INPLASY PROTOCOL

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Conflicts of interest:
The authors have declared that no conflicts of interest exists.

Whether cognitive behavioral therapy is effective for Alzheimer's disease: a protocol for systematic review and network meta-analysis

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Review question / Objective: **Through the implementation of cognitive behavioral intervention for patients with Alzheimer's disease, we will observe whether their cognitive ability has improved.**
Condition being studied: **Alzheimer's disease (AD) is a progressive neurodegenerative disease characterized by impaired memory and cognitive judgment. It is the leading cause of dementia in the elderly, and its high morbidity and mortality have also brought a significant social burden. So far, there is no method can completely cure Alzheimer's dementia, but there are many non-drug treatments that have been praised by people, especially the cognitive behavioral therapy proposed in recent years. The main purpose of this review is to evaluate the effect of cognitive behavioral therapy on the cognitive function improvement of patients with Alzheimer's dementia.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 13 November 2020 and was last updated on 13 November 2020 (registration number INPLASY2020110052).

INTRODUCTION

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METHODS

Participant or population: Elderly people with Alzheimer's disease. There were no restrictions on age, gender or race.

Intervention: Placebo; CS; AMT; NE; usual standard clinical care; CD; PT and CTRL.

Comparator: Cognitive behavioral therapy.

Study designs to be included: RCTs that explored cognitive behavioral therapy for Alzheimer's disease will be included.

Eligibility criteria: (1) Patients: Elderly people with Alzheimer's disease. There were no restrictions on age, gender or race; Alzheimer's disease without other organic diseases. (2) Intervention: Non-drug treatment. (3) Comparator: Cognitive behavioral therapy. (4) Outcome: Primary outcome measures such as MMSE and ADAS-cog. (5) Studies that their full text was available. (6) Language is English.

Information sources: We will search PubMed, the Cochrane Library, EMBASE and Web of Science for clinical randomized controlled trials investigating the cognitive behavioral therapy in patients with Alzheimer's disease, published up to date. Reference lists of articles, grey literature, and conference proceedings will also be searched. Languages of the publications will be limited to English.

Main outcome(s): MMSE and ADAS-cog scores served as dependent measures. The MMSE score is widely used as a parameter to identify a clinically significant decline in cognitive function in AD. The ADAS-Cog consists of 11 tasks measuring the disturbances of memory, language, praxis, attention and other cognitive abilities which are often referred to as the core symptoms of AD. Quality of life is measured using the Quality of Life--Alzheimer's disease Scale. The QOL-AD covers 13 domains of quality of life. The Beck Depression Inventory (BDI), State Trait Anxiety Inventory (STAI Y-1, STAI Y-2) and Lubben Social Network Scale (LSNS) assessed anxiety, depression, and social relationships. Higher scores indicated worse anxiety and depression or more frequent social relationships.

Quality assessment / Risk of bias analysis: Two reviewers will independently assess each included RCT by using the Assessment of Multiple Systematic Reviews-2 (AMSTAR-2) measurement tool and the (PRISMA) statement, for rigorous methodological quality and reporting quality . The ADDIS software and STATA 15.0 were used to analyses data. We used a random-effects model to analyze the effect sizes in this study.

Strategy of data synthesis: We conducted the pair-wise meta-analysis with the fixed-effects model with STATA software (STATA 15.0). The odds ratio (OR) was calculated for dichotomous outcomes (compliance), with 95% credible intervals (CI). We assessed statistical heterogeneity in the pair-wise comparison with an I2 statistic and the p-value. We will use the Grading of Recommendations Assessment, Development and Evaluation (GRADE) to assess the quality of evidence, these five considerations (study limitations, consistency of effect, imprecision, indirectness, and publication bias) will be applied to assess the quality of evidence. It is categorized into four levels: high level, moderate level, low level, and very low level.

Subgroup analysis: If there is significant heterogeneity in the included trials, subgroup analysis will be carried out. According to subject characteristics (e.g., age, gender, and so on), subgroup analysis will be carried out according to the data retrieved.

Sensibility analysis: If there is still significant heterogeneity in the included trials after subgroup analysis, Sensitivity analysis will be performed to assist exploring the source of heterogeneity. It will be carried out by deleting each study at a time, and other studies will be analyzed to estimate whether a single study would have a significant impact on the results.

Country(ies) involved: China.

Keywords: Alzheimer's disease; cognitive behavioral therapy; randomized controlled trials.

Contributions of each author:
Author 1 - Wan-Qiang Chen - conceived the study, developed the criteria, will draft the protocol and revise the manuscript.
Author 2 - Fang-Fang Wu - conceived the study, developed the criteria, designed the inclusion/exclusion criteria and the searching strategy, will search the literature, and analyze the data; draft the protocol and revise the manuscript.
Author 3 - Hong-Bo Lv - designed the inclusion/exclusion criteria and the searching strategy, will draft the protocol and revise the manuscript.
Author 4 - Wen-Ting Xing - will search for the literature and analyze the data.
Author 5 - Qi Liu - will extract and analyze the data.
Author 6 - Jun-Ping Liu - will design a data extraction table and extract the data.
Author 7 - Yong-Gui Ge - will extract and analyze the data.
Author 8 - Ya-Qin Lu - conceived the study, developed the criteria, will draft the protocol and revise the manuscript.