

Adherence to Direct Observed Treatment Short-Course Treatment in Tuberculosis: Application of the Health Belief Model

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ABSTRACT

Background: Tuberculosis (TB) is a disease that is a public health priority, because it was the leading infectious disease killer before COVID-19 which caused more than 1.4 million deaths in 2019. Non-compliance of TB patients to undergo regular treatment can be an obstacle in achieving a cure rate, and high treatment success. This study aimed to analyze the effect of the Health Belief Model application on Direct Observed Treatment Short-Course (DOTS) treatment adherence for Tuberculosis in Karanganyar Regency.

Subjects and Method: Cross-sectional study was conducted in Karanganyar, Central Java, Indonesia. The study population was Tuberculosis patients undergoing Direct Observed Short-Course Treatment. A total of 200 Tuberculosis Patients undergoing DOTS was selected using purposive sampling. The dependent variable was DOTS compliance. The independent variable was construct of health belief model. Data were collected using a questionnaire and analyzed using a multiple logistic regression.

Results: Perceived threat ($b = 0.20$; 95% CI = 0.06 to 0.35; $p = 0.007$), perceived benefit ($b = 0.31$; 95% CI = 0.14 – 0.49; $p = 0.001$), and self-efficacy ($b = 0.24$; 95% CI = 0.13 to 0.36; $p < 0.001$) significantly increased TB-DOTS compliance. Perceived barrier significantly decreased TB-DOTS compliance ($b = -0.21$; 95% CI = -0.31 to -0.11; $p < 0.001$).

Conclusion: Perceived threat, perceived benefit, and self-efficacy significantly increase TB-DOTS compliance. Perceived barrier significantly decreases TB-DOTS compliance.

Keywords: health belief model, tuberculosis, DOTS, TB patients.

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BACKGROUND

Tuberculosis (TB) is a disease that is a public health priority, because it was the

leading infectious disease killer before Covid-19 which caused more than 1.4 million deaths in 2019 (World Health

Organization, 2020a). Indonesia ranks second after India with 845,000 cases and 98,000 deaths, which is equivalent to 11 deaths/hour in 2020. Although there has been a decrease in new TB cases by 9%, it is not fast enough to achieve the 2020 target, namely a reduction in TB cases by 20% between 2015–2020 (Indonesian Ministry of Health, 2021).

Anti-TB treatment procedures carried out for 6 months, especially for pulmonary TB which is very sensitive to drugs, so it is low in achieving recurrence-free healing. Globally, the annual number of people reportedly accessing TB treatment has increased from around 6 million in 2015, to 7 million in 2018 and 7.1 million in 2019 (World Health Organization, 2020a). TB treatment can fail if drug guidance is inadequate, the drug dose is insufficient, medication is not taken regularly, the treatment period is less than appropriate, and drug resistance occurs, resulting in new problems such as multidrug resistant tuberculosis (MDR-TB) (Fitri, 2018). Long and intensive treatment needs to be supported by patient compliance, because non-compliant behavior can cause drug-resistant types of TB.

MDR-TB cases are caused by patients who drop out and fail treatment, so they are no longer suitable for some drugs and need special treatment under the supervision of health workers. One of the causes of failure occurs due to the patient's non-compliant behavior with their treatment. Compliance with taking medication is very important to avoid MDR-TB so direct supervision is needed by a drug swallowing supervisor (PMO) who can be played by health workers or family members who are close to the patient (Kurniasih & Sa'adah, 2017).

TB patients' non-compliance with regular treatment can be an obstacle in achieving high cure rates and treatment

success. Data from Basic Health Research shows that the success of tuberculosis treatment has decreased every year, namely 84.6% in 2018, to 82.9 in 2019, and 82.7 in 2020. If we refer to the targets set by the Ministry of Health for indicators In 2020, it is 90%, so nationally the success rate for tuberculosis treatment has not been achieved (Ministry of Health of the Republic of Indonesia, 2021).

The phenomenon of decreasing cure rates in disease control efforts certainly needs to receive great attention because it will affect the transmission of TB disease. The success of TB control efforts is measured by the recovery of sufferers. This healing can not only reduce the number of sufferers, but also prevent transmission. Therefore, to guarantee recovery, medication must be taken and the patient must be closely monitored by family and friends around him and if possible monitored by health workers to ensure patient compliance with taking medication (Dinkes, 2018). Research conducted by Fitri, (2018) found that the majority of patients with pulmonary tuberculosis were non-compliant with medication as many as 40 people (78.4%). Other research also states that the majority of TB patients (51.6%) are not compliant in taking medication (Herawati & Purwanti, 2018). In line with research conducted by Zainaro & Gunawan, (2020) that the majority of respondents with TB disease (55.1%) did not comply with taking TB medication.

The behavior of patients who are not compliant in carrying out treatment needs to be predicted based on various factors that drive patient behavior in carrying out treatment. This behavior can be seen using the Health Belief Model theory because the Health Belief Model can predict the possibility that an individual will take preventive action depending on the individual's

beliefs. The Health Belief Model is a cognitive model that can be influenced by information from the surrounding environment. The Health Belief Model explains that the possibility of an individual taking preventive action depends on that belief. The Health Belief Model is a form of explanation of socio-psychology. This model was created because of health problems that can be seen from the failure of society or individuals to accept efforts to prevent and cure disease organized by health providers (Tamim & Grant, 2017).

The Health Belief Model (HBM) has since 1950 been one of the most widely used conceptual frameworks in health behavior research. This theory is used to explain the change and maintenance of health-related behavior and as a form of orientation for health behavior interventions. In its development, HBM has been expanded to support interventions in health behavior change. HBM is used to predict why people will take action to prevent, to screen for, or to control disease conditions. HBM consists of several components, namely perceived vulnerability, perceived seriousness, perceived barriers, perceived self-efficacy, cues to action and perceived benefits. (Sakinah, 2017).

The World Health Organization recommends implementing a TB case management strategy known as Directly Observed Therapy, Short Course (DOTS) (World Health Organization, 2020b). DOTS as a strategy in TB treatment, in addition to promoting commitment to treatment, case detection, uninterrupted anti-TB drugs, and an impact measurement system, the DOT strategy mandates directly observed therapy. Families as the closest people using the DOTS method are trained to observe TB patients when they swallow anti-TB medication during the treatment process. DOT can be carried out at the health facility or

Community Health Center level. People with TB are required to visit the Community Health Center to undergo treatment under the supervision of health workers. Community health workers, peer groups, or family members can act as monitors for community-based DOTS.

TB treatment programs continue to be pursued with low cure rates, human resource constraints and difficult access to health facilities. Therefore, it is important to support TB patients by providing home-based care using volunteers or family members (Kane et al., 2018). This program allows administering medication to TB patients in their respective homes under daily supervision from the family. Family members as health volunteers will be trained in TB treatment supervision. At the start of TB treatment, patients are introduced to home-based direct treatment (HB-DOT) and Community Health Center-based direct observation treatment (FB-DOT) and given the option to continue with the preferred method (Fana & Sotana, 2021).

Caring for sick people carried out by families, especially women, is a tradition in rural communities. The World Health Organization (WHO) believes that family and community participation is a principle of a primary approach to health (WHO, 2016). The home care approach, already known as the home-based care model, has been successfully introduced for home-based care for HIV patients and TB cases, namely by supporting patients during treatment, educating patients, families and the community about TB, case finding and detection as well as recognizing side effects. and follow-up of loss to follow-up (Bragazzi et al., 2020).

Countries that have well-functioning TB programs can also benefit from a community-based approach, as this can help maintain standards in the face of growing

human resource shortages. This study aimed to analyze the effect of the application of the health belief model on compliance with direct observed short-course treatment for tuberculosis in Karanganyar district, Central Java.

SUBJECTS AND METHOD

1. Study Design

This study uses a systematic review and The cross-sectional research carried out in this study used a quantitative approach with the aim of determining the causal relationship or influence of the health belief model on Direct Observed Treatment Short-Course treatment compliance in Tuberculosis.

2. Population and Sample

The population in this study were tuberculosis patients undergoing direct observed short-course treatment in Karanganyar Regency. Sampling in the study was carried out using a purposive sampling method, so there were 200 Tuberculosis Patients undergoing direct observed treatment short-course treatment in Karanganyar Regency. The research sample criteria were as follows:

a. Inclusion Criteria

Inclusion criteria are the criteria for research subjects representing research samples that meet the requirements as samples, namely:

- 1) Tuberculosis patients undergoing direct observed treatment short-course treatment in karanganyar regency.
- 2) Tuberculosis patients undergoing direct observed treatment short-course treatment without complications.
- 3) Able to communicate.
- 4) Willing to be a research respondent.

b. Exclusion Criteria

Exclusion criteria are eliminating research subjects who meet the inclusion criteria for various reasons, namely:

- 1) Tuberculosis patients who have infections or other disorders.
- 2) Patients with chronic infections other than TB in the medical record.
- 3) Not being able to communicate well or experiencing mental disorders.

3. Study Variables

The dependent variable was direct observed treatment short-course treatment adherence for Tuberculosis. The independent variable were the healthy belief model which consists of perceived vulnerability, perceived seriousness, perceived benefit, perceived barrier and perceived self-efficacy.

4. Operational Definition of Variables

Perceived susceptibility is the extent to which an individual feels they have the potential or risk of contracting a disease.

Perceived severity is an individual's belief in the potential impact that will arise due to an illness in life.

Perceived benefit is the value and benefit that an individual feels after taking action in the form of prevention, reducing the risk of disease development or treatment.

Perceived barriers are obstacles or difficulties that will occur or be felt when making a decision or action.

Self-efficacy is an understanding that is important for understanding a health behavior or planning to change a behavior.

Direct Observed Short-Course Treatment for Tuberculosis is a strategy for controlling pulmonary TB which aims to stop the transmission of pulmonary TB disease thereby reducing the incidence of TB cases and death rates in the community.

5. Study Instruments

The method used to collect data for this research is a questionnaire. The questionnaire given contains the health belief model which consists of perceived vulnerability, perceived seriousness, perceived benefit, perceived barriers and perceived self-efficacy. and compliance with Direct Observed

Treatment Short-Course treatment for Tuberculosis. Filling out the questionnaire was carried out after listening to the researcher's explanation and signing the Informed Consent. Filling out the questionnaire is carried out by the PMO.

6. Data Analysis

Logistic regression analysis was used in this research to ensure the ability of the independent variables to predict the dependent variable, namely the application of the health belief model in predicting Direct Observed Treatment Short-Course treatment compliance for Tuberculosis in Karanganyar Regency. Logistic regression

has the ability to test the probability given by the independent variable in predicting changes in the dependent variable.

RESULTS

1. Univariate analysis

The results of univariate analysis were carried out to explain and describe perceptions regarding perceived vulnerability, perceived seriousness, perceived benefits, barriers, perceived self-efficacy and compliance with DOTS TB treatment in Tuberculosis sufferers based on the data that has been collected. The results of the univariate analysis are shown in Table 1.

Table 1. Univariate analysis of research (categorical data).

Variables	Categories	Frequency (n)	Percentage (%)
Vulnerability	Good	107	53.5
	Lacking	93	46.5
Severity	Good	136	68.0
	Lacking	64	32.0
Benefit	Good	167	83.5
	Lacking	33	16.5
Barrier	Good	151	45.5
	Lacking	49	24.5
Self-Efficacy	Good	118	59.0
	Lacking	82	41.0
Obedience	Good	112	56.0
	Lacking	88	44.0

Table 1 showed that the majority (53.5%) of research subjects have a level of perceived vulnerability which is included in the good category. For the perceived severity, the majority of research subjects are included in the good category (68.0%), the majority of research subjects (83.5%) have the level of perceived benefits is in the good category, while for perceived barriers it is known that the majority of subjects have good perceptions (75.5%). The level of self-efficacy of the research subjects showed

that the majority were in good condition (59.0%), so the level of compliance with DOTS treatment in Tuberculosis patients in Karanganya Regency was included in the high compliance category (56.0%).

2. Bivariate Analysis

Bivariate analysis was carried out to partially explain the influence of one independent variable and the dependent variable. This analysis was carried out using the statistical correlation test shown in Table 2.

Table 2. Results of bivariate correlation analysis between each HBM and DOTS TB treatment compliance.

Independent Variable	Correlation coefficient (r)	p
Perception of Threat	0.22	0.002
Perception of Benefits	0.24	< 0.001
Perception of Barriers	-0.31	< 0.001
Self-Efficacy	0.29	< 0.001

Table 2 showed that there is a positive bivariate relationship between successive HBM constructs, namely perceived threat ($r = 0.22$; $p = 0.002$), perceived benefits ($r = 0.24$; $p < 0.001$) and self-efficacy ($r = 0.29$; $p < 0.001$) with DOTS TB compliance. The results of the study also showed that there was a negative bivariate relationship between perceived barriers ($r = -0.31$; $p < 0.001$)

and DOTS TB compliance.

3. Multivariate Analysis

Multivariate analysis is carried out to explain the influence of one independent variable and the dependent variable together. This analysis was carried out using the logistic regression statistical test shown in Table 3.

Table 3. Results of multivariate analysis of the relationship between each HBM and DOTS TB treatment compliance.

HBM Construct	Coef. Regression (b)	95% CI		p
		Lower Limit	Upper Limit	
Threat perception	0.20	0.06	0.35	0.007
Perception of benefits	0.31	0.14	0.49	0.001
Perception of barriers	-0.21	-0.31	-0.11	< 0.001
Self-efficacy	0.24	0.13	0.36	< 0.001
N observation= 20				
Adjusted R ² = 22.94 %				
p < 0.001				

Table 3 shows that perceived threat increased TB-DOTS compliance ($b = 0.20$; 95% CI= 0.06 to 0.35; $p = 0.007$). Perceived benefits increased TB-DOTS compliance ($b = 0.31$; 95% CI= 0.14 to 0.49; $p = 0.001$). Self-efficacy increased TB-DOTS compliance ($b = 0.24$; 95% CI = 0.13 to 0.36; $p < 0.001$).

Table 3 shows that perceived barrier decreased TB-DOTS compliance ($b = -0.21$; 95% CI= - 0.31 to -0.11; $p < 0.001$).

Adjusted R²= 22.94% means that the linear regression model which results in several HPM constructs is able to explain variations in TB DOTS treatment adherence scores of 22.94%. The model shows that

together the HBM construct is statistically significantly related to DOTS TB compliance ($p < 0.001$).

DISCUSSION

1. The influence of perceived threat on DOTS TB treatment adherence

Threat perception is the extent to which an individual feels that he or she has the potential or risk of contracting a disease. The results of the study show that there is an influence of perceived threat on compliance with DOTS TB treatment in Tuberculosis, there is a positive relationship between perceived threat and compliance with DOTS TB treatment and this relationship is

statistically significant. Every 1 unit increase in threat perception will be followed by an increase in DOTS TB treatment compliance score of 0.20 which is higher ($b = 0.20$; 95% CI= 0.06 to 0.35; $p = 0.007$), meaning that the better the perception of vulnerability, the more TB sufferers will become Be careful in living your life, so you have a higher level of compliance compared to Tuberculosis sufferers whose level of perception of vulnerability is less.

Susceptibility can be a personal evaluation of the risk of a disease. The parameters of an individual's perception of a risk are largely based on the information or knowledge each individual has. There are still many individuals who lack information or have wrong information about a disease, such as how to prevent and treat it. If information about health behavior is obtained early, completely and correctly, then each individual can be more open to taking preventative or treatment measures (Langenhof and Komdeur, 2018). Tuberculosis sufferers who have the perception that their disease is a serious problem and will have a negative impact on their daily lives will try to find information. The information obtained can be in the form of knowledge about the disease itself or treatment measures. When sufferers are aware of their condition, they will take action to treat themselves. Research shows that there is a relationship between perceptions of seriousness and perceptions related to preventing cervical cancer, so it can be concluded from this research that someone who is aware of the dangers of the disease and that it can be prevented by vaccines will take preventative action using vaccines and vice versa (Nugrahani et al., 2017).

Perceived severity and vulnerability represent the individual's accumulated beliefs about health threats (personal health threat beliefs). This implies that

individuals are more likely to adopt a healthier lifestyle if their perceived risk of contracting a particular disease is also high and they believe that the disease can greatly affect their lives. However, if the individual believes that the danger of the disease is real, that is not enough to convince the individual to adopt preventive behavior. The likelihood of adopting a healthy lifestyle increases if the individual believes that preventive behavior is more beneficial (perceived benefits) and the constraints can be compromised (perceived barriers). The benefits received and perceived barriers together determine how individuals perceive the effectiveness of health behavior (Zein et al., 2017).

2. The influence of perceived benefits on DOTS treatment adherence

Perceived benefits are an individual's opinion about the value or benefits of a behavior. The results of the study show that there is an influence of perceived benefits on compliance with DOTS TB treatment in Tuberculosis, there is a positive relationship between perceived benefits and compliance with DOTS TB treatment and this relationship is statistically significant. Every 1 unit increase in perceived benefits will be followed by an increase in DOTS TB treatment adherence score of 0.31 which is higher ($b = 0.31$; 95% CI= 0.14 to 0.49; $p = 0.001$), meaning that the individual's opinion about the value or benefits of a behavior is better. This will further increase compliance in DOTS TB treatment.

The value and benefits that an individual feels after taking action in the form of prevention, reducing the risk of developing disease or treatment. Individuals feel the benefits that prevention and control of disease can reduce the possibility of developing disease (Rimer and Brewer, 2015). Perceived benefits are positive consequences of a behavior. Effective and successful

behavior or actions will get positive results (Riegelman and Garr, 2011).

Perceived barriers that are believed to cause individuals to carry out effective health behavior, as well as the perceived benefits of health behavior. When a person expresses confidence in their vulnerability and seriousness, recommended health interventions are usually not accepted unless proven successful and appropriate. Perceived usefulness is a person's opinion about the value or usefulness of a new behavior in reducing the risk of developing a disease. People tend to adopt healthier behavior when they believe the new behavior will reduce their chances of getting a disease. The perceived benefits of playing an important role in the implementation of secondary prevention behaviors, such as screening (Hayden, 2018). This is similar to research by Jose et al. (2020), where if people follow the established health rules, the majority of people will be able to avoid various diseases, thus having implications for a person's compliance in maintaining health (Jose et al., 2021). Joseph (2019) suggests that if the benefits of disease prevention measures are small, then the possibility of taking preventive measures is also small, conversely, if the perceived benefits are high, the person will stick to a health routine, so that the level of compliance with maintaining health is high (Joseph et al., 2019).

When tuberculosis sufferers realize how serious their condition is, they will seek treatment. If treatment is carried out, the sufferer feels that there are benefits, they will maintain this behavior until they feel the need to change their behavior to achieve optimal health. Based on the research results, it shows that there is a relationship between perceived benefits and tuberculosis prevention behavior. This explains that the more positive the sufferer's

perception of the benefits obtained, the more likely they will take action and be confident in carrying out the prevention of transmission (Nurhayati et al., 2015), this is as research conducted by Emawati (2021) states that the perception of benefits shows the results positive, where it is possible that the community has realized the benefits of compliance in maintaining health, not felt directly in the form of avoiding the risk of contracting disease (Emawati, 2021).

3. The influence of perceived barriers on DOTS TB treatment adherence

Changing behavior or taking action is not considered something that can be easily done. The results of the study show that there is an influence of perceived barriers on compliance with DOTS TB treatment in Tuberculosis, there is a negative relationship between perceived barriers and compliance with DOTS TB treatment and this relationship is statistically significant. Every 1 unit increase in perceived barriers will be followed by a lower DOTS TB treatment adherence score of -0.21 ($b = -0.21$; 95% CI = -0.31 to -0.11; $p < 0.001$), meaning the better the individual's perception of the perceived potential barriers will further increase compliance in DOTS TB treatment.

Individuals sometimes still think about the obstacles or difficulties that will occur or be felt when making a decision or action. Generally, the obstacles felt by individuals are considered to make a condition even more difficult (Rimer and Brewer, 2015). Perceived barriers can be in the form of costs, social barriers, environmental barriers or other barriers that can make it difficult for individuals to take a behavior or action (Didarloo et al., 2017). Perception of barriers is an individual's assessment of how big the obstacles are to adopting or carrying out the recommended action. Action may not be taken by someone who already has hypertension, even if the indi-

vidual believes in the benefits of taking action to manage the disease. This could be caused by perceived obstacles such as hypertension management actions which are felt to be troublesome, expensive, unpleasant, disturbing comfort so that individuals avoid or stay away from hypertension management actions (Easter, 2020). Perceptions about the obstacles that will be felt are a significant element in determining whether a change in behavior occurs or not. Regarding the new behavior to be adopted, a person must believe that the benefits of the new behavior outweigh the consequences of continuing the old behavior. This allows obstacles to be overcome from the new behavior to be adopted (Priyoto, 2014).

Perceived barriers are a potential negative aspect of health care which suggests that health care professionals should instruct patients on how to overcome barriers (Ma Chunhua, 2017). However, research conducted by Rayanti (2021) showed that the perception of barriers did not have a significant relationship, this was due to the existence of a reciprocal relationship which influenced respondents to feel that there were barriers, namely the respondent's actions which created their own barriers, seen from the lifestyle of respondents who frequently consume unhealthy food even though there is awareness of the dangers of the disease. Behavior change is not something that can happen easily for most people. This relates to the individual's own evaluation process of the obstacles they face in adopting new behavior. The greater the perceived obstacles, the lower the individual's willingness to make behavior changes.

Perceived barriers are the most important aspect in determining behavior change. A person needs to believe the benefits of the new behavior outweigh the consequences of the old behavior in order for the

new behavior to be adopted. This allows barriers to be overcome and new behaviors to be adopted (Hayden, 2018). When someone wants to change unhealthy behavior to healthy ones, of course they experience difficulties. One of the obstacles felt by tuberculosis sufferers is a lack of knowledge which has an impact on compliance with treatment, so that when sufferers lack information about tuberculosis treatment and are given information by health workers. The perceived obstacles can be resolved automatically and allow sufferers to undergo regular treatment.

4. The influence of self-efficacy on DOTS TB treatment compliance

Self-efficacy is an understanding of what is important for understanding a health behavior or planning to change a behavior. The results of the study show that there is perceived self-efficacy regarding DOTS TB treatment compliance in Tuberculosis, there is a positive relationship between self-efficacy and TB DOTS treatment compliance and this relationship is statistically significant. Every 1 unit increase in self-efficacy will be followed by an increase in DOTS TB treatment adherence score of 0.24 which is higher ($b = 0.24$; 95% CI = 0.13 to 0.36; $p < 0.001$), meaning that the individual's understanding of the importance of being able to understand a behavior is better. health or planning to change a behavior will further increase compliance in DOTS TB treatment.

The belief that an individual has in his or her ability to carry out a behavior. Self-efficacy is found in a person now, not in the past or future. Individual self-confidence has a very important role in changing behavior. Your self-confidence can be a motivation for yourself to make changes to health behavior. Individual self-confidence is important to ensure that each individual has the power to carry out health behavior

and produce a positive impact on health (Fertman and Allensworth, 2016). In research, Diana and Noviekayati (2021) said that the high self-efficacy possessed by each individual makes it easy for individuals to organize what actions they will take. This ability can influence cognitive aspects and individual motivation in adapting to environmental and social demands, even demands imposed by circumstances (Diana & Noviekayati, 2021). Self-efficacy shows that each individual has a high level of confidence and self-confidence. Self-efficacy is viewed differently by each individual, some people believe that maintaining health is the best way to stop tuberculosis. Individuals use various media to share information about tuberculosis, with the message that staying healthy can reduce the risk of contracting the disease. Self-efficacy can be encouraged by rules regarding behavior in life, and appeals from medical personnel to provide a sense of security to the community.

Self-efficacy is an individual's perceived ability to carry out the desired behavior (Williams & Rhodes, 2016). People generally don't try to do something new unless they think they can do it. If a person believes that a new behavior is useful (perceived benefits), but feels that they cannot do it (perceived barriers), it is unlikely that a person will try the new behavior. Self-efficacy can explain why people are motivated (or not) to carry out a health-related behavior, not just predict whether people are motivated (or not). Self-efficacy influences it directly and the influence can be seen, namely someone carrying out a new behavior (Williams & Rhodes, 2016).

Individuals who believe that they have the potential to contract disease will comply with health regulations. The study results show that self-efficacy and community compliance in implementing health care

have a significant relationship with community compliance. Low community compliance can be caused by an individual's belief or perception that the individual is unable to implement health behavior. However, maintaining good health can protect yourself, your family and those around you from the threat of tuberculosis. Increasing compliance related to self-efficacy can be increased with social support such as support from family such as empowering people to have healthy living behavior (Fadilah, 2020).

AUTHOR CONTRIBUTION

Pusporini as a researcher who chooses topics, searches for and collects research data. Didik Tamtomo and Hanung Prasetya analyzed data and reviewed research documents.

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CONFLICT OF INTEREST

There is no conflict of interest in this study.

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