



Effectiveness of a Karaoke-Based Digital Therapeutic in Mild Cognitive Impairment: A Randomized, 12-Week Pilot Trial

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Objective The aim of the study is to evaluate the efficacy of a karaoke-based digital therapeutic program (CogniSong) in patients with mild cognitive impairment (MCI).

Methods In a 12-week single-center, assessor-blinded randomized controlled trial, 36 patients with MCI were randomly assigned to either the CogniSong digital therapeutics (DTx) group (n=18) or standard treatment group (n=18). The intervention group underwent daily 30-minute karaoke game-based cognitive training sessions via a mobile application. The primary outcome was the change in Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) total score from baseline to week 12. Secondary outcomes included RBANS subdomain index scores, the Seoul-Instrumental Activities of Daily Living, 17-item Hamilton Depression Rating Scale, Neuropsychiatric Inventory, and Clinical Dementia Rating–Sum of Boxes.

Results The DTx group showed a significantly greater improvement in RBANS total score compared to standard treatment group (mean change +5.9 points vs. -0.2 points, p=0.041). However, there were no significant between-group differences in RBANS subdomain scores or secondary outcomes such as daily functioning, mood, neuropsychiatric symptoms, or global clinical status.

Conclusion In this randomized controlled trial, a karaoke-based DTx appeared feasible and effective in enhancing global cognition in MCI. The findings support its potential as a complementary intervention for cognitive improvement in MCI patients.

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Keywords Digital therapeutics; Mild cognitive impairment; Cognitive training; Music-based cognitive training; Randomized controlled trial.

INTRODUCTION

Alzheimer's disease (AD) is a progressive degenerative brain disorder and the most common cause of dementia, affecting an estimated 55 million people worldwide.¹ AD leads to serious memory loss, cognitive decline, and loss of independent function in older adults, posing a major public health chal-

lenge.² Mild cognitive impairment (MCI) is a prodromal stage between normal aging and dementia in which cognitive decline is present but daily activities are not yet significantly impaired.³ Individuals with MCI are at elevated risk of developing AD, with approximately 10%–15% of MCI patients progressing to Alzheimer's dementia each year.⁴ This high conversion rate has made MCI a critical window for intervention, spurring extensive research into treatments that could slow or prevent progression to AD.⁵

Pharmacological breakthroughs for early AD have begun to emerge, but their effects remain limited. In particular, monoclonal antibody therapies targeting amyloid pathology have shown only modest benefits. For example, the CLARITY-AD trial of lecanemab reported a 27% reduction in the rate of cognitive decline over 18 months compared to placebo.⁶ While sta-

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tistically significant, this translates to only a slowed trajectory of decline, not a halt, and many subjects on this trial still experienced worsening cognition.⁶ Given these limitations, there is growing interest in non-pharmacological approaches and adjunctive therapies to more fully address cognitive impairment in MCI and early AD.

Cognitive intervention strategies have gained attention as a complementary approach to delay cognitive decline.⁷ In recent years, digital therapeutics (DTx) for cognitive training have emerged as convenient, scalable tools that patients can use at home. Various software-based DTx programs utilizing computerized cognitive training have been developed and tested, and evidence suggests they can improve cognitive function in people with MCI or dementia.⁸ A recent meta-analysis of randomized controlled trials found that intensive computer-based cognitive training produced significant improvements in global cognition and memory in older adults with MCI.⁸ Reflecting this progress, several prescription DTx for cognitive impairment have become available to patients. A South Korean SUPERBRAIN study showed the efficacy of a tablet-based program combining lifestyle and cognitive training for patients with MCI.⁹ Digital platforms offer the advantage of easy accessibility and scalability, enabling cost-effective cognitive engagement for at-risk individuals. Despite the promise of DTx, sustaining user engagement over the long term remains a key challenge. Patients may struggle to adhere to generic brain training tasks, so it is crucial that interventions be designed to be user-friendly and enjoyable. Developers of cognitive DTx have emphasized engaging, easy-to-use interfaces to motivate regular use by older adults. In this context, incorporating entertaining elements—such as music and games—into cognitive therapy has drawn considerable interest.^{5,7} Musical activities are thought to be familiar and enjoyable for many patients, and a growing body of evidence suggests that music-based interventions could yield cognitive and emotional benefits in people with cognitive impairment.¹⁰ Notably, participation in singing exercises was associated with improved cognitive outcomes. For instance, one study reported that 6 months of group singing practice (including at-home karaoke sessions) led to a significant improvement in psychomotor processing speed in participants with dementia.¹¹ Likewise, a pilot randomized trial demonstrated that weekly karaoke training significantly improved executive function in elderly individuals near the MCI threshold, compared to an active control condition.¹² These findings indicate that a karaoke-based approach can actively engage patients while stimulating cognitive processes, suggesting a potential therapeutic avenue that is both effective and enjoyable.

Accordingly, we developed a novel DTx program that leverages karaoke singing as a form of cognitive stimulation for

MCI patients, termed the CogniSong version 1.0. This karaoke-based DTx is designed to deliver cognitive training exercises through an intuitive, music-driven platform that encourages patient participation and makes therapy feel like a familiar recreational activity. In the present study, we evaluated the therapeutic efficacy of the CogniSong version 1.0 in individuals with MCI. Here we report on the clinical outcomes of this karaoke-based digital intervention, examining its impact on cognitive function and its feasibility as an engaging digital treatment for cognitive impairment.

METHODS

Karaoke-based DTx (the CogniSong version 1.0)

The CogniSong version 1.0 is a karaoke-based DTx designed to enhance cognitive function in patients with MCI through a structured music-learning approach.¹² The program incorporated established cognitive training principles, including errorless learning and spaced retrieval, to maximize successful recall opportunities and strengthen memory retention through systematically spaced practice.¹³

During each session, participants were instructed to memorize and vocally reproduce the lyrics of the Korean song “Lighthouse Keeper”—adapted from the Western song “The Golden Rule.” Task difficulty progressively increased across sessions.¹¹ To minimize passive memorization and promote active encoding, lyric lines that had been learned were progressively replaced with new lines as training advanced.

As summarized in Table 1, the program consisted of ten progressive stages, by the end of which patients were expected

Table 1. Progressive structure of karaoke-based DTx training stages

Stage	Description
1	Listen to the entire song from start to finish.
2	Listen to and read aloud each lyric line one by one.
3	Sing each line following the lyrics while listening to the song.
4	Sing each line along with the musical accompaniment.
5	Listen to each line being read aloud and sing while mentally filling in the missing words.
6	Sing along with an unaccompanied version, filling in the omitted words.
7	Insert the correct lyrics into the blanks and sing with accompaniment.
8	Listen to the full lyrics of the song from beginning to end.
9	Listen to the entire song again from start to finish.
10	Sing the entire song independently with the accompaniment.

DTx, digital therapeutics.

to memorize and accurately reproduce the complete song lyrics through repeated practice and spaced recall. When the application was used for more than 15 minutes, it was regarded as one completed training session. Participants were instructed to use the program at least twice daily (≥ 30 minutes per day) and ten sessions per week throughout the study period. All sessions were administered in a standardized setting using the study application with on-screen guidance and auditory feedback

Study design

This study was a 12-week single-center, outcome assessor-blinded randomized controlled trial with a two-arm parallel design of the CogniSong version 1.0 as outlined in Figure 1. Participants were randomly assigned to either the DTx or standard treatment group in a 1:1 ratio at baseline. The participants in DTx group were instructed to perform two 15-minute sessions daily (total ≥ 30 minutes per day), equivalent to ten sessions per week, whereas those in standard treatment only received conventional treatment with medication and education. Although the standard treatment group did not receive a device, participants were scheduled for visits with the same frequency and number as the intervention group. During these visits, they underwent identical clinical and neuropsychological assessments as the DTx group. This study was conducted in accordance with the International Conference on Harmonization Good Clinical Practice Guidelines. The Institutional Review Board of Yeouido St Mary's hospital approved the study protocol (IRB No. SCDISI0214), and all consent forms before the study was initiated. Written informed consent was obtained from all participants prior to enrollment.

Study participants

The participants were recruited through outpatient clinic at Catholic Brain Health Center, Yeouido St. Mary's Hospital, The Catholic University of Korea in the Republic of Korea. The participants were recruited from September of 2024 to February of 2025. Participants who met the following inclusion criteria were included in the study: 1) individuals aged 55 to

85 years; 2) presence of memory complaints corroborated by an informant; 3) objective cognitive impairment in more than one cognitive domain on the Korean version of Consortium to Establish a Registry for Alzheimer's Disease neuropsychological assessment battery (CERAD-K)¹⁴ (at least 1.0 standard deviation [SD] below age- and education-adjusted norms); 4) intact activities of daily living; 5) CDR¹⁵ of 0.5; 6) not demented according to the Diagnostic and Statistical Manual of Mental Disorders, Fifth edition criteria; 7) having a caregiver who spends more than 8 hours per week with the participant and agrees to assist with the participant's follow-up and clinical evaluations; 8) possession of a personal smartphone and no difficulties using mobile apps; and 9) the ability to make phone calls to a caregiver independently using the smartphone.

Participants were excluded from the study if any of the following exclusion criteria were met: 1) a history of transient ischemic attack, stroke, or seizure within the past 12 months; 2) a history of severe psychiatric disorders or currently under unstable psychiatric symptoms; 3) active suicidal intent as assessed by the Columbia-Suicide Severity Rating Scale, or a history of treatment for suicidal behavior within the past 5 years; 4) unstable findings upon a physical examination, neurological examination, in vital signs, or the presence of an ongoing unstable physical illness; 5) substance dependence within the past 2 years; 6) the use of other investigational medication within 4 weeks; 7) scheduled to undergo surgery requiring general anesthesia; or 8) participation in any form of cognitive intervention within the past 3 months.

Outcome measures

The primary outcome measure was a change in the total scale index score of the the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) from baseline to after intervention and using a reference population of Korean adults to normalize the data.¹⁶ The RBANS five subdomain index scores including immediate memory, delayed memory, visuoconstruction, language and attention were also evaluated. The secondary outcome measures were changes of the Seoul-Instrumental Activity of Daily Living (S-IADL) score,

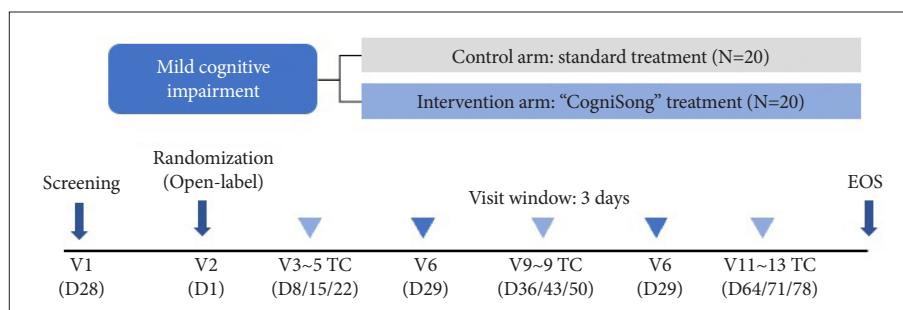


Figure 1. Study design of the clinical trial. TC, telephone contact; EOS, end-of-study.

17 item Hamilton Depression Rating Scale (HAMD17) score, the Neuropsychiatric Inventory (NPI) score, and Clinical Dementia Rating–Sum of Boxes (CDR-SB) scores.

Statistics

All participants who completed at least one post-baseline assessment were included in the modified intention-to-treat population. Baseline characteristics of each group were analyzed using Mann–Whitney U test for continuous variables and chi-squared tests for categorical variables. Treatment effects over 12 weeks were first summarized using mean change from baseline for each outcome.

Between-group differences in mean change were tested using Mann–Whitney U test. For each outcome we report, for each group, mean change±standard error of the mean, the between-group mean difference in change with 95% confidence interval, and the two-sided p-value. Effect sizes were quantified using Cohen's d computed on the change scores with the pooled SD. Statistical analyses were conducted using Python (pandas, scipy, statsmodels, matplotlib) (<https://www.python.org>).

RESULTS

Baseline demographic characteristics

A total of 42 MCI patients participated in this study. In the DTx group, 22 individuals were initially enrolled; following screening, 2 subjects were excluded, and 2 subjects were dropped out due to personal reasons, 18 completed the study. In the Standard Tx group, 20 were initially enrolled; 2 were excluded after screening, and 18 completed all study, yielding

a 90% study completion rate for both group.

At baseline (Table 2), the two treatment groups were comparable across demographic and clinical variables. The proportion of female did not differ between groups (Standard Tx 61.1% vs. DTx 66.6%; $p=0.91$). Mean age was similar (73.9 ± 8.4 years vs. 75.1 ± 7.1 years; $p=0.67$), as was education (12.2 ± 5.2 years vs. 10.8 ± 4.6 years; $p=0.43$). Global cognition (RBANS total) did not differ (74.0 ± 15.4 vs. 75.7 ± 19.1 ; $p=0.77$). RBANS subindices showed no baseline differences: immediate memory 73.6 ± 11.4 vs. 75.4 ± 15.9 ($p=0.71$), with visuoconstruction, language, attention, and delayed memory also non-significant. Functional and behavioral measures were likewise comparable, including S-IADL, HAMD17, NPI, and CDR-SB.

Effectiveness of the karaoke-based DTx

For each outcome, outcome measures change scores from baseline to 12 weeks compared between Standard Tx and karaoke-based DTx using Mann–Whitney U test (Figure 2). The RBANS total scale index improved significantly more in the DTx group than in Standard Tx (+5.94 points vs. -0.22 points), indicating a meaningful between-group difference ($p=0.041$) with a medium–large effect size (Cohen's $d=0.71$, favoring DTx group). The RBANS language index showed a trend toward greater improvement with karaoke-based DTx (+2.89 vs. -4.56; $p=0.075$), with a moderate effect ($d=0.61$). Immediate memory increased in both groups (+8.22 vs. +4.22; $p=0.246$; $d=0.39$), suggesting modest, non-significant advantage for karaoke-based DTx. Changes in visuoconstruction (DTx -2.33 vs. Standard Tx -3.89; $p=0.675$) and attention (+2.67 vs. +1.39; $p=0.775$) were small and not statistically significant.

Table 2. Baseline demographics of study participants

	Standard Tx (N=18)	DTx (N=18)	p
Age (yr)	73.94±8.40	75.05±7.14	0.67
Sex, female	11 (61.1)	12 (66.6)	0.91
Education (yr)	12.22±5.22	10.84±4.57	0.43
CDR-SB	2.44±0.84	2.25±0.58	0.62
S-IADL	4.50±5.33	3.79±2.44	0.31
HAMD17	6.67±4.47	6.37±4.51	0.84
NPI	9.88±9.94	7.44±7.37	0.49
RBANS total scale index score	74.00±15.40	75.68±19.11	0.77
Immediate memory index score of RBANS	73.61±11.37	75.37±15.93	0.71
Visuoconstruction index score of RBANS	96.44±16.63	97.00±16.88	0.92
Language index score of RBANS	87.44±18.80	87.79±16.22	0.95
Attention index score of RBANS	96.00±15.79	92.21±20.01	0.53
Delayed memory index score of RBANS	57.89±11.06	64.58±15.62	0.14

Data are presented as mean±standard deviation or number (%). Tx, treatment; DTx, digital therapeutics; CDR-SB, Clinical Dementia Rating–Sum of Boxes; S-IADL, Seoul-Instrumental Activities of Daily Living; HAMD17, 17-item Hamilton Depression Rating Scale; NPI, Neuropsychiatric Inventory; RBANS, Repeatable Battery for the Assessment of Neuropsychological Status.

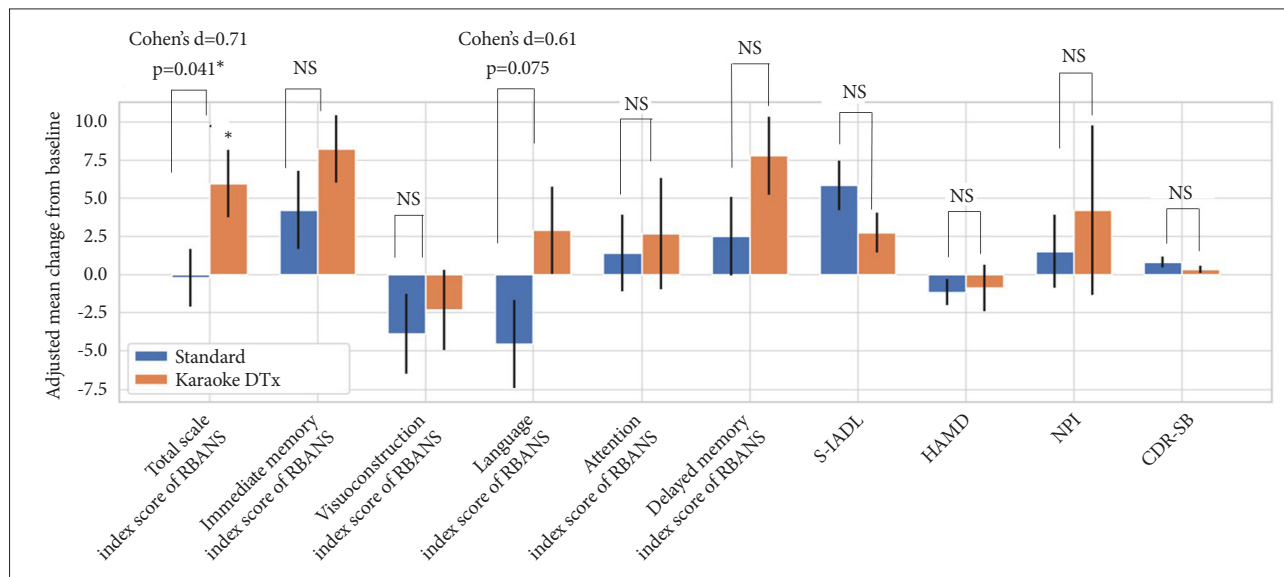


Figure 2. Mean changes of clinical measurements from baseline to 12 weeks Karaoke based DTx in mild cognitive impairment patients. Error bars indicate standard deviations. p values and NS (statistically not significant) from group comparisons were obtained using Mann–Whitney U test. DTx, digital therapeutics; S-IADL, Seoul-Instrumental Activity of Daily Living; HAMD17, 17 item Hamilton Depression Rating Scale, NPI, Neuropsychiatric Inventory; CDR-SB, Clinical Dementia Rating–Sum of Boxes.

DISCUSSION

This study demonstrated that a karaoke-based DTx program, CogniSong version 1.0, produced significant cognitive benefits in older adults with MCI. After 12 weeks of intervention, the DTx group showed a significantly greater improvement in global cognitive performance compared to the Standard Tx group. To our knowledge, this might be one of the first clinical trials of singing-driven karaoke-based digital therapy in MCI, and the positive findings showed the CogniSong version 1.0 as an effective and engaging approach for improving cognitive function in the MCI patients.

Our results were in line with previous researches indicating that digital cognitive interventions could improve outcomes in MCI. A recent network meta-analysis by Jeong et al.⁸ found that computerized cognitive training programs yielded significant gains in global cognition in older adults with MCI or dementia. Similarly, a large 24-week multidomain lifestyle intervention trial in MCI (the SUPERBRAIN-MEET study) reported significantly greater improvement in RBANS total scores in the intervention group compared to controls (+8.4 points vs. +4.3 points).⁹ The cognitive function improvement observed with the CogniSong version 1.0 in our 12-week trial (approximately +6 points of RBANS total score) were comparable in magnitude to those seen in more intensive or longer programs. This was notable given that the CogniSong version 1.0 focused on a single modality (music-based cognitive stimulation) rather than a broad multidomain approach. Our findings reinforce that even a targeted DTx can measurably im-

prove global cognition in MCI, consistent with prior evidence that various DTx modalities—from serious gaming to multidomain platforms—have potential to slow or reverse cognitive decline in this population.⁷

In addition to overall cognition, we observed suggestive domain-specific effects of the CogniSong version 1.0. Notably, the RBANS language index showed a trend toward greater improvement in the DTx group than in controls. While this difference did not reach statistical significance, the direction and moderate effect size imply a possible benefit of the karaoke-based training on language-related cognitive functions. Music-based interventions have been shown to activate brain regions tied to language and memory. A previous fMRI study of singing training in patients with AD found increased activation in the right angular gyrus and other language-associated areas post-intervention.¹¹ Thus, the trend toward language improvement in our study is consistent with the notion that musical engagement benefits verbal cognitive function. With a larger sample or longer training period, this effect might become significant. In contrast, we did not find notable between-group differences in RBANS visuospatial/construction or attention index scores. This absence of effect in certain domains was not surprising, as the CogniSong version 1.0 program primarily emphasizes auditory–verbal and memory stimulation rather than visuospatial or complex attention exercises. Other forms of cognitive training may be required to target those domains more directly. Likewise, immediate memory (RBANS immediate recall) improved modestly in both groups, and delayed memory showed no significant between-group dif-

ference, suggesting that general practice effects or the short duration of the trial may have masked any specific memory benefits. Some prior interventions have reported improvements in episodic memory with more intensive training program, indicating that a higher “dose” of cognitive stimulation or specific memory-focused exercises might be needed to significantly boost memory performance.^{17,18} Importantly, our intervention’s efficacy appears to compare favorably to other DTx in terms of user engagement and scalability. The CogniSong version 1.0 leverages music—an activity that many older adults find enjoyable and motivating—as the vehicle for cognitive training. This might be a key advantage over more conventional computer-based training tasks that can feel repetitive or game-like; singing familiar songs likely enhanced participant enjoyment and adherence. Indeed, our trial had good completion rate, and anecdotal feedback indicated that subjects looked forward to the karaoke sessions. High adherence was similarly reported in the SUPERBRAIN multidomain trial (over 84% completion of sessions), underscoring that enjoyable interventions can maintain compliance even in lengthy programs.⁹ A music-focused DTx such as CogniSong version 1.0 can be delivered at scale through a tablet or smartphone without the need for extensive staffing or in-person visits, unlike some multidomain lifestyle interventions that require supervised exercise sessions or diet management. This scalability and ease of use could make it a practical tool in real-world clinical settings or at home. Furthermore, musical interventions may confer psychosocial benefits—such as mood enhancement, social connection, and stress reduction—beyond cognitive effects.¹⁰

Despite the cognitive gains, our study did not find significant improvements on secondary outcomes such as depressive symptoms, neuropsychiatric behaviors, or daily functioning. Both the DTx and standard treatment groups had low baseline depression scores, and neither group showed a meaningful change by week 12. This is consistent with several prior trials of cognitive interventions in non-depressed MCI samples, where primary cognitive benefits often do not translate into short-term mood improvements. Some studies have reported mood enhancement from digital training. A previous RCT trial noted reduced depressive symptoms after a personalized game-based cognitive program,¹⁹ and a meta-analysis found that high-intensity cognitive training was associated with decreased depression levels.⁸ However, such effects might depend on the presence of baseline mood symptoms or longer intervention duration. In our trial, the lack of change in depression might be due to a floor effect and the relatively brief treatment period. Similarly, we observed no significant impact on the NPI or S-IADL. Other short-term DTx trials in MCI have likewise found limited effect on functional out-

comes in 2–3 months, which is understandable given that functional decline in MCI is often subtle and slow.^{20,21} Interestingly, the 6-month SUPERBRAIN trial did report improvements in quality of life and depression in the intervention group, suggesting that a broader or longer intervention could yield psychosocial benefits. It may be that the added physical exercise and social interaction in that multidomain program contributed to mood and functional gains that a purely cognitive karaoke intervention alone could not achieve in a short span.⁹ Overall, the absence of effect on non-cognitive measures in our study does not diminish the cognitive findings, but it highlights that the CogniSong version 1.0 should perhaps be combined with other strategies if comprehensive improvements in daily function or mood are desired.

Several limitations of this study should be acknowledged. First, the sample size was relatively small (n=36), which limits statistical power and generalizability. A larger trial is needed to confirm these results and more precisely estimate the effect size of CogniSong version 1.0. Second, the study duration was only 12 weeks. It remains unknown whether the cognitive improvements are sustained long-term or translate into delayed progression to dementia. Longer follow-up periods would help determine if DTx can modify the trajectory of cognitive decline in MCI. Third, our trial was single-blind; while outcome assessors were blinded to group assignment, participants were aware of their intervention. This awareness could introduce performance or expectation biases. Using active control condition in future studies would strengthen the rigor by balancing participant engagement and expectations across groups. Finally, digital literacy and socioeconomic factors may influence accessibility and adherence to DTx among older adults. Future studies should address these disparities by developing simplified interfaces and providing technical support for users with limited digital experience.

In conclusion, this study provides evidence that a karaoke-based DTx can improve cognitive function in MCI, highlighting a novel and enjoyable approach to cognitive rehabilitation. With rigorous follow-up studies and continued innovation, music-oriented digital therapies like CogniSong version 1.0 could become valuable tools in our arsenal to protect brain health and enhance quality of life for those at risk of dementia.

Availability of Data and Material

The datasets generated or analyzed during the study are available from the corresponding author on reasonable request.

Conflicts of Interest

Hyun Kook Lim, a contributing editor of the *Psychiatry Investigation*, was not involved in the editorial evaluation or decision to publish this article. All remaining authors have declared no conflicts of interest.

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