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The Evaluation of the Cognitive Training Program for Older Adults with Mild Cognitive Impairment: Protocol of a Randomized Controlled Study

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Abstract : Background: Studies show that cognitive training can effectively delay cognitive failure. However, there are several gaps in the previous studies of cognitive training in mild cognitive impairment: 1) previous studies enrolled mostly healthy older adults, with few recruiting older adults with cognitive impairment; 2) they also had limited generalizability and lacked long-term follow-up data and measurements of the activities of daily living functional impact. Moreover, only 37% were randomized controlled trials (RCT). 3) Limited cognitive training has been specifically developed for mild cognitive impairment. Objective: This study sought to investigate the changes in cognitive function, activities of daily living and degree of depressive symptoms in older adults with mild cognitive impairment after cognitive training. Methods: This double-blind randomized controlled study has a 2-arm parallel group design. Study subjects are older adults diagnosed with mild cognitive impairment in residential care facilities. 124 subjects will be randomized by the permuted block randomization, into intervention group (Cognitive training, CT), or active control group (Passive information activities, PIA). Therapeutic adherence, sample attrition rate, medication compliance and adverse events will be monitored during the study period, and missing data analyzed using intent-to-treat analysis (ITT). Results: Training sessions of the CT group are 45 minutes/day, 3 days/week, for 12 weeks (36 sessions each). The training of active control group is the same as CT group (45min/day, 3days/week, for 12 weeks, for a total of 36 sessions). The primary outcome is cognitive function, using the Mini-Mental Status Examination (MMSE); the secondary outcome indicators are: 1) activities of daily living, using the Lawton's Instrumental Activities of Daily Living (IADLs) and 2) degree of depressive symptoms, using the Geriatric Depression Scale-Short form (GDS-SF). Latent growth curve modeling will be used in the repeated measures statistical analysis to estimate the trajectory of improvement by examining the rate and pattern of change in cognitive functions, activities of daily living and degree of depressive symptoms for intervention efficacy over time, and the effects will be evaluated immediate post-test, 3 months, 6 months and one year after the last session. Conclusions: We constructed a rigorous CT program adhering to the Consolidated Standards of Reporting Trials (CONSORT) reporting guidelines. We expect to determine the improvement in cognitive function, activities of daily living and degree of depressive symptoms of older adults with mild cognitive impairment after using the CT.

Keywords : mild cognitive impairment, cognitive training, randomized controlled study
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