INPLASY PROTOCOL

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Review Stage at time of this submission: Piloting of the study selection process.

Conflicts of interest: None declared.

Does Acupuncture Improve Mental Disorders in Parkinson's Disease? A Protocol for Systematic Review and Meta-Analysis

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Review question / Objective: This work is dedicated to evaluate efficacy and safety of acupuncture treatment for PD-related mental disorders, and to provide reliable findings for decision makers.

Condition being studied: Parkinson's disease (PD) is the neurodegenerative disease with the second highest incidence. PD-related Mental disorders are common nonmotor symptoms among PD, which have negative impact on the quality of daily life.

Information sources: We will search the following databases for relevant literature: PubMed (MEDLINE), Embase, Web of Science (WOS), Cochrane Central Register of Controlled Trials (CENTRAL), Allied and Alternative Medicine (AMED), CINAHL Plus with Full Text, China National Knowledge Infrastructure (CNKI), China Biology Medicine (CMB), VIP Database and Wanfang Database from database inception to April 2021.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 May 2021 and was last updated on 12 May 2021 (registration number INPLASY202150043).

INTRODUCTION

Review question / Objective: This work is dedicated to evaluate efficacy and safety of acupuncture treatment for PD-related

mental disorders, and to provide reliable findings for decision makers.

Condition being studied: Parkinson's disease (PD) is the neurodegenerative disease with the second highest incidence.

PD-related Mental disorders are common nonmotor symptoms among PD, which have negative impact on the quality of daily life.

METHODS

Participant or population: The patient was first diagnosed with PD and then have manifestations of mental disorders will be included.

Intervention: The acupuncture treatments, include manual acupuncture, electroacupuncture, scalp acupuncture and acupoint catgut embedding, will be included.

Comparator: The control group includes sham acupuncture, placebo, or routine care.

Study designs to be included: We will include randomized control trials of acupuncture therapy for PD-related Mental Disorders reported in English or Chinese.

Eligibility criteria: We will include randomized control trials of acupuncture therapy for PD-related Mental Disorders reported in English or Chinese. Non-randomized controlled trial, cohort, case reports, laboratory studies and animal researches will be excluded.

Information sources: We will search the following databases for relevant literature: PubMed (MEDLINE), Embase, Web of Science (WOS), Cochrane Central Register of Controlled Trials (CENTRAL), Allied and Alternative Medicine (AMED), CINAHL Plus with Full Text, China National Knowledge Infrastructure (CNKI), China Biology Medicine (CMB), VIP Database and Wanfang Database from database inception to April 2021.

Main outcome(s): The primary outcomes include the Unified Parkinson's Disease Rating Scale (UPDRS), Beck Depression Inventory (BDI), Hamilton Depression Scale (HAMD), Beck Anxiety Inventory (BAI), Hamilton Anxiety Scale (HAMA), Schedule

Assessment for Positive Symptoms (SAPS) and Neuropsychiatric Inventory (NPI).

Quality assessment / Risk of bias analysis: Risk of bias assessment will be conducted using the new 'Risk of bias' tool from Cochrane Handbook for Systematic Reviews of Interventions V6.0.

Strategy of data synthesis: We will perform data synthesis through RevMan V5.4. Firstly, the effect size and its 95% confidence interval (CI) of each study will be calculated. Then, we select the appropriate statistical model according to the type of data (dichotomous data or continuous data) and heterogeneity. When the data meets the homogeneity, the fixed effect model will be selected, otherwise the random effect model will be used. If there is considerable heterogeneity or there is no RCT included, we will not perform meta-analysis.

Subgroup analysis: We will conduct subgroup analysis for different types of PD-related mental disorders: 1. Depression; 2. Anxiety; 3. Hallucinations. In addition, for the purpose of comparing subset of participants (such as different ages, different gender and different severity), Subgroup analysis will be performed when necessary.

Sensitivity analysis: Sensitivity analysis will be performed to describe whether conclusions are robust to decisions made in the process of systematic review.

Country(ies) involved: China.

Keywords: Parkinson disease; Acupuncture therapy; Mental disorders; Depression; Anxiety; Hallucinations.

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