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1 The effect of a Functioning Improvement Tool home visit program on instrumental activities of
2 daily living and depressive status in older people

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1 The number of older persons who need long-term care is rapidly increasing in Japan
2 (Health and Welfare Statistics Association, 2010). However, effective prevention strategies have not
3 been established. We previously reported the effect of a Functioning Improvement Tool (FIT) home
4 visit program which we developed based on an occupational therapy method on cognitive function
5 in 199 subjects aged 65 or older (Ukawa et al., 2011). The aim of this report was to determine
6 whether the Tokyo Metropolitan Institute of Gerontology (TMIG) index of competence, and the
7 Zung Self-Rating Depression Scale (SDS) scores of the older person could be improved as a result
8 of the FIT home visit program (UMIN-CTR number, UMIN000003877).

9 This study was conducted in two rural towns of Shinhidaka and Hidaka in Hokkaido, Japan.
10 252 participants aged 65 years or older living at home and receiving preventive services or a
11 community long-term care prevention project according to the Japanese social long-term care
12 insurance system (Tsutsui and Muramatsu, 2007) were enrolled and randomly assigned to an
13 intervention group (n=128) or a control group (n=124). Intervention group subjects received a
14 60-minute FIT home visit program once a month for 3 months. The subjects completed the FIT
15 activity with the instruction and assistance of trained health care personnel. The FIT aimed to
16 identify factors that can be changed in their daily life (Ukawa et al., 2011). Control subjects did not
17 receive any home visit at all. No subject had any restrictions in usual care involving medical or
18 formal nursing care. The study protocol was approved by the ethics board for epidemiological
19 studies at Hokkaido University Graduate School of Medicine. All participants gave their written,
20 informed consent.

21 IADL was assessed by the TMIG index of competence which is a multidimensional scale
22 composed of 13 items: five concerning instrumental independence, four concerning intellectual
23 activity, higher scores indicating a better competence and four concerning social role and has been
24 widely used in the Japanese community (Koyano et al., 1991). Depressive status was assessed by
25 the SDS (Zung, 1965), score ranges from 20 to 80, with a lower score indicating a better mental

1 state.

2 Continuous variables are presented as mean±standard deviation. Changes in TMIG and
3 SDS scores from baseline to the post-intervention were evaluated by paired t-test. Group differences
4 each scores changes between baseline and post-intervention were evaluated by student's t-test. An
5 alpha level of 0.05 was considered statistically significant. All statistical analyses were performed
6 using JMP version 9.0.2 for Windows (SAS Institute Inc., Cary, NC, USA).

7 100 subjects (45: withdrawal, hospitalization, death, relocation; 55: missing data of TMIG
8 or SDS) were excluded. Thus, 152 subjects (50 males and 102 females; mean age 78.1±7.5 years)
9 were evaluated. No significant differences between the intervention and control groups were found
10 in subjects' baseline characteristics. Table 1 shows the TMIG and SDS scores between the

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11 intervention and control groups at baseline and post-intervention. There were no significant
12 differences between intervention and control groups in the TMIG (10.1±3.2 vs. 9.0±3.5 P=0.06) and
13 SDS (36.9±9.4 vs. 36.9±8.9, P=0.91) scores at baseline. After the study, no significant scores
14 changes were observed within groups compared with those at baseline. Nor were there significant
15 improvement in the TMIG (-0.3±2.0 vs. -0.1±1.8, P=0.40) and SDS (-1.3±6.6 vs. -0.6±6.9, P=0.55)
16 scores between the intervention and control groups. These results were not change after adjusting
17 for valuables such as baseline score, age, and sex.

18 In conclusion, no significant improvement was found in the TMIG and SDS scores after 3
19 months FIT home visit program. Although we hypothesized that our FIT home visit program likely
20 stimulates subject's cognitive function through the FIT steps and dialogue between subject and
21 health care personnel, IADL and depressive status might not improved. In addition, more than twice
22 subjects were excluded due to missing data of outcome variables, especially SDS, compared to
23 previous our report which showed cognitive improvement. This may attribute to the inadequate
24 statistical power. Further studies with enough sample size are needed to elucidate the effect of our
25 FIT home visit program.

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2 Table 1. TMIG and SDS scores between the intervention and control groups at baseline and post-intervention

| | Intervention Group ^a | | Control Group ^a | | P-Value [§] |
|--|---------------------------------|----------------------|----------------------------|----------------------|----------------------|
| | Mean±SD | P-Value [†] | Mean±SD | P-Value [‡] | |
| Baseline (T ₀) | | | | | |
| TMIG | 9.7±3.3 | | 9.0±3.4 | | |
| SDS | 36.9±9.4 | | 36.9±8.9 | | |
| Post-intervention (T ₁) | | | | | |
| TMIG | 9.7±3.3 | 0.17 | 9.0±3.4 | 0.77 | |
| SDS | 35.4±9.0 | 0.09 | 35.8±9.0 | 0.41 | |
| Scores changes (T ₁ -T ₀) | | | | | |
| TMIG | -0.3±2.0 | | -0.1±1.8 | | 0.40 |
| SDS | -1.3±6.6 | | -0.6±6.9 | | 0.55 |

3 TMIG, The Tokyo Metropolitan Institute of Gerontology index of competence (range, 0 to 13); SDS, The Zung Self-Rating Depression Scale (range, 20 to 80). TMIG,
4 positive value means improvement; SDS, negative value means improvement.

5 ^a90 intervention subjects and 93 control subjects were evaluated in the TMIG scores, 74 intervention subjects and 78 control subjects were evaluated in the SDS
6 scores due to missing data.

7 [†]Paired t-test to compare scores between T₀ and T₁ in the intervention group.

8 [‡]Paired t-test to compare scores between T₀ and T₁ in the control group.

9 [§]Student's t-test to compare scores between the intervention and control groups.