors that irritate the small bowel or colon (Camilleri 2002; Talley 2002). The clinical course is chronic and relapsing, but the prognosis is basically benign with spontaneous improvement occurring in about 50% of patients at three years follow-up (Janssen 1998). Although there is no gold standard for the diagnosis of IBS, several evidence and consensus based practice guidelines have been developed (Fass 2001). The most widely accepted criteria include the Manning criteria (Manning 1978), Rome I criteria (Drossman 1994), and the recently developed Rome II criteria (Thompson 1999). There is good agreement between the Manning and Rome I criteria for diagnosis of IBS (Fass 2001).

There is no cure or curative treatment for IBS. Symptomatic treatment includes dietary fibre for constipation, opioid agents for diarrhoea, low-dose antidepressants and antispasmodics for pain, hypnotherapy, psychotherapy, peppermint oil, acupuncture, or herbal medicines (Bensoussan 1998; Pittler 1998; Jaiwala 2000;

Poynard 2001; Camilleri 2002; Sallon 2002; Thompson 2002). Newer serotonergic agents such as tegaserod - Zelnorm (for constipation) (Evans 2007), alosetron - Lotronex (for diarrhoea) (Cremonini 2003), and probiotics have been developed for treatment of IBS (Thompson 2001b). However, new treatments for IBS are awaited.

Complementary therapies are being used increasingly (Eisenberg 1998; Vickers 2000). The number of randomised trials of complementary treatments has doubled every five years, and The Cochrane Library includes nearly 50 systematic reviews of complementary medicine interventions (Vickers 2000). Many people turn to this therapy when conventional medicine fails them or when they believe strongly in the effectiveness of complementary medicine. Herbal medicine forms the main part of traditional Chinese medicine (Fulder 1996). Herbal medicines are defined in this review as products derived from plants or parts of plants (e.g., leaves, stems, buds, flowers, roots, or tubers) (raw or refined) used for treatment of diseases. The synonyms of herbal medicines include herbal remedies, herbal medications, herbal products, herbal preparations, medicinal herbs, and phytopharmaceuticals.

Herbal medicines could be categorised into four kinds, i.e., single herb, Chinese proprietary medicines, mixtures of different herbs, or any one of the three types plus western active medicines. Chinese proprietary medicines are usually based on well-established and longstanding recipes and formulated as tablets or capsules for commerce, convenience, or palatability. The mixture of herbs prescribed by Chinese herbalists depends upon the differentiation of symptoms according to Chinese diagnostic patterns (i.e., inspection, listening, smelling, inquiry, and palpation). However, the active ingredients of these herbal medicines are largely unknown and herbal medicines are often combined with different herbs. Pharmacological studies from China have shown that the clinical effectiveness of the herbs may be associated with the antagonistic effects on acetylcholine and histamine on intestinal smooth muscle, sedative and regulatory effects on the central and autonomic nervous systems, and regulatory effects on the hepato-biliary system (Lu 1999). There is an increasing number of reports in the medical literature about liver toxicity, renal damage and even cancer from some Chinese herbal products (Melchart 1999; Bensoussan 2000; Koh 2000). Therefore, this review will focus on beneficial and harmful effects regarding patient-centred outcome measures (Bertram 2001).

OBJECTIVES

The objective of this review was to assess the beneficial and harmful effects of treating IBS with herbal medicines.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised, parallel clinical trials were included irrespective of blinding, publication status, and language. Randomised cross-over trials were included only if the trial reported a wash-out period to eliminate any carry-over effect. Quasi-randomised trials and controlled clinical trials without randomisation were excluded.

Types of participants

Male or female patients, of any age or ethnic origin, who have IBS. IBS could be diagnosed on the basis of one of the following three criteria: Manning criteria (abdominal pain relieved with defecation, looser and/or more frequent stools with the onset of pain and abdominal distension); Rome I criteria (at least three months of continuous or recurrent symptoms of abdominal pain or discomfort that is relieved with defecation; and/or associated with a change in frequency of stool; and two or more of the following, at least on one-fourth of occasions or days: altered stool frequency, stool form, and stool passage, passage of mucus; and/or bloating or feeling of abdominal distension); or Rome II criteria (at least 12 weeks (not necessarily consecutive) in the preceding 12 months, of abdominal discomfort or pain that has two of three features: relieved with defecation, and/or onset associated with a change in frequency of stool; and/or onset associated with a change in form/appearance of stool).

Types of interventions

The intervention of herbal medicines included single herb (or extract from single herb), Chinese proprietary medicine, or mixture of several herbs irrespective of preparation (e.g., decoction, oral liquid, tablet, capsule, pill, powder, plaster, or injection), means of delivery (e.g., orally, plating, intramuscular or intravenous injection), dosage, and regimen of herbs. Trials of medicinal herbs plus active intervention versus active intervention alone were also included.

The control intervention included no treatment, placebo, non-specific treatment, or western active medicines.

Co-intervention was allowed as long as all arms of the randomised allocation received the same co-intervention.

Types of outcome measures

The main outcome measures sought at the end of treatment and at maximal follow-up after completion of the treatment were:

- global improvement of symptoms (patient-reported and/or clinician-evaluated);
- quality of life.

The additional outcome measures were:

- number of recurrent episodes;
- subtype of predominant symptom: abdominal pain, distension, diarrhoea or constipation;
- cost-effectiveness;
- number and type of adverse events. Two types of adverse events were analysed, serious adverse events and adverse events not considered serious. The serious adverse events were any untoward medical occurrence that resulted in death, was life-threatening, required hospitalisation or prolongation of hospitalisation, resulted in persistent or significant disability, was a congenital anomaly/birth defect or was an event that may jeopardise the patient or required intervention to prevent one of the former serious adverse events (ICH-GCP 1997). All other adverse events were considered non-serious.

Search methods for identification of studies

Electronic searches

The following electronic databases were searched irrespective of language and publication status:

- The trials registers of the Cochrane Inflammatory Bowel Disease Review Group, the Cochrane Complementary Medicine Field, and the Cochrane Central Register of Controlled Trials (CENTRAL) on The Cochrane Library (2004 Issue 1).
- MEDLINE (1966-2004), EMBASE (1998-2004), Chinese Biomedical Database (1979-2004), AMED and LILACS (www.bireme.br/bvs/I/ibd.htm) from their date of inception onwards.

The search strategy for MEDLINE was as follows:

- 1 exp colonic disease, functional/
 - 2 irritable bowel syndrome/
 - 3 or/1-2
 - 4 exp Medicine, Traditional/
 - 5 Alternative Medicine/
 - 6 exp Plant Extracts/
 - 7 exp Plants, Medicinal/
 - 8 Drugs, Non-Prescription/
 - 9 Herbs/
 - 10 (herb or herbs or herbal).tw.
 - 11 alternative medicine\$.tw.
 - 12 complementary medicine\$.tw.
 - 13 traditional medicine\$.tw.
 - 14 (plant or plants).tw.
 - 15 ((Chinese or oriental) adj3 medicine\$).tw.
 - 16 (phytodrug\$ or phyto-drug\$ or phytopharmaceutical\$).tw.
 - 17 or/4-16
 - 18 3 and 17
- [/ indicates MeSH term, exp = exploded, tw = textword, \$ = truncation]
- 19 a RCT filter (Dickersin 1994)
 - 20 18 and 19.

Handsearches

The following journals published in Chinese were searched: Chinese Journal of Digestion (1981-2003), Chinese Journal of Gastroenterology (1996-2003), Chinese Journal of Gastroenterology and Hepatology (1992-2003), Chinese Journal of Clinical Gastroenterology (1989-2003), Chinese Journal of Digestive Endoscopy (1996-2003), Chinese Journal of Integrated Traditional and Western Medicine on Digestion (1993-2003). Conference proceedings relevant to this topic were also handsearched.

Additional searches

The reference lists of identified randomised clinical trials and review articles were checked in order to find further trials not identified by the electronic searches or handsearches. Ongoing trials were searched through the National Research Register and the website www.controlled-trials.com.

Data collection and analysis

Selection of trials for inclusion

Two authors (MY and MW) independently selected the trials to be included in the review according to the prespecified selection criteria. Any disagreement was resolved by discussion.

Assessment of methodological quality

Two authors (MW and MY) assessed methodological quality independently based on quality components, i.e., adequacy of generation of the allocation sequence, allocation concealment, double blinding, and follow-up (Schulz 1995; Jadad 1996; Moher 1998; Kjaergard 2001). Any disagreement was discussed and reached consensus through a third party (JL).

The quality components were:

- generation of the allocation sequence: adequate (computer generated random numbers or similar) or inadequate (other methods or not described),
- allocation concealment: adequate (central independent unit, serially numbered, opaque, sealed envelopes, or similar) or inadequate (not described or open table of random numbers or similar),
- double blinding: adequate (identical placebo or similar) or inadequate (not performed or tablets versus injections or similar),
- follow-up: adequate (number and reasons for dropouts and withdrawals described) or inadequate (number or reasons for dropouts and withdrawals not described).

Data extraction

Data were extracted independently by two authors (MY and YL) and validated by a third party (JL) using a self-developed data extraction form. Papers not in Chinese, Norwegian, English, Japanese, or German were translated with the help of the Cochrane Inflammatory Bowel Disease Review Group. The following characteristics and data were extracted from each included trial: primary author, funding source, study setting, methodological characteristics, mean age, gender, and ethnicity of patients, number of randomised patients, reason and number dropped out or lost during follow-up, patient inclusion and exclusion criteria, predom-

inant symptoms of IBS patients, the diagnostic criteria, type of herb or herbs, route of delivery, dosage and duration of intervention, details of the comparison regime, outcome measures (end of treatment and follow-up), and number and type of adverse events. Data on the number of patients with each outcome, by allocated treatment group, irrespective of compliance or follow-up, were sought to allow an intention-to-treat analysis. If the above data were not available in the trial reports, further information were sought by correspondence with the principal investigator.

Data synthesis

Every type of herbal medicine was compared with each control (e.g., placebo) individually regardless of route of administration, dose, or preparation. Data from individual trials were combined for meta-analysis when the interventions were sufficiently similar (i.e., individual trials compare the same herb versus the same control intervention). Dichotomous data were presented as relative risk (RR) and continuous outcomes as weighted mean difference (WMD), both with 99% confidence intervals (CI). Analyses were performed by intention-to-treat where possible. For dichotomous outcomes, patients with incomplete or missing data would be included in a sensitivity analysis by counting them as treatment failures to explore the possible effect of loss to follow-up on the findings (“worst-case” scenario). Heterogeneity would be tested for using the Z score and chi square with significance being set at $P < 0.10$. Whenever there was statistically significant heterogeneity, the random effects model would be used. The analyses were carried out using MetaView 4.1 in Review Manager 4.2 (Cochrane software).

The following comparisons were tabulated where data were available: herbal medicines versus no intervention/placebo, herbal medicines versus non-specific treatment, and herbal medicines versus western active medicines. Trials of herbal medicines plus active medicine versus active medicine alone were presented as a separate comparison.

As the number of randomised trials identified was limited, the following subgroup analyses were not performed according to clinical course (duration of disease), gender of participants, different diagnostic criteria, formulation of herbs (extract, single herb, or mixture of herbs), and treatment duration (short and long term). Similarly, the number of randomised trials identified was not sufficient, we did not perform sensitivity analyses to explore the influence of trial quality on effect estimates as well as potential biases.

RESULTS

Description of studies

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#).

Our initial searches identified 312 references, 251 from the electronic searches and 61 from handsearches. After reading titles and abstracts, 226 of these articles were excluded because they were duplicates, non-clinical studies, or had study objectives different from this review. A total of 86 references published in Chinese, or English were retrieved for further assessment. Of these, 11 references were excluded because they did not meet our inclusion criteria. The reasons for exclusion were listed under ‘Characteristics of excluded studies’.

In total 75 randomised clinical trials were included in this review. They reported random allocation of patients with IBS to herbal medicines versus controls (placebo in six trials, conventional medicines in 65 trials) or herbal medicines plus active drugs versus active drugs (in nine trials). One trial tested four herbal remedies and placebo in five arms (Hentschel 1996). Two studies were designed as four-arm trials (Madisch 2004; Zhao LJ 2000), three studies as three-arm trials (Yadav 1989; Bensoussan 1998; Gu XX 1999), and the remaining studies as two-arm trials. The 75 randomised trials were listed under ‘Characteristics of included studies’, of which five trials were published in English and 70 in Chinese.

Participants

A total of 7957 patients with IBS were randomised in 75 trials. The average size of the trials was 105 patients, ranging from 45 to 453 patients per trial. Three trials included in-patients, 27 trials included outpatients, and 12 trials included both out- and in-patients. The remaining 33 trials did not specify the origin of the patients. The country origin of patients was China in 70 trials, Australia in one trial (Bensoussan 1998), Germany in one trial (Madisch 2004), India in one trial (Yadav 1989), Israel in one trial (Sallon 2002), and undefined in one trial (Hentschel 1996).

All randomised clinical trials included adults with a mean age of 40 years in the trials providing data. Three trials did not report data on sex and age (Hentschel 1996; Li H 2002; Zhou FS 2002). The overall proportion of male participants was 45.5% (3621/7957). Twenty-two trials enrolled participants with diarrhoea-predominant, five trials enrolled those with constipation-predominant, 17 trials enrolled mixture of both types of IBS. But 31 trials did not specified the type of the IBS in their participants.

Diagnosis

Eighteen trials (24%) used Rome criteria for the diagnosis of IBS, one trial used Manning criteria, one Indian trial used criteria from the literature, 45 Chinese trials used national criteria, and four trials used self-defined diagnostic criteria mainly based on Rome criteria. The Chinese national criteria for diagnosis of IBS include items of complaints of abdominal pain, bloating, diarrhoea, or constipation, with global neurological symptoms, physical examination, multiple faecal culture and examination, and radiologic or laboratory exclusion of organic gastrointestinal disease (China 1987). Five trials did not specify their diagnostic criteria (Yu ZX 1991; Hentschel 1996; Zhu YQ 1996; Xu XP 2002; Fei YM 2003).

Interventions

Seventy-one different herbal medicines were tested in 75 randomised trials (Table 1). Only three herbal medicines were tested twice or more including Gushen Changan in two trials (Du ZL 2002; Fei YM 2003), Xiaoyao San in two trials (Huang LS 2001; Xu HQ 2003), and Tongxie Yaofang in nine trials (Zhuo YC 1996; Yin WD 1998; Huang JQ 2000; Ye LJ 2000; Gong SX 2001; Rui YR 2002; Fei YM 2003; Xu J 2004). However, even when the same herbal medicines were tested the control interventions were different for each trial. Therefore, there was no trial testing exactly the same herbal medicine and the same control in this review. According to the category of medicinal herbs, four trials tested single herbs (Hentschel 1996; Chen ZJ 2002; Zhou Q 2003; Madisch 2004) and the remaining trials tested compounds of herbs. The preparation and composition of herbal medicines varied (Table 1). The average duration of treatment was 4 weeks (ranging from 9 days to 18 weeks). The control intervention included placebo in six trials (Yadav 1989; Hentschel 1996; Bensoussan 1998; Zhao LJ 2000; Sallon 2002; Madisch 2004) and conventional medicines in 66 trials. Nine trials compared herbal medicine combined with conventional therapy versus conventional therapy alone. The most commonly used control drugs were antispasmodic agents such as pinaverium bromide, mebevenine, propantheline, nifedipine, and belladonna; antidepressants such as amitriptyline, doxepin, clonazepam, diazepam, chlorthalidone, fluoxetine; anticonvulsants such as loperamide, diphenoxylate, Retardin; probiotic preparations such as bifidobigen, licheiformobigen, lacidophilin; cisapride for constipation; Smecta for diarrhoea; and oryzanol.

Outcomes

All trials reported outcome of IBS related symptoms, eight trials reported recurrent episodes of symptoms (relapse), and two trials reported outcome of quality of life. Twenty-four percent (18/75) of trials reported outcome of adverse events. No trial reported cost-effectiveness. The outcome of symptoms was mainly reported as global improvement including relief or amelioration of the symptoms. One trial used a Bowel symptom scale (Bensoussan 1998) and other four trials used scores for the measurement of symptoms (Zhou FS 2002; Shen Y 2003; Yan MX 2003; Madisch 2004). The remaining trials did not specify measurement of symptoms. Twenty-eight trials (37%) reported follow up after the completion of treatment ranging from one month to two years with median duration of three months. However, the data from follow up in most of the trials were reported inadequately.

Risk of bias in included studies

All trials were reported as parallel group randomised trials, and only one trial was a multi-centre randomised trial (Madisch 2004). Of the 75 included randomised trials, only four specified the methods for generation of allocation randomisation. Among them, one trial used drawing numbers (Cheng WJ 2000) and three trials used random number table or computer-generated numbers (Sallon 2002; Shen Y 2003; Madisch 2004). Four trials provided information

about allocation concealment, and three of them were assessed as adequate because they used sealed envelope or central control for the allocated treatment (Bensoussan 1998; Sallon 2002; Madisch 2004). One trial used a drawing method to produce the random assignment and allocation concealment was inadequate (Cheng WJ 2000). Double blinding was reported in six trials (Yadav 1989; Hentschel 1996; Bensoussan 1998; Lu ZZ 2002; Sallon 2002; Madisch 2004), and four of them were assessed to be adequate, one was unclear (Hentschel 1996), and one was inadequate because it compared herbal decoction with drug tablets (Lu ZZ 2002).

Three trials reported the numbers and reasons for loss to follow up, and intention-to-treat analysis was applied (Bensoussan 1998; Sallon 2002; Madisch 2004). These three trials also reported a pre-trial estimation of sample size. According to our quality criteria, these three randomised trials had good quality.

There was a significantly skewed distribution of participants among the allocated groups in 20 trials for which the trial reports did not explain (Yu ZX 1991; Wang JZ 1996; Zhang RZ 1996; Tong ZY 1998; Xu PH 1999; Cheng WJ 2000; Deng W 2000; Luo KQ 2000; Xin XY 2000; Ye LJ 2000; Zhao LJ 2000; Li XM 2001; Lin YZ 2001; Lu WH 2001; Ren GX 2001; Lu ZZ 2002; Ye PS 2002; Fei YM 2003; Zhang T 2003; Zhou Q 2003).

Effects of interventions

HERBAL MEDICINE VERSUS PLACEBO (Comparisons 01)

Six trials tested 12 different herbal medicines compared with placebo, and they reported outcomes included global improvement of symptoms, abdominal pain, effect on daily activities, constipation, and adverse effects (Yadav 1989; Hentschel 1996; Bensoussan 1998; Zhao LJ 2000; Sallon 2002; Madisch 2004).

Standard Chinese herbal formulation and individualised herbal formulation

Standard Chinese herbal formulation showed statistically significant global improvement of symptoms when rated by patients (RR 2.15, 99% CI 1.07 to 4.32) or by the gastroenterologist (RR 2.62, 99% CI 1.19 to 5.77), while an individualised herbal formulation showed no significant effect compared with placebo in one trial (Bensoussan 1998). However, when Bowel symptom scale (BSS) was measured, the scores were decreased in patients treated by individualised herbal formulation at the end of 16 weeks treatment (WMD -47.0, 99% CI -98.55 to 4.55) rated by the patients and (WMD -46.8, 99% CI -106.07 to 12.47) rated by gastroenterologist. The potential effect of the individualised herbal formulation was sustained at 14 weeks after completion of the treatment (WMD -56.30, 99% CI -120.80 to 8.20). The standard Chinese herbal formulation showed potential beneficial effect on decreasing BSS scores at the end of 16 weeks treatment (WMD -43.90, 99% CI -92.16 to 4.36 rated by patients and WMD -76.30, 99% CI -125.45 to -27.15 rated by gastroenterologist). However, this effect was not statistically significant at 14 weeks follow up (Bensoussan 1998).

Two patients withdrew from the trial because of discomfort associated with treatment. One patient developed upper gastrointestinal discomfort while taking standard formulation, while another patient developed headaches. No other adverse events were observed (Bensoussan 1998).

STW 5, STW 5-II, and Bitter candytuft monoextract

Both commercial herbal preparation STW 5 and research preparation STW 5-II showed global improvement of symptoms when rated by the gastroenterologist (RR 1.68, 99% CI 1.00 to 2.84 and RR 1.90, 1.15 to 3.14, respectively), while a single herb extract Bitter candytuft showed no significant effect compared with placebo (Madisch 2004). When the BSS was measured, STW 5 and STW 5-II both showed a statistically significant benefit when rated by the gastroenterologist (WMD -17.90, 99% CI -28.56 to -7.24 for STW 5, WMD -19.10, 99% CI -29.35 to -8.85 for STW 5-II). Bitter candytuft did not have a statistically significant effect on BSS (WMD -11.30, 99% CI -23.17 to 0.57).

Two minor adverse events were noted: one patient in the Bitter candytuft group developed headache, and one patient in the STW 5 group developed constipation. This did not affect the continuation of treatment. No serious adverse events were reported.

Tibetan herbal formula Padma Lax

Padma Lax showed a statistically significant effect on symptom improvement for constipation-predominant IBS patients when rated by patients in both per protocol analyses (RR 6.35, 99% CI 1.52 to 26.57) and intention-to-treat (RR 7.24, 99% CI 1.67 to 31.42) (Sallon 2002). Padma Lax significantly increased passing stool (RR 1.75, 99% CI 1.02 to 3.02) and decreased the severity of pain (RR 2.94, 99% CI 1.24 to 7.00). The effect of abdominal pain on daily activities was not statistically significant (RR 1.89, 99% CI 0.90 to 4.00).

For other continuous outcomes, Padma Lax increased the stool passing times per week (WMD 1.00, 99% CI 0.79 to 1.21), decreased the scores of effect of abdominal pain on daily activities (WMD -0.90, 99% CI -1.05 to -0.75) and the scores of abdominal pain severity (WMD -0.40, 99% CI -0.49 to -0.31). The constipation and lower abdominal pain scores (scale 0-10) were significantly lower than placebo when rated by the gastroenterologist (constipation, WMD -2.10, 99% CI -2.34 to -1.86; abdominal pain WMD -0.50, 99% CI -0.80 to -0.20).

In the 34 Padma Lax patients who completed the study, 10 complained of mild adverse events including slight headache, nausea, hoarseness, loose stool or diarrhoea. One patient also complained of a transient mild episode of dizziness, shortness of breath and chest pain which resolved within 24 hours. Of the 27 placebo patients who completed the study, five patients complained of adverse events including worsening of abdominal pain, heartburn, and nausea. There was no statistically significant difference in the incidence of adverse events between the two groups.

Tongxie Yaofang

The Chinese herbal medicine Tongxie Yaofang showed a statistically significant effect on global improvement of symptoms in di-

arrhoea-predominant IBS patients when rated by the investigators (RR 2.96, 99% CI 1.52 to 5.75) (Zhao LJ 2000). With the exception of a few patients reporting nausea, no other adverse event was observed in this trial.

Ayurvedic preparation

An Indian Ayurvedic formula of two herbs showed a statistically significant effect on global symptom improvement compared with placebo (RR 1.99, 99% CI 1.12 to 3.51) (Yadav 1989). Ayurvedic therapy compared to placebo was particularly beneficial for diarrhoea relief in diarrhoea predominant IBS (RR 2.30, 99% CI 1.08 to 4.92). There was no statistically significant difference between Ayurvedic preparation and placebo for relief of abdominal pain or constipation. Long-term follow up (median eight months) showed that Ayurvedic therapy was no better than placebo for limiting relapse (58% versus 100% respectively). However, there was a high rate of loss to follow up (34%). Two patients receiving Ayurvedic therapy complained of drowsiness compared to none in placebo group (Yadav 1989).

Hentschel 1996 treated patients for 18 weeks with *Fumaria officinalis* (250 mg), *Curcuma xanthorrhiza* (200 mg), a combination of two phytotherapeutic agents (Ayurvedic preparation), a traditional spagyric remedy or placebo and found no statistically significant differences in symptom improvement or quality of life. The placebo response rate was 35%.

HERBAL MEDICINE VERSUS CONVENTIONAL MEDICINE (Comparison 02)

Fifty-one herbal medicines were tested in 61 trials. Since no trial tested the same herbal medicine and control intervention the pooling of data for meta-analysis was not meaningful. Data regarding global improvement of symptoms were available in all the trials and the findings were summarised descriptively.

Tongxie Yaofang was tested in eight trials, but the comparators were different (Zhuo YC 1996; Yin WD 1998; Ye LJ 2000; Zhao LJ 2000; Gong SX 2001; Rui YR 2002; Fei YM 2003; Xu J 2004). Three trials showed that Tongxie Yaofang was significantly better regarding global improvement of symptoms than Gushen Changan plus oryzanol (RR 1.50, 99% CI 1.08 to 2.09), cisapride (RR 1.51, 99% CI 1.06 to 2.15), and sulfasalazine plus retardin and anisodamine (RR 1.16, 99% CI 1.00 to 1.35) respectively (Ye LJ 2000; Zhao LJ 2000; Fei YM 2003). Tongxie Yaofang was marginally better than nifedipine plus oryzanol (RR 1.45, 99% CI 0.90 to 2.36) in one trial (Yin WD 1998). There was no statistically significant difference between Tongxie Yaofang and cisapride plus loperamide (Gong SX 2001), nifedipine plus bifidobacteria and oryzanol (Xu J 2004), retardin (Zhuo YC 1996), or retardin plus cisapride respectively (Rui YR 2002).

Other comparisons that favoured herbal medicines for global improvement of symptoms:

- *Acanthopanax senticosi* injection (single herb extract) was significantly better than lactobacillus agent plus oryzanol (RR 3.93, 99% CI 2.15 to 7.17);
- Baile Ercha (extracts of two herbs) was significantly better

than SMZ-TMPco, propantheline, oryzanol, and chlordiazepoxide (RR 1.23, 99% CI 1.03 to 1.46);

- Buzhong Yiqi Tang (compound of herbs) was significantly better than oryzanol plus sodium cromoglycate (RR 1.41, 99% CI 1.22 to 1.63);

- Buzhong Yiqi Tang (compound of herbs) was significantly better than oryzanol plus bifidobacteria agent (RR 1.37, 99% CI 1.05 to 1.78);

- Chaicang Yuxiang Tang (compound of herbs) was significantly better than oryzanol (RR 1.85, 99% CI 1.05 to 3.24);

- Chaihu Shugan Yin (compound of herbs) was significantly better than cisapride (RR 1.62, 99% CI 1.11 to 2.38);

- Ganpi Lunzhi (compound of herbs) was significantly better than licheiformobigen (RR 1.74, 99% CI 1.25 to 2.43);

- Individualised herbal treatment was significantly better than pinaverium bromide (RR 1.60, 99% CI 1.04 to 2.47);

- Jiechang Kang (compound of herbs) was significantly better than oryzanol (RR 3.17, 99% CI 1.54 to 6.51);

- Lichang Tang (compound of herbs) was significantly better than licheiformobigen plus lacidophilir (RR 1.52, 99% CI 1.22 to 1.90);

- Pingheng Zhixie Jianpi (compound of herbs) was significantly better than nifedipine plus bifidobigen (RR 1.27, 99% CI 1.04 to 1.56);

- Pingyi Zhixie or Pingyi Tongbian Tang (compound of herbs) was significantly better than symptomatic treatment (RR 1.31, 99% CI 1.05 to 1.65);

- Sanbai San (compound of herbs) was significantly better than oryzanol plus berberine (RR 1.67, 99% CI 1.06 to 2.64);

- Senna leaf (single herb) was significantly better than cisapride (RR 1.47, 99% CI 1.12 to 1.93);

- Shugan Jianpi Tang (compound of herbs) was significantly better than oryzanol plus berberine (RR 1.50, 99% CI 1.09 to 2.07);

- Tiaogan Yichang Tang (compound of herbs) was significantly better than gentamycin plus berberine (RR 1.62, 99% CI 1.07 to 2.46);

- Xiaoyao San (compound of herbs) was significantly better than oryzanol plus loperamide (RR 1.37, 99% CI 1.07 to 1.74);

- Xuefu Zhuyu Tang (compound of herbs) was significantly better than oryzanol plus nifedipine (RR 1.57, 99% CI 1.20 to 2.04);

- Yichang San (compound of herbs) was significantly better than oryzanol plus berberine (RR 1.59, 99% CI 1.06 to 2.40);

- Yigan Fupi Huatan Quyu (compound of herbs) was significantly better than oryzanol plus nifedipine (RR 1.52, 99% CI 1.08 to 2.13);

- Yiji Tiaochang Tang (compound of herbs) was significantly better than doxepin plus nifedipine (RR 1.30, 99% CI 1.11 to 1.53).

There was no significant difference between herbal medicine and compared interventions among the following comparisons for the global improvement of symptoms:

- Anshen Shugan Tang (compound of herbs) versus Smecta;

- Ayurvedic preparation (two herbs) versus clidinium bromide plus

chlordiazepoxide and Isaphaghulla;

- Banxia Xiexin Tang Jiawei (compound of herbs) versus nifedipine;

- Chaimei Jiangshao Tang (compound of herbs) versus oryzanol plus nifedipine;

- Geqinshu Jiangshuocao (compound of herbs) versus Smecta plus vitamin B1;

- Gushen Changan (compound of herbs) versus nifedipine plus bifidobigen;

- Huanchang Tang (compound of herbs) versus oryzanol plus anisodamine;

- Huatan Liqi Tiaofu Tang (compound of herbs) versus Smecta;

- Huoxiang Zhengqi (compound of herbs) versus anisodamine;

- Jianpi Shugan Tang (compound of herbs) versus diazepam plus propantheline;

- Jianzhong Lichang Tang (compound of herbs) versus cisapride;

- Liqi Anchang Tang plus Jiechang Ning (compound of herbs) versus nifedipine plus hydrocortisone;

- Lizhong Tang (compound of herbs) versus sodium cromoglycate plus diazepam and vitamin B1;

- Pinggan Jianpi recipe (compound of herbs) versus diphenoxylate;

- Sanhuang Tang (compound of herbs) versus furazolidone plus Retardin;

- Shenling Baishu San (compound of herbs) versus loperamide;

- Shuchang Wan (compound of herbs) versus oryzanol plus nifedipine;

- Shugan Jianpi recipe (compound of herbs) versus diphenoxylate;

- Shugan Renchang recipe (compound of herbs) versus cisapride;

- Shugan Jianpi recipe versus cisapride;

- Sijunzi Tang (compound of herbs) versus oryzanol plus vitamin B1;

- Sishen Tang (compound of herbs) versus mebeverine;

- Suyun Zhixie Tang (compound of herbs) versus retardin plus berberine and chlorpheniramine;

- Tiaogan Shipi recipe (compound of herbs) versus mebeverine;

- Xiangsha Liujunzi Tang (compound of herbs) versus diazepam plus propantheline and domperidone;

- Xianshi capsule (compound of herbs) versus mebeverine plus Smecta;

- Xuanfei Tiaoqi Tang (compound of herbs) versus cisapride plus oryzanol;

- Yichang Jian (compound of herbs) versus pinaverium bromide;

- Yigan Fupi recipe (compound of herbs) versus domperidone plus nifedipine and oryzanol;

- Yigan Fupi Tang (compound of herbs) versus symptomatic treatment;

- Yigan Fupi recipe plus Gushen Changan (compound of herbs) versus pinaverium bromide plus Smecta;

- Zhongyao Heji (compound of herbs) versus oryzanol plus nifedipine or cisapride.

Although patients assigned to Jianpi Shugan Tang experienced less abdominal pain compared to patients assigned to diazepam plus

proprantheline the difference was not statistically significant (Yu YQ 1997). Ayurvedic preparation was inferior to standard therapy for relief of abdominal pain (RR 0.51, 99% CI 0.32 to 0.79) (Yadav 1989). Tiogagan Shipi recipe was not significantly different from mebeverine for abdominal pain score (0-3 from no pain to severe pain) (Yan MX 2003). Xianshi capsule was significantly inferior to mebeverine plus Smecta (WMD 0.70, 99% CI 0.38 to 1.02) for abdominal pain score (Ye B 2002).

Ayurvedic preparation was significantly better than standard therapy (clidinium bromide, chlordiazepoxide and isaphaghulla) for relief of diarrhoea in diarrhoea-predominant IBS patients (RR 1.80, 99% CI 1.01 to 3.21) (Yadav 1989). However, standard therapy was marginally better than Ayurvedic preparation for relieving constipation (RR 0.53, 99% CI 0.25 to 1.12) (Yadav 1989). There was no significant difference between Chinese herbal medicine Changji Tai and pinaverium bromide for relief of diarrhoea (Shen Y 2003). Changji Tai significantly decreased bowel scoring system (BSS, 0 to 500 from no symptom to most severe symptom) compared with pinaverium bromide (WMD -49.91, 99% CI -84.64 to -15.18) (Shen Y 2003).

Three trials evaluated herbal medicines for their efficacy in preventing recurrent episodes of symptoms at 6-12 months follow up (Yadav 1989; Yu ZX 1991; Zhang XQ 2000). Baile Ercha capsule for 30 days treatment significantly reduced the number of patients with symptom recurrent episodes at 12 months follow up compared to SMZ-TMPco plus proprantheline and oryzanol (RR 0.49, 99% CI 0.28 to 0.87) (Yu ZX 1991). Treatment with Shenling Baishu San for 2-5 weeks significantly reduced the number of patients with symptom recurrent episodes at six months follow up compared with loperamide (RR 0.24, 99% CI 0.09 to 0.67) (Zhang XQ 2000). There was no statistically significant difference in relapse of symptom relief between Ayurvedic preparation and standard therapy (58% versus 74%) although there was a high rate of loss to follow up (34%) (Yadav 1989).

One trial reported a quality of life outcome using the SF-36 scale, and found no statistically significant difference in quality of life between Shunji Heji and colloidal bismuth tartrate (Zhou FS 2002).

Among 17 trials comparing herbal medicines with conventional medicines, 13 trials reported adverse events. There were no serious adverse events reported in the herb group. Few adverse events were reported among patients receiving conventional drugs. Three out of 25 patients treated with pinaverium bromide experienced worse abdominal pain, and four patients developed dizziness and nausea (Cai XH 2002). Two out of 15 patients taking pinaverium bromide developed mild bloating, and one patient had dry mouth (Shen Y 2003). Two patients experienced worse abdominal pain, and three patients developed dizziness and nausea when taking pinaverium bromide and Smecta (Chen H 2000). Four patients developed constipation while taking loperamide, but the constipation disappeared when the dosage was reduced (Zhang XQ 2000). Nine patients treated by clidinium bromide, chlordiazepoxide and

isaphaghulla developed adverse events including pyrosis in five patients, difficulty in micturition in one patient, and drowsiness in three patients. Two patients treated with Ayurvedic therapy developed drowsiness (Yadav 1989).

HERBAL MEDICINE PLUS ACTIVE DRUG VERSUS ACTIVE DRUG (Comparison 03)

Nine trials compared herbal medicines plus conventional medicine with conventional medicine alone and they reported global improvement of symptoms as an outcome (Xiang N 1996; Ba T 1997; Yang SX 1998; Gu XX 1999; Lin Y 1999; Huang JQ 2000; Zhao LJ 2000; Ye PS 2002; Sun X 2004). Six trials showed a statistically significant benefit in global improvement of symptoms for herbal medicine plus conventional treatment compared to conventional treatment alone.

The comparisons for global symptom improvement were:

- Changji Fang plus phenobarbital, belladonna and Smecta versus phenobarbital, belladonna and Smecta (RR 1.16, 99% CI 0.99 to 1.35) (Ye PS 2002);
- Mongolian medicine plus oryzanol and symptomatic treatment versus oryzanol and symptomatic treatment (RR 1.16, 99% CI 1.02 to 1.31) (Ba T 1997);
- Shuchang Wan plus nifedipine and oryzanol versus nifedipine and oryzanol (RR 1.98, 99% CI 1.01 to 3.87) (Gu XX 1999);
- Shugan Jianpi recipe plus nifedipine and doxepin versus nifedipine and doxepin (RR 1.29, 99% CI 0.97 to 1.71) (Lin Y 1999);
- Shugan Lipi recipe plus oryzanol and vitamin B1 versus oryzanol and vitamin B1 (RR 1.40, 99% CI 1.03 to 1.90) (Yang SX 1998);
- Tiaoli Ganpi recipe plus oryzanol versus oryzanol (RR 1.75, 99% CI 1.11 to 2.77) (Xiang N 1996);
- Tongxie Yaofang plus nifedipine versus nifedipine (RR 1.42, 99% CI 0.96 to 2.10) (Huang JQ 2000);
- Tongxie Yaofang plus sulfasalazine, retardin and anisodamine versus sulfasalazine, retardin and anisodamine (RR 1.18, 99% CI 1.02 to 1.36) (Zhao LJ 2000).

Modified Tongxie Yaofang plus clostridium butyricum reduced the mean number of daily defecation in diarrhoea-predominant IBS patients compared to clostridium butyricum (WMD -1.40, 99% CI -2.13 to -0.67) (Sun X 2004).

Two of the nine trials reported adverse events. In one trial a few patients treated with Tongxie Yaofang plus sulfasalazine, retardin and anisodamine developed nausea (Zhao LJ 2000). No adverse events were reported in patients receiving combination therapy of Tongxie Yaofang and clostridium butyricum compared to clostridium butyricum alone (Sun X 2004).

DISCUSSION

Seventy-five randomised trials were included in this review compared with only two randomised trials on herbal therapy identified in a systematic review published in 2003 (Spanier 2003). Ninety-

three percent of these trials were conducted in China and published in Chinese between 1991 and 2004, most of which were not indexed in MEDLINE. The current randomised trials show a huge heterogeneity among the tested individual herbal medicines and compared interventions. In this review, many of the trials show symptomatic benefit of herbal medicines in patients with IBS either compared with placebo or with conventional therapy. However, there is a lack of replicable evidence because no more than one trial compared the same herbal medicine and control treatment. Thus, the benefit of herbal treatment may not be conclusive. Furthermore the findings of this review should be interpreted with caution due to the small sample sizes and generally low methodological quality of the included studies.

Compared with placebo, standard Chinese herbal formula and individualised Chinese herbal medicine show improvement in BSS and global symptom improvement as rated by IBS patients and by gastroenterologists (Bensoussan 1998). The benefit from individualised herbal treatment was maintained at 14 weeks follow up after completion of treatment. Herbal preparations STW 5 and STW 5-II are effective in alleviating symptoms (Madisch 2004), and Tibetan herbal formula Padma Lax appears to be effective for symptom improvement in constipation predominant patients (Sallon 2002). The Chinese herbal medicine Tongxie Yaofang may offer global improvement of symptoms in diarrhoea-predominant patients (Zhao LJ 2000). Ayurvedic formula appears to be effective for global improvement of symptoms and in diarrhoea predominant IBS (Yadav 1989). The first three trials that were published in English are of high quality in terms of generation of allocation sequence, concealment of allocation, double blinding, and application of intention-to-treat analysis.

Sixty-five Chinese trials (87% of the included trials) compared herbal medicines with conventional therapy. Twenty-two of 65 trials reported a statistically significant improvement in global assessment of symptoms for patients treated with herbal medicine compared to conventional therapy. Most of the herbal medicines were not compared with placebo in randomised trials included in this review. Placebo-controlled trials are uncommon in China because most Chinese investigators believe that using a placebo in trials is unethical and the China State Drug Administration encourages using standard medicine as a control for new drug development. We are not at the position to comment on this, but we notice that the conventional medicines used as controls in the included studies were variable, and for some of these drugs the efficacy for treatment of IBS has not been well established. Current systematic review evidence shows that antidepressants are recommended for diarrhoea-predominant IBS patients with severe refractory symptoms, and loperamide can be recommended in patients with painless diarrhoea (Jailwala 2000; Talley 2003; Lesbros-Pantoflickov). Cisapride was previously used for treatment of constipation predominant IBS (Van Outryve 1991; Farup 1998). However, it was withdrawn from the market in the USA and Germany due to its

cardiac toxicity (Noor 1998). Meta-analysis shows that pinaverium bromide is ineffective and mebeverine is inconclusive for the treatment of IBS (Lesbros-Pantoflickov). Evidence from several double-blind, placebo-controlled trials showed inconsistent effects of probiotic preparations on symptoms or bowel habit in IBS. Therefore, there is not sufficient evidence to recommend probiotic agents for IBS treatment (Lesbros-Pantoflickov). Based on uncertainty in some controlled drugs evaluated in herbal trials of this review, the beneficial findings from herbal medicines are not conclusive.

Six randomised trials reported a unique benefit in global symptom improvement for combination therapy (herbal medicine and conventional drugs) compared to conventional drug monotherapy. However, small study sizes and methodological flaws limit our interpretation of the findings. Further large and rigorous trials are needed to confirm this promising treatment option.

The benefit evidence from this review is not convincing enough to warrant a clinical recommendation due to the following trial characteristics.

1. The majority of herbal preparations were prescribed by the investigators without information on quality control regarding the manufacturing process, and the formulae were usually tailored to individual patients based on differentiation of the patients 'syndrome'. Therefore, the quality control issue and the flexible choice of herbs make the interpretation of the findings more difficult.
2. There is a lack of both efficacy evidence for each individual herbal preparation and placebo controlled trials for the herbal treatment of IBS. For example, the most commonly tested Chinese herbal compound in this review, Tongxie Yaofang, showed promising effect. However, there is no placebo controlled evidence of the efficacy of Tongxie Yaofang. Furthermore, the findings are not consistent among the included trials, which may be caused by heterogenous comparator treatments. Considering the lack of blinded measurement of the subjective symptoms and a large placebo effect in IBS, we suggest that the positive findings need to be confirmed in placebo controlled trials.
3. Most of the trials reported end-of-treatment responses, and there is a lack of long-term follow-up data.
4. The criteria used to define IBS varied considerably among the included trials. About one fourth of the included trials used international criteria such as the Manning or Rome criteria. The other included studies used Chinese conference criteria or did not specify the diagnostic criteria used. This inconsistency in the application of diagnostic criteria may bias the evaluation of herbal medicine due to the heterogenous mix of participants in the included trials. The included trials may have included patients with other gastrointestinal diseases with symptoms that overlap with IBS (De Giorgio 2004).

This systematic review has several methodological limitations. First, most of the included trials suffer from inadequate quality

of randomisation. The trials provided insufficient information on how the random allocation was generated and concealed. Twenty of the included trials had a significantly skewed distribution of participants among compared groups which could not be explained. These trials are highly prone to selection bias. Second, very few trials used double blinding methods. The major treatment approach in IBS is to alleviate the symptoms, which is a subjective indicator and if the outcome assessment is not blinded, then performance bias and detection bias may be a problem (Schulz 1995; Moher 1998). Third, most of the included trials were small. Although some data analyses did not demonstrate a statistically significant difference between herbal medicines and conventional therapy, the results are likely to have been underpowered. Therefore, the analyses from the small trials may not establish with confidence that two interventions have equivalent effects (Pocock 1991). Fourth, the insufficient report of loss to follow up makes it impossible to explore potential bias on an intention to treat basis. This may be associated with exaggerated effects of the herbal interventions due to systematic errors (bias). Due to the above limitations, potential bias may occur in the selection of participants, administration of treatment, and assessment of outcomes. Methodologically less rigorous trials show significantly larger intervention effects than trials with more rigor (Schulz 1995; Moher 1998; Kjaergard 2001; Egger 2003). The trials identified in this review were mostly Chinese trials. Empirical study has shown that Chinese trials are significantly affected by publication bias (Vickers 1998). Accordingly, publication bias should be taken into consideration when interpreting the present findings.

Safety of herbal medicines in IBS

The herbal medicines evaluated in this review generally appear to be safe. However, we can not conclude on the safety of using herbal medicines in patients with IBS as adverse effects were not sufficiently reported in the included trials. In clinical trials beneficial and harmful effects should receive equal attention, and the recording and reporting of adverse effects should be improved in future trials.

Western herbal medicines are often standardised extracts of single herbs used for particular conditions. In comparison, Chinese herbal medicines are quite often composed of mixtures of up to 20 different herbs. Chinese herbal medicines are sometimes customised for each individual patient by practitioners based on the differentiation of the patients' 'symptoms'. Therefore, trial design, could be adapted to the 'individualised treatment' by stratification of practitioners or the pattern of the 'syndromes'. On the other hand, it is very important to investigate herbal medicines according to a set of criteria which include preparation consistent with description in the pharmacopoeia, chemical standardisation, biological assays, animal models, and clinical testing (Yuan 2000).

Future trials should improve the description of herbal medicines being tested, e.g., plant species, geographical origin, harvest season, preparation procedures and quality of the products.

AUTHORS' CONCLUSIONS

Implications for practice

Randomised, double-blind, placebo-controlled trials showed a benefit of several herbal preparations for improving symptoms of IBS. However, most of the trials comparing herbal medicines with conventional therapies do not offer convincing evidence to support the use of herbal medicines due to methodological flaws, heterogeneity in the definition of diagnostic criteria, and lack of placebo control and blinded measurement of subjective outcomes.

Implications for research

Further well-designed, randomised, double-blind, placebo-controlled trials are needed to evaluate herbal therapies in IBS. IBS treatment trials should use international diagnostic criteria (e.g. Rome II) to identify and recruit patients with IBS. Symptomatic outcomes should be measured blinded and using validated scales by both patients and gastroenterologist. Promising herbal therapies require confirmation of efficacy in more than one trial.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Ba T 1997

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.	
Participants	132 patients randomised to combined therapy group (n=66, M/F 28/38, mean age 36.5 years, range 15-53; 32 cases with constipation), or western medicine group (n=66, M/F 30/36, mean age 37.6 years, range 16-56; 28 cases with constipation). Diagnostic criteria: Chinese national conference. Type of IBS: mixture. Study setting: hospital based. Inclusion criteria: not specified. Exclusion criteria: not specified.	
Interventions	(1) Mongolian medicine: 8 different herbs were used; plus western medicines including oryzanol, nifedipine, cisapride or indomethacin, lacidophilin; both for 3 weeks (2) Western medicine alone: same regimens as above for 3 weeks	
Outcomes	Symptoms. Adverse events: not reported. Follow up: no.	
Notes	Study location: China.	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Bensoussan 1998

Methods	Generation of allocation sequence: unclear. Allocation concealment: sealed envelope. Blinding: adequate double blinding. Loss to follow up: yes, by intention-to-treat protocol. Pre-sample size estimation.	
Participants	116 patients randomised to standard group (n=43, M/F 0.65, mean age 47.6 years), placebo group (n=35, M/F 0.46, mean age 45 years), or individualised treatment group (n=38, M/F 0.52, mean age 47.4 years).	

Bensoussan 1998 (Continued)

	Diagnostic criteria: Rome criteria. Type of IBS: mixture. Study setting: hospital based. Inclusion criteria: 18-75 years with IBS. Exclusion criteria: specified.	
Interventions	(1) Standard Chinese herbal formulation: composed of 20 herbs (2) Individualised herbal medicine prescribed by 3 independent Chinese herbalists (3) Placebo designed to taste, smell, and look similar to a Chinese herb formula Patients in all 3 groups were required to take 5 capsules 3 times daily for 16 weeks	
Outcomes	Symptoms assessed by a Bowel Symptom Scale (BSS). Adverse events: reported. Follow up: 14 weeks after completion of treatment.	
Notes	Study location: Australia.	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Low risk	A - Adequate

Cai XH 2002

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.
Participants	51 patients (M/F 29/22, mean age 32.2 years, range 22-50) randomised to herbal therapy group (n=26), or western medicine group (n=25). Diagnostic criteria: not specified, but organic disorders were excluded by colonoscopy or barium enema. Type of IBS: not specified. Study setting: outpatients. Inclusion criteria: not specified. Exclusion criteria: not specified.
Interventions	(1) Herbal medicine: prescribed based on differentiation of symptoms, decoction 1 dosage daily; plus single herb external use on stomach for 60 minutes, 1-2 times daily; for 6 weeks (2) Pinaverium bromide: 50 mg, 3 times daily, for 6 weeks.
Outcomes	Symptoms. Adverse events: reported. Follow up: no.

Cai XH 2002 (Continued)

Notes	Study location: China.	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Chen H 2000

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.	
Participants	63 patients (M/F 28/35, mean age 43.3 years, range 20-60) randomised to herbal therapy group (n=33), or western medicine group (n=30). Diagnostic criteria: Chinese conference criteria. Type of IBS: diarrhoea-predominant. Study setting: outpatients. Inclusion criteria: not specified. Exclusion criteria: not specified.	
Interventions	(1) Yigan Fupi Tang: composed of 10 herbs, and modified based on differentiation of symptoms, decoction 1 dosage daily; plus Gushen Changan (another herbal medicine), 3 capsules 3 times daily; for 4 weeks (2) Pinaverium bromide: 50 mg, 3 times daily; plus Smecta, 1 bag 3 times daily; for 4 weeks	
Outcomes	Symptoms. Adverse events: reported. Follow up: no.	
Notes	Study location: China.	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Chen M 2001

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.
Participants	60 patients randomised to herbal group (n=30, M/F 12/18, mean age 34 years, range 15-58), or western medicine group (n=30, M/F 14/16, mean age 38 years, range 20-65). Diagnostic criteria: Rome criteria. Type of IBS: diarrhoea-predominant. Study setting: outpatients. Inclusion criteria: not specified. Exclusion criteria: dysentery, inflammatory bowel disease, or colon cancer
Interventions	(1) Yichang Jian: a practitioner-prescribed formula composed of 10 herbs, and modified based on differentiation of symptoms, decoction 1 dosage daily; for 4 weeks (2) Pinaverium bromide: 50 mg, 3 times daily; for 4 weeks.
Outcomes	Symptoms. Adverse events: not reported. Follow up: 3 months.
Notes	Study location: China.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Chen P 2001

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.
Participants	116 patients randomised to herbal group (n=58, M/F 28/30, mean age 32.8 years, range 18-47), or western medicine group (n=58, M/F 26/32, mean age 31.7 years, range 17-49). Diagnostic criteria: Rome criteria 1990. Type of IBS: diarrhoea-predominant. Study setting: hospital based. Inclusion criteria: not specified. Exclusion criteria: not specified.

Chen P 2001 (Continued)

Interventions	(1) Pingheng Zhixie decoction: a practitioner-prescribed formula composed of 5 herbs, 1 dosage daily; for 10 days (2) Nifedipine: 5 mg, 3 times daily; plus live bifidobacterium preparation; for 10 days	
Outcomes	Symptoms. Adverse events: not reported. Follow up: no.	
Notes	Study location: China.	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Chen YC 2000

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.	
Participants	105 patients (M/F 56/49, aged from 21-69 years) randomised to herbal group (n=58), or western medicine group (n=47). Diagnostic criteria: Chinese conference criteria. Type of IBS: mixture. Study setting: hospital based. Inclusion criteria: not specified. Exclusion criteria: organic disorders by faecal examinations and culture, barium enema or colonoscopy	
Interventions	(1) Shugan Jianpi recipe: a practitioner-prescribed formulation composed of 11 herbs, decoction, 1 dosage daily; for 4 weeks (2) Cisapride: 10 mg, 3 times daily; for patients with diarrhoea plus loperamide 2-4 mg, 2 times daily; for 4 weeks	
Outcomes	Symptoms and relapse. Adverse events: not reported. Follow up: 1 year.	
Notes	Study location: China.	
Risk of bias		

Chen YC 2000 (Continued)

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Chen YM 1999

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.
Participants	132 patients randomised to herbal group (n=78, M/F 27/51, mean age 39 years), or western medicine group (n=54, M/F 22/32, mean age 32 years). Diagnostic criteria: Chinese conference criteria. Type of IBS: mixture. Study setting: outpatients. Inclusion criteria: not specified. Exclusion criteria: not specified.
Interventions	(1) Pingyi Zhixie Tang or Pingyi Tongbian Tang (Ditan recipe): a practitioner-prescribed formulation composed of 12 herbs, modified based on differentiation of symptoms, 1 dose decoction daily; for 2 weeks (2) Conventional symptomatic treatment: no details on drugs; for 2 weeks
Outcomes	Symptoms, signs, and relapse. Adverse events: not reported. Follow up: 6 months.
Notes	Study location: China.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Chen ZJ 2002

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.
Participants	104 patients randomised to herbal group (n=52, M/F 28/24, aged from 39-62 years), or western medicine group (n=52, M/F 36/16, age not reported). Diagnostic criteria: Chinese criteria from textbook. Type of IBS: constipation-predominant. Study setting: outpatients. Inclusion criteria: not specified. Exclusion criteria: hepato-biliary disease and organic diseases by haematological, biochemical examinations and type B ultrasound and colonoscopy
Interventions	(1) Senna leaf: a single herb decoction, 6 g daily; plus fluoxetine daily, and clonazepam 1 tablet before bed; for 15 days (2) Fluoxetine daily, cisapride 5 mg, 3 times daily, and clonazepam 1 tablet before bed; for 15 days
Outcomes	Symptoms. Adverse events: not reported. Follow up: no.
Notes	Study location: China.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Cheng WJ 2000

Methods	Generation of allocation sequence: drawing number. Allocation concealment: inadequate. Blinding: unclear. Loss to follow up: not reported.
Participants	144 patients (M/F 68/76, mean age 41.6 years, range 23-72) randomised to herbal group (n=108), or western medicine group (n=36). Diagnostic criteria: Chinese conference criteria. Type of IBS: not specified. Study setting: outpatients and inpatients. Inclusion criteria: not specified. Exclusion criteria: not specified.

Cheng WJ 2000 (Continued)

Interventions	(1) Lizhong Tang: composed of 13 herbs and modified on symptoms; decoction 1 dosage daily; for 4 weeks (2) Sodium cromoglicate, 200 mg, 3 times daily; diazepam, 2.5 mg 3 times daily; vitamin B1 100 mg, 3 times daily; for diarrhoea more than 5 times/day, loperamide 4 mg 3 times daily; for 4 weeks	
Outcomes	Symptoms. Adverse events: not reported. Follow up: 3 months.	
Notes	Study location: China. There is a skewed distribution of participants between the two groups (3:1), for which author did not explain	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	C - Inadequate

Deng W 2000

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.	
Participants	150 patients randomised to herbal group (n=110, M/F 38/72, aged from 21-53 years), or western medicine group (n=40, M/F 16/24, aged from 20-55 years). Diagnostic criteria: Chinese conference criteria. Type of IBS: diarrhoea-predominant. Study setting: hospital based. Inclusion criteria: not specified. Exclusion criteria: dysentery, ulcerative colitis, or schistosomiasis diagnosed by colonoscopy, X-ray, faecal routine and culture	
Interventions	(1) Shugan Jianpi Tang: composed of 11 herbs, decoction 1 dosage daily; for 2 weeks (2) Nifedipine, 10 mg, 3 times daily; oryzanol 30 mg 3 times daily; berberine 300 mg 3 times daily; for 2 weeks	
Outcomes	Symptoms. Adverse events: not reported. Follow up: no.	

Deng W 2000 (Continued)

Notes	Study location: China. There is a skewed distribution of participants between the two groups (2.8:1), for which author did not explain	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Deng ZT 2002

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.	
Participants	62 patients randomised to herbal group (n=32, M/F 12/20, mean age 38 years, range 20-53), or control group (n=30, M/F 10/20, mean age 37 years, range 19-55). Diagnostic criteria: Chinese conference criteria. Type of IBS: not specified. Study setting: outpatients and inpatients. Inclusion criteria: not specified. Exclusion criteria: colitis or colon tumor diagnosed by colonoscopy or barium enema	
Interventions	(1) Huanchang Tang; practitioner-prescribed formulation composed of 10 herbs, decoction 1 dosage daily; for 3 weeks (for severe type up to 6 weeks) (2) Anisodamine, 10 mg, 2 times daily; oryzanol 20 mg 3 times daily; for 3 weeks (for severe type up to 6 weeks)	
Outcomes	Symptoms. Adverse events: reported. Follow up: 1 year.	
Notes	Study location: China.	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Du ZL 2002

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.
Participants	76 patients (M/F 46/30, mean age 41.8 years, range 23-71) randomised to herbal group (n=38), or control group (n=38). Diagnostic criteria: Rome criteria. Type of IBS: diarrhoea-predominant. Study setting: outpatients. Inclusion criteria: not specified. Exclusion criteria: not specified.
Interventions	(1) Gushen Changan: 0.8 g, 3 times daily; for 4 weeks. (2) Nifedipine, 10 mg, 3 times daily; plus Bifidobacterium preparation, 2 capsules, 2 times daily; for 4 weeks
Outcomes	Symptoms. Adverse events: reported. Follow up: no.
Notes	Study location: China.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Fei YM 2003

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.
Participants	189 patients randomised to herbal group (n=157, M/F 68/89, mean age 37.6 years, range 14-58), or control group (n=32, M/F 11/21, mean age 38.2 years, range 15-57). Diagnostic criteria: self-defined by investigators. Type of IBS: not specified. Study setting: outpatients. Inclusion criteria: not specified. Exclusion criteria: not specified.

Fei YM 2003 (Continued)

Interventions	(1) Tongxie Yaofang: composed of 6 herbs, modified based on symptoms, 1 dosage daily, decoction; 10 days for 1 course, for 1-3 courses (2) Gushen Changan capsule, 0.4 g, 3 times daily; plus oryzanol 30 mg, 3 times daily; for diarrhoea patients, Smecta granule 10 g, 3 times daily; for constipation, Marenwan 6 g, 3 times daily; 10 days for 1 course, for 1-3 courses	
Outcomes	Symptoms. Adverse events: not reported. Follow up: 1 year.	
Notes	Study location: China. There is a skewed distribution of participants between the two groups (5:1), for which author did not explain	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Ge W 2002

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.	
Participants	57 patients randomised to herbal group (n=36, M/F 16/20, mean age 38.6 years, range 21-54), or control group (n=21, M/F 9/12, mean age 41.2 years, range 18-61). Diagnostic criteria: Chinese conference criteria. Type of IBS: not specified. Study setting: outpatients. Inclusion criteria: not specified. Exclusion criteria: organic disorders through X-ray, endoscopy	
Interventions	(1) Xiangsha Liujunzi Tang: composed of 8 herbs, modified based on symptoms, decoction, 1 dosage daily; for 2 weeks (2) Diazepam, propantheline, domperidone; for 2 weeks.	
Outcomes	Symptoms and signs. Adverse events: reported. Follow up: no.	
Notes	Study location: China.	

<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Gong SX 2001

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.
Participants	96 patients randomised to herbal group (n=50, M/F 26/24, mean age 45 years, range 20-65), or control group (n=46, M/F 24/22, mean age 43 years, range 22-62). Diagnostic criteria: Chinese conference criteria. Type of IBS: not specified. Study setting: hospital based. Inclusion criteria: not specified. Exclusion criteria: organic disorders through X-ray barium enema and colonoscopy
Interventions	(1) Tongxie Yaofang: composed of 4 herbs, modified based on symptoms; 1 dosage decoction daily; for 4 weeks (2) Cisapride 10 mg 3 times daily; for patients with diarrhoea, loperamide 2-4 mg 2 times daily; for 4 weeks
Outcomes	Symptoms and relapse. Adverse events: not reported. Follow up: 1 year.
Notes	Study location: China.

<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Gu XX 1999

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.
Participants	68 patients (M/F 37/31; aged from 18-56 years) randomised to herbal group (n=30), western medicine (n=20), or combined therapy group (n=18). Diagnostic criteria: Chinese conference criteria. Type of IBS: not specified. Study setting: outpatients and inpatients. Inclusion criteria: not specified. Exclusion criteria: organic disorders.
Interventions	(1) Shuchang Wan: a practitioner-prescribed formulation composed of 10 herbs, modified based on symptoms; 1 dosage decoction daily; for 3 months (2) Nifedipine 5 mg 3 times daily; oryzanol 20 mg 3 times daily; for 3 months (3) Combined therapy of (1) and (2) for 3 months.
Outcomes	Symptoms. Adverse events: not reported. Follow up: 6 months.
Notes	Study location: China.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Hentschel 1996

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: double blind. Loss to follow up: not reported.
Participants	190 patients randomised to herbal groups (n=130) and placebo group (n=60). Diagnostic criteria: not reported. Type of IBS: not specified. Study setting: unclear. Inclusion criteria: not specified. Exclusion criteria: not specified.

Hentschel 1996 (Continued)

Interventions	(1) Fumaria officinalis (FO) 250 mg, orally; (2) Curcuma xanthorrhiza (CX) 200 mg, orally; (3) Ayurvedic medication: a combination of two phytotherapeutic agents (AY); (4) a traditional spagyric remedy; (5) placebo. All for 18 weeks.	
Outcomes	Symptoms and quality of life. Adverse events: not reported. Follow up: 1 year.	
Notes	Study location: not reported.	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Hong ZM 1998

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.	
Participants	286 patients randomised to herbal group (n=156, M/F 61/95; mean age 33.4 years, range 29-61), or western medicine (n=130, M/F 52/78; mean age 33.2 years). Diagnostic criteria: not specified. Type of IBS: not specified. Study setting: outpatients. Inclusion criteria: not specified. Exclusion criteria: not specified.	
Interventions	(1) Yiji Tiaochang Tang: a practitioner-prescribed formula composed of 10 herbs, modified based on symptoms; 1 dosage decoction daily; for 2 months (2) Doxepin 25 mg 3 times daily; plus nifedipine 10 mg 3 times daily; both for 2 months	
Outcomes	Symptoms, signs, and relapse. Adverse events: reported. Follow up: 1 year.	
Notes	Study location: China.	
Risk of bias		

Hong ZM 1998 (Continued)

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Hu TM 1991

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.
Participants	65 patients (M/F 41/24; aged from 20-50 years) randomised to herbal group (n=32), or control group (n=33). Diagnostic criteria: not specified. Type of IBS: diarrhoea-predominant. Study setting: inpatients. Inclusion criteria: not specified. Exclusion criteria: not specified.
Interventions	(1) Sanhuang Tang: a formula composed of 3 herbs; decoction for maintaining enema once daily; for 2 weeks (2) Furazolidone 100 mg 3 times daily; plus retardin 2 tablets 2 times daily; both for 2 weeks Some patients in both group repeated the treatment for another 2 weeks
Outcomes	Symptoms and signs. Adverse events: not reported. Follow up: no.
Notes	Study location: China.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Huang JQ 2000

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.	
Participants	60 patients randomised to herbal group (n=30, M/F 12/18; mean age 45 years), or western medicine (n=30, M/F 14/16; mean age 43 years). Diagnostic criteria: Chinese conference criteria. Type of IBS: mixture. Study setting: outpatients. Inclusion criteria: not specified. Exclusion criteria: not specified.	
Interventions	(1) Tongxie Yaofang: a formula composed of 4 herbs, modified based on symptoms; 1 dose decoction daily; plus nifedipine 10 mg 3 times daily; for 4 weeks (2) Nifedipine 10 mg 3 times daily; for 4 weeks.	
Outcomes	Symptoms. Adverse events: not reported. Follow up: no.	
Notes	Study location: China.	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Huang LS 2001

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.	
Participants	95 patients randomised to herbal group (n=49, M/F 16/33; mean age 30 years, range 12-68), or western medicine (n=46, M/F 17/29; mean age 29 years, range 13-70). Diagnostic criteria: Chinese conference criteria. Type of IBS: not specified. Study setting: hospital based. Inclusion criteria: not specified. Exclusion criteria: not specified.	

Huang LS 2001 (Continued)

Interventions	(1) Xiaoyao San: a formula composed of 8 herbs, modified based on symptoms; 1 dose decoction daily; for 9 days (2) Oryzanol 20 mg 3 times daily; plus loperamide 20 mg 3 times daily; for 9 days	
Outcomes	Symptoms. Adverse events: not reported. Follow up: no.	
Notes	Study location: China.	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Jiang CR 1998

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.	
Participants	108 patients randomised to herbal group (n=60, M/F 26/34; mean age 42.8 years), or western medicine (n=48, M/F 21/27; mean age 41.2 years). Diagnostic criteria: Chinese conference criteria. Type of IBS: diarrhoea-predominant. Study setting: outpatients. Inclusion criteria: not specified. Exclusion criteria: organic intestinal disorders through laboratory, barium enema, or colonoscopy examinations	
Interventions	(1) Chaimei Jiangshao Tang: a practitioner-prescribed formula composed of 9 herbs, modified based on symptoms; 1 dose decoction daily; for 1 month (2) Oryzanol 20 mg, nifedipine 10 mg; both 3 times daily; plus doxepin 12.5 mg for day time and 25 mg for night daily; for 1 month	
Outcomes	Symptoms. Adverse events: not reported. Follow up: no.	
Notes	Study location: China.	
Risk of bias		

Jiang CR 1998 (Continued)

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Lei CF 2000

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.
Participants	96 patients randomised to herbal group (n=48, M/F 28/20; mean age 38 years, range 21-65), or western medicine (n=48, M/F 26/22; mean age 39.5 years, range 23-68). Diagnostic criteria: Chinese conference criteria. Type of IBS: not specified. Study setting: outpatients and inpatients. Inclusion criteria: not specified. Exclusion criteria: not specified.
Interventions	(1) Huatan Liqi Tiaofu Tang: a practitioner-prescribed formula composed of 16 herbs, modified based on symptoms; 1 dose decoction daily; for 20 days (2) Smecta: 3 g, 3 times daily; for 20 days.
Outcomes	Symptoms. Adverse events: reported. Follow up: no.
Notes	Study location: China.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Li H 2002

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.
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Li H 2002 (Continued)

Participants	51 patients randomised to herbal group (n=31), or western medicine (n=20). No information on gender and age. Diagnostic criteria: Chinese criteria from textbook. Type of IBS: mixture. Study setting: clinic patients. Inclusion criteria: not specified. Exclusion criteria: systemic and other intestinal diseases through laboratory, ultrasound, fiber colonoscopy examinations	
Interventions	(1) Sijunzi Tang: a formula composed of 4 herbs; 1 dose decoction daily; for patients with anxiety or depression, fluoxetine 20 mg 3 times daily; for 4 weeks (2) Vitamin B1 20 mg, oryzanol 20 mg, 3 times daily; for patients with abdominal pain, anisodamine 10 mg 3 times daily; for 4 weeks	
Outcomes	Symptoms. Adverse events: not reported. Follow up: no.	
Notes	Study location: China.	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Li JH 2003

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: not used. Loss to follow up: not reported.	
Participants	77 patients (M/F: 35/42; mean age 38 years, range 19-61) randomised to herbal group (n=41), or control medicine (n=36). Diagnostic criteria: Rome criteria. Type of IBS: diarrhoea-predominant. Study setting: outpatients. Inclusion criteria: not specified. Exclusion criteria: systemic and other intestinal diseases through laboratory, fiber colonoscopy examinations	
Interventions	(1) Suyun Zhixie Tang: a practitioner-prescribed formula composed of 7 herbs, modified based on symptoms; 1 dose decoction daily divided into 2 times orally; 100 ml decoction for enema every night; for 15 days (2) Berberine 0.3 g, retardin 2 tab; chlorpheniramine, 3 times daily, orally; gentamycin	

Li JH 2003 (Continued)

	240,000 units, metronidazole 1 g, in 100 ml of 0.9% of NaCl for enema every night; for 15 days	
Outcomes	Symptoms. Adverse events: not reported. Follow up: 1 year.	
Notes	Study location: China.	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Li XM 2001

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.	
Participants	203 patients randomised to herbal group (n=125, M/F 53/72; aged from 21-61 years), or control group (n=78, M/F 37/41; aged from 20-59 years). Diagnostic criteria: Chinese conference criteria. Type of IBS: mixture. Study setting: outpatients. Inclusion criteria: not specified. Exclusion criteria: not specified.	
Interventions	(1) Lichang Tang: a practitioner-prescribed formula composed of 9 herbs, modified based on symptoms; 1 dose decoction daily; for 30 days (2) Licheiformobiogen 500 mg, lacidophilin 1.2 g, 3 times daily; for 30 days	
Outcomes	Symptoms. Adverse events: not reported. Follow up: 3 months.	
Notes	Study location: China. There is a skewed distribution of participants between the two groups (1.6:1), for which author did not explain	
Risk of bias		
Bias	Authors' judgement	Support for judgement

Li XM 2001 (Continued)

Allocation concealment (selection bias)	Unclear risk	B - Unclear
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Lin QL 2002

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.
Participants	65 patients randomised to herbal group (n=36, M/F 19/17; aged from 20-56 years), or control group (n=29, M/F 17/12; aged from 19-58 years). Diagnostic criteria: Chinese conference criteria. Type of IBS: constipation-predominant. Study setting: hospital based. Inclusion criteria: specified. Exclusion criteria: specified.
Interventions	(1) Xuanfei Tiaoqi Tang: a practitioner-prescribed formula composed of 10 herbs; 1 dose decoction daily; for 2 weeks (2) Cisapride 5 mg, oryzanol 30 mg, 3 times daily; for 2 weeks
Outcomes	Symptoms. Adverse events: not reported. Follow up: 1 month.
Notes	Study location: China.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Lin Y 1999

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.
Participants	108 patients (M/F 41/67; mean age 34.3 years, range 20-65) randomised to herbal group (n=63), or control group (n=45). Diagnostic criteria: Chinese conference criteria. Type of IBS: diarrhoea-predominant.

Lin Y 1999 (Continued)

	Study setting: hospital based. Inclusion criteria: not specified. Exclusion criteria: not specified.
Interventions	(1) Shugan Jianpi formula: a practitioner-prescribed formula composed of 11 herbs; 1 dose decoction daily; plus nifedipine 10 mg and doxepin 12.5 mg, 3 times daily; for 20 days (2) Nifedipine 10 mg and doxepin 12.5 mg, 3 times daily; for 20 days
Outcomes	Symptoms. Adverse events: not reported. Follow up: no.
Notes	Study location: China.
Risk of bias	
Bias	Authors' judgement Support for judgement
Allocation concealment (selection bias)	Unclear risk B - Unclear

Lin YZ 2001

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.
Participants	61 patients randomised to herbal group (n=39, M/F 15/24; mean age 41 years, range 18-69), or control group (n=22, M/F 9/13; mean age 42 years, range 19-66). Diagnostic criteria: Rome criteria. Type of IBS: not specified. Study setting: inpatients. Inclusion criteria: not specified. Exclusion criteria: not specified.
Interventions	(1) Sishen Tang: a formula composed of 6 herbs, modified based on symptoms; 1 dose decoction daily; for 4 weeks (2) Mebevenine 50 mg, 3 times daily; for 4 weeks.
Outcomes	Symptoms. Adverse events: not reported. Follow up: no.
Notes	Study location: China. There is a skewed distribution of participants between the two groups (1.8:1), for which

Lin YZ 2001 (Continued)

	author did not explain	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Liu J 2000

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.	
Participants	58 patients (M/F 25/33; aged from 18-69 years) randomised to herbal group (n=30), or control group (n=28). Diagnostic criteria: Chinese conference criteria. Type of IBS: not specified. Study setting: hospital based. Inclusion criteria: not specified. Exclusion criteria: not specified.	
Interventions	(1) Yigan Fupi: a formula composed of 11 herbs, modified based on symptoms; 1 dose decoction daily; for 4 weeks (2) Domperidone 10 mg, nifedipine 10 mg, and oryzanol 10 mg; all 3 times daily; for 4 weeks	
Outcomes	Symptoms. Adverse events: not reported. Follow up: no.	
Notes	Study location: China.	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Lu WH 2001

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.
Participants	130 patients randomised to herbal group (n=100, M/F 59/41; aged from 20-50 years), or control group (n=30, M/F 16/14; aged from 19-50 years). Diagnostic criteria: Chinese conference criteria. Type of IBS: diarrhoea-predominant. Study setting: hospital based. Inclusion criteria: not specified. Exclusion criteria: not specified.
Interventions	(1) Anshen Shugan Tang: a practitioner-prescribed formula composed of 8 herbs, modified based on symptoms; 1 dose decoction daily; for 6 weeks (2) Smecta 3 g, 3 times daily; for 6 weeks.
Outcomes	Symptoms. Adverse events: not reported. Follow up: 3 months.
Notes	Study location: China. There is a skewed distribution of participants between the two groups (3:1), for which author did not explain

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Lu ZZ 2002

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: double blinding reported, but no information was provided to explain how double blinding was implemented. The two compared interventions were different. Loss to follow up: not reported.
Participants	453 patients randomised to herbal group (n=303, M/F 100/203; mean age 43 years), or control group (n=150, M/F 49/101; mean age 42 years). Diagnostic criteria: not specified. Type of IBS: diarrhoea-predominant. Study setting: hospital based. Inclusion criteria: not specified.

Lu ZZ 2002 (Continued)

	Exclusion criteria: not specified.	
Interventions	(1) Buzhong Yiqi Tang: a formula composed of 8 herbs, modified based on symptoms; 1 dose decoction daily; for 20 days (2) Oryzanol 40 mg, sodium cromoglicate 500 mg, 3 times daily; for 21 days	
Outcomes	Symptoms and signs. Adverse events: not reported. Follow up: no.	
Notes	Study location: China. There is a skewed distribution of participants between the two groups (2:1), for which author did not explain	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Luo KQ 2000

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.	
Participants	90 patients randomised to herbal group (n=60, M/F 22/38; aged from 16-54 years), or control group (n=30, M/F 9/21; aged from 17-54 years). Diagnostic criteria: Chinese conference criteria. Type of IBS: diarrhoea-predominant. Study setting: hospital based. Inclusion criteria: not specified. Exclusion criteria: not specified.	
Interventions	(1) Chaicang Yuxiang Tang: a practitioner-prescribed formula composed of 7 herbs, modified based on symptoms; 1 dose decoction daily; for 6 weeks (2) Oryzanol 50 mg, 3 times daily; for 6 weeks.	
Outcomes	Symptoms. Adverse events: not reported. Follow up: 3 months.	
Notes	Study location: China. There is a skewed distribution of participants between the two groups (2:1), for which	

Luo KQ 2000 (Continued)

	author did not explain	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Luo WY 2003

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.	
Participants	60 patients randomised to herbal group (n=30, M/F 10/20; mean age 45.7 years, range 20-70), or control group (n=30, M/F 14/16; mean age 41.5 years, range 18-65 years). Diagnostic criteria: Chinese criteria from textbook. Type of IBS: constipation-predominant. Study setting: hospital based. Inclusion criteria: not specified. Exclusion criteria: intestinal organic disorders through faecal routine and culture, barium enema or colonoscopy	
Interventions	(1) Jianzhong Lichang Tang: a practitioner-prescribed formula composed of 12 herbs, modified based on symptoms; 1 dose decoction daily; for 15 days (2) Cisapride 10 mg, 3 times daily; for 15 days.	
Outcomes	Symptoms. Adverse events: not reported. Follow up: no.	
Notes	Study location: China.	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Madisch 2004

Methods	Multi-centre, placebo-controlled, four arms. Generation of allocation sequence: computer programme. Allocation concealment: sealed, coded envelope. Blinding: investigators and patients; similar appearance and taste of tested medications. Loss to follow up: number and reasons for loss to follow up were reported, and intention-to-treat principle was applied. Pre-sample size estimation.	
Participants	208 patients randomised to STW 5 group (n=51, M/F 16/35; mean age 43.6 years), STW 5-II group (n=52, M/F 22/30; mean age 49.2 years), BCT group (n=53, M/F 24/29; mean age 47.5 years), or placebo group (n=52, M/F 22/30; mean age 46.1 years). Diagnostic criteria: Rome-II criteria. Type of IBS: mixture. Study setting: clinic based. Inclusion criteria: specified. Exclusion criteria: structural lesions and other organic diseases through clinical evaluation, abdominal sonography, or colonoscopy	
Interventions	(1) Commercial herbal preparation STW 5 (nine plant extracts); (2) Research herbal preparation (STW 5-II), six plant extracts; (3) Bitter candytuft mono-extract (BCT); (4) Placebo. The above trial medication was taken 3 times daily (20 drops) for 4 weeks	
Outcomes	Symptoms including abdominal pain score and total symptom score Adverse events: reported. Follow up: no.	
Notes	Study location: Germany.	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Low risk	A - Adequate

Ren GX 2001

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.	
Participants	98 patients (M/F 62/36; aged from 28-68 years) randomised to herbal group (n=64), or control group (n=34).	

Ren GX 2001 (Continued)

	Diagnostic criteria: Chinese conference criteria. Type of IBS: diarrhoea-predominant. Study setting: hospital based. Inclusion criteria: not specified. Exclusion criteria: not specified.	
Interventions	(1) Yichang San: a formula composed of 9 herbs; 1 dose decoction daily; for 4 weeks (2) Berberine plus oryzanol, 3 times daily; for 4 weeks.	
Outcomes	Symptoms. Adverse events: not reported. Follow up: no.	
Notes	Study location: China. There is a skewed distribution of participants between the two groups (1.9:1), for which author did not explain	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Rui YR 2002

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.
Participants	50 patients randomised to herbal group (n=28, M/F 12/16; mean age 64 years, range 58-72), or control group (n=22, M/F 10/12; mean age 65 years, range 57-74). Diagnostic criteria: Chinese conference criteria. Type of IBS: diarrhoea-predominant. Study setting: hospital based. Inclusion criteria: not specified. Exclusion criteria: not specified.
Interventions	(1) Tongxie Yaofang: a formula composed of 7 herbs, modified based on symptoms; 1 dose decoction daily; for 8 weeks (2) Retardin 0.2 g, plus cisapride 10 mg, 3 times daily; for 8 weeks
Outcomes	Symptoms. Adverse events: not reported. Follow up: no.

Rui YR 2002 (Continued)

Notes	Study location: China.	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Sallon 2002

Methods	Double-blind, placebo-controlled. Generation of allocation sequence: computer programme. Allocation concealment: central control. Blinding: investigators and patients; identical placebo. Loss to follow up: number and reasons of withdrawn patients were reported, and intention-to-treat principle was applied. Pre-sample size estimation.	
Participants	80 patients randomised to herbal group (n=42, M/F 12/30; mean age 47.9 years), or placebo group (n=38, M/F 10/28; mean age 46.3 years). Diagnostic criteria: Rome I criteria. Type of IBS: constipation-predominant. Study setting: hospital based. Inclusion criteria: specified. Exclusion criteria: specified.	
Interventions	(1) Tibetan herbal medicine Padma Lax: a formula composed of 15 herbs; 2 capsules/day; for 12 weeks (2) Placebo 2 capsules/day; for 12 weeks.	
Outcomes	Symptoms including number and consistency of bowel movements, abdominal pain, and overall response to the therapy Adverse events: reported. Follow up: no.	
Notes	Study location: Israel.	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Low risk	A - Adequate

Shen Y 2003

Methods	Generation of allocation sequence: block randomisation using random number table. Allocation concealment: unclear. Blinding: unblinded. Loss to follow up: not reported.
Participants	45 patients randomised to herbal group (n=30, M/F 17/13; mean age 41 years), or control group (n=15, M/F 9/6; mean age 42 years). Diagnostic criteria: Rome criteria. Type of IBS: diarrhoea-predominant. Study setting: hospital based. Inclusion criteria: diarrhoea IBS, age 18-60 years, excluded from organic disorders. Exclusion criteria: other type of IBS, organic disorders.
Interventions	(1) Changjitai: a formula of 6 herbs; 1 dose decoction daily; for 8 weeks (2) Pinaverium bromide 50 mg, 3 times daily; for 8 weeks.
Outcomes	Symptoms (measured by scoring system, and defecation state questionnaire), Adverse effects. Follow up: no.
Notes	Study location: China.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Sun X 2004

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.
Participants	60 patients (M/F 36/24; mean age 34 years, range 25-56) randomised to integrative group, or control group). Diagnostic criteria: Rome II criteria. Type of IBS: diarrhoea-predominant. Study setting: hospital based. Inclusion criteria: diarrhoea IBS excluded from organic disorders. Exclusion criteria: not specified.
Interventions	(1) Tongxie Yaofang: modified according to TCM symptoms; 1 dose decoction daily; clostridium butyricum , 2 capsules, 3 times daily; both for 4 weeks

Sun X 2004 (Continued)

	(2) Clostridium butyricum 2 capsules, 3 times daily; for 4 weeks	
Outcomes	Symptoms by counting daily number of defecation. Adverse events: reported. Follow up: no.	
Notes	Study location: China.	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Sun YS 1996

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.	
Participants	78 patients (M/F 45/33; aged from 18-56 years) randomised to herbal group (n=48), or control group (n=30). Diagnostic criteria: Chinese conference criteria. Type of IBS: mixture. Study setting: outpatients and inpatients. Inclusion criteria: not specified. Exclusion criteria: not specified.	
Interventions	(1) Huoxiang Zhengqi capsule: a patent formula of herbs; 6 g, 3 times daily; for 3 weeks (2) Anisodamine 10 mg, 3 times daily; for 3 weeks.	
Outcomes	Symptoms. Adverse events: not reported. Follow up: no.	
Notes	Study location: China.	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Tong ZY 1998

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.
Participants	86 patients randomised to herbal group (n=56, M/F 32/24; mean age 46.7 years, range 28-68), or control group (n=30, M/F 22/8; mean age 51.3 years, range 30-72). Diagnostic criteria: Chinese conference criteria. Type of IBS: mixture. Study setting: hospital based. Inclusion criteria: not specified. Exclusion criteria: not specified.
Interventions	(1) Sanbai San: a formula composed of 7 herbs; 1 dose decoction daily; for 4 weeks (2) Berberine 0.3 g, plus oryzanol 10 mg, 3 times daily; for 4 weeks
Outcomes	Symptoms. Adverse events: not reported. Follow up: no.
Notes	Study location: China. There is a skewed distribution of participants between the two groups (1.9:1), for which author did not explain

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Wang JF 2000

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.
Participants	66 patients randomised to herbal group (n=36, M/F 13/23; mean age 36.7 years, range 26-56), or control group (n=30, M/F 11/19; mean age 35.4 years, range 25-55). Diagnostic criteria: Chinese conference criteria. Type of IBS: mixture. Study setting: hospital based. Inclusion criteria: not specified. Exclusion criteria: not specified.

Wang JF 2000 (Continued)

Interventions	(1) Yigan Fupi Huatan Quyu: a formula composed of 10 herbs, modified based on symptoms; 1 dose decoction daily; for 4 weeks (2) Oryzanol 30 mg, nifedipine 10 mg, 3 times daily; for 4 weeks	
Outcomes	Symptoms. Adverse events: not reported. Follow up: 6 months.	
Notes	Study location: China.	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Wang JZ 1996

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.	
Participants	89 patients randomised to herbal group (n=59, M/F 37/22; mean age 36.8 years, range 22-51), or control group (n=30, M/F 19/11; mean age 37.4 years, range 20-52). Diagnostic criteria: Chinese conference criteria. Type of IBS: diarrhoea-predominant. Study setting: hospital based. Inclusion criteria: specified. Exclusion criteria: not specified.	
Interventions	(1) Shugan Jianpi Fang: a practitioner-prescribed formula composed of 12 herbs; 1 dose decoction daily; for 20 days (2) Retardin 2 tablets, 3 times daily; for 20 days.	
Outcomes	Symptoms. Adverse events: not reported. Follow up: no.	
Notes	Study location: China. There is a skewed distribution of participants between the two groups (2:1), for which author did not explain	
Risk of bias		

Wang JZ 1996 (Continued)

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Wang ZH 2000

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.
Participants	96 patients randomised to herbal group (n=48, M/F 21/27; mean age 38 years, range 28-62), or control group (n=48, M/F 26/22; mean age 39.5 years, range 27-64). Diagnostic criteria: Chinese conference criteria. Type of IBS: not specified. Study setting: outpatients and inpatients. Inclusion criteria: not specified. Exclusion criteria: specified.
Interventions	(1) Geqinshu Jiangshuocao Tang: a practitioner-prescribed formula composed of 6 herbs, modified based on symptoms; 1 dose decoction daily; for 20 days (2) Smecta 3 g, vitamin B1 100 mg, 3 times daily; for 20 days
Outcomes	Symptoms. Adverse events: reported. Follow up: 3 months.
Notes	Study location: China.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Xiang N 1996

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.
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Xiang N 1996 (Continued)

Participants	61 patients randomised to herbal group (n=31, M/F 15/16; mean age 42 years, range 25-65), or control group (n=30, M/F 13/17; mean age 46 years, range 22-68). Diagnostic criteria: Chinese conference criteria. Type of IBS: mixture. Study setting: hospital based. Inclusion criteria: not specified. Exclusion criteria: not specified.	
Interventions	(1) Tiaoli Ganpi recipe: a formula composed of 9 herbs; 1 dose decoction daily; plus oryzanol 30 mg, 3 times daily; for 10-30 days (average 15 days) (2) Oryzanol 30 mg, 3 times daily; for diarrhoea, loperamide 1-2 capsules, 2 times daily; for constipation, phenolphthalein 2-3 tablets, 2 times daily; for 14-35 days (average 28 days)	
Outcomes	Symptoms. Adverse events: not reported. Follow up: 1 year.	
Notes	Study location: China.	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Xie YD 2001

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.	
Participants	100 patients randomised to herbal group (n=64, M/F 24/40; mean age 39.2 years, range 22-65), or control group (n=36, M/F 14/22; mean age 40.1 years, range 25-68). Diagnostic criteria: Chinese conference criteria. Type of IBS: mixture. Study setting: outpatients and inpatients. Inclusion criteria: not specified. Exclusion criteria: not specified.	
Interventions	(1) Yigan Fupi Tang: a formula prescribed by practitioner, composed of 9 herbs, modified based on symptoms; for 30 days (2) Symptomatic therapy such as antispasmodics; for 30 days.	

Xie YD 2001 (Continued)

Outcomes	Symptoms. Adverse events: not reported. Follow up: 1 year.	
Notes	Study location: China.	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Xin XY 2000

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.	
Participants	80 patients randomised to herbal group (n=53, M/F 33/20; mean age 38.5 years, range 21-68), or control group (n=27, M/F 13/14; mean age 36.4 years, range 19-67). Diagnostic criteria: Chinese conference criteria. Type of IBS: not specified. Study setting: hospital based. Inclusion criteria: not specified. Exclusion criteria: not specified.	
Interventions	(1) Tiaogan Yichang Tang: a formula prescribed by practitioner, composed of 15 herbs, modified based on symptoms; 1 dose daily; for 4 weeks. (2) Gentamycin 80,000 U, berberine 0.3 g, daily; for patients with abdominal pain, anisodamine 10 mg, 3 times daily; for patients with constipation, phenolphthalein; for 4 weeks	
Outcomes	Symptoms. Adverse events: not reported. Follow up: 6 months.	
Notes	Study location: China. There is a skewed distribution of participants between the two groups (2:1), for which author did not explain	
Risk of bias		
Bias	Authors' judgement	Support for judgement

Xin XY 2000 (Continued)

Allocation concealment (selection bias)	Unclear risk	B - Unclear
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Xu HQ 2003

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.
Participants	65 patients randomised to herbal group (n=36, M/F 20/16; mean age 36.8 years, range 20-66), or control group (n=29, M/F 14/15; mean age 36.3 years, range 18-65). Diagnostic criteria: Chinese conference criteria. Type of IBS: diarrhoea-predominant. Study setting: outpatients. Inclusion criteria: not specified. Exclusion criteria: organic disease or hepato-biliary diseases through X-ray barium enema, colonoscopy, or ultrasound examination
Interventions	(1) Xiaoyao San: a formula composed of 7 herbs, modified based on symptoms; 1 dose daily; for 30 days. (2) Nifedipine 10 mg, oryzanol 60 mg, 3 times daily; for 30 days
Outcomes	Symptoms. Adverse events: not reported. Follow up: 3 months.
Notes	Study location: China.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Xu J 2004

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.
Participants	148 patients randomised to herbal group (n=75, M/F 42/43; mean age 42.2 years, range 25-58), or control group (n=73, M/F 43/40; mean age 41.8 years, range 21-53). Diagnostic criteria: Rome II criteria.

Xu J 2004 (Continued)

	Type of IBS: not specified. Study setting: hospital based. Inclusion criteria: not specified. Exclusion criteria: not specified.	
Interventions	(1) Tongxie Yaofang: a formula composed of 4 herbs, modified based on symptoms; 1 dose decoction daily; for 4 weeks. (2) Nifedipine 100 mg, Bifico (triple viable biogen) 3 tablets, plus oryzanol 50 mg, 3 times daily; for 4 weeks	
Outcomes	Symptoms and relapse. Adverse events: not reported. Follow up: 4 weeks after completion of treatment.	
Notes	Study location: China.	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Xu PH 1999

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.
Participants	58 patients randomised to herbal group (n=38, M/F 22/16; aged from 18-53 years), or control group (n=20, M/F 13/7; aged from 17-53 years). Diagnostic criteria: Chinese conference criteria. Type of IBS: diarrhoea-predominant. Study setting: hospital based. Inclusion criteria: specified. Exclusion criteria: not specified.
Interventions	(1) Pinggan Jianpi: a formula composed of 13 herbs; 1 dose decoction daily; for 20 days (2) Retardin 2 tablets 2 times daily; for 20 days.
Outcomes	Symptoms. Adverse events: not reported. Follow up: no.

Xu PH 1999 (Continued)

Notes	Study location: China. There is a skewed distribution of participants between the two groups (1.9:1), for which author did not explain	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Xu XP 2002

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.	
Participants	96 patients (M/F 38/58; mean age 32.4 years, range 19-63) randomised to herbal group (n=54), or control group (n=42). Diagnostic criteria: self-defined criteria. Type of IBS: not specified. Study setting: hospital based. Inclusion criteria: not specified. Exclusion criteria: specified.	
Interventions	(1) Chaihu Shugan Yin: a formula composed of 7 herbs, modified based on symptoms; 1 dose decoction daily; for 4 weeks (2) Cisapride 5 mg 3 times daily; for 4 weeks.	
Outcomes	Symptoms. Adverse events: not reported. Follow up: no.	
Notes	Study location: China.	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Yadav 1989

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: double blinding, identical colour and appearance of drugs and coded as A, B, C. Loss to follow up: 42 out of 214 participants were lost to follow up. Intention-to-treat analysis: no.	
Participants	169 patients (M/F 147/22; mean age 28 years, range 13-55); Ayurvedic group (n=57), standard group (n=60), or placebo group (n=52). Diagnostic criteria: from literature (Sandler 1984). Type of IBS: 5 categories: pain with predominant diarrhoea, pain with alternate diarrhoea and constipation, pain with predominant constipation, pain with predominant gaseousness, and painless diarrhoea. Study setting: clinic (gastroenterology department). Inclusion criteria: chronic (over 1 yr) large bowel symptoms, excluded organic GI and parasitic infestations, aged 10-60 years. Exclusion criteria: not specified.	
Interventions	(1) Ayurvedic preparation (a formula of two herbs): 6 g orally, three times daily for 6 weeks (2) Standard therapy: clidinium bromide, chlordiazepoxide and isaphaghulla; 6 g orally three times daily; for 6 weeks (3) Placebo, matched with tested drugs, for 6 weeks.	
Outcomes	Symptoms and relapse. Adverse events: yes. Follow up: median 8 months (6-14).	
Notes	Study location: India. 67 of 101 patients who had good or satisfactory response completed follow up. The rate of loss to follow up was 34%	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Yan MX 2003

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.	
Participants	58 patients randomised to herbal group (n=30, M/F 14/16; mean age 37.4 years, range 27-57), or control group (n=28, M/F 13/15; mean age 38.3 years, range 25-59).	

	Diagnostic criteria: Rome II criteria. Type of IBS: not specified. Study setting: hospital based. Inclusion criteria: specified. Exclusion criteria: specified.	
Interventions	(1) Tiaogan Shipi recipe: a practitioner-prescribed formula composed of 7 herbs; 1 dose decoction daily; for 4 weeks (2) Pinaverium 50 mg 3 times daily; for 4 weeks.	
Outcomes	Symptoms (scores of symptoms and pain). Adverse events: not reported. Follow up: no.	
Notes	Study location: China.	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Yang SX 1998

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.
Participants	70 patients (M/F 30/40; aged from 17-65 years) randomised to herbal group (n=42), or control group (n=28). Diagnostic criteria: Chinese conference criteria. Type of IBS: not specified. Study setting: outpatients. Inclusion criteria: not specified. Exclusion criteria: not specified.
Interventions	(1) Shugan Lipi recipe: a practitioner-prescribed formula composed of 7 herbs, modified based on symptoms; 1 dose daily; plus oryzanol 30 mg, vitamin B1 20 mg, 3 times daily; for 4 weeks (2) Oryzanol 30 mg, vitamin B1 20 mg, 3 times daily; for 4 weeks
Outcomes	Symptoms. Adverse events: not reported. Follow up: 6 months.

Yang SX 1998 (Continued)

Notes	Study location: China.	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Ye B 2002

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.	
Participants	80 patients randomised to herbal group (n=40, M/F 18/22; mean age 36.2 years, range 20-55), or control group (n=40, M/F 19/21; mean age 38.1 years, range 19-60). Diagnostic criteria: Rome II criteria. Type of IBS: not specified. Study setting: hospital based. Inclusion criteria: specified. Exclusion criteria: specified.	
Interventions	(1) Xianshi capsule (Shugan Jianpi recipe): a practitioner-prescribed formula composed of herbs; 4 capsules, 3 times daily; for 4 weeks (2) Pinaverium bromide 50 mg, Smecta 1 bag, 3 times daily; for 4 weeks	
Outcomes	Symptoms. Adverse events: reported. Follow up: no.	
Notes	Study location: China.	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Ye LJ 2000

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unblinded. Loss to follow up: not reported.
Participants	126 patients randomised to herbal group (n=85, M/F 50/35; mean age 38 years, range 20-50), or control group (n=41, M/F 23/18; mean age 39 years, range 19-56). Diagnostic criteria: Chinese conference criteria. Type of IBS: not specified. Study setting: hospital based. Inclusion criteria: not specified. Exclusion criteria: not specified.
Interventions	(1) Tongxie Yaofang: a formula composed of 4 herbs; 1 dose decoction for enema use daily; for 14 days (2) Cisapride 5 mg, 3 times daily; for 14 days.
Outcomes	Symptoms. Adverse events: not reported. Follow up: no.
Notes	Study location: China. There is a skewed distribution of participants between two groups (2:1), for which author did not explain

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Ye PS 2002

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.
Participants	207 patients randomised to herbal group (n=120, M/F 52/68; mean age 40 years, range 24-58), or control group (n=87, M/F 40/47; mean age 38 years, range 21-56). Diagnostic criteria: Chinese conference criteria. Type of IBS: not specified. Study setting: outpatients and inpatients. Inclusion criteria: not specified. Exclusion criteria: not specified.

Ye PS 2002 (Continued)

Interventions	(1) Changji Fang: a practitioner-prescribed formula composed of 8 herbs, modified based on symptoms; 1 dose decoction daily; plus phenobarbital 15 mg, belladonna 10 ml, Smecta 3 g, 3 times daily; for 1 month (2) Phenobarbital 15 mg, belladonna 10 ml, Smecta 3 g, 3 times daily; for 1 month	
Outcomes	Symptoms. Adverse events: not reported. Follow up: no.	
Notes	Study location: China. There is a skewed distribution of participants between two groups (1.4:1), for which author did not explain	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Yin WD 1998

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.	
Participants	57 patients (M/F 26/31; aged from 19-76 years) randomised to herbal group (n=33), or control group (n=24). Diagnostic criteria: Chinese conference criteria. Type of IBS: mixture. Study setting: hospital based. Inclusion criteria: not specified. Exclusion criteria: not specified.	
Interventions	(1) Tongxie Yaofang: a formula composed of 4 herbs, modified based on symptoms; 1 dose decoction daily; for 4 weeks (2) Nifedipine 10 mg, oryzanol 30 mg, 3 times daily; for 4 weeks	
Outcomes	Symptoms. Adverse events: not reported. Follow up: no.	
Notes	Study location: China.	

Yin WD 1998 (Continued)

<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Yu YM 2000

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.
Participants	109 patients randomised to herbal group (n=65, M/F 38/27; mean age 33.5 years, range 21-70), or control group (n=44, M/F 24/20; mean age 34 years, range 20-68). Diagnostic criteria: Manning criteria. Type of IBS: not specified. Study setting: outpatients and inpatients. Inclusion criteria: not specified. Exclusion criteria: not specified.
Interventions	(1) Liqi Anchang Tang: a practitioner-prescribed formula composed of 12 herbs, modified based on symptoms; 1 dose decoction daily; plus Jiechang Ning, another herbal preparation for enema use, once daily; for 30 days (2) Nifedipine 20 mg, 3 times daily; plus hydrocortecoid 100 mg in 200 ml of warmed water for enema, once daily; for 30 days
Outcomes	Symptoms. Adverse events: not reported. Follow up: 6 months.
Notes	Study location: China.

<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Yu YQ 1997

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.	
Participants	76 patients (M/F 43/33; mean age 36.2 years, range 20-68) randomised to herbal group (n=46), or control group (n=30). Diagnostic criteria: Chinese conference criteria. Type of IBS: mixture. Study setting: hospital based. Inclusion criteria: not specified. Exclusion criteria: not specified.	
Interventions	(1) Jianpi Shugan Tang: a formula composed of 11 herbs, modified based on symptoms; 1 dose decoction daily; for 20 days (2) Diazepam 2.5 mg, propantheline 15 mg, 3 times daily; for patients with constipation, plus phenolphthalein 0.2 g; for patients with diarrhoea, albumin tannate 1 g, 3 times daily; for 20 days	
Outcomes	Symptoms. Adverse events: not reported. Follow up: no.	
Notes	Study location: China.	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Yu ZX 1991

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: number lost to follow up was reported, but intention-to-treat analysis not applied	
Participants	157 patients randomised to herbal group (n=102, M/F 69/33; mean age 32.8 years, range 14-74), or control group (n=55, M/F 31/24; mean age 28.5 years, range 13-60). Diagnostic criteria: Self-defined criteria. Type of IBS: not specified. Study setting: outpatients and inpatients. Inclusion criteria: not specified.	

	Exclusion criteria: not specified.	
Interventions	(1) Baile Ercha: a practitioner-prepared formula composed of 2 herbs; 5 capsules, 3 times daily; for 30 days (2) SMZ-TMP-co 1 g, propantheline 30 mg, oryzanol 20 mg, chlordiazepoxide 20 mg, plus subcarbonate 0.6 g; 3 times per day; for 30 days. 100 ml of 3% berberine plus 20 ml Novocaine for enema, one time per night before sleeping, for 30 days.	
Outcomes	Symptoms and relapse at 2 years follow up. Adverse events: not reported. Follow up: 1-2 years. 8.8% (9/102) in herb group and 7.2% (4/55) were lost to follow up	
Notes	Study location: China. There is a skewed distribution of participants between two groups (2:1), for which author did not explain	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Zeng BM 2002

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.	
Participants	98 patients randomised to herbal group (n=50, M/F 23/27; mean age 38 years, range 18-60), or control group (n=48, M/F 22/26; mean age 37.5 years, range 21-55). Diagnostic criteria: Rome criteria. Type of IBS: not specified. Study setting: outpatients. Inclusion criteria: not specified. Exclusion criteria: not specified.	
Interventions	(1) Ganpi Lunzhi: a practitioner-prescribed formula composed of 7 herbs; decoction, 1 dosage daily; for 45 days (2) Licheiformobiogen, 0.5 g, 3 times daily; for 45 days.	
Outcomes	Symptoms. Adverse events: not reported. Follow up: no.	

Zeng BM 2002 (Continued)

Notes	Study location: China.	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Zhang RZ 1996

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.	
Participants	130 patients randomised to herbal group (n=100, M/F 53/47; aged from 20-74 years), or control group (n=30, M/F 16/14; aged from 16-63 years). Diagnostic criteria: Chinese conference criteria. Type of IBS: mixture. Study setting: hospital based. Inclusion criteria: not specified. Exclusion criteria: specified.	
Interventions	(1) Jiechang Kang: a hospital-prepared formula composed of 11 herbs; 4-6 tablets, 3 times daily; for 14 days (2) Oryzanol 20 mg, 3 times daily; for 14 days.	
Outcomes	Symptoms. Adverse events: not reported. Follow up: no.	
Notes	Study location: China. There is a skewed distribution of participants between two groups (3:1), for which author did not explain	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Zhang T 2003

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.
Participants	62 patients (M/F 28/34; aged from 20-60 years) randomised to herbal group (n=42), or control group (n=20). Diagnostic criteria: Rome II criteria. Type of IBS: constipation-predominant. Study setting: outpatients. Inclusion criteria: not specified. Exclusion criteria: not specified.
Interventions	(1) Sukan Renchang recipe: a practitioner-prescribed formula composed of 8 herbs; decoction, 1 dose daily; for 4 weeks (2) Cisapride 10 mg, 3 times daily; for 4 weeks.
Outcomes	Symptoms. Adverse events: not reported. Follow up: no.
Notes	Study location: China. There is a skewed distribution of participants between two groups (2:1), for which author did not explain

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Zhang XQ 2000

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.
Participants	67 patients (M/F 30/37; mean age 46 years, range 28-72) randomised to herbal group (n=37), or control group (n=30). Diagnostic criteria: Rome criteria. Type of IBS: diarrhoea-predominant. Study setting: outpatients. Inclusion criteria: not specified. Exclusion criteria: not specified.

Zhang XQ 2000 (Continued)

Interventions	(1) Shenling Baishu San: a formula composed of 12 herbs, modified based on symptoms; 1 dose decoction daily; for 2-5 weeks (2) Loperamide 2 mg, daily; for 14 days.	
Outcomes	Symptoms and relapse at 6 months. Adverse events: reported. Follow up: 6 months.	
Notes	Study location: China.	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Zhang YG 2001

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.	
Participants	129 patients randomised to herbal group (n=65, M/F 40/25; mean age 41.2 years, range 19-68), or control group (n=64, M/F 38/26; mean age 42.2 years, range 20-65). Diagnostic criteria: Chinese conference criteria. Type of IBS: not specified. Study setting: hospital based. Inclusion criteria: not specified. Exclusion criteria: not specified.	
Interventions	(1) Xuefu Zhuyu Tang: a formula composed of 13 herbs, modified based on symptoms; 1 dose decoction daily; for 4 weeks (2) Nifedipine 10 mg, oryzanol 30 mg, 3 times daily; for 4 weeks	
Outcomes	Symptoms. Adverse events: not reported. Follow up: no.	
Notes	Study location: China.	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement

Zhang YG 2001 (Continued)

Allocation concealment (selection bias)	Unclear risk	B - Unclear
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Zhao LJ 2000

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.
Participants	233 patients (M/F 79/154; mean age 39 years, range 15-71) randomised to herbal group (n=37), western medicine (n=59), Combined therapy (n=76), or placebo group (n=30). Diagnostic criteria: Rome criteria. Type of IBS: diarrhoea-predominant. Study setting: health centre and clinic patients. Inclusion criteria: not specified. Exclusion criteria: not specified.
Interventions	(1) Tongxie Yaofang: a formula composed of 11 herbs, 1 more herb added for diarrhoea patients; 1 dose decoction daily; for 15 days (2) Sulfasalazine, 0.5 g, retardin 5 mg, anisodamine 5 mg, 3 times daily; for depressive patients, amitriptyline 25 mg, 1-2 times daily; for 15 days (3) Combined therapy: above (1) and (2), same regimens. (4) Placebo (starch), 0.5 g, 4 capsules, 3 times daily.
Outcomes	Symptoms. Adverse events: reported. Follow up: 12 months.
Notes	Study location: China. There are skewed distributions of participants among the 4 groups (37 vs 59 vs 76 vs 30), for which author did not explain

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Zhou FS 2002

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.
Participants	105 patients (no information on gender or age) randomised to herbal group (n=60), or control group (n=45). Diagnostic criteria: Rome II criteria. Type of IBS: not specified. Study setting: outpatients and inpatients. Inclusion criteria: not specified. Exclusion criteria: not specified.
Interventions	(1) Shunji Heji: a formula composed of 4 herbs; 25 ml, 3 times daily; for 4 weeks (2) Colloidal bismuth tartrate, 165 mg, 3 times daily; for 4 weeks
Outcomes	Quality of life and symptom scores. Adverse events: reported. Follow up: no.
Notes	Study location: China.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Zhou Q 2003

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: not used. Loss to follow up: not reported.
Participants	177 patients (M/F 82/95; mean age 41.5 years, range 16-81) randomised to herbal group (n=106), or western medicine (n=71). Diagnostic criteria: unspecified. Type of IBS: not specified. Study setting: outpatients. Inclusion criteria: not specified. Exclusion criteria: not specified.

Zhou Q 2003 (Continued)

Interventions	(1) Ciwujia (<i>Acanthopanax senticosi</i>) injection: a herbal extract; 60-80 ml in 500 ml of 5% glucose, intravenously daily; for 15 days as 1 course, use of 1-3 course with average of 2 courses (a lag of 5-7 days between courses) (2) Lactobacillus tablets plus oryzanol, no details for usage	
Outcomes	Symptom. Adverse events: not reported. Follow up: no.	
Notes	Study location: China. There is a skewed distribution of participants between the 2 groups (1.5:1), for which author did not explain	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Zhu WE 1997

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.	
Participants	57 patients (M/F 31/26; mean age 42.5 years, range 21-67) randomised to herbal group (n=37), or western medicine (n=20). Diagnostic criteria: Chinese conference criteria. Type of IBS: diarrhoea-predominant. Study setting: health care centre. Inclusion criteria: not specified. Exclusion criteria: not specified.	
Interventions	(1) Banxia Xiexin Tang: a formula composed of 11 herbs; 1 dose decoction daily; for 4 weeks (2) Nifedipine 10 mg, 3 times daily; for 4 weeks.	
Outcomes	Symptoms. Adverse events: not reported. Follow up: no.	
Notes	Study location: China.	

Zhu WE 1997 (Continued)

<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Zhu YQ 1996

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.
Participants	141 patients randomised to herbal group (n=89, M/F 38/51; mean age 36.3 years, range 17-62), or control group (n=52, M/F 24/28; mean age 35.4 years, range 14-61). Diagnostic criteria: Self-defined criteria. Type of IBS: not specified. Study setting: outpatients. Inclusion criteria: not specified. Exclusion criteria: not specified.
Interventions	(1) Buzhong Yiqi Tang modified: a formula composed of 7 herbs, modified based on symptoms; 1 dose decoction daily; for 4 weeks (2) Live Bifidobacterium preparation 2 tablets, 2 times daily; for 4 weeks
Outcomes	Symptoms. Adverse events: not reported. Follow up: no.
Notes	Study location: China. There is a skewed distribution of participants between the 2 groups (1.7:1), for which author did not explain

<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Zhuang YH 1998

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.	
Participants	58 patients randomised to herbal group (n=31, M/F 13/18; mean age 37.4 years), or control group (n=27, M/F 12/15; mean age 39.3 years). Diagnostic criteria: Chinese conference criteria. Type of IBS: not specified. Study setting: outpatients and inpatients. Inclusion criteria: not specified. Exclusion criteria: not specified.	
Interventions	(1) Zhongyao Heji (a formula composed of more than 4 herbs): 250 ml of the extract combined with 1 billion of bifidobacteria kept in refrigerator, 50 ml 2 times daily; for 4 weeks (2) Oryzanol 20 mg, nifedipine 10 mg for diarrhoea, or cisapride 5 mg for constipation; 3 times daily; for 4 weeks	
Outcomes	Symptoms. Adverse events: reported. Follow up: no.	
Notes	Study location: China.	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Zhuo YC 1996

Methods	Generation of allocation sequence: unclear. Allocation concealment: unclear. Blinding: unclear. Loss to follow up: not reported.	
Participants	50 patients randomised to herbal group (n=25, M/F 16/9; mean age 35 years, range 15-52), or control group (n=25, M/F 14/11; mean age 40 years, range 20-55). Diagnostic criteria: Chinese conference criteria. Type of IBS: not specified. Study setting: inpatients. Inclusion criteria: not specified. Exclusion criteria: not specified.	

Interventions	(1) Tongxie Yaofang: a formula composed of 4 herbs, modified based on symptoms; 1 dose decoction orally and enema daily; for 15 days (2) Retardin 2 tablets 3 times per day; for 15 days.	
Outcomes	Symptoms. Adverse events: not reported. Follow up: 1 year.	
Notes	Study location: China.	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

IBS: irritable bowel syndrome

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Cheng CH 2003	Randomised controlled trial comparing Chinese herbal preparation Changji Ning with another herbal medicine Bupi Yichang Wan in treatment of 21 patients with irritable bowel syndrome. The control treatment did not meet the inclusion criteria
Ding ML 1997	Randomised controlled trial testing herbal preparation in 2% procaine and hormone for enema plus herbal moxibustion comparing with oryzanol plus Smecta and floxacine in treatment of 68 patients with irritable bowel syndrome. The trial was excluded because the experimental intervention was confounded with different drugs
Holtmann 2003	Placebo-controlled, randomised, multicenter trial on Artichoke leaf extract in patients with functional dyspepsia
Hu ZL 2000	Quasi-randomised controlled trial testing herbal preparation Jianwei Yuyang Pian comparing with oryzanol plus live probiotics in treatment of 120 patients with irritable bowel syndrome
Huang SP 1990	Randomised, crossover trial comparing Chinese herbal preparation Tiaogan Fang with placebo in treatment of 30 patients with irritable bowel syndrome. The trial did not report outcome at the first stage of trial (before crossing over)
Jiang SG 2000	Quasi-randomised controlled trial comparing herbal preparation Xiao Chai Hu Tang with diazepam, vitamin K3, vitamin B1, and loperamide in treatment of 58 patients with irritable bowel syndrome

(Continued)

Li H 2002b	Randomised controlled trial comparing Chinese herbal preparation Shaoyao Tang with symptomatic treatment in treatment of 60 patients with irritable bowel syndrome. The treatment duration was not reported
Qin FL 1999	Randomised controlled trial comparing Chinese herbal preparation Tongxie Yaofang plus acupuncture and massage with medical treatment (atropine, retardin and imipramine) for treatment of 81 patients with irritable bowel syndrome. The acupuncture and massage were considered to be confounders to the herbal treatment
Yang GL 2002	Randomised controlled trial comparing Chinese herbal preparation Xiaohuixiang Yin with another herbal medicine Changwei Kang in treatment of 66 patients with irritable bowel syndrome. The control treatment did meet inclusion criteria
Zheng QZ 2003	Randomised controlled trial comparing Chinese herbal preparations with symptomatic treatment in treatment of 60 patients with irritable bowel syndrome. The treatment duration was not reported
Zheng XB 2003	Quasi-randomised controlled trial testing herbal preparation Zhishu Tang comparing with cisapride in treatment of 69 patients with constipation-predominant irritable bowel syndrome

DATA AND ANALYSES

Comparison 1. Herbal medicine versus placebo

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Global improvement of symptoms rated by patient	2		Risk Ratio (M-H, Fixed, 99% CI)	Subtotals only
1.1 Individualised Chinese herbal formulation	1	73	Risk Ratio (M-H, Fixed, 99% CI)	1.51 [0.69, 3.29]
1.2 Standard Chinese herbal formulation	1	78	Risk Ratio (M-H, Fixed, 99% CI)	2.15 [1.07, 4.32]
1.3 Tibetan herbal formula Padma Lax	1	61	Risk Ratio (M-H, Fixed, 99% CI)	6.35 [1.52, 26.57]
1.4 Tibetan herbal formula Padma Lax by intention-to-treat	1	80	Risk Ratio (M-H, Fixed, 99% CI)	7.24 [1.67, 31.42]
2 Global improvement of symptoms rated by gastroenterologist	4		Risk Ratio (M-H, Fixed, 99% CI)	Subtotals only
2.1 Ayurvedic preparation	1	109	Risk Ratio (M-H, Fixed, 99% CI)	1.99 [1.12, 3.51]
2.2 Bitter candytuft mono-extract	1	105	Risk Ratio (M-H, Fixed, 99% CI)	1.23 [0.68, 2.21]
2.3 STW 5	1	103	Risk Ratio (M-H, Fixed, 99% CI)	1.68 [1.00, 2.84]
2.4 STW 5-II	1	104	Risk Ratio (M-H, Fixed, 99% CI)	1.9 [1.15, 3.14]
2.5 Individualised Chinese herbal formulation	1	73	Risk Ratio (M-H, Fixed, 99% CI)	1.54 [0.62, 3.79]
2.6 Standard Chinese herbal formulation	1	78	Risk Ratio (M-H, Fixed, 99% CI)	2.62 [1.19, 5.77]
2.7 Tongxie Yaofang modified	1	98	Risk Ratio (M-H, Fixed, 99% CI)	2.96 [1.52, 5.75]
3 Passing stool on 6-7 days/week in patients with constipation	1		Risk Ratio (M-H, Fixed, 99% CI)	Subtotals only
3.1 Tibetan herbal formula Padma Lax	1	80	Risk Ratio (M-H, Fixed, 99% CI)	1.75 [1.02, 3.02]
4 Diarrhoea relief	1		Risk Ratio (M-H, Fixed, 99% CI)	Subtotals only
4.1 Ayurvedic preparation	1	36	Risk Ratio (M-H, Fixed, 99% CI)	2.30 [1.08, 4.92]
5 No effect of abdominal pain on daily activities in patients with constipation	1		Risk Ratio (M-H, Fixed, 99% CI)	Subtotals only
5.1 Tibetan herbal formula Padma Lax	1	80	Risk Ratio (M-H, Fixed, 99% CI)	1.89 [0.90, 4.00]
6 Absence of moderate or severe pain in patients with constipation	1		Risk Ratio (M-H, Fixed, 99% CI)	Subtotals only
6.1 Tibetan herbal formula Padma Lax	1	80	Risk Ratio (M-H, Fixed, 99% CI)	2.94 [1.24, 7.00]
7 Abdominal pain relief	1		Risk Ratio (M-H, Fixed, 99% CI)	Subtotals only
7.1 Ayurvedic preparation	1	92	Risk Ratio (M-H, Fixed, 99% CI)	1.48 [0.71, 3.08]

8	Constipation relief	1		Risk Ratio (M-H, Fixed, 99% CI)	Subtotals only
8.1	Ayurvedic preparation	1	31	Risk Ratio (M-H, Fixed, 99% CI)	1.24 [0.42, 3.72]
9	Stool passed times per week in patients with constipation-predominant IBS	1		Mean Difference (IV, Fixed, 99% CI)	Subtotals only
9.1	Tibetan herbal formula Padma Lax	1	80	Mean Difference (IV, Fixed, 99% CI)	1.0 [0.79, 1.21]
10	Abdominal pain effect on daily activities (score 0-3)	1		Mean Difference (IV, Fixed, 99% CI)	Subtotals only
10.1	Tibetan herbal formula Padma Lax	1	80	Mean Difference (IV, Fixed, 99% CI)	-0.9 [-1.05, -0.75]
11	Abdominal pain severity (score 1-3)	1		Mean Difference (IV, Fixed, 99% CI)	Subtotals only
11.1	Tibetan herbal formula Padma Lax	1	80	Mean Difference (IV, Fixed, 99% CI)	-0.40 [-0.49, -0.31]
12	Constipation score (0-10) rated by gastroenterologist	1		Mean Difference (IV, Fixed, 99% CI)	Subtotals only
12.1	Tibetan herbal formula Padma Lax	1	80	Mean Difference (IV, Fixed, 99% CI)	-2.1 [-2.34, -1.86]
13	Abdominal pain score (0-10) rated by gastroenterologist	1		Mean Difference (IV, Fixed, 99% CI)	Subtotals only
13.1	Tibetan herbal formula Padma Lax	1	80	Mean Difference (IV, Fixed, 99% CI)	-0.5 [-0.80, -0.20]
14	Bowel symptom scale (BSS) scores rated by patient	1		Mean Difference (IV, Fixed, 99% CI)	Subtotals only
14.1	Individualised Chinese herbal formulation (end of treatment)	1	61	Mean Difference (IV, Fixed, 99% CI)	-47.0 [-98.55, 4.55]
14.2	Individualised Chinese herbal formulation (14 weeks follow-up)	1	42	Mean Difference (IV, Fixed, 99% CI)	-56.30 [-120.80, 8.20]
14.3	Standard Chinese herbal formulation (end of treatment)	1	70	Mean Difference (IV, Fixed, 99% CI)	-43.90 [-92.16, 4.36]
14.4	Standard Chinese herbal formulation (14 weeks follow-up)	1	53	Mean Difference (IV, Fixed, 99% CI)	-23.10 [-87.56, 41.36]
15	Bowel symptom scale (BSS) scores rated by gastroenterologist	2		Mean Difference (IV, Fixed, 99% CI)	Subtotals only
15.1	Bitter candytuft mono-extract	1	105	Mean Difference (IV, Fixed, 99% CI)	-11.30 [-23.17, 0.57]
15.2	STW 5	1	103	Mean Difference (IV, Fixed, 99% CI)	-17.90 [-28.56, -7.24]
15.3	STW 5-II	1	104	Mean Difference (IV, Fixed, 99% CI)	-19.1 [-29.35, -8.85]
15.4	Individualised Chinese herbal formulation (end of treatment)	1	55	Mean Difference (IV, Fixed, 99% CI)	-46.80 [-106.07, 12.47]
15.5	Standard Chinese herbal formulation (end of treatment)	1	65	Mean Difference (IV, Fixed, 99% CI)	-76.30 [-125.45, -27.15]

Comparison 2. Herbal medicine versus conventional medicine

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Global improvement of symptoms	61		Risk Ratio (M-H, Fixed, 99% CI)	Subtotals only
1.1 Acanthopanax senticosi injection versus lactobacillus agent plus oryzanol	1	177	Risk Ratio (M-H, Fixed, 99% CI)	3.93 [2.15, 7.17]
1.2 Anshen Shugan Tang versus Smecta	1	130	Risk Ratio (M-H, Fixed, 99% CI)	1.27 [0.95, 1.70]
1.3 Ayurvedic preparation versus clidinium bromide plus chlordiazepoxide and Isaphaghulla	1	117	Risk Ratio (M-H, Fixed, 99% CI)	0.83 [0.61, 1.13]
1.4 Baile Ercha versus conventional medicine plus berberine	1	157	Risk Ratio (M-H, Fixed, 99% CI)	1.23 [1.03, 1.46]
1.5 Banxia Xiexin Tang Jiawei versus nifedipine	1	57	Risk Ratio (M-H, Fixed, 99% CI)	1.62 [0.94, 2.79]
1.6 Buzhong Yiqi Tang versus oryzanol plus sodium cromoglicate	1	453	Risk Ratio (M-H, Fixed, 99% CI)	1.41 [1.22, 1.63]
1.7 Buzhong Yiqi Tang versus bifidobacterium agent plus oryzanol	1	141	Risk Ratio (M-H, Fixed, 99% CI)	1.37 [1.05, 1.78]
1.8 Chaicang Yuxiang Tang versus oryzanol	1	90	Risk Ratio (M-H, Fixed, 99% CI)	1.85 [1.05, 3.24]
1.9 Chaihu Shugan Yin versus cisapride	1	96	Risk Ratio (M-H, Fixed, 99% CI)	1.62 [1.11, 2.38]
1.10 Chaimei Jiangshao Tang versus oryzanol plus nifedipine	1	108	Risk Ratio (M-H, Fixed, 99% CI)	1.13 [0.96, 1.34]
1.11 Ganpi Lunzhi recipe versus licheiformobigen	1	98	Risk Ratio (M-H, Fixed, 99% CI)	1.74 [1.25, 2.43]
1.12 Geqinshu Jiangshuocao Tang versus Smecta plus vitamin B1	1	97	Risk Ratio (M-H, Fixed, 99% CI)	1.22 [0.97, 1.52]
1.13 Gushen Changan versus nifedipine plus bifidobiogen	1	76	Risk Ratio (M-H, Fixed, 99% CI)	1.29 [0.98, 1.68]
1.14 Huanchang Tang versus anisodamine plus oryzanol	1	62	Risk Ratio (M-H, Fixed, 99% CI)	1.41 [0.99, 2.00]
1.15 Huatan Liqi Tiaofu Tang versus Smecta	1	96	Risk Ratio (M-H, Fixed, 99% CI)	1.24 [1.00, 1.54]
1.16 Huoxiang Zhengqi capsules versus anisodamine (654-2)	1	78	Risk Ratio (M-H, Fixed, 99% CI)	1.41 [0.97, 2.07]
1.17 Individualised herbal treatment versus pinaverium bromide	1	51	Risk Ratio (M-H, Fixed, 99% CI)	1.60 [1.04, 2.47]

1.18 Jianpi Shugan Tang versus diazepam plus propantheline	1	76	Risk Ratio (M-H, Fixed, 99% CI)	1.01 [0.70, 1.45]
1.19 Jianzhong Lichang Tang versus cisapride	1	60	Risk Ratio (M-H, Fixed, 99% CI)	1.29 [0.91, 1.82]
1.20 Jiechang Kang versus oryzanol	1	130	Risk Ratio (M-H, Fixed, 99% CI)	3.17 [1.54, 6.51]
1.21 Lichang Tang versus licheiformobiogen plus lacidophilin	1	203	Risk Ratio (M-H, Fixed, 99% CI)	1.52 [1.22, 1.90]
1.22 Liqi Anchang Tang plus Jiechang Ning versus nifedipine plus hydrocortisone	1	109	Risk Ratio (M-H, Fixed, 99% CI)	1.41 [0.97, 2.05]
1.23 Lizhong Tang versus sodium cromoglicate plus diazepam and vitamin B1	1	144	Risk Ratio (M-H, Fixed, 99% CI)	1.22 [0.98, 1.51]
1.24 Pinggan Jianpi recipe versus diphenoxylate	1	58	Risk Ratio (M-H, Fixed, 99% CI)	1.32 [0.89, 1.96]
1.25 Pingheng Zhixie Jianji versus nifedipine plus bifidobiogen	1	116	Risk Ratio (M-H, Fixed, 99% CI)	1.27 [1.04, 1.56]
1.26 Pingyi Zhixie or Pingyi Tongbian Tang versus routine symptomatic treatment	1	132	Risk Ratio (M-H, Fixed, 99% CI)	1.31 [1.05, 1.65]
1.27 Sanbai San versus berberine plus oryzanol	1	86	Risk Ratio (M-H, Fixed, 99% CI)	1.67 [1.06, 2.64]
1.28 Sanhuang Tang versus furazolidone plus retardin	1	65	Risk Ratio (M-H, Fixed, 99% CI)	1.33 [1.00, 1.77]
1.29 Senna leaf versus cisapride	1	104	Risk Ratio (M-H, Fixed, 99% CI)	1.47 [1.12, 1.93]
1.30 Shenling Baishu San versus loperamide	1	67	Risk Ratio (M-H, Fixed, 99% CI)	1.04 [0.90, 1.20]
1.31 Shuchang Wan versus nifedipine plus oryzanol	1	50	Risk Ratio (M-H, Fixed, 99% CI)	1.93 [0.99, 3.74]
1.32 Shugan Jianpi recipe versus diphenoxylate	1	89	Risk Ratio (M-H, Fixed, 99% CI)	1.76 [1.00, 3.11]
1.33 Shugan Jianpi recipe versus cisapride	1	105	Risk Ratio (M-H, Fixed, 99% CI)	1.05 [0.88, 1.25]
1.34 Shugan Jianpi Tang versus nifedipine plus oryzanol and berberine	1	150	Risk Ratio (M-H, Fixed, 99% CI)	1.50 [1.09, 2.07]
1.35 Sugan Renchang Recipe versus cisapride	1	62	Risk Ratio (M-H, Fixed, 99% CI)	1.43 [0.98, 2.09]
1.36 Sishen Tang versus mebevenine	1	61	Risk Ratio (M-H, Fixed, 99% CI)	1.04 [0.86, 1.27]
1.37 Sijunzi Tang versus vitamin B1 and oryzanol	1	51	Risk Ratio (M-H, Fixed, 99% CI)	1.49 [0.97, 2.29]
1.38 Suyun Zhixie Tang versus Retardin plus berberine and chlorpheniramine	1	77	Risk Ratio (M-H, Fixed, 99% CI)	1.13 [0.94, 1.36]

1.39 Tiaogan Shipi recipe versus mebeverine	1	58	Risk Ratio (M-H, Fixed, 99% CI)	1.10 [0.83, 1.44]
1.40 Tiaogan Yichang Tang versus gentamycin plus berberine	1	80	Risk Ratio (M-H, Fixed, 99% CI)	1.62 [1.07, 2.46]
1.41 Tongxie Yaofang versus cisapride plus loperamide	1	96	Risk Ratio (M-H, Fixed, 99% CI)	1.03 [0.87, 1.22]
1.42 Tongxie Yaofang versus Gushen Changan plus oryzanol	1	189	Risk Ratio (M-H, Fixed, 99% CI)	1.50 [1.08, 2.09]
1.43 Tongxie Yaofang versus cisapride	1	126	Risk Ratio (M-H, Fixed, 99% CI)	1.51 [1.06, 2.15]
1.44 Tongxie Yaofang versus nifedipine plus oryzanol	1	57	Risk Ratio (M-H, Fixed, 99% CI)	1.45 [0.90, 2.36]
1.45 Tongxie Yaofang versus nifedipine plus bifidobacteria and oryzanol	1	148	Risk Ratio (M-H, Fixed, 99% CI)	1.02 [0.86, 1.21]
1.46 Tongxie Yaofang versus retardin	1	50	Risk Ratio (M-H, Fixed, 99% CI)	1.28 [0.90, 1.82]
1.47 Tongxie Yaofang versus retardin or cisapride	1	50	Risk Ratio (M-H, Fixed, 99% CI)	1.31 [0.87, 1.98]
1.48 Tongxie Yaofang modified versus sulfasalazine plus retardin and anisodamine	1	127	Risk Ratio (M-H, Fixed, 99% CI)	1.16 [1.00, 1.35]
1.49 Xiangsha Liujunzi Tang versus diazepam plus propantheline and domperidone	1	57	Risk Ratio (M-H, Fixed, 99% CI)	1.28 [0.92, 1.76]
1.50 Xianshi capsule versus mebeverine plus Smecta	1	80	Risk Ratio (M-H, Fixed, 99% CI)	1.2 [0.91, 1.57]
1.51 Xiaoyao San versus oryzanol plus loperamide	1	95	Risk Ratio (M-H, Fixed, 99% CI)	1.37 [1.07, 1.74]
1.52 Xuanfei Tiaoqi Tang versus cisapride plus oryzanol	1	65	Risk Ratio (M-H, Fixed, 99% CI)	1.27 [0.92, 1.75]
1.53 Xuefu Zhuyu Tang versus nifedipine plus oryzanol	1	129	Risk Ratio (M-H, Fixed, 99% CI)	1.57 [1.20, 2.04]
1.54 Yichang Jian versus pinaverium bromide	1	60	Risk Ratio (M-H, Fixed, 99% CI)	1.08 [0.80, 1.46]
1.55 Yichang San versus berberine plus oryzanol	1	98	Risk Ratio (M-H, Fixed, 99% CI)	1.59 [1.06, 2.40]
1.56 Yigan Fupi Huatan Quyu versus oryzanol plus nifedipine	1	66	Risk Ratio (M-H, Fixed, 99% CI)	1.52 [0.97, 2.37]
1.57 Yigan Fupi recipe versus domperidone plus nifedipine and oryzanol	1	58	Risk Ratio (M-H, Fixed, 99% CI)	1.52 [0.96, 2.40]
1.58 Yigan Fupi Tang versus symptomatic treatment	1	100	Risk Ratio (M-H, Fixed, 99% CI)	1.25 [0.96, 1.62]
1.59 Yigan Fupi Tang plus Gushen Changan versus pinaverium bromide plus Smecta	1	63	Risk Ratio (M-H, Fixed, 99% CI)	1.28 [0.94, 1.74]

1.60 Yiji Tiaochang Tang versus doxepin plus nifedipine	1	286	Risk Ratio (M-H, Fixed, 99% CI)	1.30 [1.11, 1.53]
1.61 Zhongyao Heji plus bifidobacteria versus oryzanol plus nifedipine or cisapride	1	58	Risk Ratio (M-H, Fixed, 99% CI)	1.33 [0.87, 2.05]
2 Abdominal pain relief	2		Risk Ratio (M-H, Fixed, 99% CI)	Subtotals only
2.1 Jianpi Shugan Tang versus diazepam plus propantheline	1	67	Risk Ratio (M-H, Fixed, 99% CI)	1.22 [0.92, 1.62]
2.2 Ayurvedic preparation versus clidinium bromide plus chlordiazepoxide and Isaphaghulla	1	100	Risk Ratio (M-H, Fixed, 99% CI)	0.51 [0.32, 0.79]
3 Diarrhoea relief	2		Risk Ratio (M-H, Fixed, 99% CI)	Subtotals only
3.1 Ayurvedic preparation versus clidinium bromide plus chlordiazepoxide and Isaphaghulla	1	38	Risk Ratio (M-H, Fixed, 99% CI)	1.8 [1.01, 3.21]
3.2 Changji Tai versus pinaverium bromide	1	45	Risk Ratio (M-H, Fixed, 99% CI)	1.14 [0.72, 1.79]
4 Constipation relief	1		Risk Ratio (M-H, Fixed, 99% CI)	Subtotals only
4.1 Ayurvedic preparation versus clidinium bromide plus chlordiazepoxide and Isaphaghulla	1	32	Risk Ratio (M-H, Fixed, 99% CI)	0.53 [0.25, 1.12]
5 Recurrent episodes of symptoms	2		Risk Ratio (M-H, Fixed, 99% CI)	Subtotals only
5.1 Baile Ercha versus conventional medicine plus berberine at 12 months	1	143	Risk Ratio (M-H, Fixed, 99% CI)	0.49 [0.28, 0.87]
5.2 Shenling Baishu San versus loperamide at 6 months	1	67	Risk Ratio (M-H, Fixed, 99% CI)	0.24 [0.09, 0.67]
6 Bowel scoring system (BSS)	1		Mean Difference (IV, Fixed, 99% CI)	Subtotals only
6.1 Changji Tai versus pinaverium bromide	1	45	Mean Difference (IV, Fixed, 99% CI)	-49.91 [-84.64, -15.18]
7 Abdominal pain (0-3 score from no pain to most severe)	2		Mean Difference (IV, Fixed, 99% CI)	Subtotals only
7.1 Tiaogan Shipi recipe versus mebeverine	1	58	Mean Difference (IV, Fixed, 99% CI)	0.38 [-0.35, 1.11]
7.2 Xianshi capsule versus mebeverine plus Smecta	1	80	Mean Difference (IV, Fixed, 99% CI)	0.70 [0.38, 1.02]
8 Quality of life (SF-36 score)	1		Mean Difference (IV, Fixed, 99% CI)	Subtotals only
8.1 Shunji Heji versus colloidal bismuth tartrate	1	105	Mean Difference (IV, Fixed, 99% CI)	1.40 [-3.12, 5.92]

Comparison 3. Herbal medicine plus active drug versus active drug alone

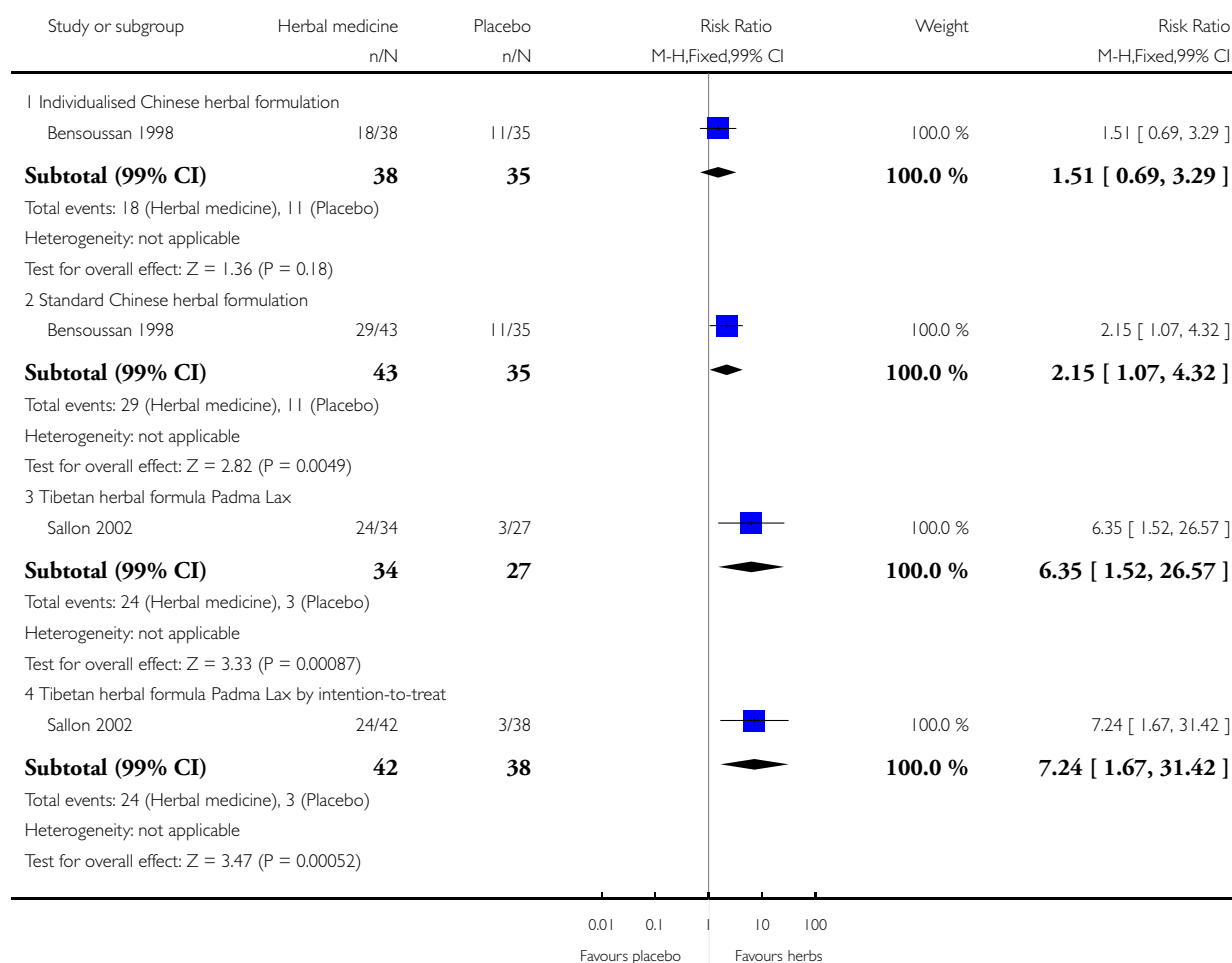
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Global improvement of symptoms	8		Risk Ratio (M-H, Fixed, 99% CI)	Subtotals only
1.1 Changji Fang + phenobarbital, belladonna and Smecta versus phenobarbital, belladonna and Smecta	1	207	Risk Ratio (M-H, Fixed, 99% CI)	1.16 [0.99, 1.35]
1.2 Mongolian medicine + active drugs versus active drugs	1	132	Risk Ratio (M-H, Fixed, 99% CI)	1.16 [1.01, 1.32]
1.3 Shuchang Wan + nifedipine and oryzanol versus nifedipine and oryzanol	1	38	Risk Ratio (M-H, Fixed, 99% CI)	1.98 [1.01, 3.87]
1.4 Shugan Jianpi recipe + nifedipine and doxepin versus nifedipine and doxepin	1	108	Risk Ratio (M-H, Fixed, 99% CI)	1.29 [0.97, 1.71]
1.5 Shugan Lipi recipe + oryzanol and vitamin B1 versus oryzanol and vitamin B1	1	70	Risk Ratio (M-H, Fixed, 99% CI)	1.40 [1.02, 1.91]
1.6 Tiaoli Ganpi recipe + oryzanol versus oryzanol	1	61	Risk Ratio (M-H, Fixed, 99% CI)	1.75 [1.11, 2.77]
1.7 Tongxie Yaofang + nifedipine versus nifedipine	1	60	Risk Ratio (M-H, Fixed, 99% CI)	1.42 [0.96, 2.10]
1.8 Tongxie Yaofang + sulfasalazine plus retardin and anisodamine versus sulfasalazine plus retardin and anisodam	1	135	Risk Ratio (M-H, Fixed, 99% CI)	1.18 [1.02, 1.37]
2 Daily defecation number of diarrhoea	1		Mean Difference (IV, Fixed, 99% CI)	Subtotals only
2.1 Tongxie Yaofang modified + clostridium butyricum versus clostridium butyricum	1	60	Mean Difference (IV, Fixed, 99% CI)	-1.4 [-2.13, -0.67]

Analysis 1.1. Comparison 1 Herbal medicine versus placebo, Outcome 1 Global improvement of symptoms rated by patient.

Review: Herbal medicines for treatment of irritable bowel syndrome

Comparison: 1 Herbal medicine versus placebo

Outcome: 1 Global improvement of symptoms rated by patient

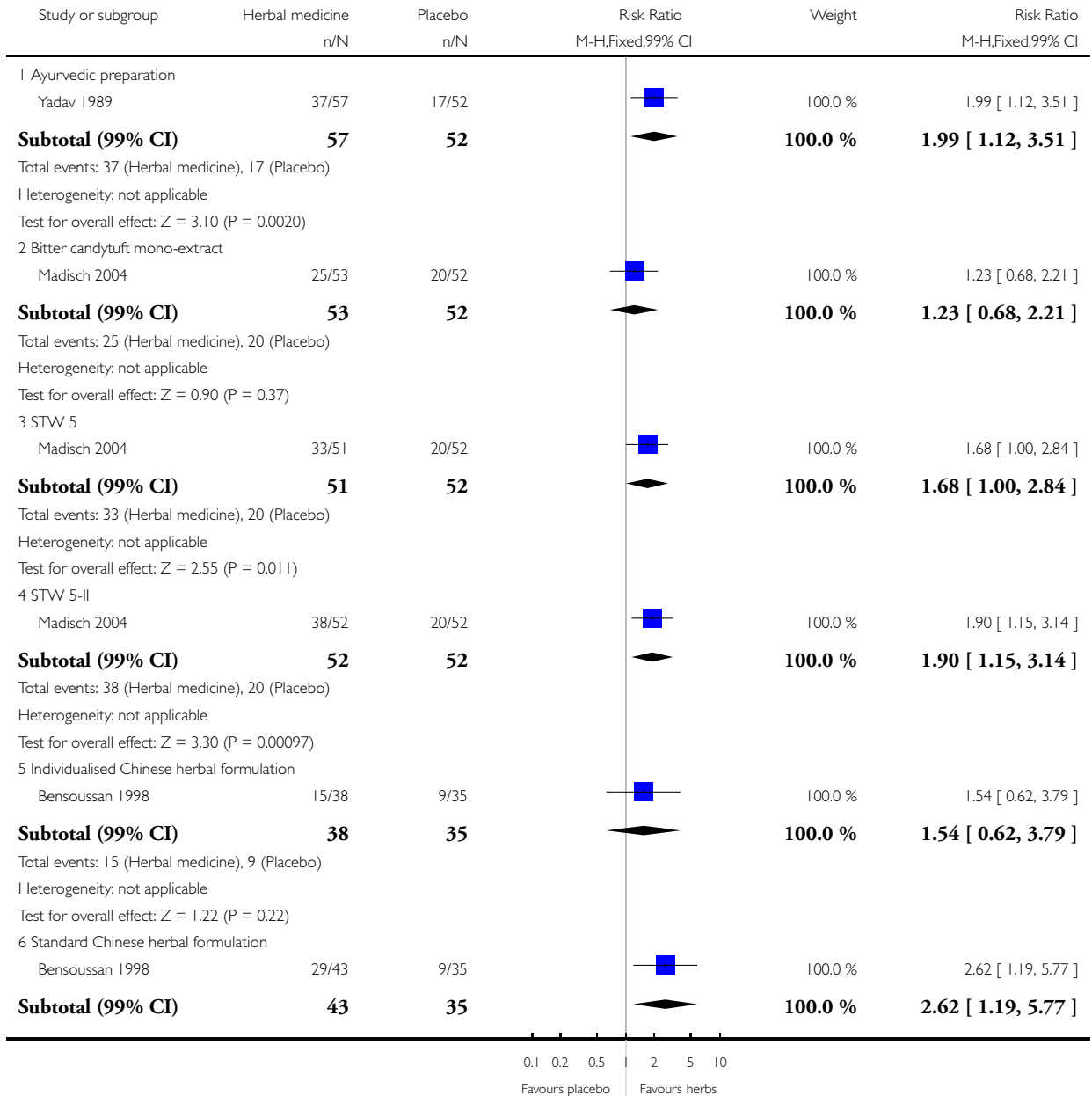


Analysis 1.2. Comparison 1 Herbal medicine versus placebo, Outcome 2 Global improvement of symptoms rated by gastroenterologist.

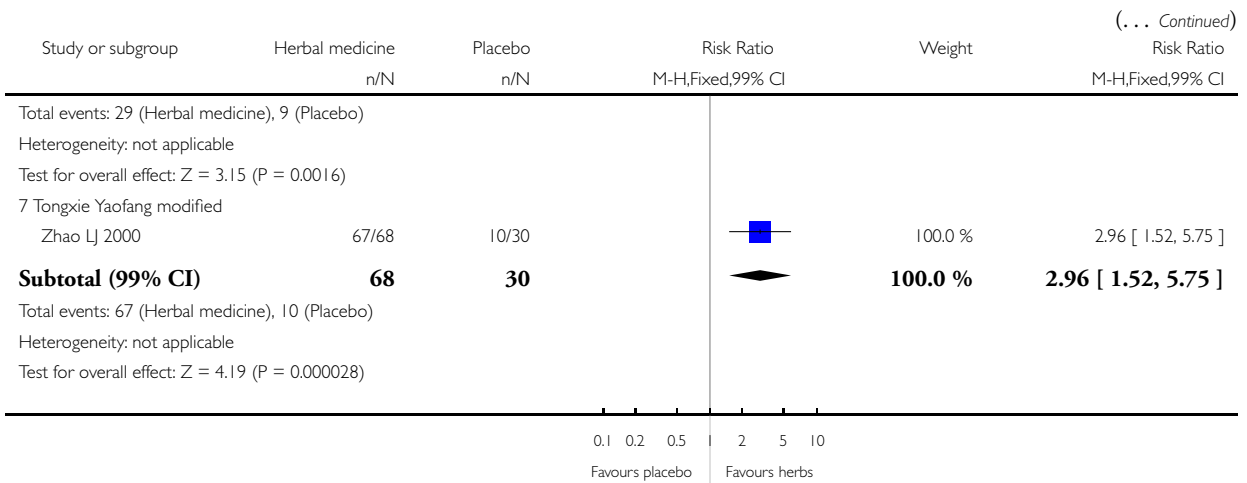
Review: Herbal medicines for treatment of irritable bowel syndrome

Comparison: 1 Herbal medicine versus placebo

Outcome: 2 Global improvement of symptoms rated by gastroenterologist



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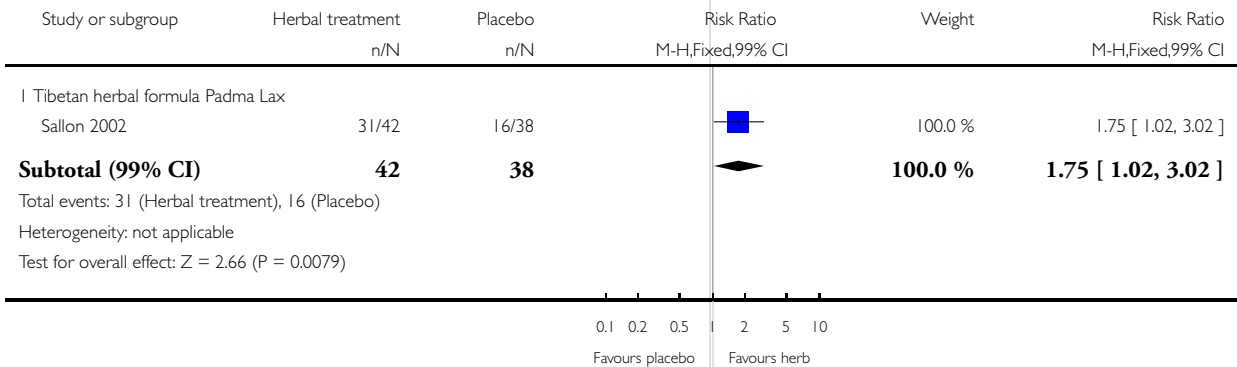


Analysis 1.3. Comparison 1 Herbal medicine versus placebo, Outcome 3 Passing stool on 6-7 days/week in patients with constipation.

Review: Herbal medicines for treatment of irritable bowel syndrome

Comparison: 1 Herbal medicine versus placebo

Outcome: 3 Passing stool on 6-7 days/week in patients with constipation

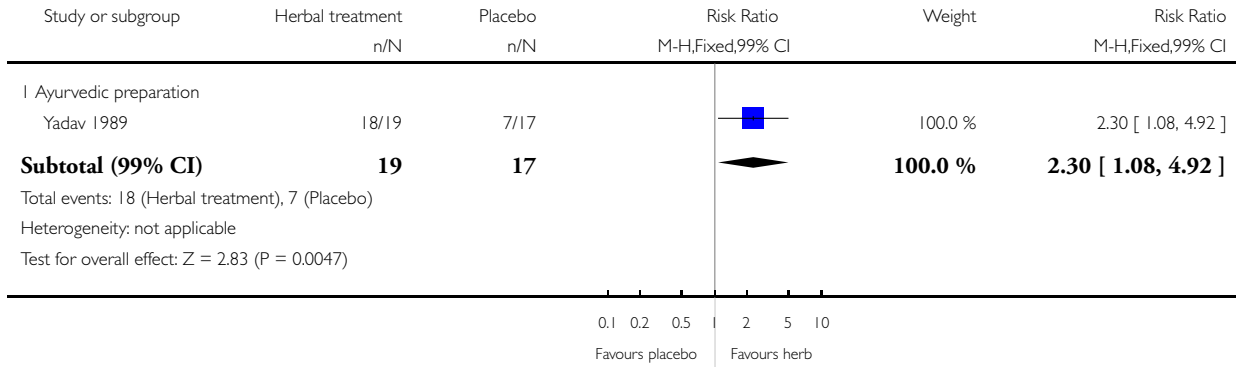


Analysis 1.4. Comparison 1 Herbal medicine versus placebo, Outcome 4 Diarrhoea relief.

Review: Herbal medicines for treatment of irritable bowel syndrome

Comparison: 1 Herbal medicine versus placebo

Outcome: 4 Diarrhoea relief

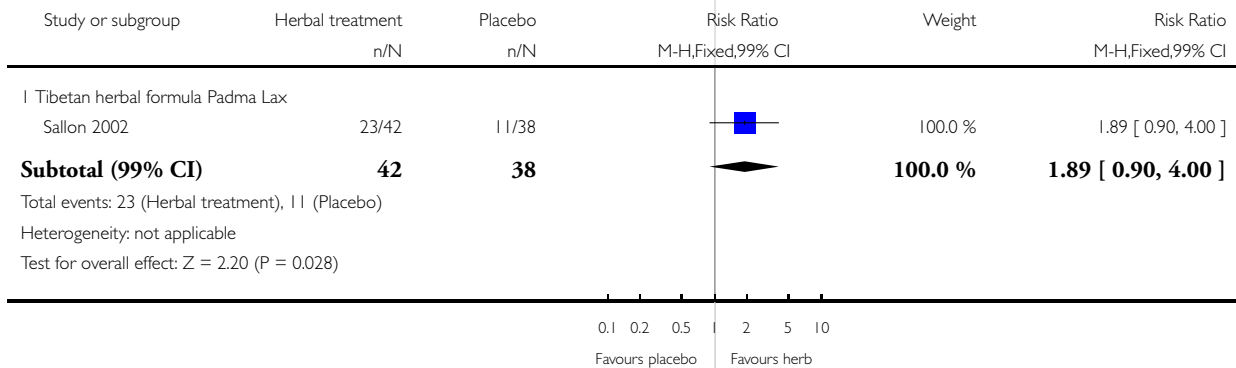


Analysis 1.5. Comparison 1 Herbal medicine versus placebo, Outcome 5 No effect of abdominal pain on daily activities in patients with constipation.

Review: Herbal medicines for treatment of irritable bowel syndrome

Comparison: 1 Herbal medicine versus placebo

Outcome: 5 No effect of abdominal pain on daily activities in patients with constipation

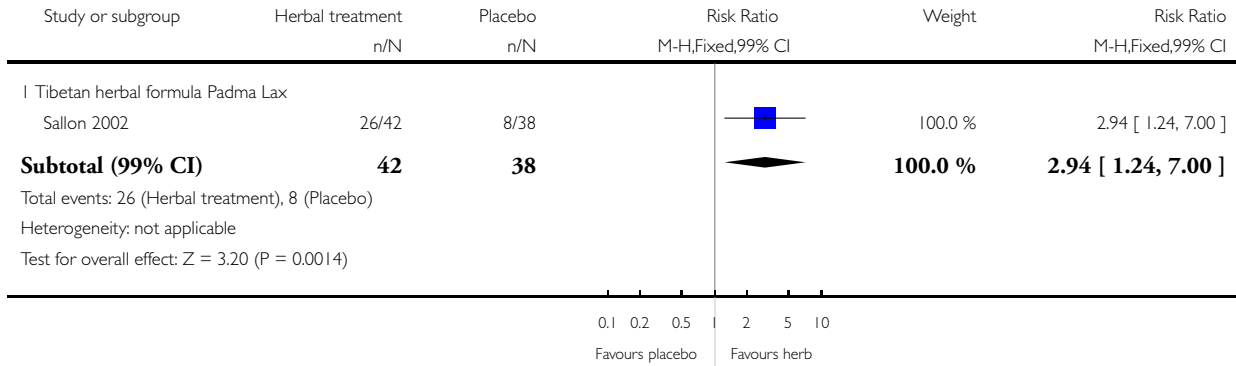


Analysis 1.6. Comparison 1 Herbal medicine versus placebo, Outcome 6 Absence of moderate or severe pain in patients with constipation.

Review: Herbal medicines for treatment of irritable bowel syndrome

Comparison: 1 Herbal medicine versus placebo

Outcome: 6 Absence of moderate or severe pain in patients with constipation

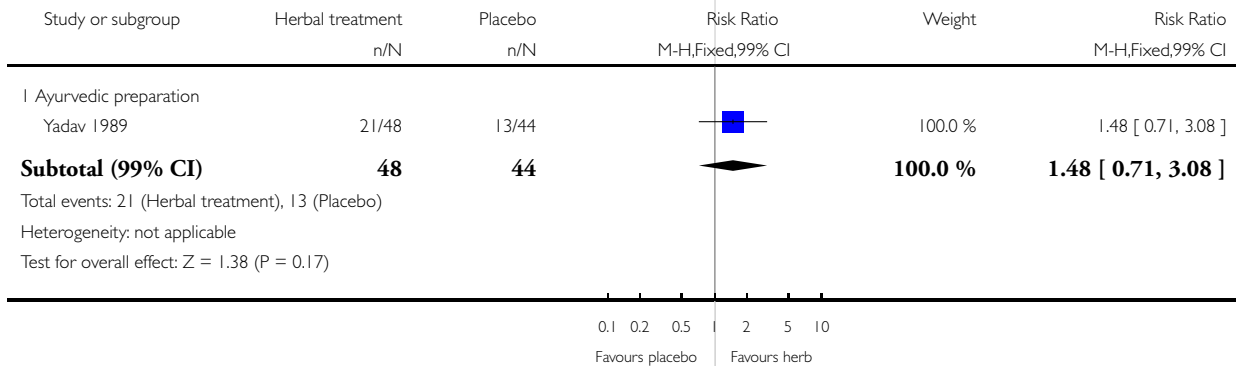


Analysis 1.7. Comparison 1 Herbal medicine versus placebo, Outcome 7 Abdominal pain relief.

Review: Herbal medicines for treatment of irritable bowel syndrome

Comparison: 1 Herbal medicine versus placebo

Outcome: 7 Abdominal pain relief

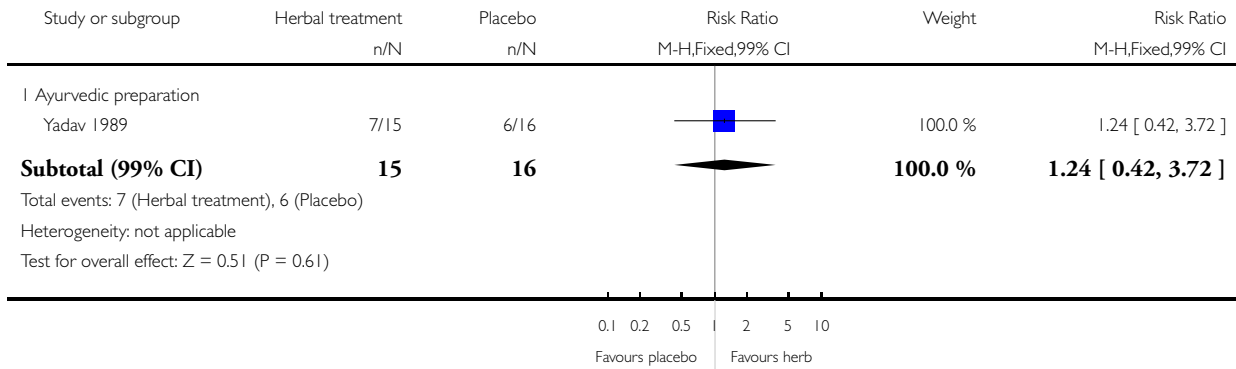


Analysis 1.8. Comparison 1 Herbal medicine versus placebo, Outcome 8 Constipation relief.

Review: Herbal medicines for treatment of irritable bowel syndrome

Comparison: 1 Herbal medicine versus placebo

Outcome: 8 Constipation relief

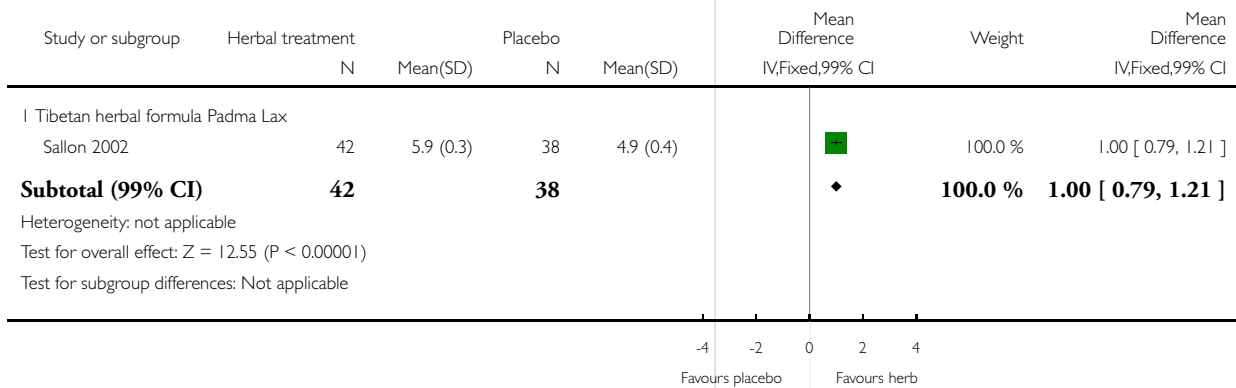


Analysis 1.9. Comparison 1 Herbal medicine versus placebo, Outcome 9 Stool passed times per week in patients with constipation-predominant IBS.

Review: Herbal medicines for treatment of irritable bowel syndrome

Comparison: 1 Herbal medicine versus placebo

Outcome: 9 Stool passed times per week in patients with constipation-predominant IBS

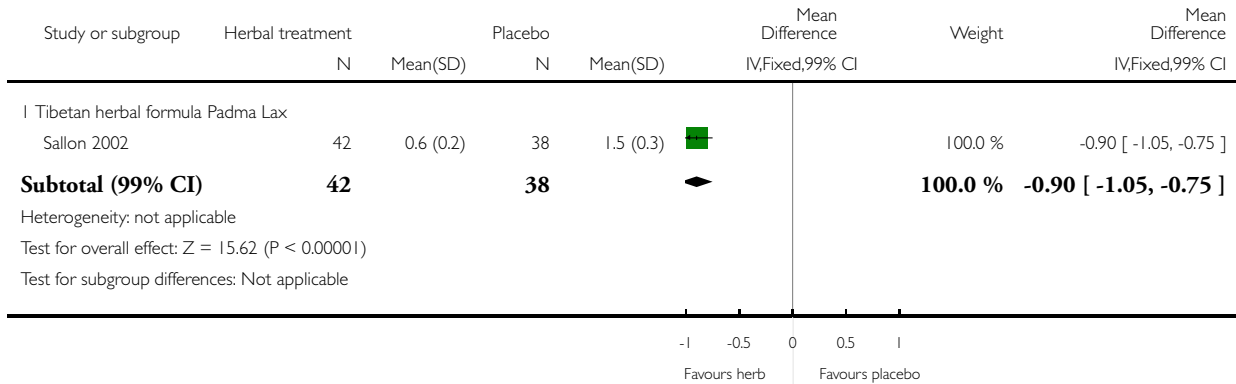


Analysis 1.10. Comparison 1 Herbal medicine versus placebo, Outcome 10 Abdominal pain effect on daily activities (score 0-3).

Review: Herbal medicines for treatment of irritable bowel syndrome

Comparison: 1 Herbal medicine versus placebo

Outcome: 10 Abdominal pain effect on daily activities (score 0-3)

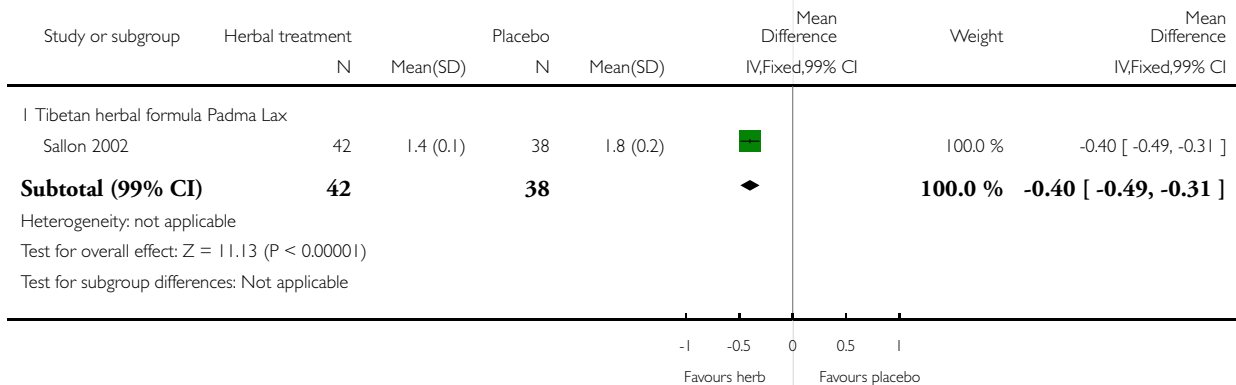


Analysis 1.11. Comparison 1 Herbal medicine versus placebo, Outcome 11 Abdominal pain severity (score 1-3).

Review: Herbal medicines for treatment of irritable bowel syndrome

Comparison: 1 Herbal medicine versus placebo

Outcome: 11 Abdominal pain severity (score 1-3)

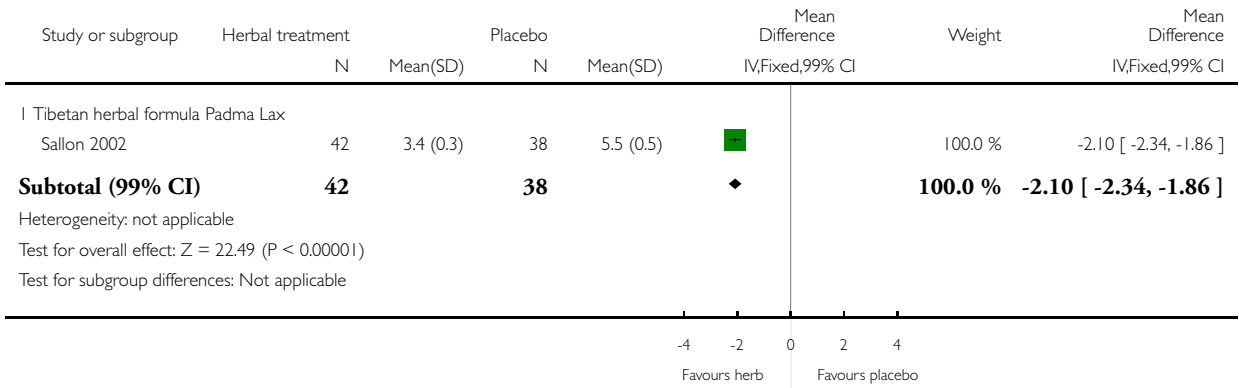


Analysis 1.12. Comparison 1 Herbal medicine versus placebo, Outcome 12 Constipation score (0-10) rated by gastroenterologist.

Review: Herbal medicines for treatment of irritable bowel syndrome

Comparison: 1 Herbal medicine versus placebo

Outcome: 12 Constipation score (0-10) rated by gastroenterologist

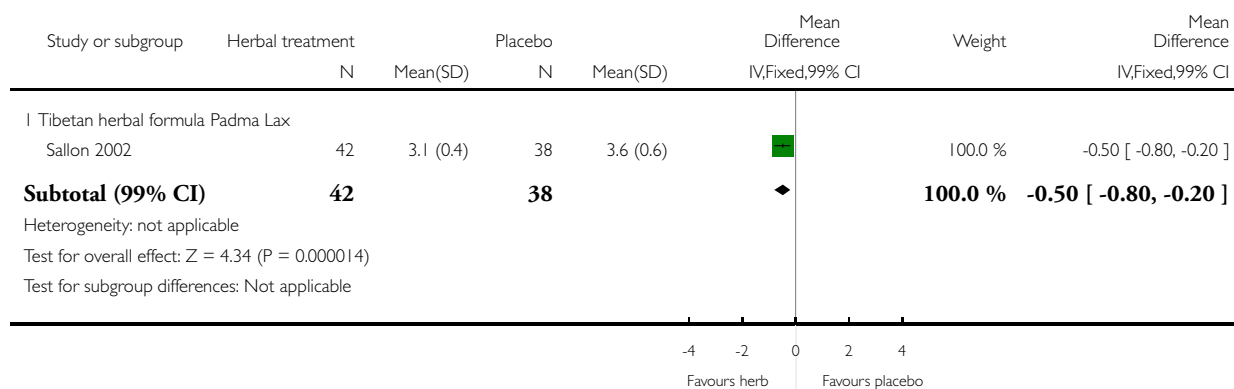


Analysis 1.13. Comparison 1 Herbal medicine versus placebo, Outcome 13 Abdominal pain score (0-10) rated by gastroenterologist.

Review: Herbal medicines for treatment of irritable bowel syndrome

Comparison: 1 Herbal medicine versus placebo

Outcome: 13 Abdominal pain score (0-10) rated by gastroenterologist

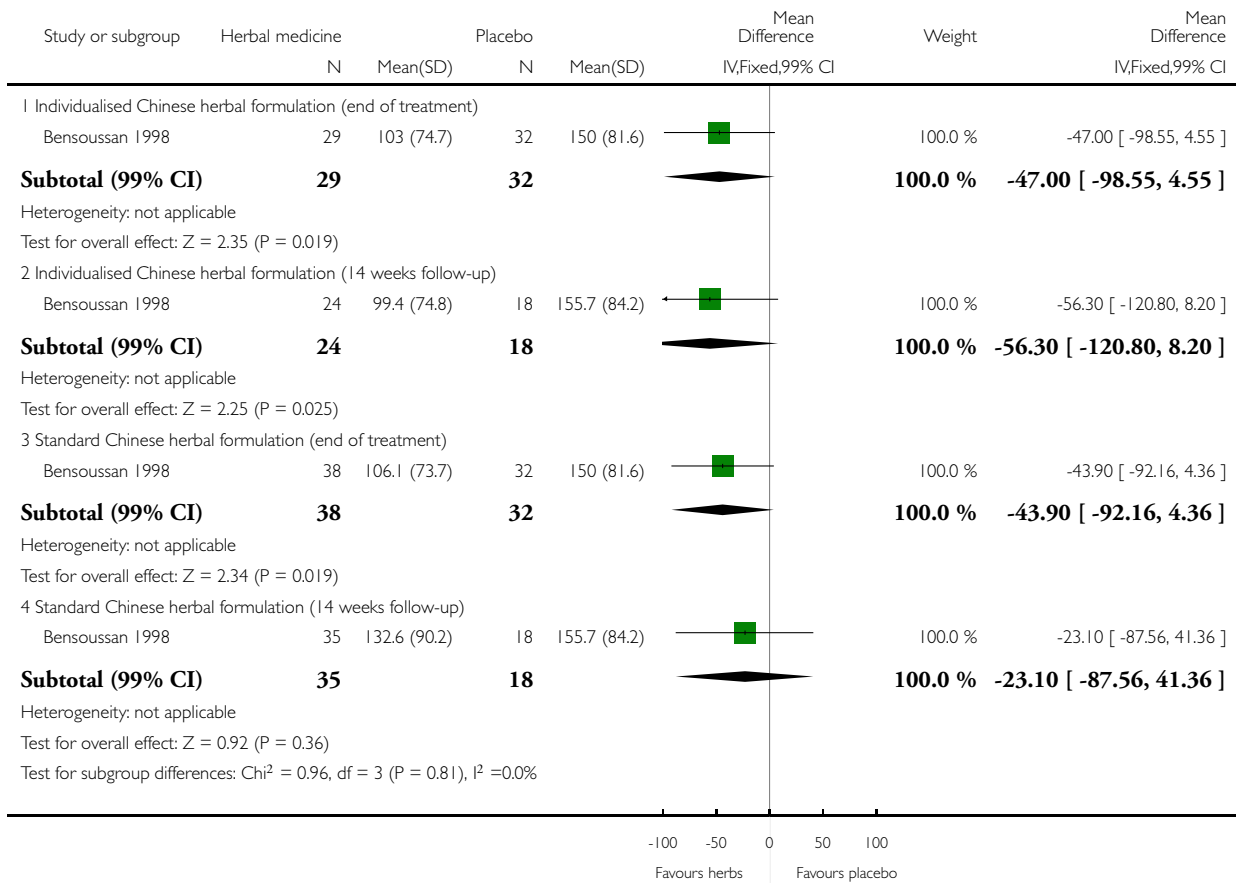


Analysis 1.14. Comparison 1 Herbal medicine versus placebo, Outcome 14 Bowel symptom scale (BSS) scores rated by patient.

Review: Herbal medicines for treatment of irritable bowel syndrome

Comparison: 1 Herbal medicine versus placebo

Outcome: 14 Bowel symptom scale (BSS) scores rated by patient

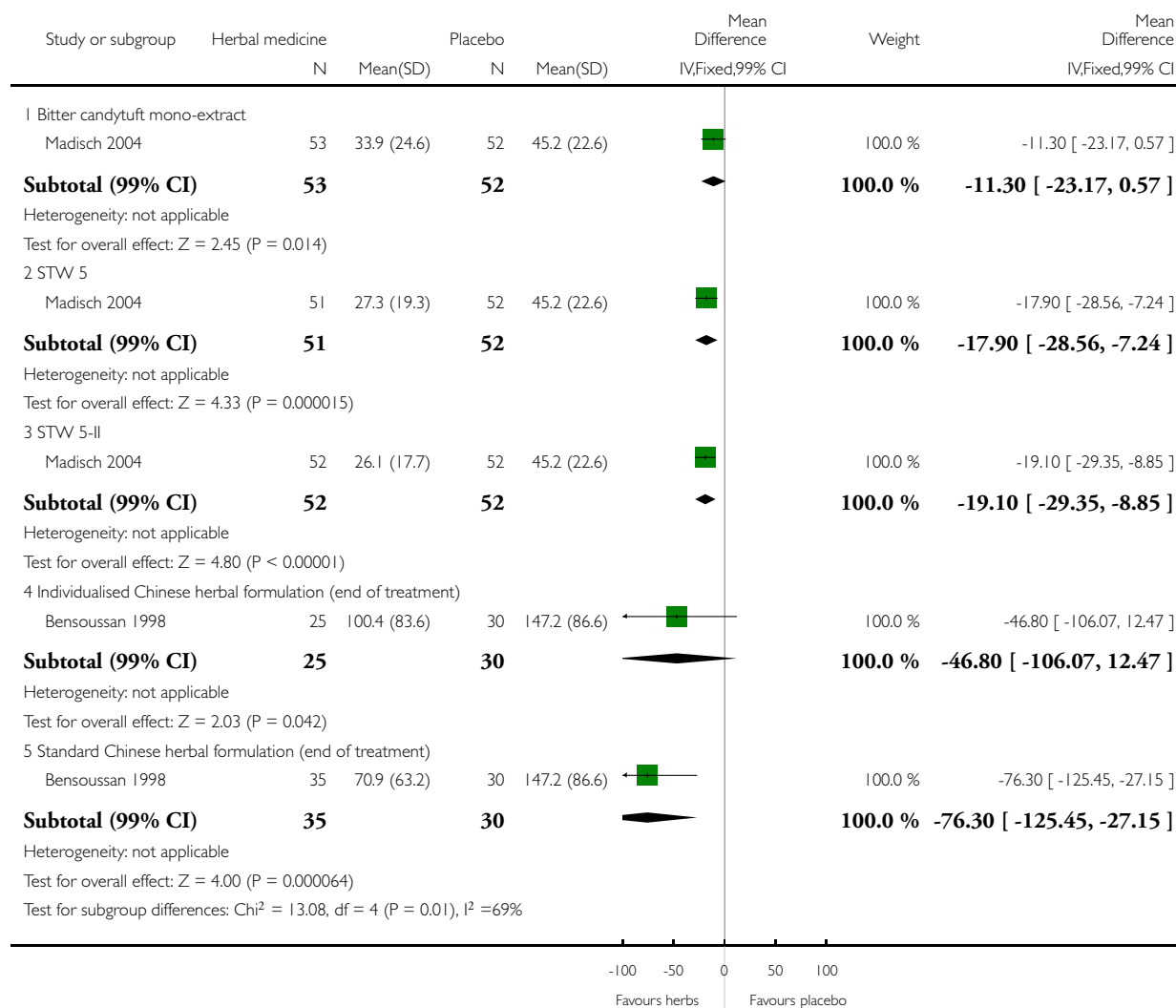


Analysis 1.15. Comparison 1 Herbal medicine versus placebo, Outcome 15 Bowel symptom scale (BSS) scores rated by gastroenterologist.

Review: Herbal medicines for treatment of irritable bowel syndrome

Comparison: 1 Herbal medicine versus placebo

Outcome: 15 Bowel symptom scale (BSS) scores rated by gastroenterologist

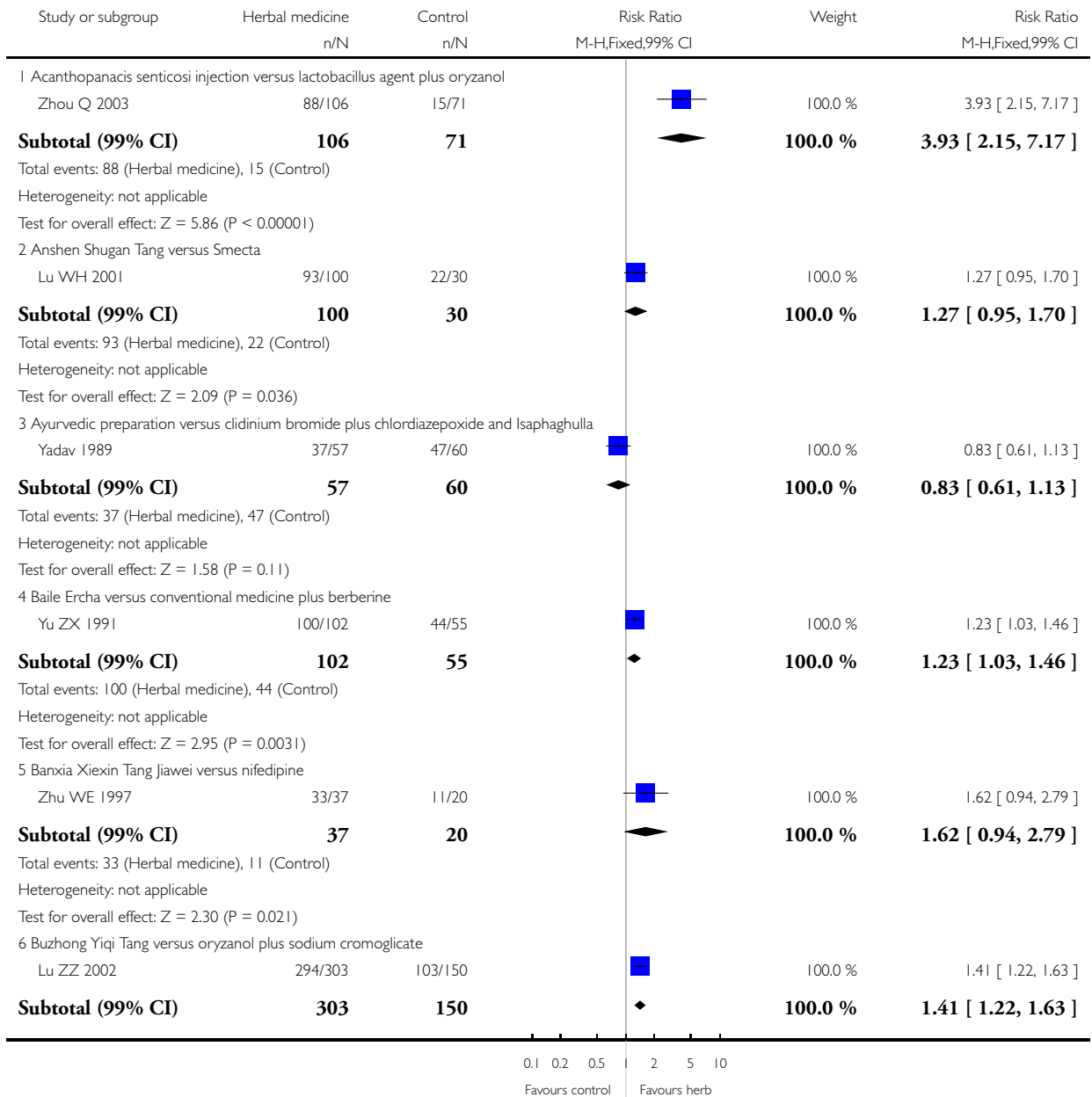


Analysis 2.1. Comparison 2 Herbal medicine versus conventional medicine, Outcome 1 Global improvement of symptoms.

Review: Herbal medicines for treatment of irritable bowel syndrome

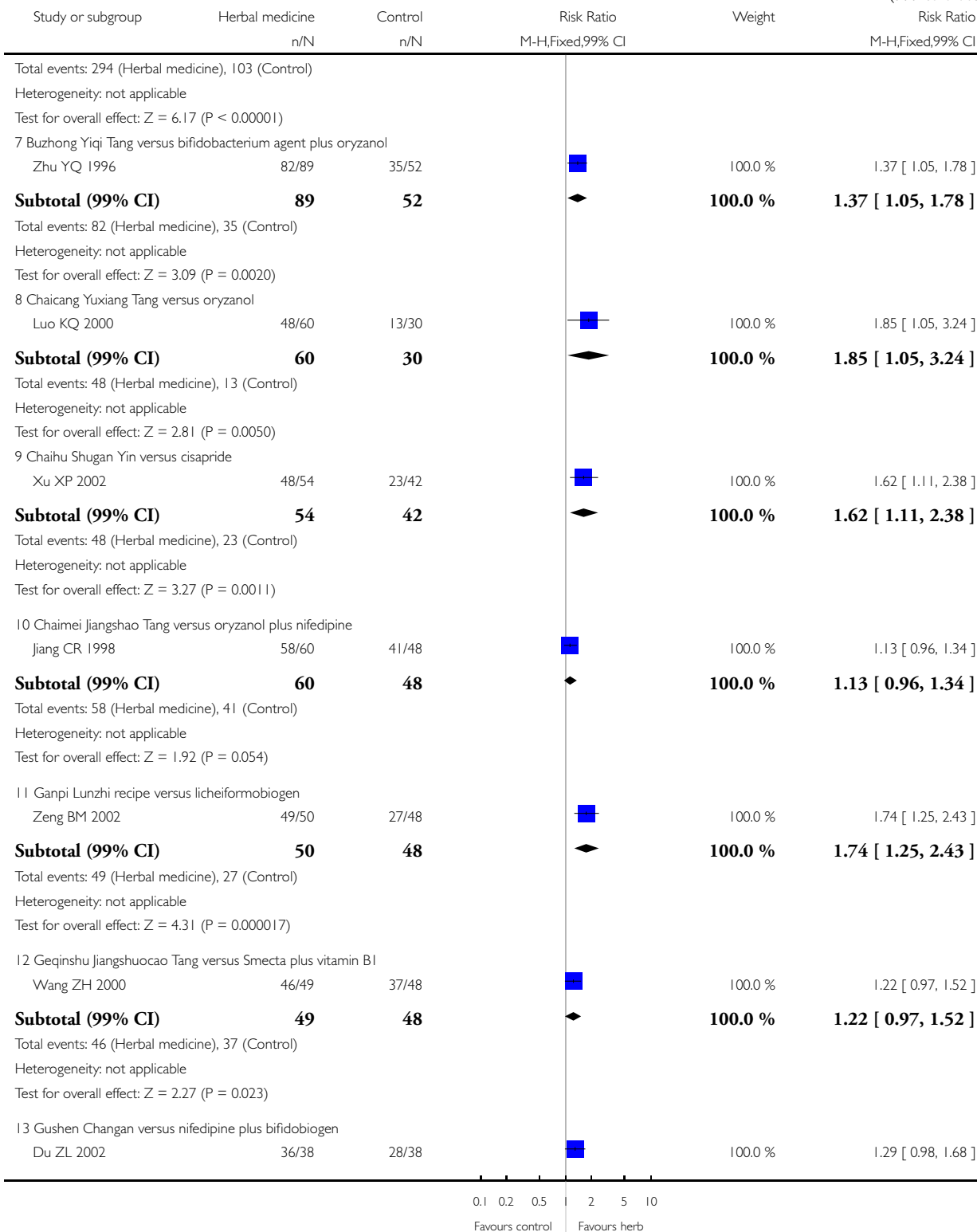
Comparison: 2 Herbal medicine versus conventional medicine

Outcome: 1 Global improvement of symptoms



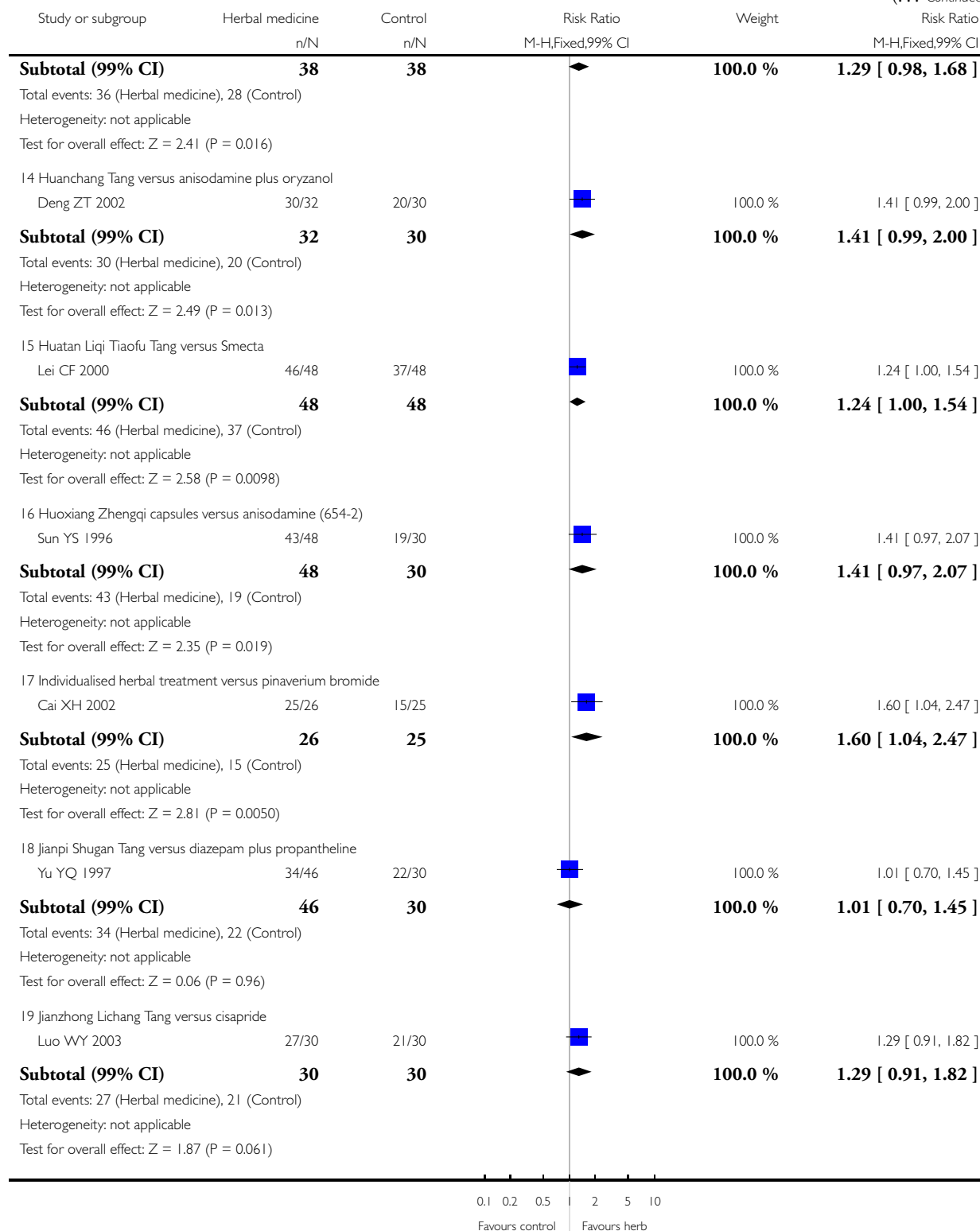
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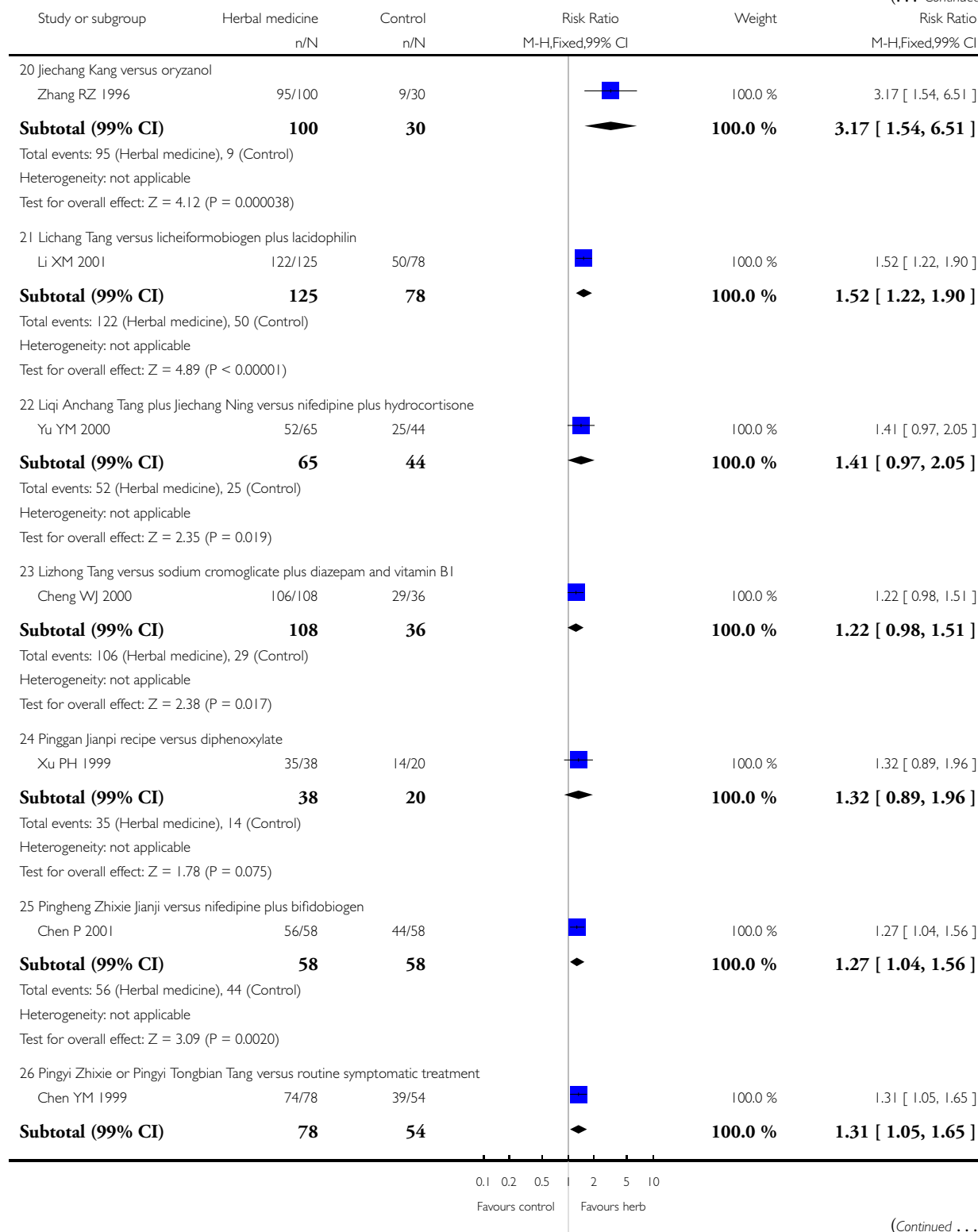
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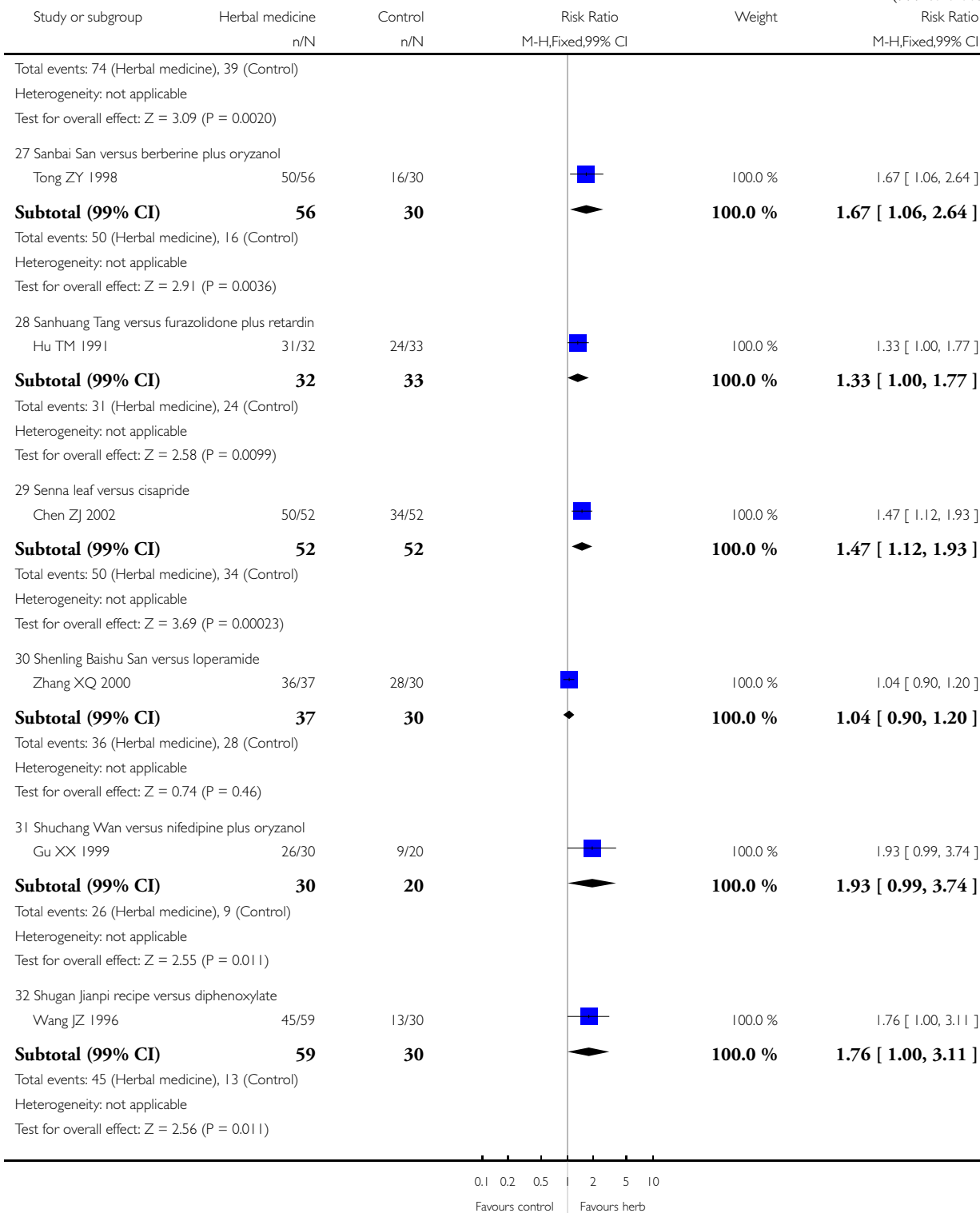
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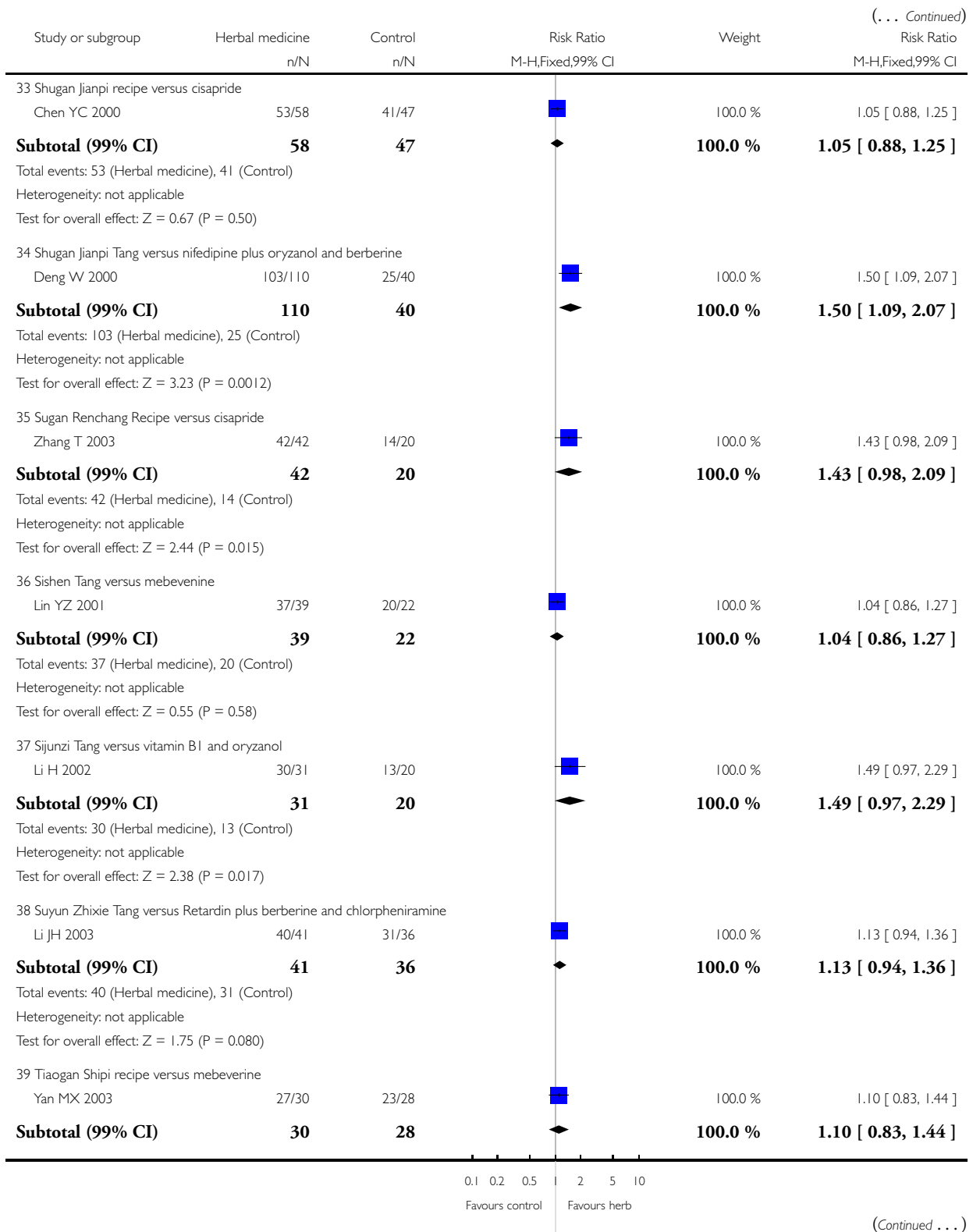


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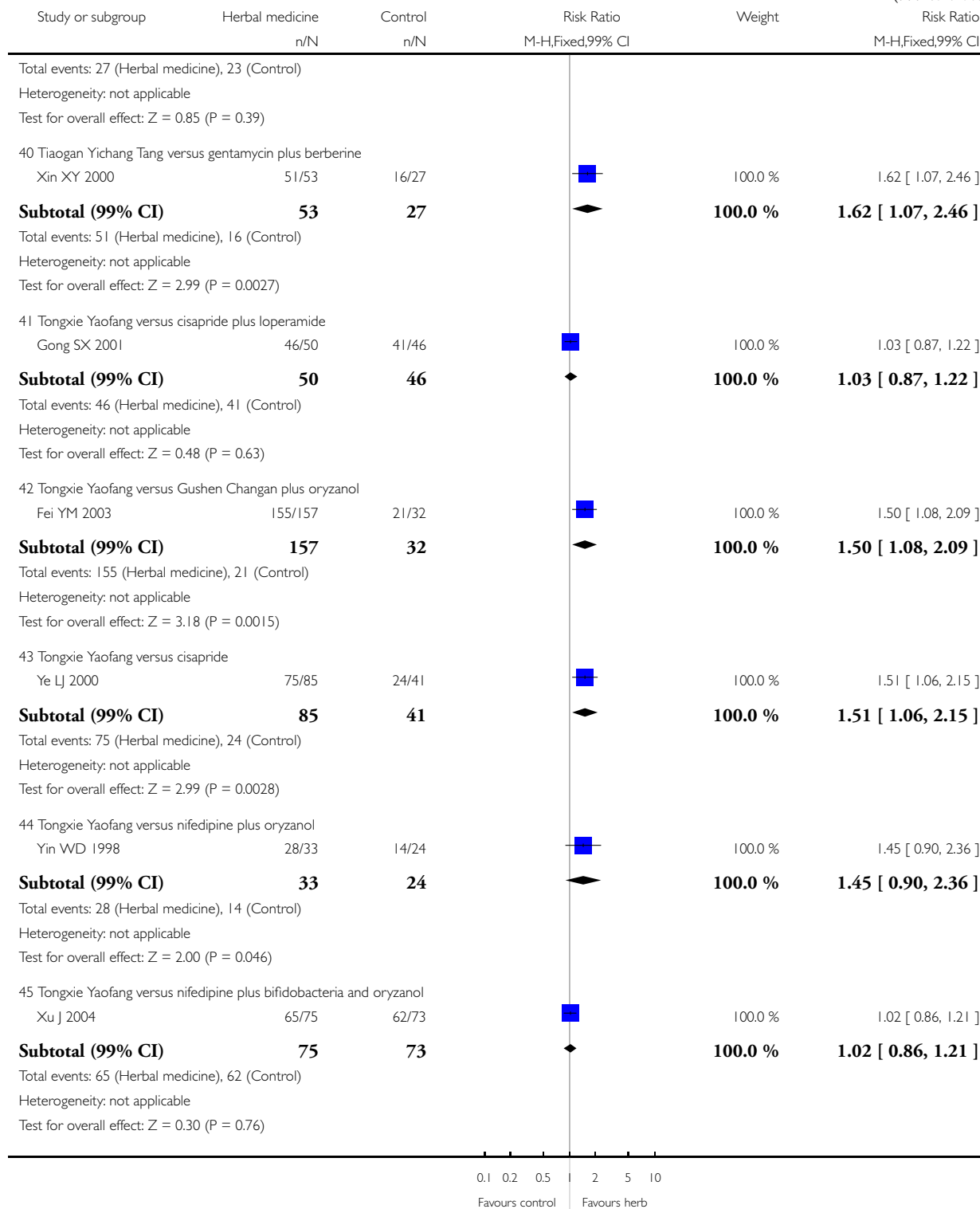
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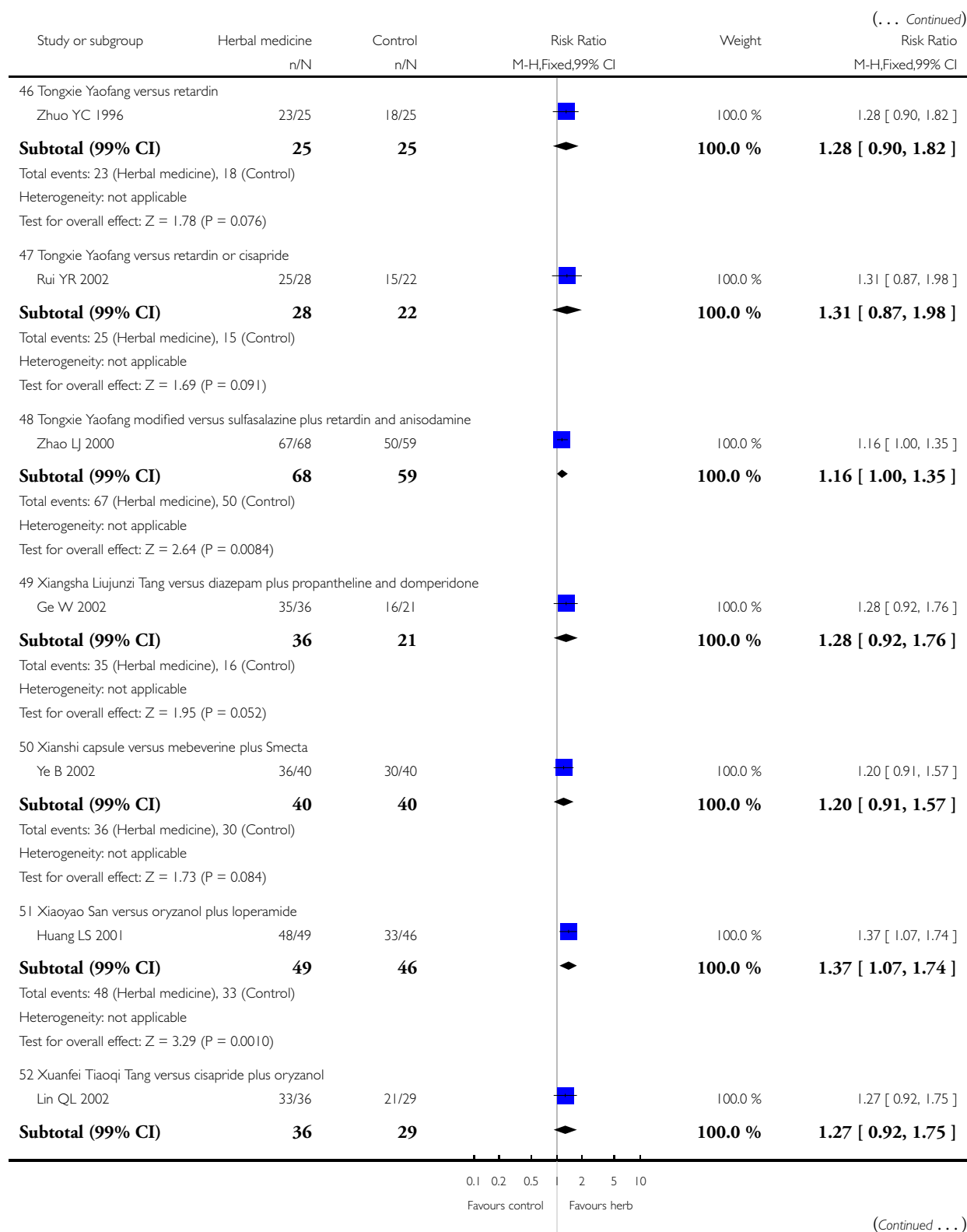
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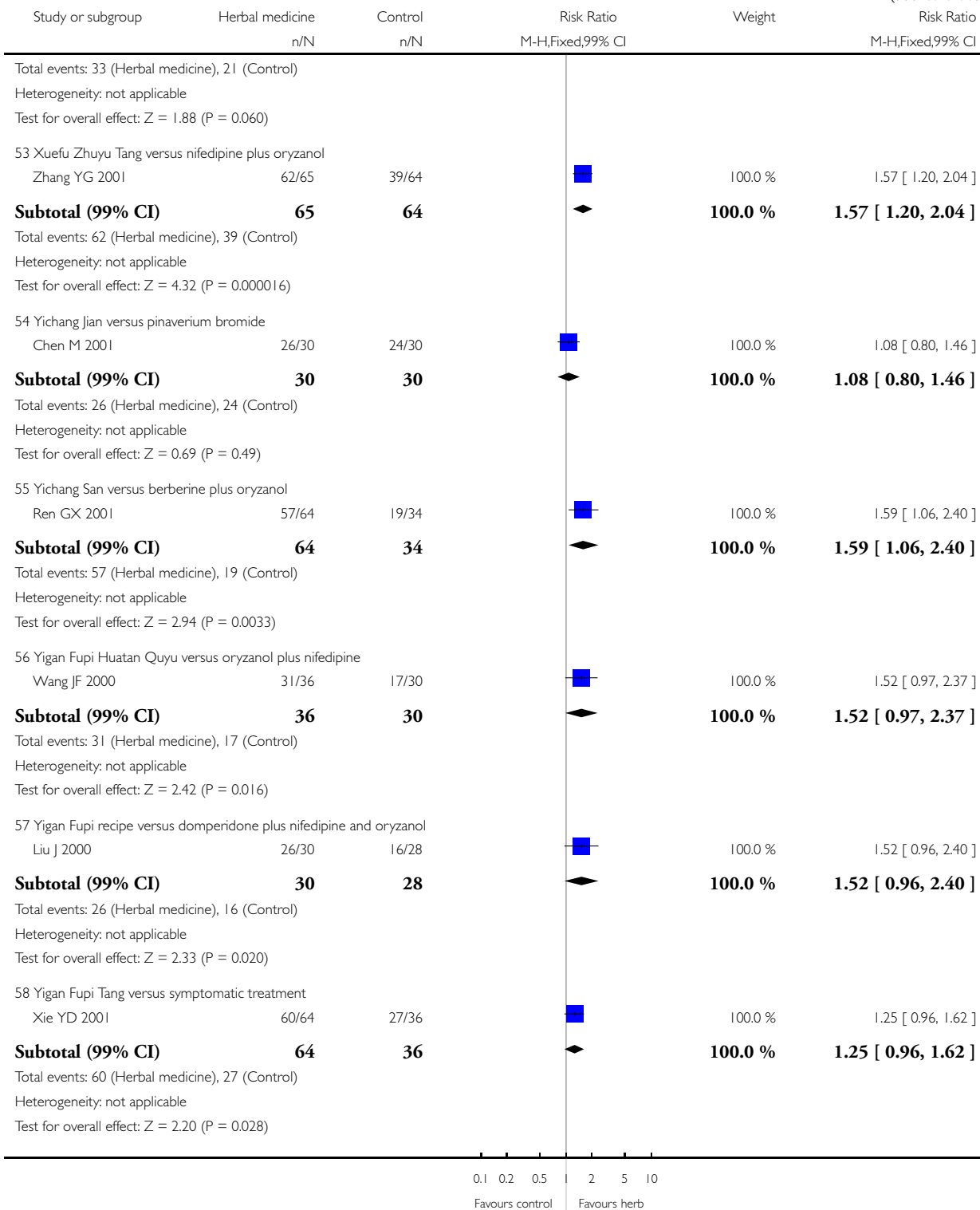
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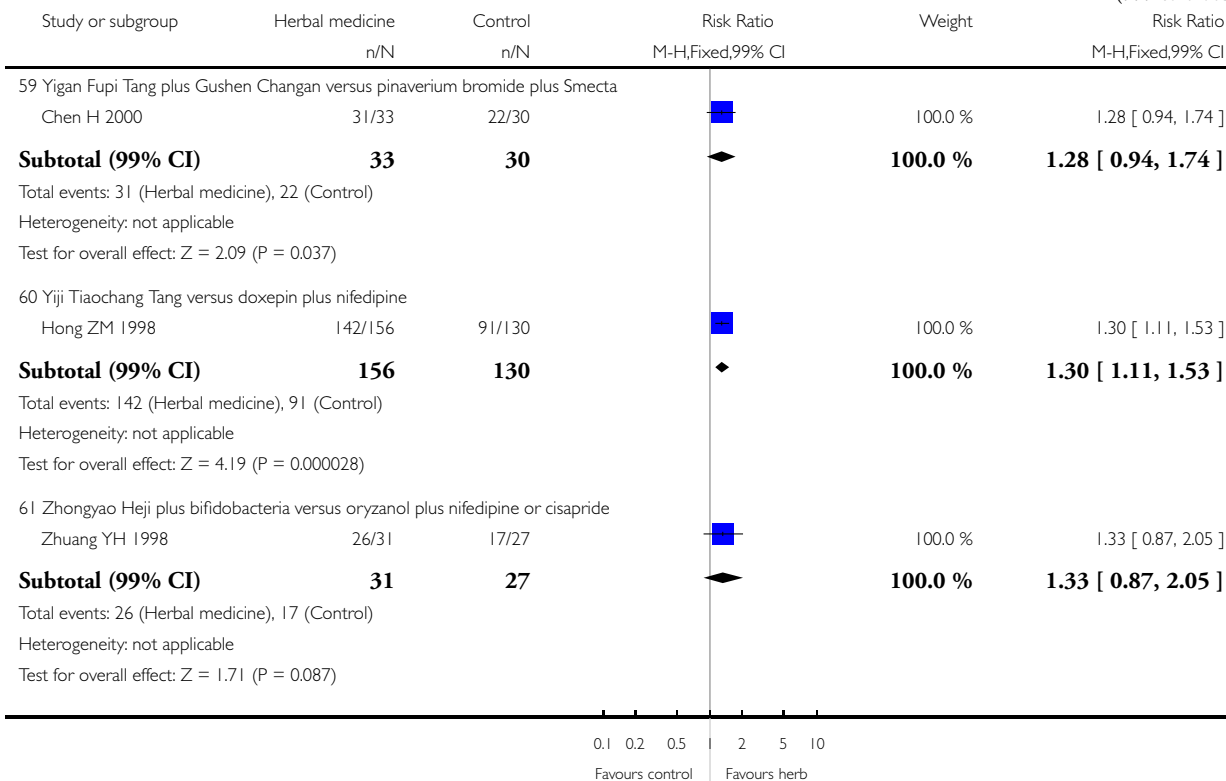


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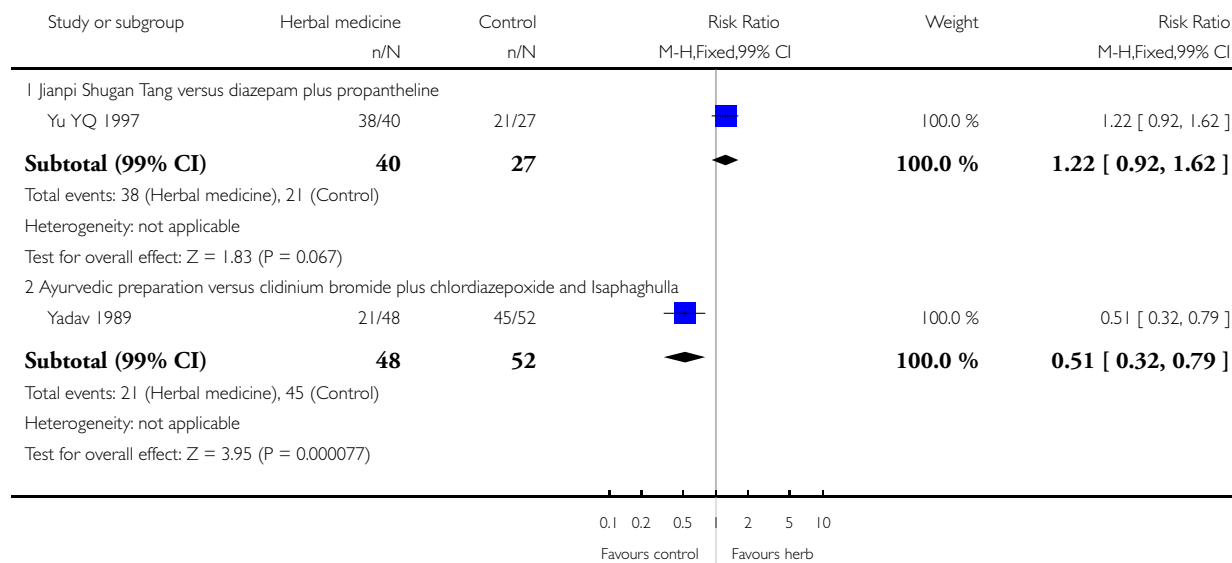


Analysis 2.2. Comparison 2 Herbal medicine versus conventional medicine, Outcome 2 Abdominal pain relief.

Review: Herbal medicines for treatment of irritable bowel syndrome

Comparison: 2 Herbal medicine versus conventional medicine

Outcome: 2 Abdominal pain relief

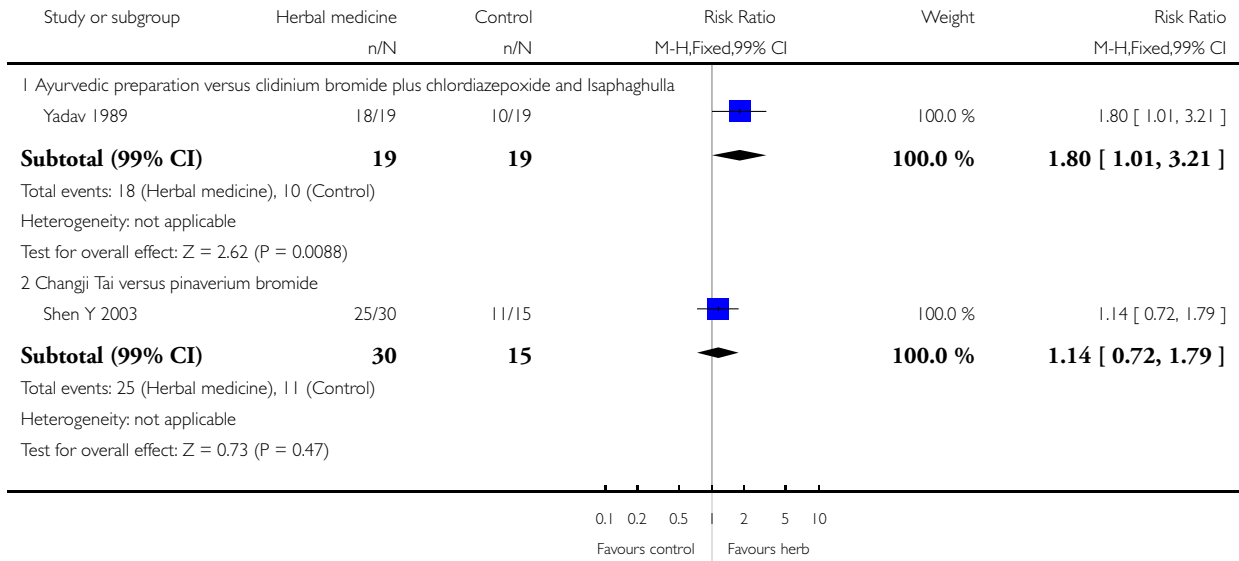


Analysis 2.3. Comparison 2 Herbal medicine versus conventional medicine, Outcome 3 Diarrhoea relief.

Review: Herbal medicines for treatment of irritable bowel syndrome

Comparison: 2 Herbal medicine versus conventional medicine

Outcome: 3 Diarrhoea relief

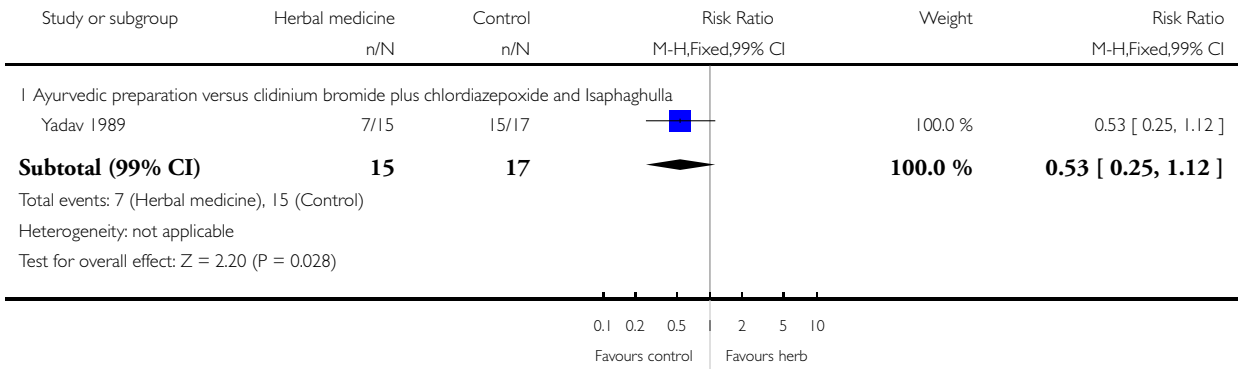


Analysis 2.4. Comparison 2 Herbal medicine versus conventional medicine, Outcome 4 Constipation relief.

Review: Herbal medicines for treatment of irritable bowel syndrome

Comparison: 2 Herbal medicine versus conventional medicine

Outcome: 4 Constipation relief

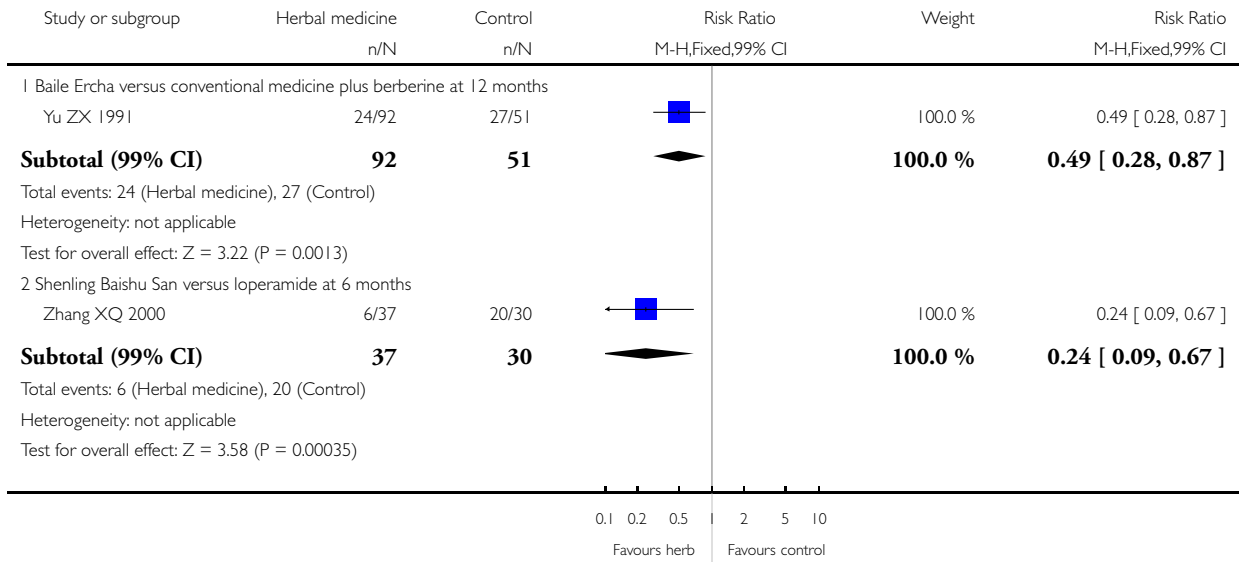


Analysis 2.5. Comparison 2 Herbal medicine versus conventional medicine, Outcome 5 Recurrent episodes of symptoms.

Review: Herbal medicines for treatment of irritable bowel syndrome

Comparison: 2 Herbal medicine versus conventional medicine

Outcome: 5 Recurrent episodes of symptoms

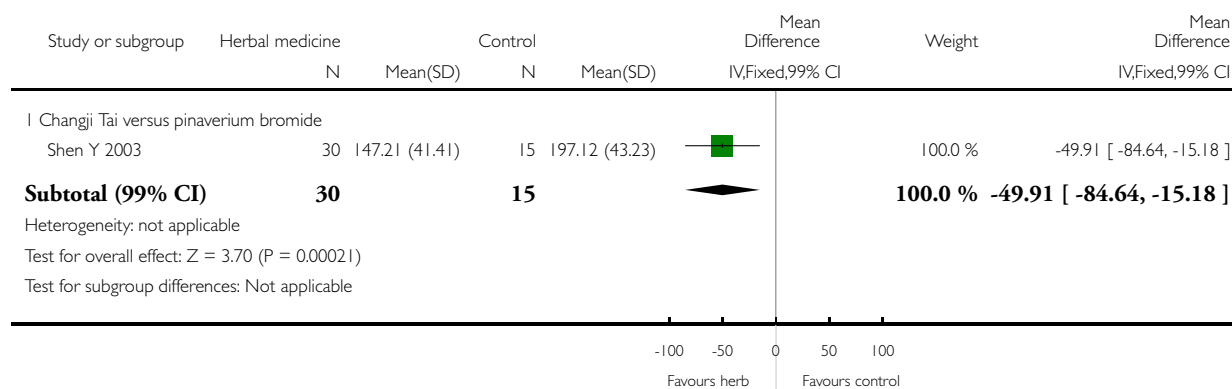


Analysis 2.6. Comparison 2 Herbal medicine versus conventional medicine, Outcome 6 Bowel scoring system (BSS).

Review: Herbal medicines for treatment of irritable bowel syndrome

Comparison: 2 Herbal medicine versus conventional medicine

Outcome: 6 Bowel scoring system (BSS)

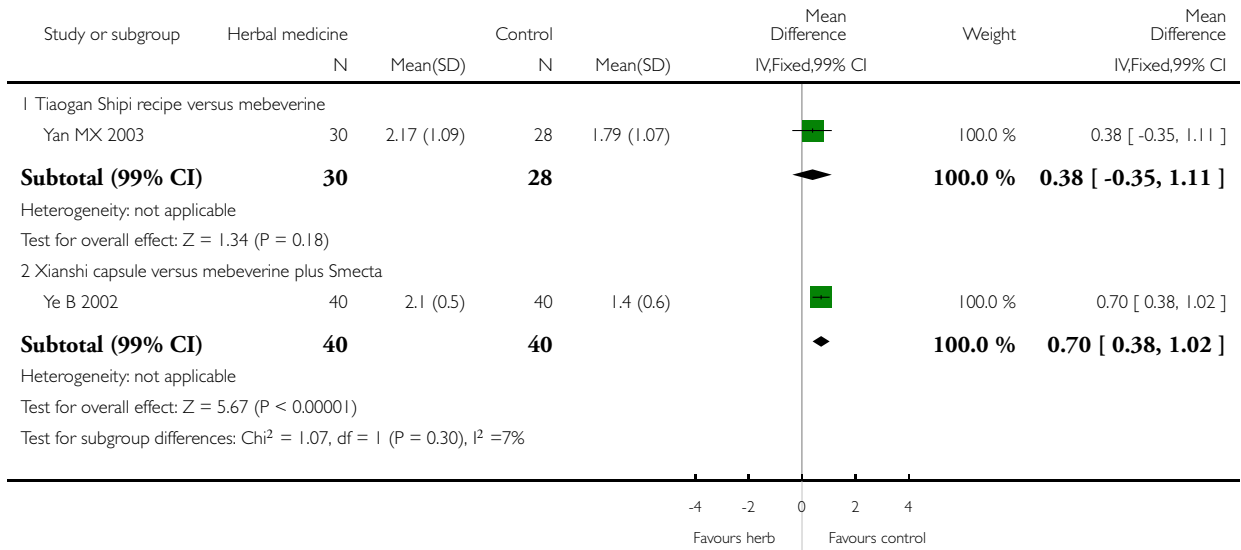


Analysis 2.7. Comparison 2 Herbal medicine versus conventional medicine, Outcome 7 Abdominal pain (0-3 score from no pain to most severe).

Review: Herbal medicines for treatment of irritable bowel syndrome

Comparison: 2 Herbal medicine versus conventional medicine

Outcome: 7 Abdominal pain (0-3 score from no pain to most severe)

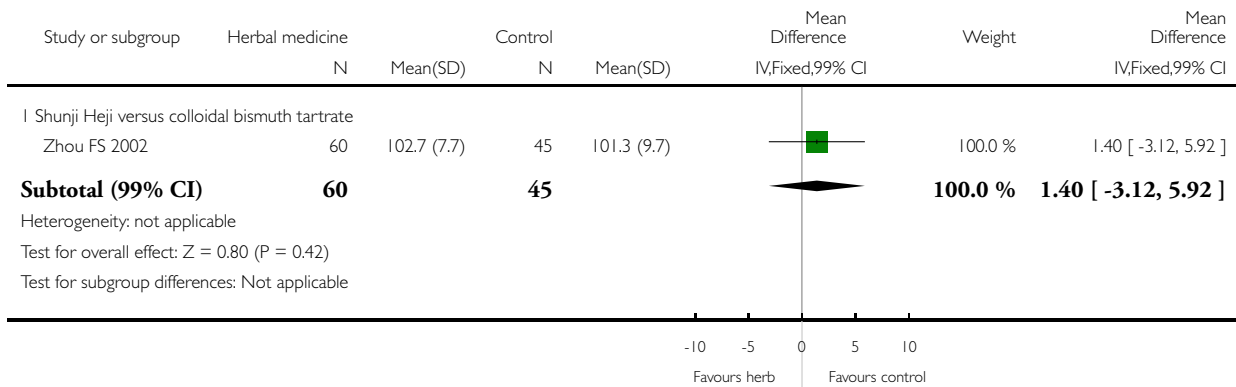


Analysis 2.8. Comparison 2 Herbal medicine versus conventional medicine, Outcome 8 Quality of life (SF-36 score).

Review: Herbal medicines for treatment of irritable bowel syndrome

Comparison: 2 Herbal medicine versus conventional medicine

Outcome: 8 Quality of life (SF-36 score)

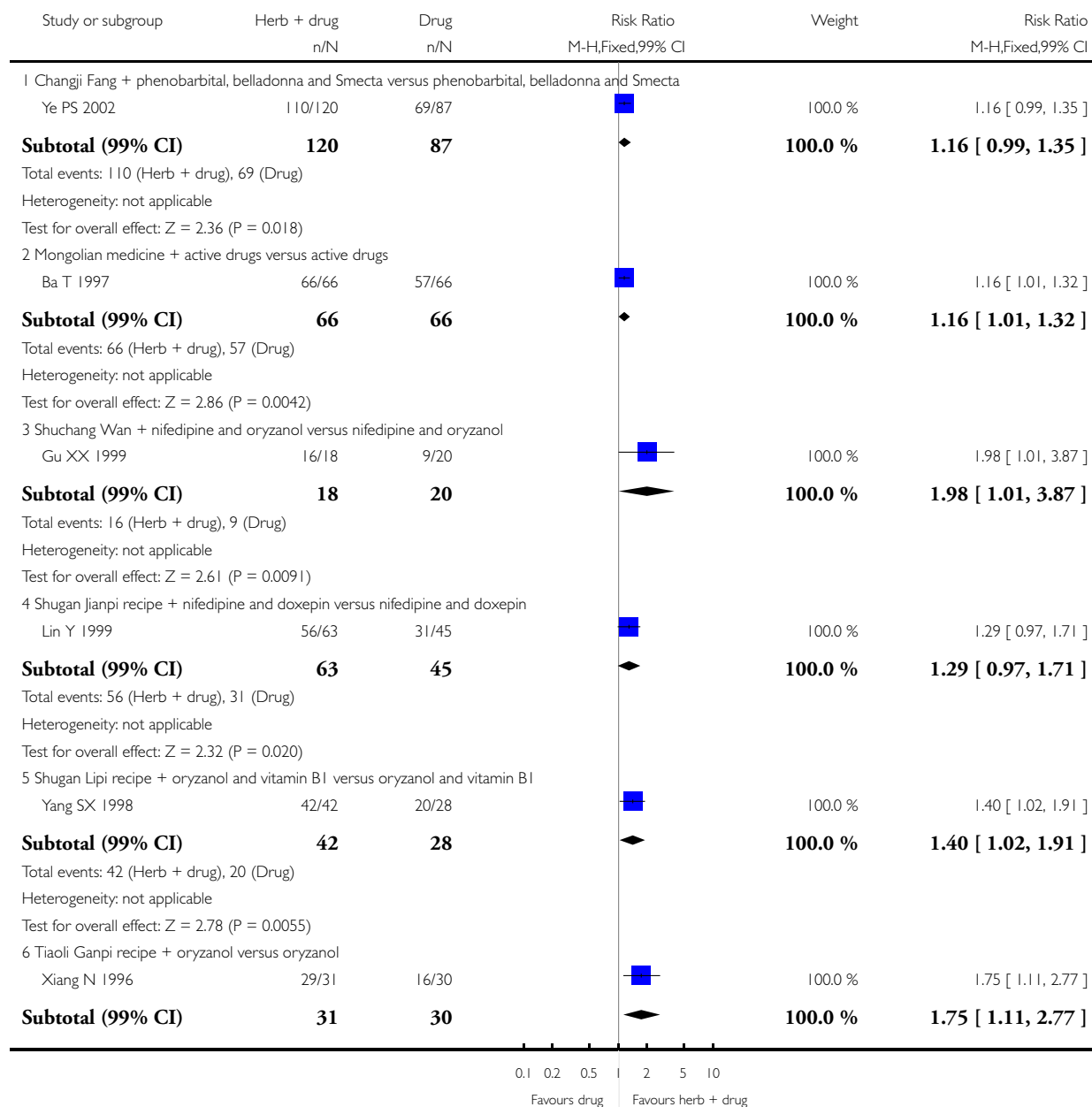


Analysis 3.1. Comparison 3 Herbal medicine plus active drug versus active drug alone, Outcome 1 Global improvement of symptoms.

Review: Herbal medicines for treatment of irritable bowel syndrome

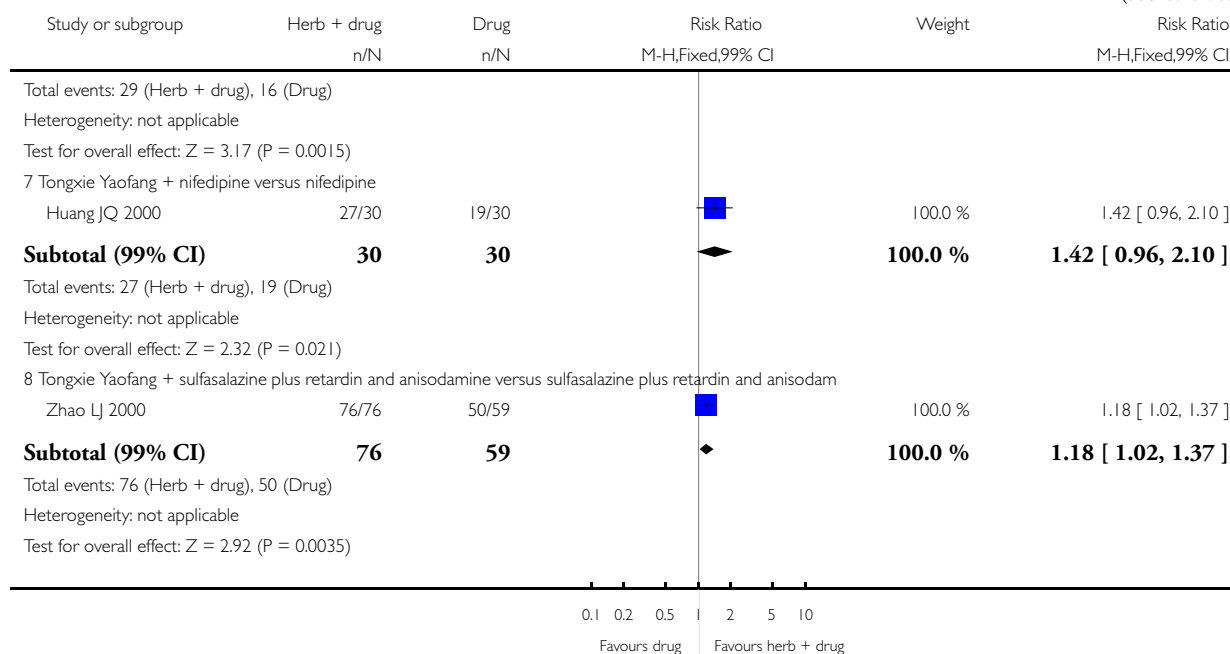
Comparison: 3 Herbal medicine plus active drug versus active drug alone

Outcome: 1 Global improvement of symptoms



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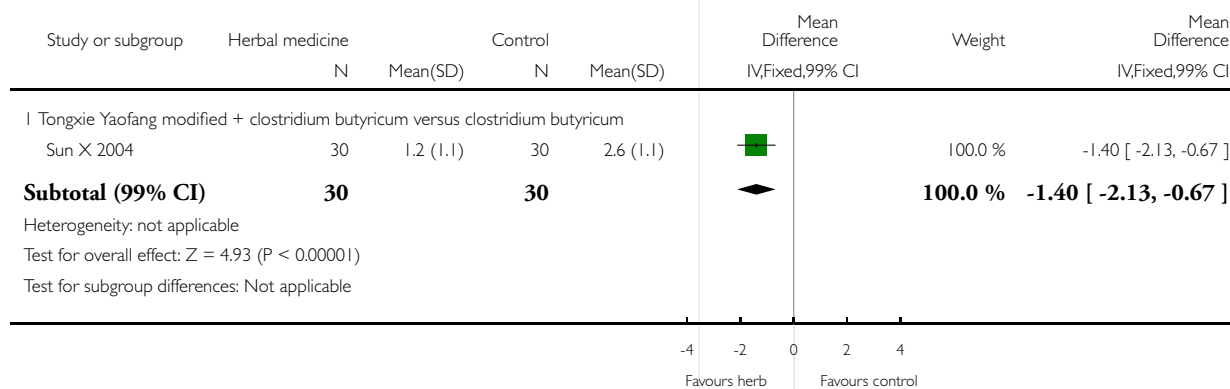


Analysis 3.2. Comparison 3 Herbal medicine plus active drug versus active drug alone, Outcome 2 Daily defecation number of diarrhoea.

Review: Herbal medicines for treatment of irritable bowel syndrome

Comparison: 3 Herbal medicine plus active drug versus active drug alone

Outcome: 2 Daily defecation number of diarrhoea



ADDITIONAL TABLES

Table 1. The preparation and composition of the herbal medicines in the included trials

Name of tested herb	Preparation	Composition	Study ID
Anshen Shugan Tang	decoction	A practitioner-prescribed formula composed of 8 herbs: Albizziae julibrissin, Polygoni multiflori, Bupleuri, Paeoniae lactiflorae, Citri aurantii, Poriae cocos, Portulacae oleraceae, Radix raphani	Lu WH 2001
Ayurvedic preparation	granule	Two indigenous Indian drugs: Marmelos correa (Bilva) fruit powder 3 g, plus Monniere Linn 2 g, and excipient 1 g	Yadav 1989
Baile Ercha	capsule	A practitioner-prescribed formula composed of 2 herbs.	Yu ZX 1991
Banxia Xiexin Tang	decoction	A traditional formula composed of 11 herbs.	Zhu WE 1997
Bitter candytuft (BCT)	drop	Mono-extract of single herb Bitter candytuft.	Madisch 2004
Buzhong Yiqi Tang	decoction	A formula composed of 8 herbs: Ginseng, Astragali membranacei, Glycyrrhizae uralensis, Angelicae sinensis, Citri reticulatae, Cimicifugae, Bupleuri, Atractylodis macrocephalae	Lu ZZ 2002
Buzhong Yiqi Tang modified	decoction	A practitioner-prescribed formula composed of 7 herbs.	Zhu YQ 1996
Chaicang Yuxiang Tang	decoction	A practitioner-prescribed formula composed of 7 herbs: Bupleuri, Pinelliae ternatae, Artractylodis, Atractylodis macrocephalae, Cyperi rotundi, Codonopsis pilosulae, Evodiae rutaecarpae	Luo KQ 2000
Chaihu Shugan Yin	decoction	Chinese herbal formula composed of 7 herbs.	Xu XP 2002
Chaimei Jiangshao Tang	decoction	A practitioner-prescribed formula composed of 9 herbs: Bupleuri, Prunum mume, Zingiberis officinalis, Paeoniae	Jiang CR 1998

Table 1. The preparation and composition of the herbal medicines in the included trials (Continued)

		lactiflorae, <i>Atractylodis macrocephalae</i> , <i>Dioscoreae oppositae</i> , <i>Ledebouriellae divaricatae</i> , <i>Citri reticulatae</i> , <i>Glycyrrhizae uralensis</i>	
Changji Fang	decoction	A practitioner-prescribed formula composed of 8 herbs: <i>Atractylodis macrocephalae</i> , <i>Cyperi rotundi</i> , <i>Fructus tritici aestivi</i> , <i>Curcumae</i> , <i>Citri reticulatae</i> , <i>Paeoniae lactiflorae</i> , <i>Schisandrae chinensis</i> , <i>Glycyrrhizae uralensis</i>	Ye PS 2002
Changji Tai	decoction	A prescription of 6 Chinese herbs including <i>Atractylodis macrocephalae</i> , <i>Ledebouriellae divaricatae</i> , <i>Paeoniae lactiflorae</i> , <i>Citri reticulatae</i> , <i>Pruni mume</i> , <i>Glycyrrhizae uralensis</i>	Shen Y 2003
Ciwujia (<i>Acanthopanax senticosum</i>)	injection	Extract of herb <i>Acanthopanax senticosum</i> .	Zhou Q 2003
Folium sennae	decoction	single herb.	Chen ZJ 2002
Ganpi Lunzhi	decoction	A practitioner-prescribed formula composed of 7 herbs.	Zeng BM 2002
Geqinshu Jiangshuocao Tang	decoction	Chinese herbal formula composed of 6 herbs.	Wang ZH 2000
Gushen Changan	capsule	Mixture composed of <i>Glycyrrhizae uralensis</i> , <i>Poriae cocos</i> , <i>Atractylodis macrocephalae</i> , and glutamine	Du ZL 2002; Fei YM 2003
Huanchang Tang	decoction	A practitioner-prescribed formula composed of 10 herbs: <i>Bupleuri</i> , <i>Paeoniae lactiflorae</i> , <i>Ledebouriellae divaricatae</i> , <i>Citri aurantii</i> , <i>Aucklandiae lappae</i> , <i>Atractylodis macrocephalae</i> , <i>Glycyrrhizae uralensis</i> , <i>Citri reticulatae</i> , <i>Fructus Crataegi</i> , <i>Alpiniae katsumadai</i>	Deng ZT 2002
Huatan Liqi Tiaofu Tang	decoction	A practitioner-prescribed formula composed of 16 herbs: <i>Atractylodis macrocephalae</i> , <i>Pinelliae ternatae</i> , <i>Citri reticulatae</i> , <i>Raphani sativi</i> , <i>Poriae cocos</i> , <i>Paeoniae lactiflorae</i> , <i>Citri aurantii</i> , <i>Bupleuri</i> , <i>Ledebouriellae divaricatae</i> , <i>Fructus Crataegi</i> , <i>Hordei vulgaris germinatus</i> , <i>Massa medicata</i> , <i>Magnoliae officinalis</i>	Lei CF 2000

Table 1. The preparation and composition of the herbal medicines in the included trials (Continued)

		nalis, Radix platycodi, Pruni armeniacae, Glycyrrhizae uralensis	
Huoxiang Zhengqi	capsule	Chinese patent medicine (no detail on constituents).	Sun YS 1996
Individualised herbal prescription	capsule	No details were provided by the trial report.	Bensoussan 1998
Individualised herbal treatment	decoction	Four different syndromes were differentiated by the traditional Chinese medicine practitioner, and four different formulations were prescribed accordingly	Cai XH 2002
Jianpi Shugan Tang	decoction	A practitioner-prescribed formula composed of 11 herbs.	Yu YQ 1997
Jianzhong Lichang Tang	decoction	A practitioner-prescribed formula composed of 12 herbs: Pseudostellariae heterophyllae, Atractylodis macrocephalae, Aucklandiae lappae, Linderae strychnifoliae, Aquilariae, Arecae catechu, Citri aurantii, Rhizoma Rhei, Rehmanniae glutinosae, Radix platycodi, Curcumae, Cyperi rotundi	Luo WY 2003
Jiechang Kang	tablet	A hospital-developed preparation composed of 11 herbs.	Zhang RZ 1996
Lichang Tang	decoction	A practitioner-prescribed formula composed of 9 herbs: Astragali membranacei, Bupleuri, Paeoniae lactiflorae, Coptidis, Atractylodis macrocephalae, Artemisiae argyi, Poriae cocos, Patriniae, Zingiberis officinalis	Li XM 2001
Liqi Anchang Tang	decoction	A practitioner-prescribed formula composed of 12 herbs.	Yu YM 2000
Lizhong Tang	decoction	A formula composed of 13 herbs: Codonopsis pilosulae, Atractylodis macrocephalae, Zingiberis officinalis, Glycyrrhizae uralensis, Citri sarcodactylis, Ledebouriellae divaricatae, Paeoniae lactiflorae, Citri reticulatae, Citri aurantii, Massa fermentata, Coicis lachryma-jobi, Dioscoreae oppositae, Dolichoris	Cheng WJ 2000

Table 1. The preparation and composition of the herbal medicines in the included trials (Continued)

Mongolian herbal medicine	NA	Seven different herbal preparations composed of one or two of the following herbs: Ruyin, Yindala, Sirixi, Shaojide, Babu, Aolegai, Tangxin, Dangma	Ba T 1997
Padma Lax (Tibetan medicine)	capsule	Herbal extracts from <i>Aloes barbadensis</i> , <i>Aloe ferox</i> , <i>Jateorhiza palmata</i> , <i>Marsdenia condurango</i> , <i>Rhamnus frangula</i> , <i>Gentiana lutea</i> , <i>Inula helenium</i> , <i>Terminalia chebula</i> , <i>Piper longum</i> , <i>Rhamnus purshiana</i> , <i>Rheum palmatum</i> , <i>Strychnos nux-vomica</i> , <i>Zingiber officinale</i>	Sallon 2002
Pinggan Jianpi	decoction	Chinese herbal formula composed of 13 herbs.	Xu PH 1999
Pingheng Zhixie Jianji	decoction	A practitioner-prescribed formula composed of 5 herbs: <i>Leonuri heterophylli</i> , <i>Citri aurantii</i> , <i>Atractylodis macrocephalae</i> , <i>Dolichoris lablab</i> , <i>Polypori umbellati</i>	Chen P 2001
Pingyi Zhixie Tang or Pingyi Tongbian Tang	decoction	Two practitioner-prescribed formulas: Pingyi Zhixie Tang: <i>Pinelliae ternatae</i> , <i>Paeoniae lactiflorae</i> , <i>Aucklandiae lappae</i> , <i>Citri reticulatae</i> , <i>Poriae cocos</i> , <i>Atractylodis macrocephalae</i> , <i>Coicis lachrymajobi</i> , <i>Dolichoris lablab</i> , <i>Fritillariae thunbergii</i> , <i>Arisaematis</i> , <i>Ledebouriellae divaricatae</i> , <i>Glycyrrhizae uralensis</i> . Pingyi Tongbian Tang: <i>Radix et Rhizoma Rhei</i> , <i>Aquilariae</i> , <i>Curcumae</i> , <i>Poriae cocos</i> , <i>Bupleuri</i> , <i>Magnoliae officinalis</i> , <i>Citri aurantii</i> , <i>Dioscoreae oppositae</i> , <i>Micae seu chloriti</i> , <i>Trichosanthis</i> , <i>Raphani sativi</i> , <i>Biotae orientalis</i>	Chen YM 1999
Sanbai San	decoction	A formula composed of 7 herbs: <i>Atractylodis macrocephalae</i> , <i>Poriae cocos</i> , <i>Paeoniae lactiflorae</i> , <i>Magnoliae officinalis</i> , <i>Pruni mume</i> , <i>Zingiberis officinalis</i> , <i>Zingiberis officinalis recens</i>	Tong ZY 1998
Sanhuang Tang	decoction	Herbal formula composed of three herbs: <i>Radix et Rhizoma Rhei</i> , <i>Scutellariae baicalensis</i> , and <i>Phellodendri</i>	Hu TM 1991
Shenling Baishu San	decoction	A practitioner-prescribed formula composed of 12 herbs.	Zhang XQ 2000

Table 1. The preparation and composition of the herbal medicines in the included trials (Continued)

Shuchang Wan	decoction	A practitioner-prescribed formula: Bupleuri, Poriae cocos, Paeoniae rubrae, Paeoniae lactiflorae, Atractylodis macrocephalae, Citri aurantii, Angelicae sinensis, Ledebouriellae divaricatae, Citri reticulatae, Glycyrrhizae uralensis	Gu XX 1999
Shugan Jianpi Fang	decoction	Chinese herbal formula composed of 12 herbs.	Wang JZ 1996
Shugan Jianpi formula	decoction	A formula composed of 11 herbs: Bupleuri, Paeoniae lactiflorae, Citri reticulatae, Ledebouriellae divaricatae, Atractylodis macrocephalae, Codonopsis pilosulae, Poriae cocos, Dioscoreae oppositae, Curcumae, Pinelliae ternatae, Glycyrrhizae uralensis	Lin Y 1999
Shugan Jianpi recipe	decoction	A practitioner-prescribed formula composed of 11 herbs: Bupleuri, Curcumae, Paeoniae lactiflorae, Citri aurantii, Aucklandiae lappae, Dioscoreae oppositae, Atractylodis macrocephalae, Poriae cocos, Citri reticulatae, Magnoliae officinalis, Glycyrrhizae uralensis	Chen YC 2000
Shugan Jianpi Tang	decoction	A formula composed of 11 herbs: Bupleuri, Citri reticulatae viride, Ledebouriellae divaricatae, Aucklandiae lappae, Citri aurantii, Atractylodis macrocephalae, Paeoniae lactiflorae, Astragali membranacei, Dioscoreae oppositae, Coicis lachryma-jobi, Glycyrrhizae uralensis	Deng W 2000
Shugan Lipi recipe	decoction	A practitioner-prescribed formula composed of 7 herbs.	Yang SX 1998
Sijunzi Tang	decoction	A formula composed of 4 herbs: Codonopsis pilosulae, Atractylodis macrocephalae, Poriae cocos, Glycyrrhizae uralensis	Li H 2002
Sishen Tang	decoction	Chinese herbal formula composed of 6 herbs.	Lin YZ 2001
Standard Chinese herbal formulation	capsule	Composed of 20 herbs: Codonopsis pilosulae, Agastaches seu pogostemi, Ledebouriellae sesloidis, Coicis lachryma-	Bensoussan 1998

Table 1. The preparation and composition of the herbal medicines in the included trials (Continued)

		jobi, Bupleurum chinense, Artemesiae capillaris, Atractylodis macrocephalae, Magnoliae officinalis, Citri reticulatae, Zingiberis officinalis, Fraxini, Poriae cocos, Angelicae dahuricae, Plantaginis, Phellodendri, Glycyrrhizae uralensis, Paeoniae lactiflorae, Saussureae seu vladimirae, Coptidis, Schisandrae	
STW 5	drop	A commercial herbal preparation composed of bitter candytuft, chamomile flower, peppermint leaves, caraway fruit, licorice root, lemon balm leaves, celandine herbs, angelica root, milk thistle fruit	Madisch 2004
STW 5-II	drop	A research herbal preparation composed of bitter candytuft, chamomile flower, peppermint leaves, caraway fruit, licorice root, and lemon balm leaves	Madisch 2004
Sugan Renchang recipe	decoction	A practitioner-prescribed formula composed of 8 herbs.	Zhang T 2003
Suyun Zhixie Tang	decoction	A formula composed of 7 herbs: Bupleuri, Citri aurantii, Aucklandiae lappae, Paeoniae lactiflorae, Atractylodis macrocephalae, Rhizoma Rhei, Glycyrrhizae uralensis	Li JH 2003
Tiaogan Shipi recipe	decoction	A practitioner-prescribed formula composed of 7 herbs.	Yan MX 2003
Tiaogan Yichang Tang	decoction	Chinese herbal formula composed of 15 herbs.	Xin XY 2000
Tiaoli Ganpi recipe	decoction	Chinese herbal formula composed of 9 herbs.	Xiang N 1996
Tongxie Yaofang	decoction	A traditional formula composed of 4 herbs: Atractylodis macrocephalae, Paeoniae lactiflorae, Ledebouriellae divaricatae, Citri reticulatae	Fei YM 2003; Gong SX 2001; Huang JQ 2000; Rui YR 2002; Xu J 2004; Ye LJ 2000; Yin WD 1998; Zhuo YC 1996; Sun X 2004
Xiangsha Liujunzi Tang	decoction	A formula composed of 8 herbs: Aucklandiae lappae, Atractylodis macrocephalae, Poriae cocos, Citri reticulatae, Pinelliae ternatae, Amomi, Glycyrrhizae uralensis, Ginseng	Ge W 2002

Table 1. The preparation and composition of the herbal medicines in the included trials (Continued)

Xianshi (Shugan Jianpi recipe)	capsule	A practitioner-prescribed herbal formula.	Ye B 2002
Xiaoyao San	decoction	A formula composed of 8 herbs: Bupleuri, Atractylodis macrocephalae, Poriae cocos, angelicae sinensis, Ledebouriellae divaricatae, Citri reticulatae, Paeoniae lactiflorae, Glycyrrhizae uralensis	Huang LS 2001; Xu HQ 2003
Xuanfei Tiaoqi Tang	decoction	A practitioner-prescribed formula composed of 10 herbs: Asteris tatarici, Pruni armeniacae, Eriobotryae japonicae, Perillae frutescentis, Citri reticulatae, Aucklandiae lappae, Arecae catechu, Citri aurantii, Magnoliae officinalis, Rhizoma Rhei	Lin QL 2002
Xuefu Zhuyu Tang	decoction	A practitioner-prescribed formula composed of 13 herbs.	Zhang YG 2001
Yichang Jian	decoction	A practitioner-prescribed formula composed of 10 herbs: Citri reticulatae, Poriae cocos, Pinelliae ternatae, Magnoliae officinalis, Caulis perillae, Atractylodis macrocephalae, Amomi, Massa medicata, Paeoniae lactiflorae, Glycyrrhizae uralensis	Chen M 2001
Yichang San	decoction	A formula composed of 9 herbs: Atractylodis macrocephalae, Paeoniae lactiflorae, Poriae cocos, Dolichoris lablab, Dioscoreae oppositae, Zingiberis officinalis, Pruni mume, Magnoliae officinalis, Coptidis	Ren GX 2001
Yigan Fupi Huatan Quyu	decoction	Chinese herbal formula composed of 10 herbs.	Wang JF 2000
Yigan Fupi Tang	decoction	A formula composed of 10 herbs: Atractylodis macrocephalae, Ledebouriellae divaricatae, Paeoniae lactiflorae, Citri reticulatae, Aucklandiae lappae, Arecae catechu, Bupleuri, Pruni mume, Citri aurantii, Polypori umbellati	Chen H 2000

Table 1. The preparation and composition of the herbal medicines in the included trials (Continued)

Yigan Fupi recipe	decoction	A formula composed of 11 herbs: <i>Atractylodis macrocephalae</i> , <i>Paeoniae lactiflorae</i> , <i>Citri aurantii</i> , <i>Rosae rugosae</i> , <i>Citri reticulatae</i> , <i>Pruni mume</i> , <i>Ledebouriellae divaricatae</i> , <i>Glycyrrhizae uralensis</i> , <i>Zizyphi jujubae</i> , <i>Coptidis</i> , <i>Evodiae rutaecarpae</i>	Liu J 2000
Yigan Fupi Tang	decoction	Chinese herbal formula composed of 9 herbs.	Xie YD 2001
Yiji Tiaochang Tang	decoction	A practitioner-prescribed formula composed of 10 herbs: <i>Paeoniae lactiflorae</i> , <i>Sanguisorbae officinalis</i> , <i>Fraxini</i> , <i>Atractylodis macrocephalae</i> , <i>Citri reticulatae</i> , <i>Ledebouriellae divaricatae</i> , <i>Corydalis yanhusuo</i> , <i>Citri aurantii</i> , <i>Codonopsis pilosulae</i> , <i>Poriae cocos</i>	Hong ZM 1998
Zhongyao Heji	decoction	A practitioner-prescribed formula composed of more than 4 herbs	Zhuang YH 1998
NA: not available			

WHAT'S NEW

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CONTRIBUTIONS OF AUTHORS

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Sameline Grimsgaard: Revision of protocol and review, and methodological perspectives.

DECLARATIONS OF INTEREST

We certify that we have no affiliations with or involvement in any organisation or entity with direct or indirect financial interest in the subject matter of the review.

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