Keywords Cervical spondylotic amyotrophy · Poor outcome · Risk factor · Surgical treatment

Abbreviations

CSA	Cervical spondylotic amyotrophy
CSM	Cervical spondylotic myelopathy
ALS	Amyotrophic lateral sclerosis
MMT	Manual muscle test
HIA	High-intensity areas
LIA	Low-intensity areas
ACDF	Anterior cervical discectomy and fusion
PSF	Posterior spinal fusion
OR	Odds ratio
EMG	Electromyography

Introduction

In 1952, Brain et al. [1] first reported on a case of cervical spondylosis with muscle atrophy of the upper extremities but without sensory disturbance. Keegan [2] later reported on this case at autopsy and described this condition as dissociated motor loss in the upper extremities with cervical spondylosis. In Japan, Yanagi et al. [3] labeled this condition "Cervical Spondylotic Amyotrophy (CSA)". After analyzing the clinical features of CSA, they concluded that this condition was caused, not only by mechanical compression of the spinal cord, but also by selective damage to the anterior horn of the spinal cord secondary to circulatory disturbance. Kameyama et al. [4] reported that the pathophysiological basis for this syndrome was multisegmental damage possibly caused by circulatory insufficiency.

Cervical spondylotic amyotrophy is classified as either a proximal or distal type of muscle atrophy. The proximal type of CSA is characterized as weakness of the deltoid and biceps, such as a drop shoulder, whereas, the distal type is characterized as weakness of the hand muscles such as a drop finger. CSA patients are in their 30s–70s, but most are over 50 years old.

Usually, patients with CSA are first treated conservatively, such as with cervical traction or a neck collar. If the conservative treatment is ineffective, surgery is performed. Most cases have been successfully treated with surgery [5–7]; however, some surgeries have resulted in poor outcomes. It is in the best interest of patients and surgeons to understand potential risk factors related to a poor outcome following surgery. Several studies on CSA mentioned risk factors related to a poor outcome following surgery [6, 7], but there has not been a full multivariate analysis on this type of data. To the best of our knowledge, this is the first report incorporating a multivariate analysis on the results of surgical treatment for CSA. Our goal was to conduct a retrospective case–control study and multivariate analysis to assess the risk factors for a poor outcome after surgical treatment for CSA.

Materials and methods

All institutions that participate in the Nagoya Spine Group (NSG) obtained institutional review board approval for this study. We performed a retrospective review on both prospectively and retrospectively collected data for this study. The medical records of patients who underwent surgical treatment from January 1991 to December 2010 were reviewed to identify those who did not improve after CSA surgery. Orthopedic spine surgeons performed all the surgical procedures on 59 patients with CSA at hospitals in the NSG. Ten institutions participated in this multicenter study, and 18 surgeons performed the operations on CSA patients. We collected data on patients' ages, types of muscle atrophy, preoperative manual muscle test (MMT) results, duration of symptoms, high-intensity areas (HIA) on T2-weighted MR images (both sagittal and axial views), low-intensity areas (LIA) on T1-weighted MR images, levels of spinal canal stenosis, presence of cervical kyphosis and surgical procedures [laminoplasty, anterior cervical discectomy and fusion (ACDF) and posterior spinal fusion (PSF)]. We examined those factors related to poor outcomes following CSA surgery by applying univariate analyses and multiple logistic regression analysis of the surgical outcomes. To evaluate the effect of surgical treatment, we used MMT, and improvements in the muscle strength of the most atrophic and impaired muscles were classified into 4 grades: "excellent", full recovery or recovery to a MMT grade of 2; "good", 1 grade of recovery; "fair", no improvement; "poor", worsening effect. Taken together, we categorized two groups: a good outcome included "excellent" and "good"; a poor outcome included "fair" and "poor". We performed statistical analyses between the two groups.

To differentiate between amyotrophic lateral sclerosis (ALS) and CSA, we always examined for the presence of sensory disturbance, bulbar symptoms and diffuse muscle atrophy, and also performed electromyography (EMG) in some cases before surgery. Furthermore, a neurologist ascertained that these patients did not have motor neuron disease before surgery. Finally, there were no cases which were diagnosed as ALS or other motor neuron disease after surgery.

Data analysis

Data were analyzed using SPSS (version 18.0). Univariate analyses were performed to examine the relationship between outcome at the final follow-up and prognostic factors. We used Mann–Whitney U tests for non-normally distributed variables, and Chi-square tests for categorical variables. Variables were included in a logistic regression model if their univariate analysis p value was ≤ 0.15. The threshold for significance was a p value of <0.05.

Results

A total of 59 patients with CSA underwent surgical treatment. There were 56 men and 3 women, with an average age of 59.4 years (range 32–78 years). The mean follow-up period was 2.7 years (range 1–12 years and 9 months). The duration of symptoms averaged 11.4 months (range 0.8 months to 15 years). Forty-one patients had proximal-type CSA, and 18 patients had distal-type CSA. HIA on T2 MRI was confirmed in 21 of 59 patients, and LIA on T1 MRI was confirmed in five of 59 patients. Spinal canal stenoses were found at an average of 2.7 intervertebral levels (range 1–5 levels). Forty-five patients received laminoplasty with or without foraminotomy, eight patients received ACDF, and six patients received PSF with laminoplasty/laminectomy. The surgical results were excellent for 33 patients, good for 8, fair for 17, and poor for 1 (Table 1). On univariate analyses of surgical outcomes, the duration of symptoms and preoperative MMT grade were statistically associated with a poor outcome after surgery ($p < 0.05$). There was a trend for patients with the distal type of muscle atrophy to have a poorer surgical outcome compared to patients with the proximal type of muscle atrophy ($p = 0.123$). Also, there was a trend in patients who received ACDF to have a better surgical outcome compared to patients receiving other surgical procedures ($p = 0.09$) (Table 2). As described in the "Materials and methods" section, potentially significant predictors of a poor outcome were used to fit a logistic regression model. On multivariate analyses of surgical outcomes, preoperative MMT grade and distal-type CSA were significant predictors of poor surgical outcome ($p \leq 0.05$) (preoperative MMT grade: OR = 0.169, and distal type of CSA: OR = 9.223), whereas, symptom duration was a highly significant predictor (OR = 1.263, $p \leq 0.001$). However, type of surgical procedure was not significantly associated with a poor surgical outcome. The full model is presented in Table 3.

Table 1 Demographic data of CSA patients

	All patients (n = 59)
Mean age (years)	59.4 (32–78)
Male/female	56/3
Mean follow-up (years)	2.7
Duration of symptoms (months)	11.4
Type of muscle atrophy	
Proximal	41
Distal	18
Preoperative MMT grade	2.3
Levels of stenosis	2.7
HIA on T2 MRI	21
LIA on T1 MRI	5
Kyphosis	17
Surgical procedure	
Laminoplasty	45
ACDF	8
PSF + laminoplasty/laminectomy	6
Surgical outcome	
Excellent	33
Good	8
Fair	17
Poor	1

CSA cervical spondylotic amyotrophy, *MMT* manual muscle test, *PSF* posterior spinal fusion, *ACDF* anterior cervical discectomy and fusion, *HIA* high-intensity area, *LIA* low-intensity area

Discussion

In our study, we demonstrated clinical features of CSA and used a logistic regression model to determine the risk factors related to having a poor postoperative outcome. We demonstrated that patients with poor surgical outcomes tended to have CSA symptoms for a longer duration and to have lower preoperative MMT grades than those patients with good outcomes (OR: 1.263, $p = 0.006$; OR: 0.169, $p = 0.015$, respectively). Based on our results, we recommend surgery for CSA patients with MMT grades of 1 or 2, and if conservative treatment has not been successful for 3–6 months. Furthermore, in our study, the surgical outcome for distal-type CSA was inferior to the outcome for proximal-type CSA (OR, 9.223; $p = 0.025$). Similarly, Uchida et al. [7] reported that surgical outcome in patients with the distal type of muscle atrophy was inferior to that in patients with the proximal type. Neuroradiologically, Kaneko et al. [8] mentioned that the pathophysiology of distal-type CSA included widespread gray matter lesions with less involvement of the lateral posterior spinal column. Fujiwara et al. reported that muscle power improved in 92 % of the proximal-type cases but only

Table 2 Univariate analyses of surgical outcome in 59 patients with CSA

	Group 1 Good ($n = 41$)	Group 2 Poor ($n = 18$)	p value
Age	58.9	60.4	0.57
Duration of symptoms (months)	4.9	27.3	<0.0001
Preoperative MMT grade	2.5	1.9	0.019
Type of muscle atrophy			
Proximal	31	10	
Distal	10	8	0.123
Levels of stenosis	2.7	2.9	0.517
HIA on T2 MRI	16	5	0.406
LIA on T1 MRI	4	1	0.514
Kyphosis ≥10	7	5	0.272
Surgical procedure			0.09
Laminoplasty	30	15	
ACDF	8	0	
PSF	3	3	

Table 3 Multiple logistic regression analysis for the risk factors of poor postoperative outcome

Variable	OR	p value	95 % CI
Duration of symptoms (months)	1.263	0.006	1.070–1.492
Preoperative MMT grade	0.169	0.015	0.040–0.710
Distal-type CSA	9.223	0.025	1.329–63.979
Surgical procedure	1.431	0.970	0.084–24.376

CI confidence interval

improved in 38 % of the distal-type cases. They speculated that the distal type basically involves impingement against the anterior horn which has less ability than the ventral nerve roots to regenerate [5].

In the present study, the HIA on T2 MRI, the LIA on T1 MRI, the number of vertebral levels with cervical canal stenosis, and the presence of cervical kyphosis were not significantly associated with a poor postoperative outcome. It has been reported that edema, myelomalacia and gliosis involve high-signal intensity on spinal cord T2-weighted MR images and low-signal intensity on T1-weighted MR images, suggesting irreversible changes of the spinal cord, and this signal intensity change was significantly associated with the poor postoperative outcome of cervical spondylotic myelopathy (CSM) [9–12]. In CSM patients, the intramedullary signal intensity change is usually consistent with damage in the central portion of the spinal cord [9]. However, CSA occurs with compression and damage of the anterior horn of the spinal cord or the ventral nerve root. This may be why there is no correlation between signal intensity change on MRI and a poor surgical outcome. In fact, in our series, all cases which showed the signal intensity change demonstrated damage to the central portion of the spinal cord.

Previous reports also suggested that cervical kyphosis ≥10 was associated with a poor surgical outcome in CSM patients [13, 14]. Although our results indicated that cervical kyphosis was not associated with a poor surgical outcome, severe kyphosis may still influence outcome when laminoplasty is performed because kyphosis limits appropriate posterior shifting of the cord from the anterior compression. However, when root impingement, not compression of the anterior horn of the cord causes the muscle atrophy in CSA patients, cervical kyphosis would not be associated with surgical outcome.

On the other hand, Inui et al. [6] reported on conservative and surgical treatments for CSA patients. They mentioned that patients who fulfilled predictive factors such as age <50 years, duration of symptoms <6 months, single-level stenosis, foraminal stenosis, and a good response to traction therapy improved with conservative treatment. Although they attempted to determine the predictive factors related to surgical outcome, there was no statistical difference between the improvement group and the no improvement group.

Both ALS and CSA can have similar symptoms, and it can be difficult to distinguish the clinical manifestations of CSA during early stages of the disease [15]. Furthermore, although the clinical presentation of ALS closely resembles CSA, and both diseases preferentially affect middle-aged and elderly populations [16], it is very important to understand the differences between the diseases in order to distinguish one from the other prior to surgery. Cervical spondylosis does not cause atrophy of the tongue or fasciculations as we see with ALS. Amyotrophic lateral sclerosis patients can also have bulbar muscle involvement, articulation disorder and dysphagia. Muscle atrophy around the neck, such as the sternocleidomastoid muscle, and diffuse muscle atrophy of upper extremities are affected in ALS patients, but CSA involves only a few muscles. Apparent segmental sensory disturbance is characteristic of cervical spondylosis but not ALS, and ALS is more likely when there are widespread denervation potentials on EMG. However, if ALS cannot be definitively ruled out, surgery should not be performed, and patients should be carefully observed because ALS is always progressive.

The appropriate surgical methods for CSA are controversial. Some authors advocated that anterior decompression is reasonable for eliminating the anterior and anterolateral lesions [17–20]. The results from our series demonstrated a tendency for a better surgical outcome with ACDF than the other procedures, but it was not significant on univariate analysis ($p = 0.09$). Srinivasa et al. [19]

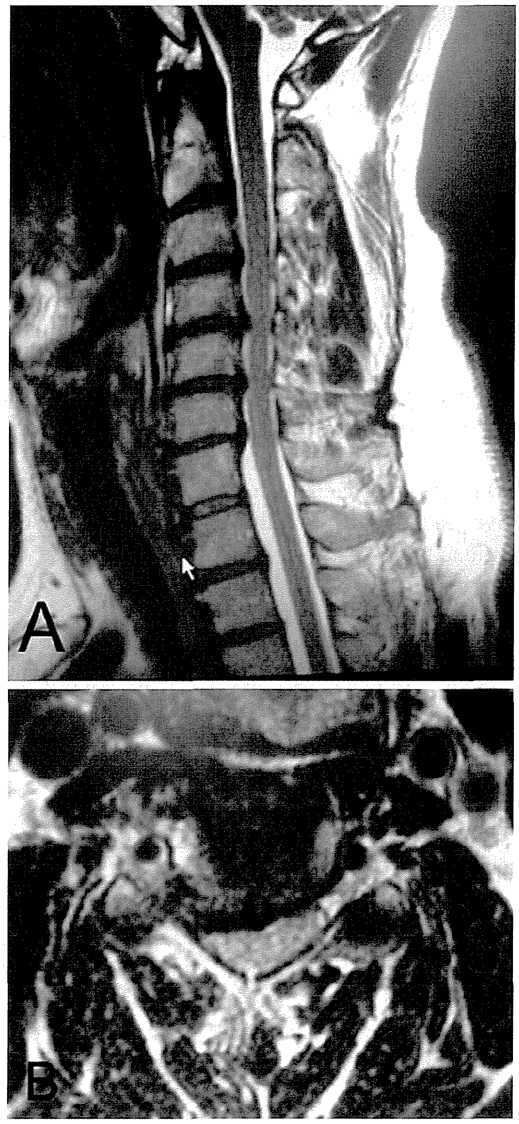

Fig. 1 **a** Sagittal image on T2 MRI showing multiple stenoses of the cervical spine. **b** Axial image on T2 MRI showing compression of the right anterior horn of the spinal cord (C4/5) and nerve root

reported that central corpectomy resulted in a good and long-lasting surgical outcome for distal-type CSA patients. However, these were elderly CSA patients with a tendency to have multiple and foraminal stenoses due to spondylosis making it difficult to correctly identify the lesion affecting the spinal cord or nerve root (Fig. 1). Thus, when patients had more than three lesions, we performed laminoplasty, whereas, with 1–2 levels of stenosis we performed ACDF. If the patients had severe kyphosis, we performed PSF with laminoplasty/laminectomy. In the present study, laminoplasty, with or without foraminotomy, was the most popular and effective operation for these patients. Our results demonstrated good outcomes for 30 of the 45 patients (67 %) treated by laminoplasty. We decided to add foraminotomy in case foraminal stenosis was causing the root impingement. Previously, some authors also reported laminoplasty and foraminotomy as effective treatments for most patients with this syndrome [5, 20].

Several limitations of our study must be acknowledged. First, this was a retrospective, observational survey, and there was no standardized treatment protocol due to the number of surgeons at different hospitals involved in the care of these patients. Second, since this was a multicenter study, different surgeons have different skill levels which might influence the surgical outcome. Third, our patient sample size is small; it was underpowered for statistically evaluating the difference in risk for a poor outcome following surgery. However, this study is the first report in which we identify the risk factors related to a poor outcome through multivariate analysis, and this series contained the largest number of surgically treated CSA patients so far reported.

In conclusion, the present study offers a foundation for a deeper understanding of the factors that influence the risks of a poor outcome following surgical treatment in CSA patients. Early surgery is recommended for CSA patients in whom conservative treatment has not been successful and the clinical status before surgery (symptom duration, preoperative MMT grade and distal type of CSA) significantly influences the surgical outcome. This information may be useful for clinicians in counseling patients and family members, and to develop more realistic treatment expectations for CSA patients.

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Utility of "loco-check," self-checklist for "locomotive syndrome" as a tool for estimating the physical dysfunction of elderly people*

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ABSTRACT

Aim: A new concept of locomotive syndrome has been proposed by the Japanese Orthopaedic Association. The aim of this study is to clarify the utility of its self-checklist, "loco-check," as a tool for estimating the physical dysfunction of elderly people. Methods*:* Subjects were 1124 community-dwelling Japanese people, 557 men and 567 women, aged 40 - 89 years. Information about the seven "loco-check" items was obtained from present inquiry sheets. Physical functions were examined by grip strength, knee extension strength, walking speed and one-leg standing time with open eyes. The averages of these test values, controlled for age and BMI, were compared between the "loco-check" (+) group and the "loco-check" (−) group. Also we examined about the trend of decline of physical function, together with SF36 physical function subscale score, as the number of the items chosen increased. Results*:* Adjusted average values of all four physical function examinations in the "loco-check" (+) group were significantly lower than those of the "loco-check" (−) group (all, $p < 0.001$). Also the adjusted average values of the majority of four tests were significantly lower in those who checked each of the "lococheck" items than those who did not, for most of the items. It was also revealed that the more items subjects checked, the lower the adjusted average values were, except for one-leg standing time. It was also the case with SF36 physical function subscale score. Conclusion: We showed the utility of "loco-check" as a simple tool not only for noticing the physical dysfunction of elderly people, but also for estimating the extent of it, except for balancing ability, particularly by counting the number of checked items.

Keywords: Locomotive Syndrome; Loco-Check; Physical Dysfunction; Estimation; Elderly People

1. INTRODUCTION

Recently, the population of elderly people has been growing larger and larger in developed countries. Among those countries, Japan has gained the top status as a super-aging society [1] and the population needing nursing care has naturally become larger. In order to cope with this situation, the Japanese Orthopaedic Association (JOA) proposed the new concept "Locomotive Syndrome" [2-4] in 2007. The JOA then used the short term "Locomo" for easy recall by Japanese people in general and to alert them about the importance of the locomotive organs in maintaining their independence all through their lives, because orthopedic problems have become one of the main reasons for the nursing care [2]. This syndrome refers to those elderly who are in need of nursing care services due to problems with their locomotive organs, or those who have risked conditions which may lead them to use such services in the future. For the greater self-awareness of the possibility of such a risk condition, the JOA prepared a self-checklist composed of seven items with which individuals can test themselves during their activities of daily living in and

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outside of the house (described in the Materials and methods section) [4]. These 7 items, called "loco-check," are very well-considered and cautiously chosen by the experts in this field, but their usefulness for estimating the physical dysfunction (particularly its extent) has not been revealed yet. Hence, the purpose of this study is to verify its usefulness in the originally targeted self-awareness of a person's physical disability, and also to investigate if it is available to surmise its extent by counting the number of checked items. We examined the relationship of the "loco-check" and the physical functional status evaluated by grip strength, leg extension strength, walking speed, one-leg standing time with eyes open, and compared with the SF36 (physical function subscale), most of which are popularly used to represent physical status. The verification of the utility of "loco-check" will help acquaint not only Japanese but people worldwide with the enlightened new notion of "Locomotive Syndrome".

2. MATERIALS AND METHODS

2.1. Subjects

The subjects were selected among people who participated in the 7th wave of the National Institute for Longevity Sciences Longitudinal Study of Aging (NILS-LSA). Details of the NILS-LSA are described elsewhere [5]. It is a biannual examination checking the physical and mental condition of ordinary Japanese people, so as to clarify the effect of aging. It is conducted by the National Center for Geriatrics and Gerontology (NCGG) in Japan. The National Institute for Longevity Sciences (NILS) is a research section of NCGG. The participants were chosen randomly from residents of Obu City and Higashiura-cho, in Aichi Prefecture, Japan. For this study, data from 1,124 persons were analyzed (61.5 ± 13.3, mean ± SD). Participants were 557 men and 567 women, whose ages ranged from 40 to 89, and the period of participation ranged from July 2010 to June 2011.

2.2. Information on Seven "Loco-Check" Items

The pre-mailed inquiry sheets completed by participants were utilized to determine whether they thought themselves to be fit in the seven "loco-check" items [4]: 1) You cannot put on a pair of socks while standing on one leg; 2) You stumble or slip in your house; 3) You need to use a handrail when going upstairs; 4) You cannot get across the road at a crossing before the traffic light changes; 5) You have difficulty walking continuously for 15 min; 6) You find it difficult to walk home carrying a shopping bag weighing about 2 kg; and 7) You find it difficult to do housework requiring physical strength. The "loco-check" (+) group was defined as those who checked at least one of the seven items, and the "loco-check" (−) group as those who checked none.

2.3. Evaluation of Physical Functions

Physical functions of participants were evaluated by the internationally commonly utilized four fundamental physical function tests; grip strength (kg), leg extension strength (kg), walking speed (m/sec), and one leg standing time with open eyes (seconds; maximum 30 seconds). Also, for comparison with the similar questionnaires about physical function, the subscale from SF36 [6,7] (SF36 PF in the following context) was used. It is composed of 10 questions and the maximum score was set as 100 points; for each item 0, 5 or 10 points were allocated; namely, very difficult—0 points, slightly difficult—5 points, and not at all difficult—10 points.

2.4. Comparison of Physical Function of Those Who Selected "Loco-Check" Items and Those Who Did Not

Average values of five tests: grip strength, leg extension strength, walking speed, and one leg standing time with open eyes, controlled for age and BMI, were compared between the "loco-check" (+) group of those who checked at least one of seven "loco-check" items, and the "loco-check" (−) group who checked none. Also, adjusted average values of five tests were compared between the group of those who checked each of the seven loco-check items, and the group of those who did not. Furthermore, the values of four tests, together with the total score of SF36 PF, were compared among groups who checked none, 1, 2, 3, 4 and 5 items and examined if there was a decreasing trend as the checked number increased. This served to find out whether the numbers of checked items have significance in judging individual levels of physical disability.

The study protocol was approved by the Committee on Ethics of Human Research of the National Institute for Longevity Sciences. Written informed consent was obtained from each subject.

Statistical analyses were conducted with a general linear model, controlled for age and BMI as mentioned above, using SAS (Ver. 9.1.3). Comparison between those who checked or did not was conducted by Student *t*-test, and investigation about the significance of the numbers checked was done by trend analysis.

3. RESULTS

Characteristics of the subjects are shown in **Table 1**. The adjusted average values of four tests (grip strength, leg extension strength, walking speed, and one leg standing time with open eyes of the "loco-check" (+) group) were significantly lower than those of the "loco-check" (−) group in all of the tests (all $p < 0.001$) as described in **Table 2**.

Also, in the comparison between the two groups (those

Table 1. Subject characteristics.

	"loco-check" (+)	"loco-check" (−) group	p
N (male/female)	310 (143/167)	814 (414/400)	0.156
Height (cm)	156.7 ± 9.5	160.6 ± 9.3	<0.0001
Weight (kg)	57.8 ± 11.6	58.1 ± 10.9	0.607
BMI	23.5 ± 3.8	22.4 ± 3.0	<0.0001

Table 2. Adjusted average values of four tests.

	"loco-check" (+) group	"loco-check" (−) group	p
Grip strength (kg)	28.8 ± 0.3	30.6 ± 0.2	<0.0001
Leg extension strength (kg)	36.6 ± 0.6	39.1 ± 0.3	0.0008
Walking speed (m/min)	77.8 ± 0.6	81.9 ± 0.4	<0.0001
One leg standing time with eyes open	50.7 ± 4.4	77.0 ± 3.6	<0.0001

who checked or did not) the adjusted average values of four examinations concerning each question on the seven items, the values of those who checked the items 1), 2), and 3) were significantly lower in all four tests (**Table 3**). Furthermore, those who checked; 4) showed lower values in the grip strength than those who did not check; those who checked; 5) showed lower values in the grip strength and walking speed than those who did not check; and those who checked; 6) and 7) showed lower values in 3 of the tests other than the one leg standing time (**Table 3**). As for the investigation of the trends in the values of the four tests, together with the SF36 PF score, with a decrease as the number of checked items increased until five, most of the tests, other than one leg standing time, showed a significant declining trend in physical function (as for the knee extension strength, p = 0.0043, and other 3 items p < 0.0001) (**Figures 1-4**).

4. DISCUSSION

The locomotive syndrome, or so-called "Locomo," is a new concept that was proposed by the Japanese Orthopaedic Association (JOA) in 2007. This concept is intended to help prevent elderly people from coming to need nursing care services due to problems with their locomotive organs. Seven items, called a "loco-check," have been prepared so that elderly people can perform a self-check of locomotive problems [4]. These items, rather than being selected after a close examination of their validity, were selected with priority for ease of communication among the general population. Thus, items that people can easily understand were selected. This study is intended to reveal the utility of the full "loco-check" list not only as a means to help people themselves become aware of their gradual decline in various motor functions but also to estimate the extent of their physical dysfunction in the general population, by comparing the "loco-check" with very popularly used indices such as grip

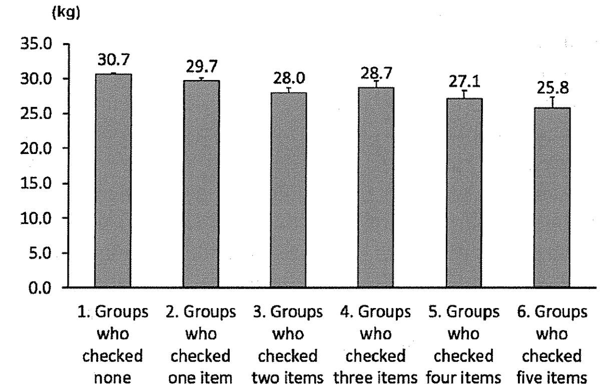

Figure 1. As the number of checked items increased, average grip strength declined significantly (p trend <0.0001).

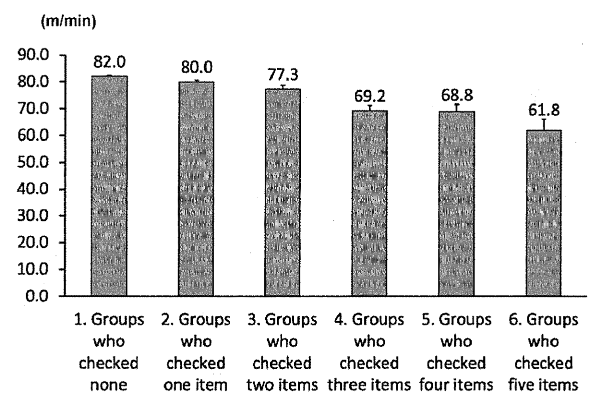

Figure 2. As the number of checked items increased, average leg extension strength declined significantly (p trend = 0.0043).

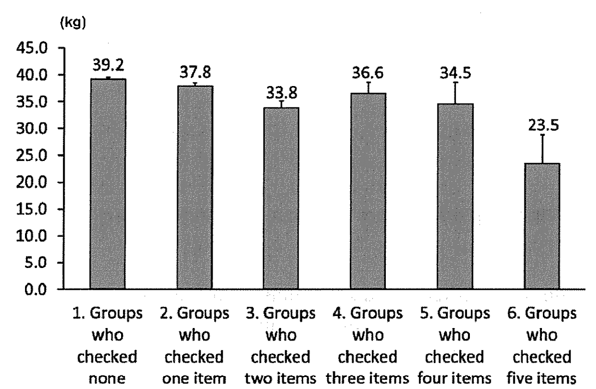

Figure 3. As the numbers of checked items increased, average walking speed declined significantly (p trend < 0.0001).

strength, knee extension strength, walking speed, one-leg standing time, and also with the internationally widely used questionnaire with the SF36 PF score as well. From this study, we have shown that the first three questions [1) You cannot put on a pair of socks while standing on one leg; 2) You stumble or slip in your house; and 3) You need to use a handrail when going upstairs] are particu-

Table 3. Comparison between two groups (those who checked or did not) and the adjusted average values from five exams concerning each question on seven items.

	Grip strength (kg)		p	Leg extension strength (kg)		p	Walking speed (m/min)		p	One leg standing time with eyes open (sec)		
"Loco-check"	(+)	(−)		(+)	(−)		(+)	(−)		(+)	(−)	
1) You cannot put on a pair of socks while standing on one leg	28.6 ± 0.4	30.5 ± 0.2	<0.0001	36.6 ± 0.8	38.9 ± 0.3	0.01	77.3 ± 0.8	81.6 ± 0.3	<0.0001	49.8 ± 5.2	72.6 ± 3.2	0.0003
2) You stumble or slip in your house	28.3 ± 0.5	30.3 ± 0.2	0.0005	36.4 ± 1.0	38.8 ± 0.3	0.031	78.5 ± 1.1	81.1 ± 0.3	0.0225	49.5 ± 8.2	68.5 ± 3.0	0.0312
3) You need to use a handrail when going upstairs	27.7 ± 0.5	30.4 ± 0.2	<0.0001	34.6 ± 1.2	38.9 ± 0.3	0.0006	71.7 ± 1.1	81.8 ± 0.3	<0.0001	50.2 ± 6.6	70.0 ± 3.1	0.0079
4) You cannot cross the road at a crossing before the traffic light changes	25.6 ± 1.7	30.2 ± 0.2	0.0063	30.4 ± 5.4	38.6 ± 0.3	n.s.	86.5 ± 7.3	80.9 ± 0.3	n.s.	68.1 ± 34.2	66.2 ± 2.8	n.s.
5) You have difficulty walking continuously for 15 min	27.4 ± 1.1	30.2 ± 0.2	0.0085	39.7 ± 3.1	38.6 ± 0.3	n.s.	69.9 ± 2.8	81.0 ± 0.3	<0.0001	43.8 ± 15.4	66.9 ± 2.8	n.s.
6) You find it difficult to walk home carrying a shopping bag weighing about 2 kg	27.0 ± 0.9	30.3 ± 0.2	0.0002	33.4 ± 2.5	38.6 ± 0.3	0.0395	72.5 ± 2.2	81.1 ± 0.3	0.0001	52.0 ± 12.8	66.9 ± 2.9	n.s.
7) You find it difficult to do housework requiring physical strength	27.1 ± 0.7	30.3 ± 0.2	<0.0001	33.5 ± 1.8	38.7 ± 0.3	0.0037	72.0 ± 1.6	81.2 ± 0.3	<0.0001	58.5 ± 10.6	66.8 ± 2.9	n.s.

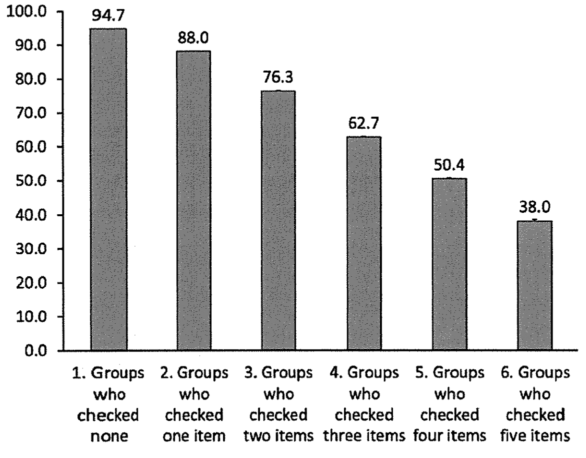

Figure 4. As the numbers of checked items increased, average SF36 PF scores declined significantly (p trend < 0.0001).

larly useful to know the decline of your physical function in strength, walking ability, as well as balancing ability. We have also shown that the number of items checked is important to understand the severity of the decline; that is, the more items are checked, the greater the physical dysfunction is, except for balancing ability.

In recent years, a new scale consisting of 25 question items, the Geriatric Locomotive Function Scale, now called "Locomo 25," was developed by Seichi *et al.* [8] as a screening tool for the risk of locomotion syndrome in elderly people. This scale has a greater number of questions and items, and also includes the level of severity of each item, so that it can express small differences in the QOL of elderly. It also shows a good correlation with the European Quality of Life Scale—5 Dimensions (EQ-5D) [9], and SF36 [10]. Therefore, this scale is considered useful in evaluating the degree of locomotive dysfunction in many situations, particularly for research purposes [11,12]. Meanwhile, our study revealed that the original loco-check and a count of the number of items checked may also be used for estimating the extent of the physical dysfunction. Thus, "loco-check" may be available particularly for people in general to know their own approximate decreased state of physical ability. The number of checked items was also recently reported to be useful for predicting the risk of requiring nursing care

[13].

The basic idea behind "Locomotive Syndrome" is to have a simple and accessible method to help people in general to become aware of their own risk of declining motor function so that they will seek help at a special orthopedic clinic at an early stage. In fact, the prevalence of orthopedic diseases has been shown to be higher than expected [14,15]. The early consultation with a specialist will lead to increased opportunities for the proper treatment at an earlier stage of disease.

The loco-check is also introduced with cartoon drawings for easier understanding by everyone [16,17]. To make this new idea of the loco-check more widely known among the general Japanese population, and even among people worldwide in the future, the greater use of these kinds of accessible question items is beneficial. The present study shows their usefulness through comparison with four fundamental physical function tests, together with the internationally-used questionnaires about physical function from SF36. In fact, some reports have shown that the loco-check (whether there are any of the applied items) is related to physical functions like muscle strength or walking speed [18,19]. Also, Sasaki *et al.* [20] recently reported that a non-loco-check group showed significantly better performances in the functional reach and reach tests than the loco-check group in males and females, as well as better grasping power and one-leg standing with the eyes open in females, by age adjusted comparison. These findings partly coincide with our own results. Increased self-awareness of a decline in physical function may also induce people to perform "loco-training" exercises [16], such as standing on one leg or half squats, which previously have been reported to be effective [18,21-23].

A limitation of our study is that the subjects accounted for only about half of all participants in the 7th wave of the NILS-SA. It is possible that the results do not accurately reflect the results of all participants. However, the number of subjects should still be large enough to discuss the trends in all participants and to show the value of the loco-check.

The strength of the study is that the subject sample was selected randomly from the local community with very little bias in the process.

In summary, we investigated the relationship between the loco-check and physical function status as evaluated by grip strength, knee extension strength, walking speed, one-leg standing time and the SF36 (physical function subscale). We thereby demonstrated the utility of the loco-check not only as a means of screening to promote self-awareness of locomotive organ impairments, but also as a simple way to surmise the severity of the impairment by counting the number of items checked, excluding balancing ability.

5. ACKNOWLEDGEMENTS

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RESEARCH ARTICLE Open Access

Community-based intervention to improve dietary habits and promote physical activity among older adults: a cluster randomized trial

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Abstract

Background: The fastest growing age group globally is older adults, and preventing the need for long-term nursing care in this group is important for social and financial reasons. A population approach to diet and physical activity through the use of social services can play an important role in prevention. This study examined the effectiveness of a social health program for community-dwelling older adults aimed at introducing and promoting physical activity in the home at each individual's pace, helping participants maintain good dietary habits by keeping self-check sheets, and determining whether long-standing unhealthy or less-than-ideal physical and dietary habits can be changed.

Method: This cluster randomized trial conducted at 6 community centers in an urban community involved 92 community-dwelling older adults aged 65–90 years. The intervention group (3 community centers; n = 57) participated in the social health program "Sumida TAKE10!" which is an educational program incorporating the "TAKE10!® for Older Adults" program, once every 2 weeks for 3 months. The control group (3 community centers; n=35) was subsequently provided with the same program as a crossover intervention group. The main outcome measures were changes in food intake frequency, food frequency score (FFS), dietary variety score (DVS), and frequency of walking and exercise. The secondary outcome measures were changes in self-rated health, appetite, and the Tokyo Metropolitan Institute of Gerontology (TMIG) Index of Competence score.

Results: Compared to baseline, post-intervention food intake frequency for 6 of 10 food groups (meat, fish/shellfish, eggs, potatoes, fruits, and seaweed), FFS, and DVS were significantly increased in the intervention group, and interaction effects of FFS and DVS were seen between the two groups. No significant differences were observed between baseline and post-intervention in the control group. Frequency of walking and exercise remained unchanged in both groups, and no significant difference in improvement rate was seen between the groups. Self-rated health was significantly increased in the intervention group. Appetite and TMIG Index of Competence score were unchanged in both groups.

Conclusions: The social health program resulted in improved dietary habits, as measured by food intake frequency, FFS, and DVS, and may improve self-rated health among community-dwelling older adults.

Trial registration number: UMIN000007357

Keywords: Social health program, Community-dwelling older adults, Dietary variety, Physical activity, Self-rated health

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Background

The fastest growing age group globally is older adults, and in Japan the percentage of older adults has increased fourfold since 1960, from 5.7% in 1960 to 23.3% in 2011 [1]. Health promotion for older adults and the prevention of long-term care are important factors in maintaining a sound society. A population approach to diet and physical activity through the use of social services can play an important role in prevention, reach a large portion of the population, and be cost effective [2]. The health benefits of physical activity have been scientifically confirmed in older adults [3,4], and many community-based interventions on physical activity have shown improved physical function [5,6], improved cognitive function [7], reduced risk of falling [8,9], reduced decline in health-reported quality of life [10], and reduced healthcare costs [11]. Based on the scientific evidence available, the World Health Organization (WHO) [12], the American College of Sports Medicine, the American Heart Association [13], and other health related organizations have published specific recommendations on physical activity for older adults. However, the number of community-based interventions on diet has been relatively small, and nutritional intervention commonly consists of individual nutritional checkups and individual dietary counselling, or nutritional education from professionals on specific nutrients and supplements [14-17]. However, in a super-aging society like Japan, too few resources are available to provide professional advice for every individual and therefore simple health programs that promote a healthy diet are needed for community-dwelling older adults.

Against this background, we developed the "TAKE10!® for Older Adults" program for community-dwelling older adults to introduce and promote physical activity in the home at each individual's pace and to help participants maintain good dietary habits by keeping self-check sheets, even in the absence of professional advice [18]. The purpose of this study was to examine the effectiveness of a social program held at community centers that used the TAKE10!® for Older Adults program, and determine whether it could change long-standing unhealthy or less-than-ideal physical and dietary habits. We conducted a cluster randomized trial to avoid contamination across individuals and to eliminate any access barriers to participation in this intervention program [19-21].

TAKE10!® for Older Adults

"TAKE10" stands for eating regularly from 10 food groups and taking 10 min of physical activity at least 2–3 times per day. The program was developed in order to help community-dwelling older adults introduce physical activity into their lives and encourage their intake of a variety of foods. Physical capability, dietary habits, health status, and living environment among older adults vary greatly among individuals, and the program was designed to help older adults adjust the strength and frequency of their exercise as well as their food intake to correspond to individual capabilities and preferences. The contents of the TAKE10!® booklet are shown in Additional file 1: Appendix 1.

The program for physical activity recommends walking, stretching, muscle strengthening, and balance training in the home environment at the individual's own pace. There are 10 simple stretching exercises in total (e.g., upward, side, hamstring, hip, Achilles tendon, and quadriceps stretching) as well as 8 muscle strengthening exercises (e.g., plantar flexions, knee flexions, side leg raises, squats, and sit-ups). None of the exercises require equipment and therefore can easily be performed at home. WHO recommends at least 150 minutes of moderate-intensity aerobic physical activity throughout the week. TAKE10!® sets the initial goal slightly lower for older adults who have no established physical activity habits. We prepared a "TAKE10!® Calendar" record to enable participants to engage in physical activity by themselves (Additional file 2: Appendix 2).

The dietary program focuses on dietary variety. Some studies have shown that dietary variety is associated with health status in older adults and therefore can be used to indicate nutritional status [22-24]. One of the simple ways to promote a balanced intake of nutrients is having dietary variety, and such variety may be a good indicator of healthy dietary habits. Over consumption of energy-dense foods, which are nutrient-poor and high in fat, sugar, and salt, and inadequate consumption of fruits and vegetables are risk factors associated with an increased incidence of non-communicable diseases [2]. Moreover, inadequate protein intake causes adverse changes in the morphology and function of skeletal muscle in older adults [25,26]. We define a healthy diet for older adults as a well-balanced diet, and promote their intake of a variety of foods using a table of 10 food groups that correspond to the 10 main food groups of the Japanese diet without rice, namely meat, fish and shellfish, eggs, milk, soybean products, green and yellow vegetables, potatoes, fruits, seaweed, and fats and oils. For this purpose, we developed the "TAKE10!® Check Sheet"(Additional file 3: Appendix 3) to allow older adults to check the variety of foods in their diet quickly and easily, and ultimately improve their dietary habits, with an overall goal of maintaining good dietary habits.

In addition, information for older adults on subjects such as oral care, incontinence, and food safety are included in the TAKE10!® booklet (Additional file 1: Appendix 1).

Methods

Participants

The study was conducted at 6 community centers, each with >90 m^2 of floor space and air-conditioning, in

Sumida Ward in the Tokyo metropolitan area. Inclusion criteria were (1) participation in the "Sumida TAKE10" social health program conducted by Sumida Ward, (2) age ≥65 years; (3) understanding of the main study objectives and provision of informed consent, and (4) ability to travel independently to the closest participating community center. Exclusion criteria were (1) heart attack or stroke within the previous 6 months; (2) acute hepatic dysfunction or chronic active viral hepatitis, (3) fasting blood glucose >200 mg/dl, (4) diastolic blood pressure >180 mmHg and/or systolic blood pressure >100 mmHg, and (5) medical advice prohibiting exercise. Candidates were recruited by Sumida Ward through notifications printed in the Sumida Ward Bulletin delivered to all homes. A questionnaire on demographic, dietary, physical, and lifestyle characteristics was administered to all participants by researchers and program staff before and after intervention at each community center. Body weight and height were measured at the community centers by researchers and staff.

Sample size

Because a clinically meaningful difference in our main outcome measures could not be determined, only a provisional sample size was used. We estimated that individual randomization would require 36 participants per group for a trial with 80% power to detect a 10% difference between groups, with a 5% significance level. We assumed an intracluster correlation of 0.02 and 20 participants for each community center. Under these assumptions, we increased the sample size to 50 per group (design effect, 1.38) and cluster size was determined to be 3 per group.

Randomization

Randomization was conducted at the community center level to avoid contamination and to eliminate access barriers to participation in this program [19-21]. The 6 community centers in Sumida Ward (total area 13.75 km2) were randomized into the intervention group (3 centers) and control group (3 centers) using opaque envelopes by a public officer who was not involved in this study. Environmental factors such as access to transportation, public services, facilities, and basic culture around each of the 6 community centers did not differ substantially and all 6 centers are within a 2-kilometer radius of each other.

Effective blinding was not possible because both the subjects and researchers clearly understood the differences between the two groups.

Participant flow

The flow of participants is shown in Figure 1. From the 141 candidates for this study who were community-dwelling older adults living in Sumida Ward and

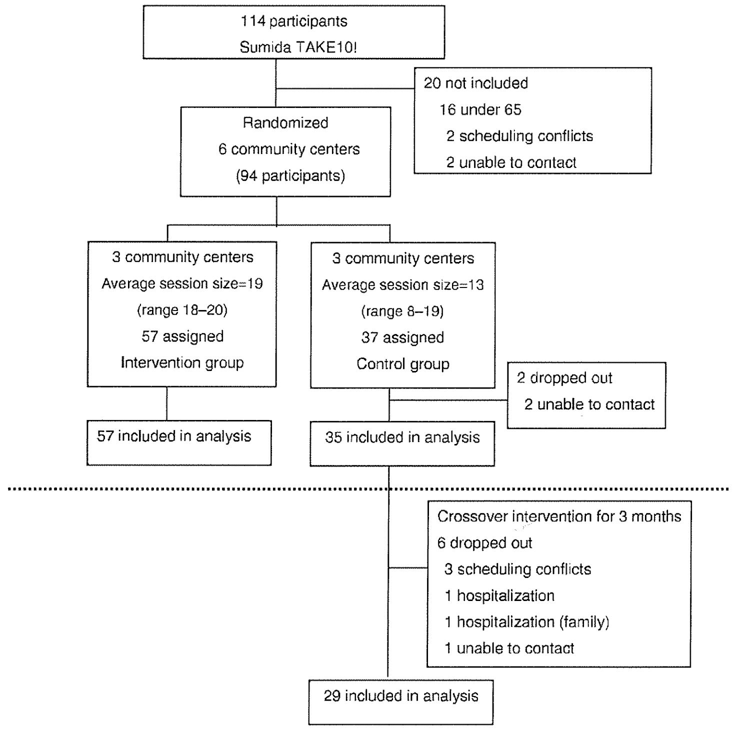

Figure 1 Participant flow.

participating in Sumida TAKE10!, 20 did not satisfy the following inclusion criteria: aged <65 years (n = 16), scheduling conflicts (n = 2), and unable to contact (n = 2). The remaining 94 participants were assigned to the intervention group (3 community centers; n = 57) or control group (3 community centers; n = 37) according to their home addresses. Baseline data was collected in October 2005 post-intervention data in January 2006. Two participants dropped out of the control group and 2 could not be contacted. Eventually, complete data were obtained for 57 participants in the intervention group and 35 participants in the control group.

Intervention

Six community centers were randomized to 3 community centers for the intervention group and 3 community centers for the control group. Participants in the intervention group participated in the Sumida TAKE10! program held from October 2005 to December 2006. Participants in the control group were required only to answer the questionnaire at the same time as the intervention group, and following the intervention, the control group was provided with the same Sumida TAKE10! program as a crossover intervention group to avoid any disadvantage and also to confirm whether the effect of the program could be verified.

The Sumida TAKE10! educational social health program was aimed at helping to prevent or delay the need for long-term nursing care. It consisted of a general lecture by a researcher on the importance of dietary variety and 5 educational sessions (1.5 hours each, held once every 2 weeks) lead by researchers and staff and held at each community center. The same researchers and staff conducted the same intervention program at each community center. The sessions, which were based on the TAKE10!® program, were comprised of approximately a 30-minute lecture on practicing good dietary habits followed by 1 hour of exercise. At the first session, each participant received an explanation on how to use the TAKE10!® Check Sheet and were then required to check their diet for the following 10 days so they could gain a better understanding of their dietary habits. At the second session, participants brought the check sheets with them and analyzed the sheets themselves in the lecture to determine which food groups were not well represented and they were encouraged to increase their intake from these food groups. The check sheet was submitted every session and returned the following session with simple comments such as "Good!" "Better than before!" and "Keep up the good work!"

During the exercise program, participants were instructed in the proper way to perform each stretching and muscle strengthening exercise and the reasoning behind each exercise. After instruction, each stretching exercise was performed 2 times to the right and to the left, and muscle strengthening exercises were each performed 3–5 times at a slow pace. Researchers and staff assisted all participants who did not currently have any physical activity habits. Exercise at home by walking at a self-determined pace, stretching daily, and doing muscle strength training once every two days was recommended. Participants recorded their daily TAKE10! exercise, or lack of exercise, on the TAKE10!® Calendar and submitted it once a month. After review, we returned the Calendar with basic comments as for the TAKE10!® Check Sheet. In all sessions, priority was placed on following any instructions from the participant's primary physician.

In this study, we aimed to determine whether decades-long habits of community-dwelling older adults could be changed by means of the TAKE10!® for Older Adults program, without receiving detailed individualized professional advice.

Main outcomes: dietary and physical activity habit outcomes

We evaluated changes in food intake (frequency of intake of the 10 food groups) and physical activity (frequency of walking and exercise). Food intake was assessed using a questionnaire on food intake frequency covering 1 week and covering the main 10 food groups in the Japanese diet mentioned above. There were 4 choices for food intake frequency for each food group: 1) eat almost every day (3 points), 2) eat 3 or 4 days a week (2 points), 3) eat 1 or 2 days a week (1 point), and 4) eat hardly ever (0 point). We then calculated a food frequency score (FFS) as the sum of scores for each of the 10 food groups to evaluate dietary habits (range 0–30). Dietary variety score (DVS) was also calculated to evaluate dietary habits [27] and was the sum of the number of times each respondent answered "eat almost every day" for the 10 food groups (maximum score 10).

In a previous study, a higher DVS was associated with a reduced risk of higher-level functional decline [27], as determined using the Tokyo Metropolitan Institute of Gerontology (TMIG) Index of Competence score [28]: relative to a reference group with a DVS of 1–3, groups with a DVS of 4–8 or 9–10 showed significantly lower declines TMIG Index of Competence scores over a period of 5 years [27].

Frequency of physical activity was assessed using the questionnaire to determine the frequency of walking and of stretching and muscle strengthening exercise over a 1-week period.

Secondary outcomes: health and health practice outcomes

Data on self-rated health, appetite, and higher-level functional capacity were obtained with the questionnaire. Higher-level functional capacity was measured using the TMIG Index of Competence, a multidimensional 13-item index comprising 3 subscales of instrumental self-maintenance (IADL, 5 items), intellectual activity (4 items), and social roles (4 items). Each item was scored 1 for 'yes '(able to do) and 0 for 'no'. The TMIG Index of Competence has been verified for validity and reliability, and it is widely accepted in Japan [28].

Data analysis

Data were analyzed on an intention-to-treat basis. Mean and standard deviation (SD) was calculated for each variable. We compared the baseline characteristics of the intervention and control groups (between-group) using Student's t-test for continuous variables, a Chi-square test, and Fisher's exact test for proportional variables and Mann-Whitney's U-test for categorical variables. Baseline and post-intervention data were compared as follows: FFS, DVS, and the TMIG Index of Competence within each group using a paired t-test; frequency of intake of each food group, walking and exercise frequency, and self-rated health within each group using the Wilcoxon signed-rank test; and appetite within each group using

Table 1 Demographic characteristics and functional capacities of participants

Characteristics	Intervention (n = 57)	Control (n = 35)	*P*
Sex, n (%)			
Men	9 (15.8)	8 (22.9)	0.419[a]
Women	48 (84.2)	27 (77.1)	
Age in years, mean ± SD	74.3 ± 5.9	74.3 ± 5.0	0.969[c]
BMI, mean ± SD	24.3 ± 2.7	24.3 ± 3.1	0.941[c]
Preexisting conditions, n (%)	20 (35.1)	11 (31.4)	0.718[a]
Hypertension	16 (28.1)	9 (25.7)	0.805[a]
Diabetes mellitus	4 (7.0)	2 (5.7)	1.000[b]
Joint pain (arthritis)	3 (5.3)	2 (5.7)	1.000[b]
Heart disease	4 (7.0)	4 (11.4)	0.474[b]
Cerebrovascular disease	1 (1.8)	0 (0.0)	1.000[b]
Have experienced falls, n (%)	7 (12.3)	5 (14.3)	0.762[b]
Lifestyle			
Ability to walk 1 km (yes, n (%))	52 (91.2)	31 (88.6)	0.727[b]
Hobby activity (yes, n (%))	48 (84.2)	28 (80.0)	0.605[a]
Volunteer activity (yes, n (%))	49 (86.0)	30 (85.7)	1.000[b]
Older adult's group activity (yes, n (%))	47 (82.5)	29 (82.6)	0.961[a]
Friendly conversation with neighbors (2 days or more/w, n (%))	45 (78.9)	27 (77.1)	0.839[a]
Going out (2 days or more/w, n (%))	56 (98.2)	34 (97.1)	1.000[b]
Appetite (yes, n (%))	55 (96.5)	32 (91.4)	0.365[b]
Food Frequency Score (FFS), mean ± SD	21.5 ± 3.7	21.1 ± 5.3	0.690[c]
Dietary Variety Score (DVS), mean ± SD	4.2 ± 2.3	3.9 ± 2.9	0.577[c]
TMG-Index of competence, mean ± SD	12.4 ± 1.1	11.9 ± 1.4	0.062[c]
Instrumental self-maintenance, mean ± SD	4.9 ± 0.2	4.9 ± 0.3	0.538[c]
Intellectual activity, mean ± SD	3.7 ± 0.6	3.8 ± 0.5	0.792[c]
Social roles, mean ± SD	3.8 ± 0.5	3.3 ± 1.1	0.014[c]
Self-rated health, n (%)			0.657[d]
Very good	7 (12.3)	3 (8.6)	
Good	41 (71.9)	26 (74.3)	
Not good	9 (15.8)	6 (17.1)	

SD Standard deviations.
Chi-square test[a] or Fisher's exact test[b] for proportional variables.
Student's t-test[c] for continuous variables.
Mann-Whitney's U test[d] for categorical variables.

McNemer's test. Fisher's exact test was used to compare the positive change in the DVS subgroup scoring 1–3 between the two groups. We compared differences in the improvement rate of walking and exercise frequency, and self-rated health between the groups using the Z-test. Interaction effects were analyzed using a two-way repeated measure analysis of variance. All data were analyzed using SPSS version 11.5 J for Windows XP, and the level of significance was set at 5%.

The study was approved by the Ethics Committee of Showa Women's University, Tokyo, Japan. All subjects provided written informed consent before being enrolled in the study.

Results

Baseline characteristics and attendance rate

Table 1 compares the baseline characteristics between the intervention and control groups. Compared with the

Table 2 Main outcomes in the intervention group and the control group

Outcomes		Intervention				Control				Between-groups
Food frequency, n (%)		Almost every day	3-4 days/ week	0-2 days/ week	*P*	Almost every day	3-4 days/ week	0-2 days/ week	*P*	*P*
Meat	Pre	12 (21.1)	21 (36.8)	24 (42.1)	0.002[a]	9 (25.7)	13 (37.1)	13 (37.1)	1.000[a]	
	Post	23 (40.4)	21 (36.8)	13 (22.8)		7 (20.0)	17 (48.6)	11 (31.4)		
Fish/Shellfish	Pre	23 (40.4)	23 (40.4)	11 (19.3)	0.020[a]	17 (48.6)	11 (31.4)	7 (20.0)	1.000[a]	
	Post	28 (49.1)	26 (45.6)	3 (5.3)		16 (45.7)	13 (37.1)	6 (17.1)		
Eggs	Pre	19 (33.3)	13 (22.8)	25 (43.9)	0.010[a]	10 (28.6)	12 (34.3)	13 (37.1)	0.527[a]	
	Post	24 (42.1)	20 (35.1)	13 (22.8)		8 (22.9)	14 (40.0)	13 (37.1)		
Milk	Pre	29 (50.9)	10 (17.5)	18 (31.6)	0.075[a]	20 (57.1)	6 (17.1)	9 (25.7)	1.000[a]	
	Post	35 (61.4)	8 (14.0)	14 (24.6)		19 (54.3)	8 (22.9)	8 (22.9)		
Soybean products	Pre	30 (52.6)	17 (29.8)	10 (17.5)	0.278[a]	17 (48.6)	11 (31.4)	7 (20.0)	0.822[a]	
	Post	34 (59.6)	15 (26.3)	8 (14.0)		16 (45.7)	12 (34.3)	7 (20.0)		
Green& Yellow vegetables	Pre	40 (70.2)	14 (24.6)	3(5.3)	0.491[a]	21 (60.0)	9 (25.7)	5 (14.3)	0.782[a]	
	Post	42(73.7)	13 (22.8)	2(3.5)		21 (60.0)	8 (22.9)	6(17.1)		
Potatoes	Pre	9 (15.8)	20 (35.1)	28 (49.1)	0.019[a]	8 (22.9)	13 (37.1)	14 (40.0)	0.225[a]	
	Post	15 (26.3)	25 (43.9)	17 (29.8)		6 (17.1)	12 (34.3)	17 (48.6)		
Fruits	Pre	42 (73.7)	9(15.8)	6(10.5)	0.029[a]	16 (45.7)	9 (25.7)	10 (28.6)	0.593[a]	
	Post	48 (84.2)	6:(10.5)	3 (5.3)		14 (40.0)	11 (31.4)	10 (28.6)		
Seaweeds	Pre	15 (26.3)	23 (40.4)	19 (33.3)	0.001[a]	7 (20.0)	17 (48.6)	11 (31.4)	0.674[a]	
	Post	28 (49.1)	21 (36.8)	8 (14.0)		10 (28.6)	13 (37.1)	12 (34.3)		
Fats & Oil	Pre	23 (40.4)	23 (40.4)	11 (19.3)	0.057[a]	13 (37.1)	12 (34.3)	10 (28.6)	0.858[a]	
	Post	33 (57.9)	16 (28.1)	8 (14.0)		10 (28.6)	17 (48.6)	8 (22.9)		
Food Frequency Score(FFS) mean ± SD	Pre		21.5 ± 3.7		0.000[b]		21.1 ± 5.4		0.631[b]	0.002[c]
	Post		23.9 ± 3.9				20.8 ± 4.3			
Dietary variety Score(DVS) mean ± SD	Pre		4.2 ± 2.3		0.001[b]		3.9 ± 2.9		0.328[b]	0.004[c]
	Post		5.4 ± 2.6				3.6 ± 2.2			
Positive change in DVS 1–3 Score group, n (%)			11 (55.0)				3 (18.8)			0.041[d]
		5-7 days	**2-4 days**	**0-1 day**	***P***	**5-7 day**	**2-4 days**	**0-1 day**	***P***	***P***
Walking, n (%)	Pre	35 (61.4)	7 (12.3)	15 (26.3)	0.664[a]	16 (45.7)	11 (31.4)	8 (22.9)	0.348[a]	n.s.[e]
	Post	31 (54.4)	17 (29.8)	9 (15.8)		14 (40.0)	10 (28.6)	11 (31.4)		
Exercise, n (%)	Pre	23 (40.4)	19 (33.3)	15 (26.3)	0.678[a]	17 (48.6)	6 (17.1)	12 (34.3)	1.000[a]	n.s.[e]
	Post	20 (35.1)	28 (49.1)	9 (15.8)		14 (40.0)	12 (34.3)	9 (25.7)		

Wilcoxon signed-rank test[a] for within-groups difference of categorical variables.
Student's t-test[b] for between-group difference of continuous variables.
Two-way Repeated-Measures ANOVA[c] for the time-by-group interaction of continuous variables.
Fisher's exact test [d] for between-group difference proportional variables.
Z-test[e] for between-group differences of improvement rate about categorical variables. P > 0.05; Z-score > 1.96.

control group, the intervention group had a significantly higher score (p = 0.014) for social roles on the TMIG Index of Competence, but no other significant differences were seen between the two groups. The participants were predominantly female (79.8%) as is typical for social programs in Japan [29], and all participants were previously unaware of the TAKE10! program. The mean attendance rate for the intervention classes was 68.1% (range 41– 95%). Eight subjects attended only the first general lecture on importance of dietary variety because of a lack of interest in the exercise programs (n = 3) and schedule conflicts (n = 5). Forty-one subjects (71.9%) participated in more than 3 sessions.

Outcomes measures

Compared to baseline, significant increases were seen in post-intervention food intake frequency for 6 food groups (meat p = 0.002; fish/shellfish p = 0.02; eggs p = 0.01; potatoes p = 0.019; fruits p = 0.029; and seaweed p = 0.001) , FFS (p = 0.000), and DVS (p = 0.001) in the intervention group, and interaction effects of FFS ($F(1, 90) = 10.582$, p = 0.002) and DVS ($F(1,90) = 8.968$, p = 0.004) were seen between the two groups. A significant difference was seen in the percentage of participants scoring 1–3 between the groups (p = 0.041) (Table 2), but no significant difference was observed between baseline and post-intervention in the control group (Table 2). Frequency of walking and stretching and muscle strengthening exercises did not change compared to baseline in either group and no significant differences were seen between two groups (walking, Z = 1.918; exercise, Z = 0.204) (Table 2).

Self-rated health was also significantly improved over baseline in the intervention group (p = 0.033), but no difference in the improvement rate was observed between the groups. Appetite and TMIG Index of Competence score did not change between baseline and post-intervention in either group (Table 3).

As shown in Tables 4 and 5, similar effects were observed for food intake frequency, FFS, DVS, and self-rated health in the crossover intervention group compared to the original intervention group. Compared to baseline, significant increases were seen in post-intervention food intake frequency for 8 food groups (meat p = 0.005; eggs p = 0.002; milk p = 0.021; soybean products p = 0.016; green & yellow vegetables p = 0.008; potatoes p = 0.003; fruits p = 0.013; and seaweed p = 0.011), FFS (p = 0.000), and DVS (p = 0.000) in the crossover intervention group. Self-rated health significantly improved (p = 0.025), and with regard to physical activity, frequency of walking did not change but frequency of exercise significantly improved in the crossover intervention group post-intervention.

Table 3 Secondary outcomes in the intervention group and control group

Outcomes		Intervention			P	Control			P	Between-groups
		mean ± SD				mean ± SD				P
TMIG Index of Competence	Pre	12.4 ± 1.1			0.083[a]	11.9 ± 1.4			0.571[a]	0.810[b]
	Post	12.5 ± 0.8				12.0 ± 1.5				
Self-maintenance	Pre	4.9 ± 0.2			0.146[a]	4.9 ± 0.3			0.422[a]	
	Post	5.0 ± 0.0				4.9 ± 0.2				
Intellectual activity	Pre	3.7 ± 0.6			0.279[a]	3.8 ± 0.5			0.763[a]	
	Post	3.9 ± 0.4				3.8 ± 0.5				
Social roles	Pre	3.8 ± 0.5			0.563[a]	3.3 ± 1.1			0.864[a]	
	Post	3.7 ± 0.6				3.2 ± 1.3				
		yes, n (%)			P	yes, n (%)			P	
Appetite	Pre	55 (96.5)			1.000[c]	32 (91.4)			0.625[c]	
	Post	56(100.0)				34 (97.1)				
		Very good n (%)	Good n (%)	Not good n (%)	P	Very good n (%)	Good n (%)	Not good n (%)	P	P
Self-rated health	Pre	7 (12.3)	41 (71.9)	9 (15.8)	0.039[d]	3 (8.6)	26 (74.3)	6 (17.1)	1.000[d]	n.s.[e]
	Post	12 (21.1)	40 (70.2)	5 (8.8)		3 (8.6)	26 (74.3)	6 (17.1)		

TMIG Tokyo Metropolitan Institute of Gerontology, *SD* standard deviation.
[a]Paired t-test for within-groups difference of continuous variables.
[b]Two-way Repeated-Measures ANOVA for the time-by-group interaction of continuous variables.
[c]McNemer's test for within-groups difference of proportional variables.
[d]Wilcoxon signed-rank test for within-groups difference of categorical variables.
[e]Z-test for between-group difference of improvement rate for categorical variables. P > 0.05; Z-score > 1.96.

Table 4 Main outcomes in the crossover intervention group

Outcomes		Almost every day	3-4 days/week	0-2 days/week	P
Food frequency, n (%)					
Meat	Pre	6 (20.7)	15 (51.7)	8 (27.6)	0.005[a]
	Post	13 (44.8)	12 (41.4)	4 (13.8)	
Fish/Shellfish	Pre	12 (41.4)	11 (37.9)	6 (20.7)	0.197[a]
	Post	15 (51.7)	10 (34.5)	4 (13.8)	
Eggs	Pre	6 (20.7)	14 (48.3)	9 (31.0)	0.002[a]
	Post	16 (55.2)	10 (34.5)	3 (10.3)	
Milk	Pre	15 (51.7)	7 (24.1)	7 (24.1)	0.021[a]
	Post	22 (75.9)	2 (6.9)	5 (17.2)	
Soybean products	Pre	13 (44.8)	11 (37.9)	5 (17.2)	0.016[a]
	Post	21 (72.4)	6 (20.7)	2 (6.9)	
Green & Yellow vegetables	Pre	17 (58.6)	6 (20.7)	6 (20.7)	0.008[a]
	Post	24 (82.8)	4 (13.8)	1 (3.4)	
Potatoes	Pre	5 (17.2)	9 (31.0)	15 (51.7)	0.003[a]
	Post	14 (48.3)	8 (27.6)	7 (24.1)	
Fruits	Pre	11 (37.9)	9 (31.0)	9 (31.0)	0.013[a]
	Post	18 (62.1)	5 (17.2)	6 (20.7)	
Seaweeds	Pre	10 (34.5)	10 (34.5)	9 (31.0)	0.011[a]
	Post	16 (55.2)	10 (34.5)	3 (10.3)	
Fats & Oil	Pre	10 (34.5)	13 (44.8)	6 (20.7)	0.115[a]
	Post	15 (51.7)	10 (34.5)	4 (13.8)	
Food Frequency Score (FFS), mean ± SD	Pre		20.9 ± 4.5		0.000[b]
	Post		24.7 ± 5.1		
Dietary variety Score (DVS), mean ± SD	Pre		3.6 ± 2.3		0.000[b]
	Post		6.0 ± 3.2		
Positive change in DVS 1–3 Score group, n (%)			7 (53.8)		
		5-7 days	**2-4 days**	**0-1 day**	**P**
Walking, n (%)	Pre	12 (41.4)	10 (34.5)	7 (24.1)	0.090[a]
	Post	15 (51.7)	11 (37.9)	3 (10.3)	
Exercise, n (%)	Pre	13 (44.8)	10 (34.5)	6 (20.7)	0.026[a]
	Post	21(72.4)	4 (13.8)	4 (13.8)	

Wilcoxon signed-rank test[a] for within-groups difference of categorical variables.
Paired t-test[b] for within-groups difference of continuous variables.

Discussion

The TAKE10!® for Older Adults program at community centers appears to have improved dietary habits among community-dwelling older adults. In addition to the food intake frequency for 6 food groups, FFS and DVS were significantly increased in the intervention group, suggesting that the participants' dietary habits changed and that dietary variety was greater than before. Increases in the frequency of intake of high-protein foods and high-fiber foods were especially positive results and may help older Japanese adults to maintain good nutritional status. There were no changes in BMI ($p = 0.561$) or appetite ($p = 1.000$) seen in the intervention group, which indicates that it was the quality not quantity of food intake in their diets that changed. The fact that 55% of participants with a baseline DVS of 1–3 improved to a post-intervention score of ≥4 indicates their risk of a decrease in higher-level functional capacity had been lowered. In addition, the interaction effects of FFS and DVS and similar results seen in the crossover intervention group indicate the efficacy of this intervention program on dietary habits.

Physical activity and good nutritional habits are important to helping community-dwelling older adults avoid or delay the need for long-term nursing care [30]. Because of difficulties in evaluating nutritional programs for older

Table 5 Secondary outcomes in the crossover intervention group

Outcomes		mean ± SD			P
TMIG Index of Competence	Pre		12.0 ± 1.7		0.869[a]
	Post		12.0 ± 1.6		
Self-maintenance	Pre		4.7 ± 0.2		0.326[a]
	Post		5.0 ± 0.0		
Intellectual activity	Pre		3.9 ± 0.7		0.083[a]
	Post		3.7 ± 0.6		
Social roles	Pre		3.2 ± 1.4		0.846[a]
	Post		3.2 ± 1.2		
			yes, n (%)f		**P**
Appetite	Pre		28(96.6)		1.000[a]
	Post		28(96.6)		
		Very good, n (%)	**Good, n (%)**	**Not good, n (%)**	**P**
Self-rated health	Pre	1 (3.4)	23 (79.3)	5 (17.2)	0.025[b]
	Post	5 (17.2)	20 (69.0)	4 (13.8)	

TMIG Tokyo Metropolitan Institute of Gerontology, *SD* standard deviation.
[a]Paired t-test for within-groups difference of continuous variables.
[b]Wilcoxon signed-rank test for within-groups difference of categorical variables.

adults, few studies on such programs have been conducted to date. However, some studies have shown associations between dietary variety and nutritional status [23,24,31], quality of life [30,32], and physical and cognitive function [33,34]. It is clear that promoting dietary variety is one of the best ways to maintain proper nutritional status among older adults. Moreover, in a super-aging society like Japan, there is an urgent need for social programs that are easy to implement and follow and that do not require individual advice and attention from professionals.

It was interesting that frequency of walking and doing stretching and muscle strengthening exercises did not change even in the intervention group. Some possible reasons are that, first, the end point of this intervention was during the coldest time of year in Japan, and many people undoubtedly preferred to stay indoors. Second, at baseline, 78% participants were already in the habit of walking or engaging in exercise 5 days per week, and in this community attending radio calisthenics (*"rajio taisou"*) broadcasts in nearby parks is very popular. Third, 8 (14%) subjects did not participate in the sessions beyond the first lecture and another 8 (14%) subjects participated in fewer than 3 sessions, so they might not have been interested in our program and thus not have mastered the exercises enough to perform them at home without assistance. However, in response to the question in the post-intervention questionnaire "Did you do TAKE10 exercises at home?" 83% participants answered "Yes", and to "How many days did you do them a week?" 78% participants answered "every 2 days or more". In the winter, it is possible that some participants replaced their attendance of the radio calisthenics broadcasts with TAKE10 exercise as it was more difficult to go outside. In addition, significant differences were observed in the frequency of exercise in the crossover intervention group, suggesting the possibility of intervention effects on physical activity.

Self-rated health improved in the intervention group compared to baseline, although a significant difference in improvement rate was not seen between groups. Self-rated health is a global measure of health, and many studies have shown correlations with relative risk of mortality [35-38], well-being, and functional capacity [39]. For community-dwelling older adults, self-rated health is a possible indicator of quality of life. However, the observed effect may have been the result of not only attending this program, but also simply gathering together with other members of the community.

This study has several limitations. First, the study design was not an ideal randomized control trial. In order to eliminate transportation barriers to participation in this program, participants were assigned to groups according to their home address. In addition, to secure the same floor conditions at the 6 community centers, randomization was conducted before recruitment. Therefore, the two groups differed in the number of participants at baseline. However, as shown in Table 1, there were no significant differences between the two groups in the variables measured at baseline. Also, we compared the 3 baseline measures (sex, age, and TMIG Index of Competence) between the 6 clusters and no significant differences were seen. The sample size was less than the ideal 50 participants per group, and as the participants were recruited through the ward's bulletin, participants who enrolled might have been more motivated and health conscious. This might also explain the large percentage of female participants [29]. Other recruitment methods should be considered in future studies.

Although we did not examine behavioral stage and self-efficacy, we did find some behavior changes among the participants. In response to "Did your awareness of diet change after participating in this program?" 94% participants answered "Yes", indicating that behavioural stage or self-efficacy might have changed, although we did not evaluate this scientifically. In addition, we used the TAKE10!® Check Sheet and the TAKE10!® Calendar only as tools to motivate participants and not to measure outcomes. The tools could be used to evaluate behavioral aspects in future studies. Also, seasonal changes in participant behavior were not considered and the intervention program did not reflect this. The program