CHAPTER 3

Methodology

This chapter presents a description of research design, population and sample, research setting, research instruments, human rights protection, data collection procedures, and data analysis.

Research Design

This study utilized a randomized controlled trial; two-group pre-posttest design was used to examine the effect of group cognitive behavior therapy program in comparison with usual care on depression reduction among older women. Single-blinded, and random assignment was employed to recruit older women in six Sub district Hospitals (SDH) of Naresuan University Hospital (NUH), Phitsanulok province in which three SDHs were experimental groups (Sao-Hin, Tha-Thong, and Tha-Pho) and another three SDHs were the control groups (Ngio-Ngam, Wat-Phick, Wang-Nam-Khu). Thirty participants from three SDHs were simple random sampling assigned to the experimental group, (10 participants per each SDH) and another thirty participants assigned to the each control group (10 participants per each SDH).

The independent variable is the program of care, which include group cognitive behavior therapy program for the experimental group, and usual care for the control group.

The dependent variable is depression as measured by the PHQ-9-Thai version.

Threats to internal validity is addressed as follows:

1. To prevent history threat, participants were randomly assigned to either the experimental or control group and data collection was done simultaneously.

2. Randomization was used for the results in equivalent methods for the control and experimental groups, which could lower selection threat. This study applied the simple random sampling technique.

3. Including the control group will minimize maturation threat and history. Depressive symptoms was measured at four points in time: At baseline, immediately after the completing group CBT program, one month follow-up, and three months follow-up.

4. To decrease instrument effect threat, the same questionnaires were used at all of the four time points in both groups. Also, at each site, the same health care providers administered the questionnaires to the participants.

5. To minimize mortality threat, an adequate sample size was used.

Threats to external validity were addressed as follow.

1. Single–blinded random assignment was used to prevent the Hawthorne effect. Neither the data collector nor the participant knew if the participant was in the control or experimental group. They were informed what activity they received, not letting them knows if they were in the experimental group, or in the control group.

2. The control group participating in the usual care received psychoeducation about depression and advise needed to exercise 30-45 minutes at least 2-3 time per week, if they do not have any complication that follow the guidebook of depressive disorders surveillance and care: provincial level for mild depressive symptoms in SDH of Department of Mental Health, Ministry of Public Health (2014), and follow-up after standard care has been completed. This ought to decrease the novelty effect.

Population and Sample

Population

The population in this study were from community-dwellings, were mildly-depressed women (using the PHQ-9 Thai version; Lotrakul et al., 2008) aged 60 or older, living in Phitsanulok province, Thailand.

Sample

The sample in this study came from community-dwellings, were mildly-depressed women, (using the PHQ-9 Thai version; Lotrakul et al., 2008), aged 60 or older, coming to Sub District Hospitals (SDHs) of the Naresuan University Hospital (NUH), Phitsanulok province. Sample size was determined based on the sample size estimates for test of differences between three or more means Eta-squared, which equals the sum of squares divided by the total sum of squares (the sum of squares between and the error term), and can be used directly as the estimate of effect size. The index indicating the proportion of variance explained in ANOVA, by using the G*Power 3.1.6, and repeated measures of analysis of variance, a total sample size of 44 was yielded, setting a modest correlation of the repeated measures at .2, an alpha at .05, a power at .80, and a medium effect size of .25. To be conservative with a 27% attrition rate in a repeated measures study, the total sample size of 60 was included (Fual, Erdfelder, Buchner, & Lang, 2009). In Thailand, a previous similar study used an estimated sample size of 27 subjects per group of older persons, when calculated found that the effect size more than .80 (Kisumban et al., 2009). Thus for this study, the researcher recruited extra numbers of participant to 20 percent above 25 subjects, anticipating the bias due to case dropouts (Polit & Beck, 2004), because a dropout rate was estimated at 20 percent, and the desire to prevent low power of the test, the researcher added 5 more subjects in each group.

Research Setting

Six Sub District Hospitals of Naresuan university hospital in Phitsanulok province were the setting that the researcher used for collecting the data during December 2014-May 2015.

As a result, eligible participants were recruited from the six SDHs of NUH using random assignment 3 of 6 to the experimental group, and another 3 SDHs were assigned to the control group, and then simple random sampling in the experimental (n =30), and three SDHs as the control group (n =30) (See figure 3-1 and Figure 3-2).

Inclusion Criteria

The participants were women and had an eligibility criteria as follows:

1. Aged 60 years or older.

2. Whose score for the PHQ-9 Thai version (Lotrakul et al., 2008) were between 5 and 8, indicating mild depression.

3. Able to communicate and write in Thai.

4. Willing to participate in the study.

Exclusion Criteria

Participants were not recruited to the study if they met the following criteria:

1. Having psychotic symptoms during an intervention, such as hallucinations or suicidal ideation.

2. Receiving psychiatric medications

3. Having cognitive impairment measured by MMSE at pretest, posttest and at the follow up.

Discontinuation Criteria

Discontinuation criteria were

1. Incomplete participating in the program.

2. Need to withdraw from research participation

Sampling Method

The health care providers screened an initial sample of community dwelling older women (n=234) who presented at six SDHs. This resulted in a pool of 120 eligible women who met the inclusion criteria, from whom 60 were selected for this study. A random number table was used for study randomization (Grove, Gray, & Burns, 2015) and for

simple random assignment to either the CBT program (n= 30) or a usual care (n= 30) comparison condition. Randomization was performed by a health care provider who was not involved in the trial.

Research Intervention

The steps of implementation of group CBT program were summarized to be schedule as illustrated in the summarized schedule of group CBT program for mild depressive symptoms for older women.

Research Instruments

The instruments used in this study included instruments for data collection, screening instrument, and instruments for intervention.

Instruments for Data Collection

1. Demographic data questionnaire, developed by the researcher, consisting of closed questions regarding demographic characteristics of the older persons, such as age, education, marital status, income, chronic illness such as hypertension, and diabetes mellitus, mental illness and family mental illness history.

2. The PHQ-9 (Thai version) which was translated by Lotrakul, Sumrithe, and Saipanish (2008) had acceptable psychometric properties for screening for major depression in general, with a demonstrated good sensitivity and specificity for a depressive disorder. As a severity measure, the PHQ-9 score ranges from 0 to 27, because each of the 9 items can be score from "0" (not at all) to "3" (nearly every day). This instrument divides the range of the score to the level of depression as, 0- 4 no depression, 5-8 mild depression, 9-14 major depressive disorder, mild or dysthymia, 15-19 major depressive disorder, moderate, and ≥ 20major depressive disorder, severe. Reliability of instrument for measuring depression in this study was the PHQ-9 (Thai version) that previous studies presented high quality to measure depression in Thai people. The PHQ-9 had satisfactory internal consistency (Cronbach's alpha = .79) and showed moderate convergent validity with the HAM-D ($r = 0.56$; $P < 0.001$). The optimal cut-off score of the PHQ-9 ≥ 9 revealed a sensitivity of 0.84, specificity of 0.77 and positive likelihood

ratio (3.71).In this study, only those with a score of 5-8 were considered eligible to participate.

The Thai version of the PHQ-9 was tested on Thai patients, and had satisfactory internal consistency (Cronbach's alpha = .79). The PHQ-9 had acceptable psychometric properties for screening for major depression in general practice (sensitivity of 0.84, specificity of 0.77) with a recommended cut-off score of nine, or greater.

Reliability of the PHQ-9 (Thai version). In this study, the instrument for measuring depression was the PHQ-9 (Thai version) that the researcher tested the reliability of this instrument on with 40 Thai older women dwelling in the areas under the responsibility of 6SDHs of NUH, who met the inclusion criteria, but were not the participants of this study, found that the Cronbach's alpha coefficient was .89 which meant that the instrument had good quality (Grove et al., 2015; Polit & Beck, 2012).

Screening Instrument

Estimating a person's peak prior level of cognitive functioning is useful in clinical and research settings. Estimated peak prior cognitive level can provide a baseline from which to access the severity of cognitive impairment following brain trauma, psychiatric or neurological disorder, or the degree of cognitive decline associated with non-pathological ageing (Dykiert, Der, Starr, & Deary, 2016).

Mini-Mental state examination (MMSE), a widely used screening test for possible cognitive pathology, and often used to index cognitive impairment. It is often used as a screening test for signs of cognitive impairment. It tests various abilities, including attention, memory, language and comprehension, figure drawing, and basic orientation. Maximum score is 30, and a score below a cut-off of 24, is often used to indicate possible dementia (Tombaugh & McIntyre, 1992). These instruments perform correlation by a Pearson coefficient was .887, and test retest reliability, the Pearson r remained high at .827 (Folstein, Folstein, & McHugh, 1975). From the study result test the quality of MMSE in German elderly present high reliability (Cronbach's α = .82) (Beyermann, Trippe, Bähr, & Püllen, 2013). In a study to test the quality of MMSE in Scottish older

person found that MMSE used to index cognitive impairment, is associated with prior cognitive ability (Dykiert et al., 2016).

In Thailand, MMSE-Thai 2002, was developed by the Institute of Geriatric Medicine for screening cognitive function for Thai older persons, it includes 11 questions with a range score of 0-30, but the cutting point of cognitive impairment is divided into three levels of education of the elderly 1) uneducated used the cutting point less than or equal to 14, and total score of 23, it has a sensitivity of 35.4%, and specificity as 81.1%, 2) primary school level used the cutting point of less than or equal to 17, and total score of 30, it has a sensitivity of 56.6%, and specificity of 93.8%, and 3) secondary school level and over, used the cutting point less of than or equal to 22, and total score of 30, it has a sensitivity of 92.0%, and specificity of 92.6%, that present a good quality of the instrument (Institute of Geriatric Medicine, 2002). Many studies use MMSE for screening cognitive function in older person, and present good quality of the instrument, such as the Thai national mental health survey in 2013, which uses MMSE to screen cognitive impairment, and found that MMSE-Thai appropriate for screening cognitive impairment in the elderly from the response rate of 99.4% (Kittirattanapaiboon, Tantirangsee, Chutha, Assanangkornchai, & Supanya, 2016). Furthermore, MMSE-Thai is recommended in use for screening for dementia in the community (Siri, 2013).

This study used MMSE-Thai 2002, as the screening instrument, because of group CBT program emphasis on interrelationship among NATs (cognitive), emotion (depression), behavior, and physical, thus this study has exclusion criteria for the participants who presented with cognitive impairments.

Instrument for Intervention

Group Cognitive behavior therapy (CBT) program was an instrument for intervention in this study, and developed by the researcher based on Beck's cognitive theory (Beck, 2011). A process of program development was carefully designed with older women, recognized the internal validity, and the generalizability. After having received suggestions about group CBT program from three experts, the researcher revised the CBT program. The researcher was qualified for the study with training in Cognitive Behavior Therapy from an expert, and received a certificate (before conducting the

intervention), from Department of Mental Health, Ministry of Public Health, Thailand (2011) and Beck Institute for Cognitive Behavior Therapy, USA during April 28-30, 2014, before trying out the program. For test possibility of group CBT program before collecting the data, the researcher used group CBT program for 5 older women with mild depressive symptoms who met inclusion criteria of the study, willing to participate with group CBT program, and dwelling in the area of THPHs of NUH, Phitsanulok province, before starting group CBT program for reducing depression among older women.

Content validity of group CBT program. The validity of group CBT program for reducing depression developed and designed by the researcher based on Beck's Cognitive Theory (2011) was investigated by being sent to three experts in the area of cognitive theory and cognitive behavior therapy: a psychiatrist, a psychologist, and a psychiatric nurse. After receiving their suggestions, the researcher modified the program, and tried this out with five older women who met inclusion criteria, but not the same participants as those of the research study. Evaluating the program found that the researcher should modify font size, have easy homework design, preparing time for checking homework assignment before start of each session, especially the design of behavior activities that are suitable for Thai older, before starting the experiment.

Group CBT program has a main structure of identifying, evaluating and responding NATs by researcher teaching and helping older women to learn these methods to deal with NATs, into a more reality based thinking, and it can reduce their depressive symptoms. Moreover, group CBT program consists of components of CBT, techniques and skills of CBT, stages of CBT, and how to apply CBT for older women, were used.

All of twelve sessions of group CBT program were conducted within 45-60 minutes, and three sessions per week. The steps of implementing group CBT program are summarized into the schedule as illustrated in Table 3-1

Table 3-1

Summary of the 12 Sessions of Group CBT Program

Session	**Time (week/day/ duration)**	**Objectives**	**Components activities of group CBT**
1	Week 1 / Monday/ 60 min.	-Participants acquire an understanding of the patterns of cognition among depressed people. -Provision of information about the CBT intervention, cognitive model, and NATs.	1. Psychoeducation 2. Homework assignment: activity daily record 3. Evaluation and feedback
2	Week 1 / Wednesday/ 60 min.	- Participants learn about case formulation - Encourage participants' understanding of how to identify NATs so they can identify NAT#1 as homework.	1. Psychoeducation 2. Case formulation 3. Identify NAT#1 4. Homework: identify NAT#1 5. Evaluation and feedback
3	Week 1 / Friday/ 60 min.	Participants learning and discussion how to evaluate NAT#1.	1. Evaluating NAT#1 2. Homework: evaluating NAT#1 3. Evaluation and feedback
4	Week2/ Monday/ 50 min.	Participants learn and discuss how to respond to NAT#1.	1. Respond to NAT#1 2. Homework: respond to NAT#1 3. Evaluation and feedback
5	Week 2 / Wednesday/ 50 min.	Participants practice skills and identify NAT#2.	1. Identify NAT#2 2. Homework: identify NAT#2 3. Evaluation and feedback
6	Week 2 / Friday/ 60 min.	Participants practice more NAT evaluation skills and evaluate NAT#2; use Buddhist teaching for cognitive reconstructuring.	1. Evaluate NAT#2 2. Homework: evaluate NAT#2 3. Evaluation and feedback

Table 3-1 (continued)

Session	Time (week/day/ duration)	Objectives	Components of group CBT
7	Week 3 / Monday/ 50 min.	Participants practice more skills to respond to NAT#2.	1. Respond to NAT#2 2. Homework: respond to NAT#2 3. Evaluation and feedback
8	Week 3 / Wednesday/ 50 min.	Participants practice skills to identify NAT#3.	1. Identify NAT#3 2. Homework: identify NAT#3 3. Evaluation and feedback
9	Week 3 / Friday/ 60 min.	Participants practice skills to evaluate NAT#3 and use Buddhist activities for cognitive reconstructuring.	1. Evaluate NAT#3 2. Homework: evaluate NAT#3 3. Evaluation and feedback
10	Week 4 / Monday/ 45 min.	Participants practice skills to respond to NAT#3, and identify benefits from changing their cognition.	1. Respond to NAT#3 2. Homework: identify, evaluate, and respond to other NATs 3. Evaluation and feedback
11 (Robust session)	Week 4 / Wednesday/ 60 min.	1. Participants practice more skills and group discussion on how to identify, evaluate, and respond to other NATs. 2. Group discussion to evaluate group-administered CBT intervention and review cognitive and behavior techniques together.	1. Identify, evaluate, and respond to NATs 2. Evaluation and feedback
12 (Robust session)	Week 3 / Friday/ 45 min.	Participants understand and have appropriate skills to identify, evaluate, and respond to NATs.	1. Identify, evaluate, and respond to NATs 2. Evaluation and feedback

Note. cognitive behavior therapy (CBT), negative automatic thought (NAT)

Usual care was provided only to those in the comparison condition and refers to the activities normally provided by nursing teams in SDHs to persons with mild depression. These activities followed guidelines for mild depressive disorders recommended by the Department of Mental Health, Ministry of Public Health, Thailand (2014) and included only psychoeducation about depression and advice to exercise 30-45 minute at least 2-3 times per week.

Participants in the control group received the same assessments as the experimental group. The control group received the usual care as the activities normally provided by nursing teams in SDHs to persons with mild depression. These activities followed guidelines for mild depressive symptoms in SDHs of the Department of Mental Health, Ministry of Public Health, Thailand (Department of Mental Health, Ministry of Public Health, Thailand, 2014) and included only psychoeducation about depression and advice to exercise 30-45 minute at least 2-3 times per week.

Human Rights Protection

Prior to data collection, the study was approved by the Research Ethics Committee (No. 102/2014) of the Faculty of Nursing, Chiang Mai University, Thailand, before conducting the research program in the research sites.

Data collecting procedures covered all aspects of human rights protection. The researcher asked each participant directly about their willingness to participate in the study, and gave an explanation, and description of the objective, process of the intervention, benefits of the program, and the protection of confidentiality of participants. The older women who agreed to participate were told that they could ask questions about the study, and could deny participating in the study, or withdrawing at any time.

In respect of the potential risks of group CBT program such as emotional distress, or overwhelming emotions, or feelings experienced by the participant, the researcher observed the problems of participants by giving them a rest for a few minutes until they felt comfortable to continue participating in the session, or provided them a private area, and provided psychosocial support. Considering the principle of fairness, the participants in the control group received usual care provided by six SDHs of NUH.

If group CBT program presented more effectiveness than usual care, and the participants in the control group would like to experience more group CBT program, the researcher will provide sessions to them after the research intervention is completed. If the participants have moderate and severe depression, the researcher refers them to the mental health, and psychiatric department of NUH, to receive appropriate care. Though, no participant demonstrated any potential risks during the study.

Data Collection Procedures

Data collection was conducted by the researcher; beginning after the research had been approved by the Research Ethics Committee, of the Faculty of Nursing, with the following steps.

1. The researcher contacted the director of Phitsanulok Provincial Health Office regarding the purpose, and procedures of the study. These were explained to the director, nursing staff, psychiatrist, and other personnel, to ensure their understanding and collaboration. Additionally, the health care providers were informed about the procedures of data collection, and how to use each questionnaire for collecting data.

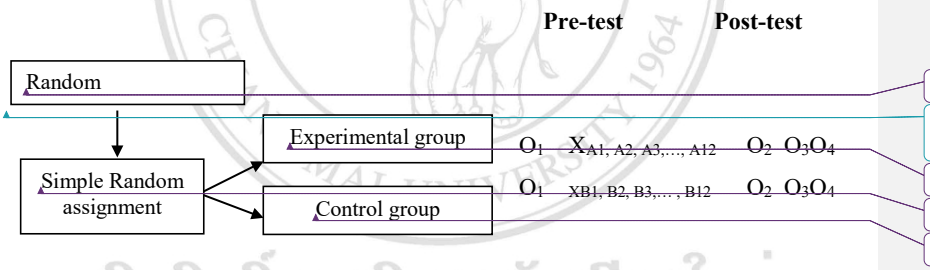
2. The researcher asked for permission to make initial contact with older women in the six SDHs of NUH, for an initial screening, and introducing the study to those who met the inclusion criteria.

3. After obtaining informed consent from participants, the researcher informed participants about the objectives, procedures, and protocol of the study.

4. After random assignment with three SDHs of NUH as either experimental group, or control group, then a simple random assignment using a random number table was used to assign the participants into the experimental, and the control group. Randomization was performed by a health care provider who was not involved in the trial. Six health care providers conducted the baseline of depression in both the experimental and control group, as well as recorded demographic data, before the beginning of group CBT program, at the same time at the six research sites. Health care providers read, and substitute wrote the answers to the questionnaire for six participants, including both the experimental and control group. The participants in both groups did

not know into which group they would participate. For the researcher blinding, the researcher did not know the score of depression of the participants in both groups.

5. After completing group CBT program, six health care providers conducted the posttest immediately, and followed-up on the first, and third month. Health care providers read the questionnaire for six the participants collecting the data at baseline. In addition, data from the control group was collected at the same time as the experimental group. Participants were evaluated three times by the researcher: immediately after completing the program in order to evaluate a short-term effectiveness of the program, and then on the first and third month was a follow-up at the three SDHs of NUH setting. This follow-up period was based on a previous study of Kitsumban et al. (2008) suggesting that the researcher needs to see how maintenance of the clinical trial outcomes of CBT program for the participants in medium time, and should be followed-up at 3 months. This study therefore set the time for evaluation at the first and third month after completing the program. The procedures of the data collection are presented below:



X_{A1} to X_{A12} = Intervention (group CBT program)

X_{B1} to X_{B12} = Usual care

O_1 = Pre-test (Time 1 as baseline)

O_2 = immediately after completing program (post-test1: Time 2)

O_3 = at one month follow up (post-test2: Time3)

O_4 = at three months follow up (post-test3: Time 4)

Figure 3-1. Diagram Showing Participant Recruitment Procedures

Procedure in the Experimental Group

1. After participants were simple random assignments to the treatment condition. The researcher set appointment dates for the experimental group to participate in group CBT program.

2. The researcher introduced the overview of the twelve sessions of group CBT program to participants in the experimental group. Participants attended three times a week, totaling twelve sessions in each private room of SDHs. The total duration of group CBT program session was conducted in approximately a one month period, and one and three months follow up after completion of group CBT program. All of the twelve sessions had homework assignment from the researcher helping the participants to learn the process of group CBT to deal with depression from the previous session and before the beginning of the next session.

3. Ten Participants in each group continued group CBT program three times a week sessions of 45-60 minutes per session. At immediately after completing group CBT program, the participants were measured (PHQ-9) again by health care follow up providers, and a measure of depression score at one and three months. At this appointment all of them completed the PHQ-9 at three SDHs by health care providers at the setting. A total of 30 participants completed group CBT program of all 12 sessions, no missing cases, because the researcher gave the procedure plan to health care providers to recall the participants, and the researcher emphasized to the participants about homework assignments, and an appointments after finishing each session.

Procedure in the Control Group

1. After participants were simple random assignments to the control group. The researcher gave participants an information sheet about common mental health service provided at SDHs of NUH.

2. The post-test measure was conducted three times: first time immediately after completing the program, second time at one month, and the last time at three months after completing the program. Each participant was measured by the PHQ-9(Thai version) score by using the same measure in the pre-test (baseline), and the same time with the

experimental group. This process was done by health care providers for blinding both the researcher, and the participants.

3. After finishing the program, and completing of 3 months follow-up data collection, the researcher offers participants a chance to participate in group CBT program. To date, no participants in this group requested group CBT program.

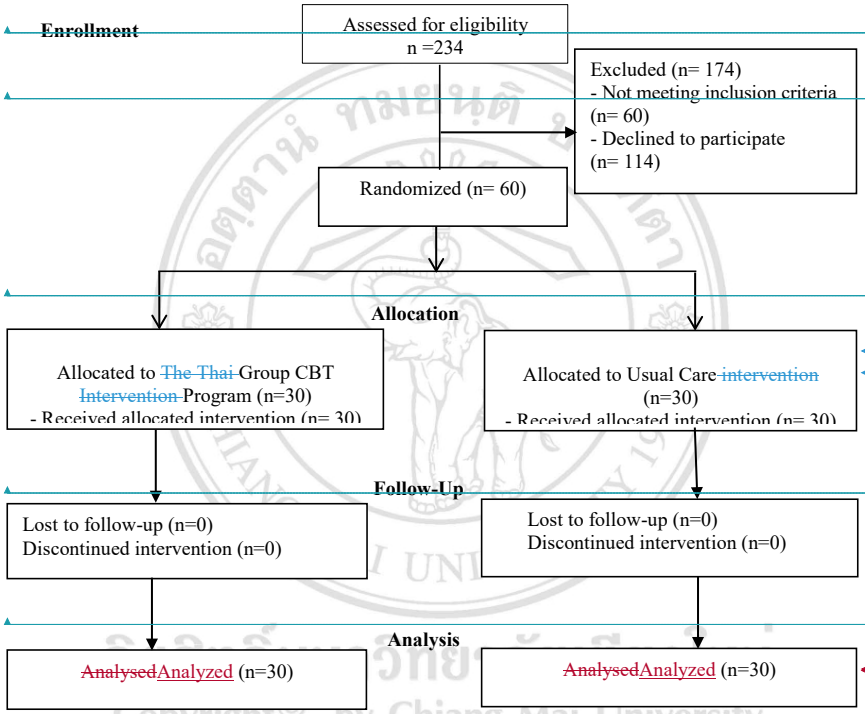


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Figure 3-2. CONSORT flow diagram of sample involvement in study

Data Analysis

Data were analyzed using the statistic package as follow:

1. Descriptive analysis in terms of frequency, mean and standard deviation, and percentage was used to describe the demographic data.

2. Chi-square test, and independent t-test were conducted to examine the differences of demographic data between the participants in the experimental group, and the control group at baseline, and before the research study begins.

3. Kolmogorov-Smirnov Test was used to test the normal distribution of the PHQ-9 scores of the participants in both groups, and F test for homogeneity of variance were tested before using One-way Repeated ANOVA. The researcher used frequency distribution for checking normality visually to look at shape of a distribution by using normal Q-Q chart plot, and Skewness and Kurtosis, not more than 1.96 and -1.96, it presented normal distribution (Field, 2009; Grove et al., 2015; Kim, 2012; Kim, 2013), no difference of homogeneity of variance in both groups. Therefore, they were appropriate to be tested by one-way repeated ANOVA.

4. The One-way Repeated-Measures ANOVA was used for testing the differences of mean scores of depression between baseline, after completing the Thai group CBT intervention program immediately, at one month, and three month follow-up in the experimental group. The assumption of homogeneity of variance was met. To test the change over time of mean scores of depression, one way Repeated ANOVA was used. The results showed a significant difference of mean scores of depression between point of times, and the Post hoc comparison for the repeated ANOVA, using Bonferroni test was calculated in order to compare the difference of mean scores of depression at each point of measurement. The results showed the significantly difference of mean scores of depression between baseline, immediately after completing the Thai group CBT intervention program, at one month, and three month follow up.

For the control group, there was no significant difference of mean scores of depression between baseline, after completing the usual care, at one month, and three months follow-up after completing the usual care. When considering the mean score of

depression at each point, it was found that the mean scores of depression at baseline was lower than the mean scores of depression immediately after completing the usual care, at one month, and three month follow-up.

5. The two-way Repeated-Measures ANOVA was used for testing the differences of mean scores of depression between the experimental group, and the control group at baseline, immediately after completing group CBT program, at one month, and three month follow up. Before two-way repeated measurement ANOVA was used, the assumptions for the homogeneity of variance were tested. The testing results indicated a depression score in both groups that were in normal distribution, and the difference of homogeneity of variance was met. Furthermore, the test of subject effects using Greenhouse-Geisser, found a significant interaction effect of time and group. The significant main effect was found, the independent t test was used to determine the differences of mean scores of depressive symptoms between the experimental and control group in each point of time (Grove, Burns, & Gray, 2013; Grove et al., 2015; LoBiondo-Wood & Haber, 2014).

The results demonstrated no significant difference of mean score of depressive symptoms between the experimental group, and the control group at baseline, whereas there was a significant difference of mean score of depressive symptoms between the experimental group, and the control group, immediately after completing group CBT program, at one month, and three months follow up. The result indicated that the mean score of depressive symptoms of the control group was higher than those of the experimental group counterparts, at each time point after intervention.