

## CHAPTER 5

### CONCLUSIONS AND RECOMMENDATIONS

The first part of this chapter concerns the methodological considerations and limitations including the study population, design biases, and confounding. The second part discusses the main findings and other findings. The implications and further study of the findings are then discussed.

5.1 Methodological consideration and limitations including the study population, design biases, and confounding.

5.1.1 In this study the researcher employed the clinical trials; there are three fundamental aspects of trial design that must be precisely defined at an early stage:

- a. Which patients are to be eligible?
- b. Which treatments are to be evaluated?
- c. How should each patient's response be assessed?

a. Which patients are to be eligible: selection of patients?

This study was a prospective, randomized, clinical intervention trial in ischemic stroke at Thammasat University Hospital. The ischemic stroke patients were recruited from in-patient wards from May 2007 to June 2008. They were consecutively screened for eligibility around 3 days after onset. Sixty-eight eligible subjects in the registry were approached and screened for eligibility to enroll. They were consecutively screened for eligibility around 3 days after onset. The main inclusion criteria for the trial were ischemic stroke, willingness to participate and provide informed consent and, living within 50 miles of the hospital. Patients were excluded if they had uncontrolled hypertension, severe dysphasia, severe cognitive impairment, been discharged to residential care, previous disability in self-care, or were living in a nursing home prior to the stroke. The main objective is to ensure that stroke patients in this trial are identified as representative of some future class of patients to whom the trial's findings may be applied.

b. Which treatments are to be evaluated? : Treatment Schedules

The study protocol will often need considerable space devoted to a precise definition of a treatment procedure. Therefore, the researcher provided the following list of the features to consider when defining the home rehabilitation program in this study protocol:

Procedure	Intervention group	Control group
1. Informed consent	Yes	Yes
2. Randomization	Yes	Yes
3. The patients and family members were given instruction for home rehabilitation prior discharge from hospital and researcher	Yes	Yes
4. The patients received the home rehabilitation manual from researcher	Yes	Yes
5. The patients received usual care after being discharged	Yes	Yes
6. The patients may include outpatient rehabilitation on the discretion of their physician; other treatments will be recorded in case report form.	Yes	Yes
7. The patients received evaluation from an assessor once a month for 3 months	Yes	Yes
8. The patients received the physical therapist's phone number for consultation about home rehabilitation program.	Yes	No

Procedure	Intervention Group	Control group
8. The patients received home rehabilitation program (intervention)	<p>The intervention was a home-based individual's exercise program provided by a physical therapist once a month for 3 months. The physical therapist evaluated a range of functions related to indoor and outdoor mobility and some basic activities of daily living before providing home rehabilitation program for the stroke patients. 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 and motor learning. It was developed by experts, stroke patients, physical therapists, occupational therapists, and speech therapists. It consisted of standard audiovisual materials (CD) of rehabilitation procedures (passive exercise, active exercise, resisted exercise, ADL: transfer, putting on and taking off the shoes, how to use the cane and wheelchair etc.). The duration and type of therapy were recorded in a protocol by the therapist. Each home program lasted approximately 1 hour. Patients or caregivers were asked to keep diaries between therapy sessions on time and type of training. Caregivers were instructed how to assist the patient in the way that allowed the patient to use his or her functional skills as much as possible.</p>	No

c. How should each patient's response be assessed? Evaluation of Patient Response

The methods for assessing and recording a patient's progress need precise definition in the study protocol.

There are four main categories to classify patient evaluation:

- i) Baseline Assessment Before Treatment Starts
- ii) Principal Criteria of Patient Response
- iii) Subsidiary Criteria, e.g. Side-Effects
- iv) Other Aspects of Patient Monitoring

All four categories require careful planning in regards to accuracy of information and consistent recording of data on specially designed forms.

i) Baseline Assessment Before Treatment Starts

Here one's main aim is to measure the patient's initial clinical condition; though in addition background information on personal characteristics (e.g. age, sex, BMI) and clinical history (e.g. type of stroke, co-disease, the in-patient hospital day before discharge) may also be collected. It is sometimes tempting to collect a large and comprehensive battery of baseline data, but this can be irrelevant in that few such data ever get used. Hence, it is useful to focus attention on those items that may influence the patient's response to treatment. For this study, there was no significant difference in personal characteristics, clinical history between intervention group and control group.

ii) Principal Criteria of Patient Response

The choice of principle response criterion will depend on whether interventions are in the early or later stages. Thus, this study was starting in the earliest on home rehabilitation. The assessor ensured the evaluation of the patient on four visits, and the physical therapist provided home rehabilitation visits three times so as to reduce non-response. The compliance with the intervention by daily record at 1, 2 and 3 months were 94, 95 and 95 percent, respectively. The response rate achieved was 100% (very high). Thus the potential for response bias was negligible.

### iii) Subsidiary Criteria, e.g. Side-Effects

After clear definition of the main criteria of patient evaluation there may be a substantial number of other features one wishes to observe. In this trial, the researcher was concerned with on the patients' safety. Participants underwent monitoring by physical therapist supervised vital sign before the home based exercise intervention. Although before the second evaluation, in control group, two patients died at home because of a cardiovascular problem. In this trial, there was no adverse event in both groups.

### iv) Other Aspects of Patient Monitoring

Although a study protocol may concentrate on those evaluation criteria most suited to comparison of interventions, one must also be careful to define other features for monitoring each patient which are required for the maintenance of sound clinical practice. Thus, this study required daily record form patients or caregivers and follow-up on the phone to check whether any unexpected developments occurred, significant enough to merit alteration in intervention or even removal from the trial.

#### 5.1.2 Methods of Randomization

The concept of random allocation when comparing different treatments has been an important aspect of the design. The purposes of such randomization were:

- a. To guard against any use of judgment, i.e. to avoid bias.
- b. To provide a basis for the standard methods of statistical analysis such as significance tests.

For each patient who might be considered suitable for inclusion in this study the following formal sequence of events should take place:

#### (1) Patient Recruitment

The identification of appropriate patients may seem an obvious step, but it is important to ensure that the patients entered in the trial are representative of the disease under investigation so that the trial's conclusions can be readily applied to the entire population of such ischemic stroke patients.

## (2) Checking Eligibility

The eligibility of each possible patient should be checked right away. The researcher was gone through the list of eligibility criteria in the protocol and excluded the patient automatically if any criterion is not fulfilled.

## (3) Patient consent

In general, there is an ethical need to inform each patient about his entry into a clinical trial and obtain his agreement before proceeding further. For this study, all eligible subjects gave informed consent. This study was approved by The Ethics Committee of Faculty of Medicine, Thammasat University, Pathumtanee, Thailand.

## (4) Agreement of Randomization

It is vital to ensure that the researcher had agreed to accept random treatment assignments before formally entering the patient into the trial.

## (5) Formal Entry In Trial

It is essential that each patient entering the trial be formally identified before random treatment assignment is revealed. This can be achieved by having the patient's name, and a few other details such as such as hospital number or assigned treatment, recorded on a log sheet of patients in this study.

## (6) Random Treatment Assignment

One essential is that the researcher does not know the order of this list and is unable to predict what the next assignment will be. For this study, immediately after informed consent was obtained, the patients were randomized 1:1 to a sequence of sealed envelopes, into either the intervention group or the control group by blocks of four methods. Thus the potential for confounding was controlled.

## (7) Documentation

After the treatment has been assigned, one should complete necessary documentation prior to start of treatment. For this study, all patients had the case report form for each patient containing all of the same relevant information prior to treatment.

#### (8) Efficiency and Reliability

All the above formalities must be completed before treatment commences. Accordingly, the whole processes of patient registration and randomization have to be prompt so that there is no delay in treatment. All patients have to stay in the trial so that their intervention and evaluation can be properly recorded. The assessor had adequate training and accreditation on using NIHSS and MRS scales. One assessor assessed all evaluation.

##### 5.1.3 Bias (systematic errors)

This study was carefully planned to minimize the usual causes of biases and errors. Selection bias can be a major problem in every clinical trial. But the potential can be reduced via randomization and a 100% follow-up rate.

Information bias occurs when the evaluator's knowledge of the patient's status affects the way he or she ascertains or records the exposure. The researcher has concerns about this bias. In the study, the researcher sought to reduce information bias by using structured, systematic assessments following a case report form from only one assessor. However, the blinding for the patient and assessor were not practical in this study.

## 5.2 Main Findings

The result from this study showed that the home rehabilitation program for ischemic stroke of recovery appears to accelerate gains in function ability and quality of life for patients 3 months after being discharged from the Thammasat University Hospital. The success of rehabilitation also depends on baseline characteristics or personal factors in persons with stroke such as age, educational level, socioeconomic status, smoking, drinking, medical history and family relationship (Heinemann, Roth, Cichowski, & Betts, 1987; Studenski, Duncan, Perera, Reker, & Lai, 2005). There was no significant difference in baseline characteristics between the intervention group and the control group.

In recent meta-analysis of home-based stroke rehabilitation interventions, it was found that the effect of stroke rehabilitation on function and quality of life is not clear due to the heterogeneity of populations and interventions. More recent intervention studies have had mixed results. The intervention during the stroke recovery produced gains in performance and conditioning but did not directly impact daily function and social activities after the stroke.

The result from this study demonstrates the BI was significantly improved in the intervention group more than the control group: 50.66 (95% CI: 28.85 to 72.47), the absolute risk reduction (ARR) 93.33 % (95% CI, 84.41% to 102.26%). The utility index: 0.18, (95% CI: -0.02 to 0.37) and all dimensions of EQ-5D in the intervention group were more significantly better for quality of life and generic health status than the control group. The present study result is in line with the result of Studenski's study (Studenski et al, 2005) indicates that the intervention group improved more than usual care in SF-36 social function (14.0 points; P=0.0051) and in SIS (strength (9.2 points; P=0.0003), emotion (5.6 points; P=0.0240), social participation (6.6 points; P=0.04880, and physical function (5.0 points; P=0.0145). Treatment was marginally more effective on Barthel score (3.3 points; P=0.0510), SF-36 (physical function (6.8 points; P=0.0586), physical role function (14.4 points; P=0.0708), and SIS upper extremity function (7.2 points; P=0.0790). This rehabilitation exercise program led to

more rapid improvement in aspects of physical, social, and role function than usual care in persons with subacute stroke.

However there were some studies that did not find the differences between with and without home rehabilitation program. Fey et al, 1998 (Fey et al, 1998) were to investigate the effect of a specific therapeutic intervention on arm function in the acute phase after stroke. Results on the Action Research Arm test and Barthel Index revealed no effect at the level of disability. The reason for the results can be explained for the intervention had to be applied for short period (6 weeks) and these results emphasize the potential beneficial effect of therapeutic interventions for the arm. The recovery process of the function of the upper extremity is often slower than that of the lower extremity.

Including, Duncan et al, 1998 (Duncan, Richards, Wallace, Stoker-Yates, & Pohl, 1998) were to evaluate the ability to recruit and retain stroke subjects; and to assess the effects of the interventions used. There were no trends in differences in change scores by the Jebsen test of hand function, Barthel Index, and Lawton Instrumental ADL scale. Twenty minimally and moderately impaired stroke patients who had completed inpatient rehabilitation and who were 30 to 90 days after stroke onset were randomized to a control group or to an experimental group that received a therapist-supervised, 8-week, 3-times-per-week, home-based exercise program. This study due to the difference of study design; small sample size, sample characteristics, short study period.

Several studies have been conducted to examine the rehabilitation in stroke patients but the results have been inconsistent. Previous studies have documented that patients usually have significant residual physical disability, functional impairment and reduced quality of life (Anderson, Rubenach, et al., 2000; Fey, De Weerd, & Selz, 1998; Studenski, et al., 2005). One study has shown that the motor function gradually returns as the result of only spontaneous recovery. In randomized controlled studies, the results of specialized home rehabilitations have also been unclear. Duncan

et al, 1998 (Duncan, et al., 1998) reported no difference in Barthel Index score and Several authors (Studenski, et al., 2005; Young & Forster, 1993) suggested that home rehabilitation is more effective and cheaper. Therefore, the stroke rehabilitation programs may not improve outcomes (Dobkin, 1989).

Pollock (Pollock, Baer, Pomeroy, & Langhorne, 2003) estimated using the standardized means differences (SMD), was 0.14 for basic activity of daily living (ADL) and 0.17 for instrumental activity of daily living (IADL). Studenski et al (Studenski, et al., 2005) estimated of 0.38 for basic daily functioning by Barthel score and 0.10 for IADL. None of the recent pooled analyses of stroke rehabilitation based on studies completed by 2002 reported effect size for quality of life indicators; whereas this study estimates range from 0.31 to 0.61 for SF-36 and 0.12 to 0.59 for stroke-specific SIS scales (Legg & Langhorne, 2004; Pollock, et al., 2003; Saunders, Greig, Young, & Mead, 2004).

Outpatient Service Trialists (Outpatient Service Trialists., 2004) did a systematic review of randomized trials of outpatient services. They identified a heterogeneous group of 14 trials (1617 patients). Therapy-based rehabilitation services for stroke patients living at home reduced the odds of deterioration in personal activities of daily living (odds ratio 0.72 (95% CI: 0.57 - 0.92), P=0.009) and increased the ability of patients to do personal activities of daily living (standardized mean difference 0.14 (95% CI: 0.02-0.25), P=0.02). For every 100-stroke patient resident in the community receiving therapy-based rehabilitation services, seven (95% CI: 2-11) would not deteriorate. They found that therapy-based rehabilitation services targeted at selected patients resident in the community after a stroke improved the ability to undertake personal activities of daily living and reduce the risk of deterioration of ability.

Myo et al (Myo, 2000) randomized 114 patients (mean age 70 years) to a 4 week, individualized home-treatment program of rehabilitation and nursing services or usual care (i.e., a variety of treatments in different settings). On average, the 2 groups received a similar number of physical, occupational, and speech therapy units,

but there was substantially more variation in the usual-care group, with some individuals receiving minimal services. At 1 and 3 months, functional outcome was similar in the 2 groups, but home intervention had beneficial effect on tasks necessary for community living and on reintegration into the community.

Dam M et al reported that stroke patients reaching a BI score of more than seventy move from dependency to assisted independence. But, in the present study recovery activity in daily living was considered satisfactory when patients achieved a BI score of more than ninety-five, which in higher magnitude and better depicts a good level of capacity in self-care.

Our intervention appears to accelerate recovery in 3 months compared with usual care. The present study has provided additional data for this remarkable benefit. This home rehabilitation intervention produced greater gains and higher rates of functional independence, ability, and quality of life than did the usual care at 3 month in all primary outcomes. At 3 months, the NIHSS was not significantly improved in the control group over the intervention group but intervention group produced greater gains than did the usual care by 10.10 (2.22) (95% CI: 5.63, 14.56). The BI was significantly improved in the intervention group over the control group was 50.66 (95% CI: 28.85 to 72.47); the absolute risk reduction (ARR) was 93.33 % (95% CI, 84.41% to 102.26%). The results are similar regarding MRS: ARR was 90 % (95% CI, 79.26% to 100.74%). It did show a benefit in reducing disability, with a NNT of 2 (95% CI, 1.0 to 1.2). The utility index was 0.18, (95% CI: -0.02 to 0.37) and all dimensions of EQ-5D in the intervention group were significantly better for quality of life and generic health status than the control group.

The success of rehabilitation can be from a home rehabilitation program and the factors responsible for this superiority of organized stroke rehabilitation may include the supports from the family system, the initiation of earlier rehabilitation, home environment of rehabilitation, individually tailored program with audiovisual materials and close follow-up (Anderson, Rubenach, et al., 2000; Fey, et al., 1998; Studenski, et al., 2005; Young & Forster, 1993).

### 1. The family system

The success of rehabilitation also depends on family relationship (Heinemann, et al., 1987; Studenski, et al., 2005) and in Thai culture, which commonly has large families living in one dwelling, the presented stroke patients had many family caregivers to take care and support them. The spouses as well as siblings were the major caregivers. Most patients and caregivers prefer home rehabilitation due to the opportunity to be closer to their families. Although people in the country have become more westernized, this strong family relationship is still common, especially in rural areas. This might reflect the strong bonds of the expanded family system and improve their quality of life (Duncan, et al., 1998; Heinemann, et al., 1987).

Moreover, physical therapist should not forget to teach the caregivers how to manage and handle their strokes patients properly in order to avoid musculoskeletal trauma caused by improper handling. Therefore, the rehabilitation program should not only be aimed at the stroke patients, but also their family and caregiver. In addition, not all stroke patients can be functionally independent and some still need a caregiver to provide physical help and psychosocial support (Heinemann, et al., 1987 & Studenski, et al., 2005).

### 1. The Initiation of Earlier Rehabilitation

Studies in the past have shown that the rehabilitation intervention for stroke patients in the early phase of recovery appears to accelerate gains in function and quality of life (Stroke Unit Trialists' Collaboration, 2004) Additionally, well-organized rehabilitation services initiated immediately after a stroke can improve long-term outcomes (Stroke Unit Trialists' Collaboration, 2004). The evaluation and intervention is being done after patients have been discharged from the hospital, therefore each evaluation time point is not measured directly from stroke onset. However, the average inpatient stay for each group was approximately 10 days after acute stroke. Therefore, the results are still applicable to the time point in this study. In this study, we have demonstrated that early support with home rehabilitation services in ischemic stroke patients during the first 3-month period has a better outcome in improving function and reducing disability compared to usual

rehabilitation practice. Rehabilitation can begin as soon as the patients are medically stabilized, typically within 72 hours. Patients may be admitted to a specific stroke unit or neurological unit with rehabilitation services. Evidence supports the benefits of such services in significantly improving functional outcomes when compared to patients not receiving those services (Heyes & Corroll, 1986; Langhorne, 1993). Whereas the home rehabilitation of patients with stroke in Thailand is limited (Anderson, Jamrozik, & Stewart-Wynne, 1994; Young, 1994). Because inpatient rehabilitation is not widely available, the demand for home rehabilitation model is increasing. Therefore, the model for effective home rehabilitation for stroke will help improve stroke care and may be applied to other countries.

Recovery from a stroke and learning is based on the brain's capacity for reorganization and adaptation. An effective rehabilitation plan capitalizes on this potential and encourages functional use of the involved segments. Activities are selected that are meaningful and important to the patient. Optimal motor learning can be ensured through attention to a number of factors, most importantly, strategy development, feedback, and practice. It seems that the first three months are of special importance in the rehabilitation of stroke patients. The intervention produced greater gains and higher rates of independence immediately after the intervention than did usual care. Much of the benefit appeared to have dissipated by 3 months after intervention, largely because of continued recovery in the control group and the intervention group. This 3-month structured, physiologically based, progressive supervised home rehabilitation program improved stroke recovery compared with usual care. Gains were observed in stroke severity, functional ability, and quality of life.

## 2. Home Environment of Rehabilitation

In a review of home-based rehabilitation and care, Tamm M. (Tamm, 1999) debates the issue as to whether the home is the best place for rehabilitation. Two studies have investigated specifically designed home rehabilitation for stroke patients. Duncan et al (Duncan, et al., 1998) in a randomized pilot study, detailed a home-based exercise program designed for individuals with mild to moderate stroke.

Patients were seen three times-a-week for eight-weeks and received a physiotherapist-supervised program aimed at maintaining or improving balance, strength, endurance, and encouraging use of the affected extremity. In another home-based practice model, designed to improve gain in stroke patients, interventions were not explicitly described but it was stated that they were aimed at normalizing passive range of motion, and improvement in standing balance and weight shift. Isolated muscle recruitment was encouraged, using surface electromyography and mirrors for feedback (Rodriquez, Black, & Kile, 1996). People frequently express the desire to be at home rather than in institutionalized care, because the home is a person's personal refuge and their private sanctuary. In this study, people with stroke have talked about their preference of location for rehabilitation when they were evaluated:

“...I do not like to get out from the house...”

“...I enjoyed exercising in my place, I feel more focused and safe....”

“...I would like to see my grandchild around me when I am exercise...”

### 3. Individually Tailored Program With Audiovisual Materials

This study has numerous strengths. It is fairly large and a physiologically based and highly reproducible intervention that could be implemented by others using this protocol.

The ability of patients to perform rehabilitation programs in the present study was called term intensive rehabilitation program. The definition of an intensive rehabilitation program is multimodal exercise, individual program and each home program is approximately 1 hour. The physical therapist evaluated a range of functions related to indoor and outdoor mobility and some basic activities of daily living before providing home rehabilitation program for the stroke patients. 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 and motor learning and was developed by experts, stroke patients, physical therapists, occupational therapists, and speech therapists. It consisted of standard audiovisual materials, (CD) of rehabilitation procedures (passive exercise, active exercise, resisted

exercise, ADL: transfer, putting on and taking off the shoes, how to use the cane and wheelchair etc.).

These results suggest that physiologically based, intensive exercise is effective in improving multiple domains of stroke recovery and increased structure, intensity, and progression may be key elements in effective therapy. The benefits found here are specifically noteworthy because the control group was also experiencing natural recovery and received prescribed rehabilitation services. The gains from usual care had to be exceeded to detect additional benefit from the intervention.

Prior studies have demonstrated the improvement of function based on six to eight hours/day of constraint-induced exercise (Lipert, et al., 2003). On the contrary, protocol of this study had only one hour/day, with encouragement to practice independently. Although, the availability of audiovisual material is helpful as a resource for an intensive, motivated, and progressive program (Shafer, Van der Loos, & Szotak, 1995).

So far, Buccino et al proposed Mirror neuron theory about the recovery of motor function and reorganization of neural network integration, which involves both motor and sensory systems. 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. Although it has been suggested that motor imagery might be beneficial to the recovery of motor functions after stroke (Page, Levine, Sisto, Johnston, 2001).

Many studies have suggested that one-fifth to one-third of home accidents that involve older adults, including recovering stroke victims (Anderson, Rubenach, et al., 2000; Legg & Langhorne, 2004 & Tamm, 1999). The safety and feasibility of an individual's home rehabilitation program after a stroke are concerns. Participants underwent a physical therapist supervised vital sign before the home based exercise intervention. No adverse events occurred during home rehabilitation program.

Intercurrent illness and hospitalization were not uncommon in both the intervention and control groups.

#### 4. Close Follow-up

The assessor ensured the evaluation of the patient on four visits, and the physical therapist provided home rehabilitation visits three times so as to reduce non-response. The patients received the physical therapist's phone number for consultation about a home rehabilitation program. The response rate achieved was 100% (very high), compliance with the intervention by daily record at 1, 2 and 3 months were 94, 95 and 95 percent, respectively.

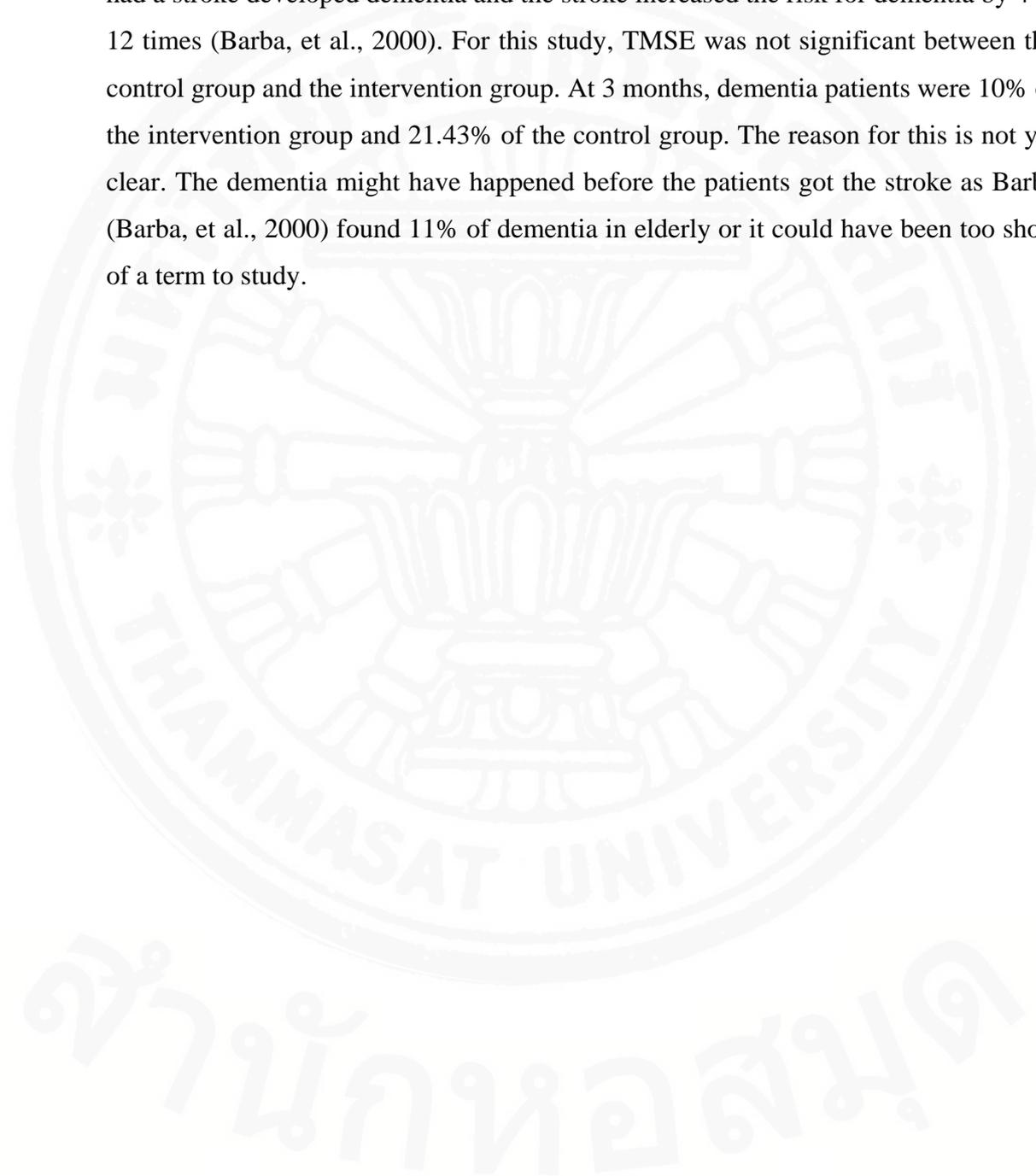
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### 5.3 Secondary findings

Neuropsychiatric disorders such as depression and dementia after stroke become increasingly important in stroke survivors (Bourgeois, Hilty, Chang, Wineinger, & Servis, 2004).

The interaction between depression and neurological disease is complex. When depression precedes the onset of neurological disease, it is often unclear whether depression is the first manifestation of the illness or coincidentally preceded the onset of an ensuing brain disease. Previous studies on the prevalence estimates of depression suggest that the prevalence very widely, ranging from 7% to 76% (Veazey, Aki, Cook, Lai, & Kunik, 2005). In Thailand, a one year cumulative incidence depression of 12% in patients after stroke is reported. (Kulkantrakorn & Jirapramukpitak, 2007). For this study, depressed patients were 66.67% patients in the intervention group 83.33% patients in control group after stroke. This variation is perhaps due to inconsistent methodology (Veazey, et al., 2005). The much higher incidence of depression among stroke patients in this study is more likely to support the cortical injury hypothesis as the major cause of depression. In this study, the scores of HADs were significantly improved in the control group over than the intervention group. There was an improvement in the Hospital Anxiety and Depression scores (HADs) in both groups but the intervention group improved more. The reason for this is not yet clear. The psychological support from the home visit and families may help reduce the depression in the intervention group more than the control group. A previous study reports a correlation between improved quality of life, improved self-care ability and decreased depression (Robinson-Smith, Johnston, & Allen, 2000). In this study, depression is also associated with low health-related quality of life. Increasing HADs scores are accompanied by decreasing scores on all 5 health-related quality of life measures.

A considerable decline in cognitive function has been reported by several studies and can occur shortly after a stroke (Sachdev, Brodaty, Valenzuela, Lorentz, & Koschera, 2004; Tham, et al., 2002). In recent study, about 30% of patients who had a stroke developed dementia and the stroke increased the risk for dementia by 4 to 12 times (Barba, et al., 2000). For this study, TMSE was not significant between the control group and the intervention group. At 3 months, dementia patients were 10% of the intervention group and 21.43% of the control group. The reason for this is not yet clear. The dementia might have happened before the patients got the stroke as Barba (Barba, et al., 2000) found 11% of dementia in elderly or it could have been too short of a term to study.



#### 5.4 The implications and further study of the finding

Stroke is leading cause of disability. The consequences after stroke are not only persistent neurological impairment, but also lifetime disability that need medical rehabilitation to enable optimal function that will overcome the patient's disability. During the past 10 years, stroke has been increasingly recognized as an important medical and societal problem. Judging from an estimated 62.8 million Thai population in 2000, of which 9.2% were aged over 60 years (National Health Security Office, 2005), and a stroke prevalence rate of 1.12 per cent among the elderly in 1998 (Viriyavejakul, et al., 1998), it is estimated that more than 60,000 of the country's elderly are disabled by stroke. Many developed countries have performed some 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 to improving function, reducing disability and increase quality of life. In this study, we have demonstrated that early support with home rehabilitation services in ischemic stroke patients during the first 3-month period has better outcome as improving function and reducing disability compared to usual rehabilitation practice.

It suggests that the rehabilitation focusing on self-management techniques or active modalities. And it can also protect against the consequence of disability. For the further community study, this study suggests that sometimes the purposive sampling from health data of the government unit is the better technique for collecting the target group although there is a large percentage of the population who do not use the government service. 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. Therefore, in future the government should distribute rehabilitation personnel and facilities throughout the country. This home rehabilitation program could be processing in health centre or

hospital and physical therapists can also train staffs in village health volunteer to take care stroke patients in the community.

Further studies should also be explored:

1. Long term outcome of this intervention

Duncan et al, 1998 (Duncan et al, 1998) has shown that the motor function for 3 months after onset gradually returns as the result of only spontaneous recovery. The stroke rehabilitation programs may not improve outcomes (Dobkin, 1989). Therefore, the long-term outcome of this intervention should also be explored:

2. Cost effectiveness of this intervention.

In Thailand, Public Health Statistics show that stroke has been on the increase (Granger & Hamilton, 1993, National Health Security Office, 2005). Judging from an estimated 62.8 million Thai population in 2000, of which 9.2% were aged over 60 years (National Health Security Office, 2005) and a stroke prevalence rate of 1.12 per cent among the elderly in 1998, it is estimated that more than 60,000 of the country's elderly are disabled by stroke (Viriyavejakul, et al., 1998). In most developed countries, including Thailand, there is a heavy reliance on hospitals for the acute care, whereas the home rehabilitation of patients with stroke is limited (Anderson, et al., 1994; Viriyavejakul, et al., 1998; Young, 1994). Because inpatient rehabilitation program in Thailand is not widely available, the demand for home rehabilitation model is increasing. Therefore, the model for effective home rehabilitation for stroke will help improving stroke care and may be applied to other countries. The financial cost of stroke rehabilitation is considerable but few cost-effectiveness studies are available to guide clinical practice. In economic aspects, cost of stroke has been valued worldwide (Evers, et al., 2004) including Thailand (Yongkong, Riewpaiboon, Towanabut, & Riewpaiboon, 2002). Evers et al reviewed literature between 1966-1988 and found six studies on economic evaluation of rehabilitation for stroke (Evers, Ament, & Blaauw, 2000). Additionally, one study compared early discharge together with home-based rehabilitation with conventional in-hospital rehabilitation together with community care (Anderson, Mhurchu, et al., 2000). Young et al showed the median cost over the first eight weeks. There were 620.00

pound (interquartile range 555.00-730.00 pound) for the day hospital patients and 385.00 pounds (interquartile range 240.00-510.00 pound) for the home physical therapy group (Young & Forster, 1993). Kalra et al have compared alternative strategies in stroke care using a randomized controlled design; the total costs of stroke per patient over the 12 month period were £ 11,450 for the stroke unit, £ 9,527 for the stroke team and £ 6,840 for home care. More than half the total costs were incurred in the first 3 months (Kalra L, et al., 2005).

To adopt this intervention, policy makers need to know how much it costs comparing the clinical achievement in Thai health setting where detail of the intervention and cost are different from other countries. Therefore, the study aims to compare costs and effects of the home rehabilitation program and conventional hospital care for ischemic stroke patients in Thai healthcare setting should also be explored.

3.A new tool in rehabilitation such as mirror neuron theory or novel virtual reality (VR)

Buccino et al 2006 (Buccino et al, 2006) discuss the possibility that a systematic activation of the observation-execution matching “ mirror” system of the premotor and parietal cortices can be used to affect functional changes in motor function in patients with ischemic stroke. There is significant reason to believe that development of these motor skills played an important evolutionary role, that this phylogenesis depended on observation-execution matching, that develop of such skill in children also depends on action imitation, a, that good recovery from stroke might also depend on use this system.

The novel virtual reality (VR) has to be based on cognitive neurorehabilitation system for improving the rehabilitation of stroke patients. Using a custom, low-cost kinematics tracking system designed for clinical or home use, patients engage in task-oriented interactions with objects in a virtual environment.

However, the present study has some limitation, it was an efficacy study targeted at ischemic stroke and the result may not be applicable to all stroke rehabilitation. Severe stroke patients were also excluded. The evaluation and intervention is being done after patients being discharged from the hospital, therefore each evaluation time point is not measured directly from stroke onset. However, the average inpatient stay for each group was approximately 10 days after acute stroke. Therefore, the results are still applicable to the time point in this study.

