CHAPTER 3

Methodology

This chapter describes the methodology of this study. It includes the research design, population and sample, research setting, research intervention, research instruments, testing for quality of research instruments, research assistant preparation, human rights protection of research participants, data collection, and data analysis.

3.1 Research design

This study utilized a randomized controlled trial, two-group post-test only design with the double-blind technique to examine the effects of the Medication Adherence Enhancement Program among newly diagnosed PTB patients. The study tested the differences in medication adherence and treatment success between newly diagnosed PTB patients who received the Medication Adherence Enhancement Program and those who received the usual care. The participants were randomized to either an intervention group or a control group. The program was delivered to the intervention group after demographic and clinical characteristics data were collected in the TB clinic during the patient registration session. The participants in the intervention and control groups were both measured for their medication adherence after participating in the program for three and six months. At the end of treatment or six months after entering the program, the participants in the intervention and control groups were evaluated for treatment success (Figure 3.1).

Intervention group X O1 O2

R

Control group - O1 O2

R = Randomization

X = Intervention

O1= Measured medication adherence at 3rd month after entering the program

O2= Measured medication adherence and evaluated treatment success at 6th month after entering the program or at the end of treatment

Figure 3.1 The Experimental Two-group Post-test Only Design Used in this Study

Variables. The independent variable was the Medication Adherence Enhancement Program for newly diagnosed PTB patients. Dependent variables included medication adherence and treatment success.

Blinding. The double-blind technique of this study was planned to conceal assignment results to the research assistant who collected medication adherence data and the participants were not informed that they were assigned to be in either the intervention group or the control group.

3.2 Population and sample

3.2.1 Population

The target population for this study consisted of newly diagnosed PTB adult patients who live in Phitsanulok province, and who are registered and visited for follow-up care at the TB clinic at Buddhachinaraj Hospital.

3.2.2 Sample

The sample for this study was drawn from all newly diagnosed PTB adult patients between November 2012 and September 2013. The participants were registered and

visiting for follow-up care at the TB clinic at Buddhachinaraj Hospital and their family supporters in the intervention group who met the inclusion criteria:

1) Newly diagnosed PTB patients

1.1) The inclusion criteria for the newly diagnosed PTB patients were as follows:

1.1.1) Aged 20-59 years,

1.1.2) Had been newly reported by physicians as having sputum smear-positive PTB,

1.1.3) Had definitely never taken anti-tuberculosis drugs,

1.1.4) Willing to start a short course of PTB drug regimen,

1.1.5) Were alert, oriented, and cooperative in the program,

1.1.6) Had the ability to communicate in Thai,

1.1.7) Willing to participate and give permission to the researcher to visit their homes and contact them by telephone,

1.1.8) Had a family member who would support them during the program session,

1.1.9) Resided in Phitsanulok province with a distance of not more than 50 kilometers from the hospital.

1.2) The exclusion criteria for the newly diagnosed PTB patients were as follows:

1.2.1) Had severe conditions which make them unable to participate in this program, such as massive hemoptysis or respiratory failure,

1.2.2) Had a condition or behavior that strongly influences medication adherence or treatment outcomes, such as alcoholism, substance abuse, or HIV infection, and

1.2.3) Had a disease that could be made more severe from TB drug treatment, such as chronic liver or kidney disease.

1.3) The discontinuation criteria for the newly diagnosed PTB patients were as follows:

1.3.1) Requiring a change in anti-tuberculosis drug regimen,

1.3.2) Were unable to complete participation in the intervention sessions,

1.3.3) Were transferred out to receive treatment elsewhere.

2) Patient's supporters

The inclusion criteria for the patient's supporters in the intervention group were as follows:

2.1) Were a participant's family member and chosen by the participant,

2.2) Were responsible for supporting patients to take medication and tackle problems involving medication adherence,

2.3) Willing to participate in the study, and

2.4) Had the ability to communicate in Thai.

3) Sample size

Sample size estimation was determined by the difference of two means (Polit & Beck, 2004), using estimated effect size of 0.80 (Chuldeja, 1997) with power of test at 0.80. Based on these calculations, the sample size were at least 25 participants in each group for a total sample of at least 50 participants. Additionally, five previous studies on newly diagnosed PTB patients in Thailand, were conducted to follow-up on medication adherence and clinical outcomes over a long period of time (6 months) and reported that the attrition rate of intervention from death rate and transfer out rate were around 0-12% (Boonpendecha, 2001; Chimbanrai, Fungladda, Kaewkungwal, & Silachamroom, 2008; Kamolratanakul et al., 1999; Suvateerapun, 1994; Wintachai, 1995). Therefore, the sample size should be estimated with consideration of a possible 12% attrition rate. Therefore, the number of subjects needed in this study was 29 participants per group, for a total of 58 participants.

The newly diagnosed PTB patients who met the study criteria were recruited. For controlling intrinsic extraneous variables, a randomization process was used. The researcher made a piece of paper equal to the required number of participants. A piece

of paper was marked with either the letter “I” or “C” of the required number. “I” refers to the intervention group; “C” refers to the control group. Then, the researcher put all slips into a box and drew them out after registration the participants who meet the inclusion criteria, allocating each 29 participants to the intervention and control groups.

Between November 2012 and September 2013, 58 newly diagnosed PTB patients met the inclusion criteria and were recruited to the study. The others did not meet the criteria; they did not visit for follow-up care at the TB clinic at Buddhachinaraj Hospital; and some of them were newly diagnosed PTB patients but had severe conditions which made them unable to participate in the program. Of the 58, 29 were randomly assigned equally to the intervention and control groups. However, only 25 participants in the intervention and control groups completed all aspects of the study within February, 2014. The attrition rate was 7% in the intervention group (n = 4) and 7% in the control group (n= 4). Two participants in the intervention group were not able to keep taking the same regimen because of the severe TB drug side-effect and two participants uncompleted all aspects of the study. Four participants in the control group dropped-out for the following reasons; two participants died and two participants changed drug regimen because of severe drug’s side-effect and severe condition of his co-morbidity. The final participants for analysis included 50 newly diagnosed PTB patients: 25 in the intervention group and 25 in the control group. Participant recruitment procedures are shown in Figure 3.2.

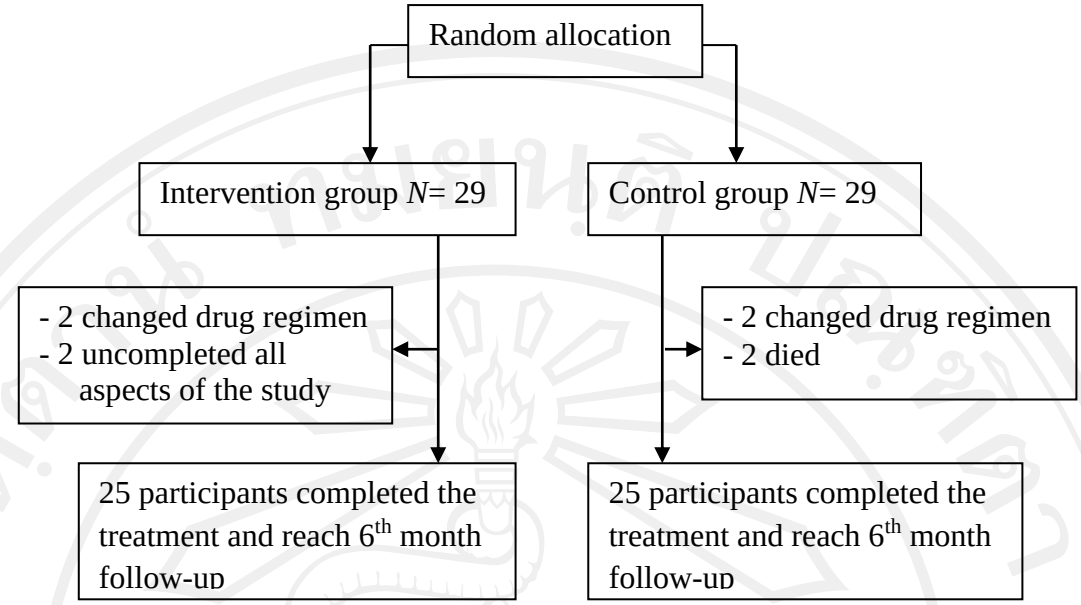

Figure 3.2 Diagram Showing Participant Recruitment Procedures

3.3 Research setting

This study was conducted at the TB clinic of Buddhachinaraj Hospital, Phitsanulok province. The clinic staffs included only one tuberculosis specialist physician, a registered nurse, and two other health care providers. This clinic serves a population of 182,250 people across 20 Districts and cooperates with 29 primary care units in the care of TB patients. When patients were confirmed as having PTB at other out-patient departments, they were submitted for registration at this TB clinic and treated using the NTP in Thailand and the treatment is free of charge. After patients had been registered, health education was provided by a registered nurse or other health care provider. Then, the patients' health information was sent to primary care units in the vicinities of patients' homes for the further care. Primary care unit staffs worked with village health volunteers to keep track of medication taken and home visits. The objectives of home visits were to ensure that patients took medications and to help them solve their problems. However, the frequency of home visit may be adjusted according to the patients' needs, depending on the discretion of the health care workers at the primary care units.

All of patients received TB treatment at the TB clinic. Staff of the clinic made appointments with the patients, the time period of appointment was four weeks in the intensive phase and ranged from one to three months in the continuous phase. The time period of appointment depended on the patient illness condition and cooperation with TB treatment. At the appointments, patients' progress of treatment, medication taking, and side effects of medication were assessed, and patients received individual consultation and advice. Generally, patients' sputum was evaluated again in the 2nd, 5th and 6th months or the end of treatment. When the patients obtained their TB medications from the pharmacist, they received advice regarding proper medication taking. If the patients failed to keep their appointments, TB clinic staff coordinated with the primary care unit staffs in their area for tracking down such patients to receive treatment.

At the time of the study period, the TB clinic had extra care provided by the Global Fund Project. This project provided all newly diagnosed PTB patients who had sputum smear-positive with a money incentive, 1,200 baht per a patient. The project manager contacted and informed the patients about the incentive at the initial start of treatment. The patients received the money incentive by cash at the end of 4th or 5th or 6th month of treatment.

3.4 Research intervention

The Medication Adherence Enhancement Program for newly diagnosed PTB patients was developed by the researcher from the comprehensive literature review. The theoretical basis of the program includes self-efficacy and self-regulation concepts of SCT (Bandura, 1986). The program aims to enhance participants' cognitive function and self-efficacy for self-regulation to adhere to medication throughout the full course of treatment. The program includes two components. The first component provides knowledge and activities for enhancing cognitive function and self-efficacy for self-regulation to adhere to TB medication. Along with this component, the participants were provided with the second component; environmental supports for facilitating these behavior changes. The program lasts eight weeks and is implemented in the first two months of TB treatment.

3.4.1 The first component of the program

The plan of the first component of the program was to provide knowledge and activities for enhancing self-efficacy for self-regulation to adhere to TB medication. The researcher provided knowledge components and activities in order to increase participants' and family supporters' level of knowledge, as well as to change negative attitudes, dysfunctional ideas, and perceptions or beliefs as motivating factors for behavior. The knowledge components included: a) pulmonary tuberculosis, its treatment, medication used for managing TB, benefits of medication, adverse effects, drug interactions, and medication management (scheduling of dosing, storage recommendations, and what to do if a dose has been missed); b) strategies for integrating dose schedule into lifestyle patterns, solving problems such as forgetting, delays, side effects, stigma of the disease, stress, and prolonged travel away from home; c) strategies for participants to manage themselves to adhere to medication: self-efficacy, self-regulation, and the use of environmental facilitators; d) environmental supports for promoting medication adherence: supporters, and telephone reminders and counseling; and e) possible consequences of non-adherence. The participants were provided with telephone counseling and the opportunity to ask questions about their prescribed medication regimen, medication- taking barriers, and strategies to solve any problems that had appeared up to that point. In addition, the family supporters were taught about their roles as supporters.

The researcher provided activities for participants to gain confidence in their ability to adhere to TB medication throughout the full course of treatment including: a) confidence in ability to do tasks consisting of integrating the dose schedule into their lifestyle pattern; solving problems such as forgetting, delaying and stigmatizing of the disease; managing TB drug side effects; stress managing; organizing medication when away from home; designing a new drug dosing schedule adapted to apparent problems; and using environmental facilitators and b) confidence in ability to self-regulate in terms of setting goals, self-monitoring and self-reflecting. The self-efficacy for self-regulation to adhere to TB medication was monitored for improving at the 4th, 6th and 8th weeks of the program.

1) The process of self-regulation to adhere to TB medication included:

1.1) Goals setting. In the 1st week and during the first three sessions of the program, participants were asked by the researcher to set sub- and main-goals. The proximal sub-goals were the motivation for achieving larger future goals. The successes of sub-goals could provide incentives and guidelines for action, as the attainment of sub-goals bolsters self-efficacy and produces a satisfaction that sustains one's efforts at personal change. The problem-solving, participation in barriers and solutions, and maintenance of new behaviors were encouraged in order to achieve goals. Possible causes of problems were identified and self problem-solving was encouraged for making adjustments to attain goals.

1.2) Self-monitoring. Participants were given a calendar diary (in the Training and Recording Forms for Self-Regulation to Adhere to Medication) and asked to keep track of non-adherence and the events that foster it. The purposes of self-monitoring were to self-diagnose the determinants of non-adherence, to self-evaluate progress toward goals, and to enhance self-regulation efficacy. During follow-up visits at the 1st, 4th, 6th, and 8th weeks of the program, the diary notes were discussed with the researcher. In addition, supportive feedback was given to the participants about how closely he or she had adhered to the prescribed dosing schedule since the last visit.

1.3) Self-reflection. Participants were encouraged to do self-reflection after they evaluated their progress compared with their goals. During follow-up visits at the 4th, 6th, and 8th weeks of the program, participants were asked to create self-incentives for attaining their sub-goals. The rationale was that individuals achieve greater self-directed change if they rewarded their successful efforts than if they provided no incentives for themselves. After this process, the patients were encouraged to set the new behavior goals.

2) The techniques used in raising self-efficacy for self-regulation to adhere to TB medication included:

2.1) Mastery experience. The researcher provided specific activities to participants for achieving mastery over a task of medication adherence through personal experience. The activities for providing mastery experience included 1) return-demonstrating how to manage medication for each dose at baseline session, 2) taking

medication activities during the first two months; start with the right medicine, dose, and amount of medicine with a short duration, 3) goals setting; at the 1st week of the program and during the three sessions at the 4th, 6th and 8th weeks of the program, 4) self-monitoring medication taking for one week at the baseline and the duration for self-monitoring increased to two or three weeks during the four sessions at the 1st, 4th, 6th and 8th weeks of the program, and 5) self-reflection; at the 4th, 6th, and 8th weeks of the program.

2.2) Modeling. The researcher promoted successful PTB patients who performed appropriate behaviors to be role models for self-regulation to adhere to medication for the participants by demonstrating desired behaviors at the 8th week of the program.

2.3) Verbal persuasion. The researcher and family supporters encouraged participants to undertake more activities than they had been accomplishing and supported them as they began making behavioral changes. The use of strong verbal encouragement was provided during the five sessions at baseline, 1st, 4th, 6th, and 8th weeks of the program as well as two sessions of telephone calls in the 3rd and 7th weeks of the program.

2.4) Physiological and emotional arousal. The participants were encouraged to re-interpret their signs and symptoms, and informed about any physical and emotional problems. Each problem, such as stress and medication side-effects, was discussed. The sessions for physiological and emotional arousal were provided during the four sessions at the 1st, 4th, 6th and 8th weeks of the program as well as two sessions of telephone call at the 3rd and 7th weeks of the program.

3.4.2 The second component of the program

The second component of the program in which environmental supports was used to facilitate participants' behavioral change for adhering to TB medication included:

1) Getting family supporters. At the initial session, each participant was asked to name a supporter to aid in enhancing medication adherence. During follow-up visits, the researcher encouraged each participant to mention the help from his or her supporter. The supporters could help the participants to tackle problems such as

forgetting, delays, and TB drug side effects, and may provide them with verbal persuasion, and physiological and emotional arousal.

2) Telephone reminders and counseling. The researcher provided participants with a telephone call a few days prior to the appointment for reminding them of the pending appointment or counseling at the 3rd and 7th weeks of the program. During the telephone call, the researcher conducted a counseling session consisting of tailored education messages based upon the initial interview and subsequent assessment and provided activities for raising self-efficacy for self-regulation to adhere to TB medication including him- or herself experiences discussion and feedback, verbal persuasion and physiological and emotional arousal. Examples of questions and sentences were used in this session included "How are you?", "Do you get cough or tired or numerous sputum?", "Please let me know your progress of TB drug side-effects", "How do you solve these problems?", "You do the best", and "Please continue to take right medicine, amount of medicine, dose, and at correct time". In addition, if the patient had any questions or problems that could not be solved by him- or herself, he or she could contact the researcher by telephone during 8.00 am through 8.00 pm, Monday through Friday, and 8.00 am until 10.00 pm on weekends throughout the program period. Telephone counseling provided a mechanism for a proactive strategy to address real-time needs, such as TB drug side effects or missing medication doses.

3.4.3 The instruments for research intervention

The instruments for research intervention consisted of the Medication Adherence Enhancement Program, lesson plan, videotaped presentations, scenarios, patient's manual, supporter's manual, Training and Recording Forms for Self-Regulation to Adhere to Medication, and Self-Efficacy for Self-Regulation of Medication Adherence Scale. The details of each instrument are explained below:

1) The Medication Adherence Enhancement Program. The Medication Adherence Enhancement Program is an individualized intervention for newly diagnosed PTB patient, based on self-efficacy and self-regulation concepts (Bandura, 1986). It was developed by the researcher in order to enhance participant's cognitive function and belief in his or her own ability to perform specific tasks for self-regulation with the intent to adhere to medication achieving the full course of the PTB regimen. The

program consists of two components: the first component is the activities for improving participant's cognitive function and enhancing self-efficacy for self-regulation to adhere medication. The activities in this component include providing knowledge, mastery experience, modeling, verbal persuasion, and physiological and emotional arousal. The second component is environmental supports for facilitating behavior change, consisting of a choice of family supporter, and telephone reminders and counseling. The program covers an 8-week period with seven sessions and implemented during the first two months of TB treatment. Five sessions are activities for enhancing cognitive function and self-efficacy for self-regulation to adhere to medication, these sessions were provided at TB clinic or participant's home and each session last approximately 30-45 minutes. The other two sessions are telephone reminders and counseling by the researcher and each session last approximately 5-15 minutes (Appendix D).

2) Lesson plan. The objectives of the lesson plan are increasing participants' and supporters' level of knowledge, as well as to change negative attitudes, dysfunction idea, and perceptions or belief as motivating factors for behavior changing. The plan consisted of six sessions, each session included; 1) pulmonary tuberculosis and its treatment, 2) supporter for medication adherence, 3) medication adherence, 4) self-regulation of medication adherence, 5) enhancing self-efficacy for self-regulation to adhere to medication (first part), and 6) enhancing self-efficacy for self-regulation to adhere to medication (second part). Each session last approximately 30-45 minutes. The first, third, and fifth sessions were provided for each participant and his or her supporter. The second session was provided for support, and the fourth and sixth sessions were provided for each participant and available for his or her supporter. The instruments and media used in this plan included video presentations, scenarios, patient's manual, supporter's manual, Training and Recording Forms for Self-Regulation to Adhere to Medication, and the Self-Efficacy for Self-Regulation of Medication Adherence Scale. The activities in this plan included providing information, demonstration and return-demonstration, practice, tailored problem-solving discussion, and feedback (Appendix E).

3) Video presentation. The video presentation was developed by the researcher and named "Pulmonary Tuberculosis and Medication Adherence". Some parts of the video presentation were modified from the Video Media for Prevention of

Tuberculosis Transmission of Newly Diagnosed Pulmonary Tuberculosis developed by Kamnon (2011) with the permission of producers (Appendix I). There were three sessions of video presentation. The first session includes the knowledge components on the definition of PTB and cause of PTB, PTB transmission, symptoms and signs of PTB patients, diagnosis of PTB and treatment of PTB patients (8 minutes). The second session includes the knowledge components on the guideline for patients to practice along the course of the TB treatment, TB drug adverse effects and how to manage, and drug storage recommendation (14 minutes). The third session includes medication adherence, the causes of non-adherence to TB medication, and how to manage (8 minutes).

4) Scenarios. Two scenarios were developed by the researcher. The first scenario aimed to demonstrate how to manage the problem of medication forgetting, delaying, or missing. The second scenario aimed to demonstrate how to manage and deal with the healthcare provider, if the participant had a prolonged travel away from home.

5) The patient's manual. The patient's manual named "Get Pulmonary Tuberculosis Cured" was developed by the researcher (Appendix F). This manual was used for participants to review the necessary contents of education. The manual's contents is composed of three parts; 1) general knowledge about PTB and its treatment, the practice guidelines along the course of TB treatment, TB drug adverse effects and how to manage, drug storage recommendations, and sputum collection; 2) medication adherence, the causes of non- adherence to TB medication, and how to manage; and 3) self-regulation to adhere to medication including goal-setting, self-monitoring and self-reflecting.

6) The supporter's manual. The supporter's manual named "You Are Vital in Curing Pulmonary Tuberculosis" was developed by the researcher (Appendix G). This manual was used for supporters to review the necessary contents of education. The manual's contents was composed of two parts; 1) the importance of a supporter for medication adherence, as well as the roles of assistance, verbal persuasion, and physiological and emotional arousal; and 2) the necessary contents including PTB treatment, the practices guidelines along the course of TB treatment, TB drug adverse

effects and how to manage, medication adherence, and self-regulation to adhere medication.

7) The Training and Recording Forms for Self-Regulation to Adhere to Medication. These forms are used for participants' training and raising self-efficacy for self-regulation to adhere to medication. Additionally, these forms are used for participants self-recording about self-regulation to adhere medication along course of treatment (Appendix H).

8) The Self-Efficacy for Self-Regulation of Medication Adherence Scale. This scale developed by the researcher (Appendix C). It was used for monitoring the level of self-efficacy for self-regulation to adherence to TB medication during the intervention period. The scale was divided into five levels with the score ranging from 1 to 5 (1 = the least confident, 2 = less confident, 3 = fair confident, 4 = more confident, and 5 = the most confident). The scale included eight items and possible scores range from 8 to 40. Examples of items were: "You can record your medication taking, signs and symptoms, or feeling" and "You can compare your activities with setting goals". A mean score was used to measure the level of confidence of participants and gave them feedback to improve or sustain the confidence to perform behavior for self-regulation to adherence to TB medication.

3.4.4 The steps of program implementing

The steps of implementing the Medication Adherence Enhancement Program were summarized to be the schedule as illustrated in Table 3.1.

Table 3.1 The Summary Schedule of Medication Adherence Enhancement Program for Newly Diagnosed Pulmonary Tuberculosis Patients

Session/ Session lasted/ Place	**Person involved in the session**	**Objectives**	**Activities**	**Instruments involved in the session**
Session 1 (Week 0: after participant registration) / 45 minutes / TB clinic	Participant and family supporter	1. To establish relationship and inform the overview of the Medication Adherence Enhancement Program	1. Introduce self, obtain name of participant and his or her family supporter. 2. Provide knowledge about PTB and its treatment, the importance of family supporter, the practice guidelines along the course of TB treatment, TB drug adverse effects	1. Video presentation: first and second session 2. Patient's manual 3. Supporter's manual

Table 3.1(Continued)

Session/ Session lasted/ Place	Person involved in the session	Objectives	Activities	Instruments involved in the session
		2. To increase participant's and family supporter's level of PTB knowledge and change negative attitude, dysfunction ideas and perceptions or beliefs. 3. To raise self-efficacy of the participant for setting goals and recording medication taking	and how to manage. 3. Gave the patient's manual to the participant and supporter's manual to family supporter. 4. Explain and discussion, demonstration and return-demonstration of how to manage medication for each dose, and how to set goals and record medication taking. 5. Gave the Training and Recording Forms for Self-Regulation to Adhere to Medication to the participant. 6. Assign participant homework to record medication taking for one week. 7. Offer the participant to contact the researcher by telephone if he/she faced some problems that could not be solved by him- or herself (during the program period).	4. The Training and Recording Forms for Self-Regulation to Adhere to Medication
Session 1 20 minutes/ TB clinic or participant's home	Family supporter (Note: if the family supporter did not come with the participant in the baseline session, the involved activities were provided in the second session in the participant' s home)	1. To increase family supporter's level of knowledge in supporter role. 2. To raise family supporter's abilities for assisting and encouraging the participant.	1. Explain and discussion how to assist the participant for self-regulation to adhere to TB medication. 2. Demonstration and return-demonstration of how to use verbal persuasion, and physiological and emotion arousal for encourage the participant for self-regulation to adhere to TB medication. 3. Demonstration and return-demonstration of how to assist the participant to use The Training and Recording Forms for Self-Regulation to Adhere to Medication.	1. Supporter's manual 2. The Training and Recording Forms for Self-Regulation to Adhere to Medication
Session 2 (Week 1) / 45 minutes / Participant's home	Participant and his or her family supporter	1. To review and provide knowledge component. 2. To review homework and progress made on	1. Review knowledge in the past session and provide knowledge about medication adherence and self-efficacy for self-regulation to adhere to TB medication. 2. Review homework assignment	1. Video presentation: third session 2. Scenarios 3. The Training and

Table 3.1(Continued)

Session/ Session lasted/ Place	Person involved in the session	Objectives	Activities	Instruments involved in the session
		recording medication taking 3. To raise self-efficacy of the participant for self-regulation to adhere to TB medication.	and reinforce progress made. 3. Conduct scenarios discussion, participant's experiences discussion and feedback based on tailored problem-solving, and use verbal persuasion and physiological and emotional arousal to encourage the participant for active solving the problem and using self-regulation processes to adhere to TB medication. 4. Demonstrate and return-demonstrate goal-setting, self-monitoring and self-reflecting techniques. 5. Encourage the family supporter to continue supporting and encouraging the participant to use self-regulation processes to adhere to TB medication. 6. Set mutual goals and assign participant homework to observe and record medication taking, sign and symptom, and feelings for three weeks. 7. Assign participant homework to compared his or her behaviors during three weeks with target goals and give yourself incentive if the behavior meet the target goals.	Recording Forms for Self-Regulation to Adhere to Medication
Session 3 (Week 3: a few days prior to the participant appointment) / 5-15 minutes / Available	Participant	1. To remind the participant of the pending appointment or provide telephone counseling. 2. To raise self-efficacy for self-regulation to adhere to TB medication.	1. Provide a telephone call for reminding the participant of the pending appointment or counseling. 2. Conduct counseling session consisted of tailored education messages based upon initial interview and subsequent assessment, participant's experiences discussion and feedback, and use verbal persuasion, and physiological and emotional arousal to encourage the participant for active solving the problem and using self-regulation processes to adhere to TB medication (during the telephone call).	-
Session 4 (Week 4) /	Participant and/or	1. To review and provide knowledge	1. Review knowledge in the past session and provide knowledge	1. The Training and

Table 3.1(Continued)

Session/ Session lasted/ Place	Person involved in the session	Objectives	Activities	Instruments involved in the session
30 minutes / TB clinic	family supporter	component. 2. To review homework and progress made on recording medication taking, sign and symptom, and feelings as well as self-evaluation and self-incentive. 3. To raise self-efficacy of the participant for self-regulation to adhere to TB medication. 4. To evaluate the self-efficacy of the participant for self-regulation to adhere to TB medication.	about how to raise self-efficacy for self-regulation to adhere to TB medication. 2. Review homework assignment and reinforce progress made. 3. Conduct participant's experiences discussion and feedback based on tailored problem-solving, and use verbal persuasion, and physiological and emotional arousal to encourage the participant for active solving the problem and using self-regulation processes to adhere to TB medication. 4. Ask the participant to demonstrate goal-setting and assign him/her homework to observe and record medication taking, sign and symptom, and feelings for two weeks. 5. Assign participant homework to compared his or her behaviors during two weeks with target goals and give yourself incentive if the behavior meet the target goals. 6. Measure the participant's level of self-efficacy for self-regulation to adhere to TB medication and made discussion how to improve or sustain the level.	Recording Forms for Self-Regulation to Adhere to Medication 2. The Self-Efficacy for Self-Regulation of Medication Adherence Scale
Session 5 (Week 6) / 30 minutes / Participant's home	Participant and family supporter	1. To review homework and progress made on recording medication taking, sign and symptom, and feelings as well as self-evaluation and self-incentive. 2. To raise self-efficacy of the participant for self-regulation to adhere to TB medication. 3. To evaluate the progress of self-	1. Review homework assignment and reinforce progress made. 2. Conduct participant's experiences discussion and feedback based on tailored problem-solving, and use verbal persuasion, and physiological and emotional arousal to encourage the participant for active solving the problem and using self-regulation processes to adhere to TB medication. 3. Ask the participant to demonstrate goal-setting and assign him/her homework to observe and record medication taking, sign and symptom, and feelings for two weeks.	1. The Training and Recording Forms for Self-Regulation to Adhere to Medication 2. The Self-Efficacy for Self-Regulation of Medication Adherence Scale

Table 3.1(Continued)

Session/ Session lasted/ Place	Person involved in the session	Objectives	Activities	Instruments involved in the session
		efficacy of the participant for self-regulation to adhere to TB medication.	4. Assign participant homework to compared his or her behaviors during two weeks with setting goals and give yourself incentive if the behavior meet the setting goals. 5. Measure the participant's level of self-efficacy for self-regulation to adhere to TB medication and made discussion how to improve or sustain the level.	
Session 6 (Week 7: a few days prior to the participant appointment) / 5-15 minutes / Available	Participant	1. To remind the participant of the pending appointment or provide telephone counseling. 2. To raise self-efficacy for self-regulation to adhere to TB medication.	1. Provide a telephone call for reminding the participant of the pending appointment or counseling. 2. Conduct counseling session consisted of tailored education messages based upon initial interview and subsequent assessment, participant's experiences discussion and feedback, and use verbal persuasion, and physiological and emotional arousal to encourage the participant for active solving the problem and using self-regulation processes to adhere to TB medication (during the telephone call).	-
Session 7 (Week 8) / 45 minutes / TB clinic	Participant, modeling, and/or family supporter	1. To review homework and progress made on recording medication taking, sign and symptom, and feelings as well as self-evaluation and self-incentive. 2. To raise self-efficacy of the participant for self-regulation to adhere to TB medication. 3. To evaluate the progress of self-efficacy of the participant for self-regulation to adhere to TB medication.	1. Review homework assignment and reinforce progress made. 2. Conduct modeling's and participant's experiences discussion and feedback, and use verbal persuasion, and physiological and emotional arousal to encourage the participant for active solving the problem and using self-regulation processes to adhere to TB medication. 3. Encourage modeling, participant, and/or family supporter to participant in the discussion and share their experiences together. 4. Ask the participant to use or adapt self-regulation processes to adhere to TB medication throughout the full course of treatment. 5. Measure the participant's level of self-efficacy for self-regulation to adhere to TB medication and	1. The Training and Recording Forms for Self-Regulation to Adhere to Medication 2. The Self-Efficacy for Self-Regulation of Medication Adherence Scale

Table 3.1(Continued)

Session/ Session lasted/ Place	Person involved in the session	Objectives	Activities	Instruments involved in the session
		4. To provide the knowledge component and close the program.	made discussion how to improve or sustain the level. 6. Provide knowledge for maintaining healthy status and closed the program.	

3.5 Research instruments

Five instruments were employed for data collection. These instruments were the Demographics and Clinical Characteristics Data Collection Form, the Pulmonary Tuberculosis-Related Characteristics Data Collection Form, the Supporter's Demographics Characteristics Data Collection Form, the Anti-Tuberculosis Medication Adherence Scale and the Criteria to Identify the TB Treatment Outcomes of WHO (WHO, 2010b). Details of each instrument are described as follows:

1) The Demographics and Clinical Characteristics Data Collection Form. This instrument was modified from the Tuberculosis Treatment Card of Ministry of Public Health, Thailand (2008) (Appendix C). It consisted of closed- and open-ended questions regarding demographics and clinical characteristics data, including age, sex, occupation, monthly income, marital status, education level, history of illness, history of smoking, alcohol consumption, and substance abuse, mode of transportation, signs and symptoms, the precise address, the direction to residence and telephone number.

2) The Pulmonary Tuberculosis-Related Characteristics Data Collection Form. This instrument was modified from the Tuberculosis Treatment Card of Ministry of Public Health, Thailand (2008) (Appendix C) including medication regimen, amount and dose, medication taken, the problem and problem-solving of medication adherence, the results of the sputum examination, chest x-rays, other laboratory investigation, and treatment outcomes consisted of cure, treatment completed, treatment failure, died, defaulted, and transfer out. The sum percentage of patients cured and those who have completed treatment is defined as treatment success.

3) The Supporter's Demographics Characteristics Data Collection Form. This instrument was developed by the researcher (Appendix C). It consisted of closed- and open-ended questions including age, sex, occupation, monthly income, marital status, education level, the relation with patient, the precise address, and telephone number.

4) The Anti-Tuberculosis Medication Adherence Scale. This scale developed by the researcher (Appendix C). It was used for measuring the extent to which the PTB patients' behaviors coincide with their prescribed medication regimens. The scale was divided to two levels with the score 0 and 1 (1 = yes, and 0 = no). The scale included five items. Examples of items were: "You take right amount of anti-tuberculosis medicine every time" and "You take anti-tuberculosis medicine once a day, every day". A total possible scores range from 0 to 5 and mean score was used to measure the level of medication adherence of the participants. A high score meant good medication adherence whereas, a low score meant poor medication adherence.

5) The Criteria to Identify the TB Treatment Outcomes of WHO (WHO, 2010b). It was used for evaluating treatment success by a physician at the 6^{th} months after implementing the program or at the end of treatment. The treatment success is the sum percentage of "cure" and "treatment completed". "Cure" is defined if a patient whose sputum smear or culture was positive at the beginning of the treatment but becomes negative in the last month of treatment and on at least one previous occasion. "Treatment completed" is defined as a patient has completed treatment but does not have a negative sputum smear or culture result in the last month of treatment and on at least one previous occasion. Therefore, the results of normal chest radiography, and sign and symptom improvement of a patient are used to support the result of treatment completed.

3.6 Testing for quality of research instruments

The content validity of the Anti-Tuberculosis Medication Adherence Scale and the Self-Efficacy for Self-Regulation of Medication Adherence Scale were evaluated by five panel experts, including a physician who is an expert in PTB and behavior change, a nurse instructor who is an expert in PTB and community, a behavioral instructor who is an expert in behavior change, a clinical nurse who had experience in caring for PTB

patients, and a supervision nurse who is an expert in TB control (Appendix J). The content validity index (CVI) of these two scales = 1. The reliability coefficient of these scales was tested with 15 PTB patients who met the eligibility criteria and who visited the TB clinic at the hospital. The reliability coefficient of the Anti-Tuberculosis Medication Adherence Scale was calculated using Kuder-Richardson 20 method (KR 20) = .76. The reliability coefficient of the Self-Efficacy for Self-Regulation of Medication Adherence Scale was calculated using Cronbach's alpha coefficient = .74.

The Medication Adherence Enhancement Program, lesson plan, patient's manual, supporter's manual, video script, scenarios and the Training and Recording Forms for Self-Regulation to Adhere Medication were approved by the same five panel experts mentioned above (Appendix J). These experts were requested to review the content in the instruments along with their appropriateness. These instruments were adjusted based on experts' suggestions for improving their clarification and appropriateness. Face validity was also used to evaluate the content validity of the patient's manual, supporter's manual, and the Training and Recording Forms for Self-Regulation to Adhere Medication by three PTB patients and their supporters to evaluate the readability and understand ability. Then, some words that were unclear and difficult to understand were revised according to their suggestions.

Prior to program implementation, a pilot study was conducted to determine whether the lesson plan did really work and had been described in sufficient detail, and to determine unanticipated effects. A pilot study was conducted with the PTB patients and their supporters, similar to those who typically received the intervention at the TB clinic, which is similar to those in which the intervention was implemented. Observation and interview technique were used to gather the information for revising the program and improving the capability of researcher in implementing the program.

3.7 Research assistant preparation

A registered nurse who was a master prepared in nursing science and working in the in-patient department at Buddhachinaraj Hospital was trained to be the research assistant. The researcher explained the Medication Adherence Enhancement Program objectives, contents, methods as well as her roles to research assistant. In addition, she

was trained how to complete the Anti-Tuberculosis Medication Adherence Scale. During the training period, the research assistant practiced collecting medication adherence data in the presence of researcher. Practical problems were discussed and solved to gain a mutual understanding. To ensure the quality of the data collected by the research assistant, the reliability of the data collected by the researcher and research assistant were determined using the interater reliability. The data were concurrently and independently collected by the researcher and the research assistant with the same patients. The interater reliability was computed using a comparison of the agreements obtained between raters with the number of possible agreements. The researcher and the research assistant collected the data of the same patients (n=5). The interrater reliability of data from the researcher and the research assistant = 1.0.

3.8 Human rights protection of research participants

Prior to data collection, the proposal for the study and the instruments were approved by the Research Ethics Committee of the Faculty of Nursing, Chiang Mai University (Appendix A). The researcher asked for permission and approval for the proposal and the instruments from the Research Ethics Committee of Buddhachinaraj Hospital, Phitsanulok province (Appendix A).

The researcher provided a full explanation and written description of the study, including objectives, procedure, subject's participation, potential risks, benefits, and the protection of confidentiality to the newly diagnosed PTB patients and their family supporters who meet the inclusion criteria at TB clinic before recruiting them to the study (Appendix B). All potential participants were informed of their rights to participate, and to withdraw from the study at anytime. Even if they refused to participate in the study; their treatments were not affected. They had an opportunity to ask questions about the study before signing the consent form. Written consent was obtained from each participant prior to data collection (Appendix B). In addition, if the newly diagnosed PTB patients had problems caused by participation in the study, their problems would be reported to the physician immediately and the subjects would receive the effective treatment until the problems were solved.

The participants in the control group also received a complete explanation and a written description of the study and the protection of confidentiality and anonymity. The researcher informed the control group that they were provided with the usual nursing care by the health care providers in the TB clinic and primary care units. After the completion of the final data collection, the researcher provided them with the necessary TB knowledge, offered them the opportunity to ask questions about their treatment or problems, and/or gave them the patients' manual.

3.9 Data collection

The researcher coordinated with the health care team and physician at the TB clinic after obtaining permission from the Research Ethics Committee of Human Subjects of Buddhachinaraj Hospital, Phitsanulok province. The nature and procedures of the study were explained to health care team at TB clinic in order to get their collaboration. After being recruited and being randomly assigned into the intervention and the control groups, the participants were informed about the objectives and procedures in the study. The study was explained to them through the reading of the consent form. Once the informed consent was obtained, they were asked to respond to the first data collection; demographics, clinical characteristics, and PTB-related characteristics data, and the next step of the study were conducted.

3.9.1 Steps in delivering usual care for the control group

1) The nurses and other health care providers at the TB clinic and primary health care units provided the usual care and home visits for the participants in the control group during the six months of the treatment. The activities included:

1.1) Providing education about PTB and its treatment, TB medication and side effects and prevention of TB transmission at baseline. When the participants' follow-up visited the TB clinic, they were asked for the medication taking problems and provided advice to solve their problems.

1.2) There were eight home visits in the first two months and four home visits in the next four months. However, the frequency of home visits may be adjusted as participants' needs, depending on the discretion of the health care providers

at the primary care units; the range of home visit in the first two months was 0-8 and in the next four months was 0-4.

1.3) Setting appointment for a follow-up visit to the TB clinic, the time period of appointment were four weeks in the intensive phase and one to three months in the continuous phase.

1.4) Providing FDCs drugs or medication packaging if the participants received single pill of TB drugs.

1.5) Providing late patient tracers, when the participants fail to keep an appointment.

1.6) Providing a money incentive for motivation to adhere to medication with 1,200 baht per a patient. The participants would receive the money incentive by cash at the end of 4^{th} or 5^{th} or 6^{th} month of treatment.

2) The research assistant who had been trained for medication adherence data collection conducted an interview of participant's medication adherence at the 3^{rd} and 6^{th} months after entering the program. The interview was conducted at the TB clinic as per follow-up schedule or by telephone if the appointment schedule was not correct with the 3^{rd} month after entering the program or in case the participants could not go to the TB clinic at those times.

3) The examinations of sputum for AFB were done following the NTP at the end of 2^{nd} and 5^{th} months of treatment and at the end of treatment (6^{th} month). The CXR was also done at the end of the treatment in order to classify the treatment outcomes.

4) After the completion of the final data collection, the researcher provided the participants with the necessary TB knowledge, offered them the opportunity to ask questions about their treatment or problems, and/or gave them the patients' manual.

3.9.2 Steps in delivering Medication Adherence Enhancement Program for the intervention group

1) The researcher set an appointment for each participant and his or her family supporter to participate in the program and set an appointment for home visits. The directions to each participant's residence, the precise address, as well as each participant's and supporter's telephone number were confirmed.

2) The researcher provided knowledge and activities schedule as mentioned in the Medication Adherence Enhancement Program in Table 3.1.

3) The research assistant conducted an interview of participant's medication adherence at the 3rd and 6th months after entering the program. The strategies used to interview the participants were like the strategies mentioned in the control group.

4) The examinations of sputum for AFB and CXR were done following the NTP in order to classify the treatment outcomes. The methods to do these like the methods mentioned in the control group.

The data collection procedures in Medication Adherence Enhancement Program are presented in Figure 3.3.

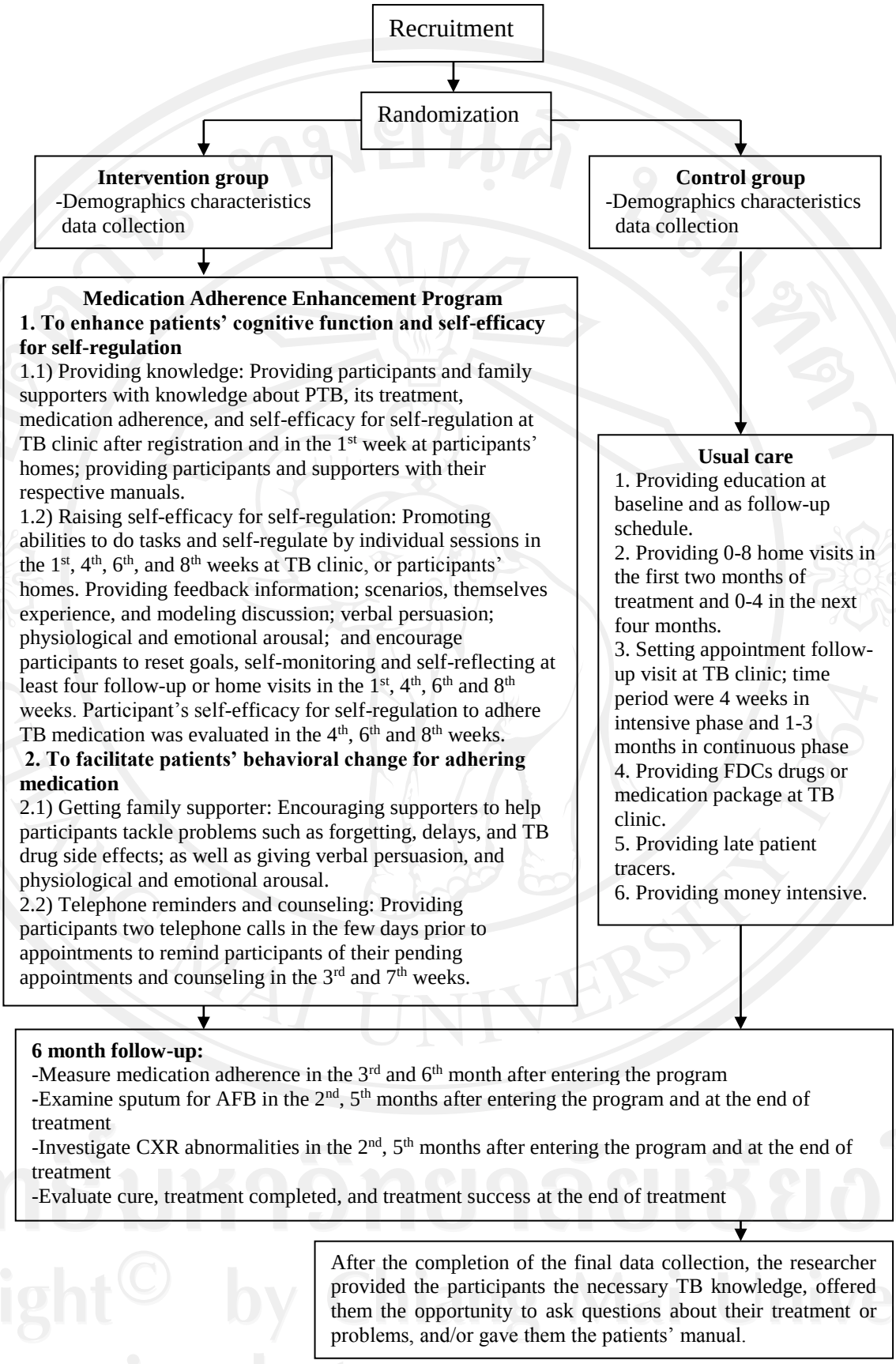

Figure 3.3 Data Collection Procedures

3.10 Data analysis

3.10.1 The demographics, clinical and PTB-related characteristics data of the participants in the intervention and control groups were summarized using descriptive statistics. Chi-square or Fisher's exact test was used to test the differences in the characteristics between the intervention and the control groups on categorical variables.

3.10.2 Mann Whitney-U test was performed to examine the differences in medication adherence scores of the participants between the intervention and the control groups at the 3rd and 6th months after entering the program because the medication adherence scores of the participants in the intervention and control groups at the 3rd and 6th months after entering the program did not distribute normally, except the medication adherence score in the control group at the 3rd month after entering the program. Kolmogorov-Smirnov test was used to examine the normal distribution.

3.10.3 Fisher's exact test was used to examine the differences in treatment success rate of the participants between the intervention and control groups at the end of treatment or 6th month after entering the program.