

INPLASY PROTOCOL

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None declared.

INTRODUCTION

Review question / Objective: This study aimed to systematically evaluate the safety and efficacy of the method of nourishing yin and quenching the wind in the treatment of PD.

Efficacy and safety evaluation of the treatment of Parkinson's disease by nourishing yin and quenching wind: A protocol for a systematic review and meta-analysis

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Review question / Objective: This study aimed to systematically evaluate the safety and efficacy of the method of nourishing yin and quenching the wind in the treatment of PD.

Eligibility criteria: Inclusion criteria: We included all randomised controlled trials (RCTs) published in Chinese and English on the use of nourishing yin and quenching wind for PD. There is no distinction between age, sex and severity of disease. The primary outcomes will be the unified Parkinson disease rating scale (UPDRS) results and the total effective rate. Exclusion criteria: Others studies such as non-RCTs. The diagnosis of PD is not clear. Low-quality articles and insufficient outcomes in the literature.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 April 2023 and was last updated on 18 April 2023 (registration number INPLASY202340060).

Condition being studied: Parkinson's disease (PD), also known as tremor paralysis, has the fastest growth rate of all neurological diseases included in the 2016 Global Burden of Disease Study (GBD) and is the second most common neurodegenerative disease after Alzheimer's disease. Epidemiological investigation shows that the prevalence of

people over 65 years old in China is 1.7% , and the number of PD in China will account for half of the global total in the future 2030 , and its clinical manifestations are highly heterogeneous , including motor symptoms such as resting tremor, slow to act, muscle stiffness, and posture gait abnormalities, as well as non-motor symptoms such as olfactory loss, sleep disorders, cognitive impairment, mood disorders, and autonomic dysfunction. At present, although the pathogenesis of PD has not yet reached a consensus, studies have shown that abnormal aggregation of α -synuclein , mitochondrial dysfunction , abnormal function of the ubiquitin-proteasome system , autophagy , microbiome-gut-brain axis mechanism , neuroinflammation and other mechanisms are closely related to the pathogenesis of the disease. Conventional drugs for the treatment of PD mainly include compound levodopa, dopamine receptor agonists, monoamine oxidase B-type inhibitors, catechol-O-methyltransferase inhibitors, anticholinergics, and amantadine. Always adhere to "dose titration" to avoid acute adverse reactions of drugs, and strive to achieve the medication principle of "achieving satisfactory clinical results in small doses as much as possible". With the progression of the disease, adverse reactions such as terminal deterioration, open-close phenomenon, and dyskinesia will occur, and the medication should be adjusted according to individual differences to balance the relationship between efficacy and adverse reactions. In recent years, TCM has shown unique advantages in the treatment of PD, with significant efficacy and few adverse reactions.

In TCM theory, PD belongs to the category of "fibrillation". The liver stores blood and tendons, and the kidney stores essence and marrow, and the two can be transformed into each other. If the sperm loses less blood and the tendons and veins are denourished, the tendons are not soft and induce tendon and pulse spasm, and the joint flexion and extension are unfavorable; The lack of yin blood in the liver and kidneys also makes the yang qi unable to submerge, and the liver and yang

are hyperactive, and the limbs tremble and shake. With the deepening of the research of TCM clinicians and researchers, most doctors believe that the cause of liver and kidney self-loss, tendons and veins are denourished; or consumption of hepato-yin kidney jin; or the onset of the wind and internal movement. Traditional Chinese medicine has achieved good clinical results in the treatment of PD by nourishing yin and quenching wind, but the effectiveness and safety of this method have not been systematically evaluated. Based on this research status, this study aims to systematically elucidate the safety and efficacy of the method of nourishing yin and quenching wind in the treatment of PD, in order to provide a new direction for the treatment of PD by integrated traditional Chinese and Western medicine.

METHODS

Search strategy: We will search the following 8 electronic databases in Chinese and English: CNKI, Wanfang Database, China Biomedical Literature Database, PubMed, EMBASE, Scopus, Science Direct, and Web of Science.

Participant or population: Parkinson's disease.

Intervention: The intervention group was treated with the method of nourishing yin and quenching wind (oral Chinese herbal medicines or proprietary Chinese medicines, etc.) on the basis of the control group. The dosage form, dosage and duration of treatment are not limited.

Comparator: Western drug therapy in the control group, including compound levodopa, dopamine receptor agonists, monoamine oxidase B-type inhibitors, catechol-O-methyltransferase inhibitors, anticholinergics, and amantadine, alone or in combination.

Study designs to be included: RCTs.

Eligibility criteria: Inclusion criteria: We included all randomised controlled trials

(RCTs) published in Chinese and English on the use of nourishing yin and quenching wind for PD. There is no distinction between age, sex and severity of disease. The primary outcomes will be the unified Parkinson disease rating scale (UPDRS) results and the total effective rate. Exclusion criteria: Others studies such as non-RCTs. The diagnosis of PD is not clear. Low-quality articles and insufficient outcomes in the literature.

Information sources: Electronic databases.

Main outcome(s): The Primary outcomes included Harmonized Parkinson's Disease Rating Scale (UPDRS) results and overall response rate.

Additional outcome(s): Secondary outcomes included physicochemical tests and occurrence of adverse effects.

Quality assessment / Risk of bias analysis: This study was independently assessed by two study members using the Cochrane risk assessment tool to assess risk of bias and trial quality in the selected literature. The following seven criteria will be assessed: randomized sequence generation; allocation sequence concealment; blinding of participants and personnel; blinding of outcome assessment; incomplete outcome data; selective outcome reporting; other biases. Each item will be assessed according to low risk of bias, high risk of bias, and unclear risk of bias. If any disagreement arises during the evaluation process, it will be resolved in consultation with a third examiner.

Strategy of data synthesis: Two review authors independently searched and screened studies, assessed the quality of the studies. If the discrepancy is large, a third author is requested to intervene, and the retrieved data extract is used in Excel for subsequent analysis. If information is missing from the literature, we will contact the authors. If data are not available in full, then the study will be excluded. Eligible studies were further screened according to

the inclusion criteria. Two review authors extracted the following information: literature information (journal, time of publication, database, language), patient information (sex, age, time of onset), study information (sample size, intervention method, course of treatment), efficacy indicators.

Subgroup analysis: If there were sufficient study data, we would perform subgroup analyses based on duration of treatment, interventions, and outcomes for PD.

Sensitivity analysis: To test the robustness and reliability of meta-analyses, we excluded low-quality studies ($I^2 < 50\%$) for sensitivity analyses.

Country(ies) involved: China.

Keywords: Parkinson's disease, Nourishing Yin, Quenching wind, protocol, Meta-analysis.

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