# INPLASY PROTOCOL

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Support: None.

Review Stage at time of this submission: The review has not yet started.

Conflicts of interest: None declared.

# Efficacy and safety of acupuncture combined with laxatives on constipation in Parkinson's patients: A protocol for systematic review and meta-analysis

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Review question / Objective: To evaluate the curative effect of acupuncture combined with laxatives on constipation in PD patients. And provide the latest evidence of evidence-based medicine for the clinical treatment of constipation in PD patients.

Condition being studied: Parkinson's disease (PD) is a common neurological disease with clinical manifestations such as resting tremor, muscle rigidity, and retardation of movement, as well as non-motor symptoms such as constipation and sleep disturbance. PD functional constipation is the most common and accompanies the entire pathogenesis of PD. Common clinical treatment methods are mainly osmotic laxatives and gastrointestinal motility drugs. Acupuncture can relieve symptoms of constipation. This study aims to systematically study the efficacy and safety of acupuncture combined with laxatives on constipation in patients with PD.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 June 2021 and was last updated on 17 June 2021 (registration number INPLASY202160055).

### INTRODUCTION

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PD. Common clinical treatment methods are mainly osmotic laxatives and gastrointestinal motility drugs. Acupuncture can relieve symptoms of constipation. This study aims to systematically study the efficacy and safety of acupuncture combined with laxatives on constipation in patients with PD.

### **METHODS**

Participant or population: All patients included in the study were diagnosed with PD with constipation, regardless of age, gender, race, and disease course.

Intervention: The treatment plan is acupuncture combined with laxatives. Acupuncture treatment includes all types, such as electric acupuncture, fire acupuncture, warm acupuncture, body acupuncture and so on.

Comparator: Conventional laxative treatment.

Study designs to be included: RCT.

Eligibility criteria: 1. All RCTs of acupuncture combined with laxatives in the treatment of constipation in PD patients, whether blinded or unblinded. 2. All patients included in the study were diagnosed with PD with constipation, regardless of age, gender, race, and disease course. 3. The treatment plan is acupuncture combined with laxatives.

Information sources: The English databases include PubMed, Embase, Web of Science, Cochrane Library, and Chinese databases include China National Knowledge Infrastructure (CNKI), Wanfang Data, VIP Database (VIP), China Biomedical Literature (CBM). From the establishment of the database to June, 2021. The key words include "acupuncture", "body acupuncture", "electro-acupuncture", "warm acupuncture", "auricular acupuncture", "laxative", "Parkinson's Disease", "constipation". In addition, we will also retrieve ongoing or unpublished trials from the International Clinical Trial

Registration Platform and Chinese Clinical Trial Registry Platform.

Main outcome(s): The main outcome indicator was constipation patients quality of life scale, (PAC-QOL).

Additional outcome(s): The secondary outcome indicators were Parkinson's patients quality of life questionnaire, (PDQ39) and adverse reactions.

Quality assessment / Risk of bias analysis:

Two reviewers will use Cochrane collaborative tools to evaluate the quality of the literature. It includes the following 7 domains: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other sources of bias. Each domain includes a judgment of low, high and unclear risk of bias according to information provided by authors. Disagreements between reviewers will be resolved through discussion with a third reviewer.

Strategy of data synthesis: For continuous data, will be used mean difference (MD) as the effect indicator with 95% confidence interval, and dichotomous data will be calculated as risk ratio (RR) or odds ratio (OR) as the effect index with 95% confidence interval. If the studies with no statistical homogeneity, the fixed-effect model can be used for analysis; if the studies with significant statistical heterogeneity, random effects model analysis will be used. The Review Manager (RevMan) V.5.3 software will be used for statistical analysis.

Subgroup analysis: Subgroup analysis will be performed if there have heterogeneity between the study results, following items will be considered: type of acupuncture, cancer stage, gender, age.

Sensitivity analysis: We will eliminate the "high-risk" low-quality articles for sensitivity analysis to judge the robustness of the results.

## Country(ies) involved: China.

**Keywords:** acupuncture, Parkinson's disease, constipation, protocol, systematic review.

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