CHAPTER 5

RESULTS

During the study period from March 1996 to February 1997, 285 diabetic patients met the inclusion criteria and were recruited into the study. Patients were stratified into 4 strata according to age and the duration of diabetes mellitus. The block randomization scheme was prepared and used to allocate the patients in each strata to the intervention and the control group. The intervention group, consisted of 144 diabetic patients, received the program of video tapes about diabetic education plus nurse aid consultation and the control group, consisted of 141 diabetic patients received diabetic nurse educator consultation.

There were no significant differences in baseline characteristics of the study population among the intervention and the control group as shown in table 1.

Table 1 Baseline characteristics of the study population

	Intervention group	Control group
Number of patients	144	141
Age(yr.)	56.9	57.8
	(55.4-58.5)	(56.3-59.3)
Sex female (%)	71.0	62.4
Duration of DM(yr.)	9.6	8.8
	(8.4-10.8)	(7.6-10.0)
Education		
primary school(%)	42.4	44.7
secondary school(%)	14.6	14.9
high school(%)	18.8	19.1
FPG(mg/dl)	200.85	203.29
	(196.45-209.45)	(194.9-211.68)
HbA_{1c} (%)	9.79	9.59
	(9.46-10.12)	(9.24-9.94)

95%CI = 95% Confidence interval in parentheses

There were statistically significant differences in the fasting plasma glucose and HbA_{1c} between baseline and the end of study ($p < 0.05$) as shown in table 2 and table 3 respectively.

Table 2 Fasting plasma glucose (FPG) after diabetic teaching

Group	FPG(mg/dl)		
	baseline	end of study	P value*
Intervention	200.85±4.42	184.26±5.01	0.01
Control	203.29±4.28	180.49±5.00	0.00

* Paired student t test

Table 3 HbA_{1C} after diabetic teaching

Group	HbA_{1C}(%)		
	baseline	end of study	P value*
Intervention	9.78±0.17	8.83±0.21	0.00
Control	9.59±0.18	8.73±0.18	0.00

* Paired student t test

The degree of reduction in plasma glucose and HbA_{1C} in the intervention group did not differ from the control group as shown in table 4.

Table 4 The degree of reduction of plasma(PG) and HbA_{1C} in intervention and control group

	Intervention group	Control group	P value
ΔPG(mg/dl)	16.59±5.89	22.80±5.30	NS
ΔHbA_{1C}(%)	0.95±0.21	0.86±0.17	NS

Unpaired student t test p >0.05

The main outcome in this study was the proportion of uncontrolled NIDDM at the end of the study. The proportion of uncontrolled NIDDM was defined as fasting plasma glucose more than 140 mg/dl at the end of the study(month 5). There was no statistical significance of the proportion of uncontrolled NIDDM in the intervention and the control group as shown in table 5.

Table 5 Proportion of uncontrolled NIDDM after diabetic teaching

	Intervention group	Control group
uncontrolled NIDDM (FPG>140 mg/dl)	114(79.2)	106(75.2)
controlled NIDDM	30(20.8)	35(24.8)

* Number in parentheses, percent

Chi-square test, p >0.05

There was a statistically significant difference in the decrease in drug use pattern between the intervention and the control groups($p < 0.05$). There were no statistically significant differences in the other secondary outcomes i,e., knowledge, change of body weight and recall of practices. (Table 6)

Table 6 The outcomes of diabetic teaching

	Intervention group	Control group	P value
Drug use pattern(%)			
no change or increase	134	121	
decrease	10	20	0.047*
Knowledge			
pretest score	13.7 (13.3-14.3)	13.7 (13.0-14.4)	NS**
posttest score	15.9 (15.3-16.5)	15.9 (15.3-16.5)	NS**
Change of body weight (kg.)			
baseline	63.3 (61.3-65.3)	64.8 (62.9-66.6)	NS**
end of study	63.8 (61.9-65.7)	65.4 (63.5-67.2)	NS**
Recall of practice			
baseline score	15.7 (15.2-16.3)	16.1 (16.5-17.5)	
1 month score	16.5 (16.0-17.0)	17.1 (16.5-17.5)	
2 month score	17.7 (17.2-18.2)	17.9 (17.5-18.5)	
5 month score	18.2 (17.8-18.6)	18.5 (18.0-19.0)	NS***

* Chi-square test, ** Student t test

*** ANOVA for repeated measurement

Number in parentheses, 95% CI

There was a higher proportion of changes of physicians during the study among the intervention group compared to the control group($p<0.05$). (Table7)

Table 7 Change of physician during study period

	Intervention group	Control group
no change	48(33.3)	79(56.0)
change	96(66.7)	62(44.0)

Number in parentheses, percent

Chi-square test ($p <0.002$)

The numbers of diabetic patients in the intervention and the control groups who had $\geq$1% reduction of HbA_{1C} at the end of study were shown in table 8.

Table 8 Number of NIDDM who had ≥1% reduction of HbA_{1C} at the end of study

	Intervention group	Control group
≥1% reduction of HbA_{1C}	55	55
<1% reduction of HbA_{1C}	89	86

Chi-square test P >0.05

Economic Evaluation

1. Description of the alternatives

1. Program of video tapes about diabetic education plus nurse aid consultation. There were three sessions of diabetic teachings. Details were described in Appendix 5.

2. Diabetic nurse educator consultation. There were three sessions of diabetic teaching. Details were described in Appendix 5.

A decision tree of the outcome of the two alternatives is given in Appendix 8.

2. The viewpoint for the study

One viewpoint from which to undertake the analysis would be that of the hospital administrators. It would be most relevant to compare costs paid by the alternatives since the result of the study can be used to plan human resource requirements for diabetic education programs in Thailand.

3. Cost analysis

Direct cost was analyzed with the discount rate of 7% for allowance of differential timing.

1. Program of video tapes about diabetic education plus nurse aid consultation

1.1. Direct medical cost.

	units	Baht/unit	Total(Baht)
video tapes	4	20,000	80,000

Equivalent annual cost(E) = $\frac{K - S/(1+r)^n}{A(n,r)}$

K = Initial outlay = 80,000 Baht in 1996

n = useful life = 5 years

r = discount rate = 7%

s = resale value = 0

A(n,r)= Annuity factor(5yr.,7% interest)= 4.1002

$$E = \frac{80,000 - 0/(1+7)^5}{4.1002}$$

= 19,511.24 Baht

Working hour/year = Official day/ year x hr./day

= 240 x 0.5/hr.

= 120/hr.

E/hr. = 19,511.24/120

= 162.59 Baht

	units	Baht/hr	Total(Baht)
video tapes	2 hr	162.59	325.18
Laboratory cost			
FPG	x4	30	120
HbA1c	x3	120	360
Profession fee			
Physician's fee	1 hrx4	300/hr	1,200
Nurse aid's fee	2 hrx4	75/hr	600

Total cost of Program of video tapes was 2,605.18 Baht per one patient.

2. Diabetic nurse educator consultation

2.1. Direct medical cost

	units	Baht/unit	Total(Baht)
Product of Posters and media	3	1,500/unit	6,000

Equivalent annual cost(E) $= \frac{K - S/(1+r)^n}{A(n,r)}$

K = Initial outlay = 6,000 Baht in 1996

n = useful life = 3 years

r = discount rate = 7%

s = resale value = 0

A = Annuity factor(3 yr, 7% interest) = 2.6243

$E = \frac{6,000 - 0/(1+7)^3}{2.6243}$

= 2,286.32 Baht

working hour/year = Official day/yr. x hr/day

= 240 x 0.5/hr

= 120 hr

E/hr = 2,286.32/120

= 19.05 Baht/hr.

	units	Baht/unit	Total(Baht)
Posters and media	2 hr	19.05	38.10
Laboratory cost			
FPG	x4	30	120
HbA_{1c}	x3	120	360

Profession fee

Physican's fee	1 hrx4	300/hr	1,200
Nurse's fee	2 hrx4	150/hr	1,200

Total cost of Diabetic nurse education consultation was 2,918.10 Baht per one patient.

4. Analysis of cost-effectiveness

The main measure of cost-effectiveness was the cost per outcome. The significant outcome in this study was the decrease of drug use pattern in each alternatives. In intervention group and the control group, there were 10 and 20 diabetic patients respectively who had a decrease of drug use pattern, indicating a good control of diabetes mellitus. The data of cost effectiveness of the two alternatives was shown in table 9.

Table 9 Cost effectiveness of program of video tapes plus nurse aid consultation versus diabetic nurse educator consultation

	Intervention group	Control group
Total cost(Baht)	375,145.92	411,452.10
Cost(Baht)/patient	2,605.18	2,918.10
Cost(Baht)/good control NIDDM	37,514.59	20,572.60

The cost effectiveness of intervention and control group when the cost/≥1% reduction of HbA_{1c} was considered as shown in table 10.

Table 10 Cost effectiveness of program of video tapes plus nurse aid consultation versus diabetic nurse education consultation

	Intervention group	Control group
Total cost(Baht)	375,145.92	411,452.10
Cost(Baht)/patient	2,605.18	2,918.10
Cost(Baht)/≥1% reduction of HbA_{1C}	6,820.83	7,480.94

Sensitivity analysis

There were many variables which could be evaluated as the "main effects" such as the number of good control NIDDM patients, patients with a ≥1% reduction of HbA_{1C}. If the main variable analyzed was the number of diabetic patients who had diabetes mellitus, the cost-effectiveness of each alternatives given the different level of "good control" could be depicted in table 11 and table 12 respectively, and the sensitivity analysis was represented in figure 1.

Table 11 Cost/good control of NIDDM in the intervention group

	Intervention group					
Cost (Baht)	No. of good control NIDDM					
	1	10	20	30	40	50
Video tapes	325.18	325.18	325.18	325.18	325.18	325.18
Lab cost						
FPG	120	1200	2400	3600	4800	6000
HbA_{1c}	360	3600	7200	10800	14400	18000
Physician's fee	1200	1200	1200	1200	1200	1200
Nurse aid's fee	600	600	600	600	600	600
cost(Baht)/patient	2605	692	586	550	533	522
cost(Baht)/good control NIDDM	37514	15630	14428	13998	13792	13641

Table 12 Cost/good control of NIDDM in the control group

	Control group					
Cost (Baht)	No. of good control NIDDM					
	1	10	20	30	40	50
Posters&media	38.10	38.10	38.10	38.10	38.10	38.10
Lab cost						
FPG	120	1200	2400	3600	4800	6000
HbA_{1C}	360	3600	7200	10800	14400	18000
Physician's fee	1200	1200	1200	1200	1200	1200
Nurse's fee	1200	1200	1200	1200	1200	1200
cost(Baht)/patient	2918	724	602	561	540	528
cost(Baht)/good control NIDDM	20572	8004	7295	7069	6926	6857

If the level of reduction of HbA_{1C} equal to or more than 1% at the end of the study was used as the "main effect" of diabetes mellitus, the cost per patient with $\geq$1% reduction of HbA_{1C} given various levels of "main

effect" could be portrayed in table 13 and table 14 respectively.

Table 13 Cost/≥1% reduction of HbA_{1C} in the intervention group

	Intervention group					
Cost (Baht)	No. of good control NIDDM					
	1	20	40	60	80	100
Video tapes	325.18	325.18	325.18	325.18	325.18	325.18
Lab cost						
FPG	120	2400	4800	7200	9600	12000
HbA_{1C}	360	7200	14400	21600	28800	36000
Physician's fee	1200	1200	1200	1200	1200	1200
Nurse aid's fee	600	600	600	600	600	600
cost(Baht)/patient	2605	586	533	515	506	501
cost(Baht)/≥1% reduction of HbA_{1C}	6820	2623	2507	2462	2444	2435

Table 14 Cost/≥1% reduction of HbA_{1C} in the control group

	Control group					
Cost (Baht)	No. of good control NIDDM					
	1	20	40	60	80	100
Posters&media	38.10	38.10	38.10	38.10	38.10	38.10
Lab cost						
FPG	120	2400	4800	7200	9600	12000
HbA_{1C}	360	7200	14400	21600	28800	36000
Physician's fee	1200	1200	1200	1200	1200	1200
Nurse's fee	1200	1200	1200	1200	1200	1200
cost(Baht)/patient	2918	601	540	520	510	504
cost(Baht)/≥1% reduction of HbA_{1C}	7480	2652	2518	2476	2452	2436

The sensitivity analysis of number of NIDDM patients who had ≥1% reduction of HbA_{1C} when compared to the cost as shown in figure 2.

Figure 1. Sensitivity analysis
The number of good control NIDDM

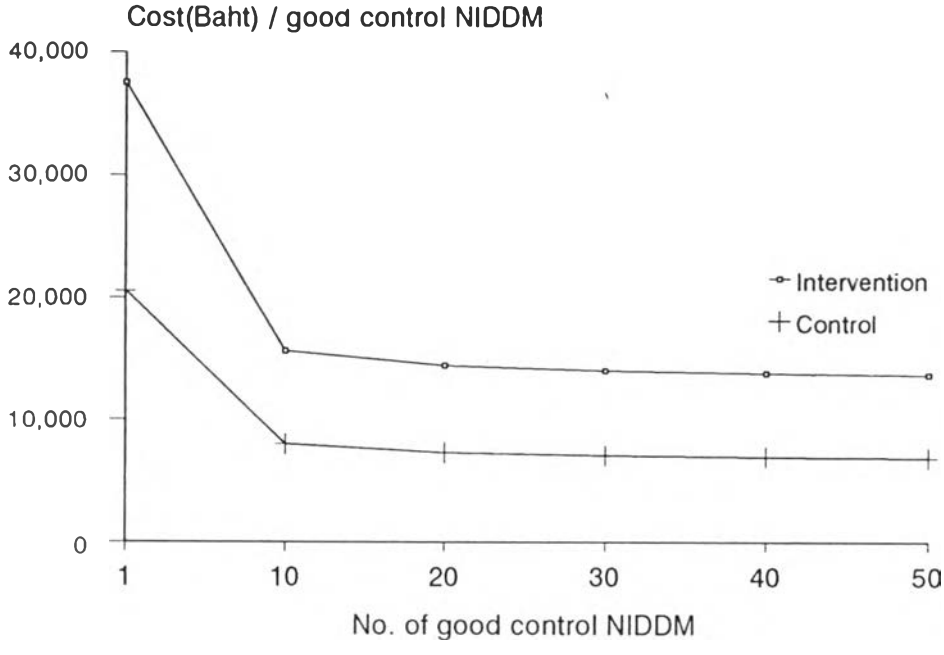

Figure 2. Sensitivity analysis
Cost/No.of NIDDM with > 1% reduction of HbA1c