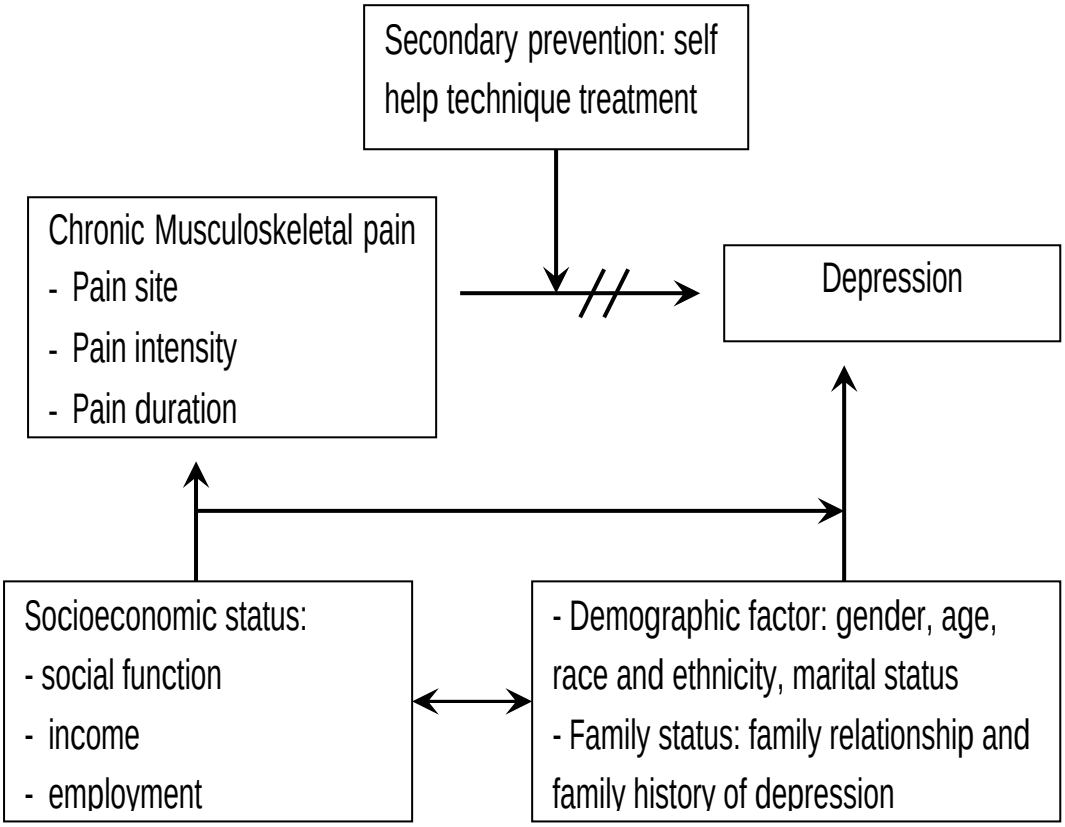
CHAPTER 3

METHODOLOGY

Conceptual Framework



The concept of this study is chronic musculoskeletal pain, major illness or injury and chronic illness can induce or trigger depression. The severity of depression depends on the pain site, pain intensity and pain duration. If chronic musculoskeletal pain is subsided, depression should be better. However, there are many factors that relate to chronic musculoskeletal pain and depression. Hard working for the sufficient income is the factors influencing chronic musculoskeletal pain. In prolong hard working under poor condition e.g., poor posture, poor work station, more work load, can injured the body and effected to mood status. The social status is the one factor that pushes the

people to frantically try to earn the income that can worsen the pain condition. Loss of job and financial problem may result in poor family relationship which in consequence to depression. The other factors, namely, demographic factor, family status relate to depression. A serious loss, poor family or social relationship, or any unwelcome change in life patterns such as, divorce, children leaving home or retirement can trigger a depression.

Aims of the Study

General aims

The general aims of this study are the study of the relationship of chronic musculoskeletal pain (CMSP) to depression (D) in the population under Tachang community health center network, Nakornluang district, Ayutthaya province and the design of the secondary prevention model for delaying the severity of depression.

Specific aims

The specific aims of this study are:

1. determination on the association of potential risk factors (demographic factors, family, social, economic and pain factors) and depression in chronic musculoskeletal pain group (CMSP group)

2. comparison of the depression occurrence between no-pain group (NP group) and chronic musculoskeletal pain group (CMSP group)

3. determination on the efficacy of self-help technique as treatment of chronic musculoskeletal pain and depression

Hypothesis of the Study

1. Demographic factors, family, social, economic factors are associated to depression in CMSP subjects

2. The CMSP subjects with higher pain intensity, more sites of pain and longer duration of pain (pain factors) have the chance to be depression more than the ones with lower pain intensity, one site of pain and shorter duration of pain

3. The probability of occurrence of depression in the CMSP group is higher than in the NP group

4. CMSP subjects receiving pain relief treatment: self management techniques (mobility, flexibility and strengthening exercise) have less pain intensity and a lower HRSR-D score.

5. CMSP subjects receiving pain relief treatment: self management techniques (mobility, flexibility and strengthening exercise) and stress relief treatment: self management technique (progressive muscular relaxation exercise) have less pain intensity and a lower HRSR-D score than the ones receiving only pain relief treatment.

Significance of the Study

The knowledge of the relationship of chronic pain and depression, the predisposing factor to both problems can conduct to the holistic healthcare management planning in prevention, promotion, treatment, and rehabilitation. The holistic healthcare management planning can delay the severity of the problem and reduce the health care cost.

Thai Questionnaire development

In this study, Thai graded chronic pain questionnaire (Thai GCPQ) and Thai pain dysfunction questionnaire (Thai PDQ) were developed for evaluation the severity of chronic pain and pain dysfunction by Cross-cultural adaptation technique.

Method

English Graded Classification of Chronic Pain (GCPQ) and English Pain Dysfunction Questionnaire (PDQ) tested the psychometric properties in the

community context were selected (appendix A, B). GCPQ was composed of 7 items, 1st-3rd item were pain intensity questions and 4th-7th item were physical disability questions. Its Cronbach's alpha was 0.74 for the patients with back pain (M. Von Korff, Ormel, Keefe, & Dworkin, 1992). PDQ was composed of 15 items, 1st-7th item and 12th-13th items were functional status but 8th-11th and 14th-15th items were psychosocial items. Its Cronbach's alpha was 0.90-0.96 for the patients with musculoskeletal problems (Anagnostis, Gatchel, & Mayer, 2004). The authors granted permission for both questionnaires to be translated into Thai.

Both questionnaires were translated into Thai by using the Cross-Cultural Adaptation technique of Gullemin et al, 1993. This Cross-Cultural Adaptation technique consisted of 3 processes (1) Translation: the process of translation from English to Thai by two Thai mother tongue translators. One was aware of the objects underlying the material to be translated and the concepts involved. The other was an English language expert, (2) Back translation: the process of translation of the Thai questionnaire from the first process to an English questionnaire by two English mother tongue translators who were Thai language experts, (3) Committee review: the process of the comparison between the original English questionnaire and back translated English questionnaire. This process was conducted by three English experts. They considered the introduction/ instruction, content and scaling of response of each questionnaire.

Psychometric properties test

Psychometric properties of the Thai GCPQ and the Thai PDQ (appendix C, D) were tested in subjects ranging in age between 15 to 59 years and who had consented to this project. There were 3 groups of subjects. The first group was no-pain subjects (NP) who had no pain in the previous 3 months and had no pain dysfunction. They responded to both questionnaires twice. The re-test was conducted on the two days following the first test. The second group consisted of subjects with pain for less than 3 months (AMSP). And the third group had suffered pain for more than 6 months (CMSP). Both AMSP and CMSP groups were diagnosed with musculoskeletal

problems by Orthopedists. They had ruled out the possibility of pain from cancer, metabolic disorder or systemic diseases. Both groups answered the questionnaire once.

Data analysis

The comparison between the mean score of each domain in the Thai GCP and the Thai PDQ from the test and re-test in the NP group were analyzed according to the Wilcoxon Match Pairs Signed Ranks Test. Independent Paired T-Test was used to compare the mean of the pain intensity score (PI score from the Thai GCP) and the pain dysfunction score (PD score from the Thai PDQ) between the AMSP and CMSP Groups. The Mann-Whitney U Test was used to compare the mean of the disability point (DP from Thai GCP) between the AMSP and CMSP Groups.

Result

There were 114 subjects in this project. Forty-nine were NP group, 31 were AMSP group, and 34 were CMSP group.

Table 3.1

The character of subjects in no pain (NP), acute musculoskeletal pain (AMSP) and chronic musculoskeletal pain (CMSP) groups

	NP (n=49)	AMSP (n= 31)	CMSP (n= 34)
Age (yr) [mean (SD)]	28.87 (11.10)	36.93 (9.78)	44.38 (8.28)
Gender (%)			
- male	46.9	61.3	41.2
- female	53.1	48.7	58.8
Education (%)			
- no education	2	0	2.9
- 1° school or lower	26.5	41.9	47.1
- high school/certificate	36.7	35.5	29.4
- Diploma	4.1	9.7	5.9
- Bachelor or higher	30.6	12.9	11.8

Table 3.1 reveals that the mean age of the CMSP group (44.38±8.28) was statistically significantly higher than the AMSP group (36.93±9.78) and the NP group (28.87±11.10). Most of the AMSP (41.9%) and the CMSP group (47.1%) had primary school or lower education.

The comparison between the mean score of each domain in the Thai GCP and the Thai PDQ from the test and re-test in the NP group showed that there were no statistically significant differences of PI score, DP และ PD score. In table 3.2, the PI score (57.06±21.75) and DP (1.44±1.40) of the CMSP group were statistically significantly higher than the PI score (41.72±18.09) and DP (0.42±0.96) of the AMSP group. But the PD score of AMSP (35.51±31.97) did not differ statistically significantly from the PD score of the CMSP group (49.56±30.78).

Table 3.2

The comparison of the mean of the pain intensity score (PI score), disability point (DP) and pain dysfunction score (PD score) between acute musculoskeletal pain (AMSP) and chronic musculoskeletal pain (CMSP) groups

Variable	AMSP (n=31) Mean (SD)	CMSP (n=34) Mean (SD)	S/NS
PI score (Thai GCPQ)	41.72 (18.09)	57.06 (21.75)	S
DP (Thai GCPQ)	0.42 (0.96)	1.44 (1.40)	S
PD score (Thai PDQ)	35.51 (31.97)	49.56 (30.78)	NS

S statistically significant difference ($p < 0.05$)

NS no statistically significant difference ($p > 0.05$)

From the result, the Thai GCPQ could show the obvious difference of pain intensity and pain disability between the acute musculoskeletal pain and chronic musculoskeletal pain groups. So, the Thai GCPQ has been selected to evaluate the pain intensity and pain disability in the longitudinal study.

.The study Design

The longitudinal study of chronic musculoskeletal pain in relation to depression consisted of 3 phases. Phase 1 was the survey study to select CMSP cases and study the association of potential risk factors (demographic factors, family, social, economic and pain factors) and depression in CMSP group. Phase 2 was the follow-up study of the occurrence of depression in the NP group and the CMSP group. Phase 3 was the study of the effect of self-help technique as treatment of chronic musculoskeletal pain and depression

Study area

The area under Tachang community health center network, Nakornluang district, Ayutthaya province was selected as the study area because of many reasons as the following:

1. The musculoskeletal and connective tissue problem were common in the population under Tachang community health center network. This pushed the MSP problem as the 4th rank problem and increased continuously ever year in Ayutthaya province during 2003-2005. And it was being the chronic problem that may effect to mental problem.
2. This problem has never been studied in this network area.
3. This area was proper for the longitudinal study because of the little of the population dynamic.
4. There was the good database system in this network. It was easy to audit the data of population and health problem.
5. The personnel in Ayutthaya public health team including the public health workers and public health volunteer in this network fully cooperated in this study and would like to learn how to research simultaneously.

Sample size

The Formula was $n = \frac{Z\alpha^2 PQN}{d^2 (N-1) + Z\alpha^2 PQ}$.

$Z\alpha$ = Critical value at $\alpha = 0.05$

P = The proportion of comorbidity of depression and chronic musculoskeletal pain (CMSP with D) that might be in the population

Q = 1 - P

N = Total population

d = Range of sample standard error was 1%

From the previous three studies, it was found that the comorbidity of depression and chronic musculoskeletal pain is approximately 1.8% (Currie & Wang, 2004), 2.59% (Von Koff, 1990) และ 2.5% (Magni et al, 1990). P in the formula was 2.3% that was the mean of the percentage of comorbidity of depression and chronic musculoskeletal pain from previous studies. N was 6,995 people aged 15-59 years old)

So $n = \frac{(1.96)^2 \times 0.023 \times (1-0.023) \times 6995}{[(0.02)^2 \times (6995-1)] + [(1.96)^2 \times 0.023 \times (1-0.023)]}$.

$= \frac{603.84}{2.88}$

= 210 คน

From 210 people, 5 CMSP with D could be found (~2.3 % of population). If 60 CMSP with D were needed for phase 3 in this study, 2,520 samples were needed.

So in the beginning of this study, 3,000 samples were selected by proportional allocation from a total of 6,995 people under Tachang community health center network, Nakornluang district, Ayutthaya province. The numbers of samples

according to age, gender and community health center were selected by systematic random sampling. The sampling interval equals N in each group / n in each group (table 3.3).

Table 3.3

The number of samples by center, age and gender for the total 3,000 samples

	Tachang community health center 1,376 samples		Pranon community health center 666 samples		Maela community health center 624 samples		Samtai community health center 334 samples	
	688 Male	688 Female	333 Male	333 Female	312 Male	312 Female	167 Male	167 Female
Age (yr.)	n	n	n	n	n	n	n	n
15-19	57	62	29	33	30	26	21	15
20-24	78	79	34	32	33	36	27	23
25-29	85	88	35	45	42	40	24	28
30-34	85	90	41	44	42	40	18	19
35-39	102	85	48	47	41	40	16	17
40-44	89	87	52	46	43	37	20	22
45-49	77	88	39	37	33	38	16	17
50-54	61	61	35	28	27	33	11	16
55-59	54	48	20	21	21	22	14	10

The Process of the study

Phase 1 was the survey study to select the no-pain subjects and CMSP subjects for phase 2 and phase 3 and study the association of potential risk factors (demographic factors, family, social, economic) and depression in CMSP group.

Selected male and female subjects (between 15 and 59 years) from 4 community health centers could read and write the document, had no history of psychiatric treatment, no drug addiction, no handicap and had to consent to cooperate in this study.

Three thousand health survey questionnaires with patient's information sheet and informed consent form (appendix E) were distributed to 3,000 samples by public health volunteers at the end of December 2005 and were picked up again during early January 2006. The contents in the questionnaire were demographic characters, socio-economic factors, Thai GCPQ, Thai PDQ and health-related self report scale: the diagnostic screening test for depression in the Thai population (HRSR). For D score, 2 cut–off points were used to identify depression. Cut-off D score of less than 20 (low risk depression) was used to select case for phase 2. And cut-off D score of 20 or more (high risk depression) was used to select case for phase 3.

All returned questionnaires were considered about the completed D score and pain questionnaire. The subjects with completed both score were sorted into three categories: (1) no-pain group (NP), (2) acute pain group (AP), and (3) chronic pain group (CP). Then a family physician and physician had screened the chronic pain group to select the chronic musculoskeletal pain (CMSP) subjects according to the screening guideline handbook (appendix F).

From phase 1, 150 NP subjects with low risk depression were selected by random sampling from NP group and 160 CMSP subjects with low risk depression were selected by screening from CP group for phase 2. The aim of phase 2 was to follow up the occurrence of depression by considering from the D score and comparing between NP group and CMSP group. The subjects with pain from other systems, metabolic disease, cancer, systemic disease, and physical handicap were excluded from this study. The follow up questionnaires were distributed to samples by public health volunteers every three months for six months. The questionnaire was the same as the questionnaire in phase 1, but in this phase the duration for pain in 2nd item to 7th item in

Thai GCPQ was changed from “In the last 6 months” to “In the last 3 months”. At the end of the follow up, CMSP subjects would be treated for their pain by the researcher.

Thirty four CMSP subjects with high risk depression were screened in phase 1 for including in phase 3. The aim of phase 3 was the study of the effect of self pain relief and self stress relief technique to CMSP and D score. This phase consisted of 2 periods: period 1 for study the effect of self pain management, while period 2 for comparison study between self pain management technique and combination of self pain and self stress management technique.

All CMSP subjects with high risk depression were evaluated and identified their musculoskeletal problem by physical therapy assessment (Gross, Fetto, & Rosen, 1996) and recorded in the physical therapy assessment record (appendix G). They were structure in-depth interviewed about socio-economic, family relationship and family history of depression according to the question guideline (appendix H). This information was used to design their individual treatment.

In period 1, 34 CMSP subjects with high risk depression were treated by self pain relief technique that was self help physical treatment (Chaitow & Delany, 2002): mobility / flexibility (appendix I) and strengthening exercises / lifestyle and working education (posture, lifting technique, work place). They had to completed the questionnaire same as in phase 2 at the beginning of the treatment and at the end of the 3rd month. During the treatment period, the subjects were follow-up in every 2 weeks for enhancing to exercise correctly and consecutively.

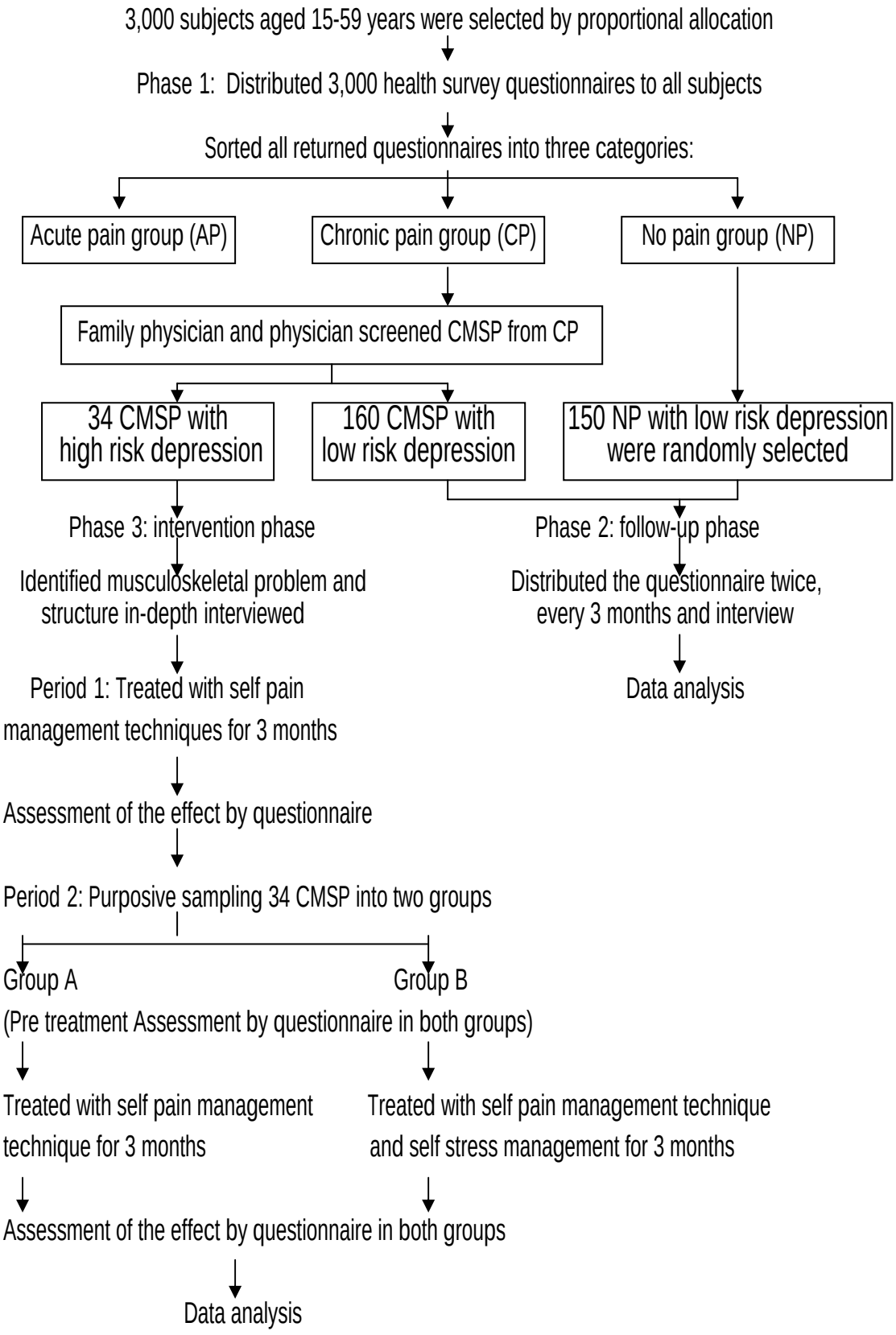
Period 2 for the second three months, all subjects in period 1 were divided into two groups by purposive sampling that was considering about the increasing of pain score and D score after period 1. All of them had to complete the questionnaire for baseline data. The first group (group A) was treated by self pain relief technique / lifestyle and working education and the other group (group B) was treated by a combination of self pain relief technique / lifestyle and working education and self stress relief technique (appendix J: progressive muscle relaxation technique) (Kaiser Permanente, 2002; Mentalhelp, 2006). The questionnaire was completed again at the

end of month 3 of period 2. The follow-up for enhancing to exercise correctly and consecutively in period 2 was limited because there were the difficulties in making appointment to the subjects and it was uncomfortable to go to some flood area.

Termination of participation

Subjects who did not consent to extend the project or who had signs and symptoms of major depression were excluded from the project.

Diagram of Experiment



Study Time Frame

Timing / Activities	June 2005 – May 2007																						Note
	jun 2005	Jul	Aug	Sep	Oct	Nov	Dec	Jan 2006	Feb	Mar	Apr	May	june	Jul	Aug	Sep	Oct	Nov	Dec	Jan 2007	Feb	Mar-May	
Develop measurement tool	←	—	—	—	—	* →																	Extended 2 months
Phase 1: Distribute questionnaire and categorize respondent							←	* →															Delayed 2 months
Screening CMSP case								←	—	→													
Phase 2: Follow up pain score and D score								←	—	—	—	—	—	—	→							*	Delayed 2 months and follow up for 6 months
Phase 3: Study the effect of physical and mental treatment in CMSP group											←	Period 1	—	→				←	Period 2	—	→	*	Delayed 2 months and study for 6 months

* Data Analysis

Data Analysis

1. Univariate analysis for the association of potential risk factors (demographic factors, family, social, economic and pain factors) and D score in CMSP subjects were analyzed by Pearson Chi Square and Fisher's Exact Test

2. Multivariate analysis for association of all potential risk factors and D score in CMSP subjects was done by Binary Logistic Regression. In each equation, the binary (0-1) dependent variable was risk depression (D score of less than 25) and probable depression (D score of 25 or more) respectively. The following dichotomous independent variables were forced to enter the model: gender [male (0) vs. female (1)]; income [sufficiency (0) vs. insufficiency (1)]; poor relationship [no (0) vs. yes (1)]; pain site [one site (0) vs. multiple sites (1)]; pain intensity [pain score of less than 50 (0) vs. pain score of 50 or more (1)].

3. The occurrence of high risk depression (D score of 20 or more) in the NP group and the CMSP group was analyzed by percent increase of D score and Cochran's Q test every 3 months.

4. The probability of high risk depression (D score of 20 or more) in NP and CMSP group was analyzed as Relative Risk: Taylor series and computed from EpiInfo version 6.

5. The effect of intervention on pain intensity and D score in CMSP was analyzed by Wilcoxon Signed Ranks Test.

6. The effect of intervention on pain intensity and D score in group A and group B was analyzed by Wilcoxon Signed Ranks Test within the same group and was analyzed by Mann-Whitney U test between the groups.

7. Point prevalence of depression based on a cut-off point D score of 25 or more (probable depression) and of 30 or more (depression) in the population under Tachang community health center, Nakornluang district, Ayutthaya province was calculated by n/N x 100

All of these analyses are based on type one error of 0.05