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ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Data extraction.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 June 2024 and was last updated on 07 June 2024.

INTRODUCTION

Review question / Objective To further understand the mechanism of PCOS occurrence, the mechanism of TCM influence on this disease and the basis for PCOS modelling protocols and timing of pharmacological interventions, we applied meta-analysis to assess the changes in the intestinal flora of the animal model of PCOS, to fill this gap in the literature, to further propose an intervention strategy (to guide the clinical trial), and to examine the potential efficacy, safety and toxicity of the TCM interventions.

Rationale Although there have been studies on the correlation between TCM treatment of PCOS animal models and intestinal flora, the results of observational studies on the correlation between intestinal flora disorders and PCOS have been contradictory due to inconsistencies in the modelling animals, modelling protocols, intervention time, and study flora, and the

conclusions of the studies are not uniform, and there is a lack of published Meta-analyses exploring the effects of TCM on the characteristics of the intestinal flora of animal models of PCOS.

Condition being studied Although there have been studies on the correlation between TCM treatment of PCOS animal models and intestinal flora, the results of observational studies on the correlation between intestinal flora disorders and PCOS have been contradictory due to inconsistencies in the modelling animals, modelling protocols, intervention time, and study flora, and the conclusions of the studies are not uniform, and there is a lack of published Meta-analyses exploring the effects of TCM on the characteristics of the intestinal flora of animal models of PCOS.

METHODS

Search strategy Five databases (PubMed, Embase, Web of Science, Cochrane Library, and China Knowledge) were searched from the date of

inception to 02/2024. that contained 'Polycystic Ovary Syndrome, "gut," and 'microbiome' in the title subheadings and main text. we also reviewed secondary references. ' "gut," and "microbiome" in the title subheadings and main text. we also reviewed secondary references. Two researchers independently screened the titles and abstracts of all articles retrieved, and manual searches were also performed from reviews and publication reference files to ensure comprehensive coverage. This study was limited to animal model studies only, and there were no language restrictions. This meta-analysis was performed in accordance with the recommendations of the Cochrane Handbook for Systematic Reviews of Interventions and followed the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) guidelines.

Participant or population PCOS animal model rat or mouse.

Intervention Chinese medicine treatment.

Comparator Control group, PCOS model and TAU group.

Study designs to be included The study design was either a single-arm study or a randomised controlled trial.

Eligibility criteria

Inclusion criteria

(1) The study design was a single-arm study or a randomised controlled trial; (2) the study animals were rats or mice, the animal model of PCOS; (3) the study featured TCM treatment; (4) the primary observation: gut microbiota analysis was performed and diversity or abundance was reported; and (5) there was no restriction on the type, route of administration, or dosage of TCM.

Exclusion criteria

(1) Studies that were not conducted on experimental rats, mice, or rats or mice in abnormal health; (2) Case reports, replicated studies, reviews, conference reports, editorials, letters, and studies that lacked full text; (3) Studies that did not reflect TCM treatment in the literature; and (4) Literature that did not reflect indicators of the intestinal flora. If more than one article analysed the same trial, we only included the most recent report.

Information sources If data were missing, the authors were contacted to request further information, clarification, or missing data. If data were presented only graphically, the authors were asked to provide numerical values, and if no

response was received, digital scale software was applied to estimate values from the graphs. If only figures were presented, two researchers independently used GetData Graph Digitizer ver. 2.26 to extract data and compute the means. Medians and inter-quartile ranges were transformed to means (M) and standard deviations (SD) using a web-based tool (<http://www.math.hkbu.edu.hk/~tongt/papers/median2mean.html>). If the required data were not provided or obtained, the study was excluded from the detailed analyses.

Main outcome(s) TCM and SCFAs, TCM and bacterial abundances, TCM and gut microbiota diversity (α -diversity).

Quality assessment / Risk of bias analysis Two authors independently assessed the risk of bias using a tool developed by the Systematic Evaluation Centre for Laboratory Animal Experiments (SYRCLE) (Hooijmans et al., 2014). The tool consists of 10 items assessing risk of bias in six domains: selection, performance, detection, attrition, reporting and other biases. The risk of bias for each domain is categorised as low, high or unclear. The SYRCLE tool lists criteria for low risk of bias in all domains. Studies that met these criteria had a low risk of bias, studies that did not meet these guidelines had a high risk of bias, and studies with unclear descriptions had an unclear risk of bias. Disagreements were resolved by discussion or consultation with a third author.

Strategy of data synthesis The means and SDs of continuous variables were recorded in Microsoft Excel (Microsoft Corp., Redmond, WA, USA). Within-study and between-study variation or heterogeneity was assessed using Cochran's Q statistic, with a significant Q statistic ($P < 50\%$); a fixed-effects model was used if no significant heterogeneity was present ($I^2 < 0.05$ suggested that publication bias was absent). Review Manager (RevMan; version 5.2. Cochrane Collaboration, Oxford, UK) and Stata software (version 12.0; StataCorp, LLC, College Station, TX, USA) were used to analyse the data.

Subgroup analysis Subgroup analyses were performed according to study type.

Sensitivity analysis Sensitivity analysis was carried out using the leave-one-out approach to determine the robustness of outcomes data.

Language restriction No language restrictions.

Country(ies) involved China.

Keywords Chinese medicine; PCOS; systematic evaluation and meta-analysis; intestinal flora.

Contributions of each author

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