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Review:

Acupuncture for treating polycystic ovary syndrome: guidance for future randomized controlled trials*

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Abstract: Objective: To provide guidance for future randomized controlled trials (RCTs) based on a review concerning acupuncture for treating polycystic ovary syndrome (PCOS). Methods: A comprehensive literature search was conducted in October 2015 using MEDLINE, EMBASE, SCISEARCH, Cumulative Index to Nursing and Allied Health Literature, the Cochrane Menstrual Disorders and Subfertility Group trials register, Allied and Complementary Medicine (AMED), China National Knowledge Infrastructure (CNKI), and the Wanfang databases. RCTs comparing either acupuncture with no/sham/pharmacological intervention or a combination of acupuncture and conventional therapy with conventional therapy in the treatment of PCOS were included in this review. A quality evaluation was performed for each of the included studies. Results: Thirty-one RCTs were included in the review and were divided into four categories according to the type of intervention used in the comparator or control group. Menstrual frequency, hormones, anthropometrics, insulin sensitivity, blood lipids, and fertility were used as the main measurements to assess the effects of acupuncture on the patients with PCOS. Thirty trials, except for one, showed an improvement in at least one of the indicators of PCOS after acupuncture treatment. However, normalizing the methodological and reporting format remains an issue. Conclusions: Based upon this review of current clinical trials concerning acupuncture for treating PCOS, we provide guidelines for better clinical trial design in the future.

Key words: Acupuncture, Polycystic ovary syndrome, Randomized controlled trial
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1 Introduction

Polycystic ovary syndrome (PCOS), a complex genetic disorder, is a significant women's health issue, which shows an increasing annual prevalence (Franks, 1995; Ehrmann, 2005; Stefanaki *et al.*, 2015). It is characterized by the presence of polycystic ovaries, chronic oligo/anovulation, hyperandrogenism, infertility, hyperinsulinemia, insulin resistance, and obesity (Norman *et al.*, 2007). Patients with PCOS often need pharmacological treatment for a long period of time. First-line therapy for PCOS is oral contraceptives, which can effectively alleviate hirsutism and acne; however, these may adversely affect glucose tolerance, coagulability, and fertility (Lanham *et al.*, 2006).

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Acupuncture has been used to treat gynecological disorders for thousands of years (Zhou and Qu, 2009). It is sometimes chosen by women with PCOS as an alternative therapy or used as an adjunct while undergoing infertility treatment (Stener-Victorin *et al.*, 2008). Previous studies have shown that acupuncture can effectively treat PCOS by: (1) modulating the sympathetic outflow through spinal reflexes; (2) affecting the hypothalamic pituitary adrenocortical (HPA) and hypothalamic pituitary ovarian (HPO) axes by increasing central β-endorphin (Johansson and Stener-Victorin, 2013). Over 50 studies have been conducted to explore the effects of acupuncture on PCOS (Stener-Victorin *et al.*, 2008; Zheng *et al.*, 2012). The aim of this review is to provide guidance to augment the accuracy of future randomized controlled trials (RCTs) relating to acupuncture for treating PCOS.

2 Methods

A review of the existing RCTs on acupuncture for the treatment of women with PCOS was performed through a systematic literature search using the following databases: MEDLINE (1966 to October 2015), EMBASE (1974 to October 2015), SCISEARCH (1974 to October 2015), Cumulative Index to Nursing and Allied Health Literature (1982 to October 2015), the Cochrane Menstrual Disorders and Subfertility Group trials register (October 2015), Allied and Complementary Medicine (AMED) (1985 to October 2015), China National Knowledge Infrastructure (CNKI) (1982 to October 2015), and the Wanfang database (1982 to October 2015). The reference lists of relevant primary and review articles were also checked to identify further published trials not uncovered in the database search. There were no restrictions placed on language or publication type in the searches.

Search terms and key words included: "polycystic ovary morphology" or "polycystic ovary syndrome" or "polycystic ovary" or "ovary polycystic disease" or "PCOS" or "oligo-amenorrhea" or "oligoamenorrhea" or "oligoanovulatory" or "oligohypomenorrhea" or "amenorrhea" or "amenorrhoea" or "hirsutism" AND "acupoint" or "acupressure" or "acupressure-acupuncture therapy" or "acupuncture" or "electro-acupuncture" or "electroacupuncture" or "moxibustion" or "Tui Na" or " traditional medicine" or "traditional Chinese medicine" or "traditional Chinese medicine combined with western medicine." All search terms were translated into Chinese terms in order to conduct the searches in Chinese databases.

PCOS was diagnosed according to the European Society for Human Reproduction and Embryology (ESHRE) and American Society for Reproductive Medicine (ASRM) (The Rotterdam ESHRE/ASRM-Sponsored PCOS Consensus Workshop Group, 2004). "Acupuncture" was defined as traditional needling acupuncture, auricular acupuncture, electro-acupuncture (EA), auricular acupressure, and warm needling acupuncture. RCTs belonging to one of the following categories were included: (1) acupuncture vs. sham/no intervention; (2) acupuncture+conventional therapy vs. conventional therapy; (3) acupuncture vs. conventional therapy; (4) two or more of the above situations. "Conventional therapy" involved pharmacotherapy for ovulation induction, ethinylestradiol and cyproterone acetate tablets (ECAT), metformin, and Chinese medicinal herbs (CMH). Case reports, reviews, animal experiments, self-control clinical studies, and studies with acupuncture in the control group were excluded.

Study selection and data extraction were performed by two authors (FQ and YW) independently, and disagreements were resolved by discussion. Data abstracted from the accepted RCTs included: details of the participants, countries, interventions, outcomes, ethical/institutional review board approval, randomization, single/multi-center, concealment of allocation, blinding, comparability at the baseline, sample size calculation, adverse effects, follow-up and background information about the acupuncture practitioner, which are based upon adherence to the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) (MacPherson *et al.*, 2010).

3 Results

3.1 Main study characteristics

A total of 31 RCTs that included 2371 women with PCOS met our inclusion criteria (Yang *et al.*, 2005; Zhao *et al.*, 2007; Shi *et al.*, 2009; Stener-Victorin *et al.*, 2009; 2012; 2013; Lai *et al.*, 2010; Li

and Han, 2010; Cui W. *et al.*, 2011; 2012; 2015; Jedel *et al.*, 2011; Li and Zhang, 2011; Li Y.L. *et al.*, 2011; Pastore *et al.*, 2011; Cui Y. *et al.*, 2012; Franasiak *et al.*, 2012; Liu *et al.*, 2012; Johansson *et al.*, 2013; Li, 2013; Liang *et al.*, 2013a; 2013b; Rashidi *et al.*, 2013; Wang and Gu, 2013; Wang and Li, 2013; Zhang, 2013; Zheng *et al.*, 2013; He, 2014; Jin *et al.*, 2014; Leonhardt *et al.*, 2014; Li L. *et al.*, 2014; Lin, 2014; Liang, 2015a; 2015b; Qiu *et al.*, 2015; Sheng, 2015; Wang, 2015). A short description of the studies included in this review was shown in Table 1. Of the 31 included trials, three were performed in Sweden (Stener-Victorin *et al.*, 2009; 2012; 2013; Jedel *et al.*, 2011; Johansson *et al.*, 2013; Leonhardt *et al.*, 2014), one in the USA (Pastore *et al.*, 2011; Franasiak *et al.*, 2012), one in Iran (Rashidi *et al.*, 2013), and all other trials were conducted in China. After the studies were divided into four categories according to interventions, five were identified as "acupuncture vs. sham/no intervention," fifteen as "acupuncture+conventional therapy vs. conventional therapy," nine as "acupuncture vs. conventional therapy," and two as "comparison between different groups containing two or more of the above situations."

3.2 Study quality of the trials

All of the included 31 RCTs were single-center trials. The average number of patients with PCOS was 75, with a range of 20 to 217. In this review, menstrual frequency, hormones, anthropometrics, insulin sensitivity, blood lipids, and fertility were used as the main measurements to assess the effects of acupuncture in treating PCOS. Menstrual frequency and hormones (follicle stimulating hormone (FSH), luteotropic hormone (LH), LH/FSH, and testosterone (T)) were the most common measurements used in evaluating the effect of a therapy on PCOS, and they were available in 25 of the 31 included trials (Zhao *et al.*, 2007; Shi *et al.*, 2009; Stener-Victorin *et al.*, 2009; 2012; 2013; Lai *et al.*, 2010; Li and Han, 2010; Jedel *et al.*, 2011; Li and Zhang, 2011; Li Y.L. *et al.*, 2011; Pastore *et al.*, 2011; Cui Y. *et al.*, 2012; Franasiak *et al.*, 2012; Liu *et al.*, 2012; Johansson *et al.*, 2013; Liang *et al.*, 2013a; 2013b; Wang and Gu, 2013; Wang and Li, 2013; Zhang, 2013; Zheng *et al.*, 2013; He, 2014; Jin *et al.*, 2014; Leonhardt *et al.*, 2014; Li L. *et al.*, 2014; Lin, 2014; Liang, 2015a; 2015b; Qiu *et al.*, 2015; Wang, 2015). Anthropometric measurements, such as body weight, body mass index (BMI), waist, waist-hip ratio (WHR), and the Ferriman-Gallwey score were available in 10 of the 31 included trials (Zhao *et al.*, 2007; Stener-Victorin *et al.*, 2009; 2012; 2013; Lai *et al.*, 2010; Jedel *et al.*, 2011; Liu *et al.*, 2012; Johansson *et al.*, 2013; Zheng *et al.*, 2013; Jin *et al.*, 2014; Leonhardt *et al.*, 2014; Liang, 2015a; 2015b). Measurements about insulin sensitivity including fasting insulin (FINS), fasting plasma glucose (FPG), and homeostasis model assessment for insulin resistance (HOMA-IR) were available in 9 of the 31 trials (Zhao *et al.*, 2007; Stener-Victorin *et al.*, 2009; 2012; 2013; Lai *et al.*, 2010; Jedel *et al.*, 2011; Liu *et al.*, 2012; Johansson *et al.*, 2013; Zheng *et al.*, 2013; Leonhardt *et al.*, 2014; Liang, 2015a; 2015b). Measurements about blood lipids including total cholesterol (TC), triglycerides (TG), low-density lipoprotein cholesterol (LDL-C), and high-density lipoprotein cholesterol (HDL-C) were available only in four trials (Lai *et al.*, 2010; Jedel *et al.*, 2011; Stener-Victorin *et al.*, 2012; 2013; Johansson *et al.*, 2013; Zheng *et al.*, 2013; Leonhardt *et al.*, 2014). Only nine trials that used acupuncture in treating infertile women with PCOS had measured ovulation rate (OR), clinical pregnancy rate (CPR), and miscarriage rate (MR) (Yang *et al.*, 2005; Cui W. *et al.*, 2011; 2012; 2015; Li, 2013; Rashidi *et al.*, 2013; Wang and Gu, 2013; Qiu *et al.*, 2015; Sheng, 2015; Wang, 2015). More outcomes used in the included trials are shown in Table 1. Acupuncture was used alone in 14 trials (Yang *et al.*, 2005; Stener-Victorin *et al.*, 2009; 2012; 2013; Lai *et al.*, 2010; Jedel *et al.*, 2011; Li and Zhang, 2011; Pastore *et al.*, 2011; Cui Y. *et al.*, 2012; Franasiak *et al.*, 2012; Johansson *et al.*, 2013; Li, 2013; Rashidi *et al.*, 2013; Wang and Li, 2013; Zheng *et al.*, 2013; He, 2014; Jin *et al.*, 2014; Leonhardt *et al.*, 2014), and along with pharmacotherapy for ovulation induction, CMH, ECAT or metformin in the other 17 trials. Among the 31 trials reviewed, blinding was only applied in three RCTs (Stener-Victorin *et al.*, 2009; Pastore *et al.*, 2011; Franasiak *et al.*, 2012; Johansson *et al.*, 2013). In one trial, researchers failed to find significant differences in the outcomes between true and sham acupuncture (control) (Pastore *et al.*, 2011; Franasiak *et al.*, 2012). In the other 30 trials, there was an improvement in at least one of the indicators of PCOS after acupuncture treatment, when compared with the control group.

Table 1 Summary of randomized controlled trials

Study	Participant	Country	Intervention	Control	Outcome
1. Acupuncture vs. sham/no intervention					
Pastore *et al.*, 2011; Franasiak *et al.*, 2012	84 PCOS women aged 18–43 years without hormonal intervention 60 d before enrollment	USA	EA	Sham acupuncture	LH, FSH, OR, longitudinal AMH
Jedel *et al.*, 2011; Stener-Victorin *et al.*, 2012; 2013; Leonhardt *et al.*, 2014	84 PCOS women aged 18–37 years	Sweden	EA	(1) Physical exercise (2) No intervention	MF, anthropometrics, T, circulating coagulation and fibrinolytic markers, insulin sensitivity (euglycemic hyperinsulinemic clamp), hemodynamics, adipose tissue morphology/function, AMH, antral follicle count, ovarian volume, MADRS-S, BSA-S, SF-36, PCOSQ
Johansson *et al.*, 2013	32 PCOS women aged 18–38 years without any intervention 3 months before enrollment	Sweden	EA	Attention control	Anthropometrics, LH, FSH, T, FINS, FPG, HOMA-IR, AMH, inhibin B, cortisol
Rashidi *et al.*, 2013	62 PCOS women aged 18–40 years undergoing IVF/ICSI	Iran	EA	No intervention	CPR, ongoing pregnancy rate, MR, metaphase II oocytes rate, FR, GQER
Stener-Victorin *et al.*, 2009	20 PCOS women without known endocrine or neoplastic causes of hyperandrogenemia	Sweden	EA	(1) Physical exercise (2) No intervention	Muscle sympathetic nerve activity, BMI, WHR, FSH, LH, T, FINS, FPG
2. Acupuncture+conventional therapy vs. conventional therapy					
Cui *et al.*, 2015	217 PCOS women undergoing IVF	China	EA+COH	COH	Number of oocytes, FR, CR, GQER, CPR, MR, spindle and oocytes quality
Cui W. *et al.*, 2011; 2012	66 PCOS women undergoing IVF	China	EA+COH	COH	Number of oocytes, FR, CR, GQER, CPR, MR, LBR, stem cell factor
Li *et al.*, 2011	60 infertile PCOS women without hormonal intervention 90 d before enrollment	China	Acupuncture+CMH+CC	CMH+CC	OR, E2, LH, P, endometrial thickness
Li *et al.*, 2014	60 PCOS women	China	Acupuncture+CC	CC	OR, follicles development, LH
Liang *et al.*, 2013a; 2013b	60 infertile PCOS women	China	Acupuncture+Gn	Gn	Oocyte maturity, FSH, LH, T, PRL, P, E2
Liang, 2015a	60 PCOS women	China	Acupuncture+CC	CC	FPG, FINS, FSH, LH, T, E2, P, MF, BMI, BBT
Liang, 2015b	80 infertile PCOS women (BMI>25 kg/m^2) without hormonal intervention 90 d before enrollment	China	Acupuncture+CMH+CC	CMH+CC	FPG, FINS, FSH, LH, T, E2, P, MF, BMI, OR, CPR
Lin, 2014	84 PCOS women aged 19–35 years	China	Acupuncture+ECAT	ECAT	MF, ovarian volume, sex hormone levels
Liu *et al.*, 2012	80 PCOS women	China	Acupuncture+ECAT	ECAT	FSH, LH, T, PRL, E2, BMI, FINS, FPG
Qiu *et al.*, 2015	80 PCOS women aged 16–40 years	China	Acupuncture+CMH	CMH	MF, T, BBT, OR, CPR
Sheng, 2015	100 infertile PCOS women resistant to CC	China	Acupuncture+HMG	HMG	OR, CPR
Shi *et al.*, 2009	63 PCOS women	China	Acupuncture+CMH	CMH	FSH, LH, T
Wang, 2015	80 infertile PCOS women aged 20–40 years	China	Acupuncture+CC	CC	Number of oocytes, OR, T, LH, E2, FSH, CPR

To be continued

Table 1

Study	Participant	Country	Intervention	Control	Outcome
Zhang, 2013	60 PCOS women	China	Acupuncture+ECAT+ metformin	ECAT+metformin	OR, FSH, LH, T
Zhao *et al.*, 2007	60 obese PCOS women (BMI>25 kg/m^2) without hormonal intervention 90 d before enrollment	China	Acupuncture+ metformin	Metformin	BMI, WHR, LH/FSH, T, FINS, FPG, HOMA-IR
3. Acupuncture vs. conventional therapy					
Cui Y. *et al.*, 2012	60 PCOS women with normal BMI, FINS and IRI	China	Acupuncture	ECAT	OR, FSH, LH, T, IGF-1, TGF-β1, EGFR
He, 2014	55 PCOS women aged 21–36 years	China	Acupuncture	CC	FSH, LH, T
Jin *et al.*, 2014	65 PCOS women	China	EA	ECAT	MF, BMI, T, LH, FSH
Lai *et al.*, 2010	86 obese PCOS women (BMI>25 kg/m^2)	China	Abdominal acupuncture	Metformin	BMI, WHR, Ferriman-Gallwey scale, MF, BMI, T, LH, FSH, FINS, FPG, TC, TG, LDL-C, HDL-C, HOMA-IR
Li and Zhang, 2011	60 PCOS women aged 16–40 years without any intervention 6 months before enrollment	China	EA	CC	OR, FSH, LH, T, MF
Li, 2013	100 PCOS women	China	Acupuncture+ auricular acupressure	CC	OR, CPR
Wang and Li, 2013	78 PCOS women aged 19–32 years	China	Acupuncture	ECAT+CC	MF, ovulation
Yang *et al.*, 2005	126 infertile PCOS women without hormonal intervention 90 d before enrollment	China	Acupuncture	CC	OR, CPR
Zheng *et al.*, 2013	86 PCOS women with BMI≥25 kg/m^2	China	Abdominal acupuncture	Metformin	BMI, WHR, ovarian volume, MF, HOMA-IR, Ferriman-Gallwey score, LH, T, FSH, FPG, FINS, TC, triglycerides, LDL-C, HDL-C
4. Comparison between different groups containing two or more of the above situations					
Li and Han, 2010	83 PCOS women	China	(1) Acupuncture (2) Acupuncture+CMH	(1) CMH (2) CC	MF, ovulation, T, FSH, LH
Wang and Gu, 2013	80 PCOS women without hormonal intervention 6 months before enrollment	China	(1) Acupuncture (2) Acupuncture+CMH	(1) CMH (2) CC	MF, CPR

PCOS: polycystic ovary syndrome; IVF: in vitro fertilization; ICSI: intra-cytoplasmic sperm injection; BMI: body mass index; FINS: fasting insulin; IRI: insulin resistance index; EA: electro-acupuncture; COH: controlled ovarian hyperstimulation; CMH: Chinese medicinal herbs; CC: clomifene citrate; Gn: gonadotropin; ECAT: ethinylestradiol and cyproterone acetate tablets; HMG: human menopausal gonadotropin; LH: luteotropic hormone; FSH: follicle stimulating hormone; OR: ovulation rate; AMH: anti-Müllerian hormone; MF: menstrual frequency; T: testosterone; MADRS-S: Montgomery-Åsberg depression rating scale-self-rated version; BSA-S: self-reported version of the brief scale for anxiety; SF-36: Swedish short form 36; PCOSQ: polycystic ovary syndrome questionnaire; FPG: fasting plasma glucose; HOMA-IR: homeostasis model assessment for insulin resistance; CPR: clinical pregnancy rate; MR: miscarriage rate; FR: fertilization rate; GQER: good-quality embryo rate; WHR: waist-hip ratio; CR: cleavage rate; LBR: live birth rate; E2: estradiol; P: progesterone; PRL: prolactin; BBT: basal body temperature; IGF-1: insulin-like growth factor-1; TGF-β1: transforming growth factor-beta 1; EGFR: epidermal growth factor receptor; TC: total cholesterol; TG: triglyceride; LDL-C: low-density lipoprotein cholesterol; HDL-C: high-density lipoprotein cholesterol

3.3 Reporting quality

As shown in Table 2, the reporting quality was evaluated for each of the 31 studies included. In the review, 18 trials (Shi *et al.*, 2009; Stener-Victorin *et al.*, 2009; 2012; 2013; Lai *et al.*, 2010; Li and Han, 2010; Cui W. *et al.*, 2011; 2012; 2015; Jedel *et al.*, 2011; Li and Zhang, 2011; Pastore *et al.*, 2011; Franasiak *et al.*, 2012; Johansson *et al.*, 2013; Li, 2013; Rashidi *et al.*, 2013; Wang and Gu, 2013; Zheng *et al.*, 2013; Leonhardt *et al.*, 2014; Li *et al.*, 2014; Liang, 2015a; 2015b; Sheng, 2015) described the method of randomization; however, 5 of them were not fully randomized as the sequence was generated by registration order (Lai *et al.*, 2010; Li and Han, 2010; Wang and Gu, 2013; Li *et al.*, 2014; Liang, 2015a). Six trials had adequate concealment of allocation (Stener-Victorin *et al.*, 2009; 2012; 2013; Jedel *et al.*, 2011; Pastore *et al.*, 2011; Franasiak *et al.*, 2012; Johansson *et al.*, 2013; Rashidi *et al.*, 2013; Zheng *et al.*, 2013; Leonhardt *et al.*, 2014). In the present review, only eight trials included information regarding ethical/institutional review board approval (Stener-Victorin *et al.*, 2009; 2012; 2013; Lai *et al.*, 2010; Jedel *et al.*, 2011; Pastore *et al.*, 2011; Franasiak *et al.*, 2012; Johansson *et al.*, 2013; Rashidi *et al.*, 2013; Zheng *et al.*, 2013; Leonhardt *et al.*, 2014; Sheng, 2015). Four trials provided a power analysis and presented a sample size calculation (Jedel *et al.*, 2011; Pastore *et al.*, 2011; Franasiak *et al.*, 2012; Stener-Victorin *et al.*, 2012; 2013; Johansson *et al.*, 2013; Rashidi *et al.*, 2013; Leonhardt *et al.*, 2014). In addition, we found only six trails adhered to STRICTA and reported the acupuncture practitioners (Stener-Victorin *et al.*, 2009; 2012; 2013; Jedel *et al.*, 2011; Pastore *et al.*, 2011; Franasiak *et al.*, 2012; Johansson *et al.*, 2013; Rashidi *et al.*, 2013; Zheng *et al.*, 2013; Leonhardt *et al.*, 2014). Seven trials in the review provided information regarding adverse effects during the research period (Yang *et al.*, 2005; Lai *et al.*, 2010; Jedel *et al.*, 2011; Stener-Victorin *et al.*, 2012; 2013; Li, 2013; Zheng *et al.*, 2013; Leonhardt *et al.*, 2014; Li *et al.*, 2014; Liang, 2015b) and four trials described the follow-up information (Jedel *et al.*, 2011; Pastore *et al.*, 2011; Franasiak *et al.*, 2012; Stener-Victorin *et al.*, 2012; 2013; Wang and Li, 2013; Zhang, 2013; Leonhardt *et al.*, 2014).

4 Discussion

4.1 About study quality

While single-center trials are excellent for investigating research hypotheses, they also have inherent limitations. In contrast, multi-center trials expand the statistical power, increase generalizability, and moderately affect the sizes to maximize overall robustness. It would be advantageous to conduct more multi-center trials in the future to confirm the generalizability of the interventions.

For clinical trials, outcome measurements, whether objective, subjective, or patient-centered, should be disease-specific and follow the international classification of diseases. In this review, a range of objective, subjective, and patient-centered outcome measurements was identified in the included RCTs. Menstrual frequency, ovulation, CPR, and hormones were the most common measurements used in the included trials, and no other measurements were used to assess the effects of acupuncture on patients with PCOS in the several trials. Due to the various clinical manifestations of PCOS, measurements of anthropometry, insulin sensitivity, and blood lipids should be more frequently used. Patient-centered outcome measurements, such as questionnaire scores of life quality among patients with PCOS, should be used in conjunction with conventional measurements.

According to the interventions and controls, the included studies were divided into four categories as mentioned above. Among these, "acupuncture vs. sham acupuncture" might be the best design to evaluate the effectiveness of acupuncture on PCOS, as it can eliminate the placebo effects of acupuncture.

For an acupuncture treatment, it may be difficult to obtain "ideal" blinding, especially for subjects who have received prior acupuncture. In an RCT that investigates the effects of acupuncture in treating PCOS, blinding should be evaluated at the beginning of the trial to minimize placebo and expectancy effects of acupuncture from verbal and non-verbal communications with enrolled subjects. For an RCT of acupuncture, it may be difficult to find an ideal placebo-control method (Vincent and Lewith, 1995; Margolin *et al.*, 1998; Tang *et al.*, 1999; Emanuel and Miller, 2001; Sherman *et al.*, 2004). For non-drug interventions including acupuncture, it has been difficult

Table 2 Quality evaluation of randomized controlled trials

Study	Description of information of ethical approval	Randomization method	Single-/ multi-centre	Concealment of allocation	Placebo intervention	Blinding	Comparability at baseline	Sample size calculation	Acupuncture practitioner	Description of adverse effects	Follow-up	Adherence to STRICTA
1. Acupuncture vs. sham/no intervention												
Pastore *et al.*, 2011; Franasiak *et al.*, 2012	Yes	A random number generator program	Single	Adequate	Yes	Yes	Yes	Yes	Acupuncturist	No	Yes	Yes
Jedel *et al.*, 2011; Stener-Victorin *et al.*, 2012; 2013; Leonhardt *et al.*, 2014	Yes	Computerized randomization	Single	Adequate	No	No	Yes	Yes	Physical therapist	Yes	Yes	Yes
Johansson *et al.*, 2013	Yes	Computerized randomization	Single	Adequate	Yes	Yes	Yes	Yes	Therapist	No	No	Yes
Rashidi *et al.*, 2013	Yes	Computerized randomization	Single	Adequate	No	No	Yes	Yes	Acupuncturist	No	No	Yes
Stener-Victorin *et al.*, 2009	Yes	Computerized randomization	Single	Adequate	No	Yes	Yes	ND	Acupuncturist	No	No	Yes
2. Acupuncture+conventional therapy vs. conventional therapy												
Cui *et al.*, 2015	No	A random number table	Single	ND	No	No	Yes	ND	ND	No	No	No
Cui W. *et al.*, 2011; 2012	No	A random number table	Single	ND	No	No	Yes	ND	ND	No	No	No
Li *et al.*, 2011	No	ND	Single	ND	No	No	Yes	ND	ND	No	No	No
Li *et al.*, 2014	No	Sequence of recruitment	Single	ND	No	No	Yes	ND	ND	Yes	No	No
Liang *et al.*, 2013a; 2013b	No	ND	Single	ND	No	No	Yes	ND	ND	No	No	No
Liang, 2015a	No	A random number table	Single	ND	No	No	Yes	ND	ND	Yes	No	No
Liang, 2015b	No	Sequence of recruitment	Single	ND	No	No	Yes	ND	ND	No	No	No
Lin, 2014	No	ND	Single	ND	No	No	Yes	ND	ND	No	No	No
Liu *et al.*, 2012	No	ND	Single	ND	No	No	ND	ND	ND	No	No	No
Qiu *et al.*, 2015	No	ND	Single	ND	No	No	Yes	ND	ND	No	No	No

To be continued

Table 2

Study	Description of information of ethical approval	Randomization method	Single-/ multi-centre	Concealment of allocation	Placebo intervention	Blinding	Comparability at baseline	Sample size calculation	Acupuncture practitioner	Description of adverse effects	Follow-up	Adherence to STRICTA
Sheng, 2015	Yes	A random number table	Single	ND	No	No	Yes	ND	ND	No	No	No
Shi *et al.*, 2009	No	A random number table	Single	ND	No	No	Yes	ND	ND	No	No	No
Wang, 2015	No	ND	Single	ND	No	No	Yes	ND	ND	No	No	No
Zhang, 2013	No	ND	Single	ND	No	No	Yes	ND	ND	No	Yes	No
Zhao *et al.*, 2007	No	ND	Single	ND	No	No	Yes	ND	ND	No	No	No
3. Acupuncture vs. conventional therapy												
Cui Y. *et al.*, 2012	No	ND	Single	ND	No	No	Yes	ND	ND	No	No	No
He, 2014	No	ND	Single	ND	No	No	ND	ND	ND	No	No	No
Jin *et al.*, 2014	No	ND	Single	ND	No	No	Yes	ND	ND	No	No	No
Lai *et al.*, 2010	Yes	Sequence of recruitment	Single	ND	No	No	Yes	ND	ND	Yes	No	No
Li and Zhang, 2011	No	A random number table	Single	ND	No	No	Yes	ND	ND	No	No	No
Li, 2013	No	A random number table	Single	ND	No	No	Yes	ND	ND	Yes	No	No
Wang and Li, 2013	No	ND	Single	ND	No	No	Yes	ND	ND	No	Yes	No
Yang *et al.*, 2005	No	ND	Single	ND	No	No	Yes	ND	ND	Yes	No	No
Zheng *et al.*, 2013	Yes	Computerized randomization	Single	Adequate	No	No	Yes	ND	Acupuncturist	Yes	No	Yes
4. Comparison between different groups containing two or more of the above situations												
Li and Han, 2010	No	Sequence of recruitment	Single	ND	No	No	Yes	ND	ND	No	No	No
Wang and Gu, 2013	No	Sequence of recruitment	Single	ND	No	No	Yes	ND	ND	No	No	No

STRICTA: Standards for Reporting Interventions in Clinical Trials of Acupuncture; ND: not described

to establish a placebo or sham control that is both inert and indistinguishable (Dincer and Linde, 2003). A baseline measurement of the effectiveness of acupuncture in treating PCOS is helpful in determining whether the active acupuncture intervention is superior or equivalent to the placebo-controls. The selection of acupoints and the visual impact of needling are all key factors that can affect the "placebo" response.

4.2 About reporting quality

An important factor in any RCT is randomization. This ensures that the baseline factors of each group are equally distributed. Detailed information on randomization should be provided in future RCTs.

As delivery, frequency, and intensity of acupuncture treatment may influence outcomes, such details should be recorded, including the number of needle insertions per subject per session (mean and range where relevant), names (or location if no standard name) of acupoints used (uni/bilateral), depth of insertion based on a specified unit of measurement or on a particular tissue level, response sought (e.g. de qi or muscle twitch response), needle stimulation (e.g. manual, electrical), needle retention time, needle type (diameter, length, and manufacturer or material), number of treatment sessions, frequency and duration of treatment sessions, and details of other interventions administered to the acupuncture group (e.g. moxibustion, cupping, herbs, exercises, lifestyle advice) (MacPherson *et al.*, 2010). A minimum of four acupuncture treatment sessions is recommended to obtain satisfactory curative effects when treating PCOS women. These details should be described in future RCTs concerning acupuncture for treating PCOS.

For all clinical trials, it is important to obtain ethical/institutional review board approval before initiation. The ethical considerations of the acupuncture trials should be described in detail, including the approval of an institutional review board and date of approval.

The sample size of RCTs concerning acupuncture should be calculated a priori based upon previous studies. Insufficient sample size will definitely lead to weakening of the statistical characteristics. To effectively calculate the adequate sample size, it is important to perform and describe an appropriate power calculation, an estimate of drop-out rates and to establish a practical recruitment strategy concerning how patients will be approached and recruited into the trial.

STRICTA, a series of guidelines to provide authors a way to structure their reports of acupuncture interventions with a minimum set of items using a checklist, not only facilitates transparency in published reports, but also describes all the necessary details to replicate the trials. The revised STRICTA guideline includes 6 items and 17 sub-items, which set the reporting guidelines for the acupuncture rationale, the details of needling, the treatment regimen, other components of treatment, the practitioner background, and the control or comparator intervention (MacPherson *et al.*, 2010). It seems that STRICTA had not yet been taken into account in most of the studies on acupuncture for PCOS. We strongly recommend that STRICTA should be used as the gold standard in designing and reporting the protocol for acupuncture in clinical trials.

The preferences and expectation of patients may be contributing factors in the effectiveness of acupuncture. Since high expectations for acupuncture may correlate with high response rates and improved outcomes in the placebo control group, it may be difficult to detect a significant difference between the active acupuncture and placebo control interventions. To address this, a run-in phase stratification for randomization and measurements of expectation should be used in RCTs involving acupuncture. A simple and effective tool to evaluate expectations at baseline is to ask questions such as: "How effective do you consider acupuncture to be in general?" with responses that include "very effective, effective, slightly effective, not effective, do not know." As the experience, expectations and knowledge of acupuncture among patients with PCOS in various countries may influence the effectiveness of acupuncture on PCOS, such information should be taken into consideration and described.

For an RCT, safety is of utmost importance. The patients should be instructed to record the time of acupuncture treatment and any adverse effects in a diary. More attention should be paid to adverse effects in the future studies concerning acupuncture for treating PCOS.

Although traditional Chinese medicine and acupuncture may have a more gradual time course of

effectiveness than pharmacotherapy, these may also provide longer-term and sustained health benefits to patients with PCOS. Consequently, it is necessary to include information related to the follow-up periods that are long enough (at least one year after cessation of treatment) to optimally evaluate the effectiveness of acupuncture in treating patients with PCOS. A long period of follow-up should be performed and described in future trials.

As the needling stimulation in traditional Chinese acupuncture is invasive and can be painful, it may lead to higher drop-out rates than non-invasive treatments. Transcutaneous acupoint electrical stimulation (TEAS), a non-invasive acupuncture, may be effective (Zhang R. *et al.*, 2011; Zhang Q. *et al.*, 2014). For patients with PCOS who are not willing to receive invasive treatment, TEAS may be a more suitable intervention, which is a new development for traditional acupuncture under the advancement of modern science (Zhang R. *et al.*, 2011; Zhang Q. *et al.*, 2014).

Based on review of the evidences for acupuncture treatment for PCOS, we highlighted how future trials can be improved and where efforts should now be focused to improve the evidence base. However, some of these may be a little limited, due to the complexity of this disease, PCOS, and the marked differences on the design of the included trials.

Compliance with ethics guidelines

Yan WU, Nicola ROBINSON, Paul J. HARDIMAN, Malcolm B. TAW, Jue ZHOU, Fang-fang WANG, and Fan QU declare that they have no conflict of interest.

This article does not contain any studies with human or animal subjects performed by any of the authors.

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Introducing editorial board member:

Fan QU, MD, PhD, Fellow in the Research Council for Complementary Medicine (FRCCM), an editorial board member of *Journal of Zhejiang University-SCIENCE B (Biomedicine & Biotechnology)*, is an Associate Professor and PhD Supervisor at the Women's Hospital, School of Medicine, Zhejiang University, China. As a Principal Investigator (PI), he has been awarded more than 10 grants in the last five years, published over 50 peer-reviewed papers and has filed 10 patents. In 2015, he was awarded the "Excellence in Integrative Medicine Research Award" by the European Society of Integrative Medicine. Dr. QU was a Work Package 10 (WP10) member in the Good Practice in Traditional Chinese Medicine (GP-TCM) Research in the Post-Genomic Era, a Coordination Action funded by the European Union's 7th Framework Program, and is now Co-Chair of the Pharmacology and Toxicology Interest Group, Good Practice in Traditional Chinese Medicine Research Association, European Union and he also serves as Vice-President of the Acupuncture Research Committee, Zhejiang Acupuncture Association, China.

中文概要

题　目：针刺治疗多囊卵巢综合征随机对照试验指南

目　的：基于对针刺治疗多囊卵巢综合征随机对照临床试验现状的系统总结和分析，提出对未来相关临床研究的建议。

创新点：首次对目前针刺治疗多囊卵巢综合征随机对照临床试验进行了全面的总结和分析，从研究设计和报告规范等方面提出了一系列改进的建议。

方　法：对 MEDLINE、EMBASE、万方和知网等八个数据库进行了针刺治疗多囊卵巢综合征相关文献的全面检索，按照纳入标准将文章进行分类和总结，并对每项研究进行了详细的质量评估。根据当前的研究情况对未来针刺治疗多囊卵巢综合征的随机对照临床试验提出了一系列建议。

结　论：从如何完善实验设计，提高研究质量，加强报告规范等方面提出了一系列改进的建议，对未来针刺治疗多囊卵巢综合征随机对照试验的设计和实施提供了指导和帮助。

关键词：针刺；多囊卵巢综合征；随机对照试验