Complementary Therapies in Medicine 42 (2019) 164–169

Contents lists available at ScienceDirect

Complementary Therapies in Medicine

journal homepage: www.elsevier.com/locate/ctim

The effect of a multicomponent intervention to promote community activity on cognitive function in older adults with mild cognitive impairment: A randomized controlled trial

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ARTICLE INFO

Keywords:
Cognitive function
Community activity
Cognitive activity
Physical activity
Social activity

ABSTRACT

Objectives: This study aimed to examine the effectiveness of a multicomponent intervention combining physical, cognitive, and social activities developed to promote community activity in improving cognitive function in older adults with mild cognitive impairment (MCI).
Design: Single-blind randomized controlled trial.
Setting: A total of 83 Japanese older adults with MCI participated in the study from April to September 2017.
Interventions: Participants were randomly assigned to either the multicomponent intervention group (n = 41), attending 90-minute physical, cognitive, or social activity sessions using community resources twice weekly, or the health education control group (n = 42).
Outcomes: The primary outcomes were cognitive functions, and the secondary outcomes were grip strength, walking speed, depressive symptoms, physical activities, number of outdoor activities, and conversation time.
Results: Analysis using linear mixed models revealed significantly greater improvements in the intervention group in spatial working memory ($p = 0.024$) following intervention compared with the control group. Time spent in moderate-to-vigorous physical activity ($p = 0.048$) and step count ($p = 0.059$) decreased from the baseline post-intervention in the control group, whereas the baseline was maintained in the intervention group. No significant between-group differences were found post-intervention in the other primary and secondary outcomes.
Conclusions: This study showed that a 24-week multicomponent intervention program was effective in improving spatial working memory and maintaining physical activity in older adults with MCI. A follow-up investigation is required to determine whether continuation of physical, cognitive, and social activity can prevent dementia or reverse MCI in older adults.

1. Introduction

Mild cognitive impairment (MCI) is a condition defined as a transitional state between normal aging and dementia.[1] Older adults with MCI higher risk of progress to dementia within five years; but more than half remain stable or return to a normal state.[2] Therefore, detection of MCI at an early stage and the development of an intervention program to prevent progression to dementia important for dementia preventia strategies.

Nonpharmacological interventions for cognitive decline have been widely studied. Recent reviews suggest that targeted physical activity or/and cognitive training are effective strategies to promote both cognitive and functional brain plasticity in older adults.[3] Further, an NIH consensus panel on dementia recently concluded that physical activity is the only intervention with enough evidence to recommend it to forestall cognitive decline.[4] However, the number of individuals who regularly engage in physical activity is relatively low. Recent estimates suggest that only 31.1% of adults adhere to the actual

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https://doi.org/10.1016/j.ctim.2018.11.011
Received 9 September 2018; Received in revised form 25 October 2018; Accepted 8 November 2018
Available online 13 November 2018
0965-2299/

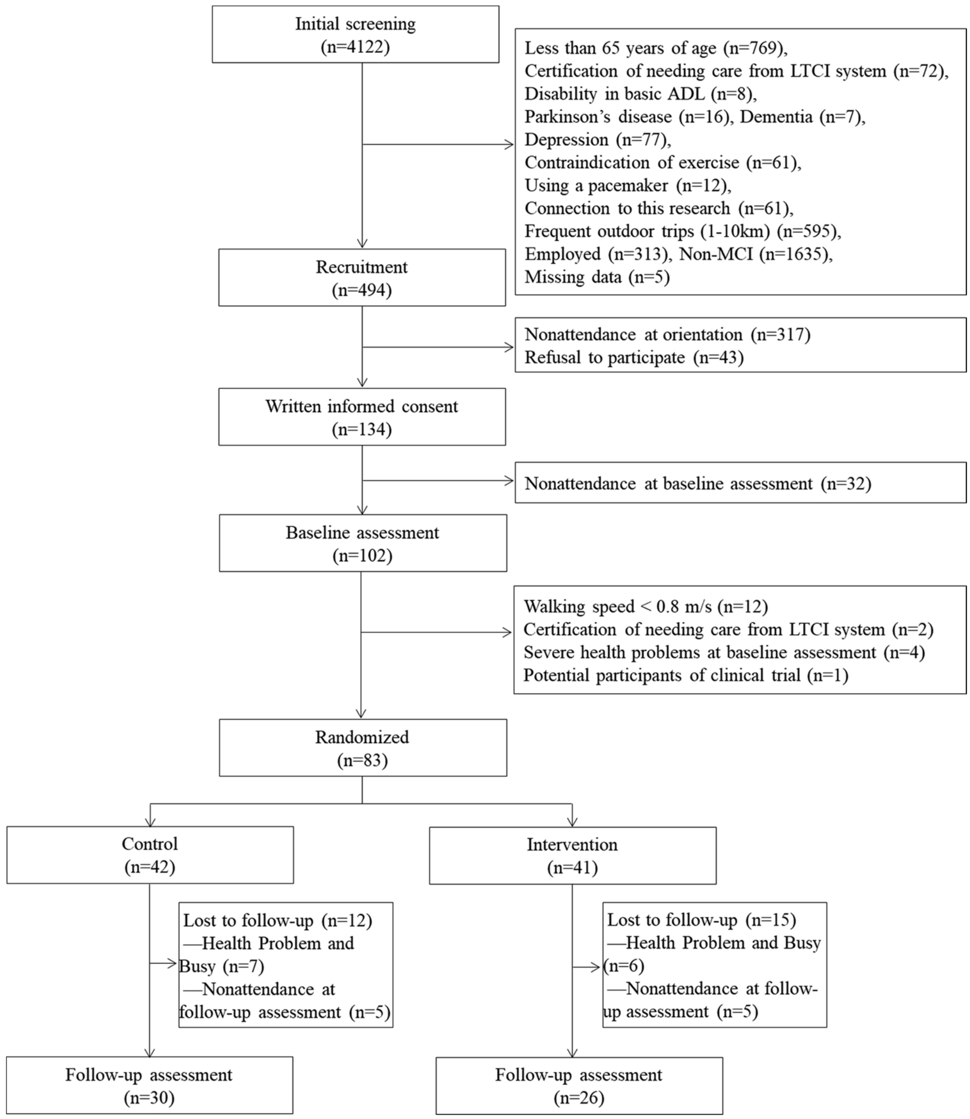

Fig. 1. Flowchart of the participant recruitment process.
LTCI: long-term care insurance; ADL: activities of daily living; MCI: mild cognitive impairment

recommendations for regular physical activity.[5] This low adherence may be attributed to several factors. Participants with a negative self-perception of their conditions or little opportunity to engage in physical activity in their neighbourhood demonstrated lower adherence to physical activity recommendations.[6] Furthermore, the elements of "fun" and "favourite activity" are considered the most important in maintaining motivation and engagement in activities. Despite this, few studies have focused on older adults' favourite activities.[7]

Encouraging older adults to participate in community activities is the cornerstone of the active aging strategy in many countries.[8] Many previous studies show that decreased social participation has been related to cognitive decline and greater risk of dementia.[9,10] Particularly in retirement, older adults must be given the opportunity to engage in social networks and activities in the community to help them detach from the social networks of coworkers.[11] However, due to the heterogeneity in measuring social activity, there are few RCT designs that promote community-based social activities.

Therefore, in the present study we developed a multicomponent intervention program using the "KENKOJISEICHI" (a place where people interact with others in the community) to promote community activity through community resources. The program focuses on encouraging participants to maintain their community activity by selecting their own favourite physical, cognitive, and social activities. Through a six-month RCT, the current study aimed to examine the effectiveness of a multicomponent intervention combining physical, cognitive, and social activities developed to promote community activity in improving cognitive function in older adults with MCI.

2. Methods

2.1. Study design and sample size

This study adopted a single-blind RCT design to compare the effects of the intervention program with the effects of a health education control program for older adults with MCI. The trial was conducted during the six-month period between April and September 2017. This study was designed and conducted in consideration the CONSORT statement and guidelines.[12] The CONSORT checklist for this trial is available as supporting document (See Checklist S1). Sample size calculations were based on predictions of change in the results of the National Center for Geriatrics and Gerontology Functional Assessment Tool (NCGG-FAT).[13,14] Using a power of 80%, significance level of 0.05, and effect size of 0.2, a sample size of 52 participants was needed. Because a dropout rate of 20–30% was expected, 70 total participants were required. The trial complied with the Declaration of Helsinki and was approved by the Ethics Committee of the National Center for Geriatrics and Gerontology (Approval Number: 861-2). All participants provided written informed consent. The protocol for this trial was registered in the University Hospital Medical Information Network Clinical Trials Registry (UMIN000026479).

2.2. Participants

The participants of the trial were recruited from a subcohort of the National Center for Geriatrics and Gerontology Study of Geriatric Syndromes (NCGG-SGS), conducted in 2015–2016 in Takahama, Aichi Prefecture, Japan. This subcohort targeted all older adults living in Takahama who were 60 years or older and did not have certification of needing care from the Japanese long-term care insurance system (LTCI). A total of 9716 individuals were invited to participate in the screening survey of physical and cognitive function; 4122 of these individuals participated in the screening. Of the 4122 participants, 494 were selected as potential participants of the trial after applying the following exclusion criteria: (1) age under 65 years; (2) certification of needing care from the LTCI; (3) disability in basic activities of daily living (ADL); (4) history of Parkinson's disease, Alzheimer's disease (AD), or depression; (5) contraindication of exercise by doctor; (6) use of a pacemaker; (7) connection to this research; (8) frequent 1 to 10 km trips outdoors; (9) current employment in a job; (10) no MCI; (11) missing data. Recruitment documents were sent to the 494 individuals selected, and 102 participated in the baseline assessment. However, 51 individuals were excluded from the trial because they withdrew their participation (n = 32) or did not meet the inclusion criteria (n = 19). The 83 eligible participants with MCI were assigned to either the intervention (n = 41) or the health education control group (n = 42) using a computerized randomization scheme at a 1:1 ratio by a researcher blinded to the study aims (Fig. 1).

The following MCI inclusion criteria were used in this study[15]: (1) objective cognitive impairment (indicated by an age- and education-adjusted score at least 1.5 standard deviations (SD) below the reference threshold in one or more specific cognitive domains); (2) normal general cognitive functioning (Mini-Mental State Examination (MMSE) scores of ≥ 24/30); (3) no evidence of functional dependency (no need for supervision or external assistance in performing basic ADL); (4) no dementia. The criterion for objective cognitive impairment was assessed for multiple domains using the NCGG-FAT. This tool incorporates four cognitive domains including memory, attention and executive function, and processing speed.[16]

2.3. Intervention program

In Takahama City, there have make a system which was admitted as "KENKOJISEICHI" a community attractive place where elderly people would like to go out and they can interact with other people in the community. We categorized 101 healthy activities in "KENKOJISEICHI" into 28 physical activities, 29 cognitive activities, and 44 social activities. We defined physical, cognitive, and social activities as follows: (1) physical activities involve considerable body movement or strength to complete (e.g., walking, muscle strength training, stretching, Tai Chi, indoor golf, dance, etc.); (2) cognitive activities predominantly require mental engagement (e.g., visiting a library or art museum, singing Karaoke, playing a game, reminiscing, arts and crafts, calligraphy, film appreciation, stamp art, etc.); (3) social activities are conducted within a community network (e.g., socializing in person with others; attending events; visiting a cafeteria, drug store, shopping mall, temple, or senior's club, etc.).

The intervention program consisted of participation in physical activities (16 times), cognitive activities (16 times), and social activities (16 times). Participants in the intervention group attended 90-minute sessions twice per week for 24 weeks (48 total). The participants were divided into nine groups to participate in activities, with four to five participants and two staff per group. Each supervised session began with a 15-minute condition check and stretching, followed by 60 min of physical, cognitive, or social activities, 15 min of report writing, and discussion of the next session's schedule. The program was designed to allow participants to choose their favourite activities as long as they strictly adhered to the set frequency of participation in physical, cognitive, and social activities. The staff confirmed attendance, managed the schedule, and provided feedback on the activity reports written by participants to maintain motivation. The majority of staff members were middle-aged women and non-health professionals. We recruited staff members from among the general population in Takahama. Before the implementation of the intervention, we provided a six-hour training for the staff. Specifically, the training emphasized staff interaction and encouragement of class participants' support for one another, and risk management to prevent accidents. During the intervention period, we regularly met with the staff to discuss problems and improvements in classroom management.

Participants in the health education control group attended two health education classes (90 min each) during the 24-week study period. Participants took the classes on oral care (e.g. dental care and swallowing exercise) and nutrition (e.g. risk factor for malnutrition, health effects, and prevention) by a professional lecturer while sitting. The classes did not contain any specific information regarding physical, cognitive, and social activities.

2.4. Outcomes

We assessed outcomes at baseline and after the intervention period using study personnel blinded to the study assignment. The primary outcomes were post-intervention changes in multiple domains of cognitive function, identified using NCGG-FAT tablet-based assessments. These tasks involved memory of a word list by immediate recognition and delayed recall of a 10-word target list. We calculated the composite score using the sum of the delayed recall and the mean immediate recognition, measured over three trials. Spatial working memory was assessed with a spatial span task, a computerized version of the Corsi block-tapping task.[17] Specifically, nine or twelve blue circles were displayed on the monitor. Subsequently, three or four circles changed from blue to white for 5 s. Participants were required to memorize the location of the circles that changed colour. Attention and executive function were assessed by the Trail Making Test Part A and B (TMT-A and TMT-B). For TMT-A, participants were asked to touch the target numbers displayed randomly on the monitor in consecutive order (1–15). For TMT-B, participants were asked to touch target numbers and letters (Japanese Kana characters). They were asked to respond as quickly as possible. Processing speed was assessed by a symbol-digit substitution test (SDST) in which nine pairs of numbers and symbols were displayed at the top of the monitor. A target symbol was presented at the centre of the monitor. Participants were asked to choose the number corresponding to the target symbol at the bottom of the monitor. Global cognitive status was assessed using the MMSE.[18]

The secondary outcomes were post-intervention changes in grip strength, walking speed, depressive symptoms, physical activities, number of outdoor activities, and conversation time. Walking speed was measured with a stopwatch while the individual walked 2.4 m at their usual pace. Participants were required to walk the 2.4 m path five times; mean walking speed (meter per second) was calculated based on the five trials. Maximum hand grip strength was measured in a standing position using a handheld dynamometer (GRIP-D; Takei, Niigata, Japan). Depressive symptoms were measured using the 15-item Geriatric Depression Scale (GDS).[19] Physical activity measurements included time spent in moderate-to-vigorous physical activity (MVPA) and step count, measured using a triaxial accelerometer (modified HW-100; Kao Co., Ltd., Tokyo, Japan). MVPA was defined as activities involving three or more metabolic equivalents. Data were recorded in 4-

second periods for up to one day and collected using the Kao system installed at the data-reading location, including public facilities, commercial facilities, and so on. Data were gathered from each individual who wore the accelerometer for 10 or more hours each day for at least seven days. Conversation time was assessed by a biosensor device (Silmee TMW20; TDK Co., Ltd., Chiba, Japan). Participants were required to wear the biosensor over their right wrist for 14 days, except while bathing or swimming, to examine their daily living activities. Number of outdoor activities was assessed by the question, “How many times did you go outdoors in a week?” Answers were used to calculate the number of times participants went outdoors per week.

2.5. Statistical analysis

Baseline characteristics were compared across the intervention and control groups and analysed using a *t*-test for continuous variables and chi-square tests for categorical variables. The primary and secondary outcomes of a continuous type were analysed using a linear mixed model to account for missing data at post-assessment. The model included analysis within time (baseline and post-intervention), between groups (intervention and control groups), and of the interaction of time and groups. The linear mixed model method is better than the general linear model for handling missing data at post-assessment and limitation of the availability of the variance-covariance structure.[20] All analyses were conducted using the IBM SPSS Statistics software package (25.0; SPSS Inc., Chicago, IL, USA). The level of statistical significance was set at $p < 0.05$.

3. Results

3.1. Baseline characteristics and completion rates

Descriptive statistics of baseline characteristics of the study participants are shown in Table 1. No significant differences were observed between the groups in terms of demographic variables, clinical variables, cognitive function, physical function, GDS, physical activity, frequency of going outdoors, and conversation time. A total of 56 participants (intervention group, n = 26; control group, n = 30) completed the intervention program or education program during the six-month period. Participant attendance rates of 70.2% and 82.9% were recorded for the intervention and control groups, respectively.

3.2. Outcome measures

Table 2 summarizes the mean difference between baseline and post-intervention values, the effect within time and between groups, and the interaction of time and groups on primary and secondary outcomes between the two groups. In the primary outcomes, the intervention group revealed significantly greater improvements in spatial working memory ($p = 0.024$) following the intervention compared with the control group. However, MMSE, composite word memory, TMT-A, TMT-B, and SDST scores showed no significant between-group differences following the intervention. We also observed no significant differences in secondary outcomes, including grip strength, walking speed, GDS score, frequency of going outdoors, and conversation time. However, MVPA time ($p = 0.048$) and step counts ($p = 0.059$) decreased from the baseline at post-intervention in the control group, whereas the baseline measures were maintained in the intervention group.

3.3. Satisfaction

The participants of the intervention group completed a questionnaire regarding their satisfaction with the program; 96.1% reported that they were satisfied with the overall program. Regarding program duration and staff support, 88.5% and 100% were satisfied, respectively. To assess change in the frequency of going outdoors, participants were asked, “Did your behaviour regarding going outdoors change through participating in the program?” A total of 86.6% of participants answered “yes.” Moreover, 80.8% of participants reported that they wanted to continue the program.

Table 1
Baseline characteristics of study participants.

	Intervention (n = 41)	Control (n = 42)	*p*-values
Age, years	75.5 (6.0)	76.4 (5.1)	0.455
Gender, % female	43.9	52.4	0.440
Body mass index, kg/m^2	23.4 (3.0)	24.1 (4.6)	0.430
Educational level, year	11.1 (2.2)	10.9 (2.3)	0.811
No. medications used	3.6 (3.3)	3.7 (3.1)	0.830
Hypertension, %	53.7	61.9	0.447
Diabetes, %	9.8	16.7	0.353
Hyperlipidemia, %	26.8	33.3	0.518
Going outdoors, no. times/day	2.4 (1.9)	2.2 (1.3)	0.682
Conversation time, min/day	225.1 (84.0)	222.5 (87.8)	0.895
Step count, steps/day	6106.4 (3458.6)	5673.3 (2782.6)	0.530
MVPA, min/day	32.2 (24.3)	31.5 (21.1)	0.822
Cognitive functions			
MMSE score	27.1 (2.1)	26.7 (2.0)	0.348
Composite word memory score	9.3 (3.0)	9.5 (2.8)	0.708
Spatial working memory score	6.6 (0.7)	6.6 (0.7)	0.956
Trail Making Test (Part A) score, s	24.5 (7.9)	24.4 (6.8)	0.971
Trail Making Test (Part B) score, s	63.6 (31.3)	53.9 (23.9)	0.118
Symbol-digit substitution test score	38.4 (10.3)	37.8 (6.9)	0.766
Physical functions			
Grip strength, kg	23.8 (7.2)	23.8 (6.8)	0.997
Walking speed, m/s	1.1 (0.2)	1.1 (0.2)	0.547
Psychological tests			
Geriatric Depression Scale score	2.9 (2.2)	2.9 (2.7)	0.959

Note: Values indicate mean (SD) or number (%). All *p*-values were generated from a *t*-test or chi-square test. MVPA: moderate-to-vigorous physical activity; MMSE: Mini-Mental State Examination.

3.4. Safety

The participants did not report any injuries or severe adverse events associated with the interventions conducted in either group.

4. Discussion

The present study revealed that a six-month, multicomponent intervention combining physical, cognitive, and social activities developed to promote community activity significantly improved spatial working memory, although effects were not observed on other cognitive domains. Additionally, daily physical activity, including step counts and MVPA time, decreased from the baseline post-intervention in the control group, whereas the baseline was maintained in the intervention group. This result indicates that the intervention might be effective for maintaining physical activity, and maintenance of physical activity in turn might lead to the desirable changes in the spatial working memory observed among the intervention group.

Spatial working memory has been defined as the ability to hold spatial information active in working memory during a short period of time,[21] and is controlled by the hippocampus and prefrontal cortex.[22,23] Spatial working memory and spatial navigation are affected by atrophy of these brain areas emerging early in the MCI stage or during the early stages of AD.[24,25] Lack of this function may lead to misremembering places and failure in navigating. In addition, spatial working memory is considered to be sensitive to a fitness and exercise effect.[26] A few studies have reported that aerobic exercise and higher cardiorespiratory fitness are associated with greater hippocampal volume, which is

Table 2
Comparison of outcomes between intervention and control groups.

	Mean difference (95% CI) between baseline and post-intervention values		Time	Group	Group × time
	Intervention (n = 41)	Control (n = 42)	*p*-values	*p*-values	*p*-values
Cognitive functions					
MMSE score	−0.51 (−1.35 to 0.34)	0.35 (−0.44 to 1.15)	0.376	0.434	0.143
Composite word memory score	0.71 (−0.07 to 1.48)	0.85 (0.12 to 1.58)	0.022	0.594	0.790
Spatial working memory score	0.27 (−0.07 to 0.62)	−0.28 (−0.60 to 0.05)	0.099	0.003	0.024
Trail Making Test (Part A) score, s	0.23 (−2.16 to 2.63)	−1.07 (−3.32 to 1.18)	0.347	0.455	0.432
Trail Making Test (Part B) score, s	2.75 (−9.67 to 15.17)	−0.82 (−12.53 to 10.90)	0.890	0.113	0.678
Symbol-digit substitution test score	−0.50 (−2.16 to 1.17)	1.70 (0.09 to 3.20)	0.038	0.449	0.065
Physical functions					
Grip strength, kg	1.52 (0.52 to 2.50)	2.29 (1.36 to 3.20)	0.001	0.633	0.255
Walking speed, m/s	0.08 (0.02 to 0.16)	0.09 (0.03 to 0.16)	0.005	0.519	0.849
Psychological tests					
Geriatric Depression Scale score	−0.11 (−0.84 to 0.61)	0.36 (−0.32 to 1.04)	0.297	0.438	0.350
Physical activity					
Step count, steps/day	31.49 (−722.48 to 785.47)	−970.33 (−1688.20 to −252.45)	0.010	0.077	0.059
MVPA, min/day	−1.16 (−6.85 to 4.52)	−9.08 (−14.50 to −3.65)	0.002	0.136	0.048
Going outdoors, no. times/day	0.78 (−0.19 to 1.77)	0.18 (−0.75 to 1.11)	0.708	0.178	0.373
Conversation time, min/day	25.92 (−6.57 to 53.31)	22.08 (−5.42 to 50.47)	0.112	0.771	0.967

Note: All *p*-values were generated from linear mixed models. MMSE: Mini-Mental State Examination; MVPA: moderate-to-vigorous physical activity.

involved in spatial working memory performance in older adults.[26,27] RCTs with older adults have demonstrated that six months of aerobic exercise training increases the volume of the anterior hippocampus, leading to improvements in spatial working memory.[26] In a cross-sectional study, it was found that higher levels of cardiorespiratory fitness showed greater hippocampal volume, which in turn was associated with more accurate and faster spatial working memory.[27] These relationships are evident not only in grey matter but in white matter microstructure as well. Associations have been found between higher cardiorespiratory fitness and spatial working memory in white matter tracts including the genu of the corpus callosum and the anterior corona radiata.[28] The mechanisms underlying physical activity's effects on cognition might be improvements in cardiovascular fitness. Higher cardiovascular fitness is considered to relate to oxygen consumption, brain changes, neurogenesis, and synaptogenesis.[29] Our results support these previous studies, and clarify that spatial working memory is also improved in older adults with MCI through a six-month multi-component intervention combining physical, cognitive, and social activities.

Epidemiological studies have found an association between cognitive training and social activities and improvements in cognitive function. A meta-analysis indicated that cognitive activities correlated with better performance in global cognition, executive functioning, memory, processing speed, and language ability, and that they lowered the risk of cognitive decline.[30] Participation in social activities has been seen to delay the onset of dementia and inhibit cognitive decline.[9,10] In addition, a systematic review of magnetic resonance imaging studies revealed that cognitive and social activities correlate with increased regional grey matter and white matter volume. These studies suggest that brain reserve is a potential mechanism underlying the link between cognitive or social activities and cognitive function.[31] Our intervention program, which combines physical, cognitive, and social activities, is a group-based activity that requires social interaction between participants. Therefore, it appears that there more social activity elements were included.

The intervention program was also designed to facilitate long-term adherence for all participants by allowing participants to choose their favorite activities, so long as they strictly adhered to the set frequency of participation in physical, cognitive, and social activities. As shown by the results of the satisfaction survey, the intervention group reported 96.1% satisfaction with the intervention program, and 80.8% of the participants reported wanting to continue the program. Favourite activities are an important potential component in interventions that achieve the individual and societal goals of reducing disease and improving well-being through participants' own motivation.[32] The results of this study have implications for preventive long-term care services and public health practitioners designing health-related interventions using older adults' favourite activities in a familiar long-term place of residence.

The strengths of this study include the RCT design, from which the authors can make causal inferences and minimize selection bias and known and unknown confounding factors. This study screened older adults with MCI, who were at high risk of developing dementia from among all community-dwelling older adults in an area, using an objective cognitive function evaluation tool. Moreover, the intervention program was conducted using community resources in and around a familiar place of residence, to facilitate long-term adherence for participants. This may be useful in providing community-based programs support for older adults with MCI or who go outdoors infrequently.

4.1. Limitations

This study has limitations. We did not find significant differences between the groups in any domains of cognitive function other than spatial working memory. A possible reason for these negative results could be that the cognitive load was smaller than what the cognitive training intervention needed to enhance cognitive function. Cognitive activity in our intervention program resembled group-based cognitive leisure activities with social demands, such as visiting a library or art museum, playing a game, singing Karaoke, or reminiscing. Differences between groups in GDS and physical function were not observed. GDS score was relatively low, because our participants did not have symptoms of depression. Additionally, if the intervention program's physical load was insufficient, it would not have led to improved physical function. Future studies using a more demanding physical function load and including older adults with depression symptoms should determine the effects of physical, cognitive, and social activities on psychological and physical functions. Other limitations of the present study include the small sample size and the short duration of the intervention period, which may have influenced the results; a study over a long-term period with a larger sample size is required. Finally, the current study did not include behavioural interventions, such as self-monitoring of daily physical, cognitive, and social activities. Therefore, the extent of these activities in daily life outside the intervention time may be insufficient. Previous studies have reported that a composite approach, including aerobic exercise and behavioural interventions, can have effects on cognitive function in older adults with amnestic MCI.[14]

5. Conclusions

This study showed that a 24-week multicomponent intervention program combining physical, cognitive, and social activities was effective in improving spatial working memory performance and maintaining physical activity in older adults with MCI. A future follow-up investigation is required to determine whether the continuation of physical, cognitive, and social activities can prevent AD or reverse MCI in older adults.

Declarations of interest

None.

Funding

Grant-in-aid for scientific research (no. 26242059) from the Japan Society for the Promotion of Science; Research Funding for Longevity Sciences (29-32) from the National Center for Geriatrics and Gerontology; Grant-in-Aid for the Japan Society for the Promotion of Science Fellows (17F17009).

Ethical approval

The study protocol was developed in accordance with the Declaration of Helsinki and was approved by the ethics committee of the National Center for Geriatrics and Gerontology. Prior to study participation, informed consent was obtained from all participants.

Acknowledgments

We would like to thank all the participants and staff who took part in this study, the Takahama office for assisting with participant recruitment, and the Kao Corporation for their offering of the triaxial accelerometer. We would like to thank Editage (www.editage.jp) for English language editing.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.ctim.2018.11.011.

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