



The 4T Approach for Smoking Cessation Compliance for Pulmonary **Tuberculosis Patients in Persahabatan Referral Hospital**

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Abstract

Background: Smoking increases the risk of tuberculosis infection and affects its treatment success rate and mortality. Most TB patients who smoke quit at the initial diagnosis, but may continue to smoke if the clinical symptoms improve. Studies show that the 4T approach (Tanya, Telaah, Tolong nasehati, and Tindak lanjut) helps smokers quit. The 4T approach was applied in Indonesia as a smoking cessation program for TB patients.

Methods: We conducted a randomized controlled trial on 43 male TB patients who smoke. The trial group received a 4T approach consisting of education, counseling, and motivation to quit smoking for three months. The control group received a self-help leaflet. Smoking status, Fagerström nicotine dependence scale, exhaled carbon monoxide level, and peak expiratory flow rate were collected. We observed the subjects at months 1, 2, and 3 after quitting smoking and reported on the Motivation and Minnesota Withdrawal Scale.

Results: Smoking cessation levels during months I, II, and III (Continuous Abstinence Rate I, II, and III) were higher in the trial group than in the control group. The trial group had a higher percentage of smoking cessation than the control group: until 4 weeks (66.7% vs. 54.5%), until 8 weeks (57.1% vs. 45.5%), and until 12 weeks (52.4% vs. 45.5%). The control group had higher numbers of smoking relapses (18.2% vs. 14.3%) and still smokers (18.2% vs. 9.5%) after the study. Withdrawal symptoms included an increase in appetite (44.1%), cigarette cravings (6.9%), agitation (2.3%), insomnia (2.3%), and irritability (2.3%). There were no significant differences in the withdrawal scale between groups (P=0.788), but the trial group showed better motivation to stop smoking during CAR II (P=0.043).

Conclusion: The 4T approach is effective in maintaining abstinence from smoking among lung tuberculosis patients until months 1, 2, and 3 after quitting. Smoking cessation programs during tuberculosis treatment can help patients quit smoking and reduce relapse.

Keywords: 4T approach, smoking cessation, pulmonary tuberculosis

INTRODUCTION

The difficulty of stopping smoking needs to be considered while pulmonary tuberculosis (TB) patients are undergoing treatment. Ng et al, in their study, stated that pulmonary TB patients on treatment who returned to smoking after 1 to 3 months of treatment amounted to 11.2%, while subjects who smoked returned after 4-6 months of treatment as much as 28%. It increased at three months and six months after completion of treatment, namely by 57% and 70%.1 Considering the facts, smoking cessation programs should be a matter of concern in treating pulmonary TB. It is common to find pulmonary TB patients who still smoke or return smoking after undergoing TB to treatment.

Evaluation of smoking habits and the success of quitting smoking is important to know during TB treatment.

Quitting smoking is not easy because it is influenced by nicotine withdrawal symptoms, the environment, low family support, and low motivation to quit smoking. Several methods have been developed to stop smoking, namely, 5A (Ask, Advice, Assess, Assist, and Arrange), later modified by the Ministry of Health in Indonesia to become 4T (Tanya (Ask), Telaah (Asses), Tolong nasehati (Advise and Advice), and Tindak lanjut (Follow-up).²

The 4Ts approach focuses on counseling and motivating patients to quit smoking. In Indonesia, we use the 4T approach to help someone quit smoking.

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Attribution-



One piece of literature suggests calculating abstinence or smoking cessation if the patient does not smoke within four weeks, considering the number of patients who return to smoking after 24 hours and are no longer smoking.^{3–5} Several studies have been conducted to determine the success rate of quitting smoking (nicotine abstinence rate). The results of these studies are promising to help someone quit smoking. According to Aryanpur et al, providing counseling with 5A increased the smoking cessation rate (33.9%), compared to the control group (9.8%), and adding medication to the 5A group increased smoking cessation (71.7%).⁶

According to El Sony et al, they were providing regular education and motivation, namely four times in 8 months during treatment in pulmonary TB patients, to stop smoking, which increased the smoking cessation rate (abstinence rate) by 56.3% compared to the 14.3% abstinence rate in the control group, which only pamphlets were given.⁷ Campbell et al also conducted a study on pulmonary TB patients who smoked by comparing the provision of education with pamphlets in the control group with the treatment group, who were given regular motivation. The smoking cessation rate in the treatment group was 39%, compared to 0% in the control group.⁸

In addition to the abstinence rate, the continuous abstinence rate (CAR) assesses the success of quitting smoking. CAR is the number of continuous smoking cessations over a certain period, usually measurable after a person quits smoking.⁴ Failure to quit smoking can be seen from the relapse rate. A relapse is a client who has stopped smoking but continues to smoke, even if it's only one cigarette.²

Siddiqi et al examined the CAR number of counseling in the treatment group with the 4T approach to TB patients who smoked compared to the control group, who were only given smoking cessation brochures. The results of this study stated that 41% of the subjects in the treatment group continued to quit smoking for up to 6 months after completing the program, while only 8.5% were in the control group.⁹

Smoking has a close relationship with pulmonary TB. Cigarettes can affect TB treatment outcomes, clinical manifestations, and sputum conversion in TB patients and increase mortality.^{10,11} Most pulmonary TB patients smoke and return to smoking during the first month to sixth months while undergoing TB treatment.¹ Because of that, a smoking cessation program should be given to smoking patients undergoing treatment for pulmonary TB. Quitting smoking is not easy, and because of that, various programs have been implemented to help someone guit smoking, one of which is the 4T approach.

This study aims to determine the success of the smoking cessation program with the 4T approach in new cases of pulmonary TB patients who will start treatment at Persahabatan Central General Hospital.

METHODS

This was a randomized clinical trial study conducted at Persahabatan Hospital/Department of Pulmonology and Respiratory Medicine, FKUI, Jakarta, from October 2019 to April 2020. The target population was all new cases of pulmonary TB patients, male gender, who have been smoking for the past month and are currently undergoing ATD (anti-tuberculosis drug) treatment at the Persahabatan Central General Hospital.

The reachable population was new male pulmonary TB patients who have been smoking for the last month and were undergoing ATD treatment at the Persahabatan General Hospital from October 2019 to April 2020. All new male pulmonary TB patients (bacteriological and clinical tuberculosis) who still smoked in the last month and underwent OAT treatment at Persahabatan General Hospital from October 2019 to April 2020 who met the inclusion-exclusion criteria.

The inclusion criteria were men aged 18–65 years who smoked >100 cigarettes in their lifetime and were still smoking in the last month, were undergoing an intensive phase of pulmonary TB treatment at Persahabatan General Hospital, and subjects were willing to participate in the study.

Exclusion criteria were subjects with a diagnosis of former TB, TB relapse, or drug withdrawal; subjects with severe conditions or decreased consciousness that made it impossible to be interviewed; subjects with exhaled CO and Peak Expiratory Flow (PEF) examined; and subjects unwilling to be included in the study.

The design of this study was a randomized control trial to determine the effectiveness of the 4T approach compared to giving self-help leaflets to stop smoking, as seen from the Continuous Abstinence Rate (CAR) at 1, 2, and 3 months. The secondary outcomes were abstinence rate, a scale of motivation to stop smoking, PEF score, and withdrawal symptoms. The research subjects were selected by consecutive sampling according to the inclusion criteria until the number of sample was fulfilled. The number of research subjects who met the inclusion criteria was 48, and 5 people who were not willing to participate in the study were excluded. The study subjects dropped out (DO) 9 people, consisting of a control group (self-help leaflet) of 4 people and five people from the treatment group (4T approach).

Operational definition study subjects from the control group were 4 people; 3 people moved out of town and did not continue the research; 1 person died from coughing up massive blood. In the control group, four people were stated to have dropped out. When CAR I, one of them died, and until CAR III, there were no more drop-outs, so at the end of the study, the total drop-out was 4 people.

Operational definition subjects in the treatment group were 5 people, with information that 4 people changed treatment and 1 person died from pneumonia with sepsis. There were 2 subjects who were declared dropped out of the treatment group during abstinence; added 1 subject. During CAR I, there were a total of 3 drop-outs. During CAR II, there was an additional drop-out; one patient died. During CAR III, one more dropped out patient was added, so, at the end of the study, there were 5 drop-out patients in the treatment group.

RESULTS

In this study, all subjects were men who had new cases of pulmonary TB to avoid matching difficulties in selecting study subjects. The basic characteristics of the research subjects are listed in Table 1. The characteristics of the treatment group include the average age of the subjects being 38.4±14.1 SD years. According to marital status, as much as 57.1% subjects were married, 38.1% were not married, and one subject was divorced. There were 19% subjects with basic education, 47.6% with secondary education, and 33.3% with higher education.

According to employment status, a total of 95.2% subjects worked. The nutritional status of 28.6% subjects was poor, 33.3% was normal, 23.8% was overweight, and 14.3% was obese. The mean BMI (body mass index) was 20.9±4.1. A total of 57.1% of subjects were diagnosed with bacteriological pulmonary TB. As many as 23.8% of subjects had DM (Diabetes Mellitus) or HIV (Human Immunodeficiency Virus) comorbidities, and 9.5% complained of coughing up blood. None of the subjects experienced depression (Table 1).

Essential characteristics in the control group include the mean age of the subject which was 32.5±12.2. About 36.4% subjects were married, 54.5% were unmarried, and 2 subjects were divorced. There were 81.8% subjects with secondary education, 13.6% with higher education, and 1 person with primary education. A total of 81.8% of the patients worked (Table 1).

According to nutritional status of the control group, 50% subjects had poor BMI, 27.3% had normal BMI, 9.1% subjects were overweight, and 13.6% were obese. The mean BMI was 19.7 ± 4.7 . A total of 59.1% of subjects were diagnosed with bacteriological pulmonary TB. As many as 31.8% of subjects complained of coughing up blood, and 18.2% had DM or HIV comorbidities. None of the subjects experienced depression. In the treatment group, the average age of starting smoking was 16 ± 2.4 , and the mean duration of smoking was 22.4 ± 14.5 years (Table 1).

Table 1. Characteristics of smoking pulmonary tuberculosis subjects

Variable Age (years) [mean±SD]	Self-help Leaflet Group (n=22) 32.5±12.2	Approach Group 4T (n=21) 38.4±14.1	P 0.149*
Marital Status	00	001121111	0.385**
Single	12 (54.5%)	8 (38.1%)	01000
Divorced	2 (9.1%)	1 (4.8%)	
Married	8 (36.4%)	12 (57.1%)	
Education Status	0 (00.170)	12 (011170)	
Elementary	1 (4.5%)	4 (19.0%)	
Intermediate (Junior/High school)	18 (81.8%)	10 (47.6%)	0.059**
High(D3/S1/S2)	3 (13.6%)	7 (33.3%)	0.000
TB Diagnosis	0 (10.070)	7 (00.070)	
Clinical	9 (40.9%)	9 (42.9%)	
Microbiological	13 (59.1%)	12 (57.1%)	0.897ª
Profession	10 (00.170)	12 (07.176)	
Student	4 (18.2%)	1 (4.8%)	
Worker	18 (81.8%)	20 (95.2%)	0.345 ^b
BMI [mean±SD]	19.7±4.7	20(93:278) 20.9±4.1	0.400*
Complaint	13.1 ±4.1	20.3I 4 .1	0.400
Coughing up blood	7(31.8%)	2 (9.5%)	
Others	15 (68.2%)	19 (90.5%)	0.132 ^b
Comorbid	13 (08.2 %)	19 (90.378)	
DM or HIV	4 (19 39/)	F (32 99/)	
None	4 (18.2%)	5 (23.8%)	0.721 ^b
	18(81.8%)	16 (76.2%)	0 400*
Nutritional Status	44 (50.09())		0.422*
Poor	11 (50.0%)	6 (28.6%)	
Normal	6 (27.3%)	7 (33.3%)	
Overweight	2 (9.1%)	5 (23.8%)	
Obesity	3 (13.6%)	3 (14.3%)	N1/A
Experiencing Depression	0 (0.0%)	0 (0.0%)	N/A
Age starting smoking (years) [mean±SD]	15.3±2.8	16±2.4	0.397*
Number of sticks per day [median (min-max)]	12 (2–32)	12 (4–32)	0.521°
Long smoking [mean±SD]	17.2±11.9	22.4±14.5	0.203*
Smoking type			
Filter	16 (72.7%)	16 (76.2%)	
Kretek	4 (18.2%)	2 (9.5%)	0.656*
Mixture	2 (9.1%)	3 (14.3%)	
Attempt Stopped			
Never	10 (45.5%)	11 (52.4%)	0.650ª
Ever	12 (54.5%)	10 (47.6%)	
Stopping Method			
Gradually	5 (22.7%)	2 (9.5%)	0.412 ^b
Instantly	17 (77.3%)	19 (90.5%)	
Brinkman Index			
Mild	14 (63.6%)	8 (38.1%)	
Moderate	5 (22.7%)	10 (47.6%)	0.194*
Severe	3 (13.6%)	3 (14.3%)	
Fagerstrom Score [median (min-max)]	4 (2–7)	3 (2–6)	0.108°
Fagerstrom Degree			
Very Low	2 (9.1%)	7 (33.3%)	
Low	11 (50.0%)	8 (38.1%)	0.275*
Moderate	4 (18.2%)	3 (14.3%)	-
High	5 (22.7%)	3 (14.3%) test: SD=Standard Deviation	

Note: *t-test; **contingency coefficient test; achi-square test; bfisher exact test; ann-whitney test; SD=Standard Deviation

Most of the types of cigarettes consumed by the subjects were filter cigarettes (76.2%). Attempts to stop smoking have been made by 47.6% of the subjects. In the smoking cessation method, 90.5% of the subjects chose to stop immediately (Table 1).

The median number of cigarettes per day is 12 (4-32) cigarettes. As many as 38.1% of subjects had the Brinkman index in the mild category, 47.6% in the moderate category, and 14.3% in the severe category. As many as 38.1% subjects had low category of Fagerstrom, 14.3% of subjects had moderate Fagerstrom category, 14.3% had high category of Fagerstrom, and the rest had very low nicotine dependence. The mean Fagerstrom score was 3 (2-6). The mean score for motivation to quit smoking at the start of the study was 8 (3-8). As many as 90.5% of patients were in the action phase and ready to quit smoking. The mean baseline PEF value of the patients was 281±90. The average baseline exhaled CO (carbon monoxide) value was 7.4±3.2 (Table 1).

The characteristics of smoking status in the treatment group are shown in Table 2. The age of starting smoking was 15.3±2.8, and the average duration of smoking was 17.2±11.9 years. Most types of cigarettes were filter cigarettes (72.7%). Attempts to stop smoking have been made by 54.5% of the subjects. In the smoking cessation method, as many as 77.3% of the subjects chose to quit immediately. The median number of cigarettes per day was 12 (2–32) cigarettes; 63.6% of subjects had mild Brinkman index, 22.7% subjects had moderate Brinkman index, and 13.6% had severe Brinkman index.

According to Fagerstrom, 50.0% subjects had low category, 22.7% subjects had high Fagerstrom category, 18.2% subjects were in moderate category of Fagerstrom, and the rest had very low nicotine dependence. The mean score for motivation to quit smoking at the start of the study was 8 (4–8). As many as 54.5% of the subjects had tried to quit smoking before, as many as 77.3% stopped immediately, and there were 22.7% of the subjects who chose to stop gradually. The mean value of the basic motivation to quit smoking in the control group was 8 (4–8). As many as 81.8% of patients were in the action phase and ready to quit smoking (Table 2). The mean of the basic PEF value is 301 ± 117 . The average baseline exhaled CO value was 6.9 ± 3.6 (Table 4).

In the 4th week of observation after recruitment, it was found that the percentage of quitting smoking in the 4T approach group was 80.9%, similar to the group with 81.8% self-help leaflets. However, in the self-help leaflet group, the number of subjects who were still smoking was 18.5% more than the 4T approach group of 9.5% (Table 2). Confirmation of abstinence was confirmed based on anamnesis, daily records, and exhaled CO <6 ppm. Smoking cessation ratings are expressed in abstinence. The value of P=0.263 statistically shows no difference in abstinence between the two groups.

Based on observations for four weeks (1 month) after quitting smoking in the 4T approach group, 66.7% of the subjects still quit smoking continuously more than the group with self-help leaflets, 54.5%, even though it was not statistically significant (P=0.816). As many as 18.2% of the subjects in the self-help leaflet group still smoked, and 18.2% dropped out, more than the 4T approach group. The value of smoking relapse in the two groups was almost the same, namely 9.5% in the 4T approach group and 9.1% in the group with self-help leaflets (Table 2). In CAR 1, the abstinence assessment was carried out by history taking, smoking cessation diaries, and exhaled CO \leq 6 (Table 2).

Based on observations for eight weeks (2 months) after quitting smoking (CAR II) in the 4T approach group, 57.1% still quit smoking more than the group with self-help leaflets (45.5%), although statistically, there was no significant difference between the two groups (P=0.809). As many as 18.2% of the subjects in the self-help leaflet group still smoked, and 18.2% of the subjects who relapsed smoked in the self-help leaflet group more than the 4T approach group, namely 9.5% and 14.3%. The two groups' drop-out values are the same (Table 2). In CAR II, the abstinence assessment was carried out by history-taking, smoking cessation diary, and exhaled CO ≤6 (Table 2).

Group	Stop	Still Smoking	Relapse	Drop-out	Р
Abstinance rate					
4T Approach	17 (80.9)	2 (9.5)	-	2 (9.5)	Ó.263*
Self-help leaflet	18 (81.8)	4 (18.2)	-	0 (0.0)	
Continous Abstinence Rate (CAR)-I					
4T Approach	14 (66.7)	2 (9.5)	2 (9.5)	3 (14.3)	0.046*
Self-help leaflet	12 (54.5)	4 (18.2)	2 (9.1)	4 (18.2)	0.816*
Continous Abstinence Rate (CAR)-II					
4T Approach	12 (57.1)	2 (9.5)	3 (14.3)	4 (19.0)	0 000*
Self-help leaflet	10 (45.5.)	4 (18.2)	4 (18.2)	4 (18.2)	0.809*
Continous Abstinence Rate (CAR)-III					
4T Approach	11 (52.4)	2 (9.5)	3 (14.3)	5 (23.8)	0.814*
Self-help leaflet	10 (45.5)	4 (18.2)	4 (18.2)	4 (18.2)	0.014

Table 2.	Success rates for quitting smoking (Abstinence Rate) and maintaining smoking cessation up to the 1st, 2nd, and 3rd months with the
	4T approach compared to controls (N=43)

Noe. Contingency Coemcient test

Based on observations for 12 weeks (3 months) after quitting smoking (CAR III) in the 4T approach group, 52.4% still quit smoking more than the group with self-help leaflets (45.5%), although statistically, there was no significant difference between the two groups (P=0.814). As many as 18.2% of subjects in the self-help leaflet group still smoked (failed), and 18.2% of relapse patients smoked more than the group with the 4T approach (Table 2). CAR III abstinence assessment was performed by history-taking, smoking cessation diary, and exhaled CO ≤6.

Table 3.	Comparison of the basic motivation scale and the	
	Minnesota Withdrawal Scale of the group given the 4T	
	approach with control	

Variable	Median self-leaflet group	Median Approach group 4T	P°
Basic Motivation	8 (4 – 8)	8 (3 – 8)	0.480
Abstinence Motivation	9 (4 – 10)	10 (5 – 10)	0.144
CAR-I Motivation	9 (4 - 10)	10 (5 – 10)	0.061
CAR-II Motivation	9 (4 – 10)	10 (5 – 10)	0.043
CAR-III Motivation	9 (4 – 10)	10 (5 – 10)	0.083
MNWS Abstinence	1 (0 – 6)	4 (0 – 6)	0.200
MNWS CAR-I	0 (0 – 4)	4 (0 – 6)	0.101
MNWS CAR-II	0 (0 – 4)	0 (0 – 4)	0.419
MNWS CAR-III	0 (0 – 4)	0 (0 – 4)	0.788

Note: ^cMann-whitney test; CAR=*Continous Abstinence Rate;* MNWS=Minnesota Withdrawal Scale

The scale of smoking cessation motivation in research subjects was observed from the beginning of the study to the CAR III month in both groups in Table 4. The motivation to stop smoking in the treatment group was better than in the control group. The result of the statistical test was that there was a significant difference in motivation to stop smoking between the two groups in the second month after the subject quit smoking (CAR II). The 4T approach group had a better motivation scale than the self-help leaflet group (P=0.043), with a mean motivation of 10 (5-10) compared to the mean motivation of the treatment group 9 (4-10) (Table 3).

The stage of behavior change in the 4T approach group at the beginning of the study was 90.5% in the action phase, and 9.5% in the precontemplation phase, while in the self-help leaflet group, 81.8% were in the action phase and 18.2% in the pre-contemplation phase. During abstinence, 80.9% of patients in the 4T approach group were in the action phase, 4.8% were in the pre-contemplation phase, 4.8% were in the contemplation phase, and in the self-help leaflet group, 81.8% were in the action phase, 13.6% in the pre-contemplation phase, and 4.5% in the contemplation phase. In CAR I, in the treatment group, there were no subjects in the contemplation phase. There were still 4.8% of subjects in the pre-contemplation phase, and as many as 9.5% in the ready phase and 71.4% in the action phase, while in the control group, there were 59.1% in the action phase, 13.6% in the precontemplation phase, and 9.1% in the contemplation phase (Table 4).

In CAR II, as many as 71.4% of the subjects in the treatment group were in the action phase and were no longer in the ready phase, while in the control group, there were still 13.6% of the subjects in the pre-contemplation phase, 9.1% in the contemplation phase, and 59.1% in the action phase. In CAR III, in the treatment group, 66.7% were already in the action phase, only 4.8% were in the contemplation phase, and 4.8% were in the pre-contemplation phase, while in the control group, 59.1% of the subjects were in the action phase. There were still 13.6% of the subjects in the pre-contemplation phase and 9.1% in the contemplation phase (Table 4).

 Table 4.
 The stage of behavior changes in the group given the 4T approach compared to the control group

Motivation Scale	Self-help Leaflet Group (n=22)	4T Approach Group (n=21)
Basic Motivation	• • •	• • •
Pre-Contemplation	4 (18.2%)	2 (9.5%)
Action	18 (81.8%)	19 (90.5%)
Abstinence motivation		
Pre-contemplation	3 (13.6%)	1 (4.8%)
Contempation	1 (4.5%)	1 (4.8%)
Ready	0 (0.0%)	0 (0.0%)
Action	18 (81.8%)	17 (80.9%)
Drop out	0 (0.0%)	2 (9.5%)
CAR-I Motivation		
Pre-contemplation	3 (13.6%)	1 (4.8%)
Contemplation	2 (9.1%)	0 (0.0%)
Ready	0 (0.0%)	2 (9.5%)
Action	13 (59.1%)	15 (71.4%)
Drop-out	4 (18.2%)	3 (14.2%)
CAR-II Motivation		
Pre-contemplation	3 (13.6%)	1 (4.8%)
Contemplation	2 (9.1%)	1 (4.8%)
Ready	0 (0.0%)	0 (0.0%)
Action	13 (59.1%)	15 (71.4%)
Drop-out	4 (18.2%)	4 (19.0%)
CAR-III Motivation		
Pre-contemplation	3 (13.6%)	1 (4.8%)
Contemplation	2 (9.1%)	1 (4.8%)
Ready	0 (0.0%)	0 (0.0%)
Action	13 (59.1%)	14 (66.7%)
Drop-out Note: CAR=Continous At	4 (18.2%)	5 (23.8%)

Note: CAR=Continous Abstinence Rate

The smoking cessation withdrawal scale in study subjects was measured from the start of the study to month 3 (CAR III) in both groups (Table 3). The study results showed no statistically significant differences between the two groups.

The median withdrawal score in CAR I was higher in the 4T approach group than in the control group because more subjects in the control group relapsed to smoking, and more patients stopped smoking in the treatment group, so the withdrawal rate increased in the treatment group (Table 3).

Variable	Self-help leaflet Group	4T Approach Group	P *
Basic CO	6.9±3.6	7.4±3.2	0.618
CO Abstinence	5.4±2.4	4.9±2.8	0.574
CO CAR-I	4.3±2.2	5.5±3.4	0.210
CO CAR-II	4.8±2.1	5.3±3.8	0.627
CO CAR-III	4.9±2.5	5.7±4.4	0.529
Basic PEF	301±117	281±90	0.525
PEF Abstinence	322±106	349±67	0.334
PEF CAR-I	345±107	369±64	0.423
PEF CAR-II	350±115	377±54	0.377
PEF CAR-III	349±114	387±65	0.246

Note: *t-test

In the study subjects, several withdrawal symptoms were found, namely increased appetite by 44.1% of subjects, desire to smoke by 6.9%, difficulty sleeping by 2.3%, impatience by 2.3%, and restlessness by 2.3%. Most of the withdrawal symptoms experienced by the subjects were an increase in appetite after the patient started to stop smoking. Not all research subjects experienced withdrawal symptoms; only several subjects did, and some subjects experienced more than one withdrawal symptom.

A total of 24 subjects experienced withdrawal symptoms, while the other 19 subjects did not experience withdrawal symptoms; in the treatment experienced withdrawal 13 subjects group, symptoms, while in the control group, 11 subjects experienced withdrawal symptoms. Of the 13 subjects in the treatment group who experienced withdrawal symptoms, there were 11 who only complained of increased appetite, one subject complained of difficulty sleeping, and one other patient complained of increased appetite and cravings for cigarettes. In the control group of 11 subjects who experienced withdrawal symptoms, eight subjects only complained of increased appetite. One person craved cigarettes; one complained of anxiety and increased appetite; and the other complained of impatience and craving cigarettes.

Exhaled CO values were measured from the study's start until the 3rd month (CAR III). Table 5 showed no statistically significant difference in CO values between the two groups. In both groups, CO levels showed a downward trend. In both groups, the

mean value of exhaled CO was not much different in abstinence, CAR I, CAR II, and CAR III. The exhaled CO value in the 4T approach group during abstinence was better than the self-help leaflet group, although it was not statistically significant. There was a significant decrease in CO levels during abstinence compared to baseline exhaled CO in the 4T approach group. In both groups, the average CO level at the end of the study was ≤6. (Table 5).

PEF values were measured from the study's start until the 3rd month (CAR III). In Table 5, the PEF value in the 4T approach group at the beginning of the study was lower than the control group, namely 281±90. Still, the PEF during CAR I, II, and III was better than the self-help leaflet group since abstinence increased to CAR III, although significant statistics are meaningless. There was a significant increase in PEF values in the 4T approach group on abstinence compared to baseline PEF. The trend in PEF values in the treatment group increased; in the self-help leaflet group, it increased to CAR II and then decreased to CAR III.

From the intention to treat analysis, the smoking cessation rate was still higher in the treatment group during follow-up at four weeks, eight weeks, and 12 weeks after abstinence. Numbers are still smoking more in the control group since abstinence, CAR I, II, and III. The percentage of smoking relapse was higher in the control group in CAR II and CAR III. Giving the 4T approach has better results for increasing smoking cessation rates and maintaining smoking cessation. A comparison of the percentages of smoking abstinence and relapse in the two groups is shown in Figures 1a and 1b.

The number of subjects who relapsed and smoked was always higher in the control group at months 1, 2, and 3 (CAR I, II, and III), according to Figure 1c. The percentage of relapse and still smoking after the 1st month (CAR I) was 27.3%, while in the treatment group, it was 19%. After the second month (CAR II), it was 36.4% in the control group and 23.8% in the treatment group. After the third month (CAR III), it was 36.4% in the control group and 23.8% in the treatment group. Abstinence rates were always higher in the treatment group at 1,2, and 3 months (CAR I, II, and III), namely 66.7%, 57.1%, and 52.4%, while in the control group, 54.5%, 45.5%, and 45.5%, respectively (Figure 1c).

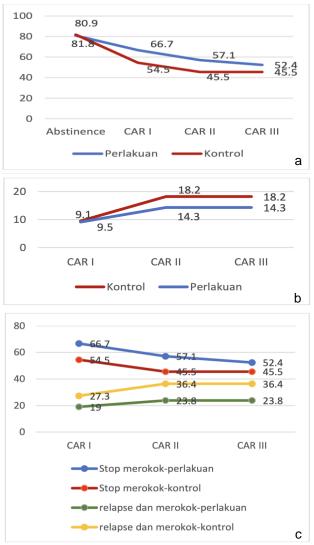


Figure 1. (a) Comparison of the percentage of smoking cessation in the treatment and control groups during abstinence, CAR I, II, and III; (b) Comparison of the percentage of smoking relapse in the treatment and control groups during CAR I, II and III; (c) Comparison of the percentage of smoking cessation with the number of relapses and still smoking in the treatment and control groups during CAR I, II and III.

DISCUSSION

Smoking has a close relationship with pulmonary TB. One of the literature states that many factors, including smoking, influence a person to suffer from pulmonary TB. In addition, smoking is also a factor that affects the outcome of TB treatment, clinical manifestations, and sputum conversion of TB patients and increases the mortality rate.^{10,11} It is known that the majority of pulmonary TB patients smoke. Pulmonary TB patients undergoing partial treatment are known to return to smoking during the first month to the sixth while undergoing TB treatment.¹ Quitting smoking is not easy because it is influenced by nicotine withdrawal symptoms, the environment, low support from family, and low motivation to quit smoking. Several methods have been developed to stop smoking, namely, 5A (Ask, Advice, Assess, Assist, and Arrange), which was later modified by the Ministry of Health in Indonesia to become 4T (Ask, Study, Help and Advise, Follow Up).²

The population of this study was male smokers with age criteria of 18–65 years who were undergoing pulmonary TB treatment. The distribution of the subject treatment groups was determined using the randomized closed envelope technique. In this study, an intention-to-treat (ITT) analysis was carried out so that all subjects included would be analyzed. This study had a total sample of 43 subjects; consisted of 21 subjects in the treatment group and 22 subjects in the control group.

Through several journals, it is known that several characteristics influence the success of programs to stop smoking and maintain smoking cessation among TB patients. Campbell et al found that in the treatment group that was given smoking cessation education, the treatment group had higher education and an older age.⁸ According to Siddiqi et al, the success of quitting smoking in the treatment group who was given smoking cessation education had a higher income than the control group.⁹

Lee et al examined sociodemographic factors and clinical factors that influenced the success of maintaining smoking cessation, including age over 65 years, marital status, higher education (college level), BMI ≥23, and patients with chronic diseases.¹² A study by Metse et al obtained that success in quitting smoking is usually preceded by previous attempts to quit smoking and having the motivation to quit smoking. Subjects who have a lower nicotine addiction will find it easier to quit smoking.¹³

This study found that the subjects in the group who stopped smoking more (the treatment) had a mean age of 38.4 ± 14.1 , older than the mean age of the control group, which was 32.5 ± 12.2 , but this was

not statistically significant. In addition, in the treatment group, there was more overweight and obese nutritional status, following research by Lee et al, which stated that the factors that influence the success of quitting smoking are having a BMI $\geq 23.^{12}$

Marital status in the 4T approach group with more subjects who quit smoking had married status, while those in the group with fewer quitters had more divorced status. According to research bv Caponnetto et al, married subjects usually receive support from their partners to quit smoking.¹⁴ West et al also found that someone who is married and gets support from family members affects the success of quitting smoking. The education variable relates to abstinence based on the theory that education level can increase knowledge and logical thinking about the bad effects of smoking.15 Research by Marti showed higher abstinence rates in smokers with higher education. Following the results found in this study, in the 4T approach group, more people have higher education.¹⁶

The diagnosis of TB in both groups was dominated by bacteriological pulmonary TB, which was enforced by the Molecular Rapid Test (MRT) or Acid-Fast Bacteria (AFB) staining. In this study, the control group had more subjects diagnosed with bacteriological pulmonary TB (59.1%) than the treatment group (57.1%), although not statistically significant. Following the study by Altet-Gomes et al, namely, in pulmonary TB patients who smoke, most have cavitary lesions and more often have positive sputum examinations.¹⁷

Leung et al also obtained the same results, namely in patients with pulmonary TB who smoked more often experienced complaints of coughing, tightness, images of infiltrates in the PEFx of the lungs, cavities, miliary appearance, and positive sptum culture.¹⁸ Statistically, the two groups had no significant difference in diagnosis or smoking cessation rates. Complaints of coughing up blood were mostly found in the control group, 31.8%, while in the treatment group, there were fewer, namely 9.5%; this could be because, in the treatment group, there were more smokers with nicotine dependence and a heavy Brinkman Index. In addition, it could be concluded that the diagnosis of pulmonary TB with AFB (+) and complaints of coughing up blood did not influence a person to quit smoking. Bonacci et al observed that smoking pulmonary TB patients had coughed up more blood and had a fever.¹⁹

The comorbidities in this study were found to be higher in the 23.8% treatment group, namely four people with DM and one with HIV. In the control group, there were 18.2%, namely two people with HIV and two with DM. Diabetes mellitus and HIV are associated with the incidence of pulmonary TB.²⁰ Siddiqi et al, through their research, found that patients with chronic diseases, including DM and HIV, have smoking habits as much or even higher than the normal population, so smoking cessation is urgently needed so that the symptoms of the disease do not worsen.²¹

This study found that the age at first smoking in the two groups was not significantly different, namely in the treatment group, 15.3±2.8, and in the control group, 16±2.4. In both groups, the age of starting smoking starts at a young age. According to a study by Awaisu et al, it was shown that TB sufferers smoked in the treatment group at 16.88±4.31 and in the control group at 17.37±3.55.22 According to research by Abdelwahab et al. most of the patients who smoked were aged ≤18 years.²³ Caponnetto et al showed that smoking at an early age is riskier for increasing the amount of cigarette consumption, smoking duration, nicotine dependence, and the risk of smoking relapse. The smoking cessation advocacy approach can be more aggressive with young smokers.14

Someone who starts smoking at a younger age will tend to become addicted, so it is important to take a smoking cessation approach from a young age.¹⁴ The mean duration of smoking in this study, namely in the treatment group, was 22.4 ± 14.5 , while in the self-help leaflet group, it was 17.2 ± 11.9 . This study found no significant association between smoking duration and abstinence. Awaisu et al obtained results in TB patients who had smoked for a long time were not statistically significantly different (*P*=0.188) between the treatment group who were given smoking cessation interventions and those who did

In this study, the median number of daily cigarettes in the treatment group was 12 (4-32), the same as the control group, with a median value of 12 (2-32). Statistically, in this study, there was no significant difference. The study by Kumar et al also obtained the same results; namely, between the treatment and control groups, there was no significant difference in the number of daily cigarettes on the abstinence value in both groups (P = 0.982).²⁴ Lin et al also obtained the same result: statistically, the number of cigarettes consumed daily was not related to success in quitting smoking.25 This was in contrast to the study by Monso et al, which discovered that the number of cigarettes consumed daily could influence success in quitting smoking.²⁶ According to Aditama's study, the average number of cigarettes per smoker in Indonesia is ten cigarettes per day.²⁷

The smoking cessation method chosen by the research subjects in the treatment group was to stop immediately (90.5%) and gradually (9.5%). In the control group, 77.3% of patients chose to stop immediately, while 22.7% of patients chose to stop gradually. In the control group, more subjects chose to stop gradually, and the study's final results showed that in the control group, more subjects failed to quit smoking. The smoking cessation method determines the success of quitting smoking because it is related to the motivation to stop smoking. For most people, the best way to quit smoking is to stop immediately.^{28–30}

In this study, the treatment group was dominated by the moderate Brinkman index (47.6%), while the control group was dominated by the mild Brinkman index (63.6%). Meanwhile, the number of subjects with a heavy Brinkman index was the same in both groups, namely three subjects. This basic characteristic can describe the good outcome of applying the 4T approach in the treatment group. Even though the Brinkman Index was higher than the treatment group, the abstinence and CAR rates were better in the treatment group. The 4T approach could increase the success of abstinence and CAR, even though it was not statistically significant in this study.

The Fagerstrom score is a nicotine addiction score. The Fagerstrom score can predict smoking cessation success, withdrawal symptoms, and the likelihood of smoking relapse. In this study, each group was dominated by low Fagerstrom degrees, namely 50% in the control group and 38.1% in the treatment group, respectively. However, the degree of severe Fagerstrom was more common in the control group, which was 22.7%, compared to the treatment group, which was 14.3%. This affected the success of quitting smoking, so there were more failures to quit smoking and smoking relapses in the control group. In this study, four subjects were still smoking until the end of the study.³¹

The control group described two people having a heavy initial Fagerstrom score, one with a moderate initial Fagerstrom score, and one with a low initial Fagerstrom. In comparison, four subjects who relapsed smoked, with the description of two people with a low initial Fagerstrom score, one with a moderate initial Fagerstrom score and one with a heavy initial Fagerstrom score. In the treatment group, two subjects were still smoking until the end of the study with a heavy initial Fagerstrom score.³¹

In comparison, three subjects who relapsed smoked with information that one subject had a heavy Fagerstrom score, one subject had a low initial Fagerstrom score, and one other had a very high initial Fagerstrom low score. Hyland et al stated that mild or moderate nicotine addiction can make it easier for someone to quit smoking.³¹ The study by Awaisu et al also showed the same results. Namely, in the control group, more subjects had high nicotine dependence; the final results of the Awaisu study showed that more subjects failed to quit smoking in the control group.²²

The motivation to stop smoking in this study showed a significant difference in CAR II, which was better in the treatment group (P=0.043) with a median of 10 (5–10) compared to the control group 9 (4–10). Motivation to stop smoking can affect the desire and success of quitting smoking. In this study, the median value of smoking motivation was better in the treatment group from abstinence to 12 weeks after abstinence. In this study, the stages of behavior change associated with motivation to quit smoking were found in subjects whose smoking relapse at the beginning of the study was already in the action phase in both groups. In contrast, at the end of the study, one subject relapsed in the control group, which was in the contemplation phase. The rest were already in the action stage in both groups.

Subjects who were still smoking until the end of the study in both groups at the beginning of the study were in the pre-contemplation phase. In contrast, at the end of the study in the control group, there were three subjects in the pre-contemplation phase and one subject in the contemplation phase. The stage of behavior changes in the treatment group who were still smoking at the end of the study was one subject in the contemplation phase and one in the pre-contemplation phase. Kotz et al, through their research, found that the motivation scale can predict attempts to quit smoking.³²

Wiratmoko et al also obtained the same results as this study, namely the success in maintaining smoking cessation in the treatment group with a motivation scale above 7.³³ In this study, it was proven that at the end of the 12th week after abstinence, more patients continued to quit smoking in the treatment group than in the the control group, namely 52.1% compared to 45.5%.

Base exhaled CO values in both groups until the end of the study tended to decrease. The decrease in CO levels in the treatment group during abstinence was greater than that of the control group, 7.4 \pm 3.2 to 4.9 \pm 2.8. During abstinence, the value of exhaled CO in the treatment group was lower than that of the control group, namely 4.9 \pm 2.8 compared to the mean control group of 5.4 \pm 2.4. The CO levels of both groups decreased below ≤6 following the increase in abstinence rates in both groups. There was no significant difference in exhaled CO values between the two groups during abstinence, CAR I, II and III. Exhaled CO numbers during CAR I, II, and III in the control group had lower exhaled CO numbers than in the treatment, even though there was no significant difference statistically. This could be influenced by limitations in measuring exhaled CO, which can be reduced by half from normal within 5-6 hours, so in some subjects in the control group, the CO value had decreased even though they were still smoking.³⁴

There was no significant difference in the mean withdrawal scores in the two groups, but in CAR I, the median withdrawal scores were higher in the 4T approach group than in the control group because more subjects in the control group smoked and relapsed and more patients stopped smoking in the treatment group, so withdrawal rates increased. Withdrawal symptoms experienced by the study subjects with most common withdrawal symptom was an increase in appetite

PEF values during the study were also observed in both groups. The results in the basic PEF treatment group were worse than the control group, with a mean value of 281±90, while the control group was 301±117, but in CAR I, II, and III the PEF values of the treatment group were better than the control group. The PEF score at the end of the study in the treatment group was better (387±65) than the control group (349±114). The PEF trend in the treatment group was increasing, while in the control group, there was a decrease in the mean PEF at the end of the study compared to the previous month. Various literature stated that PEF values were strongly influenced by smoking history.^{35,36}

Research by Boezen et al obtained that morning and evening PEF values in subjects who smoke were worse than those who had quit smoking or were non-smokers. Boezen et al found that the mean PEF in smokers was 557 (101), whereas in former smokers, it was 580 (94), and in non-smokers, it was 620 (78); however, this study was conducted in the general population, not in populations with pulmonary TB.³⁶

The abstinence rate in this study showed that the treatment group and the control group were not much different, namely 80.9% and 81.8%, but in the control group, there were still more subjects who smoked, namely 18.2%, compared to the smoking smoking habits in pulmonary TB patients, observed that most TB patients who smoke will stop smoking when diagnosed with TB, but the smoking relapse rate will increase from the first month to 6 months after completion of treatment. In this study, it was found that 9.2% of patients were still smoking when diagnosed with pulmonary TB. Two patients dropped out of the treatment group because they decided to move their treatment to a primary health care center outside the city. Ng et al suggested that it is necessary to provide education and messages to TB patients about quitting smoking.¹

treatment group, 9.5%. Ng et al, in their research on

The CAR T figure in this study showed that 66.7% of the subjects in the treatment group who received the 4T approach still stopped smoking up to 4 weeks (1 month) after quitting smoking, more than the control group, which was 54.5%. In CAR I, more subjects smoked in the control group, namely 18.2%, compared to 9.5% in the treatment group. The smoking relapse rate in the two groups was the same: two people in each group. In the control group, four people dropped out because three people moved to primary health services outside the city, and one person died from coughing up massive blood.

Previous research conducted by Siddiqi obtained 70.2% of subjects who reported quitting smoking during the first month of control (abstinence point) after participating in the 5A program. In contrast, this study had the advantage of using a different measurement method: the continuous smoking cessation rate was recorded for one month after the patient quit smoking; 66.7% of subjects quit smoking.⁹

The CAR II number in this study still showed that more subjects stopped smoking up to 8 weeks after quitting smoking in the treatment group, than in the control group. Subjects who were still smoking in CAR II were still the same as in CAR I, but the number of patients who relapsed smoked more in the control group, namely 18.2%, compared to the treatment group of 14.3%. In the treatment group, two people dropped out, one of whom died due to pneumonia and sepsis, and the other due to moving treatment outside Jakarta.

The CAR III number, which was the end of the study, showed that subjects who were still not smoking up to 12 weeks after guitting smoking were still higher in the treatment group than in the control group. The smoking relapse rate was higher in the control group (18.2%), compared to the treatment group (14.3%). There were also more patients who were still smoking until the end of the study in the control group (18.2%), compared to the treatment group (9.5%). In the treatment group, one patient dropped out due to a change in treatment. Previous research by Lin et al found that 64.9% of subjects who continued to guit smoking for ≥three months in the sixth month were given a smoking cessation program with brief education. In this study, the rate of continuous smoking cessation for three months was 52.4%.25

Siddiqi et al, in their research on TB patients who smoked, pointed out the same thing, namely than the group given the 5A approach was better at maintaining smoking cessation up to 1 and 6 months after quitting smoking compared to the control group, who were only given self-help leaflets with each RR 8.2 (95% CI=3.7–18.2) and 7.4 (95% CI=3.4–16.4).⁹ In this study, no observations were made for up to 6 months due to time constraints. Campbell et al also studied that providing brief education to TB patients who smoked increased smoking cessation rates compared to a group that was not given any education at all.⁸

Kumar et al, through their research on TB and HIV patients who smoke, get the 5A approach given by doctors to make someone stop smoking, namely 41%, compared to the group that was only given smoking cessation brochures and brief counseling, namely as much as 35%. Still, there was no statistically significant difference between the two groups.²⁴ In this study, the rate of smoking cessation (abstinence) was higher, as much as 80.9% in the group that was given the 4T approach. Awaisu et al found that the group that was given behavioral therapy and Nicotine Replacement Therapy (NRT) was better at maintaining continuous smoking cessation than the group that was only undergoing TB treatment.²² Lin et al found that 66.7% of TB patients who participated in a smoking cessation program still stopped smoking for up to 6 months. Giving a smoking cessation program, one of which is the 4T approach, is proven to be able to increase smoking cessation rates and continous abstinence rates.²⁵

This research has never been done in Indonesia, so it can be used as basic data for further research. Previous research on smoking cessation programs conducted in Indonesia was only on the general population, not TB patients. The allocation of research subjects to the treatment and control groups was randomized to avoid selection bias. All research subjects in the treatment group received education and counseling from the same counselor, reducing treatment bias. The 4T approach was given for three months so that the treatment subjects received education and counseling according to smoking cessation program standards.

LIMITATION

Limitations of the study are the limited number of samples and the short observation time to see the picture of smoking relapse in pulmonary TB patients. In some literature, the smoking relapse rate seems to increase greatly from the sixth month after quitting smoking to several months after the completion of TB treatment. Most of the motivation scales in the two study groups were good from the start, namely in the action phase. So, in the control group, many wanted to quit smoking, so the intervention in the two groups was not statistically significant. Measurement of exhaled CO has a weakness in the fast half-life of 6 hours, so CO levels often begin to decrease during the examination if the patient last smoked in the afternoon or evening before the examination.

CONCLUSION

Giving the 4T approach to TB patients is better at maintaining smoking cessation rates than the control group. A factor influencing a person to stop smoking is the motivation to stop smoking. The mean value of motivation during CAR II was better in the group given the 4T approach, which was statistically significant. The most common withdrawal symptoms after quitting smoking were increased appetite (44.1%), cigarette cravings (6.9%), insomnia (2.3%), impatience (2.3%), and anxiety (2.3%). There was no statistically significant difference in the withdrawal scores between the two groups.

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CONFLICT OF INTEREST

None.

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