# CHAPTER 4

# RESEARCH METHODOLOGY

## Research Design

A randomized controlled trial of diabetic education in a diabetic clinic at a teaching hospital.

## Research Methodology

1. Population and Sample

The target population was the Thai patients diagnosed as having NIDDM.

The sample were the NIDDM patients seeking care from the diabetic clinic at Pramongkutklao hospital, in Bangkok. The patients were stratified according to the duration of diabetes mellitus and age. They were randomized with the block of 4 in order to minimize the variation of confounders between the groups.

It order to balance the confounders between the two groups, the patients were stratified according to the two distinct predisposing factors, age and the duration of diabetes mellitus. A stratified block randomization

scheme with a block size of four patients was prepared. Each patient was then allocated to one of the four strata and to one of the education strategy based on his or her characteristics.

The four strata of diabetic patients were:

**Stratum 1**: diabetic patients, age $\leq$ 60 years old and had duration of diabetes mellitus $\leq$ 10 years.

**Stratum 2**: diabetic patients, age $\leq$ 60 years old and had duration of diabetes mellitus > 10 years.

**Stratum 3**: diabetic patients, age > 60 years old and had duration of diabetes mellitus $\leq$ 10 years.

**Stratum 4**: diabetic patients, age > 60 years old and had duration of diabetes mellitus > 10 years.

The parameters used for cost-effectiveness analysis included: 1) the cost/patient with a good control NIDDM, and 2) the cost/patient with a significant reduction of HbA1c (equal to or more than one percent).

Eligible Criteria

Inclusion Criteria: Uncomplicated NIDDM patients with the duration of treatment of disease more than 3 months, ages 30-70 years with a fasting plasma glucose level of more than 140 mg/dl at least two consecutive times before entry.

Exclusion Criteria:

1) Insulin dependent diabetes mellitus

2) NIDDM patients with the following conditions: severe obvious visual problems, severe obvious hearing problems, a history of stroke confirmed by physical examination, an evidence of a myocardial infarction detected by electrocardiograph within 6 months before entry, an evidence of a severe renal insufficiency (serum creatinine more than 3 mg/dl), a poor cognitive function (the patient age more than 60 years old, who got the Chula Mini-Mental State Examination score less than 21) and any underlying condition(s) that could prevent an adherence to the study protocol.

Sample size

The sample size was calculated from the formula

$$n/group = \frac{2 ( Z\alpha + Z\beta )^2 \pi(1 - \pi)}{(P_1 - P_2)^2}$$

$\alpha = 0.05$, $\beta = 0.20$

The baseline proportion of uncontrolled NIDDM in Pramongkutklao hospital is 0.6.[36]

$P_1$ = The expected proportion of uncontrolled NIDDM in intervention group was equal to 0.5.

$P_2$ = The expected proportion of uncontrolled NIDDM in control group was equal to 0.35.

$$n/group = \frac{2(1.645 + 0.85)^2 \ 0.42 \ (1 - 0.42)}{( 0.5 - 0.35)^2}$$

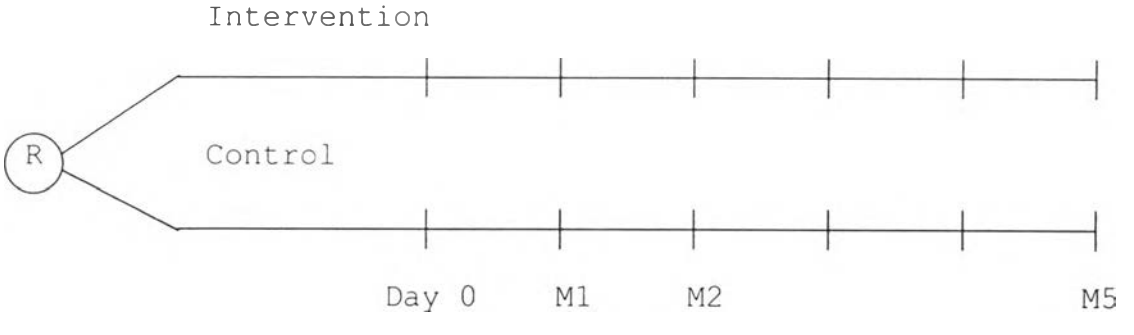
$$= 135.3$$

$$= 136$$

The sample size in each group was estimated at 136 patients. To cover the 10% dropout, the total number of recruited patients was estimated at 300 patients.

Maneuver

The intervention setting was the out-patient diabetic clinic at Pramongkutklao Hospital in Bangkok. The diabetic clinic opened 2 days a week during the study period. The patients were randomly allocated into either the intervention or the control groups. Special appointments were arranged so that the patients in the intervention group and the control groups attended the clinic on a different day. The intervention group attended the special clinic on Monday and the control group came on Friday.




On day 0

1. the diabetic drug use patterns and names of physician were recorded.

2. a sample of eight milliliters of blood was collected for baseline $HbA_{1c}$ and fasting plasma glucose.

3. a body weight of each patient was recorded as baseline data.

4. a pre-test questionnaire was administered (Appendix 2)

5. a recall for diabetic practice (Appendix 3) was also documented for each patient.

6. the first session of education started with the video tape about a general overview of diabetes mellitus and complications. This video tape took 10 minutes. After that the intervention group discussed or consulted the nurse aid about their problems according to the scope of this session. The nurse aid also checked whether the patients understood all the important points. The nurse aids were well trained about diabetic education from the researcher according to the modules as shown in Appendix 4.

At the first schedule monthly visit (M1)

1. the diabetic drug use patterns and the name of the physician in charge were recorded.

2. a recall for practice was recorded before starting the second session.

3. the second session began with the video tape about diet control, discussions and questions within the scope of this session were carried out after the end of the video tape.

At the second schedule monthly visit (M2)

1. diabetic drug use patterns and the name of the physician in charge were be recorded

2. a sample of eight milliliters of blood was taken to measure $HbA_{1c}$ and fasting plasma glucose

3. the patient's body weight was recorded.

4. a recall of the patient's practice was documented before starting the third session.

5. the third session started with the video tape about exercise and foot care and followed by discussions and questions within the scope of this session after the end of the video tape.

6. a post-test questionnaire (Appendix 2) was administered by the patients.

At the fifth month (three months after the last session)

1. diabetic drug use patterns and the name of physician in charge were recorded.

2. a sample of eight milliliters of blood was drawn on to measure $HbA_{1c}$ and fasting plasma glucose.

3. the patient's body weight was recorded.

4. a recall of the patient's practice was recorded.

The control group received the objectives, contents of diabetic education and the same schedules of outcome measurements as the intervention group, except through the different educators and the different media of teaching. The control group were taught by the well trained diabetic nurse educators and the media of teaching could be any kind except the video tape. The modules of diabetic education in the intervention group and the control group are shown in the Appendix 5.

No co-intervention was expected because the intervention group attended the special appointments on days.

Contamination was measured. Separating the intervention and control group in the different day of teaching was the strategy to minimize any contamination. On the monthly visits, the intervention group were also asked whether they told the control group about the video tapes about diabetic education, and the control group were also asked whether they received the information about video tapes from the intervention group.

**Outcome Measurement**

Primary outcome

Proportion of the uncontrolled NIDDM.

Fasting plasma glucose (FPG) - a sample of three milliliters of blood was collected in EDTA tube to measure FPG with Beckman glucose analyzer (Beckman, USA).

The criteria of an uncontrolled NIDDM in this study was defined as a patient with a fasting plasma

glucose of more than 140 mg/dl at the end of study (month 5).

$HbA_{1c}$- a sample of five milliliters of blood was collected in EDTA tube for measurement of $HbA_1$ with a low pressure cation exchange chromatography (Bio-Rad, USA).

Secondary outcomes

1. Drug use pattern: the types and dosages were recorded at day 0, the second and the fifth month.

2. Knowledge: The questionnaire about diabetic knowledge was used after testing its content validity and internal consistency (Kuder-Richardson test). A validity and a reliability score if more than 0.8 was achieved.

3. Change in body weight: A body weight was measured for each patient in light clothes without shoes by the same standard machine at the baseline data before the first diabetic education and at the fifth month intervention program.

4. Diabetic practice was documented for each patient using the record of recall of practice. Topics about diet control, exercise and foot care were included in the recall(Appendix 3). The content validity was tested

by three expertise endocrinologists and found to be acceptable.

5. Costs of the program of video tapes about diabetic education plus nurse aid consultation and the program of diabetic nurse educator consultation. Both direct and indirect costs were measured according to the standard method.[37]

**Data Collection**

The participants of the intervention and control groups were asked to come to diabetic clinic at Pramongkutklao hospital at specific appointment periods. After physical examination and blood tests, they were asked to self-complete a pre-test questionnaire. All answers on the questionnaire were checked by the researcher and corrected by the participants to minimize ambiguous answers. A post-test questionnaire was administered to each patient at the end of last session of education. The diabetic practices measured by recall were recorded at day 0 and at the beginning of the second, the third session and the end of the fifth month of the program. There were three sessions in the education program. The outcome of metabolic control, $HbA_{1c}$, fasting

plasma glucose, body weight were checked as the baseline data and at the end of the fifth month of teaching program. Time schedule for data collection is shown in Table 1.

Table 1

| Outcomes | Time | | | |
|---|---|---|---|---|
| | day0 | month1 | month2 | month5 |
| Primary outcomes | | | | |
| FPG, $HbA_{1c}$ | / | - | (/) | / |
| Secondary outcomes | | | | |
| Drug use pattern | / | / | / | / |
| Knowledge | | | | |
| pre-test | / | - | - | - |
| post-test | - | - | / | - |
| (questionnaire) | | | | |
| Body weight | / | - | (/) | / |
| Recall of | | | | |
| diabetic practice | / | / | / | / |
| Direct cost | / | / | / | / |

The form of data entry as shown in Appendix 6.

**Data Analysis**

Descriptive characteristics of the baseline continuous data were summarized as means, 95%Confidence Intervals, the Standard Errors of the Means, and categorical data were analyzed as proportions.

The inferential statistics were used as shown in Table 2.

Table 2

| Question | Outcomes | Inferential statistics |
|---|---|---|
| Primary | Proportion of uncontrolled NIDDM | Chi-square test |
| Secondary | | |
| 2.1. | Drug use pattern | Chi-square test |
| 2.2. | Knowledge | unpaired t test |
| 2.3 | Change of body weight | unpaired t test |
| 2.4. | Recall of diabetic practice | ANOVA with repeated measurement |
| 2.5. | Costs | Cost-effectiveness analysis |

All statistical tests were carried out using a one-tailed probability with $p<0.05$ as accepted significance.

**Ethical Consideration**

This study had been approved by the Ethical Committee of Pramongkutklao hospital before the study commenced. This project was not harmful to the diabetic patients since the number of qualified nurse educators was not sufficient to care for all patients. Instead, it may be beneficial to them. Every patient was informed about the details of the project and was asked to sign the written informed consent before acceptance being enrolled in the study.

**Limitation**

This study was limited for the NIDDM patients who were literate and had good cognitive function. This study may be generalizable to NIDDM patients in the central part of Thailand who have the same living cultures and diet patterns as the patients in this study.

**Benefit of the Study**

This study will have significant implications. If the video tapes about diabetic education plus nurse aid consultation show significant improvements similar to standard diabetic nurse educator consultations, then the video tapes about diabetic education plus nurse aid consultation may be used in general hospital which have inadequate diabetic nurse educators to help the diabetic education program.