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

Zhou K, Zhang J, Xu L, Wu T, Lim CED

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Chinese herbal medicine for subfertile women with polycystic ovarian syndrome.
Cochrane Database of Systematic Reviews 2016, Issue 10. Art. No.: CD007535.
DOI: 10.1002/14651858.CD007535.pub3.

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[Intervention Review]

Chinese herbal medicine for subfertile women with polycystic ovarian syndrome

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Editorial group: Cochrane Gynaecology and Fertility Group.
Publication status and date: New search for studies and content updated (no change to conclusions), published in Issue 10, 2016.
Review content assessed as up-to-date: 9 June 2016.

Citation: Zhou K, Zhang J, Xu L, Wu T, Lim CED. Chinese herbal medicine for subfertile women with polycystic ovarian syndrome. *Cochrane Database of Systematic Reviews* 2016, Issue 10. Art. No.: CD007535. DOI: 10.1002/14651858.CD007535.pub3.

ABSTRACT

Background

Polycystic ovarian syndrome (PCOS) is one of the most common reproductive endocrinology abnormalities, and affects 5% to 10% of women of reproductive age. Western medicines, such as oral contraceptives, insulin sensitizers and laparoscopic ovarian drilling (LOD), have been used to treat PCOS. Recently, many studies have been published that consider Chinese herbal medicine (CHM) as an alternative treatment for women with PCOS.

Objectives

To assess the efficacy and safety of CHM for subfertile women with PCOS.

Search methods

We searched sources, including the following databases, from inception to 9 June 2016: the Cochrane Gynaecology and Fertility Group Specialized Register, the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE, Allied and Complementary Medicine (AMED), PsycINFO, Chinese National Knowledge Infrastructure (CNKI), VIP, Wanfang and trial registries. In addition, we searched the reference lists of included trials and contacted experts in the field to locate trials.

Selection criteria

Randomized controlled trials (RCTs) that considered the use of CHM for the treatment of subfertile women with PCOS.

Data collection and analysis

Two review authors independently screened appropriate 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 (CI). We assessed the quality of the evidence using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methods.

Main results

We included five RCTs with 414 participants. The comparisons in the included trials were as follows: CHM versus clomiphene, CHM plus clomiphene versus clomiphene (with or without ethinyloestradiol cyproterone acetate (CEA)), 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 quality of the evidence for most comparisons was very low.

None of the included studies reported live birth rate, and only one study reported data on adverse events.

When CHM was compared with clomiphene (with or without LOD in both arms), there was no evidence of a difference between the groups in pregnancy rates (odds ratio (OR) 1.98, 95% confidence interval (CI) 0.78 to 5.06; two studies, 90 participants, I^2 statistic = 0%, *very low quality evidence*). No study reported data on adverse events. When CHM plus clomiphene was compared with clomiphene (with or without CEA), there was low quality evidence of a higher pregnancy rate in the CHM plus clomiphene group (OR 2.62, 95% CI 1.65 to 4.14; three RCTs, 300 women, I^2 statistic = 0%,*low quality evidence*). No data were reported on adverse events.

When CHM with follicle aspiration and ovulation induction was compared with follicle aspiration and ovulation induction alone, there was no evidence of a difference between the groups in pregnancy rates (OR 1.60, 95% CI 0.46 to 5.52; one study, 44 women, *very low quality evidence*), severe luteinized unruptured follicle syndrome (LUFS) (OR 0.60, 95% CI 0.06 to 6.14; one study, 44 women, *very low quality evidence*), ovarian hyperstimulation syndrome (OHSS) (OR 0.16, 95% CI 0.00 to 8.19; one study, 44 women, *very low quality evidence*) or multiple pregnancy (OR 0.60, 95% CI 0.06 to 6.14; one study, 44 women, *very low quality evidence*).

When CHM with LOD was compared with LOD alone, there was no evidence of a difference between the groups in rates of pregnancy (OR 3.50, 95% CI 0.72 to 17.09; one study, 30 women, *very low quality evidence*), No data were reported on adverse events.

There was no evidence of a difference between any of the comparison groups for any other outcomes. The quality 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 women with PCOS and subfertility. No data are available on live birth, and there is no consistent evidence to indicate that CHM influences fertility outcomes. However there is very limited low quality evidence to suggest that the addition of CHM to clomiphene may improve pregnancy rates. There is insufficient evidence on adverse effects to indicate whether CHM is safe.

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 medicines (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 10% 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, such as oral contraceptives, insulin sensitizers and laparoscopic ovarian drilling (LOD). CHM have 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 evidence from commonly used databases and it is current to 9 June 2016. We included five RCTs with 414 participants. These included studies comparing CHM to western medicine, CHM plus western medicine versus western medicine, and CHM plus surgery versus surgery. All the included studies were in Chinese. 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 women with PCOS and subfertility. No data were available on live birth, and there was no consistent evidence to indicate that CHM improves fertility outcomes. When CHM was compared with clomiphene (with or without laparoscopic ovarian drilling (LOD) in both arms), the pregnancy rates were no different between the groups. When CHM with follicle aspiration and ovulation induction was compared with follicle aspiration and ovulation induction alone, pregnancy rates were no different between the groups. When CHM with LOD was compared with LOD alone, the pregnancy rates were no different between the groups. However there was limited low quality evidence to suggest that the addition of CHM to clomiphene may improve pregnancy rates. There was no evidence of a difference between any of the comparison groups for any other outcomes. There was insufficient evidence on adverse effects to indicate whether CHM is safe.

Quality of the evidence

The quality 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 FOR THE MAIN COMPARISON [Explanation]

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)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Clomiphene	CHM				
Live birth rate	Not reported					
Pregnancy rate	250 per 1000	398 per 1000 (206 to 628)	OR 1.98 (0.78 to 5.06)	90 (2 RCTs)	⊕◯◯◯ Very low[1,2]	
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 quality: further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: we are very uncertain about the estimate.

[1]Downgraded one level for serious risk of bias: study methods not described in sufficient detail.
[2]Downgraded two levels for very serious imprecision: small sample size, only 32 events altogether, CIs compatible with no effect or with substantial benefit from the intervention.

BACKGROUND

Description of the condition

Polycystic ovarian syndrome (PCOS) is a complex condition that affects 5% to 10% of women of reproductive age (Carmina 1999). PCOS is characterized 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). Women with PCOS may present with irregular menstrual cycles, subfertility (failure to conceive), hirsutism (excessive hair growth), acne and obesity. The cause of PCOS remains unclear. It is proposed that high levels of androgen in serum may be the primary cause (Escobar-Morreale 2005). 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.

Traditional Chinese Medicine (TCM) follows an independent theoretical and methodological pathway to assess the cause of the disease for making the diagnosis and treatment plan. Even though there is no classification for PCOS within TCM, the symptoms and signs of women with PCOS can be grouped as two disease classes within TCM: amenorrhoea (failure to menstruate) and infertility.

Studies of PCOS and TCM have been conducted since the 1980s (Sun 1981; Yv 1981; Wang 1982). The aetiology and clinical characteristics of PCOS still remain controversial but are believed to be related to the disorders of kidneys, liver and spleen, and from the TCM perspective reproductive function is regarded as being governed by kidneys. It is believed that kidney deficiency may be the main problem in PCOS (Ni 2007; Wang 2008). In addition, in TCM 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 (Liu 2009; Hou 2012).

Description of the intervention

Many Western medicine therapies have been used for PCOS, including oral contraceptives, insulin sensitizers, exercise, diet and laparoscopic ovarian drilling (LOD). Several Cochrane reviews have addressed different approaches to PCOS using Western medical treatments (Weiss 2015; Tang 2012; Costello 2007; Farquhar 2012; Sinawat 2012). The oral contraceptive pill (OCP) is believed to be more effective than insulin-sensitizing drugs in improving menstrual patterns and reducing serum androgen levels (Costello 2007). On the other hand, metformin, an insulin-sensitizing drug (ISD), has been found to be more effective than the OCP in reducing fasting insulin levels and not increasing triglyceride levels (Costello 2007). Metformin, either alone or in combination with clomiphene, increases ovulation in women with PCOS and may reduce health risks from insulin resistance and the effect of abnormal levels of androgen. However, the possible adverse effects from using metformin could include nausea and vomiting (Tang 2012). 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 (Farquhar 2012).

Chinese herbal medicines (CHM) are used broadly in various endocrinologic disorders. CHM is used with the aim of improving menstrual patterns, hirsutism, acne and pregnancy rate in women with PCOS (Cong 2006; Yang 2006; Ma 2010). In TCM, there are three different therapeutic strategies to treat PCOS by CHM. Firstly, only one special formula comprising of 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 some minister medicinal (the ingredient that helps strengthen the principal curative action) and assistant medicinal (the ingredient that treats the combined pattern/syndrome, relieves secondary symptoms or tempers the action of the sovereign ingredient when the latter is too potent) accordingly to one's individual symptoms and signs (Cui 2004; Ning 2004; Xia 2004; Zhang 2004; Liu 2005; Wang 2005; Cong 2006; Yang 2006). Secondly, different formulae are periodically prescribed to women with PCOS according to each individual's menstrual cycle. This strategy is aimed to restore normal reproductive endocrinological function (Yuan 2003; Xue 2004). Thirdly, Chinese herbal medicines are used in combination with Western medicines for treating PCOS (Li 2000; Li 2002; Ye 2004; Lin 2005; Li 2006).

How the intervention might work

Holistic therapy and multisystem regulation are the therapeutic characteristics of TCM. Many CHM used in treating PCOS are aimed to tone the kidneys to induce ovulation. The components of different formulae act synergistically in various ways. For example, it is proposed that Baishao (*Radix paeoniae alba*), Danggui (*Radix angelicae sinensis*) and Zaojiao (*Fructus gleditsiae sinensis*) reduce release of insulin and androgen (Li 2005), and that Luole (*Basil*) has an oestrogenic effect which prompts follicles to develop and mature (Jin 1986). In addition, it is reported that Dilong (*Lumbricus*), Sanqi (*Radix notoginseng*), Zelan (*Herba lycopi*) and Zexie (*Rhizoma alismatis*) can induce ovulation (Shao 2006), and that Gancao (*Radix glycytthizae*) which possesses glucocorticoid effects, can improve ovulatory abnormality. It is reported that Zishiyin (*Fluoritum*) can improve endometrial receptivity for embryo implantation and can regulate cervical mucus for sperm passing through the uterus (Wang 2008).

Why it is important to do this review

Various Western medicine therapies have been used for PCOS in recent decades. Their effectiveness varies and some are associated with adverse events. CHM has been used for thousands of years to treat PCOS, which has a different name in TCM. In both developed and developing countries, there is increasing public interest in, and use of, a wide range of therapies which lie outside the 'mainstream' of traditional Western medical practice. Although CHM 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 (CHN) (Nortier 2000; Lord 2001; Lampert 2002).

As there is currently insufficient evidence about the safety and efficacy of CHM for the management of PCOS, a systematic review in this area was warranted. No systematic review on this topic has been done before. This is an update of a review first published in 2010 (Zhang 2010)

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

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

We excluded quasi-RCTs and non-RCTs.

Types of participants

Women with PCOS and subfertility wishing to conceive (18 to 44 years). 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 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 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

1. CHM versus: placebo, no treatment, Western medicine, exercise plus diet control, laparoscopic surgery, another type of CHM, with or without co-medications.
2. CHM combined with another treatment versus another treatment, such as Western medicine, exercise plus diet control or laparoscopic surgery.
3. 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

1. Live birth rate (per woman).

Secondary outcomes

1. Pregnancy rate per woman.
2. Ovulation rate (confirmed by ultrasound or increased progesterone) per woman.
3. Adverse events (severe or minor).

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) and they included any event that led to death, was life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, or resulted in persistent or significant disability, and any important medical event that might have jeopardized the patient or required intervention to prevent it. For example, we considered severe ovarian hyperstimulation syndrome (OHSS) and severe luteinized unruptured follicle syndrome (LUFS) that required in-patient hospitalization as serious adverse events in this review. We considered all other adverse events as non-serious.

We excluded trials that did not measure any of above outcomes.

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 9 June 2016.

1. The CGF Specialized Register.
2. The Cochrane Central Register of Controlled Trials (CENTRAL).
3. Ovid MEDLINE.
4. EMBASE.
5. Allied and Complementary Medicine (AMED).
6. PsycINFO.
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)).
8. Chinese important conference dissertations full-text database (from 2000 to June 2016), VIP (from 1989 to June 2016).
9. Wanfang database (from 1998 to June 2016).

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 (Appendix 1; Appendix 2; Appendix 3; Appendix 4; Appendix 5; Appendix 6; Appendix 7; Appendix 8; Appendix 9; Appendix 10). 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 randomized 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 search with trial filters developed by the Scottish Intercollegiate Guidelines Network (SIGN) (http://sign.ac.uk/mehodology/filters.html#random).

We searched the following for ongoing trials (9 June 2016).

1. 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) (http://www.controlled-trials.com/mrct/).
2. The World Health Organization International Trials Registry Platform search portal (http://apps.who.int/trialsearch/Default.aspx).
3. The Chinese Clinical Trial Registry (http://www.chictr.org/Site/Search.aspx?lang=CN).

Searching other resources

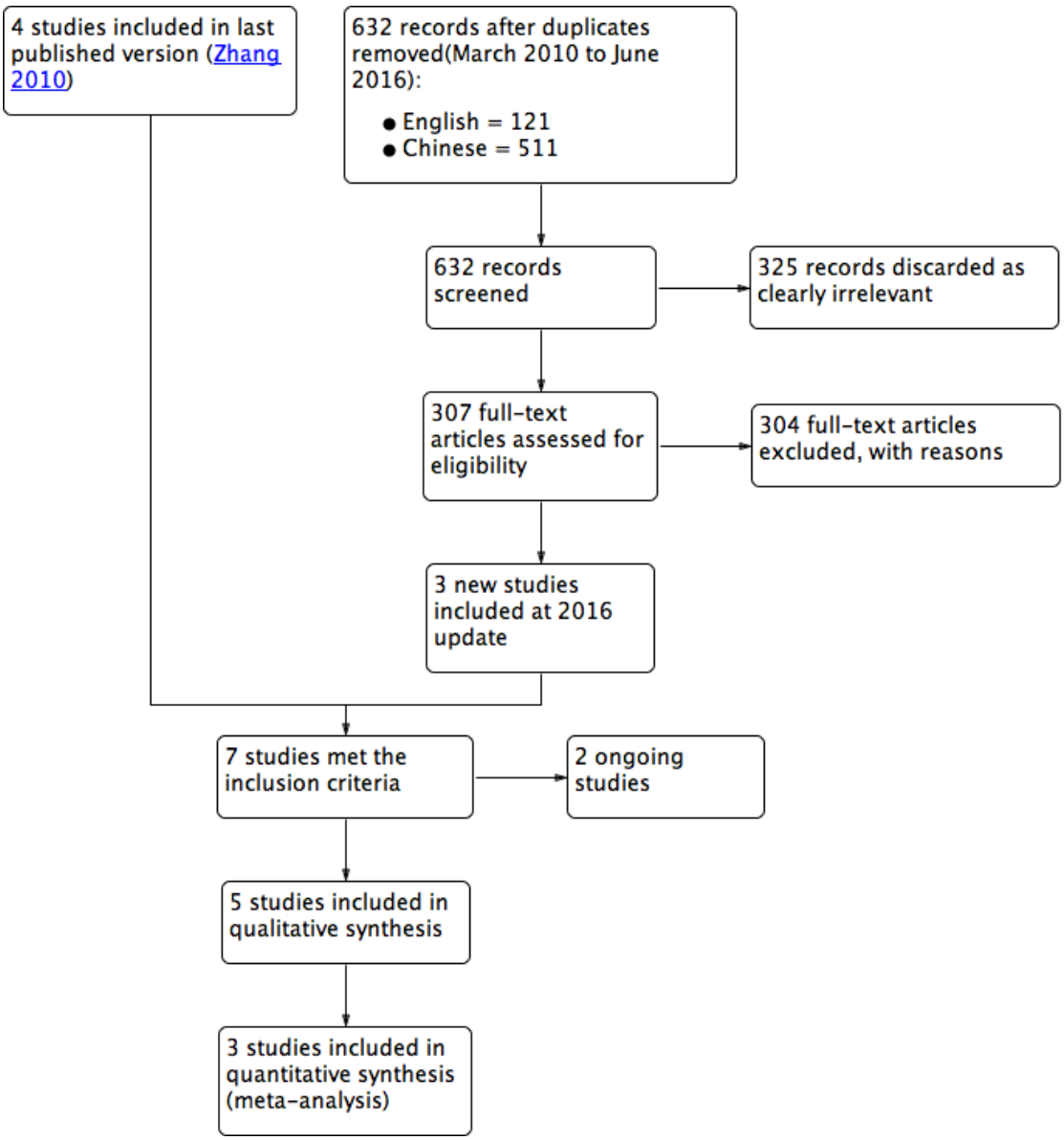
We checked the reference lists of relevant trials, reviews and textbooks. We contacted experts in the field and pharmaceutical companies for relevant trials.

Data collection and analysis

Selection of studies

Two review authors independently performed the searches and retrieved articles (ZK, ZJ). We retrieved the searched trials that claimed to be randomized; two review authors (ZK, ZJ) then confirmed that these trials were correctly randomized by telephoning the original trial authors to evaluate the methodological quality. We judged trials to be adequately randomized 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 by discussion with a third review author (WT). Also, 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 by discussion. We have listed the formulation contents of the included studies and herb names in three

languages in Table 1 and Table 2.

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, Higgins 2011, to assess the following domains.

1. Sequence generation: randomized (for example, by computer, random number tables or drawing lots) or method of randomization not described (we excluded quasi-RCTs).
2. 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).
3. Blinding of participants, personnel and outcome assessors.
4. Completeness of outcome data.
5. Selective outcome reporting.
6. Other sources of bias.

Measures of treatment effect

We only measured dichotomous data in this review. We compared the outcome measures for binary data by calculating Peto-odds ratios (Peto OR) with 95% confidence intervals (CI). To measure the treatment effect we conducted intention to treat (ITT) analyses.

Unit of analysis issues

We planned that we would 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 the trial authors to ask for missing data, but were unsuccessful. We imputed outcomes where data were missing in the present review. We assumed failure for drop-outs in the treatment group and success for drop-outs in the control group.

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 that is 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 minimize their potential impact by ensuring a comprehensive search for eligible studies and by being alert for 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 (RevMan) (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 in the following comparisons:

1. CHM versus clomiphene.
2. CHM + clomiphene versus clomiphene.
3. CHM + follicle aspiration + ovulation induction versus follicle aspiration + ovulation induction.
4. CHM + LOD versus LOD.

Subgroup analysis and investigation of heterogeneity

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

1. Different co-interventions.
2. Different treatment strategies.
3. The duration of intervention or follow-up.
4. Women with or without insulin resistance.
5. Women with or without obesity.
6. 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 anal-

yses would include consideration of whether the review conclusions would have differed under the following circumstances.

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

RESULTS

Description of studies

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

Results of the search

The search from inception to June 2016 retrieved 899 articles (excluding duplications): 163 in English and 736 in Chinese. Of these 899 articles, 146 were animal or experimental studies, 55 were non-polycystic ovarian syndrome (PCOS) studies, 69 were non-Chinese herbal medicine (CHM) studies, 92 included participants who were adolescent or had PCOS without infertility or had no wish to conceive, 19 were before-and-after studies, 18 were reviews, nine were case-control studies, nine were case reports, two were cross-sectional studies, three were parallel non-randomized controlled studies, 27 were systematic reviews , 17 were unrelated studies and 3 were duplications. Finally, 430 articles were potentially eligible and we retrieved the full-text of these articles. Seven studies met our inclusion criteria (Li 2007; Ye 2007; Liang 2008; Ma 2009a; Li 2012a; NCT01116167; ChiCTR-IOR-16008557); one was a new study to this review (Li 2012a), and two were ongoing studies (NCT01116167; ChiCTR-IOR-16008557). Finally, we included five studies in this review (Li 2007; Ye 2007; Liang 2008; Ma 2009a; Li 2012a), and excluded 426 articles. See the 'Characteristics of included studies' table and the 'Characteristics of excluded studies' table for further details.

We prepared a PRISMA flow diagram to describe the articles found from our searches (Figure 1).

Included studies

Study design

All five included studies were conducted and published in China. One was a double clinical centre design (Liang 2008), and the other four were single-centre studies. Three studies used two-arm parallel groups (Liang 2008; Ma 2009a; Li 2012a), and the other two studies used three-arm parallel groups (Li 2007; Ye 2007). The range of study duration was from one year to four years. Each included study reported the inclusion and exclusion criteria. Drop-outs and withdrawals occurred in three studies for different reasons (Li 2007; Liang 2008; Ma 2009a).

Participants

In this review update, the five studies included a total of 414 participants. Sample size ranged from 40 to 170. All participants were women of reproductive age, with PCOS (according to 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 2012a), and the other three 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), one year (Ye 2007), and unclear (Li 2007; Ma 2009a; Li 2012a), respectively.

1. CHM versus clomiphene:
   i) one study compared CHM versus clomiphene (Li 2007);
   ii) one study compared CHM plus laparoscopic ovarian drilling (LOD) and clomiphene plus LOD (Ye 2007).
2. CHM + clomiphene versus clomiphene:
   i) two studies compared CHM + clomiphene versus clomiphene (Li 2007; Li 2012a);
   ii) one study compared CHM + ethinyloestradiol cyproterone acetate (CEA) + clomiphene versus CEA + clomiphene (Ma 2009a).
3. CHM + follicle aspiration + ovulation induction versus follicle aspiration + ovulation induction:
   i) one study compared CHM+follicle aspiration+ovulation induction versus follicle aspiration+ovulation induction (Liang 2008).
4. CHM + LOD versus LOD:
   i) one study compared CHM + LOD versus LOD (Ye 2007).

Outcomes

1. No study reported live birth rate.
2. All five included studies reported clinical pregnancy rate (Li 2007; Ye 2007; Liang 2008; Ma 2009a; Li 2012a).
3. One study reported ovulation rate (Ye 2007).

4. One study reported adverse events (luteinized unruptured follicle syndrome (LUFS), ovarian hyperstimulation syndrome (OHSS) and multiple pregnancy) (Liang 2008).

Excluded studies

We excluded 424 studies from the review for the following reasons (see the 'Characteristics of excluded studies' table for further details).

1. 122/424 were not RCTs.
2. 178/424 had participants that were not of interest to this review.
3. 50/424 reported interventions that were not of interest to this review.
4. 71/424 reported outcomes that were not of interest to this review.
5. 3/424 were duplicates of already excluded studies.

Risk of bias in included studies

We have summarized 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.

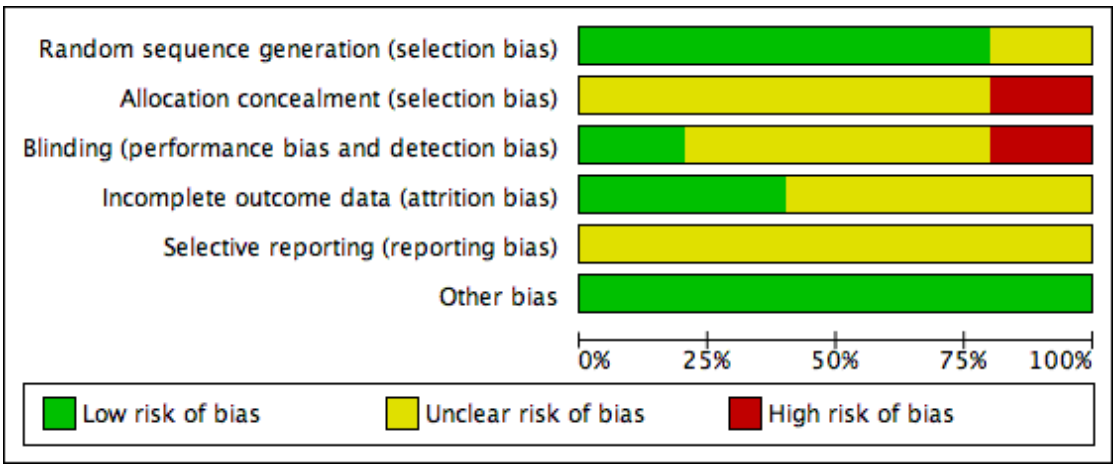
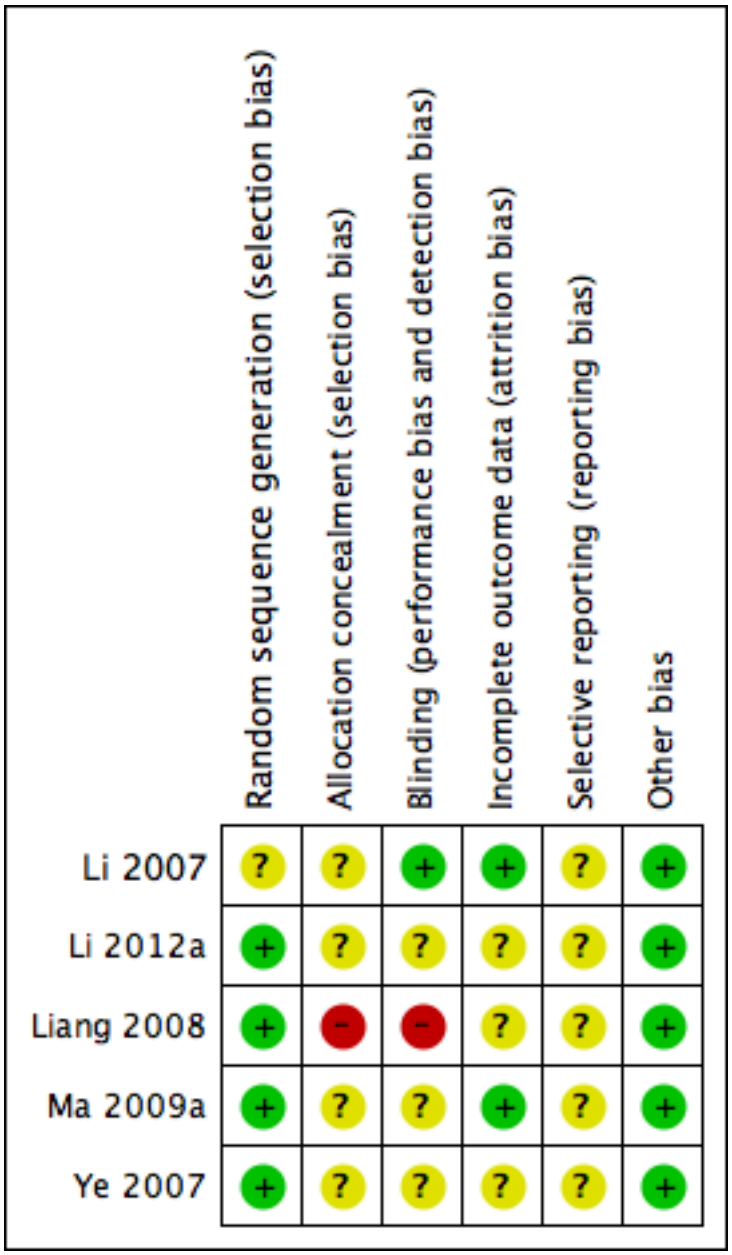


Figure 3. 'Risk of bias' summary: review authors' judgments about each 'Risk of bias' item for each included study.



Allocation

Four studies were at low risk of selection bias related to sequence generation as they used random numbers tables (Ye 2007; Liang 2008; Ma 2009a; Li 2012a). One study did not describe the method used and was at unclear risk of this bias (Li 2007).
One study was at high risk of selection bias related to allocation concealment as the random number table was open (Liang 2008).
Four studies were at unclear risk of selection bias as they did not report adequate details to establish whether an appropriate method of allocation concealment had been used (Li 2007; Ye 2007; Ma 2009a; Li 2012a).

Blinding

1. 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).
2. One study used no blinding, which the study authors confirmed. We judged it to be at high risk of bias (Liang 2008).
3. Three studies did not mention blinding. We judged them to be at unclear risk of bias (Ye 2007; Ma 2009a; Li 2012a).

Incomplete outcome data

Two studies analysed all or most (over 95%) women randomized and we judged them to be at low risk of bias (Li 2007; Ma 2009a). One study analysed only 91% of women randomized and we judged it to be at unclear risk of bias (Liang 2008). Two studies did not mention drop-outs or withdrawals, and we judged them as at unclear risk of attrition bias (Ye 2007; Li 2012a). The reasons for attrition included moving to another place, pelvic inflammation and conversion to in vitro fertilization-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 five 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 five 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 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 for the main comparison** Chinese herbal medicine (CHM) versus clomiphene for subfertile women with polycystic ovarian syndrome (PCOS); **Summary of findings 2** Chinese herbal medicine (CHM) + clomiphene versus clomiphene for subfertile women with polycystic ovarian syndrome (PCOS); **Summary of findings 3** Chinese herbal medicine (CHM) + follicle aspiration + ovulation induction versus follicle aspiration + ovulation induction for subfertile women with polycystic ovarian syndrome (PCOS); **Summary of findings 4** Chinese herbal medicine (CHM) + laparoscopic ovarian drilling (LOD) versus LOD for subfertile women with polycystic ovarian syndrome (PCOS)
We extracted summary data from the five included studies (Li 2007; Ye 2007; Liang 2008; Ma 2009a; Li 2012a). 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

Two studies made this comparison (Li 2007; Ye 2007); one of these studies administered LOD in both arms (Ye 2007).

Primary outcome

1.1 Live birth rate

None of the included studies reported this outcome.

Secondary outcomes

1.2 Pregnancy rate

When we combined the studies, there was no evidence of a difference between CHM versus clomiphene (with or without LOD in both arms) (odds ratio (OR) 1.98, 95% confidence interval (CI) 0.78 to 5.06; two studies, 90 participants, I^2 statistic = 0%, *very low quality evidence*). See Analysis 1.1.

1.3 Ovulation rate

There was no evidence of a difference between CHM versus clomiphene (OR 1.42, 95% CI 0.19 to 10.49; one study, 30 participants). See Analysis 1.2.

1.4 Adverse events

None of the included studies reported this outcome.

2. CHM + clomiphene versus clomiphene

Three studies made this comparison (Li 2007; Ma 2009a; Li 2012a); one of the studies administered ethinyloestradiol cyproterone acetate in both study arms (Ma 2009a).

Primary outcome

2.1 Live birth rate

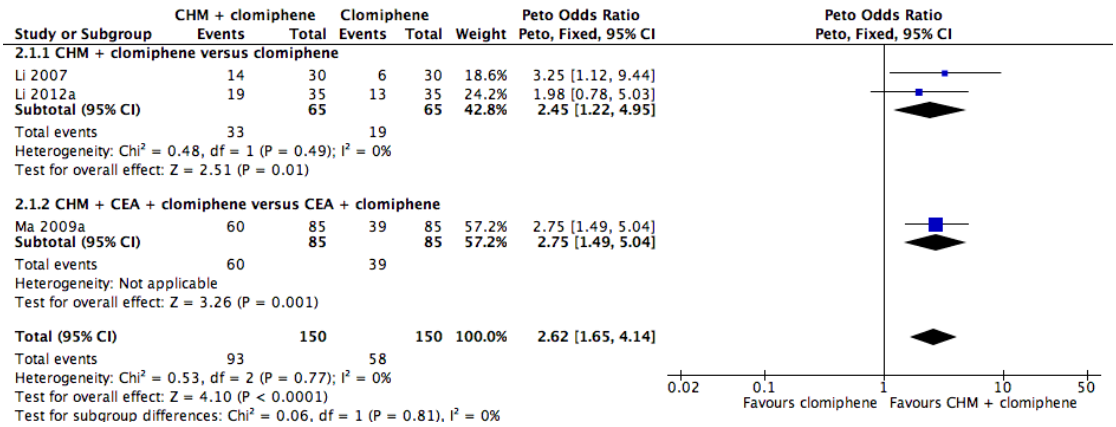
None of the included studies reported this outcome.

Secondary outcomes

2.2 Pregnancy rate

There was a higher rate of pregnancy in the CHM plus clomiphene group (OR 2.62, 95% CI 1.65 to 4.14; three studies, 300 participants, I^2 statistic = 0%, *low quality evidence*). See Analysis 2.1 and Figure 4.

Figure 4. Forest plot of comparison: 3 CHM + clomiphene versus clomiphene, outcome: 3.1 Pregnancy rate (per woman).



2.3 Ovulation rate

None of the included studies reported this outcome.

2.4 Adverse events

None of the included studies reported this outcome.

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

One study made this comparison (Liang 2008).

Primary outcome

3.1 Live birth rate

Liang 2008 did not report this outcome.

Secondary outcomes

3.2 Pregnancy rate

There was no evidence of a difference between the two groups (OR 1.60, 95% CI 0.46 to 5.52; one study, 44 women, *very low quality evidence*). See Analysis 3.1.

3.3 Ovulation rate

Liang 2008 did not report this outcome.

3.4 Adverse events

Only one study reported adverse events (Liang 2008). There was no evidence of a difference between CHM plus follicle aspiration, ovulation induction and follicle aspiration plus ovulation induction for LUFS (OR 0.60, 95% CI 0.06 to 6.14; one study, 44 women, *very low quality evidence*), OHSS (OR 0.16, 95% CI 0.00 to 8.19; one study, 44 women, *very low quality evidence*) or multiple pregnancy (OR 0.60, 95% CI 0.06 to 6.14; one study, 44 women, *very low quality evidence*). See Analysis 3.2, Analysis 3.3 and Analysis 3.4. The severity of adverse events was not reported and no other data on adverse events were available.

4. CHM + LOD versus LOD

One study made this comparison (Ye 2007).

Primary outcome

4.1 Live birth rate

Ye 2007 did not report this outcome.

Secondary outcomes

4.2 Pregnancy rate

There was no evidence of a difference between the groups (OR 3.5, 95% CI 0.72 to 17.09; one study, 30 women, *very low quality evidence*). See Analysis 4.1.

4.3 Ovulation rate

There was no evidence of a difference between the groups (OR 2.43, 95% CI 0.39 to 15.08; one study, 30 women). See Analysis 4.2.

4.4 Adverse events

Ye 2007 did not report this outcome.

ADDITIONAL SUMMARY OF FINDINGS *[Explanation]*

CHM + 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)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Clomiphene	CHM + clomiphene				
Live birth	Not reported					
Pregnancy rate (per woman)	387 per 1000	623 per 1000 (510 to 723)	OR 2.62 (1.65 to 4.14)	300 (3 RCTs)	⊕⊕◯◯ low[1,2]	
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 quality: further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: we are very uncertain about the estimate.

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

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)	Quality 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	397 per 1000 (159 to 694)	OR 1.60 (0.46 to 5.52)	44 (1 RCT)	⊕◯◯◯ Very low[1,2]	
Luteinized unruptured follicle syndrome (adverse events)	83 per 1000	52 per 1000 (5 to 358)	OR 0.60 (0.06 to 6.14)	44 (1 RCT)	⊕◯◯◯ Very low[1,2]	
Ovarian hyperstimulation syndrome (adverse events)	42 per 1000	7 per 1000 (0 to 263)	OR 0.16 (0.00 to 8.19)	44 (1 RCT)	⊕◯◯◯ Very low[1,2]	
Multiple pregnancy (adverse events)	83 per 1000	52 per 1000 (5 to 358)	OR 0.60 (0.06 to 6.14)	44 (1 RCT)	⊕◯◯◯ Very low[1,2]	

*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 quality: further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: we are very uncertain about the estimate.

[1]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.

[2]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.

CHM + 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)	Quality 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[1,2]	
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 quality: further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: we are very uncertain about the estimate.

[1]Downgraded one level for serious risk of bias: the study authors did not report the study methods in sufficient detail.
[2]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.

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.

There was very limited evidence to suggest the following.

1. For women with PCOS and infertility, the efficacy of clomiphene in improving pregnancy rate (per woman), with or without pretreatment of ethinyloestradiol cyproterone acetate, may be enhanced by Chinese herbal medicine (CHM). Inversely, that of CHM may not be enhanced by clomiphene.
2. For women with PCOS, infertility and resistance to Western drugs of ovulation induction, the efficacy of follicle aspiration or laparoscopic ovarian drilling (LOD) in improving pregnancy rate may not be strengthened by CHM. This may indicate that women resistant to Western drugs of ovulation induction may also be resistant to CHM of ovulation induction.
3. For women with PCOS, infertility and resistance to ovulation induction, there is not enough evidence to support the use of CHM in improving ovulation rate.
4. Only one included study reported adverse events, including luteinized unruptured follicle syndrome (LUFS), ovarian hyperstimulation syndrome (OHSS) and multiple pregnancy, but did not indicate the severity of the 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.

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 generalizability 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 report major clinical outcomes such as live birth, clinical pregnancy and 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 (CIs).

None of the included studies clearly reported blinding or described their method of allocation concealment, and some did not clearly report drop-out rates. Only one included study used placebo drugs (Li 2007), so the study may have used blinding. However, we were unable to obtain detailed information from the study authors.

Protocols were not registered in clinical trial registers, 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 by discussion with a third review author (WT). We attempted to obtain missing information and data by contacting the primary study authors but were not always successful. Thus, we excluded those studies that we could not classified as randomized controlled trials (RCTs) due to lack of information.

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

The review authors had no conflicts of interest.

Agreements and disagreements with other studies or reviews

In the future, well-designed RCTs with large sample size are warranted to confirm or refute the current evidence. There are no other systematic reviews on CHM for subfertile women with PCOS.

AUTHORS' CONCLUSIONS

Implications for practice

There is insufficient evidence to support the use of CHM for women with PCOS and subfertility. No data are available on live

birth, and there is no consistent evidence to indicate that CHM improves fertility outcomes. However there is very limited low quality evidence to suggest that the addition of CHM to clomiphene may improve pregnancy rates. There is insufficient evidence on adverse effects to indicate whether CHM is safe.

Implications for research

Study authors should report methodology in detail, such as randomization and allocation concealment methods. Well-designed and well-conducted RCTs with double blinding should be conducted. The duration of follow-up for assessing outcomes should also be reported. The CHM formula and dosage should be reported. Future research should expand sample size, evaluate live birth rate and other safety indexes. Interventions for PCOS, such as diet control and exercise, should be compared with CHM in future studies.

ACKNOWLEDGEMENTS

We thank Jane Clarke (Managing Editor of the original review), Helen Nagels (Managing Editor of this updated review), Marian Showell (Information Specialist) and the editorial board of the Cochrane Gynaecology and Fertility Group (CGF) for their invaluable assistance in developing this review.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Li 2007

Methods	RCT, single centre, 90 participants, 3 years' duration
Participants	90 enrolled: CHM 1 = 30, CHM 2 = 30, control = 30, 21 to 38 years, baseline were comparable 87 analysed/evaluated: CHM1 = 29 (1 converted to IVF-ET after CHM treating for 1 month), CHM2 = 30, control = 28 (1 moved to other 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 of ovulation induction, participants unable to follow-up, tumour patients, adrenal diseases, other hyper androgenic diseases
Interventions	CHM1: clomiphene simulacrum (5 to 9 day of menstrual cycle, 1 pill, once a day, 5 days) , Lingzhu infusion (5 to 14 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 (5 to 9 day of menstrual cycle, 50 mg, once a day, 5 days), Lingzhu infusion, Shenqi capsule, and MPA 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	We were unable to contact the study authors for more information

Li 2007 (*Continued*)

Allocation concealment (selection bias)	Unclear risk	We were unable to contact the study authors for more information
Blinding (performance bias and 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

Li 2012a

Methods	RCT, single centre, 70 participants, 1 year duration
Participants	70 enrolled: CHM = 35, control = 35, 22 to 39 years, baseline were 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 of 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 20 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 20 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**

Li 2012a (*Continued*)

Random sequence generation (selection bias)	Low risk	Random number table
Allocation concealment (selection bias)	Unclear risk	We were unable to contact the study authors for more information
Blinding (performance bias and 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 drop-out was reported.
Selective reporting (reporting bias)	Unclear risk	The study protocol was unavailable.
Other bias	Low risk	No other potential risk of bias identified

Liang 2008

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 Subfertility time (years): CHM 2.10 ± 0.97, control 2.0 ± 0.84 BMI (kg/m²): 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 (10000 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 were 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 150IU/d, until presence of dominant follicle), then HCG (5000 to 10000 IU) Duration: treatment: no more than 6 menstrual cycles, follow-up: 3 months after ovulation induction

Liang 2008 (*Continued*)

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 (performance bias and detection bias) All outcomes	High risk	No blinding. We contacted the study author for this information
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

Ma 2009a

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 and ovulation induction Control: CEA following with ovulation induction CHM: basic formula in CEA 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)

Ma 2009a (*Continued*)

	CEA: 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 10000 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) 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 (performance bias and 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

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

Ye 2007 (*Continued*)

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 Clomiphene: 50 mg, once a day, 5d/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 refused to provide related information
Blinding (performance bias and detection bias) All outcomes	Unclear risk	We contacted the study author who refused to provide related information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No withdrawal or drop-out 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: luteinizing hormone, FSH: follicle stimulating hormone, LUFS: luteinized unruptured follicle syndrome, OHSS: ovarian hyperstimulation syndrome, ITT: intention to treat, MPA: medroxyprogesterone acetate, CEA: ethinyloestradiol cyproterone acetate.

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
Bablis 2006	Case report
Bai 2011	Non-randomized controlled trials (RCTs)
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 2006a	No outcomes of interest; PCOS with or without infertility
Chan 2006b	Non-CHM intervention
Chen 2005	PCOS with or without infertility in this study
Chen 2006a	PCOS diagnosis is inconsistent with Rotterdam criteria; quasi-RCT
Chen 2006b	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

(*Continued*)

Chen 2010a	No outcomes of interest
Chen 2010b	No outcomes of interest
Chen 2011a	No outcomes of interest; PCOS with or without infertility
Chen 2011b	No outcomes of interest; PCOS with or without infertility
Chen 2011c	Quasi-RCT
Chen 2012a	No outcomes of interest; PCOS with or without infertility
Chen 2012b	No outcomes of interest; PCOS with or without infertility
Chen 2012c	Quasi-RCT
Chen 2012d	PCOS diagnosis is inconsistent with Rotterdam criteria; quasi-RCT
Chen 2013	Non-PCOS participants
Chen 2014a	Quasi-RCT
Chen 2014b	Not a RCT
Chen 2014c	Non-CHM intervention
Chen 2015	Participants had no wish to conceive
Chen 2016	Non-CHM intervention
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
Chu 2013	Non-PCOS participants
Craig 2015	Non-CHM intervention
Cui 2012	PCOS with or without infertility; no outcomes of interest
Dang 2012	Non-RCT, which the primary authors confirmed
Deng 2008	PCOS diagnosis is inconsistent with Rotterdam criteria; quasi-RCT
Deveci 2015	Non-CHM intervention

(*Continued*)

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
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 2011a	Non-RCT confirmed by primary authors
Feng 2011b	Quasi-RCT
Fu 2012	PCOS diagnosis is inconsistent with Rotterdam criteria; PCOS with or without infertility in this study; no outcomes of interest
Gao 2009	Intervention with acupuncture but without herbal medicine
Gao 2011a	PCOS diagnosis is inconsistent with Rotterdam criteria; quasi-RCT
Gao 2011b	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 2011a	PCOS diagnosis is inconsistent with Rotterdam criteria; quasi-RCT
Guo 2011b	No outcomes of interest; PCOS with or without infertility in this study
Haj-Husein 2016	With or without subfertility

(*Continued*)

Han 2008	PCOS diagnosis is inconsistent with Rotterdam criteria; quasi-RCT
Han 2011	PCOS diagnosis is inconsistent with Rotterdam criteria; quasi-RCT
Han 2013a	Participants had no wish to conceive
Han 2013b	Not a RCT
Han 2015	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
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 2006a	Non-RCT confirmed by primary authors
Huang 2006b	PCOS without infertility; quasi-RCT; No outcomes of interest
Huang 2007	PCOS with or without infertility in this study
Huang 2008	Review
Huang 2010	Quasi-RCT
Huang 2011a	No outcomes of interest
Huang 2011b	No outcomes of interest

(*Continued*)

Huang 2012a	No outcomes of interest; PCOS with or without infertility
Huang 2012b	PCOS diagnosis is inconsistent with Rotterdam criteria
Hung 2016	Cohort study
Huo 2008	Unrelated
Jalilian 2013	Non-CHM intervention
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 2012a	No outcomes of interest
Jia 2012b	PCOS diagnosis is inconsistent with Rotterdam criteria; quasi-RCT; no outcomes of interest; PCOS with or without infertility
Jian 2011	No outcomes of interest
Jiang 2007	PCOS diagnosis is inconsistent with Rotterdam criteria; quasi-RCT
Jiang 2011a	No outcomes of interest; PCOS with or without infertility
Jiang 2011b	No outcomes of interest; PCOS with or without infertility
Jiang 2014	Non-PCOS participants
Jiang 2015	Non-CHM intervention
Jin 2014a	Quasi-RCT
Jin 2014b	Non-CHM intervention
Jin 2016	Participants had no wish to conceive
Johnson 2015	Non-CHM intervention
Kang 2012	No outcomes of interest; PCOS with or without infertility
Kawakami 2011	Unrelated
Kitagawa 2015	Non-PCOS participants

(*Continued*)

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
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 2009a	No outcomes of interest
Li 2009b	PCOS without infertility
Li 2009c	Duplication
Li 2009d	No outcomes of interest; PCOS with or without infertility
Li 2010a	No outcomes of interest; PCOS with or without infertility; PCOS diagnosis is inconsistent with Rotterdam criteria

(*Continued*)

Li 2010b	No outcomes of interest; PCOS with or without infertility
Li 2010c	PCOS diagnosis is inconsistent with Rotterdam criteria
Li 2010d	No outcomes of interest; PCOS with or without infertility
Li 2011a	No outcomes of interest
Li 2011b	Participants had no wish to conceive
Li 2011c	PCOS with or without infertility; no outcomes of interest
Li 2011d	No outcomes of interest; PCOS with or without infertility
Li 2011e	No outcomes of interest; PCOS with or without infertility; PCOS diagnosis is inconsistent with Rotterdam criteria
Li 2011f	PCOS with or without infertility in this study
Li 2011g	No outcomes of interest
Li 2011h	No outcomes of interest; PCOS with or without infertility
Li 2011i	No outcomes of interest; PCOS with or without infertility
Li 2011j	PCOS diagnosis is inconsistent with Rotterdam criteria
Li 2011k	No outcomes of interest
Li 2012b	No outcomes of interest
Li 2012c	No outcomes of interest; PCOS with or without infertility
Li 2013a	Non-CHM intervention
Li 2013b	Participants had no wish to conceive; protocol
Li 2015	Non-CHM intervention
Li 2016	Participants had no wish to conceive
Lian 2008	Quasi-RCT
Lian 2012	Quasi-RCT
Liang 2011	Quasi-RCT
Liao 2014	Non-CHM intervention

(*Continued*)

Lim 2011	Review
Lin 2005	Non-RCT, which the primary authors confirmed
Lin 2009a	Non-RCT, which was confirmed by the author
Lin 2009b	Quasi-RCT
Lin 2011	We were unable to contact the study authors for the detailed information about the laparoscopic surgery method
Lin 2013a	Participants had no wish to conceive
Lin 2013b	Participants had no wish to conceive
Lin 2013c	Participants had no wish to conceive
Liu 2007	PCOS diagnosis is inconsistent with Rotterdam criteria; quasi-RCT
Liu 2008	Unrelated
Liu 2009	Diagnosis inconsistent with Rotterdam; quasi-RCT
Liu 2010a	Quasi-RCT
Liu 2010b	Non-RCT, which the primary study authors confirmed
Liu 2010c	No outcomes of interest; PCOS with or without infertility
Liu 2010d	No outcomes of interest; PCOS with or without infertility
Liu 2011a	Quasi-RCT
Liu 2011b	Quasi-RCT; no outcomes of interest; PCOS with or without infertility
Liu 2012a	No outcomes of interest
Liu 2012b	No outcomes of interest
Liu 2012c	No outcomes of interest
Liu 2013	Quasi-RCT
Liu 2014a	Participants had no wish to conceive
Liu 2014b	Participants had no wish to conceive

(*Continued*)

Lu 2010	PCOS diagnosis is inconsistent with Rotterdam criteria
Lu 2012	Diagnosis inconsistent with Rotterdam; quasi-RCT
Luo 2010	No outcomes of interest
Luo 2014	Not a RCT
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 2009b	Quasi-RCT
Ma 2010	No outcomes of interest
Madder 2013	Review
Mao 2003	PCOS diagnosis is inconsistent with Rotterdam criteria; quasi-RCT
Mao 2011a	No outcomes of interest
Mao 2011b	Non-RCT, which the primary authors confirmed
Mei 2010	PCOS with or without infertility
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
O'Brien 2010	Unrelated
Pan 2010	No outcomes of interest

(*Continued*)

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
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 2007a	No outcomes of interest
Ran 2007b	Case control study
Ran 2008	Case control study
Rao 2012	No PCOS
Rashidi 2013	Non CHM intervention
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
Ried 2015	SR
Sadrefozalayi 2014	Animals
Salah 2013	Non-CHM intervention

(*Continued*)

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
Sheng 2010	No outcomes of interest; PCOS with or without infertility
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 2010a	PCOS with or without infertility
Shi 2010b	No outcomes of interest
Shi 2011	PCOS with or without infertility; PCOS diagnosis is inconsistent with Rotterdam criteria
Shu 2012	No outcomes of interest
Si 2016	Participants had no wish to conceive
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 2009a	PCOS diagnosis is inconsistent with Rotterdam criteria; quasi-RCT
Sun 2009b	No outcomes of interest
Sun 2010a	PCOS with or without infertility
Sun 2010b	Intervention with acupuncture but without herbal medicine
Sun 2011	PCOS with or without infertility

(*Continued*)

Sun 2012	PCOS with or without infertility; quasi-RCT
Sun 2014	No CHM intervention
Tan 2005	Diagnosis inconsistent with Rotterdam; quasi-RCT
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
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 2005a	PCOS diagnosis is inconsistent with Rotterdam criteria; quasi-RCT
Wang 2005b	Before-and-after study
Wang 2006a	PCOS with or without infertility in this study
Wang 2006b	Quasi-RCT
Wang 2009	Intervention with acupuncture but without herbal medicine
Wang 2010a	PCOS with or without infertility; quasi-RCT
Wang 2010b	No outcomes of interest; PCOS with or without infertility

(*Continued*)

Wang 2011a	PCOS with or without infertility
Wang 2011b	Quasi-RCT
Wang 2011c	No outcomes of interest; PCOS with or without infertility
Wang 2011d	No outcomes of interest
Wang 2012a	PCOS with or without infertility
Wang 2012b	PCOS with or without infertility; quasi-RCT
Wang 2013	No CHM intervention
Wang 2016	No CHM intervention
Wei 2008	PCOS diagnosis is inconsistent with Rotterdam criteria
Wei 2011a	No outcomes of interest; PCOS with or without infertility
Wei 2011b	PCOS diagnosis is inconsistent with Rotterdam criteria; PCOS with or without infertility in this study
Wei 2011c	No outcomes of interest; PCOS with or without infertility; diagnosis inconsistent with Rotterdam criteria
Wu 2008	PCOS with or without infertility in this study
Wu 2010a	No outcomes of interest; PCOS with or without infertility in this study
Wu 2010b	PCOS diagnosis is inconsistent with Rotterdam criteria
Wu 2011	PCOS with or without infertility in this study
Wu 2012a	PCOS with or without infertility; no outcomes of interest
Wu 2012b	Non-CHM intervention
Wu 2013a	No CHM intervention
Wu 2013b	Non-PCOS participants
Wuttke 2015	Non-PCOS participants
Xia 2004	No outcomes of interest
Xia 2007	Quasi-RCT

(*Continued*)

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
Xiong 2012	No outcomes of interest; PCOS with or without infertility
Xu 2008a	PCOS with or without infertility
Xu 2008b	Diagnosis inconsistent with Rotterdam criteria; quasi-RCT
Xu 2009	PCOS with or without infertility in this study
Xu 2010a	No outcomes of interest
Xu 2010b	PCOS with or without infertility
Xu 2012	No outcomes of interest; PCOS with or without infertility
Xu 2016	Participants had no wish to conceive
Xue 2004	Diagnosis inconsistent with Rotterdam criteria; quasi-RCT
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 2010a	No outcomes of interest; PCOS with or without infertility in this study
Yang 2010b	PCOS diagnosis is inconsistent with Rotterdam criteria; no outcomes of interest; PCOS with or without infertility
Yang 2010c	No outcomes of interest; quasi-RCT
Yang 2011	PCOS diagnosis is inconsistent with Rotterdam criteria; PCOS with or without infertility in this study

(*Continued*)

Yang 2014a	No CHM intervention
Yang 2014b	Participants had no wish to conceive
Yang 2015	No CHM intervention
Yao 2011	No outcomes of interest; PCOS with or without infertility
Yao 2012a	PCOS with or without infertility
Yao 2012b	Quasi-RCT; no outcomes of interest
Ye 2004	PCOS with or without infertility; diagnosis inconsistent with Rotterdam criteria
Ye 2010	PCOS with or without infertility; no outcomes of interest
Ye 2012a	PCOS diagnosis is inconsistent with Rotterdam criteria; no outcomes of interest; quasi-RCT
Ye 2012b	No outcomes of interest
Ye 2015	Participants had no wish to conceive
Yi 2012	PCOS with or without infertility
Yin 2007	Laparoscopic ovary wedgeshaped resection was used in this study
Yu 2013	With or without subfertility
Yu 2015	Participants had no wish to conceive
Yuan 2011	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 2003a	No outcomes of interest; PCOS with or without infertility;diagnosis inconsistent with Rotterdam;quasi-RCT
Zhang 2003b	Concurrent control study
Zhang 2007a	No outcomes of interest; PCOS with or without infertility in this study
Zhang 2007b	No outcomes of interest; PCOS with or without infertility in this study

(*Continued*)

Zhang 2007c	PCOS with or without infertility in this study
Zhang 2007d	Duplication
Zhang 2009	No outcomes of interest; PCOS with or without infertility in this study
Zhang 2010a	PCOS diagnosis is inconsistent with Rotterdam criteria; no outcomes of interest
Zhang 2010b	No outcomes of interest; PCOS with or without infertility
Zhang 2010c	No outcomes of interest
Zhang 2010d	No outcomes of interest; PCOS with or without infertility
Zhang 2010e	PCOS diagnosis is inconsistent with Rotterdam criteria; no outcomes of interest
Zhang 2011a	Not a RCT
Zhang 2011b	No outcomes of interest
Zhang 2011c	No outcomes of interest; PCOS with or without infertility
Zhang 2011d	No outcomes of interest; PCOS with or without infertility
Zhang 2011e	Non-RCT, which the primary authors confirmed
Zhang 2011f	No outcomes of interest; PCOS with or without infertility
Zhang 2012a	No outcomes of interest; PCOS with or without infertility
Zhang 2012b	PCOS with or without infertility; no outcomes of interest
Zhang 2012c	PCOS with or without infertility; no outcomes of interest
Zhang 2012d	No outcomes of interest; quasi-RCT
Zhang 2014a	Participants had no wish to conceive
Zhang 2014b	Participants had no wish to conceive
Zhang 2015a	Participants had no wish to conceive
Zhang 2015b	With or without subfertility
Zhang 2015c	Participants had no wish to conceive

(*Continued*)

Zhang 2015d	Animals
Zhao 2006a	No outcomes of interest; PCOS with or without infertility in this study
Zhao 2006b	Intervention without herbal medicine
Zhao 2006c	Intervention without herbal medicine
Zhao 2007	PCOS diagnosis is inconsistent with Rotterdam criteria
Zhao 2008a	Quasi-RCT
Zhao 2008b	Duplication
Zhao 2008c	Intervention without herbal medicine
Zhao 2009	Concurrent control study; PCOS with or without infertility
Zhao 2010a	No outcomes of interest
Zhao 2010b	Non-RCT confirmed by primary authors
Zhao 2014	No interventions of interest
Zhao 2016	Participants had no wish to conceive
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 2011c	PCOS with or without infertility
Zheng 2014a	Quasi-RCT
Zheng 2014b	Participants had no wish to conceive
Zheng 2015a	Quasi-RCT
Zheng 2015b	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

(*Continued*)

Zhong 2009a	No outcomes of interest; PCOS with or without infertility in this study
Zhong 2009b	PCOS with or without infertility in this study
Zhong 2012	Non-RCT, which the primary study authors confirmed
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 2012a	No outcomes of interest
Zhou 2012b	No outcomes of interest
Zhou 2012c	No outcomes of interest; PCOS with or without infertility
Zhou 2012d	PCOS with or without infertility
Zhou 2014a	Quasi-RCT
Zhou 2014b	Quasi-RCT
Zhou 2014c	Quasi-RCT
Zhou 2015a	Quasi-RCT
Zhou 2015b	Quasi-RCT
Zhu 2009	Concurrent control study
Zhu 2012a	PCOS with or without infertility; no outcomes of interest
Zhu 2012b	No outcomes of interest
Zhu 2013a	Participants had no wish to conceive
Zhu 2013b	Participants had no wish to conceive
Zhu 2014	Quasi-RCT
Zhuang 2008	PCOS diagnosis is inconsistent with Rotterdam criteria
Zou 2012	No outcomes of interest; PCOS with or without infertility; PCOS diagnosis is inconsistent with Rotterdam criteria

(*Continued*)

Zou 2014a	Quasi-RCT
Zou 2014b	Participants had no wish to conceive
Zuo 2011	No outcomes of interest; PCOS with or without infertility

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

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

ChiCTR-IOR-16008557

Trial name or title	The Qilingwenshenxiaonang recipe in the treatment of patients with Polycystic ovary syndrome (PCOS): a multicenter, randomized, double-blind, placebo controlled trial
Methods	Randomized parallel controlled trial
Participants	Women with polycystic ovarian syndrome (PCOS)
Interventions	Qilingwenshenxiaonang recipe
Outcomes	Ovulation rate
Starting date	Unknown
Contact information	ChiCTR-IOR-16008557
Notes	

NCT01116167

Trial name or title	Letrozole, berberine, or their combination for anovulatory infertility in women with polycystic ovary syndrome: study design of a double-blind randomized controlled trial
Methods	A multicentre randomized, double-blind trial
Participants	Women with PCOS who desire pregnancy
Interventions	1. Letrozole and berberine. 2. Letrozole and berberine placebo. 3. Letrozole placebo and berberine.
Outcomes	Live birth rate

NCT01116167 (*Continued*)

Starting date	October 2009
Contact information	ClinicalTrials.gov identifier: NCT01116167
Notes	

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 Pregnancy rate (per woman)	2	90	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.98 [0.78, 5.06]
1.1 CHM versus clomiphene	1	60	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.44 [0.44, 4.73]
1.2 CHM + LOD versus clomiphene + LOD	1	30	Peto Odds Ratio (Peto, Fixed, 95% CI)	3.35 [0.73, 15.36]
2 Ovulation rate (per woman)	1	30	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.42 [0.19, 10.49]

Comparison 2. CHM + clomiphene versus clomiphene

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pregnancy rate (per woman)	3	300	Peto Odds Ratio (Peto, Fixed, 95% CI)	2.62 [1.65, 4.14]
1.1 CHM + clomiphene versus clomiphene	2	130	Peto Odds Ratio (Peto, Fixed, 95% CI)	2.45 [1.22, 4.95]
1.2 CHM + CEA + clomiphene versus CEA + clomiphene	1	170	Peto Odds Ratio (Peto, Fixed, 95% CI)	2.75 [1.49, 5.04]

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
1 Pregnancy rate (per woman)	1	44	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.60 [0.46, 5.52]
2 LUFS (adverse events)	1	44	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.60 [0.06, 6.14]
3 OHSS (adverse events)	1	44	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.16 [0.00, 8.19]
4 Multiple pregnancy (adverse events)	1	44	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.60 [0.06, 6.14]

Comparison 4. CHM + LOD versus LOD

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pregnancy rate (per woman)	1	30	Odds Ratio (Peto, Fixed, 95% CI)	3.5 [0.72, 17.09]
2 Ovulation rate (per woman)	1	30	Odds Ratio (Peto, Fixed, 95% CI)	2.43 [0.39, 15.08]

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. Luteinizing 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 2009a	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. 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.

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

Li 2012a	Compound Xuanju capsule	Ingredients: hei ma yi , yin yang huo, gou qi zi, she chuang zi (patent medicine, detailed prescription is not open)

Table 2. The name of CHM in different languages

Pingying name	Latin name	English name
Tu Si Zi	*Semen cuscutae dodder*	The seed of Chinese dodder
Shu Di	*Radix rehmanniae preparata*	Prepared rehmannia root
Sang Ji Sheng	*Parasitic loranthus*	Chinese taxillus twig
Xian Ling Pi	*Herba epimedii*	Herba epimedii
Bu Gu Zhi	*Fructus psoraleae*	Malaytea scurfpea fruit
Huang Jing	*Rhizoma polygonati*	Solomon's seal
Zao Jiao Ci	*Spina gleditsiae*	Chinese honeylocust spine
Tao Ren	*Semen persicae*	Peach seed
Shan Ci Gu	*Pseudobulbus cremastrae seu pleiones*	Pseudobulb of appendiculate cremastra
Dan Shen	Salvia miltiorrhiza	The root of red-rooted salvia
Gan Cao	Radix glycyrrhizae	Licorice roots northwest origin
Huang Qi	Stragalus membranaceus	Membranous milk vetch root
Shan Zha	*Crataegus pinnatifida bge*	The fruit of a hawthorn
Fa Ban Xia	*Rhizoma pinellinae praeparata*	Pinellia tuber
Zhi Mu	*Rhizoma anemarrhenae*	Common anemarrhena rhizome
Huang Qin	*Scutellaria baicalensis*	Baical skullcap root
Dang Shen	*Codonopsis pilosula*	Root of hairy asiabell
Ji Xue Teng	*Lignum mililettiae*	Caulis spatholobi
Fu Ling	*Tuckahoe*	Poria cocos
Dang Gui	*Radix angelica*	Chinese angelica

Table 2. The name of CHM in different languages (*Continued*)

Yin Yang Huo	*Herba epimedii*	Epimedium herb
Xian Mao	*Rhizoma curculiginis*	Common curculigo rhizome
Dan Nan Xing	*Bile arisaema*	Arisaema cum bile
Bai Zhu	*Atractylodes macrocephaia*	The rhizome of large headed atractylodes
Cang Zhu	*Rhizoma atractylodis*	The rhizome of Chinese atractylode
Zhe Bei Mu	*Fritillaria thunbergii*	Thunberbg fritillary bulb
Shi Chang Pu	*Rhizoma acori graminei*	Grassleaf sweelflag rhizome
Xiang Fu	*Rhizoma cyperi*	Nutgrass galingale rhizome
San Qi	*Pseudo-ginseng*	Panax notoginseng
Yi Mu Cao	*Leenurus heterophyllus*	Motherwort
Shan Yu Rou	*Fructus corni*	Common macrocarpium fruit
Lu Lu Tong	*Liquidambar formosana hance*	Beartiful sweetgum fruit
E Zhu	*Curcuma zedoary*	Zedoray rhizome
Bei Qi	*Radix astragali*	Northeast milkvetch root
Gui Zhi	*Ramulus cinnamomi*	Cassia twig
Rou Gui	*Cinnamomum cassia*	Chinese cinnamon
Bai Shao	*Radices paeoniae alba*	Root of herbaceous peony
Ba Ji	*Radix morindae officinalis*	Medicinal Indianmulberry root
Ren Shen	*Panax, gen-seng*	Ginseng
Shan Yao	*Rhizoma dioscoreae*	Common yam rhizome
Dan Pi	*Paeoniasuffruticosa*	The root bark of the peony tree
Ze Xie	*Rhizoma alismatic*	Oriental waterplantain rhizome
Chi Shao	*Radix paeoniae rubrathe*	Root of common peony

Table 2. The name of CHM in different languages (*Continued*)

Chuan Xiong	*Ligusticum wallichii*	The rhizome of chuanxiong
Hong Hua	*Carthamus tinctorious*	Red flower
E Jiao	*Colla dorii asini*	Donkey hide gelatin
Xu Duan	*Radix dipsaci*	Teasel root
Hei Ma Yi	*Formicae populus infirmus quae nigra*	Black Ants
Yin Yang Huo	*Herba epimedii*	Epimedium Herb
Gou Qi Zi	*Fructus lycii*	Barbary Wolfberry Fruit
She Chuang Zi	*Fructus cnidii*	Common Cnidium Fruit

WHAT'S NEW

Last assessed as up-to-date: 9 June 2016.

Date	Event	Description
10 July 2016	New search has been performed	The updated search found two ongoing studies (ChiCTR-IOR-16008557; NCT01116167), and one new study (Li 2012a).
10 July 2016	New citation required but conclusions have not changed	There is insufficient evidence for the conclusions of this review to be changed

HISTORY

Protocol first published: Issue 1, 2009

Review first published: Issue 9, 2010

Date	Event	Description
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

(*Continued*)

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, entered data entry into RevMan (RevMan 2014), extracted data, selected trials for inclusion or exclusion, and contacted the primary study authors.

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

Liangzhi Xu extracted data.

Taixiang Wu screened trials for inclusion or exclusion.

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.

Taixiang Wu 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.

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+clomiphene versus clomiphene as a comparison in last review (Zhang 2010) that was not listed in the protocol (Zhang 2009). In this 2016 updated review we deleted this comparison as it was a duplicate.

NOTES

None.

INDEX TERMS

Medical Subject Headings (MeSH)

Clomiphene [therapeutic use]; Cyproterone Acetate [therapeutic use]; Drugs, Chinese Herbal [*therapeutic use]; Ethinyl Estradiol [therapeutic use]; Fertility Agents, Female [therapeutic use]; Infertility [*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