Randomized controlled pilot study in Japan comparing a Functioning Improvement Tool home visit program with a home visit with conversation alone

Running head: FIT home visit program

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Abstract

Objective: This study aimed to determine the effect of a home visit program using a Functioning Improvement Tool (FIT) compared with a home visit using conversation alone.

Methods: Twenty-eight participants (mean age, 78.6±7.5 years) were randomly assigned to an intervention (n=13) or control (n=15) group for 3 months. The intervention group received a 60-minute FIT home visit program; the control group received a 30-minute home visit using common conversational techniques. Mini-Mental State Examination (MMSE), Frontal Assessment Battery (FAB), and Geriatric Depression Scale (GDS) scores were evaluated.

Results: The FAB score was significantly improved in the intervention group compared with the control group (2.5 vs. -0.5, P=0.02).

Conclusions: Our FIT home visit program may help prevent dementia. Further studies with larger samples and longer follow-up periods are needed to assess the long-term effectiveness of an FIT home visit program on dementia prevention. (UMIN-CTR number, UMIN000004767.)

Key words: cognitive function; elderly; home visit; Japanese; randomized controlled trial

Introduction

In Japan, the number of elderly with dementia who need long-term care is rapidly increasing [1]. However, effective prevention strategies for dementia have not been established. We previously conducted a home visit program using a Functioning Improvement Tool (FIT) developed based on an occupational therapy method [2]; this tool improves cognitive function in the elderly by identifying factors that can be changed in their daily life. This previous randomised controlled study included 199 Japanese subjects aged 65 or older [2]. The intervention subjects, especially those with mild declines in cognitive function, showed significant improvements on Mini-Mental State Examination (MMSE) cognitive function scores compared with the control group. However, it was difficult to distinguish if the effects seen in that study were due to the FIT used during the home visit or due to the conversation that took place with the investigator. Thus, we considered a comparative study to clarify the effect of the FIT using a control group who received home visits with and without a FIT.

The aim of this study was to determine whether MMSE, Frontal Assessment Battery (FAB), and Geriatric Depression Scale short form (GDS) scores of the elderly could be improved as a result of the FIT home visit program and conversation compared with a home visit with conversation alone.

Methods

Subjects aged 65 and older were recruited in two rural towns of Shinhidaka and Hidaka in Hokkaido, Japan. Inclusion criteria were (1) living at home; (2) receiving community long-term care prevention services provided by the Japanese national long-term care insurance system [3]; and (3) participation in our previous home visit study but received no intervention [2].

Participants were randomised into the intervention and control groups after a baseline assessment. Intervention subjects received home visits using the FIT once a month for 3 months. The home visit program was completed within 60 minutes: the FIT activity lasted for the first 30 minutes, and daily conversation took place for the last 30 minutes. The subjects completed the FIT activity with the instruction and assistance of trained health care personnel according to the following procedures.

The FIT consists of six steps [2]. In Step 1, the subject writes down the activities from getting up to sleeping to clarify what kinds of daily tasks the subject performed the day before. In Step 2, to clarify the objective of each daily task, the subject writes down whom each daily task was performed for. To consider the meaning of each daily task, the subject writes down whether each daily task was performed as a “duty”, and whether each daily task was performed according to that subject’s own “will”. In the context of the FIT, “duty” herein means something which the participants have to do for performing their daily life, while “will” is defined as something which the participants want to do for satisfying their daily life. In Step 3, the participants were required to distinguish “duty” from “will” among all daily tasks. The participants divides each daily task into the following four categories: it is a “duty”, and it was done according to the participant's “will”; it is a “duty”, but it was not performed according to the participant's “will”; it is not a “duty”, but it was performed according to the participant's “will”; and it is not a “duty”, and it was not the participant's “will” to do it. The participant then counts the daily tasks in each category. In Step 4, the participants calculate the percentage of daily tasks in each category. In Step 5, the participants write down the calculated percentages as a cobweb graph and create a visual daily task balance. In Step 6, the participants write down the impressions of his/her daily tasks while doing the FIT.

Control participants received 30-minute home visits that included common conversations with the health care attendant once a month for 3 months. The conversation

contents were not restricted. No participants had any restrictions in usual care involving medical or formal nursing care.

Cognitive function was assessed using the Japanese version of MMSE [7] and the FAB [8]. The total MMSE score ranges from 0 to 30, and the FAB ranges from 0 to 18, with higher scores indicating a better mental state. Depressive status was assessed by the GDS [9]. The total GDS score ranges from 0 to 15, with a lower score indicating a better mental state. All measurements and questionnaires survey were conducted at additional visits. For the purpose of keeping measurement bias to a minimum, both baseline and follow-up assessments were performed by the interviewers who were not involved in the intervention at the participants' homes.

The study protocol was approved by the ethics board for epidemiological studies at Hokkaido University Graduate School of Medicine and conformed to the principles outlined in the Declaration of Helsinki of 1975, as revised in 1983. We offered informed consent before the intervention to the participants and their family when they lived together.

Continuous variables are presented as medians; categorical variables are presented as numbers (percentages). Changes in MMSE, FAB, and GDS scores from baseline to the post-intervention were evaluated by Wilcoxon signed-rank test in each group. Group differences in MMSE, FAB, and GDS score changes between baseline and post-intervention were evaluated by Mann-Whitney U test. All statistical analyses were performed using JMP version 9.0.2 for Windows (SAS Institute Inc., Cary, NC, USA).

Results

This study was conducted from December 1, 2010, to March 31, 2011. Of 55 eligible subjects, 28 (50.9%) agreed to participate in the study, and were randomly allocated to the intervention (n=13) or control (n=15) group. Four subjects dropped out because of withdrawal

and hospitalisation during the study. Thus, 24 subjects (7 males and 17 females; mean age 78.6±7.5 years; range, 67 to 95 years) were evaluated. No significant differences between the intervention and control groups were found in subjects' baseline characteristics.

Table 1

Table 1 shows MMSE, FAB, and GDS scores between the intervention and control group at baseline and post-intervention. No significant differences were found between groups in any score at baseline. After the study, FAB scores in the intervention group were significantly improved compared with those at baseline (from 13 to 17, P=0.01), whereas subjects in the control group showed no improvement (from 13 to 13.5, P=0.80). The FAB score improvement was significantly bigger in the intervention group than in the control group (2.5 vs. -0.5, P=0.02). No significant differences were seen in MMSE and GDS scores.

Discussion

The FIT home visit program significantly improved FAB cognitive function scores in elderly subjects compared with a home visit that consisted of conversation alone. No significant improvements were obtained in MMSE. It is partly because the sample size was too small to detect group differences. In tandem, the control group in the current study might be somewhat affected by 30-minute home visit using a common conversational technique, though the control group in the previous study had no home visit at all.

FAB score improvements in the current study suggest that the FIT home visit program may stimulate cognitive function, particularly executive function [11, 12] of the elderly, compared with a home visit that uses conversation alone. Subjects in this study either needed long-term care due to difficulty in walking and getting in and out of the bathtub, or were recognized to have a high risk for needing support by the municipal government care manager [3]. At every FIT home visit, many subjects needed assistance in writing, calculating, or drawing a cobweb graph to complete the FIT activity, but some subjects tried to brush up their literacy and practice calculating with a calculator during the study. In addition, these

interventions offered many opportunities for communication as well as building trust with the health care attendant. We did not observe these changes in daily tasks in the control group. No significant improvement of GDS score was also observed. We measured GDS score for the first time, our FIT home visit program may not affect on depressive status because our result showed small change of the effect size (data not shown).

Potential weaknesses in our study include the relatively small sample size with the subsequent potential risk of type II statistical errors. However, regardless of the limitations of a small sample size and short follow-up period, these results suggest that our FIT home visit program could be a potential treatment for those with dementia who are living at home. Further studies with larger samples and longer follow-up periods are needed to assess the long-term effectiveness of an FIT home visit program on dementia prevention.

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Key Points

- The number of elderly with dementia has been rapidly increasing in Japan, but effective prevention strategies have not been established.
- A home visit program using our developed Functioning Improvement Tool improved FAB scores in elderly Japanese.
- The FIT home visit program could be a potential treatment for those with dementia who are living at home.

- Trials with longer follow-up periods and larger sample sizes are required to confirm these findings.

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Table 1. MMSE, FAB, and GDS scores between the intervention and control groups at baseline and post-intervention

	Intervention Group (n=11)		Control Group (n=13)		
	Median (Min to Max)	P-Value[†]	Median (Min to Max)	P-Value[‡]	P-Value[§]
Baseline (T_0)					
MMSE	27 (20 to 30)		26 (17 to 30)		0.73
FAB	13 (8 to 17)		13 (8 to 17		1.0
GDS	4 (1 to 8)		5 (0 to 9)		1.0
Post-intervention (T_1)					
MMSE	29 (21 to 30)	0.35	25 (19 to 30)	0.81	0.20
FAB	17 (8 to 18)	0.01	13.5 (6 to 17)	0.80	0.02
GDS	1.75 (1 to 9)	0.72	5 (0 to 9)	0.96	0.41
Scores changes (T_1-T_0)					
MMSE	2 (-5 to 5)		0 (-9 to 6)		0.36
FAB	2.5 (-2 to 7)		-0.5 (-6 to 4)		0.02
GDS	-0.5 (-7 to 4)		0 (-3 to 4)		0.89

MMSE, Mini-Mental Examination State (range, 0 to 30); FAB, Frontal Assessment Battery (range, 0 to 18). GDS, Geriatric Depression Scale short form (range, 0 to 15). MMSE and FAB, positive value means improvement; GDS, negative value means improvement.

[†]Wilcoxon signed-rank test to compare scores between T_0 and T_1 in the intervention group.

[‡]Wilcoxon signed-rank test to compare scores between T_0 and T_1 in the control group.

[§]Mann-Whitney U test to compare scores between the intervention and control groups.