Effects of a Preventive Home Visit Program in Ambulatory Frail Older People: A Randomized Controlled Trial

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Background. The aim of this study was to examine the effects on functional and psychosocial parameters and long-term care utilization of a preventive home visit program for ambulatory frail Japanese elders.

Methods. Eligible participants (n = 323) were randomly assigned to intervention (n = 161) or control group (n = 162). Nurses and care managers provided structured preventive home visits to the intervention group participants every 6 months over 2 years. Activities of daily living (ADLs), instrumental activities of daily living (IADLs), depression, and social support were collected via mail questionnaire at baseline and at 12- and 24-month follow-up points. The utilization of long-term care insurance was documented over the period.

Results. Two-way analysis of covariance did not show significant outcome differences overall. In a pre-planned subgroup analysis for participants who had at least one ADL dependency at baseline, those in the intervention group (N = 105) were significantly less likely to deteriorate over 2 years in their function and depression than those in the control group (N = 100): ADLs (p = .0311), IADLs (p = .0114), depression (p = .0001). The total long-term care costs over 2 years in the intervention group (36,601 credits) were higher than in the control group (26,022 credits) (nonsignificant), and elders in the intervention group utilized significantly more community and institutional long-term care services than those in the control group over the period 7 months to 15 months after the intervention started.

Conclusions. The results suggest that a preventive home visit program might be ineffective on functional and psychosocial status among ambulatory frail elders overall, although it might significantly improve ADLs, IADLs and depression for those with ADL dependency.

Key Words: Ambulatory frail elder—long-term care—preventive home visit—randomized controlled trial.

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OVER previous decades, preventive home visit programs of various types to prevent functional decline among community dwelling older people have been developed. Moreover, some countries have already adopted preventive home visits as a national health policy (1–3).

Some systematic reviews and meta-analyses suggest that preventive home visit programs do not have clear effects on mortality (4,5), physical and psychosocial function (4), and health status in community-dwelling elderly people. The individual trials in those systematic reviews or meta-analysis were heterogeneous. However, other meta-analyses investigating 17 randomized controlled trials (6) and 21 trials (7) concluded that preventive home visits are able to reduce disability burden among older people, if home visits program include multidimensional geriatric assessment.

Other debate in the literature concerns the ideal target group for preventive home visits. Some studies indicate that general older populations can benefit from preventive home visits in terms of a reduced risk of not living at home or nursing home admission, while frail elders who had severe disability did not benefit as much (8). However, definitions of frailty differ among trials in the meta-analyses (8). Other studies (9,10) show clinically important benefits accruing to elders in the early stage of the frailty such as ambulatory frail elders.
Ambulatory frail older people could be defined as elders who are able to walk and do not have serious cognitive disorders, but who do have difficulties in instrumental activities of daily living (IADLs). Those elders are classified into the two lowest care need levels, which are targeted for community-based long-term care reimbursement under the Japanese public Long-Term Care Insurance (LTCI) system (11). However, around 40% of these elders do not utilize long-term care services, even though they are certified as being in the early stage of the frailty under the system (12). The present study is unique in that participants are ambulatory frail elders who were selected for their use patterns of long-term care service.

Focused on those ambulatory frail elders, we have previously described our multidimensional assessment model for preventive home visits (13), and we have already conducted a small randomized controlled trial that showed that a home visit program might reduce ADL decline (14).

The aim of the present randomized controlled trial was to examine effects on functional and psychosocial parameters and public long-term care service utilization of a preventive home visit program for ambulatory frail elders over 2 years in three Japanese communities. Additionally, a pre-planned subgroup analysis was conducted to investigate these effects of the intervention among in ambulatory frail elders whose Activities of daily living (ADLs) were independent at baseline, in comparison with those who were more dependent.

**METHODS**

*Procedure and Participants*

The study design was a single-blind randomized controlled trial over 2 years and has been described in detail elsewhere (13). The study was performed at the three suburban municipalities of Izumiotsu, Sennan, and Misaki, in Osaka, Japan. Table 1 shows the population-based characteristics of the municipalities at baseline.

In the Japanese LTCI, all people aged 65 years or older could be certified as “Support Level 1 or 2” if they need any support for living at home or “Care Level 1, 2, 3, 4, or 5”, if they need continuous care at homes or care facilities. Elders certified as “Support Level 1” are the mildest frail and those as “Care Level 5” are the most severe frail. According to the latest Japanese governmental report on 2011 January (15), of all 29,090,744 older people, 4.4% were those certified as “Support Level 1 or 2” and 12.2% as “Care Level 1, 2, 3, 4, or 5”. Estimated total care minutes per a day of “Support Level 1” is from 25 to 32 minutes, those of “Support Level 2” is from 32 to 50 minutes, according to the LTCI national standardized face-to-face examination and computer-based system.

Ambulatory frail elders were defined operationally as being in the two lowest care need levels as Support Level 1 (milder level) or 2 (more severe level) in the LTCI system. We identified participants from the list of LTCI certified residents at each local government office. Eligibility criteria included: (a) aged 65 years or older, (b) certified as Support Level 1 or 2 in the LTCI, (c) living at home at the baseline survey, and (d) not having utilized formal long-term care services, which are reimbursed by the LTCI, for the past 3 months.

The derivation of study participants is shown in Figure 1. There were 1,764 listed elders certified at Support Levels 1 or 2 at the end of 2007. Of these, there were 568 eligible (ie, not using long-term care services) study participants for the baseline survey conducted between December 2007 and February 2008. After the baseline survey, a number of elders were excluded, as shown in Figure 1. The remaining 323 participants were randomized to either the intervention group (n = 161) or usual care group (n = 162) by researchers using computer-generated random numbers stratified on the basis of gender, age group, and district within each community.

Over the study period, participants lost to follow-up were 29 people in the intervention group and 35 people in the control group, which left 132 people in the intervention group and 127 people in the control group for analysis of primary outcomes but 161 people in the intervention and 162 people in the control group for analysis of secondary outcomes (see Figure 1).

We informed participants about the survey and study overview via mail. We obtained informed consent from elders in the intervention group via oral explanation and signed documents. The present study was approved by the Nursing Research Ethical Committee of Osaka City University (no.19-3-3, October 01, 2007).

The study protocol was registered for the UMIN clinical trials registry approved by ICMJE (no. UMIN000001113, April 07, 2008).

**Measures**

Primary outcomes of the intervention on functional and psychosocial parameters were measured by means of postal questionnaires at 1-year (between December 2008 and March 2009) and 2-year (between December 2009 and March 2010).
Variables included mortality, institutionalization rates, ADLs, IADLs, depression, and social support.

ADLs were measured by the Barthel Index, which has established reliability and validity and includes eating, transfers from chair to bed, grooming, toileting, walking on level surface, stairs, dressing, bathing, controlling bladder, and controlling bowels (16). Scores of ADLs range from 0 to 100.

IADLs were measured using the Index of Competence developed by the Tokyo Metropolitan Institute of Gerontology (17). The Tokyo Metropolitan Institute of Gerontology Index of Competence consists of 13 items in three subscales: five items of instrumental self-maintenance, four items of intellectual activity, and four items of social role. The response to each item was scored as 1 for ‘yes’ or 0 for ‘no’. High scores by these measurements indicate relatively high levels of ADLs and IADLs functioning.

Depression was assessed by the Japanese translation (18) of the 15-item short version (19) of the Geriatric Depression Scale (20), which is translated and widely used in Japan. Higher scores in the Geriatric Depression Scale 0–15 score range indicate worsening depression.

Figure 1. Derivation of study participants.
Social support was assessed using the Social Support Scale developed by Noguchi (21). This tool measures emotional support and instrumental support for elders from family members and friends, with higher scores indicating greater availability of social support (range 0–24).

Secondary outcomes were public long-term care costs, which indicate utilization of long-term home care services such as home aid, visiting nursing care, or day care services and institutionalized care such as nursing home or group home services. All Japanese elders aged 65 years or older must enroll in the LTCI planned by their municipal government (22). The records of utilization of subsequent the LTCI over 2 years were collected from the local governmental offices.

Preventive Home Visits

Routine preventive home visits were conducted for elders in the intervention group every 6 months for 2 years (Misaki: between January 2008 and December 2009, Izumiotsu and Sennan: between April 2008 and March 2010) by community health nurses, care managers, or social workers according to the structured multidimensional interview-based assessments of five key elements: locomotion, daily activities, social contacts or relationships with other people, health conditions, and signs of abuse (13).

Home visitors documented 40 health or psychosocial problems or difficulties and provided subsequent recommendations for each individual elder (13). Recommendation of the indicated type by each visit were categorized into five levels: ‘self-care’, ‘needs attention from community neighbors or family members’, ‘needs consultation with community care professionals’, ‘needs community-based care services’, and ‘needs urgent care’. Further information can be found in our previous descriptive article (13).

Statistical Analysis

All analyses were conducted by intention to treat (including participants who refused the intervention), using SAS version 9.2 with a two-tailed probability level <.05 to indicate statistical significance.

We performed two-way repeated measures analysis of covariance using PROC MIXED in SAS procedure, adjusting for age and each baseline score, to test both of the group and the interaction of ‘group × time’ effect comparing the changes of functional and psychosocial parameters over the time between the intervention group and the control group.

To demonstrate effect size of .50 on primary parameters (the Barthel Index and The Tokyo Metropolitan Institute of Gerontology Index of Competence), we needed 128 participants per group based on a two-sided alpha of .05, a 80% probability. With an anticipated lost to follow-up rate of 15% (14), 151 participants per group were required.

In the subgroup analysis, study participants whose ADL scores were 100 at baseline, indicating ADLs were independent, were classified as high ADL participants and those whose ADL scores were less than 100 at baseline, indicating ADLs were dependent, were classified as low ADL participants. We compared two groups by ADLs scores (100 scores at baseline vs less than 100 scores at baseline) on each baseline value using t test. According to each subgroup, we also performed two-way repeated measures analysis of covariance to detect the effect on functional and psychosocial parameters as well as an original sample.

A mean of the total public long-term care costs per person was compared between groups, utilizing a t test after a log-transformation of values. Moving average credits for each of the 3 months of care costs were calculated over the period by group. One credit is equivalent to approximately 10.5 Japanese yen. Fisher exact test was conducted to examine changes in the number of participants utilizing long-term care services at each month.

Results

Characteristics of Participants at Baseline

Characteristics of participants at baseline are shown in Table 2, participants were around 80 years old, and most of them were female. They are more likely to be independent with ADLs, but less likely to be independent with IADLs.

Process of Preventive Home Visits

The implementation of the preventive home visits to participants in the intervention group over the period is shown in Table 3, and for the majority of participants, all four visits were implemented (first visit: 87%, second: 85.7%, third: 83.9%, fourth 83.9%). A total of 13 additional home visits between the routine home visits were provided to 11 elders in the intervention group.

Primary Outcomes: Functional and Psychosocial Parameters

At the 2-year follow-up point, 82.0% (n = 132) of participants in the intervention group and 78.4% (n = 127)
of those in the control group were living at home; 6.8% 
\((n = 11)\) of those in the intervention group and 12.4% 
\((n = 20)\) of those in the control group had died; 4.4% 
\((n = 7)\) of those in the intervention group and 3.7% 
\((n = 6)\) of those in the control group were admitted to hospitals, 3.1% 
\((n = 5)\) of those in the intervention group and 1.9% 
\((n = 3)\) of those in the control group were institutionalized, and 3.8% 
\((n = 6)\) of those in the intervention group and 3.7% 
\((n = 6)\) of those in the control group had moved out of study area. Significant differences in the living state of the participants at follow-up were not found between the groups.

Changes in functional and psychosocial parameters over the 2 years in all participants \((n = 323)\) are shown in Table 4. Significant differences at baseline or changes over the study period were not found between the groups.

In subgroup participants \((n = 118)\) whose ADL were independent at baseline, there was no significant difference of changes over time between the two groups (Table 5). However, in participants \((n = 205)\) with ADL dependency at baseline, ADLs \((p = .0311)\), IADLs \((p = .0114)\), and depression \((p = .0001)\) in the control group participants \((n = 100)\) was significantly more deteriorated compared with the intervention group participants \((n = 105)\) over the 2 years (Table 6).

**Secondary Outcomes: Public Long-Term Care Services Utilization**

Total long-term care services costs over 2 years in the intervention group \((36,001 \text{ credits} = \text{around} \$273,231)\) were higher than in the control group \((26,022 \text{ credits} = \text{around} \$273,231)\) (nonsignificant).

Significantly more elders in the intervention group utilized long-term care services than those in the control group over the period at 7-month \((p = .0352)\), 8-month \((p = .0098)\), 9-month \((p = .0041)\), 10-month \((p = .0037)\), 11-month \((p = .0028)\), 12-month \((p = .0017)\), 13-month \((p = .0163)\), 14-month \((p = .0349)\), 15-month \((p = .0185)\), and 22-month \((p = .0434)\) follow-ups after the intervention started. In terms of monthly service utilization, between 7-month and 15-month follow-ups, the intervention group elders were more likely to use long-term care services than those in the control group, when looked at according to change of 3-month moving averages (see Figure 2).

**Discussion**

Overall, the results suggest that a preventive home visit program, which includes structured multidimensional assessment and recommendations, did not show measurable effectiveness on functional and psychosocial status among ambulatory frail elders who are certified as needing long-term care services but who are not yet using them and could facilitate earlier use of public long-term care services over 2 years. However, the pre-planned subgroup analysis indicates that the intervention might have positive effects on ADLs, IADLs, and depression among those, whose ADLs were dependent at baseline.

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**Table 3. Home Visit Process in Participants Allocated to Intervention \((N = 161)\)**

<table>
<thead>
<tr>
<th>Visits implementation</th>
<th>First Visit, 161 (100%)</th>
<th>Second Visit, 161 (100%)</th>
<th>Third Visit, 161 (100%)</th>
<th>Fourth Visit, 161 (100%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implemented visits</td>
<td>140 (87.0)</td>
<td>138 (85.7)</td>
<td>135 (83.9)</td>
<td>135 (83.9)</td>
</tr>
<tr>
<td>Refused or not being at home</td>
<td>17 (10.6)</td>
<td>14 (8.7)</td>
<td>10 (6.2)</td>
<td>11 (6.8)</td>
</tr>
<tr>
<td>Phone contact only</td>
<td>0 (0)</td>
<td>2 (1.2)</td>
<td>2 (1.2)</td>
<td>3 (1.9)</td>
</tr>
<tr>
<td>In hospital</td>
<td>4 (2.5)</td>
<td>5 (3.1)</td>
<td>4 (2.5)</td>
<td>2 (1.2)</td>
</tr>
<tr>
<td>Institutionalized</td>
<td>0 (0)</td>
<td>1 (0.6)</td>
<td>4 (2.5)</td>
<td>3 (1.9)</td>
</tr>
<tr>
<td>Died</td>
<td>0 (0)</td>
<td>1 (0.6)</td>
<td>6 (3.7)</td>
<td>7 (4.4)</td>
</tr>
</tbody>
</table>

**Note:** First visits were conducted between 1 and 3 months, second visits were conducted between 6 and 9 months, third visits were conducted between 12 and 15 months, and fourth visits were conducted between 18 and 21 months.

**Table 4. Change of Functional and Psychosocial Parameters Over 2 Years in All Participants \((N = 323)\)**

<table>
<thead>
<tr>
<th>Measures (bad to good)</th>
<th>Time Point</th>
<th>1 Year</th>
<th>2 Years</th>
<th>Effect*&lt;br&gt;Group, F value</th>
<th>Group x Time, F value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADLs (0–100)</td>
<td>Intervention</td>
<td>89.0 (14.3)</td>
<td>88.1 (14.7)</td>
<td>2.32</td>
<td>0.90</td>
</tr>
<tr>
<td>Control</td>
<td>89.8 (15.1)</td>
<td>89.0 (18.7)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IADLs (0–13)</td>
<td>Intervention</td>
<td>7.1 (3.8)</td>
<td>7.0 (3.8)</td>
<td>1.09</td>
<td>0.32</td>
</tr>
<tr>
<td>Control</td>
<td>7.1 (3.9)</td>
<td>7.0 (4.0)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depression (15–0)</td>
<td>Intervention</td>
<td>6.7 (4.1)</td>
<td>7.1 (4.0)</td>
<td>3.70</td>
<td>2.86</td>
</tr>
<tr>
<td>Control</td>
<td>6.9 (4.0)</td>
<td>7.2 (3.8)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social support (0–32)</td>
<td>Intervention</td>
<td>7.2 (4.2)</td>
<td>7.1 (4.1)</td>
<td>0</td>
<td>0.70</td>
</tr>
<tr>
<td>Control</td>
<td>6.9 (4.7)</td>
<td>7.3 (4.5)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Note:** ADLs = activities of daily livings; IADLs = instrumental activities of daily living. Values are unadjusted means (SD); intervention group: \(n = 161\); control group: \(n = 162\).

*Comparing on changes from baseline to follow-up between groups: Two-way repeated analysis covariance, adjusting for age and each baseline scores.
The ineffectiveness of the present program group might be interpreted from several viewpoints such as (1) intervention program characteristics, (2) nature of and adherence to the recommendations, (3) population characteristics, and (4) care setting, which are related to the effects of preventive home visits (7,23).

First of all, regarding the intervention program characteristics of the present study, frequency of home visits planned every 6 months might not be sufficient for the present study participants, even though previous meta-analysis had shown number of visits per a year did not significantly relate to decrease of nursing home admissions (7). A more intensive preventive care approach may be needed.

Second, recommendations to elders might be more likely to focus on use of long-term care services and less likely to consider the health recommendations arising from the assessment. Particularly the results have shown that the intervention actually facilitated earlier use of public long-term care services rather than obviating them. Also, the limited present assessment mainly focused on ADL or IADL status rather than medical status (eg, vital signs or blood tests), even though it did include checking certain health conditions. The explicit clinical thinking process and likelihood of adherence to the recommendations, which derives recommendations and implementation from the ADL or IADL and medical assessments initiated in the visits, needs to be confirmed clearly (24) and made into standardized guidelines through further investigation. Moreover, it is unclear that utilizing formal long-term care services could postpone or enhance subsequent need for facility-based long-term care among ambulatory frail elders based on our results alone. More work is needed to clarify this.

Thirdly, regarding population characteristics, the pre-planned subgroup analysis based on ADL dependency at baseline has shown that preventive home visits effects on long-term care services rather than obviating them. Also, the limited present assessment mainly focused on ADL or IADL status rather than medical status (eg, vital signs or blood tests), even though it did include checking certain health conditions. The explicit clinical thinking process and likelihood of adherence to the recommendations, which derives recommendations and implementation from the ADL or IADL and medical assessments initiated in the visits, needs to be confirmed clearly (24) and made into standardized guidelines through further investigation. Moreover, it is unclear that utilizing formal long-term care services could postpone or enhance subsequent need for facility-based long-term care among ambulatory frail elders based on our results alone. More work is needed to clarify this.

### Table 5. Change of Functional and Psychosocial Parameters Over 2 Years in High ADLs Participants at Baseline (N = 118)

<table>
<thead>
<tr>
<th>Measures (bad to good)</th>
<th>Time Point</th>
<th>Effect*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline 1 Year 2 Years</td>
<td>Group, F value</td>
</tr>
<tr>
<td>ADLs (0–100)</td>
<td>Intervention</td>
<td>100.0 (0)</td>
</tr>
<tr>
<td>Control</td>
<td>100.0 (0)</td>
<td>95.5 (11.4)</td>
</tr>
<tr>
<td></td>
<td>Intervention</td>
<td>9.2 (3.2)</td>
</tr>
<tr>
<td>Control</td>
<td>9.1 (2.9)</td>
<td>8.7 (3.6)</td>
</tr>
<tr>
<td>Depression (15–0)</td>
<td>Intervention</td>
<td>5.9 (4.0)</td>
</tr>
<tr>
<td>Control</td>
<td>5.9 (4.0)</td>
<td>5.3 (3.5)</td>
</tr>
<tr>
<td>Social support (0–32)</td>
<td>Intervention</td>
<td>7.3 (4.2)</td>
</tr>
<tr>
<td>Control</td>
<td>7.3 (4.9)</td>
<td>7.0 (4.7)</td>
</tr>
</tbody>
</table>

Note: ADLs = activities of daily livings; IADLs = instrumental activities of daily living. Values are unadjusted means (SD); intervention group: n = 56; control group: n = 62.
*Comparing on changes from baseline to follow-up between groups: Two-way repeated analysis covariance, adjusting for age and each baseline scores.
†Comparing functional and psychosocial parameters at baseline between groups: unpaired t test.

### Table 6. Change of Functional and Psychosocial Parameters Over 2 Years in Low ADLs Participants at Baseline (N = 205)

<table>
<thead>
<tr>
<th>Measures (bad to good)</th>
<th>Time Point</th>
<th>Effect*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline 1 Year 2 Years</td>
<td>Group, F value</td>
</tr>
<tr>
<td>ADLs (0–100)</td>
<td>Intervention</td>
<td>85.0 (15.5)</td>
</tr>
<tr>
<td>Control</td>
<td>86.0 (13.0)</td>
<td>85.7 (16.2)</td>
</tr>
<tr>
<td></td>
<td>Intervention</td>
<td>6.3 (3.2)</td>
</tr>
<tr>
<td>Control</td>
<td>6.1 (3.7)</td>
<td>6.0 (3.7)</td>
</tr>
<tr>
<td>Depression (15–0)</td>
<td>Intervention</td>
<td>7.7 (3.9)</td>
</tr>
<tr>
<td>Control</td>
<td>7.7 (4.0)</td>
<td>7.8 (4.0)</td>
</tr>
<tr>
<td>Social support (0–32)</td>
<td>Intervention</td>
<td>6.5 (4.2)</td>
</tr>
<tr>
<td>Control</td>
<td>6.3 (4.3)</td>
<td>6.8 (4.8)</td>
</tr>
</tbody>
</table>

Note: ADLs = activities of daily livings; IADLs = instrumental activities of daily living. Values are unadjusted means (SD); intervention group: n = 105; control group: n = 100.
*Comparing on changes from baseline to follow-up between groups: Two-way repeated analysis covariance, adjusting for age and each baseline scores.
†Comparing functional and psychosocial parameters at baseline between groups: unpaired t test.
*p < .05, ***p < .0001
ADLs, IADLs, and depression, were limited largely to elders whose ADL level was dependent at baseline. This is similar to some previous research, which had similar subgroup findings favoring more dependent elders (25). It seems that some of ambulatory frail elders might have unmet needs for supportive care, as shown in our subgroup analysis. Further studies should investigate the optimal participant selection criteria for ambulatory frail elders.

One of strengths of our study is the high adherence of participants to the present intervention, as the proportion who refused visits was only around 10% and the proportion of implemented visits was more than 80% throughout the period. The adherence rate of the study was similar to several other recent trials (26–28). Namely, this type of intervention could be accepted by older people living at home.

Another of strength of the study was that the participants were selected from representative older populations of each community by definite criteria.

Lastly, the intervention was provided in our specific care setting in which public long-term care services for elders are widely used. Most results from randomized controlled trials (4–8) involving preventive home visits have been reported from Western countries, whose care systems are quite different. In the present setting, more specific recommendations from reliable in-home assessments of ambulatory frail elders, including advice for promoting self-care and efficient care-service utilization should be established because formal or informal care resources are limited in this “super aging” society.

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CONFLICT OF INTEREST
The authors have no conflict of interest to disclose related to the present article.

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