CHAPTER IV

RESEARCH METHODOLOGY

4.1 Research Design

A randomized controlled trial (RCT) design with cluster randomization was chosen for this study, to compare two sets of patients, the experimental or treated group, and the control or comparison group. In addition, this method was chosen so as to avoid systematic error (bias) (Fletcher, et al., 1996).

4.1.1 Design Overview

Target population was epileptics inhabited in Nakhon Ratchasima Province who intended to be treated and followed up at a community hospital (CH). There were two levels of sample selection, the hospital and the individual epileptic levels. CHs were recruited if they fulfilled all of the following eligibility criteria: 1) not an internist or pediatrician; 2) had at least 20 registered epileptics and agreed to participate. For the individual epileptic level, after hospital agreement, the registered epileptics in the participating hospitals were invited by mail to participate. The registered epileptics who did not receive the letter of invitation and the unregistered epileptics were invited when they visited the CHs. All eligible epileptics were recruited into the study.

4.1.2 Population and Sample

4.1.2.1 Target Population

The target population (sampling frame) was epileptics of all ages who were diagnosed by a physician, and who intended to be treated and followed-up at the CH. All patients must have lived in Nakhon Ratchasima Province for at least 6 months before the beginning of the study, even though their names were not listed in the local population census. Epileptics who left this area over the past six months before the beginning of the study were excluded because they might have moved out permanently.

4.1.2.2 Study Sample

The study samples were epileptics who met the following criteria:

4.1.2.2.1 Inclusion Criteria for Intervention and Control Groups

1. Epileptics with cryptogenic unprovoked epilepsy of unknown etiology or with remote symptomatic unprovoked epilepsy or with idiopathic unprovoked epilepsy of unknown etiology who visited CHs.

2. Treated patients with seizure occurring of at least once during the previous two years.

3. Treated patients who were seizure-free for at least 2 years and wanted to continue with treatment.

4. New patients with seizure occurring at less once in the previous year.

5. New patients with seizure occurring less than once in the previous one year who wanted to take antiepileptic drug (AED) medication.

6. Those who decided to participate.

4.1.2.2.2 Exclusion Criteria for Intervention and Control Groups

1. Patients with acute symptomatic or situation-related epilepsy.

2. Patients with unprovoked epilepsy associated with progressive neurological conditions.

3. Patients with status epilepticus at the first visit.

4. Patients who were pregnant.

5. Patients with severe mental retardation (inability to do any activities of daily life by themselves and inability to communicate with other people).

6. Patients with severe disability (chair-bound or bed-bound).

7. Patients with alcoholism.

4.1.2.3 Sampling Technique

A cluster sampling technique was used in this study (Piaggio, et al., 2001). This study was about healthcare system assessment, aiming to compare conventional care (CC) and SC at CHs. For sampling, CHs were selected for the SC intervention process. It was not feasible to use individual epileptic sampling and randomization, therefore the cluster (CH) was used for sampling and randomization. All hospitals were listed, but only the CHs were selected. CHs that had no internist or pediatrician; and had at least 20 registered epileptics, were invited to participate. Since this study

intended to evaluate the healthcare process in GP-based hospitals, the provincial hospital and CHs with pediatricians or internists were not enrolled. On the other hand, CHs with fewer epileptics were difficult analyze. Therefore, at least 20 epileptics registered in each CH were required. All of the participating CHs were recruited into this study. After that, epileptics who had their names registered in the participating CHs were invited to join the study by mail. The registered epileptics who did not receive the letter of invitation, and the unregistered epileptics, were invited when they visited the CHs.

4.1.2.4 Consent

4.1.2.4.1 Hospital Consent

Two stages of hospital consent were applied to this study. The first was when the Director of an eligible CH decided to participate in the study by phone. The second was when the Director and all of the GPs at the hospital signed a hospital consent form after the education program.

4.1.2.4.2 Patient Consent

Letters of invitation to participate in this study were sent to all registered epileptics whose hospitals accepted participation. The letter consisted of two pages; one was about the study objectives, process and benefits, while the other was the consent form. Patients who agreed to participate in the study would sign the mailed consent form and go to their CHs to give their personal and epilepsy information. They were asked to sign another consent form to be kept in the hospital file. To include all of the epileptics, non-registered cases, new cases, and registered cases,

who did not receive the invitation letter, a responsible nurse at each CH was informed to look for and approach all epileptics who visited CHs. If they accepted, they would sign the consent form and give their information to the responsible nurse. For children younger than 18 and epileptics with mental abnormality, their parents or caregivers would sign the consent on their behalf.

4.1.2.5 Sample Size Calculation

The primary outcome was the number of epileptics with regular follow-up during the one-year study. Type 1 error (α) was determined at 5% significance level. Type 2 error (β) was determined at 10% and then the power of the significance test was 0.9 (90%). The chosen magnitude of difference was 50%. The null hypothesis for this study was P1=P2, where P1 was the estimated current percentage of adult patients (male and female) with regular follow-up. In accordance with our previous study (Asawavichienjinda, et al., 2003), P1 was 56.9%. P2 was the anticipated percentage of patients with regular follow-up. According to the assigned magnitude of difference, P2 was 85.4%. The calculated sample size for each group was 55 subjects (calculated by the formula of 2 independent groups with categorical data; the formula was (Dupont & Plummer, 1990):

$$\text{n/group} = \frac{[2(Z\alpha+Z\beta)^2 \bar{P} (1-\bar{P})]}{(P1 - P2)^2}$$

$$Z\alpha = 1.96$$

$$Z\beta = 1.28$$

$$\bar{P} = (P1 + P2)/2$$

Because of the design effect (cluster sampling technique) (Piaggio, et al., 2001), a percentage of 10% for the cluster effect was chosen in this study, so that the adjusted sample size was 61 subjects/group.

According to the previous study (Asawavichienjinda, et al., 2003), gender affected regular follow-up. The sample size for each gender, therefore, was calculated as follows:

4.1.2.5.1 Male Sample Size

The P1 for the adult males was in accord with our previous study, at 55.2%; P2 was 82.8%. The calculated sample size for each group was 55 subjects. Because of design effect, the adjusted sample size for the males was 63 subjects/group.

4.1.2.5.2 Female Sample Size

The P1 for the adult females was 58.1% and the P2 was 87.2%. The calculated sample size for each group was 46 subjects. Because of the design effect, the adjusted sample size for the females was 51 subjects/group.

In conclusion, the sample size for males was 63 and for females 51; therefore, the total sample was 114 in each group.

4.2 Research Procedure

4.2.1 Study Setting

4.2.1.1 Organization of the Community Hospitals and District Health Offices

There were two stages for hospital consent. At the CH, first, the hospital directors of the eligible CHs were informed briefly about the objectives and procedures of the study. If they agreed to participate, the principal investigator (PI) would proceed by calling the Heads of the District Health Offices (DHOs). If they also agreed, an educational meeting would be arranged.

For this educational program, the Hospital Director and the physicians at the CH were asked to join the meeting. They were informed about the detailed objectives, procedures of the study and the benefits for primary healthcare teams and epileptics. After that, they asked questions, discussed, and gave their opinions and suggestions.

After the meeting, the Hospital Director and the GPs were asked for their agreement to participate in this study and they signed the consent form.

The participating CHs and DHOs were stratified by the number of registered epileptics into three strata, 20-50, 51-99 and $\geq$100. Stratification was based on the number of hospitals, with even numbers for each stratum and the same number of epileptics between two groups.

In each stratum, the code of each hospital was written on different ping-pong balls collected in a tin cylinder. Ping-pong balls in the tin were randomly drawn one by one until all had been removed. The sequence in which the ball was drawn indicated the hospital sequence. After that, another two ping-pong balls for random allocation were marked as CC for Conventional Care or SC for Shared Care. The two ping-pong balls for random allocation to CC or SC were drawn one by one for allocation of the first sequence of hospitals for each stratum. If the ball inscribed with CC was drawn, it meant the first sequence of hospitals was allocated to CC; the second sequence would be SC, and the third CC again, alternating to the last hospital in each stratum.

4.2.1.2 Structure of the Study Unit

At each participating CH, a responsible nurse, who would be responsible for the epileptics, was appointed. They were provided with the educational program. The nurse's responsibility was to send the name and address of all registered epileptics at her CH to the PI. Upon receiving them, the PI would proceed to send the letters of invitation to each epileptic. The PI sent an invitation letter, enclosing a consent form, to the epileptics' homes for signature if they were willing to participate. The letter also informed them of the upcoming scheduled appointment to visit their CH with the signed consent form. If they were not available on the scheduled day, they could come before they ran out of AED, or any week the clinic was operating.

To avoid epilepsy registration error at the CHs, since they might include non-epileptics and patients who were already lost to follow-up, the responsible nurse was

asked to fill out the questionnaire created by the PI based on the information from the OPD card. These completed questionnaires were then sent to the PI, verified and confirmed again at the annual review. In addition, to catch all patients who were not previously registered, the responsible nurse was encouraged to invite the epileptics when they visited the CH.

The invitation period was 3 months from the initial study, because normally, physicians would make the next appointment for the epileptics, up to three months.

After the epileptics signed the consent form, the responsible nurse would request and gather the epileptic's information and, then send him/her to see a GP. The responsible nurse then copied the consent form with the patient's signature and the patient's information, and sent them to the PI. The ineligible epileptics were verified again at the annual review. The original consent form, patient information, and follow-up sheet, were collected in a patient file (colored yellow for CC and pink for SC). If the responsible nurses had any questions, they could contact the PI directly by mobile phone; the PI kept in contact with them regularly by phone.

4.2.1.3 Work Pattern of Nursing Personnel in Conventional Care

At the outpatient department of a CH, the responsible nurse asked for the main complaint and, recorded it on the OPD card or the patient's file on the computer, and filled in the follow-up sheet designed for this study. After that, the nurse sent the patient to a GP's room for physical assessment. After assessment, the patient came out and was given the next appointment date by the nurse.

At the due appointment date, if the patient did not come, the nurse would send a post card to remind the patient to follow the appointment schedule.

4.2.1.4 Work Pattern of the Physicians in Conventional Care

When the epileptic came to the GP's room, the GP conducted a physical assessment and prescribed medication according to the patient's symptoms and signs, and then made an appointment with the epileptic in one or two months, for example. After leaving the GP's room, the epileptic received the exact date for the next follow-up from the responsible nurse and medication from the hospital pharmacist.

4.2.2 During the Study

Every three months, the problem-based education (PBE) training session was held at the CH in the SC group. Before the session, the questionnaire evaluating the usefulness of treatment review and immediate feedback must have been completed by the GPs.

The study period started in two different periods, June 2001 to May 2002 and January to December 2002. These covered the period (May) in which the GPs could switch their positions across CHs, and some might take study leave or resign from the CHs. The vacant positions would be replaced by newly incoming GPs. Before the GP's relocation, the questionnaire evaluating the usefulness of the PBE training session for the SC group and the questionnaire evaluating communication between GPs across the treatment groups were sent to the GPs for completion. The education program for this study was provided to new (replacing) GPs.

4.2.3 Annual Review

Three months before the end of the one-year study, the PI, the participating GPs and the responsible nurses had agreed on the date on which the PI would visit the CHs for the annual review. A two-day annual review would be conducted for the CHs with 50 epileptics or fewer, and a three-day review would be conducted for those with more than 50 epileptics. The date was set three months prior to the annual review because the responsible nurses and the GPs would then have enough time to make appointments with the epileptics at the annual review date and prevent the GPs from making appointments later than the date of the annual review. In addition, the responsible nurses could inform and invite the epileptics to visit the hospitals on those days so they could see a specialist. If they could not come, they would be asked to report the reason for not visiting the hospital. To remind the GPs and responsible nurses of the date the PI was visiting the hospitals, stickers with the date written on it were sent from the PI to the nurses, to be attached to the cover of the patients' files. To remind the patients, the PI sent reminder letters to them and informed them of the date on which the PI would visit their hospital and invite them over for the annual review.

On the date of the annual review, responsible nurses and those specially hired for this task would take care of the epileptics. The director of the participating CH prepared a meeting room big enough for the PI to do the annual review for all eligible epileptics. The epileptics' OPD cards and files were taken out for review. When the epileptics and their caregivers came, the specially hired nurses would take them to the meeting room, separating them from the other patients visiting the hospital. The

specially hired nurses would then request and write down the patient's chief complaint on the OPD card, or in the patient's file on the computer. The responsible nurse would then fill in the follow-up forms in the patient's file, verify them and give them the final questionnaires for this study. The questionnaires were self-administered but the patient's caregiver or the responsible nurse could help them read if they were illiterate. After finishing the questionnaires, the epileptics were interviewed, examined and advised by the PI. The questionnaire evaluating communication between the GPs across the treatment groups was completed by the GPs, as well. If some eligible epileptics could not visit the hospitals during the annual review, the responsible nurses would ascertain the reason and a letter enclosing a questionnaire asking about their seizure occurrence, and a return envelope to the PI, would be sent to the patients' home addresses, for them to complete and send back to the PI.

4.3 Interventions

4.3.1 Pamphlet and Education

Prior to the study, the PI had taught the responsible nurses how to take good care of epileptics, with details on the following topics: self-care, precipitating factors, impacts of non-compliance with AED, follow-up schedule, activities to avoid, and first-aid management of seizure.

At the first visit, the epileptics were briefed by the responsible nurse about healthcare information in accordance with the training provided by the PI, and received a pamphlet prepared by the PI. On the following visit, the epileptics' own

cases would be explained, and the habits that should be avoided (e.g., to quit drinking or avoid sleep deprivation), if any.

4.3.2 Treatment Review and Immediate Feedback

Copies of the follow-up sheet filled out by the responsible nurse and the GPs were sent to the neurologist for treatment review and immediate feedback if any inappropriate practice was encountered. The immediate feedback letters for inappropriate practices came in three copies; one was kept with the PI, the other two copies were sent to the responsible nurse for retention in the patient's file and passed on to the GP. The neurologist would verify the GPs' practice by using appropriate practice indicators, as reported by Buetow, et al. (1996) (Table 4.1), for example:

- If a patient had recurrent seizure after a precipitating factor, there was no need to increase the dosage of AED.

- Only single AED should be prescribed for new cases.

- Phenobarbital should be prescribed for a patient once or twice daily and phenytoin should be prescribed once or thrice daily.

- If a patient had an adverse reaction to AED and was seizure-free, the dosage of AED should be reduced.

- If a patient still had recurrent seizure despite AED treatment and there were no side effects, the dosage of AED should be increased.

- AED should be changed if a patient still had recurrent seizure and adverse reaction to an AED.

- If a patient had an AED allergy, the AED had to be stopped.

- If a patient still had recurrent seizure despite taking two drugs in combination or the patient had an adverse reaction to AED, the doses of one of the AEDs should be reduced and the patient's clinical picture should be closely monitored.

Table 4.1*: Indicators for appropriate practice

Indicator	Definition
Indication	
-Explicit and valid indication	-The stated reason for prescribing the drug is upheld by the BNF
-No failure to prescribe	-Drugs are always prescribed when and how they should be, according to the recommendation in the BNF
-Drug of limited value	-Drugs of limited value are avoided or the reason for their use is stated in the medical record
Choice of drug	
-Cost minimization	-The drug prescribed is cheaper than alternative treatment(s) but just as safe and effective
-Cost effectiveness	-The benefit : cost ratio is better than for alternative treatments
-Potentially serious interaction	-Potentially hazardous drug-drug interactions, as recorded in the BNF, are avoided or the prescriber explicitly states that potential benefits outweigh risks
-Co-prescribing	-Drugs are prescribed simultaneously to make use of beneficial interactions between them
-Unnecessary duplication	-Drugs from the same chemical or pharmacological class are not prescribed simultaneously
-Adverse drug reaction	-Unexpected drug reactions (type B) are investigated and recorded. Prescribing of the drug is continued only with caution and monitoring
-Contraindication	-Contraindicated drugs, as recorded in the BNF, are not prescribed unless the prescriber explicitly indicates that the potential benefits outweigh the risks
Drug administration	
-Dose	-The total daily amount of the drug prescribed falls within the range stated in the BNF or the prescriber records the reason(s) why
-Dosing frequency and duration	-The dosing frequency and duration of the drug treatment fall within the ranges recommended in the BNF, or the prescriber records the reason(s) why
-Delivery	-The formulation, route and method of delivery are designed to maximize compliance for the individual patient
-Regimen	-The dosing schedule is made as simple as possible
Communication	
-Prescriber-patient	-The prescriber gives information on the drug(s) to the patient
-Prescriber-prescriber	-The medical record contains a comprehensive and accessible list of all prescribed drugs and regular over the counter drugs used by the patient
-Prescriber-pharmacist	-The prescription contain all the information needed for dispensing by a pharmacist
Review	
-Effectiveness	-The prescription produces a beneficial outcome for the patient
-Frequency of review	-The drug treatment is reviewed by the general practitioner at least once a year or in accordance with the guidelines in the BNF

* Buetow, S.A., Sibbald, B., Cantrill, J.A., and Halliwell, S. 1996. Prevalence of potentially inappropriate long term prescribing in general practice in the United Kingdom, 1985-1995: Systematic literature review. B.M.J. 313: 1371-1374.

BNF = British National Formulary

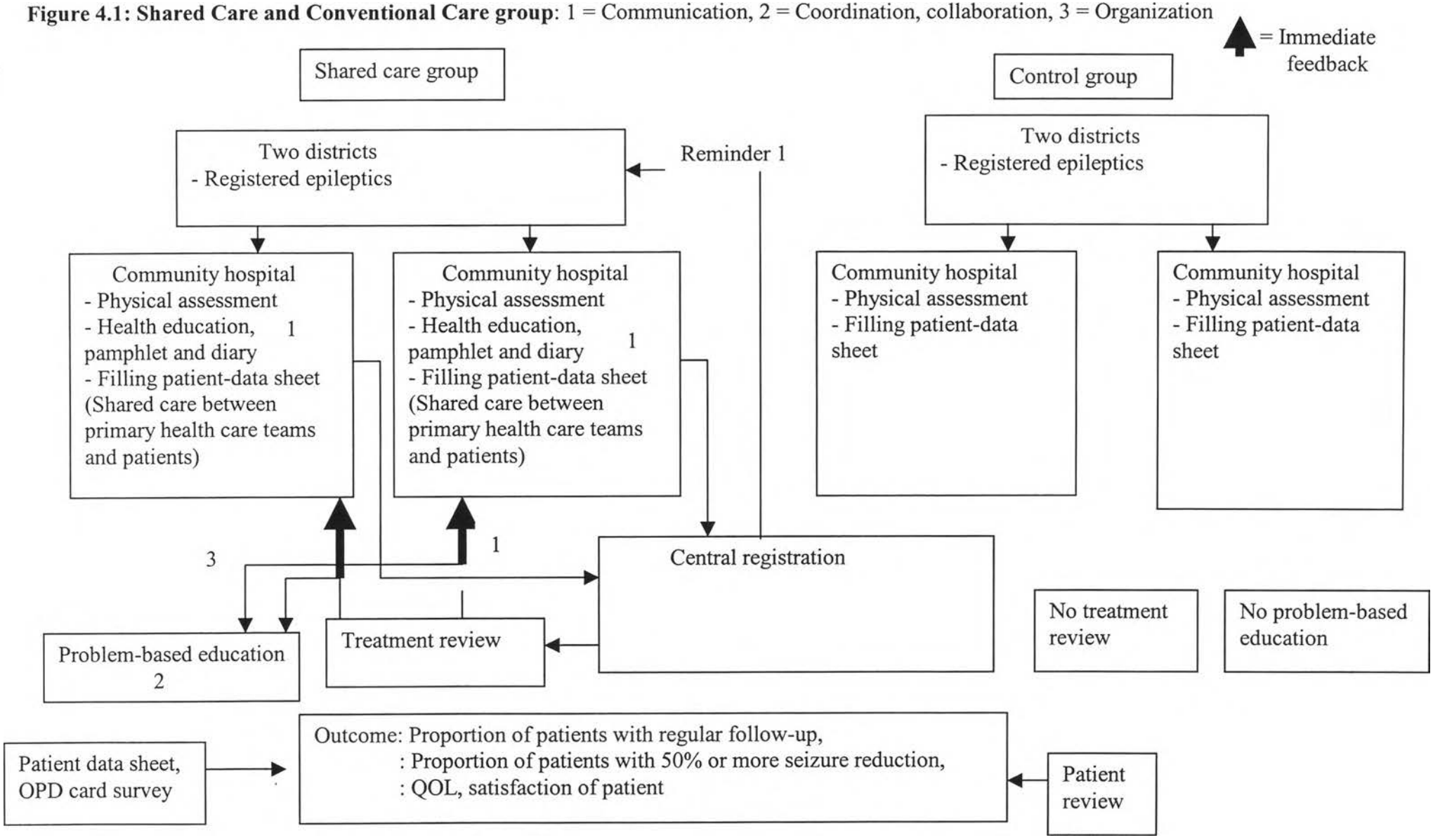
4.3.3 Problem-based Education

Every three months, the inappropriate practices were collected and reviewed. A PBE training session was set up between the GPs and the neurologist at the CH. The first PBE training session was set up one month after the beginning of the study to clarify the processes of the study, to solve problems in the study processes, to provide essential knowledge of how to handle epileptics, and to perform PBE on any inappropriate practices found. The neurologist showed each record of inappropriate practice to the GPs and opened the discussion.

4.3.4 Reminder Letter

Two weeks before the date of the appointment, as shown in the copy of the follow-up sheet of the epileptics sent to the PI at every visit, a postally-registered reminder letter was mailed to the patients to remind them of the appointment date. It was assumed that if the registered letter was not returned, the patient must have received it. In addition, the left corner of the envelope had the PI's name, the Provincial Hospital's name and address, just like an official letter. This would give the receivers the impression that the letter was of high importance, so they would read it or have someone read it for them if they were illiterate. In case the registered letter was returned, the PI asked sub-district health officials or health volunteers in that village to check the patient and his/her address, correct the details and mail it again. The overall SC process is shown in Figure 4.1.

Figure 4.1: Shared Care and Conventional Care group: 1 = Communication, 2 = Coordination, collaboration, 3 = Organization



4.4 Measurements

4.4.1 Measurement Tools

All of each epileptic's information, including management information, was gathered through a questionnaire prepared by the PI. The draft questionnaire was discussed with the responsible nurses and the PI answered questions to ensure congruity of understanding. The questionnaire was filled in by interview technique.

4.4.2 Types of Measurement

4.4.2.1 Independent Variables

The independent variables in this study were as follows: age, gender, prognostic factors (including history of febrile convulsion; family history of epilepsy; mental retardation; perinatal abnormality; history of cerebrovascular disease (CVD); history of head injury; history of central nervous system (CNS) infection; history of craniotomy), type of seizure, concomitant treatments, age of first seizure, duration of epilepsy before treatment, frequency of seizure before treatment, duration of treatment, frequency of seizure at 3- and 12-month intervals before the study, confounding factors covering marital status, educational level, employment status, alcohol drinking, number of AED taken, dosages of AED, and regularity of previous follow-ups.

4.4.2.2 Dependent Variables

The dependent variables were the number of patients with regular follow-up, rate of regular follow-up, seizure frequency, quality of life score, and patient satisfaction.

4.4.2.3 Descriptive Variables

Descriptive variables were all characteristics of the epileptics who signed the consent form to participate in the study compared with those who did not, the usefulness of the SC process, and the reduction of inappropriate practices.

4.4.3 Outcome Measurement

For regularity of follow-up, the data were collected by comparing the real date of the patient visit with the corresponding date of the scheduled appointment on the OPD card or in the patient's file. If a patient came to the emergency ward or in-patient ward and a new appointment date was made, this new date was applied to calculate the regularity of follow-up; otherwise the most recent appointment date was used.

For seizure frequency, a patient diary for recording the number of seizures and the date of occurrence was used. The number of seizures on the OPD card, the computer or the patient's file (for this study) or from the information given to the PI at the annual review, were used together. If there were discrepancies between the data from these sources, the sources were used in the following priority sequence: OPD card, computer, patient's diary, patient's file, and last the information given to the PI. If all of the data were missing, the PI would investigate for evaluation.

For overall evaluation of patient satisfaction, a self-administered questionnaire was administered, by asking whether the patient would recommend his/her friends or relatives with epilepsy to visit this hospital.

For evaluating the quality of life (QOL), the QOL in Epilepsy-31 (QOLIE-31) and the Short Form 36 Health Survey (SF-36), which were self-administered questionnaires, were used. For the QOLIE-31, the score was calculated according to the original paper (Cramer, et al., 1998). The principle was that higher scores represented higher quality of life and the original Likert score was translated to a score ranging from zero to 100. For example, Likert scores of 1, 2, 3, 4 were translated to zero, 33.3, 66.7, and 100, respectively. Each domain was composed of several items; the mean score of each domain was calculated as a summation of the item scores divided by the number of items. The mean score for the total QOL was calculated by using the following formula: (mean score of Overall QOL x 0.14) + (mean score of Social Function x 0.21) + (mean score of Energy and Fatigue x 0.12) + (mean score of Emotional Well-being x 0.15) + (mean score of Cognitive Function x 0.27) + (mean score of Seizure Worry x 0.08) + (mean score of Medication Effect x 0.03).

The other QOL score used was the SF-36, which was a measure of quality of life for general health status. The scoring was translated in the same way as the QOLIE-31. However, the total score for the SF-36 was calculated as a simple summation of all domain scores.

For the processes of the SC, each aspect was evaluated by the following methods:

- A self-administered questionnaire was used to evaluate the usefulness of the pamphlet and education. Respondents were asked how much the education met their

expectations, how much they understood it, and how much they could follow it in their real lives.

- A self-administered questionnaire was used to evaluate the usefulness of the treatment review and immediate feedback process. Respondents were asked whether or not they received the feedback, how much they understood the feedback suggestions, whether or not they agreed, how much the feedback could be applied to their practice and whether they had any suggestions.

- A self-administered questionnaire was used to evaluate the usefulness of the problem-based education training session. Respondents were asked how much they understood the content of the discussion, how much the session helped improve their knowledge, how much could be applied to their practice, and whether or not they had any suggestions.

All of the questions were scored on a five-point Likert-type scale composed of least, less, neutral, more and most. The epileptics responded to the questionnaire on their own. For those with mental abnormality, their caregivers responded to the questionnaire on their behalf. For illiterate epileptics, their caregivers helped them read the questions and then let the epileptics answer on their own. If the epileptics had no caregiver accompanying them, a nurse would help them, instead.

In assessing the inappropriate practices of the GPs, the number of inappropriate practices during each visit were accumulated and compared with the total number of patient visits during the first and last three months of the study.

4.4.4 Measurement Bias

All of the methods used for outcome measurement were prospective recording by hospital personnel who were not related to the study result. Some items, such as QOL and patient satisfaction, were self-reported by the patients (through self-administered questionnaire). For seizure attack, it was reconfirmed with the PI at the end of the study. For illiterate respondents without escorting caregivers, the questionnaires were done with the assistance of a hospital nurse. The PI realized this potential bias.

4.4.5 Co-intervention

The eligible epileptics were asked not to take alternate remedies from health services other than the CHs.

4.4.6 Contamination

For epileptics, it was very difficult to visit the CHs in the other treatment group for two reasons: one was that some CHs were located very far from one another; the other was the 30-Baht Scheme limiting patients' treatment to the assigned CH. Patients needed to visit their responsible CHs for free medication, otherwise they had to pay themselves.

For the GPs, there ay have been communication across the treatment group, so the extent to which they communicated with each other was evaluated at the end of the study.

4.5 Data Collection

Data came from primary sources. The data collection method and data summary are shown in Tables 4.2 and 4.3.

4.6 Statistical Analysis

This study was of randomized controlled trial design, and compared two independent groups, CC and SC. Data came from patient data sheets and OPD cards, which were accurate and complete. The data summary for the continuous data was by mean with standard deviation and standard mean error, with a 95% confidence interval (CI). For categorical data, the data summary was by percentage or proportion and P(1-P)/square root N with 95% CI; for survival data, it was median and 95% CI (Table 4.3).

Relative risk was used for comparative analysis of the categorical data between the two independent groups (Table 4.4). Mean differences were used for comparative analysis of the continuous data between the two independent groups (Table 4.4).

For statistical testing, analysis of the intention to treat was used for assessing regular follow-up, seizure reduction, and patient satisfaction. The McNemar Chi-square was used for analysis of proportional regular follow-up before and after study within each group. The formula for calculating the McNemar Chi-square was:

$$\text{McNemar } \chi^2 = \frac{([B-C]-1)^2}{B+C}$$

Table 4.2: Methods of data collection

Variables		Method
Demographic Variables	Name, age, gender, address	Interview
Confounding Variables	-Marital status, educational level employment status and drinking habit	Interview Interview
	-History of febrile convulsion,	Interview, extracting from records
	-Family history of epilepsy,	Interview
	-Mental retardation,	Interview
	-Perinatal abnormality, history of CVD, head injury, CNS infection, craniotomy before epilepsy	Interview
	-Type of seizure, AED side effect, number and dosages of AED	Interview, extracting from records
	-Age at first seizure, duration of epilepsy and frequency of seizure before treatment	Interview, extracting from records
	-Duration of epilepsy,	Interview, extracting from records
	-frequency of seizure at 3 and 12 months pre-study	Interview, extracting from records
	-Previous regular follow-up	Extracting From records
Co-intervention Variables	Concomitant treatment	Interview, observation
Outcome variables (Medical outcome)	-Patient with regular follow-up (within and between groups)	Interview, extracting From records and
	-Rate of regular follow-up	Prospective recording
	-Patient with 50% or more seizure reduction	
	-Seizure reduction (three months before and the last three months)	
	-QOL score (mean total score and score of each domain of the QOLIE-31 and SF-36)	Questionnaire
Outcome variables (Process of Shared Care)	- Patient satisfaction	Questionnaire
	- Usefulness of the immediate feedback process	
	- Usefulness of the problem-based education	
	- Usefulness of the pamphlet and education	
	- Reduction of inappropriate practices	Observation

Table 4.3: Demonstration of data summary

Variables		Data analysis		
		Data summary		
		Type of data	Central Tendency	Deviation
Demographic Variables	Gender	Categorical	Percentage, Proportion	P(1-P) / square root N, 95% CI
	Age	Continuous	Mean	SD/square root N, 95%CI
Confounding Variables	- Marital status, educational level, employment status and drinking habit - Mental retardation, - Family history of epilepsy - History of febrile convulsion - Perinatal abnormality - History of CVD, head injury, CNS infection and craniotomy - Type of seizure, AED side effect - Number and doses of AED - Previous regular follow-up	Categorical	Percentage, Proportion	P(1-P) / square Root N, 95% CI
	- Age at first seizure, - Duration of epilepsy and frequency of seizure before treatment - Duration of treatment - Frequency of seizure at 3 and 12 months pre-study	Continuous	Mean	SD/square root N, 95%CI
Co-Intervention	Concomitant treatment	Categorical	Percentage, Proportion	P(1-P) / square Root N, 95% CI
Outcome Variable	-Patient with regular follow-up (within and between groups) -Patient with 50% or more seizure reduction -Seizure reduction (three months before and the last three months)	Categorical	Percentage, Proportion	P(1-P)/square Root N, 95%CI
	- Patient satisfaction - Reduction of inappropriate practice	Categorical	Percentage, Proportion	P(1-P)/square Root N, 95%CI
	-QOL score (mean total score and score of each domain of the QOLIE-31 and SF-36) - Usefulness of immediate feedback process - Usefulness of problem-based education - Usefulness of pamphlet and education	Continuous	Mean	SD/square root N, 95%CI
	-Rate of regular follow-up	Ordinal	Median	0.5/square root n effective

Table 4.4: Statistical analysis of outcomes

	Data summary	Data analysis	Statistical test
Medical outcome:			
- Patients with regular follow-up (within and between groups)	- Proportion	- Relative risk - Intention to Treat	- McNemar Chi-square* Chi-square or Fisher's exact
- Time to first irregular follow-up	- Median survival time	- Median survival time difference,	- Log Rank statistic#
- 50% or more seizure reduction	- Proportion	- Relative risk, - Intention to Treat	- Chi-square or Fisher's exact
-Seizure reduction (three months before and the last three months)	- Proportion	- Relative risk, - Intention to Treat	- Chi-square test
-QOL score (mean total score and score of each domain of the QOLIE-31 and SF-36)	- Mean	- Mean difference,	- Unpaired t-test
- Overall patient satisfaction	- Proportion	- Relative risk, - Intention to Treat	- Chi-square or Fisher's exact
- Reduction in inappropriate practice	- Proportion	- Relative risk	- Chi-square or Fisher's exact
Process of Shared Care: - Usefulness of the immediate feed back process - Usefulness of the problem-based education - Usefulness of the pamphlet and education		Descriptive statistics	

* McNemar $\chi^2 = ([B-C]-1)^2 / B+C$

Log Rank statistic is $\chi^2 \cong \frac{\{\sum \text{number of irregular follow-up} - \sum \text{Expected number of irregular in Shared Care}\}^2}{\sum \text{Expected number of irregular in Shared Care}} + \frac{\{\sum \text{number of irregular follow-up} - \sum \text{Expected number of irregular in Conventional Care}\}^2}{\sum \text{Expected number of irregular in Conventional Care}}$