CHAPTER 4

FINDING AND RESULTS

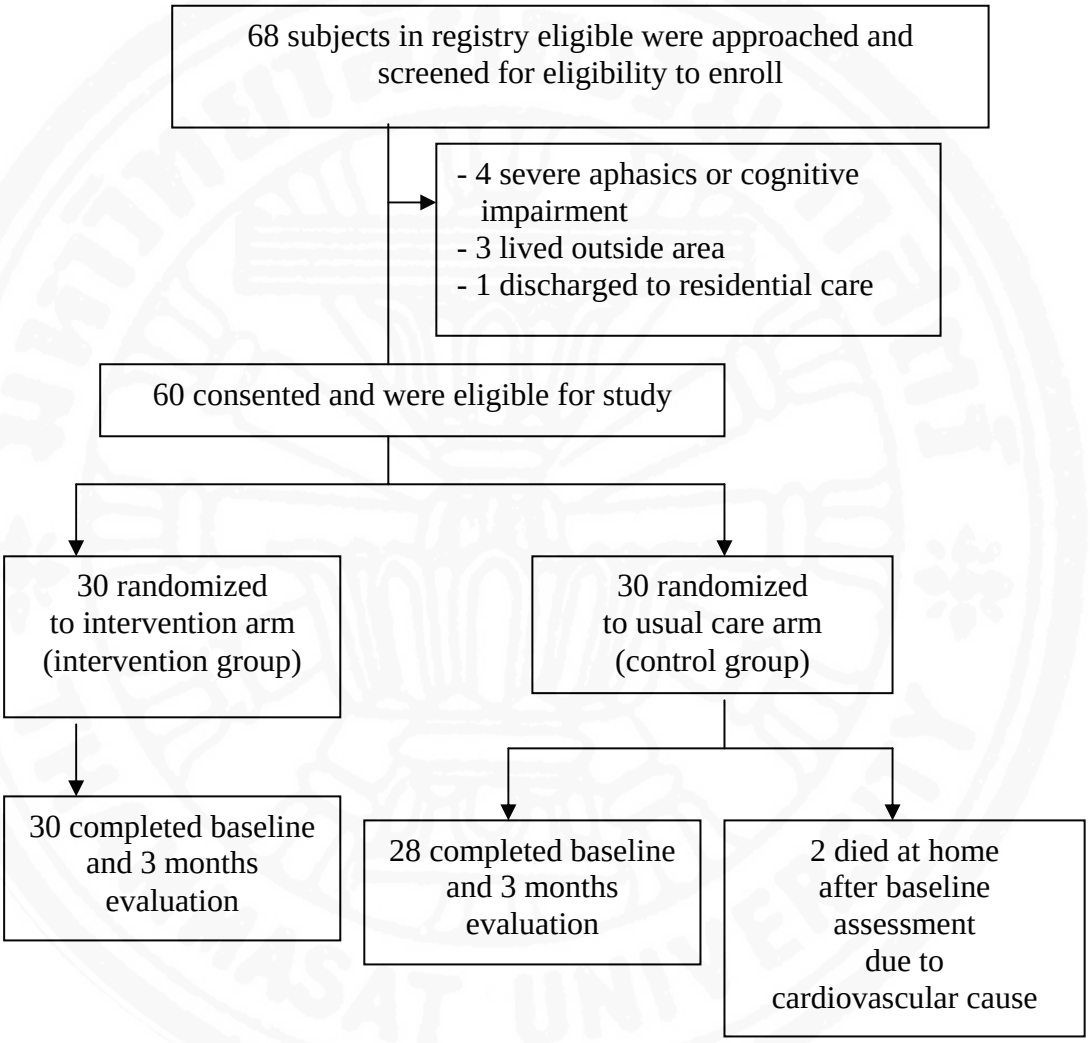


Figure 6 Study flow chart

Sixty-eight subjects were approached and screened for their eligibility to enroll in this study and 60 (88.2%) patients met the inclusion/exclusion criteria. All patients with a clinical diagnosis of ischemic stroke, only middle cerebral artery, who were admitted to the Thammasat university hospital between May 2007 and June 2008 were assessed for participation in the trial. Eight patients were excluded because of severe aphasia, severe cognitive impairment, living outside the area or being discharged to residential care. Two patients in control group died before the second evaluation at home because of their cardiovascular problem. The flow at the end of the present study, including patient status, is depicted in Figure 6. All gave their informed consent for participation.

Table 3 Subject Characteristics and Baseline Measure

Variable	Intervention Group (n=30)	Control Group (n=30)	P-value
Age (yrs), mean (SD)	67 (10)	66 (11)	0.73
Male, n (%)	14 (47)	13 (43)	1.00
BMI, mean (SD)	24.8 (1.6)	24.6 (2.4)	0.72
Elementary education, n (%)	28 (93)	28 (93)	0.95
Smoking, n (%)	5 (17)	9 (30)	0.36
Alcohol consumption, n (%)	5 (17)	11 (37)	0.14
Right hemisphere stroke , n (%)	18 (60)	12 (40)	0.20
Family income, median (IQRs)	32,000 (15,000, 53,000)	23,500 (16,000, 42,000)	0.75
Family care, n (%)	26 (87)	29 (97)	0.35
Length of stay in hospital before discharge, mean (SD)	10.9 (2,3)	10.0 (1.7)	0.83
Medical history			
Hypertension	17 (57)	17 (57)	0.49
Diabetes	16 (53)	18 (60)	0.28
High cholesterol	8 (27)	6 (20)	0.28
Atrial fibrillation / Ischemic heart disease	7 (23)	8 (27)	0.28
The National Institute of Health Stroke Scale (NIHSS),mean(SD)	16.4 (4.1)	17.8 (3.9)	0.18
Thai Mental State Examination (TMSE), mean (SD)	24.4 (2.0)	23.8 (1.9)	0.24
Dementia, n(%)	4 (13)	9 (30)	
Hospital Anxiety and Depression Scale (HADs), mean (SD)	16.1 (7.6)	16.4 (4.9)	0.87
Depression, n (%)	20 (67)	25 (83)	

* P-value by independent sample t-test and fisher exact test, significant at $p < 0.05$

Table 3 Subject Characteristics and Baseline Measures (cont.)

Variable		Intervention Group (n=30)	Control Group (n=30)	P-value
The Barthel Index, mean (SD)		31.7 (5.9)	33.2 (4.8)	0.29
Modified Rankin Scale (MRS), mean (SD)		4 (0)	4 (0)	1.00
Minimum or no disability, n (%): (0 or 1)		0	0	
Moderate disability, n (%): (2 or 3)		0	0	
Severe disability, n (%): (4 or 5)		30 (100)	30(100)	
Utility index, mean (SD)		- 0.14 (0.08)	-0.11 (0.13)	0.24
EQ VAS (Scale 0-100), mean (SD)		35 (9.1)	35 (7.8)	0.35
Minimal (Scale 0-100)		5	20	
Maximum (Scale 0-100)		50	50	
EQ-5D, n (%):				
Mobility	No problem	0 (0)	0 (0)	1.00
	Some problems	1 (3.3)	1 (3.3)	
	Severe problems	29 (96.7)	29 (96.7)	
Self-Care	No problem	0 (0)	0 (0)	1.00
	Some problems	5 (16.7)	4 (13.7)	
	Severe problems	25 (83.3)	26 (86.7)	
Usual Activities	No problem	0 (0)	0 (0)	0.06
	Some problems	7 (23.3)	15 (50.0)	
	Severe problems	23 (76.7)	15 (50.7)	
Pain/Discomfort	No problem	0 (0)	0 (0)	1.00
	Some problems	30 (100.0)	30 (100.0)	
	Severe problems	0 (0)	0 (0)	
Anxiety/Depression	No problem	0 (0)	0 (0)	0.49
	Some problems	28 (98.3)	30 (100.0)	
	Severe problems	2 (6.7)	0 (0)	

* P-value by independent sample t-test and fisher exact test, significant at $p < 0.05$

The subject characteristics and baseline measures are presented in Table 3. There were 18 (60%) patients intervention arm and 12 (40%) patients with right hemisphere stroke. The mean (SD) age of intervention group and control group were 67 (10) years and 66 (11) years, 24.8 (1.6) and 24.6 (2.4) m^2/kg were BMI, respectively. The percent of males were 47 and 43, respectively. Most of patients were elementary educated (93%). There were 5 (17%) patients with a history of smoking, 5 (17%) patients with alcohol consumption, the major medical history was hypertension 17 (57%) patients, diabetes 16 (53%) patients, high cholesterol 8 (27%) patients and atrial fibrillation/ ischemic heart disease 7 (23%) patients in intervention arm and 9 (30%) patients with a history of smoking, 11 (37%) patients with alcohol consumption, the major medical history was hypertension 17 (57%) patients, diabetes 18 (60%) patients, high cholesteral 6 (20%) patients and atrial fibrillation/ ischemic heart disease 8 (27%) patients in control arm.

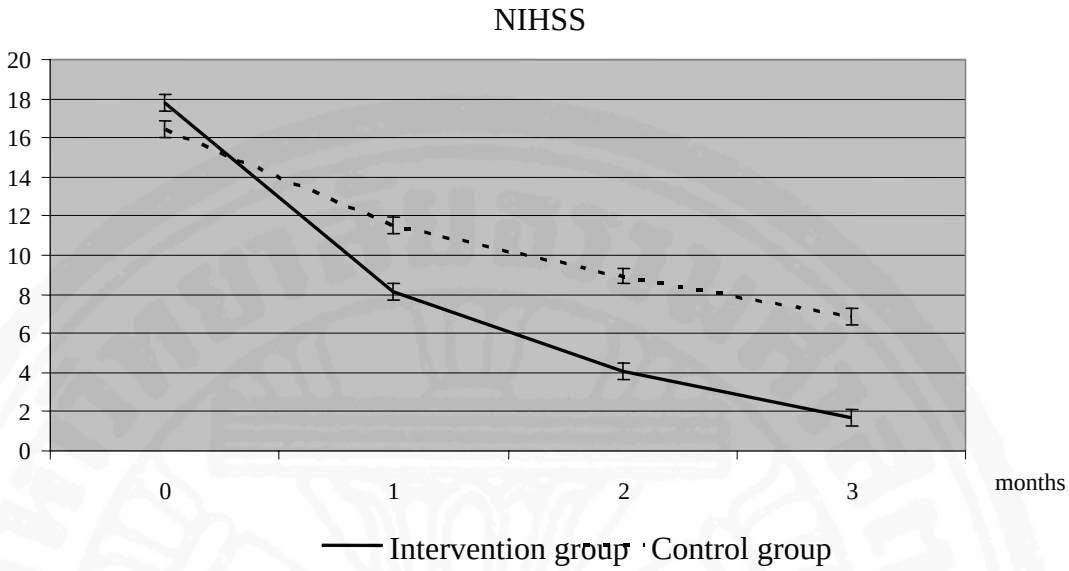
The mean scores (SD) were 16.4 (4.1), 25.4 (2.0), 31.7 (5.9) for NIHSS, TMSE and the Barthel Index in intervention arm, respectively. The mean scores (SD) were 17.8 (3.9), 24.8 (1.9), 33.2 (4.8) for NIHSS, TMSE and the Barthel Index in control arm, respectively. The depression by HADs was 20 (67%) patients for intervention group, for 25 (83%) patients of control group. Modified Rankin Scale (MRS) provides an assessment of the degree of disability, the mean (SD) MRS of both groups were 4 (0). Minor strokes are considered Grades 0 to 2; major strokes are Grades 3 to 5, while fatal is 6. All of patients were major strokes by MRS.

The mean (SD) of utility index (EQ-5D) in intervention group and control group were -0.14 (0.08) and -0.11 (0.13), respectively. The EQ VAS offers a simple method for obtaining and scoring self-rating of current health status. The both groups were found 35%. The minimal scale of EQ VAS was 5 for intervention group, for 20 of control group, the maximum scale of both groups were 50. EQ-5D on the 5-distinct dimensions is mobility, self-care, usual activities, pain/discomfort and anxiety/depression. All dimensions, no patients chose in no problem item. In the intervention group, the patients chose item of severe problem in mobility 29 (96.7%) patients, self-care 25 (83.3%) patients, usual activities 23 (76.7%) patients, anxiety or

depression 2 (6.7%) patients and no patient chose in severe problem item of pain or discomfort. For the control group, the patients chose item of severe problem in mobility 29 (96.7%) patients, self-care 26 (86.7%) patients, usual activities 15 (50.7%) patients and no patient chose in severe problem item of pain or discomfort and anxiety or depression.

Fifty-one (85%) patients were discharged from the Thammasat university hospital to their own homes, 9 (15%) patients were transferred to their spouse and/or siblings. All patients were supported by their family, spouse, siblings, and/or caregiver.

All characteristics were comparable between case and control group. There is no significant difference in baseline characteristics between the two groups.

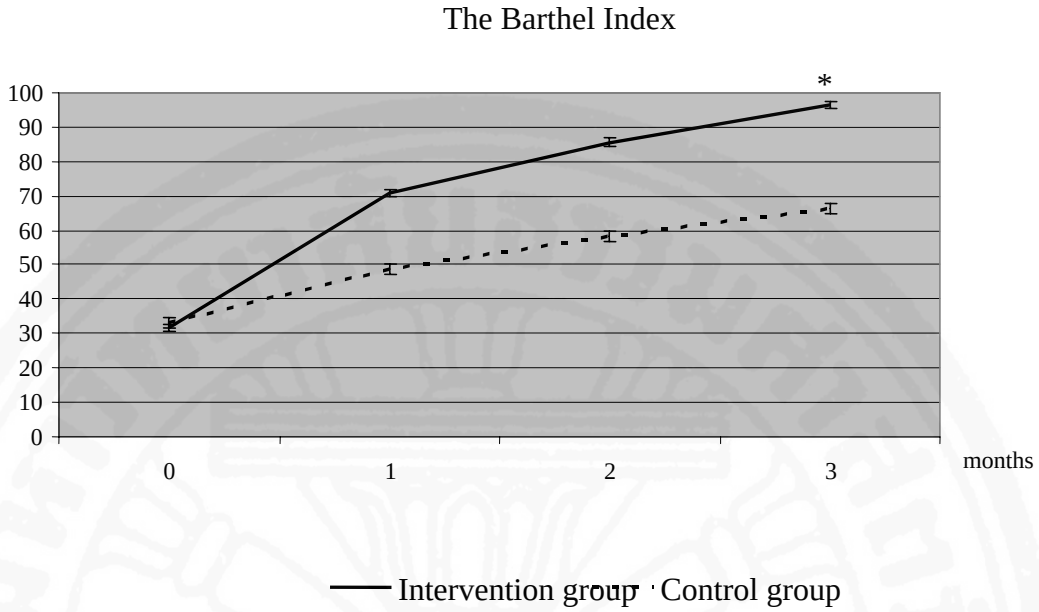


* P-value < 0.05 by analysis of covariance (ANCOVA) with the baseline as a covariate, age, depression and dementia as factors in the model.

Figure 7 Means and SEs of post-treatment effects of the intervention adjusted for age, depression, dementia and baseline measurement of outcome by NIHSS at follow-up at three months.

Table 4 Results of ANCOVA adjusted for age, depression, dementia and baseline measurement of outcome by NIHSS at three months

Months	Inervention group mean (SE)	Control group mean (SE)	Mean difference (95% CI)	P-value
1	8.2 (0.6)	11.5 (0.7)	0.76 (-8.37, 9.89)	0.868
2	4.1 (0.6)	8.9 (0.6)	3.86 (-7.84, 15.56)	0.511
3	1.2 (0.4)	6.9 (0.4)	8.03 (-1.56, 17.6)	0.099



* P-value < 0.05 by analysis of covariance (ANCOVA) with the baseline as a covariate, age, depression and dementia as factors in the model.

Figure 8 Means and SEs of post-treatment effects of the intervention adjusted for age, depression, dementia and baseline measurement of outcome by the Barthel Index at follow-up at three months.

Table 5 Results of ANCOVA adjusted for age, depression, dementia and baseline measurement of outcome by the Barthel Index at three months

Months	Inervention group mean (SE)	Control group mean (SE)	Mean difference (95% CI)	P-value
1	71.0 (2.2)	45.9 (1.7)	2.66 (-39.77, 45.08)	0.901
2	85.7 (2.3)	58.2 (1.7)	34.40 (-8.93, 77.73)	0.117
3	96.3 (1.0)	66.3 (1.6)	56.32 (25.59, 87.04)	0.001

The Barthel Index

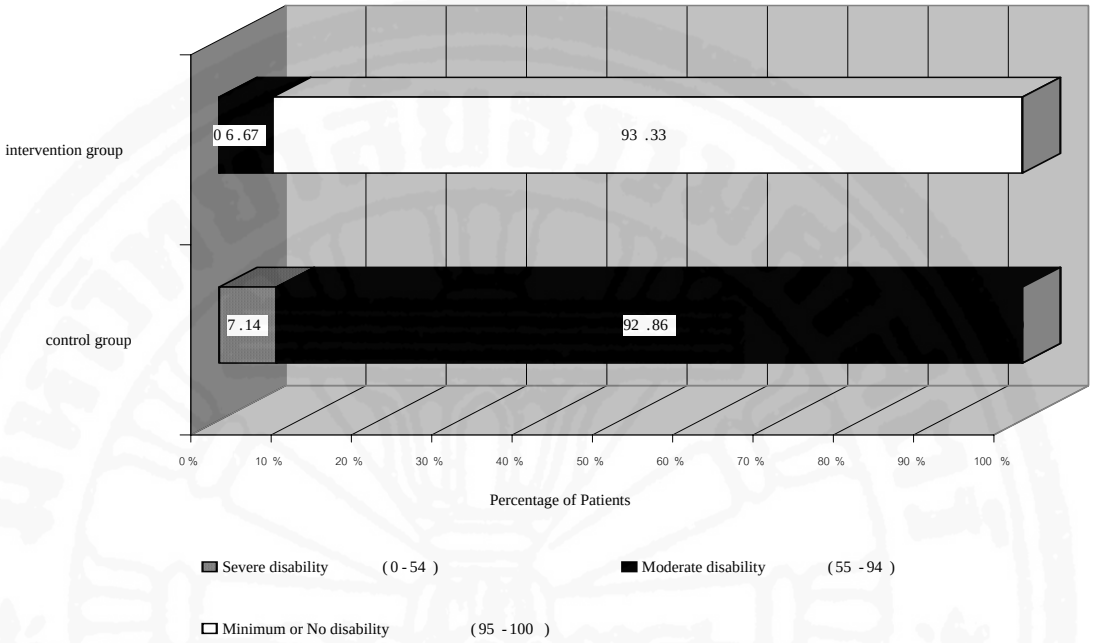


Figure 9 Outcome of the Barthel index at three months, according to treatment group

A favorable outcome was defined as minimal or no ability, as measured by scores of 95 or 100 on the Barthel index (range of scores, 0 to 100). To describe the treatment effects across the range of outcomes, outcomes were classified into one of four categories: minimal or no ability was 95 to 100 scores, moderate disability was 55 to 94 and severe disability was 0 to 54 scores and death.

Figure 9 shows the outcomes at 3 months. The greater proportion of patients in intervention group with a favorable outcome at 3 months, as compared with those in the control group, was not accompanied by an increase in severe disability or mortality. in addition, the rate of agreement in results for patients in intervention group with respect to a favorable outcome was 93.33 percent including the absolute risk reduction (ARR) 93.33 % (95% CI: 84.41%, 102.26%) and the number needed to treat is 2. This means that about one in every 2 ischemic stroke patients will benefit from the treatment (95% CI: 1.0, 1.2).

Modified Rankin Scale

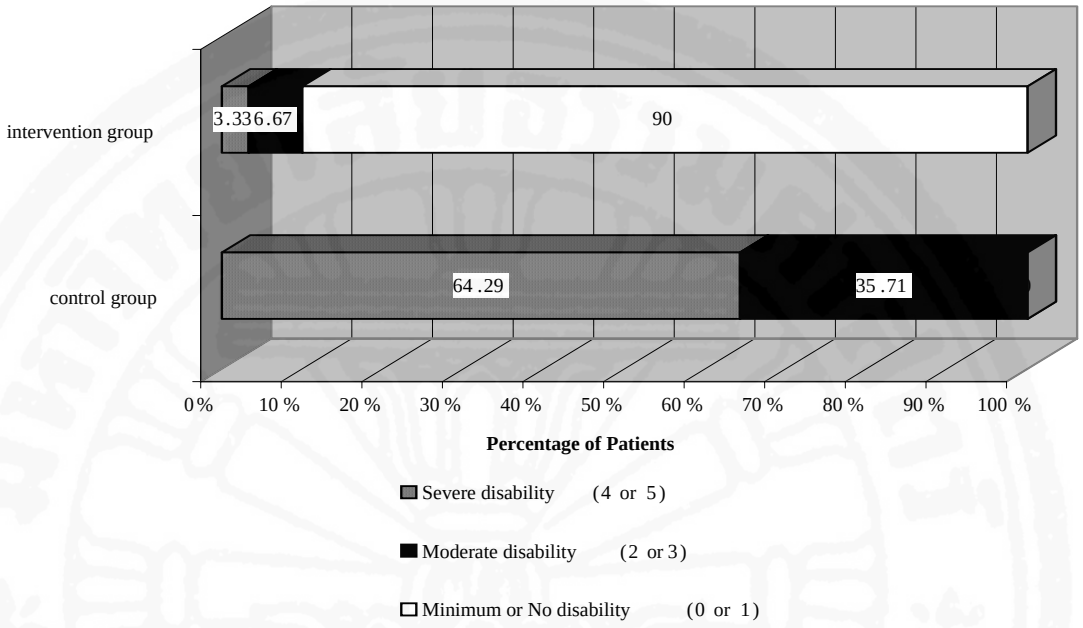
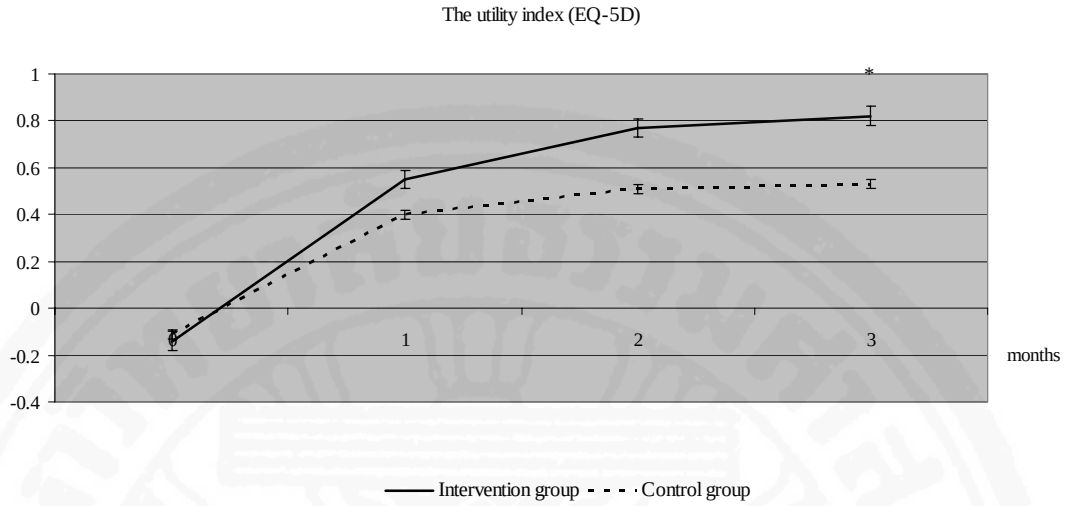


Figure 10 Outcome of the Modified Rankin Scale at three months, according to treatment group

A favorable outcome was defined as minimal or no ability, as measured by scores of 0 or 1 on the Modified Rankin Scale (range of scores, 0 to 5). To describe the treatment effects across the range of outcomes, outcomes were classified into one of four categories: minimal or no ability was 0 or 1 scores, moderate disability was 2 or 3 and severe disability was 4 to 5 scores and death.

Figure 10 shows the outcomes at 3 months. The greater proportion of patients in intervention group with a favorable outcome at 3 months, as compared with those in the control group, was not accompanied by an increase in severe disability or mortality. in addition, the rate of agreement in results for patients in the intervention group with respect to a favorable outcome was 90 percent including the absolute risk reduction (ARR) 90 % (95% CI: 79.26%, 100.74%) and the number needed to treat is 2. This means that about one in every 2 stroke patients will benefit from the treatment (95% CI: 1.0, 1.3).

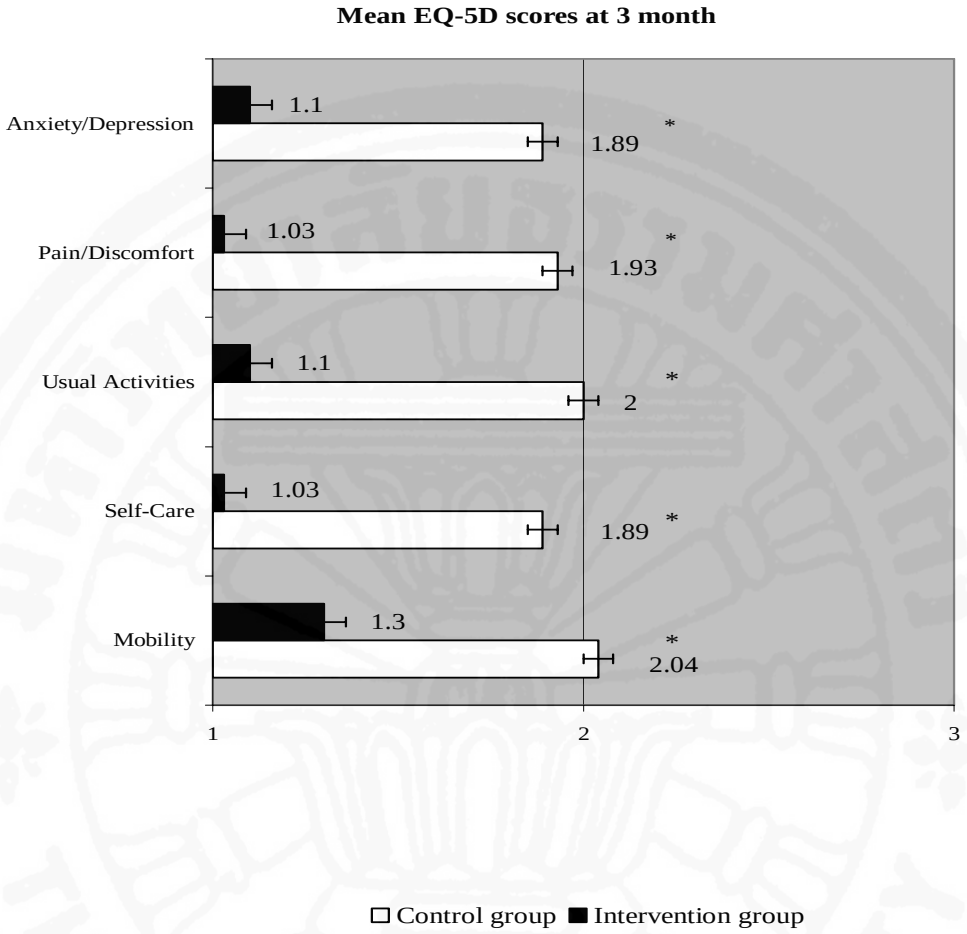


* P-value < 0.05 by analysis of covariance (ANCOVA) with the baseline as a covariate, age, depression and dementia as factors in the model.

Figure 11 Means and SEs of post-treatment effects of the intervention adjusted for age, depression, dementia and baseline measurement of outcome by the utility index (EQ-5D) at follow-up at three months.

Table 6. Results of ANCOVA adjusted for age, depression, dementia and baseline measurement of outcome by the Utility Index at three months

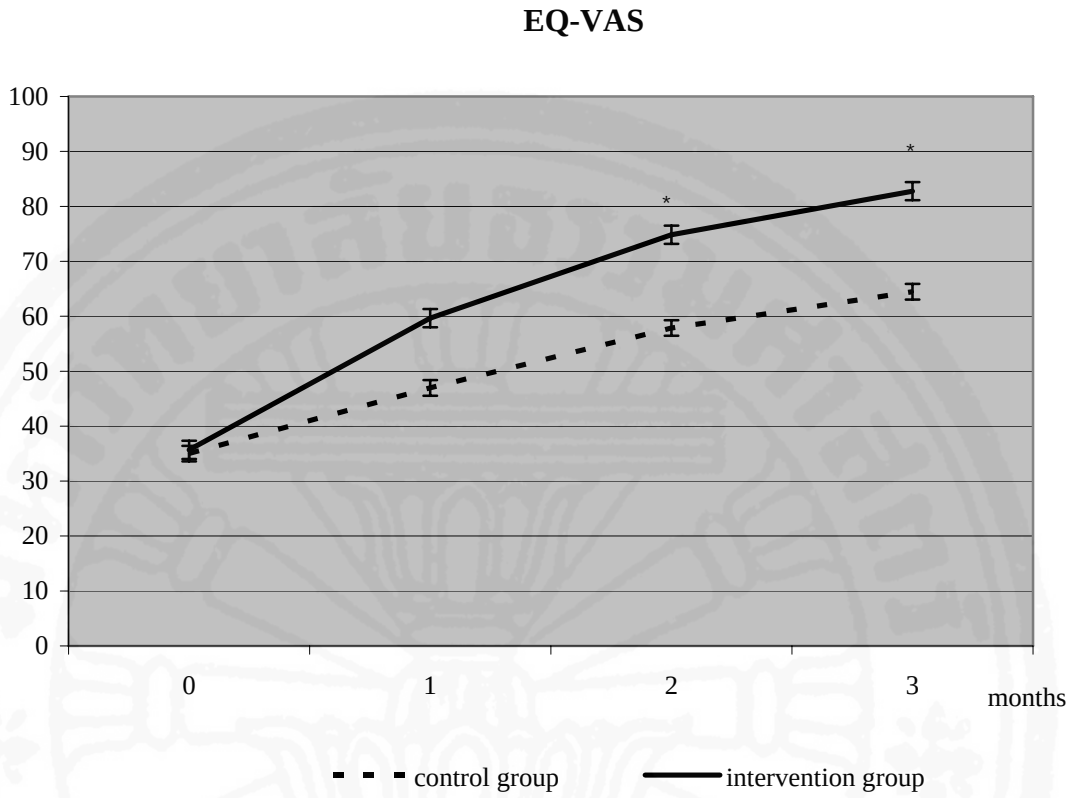
Months	Inervention group mean (SE)	Control group mean (SE)	Mean difference (95% CI)	P-value
1	0.55 (0.04)	0.40 (0.04)	0.45 (-0.40,1.31)	0.295
2	0.77 (0.04)	0.51 (0.02)	0.53 (-0.10, 1.16)	0.096
3	0.82 (0.02)	0.53 (0.02)	0.57 (0.17, 0.97)	0.006



* P-value by ANCOVA, significant at $p < 0.05$

Figure.12 Means and SEs of 5 dimensions of the EQ-5D at three months

EQ-5D on the 5-distinct dimensions is mobility, self-care, usual activities, pain/discomfort and anxiety/depression. All dimensions, no patients chose in severe problem item. In the intervention group, the patients chose item of no problem in mobility: 21 (70%) patients, self-care: 29 (96.7%) patients, usual activities: 27 (90%) patients, anxiety or depression: 29 (96.7%) patients and pain or discomfort: 27 (90%) patients. For the control group, there were 1 (3.6%) patient still had severe problem of mobility dimension. The other items, the patients chose item of no problem in self-care: 3 (10.7%) patients, usual activities: 3 (10.7%) patients, pain or discomfort: 2 (7.1%) and anxiety or depression: 3 (10.7%) patients.



* P-value < 0.05 by analysis of covariance (ANCOVA) with the baseline as a covariate, age, depression and dementia as factors in the model.

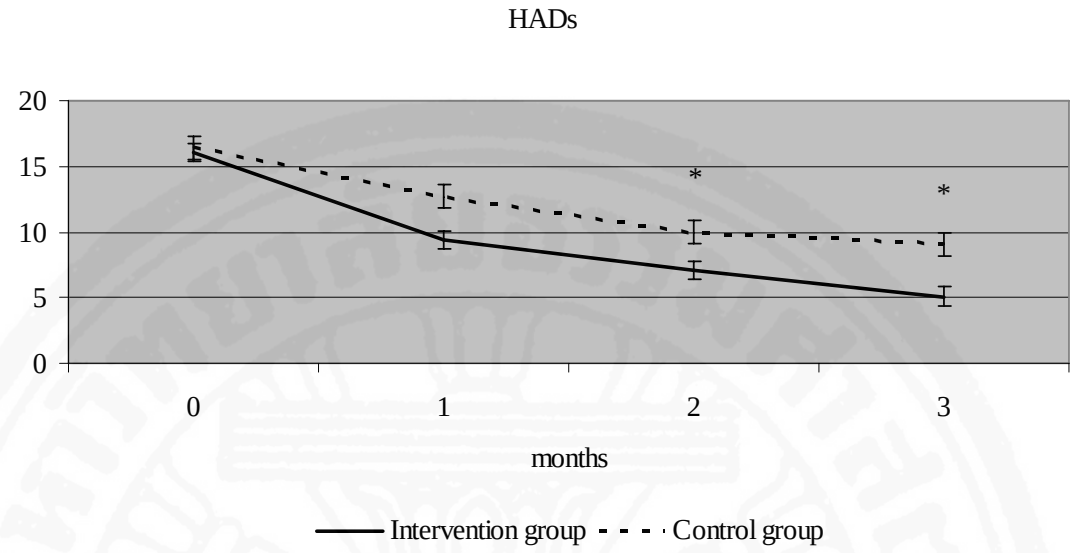
Figure 13 Means and SEs of post-treatment effects of the intervention adjusted for age, depression, dementia and baseline measurement of outcome by EQ VAS at follow-up at three months.

Table 7 Results of ANCOVA adjusted for age, depression and baseline measurement of outcome by the EQ-VAS at three months

Months	Intervention group mean (SE)	Control group mean (SE)	Mean difference (95% CI)	P-value
1	59.67 (1.64)	46.96 (1.88)	12.01 (-22.39, 46.42)	0.487
2	74.83 (1.75)	57.86 (1.46)	36.68 (1.59, 71.77)	0.041
3	82.77 (3.14)	64.46 (1.10)	40.82 (-15.12, 96.77)	0.149

The EQ VAS offers a simple method for obtaining and scoring self-rating of current health status. The EQ VAS were significantly improved in the intervention group more than the usual care group,

The minimal scales of EQ-VAS were 40, 50, 40 for intervention group and 30, 40, 50 for control group at 1, 2 and 3 months, respectively. For the maximum scales of EQ-VAS were 70, 90 and 95 for intervention group and 60, 70 and 75 for control group at 1, 2 and 3 months, respectively.



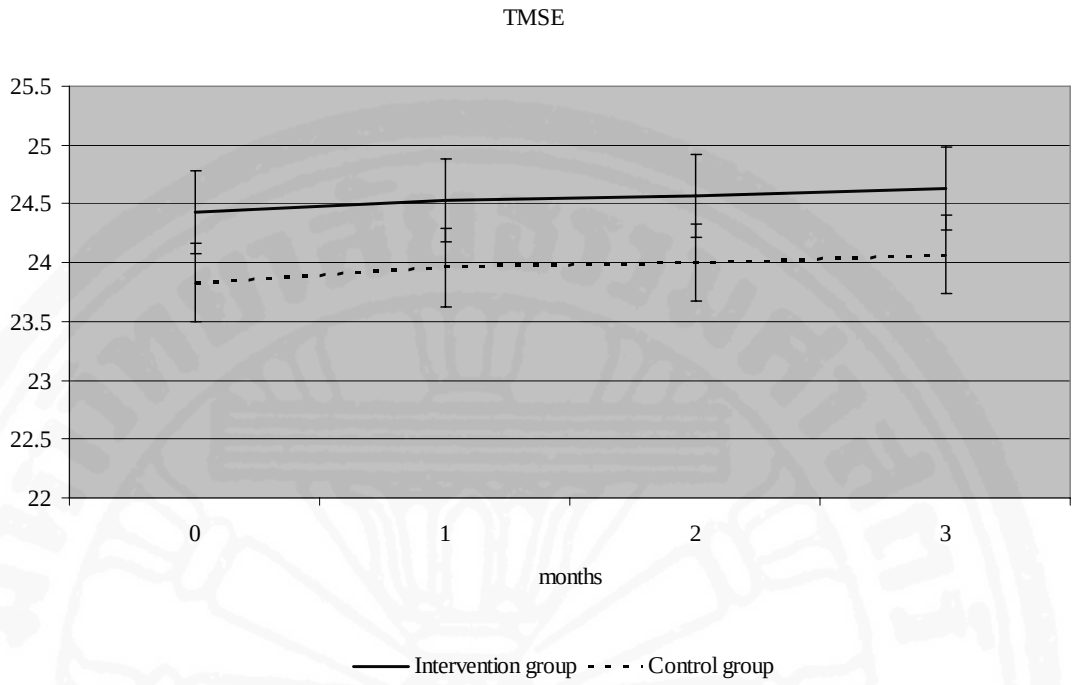
* P-value < 0.05 by analysis of covariance (ANCOVA) with the baseline as a covariate, age, depression and dementia as factors in the model.

Figure 14 Means and SEs of post-treatment effects of the intervention adjusted for age, depression, dementia and baseline measurement of outcome by HADs at follow-up at three months.

Table 8 Results of ANCOVA adjusted for age, depression, dementia and baseline measurement of outcome by HADs at three months

Months	Intervention group mean (SE)	Control group mean (SE)	Mean difference (95% CI)	P-value
1	9.40 (0.69)	12.71 (0.91)	12.82 (-1.65, 27.29)	0.081
2	7.03 (0.57)	10.00 (0.60)	13.56 (1.14, 25.98)	0.033
3	5.1 (0.72)	9.07 (0.32)	15.33 (2.88, 27.79)	0.017

A depressed outcome was defined from HADs, as measured by scores equal or more than 11 (range of scores, o to 21). Depressed patients were 20 (66.67%) patients and 1 (3.33%) patient in the intervention group at baseline and 3 months, respectively. For control group, depressed patients were 25 (83.33%) patients and 2 (7.14%) patients at baseline and 3 months, respectively.



* P-value < 0.05 by analysis of covariance (ANCOVA) with the baseline as a covariate, age, depression and dementia as factors in the model.

Figure 15 Means and SEs of post-treatment effects of the intervention adjusted for age, depression, dementia and baseline measurement of outcome by TMSE at follow-up at three months.

Table 9 Results of ANCOVA adjusted for age, depression, dementia and baseline measurement of outcome by TMSE at three months

Months	Intervention group mean (SE)	Control group mean (SE)	Mean difference (95% CI)	P-value
1	24.53 (0.36)	23.96 (0.35)	1.06 (-0.03, 2.17)	0.057
2	24.57 (0.35)	24.00 (0.35)	1.30 (-0.16, 2.75)	0.080
3	24.63 (0.35)	24.07 (0.33)	1.97 (-0.12, 4.05)	0.064

A dementia outcome was defined from TMSE, as measured by scores less than 23. Dementia patients were 4 (13.33%) patients and 3 (10%) patients in the intervention group at baseline and 3 months, respectively. For control group, dementia patients were 9 (30.00%) patients, and 6 (21.43%) patients at baseline and 3 months, respectively.

One patient in each group had co-intervention. For intervention group, the patient went to hospital for physical therapy and went to clinic for acupuncture therapy once a week in each therapy. The patient in control group went to hospital for physical therapy and to temple for massage therapy once a week in each therapy. There was no adverse event in both groups.

Compliance with the intervention by daily record at 1, 2 and 3 months were 94, 95 and 95 percent, respectively.

The Formula was

$$\text{Compliance} = \frac{\text{The number of days that patients had home rehabilitation} \times 100}{\text{90 days}}$$