

## CHAPTER 3

### METHODOLOGY

#### **3.1 Study design**

The study design of this study was a deductive cross-sectional research by telephone interview following the questionnaire guideline survey was employed for studying the relationship between calories burnt by exercise, eating behavior score, Type 2 diabetes knowledge, BMI, demographic data namely—age and gender,—and Fasting Blood Glucose in 200 Type 2 diabetic patients who visit the physician at Saraburi Hospital during the period of January 15, 2008 to March 15, 2008.

#### **3.2 Consideration of Patient Participation**

The study protocol was reviewed for approval by the staff of Saraburi Hospital Human Subjects Review Committee and Chulalongkorn Ethic Committee. Patients were telephone interviewed by the questionnaire. Identification of patients was facilitated in a manner to enable confidentiality of physician-patient relationships. Each questionnaire had a clearly identified number however it could not be link to a patient's name — with the effect that all identifying data concerning such a patient would remain anonymous. All data were collected by a prospective review of the clinical records and each patient in the study consented to the use of the clinical data.

#### **3.3 Population**

The population for this study consisted of all Type 2 diabetes patients who came to see physicians at Saraburi Hospital during the period of January 15, 2008 to March 15, 2008.

### **3.4 Sampling method**

The samples were randomly sampling by computer from Saraburi Hospital data bank of Type 2 diabetic patient and controlled for drug name "metformin". This samples were used twice times as for pilot scale testing and the final survey work.

### **3.5 Sample size calculation**

The sample size recommended by Hair et al (2000)<sup>(79)</sup> for using Multiple Regression Analysis and by using rule of thump (15 to 20 samples were suggested for one independent variable however sample size must not less than 100) since this study had seven independent variables, we then needs at least 140 samples. However, we over calculated for losing data to 200 samples. The samples were .the 200 Type 2 diabetes patients who came to see physicians during the time plan. To qualify for inclusion, a potential participant had to meet all the following requirements: 1) Literacy in Thai; 2) Having reached 18 years of age as of (as of January 15, 2008). Otherwise-eligible participants were excluded from the study database if (as of the closing analysis date) they displayed any one of these disqualifying factors: Died; Lost contact; Had otherwise not remained in contact with Saraburi Hospital; or were currently involved in other similar studies; 4) Prescribed metformin for disease treatment. By setting these protocol criterions and the calculating sampling size of 200 for computer generating random sampling diabetes patients clinical data profile with the telephone numbers.

### **3.6 Instruments**

The 11-page questionnaire consisted of 48 questions. It was divided into (5) parts: demographic data, BMI, alcohol and cigarettes consumption, Fasting Blood Glucose, calories burnt by exercise using Haskell Compendium of Physical Activities scale, the diabetes knowledge scales, eating behavior score and Sorofman's compliance scale version 2.

### **3.7 Pretest**

As part of the planned pretest of this questionnaire, 20 graduate students and 10 undergraduate students completed the survey and were then interviewed to assess its face validity and content validity. Questionnaire format was modified – largely based on suggestions from these pretest subjects. The final survey instrument and sample methodology were approved by researchers and experts.

### **3.8 Pilot Test**

An initial telephone interview of 20 questionnaires were performed on October 1, 2007, serving as a pilot test for the purpose of previewing the questions, and fine tuning of some peripheral aspects of the questionnaire. The pilot test responses showed a need for eating behavior score and diabetes knowledge score modification which were done. Review of the modified questionnaire form showed these changes to enhance understanding, reliability, sensitivity, and variation of responses.

### **3.9 Analysis Procedure**

All data were reported in the aggregate, to avoid inadvertent identification of an individual. Consideration was given to the loss of power with multiple statistical testing. Fourteen hypotheses were generated from the models in this study. The basic model for testing these fourteen hypotheses consisted of one dependent variable and seven independent variables by SPSS version 16.0

### **3.10 Variables**

#### 3.10.1 Dependent variables

There was one dependent variable in this study. The dependent variable was Fasting Blood Glucose. It was measured by lab test. Fasting Blood Glucose was obtained. The presence of Type 2 diabetes was defined by a self-report doctor's diagnosis, the use of anti-diabetic medications, or Fasting Blood Glucose (mg/dL).

### 3.10.2 Independent variables

There were seven independent variables in this study. The independent variables in this model were: gender, age, BMI, compliance score, eating behavior score, diabetes knowledge and total calories burnt by exercise.

## **3.11 Study finding**

### 3.11.1 Demographic data, BMI, alcohol and cigarettes consumption and Fasting Blood Glucose

Age, gender, education, occupation, drinking and smoking status were obtained from interviewing by telephone.

Fasting Blood Glucose was taken by physicians from lab test.

The presence of Type 2 diabetes was defined by a self-report doctor's diagnosis, the use of anti-diabetic medications, or Fasting Blood Glucose greater than 126 mg/dL.

BMI was calculated as weight in kilograms divided by the square of height in meters ( $\text{kg}/\text{m}^2$ ). BMI was categorized according to the National Institutes of Health obesity standards: BMI < 18.5 = underweight, BMI 18.50–24.99 = normal weight, BMI 25.00–30.00 = overweight, BMI > 30.0 = obesity<sup>(80)</sup>. Anyway BMI was measure in ratio (continuous) scale.

Alcohol intake was determined by interviewing “In any one month, how many glasses of alcohol do you drink? And also any type of alcohol beverage?”

Smoking habit was asked “How many cigarettes do you normally smoke everyday?”

### 3.11.2 Calories burnt by exercise

Calories burnt by exercise could be measured via Haskell Compendium of Physical Activities<sup>(81)</sup>. It was developed for use in epidemiologic studies to standardize the assignment of Metabolic Equivalent (MET) intensities in physical activity questionnaires by Haskell (2000) at Stanford University conceptualized the Compendium and developed a prototype for the document. The instrument was used first in the Survey

of Activity, Fitness, and Exercise (SAFE study - 1987 to 1989) to code and score physical activity records. Since then, it has been used in studies worldwide to assign intensity units to physical activity questionnaires and to develop innovative ways to assess energy expenditure in physical activity studies. Metabolic Equivalent: The ratio of the work metabolic rate to the resting metabolic rate. One MET is defined as 1 kcal/kg/hour and is roughly equivalent to the energy cost of sitting quietly. A MET also is defined as oxygen uptake in ml/kg/min with one MET equal to the oxygen cost of sitting quietly, equivalent To3.5ml/kg/min.

### 3.11.3 Eating behavior scale (version 2)

Eating behavior scale version 2 was developed from version 1 (3 attributes category ordinal scale) by Auamnoy, (2005) by using indicators to define a continuous ratio scale of eating behavior construct.

### 3.11.4 Sorofman Medical regimen compliance scale version 2

Sorofman Medical regimen Compliance scale version 2 was developed by Bernard Sorofman (2002). It composed of 3 questions measured 2 constructs “amount” and “punctual time”.

## **3.12 Data analysis**

Data were described as frequencies, percent, and means with standard deviations (SD.), one way ANOVA, Pearson product moment correlation method, and Multiple Regression Analysis. All analyses were performed by using the SPSS program Version 16.0 with default setting—  $p < 0.05$  —as the level of statistical significance.

Each of Hypotheses 1, 2, 3, 4, 5, 6 and 7 contains one dependent variable (Ratio scale) and one independent variable (Nominal scale); therefore, we applied One Way ANOVA to compare the means of Fasting Blood Glucose, compliance, diabetes knowledge, age, calories burnt by exercise, BMI and eating behavior score between male and female ( $P < 0.05$ ).

Ho:

- |     |                                       |   |   |
|-----|---------------------------------------|---|---|
| (1) | $\mu$ male FBG                        | = | $\mu$ female FBG                        |
| (2) | $\mu$ male compliance                 | = | $\mu$ female compliance                 |
| (3) | $\mu$ male diabetes knowledge         | = | $\mu$ female diabetes knowledge         |
| (4) | $\mu$ male age                        | = | $\mu$ female age                        |
| (5) | $\mu$ male calories burnt by exercise | = | $\mu$ female calories burnt by exercise |
| (6) | $\mu$ male BMI                        | = | $\mu$ female BMI                        |
| (7) | $\mu$ male eating behavior score      | = | $\mu$ female eating behavior score      |

Hypotheses 8, 9, 10, 11, 12 and 13 have two continuous (Ratio scale) variables. The data for these hypotheses were analyzed via Pearson product moment correlation method ( $p < 0.05$ ).

Ho:

- |      |                                       |     |
|------|---------------------------------------|-----|
| (8)  | $\rho$ BMI.FBG                        | = 0 |
| (9)  | $\rho$ Age.FBG                        | = 0 |
| (10) | $\rho$ Calories Burntby Exercise. FBG | = 0 |
| (11) | $\rho$ Diabetes Knowledge.FBG         | = 0 |
| (12) | $\rho$ Eating behavior score.FBG      | = 0 |
| (13) | $\rho$ Compliance.FBG                 | = 0 |

Hypothesis 14 has one continuous (Ratio scale) dependent variable Fasting Blood Glucose and seven independent variables—gender (male), age, BMI, eating behavior score, compliance, calories burnt by exercise and diabetes knowledge score—described in this equation. Statistical analysis of this data was calculated via Multiple Regression Analysis ( $p < .05$ ).

Ho 14:

$$\text{FBG} = b_0 + b_1 \text{ male} + b_2 \text{ age} + b_3 \text{ BMI} + b_4 \text{ calories burnt by exercise} \\ + b_5 \text{ eating behavior score} + b_6 \text{ compliance} + b_7 \text{ diabetes knowledge}$$

$$Z_{\text{FBG}} = b_1 Z_{\text{male}} + b_2 Z_{\text{age}} + b_3 Z_{\text{BMI}} + b_4 Z_{\text{calories burnt by exercise}} \\ + b_5 Z_{\text{eating behavior score}} + b_6 Z_{\text{compliance}} + b_7 Z_{\text{diabetes knowledge}}$$