CHAPTER III
MATERIALS AND METHODS

This chapter describes the research methodology in this study. It is included research design, study populations, study sample, inclusion and exclusion criteria, sample size, sample selection, research instruments, data collection, data analysis, and ethical consideration.

3.1 Research Design

This study was a cross-sectional study design.

3.2 Study Populations

Participants in this study were elderly people who aged at least 60 years old and lived in Lampang province.

3.3 Study Sample

Elderly people aged at least 60 years old who lived in Lampang province. The study was carried out from August to November, 2013 and had done by using inclusion's criteria.

3.4 Subject

3.4.1 Inclusion criteria for study subject:

1) Elderly people who were male or female, aged at least 60 years old.

2) Elderly people who did not have a depression were screened by using 2Q test or who did not have a psychotic disease during study were collected from an interview.

3) Elderly people who did not have high fever during study were collected from an interview.

4) Elderly people who had good consciousness. They could see, hear, and communicate with Thai language.

5) Having the informant had specific qualifications.*

6) Elderly people and informants were willing to participate in the study.

* *1. Male or female*

2. Aged at least 20 years old.

3. Lived or continued contacted with the elderly subjects during last ten years before the study was carried out. They should be spouse, child/children, or relatives of the subjects.

4. Can communicate in Thai language.

3.4.2 Exclusion criteria

1) Discontinuing to give information during study.

2) The elderly people or informant gave an uncompleted data in part of the screening tools.

3.5 Sample Size

The estimated sample size was calculated from the formula as follows: (115)

$$n = \frac{deff\ x\ Z^2_{\alpha/2} P(1-P)N}{Z^2_{\alpha/2} P(1-P) + Nd^2}$$

When, n = Estimated sample size

α = Level of statistical significance was set at 0.05

$Z_{\alpha/2}$ = Value from normal distribution associated with the confident interval = 1.96 for 95% CI

P = Proportion of learning disabilities, the value of 0.15 was obtained from the Lampang Provincial Public Health Office in 2011

N = Total number of elderly was

d = Absolute precision required on either side of the proportion of the study, the value of 0.05 was selected

deff = design effect, the value of 2 was selected

Then, we calculated the sample size when $Z^2_{\alpha/2}$ = 1.96, P = 0.15, N = 132,517 and d = 0.05

$$n = \frac{2 \times (1.96)^2(0.15)(1\text{-}0.15)(132{,}517)}{(1.96)^2(0.15)(1\text{-}0.15) + (132{,}517)(0.05)^2}$$

$$= 392 \text{ (n= 440)}$$

According to this study plus 10% of the total sample size for avoiding from missing of study sample and who did not have the specific qualifications. Therefore, it required 440 subjects for this study.

3.6 Sampling Technique

The sample size derived from stratified multi stage sampling:

1) Simple Random Sampling for four districts from total 13 districts.

2) Stratified sampling sort by Provincial Statistical Office (116).

3) Multistage sampling derived from district number and Stratified sampling for proportion to size derived from the formula: (117)

$$n_h = \frac{n \; x \; Nh}{N}$$

Note: n_h = Sample size

n = Estimated sample size

N_h = number of elderly

N = Total number of elderly

4) Simple Random Sampling derived from list of elderly people that sort by database of districts.

The sampling procedure was summarized as shown in Figure 3.1

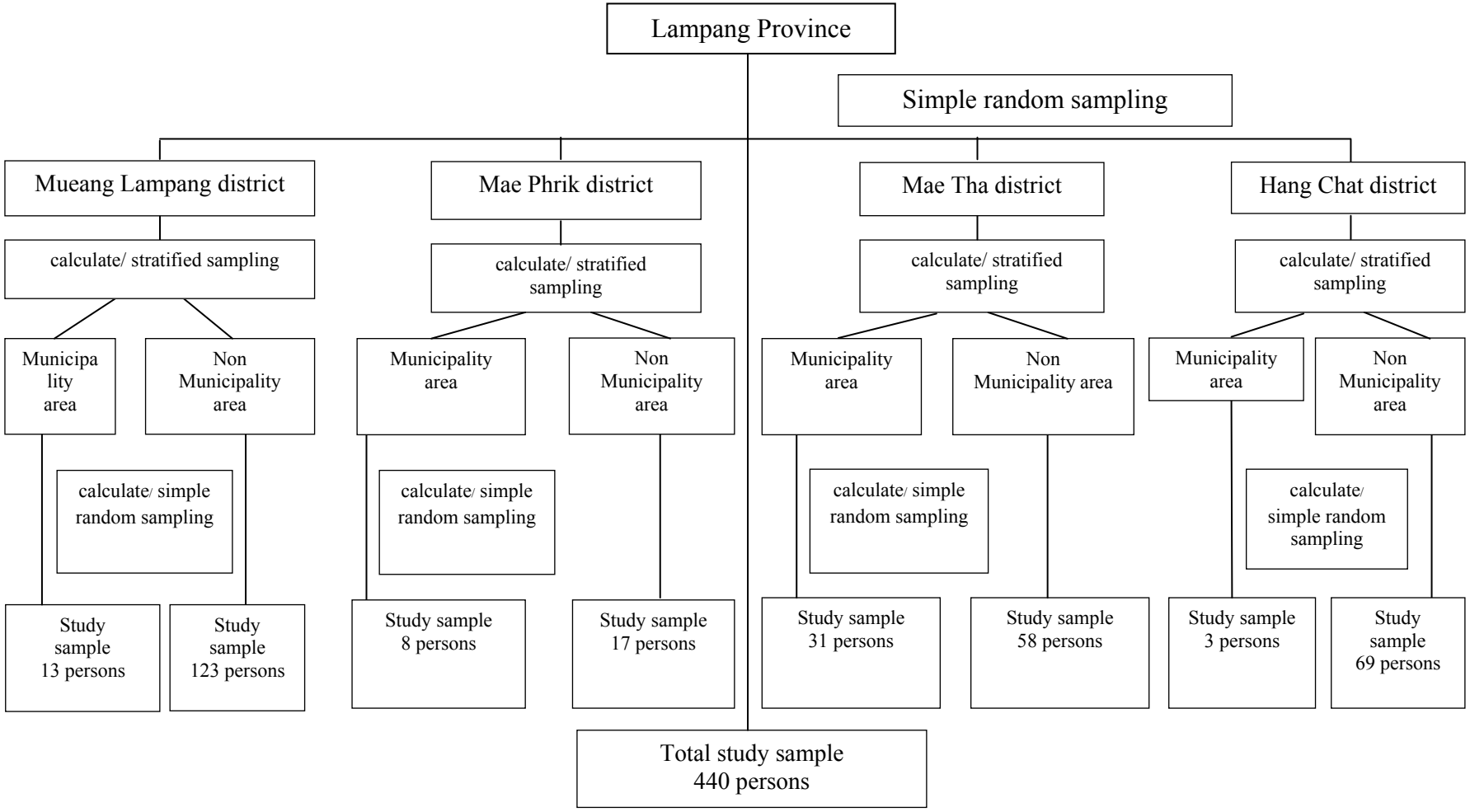

Figure 3.1 sampling procedure

3.7 Research Instruments

The research instruments of present study were a questionnaire which the researcher collected by based on conceptual framework and research objectives and dementia screening test. It consists of six parts (Appendix) as follows:

Part 1 Demographic Factors: the data were collected from an interview and comprised of eight items including:

- Gender
- Age
- Educational
- Marital status
- Income
- Occupation following: occupation (before 60 years old), occupation (after 60 years old), job characteristic, and duration of work (hours/day)
- Daily activity level
- Life crisis event following: parental death, spouse death, child death, and parental separation
- Leisure activities following: type of activity, frequency to do activity

Part 2 Family Factors: the data were collected from interview and consisted of three items including:

- Family member had history of dementia
- Living arrangement following: type of family, number of members in family, place of resident, and the relationship in family
- Caregiver following: the main caregiver

Part 3 Risk factors collect data from interview and consisted of 7 items including:

- Smoking, following: type of the smoking, frequency of smoking, volume and duration of smoke (years).
- Alcohol consumption following: type of alcohol drinking, frequency of drinking, volume and duration of drinking.

- Physical activities following: type of physical activity and frequency to do physical activity.

- Non-steroidal anti-inflammatory drug usage following: type of NSAIDs, and frequency to take NSAIDs.

- Supplement usage following: type of supplement and frequency to take supplement.

- Vitamin usage following: type of vitamin and frequency to take vitamin.

- Food consumption following: kind of food and frequency to eat food.

- History of organic solvent. type of organic solvent, frequency of exposure to organic solvent The data were collected from interview.

Part 4 Clinical factors: collected from interview as five items follows:

- Hypertension following: type of treatment, continually to treatment and duration of disease.

- Diabetes mellitus following: type of treatment, continually to treatment and duration of disease.

- Dyslipidemia following: type of treatment, continually to treatment and duration of disease.

- Body mass index (118)

  - Underweight refers to BMI<18.5 kg/m^2
  - Normal refers to BMI=18.5-23.9 kg/m2
  - Over weight refers to BMI = 24-26.9 kg/m2
  - Obesity refers to BMI>27 kg/m2

- History of depression following: type of treatment, continually to treatment and duration of disease

- History of head injury following: consciousness after got head injury, type of head injury, and frequency of head injury.

Part 5 Instrument of screening test

This study consisted of two instruments to screening for dementia as follows:

1. The Mini-Mental State Examination (MMSE-Thai 2002) (Appendix)

The score of MMSE was commonly influenced by reading and writing skill of the elderly people, due to this limitation, the MMSE-Thai 2002 was divided in to two forms depending on educational level of the elderly people (Institute of Geriatric Medicine, 2003). The questions for the educated elderly contained with 30 items and uneducated elderly contained with 23 items (items of 4, 9, and 10 required reading and writing skills so they were omitted).

The MMSE-Thai 2002 has 32 questions and consisted of 11 articles include: (50)

1) Orientation for time (5 score)
2) Orientation for place (5 score) (choose to do one of all items)
3) Registration (3 score)
4) Attention/Calculation (5 score) (choose to do one of all items)
5) Recall (3 score)
6) Naming (2 score)
7) Repetition (1 score)
8) Verbal command (3 score)
9) Written command (1 score)
10) Writing (1 score)
11) Visuoconstruction (1 score)

Furthermore, the MMSE-Thai 2002 consisted of three cutoff points as follows:

- 14 score (total 23 score) for uneducated person.
- 17 score (total 30 score) for who completed primary school.

- 22 score (total 30 score) for who completed higher than primary school.

The elderly person who got the total score below the corresponding cut-off points was possible to be dementia.

2. The modified informant questionnaire on cognitive decline in the elderly people (modified IQCODE) (Appendix)

This modified IQCODE (16) consisted of 32 items. It was used to assess the cognitive decline of the elderly people by asking his/her informant. The informant rated elder's changes in memory, intelligence, and activities of daily life during the last ten years with a five-point scale:

1 = much improved in the last ten years

2 = a bit much improved in the last ten years

3 = not changed improved in the last ten years

4 = a bit worse in the last ten years

5 = much worse in the last ten years

There were five rating scales. The scoring criteria were as follows:

Much improved = 1 point

A bit improved = 2 points

Not change = 3 points

A bit worse = 4 points

Much worse = 5 points

The modified IQCODE scores were calculated by averaging the response for all items. The average of total scores ranged from 1-5. The higher score individual got, the greater impairment he/she was had. The elderly people who got the cutoff score below 3.33 were possible to be dementia.

3. The screening multiple test results by using MMSE-Thai 2002 and modified IQCODE 2002 (13)

Table 3.1 The screening multiple test results by using MMSE-Thai 2002 and modified IQCODE 2002

MMSE-Thai 2002	modified IQCODE	result
Positive (+)	Positive (+)	Positive (+)
Positive (+)	Negative (-)	Positive (+)
Negative (-)	Positive (+)	Positive (+)
Negative (-)	Negative (-)	Negative (-)

4. The overall sensitivity and overall specificity of combined test by probability method (13) The estimated overall sensitivity and overall specificity was calculated from the formula as follows:

Overall sensitivity = P(A+)+ [1- P(A+)]. P(B+) or P(B+)+[1- P(B+)] P(A+)

when P(A+) = sensitivity of MMSE-Thai 2002
P(B+) = sensitivity of modified IQCODE

Overall specificity = P(A-) . P(B-)

when P(A-) = specificity of MMSE-Thai 2002
P(B-) = specificity of modified IQCODE

Table 3.2 The overall sensitivity and overall sensitivity of combined test by using the MMSE-Thai 2002 and the modified IQCODE

Sensitivity of MMSE-Thai 2002 / **Sensitivity of modified IQCODE**	**specificity of MMSE-Thai 2002** / **Specificity of modified IQCODE**	**Overall sensitivity (%)**	**Overall specificity (%)**
Uneducated person Sensitivity (35.4%)/ Specificity (95%)	Uneducated person Sensitivity (81.1%)/ Specificity (89%)	96.8	72.2
Who completed primary school Sensitivity (56.6%)/ Specificity (95%)	Who completed primary school Sensitivity 93.8%)/ Specificity (89%)	97.8	83.5
Who completed higher than primary school Sensitivity (92.0%)/ Specificity (95%)	Who completed higher than primary school Sensitivity (92.6%)/ Specificity (89%)	99.6	82.4

3.8 Validity and Reliability

1. Content validity of questionnaire was examined by all advisors.
2. Questionnaire was carried out by doing pre-test in pilot study with 30 elderly people who lived in Lampang province.

3.9 Data Collection

3.9.1 Before collection data

1) The research protocol was submitted and approved by Faculty of Public Health Ethical Committee, Mahidol University.

2) The questionnaire needed the pre-test with 30 elderly in similar characteristic to target population for the accuracy of the questionnaire.

3) The questionnaire were edited prior in two titles.

3.9.2 Collection data

1) An introduction letter was sent to explain Lampang Provincial Public Health Office about the objectives of this study and ask for permission and cooperation to do this study.

2) The research assistants were trained about the instruction of each question in the questionnaire.

3) Before collecting the data, the research assistants were explained the purposes of this study and asked for permission to collect the data from the subjects with the signature informed consent.

4) Data were collected according to the sequences including demographic factors, family factors, risk factors, and clinical factors. The whole processes took time around ten minutes counted by the researcher or research assistants.

5) MMSE-Thai 2002 were used with elderly people by face to face tested. The whole processes took time around ten minutes counted by the researcher or research assistants.

6) The modified IQCODE were used with informant volunteer by face to face tested. The whole processes took time around ten minutes counted by the researcher or research assistants.

7) Elderly people and informant volunteer got the screening test result after they completed the interview by the researcher or research assistants.

8) The obtained data were then completed and analyzed.

9) The screening test results were sent to four districts according to give suggestions.

Table 3.3 The screening test results by using MMSE-Thai 2002 and modified IQCODE 2002 with suggestions.

MMSE-Thai 2002	modified IQCODE	Suggestion (n)
Positive (+)	Positive (+)	Need to diagnosis (69)
Positive (+)	Negative (-)	Screening test again in next 6 months (156)
Negative (-)	Positive (+)	Screening test again in next 6 months (156)
Negative (-)	Negative (-)	Screening test again in next 1 year (371)

3.10 Data Analysis

After data collection finished, the researcher checked the questionnaire for completed and appraised codes and scores. Data was analyzed statistically by a computer program called Statistical Package for the Social Sciences (SPSS) with the significance level set at 95% CI ($p < 0.05$).

Descriptive statistics

Frequency, percentage, mean, and standard deviation were used to describe demographic characteristics of the subjects.

Analytical statistics

1. Descriptive analysis was used to describe the general characteristic of the subjects by finding percentage and standard deviation then presented data in table.

2. Univariate analysis was used to describe the associated of each factors of dementia among elderly people in this study by specified the unconditional logistic regression.

3. Multivariate analysis was used to describe the associated between factor of dementia among elderly people in this study after adjusted for other variable in the model by multiple logistic regression.

3.11 Ethical Issue

The research protocol was submitted and approved by Faculty of Public Health Ethical Committee, Mahidol University MUPH 2013-122 (APPENDIX). For participated patients, the informed consent was obtained after purpose of the study explained to them. Data collection was used only for purpose of this study. The questionnaires were completed by the subjects' themselves after they were explained about the purpose and procedure of the study, and benefits for joining the study. All information obtained from the participants and informant was kept in a secured place to avoid the access from irrelevant person. Moreover, the information and data will be deleted after finished the study.