INPLASY PROTOCOL

Art therapy as a complementary therapy for schizophrenia: a meta-analysis of randomized controlled trials following the PRISMA guidelines

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Review Stage at time of this submission: Preliminary searches.

Review question / Objective: How are the effects of art therapy on schizophrenia?

Condition being studied: Schizophrenia is a chronic and severely disabling mental disorder that is associated with impairments in cognitive, emotional and psychosocial functioning affecting the prospect of recovery. (Jablensky, 2010; Leucht, 2014).

Information sources: A comprehensive literature search will be carried out by two independent researchers (XX Luo and J Wang). Published studies will be retrieved in common databases including PubMed, Web of Science, ClinicalTrials.gov, Cochrane Library, Embase, China National Knowledge Infrastructure(CNKI), Wanfang Databases, the Chinese Scientific Journal Database, the Chinese Science Citation Database, and the Chinese Biomedical Literature Database from inception to May 30, 2022. In addition, we will search and evaluate the relevant systematic reviews and meta-analyses to select the potential studies from their references. No trial is excluded due to publication status or language.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 May 2022 and was last updated on 15 May 2022 (registration number INPLASY202250099).

INTRODUCTION

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METHODS

Search strategy: The search details will be conducted as follows (English database): {("art therapy" [MeSH] OR "color therapy" [MeSH] OR "dance therapy" [MeSH] OR "music therapy" OR "play therapy"

[MeSH]) AND ("schizophrenia, schizophrenias" [MeSH] OR "Schizophrenic Disorders" [MeSH]OR "Schizophrenic Disorder" [MeSH]OR "Disorders, Schizophrenic" [MeSH] OR "Disorder, Schizophrenic" [MeSH])}. For Chinese databases, the following keywords will be used in combined ways: ["yishu zhiliao(art therapy)" OR "yanse liaofa(color therapy)" OR "wudao liaofa(dance therapy)" OR"yinyue liaofa(music therapy)" OR"youxi liaofa(play therapy)" AND ["jingshenfenliezheng (schizophrenia)" OR"xijueshitiaozheng (schizophrenia)"].

Participant or population: Inclusion criteria The subjects included in this study should meet all the criteria as below: A formal diagnosis of schizophrenia, no restrictions on the gender, age, ethnicity and disease course, the diagnosis of schizophrenia conforms to the Chinese Classification and Diagnostic Criteria for Mental Disorders 3rd edition (CCMD-3) or CCMD-2 or ICD-10, and the 5th edition of the American Diagnostic and Statistical Manual of Mental (Disorders Diagnostic and Statistical Manual of Mental Disorders, DSM-V) and other diagnostic criteria; art therapy adjunctive interventions must comply with the British Association of Art Therapists definition; an intervention of art therapy, both individual or group, which could also include variations, e.g., color therapy , dance therapy, music therapy, color therapy, play therapy; reporting means, standard deviation and sample size for a measure of negative symptoms, e.g, Positive and Negative Syndrome Scale (PANSS), Global Assessment Function (GAF), Self-Esteem Scale (SES), and the Functional Remission of General Schizophrenia (FROGS). Exclusion criteria The trials were not RCTs; the sample size of either group was less than 30 patients; the diagnosis was not schizophrenia; the trials in which baseline data of the participants were inconsistent; there were no relevant outcome measures; unavailable full-text or unextractable data.

Intervention: Art therapy combined with standardized treatment.

Comparator: Standardized treatment only.

Study designs to be included: All randomized controlled trials comparing art therapy combined with standardized treatment versus standardized treatment alone will be selected and assessed for inclusion in our research.

Eligibility criteria: The subjects included in this study should meet all the criteria as below: A formal diagnosis of schizophrenia, no restrictions on the gender, age, ethnicity and disease course, the diagnosis of schizophrenia conforms to the Chinese Classification and Diagnostic Criteria for Mental Disorders 3rd edition (CCMD-3) or CCMD-2 or ICD-10, and the 5th edition of the American Diagnostic and Statistical Manual of Mental (Disorders Diagnostic and Statistical Manual of Mental Disorders, DSM-V) and other diagnostic criteria; art therapy adjunctive interventions must comply with the British Association of Art Therapists definition; an intervention of art therapy, both individual or group, which could also include variations, e.g., color therapy , dance therapy, music therapy, color therapy, play therapy; reporting means, standard deviation and sample size for a measure of negative symptoms, e.g, Positive and Negative Syndrome Scale (PANSS), Global Assessment Function (GAF), Self-Esteem Scale (SES), and the Functional Remission of General Schizophrenia (FROGS).

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excluded due to publication status or language.

Main outcome(s): Mental health symptoms are the primary outcome.

Additional outcome(s): Global functioning, quality of life(QOL), functional remission, and the level of self-esteem were defined as secondary outcomes.

Data management: Endnote 20, Review Manager (RM) 5.3 (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014), Comprehensive Meta-Analysis (CMA) 3.0 (Biostat, Englewood, NJ, United States; 2016), and Trial Sequential Analysis (TSA) software (Copenhagen Trial Unit, Center for Clinical Intervention Research, Copenhagen, Denmark; 2011)Review manager 5.3, Comprehensive Meta-Analysis (CMA) 3.0.

Quality assessment / Risk of bias analysis: Two independent reviewers (XX Luo and J Wang) will appraise the risk of bias in the included trials using the Cochrane Risk of Bias Tool for Randomized Controlled Trials (Miller, et al., 1981). The following criteria will be used to evaluate bias in each trial: random sequence generation; concealment of allocation; blinding of participants and personnel; blinding of outcome assessment; incomplete data; selective reporting; and other biases. The risk of bias is classified as 'unclear','low' or 'high'.

Strategy of data synthesis: A quantitative synthesis will be used if the included studies are sufficiently homogenous. All analyses will be performed using Review Manager (RM) 5.3 (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014), Comprehensive Meta-Analysis (CMA) 3.0 (Biostat, Englewood, NJ, United States; 2016), and Trial Sequential Analysis (TSA) software (Copenhagen Trial Unit, Center for Clinical Intervention Research, Copenhagen, Denmark; 2011). Dichotomous data will be shown as risk ratio (RR), Risk difference (RD) or odds ratio (OR), and continuous data as weighted mean difference (WMD), or standardized mean difference (SMD),

with their 95% confidence intervals (CI), respectively. I^2 statistic and χ^2 test will be used to assess statistical heterogeneity. Substantial heterogeneity will be considered to exist when $I^2 > 50\%$ or $P < 0.05$. If the hypothesis of homogeneity is not rejected, a fixed-effects model will be used to estimate the summary RR (or OR, RD), WMD (or SMD) and 95% CI, otherwise a random-effects model will be applied.

Subgroup analysis: None planned.

Sensitivity analysis: Sensitivity analyses based on the methodologic quality, statistical method, excluded studies, etc., need to conducting to examine the robustness of the results.

Language: No restriction.

Country(ies) involved: China.

Keywords: schizophrenia, art therapy, complementary therapy, meta-analysis, systematic review.

Contributions of each author:
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