

Research Article

Effects of an Updated Preventive Home Visit Program Based on a Systematic Structured Assessment of Care Needs for Ambulatory Frail Older Adults in Japan: A Randomized Controlled Trial

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Received August 27, 2015; Accepted March 20, 2016

Decision Editor: Stephen Kritchevsky, PhD

Abstract

Background: The aim of this randomized controlled trial was to determine the effects on functional parameters of an updated preventive home visit program for frail older adults in the Japanese Long-term Care Insurance (LTCI) system.

Methods: The program included home visits by nurses or care managers every 3 months for 24 months, with a systematic assessment of care needs to prevent functional decline. Eligible participants ($N = 360$) were randomly assigned to the visit (VG: $n = 179$) or control group (CG: $n = 181$). Functional parameters were gathered via mail questionnaires at baseline and at 12- and 24-month follow-ups. Care-need levels in the LTCI were obtained at 12-, 24-, and 36-month follow-ups and the utilization of the LTCI service through 36 months.

Results: Participants in VG were significantly more likely to maintain their activities of daily living (ADL) functioning ($p = .0113$) and less likely to increase care-needs level, compared with CG participants, over 24 months. A generalized linear model showed that the estimate of the effect on increase in care-needs level (ie, functional decline) was -0.53 ($p = .042$) over 36 months.

Conclusions: These results suggest that the updated preventive home visit program could be effective for the prevention of ADL and care-needs deterioration, and these effects could continue up to 1 year after program completion.

Keywords: Frailty—Geriatric assessment—Long-term care—Preventive home visit—Randomized controlled trial

Frailty in older adults is a clinical state of heightened risk for developing dependency requiring multidimensional care and death when exposed to a stressor (1,2). Preventive home visits (PHVs) remain as a practical strategy for maintaining independence in frail older adults living at home (2–5). Although a few meta-analyses or systematic reviews have questioned the efficacy of PHVs (6–8), conclusions of these reviews are based on examination of a heterogeneous group of studies that vary greatly in design (3–8), and various models have been suggested as being most effective (9).

Japan, an aging society with 25.1% of its adult population aged 65 years or older in 2013 (10), has been operating a public Long-term

Care Insurance (LTCI) system since 2000 (11). Using funds from the LTCI system, community-based integrated centers were established in every district with municipalities of approximately 20,000 residents. They provide outreach with home visits and preventive benefit care management to ambulatory frail older adults certified at the two lowest care-need levels (Support Level 1 or 2) (12).

We have developed and implemented for over a decade an evolving PHV program model, which includes outreach home visits to frail ambulatory older adults in community-based care settings (13–17). In our previous randomized controlled trial, we showed that an early design of the PHV program was ineffective (14–16),

possibly due to the long interval between visits (6 months) or to the fact that the clinical recommendations did not focus on the prevention of functional decline in older adults (15). The findings of the previous study led to modification of the PHV program including the use of a systematic structured needs' assessment and an increase in home visits' frequency to every 3 months for 24 months (17).

The aim of the present randomized controlled trial was to determine the effects on functional parameters of the updated PHV program over 24 months in ambulatory frail older adults certified at the two lowest care-need levels in the Japanese LTCI system. In order to confirm the long-term effects of the PHV program, we followed up care-need levels as well as the utilization of LTCI service for an additional 12-month period after the PHV program ended.

Methods

Procedure and Participants

The study design comprised a single-blind randomized controlled trial. Study settings, derivation of study participants, intervention protocol, and measurements were as described previously (17).

The PHV program was provided from October 2011 to September 2013 to participants in the visit group (VG). Participant surveys of functional parameters were conducted via mail questionnaires at baseline (ie, July 2011) and at 12- (ie, September 2012) and 24- (ie, September 2013) month follow-ups. We obtained data on care-need levels in the LTCI at 12-, 24-, and 36-month (ie, September 2014) follow-ups, as well as the monthly costs of the LTC service through 36 months from local government records.

The present population-based study was carried out in three suburban municipalities in Osaka, Japan: Daito (population at April 2011 = 126,701), Sennan (64,186), and Misaki (17,268). A total of 1,068 potential participants identified from the three local government records in May 2011, aged 65 years or older who were certified as being at Support Level 1 (less frail) or 2 (more frail), were included in the baseline survey (17). (Persons in Support Levels 1 and 2 were typically ambulatory, without serious cognitive disorder, with little difficulty in IADLs in general, and ineligible for facility-based care in the LTCI.) After the baseline survey, 505 individuals were enrolled excluding participants who did not respond, returned invalid responses, were certified with a Care Level, were institutionalized, were hospitalized, or died during the survey. From these 505 individuals, 360 potential study participants were randomly extracted in order to enroll approximately 60 participants to the intervention in each community based on sample size estimates described elsewhere (17) (Figure 1). Using computer-generated random numbers, stratified on the basis of gender, age group, and community, these 360 participants were randomized to either the visit group (VG) allocated to the updated PHV program ($n = 179$) or the control group (CG; $n = 181$). At each follow-up time points, both the VG and CG lost a few participants due to death or moving out the area.

Data regarding care-need levels or service utilization in the LTCI system were analyzed only for participants who remained in their respective follow-up groups (ie, excluding those lost to follow-up due to death or moving) at each time point or monthly over 36 months. Data from mail surveys were analyzed for participants who were living at home, hospitalized, or institutionalized at each time point. The

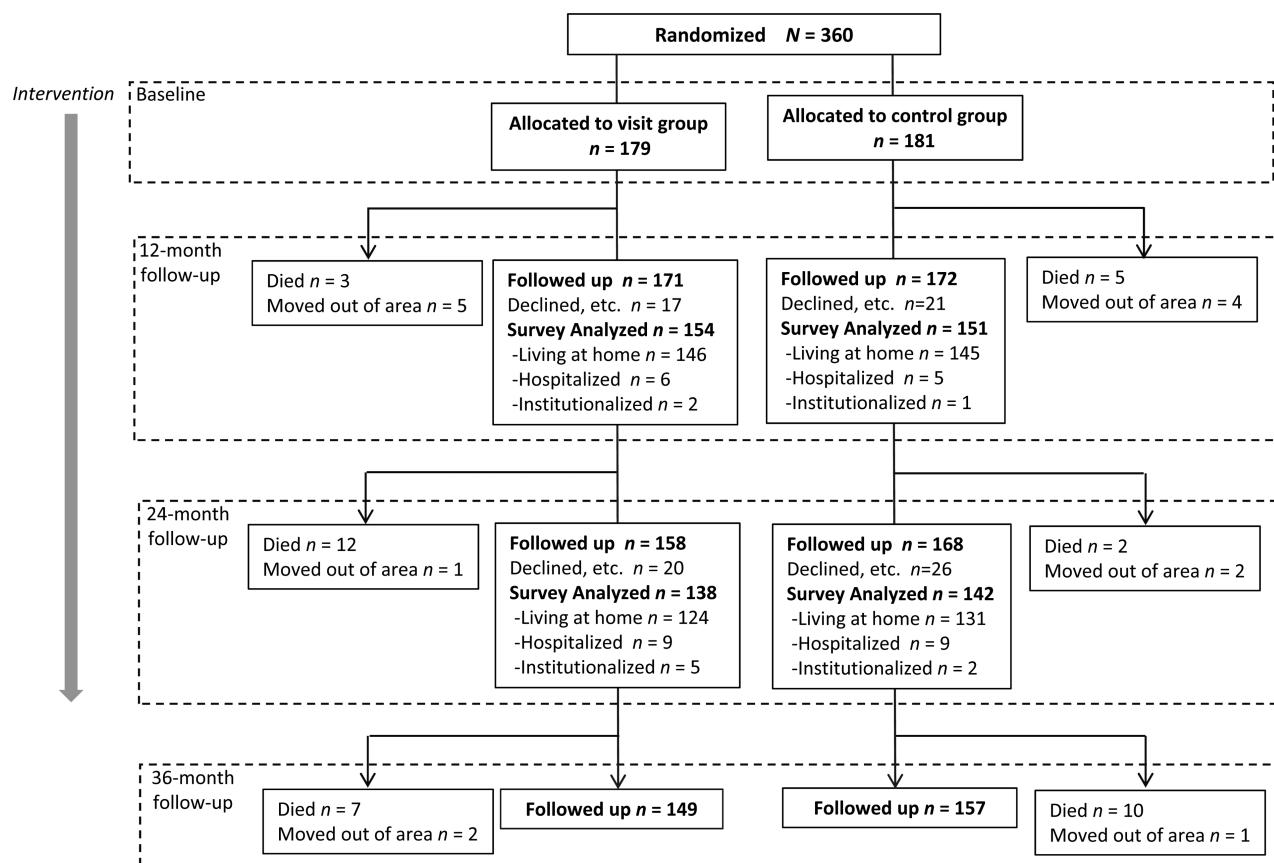


Figure 1. Flow chart of study participants.

response rates in the VG and CG at 12- and 24-month follow-ups based on the number of baseline participants were 154 (86.0%) versus 151 (83.4%) and 138 (77.1%) versus 142 (78.5%), respectively.

We informed participants about the survey and study overview via mail at baseline survey. We obtained both oral and written informed consents from participants in VG. The study was approved by the Nursing Research Ethical Committee of Osaka City University (no.23-3-4, June 22, 2011). The study protocol was registered in the UMIN Clinical Trials Registry approved by International Committee of Medical Journal Editors (no. UMIN000006463, October 4, 2011).

Outcome Measures

Primary outcome measures included functional parameters at 12- and 24-month follow-ups and care-need levels in the LTCI system at 12, 24, and 36 months. Secondary outcome measures included LTC service utilizations over the 36-month period.

Functional parameters included activities of daily living (ADLs), instrumental activities of daily living (IADLs), depression, cognitive capacity, daily life satisfaction related to social activities, and self-efficacy for health promotion. In addition, we asked about the occurrence of any health-related events in the past year which could affect functional parameters, including falls, hospitalizations, or death of a family member.

ADLs were measured by a self-rated form based on the Barthel Index (18), a well-known scale with established reliability and validity, with ADL scores ranging from 0 to 100. IADLs were measured by the Index of Competence developed by the Tokyo Metropolitan Institute of Gerontology (19), which consists of 13 items. The response to each item is given a score of either 1 for “yes” or 0 for “no” (range 0–13). High scores for instrumental self-maintenance indicate relatively high levels of ADL and IADL functioning. Depression was measured by the Japanese translation (20) of the 5-item Geriatric Depression Scale (21), which is widely used in Japan. High scores (range 0–5) indicate worsening depression. Cognitive capacity was assessed by the capacity subscale of the short Japanese version (22) of the Metamemory in Adulthood Questionnaire (23,24). It contains seven items, asking respondents to rate their agreement with statements on memory capacity. High scores (range 5–35) indicate a high level of self-reported confidence in cognitive capacity; the mean score reported for healthy older Japanese is 20.0 (22). (Although the subscale has not yet been validated for performance-based cognitive function tests, memory complaints including confidence could be an early sign of cognitive function decline (25)). Daily life satisfaction related to social activities was measured by the Social Activities-Related Life Satisfaction Scale (26), which has previously shown sufficient validity and internal consistency. It contains 14 items, and high scores (range 14–70) indicate a high degree of satisfaction from social activities. Self-efficacy for health promotion was measured by the 15-item Self-Efficacy for Health Promotion Scale (27). Items include daily activities related to general health promotion. Each item is given a score ranging from 1 for “not confident at all” to 4 for “very confident” (range 15–60).

Local governments certify care-need levels in the LTCI system according to a national standardized computer-aided system that calculates estimated care time, after comprehensive examinations by independent investigators hired by each local government. Care-need levels consist of seven categories, starting with Support Level 1 or 2 and Care Level 1 (less disabled) to 5 (most disabled). The

criteria for estimated care time for Support Level 1 is less than 25 minutes, whereas the estimated times for Support Level 2, Care Level 1, Care Level 2, Care Level 3, Care Level 4, and Care Level 5 are 25–32, 25–32, 50–70, 70–90, 90–110, and more than 110 minutes, respectively. The estimated care times for Support Level 2 and Care Level 1 are the same, and the care-need levels are determined by certificate board member discussions in each local government based on narrative descriptions of the examination and estimated care time. Typically, individuals in Care Levels 1–5 have dementia or are chair- or bed-bound, and individuals certified as Care Level 3–5 are eligible for admission to nursing facilities offering constant care. We collected data related to these seven categories and calculated the frequency of decline to Care Level 1–5 from Support Levels 1 or 2 at baseline.

We also collected data related to the monthly costs of LTC service utilization, including facility-based and home-based care.

Interventions

Routine PHVs were provided every 3 months for 24 months by community care nurses, social workers, or care managers who worked at all six community-based integrated centers in the three municipalities. PHVs were conducted with rigorous recommendations, based on a systematic structured assessment sheet of care needs, including four domains: health, mental health, activities, and participation (17). After assessing care needs and client and/or family care preference, comprehensive recommendations were made, which included “sustain self-care,” “need observation or supervision from visitors,” and “need continuous or long-term health care” (17). PHVs over the period were implemented for the majority of participants living at home in VG (first visit, 87.7%; second, 79.3%; third, 78.1%; fourth, 70.8%; fifth, 73.6%; sixth, 72.0%; seventh, 70.1%; and eighth, 74.0%), and additional visits were not conducted.

Participants in the CG received the usual care in the Japanese LTCI system, which includes unstructured visits from community-based integrated centers, every 3 months to individuals utilizing home-based LTC services. The same visitors could see participants in both the VG and CG but did not use assessment sheets for those individuals in the CG.

Visitors of community-based integrated centers could know the group allocation, but investigators related to certification of care-need levels were blinded.

Statistical Analysis

All analyses were conducted by intention to treat (including participants who declined PHVs), using SAS version 9.4, with a two-tailed probability level less than .05 indicating statistical significance.

To demonstrate the effect size of .50 on outcome parameters (ADLs and IADLs), 180 participants per group were required, as described previously (17).

In order to compare the changes in continuous variables related to functional parameters over time between groups, we performed two-way repeated analysis of covariance using PROC MIXED in SAS procedure, adjusting for each baseline score to test both groups and the interaction of “Group \times Time” effect. To compare the rate of occurrence in health-related events between groups at 12- and 24-month follow-ups, chi-square tests or Fisher’s exact tests were conducted.

To determine the effect on care-need level decline between groups, estimates over 36 months, and odds ratios at each follow-up, we performed a generalized linear model utilizing logit function, with

dependent variables including 1 for “remaining at Support Level or uncertified” and 0 for “declining to Care Level” and independent variables including group and time point.

A mean of the total LTC service costs per person over the study period was compared between groups, utilizing the *t* test after log transformation. Average LTC service costs per person per 3 months were calculated for each group.

Results

Characteristics of Participants at Baseline

Table 1 shows the characteristics of participants at baseline. The mean age was 79.2 years. About 75% of the study population was women, and about half was in each Support Levels 1 and 2.

Primary Outcomes: Functional Parameters and Care-need Levels in the LTCI System

The number of participants who died over 36 months were 22 (12.3%) in VG and 17 (9.4%) in CG, with no statistically significant difference between the groups.

Changes in functional parameters over 24 months are shown in Table 2. Two-way repeated analysis of covariance, adjusting for each baseline score of functional parameters, showed that ADLs in CG participants were significantly worse over time, compared with VG participants (*F* value of “Group × Time” effect = 4.52, *p* = .011). However, daily life satisfaction related to social activities in VG participants was significantly worse, compared with CG participants (*F* value of “Group × Time” effect = 3.25, *p* = .040). We performed the sensitivity analysis including participants (*n* = 280) who were living

at home, hospitalized, or institutionalized at 24-month follow-up in the same way. It also showed that ADLs in CG participants were worse over time, compared with VG participants (*F* value of “Group × Time” effect = 3.82, *p* = .022), but daily life satisfaction related to social activities in VG participants was worse, compared with CG participants (*F* value of “Group × Time” effect = 4.30, *p* = .014).

Analysis of the events which could affect functional parameters revealed the rates of falls occurring in the prior year in each group: 24.7% (*n* = 38) for VG (*n* = 154) and 27.8% (*n* = 42) for CG (*n* = 151) at 12-month follow-up (n.s.), and 29.7% (*n* = 41) for VG (*n* = 138) and 33.8% (*n* = 48) for CG (*n* = 142) at 24-month follow-up (n.s.). Rates of hospitalization in the prior year in each group were 16.9% (*n* = 26) for VG and 15.9% (*n* = 24) for CG at 12-month follow-up (n.s.), and 18.8% (*n* = 26) for VG and 25.3% (*n* = 36) for CG at 24-month follow-up (n.s.). Rates of death of a family member in the prior year in each group were 9.1% (*n* = 14) for VG and 5.3% (*n* = 8) for CG at 12-month follow-up (n.s.), and 5.8% (*n* = 8) for VG and 5.6% (*n* = 8) for CG at 24-month follow-up (n.s.).

Figure 2 shows the percentage changes of participants who were certified as Care Level (disabled) at follow-ups from Support Level (frail) at baseline in the LTCI system. According to the generalized linear model utilizing logit function, estimate for the effect on care-need level increase crossing from Support Level to Care Level over the study period was -0.53 (*SE* = 0.26, 95% confidence interval [CI] = -1.03 to -0.01 , *p* = .042), and the odds ratios of VG, compared with CG, were 1.01 (95% CI = 0.54 to 2.17, n.s.) at 12 months, 0.56 (95% CI = 0.32 to 0.96, *p* = .037) at 24 months, and 0.59 (95% CI = 0.35 to 0.98, *p* = .042) at 36 months.

Secondary Outcomes: LTC Service Utilization

No statistically significant differences in total LTC service costs per person over 36 months between VG and CG groups were obtained (mean credits [*SD*]: VG = 3,507 [5,400], CG = 3,562 [5,066], n.s.). Supplementary Figure 1 shows the mean of LTC service costs and those in both groups increased over the study period.

Supplementary Table 1 shows changes in mean LTC service utilization rates, which increased slightly in both groups over the study period. At least 61%–66.9% of participants in the CG received unstructured routine home visits in the LTCI system every 3 months from community-based integrated centers during the study period.

Discussion

This randomized controlled trial suggests that the PHV program with rigorous recommendations, based on the systematic structured assessment of care needs of ambulatory frail elderly individuals living at home, was effective for the prevention of decline in ADL functioning and increase in care-need level, and remained effective for the prevention of care-needs increase 1 year after PHV program completion. Because ADLs or care-need level are considered as one of strongest outcome measures related to quality of life in the elderly population, most intervention studies have targeted such measures (3–8).

Although the present PHV program has been updated from a previous randomized controlled trial (14–16) which was not effective for functional outcomes, including ADLs or care-need level, we could interpret the results as follows:

First, the positive effects of the present PHV program on ADLs could be explained by the fact that the program had a more

Table 1. Characteristics of Participants at Baseline (*N* = 360)

	Group	
	Visit (<i>n</i> = 179)	Control (<i>n</i> = 181)
Age, mean (<i>SD</i>) ^a	79.2 (6.0)	79.2 (6.3)
Gender ^a		
Male, <i>n</i> (%)	44 (24.6)	50 (27.6)
Female, <i>n</i> (%)	135 (75.4)	131 (72.4)
Care-need level ^a		
Support Level 1: less frail, <i>n</i> (%)	89 (49.7)	89 (49.2)
Support Level 2: more frail, <i>n</i> (%)	90 (50.3)	92 (50.8)
Household ^b		
Living alone, <i>n</i> (%)	74 (41.3)	84 (46.9)
Couple, <i>n</i> (%)	53 (29.6)	48 (26.8)
Living with married child, <i>n</i> (%)	33 (18.4)	25 (14.0)
Other, <i>n</i> (%)	19 (10.6)	22 (12.3)
Frequency of going outdoors ^c		
More than 4 times/week, <i>n</i> (%)	32 (18.6)	35 (19.8)
2–3 times/week, <i>n</i> (%)	77 (44.8)	80 (45.2)
Once a week, <i>n</i> (%)	40 (23.3)	42 (23.7)
Seldom, <i>n</i> (%)	23 (13.4)	20 (11.3)
Subjective health ^d		
Very good, <i>n</i> (%)	3 (1.7)	4 (2.3)
Good, <i>n</i> (%)	60 (34.5)	74 (41.6)
Bad, <i>n</i> (%)	86 (49.4)	80 (44.9)
Very bad, <i>n</i> (%)	25 (14.4)	20 (11.2)

Notes: ^aVisit group: *n* = 179; control group: *n* = 181.

^bVisit group: *n* = 179; control group: *n* = 179.

^cVisit group: *n* = 172; control group: *n* = 177.

^dVisit group: *n* = 174; control group: *n* = 178.

Table 2. Change in Functional Parameters Over 24 Months in Participants (N = 360)

Measures (unfavorable to favorable)	Group	Time Point			Effect ^a	
		Baseline	12 Months	24 Months	Group	Group × Time
		Mean (SD)	Mean (95% CI)	Mean (95% CI)	F Value (p value)	F Value (p value)
ADLs (0–100)	Visit	91.9 (10.9)	91.5 (89.5–93.5)	90.0 (87.8–92.2)	3.31 (.070)	4.52 (.011)
	Control	92.7 (10.4)	91.1 (89.1–93.1)	85.0 (83.0–87.0)		
IADLs (0–13)	Visit	8.3 (3.4)	7.8 (7.4–8.2)	7.4 (6.8–8.0)	0.03 (.870)	0.07 (.934)
	Control	8.2 (3.2)	7.8 (7.4–8.2)	7.3 (6.9–7.7)		
Depression (15–0)	Visit	2.1 (1.6)	2.2 (2.0–2.4)	2.4 (2.2–2.6)	0.51 (.474)	1.27 (.282)
	Control	2.2 (1.6)	2.2 (2.0–2.4)	2.2 (2.0–2.4)		
Cognitive capacity (5–35)	Visit	18.9 (5.9)	17.9 (17.1–18.7)	17.2 (16.3–18.1)	1.98 (.160)	0.37 (.689)
	Control	18.5 (5.9)	18.5 (17.7–19.3)	18.0 (17.2–18.8)		
Daily life satisfaction related to social activities (14–70)	Visit	36.5 (12.7)	33.7 (31.9–35.5)	31.2 (29.4–33.0)	4.82 (.029)	3.25 (.040)
	Control	35.2 (12.5)	36.5 (34.7–38.3)	33.9 (32.1–35.7)		
Self-efficacy for health promotion (15–60)	Visit	36.8 (8.7)	36.5 (35.3–37.7)	35.0 (33.6–36.4)	3.27 (.072)	1.96 (.142)
	Control	36.2 (8.1)	37.7 (36.5–38.9)	37.0 (35.8–38.2)		

Notes: 95% CI = 95% confidential interval; ADLs = activities of daily living; IADLs = instrumental activities of daily living. Values at baseline are unadjusted means (SD); values at 12- and 24-month follow-ups are adjusted means (95% CI). Visit group: n = 179; control group: n = 181.

^aComparing changes from baseline to follow-up between groups: two-way repeated analysis of covariance, adjusting for each baseline score.

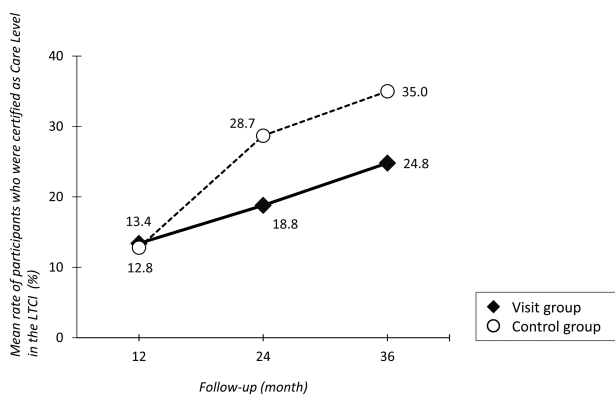


Figure 2. Change in rate of participants who were certified as Care Level in the Long-term Care Insurance (LTCI) system over 36 months (N = 306). Elderly adults who were certified as Care Level were more severely disabled than Support Level adults in the LTCI system. Participants who had died or moved out the area were excluded at 36-month follow-up. Visit group vs control group n = 149 vs n = 157. Estimating the effect of PHVs, according to a generalized linear model, over the study period, with independent variables including 0 = remain at Support Level or uncertified and 1 = decline to Care Level. Estimate = -0.53, SE = 0.26, 95% confidence interval (CI) = -1.03 to -0.01, p = .042. Odds ratio at 12-month follow-up = 1.01, 95% CI = 0.54 to 2.17, p = .817. Odds ratio at 24-month follow-up = 0.56, 95% CI = 0.32 to 0.96, p = .037. Odds ratio at 36-month follow-up = 0.59, 95% CI = 0.35 to 0.98, p = .042.

structured assessment as well as an initiating recommendation sheet provided by each home visitor, compared with the previous program (14–16). Our results are consistent with those from a recent meta-analysis showing that an intervention program with multidimensional assessment could be effective for the prevention of functional status decline (4). The recommendation sheet used in our study was designed to be as simple as possible, setting recommendations from mainly eight care-needs domains. Simple recommendation sheets are helpful in terms of feasibility, as well as to facilitate explicit clinical thinking, as home visitors are able to focus on formulating recommendations rather than complex paperwork.

Second, the effectiveness of the present study could be explained by a higher frequency of planned PHVs, that is, every 3 months, for 24 months, compared with previous PHVs provided every 6 months, although the visit frequency did not relate to the effects of PHV, according to a previous meta-analysis (4). Three-monthly visits could provide continuous recommendations to participants. However, visit compliance decreased from 87.2% at the first visit to 70.1% at the eighth visit. Of note, visit compliance remained at approximately 70% after the fourth visit. In contrast, a previous study (15) showed visit compliance remaining mostly constant, from 87.0% to 83.9%, over 24 months. It is possible that participants thought their functions had stabilized and therefore declined further 3-monthly PHVs.

Third, our findings suggest that the impact of PHVs on care-need level was effective at 24 months, lasting up to 1 year after completion of the PHV program. Although we did not find any further evidence regarding the long-term lasting effects of PHVs, we could recommend providing PHVs for at least 24 months. Clinically, it is important to emphasize the important implication of a decline to Care Level from Support Level in frail elderly people, as those certified as Care Level have a higher risk of mortality (28).

However, our PHV program was not effective in several other areas. First, there were no significant differences in the increase in LTC service cost and utilization between the two groups over the study period. It is possible that home visitors recommended LTC service utilization to participants in the present study in both groups, as well as the ambulatory frail elderly participants who did not use the LTC service at baseline in the previous study (15).

Second, our results showed that daily life satisfaction related to social activities in VG was somewhat worse than that in CG over the study period. One possible explanation is that participants in VG experienced a somewhat higher rate of death in their families, compared with those in CG, although this was not statistically significant. Such specific events can have a negative impact on psychological health and might be difficult to be addressed by the present PHV program. In addition, function-deficit-focused visits from the

formal care system might have negative effects on these perceptions. Further research on this PHV model might include self-care efficacy for social activities that might also be sensitive to large doses of PHVs of this sort. Lastly, the present PHV program had no effect on mortality, which is in agreement with results from other studies (4,5). The mean age of study participants at baseline was 79.2 years, which would make life prolongation a goal difficult to achieve (6). The process of participants' death might be investigated as an outcome of PHVs in future studies, as one of the aims of PHVs includes optimizing quality of life during the end of life, as well as prevention of functional decline.

The present study has several limitations. First, because the surveys were conducted via mail and self-reported, participants having problems (ie, cognitive impairment) might not complete the survey or provide inaccurate information related to cognitive function, medical condition, or hospitalizations. Second, home visitors could provide a similar type of PHV assessment to participants in CG even though they did not use structured sheet. Third, relationships between compliance with recommendations during the PHV and effects should be clarified in future analysis. Lastly, the present intervention could be categorized as "outreach home visits" (9) focusing on needs assessment rather than clinical care. Future programs could be built based on primary or medical care settings, targeting illness management that involves physicians or advanced nurses (29), which might prove more effective for improving major clinical outcomes.

We conclude that our PHV program with rigorous recommendations, based on the systematic structured assessment of care-needs, could be beneficially applied in clinical practice for the prevention of functional decline among ambulatory frail elderly people living at home.

Supplementary Material

Please visit the article online at <http://gerontologist.oxfordjournals.org/> to view supplementary material.

Funding

This work was supported by Kiban-B grant 22390443 (PI: Ayumi Kono) from the Japan Society for the Promotion of Science (2010–2014).

Acknowledgments

We thank the participants and family members in this study. We also express our gratitude to the staff of the Long-term Care Insurance Sections of Daito, Sennan, and Misaki Local Government Offices, and their community-based integrated care centers. To the memory of our great mentor Dr. Chieko Tsumura, Emeritus Professor of Osaka Prefecture University and Konan Women's University, who had collaborated on this research project.

Conflict of Interest

The authors have no conflict of interest to declare.

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