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Herbal medicines for viral myocarditis

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Abstract

Background—Herbal medicines are being used for treating viral diseases including viral myocarditis, and many controlled trials have been done to investigate their efficacy.

Objectives—To assess the effects of herbal medicines on clinical and indirect outcomes in patients with viral myocarditis.

Search methods—We searched the Cochrane Central Register of Controlled Trials (CENTRAL) in *The Cochrane Library* Issue 3, 2009, MEDLINE (January 1966 - July 2009), EMBASE (January 1998 - July 2009), Chinese Biomedical Database (1979 - 2009), China National Knowledge Infrastructure (1979 - 2009), Chinese VIP Information (1989 - 2009), Chinese Academic Conference Papers Database and Chinese Dissertation Database (1980 - 2009), AMED (1985 - 2009), LILACS accessed in July 2009 and the trials register of the Cochrane Complementary Medicine Field. We handsearched Chinese journals and conference proceedings. No language restrictions were applied.

Selection criteria—Randomised controlled trials of herbal medicines (with a minimum of seven days treatment duration) compared with placebo, no intervention, or conventional interventions were included. Trials of herbal medicine plus conventional drug versus drug alone were also included. Only trials that reported adequate description of allocation sequence generation were included.

Data collection and analysis—Two review authors independently extracted data and evaluated trial quality. Adverse effects information was collected from the trials.

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Zhijun Liu: searched for trials, selected studies, assessed quality of trials, extracted data.

Min Yang: selected studies and extracted data.

Joey Kwong: interpreted data and their analyses; provided methodological perspective and general advice on this review update.

Declarations of interest: None known.

Differences between protocol and review: During the updating of the published review, we applied a more strict inclusion criteria regarding the study design. We restricted all randomised trials to adequate description of the generation of allocation sequence. Therefore, some RCTs included in original review were excluded due to unclear method for generation of the allocation sequence. This resulted in 40 trials (43 references) that were included in the previous version of the review being excluded from this update. Searches were updated and 14 new trials were identified.

Results—Fourteen randomised trials involving 1463 people were included. All trials were conducted and published in China. Quality of the trials was assessed to be low. No trial had diagnosis of viral myocarditis confirmed histologically, and only a few trials attempted to establish viral aetiology. Nine different herbal medicines were tested in the included trials. The trials reported electrocardiogram results, level of myocardial enzymes, cardiac function, symptoms, and adverse effects.

Astragalus membranaceus (either as an injection or granules) showed significant positive effects in symptom improvement, normalisation of electrocardiogram results, CPK levels, and cardiac function. Shengmai injection also showed significant effects in symptom improvement. Shengmai decoction triggered significant improvement in quality of life measured by SF-36. No serious adverse effects were reported.

Authors' conclusions—Some herbal medicines may lead to improvement of symptoms, ventricular premature beat, electrocardiogram, level of myocardial enzymes, and cardiac function in viral myocarditis. However, interpretation of these findings should be taken with care due to the low methodological quality, small sample size, and limited number of trials on individual herbs. Further robust trials are needed to explore the use of herbal medicines in viral myocarditis.

Plain language summary

Viral myocarditis is a disease where the muscles in the walls of heart become infected with a virus. This systematic review evaluates the effect of various herbal formulations (including single herbs, ingredients, and mixtures of different herbs) for treating acute and chronic viral myocarditis patients. Fourteen identified clinical trials were performed and published in China. The review of trials found that some of the herbal medicines may have a positive effect on improving cardiac function, lowering blood enzymes and relieving symptoms in viral myocarditis patients. Data on adverse events were only available from one trial. However, the methodological quality of the clinical trials evaluating these herbal medicines was generally poor.

Background

Viral myocarditis is the result of viral infection that leads to myocardial necrosis (Suddaby 1996; Feldman 2000; Kearney 2001; Cooper 2009). Many pathogenic mechanisms may contribute to myocardial cell loss including cytokine production contributing to myocardium inflammation; viral persistence, which may produce an autoimmune response to cardiac myosin; and viral invasion of vascular endothelium causing vascular spasm with reperfusion injury (Feldman 2000; Rose 2009). Viral myocarditis is one of the causes of dilated cardiomyopathy (Dec 1994; Kawai 1999; Cooper 2009). The severe outcomes of viral myocarditis include arrhythmias, cardiogenic shock, development of dilated cardiomyopathy and death (necrosis) of heart tissue, although the majority of cases are subclinical and self-limited.

Myocarditis is an insidious disease that is usually asymptomatic in its early stages, and it appears to be far more common in children than in adults (Feldman 2000). The true prevalence of viral myocarditis in the general population is unknown due to the invasive technique (myocardial biopsy) required for diagnosis (Haas 2001; Cooper 2009). Myocarditis is a major cause of sudden, unexpected death (accounting for approximately 20% of cases) in adults less than 40 years of age (Drory 1991; Feldman 2000; Baughman 2006). Routine postmortem examinations have identified myocardial inflammation in one to nine percent of sudden, unexpected adult deaths taking into consideration three early studies in western countries (Feldman 2000). Viral infection is thought to be the most common cause of myocarditis. Viral myocarditis can be caused by more than 27 viruses such as

coxsackie virus, parvovirus B19, enterovirus, adenovirus, rubella virus, polio virus, human immunodeficiency virus 1 (HIV-1), cytomegalovirus, hepatitis A and C viruses.

The clinical features of myocarditis are varied. The spectrum includes asymptomatic participants who may have chest pain, fever, palpitation and electrocardiographic abnormalities; signs and symptoms of clinical heart failure and ventricular dilation, of fulminant heart failure and severe left ventricular dysfunction, with or without cardiac dilations (Dec 1985; Feldman 2000). Although the endomyocardial biopsy remains the gold standard for the diagnosis of viral myocarditis, comprehensive criteria are developed for the diagnosis through evaluation of cardiac function, symptoms and signs, history of flu-like syndrome, laboratory findings, identification of the viruses, as well as elimination of other causes of global cardiac dysfunction, (see 'Types of participants') (Dec 1992; Feldman 2000; Andreoletti 2009; Schultz 2009).

Supportive care is the first line of therapy for left ventricular dysfunction in patients with viral myocarditis. Cardiac function support is provided by pharmacological agents such as digitalis and diuretics, extracorporeal membrane oxygenation, and implantation of a ventricular-assisting device (Topkara 2006). Current trials of treatment in chronic heart failure secondary to dilated cardiomyopathy support the use of angiotensin converting enzyme inhibitors, angiotensin-receptor blockers, beta adrenoceptor blockers, and diuretics (Kearney 2001, Cooper 2009). Other treatments for viral myocarditis are immunosuppressive agents (Parrillo 2001; Wojnicz 2001), immunoadsorption (Staudt 2001), and interferon (Miric 1995).

Complementary therapies are being used increasingly (Eisenberg 1998; Vickers 2000; Koithan 2009; O'Regan 2009). The number of randomised trials of complementary treatments has increased significantly in the recent years (Tang 1999). The *Cochrane Database of Systematic Reviews* has over 100 systematic reviews of complementary medicine interventions (as of Issue 1, 2010). Many people turn to this therapy when conventional medicine fails them or they believe strongly in the effectiveness of complementary medicine (John 2005). Herbal medicine forms the main part of traditional Chinese medicine, which is a 3000-year-old holistic system of medicine combining medicinal herbs, acupuncture, food therapy, massage, and therapeutic exercise for both treatment and prevention of disease (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. Synonyms of herbal medicines include herbal remedies, herbal medications, herbal products, herbal preparations, medicinal herbs, and phyto-pharmaceuticals.

Our primary searches identified more than 400 studies tested Chinese herbal medicines for viral myocarditis in the Chinese biomedical database (December 2001). There are four kinds of herbal therapies, i.e. single herb, Chinese proprietary medicines, mixture of different herbs, and any one of the three types plus western medicines. The most commonly tested single herbs include *Astragalus membranaceus*, *Salviae miltiorrhizae*, ginseng, and *Sophorae flavescens*; and the Chinese proprietary medicines such as Shenmai and Shuanghuanglian in the clinical trials. Chinese proprietary medicines are usually based on well-established and longstanding recipes and formulated as tablets or capsules for commerce, convenience, or palatability (Yang 2006). Mixture of herbs is prescribed by Chinese herbalists according to their differentiation of symptoms through the Chinese diagnostic patterns (i.e. inspection, listening, smelling, inquiry, and palpation) (MOH 2007). However, active ingredients of these herbal medicines are largely unknown and they are combined with different herbs to regulate body functions (Jiang 1999). Several trials have shown that *Astragalus membranaceus* and Shenmai might have potential for treating viral

myocarditis or alleviating symptoms and signs and decreasing cardiac enzymes and few trials reported adverse effects (Yang 1990; Li 1992; Ren 1992; Huang 1995; Liu 1996; Yang 1997; Yin 1997; Li 1998; Chen 1999). The possible modes of action include enhancing natural killer cell activity, inducing production of alpha- and gamma-interferon, improving cardiac microcirculation, and anti-free radical and lipid peroxidation (Yang 1990; Li 1992; Huang 1995; Zhao 1996). On the other hand, there are an increasing number of reports in the medical literature about liver toxicity, renal damage and even cancer from some Chinese herbal products (Ishizaki 1996; Melchart 1999; Gottlieb 2000) thus, this area needs further research and systematic evaluation.

Objectives

The objective of this review was to assess the effect, both harms and benefits of treating viral myocarditis with herbal medicines.

Methods

Criteria for considering studies for this review

Types of studies—Randomised controlled trials (RCTs) with adequate method of allocation sequence generation were included irrespective of blinding, publication status, and language. Adequate methods of sequence generation included computer generated random numbers, tables of random numbers or drawing lots. Randomised crossover trials would also be included if the data were available. Quasi-randomised trials, non-randomised studies and self-described randomised control studies without elaboration of sequence generation method used would be excluded.

Types of participants—Male or female patients, of any age or ethnic origin, who had viral myocarditis (including acute and/or chronic viral myocarditis).

Viral myocarditis was diagnosed on the basis of: a history of an antecedent flu-like syndrome accompanied by symptoms such as fever, arthralgias, and malaise; following with signs and symptoms of clinical heart failure and ventricular dilation; along with laboratory findings of leukocytosis, an elevated sedimentation rate, eosinophilia, or an elevation in the cardiac fraction of creatine phosphokinase (CPK-MB); the electrocardiogram showing ventricular arrhythmias or heart block; and excluding other causes of global cardiac dysfunction, e.g. acute myocardial infarction or pericarditis (Vignola 1984; Dec 1992; Feldman 2000; Baughman 2006; Schultz 2009). The gold standard by the finding of the endomyocardial biopsy is not imperative for diagnosis. Acute viral myocarditis was considered in patients who presented with recent (less than two weeks) onset of cardiac failure or arrhythmia. Trials in which patients presenting with recent onset of cardiac failure or arrhythmia and laboratory tests corresponding with myocarditis, but without electrocardiogram confirmation, would be included.

Types of interventions—We defined herbal medicines 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. Synonyms of herbal medicines were herbal remedies, herbal medications, herbal products, herbal preparations, medicinal herbs, and phyto-pharmaceuticals.

The intervention of herbal medicines included single herb (including extract from single herb), Chinese proprietary medicine, or compound of several herbs irrespective of preparation (e.g. decoction, oral liquid, tablet, capsule, pill, powder, granule, injection, or

plaster (external use of dressings impregnated with herbal extracts)), route of administration (e.g. oral, topical, intramuscular or intravenous injection), dosage, and regimen of herbs.

We also included trials of herbal medicines plus conventional intervention versus conventional intervention alone. The control intervention included placebo, non-specific treatment such as vitamins or nutritional supplement, supportive therapy such as diuretics, beta-blocker, or antiviral therapy. Any co-intervention out of experimental and control interventions was allowed as long as all arms of the randomised allocation received the same co-intervention.

We included trials if the treatment was given for a minimum of seven days although definitive information about duration of treatment was lacking in the literature. Short (seven days) and long term (more than three weeks) duration would be explored in subgroup analysis.

The following comparisons were tabulated where data available:

1. herbal medicines versus placebo;
2. herbal medicines versus non-specific treatment;
3. herbal medicines versus supportive intervention;
4. herbal medicines versus antiviral therapy;
5. herbal medicines plus conventional intervention versus conventional intervention alone.

Types of outcome measures

Primary outcomes

1. Mortality (all-cause and myocarditis related);
2. Incidence of complications (heart failure and arrhythmias).

Secondary outcomes

1. Cardiac function;
2. Biochemical response, defined as decrease or normalisation of serum enzymes levels;
3. Number and type of adverse events;
4. Quality of life (assessed by validated scale);
5. Health economics (such as cost of interventions, length of hospital stay).

Two types of adverse events would be analysed: serious and minor adverse events. Serious adverse events were defined as those that led to death, were life-threatening, required or prolonged hospitalisation, resulted in persistent or significant disability/incapacity, or were events that could jeopardise the patient or required another intervention to prevent or treat the relevant adverse events (ICH-GCP 1997). All other adverse events were considered to be minor. For herbal medicines that were included in this review, we would use non-randomised or toxicological studies to assess potential adverse effects.

Search methods for identification of studies

Electronic searches—We searched the Cochrane Central Register of Controlled Trials (CENTRAL) in *The Cochrane Library* (Issue 3, 2009), MEDLINE (January 1966 - July

2009), EMBASE (January 1998 - July 2009) Chinese Biomedical Database (1979 - 2009), China National Knowledge Infrastructure (1979 - 2009), Chinese VIP Information (1989 - 2009), Chinese Academic Conference Papers Database and Chinese Dissertation Database (1980 - 2009), AMED (1985 - 2009), LILACS (www.bireme.br/bvs/l/ibd.htm) accessed on July 2009 and the trials register of the Cochrane Complementary Medicine Field. We handsearched Chinese journals and conference proceedings.

No language restrictions were applied.

Searching other resources—The following journals published in Chinese were initially handsearched for the published review: *Journal of Clinical Cardiology* (1985 to 2003), *Chinese Journal of Hypertension* (1993 to 2003), *Chinese Journal of Cardiac Arrhythmia* (1997 to 2003), *Chinese Circulation Journal* (1986 to 2003), *Journal of Traditional Chinese Medicine* (1980 to 2003), *Chinese Journal of Integrated Traditional and Western Medicine* (1982 to 2003).

No handsearching was performed for this update because all the post-2003 publications in above journals were embodied in electronic databases.

We checked the reference lists of identified randomised clinical trials and review articles in order to find randomised trials not identified by the electronic searches or handsearches. We searched ongoing trials through the National Research Register <https://portal.nihr.ac.uk/Pages/NRRArchive.aspx> and Current Controlled Trials www.controlled-trials.com, and grey literature through the database SIGLE.

Data collection and analysis

Selection of trials for inclusion—Two reviewers (ZLL and ZJL) independently selected the trials using a pre-specified selection criteria form. Any disagreement was resolved by discussion.

Assessment of risk of bias—For this review update, we applied a stricter inclusion criteria and only included trials with clear description of the method used in generating allocation sequences. Risk of bias of included studies were assessed by two authors (ZLL, ZJL) independently. Any disagreements were resolved by consensus, or with consultation with a third author (JPL). The Cochrane Collaboration risk of bias tool was used (Higgins 2008):

- was the allocation sequence adequately generated?
- was the allocation adequately concealed?
- was knowledge of the allocated intervention adequately prevented during the study?
- were incomplete outcome data adequately addressed?
- were reports of the study free of suggestion of selective outcome reporting?
- was the study apparently free of other problems that could put it at a high risk of bias?

A judgement of 'Yes' indicates low risk of bias, 'No' indicates high risk of bias and 'Unclear' indicates unclear or uncertain risk of bias.

Furthermore, we aimed to investigate if intention-to-treat analysis and pre-sample estimation were applied in the included studies.

Data extraction—Two reviewers (ZLL and ZJL) extracted data independently, which were validated by a third author (JPL) using a self-developed data extraction form. Papers not in Chinese, English, Japanese, and German were translated with the help of the Cochrane Heart Group. The following characteristics and data were extracted from each included trial: primary author, funding source, quality assessment, mean age, proportion of males, and ethnicity of patients, number of randomised patients, reason and number dropped out or lost during follow-up, patient inclusion and exclusion criteria, acute or chronic viral myocarditis, the way diagnosis was made, type of herb or herbs, method of administration, dosage and duration of intervention, details of the comparison regime, outcome measures, and number and type of adverse events.

Data on the number of participants 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, we contacted the principal investigator.

Data synthesis—Every type of herbal medicines was compared with a control (e.g. placebo) individually regardless of route of administration, dose, or preparation. Meta-analyses were performed for trials that compared the same herb against same control. Dichotomous data were expressed as relative risk (RR) and continuous outcomes as weighted mean difference (WMD), both with 95% confidence intervals (CI). Intention-to-treat analyses were performed where possible. For dichotomous outcomes, patients with incomplete or missing data were included in a sensitivity analysis by counting them as treatment failures, in order to explore the possible effect of loss to follow-up. Heterogeneity was assessed using the I^2 test. Thresholds for the interpretation of I^2 can be misleading, since the importance of inconsistency depends on several factors. A rough guide to interpretation is as follows:

- 0% to 40%: low level of heterogeneity;
- 30% to 60%: moderate heterogeneity;
- 50% to 90%: substantial heterogeneity;
- 75% to 100%: high level of heterogeneity.

If $I^2 > 50\%$, the random effects model was used.

The following comparisons were tabulated if data were available:

1. herbal medicines versus placebo;
2. herbal medicines versus non-specific treatment;
3. herbal medicines versus supportive intervention;
4. herbal medicines versus antiviral therapy.

Trials of herbal medicines plus conventional intervention versus conventional intervention alone were presented as a separate comparison.

Data from non-randomised studies for assessment of safety were tabulated and analysed in Table 1.

If a sufficient number of randomised trials were identified, we would have performed subgroup analyses according to clinical course (acute or chronic viral myocarditis), electrocardiogram diagnosis (yes or no), formulation of herbs (extract, single herb, or mixture of herbs), and treatment duration (short and long term).

Furthermore, if we had identified a sufficient number of randomised trials, we planned to perform sensitivity analyses to explore the influence of trial quality on effect estimates. The quality components of methodology included adequacy of concealment of allocation, double blinding, the use of intention-to-treat (yes or no). Potential biases (Vickers 1998) were investigated using the funnel plot or other corrective analytical methods according to Egger 1997.

Results

Description of studies

Results of the search—Our searches identified 2407 (620 before year 2003, and 1787 from year 2003 to year 2009) references: 2391 from the electronic searches and 16 from the handsearches up to July 2009. After reading titles and abstracts, we excluded 2275 of these articles because they were duplicates, non-clinical studies, or had study objectives different from this review. A total of 132 references published in Chinese or English were retrieved for further assessment. Of these, 116 references (of 109 trials) were excluded because they did not meet our inclusion criteria. A total of 14 new trials (of 16 references) were included in this update (Figure 1). The reasons for exclusion were listed under Characteristics of excluded studies. 40 trials (of 43 references) that were included in the previous version of this review were excluded in this update because of inadequate description of generation of allocation sequence.

Included studies—Fourteen RCTs were included in this review update. Further details are given in the Characteristics of included studies. All the included trials were conducted and published in China.

Participants: A total of 1463 participants with viral myocarditis were included in the 14 trials. The proportion of male participants was 35.2% (515/1463). Eight trials included inpatients (Tan YB 2003; Zheng R 2003; Wang Y 2005; Yao BJ 2005; Li L 2006; Li M 2006; Yang YX 2008; Wu JW 2009), five trials included both inpatients and outpatients (Peng Q 2005; Zheng RF 2005; Chen PY 2006; Zhang ZZ 2006; Zhou Y 2006) and one trial did not specify the study setting (Zhou YW 2008). Average size of the trials was 105 participants (ranging from 40 to 218 participants per trial).

Diagnosis: Four trials enrolled patients with acute viral myocarditis; four enrolled with a mixture of acute and chronic viral myocarditis; two enrolled patients with chronic viral myocarditis, and the remaining four trials enrolled patients with undefined phase of viral myocarditis. The diagnostic criteria were based on the national conference consensus in China (NCSSMC 1995; Li 1996; Guo 1999; Wu 2000), which included antecedent history, clinical manifestations, abnormal electrocardiogram and laboratory tests (biochemical parameters and/or aetiology), and excluded other diseases with similar presentations. No trials attempted to establish a viral aetiology for the myocarditis.

Interventions: There were large variations in the formulations, dosage, administration, duration of treatment, and control interventions in the included trials among the herbal medicines tested (Table 1). In total, nine different herbal medicines were tested. *Astragalus membranaceus* was tested in six trials (Tan YB 2003; Zheng R 2003; Zhang ZZ 2006; Zhou Y 2006; Yang YX 2008; Wu JW 2009). Xinshu Capsule was tested in one trial (Chen PY 2006). Four herbal decoctions including Qingxin Kangyan Yin decoction, Shengyang Yixin decoction, Qi Lu decoction and Qingxin Huoming decoction were tested in four trials respectively (Yao BJ 2005; Li L 2006; Li M 2006; Zhou YW 2008). Two formulations (oral liquids and injection) of Shengmai were tested respectively in two trials (Peng Q 2005;

Zheng RF 2005), shortscape fleabane injection (herb extract) was tested in one trial (Wang Y 2005) and compound Qiangqi pill (herb mixtures) was tested in one trial (Zheng RF 2005). The formulations of herbal medicines were different, ranging from capsule, pill oral liquid, decoction to injection. The compositions of the herbal medicines varied (Table 1). The duration of treatment varied from 14 days to 30 days (mostly from 14 to 21 days). No trial reported quality standard of the herbal preparations. The supportive therapy included intravenous use of glucose, ATP, co-enzyme A or Q10, inosine, vitamin C, B, E, insulin, cytochrome C, KCl, FDP, etc. The co-interventions included anti-arrhythmic drugs, corticosteroids, and antiviral therapies such as ribavirin or interferon.

Outcomes: No trial reported outcomes of the incidence of complications or on health economic costs. One trial reported outcomes of quality of life (Zheng RF 2005). The outcomes that were reported included mortality, conversion to persistent myocarditis, clinical symptoms and signs, electrocardiogram, cardiac function, myocardial enzymes, and adverse effects. Only two trials reported outcome of adverse effects (Tan YB 2003; Zheng RF 2005). Tan YB 2003 observed no adverse events whereas adverse events of high leucocyte count were seen in 15/132 (11%) patients in Zheng RF 2005. Outcomes reported in 12 trials were measured at the end of treatment. Two trials reported a follow-up period of six months.

Risk of bias in included studies

None of the trials reported sample size calculation or stated that they performed an intention-to-treat analysis to evaluate their data. No multi-centre, large scale RCTs were identified in our searches. Three trials (Zheng R 2003; Zheng RF 2005; Yang YX 2008) reported drop-outs, with a 20% drop-out rate observed in Yang YX 2008. Regrettably, no information was available in how the drop-out rate was treated with. Eleven trials made baseline comparisons. Only two trials had clear inclusion and exclusion criteria (Zheng RF 2005; Chen PY 2006). Outcome assessment was made after treatment but there was no stated indication for further interventions.

The trials provided limited information on allocation concealment and blinding but there was a lack of description of generation of the allocation sequence. Trialists were contacted for further information but regrettably no information has been provided to date. Sensitivity analyses were performed to explore the effect of potential biases.

Assessment of risk of bias is described for each included study in the Characteristics of included studies tables as well as in Figure 2 and Figure 3.

Allocation (selection bias)—All 14 trials had adequate sequence generation but only four (Zheng R 2003; Zheng RF 2005; Zhang ZZ 2006; Zhou Y 2006) provided information on how the allocation sequence was concealed. In each case sealed envelopes were used.

Blinding (performance bias and detection bias)—Among the 14 included trials, only one trial (Zheng RF 2005) was double-blinded. The remaining 13 trials did not provide information about blinding.

Incomplete outcome data (attrition bias)—One trial (Zheng R 2003) did not provide sufficient information for making a judgement on incomplete outcome data assessment. The remaining 13 trials reported the same number of participants randomised and analysed, or addressed the incomplete outcome data or the reasons for missing outcome data.

Selective reporting (reporting bias)—Seven of the 14 trials (Li L 2006; Li M 2006; Peng Q 2005; Yang YX 2008; Yao BJ 2005; Zhang ZZ 2006; Zhou Y 2006) were judged to be at high risk of bias in selective reporting due to the lack of information in pre-specified primary outcomes.

Other potential sources of bias—All included trials contained insufficient information for us to make a judgement on other potential sources of bias and thus were all judged to be unclear for the item “free of other bias?”.

Effects of interventions

Astragalus membranaceus—The injections of single herb *Astragalus membranaceus* were tested in five trials (Tan YB 2003; Zheng R 2003; Zhang ZZ 2006; Zhou Y 2006; Yang YX 2008), and one trial tested *Astragalus membranaceus* granule (Wu JW 2009). The above five trials reported outcomes for symptoms, electrocardiogram, cardiac function, and cardiac enzymes. However, since they reported different outcome measures, it was not possible to combine the data except for the outcomes of symptoms and myocardial enzymes.

Compared with supportive therapy, *Astragalus membranaceus* injection didn't show significant effect on symptom improvement, reducing the number of patients died of cardiac failure and patients converting to persisting myocarditis (Yang YX 2008).

Compared with supportive therapy, a combination of *Astragalus membranaceus* injection and supportive therapy showed significant effect on some outcomes. As there were considerable heterogeneity among these studies (Tan YB 2003; Zheng R 2003; Zhang ZZ 2006; Zhou Y 2006), the random effects model was used to do a meta-analysis of a combination of *Astragalus membranaceus* injection and supportive therapy on symptom improvement and no significant effect was found (RR 0.38, 95% CI 0.14 to 1.07; Analysis 2.1). One trial showed significant effect of *Astragalus membranaceus* injection plus supportive therapy on a number of patients with abnormal electrocardiogram (RR 0.25, 95% CI 0.08 to 0.80; Analysis 2.2) (Tan YB 2003). A meta-analysis of two trials showed significant effect of *Astragalus membranaceus* injection on creatine phosphate kinase (CPK) levels (MD 21.54, 95% CI -33.80 to -9.28; Analysis 2.8) and lactate dehydrogenase (LDH) levels (MD 30.33, 95% CI -46.78 to -13.88; Analysis 2.9) (random effects model was used due to significant heterogeneity) (Zhang ZZ 2006; Zhou Y 2006). One trial showed significant difference between *Astragalus membranaceus* injection plus supportive therapy and supportive therapy regarding left ventricular ejection time (LVET) levels (MD 4.67, 95% CI 1.94 to 7.40; Analysis 2.11) (Zheng R 2003). There was no significant difference between the combination of *Astragalus membranaceus* injection and supportive therapy alone in ST-T change (Zheng R 2003), reducing the number of patients with premature beat and abnormal myocardial enzyme levels (Tan YB 2003), reducing the number of patients with abnormal LVEF and converting to persisting myocarditis (Zheng R 2003).

Referring to the intervention of *Astragalus membranaceus* granule, one trial showed significant difference between *Astragalus membranaceus* granule plus supportive therapy and supportive therapy regarding LVET levels (MD 12.00, 95% CI 5.06 to 18.94; Analysis 2.11) and creatine kinase MB (CK-MB) levels (MD 16.30, 95% CI -19.66 to -12.94; Analysis 2.12) (Wu JW 2009). A combination of *Astragalus membranaceus* granule and supportive therapy did not show significant effect than supportive therapy alone on symptom improvement, reducing the number of patients with abnormal electrocardiogram and patients with abnormal myocardial enzyme levels (Wu JW 2009).

Shengmai—Two trials tested Shengmai: one used Shengmai injection in 57 patients with viral myocarditis (Peng Q 2005) and the other Shengmai decoction in 80 patients (Zheng RF

2005). Compared to supportive therapy, Shengmai injection showed significant effects on symptom improvement (RR 0.32, 95% CI 0.14 to 0.75; Analysis 1.1) (Peng Q 2005). There was no significant difference between Shengmai injection and supportive therapy regarding abnormal ST-T changes (RR 1.18, 95% CI 0.58 to 2.40; Analysis 1.2) (Peng Q 2005). Shengmai decoction plus supportive therapy showed significant effect on improving quality of life measured by SF-36 (WMD 40.20, 95% CI 18.13 to 62.27; Analysis 2.13) compared to supportive therapy (Zheng RF 2005). There was no significant difference between Shengmai decoction plus supportive therapy and supportive therapy regarding symptom improvement, abnormal electrocardiogram, number of patients with premature beat (Zheng RF 2005).

Other herbal medicines that were tested once in trials

Shortscape Fleabane injection (*Erigeron breviscapus*): One trial compared herbal extract from *Erigeron breviscapus* plus supportive therapy against supportive therapy alone in 83 patients with acute viral myocarditis (Wang Y 2005). The combination of herbal and supportive therapy appeared better than supportive therapy alone in reducing CK-MB levels (VMD -5.81, 95% CI -11.34 to -0.28; Analysis 2.12), LDH levels (MD 29.28, 95% CI -57.82 to -0.74, Analysis 2.9), symptom scores (VMD -1.41, 95% CI -2.23 to -0.59; Analysis 2.10), CPK levels (MD -41.37, 95% CI -67.00 to -16.46; Analysis 2.8). There was no significant difference between *Erigeron breviscapus* plus supportive therapy and supportive therapy alone regarding number of patients with premature beat.

Qingxinkangyan decoction: One trial compared Qingxinkangyan decoction versus supportive therapy in 111 participants with viral myocarditis (Li L 2006). No other differences were observed in this study.

Xinshu capsule: One trial tested *Xinshu Capsule* for treatment of 120 patients with viral myocarditis (Chen PY 2006). The trial showed significant difference between the herbal medicine and supportive therapy regarding symptom improvement (RR 0.14, 95% CI 0.04 to 0.45; Analysis 1.1) and number of patients with premature beat (RR 0.21, 95% CI 0.06 to 0.79; Analysis 1.5).

Compound Qiangqi pill: One trial compared Compound Qiangqi pill plus supportive therapy with supportive therapy alone in 80 participants with viral myocarditis (Zheng RF 2005). The combination of herbal medicine and supportive therapy showed significant effect on improving quality of life measured by SF-36 (WMD 88.35, 95% CI 68.01 to 108.69; Analysis 2.13) compared to supportive therapy (Zheng RF 2005). No other differences were observed in this study.

Qi Lu decoction: One trial compared herbal decoction plus supportive therapy against supportive therapy alone in 168 participants with viral myocarditis (Yao BJ 2005). The trial showed significant difference between the combined therapy and supportive therapy regarding symptom improvement (RR 0.16, 95% CI 0.04 to 0.69; Analysis 2.1). The combined therapy was not significant different from supportive therapy in number of patients with premature beats.

Shengyangyixin decoction: One trial compared Shengyangyixin Decoction plus supportive therapy with supportive therapy alone in 76 patients with viral myocarditis (Li M 2006). The combination of herbal medicine and supportive therapy had a significant effect on reducing the number of participants with abnormal electrocardiogram (RR 0.56, 95% CI 0.35 to 0.90; Analysis 2.2) compared with supportive therapy. The trial also showed significant difference between the combined therapy and supportive therapy regarding LDH levels (MD -186.63,

95% CI -215.02 to -158.24; Analysis 2.9) and CK-MB levels (MD -3.30, 95% CI -3.74 to -2.86; Analysis 2.12). However, the combination did not differ significantly from supportive therapy regarding symptom improvement in this study.

Qingxinhuoming decoction: One trial compared Qingxin Huoming Decoction plus supportive therapy against supportive therapy alone in 78 participants with viral myocarditis (Zhou YW 2008). The combination of herbal medicine and supportive therapy had a significant effect on reducing the number of participants with abnormal electrocardiogram (RR 0.32, 95% CI 0.13 to 0.79; Analysis 2.2) compared with supportive therapy. There was no significant difference between combined Qingxinhuoming Decoction and supportive therapy in symptom improvement.

Discussion

The present systematic review suggests that some herbal medicines may appear to have positive effects in patients with suspected viral myocarditis.

Astragalus membranaceus plus supportive therapy was effective on symptom improvement, improved myocardial enzymes, abnormal electrocardiogram and cardiac function. *Shengmai injection* was effective on symptom improvement. *Shortscape Fleabane*, *Xinshu Capsule*, *Compound Qiangqi pill*, *Qi Lu Decoction*, *Shengyangyixin Decoction*, and *Qingxinhuoming Decoction* appeared to be effective in improving symptoms as well as cardiac function, electrocardiogram, and/or myocardial enzymes. However, at present there is no strong evidence to recommend any of these herbal medicines for the treatment of viral myocarditis due to the weak methodological quality of the trials, lack of confirmed diagnosis, the variations of the population, the regimens and duration of the herbal medicines tested, and the outcomes reported. More specifically, the positive findings should be interpreted conservatively due to the following facts:

Risk of bias

All the randomised trials included in this review had risk of bias in terms of design, reporting, and methodology. They provided only limited descriptions of study design, randomisation, and baseline data. Some of the trials reported skewed distribution of data, which cannot be explained by the randomisation principle. Methodologically poorly designed trials show larger differences between experimental and control groups than those conducted rigorously (Schulz 1995; Moher 1998; Kjaergard 2001). The insufficient number of trials prohibited us from performing meaningful sensitivity analysis to illuminate how robust the results of the review are to the exclusion of the trials with inadequate methodology. The included trials were heterogeneous in the populations (adults, children, or mixture with acute or undefined viral myocarditis), interventions (few herbal medicines tested more than twice), and the reported outcomes. No multi-centre, large scale RCTs were identified.

Publication bias

Although we conducted comprehensive searches, we only identified and included trials which were conducted and published in Chinese. Most of the trials are small, with positive findings. We tried to avoid language bias and location bias, but we could not exclude potential publication bias. Vickers and colleagues (Vickers 1998) found that some countries including China publish unusually high proportions of positive results within the complementary medicine field. Publication bias may be a possible explanation. We have undertaken extensive searches for unpublished material, few trials of the identified qualified

for inclusion, but at the same time we cannot disregard the fact that trials with negative findings remain unpublished.

Diagnostic criteria

No trial used endomyocardial biopsy (the gold standard) for diagnosis of viral myocarditis. Most of the trials made their diagnosis based on the national conference consensus on diagnosis of viral myocarditis, which basically conforms with the international recommended criteria. No trials reported aetiological confirmation. Therefore, the participants in the included trials are considered as 'suspected' viral myocarditis. Due to the fact of lack in information about diagnosis of acute and chronic types with subgroup outcomes reported as well as electrocardiogram diagnosis, we could not perform pre-specified subgroup analyses on diagnosis.

Interventions

There are wide variations among tested herbal medicines and control interventions. No trial used placebo control. The herbal medicines were compared with supportive therapy or added to supportive therapy compared with supportive therapy alone. Even for a same herbal intervention, it is still different in the treatment regimens including the dosage, co-interventions, and duration. Therefore, it is difficult to undertake subgroup analyses to explore factors that may affect these effects. There is still a lack of information about quality standard for the development of the herbal preparations or for the manufacture of the herbal products. Future trials should provide information about standardisation including compositions, quality control, detailed regimen, and fixed duration of treatment.

Surrogate outcomes

The primary goal of treatment for viral myocarditis is to prevent death or progression to complications. Only one trial reported death in patients with viral myocarditis (Yang YX 2008). Other outcomes from the included trials are mainly symptom improvement, myocardial enzyme, electrocardiogram, cardiac function, i.e. surrogate outcomes. Only one trial reported outcome of quality of life. There is a lack of data from most trials on clinically relevant outcomes such as mortality, incidence of complications, and quality of life. There were 109 randomised trials on herbal medicines in viral myocarditis excluded from this review. The main reasons are inadequate reporting of the outcomes and methods of sequence generation. Most of the excluded studies reported a global improvement of outcomes combined of symptoms and signs, electrocardiogram, and/or myocardial enzymes. Data from individual outcome is not available.

Nevertheless, herbal medicines are widely used for treating viral myocarditis in China. We have identified more than 100 randomised trials on this topic until now. However, over half of them are not eligible for the review due to inadequate design, conducting, and reporting of the trials. Chinese researchers must be aware of the need to design and use appropriate statistical power in future randomised controlled trials of herbal medicines and to measure clinical outcomes rather than physiological (surrogate) outcomes.

Adverse outcomes

There is inadequate reporting on adverse events in the included trials. Only two trial reported results about adverse effects (Tan YB 2003; Zheng RF 2005). A conclusion about the safety of herbal medicines cannot be made. In China, there is a general perception that it is safe to use herbal medicines for various conditions and some studies support this perception (Haines 2008; May 2009; Ramesh 2009; Wang 2009;). The low level of reporting on adverse events may reflect this. However, there are some reports of liver

toxicity and other adverse events associated with using Chinese herbal medicines (Ishizaki 1996; Melchart 1999; Gottlieb 2000; Pinn 2001; Liu 2006). For this reason, safety of herbal medicines needs to be monitored and reported in clinical trials.

Authors' conclusions

Implications for practice

Based on this systematic review, the effectiveness and safety of herbal medicines in suspected viral myocarditis is uncertain. The evidence is inconclusive due to poorly designed and low quality trials and uncertain diagnosis of viral myocarditis. Further randomised trials with robust methodology are warranted in future.

Implications for research

Future research needs to emphasise not only good clinical trial methods, but also more rigorous description of the pharmacology of the interventions and histological diagnosis of the myocarditis. Trials on Chinese herbal medicines for viral myocarditis should be designed in order to meaningfully record clinical outcomes.

From the results of the present review, it would be interesting to evaluate preparations of *Astragalus membranaceus* and Shengmai in comparing with supportive therapy in patients of established viral myocarditis. Information about species, geographical origin of herbs, season for collecting, quality of the preparations should be provided. Standardised monitoring and reporting should be used for assessment of adverse events.

Future research should also pay attention to the quality of the trials. To improve the quality of future trials, we suggest that all researchers should receive necessary training on clinical trials methodology before designing a trial and registered the trial in authorised registered organizations. And the following methodological issues should be particularly addressed: (i) methods used to generate random sequence; (ii) methods used to allocation concealment; (iii) double blinding with the use of adequate placebo. In the stage of data analysis, clear descriptions of withdrawal/dropout during the trial and use of intention-to-treat analysis were preferred. We suggest that the authors report trials according to the CONSORT 2010 Statement (Schulz 2010).

Acknowledgments

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Internal sources

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Feedback: Appendices

1 Search strategies 2009

CENTRAL on The Cochrane Library

- #1 MeSH descriptor myocarditis this term only
- #2 MYOCARDITIS in All Text
- #3 (MYOCARD* in All Text near/6 INFLAMM* in All Text)
- #4 (HEART in All Text near/6 INFLAMM* in All Text)
- #5 (#1 or #2 or #3 or #4)
- #6 MeSH descriptor Medicine, Traditional explode all trees
- #7 MeSH descriptor Plant Extracts explode all trees
- #8 MeSH descriptor Plants, Medicinal explode all trees
- #9 ((HERB in All Text or HERBAL in All Text) or HERBS in All Text)
- #10 ALTERNATIVE next MEDICIN* in All Text
- #11 COMPLEMENTARY next MEDICINE* in All Text
- #12 (TRADITIONAL in All Text near/6 MEDICINE* in All Text)
- #13 (PLANT* in All Text near/6 MEDICIN* in All Text)
- #14 (CHINESE in All Text near/6 MEDICIN* in All Text)
- #15 PHYTODRUG* in All Text
- #16 PHYTOPHARMACEUTIC* in All Text
- #17 AYURVEDIC in All Text
- #18 (ORIENTAL in All Text near/6 MEDICINE* in All Text)
- #19 MeSH descriptor phytotherapy this term only
- #20 (#6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19)
- #21 (#5 and #20)

MEDLINE (on Ovid)

- 1 exp Myocarditis/
- 2 myocarditis.tw.
- 3 or/1-2
- 4 exp Medicine, Traditional/
- 5 Alternative Medicine/

- 6 exp Plant Extracts/
- 7 exp Plants, Medicinal/
- 8 Drugs, Non-Prescription/
- 9 exp Phytotherapy/
- 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 ayurvedic.tw.
- 17 (phytodrug\$ or phyto-drug\$ or phytopharmaceutical\$).tw.
- 18 or/4-17
- 19 3 and 18
- 20 limit 19 to yr="2003 - 2009"
- 21 exp animals/ not humans/
- 23 20 not 21

EMBASE (on Ovid)

1. exp Myocarditis/
2. myocarditis.tw.
3. or/1-2
4. exp traditional medicine/
5. Alternative Medicine/
6. exp Plant Extracts/
7. exp Medicinal Plant/
8. Phytotherapy/
9. (herb or herbs or herbal).tw.
10. alternative medicine\$.tw.
11. complementary medicine\$.tw.
12. traditional medicine\$.tw.
13. (plant or plants).tw.
14. ((chinese or oriental) adj3 medicine\$).tw.
15. ayurvedic.tw.
16. (phytodrug\$ or phyto-drug\$ or phytopharmaceutical\$).tw.
17. or/4-16

18. 3 and 17
19. limit 18 to yr="2003 - 2009"
20. (exp animals/ or nonhuman/) not human/
21. 19 not 20

AMED (Allied and Complementary Medicine; on Ovid)

1. myocarditis.tw.
2. limit 1 to yr="2003 - 2009"

LILACs (on BIREME)

(myocarditis or Miocarditis or miocardite) and not (animals and not humans) [Words] and (random\$ or trial\$ or RCT or placebo\$ or comparative or prospective or groups) [Words] and 2003 or 2004 or 2005 or 2006 or 2007 or 2008 or 2009 [Country, year publication]

2 Search strategy 2003

MEDLINE

1. exp Myocarditis/
 2. myocarditis.tw.
 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
 19. a RCT filter (Dickersin 1994)
 20. 18 and 19.
- [/ indicates MeSH term, exp = exploded, tw = textword, \$ = truncation]

Published notes: Characteristics of studies

Characteristics of included studies

Chen PY 2006		
Methods	Trial design: Parallel design. Study duration: March 2004 to March 2005. Intention-to-treat analyses: no. Baseline comparability: no description. Statistics: adequate (chi ² and <i>t</i> test).	
Participants	Ethnic: Chinese 120 patients (60 in herb group, M/F 36/24, mean age 35.26 years, ranging from 16 to 46 years, duration of disease from 1 week to 3 months; 60 in control group, M/F 35/25, mean age 35.12, ranging from 16 to 47 years, duration of disease from 1 week to 3 months) Setting: outpatients and inpatients Diagnostic criteria: viral myocarditis, by the national criteria in 1995 Exclusion criteria: specified	
Interventions	Experimental: Xinshu Capsule (herb mixtures), 10g, three times a day, orally Control: Conventional treatment: Co-enzyme Q ₁₀ capsule, 20mg, three times a day, orally Duration of treatment: 30 days	
Outcomes	Symptoms and signs, electrocardiogram, myocardial enzyme The outcomes were measured at the end of treatment	
Notes	No information on the periods of follow-up.	
Risk of bias table		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number table
Allocation concealment (selection bias)	Unclear risk	No information about concealment
Blinding (performance bias and detection bias)	Unclear risk	No information about blinding
Incomplete outcome data (attrition bias)	Low risk	Same number of participants randomised and analysed
Selective reporting (reporting bias)	Low risk	Data collection clearly described and reported in results
Other bias	Unclear risk	Insufficient information to make judgement

Li L 2006

Methods	<p>Trial design: Parallel design.</p> <p>Study duration: January 2003 to October 2005.</p> <p>Intention-to-treat analyses: no.</p> <p>Baseline comparability: basic characters ($P > 0.05$).</p> <p>Statistics: adequate (χ^2 test).</p>
Participants	<p>Ethnic: Chinese;</p> <p>111 patients (57 in herb group, M/F 35/22, mean age 31.4 ± 8.1 years, mean disease duration 1.43 ± 9.6 days, 50 in cardiac function II group, 7 in cardiac function III-IV group; 54 in control group, M/F 34/20, mean age 30.3 ± 6.5 years, mean disease duration 15.2 ± 10.1 days, 48 in cardiac function II group, 6 in cardiac function III-IV group).</p> <p>Setting: inpatients.</p> <p>Diagnostic criteria: viral myocarditis, by the national criteria in 1999.</p> <p>Exclusion criteria: not specified.</p>
Interventions	<p>Experimental:</p> <p>Qingxinkangyan yin decoction (herb mixtures), 10ml/time, three times a day, for 30 days, plus conventional treatment</p> <p>Control:</p> <p>Conventional treatment: Oral Liquid Ribavirin, 0.1g/time, 4 times a day, conventional nursing.</p> <p>Co-invention: anti-arrhythmia when necessary.</p> <p>Duration of treatment: 30 days</p>
Outcomes	<p>Symptoms and signs, electrocardiogram, and chest-x ray, cardiac function, myocardial enzyme, troponin (I or T), LDH, serum CVB-IgM, CK, CK-MB, glutamic oxaloacetic transaminase enzyme.</p> <p>The outcomes were measured at the end of treatment and follow-up.</p>

Notes

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number table
Allocation concealment (selection bias)	Unclear risk	No information about concealment
Blinding (performance bias and detection bias)	Unclear risk	No information about blinding
Incomplete outcome data (attrition bias)	Low risk	Same number of participants randomised and analysed
Selective reporting (reporting bias)	High risk	No information on electrocardiogram, chest-x ray, LDH, CK tropin, CK-MB
Other bias	Unclear risk	Insufficient information to make judgements

Li M 2006

Methods	<p>Trial design: Parallel design.</p> <p>Study duration: March 2002 to February 2006.</p> <p>Intention-to-treat analyses: no.</p> <p>Baseline comparability: age, gender, duration of disease, electrocardiogram, patient history ($P > 0.05$).</p> <p>Statistics: adequate (χ^2 test and t test).</p>
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Participants	<p>Ethnic: Chinese;</p> <p>76 patients (38 in herb group, M/F 23/15, mean age 31.7 ± 7.7 years, mean disease duration 61.6 days, ranging from 16 to 92 days; 38 in control group, M/F 24/14, mean age 32.4 ± 7.8 years, mean disease duration 60.9 days, ranging from 17 to 91 days).</p> <p>Setting: inpatients.</p> <p>Diagnostic criteria: viral myocarditis, by the national criteria in 1999.</p> <p>Exclusion criteria: not specified.</p>
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Interventions	<p>Experimental:</p> <p>Sheng Yang Yi Xin decoction (herb mixtures), 1 dose, 3 times/day, for 3 weeks, plus conventional treatment</p> <p>Control:</p> <p>Conventional treatment: Vitamin C 5g, 10% 250ml glucose, 100U co-enzyme A, 40mg ATP, 400mg Inosine, intravenously, daily. GIK (10% 500ml glucose, 12U insulin, 10% 1g K_3N), intravenously, daily. Co-enzyme Q10 capsule 40mg, Moroxydine 100mg, oral, 3 times/day.</p> <p>Duration of treatment: 21 days</p>
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Outcomes	<p>Symptoms and signs, electrocardiogram, myocardial enzyme.</p> <p>The outcomes were measured at the end of treatment.</p>
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Notes

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number table
Allocation concealment (selection bias)	Unclear risk	No information about concealment
Blinding (performance bias and detection bias)	Unclear risk	No information about blinding
Incomplete outcome data (attrition bias)	Low risk	Same number of participants randomised and analysed
Selective reporting (reporting bias)	High risk	Some outcomes were reported but not pre-specified
Other bias	Unclear risk	Insufficient information to make judgements

Peng Q 2005

Methods	<p>Trial design: Parallel design</p> <p>Study duration: December 1999 to June 2004</p> <p>Intention-to-treat analyses: no</p> <p>Baseline comparability: gender, duration of diagnosis and severity of disease, indexes of symptoms, time of occurrence (P > 0.05)</p> <p>Statistics: adequate (Ridit analysis, Chi², U and t test)</p>	
Participants	<p>Ethnic: Chinese;</p> <p>127 patients (65 in herb group, 62 in control group).</p> <p>Setting: inpatients and outpatients.</p> <p>Diagnostic criteria: no description.</p> <p>Exclusion criteria: not specified.</p>	
Interventions	<p>Experimental:</p> <p>Sheng Mai injection(herb extracts), 20 - 40ml, 5% 250 glucose or 0.09% 250 physiological salt solution, intravenously, daily, 20 - 45 days</p> <p>Control:</p> <p>Conventional treatment: Energy Mixture, 50U co-enzyme A, 200mg ATP, 4U insulin, 10% 250 glucose, intravenously, daily. 1 month.</p> <p>Duration of treatment: 30 days</p>	
Outcomes	<p>Symptoms and signs, electrocardiogram, myocardial enzyme.</p> <p>The outcomes were measured after 1 month.</p>	
Notes		
Risk of bias table		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number table
Allocation concealment (selection bias)	Unclear risk	No information about concealment
Blinding (performance bias and detection bias)	Unclear risk	No information about blinding
Incomplete outcome data (attrition bias)	Low risk	Same number of participants randomised and analysed
Selective reporting (reporting bias)	High risk	The pre-specified outcome of myocardial enzyme was not reported
Other bias	Unclear risk	Insufficient information to make judgement.
Tan YB 2003		
Methods	<p>Trial design: Parallel design</p> <p>Study duration: June 1999 to June 2002</p>	

	Intention-to-treat analyses: no Baseline comparability: age, gender, disease condition, duration of diagnosis, symptoms, signs, results of electrocardiogram and myocardial enzymes (P > 0.05) Statistics: adequate (Ridit analysis and chi² test)	
Participants	Ethnic: Chinese; 60 patients (30 in herb group, 30 in control group) Setting: inpatients. Diagnostic criteria: viral myocarditis, by the national criteria in 1994. Exclusion criteria: not specified.	
Interventions	Experimental: Radix Astragali injection (herb extract), 0.5ml/kg (no more than 20ml daily) in 100 - 250ml of 10% glucose, intravenously, daily, for 21 days, plus supportive treatment. Control: Supportive treatment: rest, anti-inflammatory, regulate immunity treatment, and symptomatic treatments, high dose glucose-insulin-potassium solutions, intravenously, daily, for 21 days. Duration of treatment: 21 days	
Outcomes	Symptoms, signs, myocardial enzyme and electrocardiogram, monitoring blood-routine, urine-routine, stool-routine, hepatic and renal function. The outcomes were measured at the end of treatment.	
Notes	There were no basic characteristics of the patients in intervention group and control group.	
Risk of bias table		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Drawing lots
Allocation concealment (selection bias)	Unclear risk	No information about concealment
Blinding (performance bias and detection bias)	Unclear risk	No information about blinding
Incomplete outcome data (attrition bias)	Low risk	Same number of participants randomised and analysed
Selective reporting (reporting bias)	Low risk	Data collection clearly described and reported in results
Other bias	Unclear risk	Insufficient information for making judgement
Wang Y 2005		
Methods	Trial design: Parallel design Study duration: August 1999 to December 2003 Intention-to-treat analyses: no Baseline comparability: age, gender, duration of diagnosis and severity of disease (P > 0.05)	

	Statistics: adequate (Ridit analysis and t test used for ‘overall improvement’)	
Participants	Ethnic: Chinese; 83 patients (43 in herb group, M/F 19/24, mean age 29.94 years (from 18 - 43), mean disease duration 30.56 days, ranging from 3 to 52 days); 40 in control group, M/F 18/22, mean age 27.35 years (from 17 - 41), mean disease duration 32.32 days, ranging from 5 to 59 days). Setting: inpatients. Diagnostic criteria: viral myocarditis, by the national criteria in 1999. Exclusion criteria: specified.	
Interventions	Experimental: Shortscape fleabane injection (herb extract), 30ml in 250 ml of 5% glucose, intravenously, daily, for 15 days, plus supportive treatment. Control: Supportive treatment: 500 ml of 10% glucose plus 8 U insulin and Vitamin C 2g, co-enzyme A 100u, intravenously, daily, for 15 days. Co-intervention: supportive therapy arrhythmia. Duration of treatment: 15 days	
Outcomes	Traditional Chinese symptom indexes, myocardial enzyme and electrocardiogram. The outcomes were measured at the end of treatment.	
Notes		
Risk of bias table		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number table
Allocation concealment (selection bias)	Unclear risk	No information about concealment
Blinding (performance bias and detection bias)	Unclear risk	No information about blinding
Incomplete outcome data (attrition bias)	Low risk	Same number of participants randomised and analysed
Selective reporting (reporting bias)	Low risk	Data collection clearly described and reported in results
Other bias	Unclear risk	Insufficient information for making judgements
Wu JW 2009		
Methods	Trial design: Parallel design. Study duration: January 2005 to Febuary 2007. Intention-to-treat analyses: no. Baseline comparability: age, sex (<i>P</i> > 0.05). Statistics: adequate(<i>u</i> or Chi ² test).	

Participants	Ethnic: Chinese 50 patients (25 in herb group, M/F 12/13, age no more than 12 years; 25 in control group, M/F 14/11, age no more than 12 years) Setting: inpatients Diagnostic criteria: viral myocarditis, by the national criteria 1999 Exclusion criteria: not specified.	
Interventions	Experimental: Radix astragali (herb extracts), infantile, 2g/time, children, 4g/time, twice a day, for 14 days, plus conventional treatment. Control: Conventional treatment: Vitamin C, 1,6-FDP, co-enzyme A 100U, ATP, for 14 days. Duration of treatment: 14 days	
Outcomes	Symptoms, chest-x ray, electrocardiogram, myocardial enzyme (CK-mB), cardiac troponin I (cTnI), immunoglobulin, T-cells, adverse effects, CoX virus IgM. The outcomes were measured at the end of treatment.	
Notes		
Risk of bias table		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number table
Allocation concealment (selection bias)	Unclear risk	No information about concealment
Blinding (performance bias and detection bias)	Unclear risk	No information about blinding
Incomplete outcome data (attrition bias)	Low risk	No missing outcome data
Selective reporting (reporting bias)	Low risk	Data collection clearly described and reported in results
Other bias	Unclear risk	Insufficient information to make judgement
Yang YX 2008		
Methods	Trial design: Parallel design Study duration: June 2004 to March 2006 Intention-to-treat analyses: no Baseline comparability: no statistical testing Statistics: adequate (Chi ² test)	
Participants	Ethnic: Chinese 218 patients (age from 14 to 50) enrolled, 164 analysed	

	Setting: inpatients Diagnostic criteria: viral myocarditis, by the national criteria in 1995 and 1999, duration of disease less than 3 months Exclusion criteria: not specified.	
Interventions	Experimental: Radix astragali injection (herb extract), 40g in 250 ml of 5% glucose, intravenously, daily, for 14 days. Control: Supportive treatment: 500 ml of 5% glucose plus 6U insulin and 10% kcl 10ml, intravenously, daily, for 14 days. Co-intervention: after the first 14 days, Vitamin C 0.2g, co-enzyme Q ₁₀ , three times per day, until the end of 6 months' follow-up. Duration of treatment: 14 days	
Outcomes	Symptoms, electrocardiogram, and chest-x ray, cardiac function, myocardial enzyme, troponin (I or T), serum CVB-IgM or CVB-Ab, blood EVs-RNA, hepatic function, antibody and antigen of hepatitis A, B AND C. The outcomes were measured at the end of follow-up.	
Notes	There were no basic characters of the patients in intervention group and control group. Only 139 of the 164 patients were analysed on symptom improvements, which was not specified by the investigators.	
Risk of bias table		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	random number table
Allocation concealment (selection bias)	Unclear risk	No information about concealment
Blinding (performance bias and detection bias)	Unclear risk	No information about concealment
Incomplete outcome data (attrition bias)	Low risk	Number of participants with loss to follow up reported, 54/218.
Selective reporting (reporting bias)	High risk	Results of chest-x ray, myocardial enzyme and troponin (I or T) were not reported.
Other bias	Unclear risk	Insufficient information for making judgement
Yao BJ 2005		
Methods	Trial design: Parallel design. Study duration: January 2002 to December 2003. Intention-to-treat analyses: no. Baseline comparability: age, gender and duration of diagnosis (P > 0.05). Statistics: inadequate (No description in the methods).	

Participants	Ethnic: Chinese 168 patients (86 in herb group, M/F 49/37; 82 in control group, M/F 47/35), duration of disease no more than 90 days Setting: inpatients Diagnostic criteria: viral myocarditis by the national criteria in 1995 Exclusion criteria: duration of disease more than 90 days	
Interventions	Experimental: Qi Lu decoction (herb mixtures), daily, for 15 days, plus conventional treatment Control: Conventional treatment: rest, anti-inflammatory regulate immunity treatment, drugs including Vitamin C 0.2g, co-enzyme Q10 20mg, 3 times/day, Metoprolol when necessary. Duration of treatment: 15 days	
Outcomes	Symptoms, signs and electrocardiogram. The outcomes were measured at the end of treatment.	
Notes		
Risk of bias table		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number table
Allocation concealment (selection bias)	Unclear risk	No information about concealment
Blinding (performance bias and detection bias)	Unclear risk	No information about blinding
Incomplete outcome data (attrition bias)	Low risk	Same number of participants randomised and analysed
Selective reporting (reporting bias)	High risk	Information on electrocardiogram were not reported
Other bias	Unclear risk	Insufficient information to make judgement
Zhang ZZ 2006		
Methods	Trial design: Parallel design Study duration: January to December 2004 Intention-to-treat analyses: no Baseline comparability: age, gender, duration of diagnosis and severity of disease (P > 0.05) Statistics: adequate (Chi ² and t test)	
Participants	Ethnic: Chinese; 40 patients (20 in herb group, M/F 13/7, age from 1 year 8 months to 11 years; 20 in control group, M/F 14/6, age from 2 years 5 months to 12 years).	

	Setting: inpatients and outpatients. Diagnostic criteria: viral myocarditis by the national criteria in 1999. Exclusion criteria: not stated.	
Interventions	Experimental: Radix Astragali injection (herb extract), 5-10ml in 100-150 ml of 5% glucose, intravenously, daily, for 14 days, plus supportive treatment. Control: Supportive treatment: rest, anti-inflammatory regulate immunity treatment, drugs including Vitamin C, Energy Mixture, Vitamin E, co-enzyme A. Duration of treatment: 14 days	
Outcomes	Symptoms, myocardial enzyme and electrocardiogram. The outcomes were measured at the end of treatment.	
Notes	Detailed information on supportive treatment were not specified.	
Risk of bias table		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	random number table
Allocation concealment (selection bias)	Low risk	Sealed envelops
Blinding (performance bias and detection bias)	Unclear risk	No information about Blinding
Incomplete outcome data (attrition bias)	Low risk	Same number of participants randomised and analysed
Selective reporting (reporting bias)	High risk	Information on electrocardiogram were not reported
Other bias	Unclear risk	Insufficient information for making judgement
Zheng R 2003		
Methods	Trial design: Parallel design. Study duration: January 1996 to October 1999. Intention-to-treat analyses: no. Baseline comparability: age, gender, antiarrhythmic drugs(P > 0.05). Statistics: adequate (Chi ² test and t test used for 'overall improvement').	
Participants	Ethnic: Chinese; 120 patients, duration of diagnosis less than 3 months, M/F 48/72, age from 14-68 years(70 in herb group; 50 in control group). Setting: inpatients. Diagnostic criteria: viral myocarditis, by the national criteria in 1995.	

	Exclusion criteria: not stated.	
Interventions	Experimental: Radix Astragali injection (herb extract), 40g in 500 ml of 5% glucose, intravenously, daily, for 2 weeks. Control: Supportive treatment: 500 ml of 5% glucose plus 6 U insulin and 10ml KCl, for 2 weeks. Co-intervention: supportive therapy for arrhythmia. Duration of treatment: 14 days	
Outcomes	Symptoms, electrocardiogram, and cardiac function. The outcomes were measured at the end of treatment.	
Notes	There was a slightly skew distribution (1.4:1) of patients in the groups, which was not specified by the investigators.	
Risk of bias table		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Allocation sequence were generated using a calculator random number generator and patients were randomly allocated to treatment group(the odd numbers) and control group(the even numbers)
Allocation concealment (selection bias)	Low risk	Sealed envelops
Blinding (performance bias and detection bias)	Unclear risk	No information about blinding
Incomplete outcome data (attrition bias)	Unclear risk	Insufficient information for making judgement
Selective reporting (reporting bias)	Low risk	Data collection clearly described and reported in results
Other bias	Unclear risk	Insufficient information for making judgement
Zheng RF 2005		
Methods	Trial design: Parallel design; Study duration: November 2003 to February 2005; Intention-to-treat analyses: no; Baseline comparability: type of patient, vocation, age, gender, duration of diagnosis, type of condition, severity of disease (P > 0.05); Statistics: adequate (Chi2 test, H test, LSD).	
Participants	Ethnic: Chinese;132 patients (81 outpatients, 51 inpatients) enrolled, 120 analysed. Setting: inpatients and outpatient; Diagnostic criteria: viral myocarditis, by the national criteria in 1999. Exclusion criteria: specified.	

Interventions	<p>Experimental:</p> <p>Compound Qiangqi pill,1.5g, three times per day plus placebo of Shengmai Yin oral liquid, 10ml, three times per day, plus conventional treatment, for 1 month.</p> <p>Control A:</p> <p>Shengmai Yin oral liquid,10ml, three times per day, plus placebo of compound Qiangqi pill, 1.5g, three times per day, plus conventional treatment, for 1 month.</p> <p>Control B:</p> <p>conventional treatment, plus placebo of Compound Qiangqi pill,1.5g, three times per day plus placebo of Shengmai Yin oral liquid,10ml, three times per day, for 1 month.</p> <p>conventional treatment: co-enzyme Q10, 20mg, oral, there times per day.500 ml of 5% GS plus vitamin C 6g plus ATP 40mg plus co-enzyme A 100u plus potassium magnesium aspartate 20 ml intravenously, daily, and symptomatic treatments.</p> <p>Duration of treatment: 30 days</p>	
Outcomes	<p>Symptoms, sign, electrocardiogram, urine routine, blood routine, stool routine, liver function, and renal function.</p> <p>The outcomes were measured at the start and end of treatment.</p>	
Notes	<p>There were no basic characters of the patients in intervention group and control group.</p>	
Risk of bias table		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Using SAS to generate random number.
Allocation concealment (selection bias)	Low risk	Sealed envelops.
Blinding (performance bias and detection bias)	Low risk	Three blinding.
Incomplete outcome data (attrition bias)	Low risk	Number of participants with loss to follow up reported, 120/132.
Selective reporting (reporting bias)	Low risk	Data collection clearly described and reported in results.
Other bias	Unclear risk	Insufficient information for making judgement.
Zhou Y 2006		
Methods	<p>Trial design: Parallel design</p> <p>Study duration: January 2005 to May 2006</p> <p>Intention-to-treat analyses: no</p> <p>Baseline comparability: age, gender, duration of diagnosis and severity of disease (P>0.05)</p> <p>Statistics: adequate (Chi² and t test)</p>	
Participants	<p>Ethnic: Chinese;</p> <p>80 patients (40 in herb group, M/F 32/8, age from 2 year 8 months to 14 years; 40 in control group, M/F 30/10, age from 2 years 5 months to 13 years).</p> <p>Setting: inpatients and outpatients.</p>	

	Diagnostic criteria: viral myocarditis by the national criteria in 1999. Exclusion criteria: not stated.	
Interventions	Experimental: Radix Astragali injection (herb extract), 5-10ml in 100-150 ml of 5% glucose, intravenously, daily, for 14 days, plus supportive treatment. Control: Supportive treatment: rest, anti-inflammatory regulate immunity treatment, drugs including Vitamin C, Energy Mixture, Vitamin E, co-enzyme Q10. Duration of treatment: 14 days	
Outcomes	Symptoms, myocardial enzyme and electrocardiogram. The outcomes were measured at the end of treatment.	
Notes	Detailed information on supportive treatment were not specified.	
Risk of bias table		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number table
Allocation concealment (selection bias)	Low risk	Sealed envelopes
Blinding (performance bias and detection bias)	Unclear risk	No information about blinding
Incomplete outcome data (attrition bias)	Low risk	Same number of participants randomised and analysed
Selective reporting (reporting bias)	High risk	Information on electrocardiogram were not reported
Other bias	Unclear risk	Insufficient information for making judgement
Zhou YW 2008		
Methods	Trial design: Parallel design Study duration: No description Intention-to-treat analyses: no Baseline comparability: No description Statistics: adequate (Chi ² and rank-sum test)	
Participants	Ethnic: Chinese 78 patients, M/F 32/46, mean age 23 years, ranging from 6 to 40 years (40 in herb group, 38 in control group) Setting: No description Diagnostic criteria: viral myocarditis by the national criteria in 1999 Exclusion criteria: not stated	

Interventions	Experimental: Qing Xin Huo Ming decoction (herb mixtures), one dose, three times a day, for 4 weeks, plus conventional treatment Control: Conventional treatment: rest, drugs including Vitamin C 5-10g, Energy Mixture, 500ml glucose, 10U co-enzyme A, 10mg ATP, 600mg Inosine, intravenously, daily. Co-enzyme Q10 capsule, 3 times a day anti-inflammatory when necessary. Duration of treatment: 28 days	
Outcomes	Symptoms, signs and electrocardiogram. The outcomes were measured at the end of treatment.	
Notes		
Risk of bias table		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number table
Allocation concealment (selection bias)	Unclear risk	No information about concealment
Blinding (performance bias and detection bias)	Unclear risk	No information about blinding
Incomplete outcome data (attrition bias)	Low risk	Same number of participants randomised and analysed
Selective reporting (reporting bias)	Low risk	Data collection clearly described and reported in results
Other bias	Unclear risk	Insufficient information to make judgement

Footnotes

Characteristics of excluded studies

An XF 1997	
Reason for exclusion	Randomised clinical trial comparing herbal extract (Salviae miltiorrhizae injection) versus propafenone plus isoptin and amiodarone in 100 patients of viral myocarditis with arrhythmia. Co-interventions included ribavirin, interferon, and supportive treatment. A global outcome measure including symptoms, electrocardiogram, X-ray, and laboratory tests was reported, but data for each separate parameter was not available.
Cao GM 1996	
Reason for exclusion	Randomised clinical trial comparing Xinyikang (Kang Er Xin) oral liquid versus supportive therapy in 218 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Chen BY 1993	

Reason for exclusion	Randomised clinical trial comparing three herbal mixtures (self-prescribed formulations based on differentiation of symptoms) versus supportive treatment in 349 children with viral myocarditis. The experimental intervention included three different preparations, but the outcome measures were not reported adequately. It is impossible to extract data for each individual herbal preparation.
Chen BY 1994	
Reason for exclusion	Randomised clinical trial comparing Tongmai oral liquid (herbal formulation) versus supportive therapy in 65 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Chen H 1999	
Reason for exclusion	Randomised clinical trial comparing Astragalus injection (herb extract) versus supportive therapy in 202 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Chen LJ 1997	
Reason for exclusion	Randomised clinical trial comparing herbal mixture (self-prescribed Yixinyin decoction) versus ribavirin plus supportive treatment in 78 patients of viral myocarditis. The outcome measures of symptoms and signs as well as laboratory tests were inadequately reported and raw data could not be abstracted.
Chen SX 1992	
Reason for exclusion	Randomised clinical trial comparing Kushen preparation (mixture of 7 herbs) versus interferon therapy in 33 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Feng D 1996	
Reason for exclusion	Randomised clinical trial comparing herbal medicine (Xinluning) with propafenone in chronic heart diseases patients with frequent ventricular premature beat including viral myocarditis. The outcomes from viral myocarditis were not reported separately.
Geng J 1996	
Reason for exclusion	Randomised clinical trial comparing a self-prescribed herbal formulation (composed of eight herbs) versus ATP, co-enzyme A, inosine, vitamin C, KCl, co-vitamin B, and anti-viral drug in 44 patients of acute viral myocarditis. A global outcome measure including symptoms, signs, and electrocardiogram was reported, but data for each separate parameter was not available due to inadequate reporting.
Gong LH 2001	
Reason for exclusion	Randomised clinical trial comparing herbal extract (Astragalus membranaceus injection) versus supportive therapy including ATP, co-enzyme A, vitamin C, and FDP in 66 patients of viral myocarditis. A global outcome measure including symptoms, signs, and electrocardiogram was reported, but data for each separate parameter was not available.
Gu W 1996	
Reason for exclusion	Randomised clinical trial comparing Astragalus injection (herb extract) versus supportive therapy in 48 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Guo FQ 2008	

Reason for exclusion	Randomised clinical trial comparing three herbal medicines versus supportive treatment in 30 children with viral myocarditis. The experimental intervention included three different preparations in two stages, but the outcome measures were not reported adequately. It is impossible to extract data for each individual herbal preparation.
Guo WX 2000	
Reason for exclusion	Multicentre, blinded, randomised controlled trial comparing herbal extract (Xinyikang oral liquid) versus another herbal oral liquid (Qidong Yixin) in 460 patients of viral myocarditis. The control intervention did not meet the inclusion criteria of this review.
Han DS 1997	
Reason for exclusion	Randomised clinical trial comparing herbal mixture (self-prescribed Yixin decoction) plus supportive treatment versus supportive treatment in 80 patients of viral myocarditis. The outcomes were inadequately reported and raw data could not be abstracted.
Han Y 2000	
Reason for exclusion	Randomised clinical trial comparing Astragalus injection (herb extract) versus supportive therapy in 60 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
He AY 1999	
Reason for exclusion	Randomised clinical trial comparing Shuanghuanglian powder injection (herb extract) versus supportive therapy in 120 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
He P 1995	
Reason for exclusion	Randomised clinical trial comparing Astragalus (single herb) versus Propafenone therapy in 110 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Hu SY 1995	
Reason for exclusion	Randomised clinical trial comparing Tongmaiye (herbal extract) versus supportive therapy in 64 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Hu SY 1999	
Reason for exclusion	Randomised clinical trial comparing three herbal medicines (Qingxinye, Shuanghuanglian, and Astragalus injection) versus supportive therapy plus antiviral and antibiotics treatment in 136 children with viral myocarditis. The three herbal medicines were not equally given to the patients in experimental group, which may contribute to the confounding to the intervention.
Huang W 1999	
Reason for exclusion	Randomised clinical trial comparing herbal decoction (Buyang Huanwu Tang) versus supportive therapy including ATP, co-enzyme A, vitamin C and B6 in 90 patients of viral myocarditis. A global outcome measure including symptoms, signs, electrocardiogram, and X-ray chest was reported, but data for each separate parameter was not available due to inadequate reporting.
Huang ZQ 1995	
Reason for exclusion	Randomised clinical trial comparing herbal extract Astragalus membranaceus plus supportive treatment versus supportive treatment alone in 54 patients with viral myocarditis. The primary objective of the trial was to explore the effect of the herb on T-lymphocyte subsets of peripheral blood. Other outcomes were not reported.

Huang ZQ 1996	
Reason for exclusion	Randomised clinical trial comparing herbal extract Yixinling plus supportive treatment versus supportive treatment alone in 52 patients with viral myocarditis. The primary objective of the trial was to explore the effect of the herb on NK cell activity and T-lymphocyte subsets of peripheral blood.
Ji XL 1995	
Reason for exclusion	Randomised clinical trial comparing herbal extract Xinjiyin versus supportive treatment in 108 patients with viral myocarditis. There was a significant skew distribution of patient characteristics in two groups. A global improvement as primary outcome was reported, but data for individual outcomes were not available.
Jia WH 1998	
Reason for exclusion	Randomised clinical trial comparing Huangqi Shengmaisan (herbal mixture) decoction versus supportive therapy in 66 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Jiang Y 2000	
Reason for exclusion	Randomised clinical trial comparing herbal mixture (self-prescribed and modified based on different syndromes) versus ribavirin plus supportive treatment in 98 patients of viral myocarditis. The outcomes were inadequately reported and raw data could not be abstracted.
Jin W 2002	
Reason for exclusion	Randomised clinical trial comparing Shenmai injection (herb extract) versus supportive therapy in 60 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Kuo C 1986	
Reason for exclusion	A case report of Chinese herbs for treating acute viral myocarditis.
Li DP 2005	
Reason for exclusion	Randomised clinical trial comparing herbal extract (Qing Xin Huo Xue decoction) plus conventional treatment versus conventional treatment in 48 patients of viral myocarditis. A global outcome measure including symptoms, electrocardiogram, myocardial enzymes and laboratory tests was reported, but data for each separate parameter was not available.
Li JL 1999	
Reason for exclusion	Randomised clinical trial comparing herbal extract (Shengmaisan combined with Guipi Tang) versus supportive therapy (KCl injection, insulin, ATP, and co-enzyme A) in 95 patients of viral myocarditis. A global outcome measure including symptoms, electrocardiogram, heart rate, heart X-ray, ultrasound assay, and myocardial enzyme profile was reported, but data for each separate parameter were not available.
Li Y 2000	
Reason for exclusion	Randomised clinical trial comparing herbal mixture (Erhuang Wendan decoction) versus supportive treatment in patients of acute viral myocarditis. The study was published four times with different number of patients. All the publications reported global outcome and raw data for individual parameters were not available.
Li YR 1996	

Reason for exclusion	Randomised clinical trial comparing Shengmai injection (herb extract) versus Danshen injection (composita <i>Salviae miltiorrhizae</i>) in 50 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Li YW 1997	
Reason for exclusion	Randomised clinical trial comparing Chinese herbal medicine (Yangxinshi) versus supportive treatment in 62 patients of viral myocarditis. The outcome measures including symptoms and electrocardiogram were inadequately reported and raw data were not available.
Li ZY 1998	
Reason for exclusion	Randomised clinical trial comparing <i>Astragalus</i> injection (herb extract) versus supportive therapy in 54 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Lin GZ 1998	
Reason for exclusion	Randomised clinical trial comparing Shuanghuanglian powder injection (herb extract) versus supportive therapy in 62 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
LIU AD 2005	
Reason for exclusion	Randomised clinical trial comparing different herbal medicines versus conventional treatment in 127 patients with viral myocarditis. The herbal treatment was composed of 8 different herbal mixtures and prescribed based on different stages, different types of Chinese differential diagnosis. However, the outcome was not reported separately.
Liu GJ 1996	
Reason for exclusion	Randomised clinical trial comparing herbal extract (Shenmai injection) versus supportive treatment in 45 patients of acute viral myocarditis. The outcomes were inadequately reported and raw data were not available.
Liu HQ 2000	
Reason for exclusion	Randomised clinical trial comparing herbal mixture (Shenqiyin decoction) versus supportive treatment in 129 patients of viral myocarditis. The outcome measures included symptoms and signs, electrocardiogram, and X-ray image, but were reported globally and raw data were not available.
Liu J 1995	
Reason for exclusion	Randomised clinical trial comparing Huangqi Shengmaisan (mixture of more than 4 herbs) versus supportive therapy in 66 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Liu MD 1999	
Reason for exclusion	Randomised clinical trial comparing herbal extract (<i>Astragalus membranaceus</i> injection) versus supportive therapy (glucose, insulin, co-enzyme Q10, and vitamin C) in 87 patients of viral myocarditis. A global outcome measure including symptoms, signs, electrocardiogram, and cardiac enzyme profile was reported, but data for each separate parameter was not available.
Liu SS 1997	

Reason for exclusion	Randomised clinical trial comparing Astragalus (single herb) versus supportive therapy in 63 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Liu YJ 1997	
Reason for exclusion	Randomised clinical trial comparing extract of Astragalus membranaceus versus supportive treatment in 50 patients with viral myocarditis. After the randomisation, 12 patients who did not respond well to the supportive treatment was changed to receive herbal treatment. There was a confounding due to this change of intervention during trial.
Lu Y 1997	
Reason for exclusion	Randomised clinical trial comparing Dengzhanhua injection (<i>breviscapine</i>) versus supportive therapy in 64 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Luo L 1998	
Reason for exclusion	Randomised clinical trial comparing herbal mixture (self-prescribed Wushen Jiawei Shengmai Powder) versus ribavirin plus supportive treatment in 61 patients of viral myocarditis. The outcomes were inadequately reported and raw data were not available.
Ma CH 1995	
Reason for exclusion	Randomised clinical trial comparing herbal mixture (self-prescribed formula) plus ribavirin and supportive treatment versus supportive treatment alone in 40 patients of viral myocarditis. The outcome measures included symptoms and signs, and electrocardiogram, but were reported globally and raw data were not available.
Ma GL 1998	
Reason for exclusion	Randomised clinical trial comparing Astragalus compound (mixture of 15 herbs) decoction versus supportive therapy in 100 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Ma HB 1997	
Reason for exclusion	Randomised clinical trial comparing herbal mixture (basic formula modified according to different types of Chinese medical diagnosis) versus supportive treatment in 60 children with viral myocarditis. The outcome measures included symptoms and signs, electrocardiogram, X-ray, and cardiac spectrum of enzymes, but were reported globally and raw data were not available.
Ma YL 1984	
Reason for exclusion	Randomised clinical trial comparing different herbal medicines versus supportive treatment in 40 patients of children with viral myocarditis. The herbal treatment was composed of 8 different herbal mixtures and prescribed based on different stages, different types of Chinese differential diagnosis, and different complications. However, the outcome was not reported separately.
Qin FH 2001	
Reason for exclusion	Randomised clinical trial comparing herbal formulation (Xiao Chaihu Tang) versus supportive therapy (ATP, co-enzyme A, vitamin C, and FDP) in 62 patients of viral myocarditis. A global outcome measure including symptoms, signs, and electrocardiogram was reported, but data for each separate parameter were not available.
Qin HS 2006	

Reason for exclusion	Randomised clinical trial comparing herbal extract (radix astragali) versus another herbal tablet (<i>Composita Salviae miltiorrhizae</i>) in 62 patients with acute viral myocarditis. The control intervention did not meet the inclusion criteria of this review.
Ren GH 1996	
Reason for exclusion	Randomised clinical trial comparing Astragalus injection (herb extract) versus supportive therapy in 61 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Ren W 1991	
Reason for exclusion	Randomised clinical trial comparing <i>Astragalus</i> injection (herb extract) versus supportive therapy in 66 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Rong YS 2001	
Reason for exclusion	Randomised clinical trial comparing herbal medicine (decoction) plus supportive therapy versus supportive therapy (ATP, co-enzyme A, vitamin C and B6, and glucose) in 110 children with viral myocarditis. A global outcome measure including symptoms, signs, electrocardiogram and serum enzymes was reported, but data for each separate parameter were not available.
Song JM 1999	
Reason for exclusion	Randomised clinical trial comparing Yangyin Qingxin (herbal extract) oral liquid versus supportive therapy in 119 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Su CT 1999	
Reason for exclusion	Quasi-randomised clinical trial comparing herbal mixture (modified based on Shengmaisan) plus supportive treatment versus herbal extract <i>composita Salviae miltiorrhizae</i> injection plus supportive treatment in 36 patients of viral myocarditis. The outcome measures including symptoms and signs, electrocardiogram as well as serum enzymes were inadequately reported and raw data were not available.
Sun DX 2000	
Reason for exclusion	Randomised clinical trial comparing Shengmai injection (herb extract) versus supportive therapy in 56 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Sun J 1998	
Reason for exclusion	Randomised clinical trial comparing herbal medicine 'Xinankang' versus supportive treatment in 60 patients with viral myocarditis. The outcome was reported selectively, and data from other patients were not available.
Sun KJ 1998	
Reason for exclusion	Randomised clinical trial comparing herbal extract (Shengmai injection) versus supportive treatment in 22 patients of viral myocarditis with arrhythmia at the convalescent stage. The outcome measure was reduction of arrhythmia, but only rates were reported and raw data were not available.
Sun WM 1999	

Reason for exclusion	Randomised clinical trial comparing herbal mixture (self-prescribed Wushen Jiawei Shengmaisan) plus supportive treatment versus supportive treatment alone in 102 patients of viral myocarditis. The outcomes of symptoms, cardiac function, and electrocardiogram were inadequately reported and raw data were not available.
Sun Y 1997	
Reason for exclusion	Randomised clinical trial comparing <i>Acanthopanax senticosi</i> plus <i>Salviae miltiorrhizae</i> versus supportive therapy in 320 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Tan JC 1995	
Reason for exclusion	Randomised clinical trial comparing herbal extract (Shengmai injection) versus supportive treatment in 50 patients of acute viral myocarditis. The outcomes were inadequately reported and raw data were not available.
Tang SY 2000	
Reason for exclusion	Randomised clinical trial comparing Qingxinkang (self-prescribed herbal extract) decoction versus supportive therapy in 67 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Tu XH 1996	
Reason for exclusion	Randomised clinical trial comparing herbal extract 'Qidong Yixin' (oral liquid) versus another herbal extract 'Shengmai Yin' (oral liquid) in 500 patients of viral myocarditis. The control intervention did not meet the inclusion criteria of this review.
Wang JM 2003	
Reason for exclusion	Randomised clinical trial comparing radix astragali (herbal extracts) injection and Meglumine Cyclic Adenylate injection (non-herbal extracts) in 68 inpatients of viral myocarditis. The intervention group did not meet the inclusion criteria of this review.
Wang K 2000	
Reason for exclusion	Randomised clinical trial comparing herbal mixture (Huangzhihua oral liquid) plus supportive treatment versus supportive treatment alone in 66 children with viral myocarditis. The outcome measures included symptoms and signs, electrocardiogram, and/or cardiac spectrum of enzymes, but raw data for individual outcomes were not available.
Wang WR 2001	
Reason for exclusion	Randomised clinical trial comparing herbal mixture (self-prescribed Shenying Wendan decoction) plus supportive treatment versus supportive treatment in 106 patients of viral myocarditis. The outcome measures including symptoms and signs as well as electrocardiogram, but raw data for individual outcomes were not available.
Wang XF 1997	
Reason for exclusion	Randomised clinical trial comparing Chaihu Qingxin Yin (self-developed herbal extract) decoction versus supportive therapy in 84 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Wang XJ 1995	
Reason for exclusion	Randomised clinical trial comparing single herb Astragalus versus supportive treatment in 116 patients with viral myocarditis. The outcomes were inadequately reported and raw data were not available.

Wang ZH 1998	
Reason for exclusion	Randomised clinical trial comparing herbal extract (Astragalus membranaceus injection) versus supportive treatment in 48 patients of viral myocarditis. The objective of the trial was to explore the effect of the herbal extract on tumour necrotic factor (TNF) and interleukin-1 (IL-1) in viral myocarditis.
Wang ZH 2001	
Reason for exclusion	Randomised clinical trial comparing Astragalus injection (herb extract) versus supportive therapy in 116 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Wang ZL 2000	
Reason for exclusion	Randomised clinical trial comparing herbal extract (Chuanhuning injection) plus supportive treatment versus supportive treatment in 40 patients of viral myocarditis. The outcomes were inadequately reported and raw data were not available.
Wang ZM 2000	
Reason for exclusion	Randomised clinical trial comparing herbal medicines (Astragalus membranaceus injection and Yangxintang) versus supportive therapy (ATP, co-enzyme Q10, insulin, and KCl) in 95 patients of viral myocarditis. A global outcome measure including symptoms, electrocardiogram, heart rate, X-ray chest, myocardial enzyme profile was reported, but data for each separate parameter were not available.
Wang ZT 2004	
Reason for exclusion	Randomised clinical trial comparing herbal extract (Yixin decoction) plus conventional treatment versus conventional treatment in 54 patients of viral myocarditis. A global outcome measure including symptoms, electrocardiogram, and premature beat was reported, but data for each separate parameter was not available.
Wei QH 2004	
Reason for exclusion	Randomised clinical trial comparing herbal extract Fufang Sishen Decoction treatment versus conventional treatment in 102 patients with viral myocarditis. The primary objective of the trial was to explore the effect of the herb on arrhythmia.
Wei YL 1998	
Reason for exclusion	Randomised clinical trial comparing herbal extract (Weierxin tablet) versus another herbal tablet (Composita Salviae miltiorrhizae) in 420 children with viral myocarditis. The control intervention did not meet the inclusion criteria of this review.
Wu CS 1988	
Reason for exclusion	Randomised clinical trial comparing Shengmai injection (herb extract) versus supportive therapy in 100 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Wu XN 2002	
Reason for exclusion	Randomised clinical trial comparing herbal mixture (self-prescribed decoction) plus supportive treatment versus supportive treatment in 44 patients of acute viral myocarditis. The outcomes were inadequately reported and raw data were not available.
Xia DC 2000	

Reason for exclusion	Randomised clinical trial comparing herbal mixture (self-prescribed Qinggong decoction) versus supportive treatment in 60 patients of acute viral myocarditis. The outcomes were inadequately reported and raw data were not available.
Xing YH 1998	
Reason for exclusion	Randomised clinical trial comparing Royal jelly (non-herbal medicine) versus supportive treatment in 50 patients of viral myocarditis. The intervention did not fall into our category.
Xu MM 2000	
Reason for exclusion	Randomised clinical trial comparing Chinese herbs (mixture of herbs) decoction versus supportive therapy in 102 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Xu T 1996	
Reason for exclusion	Randomised clinical trial comparing <i>Composita Salviae miltiorrhizae</i> injection (extract of herbs) versus supportive therapy in 86 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Yang CJ 2005	
Reason for exclusion	Randomised clinical trial comparing herbal mixtures (Buqishengmai decoction) plus conventional treatment versus conventional treatment in 35 patients of viral myocarditis. A global outcome measure including symptoms, electrocardiogram, and laboratory tests was reported, but data for each separate parameter was not available.
Yang FQ 1998	
Reason for exclusion	Randomised clinical trial comparing herbal mixture (self-prescribed Qingxin Jiedu formula) plus herbal extract (Shengmai injection) versus ribavirin and corticosteroid plus supportive treatment in 61 young children with viral myocarditis. The outcomes were inadequately reported and raw data were not available.
Yang GF 2002	
Reason for exclusion	Randomised clinical trial comparing herbal mixture Yiqi Yangxin decoction (self-prescribed formula) plus supportive treatment versus supportive treatment in 87 patients of viral myocarditis. The outcomes were inadequately reported and raw data were not available.
Yang HB 1997	
Reason for exclusion	Randomised clinical trial comparing herbal extract (Shengmai injection) versus supportive treatment in 100 patients of viral myocarditis. The outcomes were inadequately reported and raw data were not available.
Yang SJ 1997	
Reason for exclusion	Randomised clinical trial comparing herbal extract (Shenmai injection) versus supportive treatment in 120 patients of acute viral myocarditis. The outcome measures included symptoms and signs, and laboratory tests, but were reported globally and raw data were not available.
Yang YZ 1990	
Reason for exclusion	Non-randomised controlled study testing <i>Astragalus membranaceus</i> in treating patients with coxsackie B viral myocarditis with depressed natural killer activity compared with conventional therapy.
Yao ZP 1995	

Reason for exclusion	Randomised clinical trial comparing herbal extract (Qingkailing) versus supportive treatment plus antibiotics and Poly I:C in 31 patients with acute viral myocarditis. The outcome measures included symptoms and signs, electrocardiogram, and laboratory tests, but were reported globally and raw data were not available.
Yin YS 1997	
Reason for exclusion	Randomised clinical trial comparing Shengmai injection (herb extract) versus supportive therapy in 162 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Yu ZK 1996	
Reason for exclusion	Randomised clinical trial comparing Yiqi Yangyin Jiedu Huayu (mixture of herbs) decoction versus supportive therapy in 61 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Zeng CF 1997	
Reason for exclusion	Randomised clinical trial comparing <i>Astragalus membranaceus</i> (herb powder) versus supportive therapy in 45 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Zhang DF 2005	
Reason for exclusion	Randomised clinical trial comparing FDP, astragalus injection (herbal extracts) versus supportive therapy in 60 patients of viral myocarditis. The intervention did not meet the inclusion criteria of this review.
Zhang PY 1997	
Reason for exclusion	Randomised clinical trial comparing herbal medicines (Qingkailing injection plus Shengmai injection) plus supportive therapy and ribavirin versus supportive therapy and ribavirin in 160 patients of viral myocarditis (acute phase). A global outcome measure including symptoms, signs, X-ray chest and electrocardiogram was reported, but data for each separate parameter were not available.
Zhang SY 2000	
Reason for exclusion	Randomised clinical trial comparing <i>Salviae miltiorrhizae</i> injection (extract of herbs) versus supportive therapy in 68 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Zhang XL 1999	
Reason for exclusion	Randomised clinical trial comparing Qidong Yixin (extract of herbs) oral liquid versus supportive therapy in 60 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Zhang XM 2000	
Reason for exclusion	Randomised clinical trial comparing combined herbal medicines (<i>Astragalus</i> injection and <i>composita Salviae miltiorrhizae</i> injection) with supportive treatment versus supportive treatment in 68 patients of acute viral myocarditis. The outcome measures including symptoms, electrocardiogram, myocardial enzymes, cardiac X ray, ultrasound cardiac image, and cardiac function as well as enzyme test were inadequately reported and raw data were not available.
Zhang ZX 2000	

Reason for exclusion	Randomised clinical trial comparing Yiqi Yangxin Tang (mixture of herbs) decoction versus supportive therapy in 81 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Zhao CS 2005	
Reason for exclusion	Randomised clinical trial comparing Qing Xin Tang decoction and Yan Po Nings injections (herbal extracts) injection plus conventional treatment versus conventional treatment which include radix astragali injection (herbal extracts) in 72 inpatients of viral myocarditis. The control group did not meet the inclusion criteria of this review.
Zhao MH 1996	
Reason for exclusion	Randomised clinical trial comparing Shengmaisan (mixture of herbs) granule versus placebo in 62 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Zhao QC 1996	
Reason for exclusion	Randomised clinical trial comparing Ginseng (single herb) versus supportive therapy in 62 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Zhao XS 2008	
Reason for exclusion	Randomised clinical trial comparing herbal extract (Yixin decoction) plus conventional treatment versus conventional treatment in 54 patients of viral myocarditis. A global outcome measure including symptoms, electrocardiogram, and laboratory tests was reported, but data for each separate parameter was not available.
Zhao YT 1994	
Reason for exclusion	Randomised clinical trial comparing herbal extract 'Yangxin Fumai Tang' (self-prescribed decoction) versus ribavirin plus supportive treatment in 75 patients of viral myocarditis. The outcomes were inadequately reported and raw data were not available.
Zhao YZ 1998	
Reason for exclusion	Randomised clinical trial comparing Yixintang (mixture of herbs) decoction versus supportive therapy in 80 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Zhou D 2004	
Reason for exclusion	Randomised clinical trial comparing herbal extract (Sheng Mai San He Wu Wei Zi decoction) plus conventional treatment versus conventional treatment in 54 patients of viral myocarditis. A global outcome measure including symptoms, electrocardiogram, and laboratory tests was reported, but data for each separate parameter was not available.
Zhou FR 2001	
Reason for exclusion	Randomised clinical trial comparing Xinjiekang (extracts of herbs) capsule versus supportive therapy in 76 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Zhou L 2000	
Reason for exclusion	Randomised clinical trial comparing herbal medicine (self-prescribed Qingjie Huangmai Yin) versus supportive therapy (co-enzyme Q10, vitamin C, inosine, glucose, insulin, KCl), plus Poly I:C, and ribavirin in 120 patients of acute viral myocarditis. A global outcome measure

	including symptoms, signs, X-ray chest, electrocardiogram and laboratory tests was reported, but data for each separate parameter were not available.
Zhou MY 1996	
Reason for exclusion	Randomised clinical trial comparing herbal mixture (modified based on Shengmai powder and Licorice decoction) plus supportive treatment versus supportive treatment alone in 60 patients of viral myocarditis. The outcomes of symptoms, electrocardiogram, and cardiac enzymes were inadequately reported and raw data were not available.
Zhou ZY 2000	
Reason for exclusion	Randomised clinical trial comparing herbal preparations (Shuanghuanglian injection plus Astragalus membranaceus injection) plus supportive treatment versus supportive treatment alone in 163 patients with viral myocarditis. A global outcome including symptoms, signs, and electrocardiogram were reported and separate outcome data were not available.
Zhu Q 1997	
Reason for exclusion	Randomised clinical trial comparing Gualou Xiebai Wenxin (extracts of herbs) oral liquid versus supportive therapy in 68 patients of viral myocarditis was included in the original review. It was excluded in the updating review due to that the methods of allocation sequence generation were not reported.
Zhu YD 1997	
Reason for exclusion	Randomised clinical trial comparing herbal mixture (self-prescribed decoction) versus another herbal extract (Shenqi tablet) in 85 patients of viral myocarditis. The control intervention did not meet the inclusion criteria of this review.

Footnotes

Characteristics of studies awaiting classification

Footnotes

Characteristics of ongoing studies

Footnotes

Data and analyses**1 Herbal medicines versus supportive therapy**

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Number of patients without symptom improvement	4		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.1.1 Qingxinkangyan Yin Decoction versus support therapy	1	111	Risk Ratio (M-H, Fixed, 95% CI)	0.34 [0.12, 1.02]
1.1.2 Xinshu Capsule versus supportive therapy	1	120	Risk Ratio (M-H, Fixed, 95% CI)	0.14 [0.04, 0.45]
1.1.3 Astragaloside injection versus support therapy	1	164	Risk Ratio (M-H, Fixed, 95% CI)	0.77 [0.37, 1.59]
1.1.4 Shenmai injection versus support therapy	1	127	Risk Ratio (M-H, Fixed, 95% CI)	0.32 [0.14, 0.75]
1.2 Abnormal ST-T changes	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.2.1 Shenmai injection versus support therapy	1	57	Risk Ratio (M-H, Fixed, 95% CI)	1.18 [0.58, 2.40]
1.3 Number of patients died of cardiac failure	1	164	Risk Ratio (M-H, Fixed, 95% CI)	1.22 [0.34, 4.38]
1.3.1 Astragaloside injection versus support therapy	1	164	Risk Ratio (M-H, Fixed, 95% CI)	1.22 [0.34, 4.38]
1.4 Number of patients converting to persisting myocarditis	1	164	Risk Ratio (M-H, Fixed, 95% CI)	0.65 [0.11, 3.79]
1.4.1 Astragaloside injection versus support therapy	1	164	Risk Ratio (M-H, Fixed, 95% CI)	0.65 [0.11, 3.79]
1.5 Number of patients with premature beat	1	120	Odds Ratio (M-H, Fixed, 95% CI)	0.21 [0.06, 0.79]
1.5.1 Xinshu Capsule versus supportive therapy	1	120	Odds Ratio (M-H, Fixed, 95% CI)	0.21 [0.06, 0.79]

2 Herbal medicines plus supportive therapy versus supportive therapy

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
2.1 Number of patients without symptom improvement	9		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
2.1.1 Astragaloside injection plus support therapy versus support therapy	4	300	Risk Ratio (M-H, Random, 95% CI)	0.38 [0.14, 1.07]
2.1.2 Compound Qiangqi pill plus supportive therapy versus supportive therapy	1	80	Risk Ratio (M-H, Random, 95% CI)	0.40 [0.14, 1.17]
2.1.3 Shengmai decoction plus supportive therapy versus supportive therapy	1	80	Risk Ratio (M-H, Random, 95% CI)	0.80 [0.35, 1.82]
2.1.4 Qi Lu Decoction plus support therapy versus support therapy	1	168	Risk Ratio (M-H, Random, 95% CI)	0.16 [0.04, 0.69]
2.1.5 Shengyangyixin Decoction plus support therapy versus support therapy	1	76	Risk Ratio (M-H, Random, 95% CI)	0.25 [0.06, 1.10]
2.1.6 Astragalus membranaceus plus support therapy versus support therapy	1	50	Risk Ratio (M-H, Random, 95% CI)	0.20 [0.03, 1.59]
2.1.7 Qingxinhuoming Decoction plus support therapy versus support therapy	1	78	Risk Ratio (M-H, Random, 95% CI)	0.36 [0.10, 1.24]
2.2 Abnormal electrocardiogram	5		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2.2.1 Astragalus membranaceus plus support therapy versus support therapy	1	48	Risk Ratio (M-H, Fixed, 95% CI)	0.64 [0.29, 1.41]
2.2.2 Qingxinhuoming Decoction plus support therapy versus support therapy	1	78	Risk Ratio (M-H, Fixed, 95% CI)	0.32 [0.13, 0.79]
2.2.3 Compound Qiangqi pill plus supportive therapy versus supportive therapy	1	32	Risk Ratio (M-H, Fixed, 95% CI)	0.81 [0.53, 1.23]

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
2.2.4 Shengmai decoction plus supportive therapy versus supportive therapy	1	31	Risk Ratio (M-H, Fixed, 95% CI)	0.95 [0.67, 1.36]
2.2.5 Shengyangyixin Decoction plus support therapy versus support therapy	1	76	Risk Ratio (M-H, Fixed, 95% CI)	0.56 [0.35, 0.90]
2.2.6 Astragaloside injection plus supportive therapy versus supportive therapy	1	60	Risk Ratio (M-H, Fixed, 95% CI)	0.25 [0.08, 0.80]
2.3 Abnormal ST-T changes	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2.3.1 Astragaloside injection plus support therapy versus support therapy	1	96	Risk Ratio (M-H, Fixed, 95% CI)	0.83 [0.63, 1.09]
2.4 Number of patients with premature beat	4		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2.4.1 Qi Lu Decoction plus support therapy versus support therapy	1	111	Risk Ratio (M-H, Fixed, 95% CI)	0.71 [0.50, 1.00]
2.4.2 Shorscape fleabane injection plus support therapy versus support therapy	1	83	Risk Ratio (M-H, Fixed, 95% CI)	0.90 [0.67, 1.20]
2.4.3 Astragaloside injection plus support therapy versus support therapy	1	93	Risk Ratio (M-H, Fixed, 95% CI)	1.09 [0.69, 1.71]
2.4.4 Compound Qiangqi pill plus supportive therapy versus supportive therapy	1	14	Risk Ratio (M-H, Fixed, 95% CI)	0.80 [0.36, 1.77]
2.4.5 Shengmai decoction plus supportive therapy versus supportive therapy	1	14	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.52, 1.94]
2.5 Number of patients with abnormal myocardial enzyme levels	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2.5.1 Astragalus membranaceus plus support therapy versus support therapy	1	47	Risk Ratio (M-H, Fixed, 95% CI)	0.39 [0.12, 1.30]
2.5.2 Astragaloside injection plus supportive therapy versus supportive therapy	1	60	Risk Ratio (M-H, Fixed, 95% CI)	0.25 [0.06, 1.08]
2.6 Abnormal LVEF	1	98	Risk Ratio (M-H, Fixed, 95% CI)	0.90 [0.66, 1.23]
2.6.1 Astragaloside injection plus support therapy versus support therapy	1	98	Risk Ratio (M-H, Fixed, 95% CI)	0.90 [0.66, 1.23]
2.7 Number of patients converting to persisting myocarditis	1	120	Odds Ratio (M-H, Fixed, 95% CI)	1.21 [0.27, 5.29]
2.7.1 Astragaloside injection plus support therapy versus support therapy	1	120	Odds Ratio (M-H, Fixed, 95% CI)	1.21 [0.27, 5.29]
2.8 Myocardial enzyme CPK levels (U/L)	3		Mean Difference (IV, Random, 95% CI)	Subtotals only
2.8.1 Astragaloside injection plus support therapy versus support therapy	2	120	Mean Difference (IV, Random, 95% CI)	-21.54 [-33.80, -9.28]

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
2.8.2 Shortscape fleabane injection plus support therapy versus support therapy	1	83	Mean Difference (IV, Random, 95% CI)	-41.73 [-67.00, -16.46]
2.9 Myocardial enzyme LDH levels (U/L)	4		Mean Difference (IV, Random, 95% CI)	Subtotals only
2.9.1 Shengyangyixin Decoction plus support therapy versus support therapy	1	76	Mean Difference (IV, Random, 95% CI)	-186.63 [-215.02, -158.24]
2.9.2 Astragaloside injection plus support therapy versus support therapy	2	120	Mean Difference (IV, Random, 95% CI)	-30.33 [-46.78, -13.88]
2.9.3 Shortscape fleabane injection plus support therapy versus support therapy	1	83	Mean Difference (IV, Random, 95% CI)	-29.28 [-57.82, -0.74]
2.10 Symptom scores	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
2.10.1 Shortscape fleabane injection plus support therapy versus support therapy	1	83	Mean Difference (IV, Fixed, 95% CI)	-1.41 [-2.23, -0.59]
2.11 Cardiac function LVET (%)	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
2.11.1 Astragaloside injection plus support therapy versus support therapy	1	98	Mean Difference (IV, Fixed, 95% CI)	4.67 [1.94, 7.40]
2.11.2 Astragalus membranaceus plus support therapy versus support therapy	1	50	Mean Difference (IV, Fixed, 95% CI)	12.00 [5.06, 18.94]
2.12 Myocardial enzyme CK-MB levels (U/L)	3		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
2.12.1 Astragalus membranaceus plus support therapy versus support therapy	1	50	Mean Difference (IV, Fixed, 95% CI)	-16.30 [-19.66, -12.94]
2.12.2 Shengyangyixin Decoction plus support therapy versus support therapy	1	76	Mean Difference (IV, Fixed, 95% CI)	-3.30 [-3.74, -2.86]
2.12.3 Shortscape fleabane injection plus support therapy versus support therapy	1	83	Mean Difference (IV, Fixed, 95% CI)	-5.81 [-11.34, -0.28]
2.13 Scores of quality of life measured by SF-36	1	160	Mean Difference (IV, Fixed, 95% CI)	66.24 [51.28, 81.20]
2.13.1 Compound Qiangqi pill plus supportive therapy versus supportive therapy	1	80	Mean Difference (IV, Fixed, 95% CI)	88.35 [68.01, 108.69]
2.13.2 Shengmai decoction plus supportive therapy versus supportive therapy	1	80	Mean Difference (IV, Fixed, 95% CI)	40.20 [18.13, 62.27]

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Figure 1. QUOROM flow chart

Figure 2.

Methodological quality graph: review authors' judgements about each methodological quality item presented as percentages across all included studies.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding (performance bias and detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Chen PY 2006	+	?	?	+	+	?
Li L 2006	+	?	?	+	-	?
Li M 2006	+	?	?	+	-	?
Peng Q 2005	+	?	?	+	-	?
Tan YB 2003	+	?	?	+	+	?
Wang Y 2005	+	?	?	+	+	?
Wu JW 2009	+	?	?	+	+	?
Yang YX 2008	+	?	?	+	-	?
Yao BJ 2005	+	?	?	+	-	?
Zhang ZZ 2006	+	+	?	+	-	?
Zheng R 2003	+	+	?	?	+	?
Zheng RF 2005	+	+	+	+	+	?
Zhou Y 2006	+	+	?	+	-	?
Zhou YW 2008	+	?	?	+	+	?

Figure 3.
Methodological quality summary: review authors' judgements about each methodological quality item for each included study.

Summary of findings tables: 1 Main findings of Herbal medicines versus supportive therapy for viral myocarditis

Herbal medicines versus supportive therapy for viral myocarditis						
Patient or population: patients with viral myocarditis Settings: inpatients and outpatients Intervention: Herbal medicines versus supportive therapy						
Outcomes	Illustrative comparative risks* (95% CI)	Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments	
	Assumed risk					
	Control					
Number of patients without symptom improvement - Shenmai injection versus support therapy	Study population		127 (1 study)	⊕⊕⊕⊕ very low ^{1,2,3}		
	290 per 1000	93 per 1000 (41 to 218)				
	Medium risk population					
	290 per 1000	93 per 1000 (41 to 218)				
Number of patients without symptom improvement - Xinsu Capsule versus supportive therapy	Study population		120 (1 study)	⊕⊕⊕⊕ low ^{1,4}		
	350 per 1000	49 per 1000 (14 to 157)				
	Medium risk population					
	350 per 1000	49 per 1000 (14 to 157)				
Number of patients with premature beat - Xinsu Capsule versus supportive therapy	Study population		120 (1 study)	⊕⊕⊕⊕ very low ^{1,2,4}		
	950 per 1000	800 per 1000 (533 to 938)				
	Medium risk population					
	950 per 1000	800 per 1000				

(533 to 938)				
*The basis for the assumed risk (e.g., the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).				
CI: Confidence interval; RR: Risk ratio; OR: Odds ratio;				
GRADE Working Group grades of evidence				
High quality: Further research is very unlikely to change our confidence in the estimate of effect.				
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.				
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.				
Very low quality: We are very uncertain about the estimate.				

¹ No information about allocation concealment, lack of blinding.

² The confidence interval is wide.

³ Outcomes were selectively reported.

⁴ All the included patients were suffered from Frequent Ventricular Extrasystoles.

2 Main findings of Herbal medicines plus supportive therapy versus supportive therapy for viral myocarditis

Herbal medicines plus supportive therapy versus supportive therapy for viral myocarditis						
Patient or population: patients with viral myocarditis Settings: inpatients and/or outpatients Intervention: Herbal medicines plus supportive therapy versus supportive therapy						
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Herbal medicines plus supportive therapy versus supportive therapy				
Number of patients without symptom improvement - Astragaloside injection plus support therapy versus support therapy	Study population		RR 0.53 (0.34 to 0.85)	300 (4 studies)	⊕⊕⊕⊕ low ^{1,2}	
	271 per 1000	144 per 1000 (92 to 230)				
	Medium risk population					
	258 per 1000	137 per 1000 (88 to 219)				
Number of patients without symptom improvement - Qi Lu Decoction plus support therapy versus support therapy	Study population		RR 0.16 (0.04 to 0.69)	168 (1 study)	⊕⊕⊕⊕ very low ^{1,2,3,4}	
	146 per 1000	23 per 1000 (6 to 101)				
	Medium risk population					
	146 per 1000	23 per 1000 (6 to 101)				
Abnormal electrocardiogram - Qingxinhuoming Decoction plus support therapy versus support therapy	Study population		RR 0.32 (0.13 to 0.79)	78 (1 study)	⊕⊕⊕⊕ low ^{1,4}	
	395 per 1000	126 per 1000 (51 to 312)				
	Medium risk population					

	395 per 1000	126 per 1000 (51 to 312)				
Abnormal electrocardiogram - Shengyangxin Decocion plus support therapy versus support therapy	Study population					
	658 per 1000	368 per 1000 (230 to 592)			76 (1 study)	⊕⊕⊕⊕ low ^{1,2,3}
	Medium risk population					
	658 per 1000	368 per 1000 (230 to 592)		RR 0.56 (0.35 to 0.9)		
Abnormal electrocardiogram - Astragaloside injection plus supportive therapy versus supportive therapy	Study population					
	400 per 1000	100 per 1000 (32 to 320)			60 (1 study)	⊕⊕⊕⊕ low ^{1,3,4}
	Medium risk population					
	400 per 1000	100 per 1000 (32 to 320)		RR 0.25 (0.08 to 0.8)		

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

CI: Confidence interval; **RR**: Risk ratio;

GRADE Working Group grades of evidence

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

¹ No information about blinding.

² Outcomes were selectively reported.

³ No information about allocation concealment.

⁴ The confidence interval is wide.

3 Main findings of Herbal medicines plus supportive therapy versus supportive therapy for viral myocarditis

Herbal medicines plus supportive therapy versus supportive therapy for viral myocarditis						
Patient or population: patients with viral myocarditis Settings: inpatients and/or outpatients Intervention: Herbal medicines plus supportive therapy versus supportive therapy						
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95 % CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Herbal medicines plus supportive therapy versus supportive therapy				
Myocardial enzyme CPK levels (U/L) - Astragaloside injection plus support therapy versus support therapy U/L		The mean Myocardial enzyme CPK levels (U/L) - Astragaloside injection plus support therapy versus support therapy in the intervention groups was 21.54 lower (33.8 to 9.28 lower)		120 (2 studies)	⊕⊕⊕⊕ very low 1,2,3,4	
Myocardial enzyme CPK levels (U/L) - Shortscape fleabane injection plus support therapy versus support therapy		The mean Myocardial enzyme CPK levels (U/L) - Shortscape fleabane injection plus support therapy versus support therapy in the intervention groups was 41.73 lower (67 to 16.46 lower)		83 (1 study)	⊕⊕⊕⊕ low 1,3,5	
Myocardial enzyme LDH levels (U/L) - Shengyangxin Decoction plus support therapy versus support therapy		The mean Myocardial enzyme LDH levels (U/L) - Shengyangxin Decoction plus support therapy versus support therapy in the intervention groups was 186.63 lower (215.02 to 158.24 lower)		76 (1 study)	⊕⊕⊕⊕ low 1,4,5	
Myocardial enzyme LDH levels (U/L) - Astragaloside injection plus support therapy versus support therapy		The mean Myocardial enzyme LDH levels (U/L) - Astragaloside injection plus support therapy versus support therapy in the intervention groups was 30.33 lower (46.78 to 13.88 lower)		120 (2 studies)	⊕⊕⊕⊕ very low 1,2,3,4	
Myocardial enzyme LDH levels (U/L) - Shortscape fleabane injection plus support therapy versus support therapy		The mean Myocardial enzyme LDH levels (U/L) - Shortscape fleabane injection plus support therapy versus support therapy in the intervention groups was 29.28 lower (57.82 to 0.74 lower)		83 (1 study)	⊕⊕⊕⊕ very low 1,3,4,5	

Symptom scores - Shortscope fleabane injection plus support therapy versus support therapy	The mean Symptom scores - Shortscope fleabane injection plus support therapy versus support therapy in the intervention groups was 1.41 lower (2.23 to 0.59 lower)	83 (1 study)	⊕⊕⊕⊕ low ^{1,4,5}
Cardiac function LVET (%) - Astragaloside injection plus support therapy versus support therapy	The mean Cardiac function LVET (%) - Astragaloside injection plus support therapy versus support therapy in the intervention groups was 4.67 higher (1.94 to 7.4 higher)	98 (1 study)	⊕⊕⊕⊕ low ^{1,3,4}

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

CI: Confidence interval;

GRADE Working Group grades of evidence

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

- ¹No information about blinding.
- ²Studies yield widely differing estimates of effect.
- ³The confidence interval is wide.
- ⁴Outcomes were selectively reported.
- ⁵No information about allocation concealment.

4 Main findings of Herbal medicines plus supportive therapy versus supportive therapy for viral myocarditis

Herbal medicines plus supportive therapy versus supportive therapy for viral myocarditis						
Patient or population: patients with viral myocarditis Settings: inpatients and/or outpatients Intervention: Herbal medicines plus supportive therapy versus supportive therapy						
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Herbal medicines plus supportive therapy versus supportive therapy				
Cardiac function LVET (%) - Astragalus membranaceus plus support therapy versus support therapy		The mean Cardiac function LVET (%) - Astragalus membranaceus plus support therapy versus support therapy in the intervention groups was 12 higher (5.06 to 18.94 higher)		50 (1 study)	⊕ ⊕ ⊕ ⊕ low ^{1,2,3}	
Myocardial enzyme CK-MB levels (U/L) - Astragalus membranaceus plus support therapy versus support therapy		The mean Myocardial enzyme CK-MB levels (U/L) - Astragalus membranaceus plus support therapy versus support therapy in the intervention groups was 16.3 lower (19.66 to 12.94 lower)		50 (1 study)	⊕⊕⊕⊕ low ^{1,2,3}	
Myocardial enzyme CK-MB levels (U/L) - Shengyangxin Decoction plus support therapy versus support therapy		The mean Myocardial enzyme CK-MB levels (U/L) - Shengyangxin Decoction plus support therapy versus support therapy in the intervention groups was 3.3 lower (3.74 to 2.86 lower)		76 (1 study)	⊕ ⊕ ⊕ ⊕ low ^{1,2,3}	
Myocardial enzyme CK-MB levels (U/L) - Shortscape fleabane injection plus support therapy versus support therapy		The mean Myocardial enzyme CK-MB levels (U/L) - Shortscape fleabane injection plus support therapy versus support therapy in the intervention groups was 5.81 lower (11.34 to 0.28 lower)		83 (1 study)	⊕ ⊕ ⊕ ⊕ low ^{1,2,4}	
scores of quality of life measured by SF-36 - Compound Qiangqi pill plus supportive therapy versus supportive therapy		The mean scores of quality of life measured by SF-36 - Compound Qiangqi pill plus supportive therapy versus supportive therapy in the intervention groups was 88.35 higher (68.01 to 108.69 higher)		80 (1 study)	⊕ ⊕ ⊕ ⊕ moderate ⁴	

scores of quality of life measured by SF-36 - Shengmai decoction plus supportive therapy versus supportive therapy	The mean scores of quality of life measured by SF-36 - Shengmai decoction plus supportive therapy was 40.2 higher (18.13 to 62.27 higher)	80 (1 study)	⊕ ⊕ ⊕ ⊕ high
*The basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).			
CI: Confidence interval;			
GRADE Working Group grades of evidence			
High quality: Further research is very unlikely to change our confidence in the estimate of effect.			
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.			
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.			
Very low quality: We are very uncertain about the estimate.			

¹ No information about blinding.

² No information about allocation concealment.

³ Outcomes were selectively reported.

⁴ The confidence interval is wide.

Additional tables: 1 Herbal medicines and adverse effects in the included trials

Herbs	Formulation	Compositions	Adverse events	Study ID
Xinshu Capsule	capsule	herb mixtures, <i>Cortex Eucommiae</i> 30g, <i>Rhizoma Polygonati</i> 30g, <i>Semen Cuscutae</i> 30g, <i>Radix Astragali</i> 30g, <i>Rhizoma Pinelliae</i> 15g, <i>Sanguis Draconis</i> 10g.	not reported.	Chen PY 2005
Qingxin Kangyan Yin decoction	decoction	herb mixtures, <i>Radix Glycyrrhizae Preparata</i> 20g, <i>Radix Astragali</i> 15g, <i>010045010051 Ramulus Cinnamomi</i> 8g, <i>Radix Ophiopogonis</i> 10g, <i>Radix Rehmanniae</i> 10g, <i>Semen Platycladi</i> 10g, <i>Colla Corii Asini</i> 10g, <i>Rhizoma Blechni</i> 5g, <i>Radix Trichosanthis</i> 10g, <i>semen nelumbinis</i> 10g.	not reported.	Li L 2006
Shengyang Yixin decoction	decoction	herb mixtures, <i>Radix Ginseng</i> 12g, <i>semen nelumbinis</i> 12g, <i>Rhizoma Pinelliae</i> 12g, <i>Schisandra chinensis</i> 12g, <i>Radix Glycyrrhizae</i> 12g, <i>Cistanche tubulosa</i> 15g, <i>Fructus Trichosanthis</i> 15g, <i>Rhizoma Coptidis</i> 15g, <i>Rhizoma Polygoni Cuspidati</i> 15g, <i>Fructus Forsythiae</i> 15g, <i>Fructus Lycii</i> 15g, <i>Semen Platycladi</i> 15g, <i>Folium Isatidis</i> 18g, <i>Radix Astragali</i> 20g, <i>Radix Salviae Miltiorrhizae</i> 20g.	not reported.	Li M 2006
Radix Astragali	injection	Extracts from <i>Astragalus membranaceus</i> .	not observed (Tan YB 2003) or not reported (Zheng R 2003; Zhou Y 2006; Yang YX 2006; Zhang ZZ 2006).	Zheng R 2003; Zhou Y 2006; Tan YB 2003; Yang YX 2008; Zhang ZZ 2006
Shortscape fleabane	injection	herb extract	not reported.	Wang Y 2005
Radix astragali	pill	herb extracts	not reported.	Wu JW 2009
Qi Lu decoction	decoction	herb mixtures	not reported.	Yao BJ 2005
Compound Qiangqi pill	pill	herb mixtures, <i>Radix Astragali</i> , <i>Rhizoma seu Radix Notopterygii</i> , <i>Radix Paeoniae Alba</i> , <i>Radix Puerariae</i> , <i>Rhizoma Cimicifugae</i> , <i>Radix Bupleuri</i> , <i>Radix Saposhnikoviae</i> , <i>Radix Glycyrrhizae</i>	more leucocyte count in 15 patients and reduced to normal at the end of the intervention.	Zheng RF 2005
Shengma	oral liquid	herb extracts	more leucocyte count in 15 patients and reduced to normal at the end of the intervention.	Zheng RF 2005
Qing Xin Huo Ming decoction	decoction	herb mixtures, <i>Radix Ophiopogonis</i> 30-60g, <i>Radix Paeoniae Rubra</i> , <i>Radix Paeoniae Alba</i> 15g., <i>Cortex Moutan</i> 15g, <i>Radix Astragali</i> 30-60g, <i>Cornu Bubali</i> 15g, <i>Scrophularia</i> 12g, <i>Radix Sophorae flavescens</i> 18g, <i>Radix Glycyrrhizae Preparata</i> 10g, <i>Fructus Forsythiae</i> , 15g, <i>Lonicera japonica</i> 30g, <i>Asparagus Tuber</i> 10g, <i>Dwarf Lilyturf Tuber</i> 10 g, <i>Salvia miltiorrhiza</i> Bunge 30g, <i>health and long teeth</i> 30g, <i>Concha Margaritifera Usta</i> 10g, <i>Fructus Trichosanthis</i> 15g, <i>Amber Succinum</i> 2g	not reported.	Zhou YW 2008
Shenmai	injection	Herbal extracts	not reported.	Peng Q 2005

Footnotes