INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Efficacy of traditional herbal medicine treatment based on pattern identification for idiopathic Parkinson's disease: A protocol for systematic review and meta-analysis

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Review question / Objective: **What is the evidence on the effectiveness by traditional herbal medicines for pattern identification in patient with Parkinson disease?**
Condition being studied: **Parkinson disease is the second-most common neurodegenerative disorder that affects 2–3% of the population ≥65 years of age. A group of neurological disorders with Parkinson disease–like movement problems such as rigidity, slowness, and tremor. Traditional oriental medicine, which is a personalized approach based on pattern identification (PI), has been reported to relieve symptoms, halt disease progression, and improve the quality of life in PD. However, a systematic review of the efficacy of traditional therapies based on PI in PD has not yet been reported.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 October 2021 and was last updated on 07 October 2021 (registration number INPLASY2021100020).

INTRODUCTION

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is a personalized approach based on pattern identification (PI), has been reported to relieve symptoms, halt disease progression, and improve the quality of life in PD. However, a systematic review of the efficacy of traditional therapies based on PI in PD has not yet been reported.

METHODS

Participant or population: Participants in this study will be those diagnosed with idiopathic PD by a physician based on the UK Parkinson's Disease Society Brain Bank Criteria, as well as those treated with traditional herbal medicines based on PI. In addition, patients will be included with no restrictions on other conditions, such as age, sex, country of origin, or severity of symptoms.

Intervention: The interventions will include traditional herbal medications prescribed after PI, regardless of the formulae, form of administration, dosage, frequency, or duration of treatment, in combination with conventional medications, physical therapy, or other therapies, or alone. Only studies with PI and administration of traditional herbal medicine according to the pattern diagnosed will be included.

Comparator: Trials with any type of comparator will be included.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: The searched studies have classified the PI and evaluated the efficacy of traditional medicine for PD, and any type of control intervention will be included. Observational studies, single case reports, literature reviews, re-published research papers, re-cited literature, and other studies that fail to meet the inclusion criteria will be excluded.

Information sources: 1. Database in English: MEDLINE(PubMed), EMBASE, Cochrane Library 2. Database in Korean: KoreaMed, OASIS, KISS 3. Database in Chinese: China National Knowledge Infrastructure [CNKI] and WanFang Data, China Science and Technology Journal Database [VIP], China Biology Medicine disc [CBMdisc]. If missing data are included, we will try to contact the first corresponding authors by email, phone or fax.

Main outcome(s): The primary outcome measure will be Unified Parkinson's Disease Rating Scale (UPDSR).

Quality assessment / Risk of bias analysis: The risk of bias will be accessed following the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions by two independent investigators. If any disagreements occurred, in-depth discussions will be required before reaching a consensus. An assessment of 'high risk', 'low risk' or 'unclear' will be recorded for random sequence generation, allocation concealment, blinding of participants, blinding of personnel, blinding of caregivers, blinding of outcome assessors, incomplete outcome data and selective outcome reporting.

Strategy of data synthesis: All primary and secondary outcome measures will be combined and analyzed for evidence of homogeneity ($p>0.1$) using a random-effects model. Dichotomous results will be expressed as relative risk with 95% CI. For continuous variables, mean difference or standard mean difference, the difference between the treatment and control pooled means at the end points and their 95% CIs will be calculated. A random-effects model will be used if there is substantial statistical heterogeneity (I^2 >50%). A narrative synthesis will be provided if the meta-analysis cannot be performed for all or some of the expected data from the included studies.

Subgroup analysis: If enough trials are identified, subgroups of different types of symptoms in PD will be analyzed separately (e.g. tremor).

Sensitivity analysis: If there is high-quality methodology, sufficient sample size, and low heterogeneity, a sensitivity analysis will

be carried out to analyze the robustness of the study.

Language: English, Chinese and Korean.

Country(ies) involved: China and Korea.

Keywords: Study protocol, Meta-analysis, Neurodegenerative disease, Parkinson's disease, Systematic review, Traditional herbal medicine.

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