

KC-150 Improves Cognitive Function and fNRS Task Activation in Patients with aMCI

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Abstract

Background: With the progression of China's aging society, the prevalence of cognitive impairment and dementia has shown an annual upward trend. Among these, Alzheimer's disease (AD) imposes a heavy burden on families and society, and non-pharmacological interventions may potentially prevent and curb the progression and evolution of the disease.

Objective: This study aimed to investigate the possible effects and mechanisms of oral administration of ferulic acid and fumaric acid extracts as KC-150 (Jianzhi Su), on cognitive function in patients with AD-originated mild cognitive impairment (aMCI).

Methods: Through neuropsychological assessments, functional near-infrared spectroscopy (fNRS), verbal fluency tasks (VFT), and detection of serum and cerebrospinal fluid dementia markers, 50 patients diagnosed with aMCI in the neurology outpatient department of our hospital from February 2024 to February 2025 were enrolled in this study. The brain activity during the MMSE, MoCA, and VFT tasks, as well as the levels and distribution of oxyhemoglobin (HbO) in the brain, were compared using blocked t-tests before and after 8 weeks of KC-150 administration.

Results: MoCA scores improved but lack of significance after KC-150 intervention ($P > 0.05$). In AD patients, HbO levels related to the VFT task increased markedly after KC-150 administration ($P < 0.05$), with significant differences observed in CH37, CH39, and CH9 ($P < 0.05$).

Conclusion: KC-150 can significantly improve cognitive function in aMCI patients. This effect is associated with increased activation of functional networks in the right frontal lobe, left frontal-parietal lobe, and insular lobe as measured by fNRS.

Keywords: aMCI; KC-150; MoCA; fNRS; VFT

1.Introduction

Alzheimer's disease (AD), due to the complexity of dementia etiology and its incurable nature, the World Health Organization (WHO) has specifically issued a report classifying AD as a global public health priority. Mild cognitive impairment (MCI) is an intermediate state between normal objective cognition and dementia, characterized by cognitive dysfunction that has not yet affected daily living abilities. MCI Studies indicate that the annual incidence of MCI among elderly individuals in China is 15%. AD-originated MCI (aMCI), as a pre-dementia stage, is termed as the optimal window for dementia prevention due to its relatively mild cognitive impairment and certain reversibility.

AD is in lack of effective treatment, which partially due to the late interventions. The targeted therapy for the early stage of AD, such as aMCI would be probable adoptive treatment. The non-pharmacological method like KC-150 (Jianzhi Su, as a brand name), which was rich in ferulic acid and fumaric acid, would be a non-pharmacological intervention for aMCI patients [1,2]. Ferulic acid can rapidly interact with β -amyloid monomers/oligomers to form unstable aggregates [3], thereby inhibiting the production of β -amyloid and reducing the oxidative stress response induced by β -amyloid4. It also restores mitochondrial membrane potential and blocks the apoptosis pathway, demonstrating significant effects on improving cognitive and memory functions [5]. The anti-aging gene Sirtuin 1 is important to the treatment of cognition and Alzheimer's

disease [6]. Ferulic acid and Fumaric acid are potent activators of Sirtuin 1 and oral administration of KC-150 is possibly linked to Sirtuin 1 activation with effects on neuron proliferation, cognition and Alzheimer’s disease [7]. However, the mechanism as macroscopic brain network level has not been well investigated. Functional near-infrared spectroscopy (fNRS) is a convenient and insightful technology for the brain network analysis for neurology diseases including AD8. In this study, we employed KC-150 for aMCI patients, evaluated both by assessment for the outcome, and fNRS for the mechanism.

2. Subjects and Methods:

2.1 Subjects: A total of 50 patients with aMCI patients, diagnosed in the neurology outpatient department of our hospital from August 2024 to May 2025, were enrolled as study subjects.

2.1.1 Inclusion Criteria: (1) Meeting the diagnostic criteria for MCI as defined in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), and satisfying the Minimum Mental State Examination(MMSE), Montreal Cognitive Assessment (MoCA) and Clinical Dementia Rating(CDR) scoring criteria for MCI; (2) All patients underwent cerebrospinal fluid or serum dementia marker testing, meeting the ATN diagnostic criteria for aMCI(A+ (serum Aβ42/40↓, CSF Aβ↓ or Aβ42/40↓); T+(serum p-Tau217↑ or 181↑;CSF p-Tau↑), A+T+)9 and (MMSE ≥19 points, CDR ≤0.5) ; (3) Age between 55 and 75 years; (4) Voluntary participation in the study and signing of an informed consent form.

2.1.2 Exclusion Criteria: (1) Individuals with visual or auditory impairments that affect normal reading and communication; (2) Patients currently taking other medications for dementia prevention or treatment; (3) Patients undergoing antipsychotic therapy; (4) Patients with Geriatric Depression Scale (GDS-15) scores ≥610; (5) Patients with severe cardiovascular, hepatic, or renal diseases; (6) Patients with positive serum syphilis antibody or cranial MRI findings suggestive of vascular dementia or cognitive impairment; (7) Patients with hypersensitivity to the active ingredient of KC-150.

2.2 Methods:

2.2.1 Study Protocol Experimental group: Administered KC-150, taken orally at a dose of 3g (1.5g per packet with main contents as ferulic acid from rice bran extract and cumaric acid from angelica archangelica extract) twice daily for 8 weeks. Prior to intervention initiation, the enrolled patients underwent assessments using the MMSE, MoCA, CDR,

and GDS-15 scales, along with fNRS monitoring. Subsequently, at the end of week 8 of treatment, both groups were re-evaluated using the MMSE and MoCA scales. To ensure consistency in scoring, all assessments were conducted by the same physician.

2.2.2 Research Tools:

(1) The general information questionnaire included participants' gender, age, educational level, etc. (2) MMSE, MoCA, and CDR assessment scales. The MMSE is a commonly used comprehensive screening tool for cognitive impairment; the MoCA scale was specifically developed for screening patients with mild cognitive impairment (MCI), and the most widely used version in China is the English version directly translated. The CDR scale is used to assess the degree of cognitive impairment in patients. (3) The GDS-15 is a scale specifically designed to measure the severity of depressive symptoms in elderly individuals, with higher scores indicating more severe symptoms. Generally, a score greater than 6 is considered positive for depressive symptoms10.(4) Serum and cerebrospinal fluid samples were analyzed using ELISA or single-molecule immunology assays to detect antibodies (Aβ), Aβ42, Aβ42/40, ptau-181, ptau-217, and t-tau.(5) In this experiment, NirSmart-6000A equipment (Danyang Huichuang Medical Equipment Co., Ltd., China) was used to continuously measure and record the concentration changes of brain oxyhemoglobin (HbO) during the VFT task. The system consists of a near-infrared light source (light emitting diodes, LED) and an avalanche photodiode (APD) as detectors, with wavelengths of 730nm and 850 nm, respectively, and a sampling rage of 11Hz. The experiment uses 24 light sources and 16 detectors to form 63 effective channels. The VFT paradigm was used to detect task-related brain activation in patients before and after intervention. VFT block waveforms were calculated with a block range set of 0-125s, a pre-baseline range set of 0-10s, and a post baseline range set of 70-125s. We used a 60s task period of constructing phrases as the time window to analyze mean Oxy-Hb changes [11].

2.3 Statistical analysis was performed using SPSS 26.0. Paired samples T-tests were conducted for all data in the experimental group before and after intervention, with a significance level of P<0.05.

3. Results

3.1 General Data Fifty patients with mild cognitive impairment (aMCI) were enrolled in this study, with their general characteristics presented in Table 1.

Table 1 General Patient Information	
Patient condition	Number of cases
gender	Male 24
age	67±11.3
A(+)	35
T(+)	10
A(+)T(+)	5

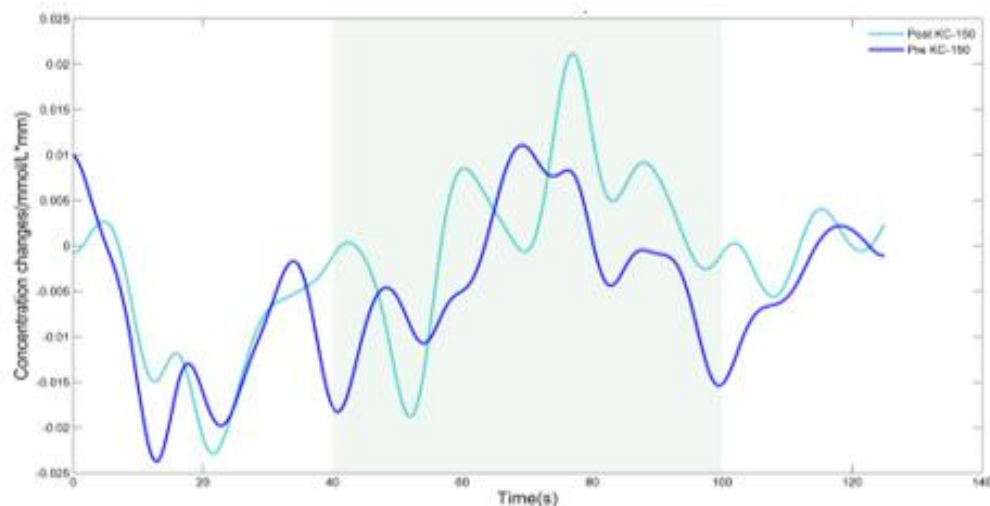
Table 1: General Patient Information.

3.2 Comparison of MMSE and MoCa scores before and after KC-150 intervention in patients, as shown in Table 2, with a total improvement rate as high as 70%.

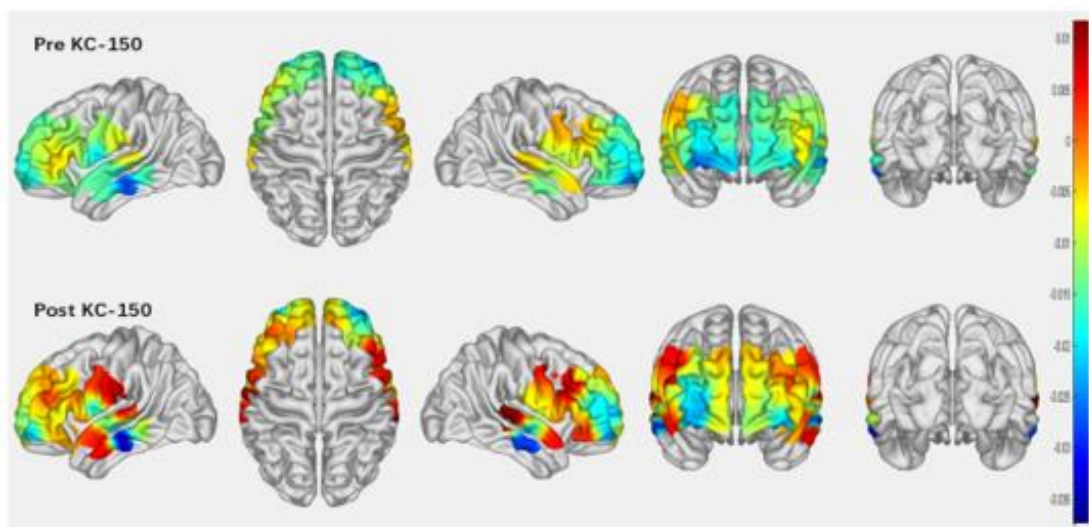
	Pre KC-150	Post KC-150	P
MMSE	22.5(±2.5)	23.28(±1.9)	>0.05
MoCA	18.2(±3.1)	19.3(±2.7)	>0.05

Table 2: Comparison of MMSE and MoCa scores.

3.3 The hemoglobin oxygen concentration (HbO) curve of the VFT task before and after KC-150 intervention in patients is shown in Figure 1.



3.4 Distribution of HbO brain activation in VFT tasks before and after KC-150 intervention in patients, as shown in Figure 2.



3.5 The channels and corresponding brain regions with statistically significant differences in HbO brain activation distribution during the VFT task before and after KC-150 intervention in patients are shown in Table 3.

CH	T	P	Corresponding brain regions
37	2.8611	0.0096559	Precentral_R ; Frontal_Mid_R ; Frontal_Inf_Oper_R
39	2.5114	0.020724	Frontal_Mid_R
9	-2.1815	0.041253	Frontal_Sup_L ; Frontal_Sup_Orb_L ; Frontal_Mid_Orb_L Frontal_Sup_Medial_L ; Frontal_Mid_Orb_L

R refers to right; L refers to left

Table 3: Channels with significant changes in fNRS.

4. Discussion

Approximately one-third of elderly patients with MCI eventually progress to AD. With the application of molecular diagnostics, we have identified AD as a disease spectrum encompassing cognitive normality, subjective cognitive impairment, MCI, and various stages of dementia [12]. According to the ATN diagnostic criteria, we define MCI patients with positive AD biomarkers as aMCI patients. Although the neurobiological mechanisms underlying aMCI remain incompletely understood, previous studies suggest that the primary causes of cognitive dysfunction may include: mitochondrial dysfunction, oxidative stress induced by β -amyloid deposition [13], reduced levels of cholinergic neuron markers such as acetylcholine, and abnormal tau protein phosphorylation [14]. The limitations of pharmacological treatments for AD are multifaceted, and non-pharmacological therapies are increasingly attracting scholarly attention [15]. This study, which employed KC-150 for an 8-week observation and reporting clinical trial in aMCI, was consistent with previous findings [14]. We took the experimental group for the evaluation of pre and post comparison without control group, and this is a limitation of this study. The results showed an improving trend in the MMSE and MoCA scores among the experimental group of aMCI patients (Table 2), with a total improvement rate as high as 70%. The result didn't reach significant change, but still indicated the tendency of improvement. However, the mechanisms underlying cognitive function improvement remain unclear. Changes in brain network connectivity, as a novel research approach [1], provide an objective means for early assessment of neurodegenerative diseases such as Alzheimer's disease (AD) [16]. Analysis of dynamic functional connectivity (dFC) in resting-state functional magnetic resonance imaging (rs-fMRI) can capture recurrent connectivity states across a large cohort of subjects spanning the Alzheimer's disease continuum, including healthy controls, individuals with mild cognitive impairment (MCI), and those clinically diagnosed with aMCI. The secondary visual (VIS2)17, frontoparietal network (FPN) [18], and default mode network (DMN)19 exhibit the strongest associations with cognitive decline [17]. This study not only evaluated the effects of KC150 intervention on aMCI through pre-and post-intervention cognitive assessments but also employed brain network analysis to further investigate this phenomenon. Brain network alterations in AD patients are reflected in MRI imaging, and fNRS, as a novel imaging technique, has been widely applied in cognitive-related fields in recent years [20]. AD patients have been observed to exhibit reduced frontal lobe activation during the visual free-form task (VFT) compared to normal controls. In this study, we utilized this technique to monitor the hemoglobin oxygen (HbO) concentration curve and distribution in aMCI patients during the VFT task. The results indicated that KC-150 intervention led to an increase in HbO levels associated with the VFT task (Figure 2), with significant differences observed in CH37, CH39, and CH9 (Table 2). These changes corresponded to elevated HbO levels in the right frontal lobe, left frontal lobe, and left insular cortex (Figure 3), suggesting alterations in the control of the frontoparietal network (FPN) and attentional network functions by the frontal lobe before and after intervention. This change is different from the previous study of Tea polymers on the SCD(subjective cognitive decline) patients as increased cerebral activity was observed in left dorsolateral prefrontal cortex (DLPFC), left premotor cortex (PMC), left primary somatosensory cortex (PSC), right inferior frontal gyrus (IFG), and premotor cortex (PMC)15, which indicate the different brain network activation both in SCD and different non pharma logical interventions. The changes may be related

to the brain network alterations in patients with Alzheimer's disease (AD) and could also explain the improvement in aMCI patients following KC-150 intervention.

5. Conclusion

In conclusion, oral administration of KC-150 could improve cognitive function in aMCI patients, which might be associated with activation of the corresponding frontoparietal network (FPN) in the ventral frontotemporal (VFT) and insular regions of the brain. However, this study also has certain limitations. Future research could involve multicenter, large-sample clinical trials, increased control groups, and the inclusion of other relevant objective indicators and follow-up periods to more accurately investigate the efficacy and potential mechanisms of KC-150 in treating MCI. Also, the further molecular mechanism on the Sirtuin 1 activation would also be included in the future study.

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