# INPLASY PROTOCOL

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## Music intervention affects the quality of life on Alzheimer's disease: a metaanalysis

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Review guestion / Objective: Inclusion criteria: population: 1) A randomized controlled study on the impact of music intervention on the QOL of patients with AD; 2) The participants in this study is patients with AD; 3) There is no significant difference among age, gender and education background in sorted groups before analysis which make these groups comparable; intervention: 1)Intervention Modality Music-based intervention; comparison: 1) All data were sorted into two groups: the music intervention group and the control group without any music intervention; outcome: 1) The indicators evaluated in the literature included the score of QOL-AD or WHOQOL-BERF scale, at least one of the two scales summarized in selected publications; language: 1) Only articles published in English and Chinese were considered. Exclusion criteria: 1) The participants were not diagnosed with AD; 2) Non-musical intervention;3) Non-RCTs; 4) No specific values for outcome variables; 5) Articles lacking original data; 6) Repeat published reports; 7) Full text could not be obtained.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 11 December 2021 and was last updated on 11 December 2021 (registration number INPLASY2021120055).

### **INTRODUCTION**

**Review question / Objective:** Inclusion criteria: population: 1) A randomized controlled study on the impact of music intervention on the QOL of patients with AD; 2) The participants in this study is patients with AD; 3) There is no significant difference among age, gender and education background in sorted groups before analysis which make these groups comparable; intervention: 1)Intervention Modality Music-based intervention; comparison: 1) All data were sorted into two groups: the music intervention group and the control group without any music intervention; outcome: 1) The indicators evaluated in the literature included the score of QOL-AD or WHOQOL-BERF scale, at least one of the two scales summarized in selected publications; language: 1) Only articles published in English and Chinese were considered.Exclusion criteria: 1) The participants were not diagnosed with AD; 2) Non-musical intervention;3) Non-RCTs; 4) No specific values for outcome variables; 5) Articles lacking original data; 6) Repeat published reports; 7) Full text could not be obtained.

Rationale: Alzheimer's disease (AD) is a neurodegenerative disease which frequently occurs in the elderly population . It accounts for most of dementia cases (~60-70%) worldwide. AD-related pathologies include abnormal deposition of  $\beta$ -amyloid (A $\beta$ ), formation of senile plaques and neurofibrillary tangles in brain. Its clinical manifestations are severe defects in cognition, such as memory, sensory and motor functions . Motor dysfunction is characterized by slow walking, great gait variability, impaired balance and postural control, and deteriorated fine motor control in AD patients . These symptoms have clearly reduced the quality of life of AD patients. So far there is no effective cure for the disease, however it is urgent needed to develop effective treatment methods, or prevention strategies to prolong the progression of AD. The clinical situation of AD patient is one of the main factors affecting the quality of life. The World Health Organization (WHO) defined Quality of life as "individual's perception of their position in life in the context of culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns". Improving the quality of life in AD is important for patients, caregivers and health care professions. QOL mainly refers to the assessment of the status of an individual's physical, psychological, and social functions .Previous studies indicated that the cognitive impairment in elderly chronic diseases is a determinant of poor QOL. The relationship between quality of life and mortality is time dependent. A decrease in quality of life may increase the risk of mortality, therefore the quality of life would be used as a predictor of mortality. The

QOL has been accepted as an indicator for the evaluation for AD treatment because it can indicate the processing of AD, activactivities of daily living and achievement under treatment. Reduced QOL, may have serious impacts on the psychological, physical, behavioral, and social levels of an individual.

**Condition being studied: Music intervention** has been found to be beneficial for neurological diseases, especially in slowing down the progression of clinical symptom in patients. However, it remains unclear to what extend can music intervention may affect patients with Alzheimer's disease (AD). To our best knowledge, there is no work conducted by systematic review and meta-analyses on the improvement of QOL by music intervention in AD patients previously. To clarify whether music intervention is an effective intervention contribute to improve the QOL of patients with AD, we employed a detailed search strategy to comprehensively summarize Chinese and internationally published literatures, and the impact of music intervention on the QOL in AD patients were analyzed.

### **METHODS**

Search strategy: To our best knowledge, there is no work conducted by systematic review and meta-analyses on the improvement of QOL by music intervention in AD patients previously. To clarify whether music intervention is an effective intervention contribute to improve the QOL of patients with AD, we employed a detailed search strategy to comprehensively summarize Chinese and internationally published literatures, and the impact of music intervention on the QOL in AD patients were analyzed.

Participant or population: The participants in this study is patients with AD.

Intervention: Music-based intervention.

**Comparator:** Interactive; Passive.

Study designs to be included: 1) A randomized controlled study on the impact of music intervention on the QOL of patients with AD.

Eligibility criteria: Inclusion criteria: population: 1) A randomized controlled study on the impact of music intervention on the QOL of patients with AD; 2) The participants in this study is patients with AD: 3) There is no significant difference among age, gender and education background in sorted groups before analysis which make these groups comparable; intervention: 1)Intervention Modality Music-based intervention; comparison: 1) All data were sorted into two groups: the music intervention group and the control group without any music intervention; outcome: 1) The indicators evaluated in the literature included the score of QOL-AD or WHOQOL-BERF scale, at least one of the two scales summarized in selected publications; language: 1) Only articles published in English and Chinese were considered.

Information sources: PubMed, the Cochrane Library, and Wanfang Database, were systematically searched from January 1986 to March 2021. The search was performed parallel by author LYZ and FTZ.If not, sought a third person's opinion. Key words including "cognitive impairment", "mild cognitive impairment", "Alzheimer's disease", "music intervention", "Music therapy", "music listening", "musical instrument", "music performance", "musical rhythms", "randomized controlled trial", "clinical trial" and "clinical study" were searched and an updated final repeat search was carried out on 24 March 2021.

Main outcome(s): Our initial literature search yielded 298 unique recordings, 255 articles were extracted after duplicates were removed, and there were 32 records left after screening of the titles and abstracts. There are 6 studies (396 patients) with full text were eligible and included in these meta-analyses, The detailed screening process is shown in the flow chart in Figure.1. Quality assessment / Risk of bias analysis: The Cochrane's Risk of Bias tool was used to evaluate the quality of collected studies. A total of 7 domains were counted in these studies such as random sequence generation, allocation concealment, masking of participants and personal, masking of outcome assessment, incomplete outcome data, selective reporting, and other biases. These domains were classified as high, unclear, and low risk of bias. Low risk of bias means that it has little effect on the results of our study and high degree of risk of bias indicates that it will greatly affect the results in this study. Unclear-bias risk implies potential risks.

Strategy of data synthesis: A standardized template was used to extract data by two independent reviewers to show the population characteristics (The diagnosis was made according to the National Institute of Neurological and **Communicative Disorders and Stroke and** the Alzheimer's Disease and Related **Disorders Association (NINCDS-ADRDA)** criteria, Diagnostic and Statistical Manual of Mental Disorders (DSM-V) criteria, International Classification of diseases (ICD-10) criteria and in combination with clinical symptoms, medical history, neurological physical examination, neuropsychological scale test results (CERAD) and pathological scoring scale (BEHAVE-AD); The AD patients included in the study (early-onset AD and late-onset AD) were elderly between 55 and 97 years of age)and the outcomes, and the name of the first author, region, year of publication, clinical study design, study participants, intervention modalities, intervention period, and outcome measurement were included. Meta-analysis was performed by using RevMan software (Version 5.3; Cochrane Collaboration, Oxford, England). Heterogeneity test was conducted for the filtration of collected studies and P50% and random effect model should be used.

Subgroup analysis: We here adopted two scales as outcome measures: Quality of Life in Alzheimer's Disease (QoL-AD) and The World Health Organization Quality of Life (WHOQOL)-BREF.

Sensitivity analysis: There are various forms of music intervention, and it is believed that each individual would find a suitable music mode for their characterized treatment and this patient management strategy might great possibly contribute to improve the QOL in AD patients.

Country(ies) involved: China.

Keywords: Alzheimer's disease, music intervention, quality of life, meta-analysis, neurological diseases.

#### Contributions of each author:

Author 1 - Lingyan Zuo wrote the manuscript. Email: 784805276@qq.com Author 2 - Fengting Zhu wrote the manuscript. Email: 763719204@qq.com Author 3 - Rui Wang analyzed the data revised the manuscript. Email: rui.wang@ki.se Author 4 - Hongyan Shuai conceived the idea and revised the manuscript. Email: shuaihy@live.com Author 5 - Xin Yu. Email: dalahu.cool@qq.com