

# INPLASY PROTOCOL

To cite: Liu et al. Efficacy and safety of Ganmai Dazao decoction in the Treatment of Perimenopausal Syndrome: A Systematic Review and Meta-Analysis. Inplasy protocol 202280035. doi: 10.37766/inplasy2022.8.0035

Received: 10 August 2022

Published: 10 August 2022

**Corresponding author:**  
Liu Gengxin

lgxjzzydx@163.com

**Author Affiliation:**  
Jiangxi University of  
Traditional Chinese Medicine.

**Support:** National Natural  
SFoC 81960843.

**Review Stage at time of this  
submission:** Preliminary  
searches.

**Conflicts of interest:**  
None declared.

## Efficacy and safety of Ganmai Dazao decoction in the Treatment of Perimenopausal Syndrome: A Systematic Review and Meta-Analysis

Liu, GX<sup>1</sup>; Zhang, X<sup>2</sup>; Yan, ZY<sup>3</sup>; Zhang, GD<sup>4</sup>; Pi, CH<sup>5</sup>.

**Review question / Objective:** Perimenopause syndrome seriously affects the quality of life of patients and their families. Improving the quality of life of perimenopausal women has been listed as one of the important issues of health in the 21st century. The potential risks and adverse reactions of the currently used hormone replacement therapy are still controversial. Some researchers found that patients treated with HRT suffered from abnormal uterine bleeding, endometrial hyperplasia, Thromboembolic disease, estrogen-progesterone-related malignancy is more likely. Ganmai Dazao Decoction is widely used in the treatment of perimenopausal syndrome in China with good effect and few side effects, this study aimed to evaluate the efficacy and safety of Ganmai Dazao Decoction alone or in combination in the treatment of perimenopausal syndrome. **P:** Patients with perimenopausal syndrome; **Ganmai Dazao Decoction alone or in combination with western medicine or psychotherapy** **C:** Western medicine or psychotherapy **O:** effective rate, Kupperman score, SRHMS score, incidence of adverse reactions **S:** RCT.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 10 August 2022 and was last updated on 10 August 2022 (registration number INPLASY202280035).

### INTRODUCTION

**Review question / Objective:** Perimenopause syndrome seriously affects the quality of life of patients and their families. Improving the quality of life of perimenopausal women has been listed as one of the important issues of health in the

21st century. The potential risks and adverse reactions of the currently used hormone replacement therapy are still controversial. Some researchers found that patients treated with HRT suffered from abnormal uterine bleeding, endometrial hyperplasia, Thromboembolic disease, estrogen-progesterone-related malignancy

is more likely. Ganmai Dazao Decoction is widely used in the treatment of perimenopausal syndrome in China with good effect and few side effects, this study aimed to evaluate the efficacy and safety of Ganmai Dazao Decoction alone or in combination in the treatment of perimenopausal syndrome. P: Patients with perimenopausal syndrome; Ganmai Dazao Decoction alone or in combination with western medicine or psychotherapy C: Western medicine or psychotherapy O: effective rate, Kupperman score, SRHMS score, incidence of adverse reactions S: RCT.

**Condition being studied:** Perimenopause refers to the period before and after menopause in women (from about age 45 to within 12 months after menopause). In some women, during this period, with the decline of ovarian function, decreased levels of sex hormones will lead to a series of clinical syndromes characterized by disorders of the autonomic nervous system and endocrine system. The perimenopausal syndrome. These symptoms seriously affect the quality of life of patients and their families. According to a survey by the World Health Organization, by 2030, the number of perimenopausal women worldwide will grow to 1.2 billion. Improving the quality of life of perimenopausal women has been listed as one of the important issues of health in the 21st century. Currently, hormone replacement therapy (HRT) is a recognized and effective treatment for the disease, especially for vasomotor symptoms. However, the potential risks and adverse reactions of hormone replacement therapy are still controversial. Some researchers have found that patients treated with HRT suffer from abnormal uterine bleeding, higher rates of endometrial hyperplasia, thromboembolic disease, and estrogen-progesterone-related malignancies. Chinese herbal medicine treatment is one of perimenopausal syndrome and complementary and replacement therapy. With its small adverse reactions, multiple targets, the multi-mechanism features play

a unique advantage in the treatment of perimenopausal syndrome. Ganmai Dazao Decoction is an ancient prescription of traditional Chinese medicine. It is widely used in China to treat perimenopausal syndrome with good effect and few side effects. However, no studies have systematically reviewed the evidence for Ganmai Dazao decoction in the treatment of perimenopausal syndrome. Therefore, it is necessary to conduct a systematic review and meta-analysis on the efficacy and safety of Ganmai Dazao Decoction in the treatment of perimenopausal syndrome.

## METHODS

**Search strategy:** The search period was from the establishment of the database to August 2022, and the following databases were searched: PubMed, Embase, Cochrane Central Register of Controlled Trials and four Chinese databases [Wanfang Medical Database, China Biomedical Database, China VIP Database and China National Knowledge Base facility (CNKI)]. The retrieval method adopts the combination of Medical Subject Heading (MeSH) terms and free terms, including "GanMai DaZao decoction", "Menopause", "Climacteric", "Perimenopausal syndrome", "Syndromes", "randomized controlled trial", etc. PubMed search strategy: (((("Climacteric"[Mesh]) OR (((Menopause[Title/Abstract]) OR (Perimenopause[Title/Abstract])) OR (Postmenopause[Title/Abstract])) OR (Premenopause[Title/Abstract] ]))) AND ("Syndrome"[Mesh]) OR (((Syndromes[Title/Abstract]) OR (Symptom Cluster[Title/Abstract])) OR (Clusters[Title/Abstract])) OR (Symptom [Title/Abstract]))) AND ((ganmaidazao) OR (GanMai DaZao decoction)) AND (randomized controlled trial[Publication Type] OR randomized[Title/Abstract] OR placebo[Title/Abstract]).

**Participant or population:** The World Health Organization (WHO) definite diagnostic criteria for patients diagnosed with perimenopausal syndrome. Accompanying symptoms: Menstrual disorders, vasomotor

symptoms (hot flashes, sweating, etc.), autonomic dysfunction symptoms (palpitations, insomnia, etc.), psychoneurological symptoms (depression, etc.), genitourinary symptoms (vaginal dryness, burning sensation, etc.) ), osteoporosis and other E2/FSH are elevated or normal. There are no restrictions on nationality, race, and duration of disease.patients with perimenopausal syndrome.

**Intervention:** Ganmai Dazao Decoction alone or in combination with western medicine orpsychotherapy.

**Comparator:** Western medicine- orpsychotherapy.

**Study designs to be included:** randomised controlled trials.

**Eligibility criteria:** Inclusion criteria: (1) The included literatures are all randomized controlled trials, regardless of whether the randomization method is stated or not, whether allocation concealment is mentioned or not, and blinded.Cohort studies, case-control studies, retrospective studies, reviews, qualitative studies and uncontrolled trials were excluded. There are no restrictions on language and publication time.(2) Patients with a definite diagnosis of perimenopausal syndrome(3) The intervention measures in the experimental group included Ganmai Dazao decoction alone or combined with western medicine or psychotherapy. The intervention in the control group was Western medicine or psychotherapy.(4) Outcome indicators included: total effective rate Kupperman Menopause Index (KMI) score, Self-Rating Health Rating Scale of Mental State (SRHMS) and adverse reactions.Exclusion criteria: (1) Those who do not meet the clinical diagnostic criteria or the diagnosis is not clear; (2) Those whose intervention measures are Ganmai Dazao Decoction combined with other Chinese herbal formulas or Chinese medicine treatment methods (3) Literatures that have been published repeatedly or whose full text cannot be obtained; (4) Non-RCTs such as

reviews, expert comments, and animal experiments; (5) Studies with unreasonable experimental design or inconsistent outcome indicators.(6) Studies that provide incomplete data or data with obvious errors, and the original data cannot be obtained after contacting the authors.

**Information sources:** PubMed, Embase, Cochrane Central Register of Controlled Trials and four Chinese databases [Wanfang Medical Database, China Biomedical Database, China VIP Database and China National Knowledge Infrastructure (CNKI)].

**Main outcome(s):** Efficient.

**Additional outcome(s):** Kupperman Menopause Index (KMI) score, Mental State Self-Rating Health Rating Scale (SRHMS), and Adverse Effects.

**Data management:** Use EndNote x9 software for data deduplication. Extract and check the data, read the title and abstract of the literature strictly according to the inclusion criteria, and further read the full text to finally determine whether to include.

**Quality assessment / Risk of bias analysis:** Cochrane TOOL.

**Strategy of data synthesis:** Meta-analyses were performed using RevMan5.3 software provided by The Cochrane Collaboration (www.cochrane.org). The standardized mean difference (SMD) was selected for continuous variable analysis, and the hazard ratio (OR) was used as the effect size for dichotomous variables, and 95% confidence interval (CI) was used for both. The heterogeneity test was performed on the included RCT literature. If the heterogeneity among the studies was small ( $P \geq 0.1$ ,  $I^2 \leq 50\%$ ), the fixed-effect model was selected; if the heterogeneity among the studies was large, the sources of analysis were After excluding obvious clinical factors or the influence of research heterogeneity, a random effect model was selected for analysis. Obvious clinical heterogeneity was treated by subgroup

---

analysis or sensitivity analysis. When the heterogeneity was too large, only descriptive analysis was performed.

**Subgroup analysis:** Subgroup studies based on patient intervention and control measures or disease duration.

**Sensitivity analysis:** After deleting any one of them, the combined results of the remaining documents are not much different from those when they were not deleted, which means that the sensitivity analysis has passed.

**Country(ies) involved:** China.

**Keywords:** Perimenopause syndrome, Ganmai Dazao decoction, meta-analysis, systematic review.

**Contributions of each author:**

Author 1 - Liu Gengxin.

Email: [lgxjzzydx@163.com](mailto:lgxjzzydx@163.com)

Author 2 - Zhang xing.

Author 3 - Yan Ziyou.

Author 4 - Zhang Gedi.

Author 5 - Pi Chiheng.