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Effectiveness of a 52-week multidomain intervention to maintain cognitive function in patients with mild cognitive impairment: a randomized controlled trial

Ha Yeong Choi¹, Yeo Jin Kim^{2,3}, Dae-Soon Son⁴, Moo Eob Ahn⁵ & Sang-Kyu Lee⁶✉

Mild cognitive impairment (MCI) increases the risk of dementia. Reducing modifiable lifestyle-related risk factors can help prevent cognitive decline in patients with MCI. We examined whether a multidomain intervention using a mobile application can prevent cognitive decline in patients with MCI. The trial is designed in accordance with the CONSORT Statement. We conducted an assessor-blind, randomized controlled trial. Patients with MCI, aged over 60 years and presenting with at least one modifiable risk factor for dementia, were recruited from three dementia centers in Gangwon-do, Korea, and outpatient clinics at Chuncheon Sacred Heart Hospital. Participants were randomly assigned to either the intervention group or the control group in a 1:1 ratio. Each participant received a 52-week intervention. The intervention group used a mobile application to manage their diet and physical activity at least three times per week, while the control group received general dietary and physical activity recommendations twice a year. The primary outcome was the change in cognitive function measured based on the mini-mental state examination in the Korean version of the CERAD assessment packet (MMSE-KC) score. Between October 2020 and September 2021, 84 people were screened, and 80 participants were randomly assigned to either the control or intervention group (intervention group = 42, control group = 38). Participants in both groups underwent a post-baseline assessment and their data were included in the analysis. We found a positive effect of the multidomain intervention using a mobile application on the change in cognitive function score in the intervention group compared to the control group at the 52-week follow-up. The MMSE-KC ($F=10.6$, $p<.001$) and modified Boston Naming test ($F=8.3$, $p<.01$) scores were significantly higher in the intervention group than in the control group. The results suggest that a multidomain mobile application intervention could help improve cognition in patients with MCI.

The study protocol was prospectively registered with the Clinical Research Information Service (CRIS, Republic of Korea; KCT0008315) on March 16, 2023. The full trial details can be accessed at <https://cris.nih.go.kr/cris/search/detailSearch.do?seq=22920>.

Keywords Dementia, Mild cognitive impairment, Risk management, Multidomain mobile application

¹Hallym University College of Medicine, Hallym University, Chuncheon, Republic of Korea. ²Department of Neurology, Kangdong Sacred Heart Hospital, Seoul, Republic of Korea. ³Ezcog.lab Inc., Chuncheon, Gangwon-do, Republic of Korea. ⁴Major in Bio-Healthcare Convergence, College of Natural Science, Hallym University, Chuncheon, Republic of Korea. ⁵Department of Emergency Medicine, Hallym University Chuncheon Sacred Heart Hospital, Hallym University College of Medicine, Chuncheon, Republic of Korea. ⁶Department of Psychiatry, Hallym University Chuncheon Sacred Heart Hospital, Hallym University College of Medicine, Chuncheon, Republic of Korea. ✉email: skmind@hallym.ac.kr

Abbreviations

MCI	Mild cognitive impairment
MMSE-KC	Mini-mental state examination in the Korean version of the consortium to establish a registry for Alzheimer's disease assessment packet
eHealth	Electronic health
CERAD-K	Korean version of the consortium to establish a registry for Alzheimer's disease assessment packet
TMT	Trail making test
ANCOVA	Analysis of covariance
MICE	Multiple imputation chained equations

Introduction

Mild cognitive impairment (MCI) describes a condition between normal cognitive decline due to aging and pathological decline due to dementia. This condition is highly likely to progress to dementia¹. However, there are limited pharmacological therapies that can prevent MCI from progressing to dementia^{2,3}. Thus, it is essential to focus on non-pharmacological treatments to help improve patients' quality of life.

Several systematic reviews and meta-analyses have investigated the efficacy of various non-pharmacological interventions for MCI populations. Cognitive training and stimulation have been shown to improve memory and executive function⁴, while physical exercise interventions, including aerobic and resistance training, have demonstrated positive effects on cognitive outcomes^{5,6}. Additionally, lifestyle modifications such as diet and social engagement have also been explored as potential means to support cognitive health^{7,8}.

Despite these promising findings, existing research has notable limitations. Multidomain interventions have proven effective, yet they are often conducted face-to-face^{9–11}. Another critical limitation is that while multidomain interventions are believed to be more effective than single-domain interventions¹², few studies have assessed their effectiveness using accessible and scalable delivery methods such as digital technology.

To address these challenges, electronic health (eHealth) interventions offer a more accessible and economically feasible solution¹³. Recent evidence supports the efficacy of eHealth in promoting self-management of cardiovascular risk factors and suggests that such interventions are more effective when coupled with human coaching^{14,15}. Following this rationale, mobile applications that combine digital interventions with human feedback can support individuals in managing their lifestyle and reducing the risk of dementia. Interventions involving exercise, diet, social engagement, and cognitive activities have shown promise in reducing dementia risk and improving cognitive function in MCI patients. Despite the promising potential, there is a lack of studies specifically examining the effects of mobile-based multidomain interventions on cognitive function, and long-term follow-up research on the sustainability of cognitive benefits is also scarce.

This study aimed to investigate whether multidomain interventions using a mobile application can help maintain cognitive function in patients with MCI.

Methods

Study design and participants

This study was a 52-week assessor-blind randomized controlled trial, conducted at Sacred Heart Hospital in Chuncheon, South Korea, recruited participants between October 2020 and September 2021. After enrollment, participants underwent a 52-week intervention period. Following the completion of the intervention, participants were followed up for an additional year. Participants were randomly assigned to either an intervention group, which received a multidomain intervention via a mobile application, or a control group, which received standard health care guidelines. Cognitive function assessments were conducted at baseline and at the 52-week follow-up.

The inclusion criteria were individuals aged over 60 years with at least one modifiable dementia risk factor. These risk factors included hypertension (systolic blood pressure ≥ 140 mmHg or diastolic blood pressure ≥ 90 mmHg)¹⁶, diabetes (random plasma glucose ≥ 200 mg/dL, fasting plasma glucose ≥ 126 mg/dL after 8 h of fasting, 2-hour plasma glucose ≥ 200 mg/dL during a 75 g oral glucose tolerance test, or hemoglobin A1c $\geq 6.5\%$)¹⁷, dyslipidemia (total cholesterol ≥ 240 mg/dL, LDL cholesterol ≥ 160 mg/dL, HDL cholesterol < 40 mg/dL, or triglycerides ≥ 200 mg/dL)¹⁸, obesity (body mass index ≥ 25 kg/m²)¹⁹, and metabolic syndrome (defined by the presence of a combination of factors, such as hypertension, high blood sugar, excess body fat around the waist [waist circumference ≥ 90 cm in men or ≥ 85 cm in women]²⁰, and abnormal cholesterol levels)²¹. Additional risk factors included low education level (≤ 9 years of schooling) and physical inactivity (< 150 min of moderate-intensity activity per week, < 75 min of vigorous-intensity activity per week, or an equivalent combination of both)²². In addition, participants were required to have a z-score ≤ -1.0 SD in at least one test of the Korean Version of the Consortium to Establish a Registry for Alzheimer's Disease Assessment Packet (CERAD-K) and a Clinical Dementia Rating (CDR) global score of 0.5.

Exclusion criteria included a diagnosis of dementia, severe visual or hearing impairment, or communication difficulties. Written informed consent was obtained from all participants before enrollment, and the study protocol was approved by the Institutional Review Board of Chuncheon Sacred Heart Hospital (CHUNCHEON 2020-09-005, 12/10/2021).

Randomization and masking

Participants were randomly assigned to either the intervention or control group using a computer-generated list of random numbers. A simple randomization method was applied, and the allocation sequence was managed by

statisticians who were not involved in the study. Due to the nature of the intervention, blinding of participants was not feasible, but outcome assessors remained blind to the group assignments.

Procedures

Participants visited the hospital twice during the study period: at baseline and at the 52-week follow-up. CERAD-K was administered by trained clinical psychologists, and CERAD-K was used to assess the cognitive function of participants. The assessment packet consists of eight items: (1) verbal fluency (saying words from the animal category); (2) modified Boston naming test (naming of drawings); (3) mini-mental state examination (MMSE-KC); (4) word list memory (learning a visually presented list of 10 words through three trials); (5) word list recall (delayed word recall); (6) word list recognition (distinguishing words that have been learned previously from those that have not); (7) constructional praxis (copying figures); (8) constructional praxis recall (delayed figure recall); and (9) the trail making test (TMT)-A/B (connecting a circle within a label in a set time). A longer time to complete the TMT test indicated poor performance. These tests enabled us to assess the functional abilities of various cognitive domains: (1) general cognitive function using the MMSE-KC, (2) attention using the TMT-A test, (3) memory using word list memory, word list recall, word list recognition, and constructional praxis recall, (4) language using the modified Boston naming test, (5) visuospatial function using constructional praxis, and (6) executive function using the TMT-B test and word fluency.

Intervention

Intervention group

Multidomain interventions were conducted in the intervention group using a mobile application throughout the 52-week study period. Three interventions were administered to the intervention group: (1) Diet (2) Physical activity (3) Metabolic and vascular risk check and management. Concerning diet, participants were requested to send information regarding their diet three times a day. A nutritionist or research nurse provided feedback on the diet three times a week. Regarding physical activity, participants set their own physical activity goals. When participants achieved the target amount of activity, positive feedback was provided on the goal achievement rate and the effectiveness of the exercise. Alternatively, if the participant did not meet their target, feedback on this was provided, along with guidance to adjust the goal so that the participant could continue to use the program. Vascular and metabolic risk factors were measured at baseline through blood tests, weight measurement, and blood pressure measurement. Feedback on blood pressure and blood sugar was provided once a month or when blood pressure or blood sugar was outside the normal range as set by an internal medicine specialist (Fig. 1).

Control group

The control group intervention was conducted under the same conditions as the experimental group. The control group did not use the application and received face-to-face health management guidelines related to dementia prevention for approximately 20 to 30 min twice a year, at baseline and 52 weeks follow up. Specifically, the research team guided the participants on diet for dementia prevention, the benefits of regular physical activity, and management guidelines for preventing metabolic and vascular diseases.

Outcomes

The primary outcome was the MMSE-KC score at the 52-week follow-up. The secondary outcome was the eight items included in the CERAD-K, excluding the MMSE-KC, at the 52-week follow-up: (1) Verbal fluency (score); (2) Modified Boston naming test (score); (3) Word list memory (score); (4) Constructional praxis (score); (5) Word list recall (score); (6) Word list recognition (score); (7) Constructional praxis recall (score); (8) TMT-A/B (seconds). The researchers asked the participants if they experienced any adverse events and recorded them.

Statistical analyses

To calculate the minimum sample size for the analysis of covariance (ANCOVA), we fixed the two-sided significance level at 5% and statistical power at 80%, with an effect size of 0.5 determined from a previous study²³. Assuming a baseline–follow-up correlation of $\rho = 0.70$, the required sample size was 72 participants. Allowing for a 10% attrition rate, we set a recruitment target of 80 participants.

A χ^2 test was performed to analyze the association between categorical variables, such as sex, education level, and APOE ε4 carriers. A two-sample t-test was performed if there was a mean difference between the two groups in age and MMSE-KC score, which are continuous variables. ANCOVA was performed to verify the impact of mobile multidomain interventions on the CERAD-K score at the 52-week follow-up, using the baseline measurement as a covariate.

Component	Intervention group	Control group
Diet	Participants submitted dietary logs three times daily. A nutritionist or research nurse provided personalized feedback three times per week.	General dietary guidelines provided face-to-face twice a year.
Physical activity	Participants set personal activity goals. Feedback was provided based on goal achievement, encouraging adherence.	General physical activity recommendations provided twice a year.
Metabolic and vascular risk management	Baseline blood tests, weight, and blood pressure measurements were conducted. Monthly feedback was given based on results.	Health monitoring conducted only at baseline and follow-up.

Table 1. Multidomain intervention.

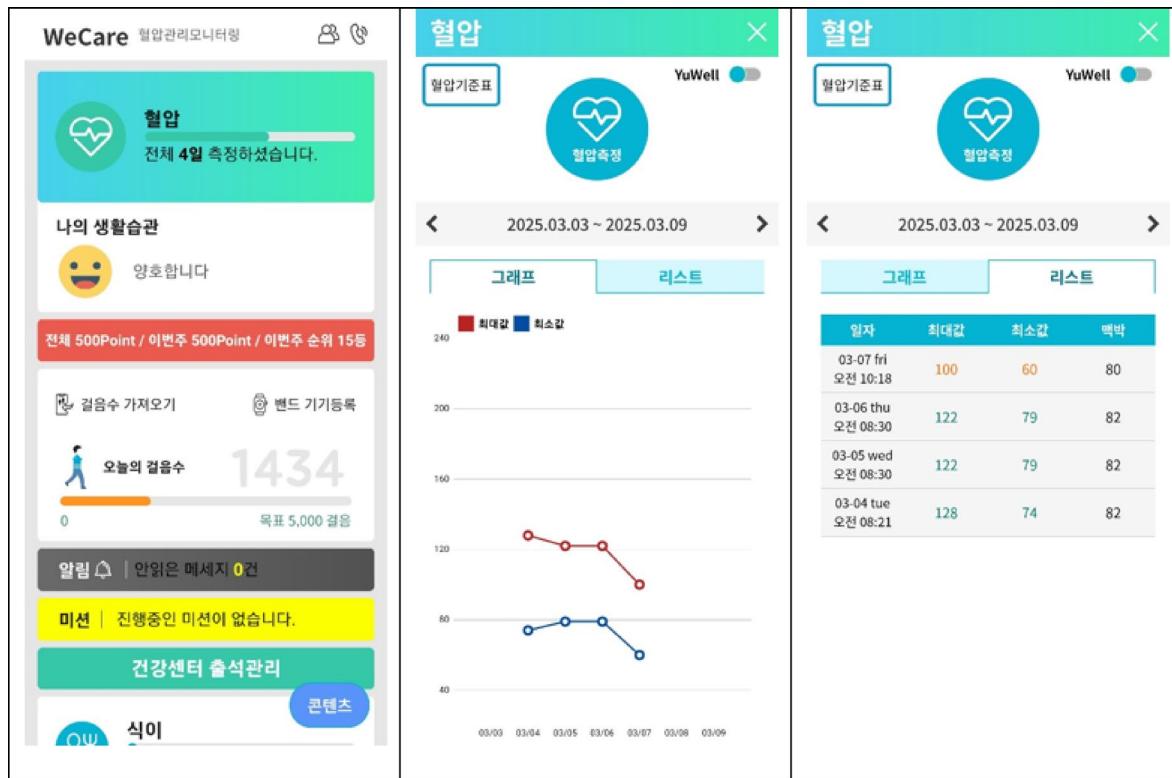


Fig. 1. Screenshots of mobile application.

Characteristics		Overall (N=80)	Intervention group (n=42)	Control group (n=38)	χ^2 or T	p-value
Sex(n=80), ,n (%)	Male	22(27.5)	10(23.8)	12(31.6)	0.6	0.44
	Female	58(72.5)	32(76.2)	26(68.4)		
Age at the baseline visit(n=80), year, mean (sd)	73.2 (5.7)	73.4 (5.7)	73.0 (5.6)	0.3	0.77	
Education level(n=80),n (%)	0–6	24(42.1)	23 (54.8)	24 (63.2)	2.7	0.44
	7–9	14(24.6)	6 (14.3)	8 (21.1)		
	10–12	16(28.1)	11 (26.2)	5 (13.2)		
	13+	3(5.3)	2 (4.8)	1 (2.6)		
APOE ε4 carriers(n=80),n (%)	15/80(18.8)	8/42(19.0)	7/38(18.4)	0.6	0.44	
Cognition						
Mini-mental state examination(n=80) score, mean (SD)	23.0(3.7)	23.7 (3.8)	22.1 (3.5)	-1.9	0.06	

Table 2. Comparison of general characteristics between the intervention group and control group at baseline (N=80). MMSE-KC: Korean version of the mini-mental state examination.

This study used SPSS Statistics version 25.0 (IBM Corp., Armonk, NY, USA) and R version 4.2.2 (R Foundation for Statistical Computing, Vienna, Austria) to analyze the data. Missing data were imputed using the multiple imputation chained equations (MICE) R package. For all tests, the significance level was set at 5% and two-tailed p-values are reported (Fig. 2).

Results

The demographic characteristics of the participants are presented in Table 2. There were no significant differences between the intervention group and the control group in age ($p=.77$), sex ($p=.44$), educational level ($p=.44$), APOE ε4 carrier status ($p=.44$), and MMSE-KC scores ($p=.06$).

Effectiveness of intervention is presented in Table 3. After adjusting for baseline measurements, analyses of intervention effectiveness revealed significant differences in MMSE-KC and modified Boston naming test scores between the intervention group and the control group at 52 weeks. The intervention group was found

		Intervention group (n=42)		Control group (n=38)		F	p
		Mean	±SD	Mean	±SD		
Primary outcome							
MMSE-KC	Baseline (n=80)	23.7	3.8	22.1	3.5	10.6	0.00**
	52-week (n=71)	23.7	2.9	20.8	3.8		
Secondary outcome							
Verbal fluency	Baseline(n=80)	13.4	4.3	11.9	4.8	1.2	0.3
	52-week (n=71)	14.0	4.5	12.0	5.6		
Modified Boston naming test	Baseline(n=80)	10.5	2.4	9.0	2.8	8.3	0.01*
	52-week (n=71)	10.7	2.2	8.7	2.8		
Word list memory	Baseline(n=80)	13.8	4.4	12.0	5.1	2.6	0.1
	52-week(n=71)	16.7	18.6	11.3	4.2		
Constructional praxis	Baseline(n=80)	8.8	1.7	7.9	2.2	0.6	0.5
	52-week(n=71)	9.1	1.4	8.5	1.7		
Word list recall	Baseline(n=80)	4.5	2.2	3.8	2.2	0.9	0.3
	52-week(n=71)	4.6	1.9	3.9	2.1		
Word list recognition	Baseline(n=80)	7.5	2.8	6.9	3.0	0.0	0.9
	52-week(n=71)	8.0	2.2	7.6	2.3		
Constructional praxis recall	Baseline(n=80)	5.8	2.7	4.2	3.0	0.2	0.7
	52-week(n=71)	5.4	2.9	4.5	3.2		
Trail making test A	Baseline(n=80)	92.6	83.0	140.7	113.8	3.9	0.05
	52-week(n=71)	84.9	68.6	140.3	97.7		
Trail making test B	Baseline(n=80)	279.9	51.0	280.4	54.1	0.9	0.4
	52-week(n=71)	284.4	49.1	273.4	66.9		

Table 3. Effectiveness of a multidomain intervention using a mobile application on the CERAD-K score using ANCOVA (N=80). ANCOVA was conducted using baseline scores as covariates; values are presented as Mean ± SD. Missing data for 9 participants at week 52 (7 in the control group and 2 in the intervention group) were imputed using baseline data with the MICE method in R. The analysis was conducted on a total of 80 participants. $p < .05$ indicates statistical significance; $p < .01$ indicates high statistical significance. MMSE-KC = Mini-Mental State Examination–Korean version.

to have higher scores than the control group on both tests. A similar trend was seen for the TMT. However, no significant difference was found in the secondary outcomes, including verbal fluency, word list memory, constructional praxis, word list recall, word list recognition, and constructional praxis recall (Figs. 3 and 4).

There were no serious side effects associated with the intervention. Adverse events included stress and time burden, observed in 5% (4) and 3.8% (1) of participants, respectively.

A total of 9 (11.3%) individuals were lost to follow-up. The dropout rate was higher in the control group (7 participants, 77.8%) than in the intervention group (2 participants, 22.2%; $p = .003$). The reasons for withdrawal were health-related issues (6 participants, 67%), time burden or low motivation (2 participants, 22%), and death (1 participant, 1%) (Table S1).

Discussion

This clinical trial aimed to enhance cognitive function in patients with MCI at high risk of developing dementia through a mobile-based multidomain intervention. The mobile-based multidomain intervention was more effective at improving cognitive function than offline education was. The intervention group showed greater improvements in global cognitive function (MMSE-KC) and language function (modified Boston naming test) compared to the control group.

Prior studies have shown that multidomain interventions improve cognitive function in patients with MCI²⁴. In this population, simultaneously modifying multiple modifiable dementia risk factors appears to be more effective than addressing single factors in isolation or training cognition alone²⁵. On this basis, multidomain interventions are currently being implemented in MCI cohorts²⁶. However, most of this work has relied on offline delivery, which entails spatial and temporal constraints. Using a mobile application enables investigators to remotely monitor patients' progress and provide timely feedback at any time, allowing individuals with MCI to manage dementia risk factors in their own homes^{27,28}. In studies of older adults at risk for cognitive decline, home-based interventions have produced cognitive training effects comparable to those of facility-based programs, with high retention in both groups—suggesting that, if adherence is maintained, home-based delivery can yield cognitive benefits similar to those achieved with offline, facility-based formats²³. Multiple reports have also found that cognitive interventions delivered via mobile devices are equivalent to pencil-and-paper formats^{29,30}. Moreover, mobile platforms permit ongoing monitoring of cognitive performance, enabling earlier

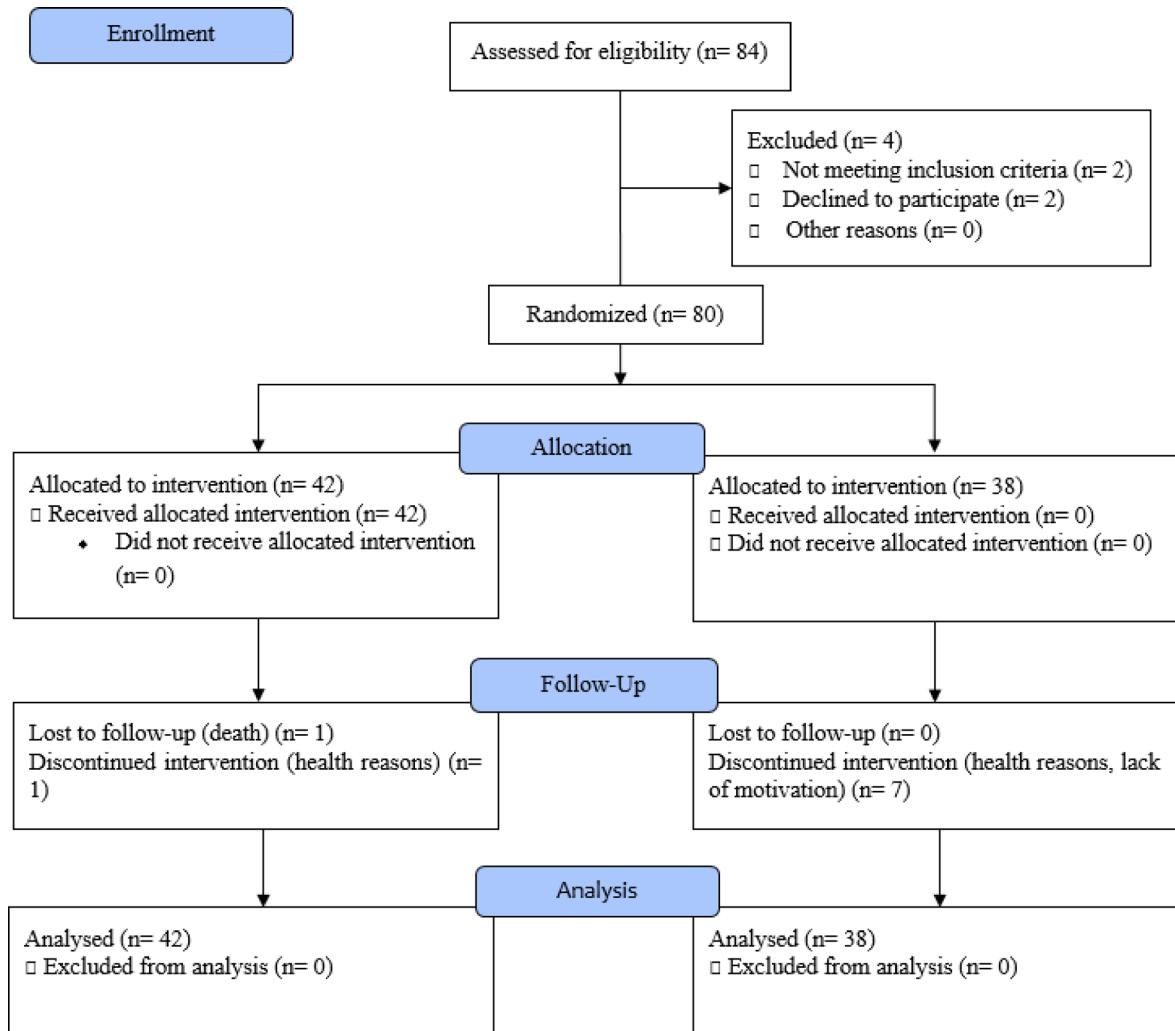


Fig. 2. Trial profile.

detection of change and timely, tailored intervention³¹. Recently, mobile-based multidomain programs have also been reported to confer cognitive benefits^{32,33}. Taken together, these observations support the effectiveness of multidomain interventions in maintaining cognitive function, with the added advantage of mobile accessibility.

In addition, we targeted patients with MCI who had risk factors for dementia but were not diagnosed with dementia. Focusing on individuals at risk of developing dementia is crucial because interventions to reduce risk are more likely to translate into cognitive benefits before extensive neurodegeneration occurs^{34,35}. A recent meta-analysis reported that, among patients with dementia, multidomain interventions were the only approach associated with improvements in global cognition³⁶, and accumulating evidence suggests that cognitive interventions yield diminishing returns as pathology advances³⁴. This study demonstrated the effectiveness of improving cognitive function by providing multidomain intervention via mobile to patients with mild cognitive impairment, which is the previous stage of dementia. This is in line with the findings of prior research that demonstrated the efficacy of multidomain interventions for enhancing cognitive function prior to dementia diagnosis. This study also has notable strengths. It used a randomized controlled design, delivered the intervention over an extended 52-week period, and leveraged a mobile platform that enabled home-based access, remote monitoring, and timely feedback. Together, these features support the feasibility and potential effectiveness of mobile multidomain interventions for preventing cognitive decline in at-risk older adults.

Limitations

This study had some limitations. First, although adherence was not considered in the analysis of this study, it is important to note that digital interventions are significantly affected by adherence. Therefore, caution is needed when interpreting the data, as adherence can influence the outcomes of these interventions. Second, when implementing mobile multidomain interventions for the elderly, difficulties may arise due to limited digital literacy, and this study may be limited in that it did not reflect the digital literacy of the elderly³⁷. Third, Although the baseline cognitive function was not statistically significant, the control group had a lower baseline score, and the small sample size may have influenced the results. Therefore, caution is required when interpreting the

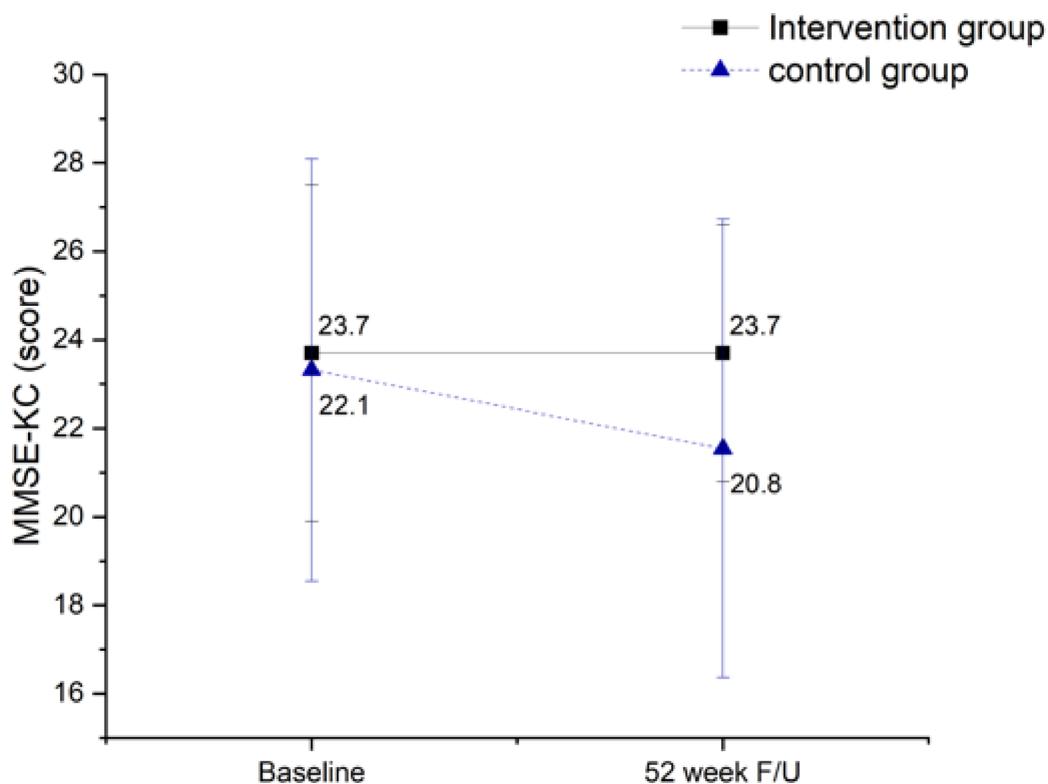


Fig. 3. Pre/post mini-mental state examination (MMSE-KC) score for each group.

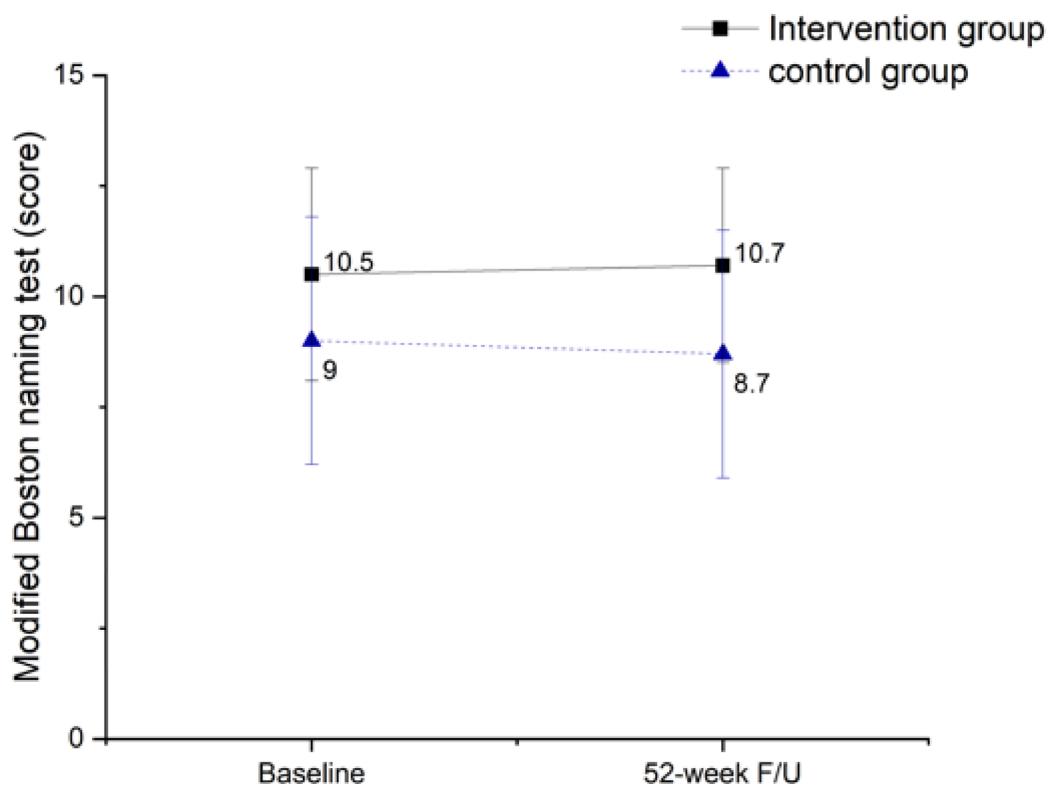


Fig. 4. Pre/post modified Boston naming test score for each group.

findings. Fourth, we did not conduct pre-study usability testing of the application, which may have introduced interface-related barriers, reduced adherence, and limited generalisability. However, this study attempted to compensate for this limitation by continuously educating the research nurse on the application and how to use smart devices effectively and on the application.

Conclusions

Our trial provides evidence that mobile multidomain interventions are an effective method for decreasing the risk of dementia in patients with MCI. Mobile technologies that support daily activities and health can compensate for decreased function owing to dementia. Additional research is required to confirm the effect of multidomain interventions on dementia prevention based on patient compliance.

Data availability

The data used in this study contain identifiable or sensitive patient information and cannot be shared publicly due to restrictions from the Ethics Committee of Chuncheon Sacred Heart Hospital. However, the dataset used and analyzed during the current study is available from the corresponding author on a reasonable request.

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Author contributions

H.Y.C.: the interpretation of the data, manuscript drafting, and statistical analysis.Y.J.K.: the data acquisition, interpretation of the data, and revision of the manuscript.D.S.S.: the statistical analysis, interpretation of the data, and revision of the manuscript. M.E.A.: the conceptualization, design, and data acquisition.S.K.L.: the conceptualization and design, data acquisition, interpretation of the data, and revision of the manuscript. All authors have read and agreed to the published version of the manuscript.

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Declarations

Competing interests

The authors declare no competing interests.

Additional information

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Correspondence and requests for materials should be addressed to S.-K.L.

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