A randomized controlled trial of a Functioning Improvement Tool home visit program and its effect on cognitive function in older persons

Running head: The FIT home visit program

Key words: cognitive function; home visit; elderly; Japanese; Mini Mental State Examination; randomized trial

Key Points:

Our new Functioning Improvement Tool home visit program improved MMSE scores in Japanese elderly subjects.

The intervention was most effective in subjects with mild cognitive decline.

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Abstract

Objective: The aim was to determine whether MMSE scores improved in elderly participants of a Functioning Improvement Tool (FIT) home visit program.

Methods: 252 participants aged 65 years or older living at home and receiving preventive services or a community long-term care prevention project according to the Japanese social long-term care insurance system were enrolled and randomly assigned to an intervention group (n=128) or a control group (n=124). Intervention group subjects received a 60-minute FIT home visit program for 3 months which included guidance, assistance, and help in writing, and teaching calculation in order to complete the FIT. Control subjects did not receive any home visits. Cognitive function was evaluated by Mini-Mental State Examination (MMSE). Analysis of covariance was used to examine the effects of the FIT adjusting for baseline MMSE scores, age, and sex.

Results: 53 subjects were excluded because of withdrawal, hospitalization, death, relocation, or missing data of MMSE; 199 subjects (60 males, 139 females; age 78.6±7.4 years) were analyzed. The baseline MMSE scores did not differ between the intervention and control groups (24.2±4.3 vs. 24.1±4.7, p=0.90). After the study period, the change in the MMSE score was significantly better in the intervention group than in the control group (0.8±0.3 vs. -0.1±0.2, p=0.04). Stratified analyses showed that the intervention strategy was most effective in subjects with mild cognitive decline, with baseline MMSE scores from 18 to 23 points (1.9±0.5 vs. -0.1±2.8, p=0.04).

Conclusions: Our FIT home visit program improved MMSE scores in elderly participants with mild cognitive decline.

Introduction

The number of dementia subjects who need long-term care has recently been increasing. An epidemiological study reported that the prevalence of dementia in the elderly Japanese population older than 65 years was 11.0 cases /100 persons (Wada-Isoe et al. 2009). The Japanese social long-term care insurance system was reformed in 2005. The reformed system focuses more on preventive services for elderly whose care needs are light at the moment but at high risk for needing care in the near future. However, effective prevention strategies have not been fully established.

Several studies have reported that pharmacological interventions such as a cholinesterase inhibitor (Hansen et al. 2008), beta carotene (Grodstein et al. 2007), vitamins (Chandra 2001), and testosterone (Cherrier et al. 2005) were valid methods to improve impaired cognitive function. Recently, a clinical review demonstrated that non-pharmacological intervention can be as powerful as pharmacological intervention (Burns and Iliffe 2009). Therefore, non-pharmacological interventions may be valid methods for preventing impaired cognitive function. Several studies have reported that non-pharmacological interventions such as reminiscence therapy (Woods et al. 2005), reality orientation therapy (Spector et al. 2003; Spector et al. 2008), cognitive tasks (Kawashima et al. 2005), and exercises (Cancela Carral and Ayan Perez 2007; Cassilhas et al. 2007; Kwak et al. 2008; Liu Ambrose and Donaldson 2009; Van de Winckel et al. 2004) were effective for improving cognitive function. However, these interventions were uniform group programs. Subjects who could not participate in these group programs due to illness or geographical restrictions could not receive these treatments; therefore, individual programs for subjects living at home may be required.

In northern Europe, individual home visits for elderly subjects are formalized as a program. Several studies have indicated that such programs reduced nursing home admissions

(Hendriksen et al. 1984) and the mortality rate (Elkan et al. 2001). However, these home visiting studies have not focused on cognitive function. In Japan, Ikeno (2009) conducted a home visiting study using the Self Assessment of Occupational Balance (SAOB) (Kobayashi 2004), which is a tool for identifying problems in daily life developed based on occupational therapy (Ikeno 2009). Ikeno's study was conducted in 36 Japanese subjects who were 75 years or older with a crossover design for 3 months. Although there was a tendency for MMSE scores to improve (P=0.1), no significant change was found due to the small sample size.

Methods

Study Subjects

This study was conducted in two rural towns of Shinhidaka and Hidaka in Hokkaido, northern Japan. The study subjects were screened for the following inclusion criteria: (1) aged 65 years or older; (2) living at home; and (3) receiving preventive services or a community long-term care prevention project according to the Japanese social long-term care insurance system (Health and Welfare Statistics Association 2010).

The eligible subjects' information, such as age, sex, and levels of need for care, were obtained from the municipal government. The subjects were recruited by direct mail that included a self-addressed post card. A reminder was sent to the subjects who did not respond by mail after 2 weeks. Then, all subjects gave their written, informed consent in a face to face meeting before the baseline assessment; the meeting included the subject's family when the subject lived with his or her family. The subject's family was also allowed to attend during the intervention. The study protocol was approved by the ethics board for epidemiological studies at Hokkaido University Graduate School of Medicine and conformed to the principles

outlined in the Declaration of Helsinki of 1975, as revised in 1983.

Interventions

The intervention subjects participated in the Functioning Improvement Tool (FIT) home visit program once a month for 3 months (Appendix 1). Each program is completed within 60 minutes. Qualified medical care personnel were in charge of the home visits. Five nurses and one dental hygienist conducted the FIT home visit program. For the purpose of standardizing the intervention, they were trained in the appropriate use of the FIT by lectures and role playing. During a home visit, they provided guidance on how to fill in the FIT. They also assisted in writing and calculation when needed in order to complete the FIT.

The FIT was based on the SAOB (Kobayashi 2004). In occupational therapy, Reilly reported that the appropriate proportion of work, leisure, and rest was important for people's health (Reilly 1962). Yoshikawa et al. reported that a daily task consisted of a combination of "duty" and "obligation" (Yoshikawa and Tsuru 1998). With such a background, the SAOB was made, and it was reported that subjects whose daily tasks that were not their "duty" and "will" occupied more than 20% of their time had a low quality of life (QOL) in 154 subjects 18 years or older (Kobayashi 2004).

In Ikeno's study, it was difficult for elderly subjects to understand the meaning of "duty" and "obligation" (Ikeno 2009). Based on subjects' feedback, we have modified the SAOB to the FIT by adding the item "whom you worked for", so that elderly subjects could consider the meaning of their activities more clearly.

The FIT consists of six steps. In Step 1, the subject writes down the activities from getting up to sleeping in order to clarify what kinds of daily tasks the subject performed the day before. In Step 2, in order to clarify the objective of each daily task, the subject writes down whom each daily task was performed for. In order to consider the meaning of each daily

task, the subject writes down whether each daily task was performed as a “duty”, and whether each daily task was performed according to that subject’s own “will”. In Step 3, the subject divides each daily task into the following four categories; it is a “duty”, and it was done according to the subject’s “will”; it is a “duty”, but it was not performed according to the subject’s “will”; it is not a “duty”, but it was performed according to the subject’s “will”; and it is not a “duty”, and it was not the subject’s “will” to do it. The subject then counts the daily tasks in each category. In Step 4, the subject calculates the percentage of daily tasks in each category. In Step 5, the subject writes down the calculated percentages as a cobweb graph, and the subject makes a visual daily task balance. In Step 6, the subject writes down the impressions of his/her daily tasks while doing the FIT. We hypothesized that the FIT home visit program stimulates subject’s cognition, such as memory, orientation, emotion, attention, calculation, and speech, through these six steps with conversation.

The control subjects did not receive any home visits, contacts, or information. All of the subjects had no restriction in usual care involving medical and formal nursing care.

Objectives

The aim was to determine whether MMSE scores improved as a result of the FIT home visit program in men and women aged 65 years or older who were receiving preventive services or a community long-term care prevention project.

Outcome measurements

Cognitive function was assessed using the Japanese version of the Mini-Mental State Examination (MMSE) (Folstein et al. 1975) including eight items: orientation to time, 0 to 5; orientation to place, 0 to 5; registration, 0 to 3; attention and calculation, 0 to 5; recall, 0 to 3; language, 0 to 2; repetition, 0 to 1; and complex commands, 0 to 6. The total MMSE score

range is from 0 to 30, with higher scores indicating a better mental state. Demographic information such as age, sex, educational level (elementary school, junior high school, and high school), marital status (single, married, divorced/widowed), living arrangements (living alone, living with any family and relatives), dementia and depression medication, and participation in regional activities were collected. All measurements and questionnaires were conducted by the interviewers at the subjects' homes at baseline and at the end of follow-up.

Sample size

It was estimated that 133 participants in each of the two study groups were necessary to detect a difference of 1 point for the MMSE (standard deviation, 2.9) (Ikeno 2009), with a power of 80 percent and a two-sided alpha level of 0.05.

Randomization and masking

Using a computerized random allocation scheme, the study subjects were randomly divided into two groups after baseline assessment. Random numbers from 0 to 9 were generated for each person. Those with odd numbers were assigned to the intervention group, and the others were assigned to the control group. There was one couple among the subjects; both were assigned to the control group by chance. For the purpose of keeping measurement bias to a minimum, both baseline and follow-up assessments were performed by study staff who were not involved in the intervention.

Statistical analysis

Continuous variables are presented as means±standard deviation (SD); categorical variables are presented as numbers (percentages). The baseline characteristics of the study subjects in the intervention and control groups were compared using the *t*-test, χ^2 test, and

Fisher's exact test. The changes in MMSE scores from the baseline to the end of follow-up were evaluated by paired *t*-tests in the intervention and control groups. Group differences in the MMSE score changes between baseline and end of follow-up were evaluated by analysis of covariance (ANCOVA) adjusted for baseline MMSE scores, age, and sex. The study subjects were divided into three groups according to baseline MMSE scores, and a stratified analysis was performed using the following cut-offs: MMSE < 17, severe cognitive decline; 18 ≤ MMSE ≤ 23, mild cognitive decline; and MMSE > 24, no cognitive decline (Geoge et al. 1991; Tombaugh and McIntyre 1992). An alpha level of 0.05 was considered statistically significant. All statistical analyses were performed using SPSS version 15.0 for Windows (SPSS Inc., Chicago, IL).

Results

Recruitment was conducted from October 1 to 24, 2008. The follow-up of subjects was completed on March 31, 2009. Of 630 eligible subjects, 252 (40.0%) agreed to participate in the study, and they were randomly allocated to an intervention group (n=128) or a control group (n=124). Fourty-five subjects were dropped out because of withdrawal, hospitalization, death, or relocation during the study period. After eight subjects were excluded due to missing MMSE data, 199 subjects (60 males and 139 females; mean age 78.6±7.4 years; age range, 65 to 95 years) were evaluated (Figure 1).

Figure 1

Table 1 shows the subjects' baseline characteristics. Variables such as age, sex, educational level, marital status, living arrangements, dementia and depression medication, participation in regional activities, and MMSE scores did not differ between the intervention and control groups. Although not significant, there were small differences between the intervention and the control group in living arrangements and dementia medication.

Table 1

Figure 2 shows the change in MMSE scores at baseline and at end of follow-up.

Figure 2

MMSE scores in the intervention group at the end of follow-up were significantly improved compare to those at baseline (from 24.2±4.3 to 25.0±4.8, p=0.004). Subjects in the control group showed no improvement (from 24.1±4.7 to 24.1±5.4, p=0.84).

Table 2 shows the change in MMSE scores, follow-up MMSE scores minus baseline MMSE scores (positive value means improvement), of the intervention and control groups. The mean MMSE score improvement was significantly larger in the intervention group than in the control group (0.8±0.3 vs. -0.1±0.2, p=0.04). Table 2

Table 3 shows the stratified analysis by severity of cognitive decline of the change in MMSE scores at baseline and end of follow-up. In the mild cognitive decline subjects, the mean MMSE score change was significantly improved in the intervention group compared to the control group (1.9±0.5 vs. -0.1±2.8; p=0.04); no differences were seen in the severe and no cognitive decline subjects. Table 3

No adverse events were reported during the study period in the present study.

Discussion

Our new 3-month FIT home visit program significantly improved MMSE scores of cognitive function in elderly subjects, especially in those with mild cognitive decline.

Several prevention studies have indicated that non-pharmacological interventions were effective for improving cognitive function (Kawashima et al. 2005; Lautenschlager et al. 2008; Onder et al. 2005; Wang 2007). Kawashima et al. (2005) reported that performing a task that consisted of reading aloud and arithmetic for 6 months improved cognitive function in 32 dementia patients. Wang et al. (2007) reported that group reminiscence therapy performed eight times improved cognitive function in 102 dementia patients. These studies were performed using a group intervention for subjects in nursing homes. In contrast, our FIT

home visit program targeted elderly living at home. The Japanese social long-term care insurance system, a universal entitlement for all elderly persons, was established in 2000. The number of Japanese social long-term care insurance users was 4.56 million in 2006; 23% were institutional service users, while 77% were home care users, including assistance with activities of daily living (Tsutsui *et al*. 2007). Because of these social backgrounds, individual programs for subjects living in the community may be needed. We selected study subjects according to the Japanese social long-term care insurance system. Selected subjects' conditions were either certified as long-term care need due to a little difficulty in walking, standing on one leg, and getting in and out of the bathtub (Tsutsui and Muramatsu 2007), or uncertified but recognized as a high risk for needing care or support by the municipal government manager on an annual care needs examination (Health and Welfare Statistics Association 2010). Lautenschlager *et al*. (2008) reported that an intervention involving exercises for 24 weeks improved cognitive function in 170 subjects with memory deficits, but subjects with cardiovascular disease and those who were physically impaired could not receive these interventions. Onder *et al*. (2005) reported that, when an informal caregiver who received training from the researcher gave 156 dementia subjects orientation information for 25 weeks, cognitive function was improved. In contrast, the FIT home visit program involved qualified medical care personnel. Our program does not increase a family's care burden or affect physically impaired subjects.

The mean age of the intervention group was 1 year younger than that of the control group, but this was not significant. As a result of randomization, however, there were no significant differences between the intervention group and the control group in the baseline MMSE scores. In addition, group differences in the MMSE score changes between baseline and end of follow-up were evaluated by analysis of covariance adjusted for baseline MMSE scores, age, and sex. Therefore, these differences may not affect our results. The proportion of

male subjects in the control group was marginally higher than that in the intervention group ($p<0.07$). This may indicate that male subjects tend to drop out, and that the program tends to be accepted by females.

There were twice as many withdrawals in the intervention group. However, no significant differences were seen in baseline MMSE scores between the subjects who completed the study and those who withdrew from the study (data not shown). Overall, 25 of 33 subjects (75.8%) who withdrew had MMSE scores greater than 24 points. Given these findings, our FIT home visit program may not be preferred by subjects who have maintained cognitive function.

Our FIT home visit program was most effective in subjects with mild cognitive decline. They needed help for writing, calculating, or drawing a cobweb graph in order to complete the FIT. On the other hand, many subjects with mild cognitive decline tried to learn a letter and practice writing work with a calculator during the study period. In the result of stratified analysis by MMSE subscale, complex commands were significantly improved in the intervention group compared to the control group in mild cognitive decline subjects (data not shown). Roland et al. (1985) reported that tasks that stimulate cognitive function increased the related regional cerebral blood flows and brain metabolism (Roland and Friberg 1985). In contrast, many subjects with severe cognitive decline could not remember the daily tasks they performed on the day before the home visit. Among subjects with no cognitive decline, many could easily complete the FIT. Thus, our FIT home visit program may be appropriate for mild cognitive decline subjects.

Because of the increase in dementia patients, the number of long-term care participants has been increasing in Japan. Our new 3-month FIT home visit program significantly increased the MMSE scores of the intervention group by 0.8 points. Particularly in the mild cognitive impairment group, the FIT home visit program significantly increased

the MMSE scores of the intervention group by 1.9 points. In a population-based study in Sweden in which subjects older than 75 years were observed over time, a decrease in the MMSE score by 1 point was associated with an increase in the cost of care by 15,000 Swedish kronor (Jonsson et al. 1999). The present results suggest the possibility of reducing long-term care expenses with the FIT home visit program; thus, future studies including cost-effectiveness evaluation are needed.

Three subjects died during the study period in the control group, but none in the intervention group died. This could be just a chance finding, or could be related to the fact that the intervention group subjects received more attention. During the study period, some intervention group subjects were advised to see a medical doctor. Although we did not find any new dementia cases, our FIT home visit program may increase the chance of early detection of an illness.

This study had some limitations. First, 53 participants dropped-out during the study period. The selection of more healthy subjects as participants may have occurred, but since the treatment was randomized, this selection should not have affected the results. However, since the participation rate was 40%, it was difficult to generalize the results. Second, since we were not able to blind the study subjects to their allocation, the Hawthorne effect may have affected the result (Jones 1992). Considering a third group receiving home visits without the FIT program may solve this limitation.

In a study of nursing home admissions, cognitive impairment was one of the primary indications for nursing home placement (Smith et al. 2000). We measured MMSE scores of cognitive function only before and after intervention. Long-term effects on preventing progress of clinical stages need to be assessed in future studies. In order to clarify this point, our home visit program will require longer follow-up periods.

In summary, our new FIT home visit program significantly improved MMSE scores

of cognitive function, especially in elderly, mild cognitive decline subjects. These results suggest that our home visits will prevent dementia or decrease the need for long-term care due to a decline in cognitive functioning.

Conflict of Interest

None declared. The study sponsor played no role in the study design, the collection, analysis and interpretation of data, the writing of the report, or the decision to submit the report for publication.

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References

Burns A, Iliffe S. 2009. Dementia. *BMJ* **338:** b75.

Cancela Carral JM, Ayan Perez C. 2007. Effects of high-intensity combined training on women over 65. *Gerontology* **53:** 340-346.

Cassilhas RC, Viana VA, Grassmann V, Santos RT, Santos RF, Tufik S, Mello MT. 2007. The impact of resistance exercise on the cognitive function of the elderly. *Med Sci Sports Exerc* **39:** 1401-1407.

Chandra RK. 2001. Effect of vitamin and trace-element supplementation on cognitive function in elderly subjects. *Nutrition* **17:** 709-712.

Cherrier MM, Matsumoto AM, Amory JK, Ahmed S, Bremner W, Peskind ER, Raskind MA, Johnson M, Craft S. 2005. The role of aromatization in testosterone supplementation: effects on cognition in older men. *Neurology* **64:** 290-296.

Elkan R, Kendrick D, Dewey M, Hewitt M, Robinson J, Blair M, Williams D, Brummell K. 2001. Effectiveness of home based support for older people: systematic review and meta-analysis. *BMJ* **323:** 719-725.

Folstein MF, Folstein SE, McHugh PR. 1975. "Mini-mental state". A practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res* **12:** 189-198.

Geoge LK, Landarman R, Blazer DG. 1991. Cognitive impairment. In *Psychiatric Disorder in America.*, pp 291-327. Robbins LN, Regier DA (eds). Free Press: New York; 2.

Grodstein F, Kang JH, Glynn RJ, Cook NR, Gaziano JM. 2007. A randomized trial of beta carotene supplementation and cognitive function in men: the Physicians' Health Study II. *Arch Intern Med* **167:** 2184-2190.

Health and Welfare Statistics Association. 2010. *Health State of The Nation, annual report*. Japan: Ministry of Health and Welfare.

Hansen RA, Gartlehner G, Webb AP, Morgan LC, Moore CG, Jonas DE. 2008. Efficacy and

safety of donepezil, galantamine, and rivastigmine for the treatment of Alzheimer's disease: a systematic review and meta-analysis. *Clin Interv Aging* **3:** 211-225.

Hendriksen C, Lund E, Stromgard E. 1984. Consequences of assessment and intervention among elderly people: a three year randomised controlled trial. *Br. Med. J. (Clin. Res. Ed.)* **289:** 1522-1524.

Ikeno T. 2009. A pilot study of preventive home visits applying occupational therapeutic theory for improving functional capacity. *Thesis (Phd)*, Hokkaido University (in Japanese).

Jones SR. 1992. Was there a Hawthorne effect? *American Journal of Sociology* **98:** 451-468.

Jonsson L, Lindgren P, Wimo A, Jonsson B, Winblad B. 1999. Costs of Mini Mental State Examination-related cognitive impairment. *Pharmacoeconomics* **16:** 409-416.

Kawashima R, Okita K, Yamazaki R, Tajima N, Yoshida H, Taira M, Iwata K, Sasaki T, Maeyama K, Usui N. 2005. Reading aloud and arithmetic calculation improve frontal function of people with dementia. *J Geronto. A Biol Sci Med Sc* **60:** 380-384.

Kobayashi N. 2004. Development of the Self Assessment of Occupational Balance. *Thesis (Phd)*, Hiroshima University (in Japanese).

Kwak YS, Um SY, Son TG, Kim DJ. 2008. Effect of regular exercise on senile dementia patients. *Int J Sports Med* **29:** 471-474.

Lautenschlager NT, Cox KL, Flicker L, Foster JK, van Bockxmeer FM, Xiao J, Greenop KR, Almeida OP. 2008. Effect of physical activity on cognitive function in older adults at risk for Alzheimer disease: a randomized trial. *JAMA* **300:** 1027-1037.

Liu Ambrose T, Donaldson MG. 2009. Exercise and cognition in older adults: is there a role for resistance training programmes? *Br J Sports Med* **43:** 25-27.

Onder G, Zanetti O, Giacobini E, Frisoni GB, Bartorelli L, Carbone G, Lambertucci P, Silveri MC, Bernabei R. 2005. Reality orientation therapy combined with cholinesterase

inhibitors in Alzheimer's disease: randomised controlled trial. *Br J Psychiatry* **187:** 450-455.

Reilly M. 1962. Occupational therapy can be one of the great ideas of 20th century medicine. *Am J Occup Ther* **16:** 1-9.

Roland PE, Friberg L. 1985. Localization of cortical areas activated by thinking. *J. Neurophysiol* **53:** 1219-1243.

Smith GE, Kokmen E, O'Brien PC. 2000. Risk factors for nursing home placement in a population-based dementia cohort. *J Am Geriatr Soc* **48:** 519-525.

Spector A, Thorgrimsen L, Woods B, Royan L, Davies S, Butterworth M, Orrell M. 2003. Efficacy of an evidence-based cognitive stimulation therapy programme for people with dementia: randomised controlled trial. *Br J Psychiatry* **183:** 248-254.

Spector A, Woods B, Orrell M. 2008. Cognitive stimulation for the treatment of Alzheimer's disease. *Expert Rev Neurother* **8:** 751-757.

Tombaugh TN, McIntyre NJ. 1992. The mini-mental state examination: a comprehensive review. *J Am Geriatr Soc* **40:** 922-935.

Tsutsui T, Muramatsu N. 2007. Japan's universal long-term care system reform of 2005: containing costs and realizing a vision. *J Am Geriatr Soc* **55:** 1458-1463.

Van de Winckel A, Feys H, De Weerdt W, Dom R. 2004. Cognitive and behavioural effects of music-based exercises in patients with dementia. *Clin Rehabil* **18:** 253-260.

Wada-Isoe K, Uemura Y, Suto Y, Doi K, Imamura K, Hayashi A, Kitayama M, Watanabe Y, Adachi Y, Nakashima K. 2009. Prevalence of dementia in the rural island town of Ama-cho, Japan. *Neuroepidemiology* **32:** 101-106.

Wang JJ. 2007. Group reminiscence therapy for cognitive and affective function of demented elderly in Taiwan. *Int J Geriatr Psychiatry* **22:** 1235-1240.

Woods B, Spector A, Jones C, Orrell M, Davies S. 2005. Reminiscence therapy for dementia.

Cochrane Database Syst Rev CD001120.

Yoshikawa H, Tsuru S, Miyamae T, Ishibashi Y. 1998. The relationship between desire and obligation in role commitment. Abstracts Book, 12th International Congress of the World Federation of Occupational Therapists.

Table 1. Baseline characteristics of the study participants

Variable	Intervention (n=99)	Control (n=100)	p-value
Age (years)	78.0±7.2	79.3±7.6	0.22
Sex (male), n. (%)	24 (24.2)	36 (36.0)	0.07
Educational level, n. (%)			
Elementary school	23 (23.2)	34 (34.0)	0.33
Junior high school	47 (47.5)	38 (38.0)	
High school	26 (26.3)	24 (24.0)	
Marital status, n. (%)			
Married	55 (55.6)	53 (53.0)	0.78
Divorced/widowed	43 (43.4)	46 (46.0)	
Living arrangements, n. (%)			
Living alone	33 (33.3)	40 (40.0)	0.77
Medication, n. (%)			
Dementia	6 (6.1)	4 (3.0)	0.75
Depression	4 (4.0)	2 (2.0)	0.68
Participation in regional activities, n. (%)	52 (52.5)	49 (49.0)	0.57
MMSE	24.2±4.3	24.1±4.7	0.90

Plus-minus values are means±SD. MMSE, Japanese version of the Mini-Mental State Examination.

Table 2. The change in MMSE scores between intervention and control groups

	Intervention (n=99)	Control (n=100)	F	p-value
MMSE scores	0.8±2.7	-0.1±0.2	4.36	0.04

Values are expressed as means±standard deviation. MMSE scores, follow-up MMSE scores minus baseline MMSE scores (positive value means improvement). MMSE, Japanese version of the Mini-Mental State Examination. P value of group differences were calculated by analysis of covariance adjusted for baseline MMSE scores, age, and sex.

Table 3. Stratified analysis of the change in MMSE scores between intervention and control groups by severity of cognitive decline

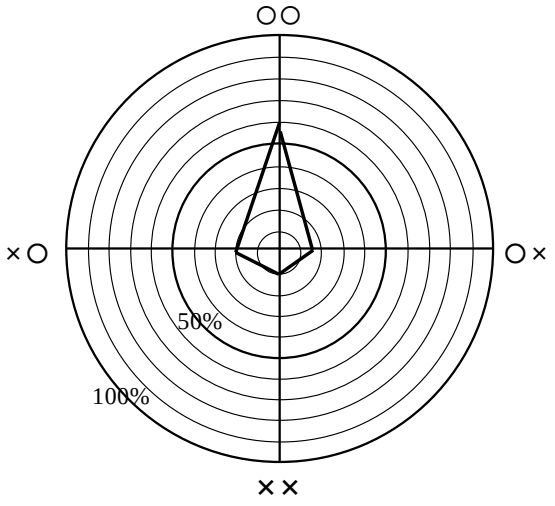
Severe cognitive decline				
	Intervention (n=7)	Control (n=6)	F	p-value
MMSE scores	-0.7±3.9	-1.1±2.3	0.24	0.64
Mild cognitive decline				
	Intervention (n=27)	Control (n=29)	F	p-value
MMSE scores	1.9±2.7	-0.1±2.8	4.39	0.04
No cognitive decline				
	Intervention (n=65)	Control (n=65)	F	p-value
MMSE scores	0.5±2.5	0.1±2.2	0.45	0.51

Severe cognitive decline, baseline MMSE scores from 0 to 17; Mild cognitive decline, baseline MMSE scores from 17 to 23; No cognitive decline, baseline MMSE scores from 24 to 30. Values are expressed as means±standard deviation. MMSE scores, follow-up MMSE scores minus baseline MMSE scores (positive value means improvement). MMSE, Japanese version of the Mini-Mental State Examination. P value of group differences were calculated by analysis of covariance adjusted for baseline MMSE scores, age, and sex.

★Step 1★		★Step 2★		
How did you spend yesterday? **What time did you get up yesterday?** **7:30** **What time did you go to sleep yesterday?** **22:00**		**Duty/Obligation** **○ Duty/Obligation** **× Not duty/ Not obligation**	**Will/Desire** **○ Will/desire** **× Not will/ Not desire**	**For whom?**
Time	**Daily Task**			
7:40	Washed my face	×	○	For myself
7:50	Picked up a newspaper.	×	×	For husband
8:00	Set the table for breakfast	○	○	For myself, For husband
8:20	Ate breakfast with my husband	○	○	For myself
8:50	Took medicine	○	×	For myself
9:00	Cleaned the dishes	○	×	For myself
≈				
22:00	Went to bed	×	○	For myself

★Step 3★	★Step 4★
Number of tasks **A= 19** **○○ B=10** **○× C= 3** **×○ D= 4** **×× E= 2**	**○○ B÷A×100= 10 ÷ 19 ×100= 53** **○× C÷A×100= 3 ÷ 19 ×100= 16** **×○ D÷A×100= 4 ÷ 19 ×100= 21** **×× E÷A×100= 2 ÷ 19 ×100= 11**

★Step 5★



★Step 6★

Please describe what you found by looking back on your yesterday's activities.

Recently, I am worrying about forgetfulness. But, I could remember the task the day before. This makes me feel self-confident.

I want to write a letter without any assistance.

I would like to spend more time with my husband.

Appendix 1. Example of the Functioning Improvement Tool. For the purpose of looking back on the previous day's tasks, the subjects classify their tasks and calculate the percent for each classified task in steps 1-4. Then, the subjects visualize activity balance and describe their feelings in steps 5-6. Qualified medical care personnel were in charge of the home visits. During a home visit, they provided guidance in how to fill in the FIT and assisted with writing and calculation when needed in order to complete the FIT.

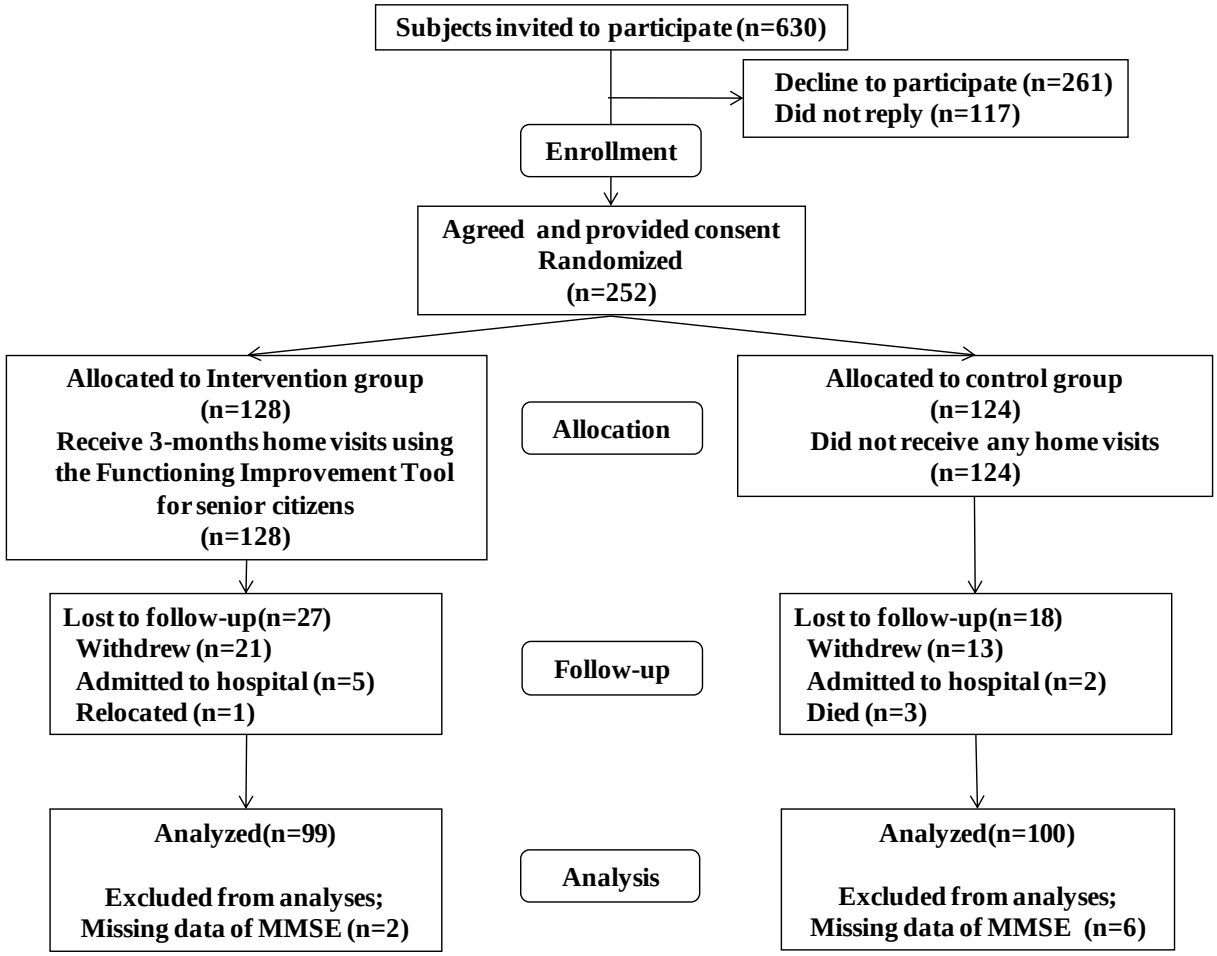


Figure 1. Sample selection and randomization. MMSE, Japanese version of the Mini-Mental State Examination.

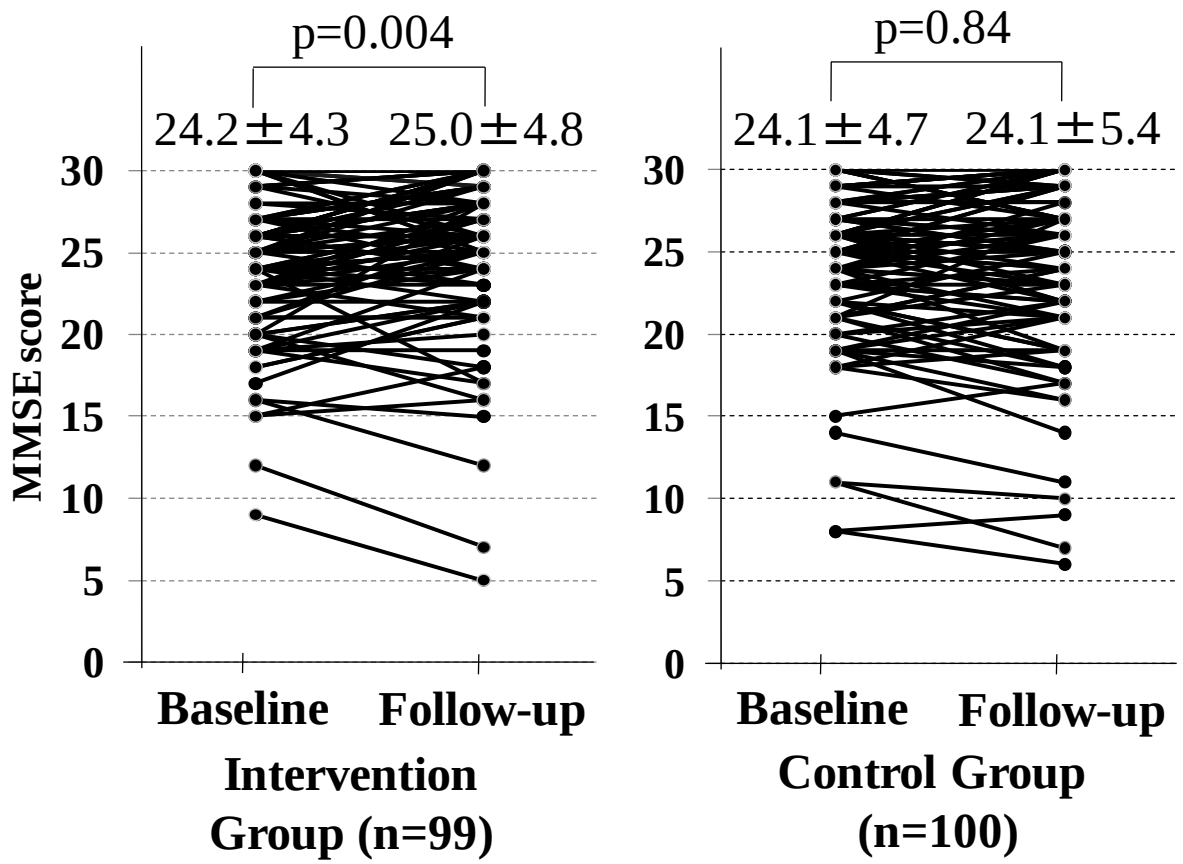


Figure 2. MMSE scores at baseline and at 3 months follow-up. Values are expressed as means±SD. MMSE, Japanese version of the Mini-mental state examination.