CHAPTER 3

RESEARCH METHODOLOGY

Research Design

This study is a descriptive correlation study. A cross-sectional design was used to examine data at period November 2006 to March 2007 in three hospitals in Medan, Indonesia.

Population and Setting

The population of the study was cancer patients who experienced chronic cancer-related pain. This study was conducted in Medan, Indonesia at H. Adam Malik and Dr. Pirngadi Hospitals. These two hospitals were purposively selected based on the following conditions: H. Adam Malik and Dr. Pirngadi Hospitals are the two biggest hospitals in Medan, Sumatera Utara, also H. Adam Malik and Dr. Pirngadi Hospitals are the referral hospitals in Sumatera Utara and other nearby provinces such as Nangroe Aceh Darussalam and the Province of Riau. However, the number of subjects was lower than the desired sample size, the researcher then added Haji

hospital which has similar patients and services to H. Adam Malik and Dr. Pirngadi Hospital.

Moreover, all these three hospitals were teaching hospitals and the referral hospitals in Medan.

Sample

Sample Size

The sample size of the study was estimated by using power analysis. The accepted

minimum level of significance (α) to estimate the number of sample size was .05 with power of

.80 (1-β). The values of α and 1-β were the conventional standard for most nursing studies

(Polit & Hungler, 1999). The estimated population effect size was predicted based on available

evidence from previous studies. McCracken's study examined the relationship between pain

intensity and pain acceptance in patients with chronic pain and revealed r =-.28 (p<.001). In the

same study, McCracken also examined the relationship between pain acceptance and avoidance

behavior and found r =-.55 ($p<.001$) (McCracken, 1998). Another study examined the

relationship between pain intensity and pain behavior in chronic pain patients and found r =.33 (p

<.001) (Asghari & Nicholas, 2001). Averaging the result of these previous studies, the medium

effect size was approximately .40 (γ). Therefore, the sample size of 60 was considered adequate.

During the data collection period, only 58 subjects' purposively sampling, met the following

inclusion criteria:

Inclusion criteria

1. Adult cancer patients aged 20 years and above

2. Experience with a certain amount of pain for at least 3 months

3. Ethnicity of Batak

4. Fully conscious and able to communicate in the Indonesian language

Instrumentation

Instruments

Instruments used in this study were: (1) The Demographic Data and Disease-Related Data Form, (2) The Pain Numerical Rating Scale (NRS), (3) The Chronic Pain Acceptance Questionnaire (CPAQ), and (4) The Pain Behavior Observation Protocol.

Part 1: The Demographic Data and Disease-Related Data Form.

The Demographic Data and Disease-Related Data Form was designed by the researcher to gather the data of patients regarding, gender, religion, level of education, occupation, income, stage of cancer, location of pain, pain medication in past 24 hours, and cancer treatments.

Part 2: The Pain Numerical Rating Scale (PNRS)

The Pain Numerical Rating Scale was used to measure the pain intensity (right now or current). The scale consisted of 11 points which is 0 represents "no pain" and 10 represents "worst pain possible." Ratings of 1-4 correspond to mild pain, 5-6 to moderate pain, and 7-10 to severe pain (Serlin et al., 1995).

Part 3: The Chronic Pain Acceptance Questionnaire (CPAQ)

The Chronic Pain Acceptance Questionnaire was used to measure the subjects'

pain acceptance and divided into two subscales; Activity engagement and Pain willingness. The

CPAQ consisted of 20 items: 11 items measure activity engagement (items number: 1, 2, 3, 5, 6,

8, 9, 10, 12, 15, and 19), 9 items measure pain willingness (reversed score items, items number: 4,

7, 11, 13, 14, 16, 17, 18, and 20). The original CPAQ was rated on the following seven-point

Likert scale: 0 = never true, 1 = very rarely true, 2 = seldom true, 3 = sometimes true, 4 = often

true, 5 = almost always true, and 6 = always true. However, based on the advice from the experts,

the seven-point Likert scale was too complicated and might not be appropriate in Indonesian

patients who relatively have low level of educational background. Therefore, the seven-point

Likert scale was reduced to five points consisting of: 0 = never true, 1 = seldom true, 2 = true, 3 =

often true, and 4 = always true. The total pain acceptance is a summation of activity engagements

and pain willingness (McCracken et al., 2004). The higher scores of the CPAQ indicate the higher

level of pain acceptance. In other words, the higher scores reflect subjects who are more likely to

accept their pain well. For interpretation of the scores, the researcher divided the total pain

acceptance, the subscale, and the items' score of CPAQ into 4 levels, by calculating interval of each level as follows:

$$\text{Interval} = \frac{\text{Total Score}}{\text{Number of Levels}}$$

The 4 levels of CPAQ and the subscale were: very low, low, moderate, and high (Table 2). The CPAQ item scores were divided into four levels: very low (0-.99), low (1.00-1.99), moderate (2.00-2.99), and high (3.00-4.00).

Table 2

The pain acceptance, activity engagement and pain willingness score level

	Score	Level
Pain Acceptance (total)	0-20	Very low
	21-40	Low
	41-60	Moderate
	61-80	High

Table 2 (continued)

	Score	Level
Activity Engagement	0-11	Very low
	12-22	Low
	23-33	Moderate
	34-44	High
Pain Willingness	0-9	Very low
	10-19	Low
	19-27	Moderate
	28-36	High

Part 4: The Pain Behavior Observation Protocol (PBOP)

The Pain Behavior Observation Protocol consisted of five items of pain behaviors including; guarding, bracing, rubbing, grimacing, and sighing. During the 10-minutes protocol, pain behaviors were observed directly while the patients performed a sequence of eight different tasks. The eight tasks were adapted from Keefe and Block's standardized protocol of 1982, consisting of sitting for a period of 1 minute and again for 2 minutes, standing for a period

of 1 minute and again for 2 minutes, reclining twice for 1 minute each, and walking twice for 1

minute (Keefe & Block, 1982 as cited in Keefe & Smith, 2002). The pain behaviors were rated as

one of three points of the Likert-Scale: 0 = none, 1 = frequently occurs, and 2 = always occurs.

The total pain behaviors were the summation of the five pain behaviors. The highest score (10)

indicates the highest level of expressing pain behaviors. In addition, to allow cultural-relevant

behaviors that were not observed in western cultures, other behaviors that might be expressed by

the subjects as a result of pain were observed and recorded but was not scored in the total score of

pain behaviors. For interpretation of the PBOP scores, the sum score of pain behaviors was

divided into 3 level including: low, moderate, and high (Table 3). Each item score of the PBOP

also was divided into three levels including: low (0-.67), moderate (0.77-1.24), and high (1.34-

2.00).

Table 3

The pain behaviors score's level

Score	Level
0-3	Low
4-7	Moderate

8-10	high

Validity of the Instruments

The instruments were validated by three experts. There were two nurse educators from the Faculty of Nursing, Prince of Songkla University, and one medical doctor from the Faculty of Medicine, University of Sumatera Utara. All experts were skillful in the care of medical-surgical patients. The experts assessed and evaluated the construct of the instruments whether they were relevant and adequately measured the variables of the study. The experts were asked to rate the items on a four-point scale ranging from 1 = not relevant to 4 = very relevant. The Content Validity Index (CVI) of CPAQ achieved .94 of agreement. According to Polit and Beck (2004), the CVI score of .80 or better indicates that the instrument's content validity is good. The researcher then modified the content based on the recommendation of the experts.

Reliability of the Instruments

The CPAQ has been reported to achieve adequately reliability $\propto$ = .72–.82 (McCracken & Eccleston, 2006). The inter-rater reliability of the PBOP in previous study demonstrated satisfactory result, ranging from 96 to 99% of agreement (Ahles et al., 1990 as cited in McGuire, 1997). For certain types of observational data such as ratings, correlation techniques are suitable to measure the reliability of the instruments (Polit & Beck, 2004).

In order to test the reliability of the instruments, the researcher tried out the translated instruments with 20 subjects who had similar characteristics to the population of the study. The internal consistency reliability was examined and revealed Cronbach's alpha coefficient ($\propto$) of CPAQ = .77. The inter-rater reliability of the PBOP achieved .93. These values were considered to be adequate and acceptable.

Translation of the Instruments

The original instruments of this study were developed in the English language. In order to use them with Indonesians, the English versions of the instrument were translated into the Indonesian language using the back translation technique (Burns and Grove, 2001).

Three bilingual translators who had ability in English as well as the Indonesian language translated the instruments to obtain the accuracy of the translation and discrepancies between two versions. The translators identified whether the content of items were relevant to Indonesian culture. The back translation process was conducted as follows: the first bilingual translator from language center (Pusat Bahasa) of University of Sumatera Utara translated the instruments from the English version into an Indonesian version. Then, the second bilingual translator from Philadelphia private English Course translated the instruments from the Indonesian version into an English version. Finally, third bilingual translator from the same institution with the second translator clarified and identified the discrepancies in some items between the two versions.

According to the third bilingual translator wording of "concentrate" and "struggle" (item 7 and 20) had potential to make patients confused and were difficult to understand especially by those with low level of education. Therefore, he suggested to change the word of concentrate to "a moment to rest and gathering energy to reduce pain" and struggle to "forcing or pushing myself". The researcher then changed, modified, and added words in order to convey the same meaning as in the English version and overcome the discrepancies in Indonesian culture.

Protection of Human Rights

     1. Permission from the Ethical Committee Faculty of Nursing, Prince of Songkla University was obtained.

     2. Permission for data collection was obtained from the Directors of H. Adam Malik, Dr. Pirngadi, and Haji Hospitals in Medan, Indonesia.

     3. Subjects who were willing to participate in this study provided oral or written consent to the researcher or the research assistant (Appendix A). Subjects had freedom to ask for explanation regarding the instrument or to withdraw form the study at any time with no consequences.

     4. Subjects who were willing to participate in this study, but experienced with high level of pain intensity (score 7 and above) were not included to prevent inducing excruciating pain during data collection.

     5. Subjects participating in this study were informed the possibility to have pain during the induction of activities for 10 to 12 minutes. If subjects experienced unacceptable level of pain,

the activities were terminated and the researcher or the research assistant informed staff nurses

and or physician to relieve the pain.

6. Subjects were assured that the data would be kept confidential. The researcher used

coding system for subjects' identity and protected privacy through anonymity. Then, all

documents were destroyed at the end of the study.

Data Collection

Data collection was conducted at Haji Adam Malik, Dr. Pirngadi, and Haji Hospitals,

Medan, Indonesia, in November 2006 to March 2007. The steps of data collection were as

follows:

Preparation Phase

1. Permission for data collection was obtained from the Directors of the target

hospitals.

2. The head nurses and staff nurses in the medical, surgical and gynecologic wards

were informed about the objectives of the study.

3. One research assistant who met the following criteria was recruited: had an educational background of at least bachelor degree in nursing, experience in caring of cancer patients, and had knowledge in research methodology.

4. Research assistant training was conducted. The training consisted of five steps adapted and modified from Keefe and colleagues (1990). Five steps of research assistant training were included: discussing, providing, exampling, applying, and involving. Each step was explained as follows:

4.1. Discussing: the researcher and the research assistant discussed the definitions, descriptions and related issues in the study.

4.2. Providing: the researcher provided a manual of the study including: short form of the study's proposal, procedures of collecting data and scoring, and photo copy of instruments that can be used as a reference guide.

4.3. Exampling: the researcher gave the examples of situations in which it might be or might not be appropriate to score the pain intensity, pain acceptance and pain behavior of the patients directly and the research assistant was asked to respond to the instruments.

4.4. Applying: the researcher asked the research assistant to administer the instruments to selected cases, and then the researcher supervised the research assistant during the activities.

4.5. Involving: the researcher and research assistant involved in data collection periodically to ensure the adherence to instruments and the protocol, during the session, the research assistant compared his records with the researcher and the reliability was calculated.

Implementation Phase

1. Subjects who met the inclusion criteria were identified. Then the researcher and/or research assistant approached them to participate in the study.

2. The subjects were given explanation regarding the objectives of the study and the subject's rights.

3. The subjects were asked to fill out the Demographic and Disease Related Data Forms, for some data was retrieved from patients' medical record.

4. The subjects were asked to respond to the instruments. As the order of responding to

the questionnaires may have contributed to pain behaviors, 2 different sequential orders of data

collection were performed. For the first 30 subjects, pain intensity and pain acceptance

questionnaire were collected, followed by pain behaviors. For the next 28 subjects, pain intensity

was measured first, followed by pain behaviors and pain acceptance. Subjects were requested to

complete the CPAQ for 15-25 minutes. Gathering data regarding pain behaviors was performed

as follows:

4.1. Each subject was asked to perform activities as described in the instruction

including two periods of sitting, standing, reclining, and walking.

4.2. Pain behaviors were observed during the activities and recorded on the PBOP

Form. Pain behaviors assessment lasted approximately 10-12 minutes.

Data Analysis

The collected data were processed using the statistical analyses including descriptive

statistics and inferential statistics.

Descriptive Statistics

Descriptive statistics was used for presentation of the subjects' demographic and disease-

related data, pain intensity, pain acceptance, and pain behaviors. The data were described in

frequency, percentage, mean, standard deviation (*SD*), and range.

Inferential Statistics

The assumptions of correlation tests were conducted initially to test the assumptions prior

to running parametric tests. These assumptions included the subjects must be representative of the

population, the variables that were being correlated have a normal distribution, approximate the

normal curve, and be linear. In this study, the assumptions of normality were met. Then,

Pearson's moment correlation coefficient (*r*) was used to test the correlations among pain

intensity, pain acceptance, and pain behaviors.