

# Effects of Intervention Using a Community-Based Walking Program for Prevention of Mental Decline: A Randomized Controlled Trial

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**OBJECTIVES:** To evaluate the efficacy of a municipality-led walking program under the Japanese public Long-Term Care Insurance Act to prevent mental decline.

**DESIGN:** Randomized controlled trial.

**SETTING:** The city of Takasaki.

**PARTICIPANTS:** One hundred fifty community members aged  $72.0 \pm 4.0$  were randomly divided into intervention ( $n = 75$ ) and control ( $n = 75$ ) groups.

**INTERVENTION:** A walking program was conducted once a week for 90 minutes for 3 months. The program encouraged participants to walk on a regular basis and to increase their steps per day gradually. The intervention was conducted in small groups of approximately six, so combined benefits of exercise and social interaction were expected.

**MEASUREMENTS:** Cognitive function was evaluated focusing on nine tests in five domains: memory, executive function, word fluency, visuospatial abilities, and sustained attention. Quality of life (QOL), depressive state, functional capacity, range of activities, and social network were assessed using questionnaires, and motor function was evaluated.

**RESULTS:** Significant differences between the intervention and control groups were shown in word fluency related to frontal lobe function ( $F(1, 128) = 6.833, P = .01$ ), QOL ( $F(1,128) = 9.751, P = .002$ ), functional capacity including social interaction ( $F(1,128) = 13.055, P < .001$ ), and motor function (Timed Up and Go Test:  $F(1,127)$

$= 10.117, P = .002$ ). No significant differences were observed in other cognitive tests.

**CONCLUSION:** Walking programs may provide benefits in some aspects of cognition, QOL, and functional capacity including social interaction in elderly community members. This study could serve as the basis for implementation of a community-based intervention to prevent mental decline. *J Am Geriatr Soc* 60:505–510, 2012.

**Key words:** prevention of mental decline; social interaction; dementia; Alzheimer's disease; mild cognitive impairment

The Japanese public Long-Term Care Insurance Act was launched in April 2000 to respond to the growing elderly population. The revision of the act in 2008 led to a greater emphasis on preventive long-term care, and municipalities are expected to play leading roles in building the platform and network for preventive activities.<sup>1</sup>

The Preventive Long-Term Care program was initiated under the leadership of the Ministry of Health, Labor, and Welfare in Japan, where municipality-led preventive interventions have been encouraged in agreement with the concept of community-based rehabilitation,<sup>2</sup> but prevention against mental decline remains a concern, so three areas in Japan (Tokyo, Ohbu, and Takasaki) were selected as model areas to evaluate the efficacy of a community-based program for prevention of mental decline. An intervention program was conducted in Takasaki: the Takasaki Project.

In the Takasaki Project, a walking program was chosen for intervention. Previous studies have reported that regular exercise is beneficial for lowering the risk of mental decline in elderly individuals,<sup>3–5</sup> and the efficacy of

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walking for preventing mental decline has been reported.<sup>6,7</sup> Another merit of walking is its low cost; effective prevention strategies would also have public health implications by reducing economic and social burdens.

The program adopted in this intervention encouraged participants to acquire a walking habit by gradually increasing their walking steps in a group setting. Thus, combined benefits of exercise and social interaction could be expected. Social isolation is associated with greater risk of mental decline,<sup>8,9</sup> whereas a rich social network and interaction may protect against mental decline.<sup>10,11</sup>

Based on the intervention described above, the present randomized controlled trial was designed to test whether a walking program was effective in preventing mental decline in elderly individuals without dementia.

## METHODS

### Participants

The Takasaki Project was conducted between September and November 2010. The flow of participants is shown in Figure 1. As the first step, participants were screened using a questionnaire. The questionnaire consisted of 25 self-completed items, including three items concerning mental decline: “Have others indicated that you may have memory problems, such as ‘you often ask the same things repeatedly?’” “Do you need to look up commonly used telephone numbers?” and “Do you sometimes fail to remember the date?” The questionnaire was mailed to inhabitants aged 65 and older; 2,387 residents younger than 80 answered yes to at least one of the three items, and these respondents were regarded to be at high risk of

mental decline. Leaflets describing the Takasaki Project were mailed to them, and 153 agreed to participate. An additional 13 participants were also recruited at a municipal center for elderly adults. One hundred sixty-six individuals attended information meetings, and written informed consent was obtained from 162. At the initial baseline assessment, each volunteer completed the Mini-Mental State Examination (MMSE) and a medical interview with a specialist in dementia medicine. During the interview, 12 volunteers were excluded: five meeting *International Classification of Diseases, Tenth Revision*, criteria for the diagnosis of dementia, five aged 80 and older (those who reached 80 after the 25-item self-check questionnaire was mailed), and two with chronic illness. Therefore, 150 volunteers were eligible for randomization as participants. The ethics board of Gunma University School of Health Sciences approved all procedures (No. 21–47).

### Assessment

#### Cognitive Tests

The major outcome variable was change in cognitive function. Cognitive function comprises various components; the Cognitive and Emotional Health Project in the United States focuses on five domains: learning and memory, executive function abilities (e.g., concept formation and abstract thought), language, visuospatial abilities, and sustained attention (ability to focus and perform a simple task).<sup>12</sup> The 5-Cog test<sup>13</sup> consists of five tests covering the following domains: learning and memory (category cued delayed recall test consisting of 32 words in eight

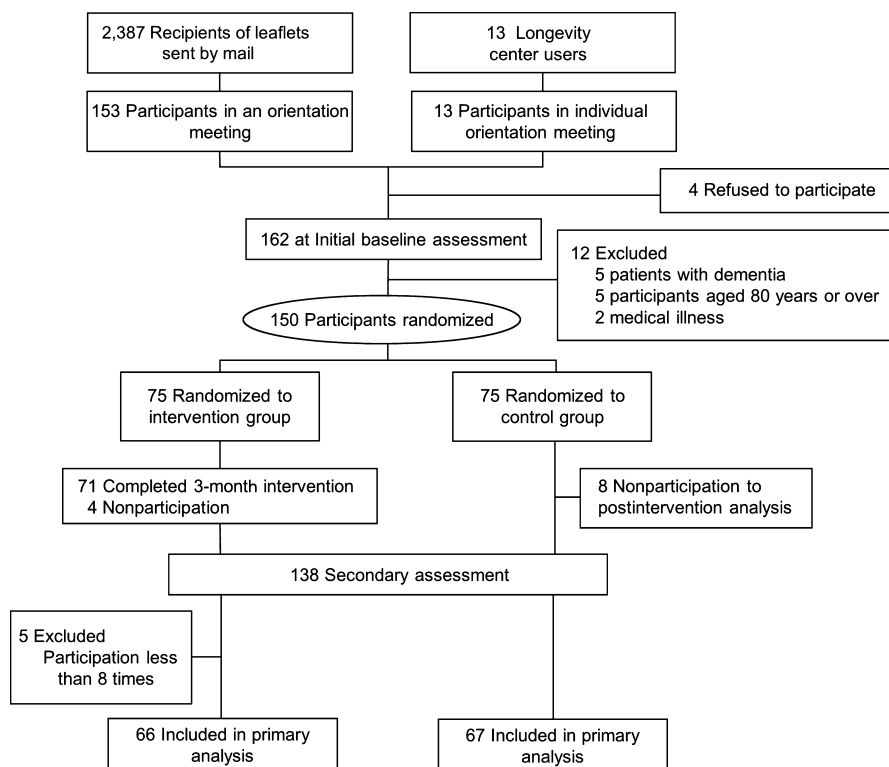


Figure 1. Flow of participants from the time of recruitment through study completion at 3 months.

categories), executive function abilities (dual-task test that requires alternating attention, abstract reasoning test similar to the Wechsler Adult Intelligence Scale-III (WAIS-III)), language (a categorical word fluency test of “animals” completed in two minutes), and visuospatial abilities (a Clock Drawing test to draw clock hands showing the time at “ten after eleven”). Mean scores  $\pm$  standard deviations (SDs) in participants aged 65 to 80 ( $n = 800$ ) were as follows: delayed recall test,  $12.0 \pm 5.8$ ; dual-task test,  $20.1 \pm 9.1$ ; abstract reasoning test,  $10.8 \pm 4.3$ ; word fluency test,  $13.9 \pm 6.0$ ; and Clock Drawing test,  $6.7 \pm 1.4$ . The 5-Cog is intended to be conducted in a group setting with a maximum of 50 individuals. The test set is distributed with a 35-minute-long instruction DVD so that the instructions are identical every time. Sustained attention was measured using the Digit-Symbol Substitution Test (DSST), a subset of WAIS-III, and the Yamaguchi Kanji-Symbol Substitution Test (YKSST).<sup>14</sup> The YKSST was developed for Japanese elderly individuals as an adaptation of the DSST; Japanese characters, kanji, were used instead of numbers, as in DSST, because elderly adults in Japan are more familiar with kanji. Mean YKSST scores were  $46.9 \pm 10.9$  in individuals aged 65 to 79 ( $n = 170$ ). The Trail-Making Test (TMT) was also administered to evaluate executive function abilities. Higher 5-Cog, DSST, and YKSST scores and lower TMT scores indicate better performance.

#### *Questionnaires on Quality of Life, Mood, Functional Capacity, Range of Activity, and Social Network*

Participants were required to complete the self-assessment questionnaires. Quality of life (QOL) was measured using a questionnaire on satisfaction in daily life (SDL).<sup>15</sup> Depressive state was evaluated using the Geriatric Depression Scale (GDS).<sup>16</sup> Functional capacity for independent living was assessed using the Tokyo Metropolitan Institute of Gerontology Index of Competence (TMIG-IC).<sup>17</sup> The TMIG-IC was designed to measure higher-level functional capacities in community-dwelling elderly individuals and consists of 13 items divided into three subscales: instrumental self-maintenance, intellectual activity, and social role.

The range of activity was measured using the Life-Space Assessment (LSA), which assesses how far and how often a person moves, ranging from moving around the bedroom only to traveling out of the person’s town.<sup>18</sup> Social network size was assessed using the Japanese version of the abbreviated Lubben Social Network Scale (Lubben).<sup>19</sup> Higher QOL, TMIG-IC, LSA, and Lubben scores and lower GDS scores indicate better performance.

#### *Assessment of Motor Function*

Four tests were conducted: grip force to assess muscle strength, balance time on one foot (60 seconds as cutoff time), Timed Up and Go Test (TUG), and maximum walking speed for 5 meters. Improvement is reflected by an increase in grip force and balance, and by a decrease in TUG and walking speed for 5 meters. In addition to the outcome measures above, average steps per day for 7 days were measured to evaluate the direct effect of the intervention program. All participants wore a pedometer (EX-500; Yamasa Tokei Co. Ltd., Tokyo, Japan) to record the total

number of steps walked in a day. Pedometers were sealed so that participants could not see the counters. The effect was assessed by comparing the average steps for 7 days just before and after the intervention.

#### *Randomization*

Randomization was conducted at the end of the initial baseline assessment; 150 participants were randomly allocated to the intervention group or control group. Research staff undertaking cognitive assessment, physical assessment, and intervention were separated.

#### *Intervention*

The intervention was conducted using the Tokyo Metropolitan Institute of Gerontology method. The program aimed to facilitate walking habits. The 90-minute intervention program was conducted once a week for 12 weeks and consisted of a 30-minute exercise period and 60-minute group work with five to eight people. Each participant was required to set a clear short-term goal on a weekly basis in order to achieve long-term goals. They were required to record their steps every day using a pedometer (during the intervention period, the pedometer was not sealed) and to write a self-assessment of daily activities. In addition to daily walking, participants planned and executed walking events (excursion) with other group members during the intervention period.

#### *The Facilitators*

Registered physical trainers or health nurses working at hospitals or healthcare providers commissioned by the local government of Takasaki City conducted the intervention program. They received lectures before the intervention, and they were supervised so that the program was administered appropriately. They were required to behave as facilitators to motivate participants, to maintain smooth communication, and to create a comfortable atmosphere.

#### *Control Group*

Participants in this group received educational lectures on food, nutrition, and oral care that were not directly related to the prevention of mental decline.

#### *Analysis of the Data*

The data were analyzed using the Japanese version of SPSS for Windows version 19.0 (IBM Corporation, New York). For initial baseline comparison between the intervention and control groups, two-sample *t*-tests were conducted for randomization; there was no significant difference between the two groups for any outcome measure. Participants who underwent the initial baseline and postintervention assessments were included in the final analysis; participants who dropped out and those who were present at the intervention fewer than eight of 12 times were excluded from the analysis. Repeated-measures analysis of covariance, with covariates of age, sex, and years of education, was used to analyze the completed cases. The interaction was examined to assess the differential effect between the intervention

and control groups, and post hoc analysis of within-subject analysis was conducted using Bonferroni correction. Nine cognitive tests, five questionnaires, and four tests of motor function that were independent of each other were conducted. Multiple corrections were not done among these independent measures. Concerning the measures where significant interaction was shown, intention-to-treat analysis was also conducted; five participants who attended fewer than eight times were included in the intention-to-treat analysis.

## RESULTS

Demographic data of the participants are shown in Table 1. The attendance rate during the intervention was 87.5%. The analysis was conducted with 66 participants in the intervention group and 67 in the control group (Figure 1).

### Direct Effect of Walking Program

The intervention group had a significantly greater increase in average number of steps taken over 7 days from the pre- to the postintervention period than the control group ( $F(1,123) = 7.184, P = .008$ ; intervention group, preintervention  $5,621 \pm 2,494$  steps per day, postintervention  $7,044 \pm 2,891$ ; control group, preintervention  $4,639 \pm 2,011$ , postintervention  $4,940 \pm 2,552$ ).

### Cognitive Tests

Word fluency scores of participants in the intervention group improved significantly more than those in the control group (interaction  $F(1, 128) = 6.833, P = .01$ ). There were no significant differences in other tests of delayed recall, dual task, clock drawing, abstract reasoning, TMT, DSST, or YKSST (Table 2).

### Questionnaires on QOL, Mood, Functional Capacity, Range of Activity, and Social Network

The intervention group had significantly greater improvement in QOL than the control group ( $F(1,128) = 9.751, P = .002$ ). A significant difference was found for functional capacity, which resulted from a significant decrease

in the control group ( $F(1,128) = 13.055, P < .001$ ). There was also a significant difference in all three subscales due to a significant decrease in the control group: instrumental self-maintenance ( $F(1,128) = 9.801, P = .002$ ), intellectual activity ( $F(1,128) = 5.543, P = .02$ ), and social role ( $F(1,128) = 24.925, P < .001$ ). There were no significant differences observed in other questionnaires on mood, range of activity, or social network (Table 2).

### Assessment of Motor Function

The intervention group had significantly greater improvement on the TUG than the control group ( $F(1,127) = 10.117, P = .002$ ); one participant withdrew because of knee pain. There were no significant differences between the treatment and control groups in grip force, balance time, or walking speed tests, although the control group had a significant increase in grip force (Table 2).

All differences remained in the intention-to-treat analysis (word fluency score interaction  $F(1, 133) = 7.420, P = .007$ , post hoc analysis within subjects (intervention group  $P = .001$ , control group  $P = .55$ ); QOL interaction  $F(1, 133) = 6.936, P = .009$ , post hoc analysis (intervention group  $P = .03$ , control group  $P = .14$ ); TMIG-IC interaction  $F(1, 133) = 12.035, P = .001$ , post hoc analysis (intervention group  $P = .21$ , control group  $P < .001$ ); TUG interaction  $F(1, 131) = 9.013, P = .003$ , post-hoc analysis (intervention group  $P < .001$ , control group  $P < .001$ )).

## DISCUSSION

Significant interventional benefits were shown in word fluency, QOL, functional capacity including social interaction, and motor function. Some beneficial changes were observed in the control group, such as grip force, possibly due to effects by participation.

### Optimal Cognitive Health

The benefits of a walking program in a small group setting could result from synergistic effects of enhanced motivation, positive emotion, and social interaction. The importance of motivation has been emphasized in rehabilitation,<sup>20</sup> and cognition and emotions interact closely, based on dynamic coordination of networks in the brain.<sup>21</sup>

The Cognitive and Emotional Health Project proposed that optimal cognitive health is not just the absence of cognitive deficits, but also the enhancement of cognitive and emotional health to maintain social connectedness and the ability to function independently. It has also been emphasized that cognitive and emotional health should be evaluated in the context of social functioning.<sup>12</sup> Concerning social interaction, an interventional effect was shown in the self-reported awareness of social role (the subscale of TMIG-IC). It was reported that elderly individuals tend to feel alienation from society without a social role, and emotional isolation could be a risk factor of mental decline.<sup>9</sup> We assumed that the participants would feel a sense of participation in the community through intervention.

**Table 1. Baseline Characteristics of Trial Participants**

Characteristic	Intervention (n = 75)	Control (n = 75)	Total (N = 150)
Age, mean $\pm$ SD	71.9 $\pm$ 4.1	72.0 $\pm$ 3.9	72.0 $\pm$ 4.0
Sex, n			
Male	23	21	44
Female	52	54	106
Education, years, mean $\pm$ SD	11.8 $\pm$ 2.5	11.9 $\pm$ 2.3	11.9 $\pm$ 2.4
Mini-Mental State Examination score, mean $\pm$ SD	27.7 $\pm$ 1.9	27.9 $\pm$ 2.0	27.8 $\pm$ 1.9

SD = standard deviation.

**Table 2. Results of All Participants**

Classification	Mean ± Standard Deviation						Post Hoc Analysis, P-Value	
	Intervention		Control		Interaction		Intervention	Control
	Before	After	Before	After	F-Value	P-Value		
<b>Cognition</b>								
Dual task test	21.2 ± 6.4	22.9 ± 6.7	19.1 ± 8.0	21.6 ± 7.1	1.176	.28	.008	<.001
Delayed recall	14.2 ± 5.2	17.3 ± 5.9	13.3 ± 5.2	16.1 ± 5.6	0.395	.53	<.001	<.001
Clock drawing	6.8 ± 0.7	6.9 ± 0.3	6.8 ± 0.7	6.9 ± 0.6	0.236	.63	.09	.31
Categorical word fluency	16.0 ± 4.0	17.2 ± 4.8	15.8 ± 4.9	15.6 ± 4.3	6.833	.01	.003	.53
Abstract reasoning	10.1 ± 3.6	10.4 ± 3.5	10.2 ± 3.5	10.8 ± 3.0	0.433	.51	.26	.04
<b>TMT</b>								
Part A	41.7 ± 14.8	41.2 ± 17.5	43.4 ± 15.8	43.0 ± 17.5	0.024	.88	.70	.87
Part B	119.3 ± 46.4	109.4 ± 35.0	125.9 ± 43.6	123.6 ± 49.3	1.010	.32	.06	.67
DSST	54.8 ± 12.9	58.8 ± 15.7	53.4 ± 14.4	57.4 ± 15.4	0.002	.96	<.001	<.001
YKSST	45.0 ± 11.2	48.3 ± 12.1	43.6 ± 10.5	45.7 ± 10.1	1.735	.19	<.001	.001
<b>Questionnaire</b>								
QOL	44.0 ± 5.8	45.3 ± 4.4	45.1 ± 5.3	44.5 ± 5.8	9.751	.002	.005	.12
GDS	3.7 ± 3.4	3.2 ± 3.0	3.4 ± 2.9	3.4 ± 3.0	2.075	.15	.04	.97
TMIG-IC	11.7 ± 1.6	11.9 ± 1.4	12.0 ± 1.4	11.6 ± 1.6	13.055	<.001	.15	<.001
LSA	94.5 ± 16.6	101.1 ± 15.4	90.4 ± 20.0	95.9 ± 18.0	0.134	.71	.002	.009
Lubben	16.1 ± 6.3	16.3 ± 5.7	17.8 ± 5.1	16.8 ± 5.2	2.033	.16	.78	.09
<b>Motor</b>								
Grip force	27.5 ± 6.8	28.4 ± 7.5	25.9 ± 6.9	28.1 ± 7.0	3.397	.07	.05	<.001
Balance	47.2 ± 19.2	48.6 ± 16.1	39.7 ± 21.6	40.0 ± 21.6	0.228	.63	.43	.90
TUG	5.6 ± 0.9	4.9 ± 0.7	5.7 ± 1.0	5.4 ± 0.8	10.117	.002	<.001	<.001
Speed	2.6 ± 0.4	2.5 ± 0.3	2.7 ± 0.4	2.5 ± 0.4	0.904	.34	<.001	<.001

The interaction was examined to assess the differential effect between the intervention and control groups, and post hoc analysis was conducted within-subject with Bonferroni correction.

The Trail-Making Test (TMT) was assessed according to time required, and other tests were assessed according to scores. Higher Dual task, Delayed recall, Clock drawing, Categorical word fluency, Abstract reasoning, Digit-Symbol Substitution Test (DSST), and Yamaguchi Kanji-Symbol Substitution Test (YKSST) scores and lower TMT scores indicate better performance.

Higher QOL, Tokyo Metropolitan Institute of Gerontology Index of Competence (TMIG-IC), Life Space Assessment (LSA), and Lubben Social Network Scale scores (Lubben) and lower Geriatric Depression Scale (GDS) scores indicate better performance.

Higher grip force and balance scores and lower Timed Up and Go (TUG) and speed scores indicate better performance.

**Walking Program Emphasizing Mutual Support for Self-Management**

This study showed that the acquisition of a walking habit is beneficial for the prevention of mental decline in elderly individuals, as previous observational studies suggested.<sup>6,7</sup> Exercise could have a larger effect in combination with social interaction. Animal studies suggest that greater benefits may be expected when exercise is conducted voluntarily in enriched environments (e.g., housing animals in groups in large cages with structures for exploration, physical activity, and sensorimotor learning).<sup>22-24</sup> The results could be applied to humans; exercise may have greater benefits when conducted voluntarily with social interactions in a pleasant atmosphere. Regarding voluntary involvement, the program gave priority to self-management. The participants would be encouraged toward a self-help effort to achieve the goal that they set for themselves, and the facilitators were required only to enhance participants' motivation in their self-managed activity. It has been recommended that rehabilitation for individuals with dementia should be based on five principles: keeping a pleasant atmosphere, enhancing participants' motivation and self-directed thinking, maintaining interactive communication, providing social roles to each

participant, and errorless learning.<sup>25</sup> Although these principles focus on individuals with dementia, the concept underlying the present intervention was in accord with these principles. Motivation is essential for developing good habits. Interactive communication and sharing roles are helpful for smooth group activity. The role of facilitators is to keep the atmosphere pleasant and encourage group activities.

**Feasibility of Implementation of the Community-Led Intervention Program**

The intervention presented here is simple, and other municipalities can implement it easily and effectively. Regarding the time period, the 3-month period was determined in accordance with the Preventive Long-Term Care programs, which are implemented for a 3-month period. Previous randomized controlled trials of exercise intervention for prevention of mental decline set longer periods; one study used a 24-week home-based program of physical activity,<sup>4</sup> and another reported the effects of resistance training and balance training over periods of 6 months and 1 year.<sup>26,27</sup> The current study suggested that cognitive improvement could be achieved using a short-term 3-month intervention, although continuity is important to

ensure the positive effects, and thus a longer-term follow-up of the participants should be conducted.

Cost is a major concern because effective prevention strategies would have large public health implications in reducing economic and social burdens, especially in the face of progressive aging of the population. The walking program can be conducted at a low cost.

The walking program is simple enough that healthcare staff who have undergone effective training programs can conduct it. In this regard, municipality-led community-based rehabilitation could provide an effective application of the World Health Organization's task-shifting concept.<sup>28</sup> In recent years, the notion of task shifting has gained popularity as a potential means of providing care to greater numbers of patients in underresourced areas.<sup>29</sup> The Japanese policy of preventing mental decline takes advantage of the essence of task shifting to drive community-based rehabilitation and to organize and train volunteers as community rehabilitation facilitators. Those who have completed the intervention could become community rehabilitation facilitators to promote the prevention program throughout the community.

### Limitations

One limitation of the study is that the participants might have been healthier people than the general population. The sample was self-selected, and fewer than 10% of those who received informational mailings were enrolled in the trial. Another bias was related to the difference of steps. The intervention group walked an average of 1,000 steps more at baseline than the control group.

This exploratory study lays the groundwork for a large intervention, and its efficacy should be examined with a larger population. This study could serve as the basis for implementation of a community-based intervention program to prevent mental decline.

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