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Effectiveness of home rehabilitation program for ischemic stroke upon disability and quality of life: A randomized controlled trial

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ABSTRACT

Background: To develop and examine the effectiveness of individual 6-month home rehabilitation program in ischemic stroke patients upon disability and quality of life at 2 years.
Methods: This is a prospective randomized controlled trial (RCT) in 60 patients with recent ischemic stroke. They were randomly assigned to receive either home rehabilitation program once a month for 6 months with audiovisual materials (intervention group) or usual care (control group). We collected outcome data after discharge from the hospital until 2 years. The Barthel index (BI), the modified Rankin Scale (mRS) and utility index (EQ-5D) were measured for function, disability and quality of life respectively.
Results: At 2 years, the BI was significantly improved in the intervention group more than the control group: 97.2 ± 2.8 vs. 76.4 ± 9.4, $p < 0.001$. The good outcome, defined as BI 95–100, or mRS 0 or 1. For BI, there were 29 patients (96.7%) in intervention group vs 12 patients (42.9%) in usual care group (95% CI, 42.0, 85.0, $p = 0.03$). For mRS, there were 28 patients (93.3%) in intervention group vs 9 patients (32.1%) in usual care group (95% CI, 38.2, 87.0, $p = 0.02$). Number needed to treat for good outcome in mRS was 2.0 (95% CI: 1.0, 1.3). The mean (SD) of utility index in intervention group and control group were 0.9 ± 0.02 and 0.7 ± 0.04 respectively ($p = 0.03$). There was no significant interaction in baseline characteristics and treatment outcome.
Conclusions: Early home rehabilitation program in the first 6 months period after ischemic stroke leads to more rapid improvement in function, reducing disability and increase quality of life than usual care.

1. Introduction

During the past 10 years, stroke has been increasingly recognized as an important medical and societal problem [1]. Stroke disability may persist for life and limit independence and quality of life, even in those deemed recovered on the basis of independence in self-care [2]. Many developed countries have paid more attention to stroke rehabilitation to improve stroke survivors' ability and to decrease burden to their family and society. Thailand was among such and needed to have effective stroke rehabilitation program to help stroke patients improve their function, reduce disability and increase quality of life. While the duration of acute rehabilitation hospital stay for stroke patients have decreased so that recovery is often not complete at discharge [3].

Because intensive inpatient rehabilitation programs in Thailand are not widely available, the demand for home rehabilitation is increasing. Additionally, observational studies have found that family support and participation have an impact on long term rehabilitation, and well-dynamic family has been shown to result in improved function for stroke survivors. It is therefore important to not only consider the patients but their social environment as well [4,5]. Our previous study has shown that an early home rehabilitation program for patients with ischemic stroke in the first three months periods provides significant better outcome in improving function, reducing disability, increasing quality of life, and reducing depression than usual care group [6].

To date, no randomized controlled trial study has assessed the long term effectiveness of a home rehabilitation program for patients with ischemic stroke. Therefore, we developed a 6-month home rehabilitation program for patients with middle cerebral artery infarction and evaluated its long term effectiveness in this randomized controlled trial. We postulated that the program would be able to improve the activities of daily livings and function, decrease disability and increase quality of life. The result of this

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study may help to improve stroke care, and could be applied to other countries.

2. Materials and methods

2.1. Design

This was a randomized controlled trial (RCT). All eligible subjects gave their informed consent, and the study was approved by the ethical committee of Faculty of Medicine, Thammasat University.

2.2. Inclusion an exclusion criteria

Patients with stroke due to middle cerebral artery infarction were recruited from inpatient wards at Thammasat University Hospital from May 2007 to June 2008. They were screened for eligibility around three days after stroke onset. Screening was either based on a clinical diagnosis, or was performed exclusively with or aided by CT or MRI scanning. The main inclusion criteria of the trial were: stroke from middle cerebral artery infarction; patient and caregiver's willingness to participate; ability to provide informed consent; and living within 50 miles of the hospital. Patients were excluded if they had severe stroke: they were notorious for causing severe disability and/or a rapid progression to death, uncontrolled hypertension, severe dysphasia, or severe cognitive impairment; had already been discharged to residential care; had demonstrated previous disability in self-care; or had been living in a nursing home prior to the stroke.

2.3. Sample size and randomization

Based on previous study [7], if the mean differences between the Barthel Index score and the group and the standard deviation were 4.8 and 6.7, respectively, this study, with 30 patients per group, had an 80% probability of achieving a statistically significant result at a two-sided 5% level.

Eligible patients were stratified by gender and age ($\leq$40 years, >40 years). After giving informed consent, patients were then randomly allocated to receive either a home rehabilitation program (intervention group) or usual care (control group). Randomization was performed by a sequence of sealed envelopes in which the treatment assignment was given, using a random number table and block randomization in a fixed box of each strata.

2.4. Intervention and control group

Intervention consisted of a home-based individual's exercise program provided by a physical therapist once a month for 6 months. The physical therapist evaluated a range of functions related to indoor and outdoor mobility, as well as some basic activities of daily living, before providing a home rehabilitation program for the stroke patient. Individual counseling, which focused on education, applying information learned in practical situations, and solving problems occurring at home, was offered to the caregiver if needed.

The intervention strategy was based on principles of exercise physiology, motor learning and mirror neuron concept [8–13], and had been developed through the combined input of experts, stroke patients, physical therapists, occupational therapists, and speech therapists. It consisted of standard materials on an audiovisual CD of rehabilitation procedures: passive exercise, active exercise, resistance exercise, and activities of daily living (ADL), including preparing a drink, lock and key, putting on and taking off shoes, how to use a cane or wheelchair, etc. The duration and type of therapy were recorded on a case report form by the therapist. Each home program lasted approximately 1 h. Patients or caregivers were asked to keep diaries between therapy sessions on the time and type of training. Caregivers were instructed on how to assist patients in ways that allowed patients to use their functional skills as much as possible.

The patients in the control group and family members were given instructions for home rehabilitation prior to discharge from the hospital. The usual care after being discharged may include outpatient rehabilitation and instruction for home rehabilitation at the discretion of their physicians. All patients had physical therapy when they were admitted to the hospital. Other treatments were to be recorded in the case report form. The control group did not include follow-up home visits.

2.5. Outcomes and follow up

The Barthel Index (BI) is a weighted scale of 10 items of basic activities of daily living. The possible range of BI scores is 0–100; a score equal to or more than 95 is considered as having the ability of independent self-care Modified Rankin Scale provides (mRS) an assessment of the degree of disability. Minor strokes are considered Grades 0–2; major strokes are Grades 3–5, while fatal is 6. Therefore, the good outcome was defined as minimal or no disability, as measured by scores of 95–100 on the BI, or 0 or 1 on mRS [14–16]. EQ-5D on the 5-distinct dimensions is mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The EQ-5D can be informative in describing the dynamics of health-related quality of life during treatment and follow-up [17].

Follow-up visits at patients' residences were scheduled every month for the first 6 months after being discharged from the hospital. All patients and caregivers were interviewed and evaluated at their residences. Systematic assessments followed a case report from only one assessor. However, a blind study including patient and assessor was not practical for this study.

2.6. Statistical analysis

Data were analyzed by STATA for Windows version 10 software (Stata Corp, College Station, Texas, USA). Descriptive statistics were used to characterize demographics, performance and clinical characteristics for each group. All analyses were performed on an intention-to-treat (ITT) basis. The continuous outcomes of the Barthel Index and utility index (EQ-5D) were analyzed by analysis of covariance (ANCOVA), with the baseline as a covariate and age and depression as factors in the model. The level of significance was set to 0.05.

3. Results

Sixty-eight subjects were approached and screened for their eligibility to enroll in this study; 60 patients met the inclusion/exclusion criteria. All gave their informed consent for participation (Fig. 1). Eight patients were excluded because of severe aphasia, severe cognitive impairment, living outside the area, or being discharged to residential care. Two patients in the usual care group died before the second evaluation at home because of cardiovascular diseases. Almost all patients were elders with multiple medical illnesses. All strokes were major and caused significant impairment in both physical and cognitive function. There was no significant difference in baseline characteristics and inpatient hospital days between the two groups (Table 1).

All planned follow up visits were at patients' residences, which were scheduled at 1, 2, 3, 12 and 24 months after being discharged from the hospital were completed. Telephone follow up were made at 24 months in eight patients in control group and twelve patients

Table 1
Baseline subject characteristics.

	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
Body mass index, mean (SD)	24.8 (1.6)	24.6 (2.4)	0.72
Elementary education, n (%)	28 (93)	28 (93)	0.95
Length of stay in hospital (days), mean (SD)	10 (1.7)	10.9 (2.3)	0.83
Right hemisphere stroke, n (%)	18 (60)	12 (40)	0.20
Medical history, n (%)			
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
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
Hospital Anxiety and Depression Scale (HADs), mean (SD)	16.1 (7.6)	16.4 (4.9)	0.87
Barthel Index, mean (SD)	31.7 (5.9)	33.2 (4.8)	0.29
Utility index, mean (SD)	−0.14 (0.08)	−0.11 (0.13)	0.24

p-Value by independent sample t-test and Fisher's exact test, significant at $p<0.05$.

in intervention group, because they had moved back to their hometown to live with their spouses and/or siblings and the distance of their living places were more than 50 miles from the hospital.

The measurable outcomes are summarized in Table 2. This study showed the outcomes over 2 years. The BI, mRS and utility index improved in both groups, but significantly better for intervention group. The BI was significantly improved in the intervention group more than the control group: 97.2 ± 2.8 vs 76.4 ± 9.4, $p<0.001$ (Fig. 2). The good outcome, defined as BI 95–100, or mRS 0 or 1. For BI, there were 29 patients (96.7%) in intervention group vs 12 patients (42.9%) in usual care group (95% CI, 42.0, 85.0, $p=0.03$). For mRS, there were 28 patients (93.3%) in intervention group vs 9 patients (32.1%) in usual care group (95% CI, 38.2, 87.0, $p=0.02$). Number needed to treat for good outcome in mRS was 2.0 (95% CI: 1.0, 1.3). This means that about one in every 2 stroke patients will benefit from the treatment (95% CI: 1.0, 1.3). EQ-5D on the 5-distinct dimensions is mobility, self-care, usual activities, pain/discomfort and anxiety/depression. All dimensions, no patient chose in severe problem item. The mean (SD) of utility index (EQ-5D) in intervention group and control group were 0.9 ± 0.02 and 0.7 ± 0.04, $p=0.03$ respectively (Fig. 3). There were no serious adverse events in either group. Compliance with the intervention, based on daily records, was 92–95 percent.

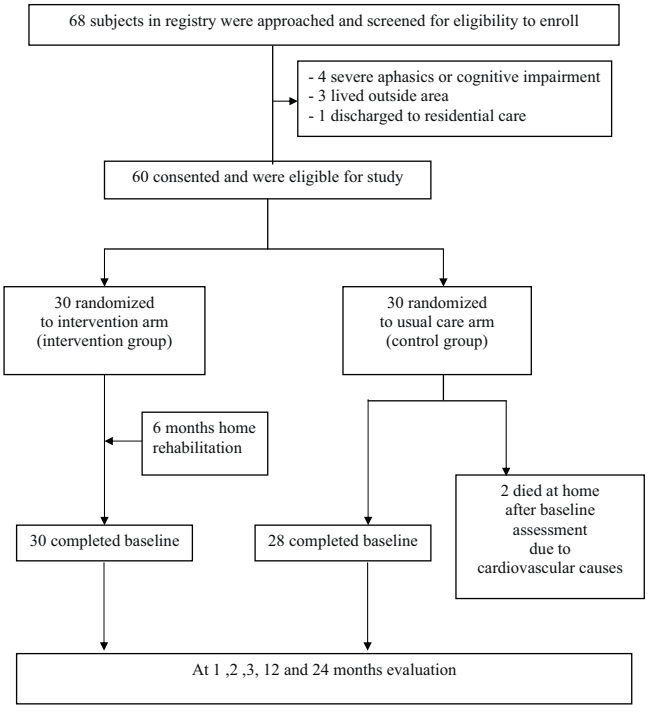

Fig. 1. Study flow chart.

4. Discussion

The present study has provided important data supporting the remarkable benefits of a home rehabilitation program. After 2 years, a 6-month home rehabilitation intervention produced greater gains and higher rates of functional independence and ability than did the usual care. Intervention appeared to accelerate recovery within

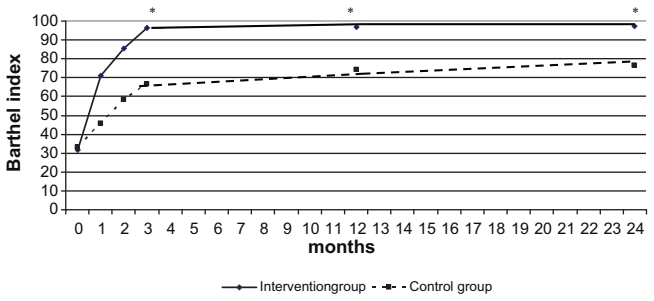

Fig. 2. Means of post-treatment effects of the intervention for two years, adjusted for age, depression and baseline measurement of outcome by the Barthel index. * p-value by ANCOVA, significant at $p<0.05$.

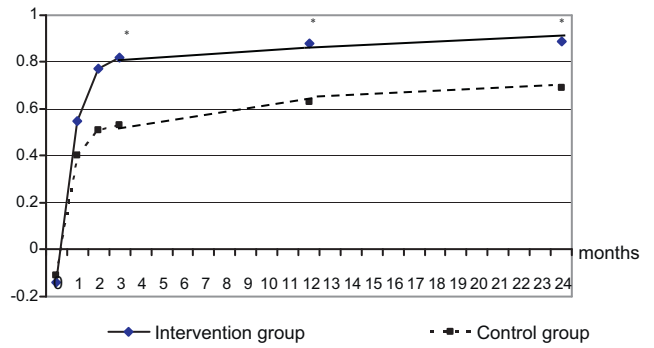

Fig. 3. Means of post-treatment effects of the intervention for two years, adjusted for age, depression and baseline measurement of outcome by the Utility index. * p-value by ANCOVA, significant at $p<0.05$.

Table 2
Results of ANCOVA adjusted for age, depression, dementia and baseline measurement of outcome at two years.

	Intervention group ($n = 30$)	Control group ($n = 28$)	p value
Barthel index, mean (SE)	97.2 (2.8)	76.4 (9.4)	<0.001
Modified Rankin Scale (MRS), mean (SD)			
Minimum or no disability, n (%): (0 or 1)	28 (93.3)	9 (32.1)	0.02
Moderate disability, n (%): (2 or 3)	2 (6.7)	19 (67.9)	
Severe disability, n (%): (4 or 5)	0 (0)	0 (0)	
Utility index, mean (SD)	0.9 (0.02)	0.7 (0.04)	0.03
EQ-5D, n (%):			
Mobility			
No problem	29 (96.7)	12 (42.9)	0.04
Some problems	1 (3.3)	16 (57.1)	
Severe problems	0 (0)	0 (0)	
Self-care			
No problem	30 (100)	12 (42.9)	0.03
Some problems	0 (0)	16 (57.1)	
Severe problems	0 (0)	0 (0)	
Usual activities			
No problem	28 (93.3)	10 (35.7)	0.03
Some problems	2 (6.7)	18 (64.3)	
Severe problems	0 (0)	0 (0)	
Pain/discomfort			
No problem	29 (96.7)	9 (32.1)	0.02
Some problems	1 (3.3)	19 (67.9)	
Severe problems	0 (0)	0 (0)	
Anxiety/depression			
No problem	28 (93.3)	1 (3.6)	0.001
Some problems	2 (6.7)	27 (96.4)	
Severe problems	0 (0)	0 (0)	

p-Value by ANCOVA, significant at $p < 0.05$.

3 months compared to usual care. After 3 months, the benefits slightly improved and reached plateau after 1 year.

Although models of neuroplasticity suggest that training results in an up regulation of growth-promoting factors mostly in the first 3 months after stroke [8], this process needs to be further explored in long term effect. We found that functional improvements could be seen as late as one year after the stroke, which goes against the conventional wisdom that most recovery is complete by 6 months. The trial showed that 94 percent of the participants made significant improvements in independency and quality of life, regardless of how severe their impairment was, or whether they started the initiation of earlier rehabilitation. Support from the family system, the home environment of rehabilitation, an individually tailored program with audiovisual materials, and close follow-up were all important [3,6,7,18–20]. An assessor evaluated each patient on 6 separate occasions, and a physical therapist provided home rehabilitation visits once a month for 6 months. The patients and their caregivers also received the physical therapist's telephone number for consultation about the home rehabilitation program. Compliance with the intervention, as indicated by daily records was high. All of which contributed to reduce non-responders.

The success of rehabilitation also depended on personal factors of stroke patients, such as age, education, socioeconomic status, medical history and family relationship [14,21,22]. Audiovisual materials (video CDs) may also aid in recovery, which could be explained by the mirror neuron theory. The mirror neuron theory has been proposed in the recovery of motor function and the reorganization of neural network integration, involving both the motor and sensory systems [13]. Motor imitation is a complex cognitive function that incorporates several stages, including motor observation (i.e., visual perception of ecologically valid movements), motor imagery, and motor execution. Moreover, it has been suggested that motor imagery might be beneficial to the recovery of motor functions after stroke [23].

Most patients and caregivers prefer home rehabilitation, due to the opportunity to be closer to their families. This might reflect the strong bonds of the extended family system, which could improve their ability [22]. Prior studies have also demonstrated an improvement of function based on 6–8 h/day of constraint-induced exercise [24]. On the contrary, our protocol had only 1 h/day, with encouragement to practice independently. The available audiovisual material was helpful as a resource for an intensive, motivated and progressive program.

The audiovisual materials in video CD of home rehabilitation program are very important because they will bring about a good co-operation and understanding between the therapist and the patients. It may be more appropriate than a book or demonstration for patients or their relatives in the Thai population with an educational status lower than high school. The implementation of this program will certainly enhance stroke survivor's recovery and quality of life. Our previous study has shown the cost-effectiveness of the 3-month program. It cost approximately 800 US dollars for each additional disability-avoided patient when switching from conventional hospital care to a home rehabilitation program [25]. This was assumed to be cost-effective when compared to per capita gross domestic product. Therefore, this program is the example of how the government can implement out-of-hospital stroke rehabilitation service by distributing rehabilitation personnel and facilities throughout the country. This home rehabilitation program could be initiated in community health center or hospital and physical therapists can also train staffs in village health volunteer to take care stroke patients in the community.

However, this study also had some limitations. It was an efficacy study targeted at ischemic stroke from middle cerebral artery infarction, and so the result may not be applicable to all stroke patients. Very severe stroke patients were also excluded. Additionally, the sham/placebo response may not be totally excluded. The usual care group did not receive additional sham/placebo treatment because it is difficult and not practical to provide sham or placebo treatment in this scenario of rehabilitation, which differed from drug trial. The evaluation and intervention were done after patients had been discharged from the hospital; therefore each evaluation time point was not measured directly from the stroke onset. However, the average inpatient stay for each group was approximately

10 days after acute stroke. Therefore, the results were still applicable to the time point in this study. Adherence to interventions for continuous training may be needed to continue the benefit.

5. Conclusion

This study have demonstrated that early home rehabilitation program in the first 6 months period led to faster recovery, reducing disability and increasing quality of life than usual care. The benefits remained for at least 2 years. Further studies on long term cost-effectiveness of this intervention should also be explored.

Conflicts of interest

The authors report no conflicts of interest.

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