Effects of the Family Empowerment Program on Medication Adherence and Treatment Success Among Adults with Pulmonary Tuberculosis: A Randomized Controlled Trial

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Abstract: Unsuccessful treatment of pulmonary tuberculosis results from medication non-adherence. Family is a significant source of support for adults with pulmonary tuberculosis but has limited ability to continuously support in the first six months of treatments. This randomized controlled trial, a two-arm post-test-only design was utilized to investigate the effects of the family empowerment program on medication adherence and treatment success among adults with pulmonary tuberculosis. The sample comprised 64 family members caring for newly diagnosed adults with pulmonary tuberculosis who visited a tuberculosis clinic of a university hospital in central Thailand. The participants were assigned randomly to either the experimental arm (n = 32) to receive the program or the control arm (n = 32) to receive only usual care. Data were collected using the Demographic and Pulmonary Tuberculosis-related Characteristic Data Collection Form, Family Member's Demographic Characteristic Data Collection Form, Tuberculosis Medication Adherence Scale, and criteria to identify tuberculosis treatment success of the World Health Organization. Data were analyzed using descriptive statistics, Pearson's chi-square, Fisher's Exact, and McNemar tests.

The results showed that the experimental arm had significantly higher medication adherence at the 3rd and 19th weeks after the program ended than the control arm. The experimental arm had a significantly higher treatment success rate at the 19th week than the control arm. The family empowerment program was effective in improving medication adherence and treatment success. Nurses need to be trained to empower family members in providing continuous support for adults with pulmonary tuberculosis. To fully assess the program's effectiveness, additional research is required to investigate its performance in different contexts and with various samples.

Keywords: Family empowerment, Medication adherence, Pulmonary tuberculosis, Randomized controlled trial, Treatment success

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Introduction

Pulmonary tuberculosis (PTB) is a major communicable disease and a leading cause of mortality globally from a single infection.[1] PTB refers to a case of TB that has been confirmed through bacteriology or diagnosed through clinical means and involves either the lung parenchyma or the tracheobronchial tree[2] caused by the bacillus *Mycobacterium tuberculosis* (MTB) that spreads from bacteria expelled into the

air by individuals with TB, such as by coughing.[1] Approximately one-quarter of the global population is affected by MTB infection. It is estimated that the incidence of PTB has affected 9.9 million people globally, with a mortality rate of 13 per 100,000 population.[1] Geographically, most PTB cases in 2020 were in South-East Asia (43%).[1] In 2020, Thailand experienced a staggering 143,000 incidences of PTB, placing it among the top 30 countries with the highest incidence of the disease[1] and also considered a high-burden country because 85% of its TB cases are PTB, and 99% of those are found in people over 15 years old.[3] From this evidence, PTB infection in Thailand remains a major concern and thus requires effective treatment.

The term "treatment success" encompasses both the number of patients who have been cured (those who have tested negative for smear or culture in the last month of treatment and on at least one previous occasion) and those who have completed their treatment (meaning they have taken all prescribed medication without evidence of failure).[4] Treatment success directly leads to improved symptoms and reduced risks of infection.[5] However, treatment success rates in Thailand are 84%, which is lower than the acceptable target of 90%,[1] suggesting that there is still unsuccessful treatment among adults with PTB. In particular, the rate of unsuccessful TB treatment ranged from 18.7%[6] to 21.5%.[6,7] The gravity of this percentage delineates the significance of the treatment success problem in Thailand, which is commonly caused by poor adherence to medication during the course of treatment.

Medication adherence is crucial to TB treatment success. Proper medication adherence is crucial for the effectiveness of PTB drugs. This involves taking the correct medication, at the appropriate dosage, timing, schedule, conditions, and with the necessary precautions.[8] Adherence to a treatment regimen that contains multiple drugs to which the MTB organism is susceptible, taking therapeutic agents regularly, and continuing treatments for a sufficient period can ensure the effectiveness of the medications, which contributes to treatment success.[8] Regrettably, a considerable amount of adults suffering from PTB fail to adhere to their medication regimen and discontinue their treatment before finishing the prescribed course. This is especially true for individuals who are newly diagnosed with PTB and have either never received treatment or have been taking anti-PTB medication for less than a month.[4] In Thailand, 11-60% of newly diagnosed PTB adults had medication non-adherence.[7] Newly diagnosed PTB adults tend to have inadequate knowledge of PTB and its treatment, such as the side effects of treatment and the duration of the treatment that needs to be completed,[9] which was associated with medication non-adherence.[10] As adults with PTB usually become asymptomatic following a 2-month intensive phase of treatment, they stop taking medications due to the misperception of being cured or feeling better.[11] This situation is an important issue because newly diagnosed PTB adults require a regimen of 6 months[1]. Adults with PTB encounter several barriers to medication adherence and treatment success, suggesting that support from their significant others is essential.

Families play a significant part in the treatment process of adults with PTB. Family members are the first to learn about their disease, as well as the ones who are closest to them and have daily contact with them. Research showed that family members performed various roles to support adults with PTB, such as urging them to take their medications and escort them to the hospital, preparing nutritious meals to enhance physical strength, and giving encouragement to motivate them to continue their treatments.[12] Additionally, support from family was effective in improving treatment success for adults with PTB by motivating them to adhere to medication and giving encouragement when dealing with barriers related to medication taking.[13] Unfortunately, most adults with PTB lack support from family,[14] which is pivotal in enhancing medication adherence[15] and treatment success[16] in PTB. Family members who support to adults with PTB often encounter obstacles

that hinder their ability to effectively manage and provide adequate care. Additionally, they may not feel empowered to apply the knowledge they have acquired to real-life situations or synthesize their understanding to improve their caregiving performance.[9] Thus, family members are powerless and need to develop a program to strengthen their ability to continuously support adults with PTB throughout PTB treatment.

Conceptual Framework and Review of Literature

The conceptual framework for this study was based on family empowerment[17] to improve medication adherence and treatment success. Family empowerment is a social process that involves acknowledging, promoting, and strengthening the abilities of family members to address their own needs, find solutions to problems, and access the resources they require.[18] Family empowerment changes the attitude and actions of family in care through the learning process, which involves transferring PTB knowledge from healthcare providers to family members.[19] The family empowerment process increases knowledge and self-care initiatives,[20] thus enhancing the family's ability and awareness of their responsibility in PTB care. Once family members become aware of their strengths and ability with the knowledge of PTB, they can take action by providing support to adults with PTB and maintain their own sense of power even during changing circumstances.[17]

Family empowerment supports and assists families in reaching the stage of independence by guiding them through the four phases.[17] First, discovering reality enables family members to have proper emotional, cognitive, and behavioral responses to the situation, accept the reality of the situation, and understand information. Second, critical reflection helps family members carefully contemplate the situation to make appropriate decisions and manage problems to develop a new perspective. Third, taking charge enables family members to make

a decision to select the best way to control and manage related factors through exchanging information with others for self-determination. Lastly, holding on to help family members make a commitment to maintaining the proper behaviors of the ill person.[17]

Medication adherence involves the active participation of clients in their treatment process.[21] Family empowerment ensures that family members have the ability to continuously provide support to adults with PTB by performing their supporter roles in urging them to maintain medication adherence by giving encouragement when dealing with various symptoms from treatment and reminding adults with PTB to maintain every appointment schedule. As a result, adults with PTB can take their PTB medications regularly, which leads to better medication adherence. The efficiency of the medications can be ensured by adhering to a treatment plan that includes several drugs to which the MTB organism is susceptible, taking therapeutic agents on a regular basis, and continuing treatments for a sufficient amount of time,[8] leading to treatment success. Studies showed that medication adherence contributed to higher rates of treatment success in PTB.[22,23]

Although family empowerment was originally developed in non-PTB populations, it has been adopted in many PTB studies with evidence for its effectiveness.[20,24,25] Family empowerment was effective in enhancing TB medication adherence behaviors[20,24,25] and a higher rate of sputum smear conversion to negative at 2 months.[20] However, it was found that, despite family involvement, the previous studies lacked clear details of activities that focused on empowering family members to effectively engage in supporting adults with PTB. Moreover, the rate of sputum smear conversion to negative was measured at two months only, which was not the completion of TB treatment and might not provide evidence of cure. To the best of our knowledge, there is a lack of a program that focuses on empowering family members to strengthen their ability to continuously

perform their supporter roles for adults with PTB to achieve medication adherence and treatment success.

Study Aim and Hypotheses

The purpose of this study was to investigate the effects of the family empowerment program on medication adherence as the primary outcome and treatment success as the secondary outcome among persons with PTB. It was hypothesized that the experimental arm would have higher medication adherence scores at the 3rd and 19th weeks after the program ended and a higher treatment success rate at the 19th week after the program ended than the control arm. Within the group, the experimental arm would have higher medication adherence scores at the 3rd and 19th weeks after the program ended than the control arm.

Methods

Design: This study was a randomized controlled trial with a two-arm post-test-only design. The study's report adhered to the Consolidated Standards of Reporting Trials (CONSORT).

Sampling and settings: The sample size was calculated using the power table for a mean test with a significant level of .05 and power of .80.[26] This resulted in 58 participants, added with 10% of the estimated sample size, which is usually the minimum effect size considered acceptable in RCT.[26] Consequently, the sample was 32 pairs of family members and adults with PTB per arm, totaling 64 pairs of participants.

The participants were recruited from a TB clinic of a university hospital in the central region of Thailand where there were 304 registered adults newly diagnosed with PTB in 2021.[27] In this hospital, the physician performed a diagnosis of PTB based on a sputum smear-positive result. The short-course PTB drug regimen follows the National Tuberculosis Program (NTP)[3] guided by WHO,[1] requiring six months of treatment that comprises isoniazid, rifampicin, pyrazinamide, and ethambutol given daily in the intensive phase (the first 2 months of TB treatment), followed by pyrazinamide and ethambutol in the continuous phase (the last 4 months of TB treatment). Routine follow-ups are conducted monthly for examination, laboratory tests, and medication fill.

The adults with PTB were selected based on the inclusion criteria: 1) age 20-59 years; 2) having been diagnosed by physicians as having PTB; 3) currently on a short-course PTB drug regimen; 4) never having taken anti-TB drugs prior to the study period; 5) being able to communicate in Thai; and 6) having a family member who would support them during the program session. They were excluded if they had extrapulmonary TB, severe conditions preventing them from participating in this program (e.g., massive hemoptysis or respiratory failure), strong conditions or behaviors that might influence the medication adherence or the treatment outcomes (e.g., alcoholism or substance abuse), and had treatment failure at the 2nd month of the treatment regimen. Then, the adults with PTB identified their family members who were also screened by nurses at the TB clinic for their eligibility based on the inclusion criteria: 1) age 18 years or older; 2) identified by adults with PTB as the significant person responsible for supporting persons with PTB to take medication; 3) living in the same household as adults with PTB; 4) no infection with PTB; 5) cognitively intact assessed by the Short Portable Mental State Questionnaire (SPMSQ) with a score of more than 8 points in Thai version by Chiang Mai Provincial Public Health Office;[28] and 6) being able to understand, speak, read, and communicate in Thai.

Initially, 92 adults with PTB were approached, but after screening for eligibility criteria, 28 individuals were excluded. Throughout the study period, all of the participants remained in the study. The final number of participants used for data analysis was 32 in each arm (**Figure 1**).
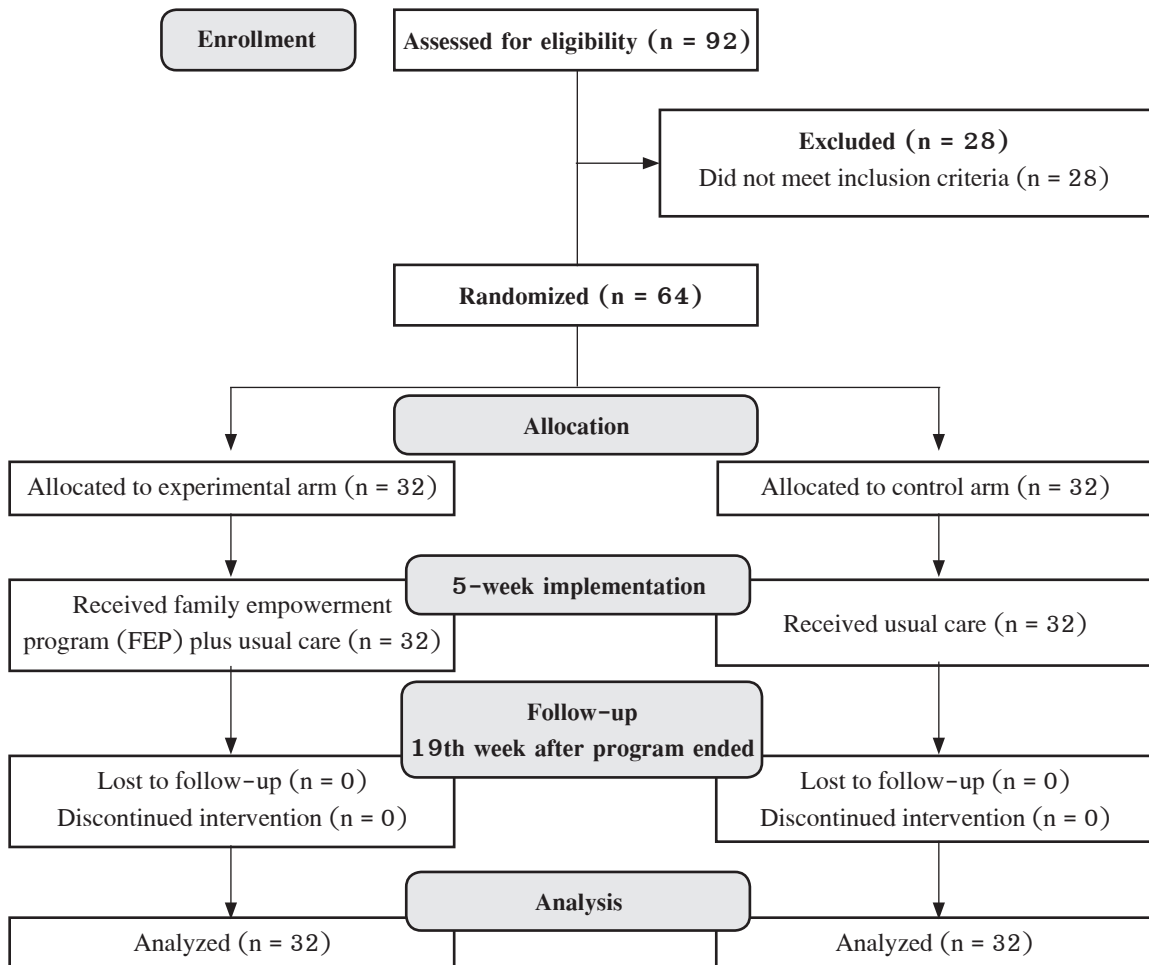
Figure 1. Flow chart of the participants throughout the trial

Randomization: Participants were assigned to either the experimental or control group at random, utilizing the permuted block design method with a block size of four. For a fixed block size of four and two treatments (E or C), there were six possible permutations: EECC, CCEE, ECEC, CECE, ECCE, or CEEC. In this study, the participants were 64, so 16 blocks of four were used by randomly selecting one of six possible permutations to assign the participants to the control arm or the experimental arm. Central allocation was performed by a nurse not involved in the trial using sequential numbers placed in a sealed opaque envelope.

Ethical Considerations: Approval for this research was granted by the Research Ethics Committee of the Faculty of Nursing, Chiang Mai University (No. 2021-FULL013), and the university hospital. The participants were given a full explanation and written description of the study, including objectives, procedures, participation conditions, potential risks, benefits, and the protection of confidentiality. They were informed that they had the right to participate in or withdraw from the study at any time without any impact on their treatments. After agreeing to participate, participants signed a consent form. Anonymity was protected by using code numbers instead of participants' names.

There were measures to prevent COVID-19 transmission through stringent compliance with public health policies.

Research Instruments: Four research instruments were used to obtain the data.

The Demographics and PTB-related Characteristics Data Collection Form was modified by the principal investigator (PI) from the tuberculosis treatment card of the Division of Tuberculosis.[3] It has close-ended questions on age, gender, marital status, educational level, occupation, monthly income, residence type, living with, number of persons living with, comorbidity besides PTB, history of smoking/alcohol, family members with TB history, and family members providing care.

The Family Member's Demographic Characteristics Data Collection Form was developed by the PI with questions on age, gender, marital status, educational level, occupation, monthly income, residence type, and relationship with adults with PTB.

The Tuberculosis Medication Adherence Scale (TBMAS) was developed by Yin et al.[29] With permission from the original authors, it was translated by the PI using back-translation[30] and used to measure medication adherence. It includes 30 items in 9 subscales: 1) communication with healthcare providers (6 items), 2) personal traits (5 items), 3) confidence in curing TB (4 items), 4) social support (4 items), 5) mood disorders (3 items), 6) lifestyle and habits (2 items), 7) coping style (2 items), 8) access to healthcare (2 items), and 9) forgetfulness (2 items). The scoring of items is based on a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). The total possible score ranges from 1 to 150, with a cut-off point of 113, so a score less than 113 is considered non-adherence and a score of 113 or higher indicates adherence. The positive predictive value (PPV) and sensitivity of TBMAS were calculated by comparing non-adherent cases identified by TBMAS using 113 as the cut-off with the gold standard of Continuous Multiple-Interval Medication Gaps (CMG) and assessing the concordance and discrepancy between them.

TBMAS has a PPV of 65.5% and a sensitivity of 82.9%.[29] From confirmatory factor analysis, the nine factors correlated well with conceptualized factor structure, without significant cross-loadings, showing high construct validity.[29] In this study, the content validity of the translated TBMAS was examined by six experts, yielding a content validity index (CVI) of 0.97. The Cronbach's alpha was .90 in a pilot test with 10 adults with PTB and 0.89 in the actual sample.

The criteria to identify TB treatment success by the WHO[4] was used for evaluating the treatment success by a physician in the 6th month after starting TB treatment. Treatment success was indicated by the sum percentage of "cured" and "treatment completed." The term "cured" refers to an adult with PTB whose sputum smear or culture was positive at the start of treatment but turned negative during the final month of treatment. When referring to an adult with PTB, "treatment completed" means that they have finished their treatment without any signs of failure. However, there was no record to indicate that their sputum smear or culture results were negative in the last month of treatment or on at least one previous occasion. This could be due to tests not being conducted or results being unavailable.[4] Therefore, the results of normal chest radiography and sign and symptom improvement are used to support the result of treatment completed.

The Family Empowerment Program (FEP)

The FEP was developed by the PI based on empowerment theory[17] to facilitate medication adherence behavior through the family empowerment process classified into discovering reality, critical reflection, taking charge, and holding on. The FEP contained a total of five sessions, which lasted over a period of five weeks. The first three sessions took place at the participants' homes (90 minutes for Session 1, 60 minutes for Session 2, and 45 minutes for Session 3), and the last two sessions were conducted via telephone (30 minutes/session). The FEP was reviewed by a panel of six experts, including a physician in PTB,

two expert nurse instructors in PTB and community, two behavioral expert instructors in behavior change, and a supervision nurse in TB control. The FEP was revised based on expert suggestions before implementation. The activities in each session of the FEP are presented in **Table 1 (Appendix)**.

Usual care refers to nursing activities that include monthly individual education about TB medication and counseling for directly observed treatment, short-course (DOTS) at home in the intensive and continuous phases.

Data Collection: Data were collected from January to August 2022. After ethics approval, the PI approached the participants face-to-face to inform them of the study information and obtain their written consent. The intervention was provided by the PI. The PI recruited a research assistant (RA) who was a nurse in a TB clinic and had at least two years of experience in infectious care and trained the RA on the administration of the questionnaires for data collection. The RA collected data face-to-face at the TB clinic, demographic characteristics at the first visit before the program was initiated, and medication adherence at the 3rd and 19th weeks after the program ended (8th and 24th weeks since the initiation of the TB treatment regimen). Treatment success was collected from a physician report at the TB clinic at the 19th week after the program ended (24th week since the initiation of the TB treatment regimen). A single-blind technique was employed to prevent the RA from knowing which arm participants were in.

Data Analysis: Demographic data were analyzed using descriptive statistics (frequency, percentage, mean, and standard deviation), and compared using independent samples t-test, Chi-square test, and Fisher's exact test. Medication adherence was compared using the chi-square test for independence and the McNemar test. Treatment success was compared using Pearson's Chi-square test (Phi and Cramer's V test). Prior to analysis, all statistical assumptions were tested. The results showed no violations of the assumptions.

Results

There were 32 pairs of adults with PTB and family members in each arm. Regarding the adults with PTB in both arms, their ages ranged from 20-59 years. They were male and married and held Bachelor's degree. The participants in the experimental arm worked as general employees with an income of 15,001-20,000 baht (USD 439.98-586.60), while those in the control arm were self-employed with an income of 10,001-15,000 baht (USD 293.33-439.95). They lived in a detached house, with their husband/wife, along with 3-4 persons in their household. They reported no comorbidity or history of smoking and no family members with a history of TB. The participants in both arms received care from their husbands/wives. When comparing both arms, no significant differences in demographic and PTB-related characteristics were found (**Table 2**).

Regarding family members, the age of the participants in the experimental arm and control arm ranged from 20 to 60 years and 18 to 60 years, respectively. They were female and married, and held a Bachelor's degree. The participants in the experimental arm were self-employed, while those in the control arm were employees with an income of 15,001-20,000 THB (439.98-586.60 USD) and 20,001 THB (USD 586.63) or higher, respectively. They lived in a detached house. The family members in both arms were the husband/wife of adults with PTB. After analyzing the family members in both arms, no significant differences in their characteristics were found (**Table 2**).

Table 2. Demographic data and PTB-related characteristics of adults with PTB (n = 64) and family members (n = 64)

Characteristics	Adults with PTB		p-value	Family members		p-value
	Experiment (n = 32)	Control (n = 32)		Experiment (n = 32)	Control (n = 32)	
	n (%)	n (%)		n (%)	n (%)	
Age (years)						
Range	20-59	20-59		20-60	18-60	
Mean (SD)	43.91 (12.87)	40.88 (12.22)	0.388[b]	39.63 (10.62)	38.06 (7.91)	0.507[b]
Gender						
Male	19 (59.38)	18 (56.25)	0.800[a]	8 (25.00)	7 (21.87)	0.768[a]
Female	13 (40.62)	14 (43.75)		24 (75.00)	25 (78.13)	
Marital status						
Married	21 (65.62)	16 (50.00)	0.447[a]	23 (71.87)	26 (81.25)	0.136[c]
Single	6 (18.75)	9 (28.13)		9 (28.13)	4 (12.50)	
Widow/Divorced	5 (15.63)	7 (21.87)		0 (0.00)	2 (6.25)	
Educational level						
No formal education	1 (3.13)	0 (0.00)	0.746[c]	–	–	–
Primary	7 (21.87)	5 (15.63)		3 (9.37)	0 (0.00)	0.384[c]
Lower secondary	5 (15.63)	6 (18.74)		5 (15.63)	5 (15.63)	
Upper secondary	7 (21.87)	5 (15.63)		9 (28.13)	8 (25.00)	
Bachelor's degree	12 (37.50)	16 (50.00)		15 (46.87)	19 (59.37)	
Occupation						
Unemployed	5 (15.63)	15 (15.63)	0.968[c]	–	–	–
General employee	8 (25.00)	6 (18.74)		7 (21.87)	4 (12.50)	0.198[c]
Self-employed	7 (21.87)	7 (21.87)		13 (40.63)	8 (25.00)	
Private sector employee	5 (15.63)	4 (12.50)		4 (12.50)	10 (31.25)	
Government employee	4 (12.50)	5 (15.63)		5 (15.63)	9 (28.13)	
Student	3 (9.37)	5 (15.63)		2 (6.25)	1 (3.12)	
Farmer	–	–		1 (3.12)	0 (0.00)	
Monthly income in THB (US$)						
No income	1 (3.13)	0 (0.00)	0.316[c]	–	–	–
5,000 (146.65)	1 (3.13)	1 (3.13)		–	–	–
5,001-10,000 (146.68-293.30)	1 (3.13)	5 (15.63)		0 (0.00)	1 (3.12)	0.101[c]
10,001-15,000 (293.33-439.95)	11 (34.37)	10 (31.25)		7 (21.87)	2 (6.25)	
15,001-20,000 (439.98-586.60)	12 (37.50)	7 (21.87)		12 (37.50)	9 (28.13)	
> 20,000 (586.63)	6 (18.74)	9 (28.12)		13 (40.63)	20 (62.50)	
Residence type						
Detached house	17 (53.13)	11 (34.37)	0.144[c]	16 (50.00)	12 (37.50)	0.169[a]
Apartment/Dormitory	8 (25.00)	6 (18.75)		8 (25.00)	5 (15.63)	
Commercial building	4 (12.50)	5 (15.63)		5 (15.63)	5 (15.63)	
Townhouse	3 (9.37)	10 (31.25)		3 (9.37)	10 (31.24)	
Living with						
Husband/Wife	15 (46.88)	14 (43.75)	0.827[c]	–	–	–
Daughter/Son	8 (25.00)	9 (28.12)		–	–	
Relatives	6 (18.75)	4 (12.50)		–	–	
Father/Mother	3 (9.37)	5 (15.63)		–	–	

Table 2. Demographic data and PTB-related characteristics of adults with PTB (n = 64) and family members (n = 64) (Cont.)

Characteristics	Adults with PTB			Family members		
	Experiment (n = 32)	Control (n = 32)	p-value	Experiment (n = 32)	Control (n = 32)	p-value
	n (%)	n (%)		n (%)	n (%)	
Number of persons living with						
2 persons	8 (25.00)	8 (25.00)	0.368[c]	–	–	–
3 persons	14 (43.75)	9 (28.12)		–	–	
4 persons	7 (21.88)	13 (40.63)		–	–	
5 persons or more	3 (9.37)	2 (6.25)		–	–	
Comorbidity besides PTB						
No	19 (59.37)	16 (50.00)	0.451[a]	–	–	–
Yes	13 (40.63)	16 (50.00)		–	–	
History of smoking/alcohol						
No	17 (53.13)	23 (71.88)	0.121[a]	–	–	–
Yes	15 (46.87)	9 (28.12)		–	–	
Family members with TB history						
No	29 (90.62)	25 (78.11)	0.461[c]	–	–	–
Father/Mother	1 (3.13)	1 (3.13)		–	–	
Relatives	2 (6.25)	5 (15.63)		–	–	
Son	0 (0.00)	1 (3.13)		–	–	
Family members providing care						
Husband/Wife	15 (46.87)	13 (40.63)	0.824[c]	–	–	–
Daughter/Son	9 (28.12)	9 (28.12)		–	–	
Relatives	5 (15.63)	4 (12.50)		–	–	
Father/Mother	3 (9.37)	6 (18.50)		–	–	
Relationship with adults with PTB						
Husband/Wife	–	–		12 (37.50)	14 (43.75)	0.513[c]
Daughter/Son	–	–		10 (31.25)	9 (28.12)	
Relatives	–	–		8 (25.00)	4 (12.50)	
Father/Mother	–	–		2 (6.25)	5 (15.63)	

Note. [a] = Pearson Chi-square test, [b] = independent test, [c] = Fisher's exact test

For medication adherence, the possible scores ranged from 1 to 150, with a cut-off point of 113. A TBMAS score below 113 is considered non-adherence. The scores of medication adherence at each point of measurement between the control and experimental arms were compared using the chi-square test for independence. From the results, there were significant differences between the experimental and control arms at the 3rd week (χ^2=19.522, p < 0.001) and the 19th week (χ^2=13.956, p = 0.002) after the program ended (**Table 3**).

Table 3. Comparison of medication adherence between the 3rd and 19th weeks after receiving the FEP

Medication adherence	Experimental group (n = 32)		Control group (n = 32)		χ^2	p-value
	n	(%)	n	(%)		
At 3rd week						
Adherence	32	(100.00)	17	(53.10)	19.522	<.001
Non-adherence	0	(0.00)	15	(46.90)		
At 19th week						
Adherence	32	(100.00)	23	(71.90)	6.234	.002
Non-adherence	0	(0.00)	9	(28.10)		

In addition, within-group comparisons between each point of measurement were carried out using the McNemar test. In the experimental arm, there was a difference in the proportion of medication adherence and non-adherence between the 3rd and 19th weeks after the program ended. However, the differences in the proportion of medication adherence at the 3rd and 19th weeks after the program ended were not significant in the control arm (p = 0.146) (**Table 4**).

Table 4. Within-group comparison of medication adherence at the 3rd and 19th weeks after the program ended

Medication adherence	At 19th week		Total	McNemar[a] p-value
	Adherence	Non-adherence		
Experimental arm				
At 3rd week				
Adherence	32	0	32	a
Non-adherence	0	0	0	
Total	32	0	32	
Control arm				
At 3rd week				
Adherence	14	3	17	0.146
Non-adherence	9	6	15	
Total	23	9	32	

Note: a = The McNemar test for medication adherence of the experimental arm at 3rd and 19th weeks was not performed because both variables were not dichotomous with the same values.

In this study, treatment success in the 19th week after the program ended was compared between the experimental arm and the control arm using Pearson's Chi-square test (Phi and Cramer's V test). From the findings, the percentage of participants in the experimental arm who had treatment success was 100.00% (93.75% cured and 6.25% treatment completed), whereas, in the control arm, the treatment success was 90.62% (68.75% cured and 21.87% treatment completed). Based on the results, it was observed that the treatment success rate varied significantly between the control and experimental arms (p = 0.046) (**Table 5**).

Table 5. Comparison of treatment success between adults with PTB receiving the FEP and those receiving the usual care on the 19th week after the program ended

Treatment success	Experimental group (n = 32)		Control group (n = 32)		χ^2	p-value
	n	(%)	n	(%)		
Treatment success	32	(100.00)	29	(90.62)	4.267	.046
Cured	30	(93.75)	22	(68.75)	6.564	.010
Treatment completed	2	(6.25)	7	(21.87)	3.232	.072
Treatment failed			3	(9.38)		

Discussion

The findings revealed that the FEP was effective in increasing medication adherence and treatment success among adults with PTB, which lent support to the family empowerment process through discovering reality, critical reflection, taking charge, and holding on.[17]

Discovering reality enhanced the cognitive response of the family members by raising their awareness of the actual PTB situation. This facilitated the assessment of prior beliefs, feelings, and perceptions to discover their strengths and weaknesses in supporting adults with PTB. Awareness of the issues allows individuals to seek more knowledge and skills necessary to solve the problem.[17] Our participants engaged in specific activities to promote their understanding of PTB, treatments, and their roles in supporting adults with PTB. Similarly, knowledge and awareness of ways to maintain and improve health were the beginning of the family's independence in taking care of adults with PTB.[19]

Then, critical reflection was promoted by asking family members questions to reevaluate their problems and re-consider their situations from different perspectives, which led to a clearer understanding of the issues and, ultimately, better solutions and changes. This is consistent with Gibson[17] that critical reflection enables family members to take action on their circumstances proactively by developing a sense of personal power and awareness of their strengths and resources. In the PTB context, critical reflection through sharing opinions and experiences increased the family's knowledge and ability to seek solutions to possible issues in PTB care.[20]

Moreover, taking charge was promoted through seeking knowledge and developing skills to improve activity plans and preparations for changes. Family members shared problems about PTB medication taking that arose from supporting adults with PTB, allowing them to analyze problems and barriers to their attempt to support the adults with PTB. Our study was supported by the previous study in that the family empowerment program encouraged family members to share problems in PTB care at home, which helped the family to analyze what needed to be done to improve their actions.[24] In our study, family members engaged in discussions to discover options for taking charge that were suitable for their ability, which helped establish a partnership to have the family's voices and needs heard.[17] Family members could perform their supporter roles to promote medication adherence by supervising medication adherence at home, giving encouragement when dealing with symptoms from treatment, maintaining understanding and sympathy, and reminding to maintain every appointment schedule. Engagement in an activity where family members could decide on the solution that they thought would be appropriate and the best for their context enabled them to take effective action in supporting adults with PTB.[20]

Ultimately, holding on was the last step of the FEP, where family members shared their progress and problems related to PTB medication adherence, their experience in coping with problems with medication adherence, and reflection on their strength and ability to perform the supporter roles. They were more confident in themselves, with the feeling of being in power, and were committed to maintaining the support for adults with PTB and integrating medication taking into their lifestyle. In line with previous research, discussing the problems related to practice and reinforcement helped to maintain PTB self-care practice.[20]

These family empowerment phases enabled the family to discover their actual circumstance of living with PTB. They developed a better understanding of the issues and a full sense of power to take the most appropriate course of action to continuously support adults with PTB, resulting in higher PTB medication adherence. Consistently, high medication adherence was reported by clients whose family members frequently supervised their medication and supported them in taking medication.[31] Our findings on the effectiveness of the FEP on PTB medication adherence were in line with other studies based on the theory of empowerment.[20,24,25,32] Nevertheless, it is noteworthy that no data on the experience of TB treatment side effects were presented, which might have affected the participants' medication adherence as observed in another study.[33]

Then, we found that the experimental arm could achieve 100% of treatment success after receiving the FEP, which was higher than the 90% target set by WHO.[1] This achievement of treatment success is attributable to increased medication adherence behaviors. This resulted in having sputum smear-negative in the 6-month duration of prescribed doses for the TB treatment regimen, as evidenced by the 93.75% cure rate in the experimental arm, which was higher than 68.75% in the control arm. Adherence to medications to which the MTB organism is susceptible by taking therapeutic agents regularly and continuing treatments for a sufficient period is essential to the effectiveness of PTB drugs and successful TB treatment.[8,23,34] Consistent with a systematic review and meta-analysis of interventions in the PTB context, support from the family was effective in improving treatment success for adults with PTB through motivation to adhere to medication and facilitation when coping with barriers to medication taking.[13] Our finding also aligned with a previous health promotion program based on empowerment theory that could enhance treatment adherence and lead to the rate of sputum smear conversion to become negative at two months among new smear-positive PTB adults.[32]

Limitations

Our study had some limitations. Participants of both family members and adults with PTB were from a university hospital in the central region of Thailand, which might limit the generalizability to other settings. Also, for adults with PTB, no baseline characteristics on TB regimens, length of TB treatment, time of starting TB treatment, and experience of side effects were collected, which might lead to bias. Further study should develop a family empowerment program tailored to a specific group of family members to correspond to their perception and ability by incorporating modern technology for more convenient access to the program activities. In order to comprehensively evaluate the efficiency of the program, further investigation is necessary to analyze its performance in diverse contexts and with various samples.

Conclusions and Implications for Nursing Practice

The finding confirmed that the FEP effectively improved medication adherence and treatment success among adults with PTB. The FEP was quite user-friendly,

with clear instructions for implementation. However, nurses may need training to incorporate empowerment strategies into work procedures to empower family support for medication adherence and treatment success in adults with PTB because training is crucial to ensure nurses' knowledge, skills, and competence in their actual practices.[35,36]

Acknowledgments

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Appendix

Table 1. Activities in the FEP

Week/ Session/Time	Steps/ Strategies	Objectives	Activities
Week 1/ Session 1/ (90 min)	Step 1–2 of empowerment process/ 1. Discovering reality 2. Critical reflection	1. To encourage family members to feel sense of personal power 2. To promote family members' understanding about PTB, treatments, and their roles in the care of adults with PTB 3. To allow family members to discover options and make a decision to choose options to take action	1. Self-introduction to make a good mutual relationship 2. Program introduction, including objectives and procedures of the study 3. Discussion in real situation and reflective questions in the activity called "Know Yourself and Others: 50/50" that included 1) awareness and facing real situation, 2) assessment of prior beliefs and knowledge, and 3) self-exploration 4. Encouraged family members to have self-reflection through the activity called "Know Yourself and Self-analysis" by asking critical reflection questions and make a decision to take action by 1) sharing ideas and feelings, and 2) discovering new roles 5. Discussed and exchanged opinions about medication adherence: 1) asked reflective questions about family member's perspectives in problem solving; and 2) asked them to share opinions about their ability to solve problems 6. Introduced the use of observation record form for medication adherence and assign family members to record about: 1) medication taking, 2) problems about medication taking, and 3) feelings of family member with PTB for discussion in Session 2
Week 2/ Session 2/ (60min)	Step 3 of empowerment process/ Taking charge	To encourage family members to take charge in the care of adults with PTB and learn how to manage problems efficiently	1. Encourage using activity titled "We Love Each Other to Fight TB" that allowed family members to make their actions about how to promote medication adherence, the outcomes and changes, and problem management for taking charge successfully in 2 steps: 1) seeking knowledge and developing skills to improve activity plans, and 2) preparations for changes in activity 2. Encouraged family members to perform their PTB five supporter roles 3. Reminded family members to use the observation record form for medication adherence and assigned family members to record problem solving methods for discussion in Session 3

Table 1. Activities in the FEP (Cont.)

Week/ Session/Time	Steps/ Strategies	Objectives	Activities
Week 3/ Session 3/ (45 min)	Step 4 of empowerment process/ Holding on	1. To encourage holding on for family members despite changing circumstances 2. To increase family members' commitment to their supporter roles	1. Encourage family members to perform their roles continuously, constantly, and sustainably using an activity called "We Win TB Together" that included "building self-confidence with new roles in changing activities" by monitoring the continuity of activities 2. Discussed with family members to sharing problems and success of PTB care based on the five supporters and encourage family members to improve their abilities 3. Reminded family members to use the observation record form for medication adherence to record problems of medication taking, and problem solving methods for discussion in Session 4
Week 4, 5/ Session 4, 5/ (30 min)	Step 4 of empowerment process/ Holding on	To maintain the ability of family members to provide persons with PTB with support for medication adherence	1. Discussed with family members through the activity called "Integrating Knowledge and Experience into Daily Life" by explaining how to integrate medication taking schedules into daily life patterns and how to solve problems such as forgetfulness, side effects, and travelling away from home 2. Gave verbal reinforcement to family members for supporting adults with PTB in medication adherence 3. Reminded family members to use the observation record form for medication adherence and assign family members to record about: 1) medication taking, 2) problems about medication taking (e.g., side effects), 3) feelings of family member with PTB, and 4) problem solving methods by asking and observing until adults with PTB take their medication for 6 months or 180 doses 4. In session 5, summarized the knowledge and skills for family members in providing support to adults with PTB for medication adherence for 6 months and ended the program

ผลของโปรแกรมการเสริมสร้างพลังอำนาจของครอบครัวต่อความร่วมมือในการรับประทานยาและความสำเร็จของการรักษาในผู้ใหญ่ที่เป็นวัณโรคปอด: การทดลองแบบสุ่มและมีกลุ่มควบคุม

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บทคัดย่อ: การรักษาวัณโรคปอดที่ไม่ประสบความสำเร็จเป็นผลมาจากการขาดความร่วมมือในการรับประทานยา ครอบครัวเป็นแหล่งสนับสนุนที่สำคัญสำหรับผู้ใหญ่ที่เป็นวัณโรคปอด แต่มีความสามารถจำกัดในการสนับสนุนอย่างต่อเนื่องในช่วง 6 เดือนแรกของการรักษา การศึกษานี้เป็นการทดลองแบบสุ่มที่มีกลุ่มควบคุมวัดผลหลังการทดลองอย่างเดียว มีวัตถุประสงค์เพื่อศึกษาผลของโปรแกรมการเสริมสร้างพลังอำนาจของครอบครัวต่อความร่วมมือในการรับประทานยาและความสำเร็จของการรักษาในผู้ใหญ่ที่เป็นวัณโรคปอด กลุ่มตัวอย่างคือสมาชิกในครอบครัวจำนวน 64 คน ที่ดูแลผู้ใหญ่ที่เป็นวัณโรคปอดรายใหม่ที่รับการรักษาที่คลินิกวัณโรคของโรงพยาบาลมหาวิทยาลัยแห่งหนึ่งในภาคกลางของประเทศไทย ได้รับการสุ่มเข้ากลุ่มทดลอง (n = 32) เพื่อรับโปรแกรม และกลุ่มควบคุม (n = 32) ได้รับเฉพาะการดูแลตามปกติ เก็บรวบรวมข้อมูลโดยใช้แบบสอบถามข้อมูลส่วนบุคคลสำหรับผู้ที่เป็นวัณโรคปอด แบบสอบถามข้อมูลส่วนบุคคลสำหรับสมาชิกในครอบครัว แบบวัดความร่วมมือในการรับประทานยาวัณโรค และเกณฑ์การประเมินความสำเร็จของการรักษาวัณโรคขององค์การอนามัยโลก วิเคราะห์ข้อมูลโดยใช้สถิติเชิงพรรณนา การทดสอบไคสแควร์ของเพียร์สัน การทดสอบของฟิสเชอร์และการทดสอบของแมคนีมาร์

จากผลการทดลองพบว่า กลุ่มทดลองมีความร่วมมือในการรับประทานยาสูงขึ้นกว่ากลุ่มควบคุมในสัปดาห์ที่ 3 และ 19 หลังสิ้นสุดโปรแกรมอย่างมีนัยสำคัญ พบอัตราความสำเร็จของการรักษาในสัปดาห์ที่ 19 ของกลุ่มทดลองสูงกว่ากลุ่มควบคุม โปรแกรมการเสริมสร้างพลังอำนาจของครอบครัวมีประสิทธิภาพในการเพิ่มความร่วมมือในการรับประทานยาและความสำเร็จของการรักษา พยาบาลควรได้รับการฝึกให้ใช้กระบวนการเสริมสร้างพลังอำนาจของครอบครัวเพื่อให้การสนับสนุนผู้ใหญ่ที่เป็นวัณโรคปอดอย่างต่อเนื่อง ทั้งนี้จำเป็นต้องมีการศึกษาวิจัยเพิ่มเติมเพื่อตรวจสอบประสิทธิผลของโปรแกรมในบริบทที่แตกต่างและกลุ่มตัวอย่างที่หลากหลาย

คำสำคัญ: การเสริมสร้างพลังอำนาจของครอบครัว ความร่วมมือในการรับประทานยา วัณโรคปอด การทดลองแบบสุ่มและมีกลุ่มควบคุม ความสำเร็จของการรักษา

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