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Chinese herbal medicine for subfertile women with polycystic ovarian syndrome (Review)

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TABLE OF CONTENTS

[Intervention Review]

Chinese herbal medicine for subfertile women with polycystic ovarian syndrome

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ABSTRACT

Background

Polycystic ovarian syndrome (PCOS) is characterised by both metabolic and reproductive disorders, and affects 5% to 15% of women of reproductive age. Different western medicines have been proposed for PCOS-related subfertility, such as oral contraceptives, insulin sensitisers and laparoscopic ovarian drilling (LOD). Chinese herbal medicines (CHM) have also been used for subfertility caused by PCOS for decades, and are expected to become an alternative treatment for subfertile women with PCOS.

Objectives

To assess the efficacy and safety of Chinese herbal medicine (CHM) for subfertile women with polycystic ovarian syndrome (PCOS).

Search methods

We searched the Cochrane Gynaecology and Fertility Group Specialised Register, CENTRAL, MEDLINE, Embase and six other databases, from inception to 2 June 2020. In addition, we searched three trials registries, the reference lists of included trials and contacted experts in the field to locate trials.

Selection criteria

We included randomised controlled trials (RCTs) comparing CHM versus placebo, no treatment or conventional (western) therapies for the treatment of subfertile women with PCOS.

Data collection and analysis

Two review authors independently screened trials for inclusion, assessed the risk of bias in included studies and extracted data. We contacted primary study authors for additional information. We conducted meta-analyses. We used the odds ratios (ORs) to report dichotomous data, with 95% confidence intervals (CIs). We assessed the certainty of the evidence using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methods.

Main results

We included eight RCTs with 609 participants. The comparisons in the included trials were as follows: CHM versus clomiphene, CHM plus clomiphene versus clomiphene (with or without ethinyloestradiol cyproterone acetate (EE/CPA)), CHM plus follicle aspiration plus ovulation induction versus follicle aspiration plus ovulation induction alone, and CHM plus laparoscopic ovarian drilling (LOD) versus LOD alone. The overall certainty of the evidence for most comparisons was very low.

None of the included studies reported the primary outcome, live birth rate. Most studies reported the secondary outcomes, and only one study reported data on adverse events.

In trials that compared CHM to clomiphene (with or without LOD in both study arms), we are uncertain of the effect of CHM on pregnancy rates (odds ratio (OR) 1.41, 95% confidence interval (CI) 0.63 to 3.19; I^2 = 28%; 3 studies, 140 participants; very low certainty evidence). Results suggest that if the chance of pregnancy following clomiphene is assumed to be 21.5%, the chance following CHM would vary between 14.7% and 46.7%. No study reported data on adverse events.

When CHM plus clomiphene was compared to clomiphene (with or without EE/CPA), there was low certainty evidence of a higher pregnancy rate in the CHM plus clomiphene group (OR 3.06, 95% CI 2.05 to 4.55; I^2 = 10%; 6 studies, 470 participants; low certainty evidence). Results suggest that if the chance of pregnancy following clomiphene is assumed to be 31.5%, the chance following CHM plus clomiphene would vary between 48.5% and 67.7%.
No data were reported on adverse events.

In trials that compared CHM plus follicle aspiration and ovulation induction to follicle aspiration and ovulation induction alone, we are uncertain of the effect of CHM on pregnancy rates (OR 1.62, 95% CI 0.46 to 5.68; 1 study, 44 women; very low certainty evidence). Results suggest that if the chance of pregnancy following follicle aspiration and ovulation induction is assumed to be 29.2%, the chance following CHM with follicle aspiration and ovulation induction would vary between 15.9% and 70%. Reported adverse events included severe luteinised unruptured follicle syndrome (LUFS) (Peto OR 0.60, 95% CI 0.06 to 6.14; 1 study, 44 women; very low certainty evidence), ovarian hyperstimulation syndrome (OHSS) (Peto OR 0.16, 95% CI 0.00 to 8.19; 1 study, 44 women; very low certainty evidence) or multiple pregnancy (Peto OR 0.60, 95% CI 0.06 to 6.14; 1 study, 44 women; very low certainty evidence). These results suggest that if the chances of LUFS, OHSS, and multiple pregnancy following follicle aspiration and ovulation induction are assumed to be 8.3%, 4.2%, and 8.3% respectively, the chances following CHM with follicle aspiration and ovulation induction would be 0.5% to 35.8%, 0% to 26.3% and 0.5% to 35.8% respectively.

In trials that compared CHM plus LOD to LOD alone, we are uncertain if CHM improves pregnancy rates (OR 3.50, 95% CI 0.72 to 17.09; 1 study, 30 women; very low certainty evidence). Results suggest that if the chance of pregnancy following LOD is assumed to be 40%, the chance following CHM with LOD would vary between 32.4% and 91.9%. No data were reported on adverse events.

We are uncertain of the results in the comparison groups for all outcomes. The certainty of the evidence for all other comparisons and outcomes was very low. The main limitations in the evidence were failure to report live birth or adverse events, failure to describe study methods in adequate detail and imprecision due to very low event rates and wide CIs.

Authors' conclusions

There is insufficient evidence to support the use of CHM for subfertile women with PCOS. No data are available on live birth. We are uncertain of the effect of CHM on pregnancy rates for there is no consistent evidence to indicate that CHM influences fertility outcomes. However, we find that the addition of CHM to clomiphene may improve pregnancy rates, but there is very limited, low certainty evidence for this outcome. Furthermore, there is insufficient evidence on adverse effects to indicate whether CHM is safe. In the future, well-designed, carefully conducted RCTs are needed, with a particular focus on the live birth rate and other safety indexes.

PLAIN LANGUAGE SUMMARY

Chinese herbal medicines for subfertile women with polycystic ovarian syndrome

Review question

We reviewed the evidence about the effect of Chinese herbal medicine (CHM) on rates of live birth pregnancy and adverse events in subfertile women with polycystic ovarian syndrome (PCOS).

Background

PCOS is a common and complex reproductive endocrine disorder, affecting 5% to 15% of women of reproductive age. Women with PCOS may present with irregular menstrual cycles, subfertility (failure to conceive), hirsutism (excessive hair growth), acne and obesity. Many western medical therapies have been used to manage PCOS, including oral contraceptives, clomiphene (drugs used to induce ovulation in women), insulin sensitisers (drugs that help return the blood sugar to the normal range) and laparoscopic ovarian drilling (LOD) which is a surgical treatment that can trigger ovulation in women with PCOS. CHM has been suggested as an alternative approach for subfertile women with PCOS. We wanted to investigate the effectiveness and safety of CHM compared to other therapies for subfertile women with PCOS.

Study characteristics

We searched for evidence in commonly used databases. The evidence is current to June 2020. We included eight randomised controlled trials (RCTs) with 609 participants (three new RCTs with 195 women in this updated review). These included studies comparing CHM to western medicine, CHM plus western medicine versus western medicine, and CHM plus surgery versus surgery. Seven of the included

studies were conducted and published in Chinese, and the remaining one was in English. All studies had fewer than six menstrual cycles' treatment duration and less than one year follow-up duration. None of the included studies reported live birth, all reported pregnancy, two reported ovulation and only one reported adverse events.

Key results

There was insufficient evidence to support the use of CHM for subfertile women with PCOS. No data were available on live birth. There was no consistent evidence to indicate that CHM improves fertility outcomes.

When CHM was compared to clomiphene (with or without laparoscopic ovarian drilling (LOD) in both study arms), the pregnancy rates were no different between the treatment and control groups. When CHM plus follicle aspiration and ovulation induction was compared to follicle aspiration and ovulation induction alone, pregnancy rates were no different between the groups. When CHM plus LOD was compared to LOD alone, pregnancy rates were no different between the groups. The certainty of the evidence was very low and therefore we could not draw any conclusions about the results.

There was, however, limited low certainty evidence to suggest that the addition of CHM to clomiphene may improve pregnancy rates.

Due to the very low certainty evidence for all comparison groups for all outcomes, we were unable to draw conclusions. There was insufficient evidence on adverse effects to indicate whether CHM is safe.

Certainty of the evidence

The certainty of the evidence was low or very low. The main limitations in the evidence were failure to report live birth or adverse events, failure to describe study methods in adequate detail, and imprecision, with very low event rates and wide confidence intervals.

Summary of findings 1. Chinese herbal medicine (CHM) versus clomiphene for subfertile women with PCOS

CHM versus clomiphene for subfertile women with PCOS

Population: subfertile women with PCOS

Setting: fertility clinics
Intervention: Chinese herbal medicine (CHM)
Comparison: clomiphene

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Clomiphene	CHM				
Live birth rate	Not reported					
Pregnancy rate	215 per 1000	279 per 1000 (147 to 467)	OR 1.41 (0.63 to 3.19)	140 (3 RCTs)	⊕⊖⊖⊖ Very low[a,b]	
Adverse effects	Not reported					

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

Abbreviations: CI: confidence interval; OR: odds ratio

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

[a]Downgraded one level for serious risk of bias: study methods not described in sufficient detail.
[b]Downgraded two levels for very serious imprecision: small sample size, only 38 events altogether, CIs compatible with no effect or with substantial benefit from the intervention.

Summary of findings 2. Chinese herbal medicine (CHM) plus clomiphene versus clomiphene for subfertile women with PCOS

CHM plus clomiphene compared to clomiphene for subfertile women with PCOS

Population: subfertile women with PCOS

Setting: fertility clinics
Intervention: Chinese herbal medicine (CHM) + clomiphene
Comparison: clomiphene

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Clomiphene	CHM + clomiphene				
Live birth	Not reported					
Pregnancy rate (per woman)	315 per 1000	584 per 1000 (485 to 677)	OR 3.06 (2.05 to 4.55)	470 (6 RCTs)	⊕⊕⊖⊖ low[a,b]	
Adverse events	Not reported					

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

Abbreviations: CI: confidence interval; OR: odds ratio.

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

[a]Downgraded one level for serious risk of bias: study methods not described in sufficient detail.
[b]Downgraded one level for serious imprecision: small studies, low overall event rate.

Summary of findings 3. Chinese herbal medicine (CHM) plus follicle aspiration plus ovulation induction versus follicle aspiration plus ovulation induction for subfertile women with PCOS

CHM + follicle aspiration + ovulation induction compared to follicle aspiration + ovulation induction for subfertile women with PCOS

Population: subfertile women with PCOS

Setting: fertility clinics
Intervention: Chinese herbal medicine + follicle aspiration + ovulation induction
Comparison: follicle aspiration + ovulation induction

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Follicle aspiration + ovulation induction	CHM + follicle aspiration + ovulation induction				
Live birth	Not reported					
Pregnancy rate	292 per 1000	400 per 1000 (159 to 700)	OR 1.62 (0.46 to 5.68)	44 (1 RCT)	⊕⊖⊖⊖ Very low[a,b]	
Luteinised unruptured follicle syndrome (adverse events)	83 per 1000	52 per 1000 (5 to 358)	Peto OR 0.60 (0.06 to 6.14)	44 (1 RCT)	⊕⊖⊖⊖ Very low[a,b]	
Ovarian hyperstimulation syndrome (adverse events)	42 per 1000	7 per 1000 (0 to 263)	Peto OR 0.16 (0.00 to 8.19)	44 (1 RCT)	⊕⊖⊖⊖ Very low[a,b]	
Multiple pregnancy (adverse events)	83 per 1000	52 per 1000 (5 to 358)	Peto OR 0.60 (0.06 to 6.14)	44 (1 RCT)	⊕⊖⊖⊖ Very low[a,b]	

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

Abbreviations: CI: confidence interval; OR: odds ratio

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

[a]Downgraded one level for serious risk of bias: the study authors did not report the study methods in sufficient detail, and the study authors did not describe the allocation concealment method.
[b]Downgraded two levels for very serious imprecision: small study, few events, CIs compatible with no effect or with substantial harm or benefit in either arm.

Summary of findings 4. Chinese herbal medicine (CHM) plus laparoscopic ovarian drilling (LOD) versus LOD for subfertile women with PCOS

CHM plus LOD compared to LOD for subfertile women with PCOS

Population: subfertile women with PCOS
Setting: fertility clinics
Intervention: CHM + LOD
Comparison: LOD

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	LOD	CHM + LOD				
Live birth	Not reported					
Pregnancy rate (per woman)	400 per 1000	700 per 1000 (324 to 919)	OR 3.50 (0.72 to 17.09)	30 (1 RCT)	⊕⊖⊖⊖ Very low[a,b]	
Adverse events	Not reported					

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

Abbreviations: CI: confidence interval; OR: odds ratio

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

[a]Downgraded one level for serious risk of bias: the study authors did not report the study methods in sufficient detail.
[b]Downgraded two levels for very serious imprecision: small study, few events, and CIs were compatible with no effect or with substantial harm in the CHM group.

BACKGROUND

Description of the condition

Polycystic ovarian syndrome (PCOS) is a complex endocrine condition that affects 5% to 15% of women of reproductive age (Carmina 1999; Yildiz 2012; Bozdag 2016). PCOS is characterised by chronic anovulation (ongoing failure or absence of ovulation), hyperandrogenism (excessive production of androgen in women), dyslipidaemia (lipid metabolism disorder), and insulin resistance (a reduced glucose response to a given amount of insulin) leading to hyperinsulinaemia (compensatory serum insulin increase) (Bani 2017). Women with PCOS may present with irregular menstrual cycles, subfertility (failure to conceive), hirsutism (excessive hair growth), acne and obesity. PCOS is a complex multifactorial disease with genetic and environmental origins. The aetiology of PCOS is still unclear. It is proposed that high levels of androgen in serum may be the primary cause (Escobar-Morreale 2005). Recent studies have proposed that prenatal exposure to androgens is a major risk factor for the next generation developing PCOS (Filippou 2017). However, insulin resistance and obesity may also trigger the development of this hormonal defect (Dunaif 1997; Alvarez-Blasco 2006; Gambineri 2006). Other conditions associated with PCOS include type 2 diabetes mellitus (Ehrmann 1999; Legro 1999), gestational diabetes (Boomsma 2006; Lo 2006a), decreased high density lipoprotein cholesterol (HDL-C) (Rajkhowa 1997; Berneis 2007), increased triglycerides (TG) and low density lipoprotein cholesterol (LDL-C) (Talbott 1998; Legro 2001), increased risk of hypertension (high blood pressure) (Lo 2006b), and increased prevalence of metabolic syndrome (Ali 2015).

Traditional Chinese medicine follows an independent theoretical and methodological pathway to assess the cause of a disease in order to make a diagnosis and treatment plan. There is no classification for PCOS within traditional Chinese medicine. However, the symptoms and signs of women with PCOS can be grouped as two disease classes within traditional Chinese medicine: amenorrhoea (failure to menstruate) and infertility.

Description of the intervention

Studies of PCOS and traditional Chinese medicine have been conducted since the 1980s (Sun 1981; Yv 1981; Wang 1982). A small proportion of women in western countries have recently begun using traditional Chinese medicines for fertility. One survey showed that in subfertility clinics, 5% of women in southern Australia, 10% in the United Kingdom, and 18% in the USA used traditional Chinese medicines (Ried 2015). The aetiology and clinical characteristics of PCOS remain controversial but are believed to be related to disorders of the kidneys, liver and spleen. Traditional Chinese medicine regards reproductive function as being governed by the kidneys. It is believed that kidney deficiency may be the main problem in PCOS (Ni 2007; Wang 2008; Huang C 2019). Additionally, in traditional Chinese medicine, there is an association between the liver and the regulation of blood and the menstrual cycle, and the spleen is associated with body type, obesity and hirsutism (Hou 2012).

Many western medical therapies have been used for PCOS, including oral contraceptives, insulin sensitisers, exercise, diet and laparoscopic ovarian drilling (LOD). Several Cochrane Reviews have addressed different approaches to PCOS using western medical treatments (Costello 2007; Bordewijk 2020; Sinawat 2012; Tang 2012a; Weiss 2015). The oral contraceptive pill (OCP) is believed to be more effective than insulin-sensitising drugs in improving menstrual patterns and reducing serum androgen levels (Costello 2007). On the other hand, metformin, an insulin-sensitising drug (ISD), has been found to be more effective than the OCP in reducing fasting insulin levels and not increasing triglyceride levels (Costello 2007). An American guideline suggested that metformin increases the ovulation rate in women with PCOS, while ovulation induction agents (such as clomiphene citrate or letrozole) alone are much more effective than metformin in increasing ovulation, pregnancy and live-birth rates in women with PCOS (ASRM 2017). However, the possible adverse effects of using metformin include nausea and vomiting (Tang 2012a). The optimal duration for metformin pretreatment before initiation of clomiphene citrate is unknown (Sinawat 2012). Gonadotrophin is used for ovulation induction but it may also cause overstimulation of the ovaries. A reduced incidence of overstimulation was found with the use of more expensive urinary follicle stimulating hormone (uFSH) compared to human menopausal gonadotrophin (HMG). A higher overstimulation rate with the addition of gonadotrophin-releasing hormone analogues (GnRH-a) to gonadotrophins is suggested (Weiss 2015). LOD followed by clomiphene or gonadotrophins, if necessary, are suggested to be as effective as gonadotrophin therapy alone in inducing ovulation. However, LOD is associated with a lower risk of multiple pregnancy (Bordewijk 2020).

Acupuncture Is not as effective as infertility treatment in women with PCOS (Xu L 2017). Lifestyle changes incorporating diet, exercise and behavioural interventions may improve clinical features, such as free androgen index (FAI), weight and body mass index (BMI) in women with PCOS, but these interventions are unclear for infertility outcomes (Lim 2019).

How the intervention might work

Holistic therapy and multisystem regulation are the therapeutic characteristics of traditional Chinese medicine. Many Chinese herbal medicines used in treating PCOS aim to tone the kidneys to induce ovulation. In the following description, we have replaced Latin terms for plant parts with their English equivalents, as follows: 'radix' is root; 'semen' is seed; 'fructus' is fruit, and 'rhizoma' is rhizome. The components of different formulae act synergistically in various ways. For example, it is proposed that baishao (*Paeonia alba* root), dang gui (*Angelica sinensis* root), zao jiao (*Gleditsia sinensis* fruit) and huang qi (*Astragalus membranaceus* Bunge) may reduce release of insulin and androgen through phosphatidylinositol 3-hydroxy kinase(PI3K)/protein kinase B (AKT)/glucose transporter 4 (GLUT4) signal pathway and oxidative stress (Li 2005; Jin 2018; Peng 2019). Recently, research has found that huang lian (*Coptis chinensis* Franch.) may reduce androgen through the tumor necrosis factor(TNF) and forkhead box O(FoxO) signal pathway (He 2020). Luo le (basil) has an oestrogenic effect which prompts follicles to develop and mature (Jin 1986). In addition, it is reported that the CHM di long (*Lumbricus*), san qi (*Panax notoginseng* root), zelan (*Lycopus lucidus*), and ze xie (*Alisma orientale* rhizomes) can induce ovulation (Shao 2006), and that gan cao (*Glycyrrhiza uralensis* root), which possesses glucocorticoid effects, can improve ovulatory abnormality. It is reported that zi shi yin (*Fluorite*) can improve endometrial receptivity for embryo implantation and can regulate cervical mucus for sperm passing through the uterus (Wang 2008).

Chinese herbal medicines are widely used in various endocrinologic disorders. Their aim is to improve menstrual patterns, hirsutism, acne and pregnancy rate in women with PCOS (Cong 2006; Yang 2006; Ma 2010; Huang C 2019). In traditional Chinese medicine, there are three different therapeutic strategies to treat PCOS with Chinese herbal medicine. First, only one special formula comprised of the sovereign medicinal (the ingredient that provides the principal curative action on the main pattern, syndrome or primary symptom) is prescribed to women for the whole menstrual cycle. This formula is occasionally combined with a minister medicinal (the ingredient that helps strengthen the principal curative action) and assistant medicinal (the ingredient that treats the combined pattern or syndrome, relieves secondary symptoms or tempers the action of the sovereign ingredient when the latter is too potent) according to women's individual symptoms and signs (Cui 2004; Ning 2004; Xia 2004; Zhang 2004; Liu 2005; Wang 2005; Cong 2006; Yang 2006; Chen 2018; Huang C 2019). Second, different formulae are periodically prescribed to women with PCOS according to their individual menstrual cycle. This strategy aims to restore normal reproductive endocrinological function (Yuan 2003; Xue 2004). Third, Chinese herbal medicines are used in combination with western medicines for treating PCOS (Li 2000; Li 2002; Ye 2004; Lin 2005; Li 2006; Rao 2019).

Why it is important to do this review

Various western medical therapies have been used for PCOS in recent decades. Their effectiveness varies and some are associated with adverse events. Chinese herbal medicine has been used for thousands of years to treat gynaecological and infertility problems of PCOS, which has a different name in traditional Chinese medicine. There is increasing public interest in, and use of, a wide range of therapies which lie outside the 'mainstream' of traditional western medical practice (Ried 2015). Although Chinese herbal medicine is generally considered safe when used properly by qualified practitioners, many herbs and formulae have contraindications, and some can be toxic. There are concerns about adverse events, including allergic reactions and Chinese herbal nephropathy (Nortier 2000; Lord 2001; Lampert 2002). A population-based survey of Hong Kong Chinese showed 71.7% reported past-year over-the-counter traditional Chinese herbal medicine use and 2.3% reported over-the-counter traditional Chinese herbal medicine related adverse events (e.g. allergic reaction and dizziness) (Kim 2013).

There is currently insufficient evidence about the safety and efficacy of Chinese herbal medicine for the management of PCOS. Thus, there is an emerging need to summarise current evidence and provide a clear view on the effectiveness of this intervention. This is a review update. The first version was published in 2010 (Zhang 2010), and the second version published in 2016 (Zhou 2016).

OBJECTIVES

To assess the efficacy and safety of Chinese herbal medicine (CHM) for subfertile women with polycystic ovarian syndrome (PCOS).

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) studying the efficacy of Chinese herbal medicine for subfertile women with polycystic ovarian syndrome (PCOS).

We excluded quasi-RCTs and non-RCTs.

Types of participants

We included women (18 to 44 years old) with PCOS and subfertility, wishing to conceive naturally. We excluded women undergoing assisted reproductive technology (ART) or intrauterine insemination (IUI). We also excluded women with subfertility caused by endometriosis, fallopian tube blockage or other reasons not related to PCOS, and women with unexplained infertility. We excluded trials that included both fertile and infertile women with PCOS unless there was a stratified analysis based on fertility.

We defined PCOS using the diagnostic criteria of the European Society of Human Reproduction and Embryology (ESHRE) and the American Society of Reproductive Medicine (ASRM) consensus in Rotterdam 2003 (ESHRE/ASRM 2004). PCOS can be diagnosed if a woman has two out of three criteria: oligo-ovulation or anovulation, clinical or biochemical signs of hyperandrogenism and polycystic ovaries by ultrasonography. These diagnostic criteria exclude individuals who have other aetiologies of hyperandrogenism (such as androgen secreting tumour, hyperprolactinaemia, dysthyroid disease, Cushing syndrome and congenital adrenal cortical hyperplasia).

Ideally, the trials that we considered for inclusion in this review stated and described the diagnostic criteria of PCOS. If the primary study did not employ the Rotterdam criteria, we evaluated the stated diagnostic criteria in each individual study to confirm whether they met the Rotterdam criteria.

We excluded trials whose diagnostic criteria were inconsistent with the Rotterdam criteria. If the trial did not clearly state the diagnostic criteria, we contacted the primary study authors for clarification. If clarification was unavailable, we also excluded these trials. Changes in diagnostic criteria might produce variability in the clinical characteristics of the women included and the results obtained. We considered and documented these changes. We plan to perform sensitivity analyses based on these changes when we locate more RCTs that meet the inclusion criteria of this review in the future.

Types of interventions

- CHM versus placebo, no treatment, western medicine, exercise plus diet control, laparoscopic surgery, another type of CHM, with or without co-medications in both arms of the comparison.
- CHM combined with another treatment versus another treatment, such as western medicine, exercise plus diet control or laparoscopic surgery.
- CHM alone or combined with another treatment versus CHM combined with another treatment.

We excluded trials that included ovarian wedge resection as the control intervention because physicians have not used this method since the application of laparoscopic ovarian drilling (LOD).

We excluded trials without CHM application.

Types of outcome measures

Primary outcomes

- Live birth rate (per woman). Live birth is defined as the delivery of a live foetus more than 20 completed weeks of gestational age. Ongoing pregnancy is defined as the presence of a foetal heart beat on ultrasound scan over 12 weeks of gestation per woman or couple randomised. Cumulative live birth was also to be reported, if data were available.

Secondary outcomes

- Pregnancy rate per woman. We defined pregnancy as a positive beta human chorionic gonadotropin (hCG) level, and an ultrasound showed a gestational sac.
- Ovulation rate (confirmed by ultrasound or increased progesterone) per woman
- Adverse events (serious and non-serious)

We defined serious adverse events according to the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidelines (ICHEWG 1997). These include any event that led to death, was life-threatening, required inpatient hospitalisation or prolongation of existing hospitalisation, or resulted in persistent or significant disability, and any important medical event that might have jeopardised the patient or required intervention to prevent it. For example, we considered severe ovarian hyperstimulation syndrome (OHSS) and severe luteinised unruptured follicle syndrome (LUFS) as serious adverse events in this review. We considered all other adverse events as non-serious.

Search methods for identification of studies

In consultation with the Cochrane Gynaecology and Fertility Group (CGF) Information Specialist, we formulated a comprehensive search strategy in order to identify all RCTs regardless of language or publication status (published, unpublished, in press or in progress).

Electronic searches

In this review update, we searched the following databases up to 2 June 2020:

- The Cochrane Gynaecology and Fertility Group Specialised Register; ProCite platform, searched 2 June 2020 (Appendix 1);
- CENTRAL via the Cochrane Register of Studies Online (CRSO) Web platform, searched 2 June 2020 (Appendix 2);
- MEDLINE; OVID platform, searched from 1946 to 2 June 2020 (Appendix 3);
- Embase; OVID platform, searched from 1980 to 2 June 2020 (Appendix 4);
- PsycINFO; OVID platform, searched from 1806 to 2 June 2020 (Appendix 5);
- CINAHL; EBSCO platform, searched from 1961 to 2 June 2020 (Appendix 6);
- Allied and Complementary Medicine (AMED); OVID platform, searched from 1985 to 2 June 2020 (Appendix 7);
- Chinese National Knowledge Infrastructure (CNKI, including Chinese journal full-text database (CJFD), Chinese selected doctoral dissertations and Master's theses full-text databases (CDMD)); Web platform, searched 2 June 2020 (Appendix 8);
- Wanfang database; Web platform, searched 2 June 2020 (Appendix 9);
- VIP: Chinese important conference dissertations full-text database; Web platform, searched 2 June 2020 (Appendix 10).

We constructed search strategies using a combination of subject headings and text words relating to the use of traditional Chinese herbal medicines for the management of PCOS. We translated all of the search terms into Chinese terms when we conducted the searches in Chinese databases.

We combined the MEDLINE search with the Cochrane highly sensitive search strategy for identifying randomised trials which appears in the *Cochrane Handbook of Systematic Reviews of Interventions* (Version 5.0.2, Chapter 6, 6.4.11) (Higgins 2011).

We combined the Embase and CINAHL search with trial filters developed by the Scottish Intercollegiate Guidelines Network (SIGN) https://www.sign.ac.uk/what-we-do/methodology/search-filters/.

We searched the following trials registries for ongoing trials (searched 2 June 2020):

- The ISRCTN Register (international); Action Medical Research (UK); NIHR Health Technology Assessment Programme (HTA) (UK); The Wellcome Trust (UK); Medical Research Council (UK); UK trials (UK); NIH Clinical Trials.gov Register (International) (www.isrctn.com/);
- The World Health Organization International Trials Registry Platform search portal (apps.who.int/trialsearch/Default.aspx);
- The Chinese Clinical Trial Registry (www.chictr.org.cn/index.aspx).

Searching other resources

We checked the reference lists of relevant trials, reviews and textbooks. We also used Epistemonikos database (www.epistemonikos.org/en) for reference checking from systematic reviews. We contacted experts in the field and pharmaceutical companies for relevant trials.

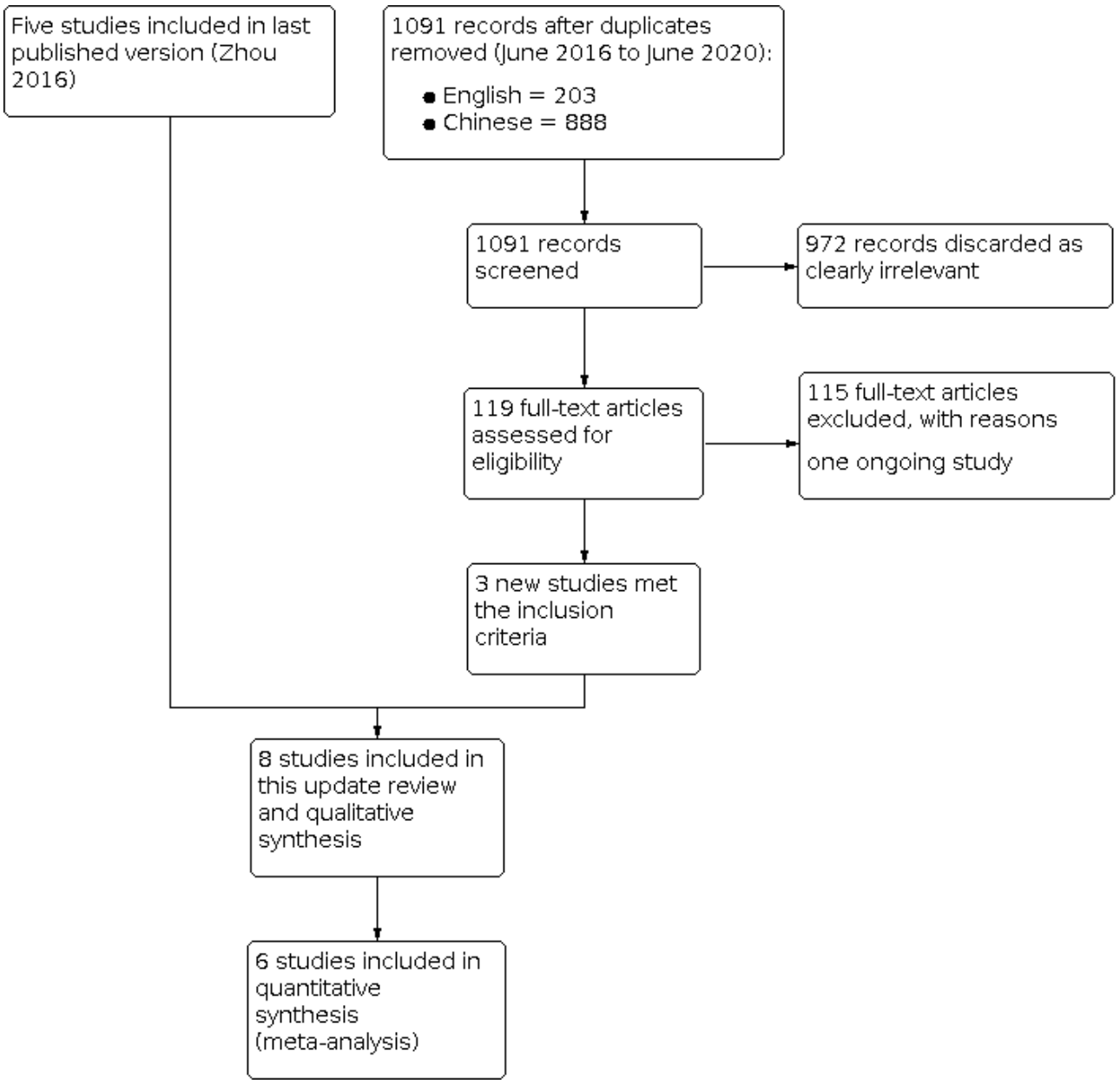
Data collection and analysis

Selection of studies

Two review authors (ZK, ZJ) independently performed the searches and retrieved articles. We retrieved the searched trials that claimed to be randomised. Two review authors (ZK, ZJ) then confirmed that these trials were correctly randomised by telephoning the original trial authors to evaluate the methodological quality. We judged trials to be adequately randomised if they met the set criteria (Schulz 1995; Jadad 1996; Moher 1998; Jüni 2001; Kjaergard 2001). Two review authors (ZK, ZJ) selected the trials to be included in the review and resolved any disagreements through discussion with a third review author (XL). We listed the excluded studies and the reasons for exclusion in the Characteristics of excluded

studies table. See Figure 1 for details of the screening and selection process.

Figure 1. Study flow diagram



Data extraction and management

Two review authors (ZK, XL) independently extracted data using a piloted data extraction form. We extracted data on study characteristics including methods, participants, interventions and outcomes (see the Characteristics of included studies table). We resolved any disagreements through discussion. We have listed the formulation contents and herb names used in the included studies in three languages in Table 1 ;Table 2.;Table 3

Assessment of risk of bias in included studies

Two review authors (ZJ, XL) independently performed the risk of bias assessments using the Cochrane risk of bias tool to assess the following domains (Higgins 2011).

- Sequence generation: randomised (for example, by computer, random number tables or drawing lots) or method of randomisation not described (we excluded quasi-RCTs).
- Allocation concealment: low risk of bias (for example, by third party, sealed opaque envelopes); high risk of bias (for example, open list of allocation codes); unclear risk of bias (for example, not stated, or 'envelopes' stated without further description).

- Blinding of participants and personnel.
- Blinding of outcome assessors.
- Completeness of outcome data.
- Selective outcome reporting.
- Other sources of bias.

Measures of treatment effect

We only measured dichotomous data in this review. We calculated Mantel-Haenszel odds ratios (ORs) with 95% confidence intervals (CIs) for all outcomes (except for adverse events). We compared the adverse events outcome measures for binary data by calculating Peto odds ratios (Peto OR) with 95% confidence intervals (CIs). To measure the treatment effect, we conducted intention-to-treat (ITT) analyses.

Unit of analysis issues

We planned to assess any studies with non-standard designs, such as cluster-RCTs, to avoid unit of analysis errors including: recruitment bias, baseline imbalance, loss of clusters, incorrect analysis and comparability with individually RCTs.

Dealing with missing data

We attempted to contact trial authors to request missing data, but were unsuccessful. In the present review, we imputed outcomes where data were missing.

Assessment of heterogeneity

We considered whether the clinical and methodological characteristics of the included studies were sufficiently similar for meta-analysis to provide a clinically meaningful summary. We assessed statistical heterogeneity by using the Chi^2 test with a 10% level of statistical significance and by the I^2 statistic to estimate the total variation across studies due to heterogeneity rather than chance. We considered less than 25% to indicate low level heterogeneity; 25% to 50% as a moderate level; and greater than 50% to indicate substantial heterogeneity (Higgins 2002; Higgins 2011).

Assessment of reporting biases

In view of the difficulty of detection of and correction for publication bias and other reporting biases, we planned to minimise their potential impact by ensuring a comprehensive search for eligible studies and by being alert to the duplication of data. If there were 10 or more studies in an analysis, we planned to use a funnel plot to explore the possibility of small study effects (a tendency for estimates of the intervention effect to be more beneficial in smaller studies).

Data synthesis

We planned that two review authors (ZK, ZJ) would pool data if studies were sufficiently similar, using Review Manager 5 (RevMan 5) (RevMan 2014). If pooling was inappropriate, we planned to perform only descriptive analysis. We planned to use a fixed-effect model unless there was substantial heterogeneity, in which case we would use a random-effects model.

We planned to combine the data from primary studies for the following comparisons.

- CHM versus clomiphene.
- CHM plus clomiphene versus clomiphene.
- CHM plus follicle aspiration plus ovulation induction versus follicle aspiration plus ovulation induction.
- CHM plus LOD versus LOD.

Subgroup analysis and investigation of heterogeneity

Where data were available, we planned to conduct subgroup analyses to determine the separate evidence for the following subgroups.

- Different co-interventions.
- Different treatment strategies.
- The duration of intervention or follow-up.
- Women with or without insulin resistance.
- Women who were or were not obese.
- Ethnicity.

If we detected substantial heterogeneity, we planned to explore possible explanations in sensitivity analyses and to take any statistical heterogeneity into account when we interpreted the results, especially if there was any variation in the direction of effect.

Sensitivity analysis

We planned to conduct sensitivity analyses for the primary outcomes to determine whether the conclusions were robust to arbitrary decisions made regarding eligibility and analysis. These analyses would include consideration of whether the review conclusions would have differed under the following circumstances.

- We restricted eligibility to studies without high risk of bias.
- We adopted a random-effects model.
- We restricted eligibility to studies without commercial funding.

Summary of findings and assessment of the certainty of the evidence

One review author (ZK) prepared a summary of findings table using GRADEpro and Cochrane methods (Higgins 2011; GRADEpro GDT). This table evaluated the overall certainty of the body of evidence for the main review outcomes (live birth, pregnancy rate, adverse events) for the main review comparison of Chinese herbal medicine (CHM) versus clomiphene. We also prepared additional summary of findings tables for the main review outcomes for these other important comparisons: CHM plus clomiphene versus clomiphene; CHM plus follicle aspiration and ovulation induction versus follicle aspiration plus ovulation induction; and CHM plus laparoscopic ovarian drilling (LOD) versus LOD. We assessed the certainty of the evidence using GRADE criteria: risk of bias, consistency of effect, imprecision, indirectness and publication bias.

RESULTS

Description of studies

We have reported the characteristics of the included and excluded studies in the Characteristics of included studies tables and the Characteristics of excluded studies tables.

Results of the search

The update search from June 2016 to 2 June 2020 retrieved 1091 articles (excluding duplications): 203 in English and 888 in Chinese. Of these 1091 articles, 70 were animal or experimental studies, 44 were non-polycystic ovarian syndrome (PCOS) studies, 103 were non-Chinese herbal medicine (CHM) studies, 239 included participants who were adolescent or had PCOS without infertility or had no wish to conceive, 6 were before-and-after studies, 24 were reviews, 11 were case-control studies, 0 were case reports, 26 were cross-sectional studies, 289 were parallel non-randomised controlled studies, 45 were systematic reviews, 95 were unrelated studies and 20 were duplications. Finally, 119 articles were potentially eligible for inclusion, and we retrieved the full texts of these articles. Eight studies met our inclusion criteria and were included in this review (Li 2007; Ye 2007; Liang 2008; Ma HX 2009; Li Y 2012; Jin F 2016; Liang YM 2017; Ainehchi 2019). Three were new studies to this update review (Jin F 2016; Liang YM 2017; Ainehchi 2019). There was one ongoing study (Xu 2020). We excluded 115 articles. See the Characteristics of included studies tables and the Characteristics of excluded studies tables for further details.

We prepared a PRISMA flow diagram to illustrate the inclusion and exclusion process (Figure 1).

Included studies

Study design

Seven included studies were conducted and published in Chinese. Only one included study was published in English (Ainehchi 2019). One was a double clinical centre design (Liang 2008), and the other seven were single-centre studies. Five studies used two-arm parallel groups (Liang 2008; Ma HX 2009; Li Y 2012; Jin F 2016; Liang YM 2017), and the other three studies used three-arm parallel groups (Li 2007; Ye 2007; Ainehchi 2019). The range of study duration was from one year to four years. Each included study reported the inclusion and exclusion criteria. Dropouts and withdrawals occurred in five studies for different reasons (Li 2007; Liang 2008; Ma HX 2009; Jin F 2016; Ainehchi 2019).

Participants

In this review update, the eight studies included a total of 609 participants. Sample size ranged from 40 to 170. All participants were women of reproductive age, with PCOS (according to the Rotterdam criteria) and subfertility. Furthermore, two included studies also had the inclusion criterion that participants were resistant to western medicines for ovulation induction (Ye 2007; Liang 2008). The baseline characteristics among groups were comparable for each study.

Interventions

Two studies used Chinese patent drugs (Li 2007; Li Y 2012), and the other six included studies used Chinese herbal formulas. We have listed the contents of each CHM preparation in Table 1, and the names of each herbal medicinal in three languages in Table 2. The treatment duration was less than six menstrual cycles for all included studies. However, the duration of follow-up was three months (Liang 2008; Liang YM 2017), six months (Ainehchi 2019), one year (Ye 2007), and unclear (Li 2007; Ma HX 2009; Li Y 2012; Jin F 2016), respectively.

- CHM versus clomiphene:
  - two studies compared CHM versus clomiphene (Li 2007; Ainehchi 2019);
  - one study compared CHM plus laparoscopic ovarian drilling (LOD) versus clomiphene plus LOD (Ye 2007).
- CHM plus clomiphene versus clomiphene:
  - five studies compared CHM plus clomiphene versus clomiphene (Li 2007; Li Y 2012; Jin F 2016; Liang YM 2017; Ainehchi 2019);
  - one study compared CHM plus ethinyloestradiol cyproterone acetate (EE/CPA) plus clomiphene versus EE/CPA plus clomiphene (Ma HX 2009).
- CHM plus follicle aspiration plus ovulation induction versus follicle aspiration plus ovulation induction:
  - one study compared CHM plus follicle aspiration plus ovulation induction versus follicle aspiration plus ovulation induction (Liang 2008).
- CHM plus LOD versus LOD:
  - one study compared CHM plus LOD versus LOD (Ye 2007).

Outcomes

- No study reported live birth rate.
- All eight included studies reported clinical pregnancy rate (Li 2007; Ye 2007; Liang 2008; Ma HX 2009; Li Y 2012; Jin F 2016; Liang YM 2017; Ainehchi 2019).
- Two studies reported ovulation rate (Ye 2007; Ainehchi 2019).
- One study reported adverse events (luteinised unruptured follicle syndrome (LUFS), ovarian hyperstimulation syndrome (OHSS) and multiple pregnancy) (Liang 2008).

Excluded studies

We excluded a total of 540 studies from the review (115 excluded in the 2021 update) for the following reasons (see the Characteristics of excluded studies tables for further details).

- 147 were not RCTs.
- 248 had participants that were not of interest to this review.
- 56 reported interventions that were not of interest to this review.
- 84 reported outcomes that were not of interest to this review.
- Five were duplicates of already excluded studies.

Risk of bias in included studies

We have summarised the risks of bias of the included studies in Figure 2 and Figure 3.

Figure 2. Risk of bias graph: review authors' judgments about each risk of bias item presented as percentages across all included studies.

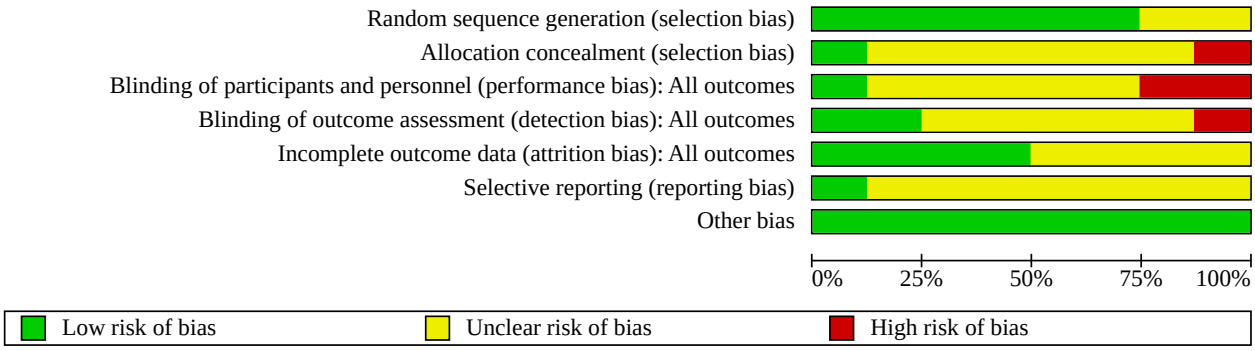
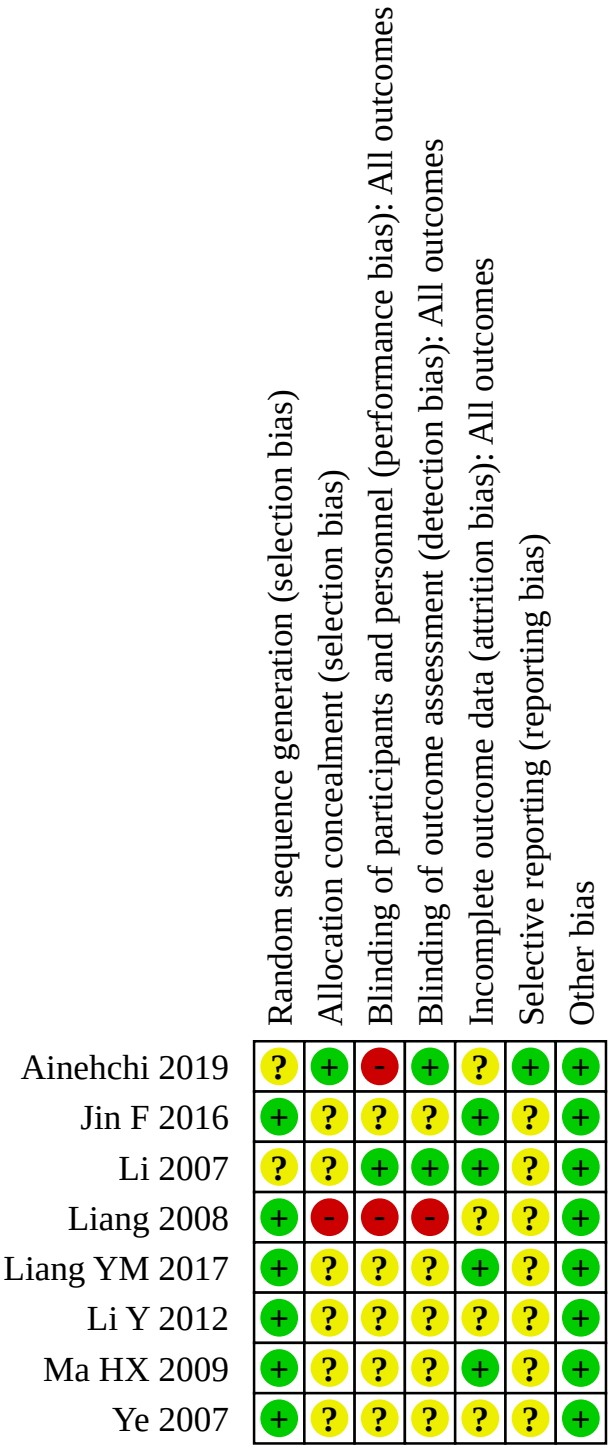


Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.



Allocation

Six studies were at low risk of selection bias related to sequence generation as they used random numbers tables (Ye 2007; Liang 2008; Ma HX 2009; Li Y 2012; Jin F 2016; Liang YM 2017). One study used random allocation software and randomised blocks of three and six with an allocation ratio of 1:1:1 (Ainehchi 2019). This randomisation method is very unlikely to produce perfectly equal sample sizes, so we judged it as being at unclear risk of selection bias. One study did not describe the method used and we judged it to be at unclear risk of bias (Li 2007).

One study was at low risk of selection bias related to allocation concealment as it used sealed, numbered envelopes (Ainehchi 2019). One study was at high risk of selection bias related to allocation concealment as the random number table was open (Liang 2008). Six studies were at unclear risk of selection bias related to allocation concealment as they did not report adequate details to establish whether an appropriate method of allocation concealment had been used (Li 2007; Ye 2007; Ma HX 2009; Li Y 2012; Jin F 2016; Liang YM 2017).

Blinding

One study used placebo drugs and described blinding of participants and outcome assessors. We judged it to be at low risk of detection bias (Li 2007). One study claimed only the statistician was blind to the study. We judged it to be at low risk of detection bias and high risk of performance bias (Ainehchi 2019).

One study used no blinding, which the study authors confirmed. We judged it to be at high risk of bias (Liang 2008).

Three studies did not mention blinding. We judged them to be at unclear risk of bias (Ye 2007; Ma HX 2009; Li Y 2012;Jin F 2016; Liang YM 2017).

Incomplete outcome data

Four studies analysed all or most (over 95%) women randomised, and we judged them to be at low risk of bias (Li 2007; Ma HX 2009; Jin F 2016; Liang YM 2017). Two studies analysed less than 95% of women randomised, and we judged them to be at unclear risk of bias (Liang 2008; Ainehchi 2019). Two studies did not mention dropouts or withdrawals, and we judged them to be at unclear risk of attrition bias (Ye 2007; Li Y 2012). The reasons for attrition included moving to another place, pelvic inflammation and conversion to in vitro fertilisation-embryo transfer (IVF-ET).

Selective reporting

The risk of selective reporting was unclear in each of the included studies, as the protocols of the included studies were unavailable. The eight studies did not assess live birth rate. Only one study reported adverse events (Liang 2008). We were unable to obtain detailed information from the primary study authors. The outcomes of these eight included studies might be influenced by the bias of selective reporting or publication bias, and we rated all as at unclear risk of selective reporting bias.

Other potential sources of bias

We did not identify any other potential sources of bias in the included studies, and judged each of the included studies to be at low risk of other potential sources of bias.

Publication bias

As there were fewer than 10 included studies, we did not assess potential publication bias using a funnel plot or other corrective analytical methods (Egger 1997).

Effects of interventions

See: **Summary of findings 1** Chinese herbal medicine (CHM) versus clomiphene for subfertile women with PCOS; **Summary of findings 2** Chinese herbal medicine (CHM) plus clomiphene versus clomiphene for subfertile women with PCOS; **Summary of findings 3** Chinese herbal medicine (CHM) plus follicle aspiration plus ovulation induction versus follicle aspiration plus ovulation induction for subfertile women with PCOS; **Summary of findings 4** Chinese herbal medicine (CHM) plus laparoscopic ovarian drilling (LOD) versus LOD for subfertile women with PCOS

We extracted summary data from the eight included studies (Li 2007; Ye 2007; Liang 2008; Ma HX 2009; Li Y 2012; Jin F 2016; Liang YM 2017; Ainehchi 2019). The clinical heterogeneity, which we have documented in the Characteristics of included studies table, was high among these studies, especially regarding the interventions used. We therefore subgrouped the analyses by co-intervention (see Analysis 1.1 and Analysis 2.1).

1. CHM versus clomiphene

Three studies made this comparison (Li 2007; Ye 2007; Ainehchi 2019). One of these studies administered LOD in both study arms (Ye 2007).

Primary outcome

Live birth rate

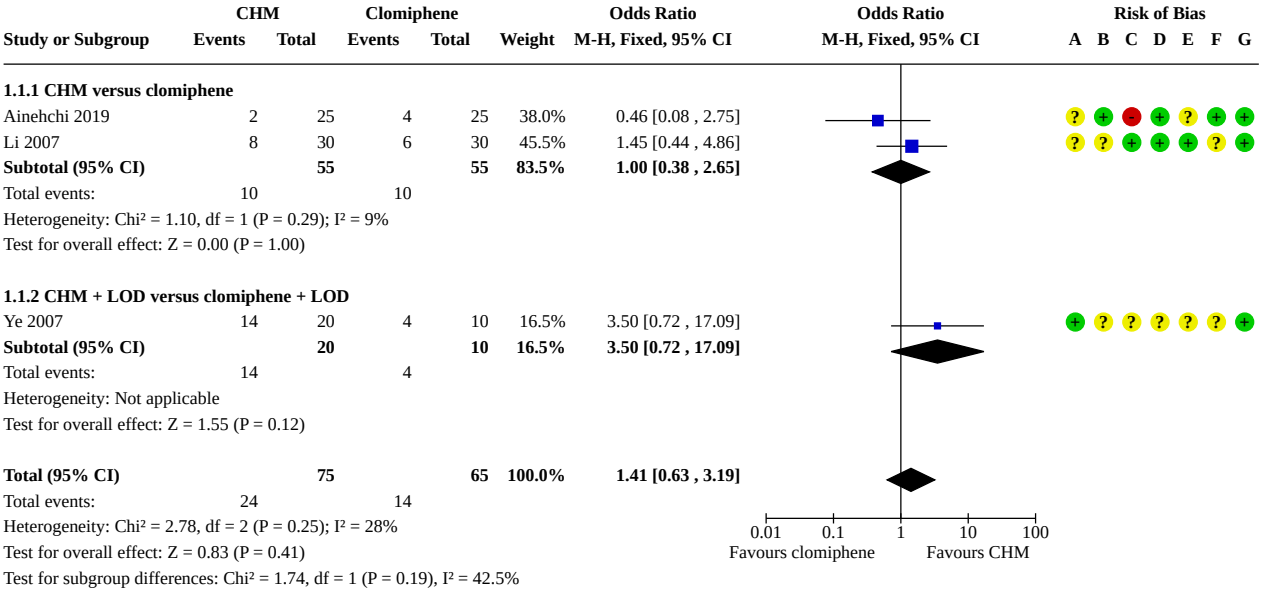
None of the included studies reported this outcome.

Secondary outcomes

Pregnancy rate

In studies that compared CHM to clomiphene (with or without LOD in both study arms), we are uncertain of the effect of CHM on pregnancy rates (odds ratio (OR) 1.41, 95% confidence interval (CI) 0.63 to 3.19; I^2 = 28%; three studies, 140 participants; very low certainty evidence). Results suggest that if the chance of pregnancy following clomiphene is assumed to be 21.5%, the chance following CHM would vary between 14.7% and 46.7%. See Analysis 1.1, Figure 4 and Summary of findings 1.

Figure 4. Forest plot of comparison: 1 CHM versus clomiphene, outcome: 1.1 Pregnancy rate (per woman).



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Ovulation rate

In studies that compared CHM to clomiphene, we are uncertain of the effect of CHM on ovulation rates (OR 1.42, 95% CI 0.20 to 10.23; one study, 30 participants). See Analysis 1.2.

Adverse events

None of the included studies reported this outcome.

2. CHM plus clomiphene versus clomiphene

Six studies made this comparison (Li 2007; Ma HX 2009; Li Y 2012; Jin F 2016; Liang YM 2017; Ainehchi 2019). One of the studies administered ethinyloestradiol cyproterone acetate (EE/CPA) in both study arms (Ma HX 2009).

Primary outcome

Live birth rate

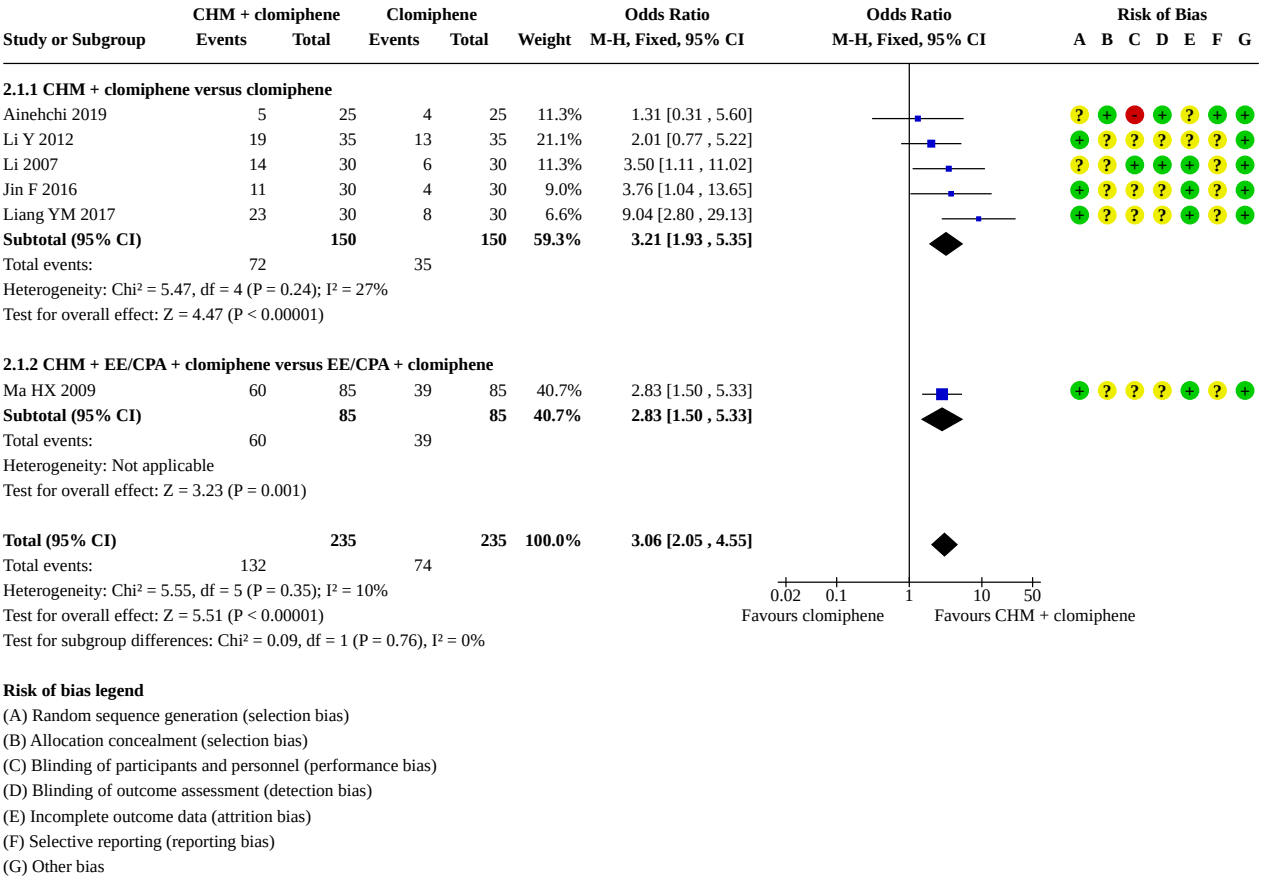
None of the included studies reported this outcome.

Secondary outcomes

Pregnancy rate

When CHM plus clomiphene was compared to clomiphene (with or without EE/CPA), there was low certainty evidence of a higher pregnancy rate in the CHM plus clomiphene group (OR 3.06, 95% CI 2.05 to 4.55; I^2 = 10%; six studies, 470 participants; low certainty evidence). Results suggest that if the chance of pregnancy following clomiphene is assumed to be 31.5%, the chance following CHM plus clomiphene would vary between 48.5% and 67.7%. See Analysis 2.1, Figure 5 and Summary of findings 2.

Figure 5. Forest plot of comparison: 3 CHM + clomiphene versus clomiphene, outcome: 3.1 Pregnancy rate (per woman).



Ovulation rate

None of the included studies reported this outcome.

Adverse events

None of the included studies reported this outcome.

3. CHM plus follicle aspiration and ovulation induction versus follicle aspiration plus ovulation induction

One study made this comparison (Liang 2008).

Primary outcome

Live birth rate

Liang 2008 did not report this outcome.

Secondary outcomes

Pregnancy rate

In the study that compared CHM plus follicle aspiration and ovulation induction to follicle aspiration and ovulation induction alone, we are uncertain of the effect of CHM on pregnancy rates (OR 1.62, 95% CI 0.46 to 5.68; one study, 44 women; very low certainty evidence). Results suggest that if the chance of pregnancy following follicle aspiration and ovulation induction is assumed to be 29.2%, the chance following CHM with follicle aspiration and ovulation induction would vary between 15.9% and 70%. See Analysis 3.1 and Summary of findings 3.

Ovulation rate

Liang 2008 did not report this outcome.

Adverse events

Liang 2008 reported adverse events. When CHM plus follicle aspiration and ovulation induction were compared with follicle aspiration and ovulation induction alone, we are uncertain of the effect of CHM on LUFS (Peto OR 0.60, 95% CI 0.06 to 6.14; one study, 44 women; very low certainty evidence), OHSS (Peto OR 0.16, 95% CI 0.00 to 8.19; one study, 44 women; very low certainty evidence) or multiple pregnancy (Peto OR 0.60, 95% CI 0.06 to 6.14; one study, 44 women; very low certainty evidence). In adverse events, results suggest that if the chances of LUFS, OHSS and multiple pregnancy following follicle aspiration and ovulation induction are assumed to be 8.3%, 4.2%, and 8.3%, respectively, the chances following CHM plus follicle aspiration and ovulation induction would be 0.5% to 35.8%, 0% to 26.3% and 0.5% to 35.8%, respectively. See Analysis 3.2, Analysis 3.3, Analysis 3.4 and Summary of findings 3. The severity of adverse events was not reported and no other data on adverse events were available.

4. CHM plus LOD versus LOD

One study made this comparison (Ye 2007).

Primary outcome

Live birth rate

Ye 2007 did not report this outcome.

Secondary outcomes

Pregnancy rate

In the study that compared CHM plus LOD to LOD alone, we are uncertain if CHM improves pregnancy rates (OR 3.50, 95% CI 0.72 to 17.09; one study, 30 women; very low certainty evidence). Results suggest that if the chance of pregnancy following LOD is assumed to be 40%, the chance following CHM with LOD would vary between 32.4% and 91.9%. See Analysis 4.1 and Summary of findings 4.

Ovulation rate

When CHM plus LOD were compared with LOD alone, we are uncertain if CHM improves ovulation rates (OR 2.43, 95% CI 0.39 to 15.08; one study, 30 women). See Analysis 4.2.

Adverse events

Ye 2007 did not report this outcome.

This update review did not carry out the planned sensitivity and subgroups analyses as there were an insufficient number of studies and available data.

DISCUSSION

Summary of main results

There is insufficient evidence to support the use of CHM in treating women with polycystic ovarian syndrome (PCOS) and subfertility. None of the included studies reported live birth rate, and only very limited data were available for the other review outcomes.

This review reported that CHM plus clomiphene was more effective in improving pregnancy rate (per woman) for subfertile women with PCOS than clomiphene only, with or without pretreatment of ethinyloestradiol cyproterone acetate. PCOS is characterised by irregular menstrual cycles, chronic anovulation, subfertility, hyperandrogenism and insulin resistance, which are cause and effect on each other (Ozcan 2017). Clomiphene is an ovulation induction drug. Herbs used for PCOS in women could impact on menstrual and ovulatory dysfunctions, insulin resistance and androgen excess-related conditions (Moini 2019). Thus, the combination of CHM and clomiphene significantly improve subfertility in women with PCOS. However, only six studies were included in this meta-analysis. Further studies are warranted to investigate whether this recommendation can be supported.

For women with PCOS, infertility and resistance to western drugs that induce ovulation, there is not enough evidence to support the use of CHM in improving ovulation rate. Furthermore, there is also not enough evidence to support the hypothesis that the efficacy of follicle aspiration or laparoscopic ovarian drilling (LOD) in improving pregnancy rate may be strengthened by CHM.

Only one included study reported adverse events, including luteinised unruptured follicle syndrome (LUFS), ovarian hyperstimulation syndrome (OHSS) and multiple pregnancy. However, it did not indicate the severity of these adverse events. None of the included studies reported some of the adverse events thought to be associated with CHM (e.g. impairment of liver and kidney, allergies). Therefore, the safety of CHM for women with PCOS and subfertility remains unclear.

There was very limited evidence that the addition of CHM to clomiphene was associated with improved clinical pregnancy outcomes but no other evidence of any other effect. This finding requires extremely cautious interpretation because the CHM ingredients used in the six trials which made this comparison were heterogeneous. CHMs are mixtures with multiple herbs. The ingredients varied according to the doctor's experience and participants' traditional Chinese medicine manifestation pattern diagnosis (including pulse and tongue diagnosis, colour and flow of the menstrual blood and clot formation, mucus changes, and any associated pain).

Overall completeness and applicability of evidence

The included studies only partially addressed the objectives of this review. We were unable to reach definite conclusions due to the lack of data for each comparison group. The high heterogeneity of CHM preparations in the included studies may limit the generalisability of the results regarding the effectiveness of CHM for subfertile women with PCOS in general. The included studies failed to report the most important outcome, which is live birth rate. Future studies should use the same formulae of CHMs as much as possible to standardise treatment options, and report major clinical outcomes such as live birth, clinical pregnancy and important adverse events.

The included studies were clinically heterogeneous and differed in (or failed to report) factors such as the duration of treatment, CHM formula, dosage and length of follow-up. Moreover, no studies compared CHM with the first-line interventions for PCOS, such as diet control and exercise. These interventions should be compared with CHM in future studies.

Quality of the evidence

The quality of the evidence for most comparisons was very low. The main limitations in the evidence were failure to report live birth or adverse events, failure to describe study methods in adequate detail, and imprecision, with very low event rates and wide confidence intervals.

Only one study claimed the statistician was blind to the study and used random allocation software (Ainehchi 2019). One included study used placebo drugs (Li 2007), so this study may have used blinding. Some included studies did not clearly report dropout rates. However, we were unable to obtain detailed information from the study authors.

Only one study protocol was registered in a clinical trial register (Ainehchi 2019), so we could not evaluate the risk of selective reporting bias.

Potential biases in the review process

In order to limit bias in the review process, the Cochrane Gynaecology and Fertility Group guided and developed the literature search. We did not apply any restrictions on language to the searches. Two review authors (ZK, ZJ) independently performed study selection, risk of bias assessments and data collection but without blinding. We resolved any disagreements

through discussion with a third review author (XL). We attempted to obtain missing information and data by contacting the primary study authors, but our attempts were unsuccessful. Thus, we excluded those studies that we could not classify as randomised controlled trials (RCTs) due to lack of information. We also noted when this was the reason for excluding a study.

In our review, we performed intention-to-treat (ITT) analyses by assuming failure for dropouts in the treatment groups and success for dropouts in the control groups.

The review authors had no conflicts of interest.

Agreements and disagreements with other studies or reviews

A systematic review about CHM for infertility with anovulation found that CHM significantly increased the pregnancy rate and the ovulation rate compared to clomiphene (Tan 2012). However, this systematic review included subfertile women with anovulation, who were with or without PCOS. Another systematic review about CHM for female infertility suggested that management of female infertility with CHM can improve pregnancy rates twofold within a three- to six-month period compared with western medical fertility drug therapy (Ried 2015). This systematic review included women whose subfertility was caused by PCOS, anovulation, endometriosis, amenorrhoea, fallopian tube blockage, or unexplained infertility. It was hard to for us to judge where CHM was effective for subfertile women with PCOS as it's compound reasons for subfertility. A recent systematic review about acupuncture and herbal medicine for female infertility (with or without PCOS) found that herbal medicine tended to be effective in infertility, but acupuncture had low certainty evidence of an effect on infertility (Lee 2021). However, all these systematic reviews, owing to the low quality of the studies investigated, didn't give any certain conclusions about CHM for subfertility with PCOS. In the future, well-designed RCTs with large sample sizes are needed to confirm or refute the current evidence.

AUTHORS' CONCLUSIONS

Implications for practice

This review has identified that there are limited well-designed studies available to guide clinical practice for subfertile women with PCOS. No data are available on live birth. Current evidence shows that the addition of CHM to clomiphene may improve pregnancy rates compared to clomiphene alone. However, there is very limited, low certainty evidence to support this. For women with PCOS, infertility and resistance to western drugs for inducing ovulation, there is not enough evidence to support the use of CHM in improving ovulation rate. Furthermore, the efficacy of follicle aspiration or laparoscopic ovarian drilling (LOD) in improving pregnancy rate may not be strengthened by CHM. Thus, there is no consistent evidence to indicate that CHM improves fertility outcomes. There is insufficient evidence on adverse effects to indicate whether CHM is safe.

Implications for research

This review has identified that more high-quality research is needed into CHM for subfertile women with PCOS. Future research should focus on well-designed (adequate randomisation and double-blinded) and well-conducted studies with sufficient follow-up durations that address the gaps identified by this review; specifically, live birth, ovulation rate, pregnancy rate and adverse events. In addition, miscarriage rate also could be reported as a valuable indicator. Study authors should report methodology in detail, including randomisation and allocation concealment methods. The duration of follow-up for assessing outcomes should also be reported. The CHM formulae and dosage should be reported. Future research should expand sample size, evaluate live birth rate and other safety indexes. The first-line treatment interventions for PCOS, such as diet control and exercise, should be compared with CHM in future studies.

ACKNOWLEDGEMENTS

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CHARACTERISTICS OF STUDIES

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

Ainehchi 2019

Study characteristics	
Methods	RCT, single-blind, single centre, 60 participants, 9 months duration
Participants	75 enrolled: CHM1 = 25, CHM2 = 25, control = 25, 18 to 35 years, baseline was comparable 60 analysed/evaluated: CHM1 = 20 (3 converted to IVF/ IUI ; 2 did not feel comfortable enough to participate) CHM2 = 20 (2 did not take an initial blood test; 2 converted to IVF/ IUI; 1 did not feel comfortable enough to participate) Control = 20 (2 participants lost to follow-up for consuming other medication along with treatment; 3 did not feel comfortable enough to participate) PCOS diagnosis criteria (DC): consistent with 2003 Rotterdam criteria (evaluated by review authors)

Ainehchi 2019 *(Continued)*

	Inclusion criteria (In): PCOS, infertility and willing to be pregnant; 18-35 years old; BMI < 30 kg/m^2. Exclusion criteria (Ex): diabetes mellitus, the use of medications such as those helping ovulation or insulin sensitisers, thyroid disorders, cholesterol-lowering drugs, smoking, current treatment for infertility, hypertension, cardiovascular diseases, Cushing syndrome, and allergy to spearmint, ginger, cinnamon, and *C sinensis*. Abbreviations: IUI: intrauterine insemination; IVF: in vitro fertilisation.
Interventions	CHM1: 700 mg herbal mixture capsule daily for three months CHM2: 700 mg herbal mixture capsule daily + CC (50-150 mg) for three menstrual cycles from the fifth day of menstruation for five days clomiphene, for the duration of three months Control: CC (50–150 mg) from the fifth day of menstruation for five days clomiphene, for the duration of three months Duration: treat for 3 months, follow-up 6 months. Abbreviation: CC: Clomiphene citrate.
Outcomes	Pregnancy rate (per woman) Ovulation rate (per cycle) FBS: Fast blood sugar, HOMA-IR: Homeostatic model assessment for insulin resistance, insulin, CAT: Catalase, GPx: Glutathione peroxidase, SOD: Superoxide dismutase, MDA: Malondialdehyde Side effects
Notes	Herbal mixture = 250 mg Mentha spicata + 200 mg Zingiber ocinale + 150 mg Cinnamomum zeylanicum + 100 mg Citrus sinensis; hospital preparation, 700 mg/capsule Clomiphene: Manufacturer not mentioned Iranian Registry of Clinical Trials (IRCT201509295563N7)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The participants were divided into three groups by random allocation software (RAS/ version 1.0.0, M Saghaei, Isfahan, Iran) randomised blocks of three and six with an allocation ratio of 1:1:1 by a person who was not involved in the study. This randomisation method is very unlikely to produce a perfect 25 vs 25 vs 25, so we assessed it as unclear risk.
Allocation concealment (selection bias)	Low risk	For allocation concealment, according to sequence generation, opaque and sealed envelopes numbered from 1 to 75; each contained a letter designating the allocation. The first envelope was dedicated to the first participant and this process was followed to the end of the study.
Blinding of participants and personnel (performance bias) All outcomes	High risk	single-blind; only the statistician was blind to the study
Blinding of outcome assessment (detection bias)	Low risk	single-blind; only the statistician was blind to the study

Ainehchi 2019 *(Continued)*

All outcomes		
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No intention-to-treat (ITT) analysis. The analysis rate was 80% (60/75)
Selective reporting (reporting bias)	Low risk	This published study was consistent with the protocol
Other bias	Low risk	No other potential risk of bias identified

Jin F 2016

Study characteristics	
Methods	RCT, single centre, 60 participants, 1.5 years' duration
Participants	60 enrolled: CHM = 30, control = 30, 20 to 35 years, baseline was comparable 57 analysed/evaluated: CHM = 29 (1 ruled out because of irregular medication use), control = 28 (2 moved to IVF) PCOS DC: consistent with Rotterdam criteria (evaluated by review authors) In: PCOS and infertility Ex: using other drugs for ovulation induction, participants unable to follow-up, tumour patients, adrenal diseases, non-ovulatory infertility, other hyperandrogenic diseases
Interventions	CHM (bu shen huo xue yang mo decoction) + CC versus CC CHM: bu shen huo xue yang mo decoction (5th day of menstrual cycle, 1 dose per day, 20 days) + clomiphene (5th day of menstrual cycle, 50 mg, once a day, 5 days) Control: clomiphene (5th day of menstrual cycle, 50 mg, once a day, 5 days) If amenorrhoea for 45 days and HCG negative then use progesterone capsules (100 mg, once a day, 5 days) Duration: 3 menstrual cycles (stop treatment when pregnancy was founded); follow-up duration unclear
Outcomes	Pregnancy rate Ovularion rate (per cycle) symptoms, endometrial thickness
Notes	This is a dissertation

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Random number table

Jin F 2016 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Envelope. The study did not report if the envelopes were opaque.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Failed to obtain this information from the author
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Failed to obtain this information from the author
Incomplete outcome data (attrition bias) All outcomes	Low risk	No intention-to-treat (ITT) analysis. The analysis rate was 95% (57/60)
Selective reporting (reporting bias)	Unclear risk	The study protocol was unavailable.
Other bias	Low risk	No other potential risk of bias identified

Li 2007

Study characteristics	
Methods	RCT, single centre, 90 participants, 3 years' duration
Participants	90 enrolled: CHM1 = 30, CHM2 = 30, control = 30, 21 to 38 years, baseline was comparable 87 analysed/evaluated: CHM1 = 29 (1 converted to IVF-ET after CHM treatment for 1 month), CHM2 = 30, control = 28 (1 moved to another place, 1 discontinued therapy because of pelvic inflammation) Obesity: CHM1 = 7, CHM2 = 6, control = 6 Hirsutism: CHM1 = 19, CHM2 = 18, control = 21 LH/FSH > 2.5: CHM1 = 20, CHM2 = 19, control = 21 High testosterone: CHM1 = 16, CHM2 = 17, control = 15 Follicle number > 10: CHM1 = 25, CHM2 = 24, control = 22 Enlarged ovary: CHM1 = 5, CHM2 = 6, control = 7 PCOS DC: consistent with Rotterdam criteria (evaluated by review authors) In: PCOS and infertility Ex: using other drugs for ovulation induction, participants unable to follow-up, tumour patients, adrenal diseases, other hyperandrogenic diseases
Interventions	CHM1: clomiphene simulacrum (5th to 9th day of menstrual cycle, 1 pill, once a day, 5 days), Lingzhu infusion (5th to 14th day of menstrual cycle, 1 bag, tid, 10 days), Shenqi capsule (from 14th day of menstrual cycle or after ovulation, 4 grains, tid, until menstrual onset or pregnancy or the 45th day of menstrual cycle), if amenorrhoea for 45 days then MPA would be prescribed (10 mg, once a day, 5 days) CHM2: clomiphene (5th to 9th day of menstrual cycle, 50 mg, once a day, 5 days), Lingzhu infusion, Shenqi capsule, and MPA

Li 2007 *(Continued)*

	Control: clomiphene, Lingzhu simulacrum, Shenqi simulacrum, and MPA
	Duration: treated no more than 6 menstrual cycles, follow-up time was unclear.
Outcomes	LH, testosterone, LH/FSH, estradiol, insulin, BMI, cervical mucus
	Pregnancy rate (per woman)
	Ovulation rate (per cycle)
Notes	Clomiphene: Codal Synto Ltd. batch number: H20020325
	Lingzhu infusion: hospital preparation, batch number Z03020211, 6 g/bag
	Shenqi capsule: hospital preparation, batch number Z03020212, 0.5 g/pill

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The study reported random method without the details. We were unable to contact the study authors for more information.
Allocation concealment (selection bias)	Unclear risk	We were unable to contact the study authors for more information.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	The study used mimic drugs. Participants and the outcome assessor were blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The study used mimic drugs. Participants and the outcome assessor were blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No intention-to-treat (ITT) analysis. The analysis rate was 96.7% (87/90).
Selective reporting (reporting bias)	Unclear risk	The study protocol was unavailable.
Other bias	Low risk	No other potential risk of bias identified

Liang 2008

Study characteristics

Methods	RCT, 2 clinical centres, 44 participants, 1 year duration
Participants	44 enrolled: CHM = 20, control = 24, baseline was comparable
	44 analysed/evaluated: CHM = 20, control = 24
	40 ovulation induction: CHM = 18, control = 22 (follicle aspiration was ineffective for 4)
	Age (years): CHM 27.4 ± 2.7, control 27.1 ± 3.2

Liang 2008 *(Continued)*

	Subfertility time (years): CHM 2.10 ± 0.97, control 2.0 ± 0.84 BMI (kg/m^2): CHM 24.2 ± 2.9, control 25.2 ± 3.1 PCOS DC: 2003 Rotterdam criteria In: PCOS patients with infertility and clomiphene resistance (clomiphene 150 mg/d, 5 d/month, 3 months, but without follicle growth) Ex: other endocrinology diseases, tubal infertility, male sterility
Interventions	CHM interventions: Bushen Huoxue formula combined with ultrasound guided follicle aspiration and ovulation induction Control interventions: ultrasound guided follicle aspiration and ovulation induction Ultrasound guided follicle aspiration: on 10th to 12th day of menstrual cycle, 36 hours after HCG (10,000 IU) injection, bilateral ovaries, 2 to 4 times of inserting per ovary, once a month until presence of efficacy but no more than 3 months (efficacy was defined as testosterone < 1.6 nmol/L, LH/FSH < 2, number of antral follicle in each ovary was less than 10 at early follicle phase of the following menstrual cycle) Bushen Huoxue formula: from 5th day of menstrual cycle, 1 dose/day, 14 days Ovulation induction: after effective follicle aspiration, no more than 3 cycles, human menopausal gonadotrophin (HMG) (from 5th day of menstrual cycle, 15 to 150 IU/d, until presence of dominant follicle), then HCG (5000 to 10,000 IU) Duration: treatment: no more than 6 menstrual cycles, follow-up: 3 months after ovulation induction
Outcomes	FSH, LH, testosterone Number of antral follicle Pregnancy rate (per woman) Dosage of HMG Side effects: LUFS, OHSS, multiple pregnancy Number of mature follicles
Notes	Blood hormone level and ultrasound were usually measured at 3rd day of menstrual cycle.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number table
Allocation concealment (selection bias)	High risk	Random number was open
Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding. We contacted the study author for this information.
Blinding of outcome assessment (detection bias) All outcomes	High risk	No blinding. We contacted the study author for this information.

Liang 2008 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No ITT analysis. The analysis rate was 90.9% (40/44).
Selective reporting (reporting bias)	Unclear risk	The study protocol was unavailable.
Other bias	Low risk	No other potential risk of bias identified.

Liang YM 2017

Study characteristics		
Methods	RCT, single centre, 60 participants, 1 year duration	
Participants	60 enrolled: CHM = 30, control = 30, 20 to 40 years, baseline was comparable 60 analysed/evaluated: CHM = 30, control = 30 PCOS DC: consistent with Rotterdam criteria (evaluated by review authors) In: PCOS and infertility Ex: using other drugs for ovulation induction, participants unable to follow-up, tumour patients, adrenal diseases, non-ovulatory infertility, other hyperandrogenic diseases	
Interventions	CHM + CC versus CC CHM: bu shen huo xue decoction (day 5 of menstrual cycle, one dose per day, decocted in water, bid, 3 weeks), clomiphene (day 5 of menstrual cycle, 50 mg, once a day, 5 days) Control: clomiphene (day 5 of menstrual cycle, 50 mg, once a day, 5 days) Duration: 3 menstrual cycles (stop treatment when pregnancy was founded); follow-up three months	
Outcomes	Pregnancy rate Ovulation rate (per cycle) BMI, sex hormones, blood lipid	
Notes	This is a dissertation.	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Random number table
Allocation concealment (selection bias)	Unclear risk	Failed to obtain this information from the author
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Failed to obtain this information from the author

Liang YM 2017 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Failed to obtain this information from the author
Incomplete outcome data (attrition bias) All outcomes	Low risk	No withdrawal or dropout
Selective reporting (reporting bias)	Unclear risk	The study protocol was unavailable
Other bias	Low risk	No other potential risk of bias identified

Li Y 2012

Study characteristics	
Methods	RCT, single centre, 70 participants, 1 year duration
Participants	70 enrolled: CHM = 35, control = 35, 22 to 39 years, baseline was comparable 70 analysed/evaluated: CHM = 35, control = 35 Age (years): CHM 28.5 ± 3.8, control 26.2 ± 3.6 Subfertility time (years): CHM 5 ± 2.7, control 4.6 ± 2.4 PCOS DC: consistent with Rotterdam criteria (evaluated by review authors) In: PCOS, infertility, 20 to 40 years Ex: using hormone or drugs for ovulation induction in the last 3 months, tubal infertility, uterine infertility, male sterility
Interventions	CHM: Xuanju capsule (day 3 of menstrual cycle, 3 pills, tid, 4 weeks), clomiphene (day 3 of menstrual cycle, 50 mg, once a day, 5 days), HCG was injected when dominant follicle was present, if dominant follicle was absent until the 20th day of menstrual cycle, progesterone was injected 20 mg, once a day, 5 days Control: clomiphene (day 3 of menstrual cycle, 50 mg, once a day, 5 days), HCG was injected when dominant follicle was present, if dominant follicle was absent until the 20th day of menstrual cycle, progesterone was injected 20 mg, once a day, 5 days Duration: treatment until pregnancy but no more than 3 cycles; follow-up duration was unclear
Outcomes	Pregnancy rate (per woman) Ovulation rate (per cycle)
Notes	Xuanju capsule: Zhejiang Shiqiang Pharmaceutical Company, batch number: Z20060462

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Random number table

Li Y 2012 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	We were unable to contact the study authors for more information.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	We were unable to contact the study authors for more information.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	We were unable to contact the study authors for more information.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No withdrawal or dropout was reported.
Selective reporting (reporting bias)	Unclear risk	The study protocol was unavailable.
Other bias	Low risk	No other potential risk of bias identified.

Ma HX 2009

Study characteristics	
Methods	RCT, single centre, 170 participants, 4 years' duration
Participants	170 enrolled: CHM = 85, control = 85, baseline was comparable 165 analysed/evaluated: CHM = 85, control = 80 (5 withdrawals for personal reasons) Age (years): CHM: 28.4 ± 5.3, control: 27.9 ± 4.9 Infertility time (years): CHM: 3.8 ± 2.1, control: 3.6 ± 1.9 PCOS DC: 2003 Rotterdam criteria In: PCOS and infertility Ex: other endocrinology diseases, hormone user in the last 3 months, male infertility, tubal infertility
Interventions	CHM: CHM combined with ethinyloestradiol cyproterone acetate (EE/CPA) and ovulation induction Control: EE/CPA followed by ovulation induction CHM: basic formula in EE/CPA therapy duration, CHM periodic therapy in ovulation induction phase (gui shao di huang soup in 5th to 14th day of menstrual cycle, tao hong si wu soup in 12th to 16th day of menstrual cycle, shou tai pellet after ovulation) EE/CPA: from 5th day of menstrual cycle, 1 pill, once a day, 21 days/m, treated for 3 cycles and then ovulation induction ovulation induction: clomiphene (from 5th day of menstrual cycle, 50 mg, once a day, 5 days/m), 5000 to 10,000 IU HCG was injected when dominant follicle was present, ovulation induction until pregnancy but no more than 3 cycles Duration: treatment: no more than 6 menstrual cycles, follow-up time was unclear.
Outcomes	Ovulation rate (per cycle)

Ma HX 2009 *(Continued)*

	Pregnancy rate (per woman)
	Miscarriage rate
Notes	Ethinyloestradiol cyproterone acetate: Germany Schering company, batch number: G20040104

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number table
Allocation concealment (selection bias)	Unclear risk	We contacted the study author who declined to provide related information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	We contacted the study author who declined to provide related information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	We contacted the study author who declined to provide related information
Incomplete outcome data (attrition bias) All outcomes	Low risk	No ITT analysis. The analysis rate was 97.1% (165/170)
Selective reporting (reporting bias)	Unclear risk	The study protocol was unavailable
Other bias	Low risk	No other potential risk of bias identified

Ye 2007

Study characteristics	
Methods	RCT, single centre, 40 participants, 20 months' duration
Participants	40 enrolled: CHM = 20, control 1 = 10, control 2 = 10, baseline were comparable, 27.4 ± 2.7 years
	40 analysed/evaluated: CHM = 20, control 1 = 10, control 2 = 10
	PCOS DC: 2003 Rotterdam criteria
	In: PCOS and infertility and resistance to ovulation induction drugs
	Ex: tubal infertility, male infertility, malformation of genital organ, immunological infertility
Interventions	CHM: CHM periodic therapy combined with laparoscopic ovary drilling
	Control 1: clomiphene combined with laparoscopic ovary drilling
	Control 2: laparoscopic ovary drilling
	Duration: treatment: 6 months, follow-up: 1 year

Ye 2007 *(Continued)*

	Clomiphene: 50 mg, once a day, 5 d/m (if without efficacy, add 50 mg, maximum 150 mg/d)
Outcomes	LH, FSH, testosterone Ovulation rate (per woman) Pregnancy rate (per woman)
Notes	Laparoscopic ovary drilling: 8 to 10 holes per ovary, injected 300 mL of low molecular dextran or 4 mL of sodium hyaluronate in abdomen after surgery.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number table
Allocation concealment (selection bias)	Unclear risk	We contacted the study author who declined to provide related information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	We contacted the study author who declined to provide related information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	We contacted the study author who declined to provide related information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No withdrawal or dropout was reported
Selective reporting (reporting bias)	Unclear risk	The study protocol was unavailable
Other bias	Low risk	No other potential risk of bias identified

Abbreviations: CHM: Chinese herbal medicine, BMI: body mass index, PCOS: polycystic ovarian syndrome, DC: diagnosis criteria, In: inclusion criteria, Ex: exclusion criteria, HCG: human chorionic gonadotrophin, HMG: human menopausal gonadotropin, LH: luteinising hormone, FSH: follicle stimulating hormone, LUFS: luteinised unruptured follicle syndrome, OHSS: ovarian hyperstimulation syndrome, ITT: intention-to-treat, MPA: medroxyprogesterone acetate, EE/CPA: ethinyloestradiol cyproterone acetate, tid:three times a day, bid: twice a day, IU:International Units.

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

Study	Reason for exclusion
An 2009	No outcomes of interest
An 2012	Diagnosis is inconsistent with Rotterdam criteria
Arentz 2014	Review
Arentz 2017a	PCOS with and without infertility

Study	Reason for exclusion
Arentz 2017b	This is conference data and duplicates the published article
Bablis 2006	Case report
Bai 2011	Non-randomised controlled trial (RCT)
Bao 2009	No outcomes of interest; polycystic ovarian syndrome (PCOS) with or without infertility in this study
Bao 2014	No Chinese herbal medicine (CHM) intervention
Bei 2010	Non-RCT, which the primary study authors confirmed
Cai 2006	Adolescent PCOS without infertility; no outcomes of interest
Cai 2011	Quasi-RCT, which the primary study authors confirmed
Cai 2012	PCOS diagnosis is inconsistent with Rotterdam criteria
Cai 2014	Not a RCT
Cao 2010	Non-RCT, which the primary study authors confirmed
Cao 2012	Non-RCT, which the primary study authors confirmed
Chan CC 2006	No outcomes of interest; PCOS with or without infertility
Chan LY 2006	Non-CHM intervention
Chen 2005	PCOS with or without infertility in this study
Chen 2007	Intervention with acupuncture but without herbal medicine
Chen 2008	No outcomes of interest; PCOS with or without infertility in this study
Chen 2009	Intervention with acupuncture but without herbal medicine
Chen 2013	Non-PCOS participants
Chen 2015	Participants had no wish to conceive
Chen 2016	Non-CHM intervention
Chen 2017	Quasi-RCT
Cheng 2009	No outcomes of interest; PCOS with or without infertility in this study
Cheng 2014	Non-CHM intervention
Cheng 2015	Participants had no wish to conceive
Chen H 2010	No outcomes of interest
Chen JL 2006	PCOS with or without infertility in this study

Study	Reason for exclusion
Chen JX 2017	Diagnosis is inconsistent with Rotterdam criteria
Chen L 2006	PCOS diagnosis is inconsistent with Rotterdam criteria; quasi-RCT
Chen LS 2012	PCOS diagnosis is inconsistent with Rotterdam criteria; quasi-RCT
Chen N 2012	No outcomes of interest; PCOS with or without infertility
Chen PL 2011	No outcomes of interest; PCOS with or without infertility
Chen QZ 2014	Quasi-RCT
Chen R 2014	Non-CHM intervention
Chen RJ 2012	No outcomes of interest; PCOS with or without infertility
Chen RR 2011	No outcomes of interest; PCOS with or without infertility
Chen WY 2012	Quasi-RCT
Chen XF 2011	Quasi-RCT
Chen XF 2017	Diagnosis is inconsistent with Rotterdam criteria
Chen XH 2010	No outcomes of interest
Chen Y 2014	Not a RCT
ChiCTR1800016219	no interventions of interest
ChiCTR1800016792	no interventions of interest
ChiCTR1800018597	No outcomes of interest
ChiCTR-IOR-16008557	PCOS with and without infertility; PCOS diagnosis is inconsistent with Rotterdam criteria
ChiCTR-IOR-16008557 a	Duplicate with ChiCTR-IOR-16008557, and PCOS with and without infertility; PCOS diagnosis is inconsistent with Rotterdam criteria
ChiCTR-IPR-16009166	PCOS with and without infertility
Chou 2018	Quasi-RCT
Chu 2013	Non-PCOS participants
Craig 2015	Non-CHM intervention
Cui 2012	PCOS with or without infertility; no outcomes of interest
Cui 2017	Non-CHM intervention
Dang 2012	Non-RCT, which the primary authors confirmed
Deng 2008	PCOS diagnosis is inconsistent with Rotterdam criteria; quasi-RCT

Study	Reason for exclusion
Deng 2016	Quasi-RCT
Deng 2018	Diagnosis is inconsistent with Rotterdam criteria
Deveci 2015	Non-CHM intervention
Ding 2015	Unrelated study
Dong 2009	No outcomes of interest
Dong 2010	No outcomes of interest
Du 2012	PCOS with or without infertility; no outcomes of interest
Du 2013	Participants had no wish to conceive
Fan 2017	No outcomes of interest
Fang 2004	No outcomes of interest
Feng 2009a	No outcomes of interest; PCOS with or without infertility in this study
Feng 2009b	No outcomes of interest; PCOS with or without infertility
Feng J 2011	Quasi-RCT
Feng X 2011	Non-RCT confirmed by primary authors
Fu 2012	PCOS diagnosis is inconsistent with Rotterdam criteria; PCOS with or without infertility in this study; no outcomes of interest
Fu BJ 2019	No outcomes of interest
Fu JR 2019	Diagnosis is inconsistent with Rotterdam criteria
Gao 2009	Intervention with acupuncture but without herbal medicine
Gao XL 2011	PCOS diagnosis is inconsistent with Rotterdam criteria; quasi-RCT
Gao YH 2011	PCOS with or without infertility in this study
Ghavi 2015	With or without subfertility
Gong 2012	PCOS with or without infertility in this study
Grant 2010	No outcomes of interest; PCOS with or without infertility
Gu 2015	Participants had no wish to conceive
Guo 2008	No outcomes of interest; PCOS with or without infertility
Guo 2009	PCOS with or without infertility in this study
Guo AP 2011	PCOS diagnosis is inconsistent with Rotterdam criteria; quasi-RCT

Study	Reason for exclusion
Guo SX 2011	No outcomes of interest; PCOS with or without infertility in this study
Haidari 2020	PCOS with and without infertility; participants had no wish to conceive; no outcomes of interest
Haj-Husein 2016	Women with or without subfertility
Han 2008	PCOS diagnosis is inconsistent with Rotterdam criteria; quasi-RCT
Han 2011	PCOS diagnosis is inconsistent with Rotterdam criteria; quasi-RCT
Han 2015	Not a RCT
Han M 2013	Participants had no wish to conceive
Han SX 2013	Not a RCT
Hao 2012	Quasi-RCT, which the primary authors confirmed
Harman 2001	Non-PCOS
Hassanzadeh Bashtian 2013	Participants had no wish to conceive
He 2009	PCOS with or without infertility in this study
He 2010	Quasi-RCT
He 2014	Quasi-RCT
Heshmati 2020	PCOS with and without infertility; participants had no wish to conceive; no outcomes of interest
Hou 2000	No outcomes of interest
Hu 2009a	Intervention with acupuncture but without herbal medicine; PCOS with and without infertility
Hu 2009b	Intervention with acupuncture but without herbal medicine
Hu 2014	Participants had no wish to conceive
Hua 2003	Case control study
Huang 2004	Quasi-RCT confirmed by primary authors
Huang 2007	PCOS with or without infertility in this study
Huang 2008	Review
Huang 2010	Quasi-RCT
Huang DL 2011	No outcomes of interest
Huang L 2012	No outcomes of interest; PCOS with or without infertility
Huang LH 2011	No outcomes of interest
Huang LY 2006	Non-RCT confirmed by primary authors

Study	Reason for exclusion
Huang XT 2012	PCOS diagnosis is inconsistent with Rotterdam criteria
Huang YL 2019	Diagnosis is inconsistent with Rotterdam criteria
Huang YY 2006	PCOS without infertility; quasi-RCT; no outcomes of interest
Huang YZ 2019	Quasi-RCT
Hung 2016	Cohort study
Huo 2008	Unrelated
IRCT2017082016911N4	No outcomes of interest
Jalilian 2013	Non-CHM intervention
Jamilian 2020	PCOS with and without infertility; participants had no wish to conceive; no outcomes of interest
Jia, 2019	Quasi-RCT; PCOS with and without infertility
Jia 2004	Diagnosis inconsistent with Rotterdam; quasi-RCT
Jia 2008	Concurrent control study
Jia 2010	PCOS with or without infertility; PCOS diagnosis is inconsistent with Rotterdam criteria
Jia CM 2012	No outcomes of interest
Jian 2011	No outcomes of interest
Jiang 2007	PCOS diagnosis is inconsistent with Rotterdam criteria; quasi-RCT
Jiang 2014	Non-PCOS participants
Jiang 2015	Non-CHM intervention
Jiang JH 2011	No outcomes of interest; PCOS with or without infertility
Jiang MF 2011	No outcomes of interest; PCOS with or without infertility
Jia WH 2012	PCOS diagnosis is inconsistent with Rotterdam criteria; quasi-RCT; no outcomes of interest; PCOS with or without infertility
Jin 2017	Quasi-RCT
Jin CL 2014	Non-CHM intervention
Jing 2017	No outcomes of interest
Jin JH 2016	Participants had no wish to conceive
Jin XT 2014	Quasi-RCT
Johnson 2015	Non-CHM intervention

Study	Reason for exclusion
Kang 2012	No outcomes of interest; PCOS with or without infertility
Kawakami 2011	Unrelated
Kitagawa 2015	Non-PCOS participants
Kort 2014	With or without subfertility
Kuang 2012	Quasi-RCT, which the primary authors confirmed
Kuang 2013	Non-CHM intervention
Kuang 2015	Non-CHM intervention
Kuek 2011	No outcomes of interest; PCOS with or without infertility in this study
Lai 2006	No outcomes of interest; PCOS with or without infertility; PCOS diagnosis is inconsistent with Rotterdam criteria
Lai 2011	Quasi-RCT
Lai 2014a	Participants had no wish to conceive
Lai 2014b	Participants had no wish to conceive
Lai 2014c	Participants had no wish to conceive
Lai 2015a	Review
Lai 2015b	Participants had no wish to conceive
Lai 2015c	Participants had no wish to conceive
Lai 2015d	Participants had no wish to conceive
Lai 2017	Participants had no wish to conceive
León-Gonzalez 2014	Unrelated
Li 2000	PCOS with or without infertility in this study
Li 2002	PCOS diagnosis is inconsistent with Rotterdam criteria
Li 2005	PCOS diagnosis is inconsistent with Rotterdam criteria; quasi-RCT
Li 2009	Duplication
Li 2011a	Participants had no wish to conceive
Li 2011b	PCOS with or without infertility; no outcomes of interest
Li 2015	Non-CHM intervention
Li 2018a	Diagnosis is inconsistent with Rotterdam criteria

Study	Reason for exclusion
Li 2018b	PCOS with and without infertility
Li 2019a	PCOS diagnosis is inconsistent with Rotterdam criteria
Li 2019b	Quasi-RCT; patients with and without infertility
Lian 2008	Quasi-RCT
Lian 2012	Quasi-RCT
Liang 2011	Quasi-RCT
Liang 2017	Diagnosis is inconsistent with Rotterdam criteria
Liang 2019	PCOS with and without infertility ; Participants had no wish to conceive ; No outcomes of interest
Liang HY 2018	Quasi-RCT
Liang XQ 2018	Diagnosis is inconsistent with Rotterdam criteria
Liao 2014	Non-CHM intervention
Li B 2010	No outcomes of interest; PCOS with or without infertility; PCOS diagnosis is inconsistent with Rotterdam criteria
Li C 2011	No outcomes of interest; PCOS with or without infertility; PCOS diagnosis is inconsistent with Rotterdam criteria
Li FY 2010	No outcomes of interest; PCOS with or without infertility
Li FY 2011	PCOS with or without infertility in this study
Li HC 2011	No outcomes of interest
Li HX 2011	No outcomes of interest
Li HX 2012	No outcomes of interest; PCOS with or without infertility
Li J 2012	No outcomes of interest
Li JY 2017	No outcomes of interest
Li K 2017	Non-CHM intervention
Li L 2009	No outcomes of interest; PCOS with or without infertility
Lim 2011	Review
Li M 2016	With and without PCOS
Lin 2005	Non-RCT, which the primary authors confirmed
Lin 2011	We were unable to contact the study authors for the detailed information about the laparoscopic surgery method

Study	Reason for exclusion
Li N 2013	Non-CHM intervention
Lin 2017	PCOS with and without infertility
Lin 2017a	PCOS with and without infertility ; No outcomes of interest
Lin BQ 2013	Participants had no wish to conceive
Lin H 2013	Participants had no wish to conceive
Lin HM 2009	Non-RCT, which was confirmed by the author
Lin HM 2013	Participants had no wish to conceive
Lin Y 2009	Quasi-RCT
Li Q 2016	Participants had no wish to conceive
Li SP 2011	No outcomes of interest; PCOS with or without infertility
Li SZ 2010	PCOS diagnosis is inconsistent with Rotterdam criteria
Liu 2007	PCOS diagnosis is inconsistent with Rotterdam criteria; quasi-RCT
Liu 2008	Unrelated
Liu 2009	Diagnosis inconsistent with Rotterdam; quasi-RCT
Liu 2017	No outcomes of interest
Liu 2018	Diagnosis is inconsistent with Rotterdam criteria ; PCOS with and without infertility
Liu B 2017	Quasi-RCT
Liu CN 2017	PCOS with and without infertility
Liu DP 2011	Quasi-RCT
Liu GY 2010	No outcomes of interest; PCOS with or without infertility
Liu HL 2011	Quasi-RCT; no outcomes of interest; PCOS with or without infertility
Liu HX 2016	Quasi-RCT
Liu JJ 2016	Quasi-RCT
Liu Q 2014	Participants had no wish to conceive
Liu RX 2010	No outcomes of interest; PCOS with or without infertility
Liu XL 2014	Participants had no wish to conceive
Liu XX 2010	Non-RCT, which the primary study authors confirmed
Liu XX 2012	No outcomes of interest

Study	Reason for exclusion
Liu Y 2013	Quasi-RCT
Liu YH 2010	Quasi-RCT
Liu YP 2012	No outcomes of interest
Liu YQ 2012	No outcomes of interest
Li XB 2011	No outcomes of interest; PCOS with or without infertility
Li XH 2011	PCOS diagnosis is inconsistent with Rotterdam criteria
Li XL 2009	PCOS without infertility
Li XP 2011	No outcomes of interest; PCOS with or without infertility
Li XW 2009	No outcomes of interest
Li XY 2017	Quasi-RCT
Li Y 2013	Participants had no wish to conceive; protocol
Li YL 2011	No outcomes of interest
Li ZZ 2010	No outcomes of interest; PCOS with or without infertility
Lu 2010	PCOS diagnosis is inconsistent with Rotterdam criteria
Lu 2012	Diagnosis inconsistent with Rotterdam; quasi-RCT
Lu 2018	Diagnosis is inconsistent with Rotterdam criteria
Luo, 2019	Quasi-RCT
Luo 2010	No outcomes of interest
Luo 2014	Not a RCT
Luo 2018	PCOS diagnosis is inconsistent with Rotterdam criteria
Luo 2019	PCOS with and without infertility ;No outcomes of interest
Lv 2007	Intervention with acupuncture but without herbal medicine
Lv 2009	No outcomes of interest; PCOS with or without infertility in this study
Lv 2010	No outcomes of interest; PCOS with or without infertility in this study
Ma 2009	Quasi-RCT
Ma 2010	No outcomes of interest
Ma 2017	Diagnosis is inconsistent with Rotterdam criteria
Ma 2018	Quasi-RCT

Study	Reason for exclusion
Madder 2013	Review
Mao 2003	PCOS diagnosis is inconsistent with Rotterdam criteria; quasi-RCT
Mao XG 2011	No outcomes of interest
Mao XH 2011	Non-RCT, which the primary authors confirmed
Mei 2010	PCOS with or without infertility
Men 2017	All interventions were CHM, while no this review intrested intervention
Meng 2011	No outcomes of interest; part of the study was about animals
Miao 2012	PCOS diagnosis is inconsistent with Rotterdam criteria; quasi-RCT; PCOS diagnosis is inconsistent with Rotterdam criteria
Ming-Wei 2011	Non-PCOS participants
Mohammad Hosseinzadeh 2016	Non-CHM intervention
Moradan 2012	Review
Mosalanejad 2015	Not a RCT
Motoo 2014	SR
Musumeci 2006	Review
Naeimi 2020	PCOS diagnosis is inconsistent with Rotterdam criteria
NCT01116167	this protocol has completed and duplicated with the published article
NCT03264638	this protocol has completed and duplicated with the published article; PCOS with and without infertility
Nie 2018	PCOS diagnosis is inconsistent with Rotterdam criteria
O'Brien 2010	Unrelated
Pan 2010	No outcomes of interest
Pan 2012	No outcomes of interest
Pastore 2011	Non-CHM intervention
Pazyar 2012	Unrelated study
Pei 2012	PCOS with or without infertility in this study
Peng 2012	No outcomes of interest
Qiao 2012	Quasi-RCT

Study	Reason for exclusion
Qin 2016	PCOS with and without infertility
Qiu 2006	No outcomes of interest; PCOS with or without infertility in this study
Qu 2015	Unrelated
Qv 2011	PCOS with or without infertility
Ran 2008	Case control study
Ran MX 2007	No outcomes of interest
Ran XM 2007	Case control study
Rao 2012	No PCOS
Rashidi 2013	Non CHM intervention
Ren, 2019	Quasi-RCT
Ren 2002a	PCOS diagnosis is inconsistent with Rotterdam criteria; quasi-RCT
Ren 2002b	Duplication
Ren 2006	No outcomes of interest; PCOS with or without infertility
Ren 2008	No outcomes of interest; PCOS with or without infertility
Ren 2011	PCOS with or without infertility
Ren 2013	No PCOS
Ren 2014	SR
Ren 2019	PCOS diagnosis is inconsistent with Rotterdam criteria
Ried 2015	SR
Ruan 2016	Quasi-RCT
Sadrefozalayi 2014	Animals
Salah 2013	Non-CHM intervention
See 2011	SR
Shah 2016	Non-CHM intervention
Shao 2004	PCOS diagnosis is inconsistent with Rotterdam criteria
Shao 2006	PCOS diagnosis is inconsistent with Rotterdam criteria
Shen 2008	PCOS diagnosis is inconsistent with Rotterdam criteria
Shen 2013	Participants were not subfertile

Study	Reason for exclusion
Sheng 2010	No outcomes of interest; PCOS with or without infertility
Sheng 2018	PCOS diagnosis is inconsistent with Rotterdam criteria
Shi 2009a	No outcomes of interest; PCOS with or without infertility in this study
Shi 2009b	No outcomes of interest; PCOS with or without infertility in this study
Shi 2011	PCOS with or without infertility; PCOS diagnosis is inconsistent with Rotterdam criteria
Shi 2016	Quasi-RCT
Shi 2017	PCOS diagnosis is inconsistent with Rotterdam criteria
Shi F 2010	No outcomes of interest
Shi LJ 2010	PCOS with or without infertility
Shu 2012	No outcomes of interest
Si 2016	Participants had no wish to conceive
Sohaei 2019	PCOS with and without infertility;Participants had no wish to conceive; No outcomes of interest
Song 2010	No outcomes of interest; PCOS with or without infertility
Song 2011	PCOS diagnosis is inconsistent with Rotterdam criteria; no outcomes of interest
Stone 2009	Case report
Su 2012	No outcomes of interest; PCOS with or without infertility
Sui 2011	PCOS diagnosis is inconsistent with Rotterdam criteria; no outcomes of interest
Sun 2011	PCOS with or without infertility
Sun 2012	PCOS with or without infertility; quasi-RCT
Sun 2014	No CHM intervention
Sun C 2010	PCOS with or without infertility
Sun FX 2016	Diagnosis is inconsistent with Rotterdam criteria
Sun J 2009	PCOS diagnosis is inconsistent with Rotterdam criteria; quasi-RCT
Sun L 2016	Diagnosis is inconsistent with Rotterdam criteria
Sun W 2010	Intervention with acupuncture but without herbal medicine
Sun Y 2009	No outcomes of interest
Talaat 2018	PCOS with and without infertility; No outcomes of interest
Tan 2005	Diagnosis inconsistent with Rotterdam; quasi-RCT

Study	Reason for exclusion
Tan 2012	SR
Tang 2012	No outcomes of interest; PCOS with or without infertility
Tao 2003	Diagnosis inconsistent with Rotterdam; PCOS with or without infertility
Tao 2006	Concurrent control study
Tao 2008	No outcomes of interest; PCOS with or without infertility in this study
Tao 2009	No outcomes of interest; PCOS with or without infertility in this study
Tao 2010	No outcomes of interest; PCOS with or without infertility
Tao 2011	No outcomes of interest; PCOS with or without infertility
Tao 2017	Diagnosis is inconsistent with Rotterdam criteria
Tian 2017	PCOS with and without infertility
Tong 2017	Quasi-RCT
Ulbricht 2016	SR
Ushiroyama 2001	Diagnosis inconsistent with Rotterdam, participants including PCOS and non-PCOS
Ushiroyama 2006	Diagnosis inconsistent with Rotterdam
Vajda 2013	Not a RCT
van Oppen 2015	Non-PCOS
Wan 2012	No outcomes of interest; PCOS with or without infertility
Wang 2006a	PCOS with or without infertility in this study
Wang 2006b	Quasi-RCT
Wang 2011a	No outcomes of interest; PCOS with or without infertility
Wang 2011b	No outcomes of interest
Wang 2013	No CHM intervention
Wang 2017	Conference paper; No CHM intervention
Wang 2019	PCOS diagnosis is inconsistent with Rotterdam `criteria` ; PCOS with and without infertility
Wang CX 2016	Diagnosis is inconsistent with Rotterdam criteria
Wang JL 2009	Intervention with acupuncture but without herbal medicine
Wang LL 2016	No CHM intervention
Wang NS 2011	PCOS with or without infertility

Study	Reason for exclusion
Wang Q 2010	No outcomes of interest; PCOS with or without infertility
Wang Q 2011	Quasi-RCT
Wang Q 2012	PCOS with or without infertility
Wang QH 2012	PCOS with or without infertility; quasi-RCT
Wang YH 2005	Before-and-after study
Wang YH 2010	PCOS with or without infertility; quasi-RCT
Wang YL 2005	PCOS diagnosis is inconsistent with Rotterdam criteria; quasi-RCT
Wei 2008	PCOS diagnosis is inconsistent with Rotterdam criteria
Wei 2018	Quasi-RCT
Wei CL 2011	No outcomes of interest; PCOS with or without infertility
Wei XX 2011	PCOS diagnosis is inconsistent with Rotterdam criteria; PCOS with or without infertility in this study
Wei YQ 2011	No outcomes of interest; PCOS with or without infertility; diagnosis inconsistent with Rotterdam criteria
Wong 2017	PCOS with and without infertility
Wu 2008	PCOS with or without infertility in this study
Wu 2011	PCOS with or without infertility in this study
Wu 2016	No CHM, berberine is a purified chemical
Wu 2017	Quasi-RCT
Wu 2019	PCOS with and without infertility
Wu CC 2012	Non-CHM intervention
Wu D 2012	PCOS with or without infertility; no outcomes of interest
Wu MY 2010	No outcomes of interest; PCOS with or without infertility in this study
Wuttke 2015	Non-PCOS participants
Wu XY 2010	PCOS diagnosis is inconsistent with Rotterdam criteria
Wu Y 2013	Non-PCOS participants
Wu YY 2013	No CHM intervention
Xia 2004	No outcomes of interest
Xia 2007	Quasi-RCT

Study	Reason for exclusion
Xia 2011	PCOS diagnosis is inconsistent with Rotterdam criteria
Xiao 2014	No CHM intervention
Xie 2005	Diagnosis inconsistent with Rotterdam criteria
Xie 2010	PCOS with or without infertility
Xie 2012	PCOS with or without infertility
Xin, 2019	Quasi-RCT
Xiong 2012	No outcomes of interest; PCOS with or without infertility
Xiong 2018	Quasi-RCT
Xu, 2019	Diagnosis is inconsistent with Rotterdam criteria
Xu 2009	PCOS with or without infertility in this study
Xu 2012	No outcomes of interest; PCOS with or without infertility
Xu 2018	Quasi-RCT
Xu 2019	Diagnosis is inconsistent with Rotterdam criteria
Xu BH 2016	Participants had no wish to conceive
Xu DW 2010	No outcomes of interest
Xue 2004	Diagnosis inconsistent with Rotterdam criteria; quasi-RCT
Xu HO 2008	Diagnosis inconsistent with Rotterdam criteria; quasi-RCT
Xu JH 2008	PCOS with or without infertility
Xu QZ 2016	PCOS with and without infertility
Xu RQ 2017	PCOS with and without infertility
Xu SQ 2010	PCOS with or without infertility
Xu ZZ 2017	No outcomes of interest
Yan 2003	Duplication
Yan 2005	PCOS diagnosis is inconsistent with Rotterdam criteria
Yan 2012	PCOS diagnosis is inconsistent with Rotterdam criteria; quasi-RCT
Yang 2005	Intervention with acupuncture but without herbal medicine
Yang 2008	Animal study
Yang 2011	PCOS diagnosis is inconsistent with Rotterdam criteria; PCOS with or without infertility in this study

Study	Reason for exclusion
Yang 2015	No CHM intervention
Yang 2017a	No outcomes of interest
Yang 2017b	This dissertation was duplicated with the published article
Yang D 2014	No CHM intervention
Yang GM 2010	No outcomes of interest; PCOS with or without infertility in this study
Yang H 2014	Participants had no wish to conceive
Yang JB 2010	No outcomes of interest; quasi-RCT
Yang LF 2017	Diagnosis is inconsistent with Rotterdam criteria
Yang P 2010	PCOS diagnosis is inconsistent with Rotterdam criteria; no outcomes of interest; PCOS with or without infertility
Yang Y 2016	PCOS with and without infertility
Yang YQ 2016	Diagnosis is inconsistent with Rotterdam criteria
Yao 2011	No outcomes of interest; PCOS with or without infertility
Yao XY 2012	Quasi-RCT; no outcomes of interest
Yao Y 2012	PCOS with or without infertility
Ye 2004	PCOS with or without infertility; diagnosis inconsistent with Rotterdam criteria
Ye 2010	PCOS with or without infertility; no outcomes of interest
Ye 2015	Participants had no wish to conceive
Ye 2017	No outcomes of interest
Ye 2018	PCOS with and without infertility ; No outcomes of interest
Ye HJ 2012	No outcomes of interest
Ye YY 2012	PCOS diagnosis is inconsistent with Rotterdam criteria; no outcomes of interest; quasi-RCT
Yi 2012	PCOS with or without infertility
Yi 2017	Diagnosis is inconsistent with Rotterdam criteria;PCOS with and without infertility
Yin 2007	Laparoscopic ovary wedgeshaped resection was used in this study
Ying L 2016	PCOS with and without infertility
Ying Z 2016	Participants had no wish to conceive
Yu 2013	With or without subfertility

Study	Reason for exclusion
Yu 2015	Participants had no wish to conceive
Yu 2018	No outcomes of interest
Yu 2019	Diagnosis is inconsistent with Rotterdam criteria ; patients with and without infertility
Yuan 2011	No outcomes of interest
Yuan 2016	Quasi-RCT
Yuan 2018	No outcomes of interest
Yv 2011	No outcomes of interest; PCOS with or without infertility
Zeng 2007	PCOS diagnosis is inconsistent with Rotterdam criteria; quasi-RCT
Zeng 2012	No interventions of interest
Zhang 2007a	Duplication
Zhang 2009	No outcomes of interest; PCOS with or without infertility in this study
Zhang 2011a	Not a RCT
Zhang 2011b	No outcomes of interest
Zhang 2015a	With or without subfertility
Zhang 2015b	Participants had no wish to conceive
Zhang 2015c	Animals
Zhang 2016	Diagnosis is inconsistent with Rotterdam criteria
Zhang 2019a	Diagnosis is inconsistent with Rotterdam criteria
Zhang 2019b	Diagnosis is inconsistent with Rotterdam criteria ; patients with and without infertility
Zhang FC 2007	No outcomes of interest; PCOS with or without infertility in this study
Zhang H 2007b	No outcomes of interest; PCOS with or without infertility in this study
Zhang H 2010	PCOS diagnosis is inconsistent with Rotterdam criteria; no outcomes of interest
Zhang H 2014	Participants had no wish to conceive
Zhang HH 2011	No outcomes of interest; PCOS with or without infertility
Zhang HM 2011	No outcomes of interest; PCOS with or without infertility
Zhang J 2011	Non-RCT, which the primary authors confirmed
Zhang JH 2018	Quasi-RCT
Zhang JJ 2012	No outcomes of interest; PCOS with or without infertility

Study	Reason for exclusion
Zhang JX 2015	Participants had no wish to conceive
Zhang L 2010	No outcomes of interest
Zhang LM 2003	No outcomes of interest; PCOS with or without infertility;diagnosis inconsistent with Rotterdam;quasi-RCT
Zhang LX 2012	PCOS with or without infertility; no outcomes of interest
Zhang M 2010	No outcomes of interest; PCOS with or without infertility
Zhang MM 2003	Concurrent control study
Zhang Q 2010	No outcomes of interest; PCOS with or without infertility
Zhang SM 2018	No outcomes of interest
Zhang T 2010	PCOS diagnosis is inconsistent with Rotterdam criteria; no outcomes of interest
Zhang TH 2011	No outcomes of interest; PCOS with or without infertility
Zhang TY 2012	No outcomes of interest; quasi-RCT
Zhang XY 2014	Participants had no wish to conceive
Zhang Y 2007	PCOS with or without infertility in this study
Zhang YH 2012	PCOS with or without infertility; no outcomes of interest
Zhao 2006a	Intervention without herbal medicine
Zhao 2006b	Intervention without herbal medicine
Zhao 2007	PCOS diagnosis is inconsistent with Rotterdam criteria
Zhao 2009	Concurrent control study; PCOS with or without infertility
Zhao 2014	No interventions of interest
Zhao 2016	Participants had no wish to conceive
Zhao 2019	Diagnosis is inconsistent with Rotterdam criteria
Zhao CP 2006	No outcomes of interest; PCOS with or without infertility in this study
Zhao H 2008	Duplication
Zhao HB 2008	Quasi-RCT
Zhao J 2010	No outcomes of interest
Zhao XL 2010	Non-RCT confirmed by primary authors
Zhao Y 2008	Intervention without herbal medicine

Study	Reason for exclusion
Zheng 2011	No outcomes of interest; PCOS with or without infertility
Zheng 2011a	PCOS with or without infertility
Zheng 2011b	No outcomes of interest; PCOS with or without infertility
Zheng 2014a	Quasi-RCT
Zheng 2014b	Participants had no wish to conceive
Zheng 2018	Diagnosis is inconsistent with Rotterdam criteria
Zheng GJ 2011	PCOS with or without infertility
Zheng SJ 2015	Quasi-RCT
Zheng XH 2015	Participants had no wish to conceive
Zhi 2012	No outcomes of interest; PCOS with or without infertility
Zhong 2006	PCOS with or without infertility in this study
Zhong 2008	PCOS with or without infertility
Zhong 2012	Non-RCT, which the primary study authors confirmed
Zhong 2016	Diagnosis is inconsistent with Rotterdam criteria
Zhong XC 2009	PCOS with or without infertility in this study
Zhong XL2009	No outcomes of interest; PCOS with or without infertility in this study
Zhou 1996	PCOS diagnosis is inconsistent with Rotterdam criteria
Zhou 2010a	PCOS with or without infertility
Zhou 2010b	Non-RCT, which the primary authors confirmed
Zhou 2016	Quasi-RCT
Zhou F 2015	Quasi-RCT
Zhou FB 2014	Quasi-RCT
Zhou JH 2012	No outcomes of interest; PCOS with or without infertility
Zhou LL 2012	No outcomes of interest
Zhou M 2015	Quasi-RCT
Zhou MS 2018	No outcomes of interest
Zhou WQ 2018	PCOS with and without infertility
Zhou XL 2012	No outcomes of interest

Study	Reason for exclusion
Zhou XY 2012	PCOS with or without infertility
Zhou YX 2014	Quasi-RCT
Zhou Z 2014	Quasi-RCT
Zhu 2009	Concurrent control study
Zhu 2014	Quasi-RCT
Zhu 2019	Diagnosis is inconsistent with Rotterdam criteria
Zhu 2020	Diagnosis is inconsistent with Rotterdam criteria
Zhuang 2008	PCOS diagnosis is inconsistent with Rotterdam criteria
Zhu JQ 2012	PCOS with or without infertility; no outcomes of interest
Zhu M 2012	No outcomes of interest
Zhu TC 2013	Participants had no wish to conceive
Zhu Y 2013	Participants had no wish to conceive
Zou 2012	No outcomes of interest; PCOS with or without infertility; PCOS diagnosis is inconsistent with Rotterdam criteria
Zou L 2014	Participants had no wish to conceive
Zou Y 2014	Quasi-RCT
Zuo 2011	No outcomes of interest; PCOS with or without infertility

Abbreviations: RCT: randomised controlled trial, CHM: Chinese herbal medicine, PCOS: polycystic ovarian syndrome, SR: systematic review.

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

Xu 2020

Study name	Clinical effects of Shou-Wu Jiang-Qi decoction combined with acupuncture on the treatment of Polycystic Ovarian Syndrome with kidney deficiency, phlegm and blood stasisness: Study protocol clinical trial (SPIRIT Compliant)
Methods	Randomised controlled trial
Participants	Rotterdam PCOS
Interventions	Group A: SWJQD (Shouwu Jiangqi decoction) combined with acupuncture for 3 months; Group B: SWJQD combined with sham acupuncture for 3 months; Group C: Metformin at a dose of 500mg 3 times/day for 3 months.
Outcomes	HOMA-IR index; Sex hormone profile; Ovulation rate in every menstrual period; Clinical pregnancy rate

Xu 2020 *(Continued)*

Starting date	January 2020 and is expected to be completed in March 2022
Contact information	e-mail: zjgzywlh@njucm.edu.cn
Notes	Chinese Clinical Trial Registry: ChiCTR1900028106, ChiMCT1900002826 (registered on 12 December 2019)

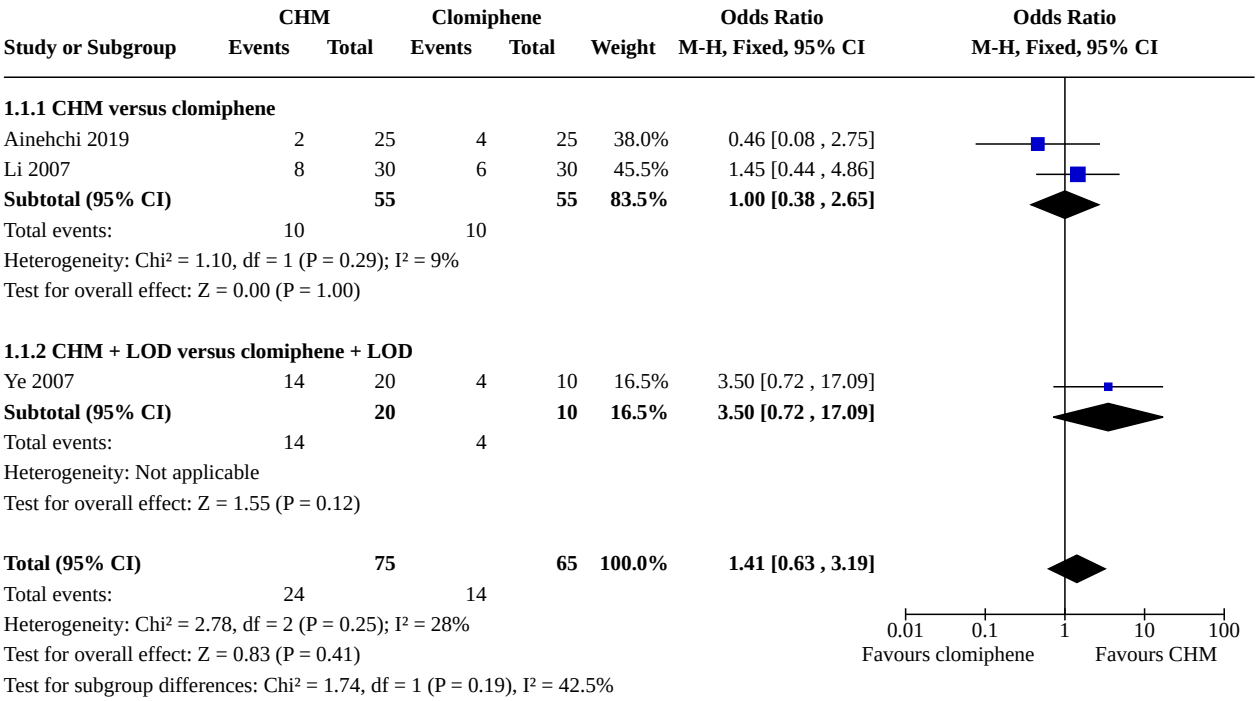
Abbreviations: PCOS: polycystic ovarian syndrome.

DATA AND ANALYSES

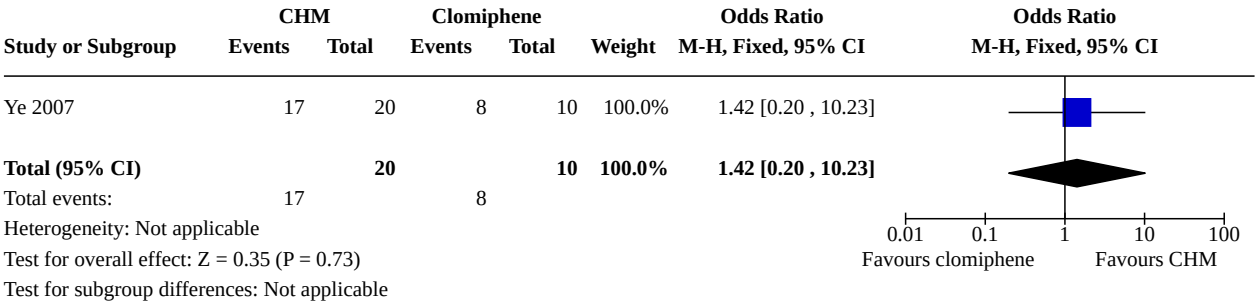
Comparison 1. CHM versus clomiphene

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 Pregnancy rate (per woman)	3	140	Odds Ratio (M-H, Fixed, 95% CI)	1.41 [0.63, 3.19]
1.1.1 CHM versus clomiphene	2	110	Odds Ratio (M-H, Fixed, 95% CI)	1.00 [0.38, 2.65]
1.1.2 CHM + LOD versus clomiphene + LOD	1	30	Odds Ratio (M-H, Fixed, 95% CI)	3.50 [0.72, 17.09]
1.2 Ovulation rate (per woman)	1	30	Odds Ratio (M-H, Fixed, 95% CI)	1.42 [0.20, 10.23]

Analysis 1.1. Comparison 1: CHM versus clomiphene, Outcome 1: Pregnancy rate (per woman)



Analysis 1.2. Comparison 1: CHM versus clomiphene, Outcome 2: Ovulation rate (per woman)

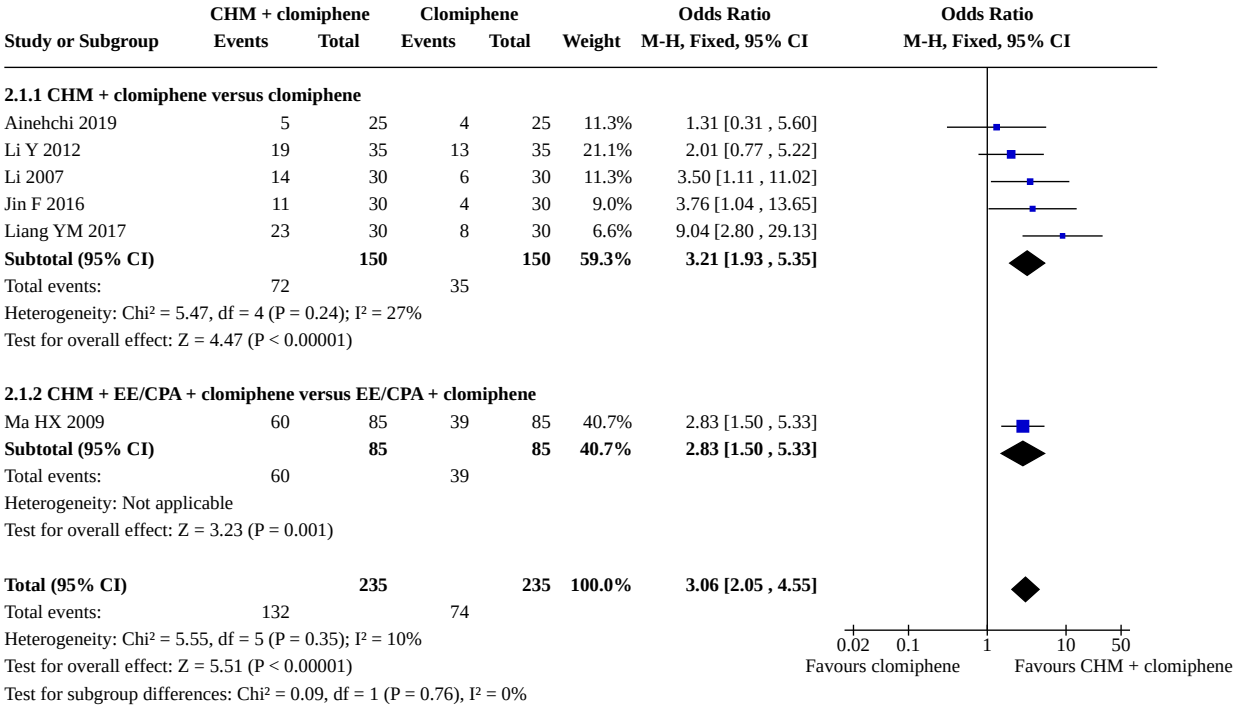


Comparison 2. CHM + clomiphene versus clomiphene

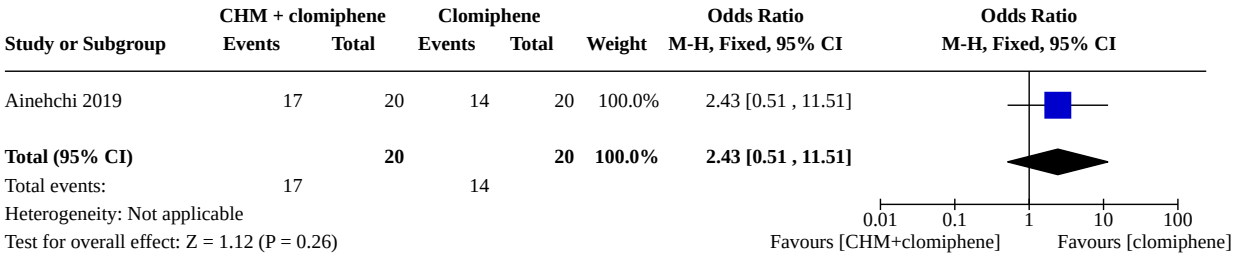
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.1 Pregnancy rate (per woman)	6	470	Odds Ratio (M-H, Fixed, 95% CI)	3.06 [2.05, 4.55]
2.1.1 CHM + clomiphene versus clomiphene	5	300	Odds Ratio (M-H, Fixed, 95% CI)	3.21 [1.93, 5.35]
2.1.2 CHM + EE/CPA + clomiphene versus EE/CPA + clomiphene	1	170	Odds Ratio (M-H, Fixed, 95% CI)	2.83 [1.50, 5.33]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.2 Ovulation rate (per woman)	1	40	Odds Ratio (M-H, Fixed, 95% CI)	2.43 [0.51, 11.51]

Analysis 2.1. Comparison 2: CHM + clomiphene versus clomiphene, Outcome 1: Pregnancy rate (per woman)



Analysis 2.2. Comparison 2: CHM + clomiphene versus clomiphene, Outcome 2: Ovulation rate (per woman)



Comparison 3. CHM + follicle aspiration + ovulation induction versus follicle aspiration + ovulation induction

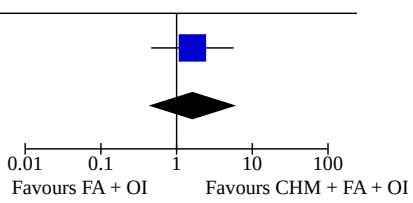
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.1 Pregnancy rate (per woman)	1	44	Odds Ratio (M-H, Fixed, 95% CI)	1.62 [0.46, 5.68]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.2 LUFS (adverse events)	1	44	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.60 [0.06, 6.14]
3.3 OHSS (adverse events)	1	44	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.16 [0.00, 8.19]
3.4 Multiple pregnancy (adverse events)	1	44	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.60 [0.06, 6.14]

Analysis 3.1. Comparison 3: CHM + follicle aspiration + ovulation induction versus follicle aspiration + ovulation induction, Outcome 1: Pregnancy rate (per woman)

Study or Subgroup	CHM +FA + OI Events	Total	FA + OI Events	Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Liang 2008	8	20	7	24	100.0%	1.62 [0.46 , 5.68]
Total (95% CI)		**20**		**24**	**100.0%**	**1.62 [0.46 , 5.68]**
Total events:	8		7			

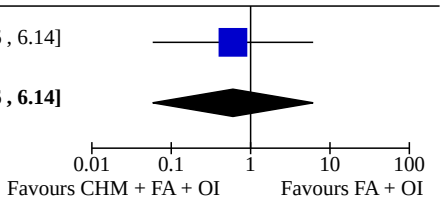
Heterogeneity: Not applicable
Test for overall effect: Z = 0.75 (P = 0.45)
Test for subgroup differences: Not applicable



Analysis 3.2. Comparison 3: CHM + follicle aspiration + ovulation induction versus follicle aspiration + ovulation induction, Outcome 2: LUFS (adverse events)

Study or Subgroup	CHM + FA + OI Events	Total	FA + OI Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Liang 2008	1	20	2	24	100.0%	0.60 [0.06 , 6.14]
Total (95% CI)		**20**		**24**	**100.0%**	**0.60 [0.06 , 6.14]**
Total events:	1		2			

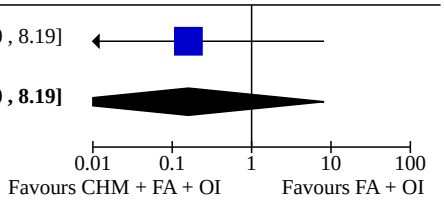
Heterogeneity: Not applicable
Test for overall effect: Z = 0.43 (P = 0.67)
Test for subgroup differences: Not applicable



Analysis 3.3. Comparison 3: CHM + follicle aspiration + ovulation induction versus follicle aspiration + ovulation induction, Outcome 3: OHSS (adverse events)

Study or Subgroup	CHM + FA + OI Events	CHM + FA + OI Total	FA + OI Events	FA + OI Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Liang 2008	0	20	1	24	100.0%	0.16 [0.00 , 8.19]
Total (95% CI)		**20**		**24**	**100.0%**	**0.16 [0.00 , 8.19]**
Total events:	0		1			

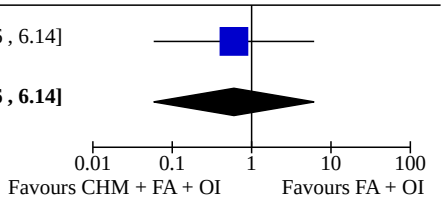
Heterogeneity: Not applicable
Test for overall effect: Z = 0.91 (P = 0.36)
Test for subgroup differences: Not applicable



Analysis 3.4. Comparison 3: CHM + follicle aspiration + ovulation induction versus follicle aspiration + ovulation induction, Outcome 4: Multiple pregnancy (adverse events)

Study or Subgroup	CHM + FA + OI Events	CHM + FA + OI Total	FA + OI Events	FA + OI Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Liang 2008	1	20	2	24	100.0%	0.60 [0.06 , 6.14]
Total (95% CI)		**20**		**24**	**100.0%**	**0.60 [0.06 , 6.14]**
Total events:	1		2			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.43 (P = 0.67)
Test for subgroup differences: Not applicable



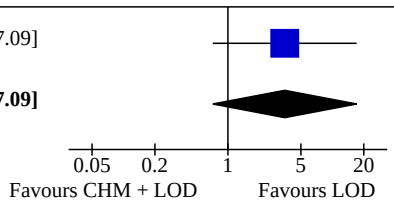
Comparison 4. CHM + LOD versus LOD

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.1 Pregnancy rate (per woman)	1	30	Odds Ratio (M-H, Fixed, 95% CI)	3.50 [0.72, 17.09]
4.2 Ovulation rate (per woman)	1	30	Odds Ratio (M-H, Fixed, 95% CI)	2.43 [0.39, 15.08]

Analysis 4.1. Comparison 4: CHM + LOD versus LOD, Outcome 1: Pregnancy rate (per woman)

Study or Subgroup	CHM + LOD Events	CHM + LOD Total	LOD Events	LOD Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Ye 2007	14	20	4	10	100.0%	3.50 [0.72 , 17.09]
Total (95% CI)		**20**		**10**	**100.0%**	**3.50 [0.72 , 17.09]**
Total events:	14		4			

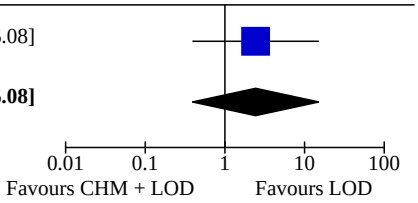
Heterogeneity: Not applicable
Test for overall effect: Z = 1.55 (P = 0.12)
Test for subgroup differences: Not applicable



Analysis 4.2. Comparison 4: CHM + LOD versus LOD, Outcome 2: Ovulation rate (per woman)

Study or Subgroup	CHM + LOD Events	CHM + LOD Total	LOD Events	LOD Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Ye 2007	17	20	7	10	100.0%	2.43 [0.39 , 15.08]
Total (95% CI)		**20**		**10**	**100.0%**	**2.43 [0.39 , 15.08]**
Total events:	17		7			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.95 (P = 0.34)
Test for subgroup differences: Not applicable



ADDITIONAL TABLES

Table 1. Contents of the formulations used in included studies

Study	Type of intervention	Formula
Liang 2008	Bushen Huoxue formula	Basic formula: tu si zi 20 g, shu di 10 g, sang ji sheng 20 g, xian ling pi 15 g, bu gu zhi 10 g, huang jing 10 g, zao jiao ci 15 g, tao ren 10 g, shan ci gu 10 g, dan shen 10 g, gan cao 6 g plus huang qi 20 g, shan zha 10 g, fa ban xia 10 g in obese patients plus zhi mu 10 g, huang qin 10 g in hirsutism or acne patients
Li 2007	CHM preparations	Shenqi capsule: tu si zi 15 g, dang shen 20 g, ji xue teng 20 g, fu ling 15 g, dang gui 9 g, dan shen 15 g Ling zhu infusion: yin yang huo 9 g, xian mao 9 g, dan nan xing 9 g, bai zhu 15 g, dang gui 9 g, fa ban xia 9 g, fu ling 15 g
Ye 2007	CHM periodic therapy	Basic formula: cang zhu 10 g, bai zhu 10 g, zhe bei mu 15 g, shi chang pu 15 g, dan shen 10 g, xiang fu 10 g. 1. Menstrual phase: basic formula plus tao ren 10 g, san qi 10 g, yi mu cao 15 g, for 3 to 5 days. 2. Late follicular phase: basic formula plus tu si zi 15 g, dang gui 9 g, shi di 10 g, shan yu rou 10 g, fu ling 15 g, for 7 to 10 days. 3. Ovulation phase: basic formula plus lu lu tong 20 g, e zhu 10 g, bei qi 20 g, gui zhi 9 g, for 3 days. 4. Luteinising phase: basic formula plus tu si zi 15 g, dang gui 10 g, yin yang huo 10 g, rou gui 6 g, for 7 to 10 days.
Ma HX 2009	CHM formula	Basic formula in ethinyloestradiol cyproterone acetate therapy phase. 1. Yin deficiency of liver and kidney: shu di 30 g, dang gui 15 g, bai shao 15 g, shan yu rou 15 g. 2. Deficiency of spleen and kidney: shu di 30 g, ba ji 30 g, fried bai zhu 30 g, ren shen 15 g, raw huang qi 15 g, shan yu rou 9 g, gou qi zi 6 g, chai hu 1.5 g. Periodic formula 1. Gui shao di huang soup at day 5 to 14 of menstrual cycle: dang gui 10 g, bai shao 15 g, shu di 15 g, shan yu rou 10 g, shan yao 10 g, fu ling 15 g, dan pi 10 g, ze xie 15 g.

Table 1. Contents of the formulations used in included studies *(Continued)*

		2. Tao hong si wu soup at day 12 to 16 of menstrual cycle: shu di 10 g, dang gui 15 g, chi shao 15 g, chuan xiong 10 g, tao ren 10 g, hong hua 10 g. 3. Shou tao pellet after ovulation: tu si zi 20 g, sang ji sheng 15 g, e jiao 10 g, xu duan.
Li Y 2012	Compound Xuanju capsule	Ingredients: hei ma yi, yin yang huo, gou qi zi, she chuang zi (patent medicine, detailed prescription is not open)
Ainehchi 2019	Herbal mixture capsule	The powders were mixed with 5 (250 mg): 4 (200 mg): 3 (150 mg): 2 (100 mg) weight ratios of spearmint, ginger, cinnamon, and C. sinensis, respectively. Finally, obtained powder was used for preparation of 700 mg capsules.
Jin F 2016	CHM formula	bu shen huo xue yang mo decoction：shu di 20g, tu si zi 10g, dan shen 12g,chi shao 10g, xiang fu 10g, zi he che 10g, chuan xiong 10g, shan zhu yu 10g, dang gui 10g, chuan xu duan 10g, gou qi zi 10g, lu jiao jiao 10g, niu xi 10g.
Liang YM 2017	CHM formula	bu shen huo xue decoction: lu jiao shuang 15g, yu jin 10g, sang ji sheng 10g, dan shen 15g, ji xue teng 10g, gan cao 5g, tu si zi 10g, bu gu zhi 10g, san qi 5g, rou cong rong 10g, bai shu 10g, cang shu 10g, ze lan 10g, ze xie 10g.

Table 2. CHM names in different languages

Pinyin name	Latin binomial name[a]	English name
Tu si zi	*Cuscuta chinensis* seed	Chinese dodder seed
Shu di	*Rehmannia glutinosa* root	Prepared rehmannia root
Sang ji sheng	*Taxillus chinensis*	Chinese taxillus twig
Xian ling pi	*Epimedium sp*	Horny goat weed
Bu gu zhi	*Psoralea corylifolia* Linn.	Malaytea scurfpea fruit
Huang jing	*Polygonatum sp* rhizome	Solomon's seal
Zao jiao ci	*Gleditsia sinensis* spine	Chinese honey locust spine
Tao ren	*Prunus persica* seed	Peach seed
Shan ci gu	*Pseudobulbus cremastrae seu pleiones*	Appendiculate Cremastra orchid pseudobulb
Dan shen	*Salvia miltiorrhiza*	Red-rooted salvia root
Gan cao	*Glycyrrhiza uralensis* root	Licorice roots (northwest origin)
Huang qi	*Astragalus membranaceus* Bunge.	Membranous milkvetch root
Shan zha	*Crataegus pinnatifida* fruit	Hawthorn fruit
Fa ban xia	*Pinellia sp* rhizome	Pinellia tuber
Zhi mu	*Anemarrhena sp* rhizome	Common anemarrhena rhizome
Huang qin	*Scutellaria baicalensis*	Baical skullcap root

Table 2. CHM names in different languages *(Continued)*

Dang shen	*Codonopsis pilosula*	Hairy asiabell root
Ji xue teng	*Millettia* wood	Spatholobus stem
Fu ling	*Wolfiporia extensa*	Chinese Tuckahoe
Dang gui	*Angelica sinensis* root	Chinese Angelica root
Yin yang huo	*Epimedium sp*	Epimedium herb
Xian mao	*Curculigo sp*	Common curculigo rhizome
Dan nan xing	*Arisaema sp*	Arisaema cum bile
Bai zhu (also spelled bai shu)	*Atractylodes macrocephala*	Large-headed atractylode rhizome
Cang zhu	*Atractylodes sp* rhizome	Chinese atractylode rhizome
Zhe bei mu	*Fritillaria thunbergii*	Thunberg fritillary bulb
Shi chang pu	*Acorus tatarinowii*	Acori Tatarinowii Rhizoma
Xiang fu	*Cyperus rotundus* rhizome	Nutgrass galingale rhizome
San qi	*Panax notoginseng* root	Chinese ginseng
Yi mu cao	*Leonurus japonicus)*	Motherwort
Shan zhu yu	*Cornus officinalis sieb*	Fructus corni
Lu lu tong	*Liquidambar formosana*	Beautiful sweetgum fruit
E zhu	*Curcuma zedoaria*	Zedoray rhizome
Bei qi	*Astragalus sp* root	Northeast milkvetch root
Gui zhi	*Ramulus cinnamomi*	Cassia twig
Rou gui	*Cinnamomum cassia*	Chinese cinnamon
Bai shao	*Paeonia alba* root	Herbaceous peony root
Ba ji	*Morinda officinalis* root	Medicinal Indian mulberry root
Ren shen	*Panax ginseng*	Ginseng
Shan yao	*Dioscorea sp* rhizome	Common yam rhizome
Dan pi	*Paeonia x suffruticosa*	Peony tree root bark
Ze xie	*Alisma orientale* rhizome	Oriental water plantain rhizome
Chi shao	*Paeonia rubrathe* root	Common peony root
Chuan xiong	*Ligusticum striatum* rhizome	Szechuan lovage

Table 2. CHM names in different languages *(Continued)*

Hong hua	*Carthamus tinctorius*	Red flower
Xu duan	*Dipsacus sp* root	Teasel root
Gou qi zi	*Lycium barbarum* fruit	Barbary wolfberry fruit
She chuang zi	*Cnidium sp* fruit	Common cnidium fruit
Ze lan	*Lycopus lucidus*	Lycopi rhizome
Huang lian	*Coptis chinensis* Franch.	Chinese goldthread rhizome

[a]We have replaced Latin terms for plant parts with their English equivalents, as follows: 'radix' is root; 'semen' is seed; 'fructus' is fruit, 'rhizoma' is rhizome, 'lignum' is wood. '*Sp*' means 'species'.

Table 3. Name of Non-plant ingredients of traditional Chinese medicine in different languages

Pinyin name	Latin binomial name	English name
E jiao	*Colla dorii asini*	Donkey hide gelatin
Hei ma yi	*Formicae populus infirmus quae nigra*	Black ants

APPENDICES

Appendix 1. Cochrane Gynaecology and Fertility specialised register search strategy

ProCite platform

Searched 2 June 2020

Keywords CONTAINS "Polycystic Ovary Syndrome Health-Related Quality of Life Questionnaire [PCOSQ]" or "Polycystic Ovary Syndrome" or "polycystic ovary morphology" or "PCOS" or "anovulation" or Title CONTAINS "PCOS" or "Polycystic Ovary Syndrome Health-Related Quality of Life Questionnaire [PCOSQ]" or "Polycystic Ovary Syndrome" or "polycystic ovary morphology" or "anovulation"

AND

Keywords CONTAINS "Chinese" or "Chinese herbal medicine" or "Chinese drugs" or "chinese herbal preparations" or "Chinese herbal remedy" or "Chinese traditional medicine" or "traditional Chinese medicine" or "traditional medicine" or "herbal preparations" or "herbal remedy" or "herbal supplement" or "herbal supplements" or Title CONTAINS "Chinese" or "Chinese herbal medicine" or "Chinese drugs" or "chinese herbal preparations" or "Chinese herbal remedy" or "Chinese traditional medicine" or "traditional Chinese medicine" or "traditional medicine" or "herbal preparations" or "herbal remedy" or "herbal supplement" or "herbal supplements" (107 records)

Appendix 2. CENTRAL via the Cochrane Register of Studies Online (CRSO) search strategy

Web platform

Searched 2 June 2020

#1 MESH DESCRIPTOR Polycystic Ovary Syndrome EXPLODE ALL TREES 1467

#2 (Polycystic Ovar*):TI,AB,KY 3476

#3 (stein leventhal):TI,AB,KY 31

#4 PCOS:TI,AB,KY 2794

#5 hirsut*:TI,AB,KY 808

#6 anovulat*:TI,AB,KY 892

#7 #1 OR #2 OR #3 OR #4 OR #5 OR #6 4602

#8 MESH DESCRIPTOR Drugs, Chinese Herbal EXPLODE ALL TREES 3403

#9 MESH DESCRIPTOR Medicine, Chinese Traditional EXPLODE ALL TREES 1124

#10 MESH DESCRIPTOR Medicine, East Asian Traditional EXPLODE ALL TREES 1236

#11 (Chinese adj5 Tradition*):TI,AB,KY 1557

#12 (Oriental medicine*):TI,AB,KY 61

#13 herb*:TI,AB,KY 10510

#14 TCM:TI,AB,KY 4701

#15 (traditional adj5 medicine*):TI,AB,KY 7649

#16 (Chinese adj5 medicine*):TI,AB,KY 10280

#17 #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 21920

#18 #7 AND #17 182

Appendix 3. MEDLINE search strategy

OVID platform

Searched from 1946 to 2 June 2020

1 exp Polycystic Ovary Syndrome/ (14331)
2 Polycystic Ovar$.tw. (16552)
3 stein leventhal.tw. (611)
4 PCOS.tw. (11148)
5 hirsut$.tw. (9336)
6 anovulat$.tw. (5548)
7 or/1-6 (30340)
8 exp Drugs, Chinese Herbal/ or exp Medicine, Chinese Traditional/ or exp Medicine, Oriental Traditional/ (58864)
9 (Chinese adj5 Traditional).tw. (28676)
10 Oriental medicine$.tw. (1070)
11 herb$.tw. (104576)
12 TCM.tw. (10078)
13 (traditional adj5 medicine$).tw. (40202)
14 (Chinese adj5 medicine$).tw. (32538)
15 or/8-14 (176343)
16 randomized controlled trial.pt. (506562)
17 controlled clinical trial.pt. (93691)
18 randomized.ab. (480797)
19 placebo.tw. (213756)
20 clinical trials as topic.sh. (191369)
21 randomly.ab. (334031)
22 trial.ti. (218990)
23 (crossover or cross-over or cross over).tw. (84755)
24 or/16-23 (1321363)
25 (animals not (humans and animals)).sh. (4669626)
26 24 not 25 (1214719)
27 7 and 15 and 26 (103)

Appendix 4. Embase search strategy

OVID platform

Searched from 1980 to 2 June 2020

1 exp ovary polycystic disease/ or exp stein leventhal syndrome/ (26551)
2 (polycystic adj5 ovar$).tw. (23018)
3 stein leventhal.tw. (128)
4 PCOS.tw. (16968)
5 hirsut$.tw. (10396)
6 anovulat$.tw. (6336)
7 or/1-6 (41343)
8 exp Chinese Drug/ or exp Herbal Medicine/ or exp Chinese Medicine/ or exp Chinese Herb/ (71309)
9 (Chinese Drug$ or Herbal Medicine$ or Chinese Medicine or Chinese Herb$).tw. (57919)
10 Oriental medicine$.tw. (1489)
11 traditional.tw. (398295)
12 TCM.tw. (14190)
13 or/8-12 (458798)
14 7 and 13 (746)
15 Clinical Trial/ (965373)
16 Randomized Controlled Trial/ (601433)
17 exp randomization/ (86982)
18 Single Blind Procedure/ (38987)
19 Double Blind Procedure/ (170021)
20 Crossover Procedure/ (63210)
21 Placebo/ (337058)
22 Randomi?ed controlled trial$.tw. (228578)
23 Rct.tw. (37126)
24 random allocation.tw. (2005)
25 randomly allocated.tw. (35069)
26 allocated randomly.tw. (2564)
27 (allocated adj2 random).tw. (815)
28 Single blind$.tw. (24620)
29 Double blind$.tw. (202376)
30 ((treble or triple) adj blind$).tw. (1137)
31 placebo$.tw. (302360)
32 prospective study/ (601908)
33 or/15-32 (2184078)
34 case study/ (69167)
35 case report.tw. (401533)
36 abstract report/ or letter/ (1095899)
37 or/34-36 (1556119)
38 33 not 37 (2130761)
39 14 and 38 (190)

Appendix 5. PsycINFO search strategy

OVID platform

Searched from 1806 to 2 June 2020

1 Polycystic Ovar$.tw. (417)
2 stein leventhal.tw. (2)
3 PCOS.tw. (282)
4 hirsut$.tw. (157)
5 or/1-4 (540)
6 exp "medicinal herbs and plants"/ or exp "plants (botanical)"/ (3280)
7 Chinese Herb$.tw. (237)
8 (Chinese adj5 Traditional).tw. (1727)
9 Oriental medicine$.tw. (62)
10 (herbal adj5 medicine$).tw. (665)
11 herb$.tw. (6885)
12 or/6-11 (10784)
13 5 and 12 (2)

Appendix 6. CINAHL search strategy

EBSCO platform

Searched from 1961 to 2 June 2020

#	Query	Results
S28	S15 AND S27	120
S27	S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26	1,602,363
S26	TX allocat* random*	13,308
S25	(MH "Quantitative Studies")	30,594
S24	(MH "Placebos")	13,723
S23	TX placebo*	71,439
S22	TX random* allocat*	13,308
S21	(MH "Random Assignment")	68,328
S20	TX randomi* control* trial*	221,958
S19	TX ((singl* n1 blind*) or (singl* n1 mask*)) or TX ((doubl* n1 blind*) or (doubl* n1 mask*)) or TX ((tripl* n1 blind*) or (tripl* n1 mask*)) or TX ((trebl* n1 blind*) or (trebl* n1 mask*))	1,218,806
S18	TX clinic* n1 trial*	295,324
S17	PT Clinical trial	110,850
S16	(MH "Clinical Trials+")	319,938
S15	S7 AND S14	375
S14	S8 OR S9 OR S10 OR S11 OR S12 OR S13	143,597
S13	TX traditional N2 medicine*	39,200
S12	TX CHM	582
S11	TX TCM	5,291
S10	TX oriental	7,239
S9	TX chinese	118,470
S8	(MM "Medicine, Chinese Traditional") OR (MM "Drugs, Chinese Herbal") OR (MM "Medicine, Herbal") OR (MM "Medicine, Oriental Traditional")	21,378
S7	S1 OR S2 OR S3 OR S4 OR S5 OR S6	6,617

(Continued)

S6	TX anovulat*	858
S5	TX hirsut*	1,004
S4	TX PCOS	3,142
S3	TX stein leventhal	20
S2	TX Polycystic Ovar*	4,999
S1	(MM "Polycystic Ovary Syndrome")	3,135

Appendix 7. AMED search strategy

OVID platform

Searched from 1985 to 2 June 2020

1 exp Ovarian disease/ (268)
2 (polycystic adj5 ovar$).tw. (95)
3 stein leventhal.tw. (1)
4 PCOS.tw. (51)
5 anovulat$.tw. (28)
6 hirsut$.tw. (79)
7 or/1-5 (309)
8 exp Traditional medicine chinese/ or exp Drugs chinese herbal/ (9305)
9 (Chinese Drug$ or Herbal Medicine$ or Chinese Medicine$ or Chinese Herb$).tw. (7165)
10 traditional.tw. (15760)
11 or/8-10 (19321)
12 7 and 11 (52)

Appendix 8. CNKI search strategy

Web platform

Searched 2 June 2020

1.polycystic ovary syndrome (1794)
2.polycystic ovary (1700)
3.1~2/or (1821)
4.Chinese herbal medicine (10481)
5.herbal medicine (1801)
6.traditional medicine (6591)
7.traditional Chinese medicine (21710)
8.traditional Chinese medicine combined with western medicine (4350) 9.4~8/or (24597)
10.random* (21449)
11.3 and 9 and 10 (826)

Appendix 9. Wanfang search strategy

Web platform

Searched 2 June 2020

1.polycystic ovary syndrome (19400)
2.polycystic ovary (20674)
3.1~2/or (20674)
4.Chinese herbal medicine (519821)
5.herbal medicine (46258)
6.traditional medicine (76557)

7.traditional Chinese medicine (700149)
8.traditional Chinese medicine combined with western medicine (197788) 9.4~8/or (1309404)
10.random* (2374533)
11.3 and 9 and 10 (1502)

Appendix 10. VIP search strategy

Weipu (VIP) web platform

searched 2 June 2020

1.polycystic ovary syndrome (13971)
2.polycystic ovary (14588)
3.1~2/or (14588)
4.Chinese herbal medicine (222089)
5.herbal medicine (13017)
6.traditional medicine (3026)
7.traditional Chinese medicine (404401)
8.traditional Chinese medicine combined with western medicine (141954) 9.4~8/or (725100)
10.random* (30184)
11.3 and 9 and 10 (30)

WHAT'S NEW

Date	Event	Description
6 March 2021	New citation required but conclusions have not changed	There is insufficient evidence for the conclusions of this review to be changed.
6 March 2021	New search has been performed	This update review includes three new studies (Ainehchi 2019; Jin F 2016; Liang YM 2017) in analysis and one ongoing study (Xu 2020).

HISTORY

Protocol first published: Issue 1, 2009
Review first published: Issue 9, 2010

Date	Event	Description
10 July 2016	New citation required but conclusions have not changed	There is insufficient evidence for the conclusions of this review to be changed.
10 July 2016	New search has been performed	The updated search found two ongoing studies (ChiCTR-IOR-16008557a; NCT01116167a), and one new study (Li Y 2012).
20 September 2010	Amended	Contact details updated.
25 September 2008	Amended	Title changed from 'Chinese herbal medicine for polycystic ovarian syndrome' to 'Chinese herbal medicine for subfertile women with polycystic ovary syndrome'; objectives were also changed.
22 September 2008	Amended	Title changed from 'Chinese herbal medicine for the managment of polycystic ovarian syndrome' to 'Chinese herbal medicine for polycystic ovarian syndrome'.

CONTRIBUTIONS OF AUTHORS

Kunyan Zhou updated the review, searched for trials, screened trials for inclusion or exclusion, extracted data, entered data into RevMan 5 (RevMan 2014), and contacted the primary study authors.

Jing Zhang drafted the protocol and original review, screened trials for inclusion or exclusion and entered data into RevMan 5 (RevMan 2014).

Liangzhi Xu and Kunyan Zhou extracted data.

Kunyan Zhou and Jing Zhang screened trials for inclusion or exclusion.

Chi Eung Danforn Lim revised and corrected the text.

DECLARATIONS OF INTEREST

Kuanyan Zhou has no known conflicts of interest.

Jing Zhan has no known conflicts of interest.

Liangzhi Xu has no known conflicts of interest.

Chi Eung Danforn Lim has no known conflicts of interest.

SOURCES OF SUPPORT

Internal sources

- West China Second University Hospital, Sichuan Universtiy, China
- Key Laboratory of Birth Defects and Related Diseases of Women and Children (Sichuan University), Ministry of Education, China
- Chinese Cochrane Center, West China Hospital, Sichuan University, China
- National Natural Science Foundation of China (81270665), China
- National Natural Science Foundation of China (41473097), China
- Science and Technology Program Project of Sichuan,China(2019YFS0422), China

External sources

- None, Other

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We searched more electronic databases in this review update than we listed in the original protocol (Zhang 2009).

We added CHM plus clomiphene versus clomiphene as a comparison in the last review update (Zhang 2010), which was not listed in the original protocol (Zhang 2009). In the 2016 updated review, we deleted this comparison as it was a duplicate.

We used Peto OR only for adverse events, and OR for other outcomes in the 2021 updated review. In the protocol, we planned to use Peto OR for all the outcomes.

NOTES

None.

INDEX TERMS

Medical Subject Headings (MeSH)

Bias; Clomiphene [therapeutic use]; Cyproterone Acetate [therapeutic use]; Drug Combinations; Drugs, Chinese Herbal [*therapeutic use]; Ethinyl Estradiol [therapeutic use]; Fertility Agents, Female [therapeutic use]; Infertility, Female [*drug therapy] [etiology]; Laparoscopy; Ovulation Induction [methods]; Polycystic Ovary Syndrome [complications] [*therapy]; Pregnancy Rate; Randomized Controlled Trials as Topic; Suction

MeSH check words

Adult; Female; Humans; Pregnancy; Young Adult