

Traditional Chinese medicine for adults with overweight and obesity: a protocol for an umbrella review and meta-analysis of randomized controlled trials

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Traditional Chinese medicine for adults with overweight and obesity: a protocol for an umbrella review and meta-analysis of randomized controlled trials

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Abstract

Background: Many of these systematic reviews have focused on a single modality of TCM for adults with overweight and obesity.

Objective: To compare the efficacy of different traditional Chinese medicine (TCM) therapies for adults with overweight and obesity and provide a higher level of evidence in the form of umbrella review of systematic reviews and meta-analysis of randomized controlled trials.

Methods: Systematic reviews (SRs) and meta analyses (MAs) of TCM for adults with overweight and obesity will be identified and retrieved in databases of Wanfang, China National Knowledge Infrastructure (CNKI), Chinese Biological Medicine (CBM), PubMed, Embase, and Cochrane Database of Systematic Review (CDSR) from their establishment to March 2025. The included SRs/MAs reported body mass index (BMI), body weight, waist circumference (WC), hip circumference (HC), waist-to-hip ratio (WHR), low-density lipoprotein cholesterol, total cholesterol, triglycerides, fasting plasma glucose, fasting insulin, homeostatic model assessment of insulin resistance, and blood pressure will be extracted independently by two authors. In cases of disagreement, a consensus will be reached by consulting a third author. GRADE (Grading of Recommendations, Assessment, Development, and Evaluations) analysis using the guideline development tool and AMSTAR-2 (A Measure Tool to Assess Systematic Reviews-2) will be used to evaluate the methodological quality of SRs and MAs, respectively. The meta-analysis will be conducted by R studio (metaumbrella packages) under the random-effects model, as well as assessment of heterogeneity, tests for small-study effects, tests for excess statistical significance, and Jackknife leave-one-out analysis. P value <0.05 will be considered statistically significant.

Results: No Applicable

Conclusions: No Applicable Clinical Trial: PROSPERO (CRD42024551788)

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Original Manuscript

Traditional Chinese medicine for adults with overweight and obesity: a protocol for an umbrella review and meta-analysis of randomized controlled trials

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Abstract

Introduction To compare the efficacy of different traditional Chinese medicine (TCM) therapies for adults with overweight and obesity and provide a higher level of evidence in the form of umbrella review of systematic reviews and meta-analysis of randomized controlled trials.

Methods Systematic reviews (SRs) and meta analyses (MAs) of TCM for adults with overweight and obesity will be identified and retrieved in databases of Wanfang, China National Knowledge Infrastructure (CNKI), Chinese Biological Medicine (CBM), PubMed, Embase, and Cochrane Database of Systematic Review (CDSR) from their establishment to March 2025. The included SRs/MAs reported body mass index (BMI), body weight, waist circumference (WC), hip circumference (HC), waist-to-hip ratio (WHR), low-density lipoprotein cholesterol, total cholesterol, triglycerides, fasting plasma glucose, fasting insulin, homeostatic model assessment of insulin resistance, and blood pressure will be extracted independently by two authors. In cases of disagreement, a consensus will be reached by consulting a third author. GRADE (Grading of Recommendations, Assessment, Development, and Evaluations) analysis using the guideline development tool and AMSTAR-2 (A Measure Tool to Assess Systematic Reviews-2) will be used to evaluate the methodological quality of SRs and MAs, respectively. The meta-analysis will be conducted by R studio (metaumbrella packages) under the random-effects model, as well as assessment of heterogeneity, tests for small-study effects, tests for excess statistical significance, and Jackknife leave-one-out analysis. *P* value <0.05 will be considered statistically significant.

PROSPERO registration number: CRD42024551788

Ethics and dissemination: As for umbrella review, ethics are not required because the data used in it are derived from published papers. We will disseminate the results of this umbrella review through a peer-reviewed journal.

Introduction

Recently, overweight and obesity have become a growing concern worldwide. The trend of increasing obesity rates is alarming, with sedentary lifestyles, poor dietary habits, and genetic factors contributing to this epidemic.^{1, 2} The consequences of obesity are multifaceted and severe. Individuals who are obese are at a higher risk of developing a wide range of health problems, including heart disease, type 2 diabetes, high blood pressure, stroke, and certain cancers. Addressing the escalating trend of obesity is crucial to safeguard public health and reduce the burden on healthcare systems globally.^{3, 4}

The diversity of obesity-related management methods today ranges from bariatric surgery, medication, lifestyle interventions and so on. Bariatric surgery offers significant and sustained weight loss benefits for severe obesity, improving health and quality of life. However, these procedures carry risks such as infections, bleeding, gastric leakage, and the potential for nutritional deficiencies post-surgery.^{5, 6} Medication, like Glucagon-Like Peptide-1 (GLP-1) for obesity can aid weight reduction by suppressing appetite or increasing metabolism, providing support for individuals struggling with lifestyle changes. However, these weight loss drugs may come with side effects like gastrointestinal issues and mood changes, and long-term safety and efficacy considerations need to be addressed.⁷ Lifestyle interventions for obesity, such as dietary modifications and increased physical activity, offer sustainable health benefits and empower individuals to take control of their well-being. However, maintaining consistent lifestyle changes can be challenging over time, requiring dedication and perseverance to achieve long-term weight management goals.

In Traditional Chinese Medicine (TCM) theory, overweight/obesity is primarily categorized into distinct syndrome patterns (Zheng) based on its underlying pathological mechanisms.⁸⁻¹⁰ The main classifications include:

Dampness-Phlegm Accumulation (Dysfunction of spleen in water metabolism leading to fluid retention), Spleen Qi Deficiency (Impaired transformative function of spleen causing metabolic stagnation), Liver Qi Stagnation (Disrupted Qi flow affecting bile secretion and fat metabolism), and

Yang Deficiency (Insufficient kidney yang failing to “steam” bodily fluids). TCM, as an important form of complementary and alternative medicine, offers unique advantages in treating obesity by emphasizing a holistic approach to health. TCM views obesity as an imbalance in the body’s energy, or qi, and often treats it by addressing the root causes rather than just the symptoms.¹¹ Oral administration of TCM prescription, TCM external application (e.g: acupoint stimulation, cupping, moxibustion, etc.), or TCM exercise (e.g: Taichi, Baduanjin, Qigong, etc.) adjustments are TCM treatments for obesity and overweight. These methods aim to restore harmony in the body, improve digestion and metabolism, and promote overall well-being.¹² Additionally, TCM practitioners consider each individual’s constitution, lifestyle, and emotional state in developing a personalized treatment plan, which can lead to long-term weight management and improved health outcomes.^{13, 14} Many of these systematic reviews have focused on a single modality of TCM for adults with overweight and obesity. Therefore, a comprehensive and up-to-date umbrella review of systematic reviews (SRs) and meta analyses (MAs) is needed to summarize their findings and evaluate the strength of the evidence, providing a holistic overview of the benefits associated with each type of TCM in relation to obesity-related health outcomes.

Methods

The protocol of this review was registered in PROSPERO (CRD42024551788). We will follow the Preferred Reporting Items for Overviews of Reviews (PRIOR) guidelines.¹⁵ The protocol is reported in accordance with the PRISMA-P 2015.¹⁶ (Supplement file 1)

Search Strategy

We will search the following databases from inception to March 2025: Wanfang, China National Knowledge Infrastructure (CNKI), Chinese Biological Medicine (CBM), PubMed, Embase, and Cochrane Database of Systematic Review (CDSR). The following MeSH and free text terms will be used: *Obesity, obese, overweight, body weight, excess weight, Traditional Chinese medicine, Chinese herbs, Chinese patent medicine, acupuncture, electroacupuncture, auricular acupuncture, needle-embedding therapy, auricular, auricular point sticking, auricular plaster, acupressure, moxibustion, tuina, massage cupping, scraping, hot compress, Traditional Chinese exercise, qi gong, Taichi, Baduanjin, systematic review, systematic literature review, meta-analysis, meta-analyses, meta analysis and meta analyses*. The detailed search strategy in databases is presented in Supplement file 2. Additionally, we will manually screen the references cited in the included articles to identify as many eligible studies as possible.

Eligibility Criteria

To prepare and structure this umbrella review, the included SRs/MAs studies should focus question is formulated using the PICOS format (population, intervention, comparison, outcomes and study design) as detailed below:

- ☐ population, the overweight/obesity participates (the diagnostic criteria will not be restricted) with or without any medical conditions aged between 18 and 65 years old;
- ☐ intervention, oral administration of TCM prescription, TCM external application (e.g: acupoint stimulation, cupping, moxibustion, etc.), or TCM exercise (e.g: Taichi, Baduanjin, Qigong, etc.) ;
- ☐ comparison, placebo, life modification or no treatment;
- ☐ outcomes, the included studies that reported one of the following outcomes will be included. The primary outcomes include body mass index (BMI) and body weight, while secondary outcomes include waist circumference (WC), hip circumference (HC), waist-to-hip ratio (WHR), low-density lipoprotein cholesterol, total cholesterol, triglycerides, fasting plasma glucose, fasting insulin, homeostatic model assessment of insulin resistance, and blood pressure;
- ☐ study design, SRs/MAs of RCTs.

Studies will be excluded if they are:

- ☐ SRs/MAs exclusively observational studies including a cohort, case-control, case report, or cross-sectional study design;
- ☐ MAs of non-SRs;

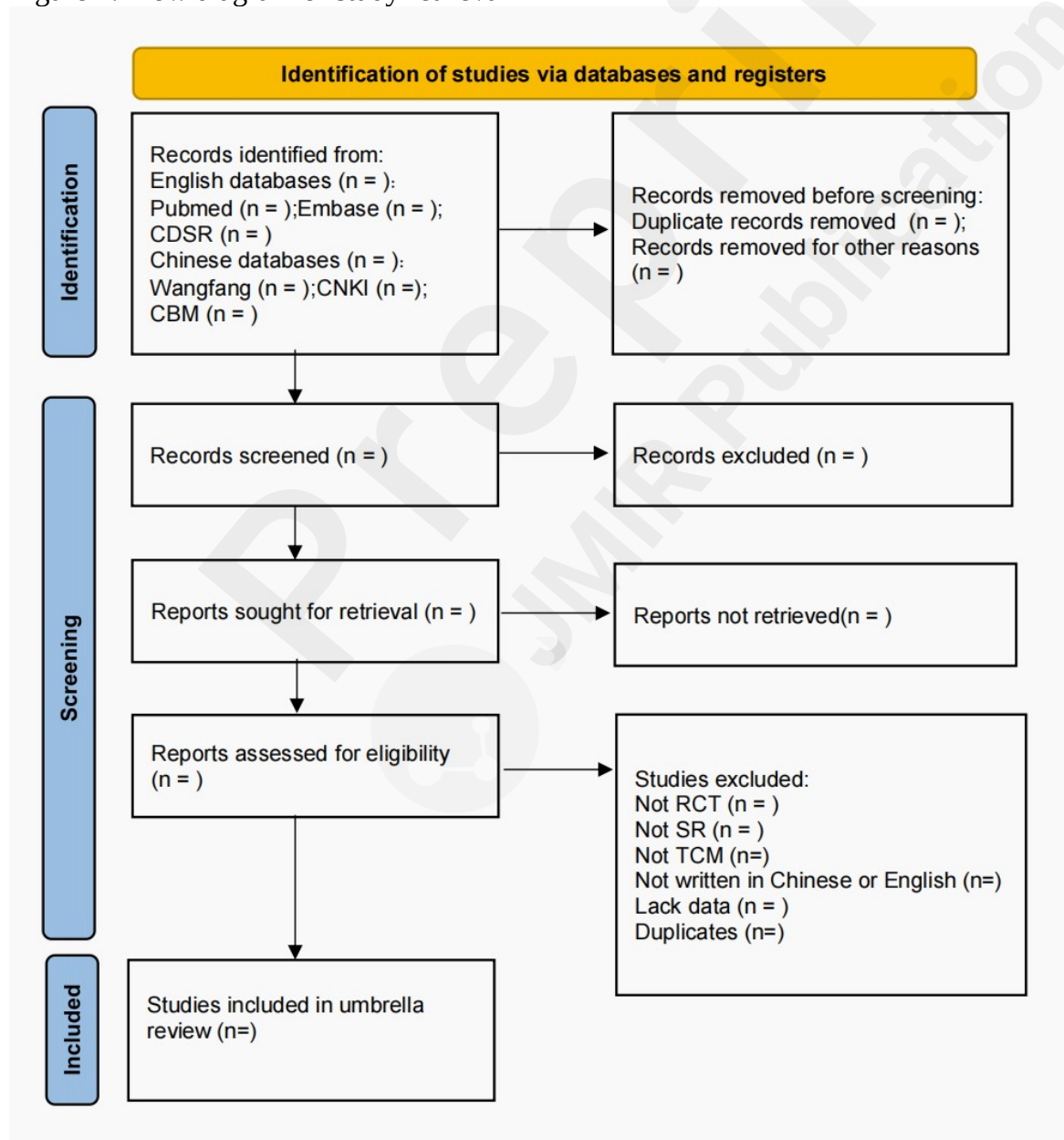
- MAs which provide insufficient data including pooled trials, participant numbers, and relative effect with 95% confidence intervals (CI);
- the studies written in not English or Chinese.

Notably, if a MA pooled both RCTs and other kind studies we will consider RCTs studies only. When more than 1 MA was available for the same research question, the graphical representation of overlap for overviews (GROOVE) tool will be employed to calculate the corrected covered area (CCA). If the CCA value exceeds 10%, SR/MAs will be selectively included based on comparative quality assessment. If the CCA is $\leq 10\%$, both publications will be retained. ^{17, 18}

Study Screening

Study screening will be conducted in EndnoteX9 in two stages. In the first stage, two authors (XYH&GY) will independently screen the titles and abstracts of and will include eligible studies. A third author (ZHM) will be available for discrepancies to reach consensus. The full texts of eligible studies will be retrieved and the same two authors (XYH&GY) will independently assess for inclusion with discrepancies resolved by a third author (ZHM). At the second stage, individual studies from eligible SRs/MAs will also be screened against inclusion criteria, with the same authors conducting the work. The study screen will be shown in a flow diagram (Figure 1).

Figure 1. Flow diagram of study retrieval



CDSR: Cochrane Database of Systematic Review; CNKI:China National Knowledge Infrastructure; CBM:Chinese Biological Medicine; RCT: Randomized Controlled Trial; SR: Systematic Review; TCM: Traditional Chinese Medicine

Data Extraction

Included studies will be independently extracted by two authors (XYH&GY) including authors, year of publication, the number of studies included in the SR/MA, sample size, population, TCM syndrome patterns, type of TCM and control, reported outcomes, metric, 95% confidence intervals, I^2 statistics, P values, and methodological quality evaluation of included studies (Table1). Any disagreements were be resolved through discussion or consultation with the third author (ZHM).

Quality Assessment

The included SRs will be evaluated using AMSTAR-2 (A MeaSurement Tool to Assess Systematic Reviews 2), which consists of 16 items categorized into 7 critical domains and 9 non-critical domains. Based on rigorous evaluation of these 16 items including search strategy, study selection, data extraction, study limitations, risk of bias assessment etc. we will further classify the methodological quality of each SRs into four levels: high, moderate, low, and very low quality. Concurrently, the GRADE (Grading of Recommendations Assessment, Development and Evaluation) system will be classified the evidence quality for included MAs outcomes by R studio (metaumbrella). This will involve systematic evaluation across five domains: risk of bias, inconsistency, indirectness, imprecision, and other considerations. Metaumbrella's evidence classification follows the GRADE framework, using both a 4-level hierarchy (Class I-ns) and standard GRADE ratings: high, moderate, low, and very low.

Two authors (XYH and GY) will conduct all quality assessments. Any disagreements in evaluation will be resolved through consultation with a third author (ZHM) to reach consensus.

Table 1 Characteristics of included studies

Study	No. of studies	Sample size (TCM/control)	Population n	TCM syndrome patterns	Type of TCM	Control	Outcome	Metric	Random effect size (95% CI)	P value	I ² , %	AMSTAR-2	GRADE rating
Study 1													
Study 2													
Study 3													
.....													

Statistical analysis

In this umbrella review, all analyses will be conducted using R studio (metaumbrella packages). Statistical significance will be set at $P < 0.05$ (two-tailed). Random-effects models using the DerSimonian-Laird estimator will be performed to pool effect sizes reported as mean differences (continuous outcomes) with 95% confidence intervals (CI). Meanwhile effect sizes will be standardized as equivalent Hedges'g (eG) for continuous outcomes (BMI, body weight, WC, HC, WHR, low-density lipoprotein cholesterol, total cholesterol, triglycerides, fasting plasma glucose, fasting insulin, homeostatic model assessment of insulin resistance, and blood pressure). Heterogeneity will be evaluated using the Q test method, which calculates χ^2 and I^2 values. For unpooled or single-study outcomes, we will report effect direction and significance using standardized terminology.

Subgroup analyses

To explore the heterogeneity sources and evaluate the robustness of pooled effect estimates, the pre-defined subgroup analyses and Jackknife leave-one-out sensitivity analysis will be conducted. The pre-defined subgroups as follows will be analyzed:

- By TCM intervention type (oral administration of TCM prescription vs. TCM external application vs. TCM exercise);
- By TCM syndrome patterns (Dampness-phlegm accumulation vs. Spleen qi deficiency vs. Liver qi stagnation vs. Yang deficiency)
- By treatment duration (short-term [<12 weeks] vs. long-term [≥ 12 weeks]);
- By baseline obesity severity (overweight [BMI 25–29.9] vs. obese [BMI ≥ 30]);
- By obesity-related comorbidities (simple obesity vs. obesity with 1 comorbidity vs. obesity with ≥ 2 comorbidities);
- By risk of bias (low vs. high/unclear, per Cochrane ROB tool).

Sensitivity analyses

sensitivity analyses will be conducted to evaluate the robustness of the pooled effect estimates. We will perform Jackknife leave-one-out analyses by iteratively excluding each included SRs/MAs to assess whether any single study disproportionately influences the overall results.

Publication bias

To test the small-study effects, Egger's regression test will be employed when ≥ 3 SR/MAs are available for a given outcome. Funnel plots will be visually inspected for asymmetry, complemented by trim-and-fill analysis to estimate potential missing studies. For outcomes with insufficient SRs/MAs ($n^* < 3$), publication bias will not be

quantitatively assessed due to limited power, but potential selective reporting will be discussed qualitatively. Furthermore, we will examine excess significance bias by comparing observed versus expected numbers of statistically significant studies.

Discussion

The treatment of obesity in TCM is fundamentally guided by the therapeutic principles of resolving dampness-phlegm stagnation and activating meridian circulation.^{19, 20} Although several systematic reviews and meta-analyses have evaluated the efficacy of specific TCM interventions, the overall evidence remains fragmented, with no comprehensive assessment of different TCM modalities. To our knowledge, this will be the first umbrella review to comprehensively assess TCM for overweight/obesity, providing clinicians and researchers with an evidence-based hierarchy of therapeutic options.

Limitations and strengths

This umbrella review will employ next-generation meta-analytical methods to: (1) systematically synthesize multiple SRs/MAs on TCM interventions for overweight/obesity; (2) critically appraise the quality and strength of SRs/MAs using both qualitative and quantitative approaches; (3) Our study will identify robust clinical recommendations by stratifying evidence strength and highlighting knowledge gaps in TCM for overweight/obesity management. However, several challenges are anticipated. First, clinical heterogeneity (e.g., variations in TCM syndrome differentiation, treatment, and outcome measures) may complicate data synthesis. We will address this through sensitivity analyses and subgroup analyses. Second, overlapping primary studies across reviews may introduce bias; we will quantify this using the Corrected Covered Area (CCA) index and account for it in our interpretations. Publication bias will be assessed via Egger's test and excess significance bias testing where applicable ($n \geq 3$ studies). Despite these limitations, this review will adhere to PRISMA and umbrella review guidelines to ensure methodological rigor. The findings will advance the evidence-based integration of TCM into weight management strategies and highlight priorities for future research.

Conclusion

This protocol addresses the growing concern about overweight and obesity among adults by providing robust evidence of the effects of TCM interventions on weight management and metabolic health. By synthesizing data from randomized controlled trials, our findings will enhance the understanding of TCM's efficacy and safety, informing clinical guidelines and public health strategies for obesity management. Implementing evidence-based TCM approaches could improve therapeutic options and promote long-term health outcomes in this population.

Funding

This project was funded by Chengdu High-level Key Clinical Specialty Construction Project and Chengdu Medical Research Project (2022188).

Ethics approval

As for systematic review and meta-analysis, Ethical Approval is not required because the data used in them are derived from published papers.

Authors' contribution

Conceptualization: Hongmei Zhu and Yue Gou.

Formal analysis: Yunhui Xie.

Investigation: Yunhui Xie and Liu Yanjun.

Methodology: Hongmei Zhu.

Supervision: Yanjun Liu.

Validation: Hongmei Zhu and Yunhui Xie.

Visualization: Hongmei Zhu.

Writing – original draft: Yunhui Xie.

Writing – review & editing: Yunhui Xie, Yue Gou, Hongmei Zhu, and Yanjun Liu

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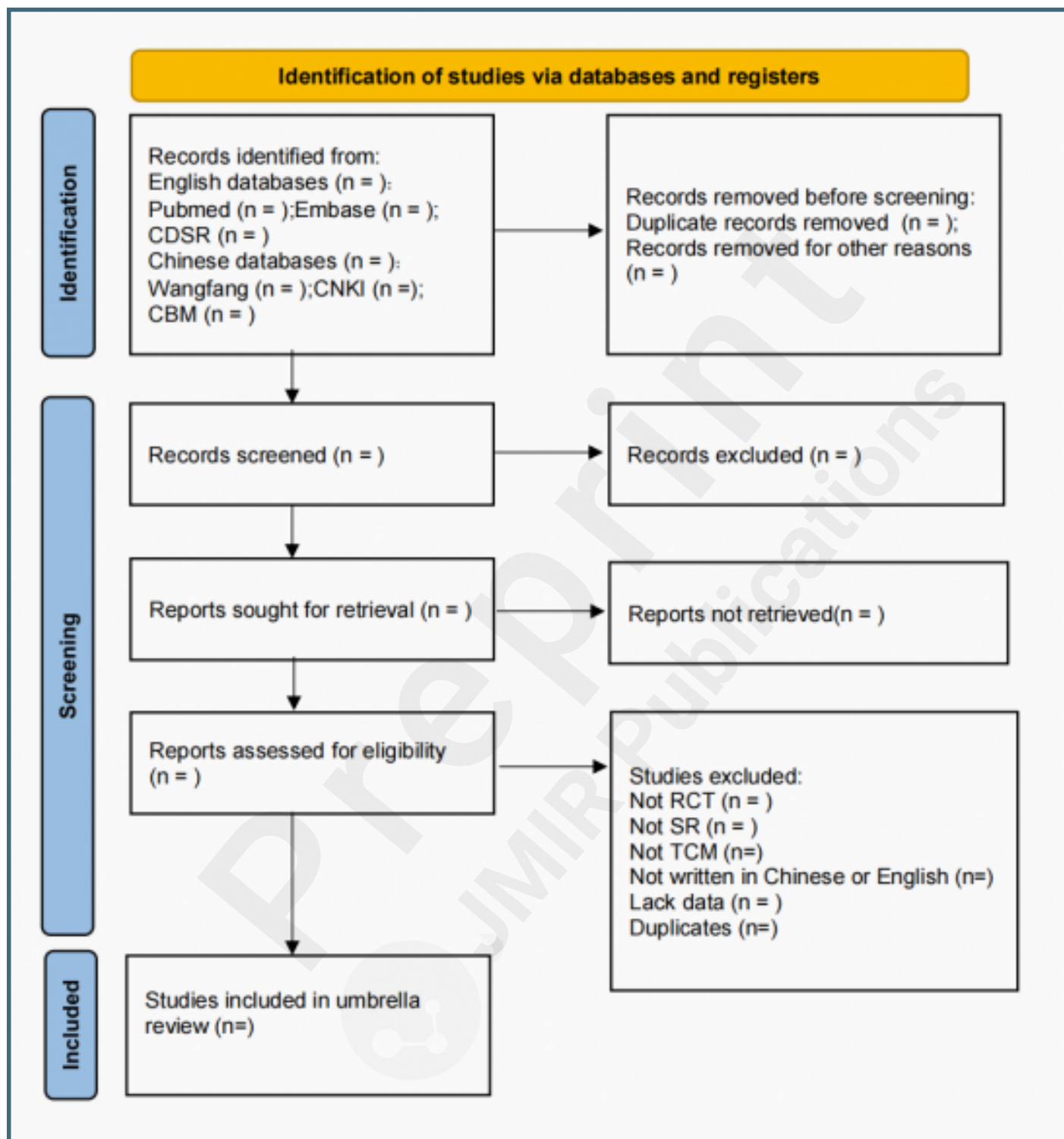
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Supplementary Files

Figures

Identification of studies via databases and registers.



Related publication(s) - for reviewers eyes onlies

PRISMA-P 2015 Checklist.

URL: <http://asset.jmir.pub/assets/2e1f9fc1dbbdba946416f55899c95732.pdf>

