CHAPTER 3

RESEARCH METHODOLOGY

RESEARCH QUESTIONS

1. Is the proportion of the independence ADL in the stroke patients who were treated with the home rehabilitation program significantly different from those treated with the hospital program?

2. Is the duration of dependent ADL.stage in both groups significantly different?

OBJECTIVES

1. To evaluate the proportion of the stroke patients who improve to the independence ADL. stage, comparing the home program and the hospital program.

2. To measure the duration of dependent ADL. stage in the two programs of treatment.

HYPOTHESES

1. The proportion of the independence ADL. in the stroke patients who were treated with the home rehabilitation program is not significantly different from those treated with the hospital program.

From natural history, the proportion of patients who recover in the rehabilitation ward to independence is about 80%. If the number of independence patients in home program is no more than 20% less than the rehabilitation ward program, the difference will not be considered clinically significant.

2. The duration of dependent ADL. stage in both groups is not significantly different.

CONCEPTUAL FRAMEWORK

After the stroke patients recover from the acute phase, they still have some residual disabilities. They can not take care of themselves and go back to work. The rehabilitation program will help them to promote ambulation and self care and support their psychosocial status.

If the patients stay in the hospital, they will be treated by the standard rehabilitation program. However this program has some disadvantages. It takes a period of time in the hospital, the hospitalization cost is expensive and in the real situation, the staff do not have enough time to take care of the patients exactly due to work load. So if the relatives are the caregiver to treat the patient at home, the sympathy, love and mental support should be better than the busy staff in the hospital. Moreover the hospitalization time, cost, and work load of staff will be decreased. The disadvantages of this program are unreliable relatives' care and the economic loss of caregivers. There are advantages and disadvantages of each program,

The functional recovery is a main outcome to compare between the hospital and home program. If the functional outcome of both program are not different, the improvement of quality of life and economic gain will be considered as the benefit of home program.

RESEARCH DESIGN

A randomized controlled trial.

TARGET POPULATION

The stroke attack patients, were sent to Srinagarind Hospital. The patients were investigated to confirm diagnosis, pathology of stroke, location in brain and underlying disease. History, physical examination, routine laboratory examination (complete blood count, urinary analysis, blood sugar, electrolyte) was done. The stroke patients were evaluated by using the Siriraj Stroke Score (SSS). If the Siriraj Stroke Score was between -1 and 1, CT scan would be done to differentiate these strokes occurring as result of cerebral hemorrhage (usually, SSS>1) or as result of cerebral infarction (usually, SSS<1). The patient was admitted to the neurological department for medical treatment until the vital signs and neurological signs were stable. In general if there were no complications, it was about 48 hours after acute attack. The patient would be sent to the Rehabilitation Department. The patient was reexamined by the rehabilitation doctors.

Demographic data eg. age, sex, marital status was collected and information was recorded concerning neurologic status at stroke onset including (a) etiology of stroke (thromboembolic, hemorrhagic), (b) side of infarction (dominant, nondominant), (c) side of paresis (right, left), (d) severity of paresis (plegia, paresis) (e) presence of aphasia, apraxia, (f) sensory neglect, (g) visual field defect, (h) impaired joint position sense and (i) urinary incontinence.

After the vital signs and neurological signs were stable (usually 48 hours after the acute onset), the patients would be randomly allocated into 2 groups (hospital , home) after stratified based on prognostic factors :

1. side of lesion (right,left)
2. severity (complete and incomplete)
    complete : muscle power of weakness side grade 0
    incomplete : muscle power of weakness side grade 1 to 4

Before randomization the patient or family would give inform consent.

. Group 1 was the control group that received a conventional rehabilitation program in the hospital.

Group 2 was the trial group. The patients must be discharged from the hospital. Before being discharged, the relatives would be trained in the rehabilitation home program; physical therapy, occupational therapy, and speech therapy.

INCLUSION CRITERIA

1. age 20-80 years
2. the first onset of stroke
3. supratentorial lesion
4. having a level of consciousness to follow two or three step commands
5. informed consent

EXCLUSION CRITERIA

1. hemorrhagic stroke
2. other central nervous system disorders (eg. epilepsy or multiple sclerosis)

3. serious medical diseases
   (eg. uncontrolled diabetic mellitus, uncontrolled
   hypertension, congestive heart failure,
   unstable myocardial infarction)
4. psychotic disorders

INTERVENTION

The interventions were 2 methods of treatment; conventional rehabilitation program in the hospital and rehabilitation home program.

. 1. Conventional rehabilitation program in the hospital

The patients received rehabilitation treatment from the rehabilitation team. The rehabilitation doctor attended the patients everyday in the morning. The rehabilitation nurse took care of them in the ward. They received a physical therapy program (exercise, ambulation training) 1/2 hour everyday in the morning and an occupational therapy program (activities of daily living; ADL training) in the afternoon. If they had a speech problem, they would be sent to the speech therapist.

The protocol of conventional rehabilitation treatment was used to guide the staff to treat the patients in the same way.

The patients were discharged from the hospital either (a) when they had achieved success in the rehabilitation goals (independent ADL, independent ambulation) or (b) when there had been no functional improvement within 1 month, which indicated poor prognosis for functional recovery. In general, the average duration at hospital care was about 1 month.

After discharge, the independent patients continued the rehabilitation program at home by themselves to maintain physical

functions. For the no functional recovery patients, their relatives were instructed home rehabilitation program. The patients were follow up every month by assessing functional level at OPD.

2. Rehabilitation home program

The patients must be discharged from the hospital. Before discharge, the relatives would be trained in the rehabilitation home program by rehabilitation staff: physical therapy (exercise, ambulation training) 3 hours, occupational therapy (ADL. training) 3 hours, rehabilitation nurse and speech therapist for individual patient. The rehabilitation staff taught the relatives until they can do it correctly by themselves. The total training time was about 1 day.

The protocol of the rehabilitation home program was performed to guide the rehabilitation staff to teach the relatives in the same way.

After discharge, the patients were followed up every month by assessing functional level at OPD. and the relatives were evaluated for compliance as well.

2.1 selection of relatives

1. chief caregiver
2. age 17-60 years

The level of education, occupation, economic status were not limited because the home program was not difficult to learn. However there might be some different between each level of socioeconomic status. This data was recorded to analyzed in subgroup analysis.

Summary of program

Program in hospital

1. exercise :
   range of motion exercise, strengthening exercise
   by physical therapist : at least 1/2 hour per day,
   5 days per week
2. ambulation :
   bed activities, sitting, transfer, standing, walking
   by physical therapist : at least 1/2 hour per day,
   5 days per week
3. activities of daily living :
   eating, grooming, toilet, bathing, dressing
   by occupational therapist : at least 1/2 hour per
   hour, 5 days per week
4. speech therapy :
   Consulted speech therapist if the patient had a speech
   problem at least 1/2 hour per time, 5 days per week.
5. psychological therapy :
   Consulted psychiatrist and psychologist if the patient
   had a psychological problem.   1 time per day
6. social and vocational management :
   Consulted social worker if the patient had a social or
   vocational problem.

Home program

1. exercise :
   range of motion exercise, strengthening exercise.   The
   physical therapist taught the caregiver for 1 hour before
   discharge. The caregiver treated the patient at least 1/2
   hour per day, everyday.

2. ambulation :

    bed activities, sitting, transfer, standing, walking

    The physical therapist taught the caregiver for 2 hours before discharge. The caregiver taught the patient at least 1/2 hour per day, everyday.

3. activities of daily living :

    eating, grooming, toilet, bathing, dressing   The occupational therapist taught the caregiver for 3 hours before discharge. The caregiver taught the patient at least 1/2 hour per day everyday.

4. speech therapy:

    Consulted speech therapist if the patient had a speech problem. The speech therapist taught the caregiver. The caregiver treated the patient at least 1/2 hour per day. everyday.

5. psychological therapy:

    Consulted psychiatrist or psychologist if the patient had a psychological problem.

6. social and vocational

    Consulted social worker if the patient had a social or vocational problem.

DURATION OF STUDY

In this study, the functional outcome was measured by a standard scale; the Barthel Index. The functional assessment was done at 1st admission to the Rehabilitation Ward prior to discharge and every month until the 6th month after the onset of disease. 90 percent of the neurological recovery had occurred by the end of 3 months following the onset of the stroke[12].

BLIND

The evaluation of the patients in both groups used blinded observers. The observer were physical therapists who did not know the patients before. All patients were changed their clothes and wore the inpatient hospital clothes, therefore, the observers did not know the patients. The Barthel Index was used by the two observers independently.

COMPLIANCE

1. Trial group

Compliance was a major problem of the trial group. The relatives must co-operate in treatment and the patients must come to follow up every month.

1.1 Co-operation of relatives in treatment

The investigator explained the importance of the home program. A checklist for the number of treatments and duration of treatment of relatives were created. When the relatives treated the patient, they must check the checklist every time. The patients were followed up every month. The investigator evaluated the checklist for compliance. The validity of checklist was tested by visiting the patients at home to see whether they really carried out the treatment.

1.2 Following the patients

When the patients came to follow up, they would receive incentives (eg. free treatment, support for travel expenses). If the patients did not attend for the follow up, the staff would go to visit them at home.

2. Control group

2.1 Co-operation of rehabilitation staff in treatment

For the control group, a checklist for the number of treatments and duration of treatment of physical therapy and occupational therapy were created. When the rehabilitation staffs treated the patient, they must check the checklist as well.

2.2 Following the patients after discharge

The control group received incentives as well as the trial group and if they did not attend for the follow up, the staff would go to visit them at home.

CO-INTERVENTION

. Some patients might receive traditional massage or the outpatient rehabilitation program from another hospital. The patient was asked about other treatments when they came to follow up. The co-intervention occurring from treatment of staffs was controlled by asking staffs to follow the protocol strictly.

CONTAMINATION

The Srinagarind Rehabilitation Center was the largest rehabilitation center in the northeast of Thailand. This center was the only center that can treat the patient in a rehabilitation ward. The trial group did not received a full rehabilitation program by admission from surrounding hospitals.

SAMPLE SIZE

This study was done in two independent groups; a conventional rehabilitation program in the hospital and a rehabilitation home program.

For calculating the sample size, the outcome of each method was categorized in two groups; total independence and non total independence.

The outcome was a nominal scale. The proportion of total independence patients per total patients of each method was calculated. The formula for calculating sample size in this study was

$$n/gr. = \frac{2 (Z\alpha + Z_\beta)^2 \ \pi (1-\pi)}{(\pi_c - \pi_t)^2}$$

$Z\alpha$ = type I error = 5% = 1.96

Z_β = type II error = 10% = 1.28

π_c = expected event rate in control group

π_t = expected event rate in trial group

π = $(\pi_c + \pi_t)/2$

From literature review, π_c , π_t will be estimated:

π_c = 0.8 π_t = 0.6

n/gr = 110 cases , drop out 20%

.. n/gr = 132 cases

MEASUREMENT

Variable to be measured

1. Functional assessment

The functional assessment was a primary outcome to be measured. To assess the basic function, the activity of daily living (ADL) was used as the indicator. There were many methods to measure ADL. In this study the Barthel Index was selected because it was simple and designed for measurement of moderate to severe disability that was compatible with a stroke patient. It was a high validity and reliability scale.

Instrumental design

The Barthel Index, developed in 1965 by Barthel and Mahoney, consisted of 10 activities of daily living (ADL.) variables in which the patient received a score [13]. Items were weighted according to importance. For example, continence was weighted heavily as the incontinent client was seen as socially unacceptable to many persons in the environment. The values for each item were based on the time and amount of assistance needed by the patient in performing an activity. Score ranged from 0 to 100. Score of 100 implied complete independence for this range of activity. A score of 60 or less indicated severe disability [14].

Validity and reliability

The Barthel Index had been shown to have both high test re-test reliability and interpersonal reliability. Granger, Albrecht, and Hamilton[15] reported test re-test reliability of 0.89 and inter personal reliability of 0.95. High internal reliability had also been found in studies at the Hebrew Rehabilitation Center for the aged (alpha scores of between 0.953 and 0.965)[16].

A number of construct validity results had been reported for the Barthel Index. The scale was highly correlated with both the Katz scale and the Kenny Self-Care Evaluation [17], and the Pulses Profile[18] . For patients in a comprehensive stroke program, the admission Barthel Index score discriminated between those who died and those who survived [19,20]. The scale also predicted the likelihood of discharge home. Those with a score of 60 or less were less likely to be discharged home than those with a discharge score of more than 60[21,22].

2. Recovery time

The recovery time was time from onset of stroke to independence stage. The recovery time was compared between the two groups.

DATA COLLECTION

All stroke patients had been recorded the demographic data of patient, demographic data of caregiver and neurological status of patient.

1. Demographic data

1.1 Demographic data of patient eg. age, sex, marital status, education, occupation and underlying disease was recorded.

1.2 Demographic data of caregiver eg. relationship with patient, age, sex, marital status, education, occupation.

2. Neurological status

Information concerning neurological status at stroke onset including etiology of stroke (thrombosis, emboli), side of infarction (dominant, nondominant), side of paresis (right, left), severity of paresis (plegia, paresis), presence of aphasia, dysarthria, and impair joint position sense were recorded.

DATA ANALYSIS

Survival Analysis

The patients who were assessed by the Barthel Index were classified into 2 groups. The score of 60 or less indicates dependent group and the score more than 60 indicates the independent group. The outcomes were dichotomous data. The outcomes were measured every month until 6 months. Some patients might be lost to follow up. The appropriate statistical method was Survival Analysis.

Subgroup Analysis

The demographic data of patient, relative and information concerning neurological status was analyzed in subgroup analysis.

ETHICAL CONSIDERATIONS

This study was performed under informed consent and ethical committee permission. The rehabilitation home program was routine practice when the patients can not be admitted. The benefit of patients who received only a rehabilitation home program had never been studied however it was not harm to the patients.
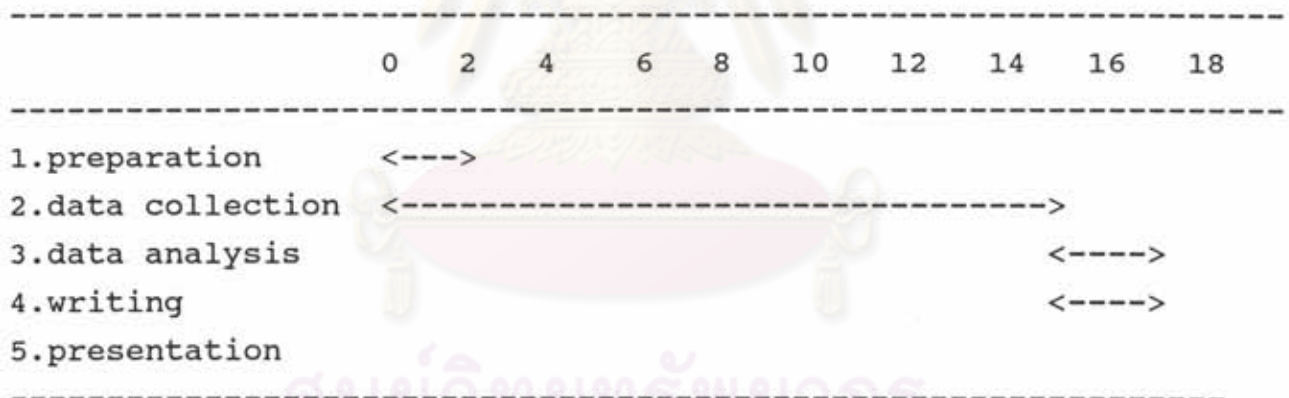
LIMITATION

The most important limitation was compliance of patient and staff. However this study tried to control it as was mentioned in research methodology.

EXPECTED BENEFIT AND APPLICATION

If the results of the conventional program in the hospital are not different from the home program, the home program should be considered the alterative way to manage patients to be admitted to a rehabilitation department. The home program will decrease hospitalization time and hospitalization cost.

ADMINISTRATION AND TIME SCHEDULE

There were about 30 cases per month. The total sample size was 264 cases. The patients would be collected within 8.8 months. The follow up time was 6 months. The total time for data collection was 14.8 months.

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---------------------------------------------------------------
                    0    2    4    6    8   10   12   14   16   18
---------------------------------------------------------------
1.preparation      <--->
2.data collection  <--------------------------------->
3.data analysis                                      <---->
4.writing                                            <---->
5.presentation
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BUDGET

	Bahts	US$
1. personnel		
1.1) two observers	13,000	520
2. subject cost		
2.1) travel expenses	80,000	3,200
264 subjects		
6 follow up per person		
3. transportation facilities	20,000	800
monitor, supervision		
4. Other cost		
office facilities, final report	10,000	480
Total	125,000	5,000

Rate of conversion 1 US$ = 25 Bahts

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