

Efficacy and Safety of Diankuang Mengxing Decoction Combined with Conventional Western Medicine in the Treatment of Schizophrenia: a Meta-analysis of randomized controlled trials

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ADMINISTRATIVE INFORMATION

Support - National Key R&D Programme Project.**Review Stage at time of this submission** - Piloting of the study selection process.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY202430006**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 March 2024 and was last updated on 01 March 2024.

INTRODUCTION

Review question / Objective To systematically evaluate the efficacy and safety of Diankuang Mengxing Decoction combined with conventional western medicine in the treatment of Schizophrenia.

Condition being studied Schizophrenia is a group of mental disorders characterised by marked positive symptoms, negative symptoms, psychomotor disorders and severely impaired reality-testing abilities. According to a cross-sectional epidemiological study, as of 2015, the December prevalence of mental disorders in 31 provinces (municipalities and autonomous regions) in China was 9.3%, and the lifetime prevalence was 16.6%, of which the December prevalence and lifetime prevalence of schizophrenia was 0.6%, and fewer than 1% of the patients received adequate treatment. Mental disorders, including schizophrenia, impose a very serious economic and mental burden on patients and their families, and give rise to many serious social problems.

METHODS

Search strategy PubMed (MEDLINE), the Cochrane Central Register of Controlled Trials (CENTRAL), Web of Science and Chinese language literature: China National Knowledge Infrastructure(CNKI), Wanfang Data Knowledge Service Platform, Weipu and Sinomed.

Participant or population Adults with schizophrenia (as diagnosed by a clinician, or using any recognized diagnostic criteria) will be included.

Intervention Patients taking Diankuang Mengxing Decoction combined with conventional western medicine.

Comparator Patients taking conventional western medicine.

Study designs to be included Randomized controlled trials (RCTs) will be included.

Eligibility criteria Studies were included if they fulfilled the following inclusion criteria:a) Reported data on schizophrenia as the primary diagnosis;b) Patients were diagnosed according to standardized diagnostic criteria (ICD, DSM or equivalent);c) Randomized controlled trials included experimental group and control group.Studies were excluded if:a) They did not include schizophrenia-specific data;b) They did not provide information on diagnostic procedures;c) They were case reports or small case series.

Information sources Electronic databases: PubMed (MEDLINE), the Cochrane Central Register of Controlled Trials (CENTRAL) , Web of Science and Chinese language literature: China National Knowledge Infrastructure (CNKI, Wanfang Data Knowledge Service Platform, Weipu and Sinomed. contact with authors: 18810075677@163.com; 20185101@bucm.edu.cn.

Main outcome(s) Total clinical effective rate; total adverse reaction; total PANSS score.

Additional outcome(s) PANSS positive symptom score; PANSS negative symptom score; psychopathology score.

Quality assessment / Risk of bias analysis Two reviewers will independently assess risk of bias based on the following domains from recommendations from the Cochrane handbook: 1. Adequate sequence generation; 2. Allocation concealment; 3. Blinding; 4. Incomplete outcome data and how it was addressed; 5. Selective reporting of the outcome; 6. Any other biases. results of bias assessment will be presented in a figure and a graph indicating low, high or unclear risk of bias for each of the 6 items in each trial. Sensitivity analysis will be conducted based on the bias assessment to assess robustness of results.

Strategy of data synthesis Two reviewers will independently assess risk of bias based on the following domains from recommendations from the Cochrane handbook: 1. Adequate sequence generation; 2. Allocation concealment; 3. Blinding; 4. Incomplete outcome data and how it was addressed; 5. Selective reporting of the outcome; 6. Any other biases. results of bias assessment will be presented in a figure and a graph indicating low, high or unclear risk of bias for each of the 6 items in each trial. Sensitivity analysis will be conducted based on the bias assessment to assess robustness of results.

Subgroup analysis Subgroups: treatment for the course; Western medicine treatment in the control

group Treatment for the course 4 weeks, 8 weeks, 12 weeks; Western medicine treatment for risperidone, olanzapine, clozapine, etc.

Sensitivity analysis Sensitivity analysis will be conducted based on the bias assessment to assess robustness of results.

Country(ies) involved China.

Keywords Diankuang Mengxing Decoction; Schizophrenia; Randomized controlled trial; Meta-analysis.

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