INPLASY PROTOCOL

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Review Stage at time of this submission: **The review has not yet started.**

Conflicts of interest:
None.

A comparison of the efficacy and safety of complementary and alternative therapies for Polycystic Ovary Syndrome

Pan, J[1]; Zhang, J[2]; Xiang, S[3]; Dong, S[4]; Qin, X[5].

Review question / Objective: **1. Types of patients. The type of patients was selected on the basis of the European Society of Human Reproduction and Embryology (ESHRE) PCOS diagnostic criteria, which included the following: 1. age between 18 and 35 years; 2. no pregnancy within the past 4 months; 3. oligomenorrhoea (menstrual cycle length >35 days, and less than eight cycles per year), or amenorrhea (menstrual cycle length >90 days) and one of the following two criteria: clinical or biochemical hyperandrogenism (biochemical hyperandrogenemia is defined as a total serum testosterone concentration > 60 ng/ dL and clinical hyperandrogenism is defined as a Ferriman-Gallwey (FG) score ≥ 5 in mainland China) and/or polycystic ovarian morphology (this is defined as ≥ 12 antral follicles (2–9 mm in diameter) or an ovarian volume > 10 mL on transvaginal scanning).2. Interventions. The treatment group will receive alternative and complementary therapies, such as Chinese herbal drugs, acupuncture, and moxibustion. Besides, combined interventions with other treatments will be included. The control group will include placebo, sham acupuncture, no treatment, HRT, and western medicine.3. Outcomes. The main outcome indicators are: 1. Improvement of menstrual symptoms; 2. the body mass index (BMI); 3. Comparison of serum FSH, LH, and E2 levels between day 2 to day 5 of the menstrual cycle; 4. Antral follicle count between day 2 to day 5 of the menstrual cycle (assessed by transvaginal ultrasound).**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 20 January 2021 and was last updated on 20 January 2021 (registration number INPLASY202110077).

INTRODUCTION

Review question / Objective: **1. Types of patients. The type of patients was selected on the basis of the European Society of Human Reproduction and Embryology (ESHRE) PCOS diagnostic criteria, which included the following: 1. age between 18**

and 35 years; 2. no pregnancy within the past 4 months; 3. oligomenorrhoea (menstrual cycle length >35 days, and less than eight cycles per year), or amenorrhea (menstrual cycle length >90 days) and one of the following two criteria: clinical or biochemical hyperandrogenism (biochemical hyperandrogenemia is defined as a total serum testosterone concentration > 60 ng/ dL and clinical hyperandrogenism is defined as a Ferriman-Gallwey (FG) score ≥ 5 in mainland China) and/or polycystic ovarian morphology (this is defined as ≥ 12 antral follicles (2–9 mm in diameter) or an ovarian volume > 10 mL on transvaginal scanning).2. Interventions. The treatment group will receive alternative and complementary therapies, such as Chinese herbal drugs, acupuncture, and moxibustion. Besides, combined interventions with other treatments will be included. The control group will include placebo, sham acupuncture, no treatment, HRT, and western medicine.3. Outcomes. The main outcome indicators are: 1. Improvement of menstrual symptoms; 2. the body mass index (BMI); 3. Comparison of serum FSH, LH, and E2 levels between day 2 to day 5 of the menstrual cycle; 4. Antral follicle count between day 2 to day 5 of the menstrual cycle (assessed by transvaginal ultrasound).

Condition being studied: With the increase in the incidence of Polycystic Ovary Syndrome (PCOS) over the years, restoring ovulation function has become one of the important contents of reproductive medicine research today. PCOS affects reproductive ability and harms physical and mental health. Studies show both complementary and alternative therapies to be effective in treating PCOS. However, the consistency of the conclusion is still inadequated. In view of this, we will develop a research to evaluate the effectiveness and safety of complementary and alternative therapies for PCOS. We therefore carry on a study protocol for a proposed network meta-analysis (NMA) and systematic review on PCOS.

METHODS

Participant or population: The type of patients was selected on the basis of the European Society of Human Reproduction and Embryology (ESHRE) PCOS diagnostic criteria, [30] which included the following: 1. age between 18 and 28 years; 2. no pregnancy within the past 4 months; 3. oligomenorrhoea (menstrual cycle length >35 days, and less than eight cycles per year), or amenorrhoea (menstrual cycle length >90 days) and one of the following two criteria: clinical or biochemical hyperandrogenism (biochemical hyperandrogenemia is defined as a total serum testosterone concentration > 60 ng/ dL and clinical hyperandrogenism is defined as a Ferriman-Gallwey (FG) score ≥ 5 in mainland China) and/or polycystic ovarian morphology (this is defined as ≥ 12 antral follicles (2–9 mm in diameter) or an ovarian volume > 10 mL on transvaginal scanning)

Intervention: The treatment group will receive alternative and complementary therapies, such as Chinese herbal drugs, acupuncture, and moxibustion. Besides, combined interventions with other treatments will be included. The control group will include placebo, sham acupuncture, no treatment, HRT, and western medicine.

Comparator: The control group will include placebo, sham acupuncture, no treatment, HRT, and western medicine.

Study designs to be included: 1. Search electronic bibliographic database ; 2. EndNote X9.1 software will be used for document management; 3. Data collection; 4. Statistical analysis

Eligibility criteria: All relevant complementary and alternative randomized controlled trials (RCTs) for PCOS will be included.

Information sources: PubMed, CNKI, Wanfang database, VIP database, Web of Science, The Cochrane Library, and EMBASE.

Main outcome(s): The main outcome indicators are: 1. Improvement of menstrual symptoms; 2. the body mass index (BMI); 3. Comparison of serum FSH, LH, and E2 levels between day 2 to day 5 of the menstrual cycle; 4. Antral follicle count between day 2 to day 5 of the menstrual cycle (assessed by transvaginal ultrasound).

Quality assessment / Risk of bias analysis: Two researchers will independently evaluate the quality of each included trial according to the Cochrane Risk of Bias Tool recommended by Cochrane Handbook Version 5.1.0 Evaluation criteria includes seven items and each aspect will be categorized as “low” “high” or “unclear”. In the process of evaluation, if there are disagreements, they will be resolved through discussion or a third reviewer.

Strategy of data synthesis: Different types of data need to be converted into binary or continuous variables for Meta analysis.

Subgroup analysis: If I2>50%, heterogeneity sources will be determined through a subgroup analysis. A detailed subgroup analysis will be listed. 1. Patient characteristics: age and course of the disease. 2. Interventions: acupuncture; traditional Chinese medicine; psychosomatic techniques; exercise and other treatments.

Sensibility analysis: As a commonly used method, sensitivity analysis will be applied to check the certainty of results and evaluate the effect of each study with a high risk of bias.

Country(ies) involved: China.

Keywords: polycystic ovarian syndrome, complementary and alternative therapies, network meta-analysis, protocol.

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