Chapter 3

Methodology

Study Design

A Cross-sectional study of school pupils aged 8 to 18 years and their parent. Health-related quality of life assessment was performed using the Pediatric Quality of Life Inventory^{TM} Generic Core Scales (PedsQL^{TM} 4.0), Thai version which include physical functioning, emotional functioning, social functioning and role (school) functioning for child-self report (age range 8 – 12, 13 – 18 years) and parent-proxy report (age range 8 – 12, 13 – 18 years).

Study Setting and Study period

The settings were recruited from two schools, which selected by purposive sampling, at Pathumthani province. The study was collected data between June, 2007 and February, 2008.

Population and Sample

Participants were recruited from schoolchildren, who presence in the classroom at the data collection times, age between 8 - 18 years and their parents. The schools in the study were selected from elementary and high school that performed in Pathumthani province. Classes at schools were randomly selected within grade. Then, all of pupils of classes were recruited in the study. The pupils were administered the questionnaires in their classroom and carried mail to their parent fulfilled at home. Exclusion criteria were pupils who absence at time collected and their parent. Age of pupils were <8 and ≥ 19 years.

Sample size

The formula was

$$n = \frac{(Z_\alpha)^2 \text{ X } \delta^2}{(d)^2}$$

n = sample size

Z_α = 1.96 Type I error at 95% CI

δ = 300 (standard error in population)

d = 50 (except error of the mean score)

n = 144 per year

The sample size in age range 8 – 18 years (10 year of study)

n = 144*10 =1,444

The response rate was 70%

So, n = 1,877

An estimate sample size was 1,877 participants.

Study instrument

In this study, we used PedsQL^{TM} 4.0 generic core scale, Thai version questionnaires for measurement pediatric health-related quality of life.

Study procedure and Data collection

User agreement was sign with Mapi Research Institute, Lyon, France prior to using the questionnaires. The PedsQL^{TM} 4.0 Generic Core Scales has also been translated into many languages and we use the Thai version as appropriate.

After informed consent and assent were obtained, the PedsQL^{TM} 4.0 and study questionnaire, information about this study and informed consent forms were sent to their parents by mail. Parents were asked to return the completed questionnaire by giving it to their child who put it into a box installed at the classroom. The boxes were collected from the classroom by the researcher about 2 weeks later.

School pupils were given verbal information before completing questionnaires in class. The PedsQL^{TM} 4.0 self-reports were administered to children and their parent in age 8 – 18 in 46 classes (20 elementary classes, and 26 high school classes) and completed in the classroom under the guidance and supervision of a researcher. A research assistant and researcher are available to answer questions participants.

Child self-report and parent-proxy report were linked data by Child's student identification number (ID) in each school. Each from was coded with an ID number for confidentiality purpose. The approval of the ethic committee was obtained before the study onset by the Human Subjects Committee at the Faculty of Medical science, Thammasat University.

The Health-related quality of life questionnaire

The PedsQL^{TM} 4.0 (Pediatric Quality of Life Inventory^{TM}) Thai version was used for the quality of life assessment. The PedsQL^{TM} 4.0 Generic Core Scale includes parallel child-self report and parent proxy-report formats. Child-self report includes ages 8-12 and 13-18 years. Parent proxy-report includes ages range 8-12 (child), and 13-18 (adolescent), and assesses parent's perceptions of their child's HRQOL. The PedsQL^{TM} Measurement Model integrates both generic core scales and disease-specific models into one measurement system (Varni et al., 1999). The 23-item PedsQL^{TM} 4.0 Generic Core Scales, designed to enable comparison across patient and healthy popultions, measure the core dimensions of heath as delineated by the WHO, as well as role (school) functioning. Thus, the multidimensional PedsQL^{TM} 4.0 Generic Core Scales encompass the essential core domains for pediatric HRQOL measurement: (1) Physical Functioning (8 items), (2) Emotional Functioning (5 items), (3) Social Functioning (5 items), and (4) School Functioning (5 items). The instructions ask how much of a problem each item has been during the past one month. A 5-point response scale is utilized across child self-report and parent proxy-report. The response scale for each item was "never" (0), "almost never" (1), "sometimes" (2), "often" (3), and "almost always" (4).

Items are reverse-scored and linearly transformed to a 0 – 100 scale (0 = 100, 1 = 75, 2 = 50, 4 = 0), so that higher scores indicate better HRQOL. Scale scores are computed as the sum of the items divided by the number of items answered (this accounts for missing data). If more than 50% of the items in the scale are missing, the scale score is not computed. The Physical Health Summary score (8 items) is the same as the Physical Functioning Subscale. To create the Psychosocial Health Summary Score (15 items), the mean is computed as the sum of the items divided by the number of items answered in the Emotional, Social, and School Functioning Subscales.

The General record form

Demographic and characteristic were derived from child self-report and parent proxy-report. Children's weight, height, ID number, and birth of date were derived from the first aid's room in each school.

In this study, the classifications of students in each school are dividing into 2 groups; as obese and non-obese. Weight (in kilogram) and height (in centimeters) was received from Health's room from each school. We used standard weight-for-height for gender of Thailand children that derived data from the recent survey of Thailand children of the Ministry of Public Health of Thailand to classify each group. The obese was defined as at or above the 120% of standard weight-for-height and same gender of Thailand children. The non-obese was defined as below 120% of standard weight-for-height for gender of Thailand children (Jirapinyo, 2005a, 2005b; Sahakitrungruang, 2007). The HRQOL in each group was calculated when these children divided into 2 groups.

Data analysis

Data entry was used EpiData version 3.02 and analyzed by Stata^{tm} version 9.0, as follows,

Part I Descriptive analysis

In this part, demographic and general characteristics of children, including socio-demographic of their parents, were described. The results were presented by frequency, percentage, mean, and standard deviation.

Part II Assessment of Health-related Quality of Life

Items on PedsQL^{TM} 4.0 were reverse-scored and linearly transformed to a 0 – 100 scale (0 = 100, 1 = 75, 2 = 50, 4 = 0), so that higher scores indicate better health-related quality of life. A total Scale Scores (derived by the mean of all 23 items) and Psychosocial Health Summary Score (composed of the mean of the items in emotional, social, and school functioning subscales) were calculated to provide a summary of the child's health-related quality of life.

The mean and standard deviation of PedsQL^{TM} 4.0 score both child self-report and parent proxy-report were presented. Also, the comparison of PedsQL^{TM} scores, including total score, physical functioning, and psychosocial health summary score, both child self-report and parent proxy-report was conducted using t-test. Non-parametric statistic was performed if the data was not normally distributed. Chi-square was used to examine relationship between selected factors and quality of life of children with obesity.

Scale internal consistency reliability was determined by calculating Cronbach's coefficients alpha (Cronbach, 1951). The Cronbach's alpha were computed on the PedsQL^{TM} score total scale score, physical functioning, and psychosocial physical health summary score for both child self-report and parent-proxy report. Scales with reliabilities indicated 0.7 or greater are acceptable reliability (Nunnally, 1978).