CHAPTER 3
METHODOLOGY

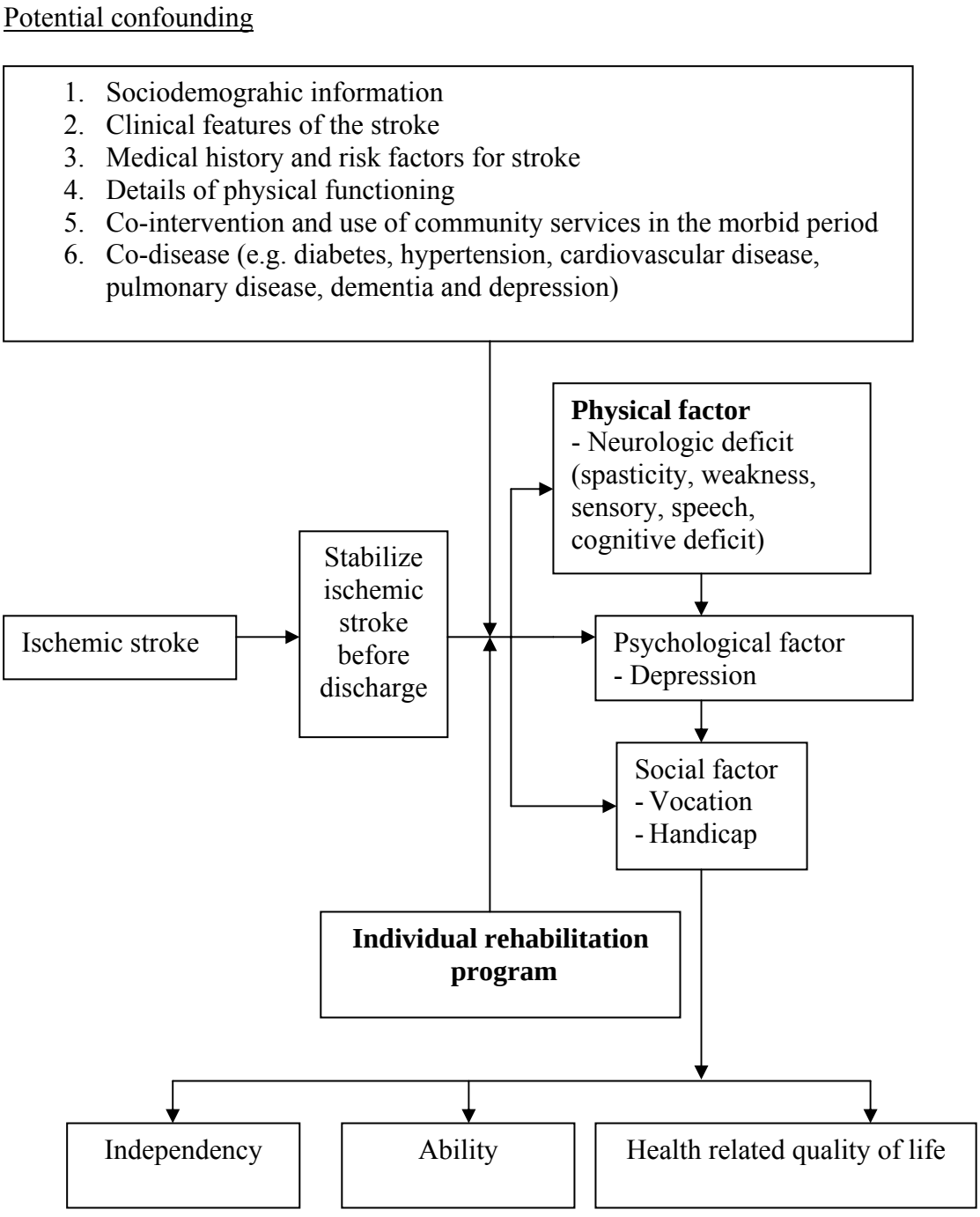


Figure 4 Conceptual Framework

Aims of the Study

General aims

The general aims of this study were to develop and evaluate the effectiveness of home rehabilitation program for ischemic stroke in the population under Thammasat university hospital.

Specific aims

The specific aims of this study were to:

1. Develop the home rehabilitation program based on principles of exercise physiology and motor learning and to deliver it in the home to individuals with ischemic stroke

2. compare the independency occurrence between with (intervention group) and without home rehabilitation program (control group) by the Barthel Index at 1 month, 2 months and 3 months.

3. compare the of ability occurrence between with (intervention group) and without home rehabilitation program (control group) by Modified Rankin Scale at 1 month, 2 months and 3 months.

4. compare the of quality of life occurrence between with (intervention group) and without home rehabilitation program (control group) by utility index (EQ-5D) at 1 month, 2 months and 3 months.

Hypothesis of the Study

The home rehabilitation program would be able to improve activity daily living (ADL), reduce disability and increase quality of life of stroke patients.

Design

This is randomized control trial (RCT). All eligible subjects gave informed consent. The Thammasat University Institutional Review Board approved this study.

Subjects

Ischemic stroke patients were recruited from in-patient wards at Thammasat University Hospital from May 2007 to June 2008. They were consecutively screened for eligibility around 3 days after onset.

The main inclusion criteria for the trial were

(1) Ischemic stroke
(2) Willingness to participate
(3) Provide informed consent
(4) Living within 50 miles of the hospital

Patients were excluded if they had

(1) Uncontrolled hypertension
(2) Severe dysphasia
(3) Severe cognitive impairment
(4) Being discharged to residential care
(5) Previous disability in self-care
(6) Living in a nursing home prior to the stroke.

Discontinuation criteria were

(1) Dead
(2) Willingness to terminate
(3) Performed for 3 months after the baseline assessment

Outcome assessment

Stroke severity was assessed with the National Institute of Health Stroke Scale (NIHSS), a brief screen of upper and lower motor function, proprioception, balance, and cognition. It is reliable, valid, and predictive of 3-month stroke-related outcomes (Goldstein & Samsa, 1997).

The Barthel index (BI) is weighted scale of 10 items of basic activities of daily living. The range possible score of the BI is 0 to 100 and equal or more than 95 is independence care (Sulter, Steen, & Keyser De, 1999; Uyttenboogaart, Stewart, Vroomen, Keyser De, & Luijckx, 2005).

Modified Rankin Scale (MRS) provides an assessment of the degree of disability. Minor strokes are considered Grades 0 to 2; major strokes are Grades 3 to 5, while fatal is 6 (Sulter, et al., 1999; Uyttenboogaart, et al., 2005).

EQ-5D on the 5-distinct dimensions is mobility, self-care, usual activities, pain/discomfort and anxiety/depression, the 2 parts of a researcher interesting are outlined, 1) the 5 EQ-5D dimensions comprise 3 levels, generating a total of 243 theoretically possible health states and 2) EQ VAS: the EQ VAS offers a simple method for obtaining and scoring self-rating of current health status. The EQ-5D can be informative in describing the dynamics of Health-related Quality of life during treatment and follow-up (Brooks, Rabin, & Charro de, 2005)

Baseline Assessment

The assessor collected baseline data before randomization. This included sociodemographic information, clinical features of the stroke, medical history and risk factors for stroke, details of physical functioning, and use of treatment services in the morbid period. The National Institute of Health Stroke Scale (NIHSS) was used to assess the stroke severity, a brief screen of upper and lower motor function, proprioception, balance, and cognition. It is reliable, valid, and predictive of 3-month

stroke-related outcomes. TMSE was used to assess the dementia. The Hamilton and HADs were used to assess, respectively. The Barthel Index (BI) is weighted scale of 10 items of basic activities of daily living. The range possible score of the BI is 0 to 100 and equal or more than 95 is independence care. Modified Rankin Scale (MRS) provides an assessment of the degree of disability. Minor strokes are considered Grades 0 to 2; major strokes are Grades 3 to 5, while fatal is 6. EQ-5D on the 5-distinct dimensions is mobility, self-care, usual activities, pain/discomfort and anxiety/depression, the 2 parts of a researcher interesting are outlined, 1) the 5 EQ-5D dimensions comprise 3 levels, generating a total of 243 theoretically possible health states and 2) EQ VAS: the EQ VAS offers a simple method for obtaining and scoring self-rating of current health status. The EQ-5D can be informative in describing the dynamics of Health-related Quality of life during treatment and follow-up.

Randomization

Eligible patients were stratified by gender and age (≤ 40 years, > 40 years). Hence, the participants were divided into the following 4 categories: male/ ≤ 40 years, female/ ≤40 years, male/ > 40 years, female/ > 40 years. In each stratum, each individual was numbered consecutively. These numbers had been previously randomized to the intervention group or control group equally. And then randomly allocated to receive the home rehabilitation program as the intervention group or to receive usual care as the control group after obtaining the inform consents.

This method was used to ensure that the number of patients who were allocated to the intervention, which would have resulted in a significant bias in the study. In addition, block randomization allowed fair allocation of independent person against the potential bias due to changing practice over 3 months duration of the study, which would have resulted from uneven recruitment between intervention at the beginning or the end of the study.

The randomization was done by opening envelop in which the treatment assignment was given, using a random number table and block randomization in fixed box of each strata. The allocation schedule was prepared using random table numbers

in blocks of 4 before the study began. The block size of 4 was used with 1:1 allocation and two treatment arms. The two arms will never differ at any time by more than two patients, or half of the block length. There are six possible assignment orders for each block of four patients: AABB, ABAB, ABBA, BAAB, BABA, and BBAA. Because important prognostic factors will be balanced, stratified randomization can decrease the chance of a type I error and can increase the power.

Intervention group

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 visit 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.

Control group

The patients in the control group and family members were given instruction for home rehabilitation prior discharge from hospital and received usual care after being discharged, which may include outpatient rehabilitation on the discretion of

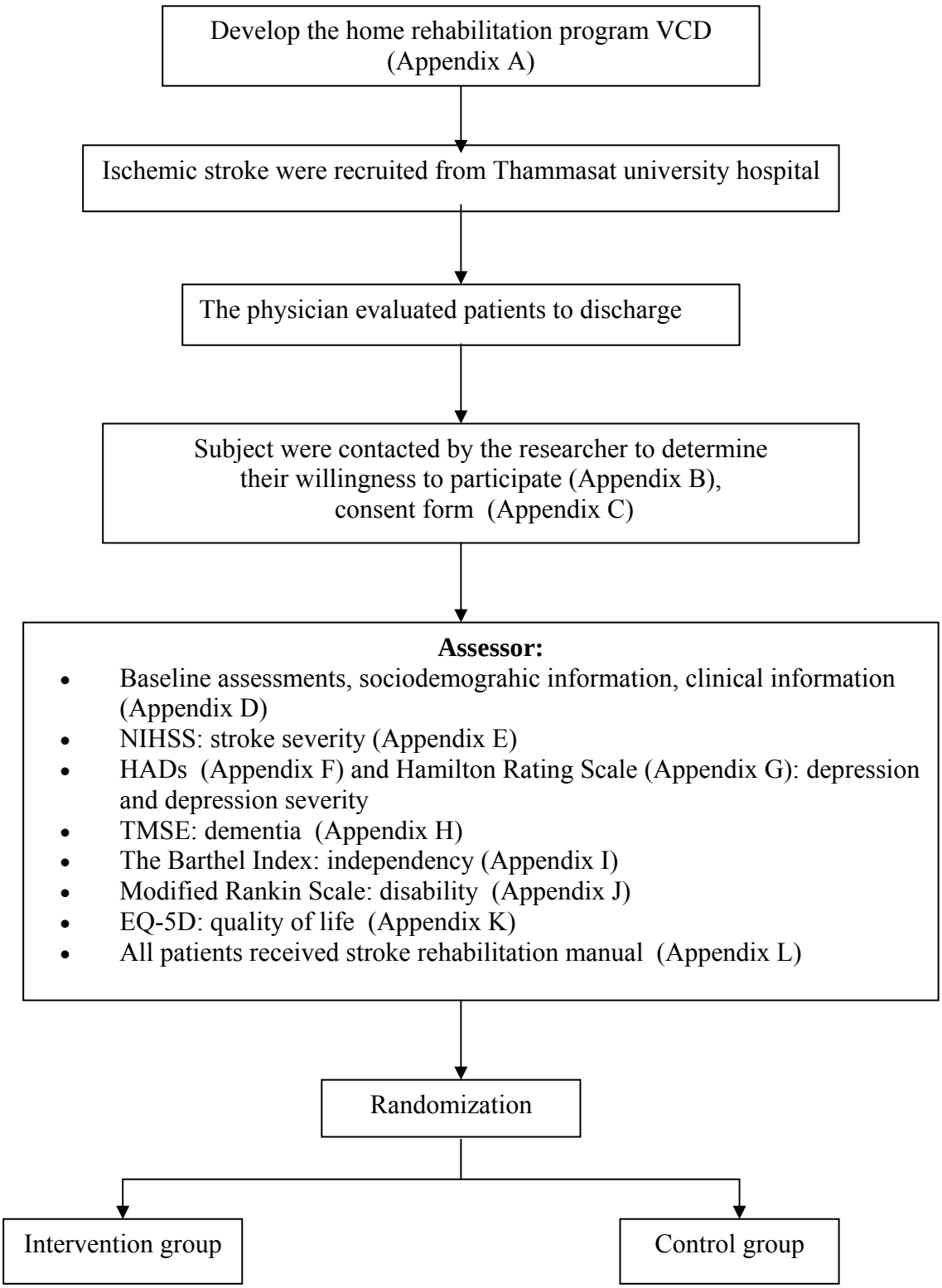
their physicians. Other treatments will be recorded in case report form. Control group did not include follow-up home visits.

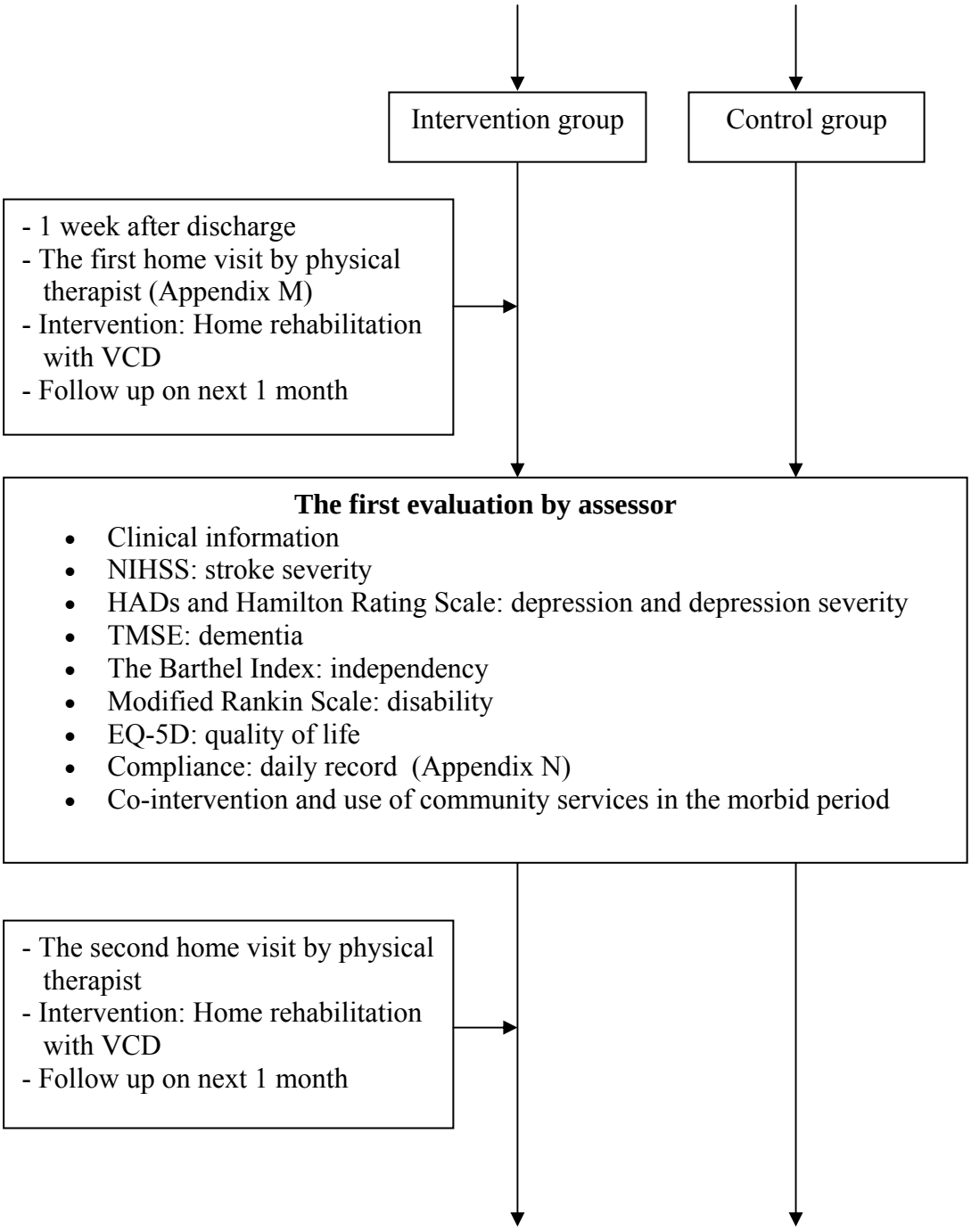
Usual care

1. Subjects had services as prescribed by their physicians:
2. All patients had physical therapy when they were admitted at hospital.
3. The patients and family members were given instruction for home rehabilitation prior discharge from hospital.
4. The patients may include outpatient rehabilitation on the discretion of their physician.

Follow-up

Follow-up visits at patient's residents were scheduled at 1, 2 and 3 months after discharged from hospital. All patients and caregivers were interviewed and evaluated at their residents. 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. The assessor had adequate training and accredited on using NIHSS and MRS scales.


Develop the home rehabilitation program VCD (Appendix A)
Ischemic stroke were recruited from Thammasat university hospital
The physician evaluated patients to discharge
Subject were contacted by the researcher to determine their willingness to participate (Appendix B), consent form (Appendix C)
Assessor:
Baseline assessments, sociodemograhic information, clinical information (Appendix D)
NIHSS: stroke severity (Appendix E)
HADs (Appendix F) and Hamilton Rating Scale (Appendix G): depression and depression severity
TMSE: dementia (Appendix H)
The Barthel Index: independency (Appendix I)
Modified Rankin Scale: disability (Appendix J)
EQ-5D: quality of life (Appendix K)
All patients received stroke rehabilitation manual (Appendix L)
Randomization
Intervention group
Control group


Intervention group
Control group
- 1 week after discharge
- The first home visit by physical therapist (Appendix M)
- Intervention: Home rehabilitation with VCD
- Follow up on next 1 month
The first evaluation by assessor
Clinical information
NIHSS: stroke severity
HADs and Hamilton Rating Scale: depression and depression severity
TMSE: dementia
The Barthel Index: independency
Modified Rankin Scale: disability
EQ-5D: quality of life
Compliance: daily record (Appendix N)
Co-intervention and use of community services in the morbid period
- The second home visit by physical therapist
- Intervention: Home rehabilitation with VCD
- Follow up on next 1 month

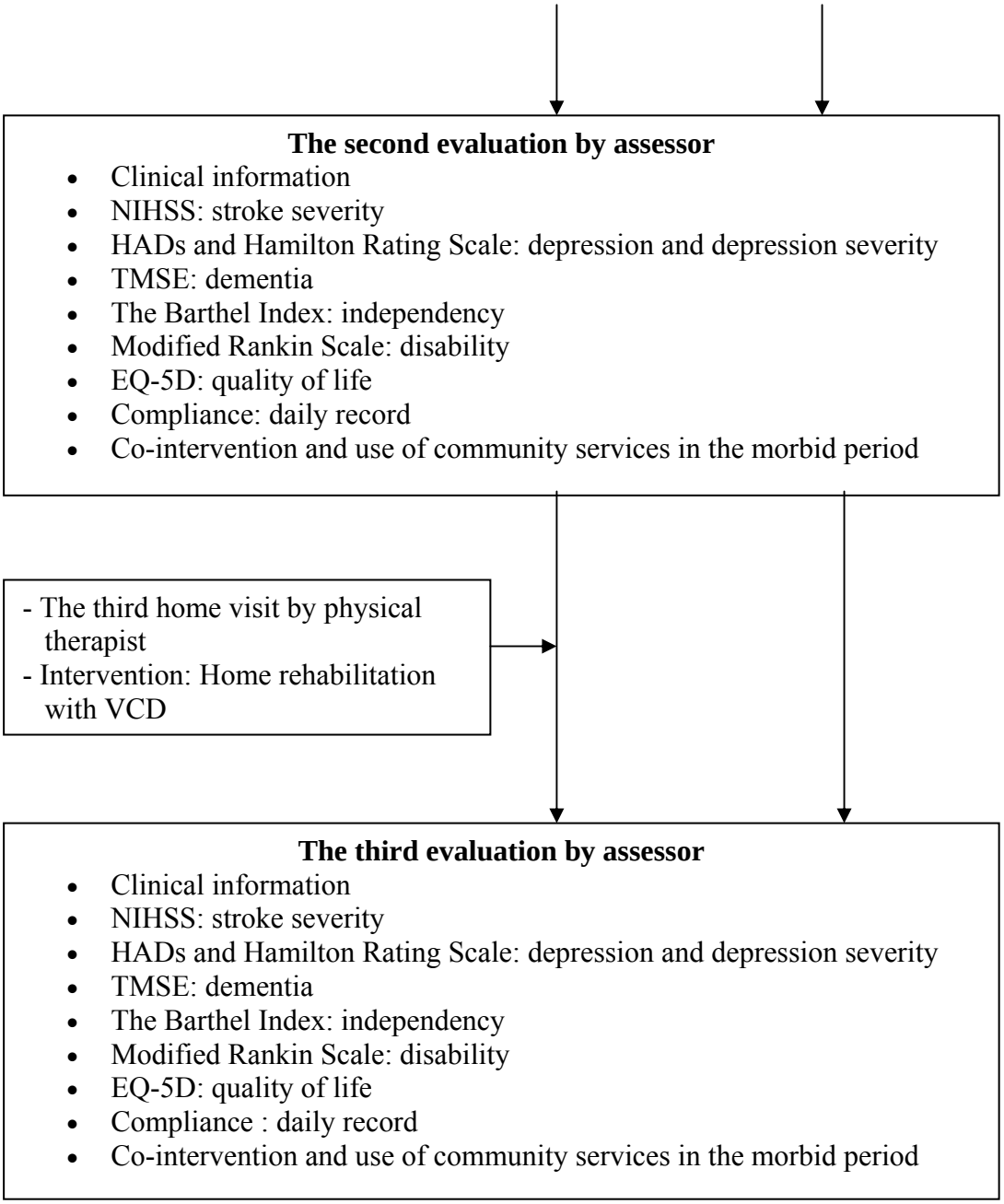


Figure 5 Procedures

Sample size (Studenski, Duncan, Perera, Reker, & Lai, 2005)

The Formula was

$$n \geq \frac{2\sigma^2 (Z_{\alpha/2} + Z_{\beta})^2}{(\mu_1 - \mu_0)^2}$$

n = sample size

Z_α = 1.96 at $\alpha = 0.05$

Z_β = 0.84 at $\beta = 0.20$

σ = population standard deviation ($\sigma = 6.7$)

μ_0 = a priori estimate of population mean in control group ($\mu_0 = 89.6$)

μ_1 = a priori estimate of population mean in intervention group ($\mu_0 = 94.4$)

N = 30.6

The number of patients needed for the study was calculated a priori to ensure sufficient statistical power. The variance and effect size needed to calculate the numbers of patients were estimated from the results of a randomized controlled trial for subacute stroke survivors (6). This revealed that a sample of 30 patients was necessary to achieve an 80% chance (power=0.80) of detecting a 20% difference (α=0.05) in improvement between the two groups in the main outcome measure (Barthel Index).

Statistical Analyses

Data were analyzed by STATA for windows version 10 software. 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 as Barthel Index and utility index 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.

Outcomes were classified into one of four categories: minimal or no disability (score on BI, 95 to 100 or score on MRS, 0 or 1), moderate disability (BI, 55 to 94 or MRS, 2 or 3), severe disability (BI, 0 to 54 or MRS, 4 or 5) and death. Undesirable outcome is defined as BI less than 95 or MRS grade 2 to 5. A favorable outcome was defined as minimal or no disability, as measured by scores of 95 or 100 on the BI and 0 or 1 on the MRS.

Ethics (Appendix O)

The study was approved by the ethics committee of Faculty of Medicine, Thammasat University, Pathumthanee, Thailand.

Table 2 Study Time Frame

Timing / Activities	June 2006 – February 2009																
	Jul Aug 2006	Sep Oct 2006	Nov Dec 2006	Jan Feb 2007	Mar Apr 2007	May Jun 2007	Jul Aug 2007	Sep Oct 2007	Nov Dec 2007	Jan Feb 2008	Mar Apr 2008	May Jun 2008	Jul Aug 2008	Sep Oct 2008	Nov Dec 2008	Jan Feb 2009	Note
Develop tool (VCD)	←	—	→														
Pilot study				←	—	→											
Study the effectiveness of home rehabilitation							←	—	—	—	—	* →					Delayed 2 months and follow up for 3 months
Writing: Journal and Thesis													←	—	—	→	
Presentation																↔	

* Data Analysis