

Prevalence and Associated Factors to Acceptance of Tuberculosis Preventive Treatment for Latent Tuberculosis at Health Clinics in Putrajaya, Malaysia

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Introduction: Latent tuberculosis infection (LTBI) is defined as the presence of Mycobacterium tuberculosis antigen without the evidence of tuberculosis infection. Approximately 5-10% of untreated LTBI would progress to clinically active tuberculosis during their lifetime or usually within 5 years. This study aimed to determine the facilitators, barriers, and associated factors to acceptance of Tuberculosis Preventive Treatment (TPT) among patients attending health clinics in Putrajaya.

Methods: A cross-sectional study utilizing a questionnaire that included sections on demographic data along with facilitators and barriers to TPT were distributed to newly diagnosed and active LTBI patients who were attending health clinics in Putrajaya between December 2021 to June 2022. Data analysis was done with SPSS v26.0.

Results: 63.8% of 177 patients who were involved in this study accepted TPT. The identified facilitators were, perceived ability to comply with the treatment, able to come for follow up and received comprehensive information about Latent Tuberculosis and its treatment. The most reported barriers to acceptance for TPT were concern about the side effects from treatment, long-waiting time and stigma. Older aged participants (median 37 years old, IQR=11), male gender (71%), other ethnic groups (80%), self-employed (100%), lower education level (100%) and good knowledge (68%) had higher acceptance for TPT. Female patients had 0.43 lower odds of accepting TPT than male patients (95% CI=0.21-0.86, p=0.02).

Conclusion: The prevalence of acceptance of TPT was 63.8%. The identified facilitators, barriers and determinants can be used in planning strategies to better educate patients on the benefits of TPT.

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Tuberculosis (TB) is an infectious disease primarily impacting the pulmonary system, caused by *Mycobacterium tuberculosis* bacteria. Transmission occurs through airborne droplets released when infected individuals cough, sneeze, or expectorate. Malaysia faces a substantial public health challenge due to TB. According to the Global Tuberculosis Report 2020, approximately 10.0 million individuals contracted TB, resulting in 1.4 million deaths in 2019¹ In 2020, Malaysia reported 23,644 TB cases, of which 91.7% were newly diagnosed cases and 58.0% were smear positive pulmonary TB cases.² The TB mortality rate in 2019 was 7.1 per 100,000, exceeding the WHO's End TB Strategy target. Malaysia aims to decrease TB-related deaths to less than 85 per year by 2035.¹ One of the key strategies to achieve this goal is the active detection of Latent Tuberculosis Infection (LTBI) and prompt initiation of treatment.

Latent tuberculosis infection (LTBI) refers to a condition where the immune system maintains a persistent response to *Mycobacterium tuberculosis* antigens without any clinically evident active TB manifestation.³ Globally, approximately a quarter of the population, around 1.7 billion people, have LTBI.⁴ Diagnosis of LTBI is based on positive Tuberculin Test or Interferon Gamma Release Assay (IGRA) results, along with the absence of symptoms suggestive of active TB and normal or unchanged chest X-ray findings. [Table 1](#) presents the different cut-off values applicable to various patient groups.

In Asia, the prevalence of Latent Tuberculosis Infection (LTBI) is highest in Southeast Asia, approximately 31%, followed by 28% in the Western Pacific region. In contrast, other regions worldwide have LTBI prevalence rates ranging from 11% to 22%.⁴ Individuals with LTBI face a lifetime risk of developing active TB estimated to be between 5% to 10%. This risk is particularly elevated in children under five years of age and individuals with compromised immune systems.

Treating LTBI can effectively prevent the progression of 60% to 90% of cases into active TB.⁵ The management of latent TB infection is of paramount importance in the context of the country's high burden of TB and overall disease burden. For adults with LTBI, there are four treatment options available, as outlined in [Table 2](#) below.

The primary objective of this study is to investigate the facilitators, barriers, prevalence, and related factors influencing the acceptance of Tuberculosis Preventive Treatment (TPT) among patients visiting health clinics in Putrajaya, Malaysia. The lack of previous research on the determinants of TPT acceptance in Malaysia, along with the prevalence of Latent Tuberculosis Infection (LTBI) in the country, serves as the driving force behind conducting this study. By identifying the factors that promote or hinder TPT acceptance, the research aims to provide valuable insights that can contribute to enhancing TB prevention and control strategies in the region.

Table 1 TST Cut-off values for different groups

Positive (TST) reactions	At-risk groups
>=5mm	• PLHIV • Organ transplant recipients • Persons who are immunosuppressed for other reasons (e.g. those taking the equivalent of >15 mg/day prednisolone for 2:1 month or taking anti-TNF treatment)
	All other high risk individuals including healthcare workers and children (except newborns and infants <3 months)
	Individuals from countries with low incidence of TB

Table 2 Treatment option for latent tuberculosis infection

Drug	Duration	Interval	Dosage
Isoniazid	Six months/ nine months	Daily	5 mg/kg, max 300 mg
Isoniazid+ rifampicin	Three months	Daily	INH: 5 mg/kg, max 300 mg RIF: 10 mg/kg, max 600 mg
Rifapentine+ isoniazid	Three months	Weekly	INH: 15 mg/kg, max 900 mg RPT: <50 kg; 750 mg >50 kg: 900 mg
Rifampicin	Four months	Daily	10 mg/kg, max 600 mg

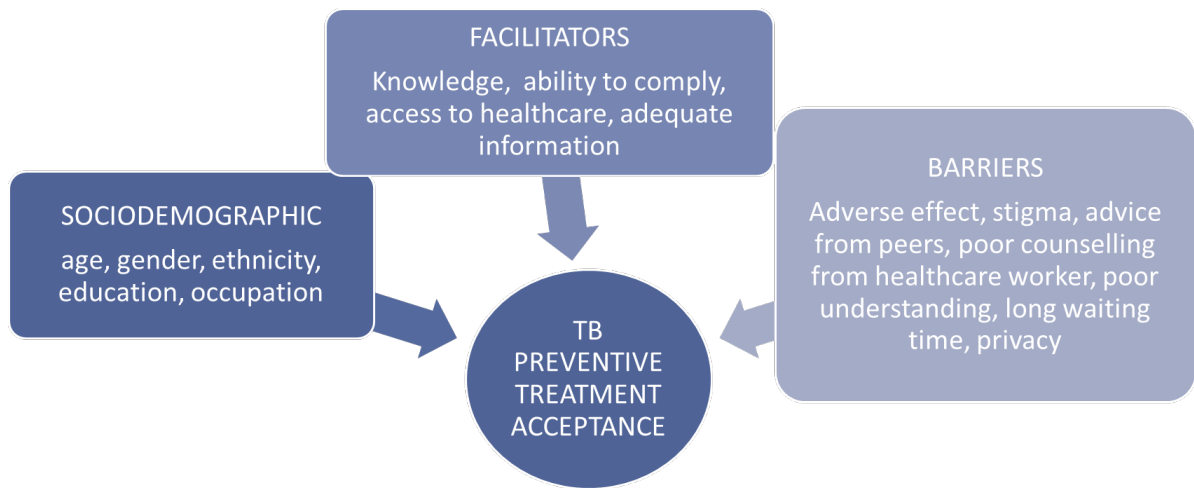


Figure 1 *The conceptual framework of this study*

Figure 1 shows the conceptual framework of this study.

METHODS

Study design and population

From December 2021 to June 2022, a cross-sectional study was done at two health clinics in Putrajaya Presint 9 and 18, Wilayah Persekutuan Putrajaya. These clinics cater to patients with various infectious diseases, including LTBI, active Tuberculosis (TB), and other outpatient conditions. The study enrolled patients diagnosed with LTBI who had scheduled follow-up appointments with healthcare providers. These participants were screened for active TB and adverse effects related to TPT at three different time points: 3 months, 9 months, and 12 months after their initial visit. These follow-up intervals are following the recommendation of the Malaysian Clinical Practice Guideline of Tuberculosis.¹

The study's inclusion criteria encompassed patients aged 18 years and above, who had been diagnosed with LTBI (Criteria used to diagnose latent tuberculosis infection among adults in this study are tuberculin test of more than 10mm or a positive Interferon-Gamma Release Assay [IGRA] test, a normal chest X ray and must be asymptomatic of tuberculosis symptoms) and received routine follow-up care at the designated health clinics. Inclusion into this study also required participants to provide informed consent, test negative for active TB, and demonstrate proficiency in either the English or

Malay language. On the other hand, the exclusion criteria comprised pregnant individuals, those below 18 years of age, those with active TB, patients with current acute critical conditions, and individuals with severe psychiatric illnesses affecting their ability to adhere to medication or respond to the questionnaires.

Educational level was categorized into four groups: no formal education, primary education, secondary education, and tertiary education. "No formal education" pertained to individuals who had not received any schooling through formal systems. "Primary education" denoted those who had completed formal schooling between the ages of 7 and 12 years. "Secondary education" encompassed those who had completed formal schooling between the ages of 13 and 17 years. Finally, "tertiary education" referred to individuals who had pursued any formal education beyond high school within formal institutions, such as undergraduate or postgraduate degrees.

Occupation was classified into five groups: unemployed, retired, self-employed, government servant, and private sector workforce. "Unemployed" individuals were those available for work but had not secured employment. "Retired" participants are those who had ended or completed their professional activities. "Self-employed" refers to individuals working on their own. "Government servant" included those working with the Malaysian government, while "private sector workforce" indicated individuals employed by private companies.

Sample size determination

The Raosoft method was used to determine the required sample size for this study. With a 95% confidence level and a 5% margin of error, considering a population size of 91,900 (based on local data from the Dept. of Statistics Malaysia in the 4th quarter of 2018), the estimated sample size was 383. However, to account for a 10% non-response rate, we increased the sample size to 421.

To optimize the number of participants with LTBI within the constraints of the study site, we adopted convenience sampling. Out of the 181 LTBI individuals approached, 4 declined to participate, resulting in 177 LTBI respondents who completed the study. This yielded a high response rate of 97.8%.

Study procedure

The data collection for this research was conducted using self-administered questionnaires. The study population was invited to participate in the research during their initial or subsequent visits to the health clinics. Once they expressed their willingness to take part, the investigators provided them with detailed information about the study, including its purpose and methodology. This information was conveyed both in written form and verbally.

The participants were assured of the confidentiality of their responses, and they were informed about the voluntary nature of their involvement. They were explicitly informed of their right to withdraw from the study at any point without any impact on their follow-up care in the clinic. To formalize their participation, each participant received and signed a patient information sheet and a consent form.

The questionnaire was made available to the participants in both online and hardcopy paper formats, allowing them to choose their preferred mode of answering the questionnaire.

Study instrument

The research team developed a questionnaire by drawing upon existing published literature and subjected it to face validation by 16 individuals from diverse backgrounds.⁶⁻⁷ Additionally, feedback was obtained from 4 expert panels, consisting of 2 family

medicine specialists, a respiratory physician, and a public health specialist.

Following the validation process, a pilot study was carried out involving 20 patients. The sections of the questionnaire that assessed facilitators and barriers demonstrated good internal reliability, as evidenced by Cronbach's α coefficients of 0.796 and 0.906, respectively. These coefficients indicate the consistency and homogeneity of responses within each section of the questionnaire.

Data analysis

The data analysis was conducted using SPSS version 26.0 for Windows. Categorical data were presented as frequencies and percentages, providing a clear representation of the distribution of each category within the dataset. Numerical data were reported as means and standard deviations, offering a summary of the central tendency and dispersion of the quantitative variables.

To investigate the factors associated with the acceptance of TPT, a simple logistic regression analysis was performed. This analysis was done to assess the individual relationships between each variable and the likelihood of TPT acceptance.

Subsequently, variables with a p-value less than 0.25 in the simple logistic regression analysis were selected as candidates for the multiple logistic regression model. This step aimed to identify the determinants of TPT acceptance while considering the potential influence of multiple confounding factors simultaneously.

The final results of the multiple logistic regression model were presented as adjusted odds ratios, indicating the strength of association between each independent variable and the likelihood of TPT acceptance after adjusting for other factors in the model. Statistical significance was determined using a significance level of $p < 0.05$.

Ethical approval

The study received ethical approval from the Medical Research and Ethics Committee of the National Institute of Health Malaysia (NMRR-22-00209-4EV (IIR)).

RESULTS

Socio-demographics of the participants

The researchers approached a total of 181 potential participants for the study. Among them, 4 individuals declined to participate, resulting in a response rate of 97.8%. The remaining participants were enrolled in the study after ensuring that they met all the inclusion criteria and did not have any of the exclusion criteria (Figure 2).

The participants' median age was 36 years old, with a standard deviation of ± 12 years. The majority of the participants were male, of Malay ethnic group, employed in the government sector, and had attained a tertiary level of education (Table 3).

The overall acceptance rate of TPT among the participants was 63.8% (N=177).

Among the participants, the most reported facilitators for TPT uptake included their perceived ability to adhere to the treatment, ensuring attendance at follow-up visits, and receiving sufficient and comprehensive information regarding latent tuberculosis and its treatment (Table 4).

The median knowledge score related to TPT acceptance was 16, with an interquartile range of 4.5. A score of 16 and above was considered indicative of good knowledge, while scores below 16 suggested poor knowledge regarding the importance of TPT acceptance.

The primary barrier to the acceptance of TPT among the participants was the fear of treatment-related adverse effects. The second most prevalent obstacle was the lengthy waiting time experienced by the participants. The third most reported barrier was the social stigma associated with TPT (Table 5). These findings highlight the challenges faced by individuals in accepting TPT, which may impact their willingness to undergo preventive treatment.

Latent TB infection and TB preventive therapy knowledge association with acceptance

In the study, it was observed that majority of the participants (68.1%) with good knowledge about latent tuberculosis and its prevention agreed to undergo preventive therapy for latent TB. However, upon

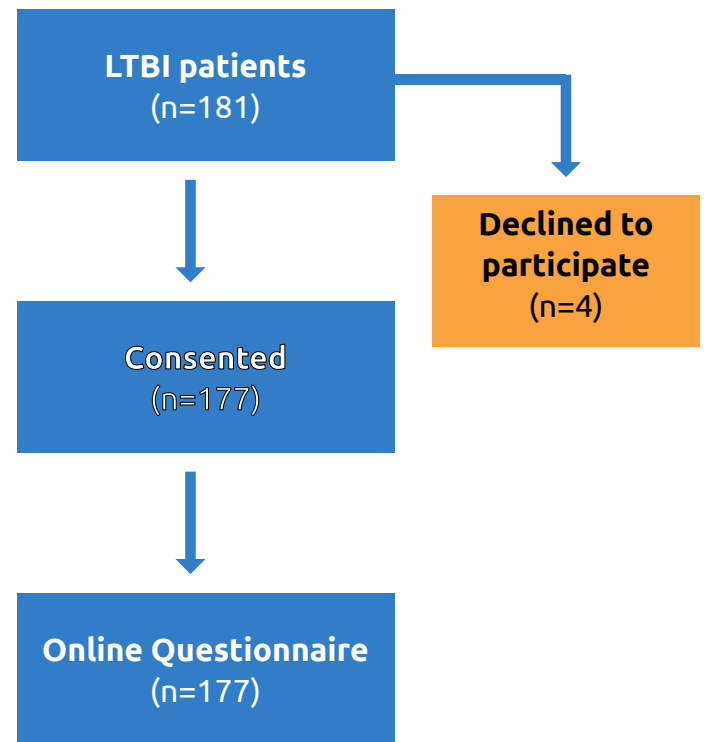


Figure 1 Study enrolment flow

Table 3 Sociodemographic characteristics of the participants (N=177)

Variable	Frequency, N (%)
Age (Years) - Median +/- IQR	36 +/- 12
Gender	
Male	93 (52.3)
Female	84 (47.7)
Ethnicity	
Malay	164 (92.7)
Chinese	5 (2.8)
Indian	3 (1.7)
Others	5 (2.8)
Occupation	
Unemployed	19 (10.7)
Pensioner	2 (1.1)
Self-employed	1 (0.6)
Government sector	132 (74.6)
Private sector	23 (13.0)
Level of education	
None	0 (0.0)
Primary	1 (0.6)
Secondary	39 (22.0)
Tertiary	137 (77.4)

Table 4 Responses towards different facilitating domains for latent TB preventive therapy acceptance (N=177)

Facilitator	Strongly disagree n (%)	Disagree n (%)	Agree n (%)	Strongly agree n (%)
Knowledge				
Q1 Active Tuberculosis is an airborne disease	2 (1.1)	14 (7.9)	84 (47.5)	77 (43.5)
Q2 Active Tuberculosis is fatal if left untreated	1 (0.6)	2 (1.1)	84 (47.5)	90 (50.8)
Q3 5–10% of Latent Tuberculosis patients will progress to Active Tuberculosis in their lifetime if not treated	2 (1.1)	17 (9.6)	97 (54.8)	61 (34.5)
Q4 Latent Tuberculosis is not infectious	8 (4.5)	22 (12.4)	83 (46.9)	64 (36.2)
Q5 People with HIV, organ transplant recipients and intravenous drug user are at high risk of acquiring Latent Tuberculosis	6 (3.4)	26 (14.7)	89 (50.3)	56 (31.6)
Q6 I am NOT at risk of getting Drug Resistant TB if I stop Tuberculosis Preventive Therapy before the due period	16 (9.0)	98 (55.4)	56 (31.6)	7 (4.0)
Q7 will NEVER develop any symptoms after infection with Latent Tuberculosis	9 (5.1)	76 (42.9)	77 (43.5)	15 (8.5)
Q8 I am at LOW risk of getting Active Tuberculosis	14 (7.9)	73 (41.2)	78 (44.1)	12 (6.8)
Able to comply to treatment				
I have no problem taking Isoniazid treatment for 6 months	6 (3.4)	39 (22.0)	95 (53.7)	37 (20.9)
Able to come for follow up				
I have no problem coming to regular appointments at the clinic	4 (2.3)	34 (19.2)	99 (55.9)	40 (22.6)
Adequate information				
I have received in-depth information of LTBI and the treatment	5 (2.8)	53 (29.9)	94 (53.1)	25 (14.1)

Table 5 Response towards different barrier domains for latent TB preventive therapy acceptance (N=177)

Barrier	Strongly disagree n (%)	Disagree n (%)	Agree n (%)	Strongly agree n (%)
Therapy related factors				
I am afraid of getting side effects from the treatment	6 (3.4)	59 (33.3)	100 (56.5)	12 (6.8)
Social related factors				
I fear the stigma from society if I take the treatment	13 (7.3)	41 (23.2)	80 (45.2)	43 (24.3)
I was told by others NOT to take the treatment	96 (54.2)	63 (35.6)	35 (19.8)	5 (2.8)
Clinic related matters				
My concerns were NOT taken into account by the health workers during the consultation	25 (14.1)	108 (61.0)	39 (22.0)	5 (2.8)
I had to wait for a long time to see the doctor	11 (6.2)	67 (37.9)	85 (48.0)	14 (7.9)
There is NO privacy during the consultation	29 (16.4)	88 (49.7)	55 (31.1)	5 (2.8)

statistical analysis using logistic regression, this relationship was found to be not statistically significant (adjusted OR:1.9; 95%CI:0.95-3.82) (Table 6).

Sociodemographic factors association with acceptance

The study found that a higher proportion of male participants (71%) agreed to take TPT compared to female participants (56%) (Table 6).

The uptake of TPT was higher among participants with certain sociodemographic factors, including older age, male sex, ethnicity other than Malay, Chinese or Indian, self-employment, and a lower level of formal education (Table 6).

However, upon conducting multiple logistic regression analysis to examine the factors associated with the acceptance of TPT, it was

Table 1 Response towards different barrier domains for latent TB preventive therapy acceptance (N=177)

Variable	LTBI Agree to take n (%)	LTBI Disagree to take n (%)	Crude OR (95% CI)	P value	Adjusted OR (95% CI)	P value
Social demography						
Age (Median, IQR)	37 (IQR 11)	35 (IQR 10)	1.005 (0.974 – 1.039)	0.747	Exclude	
Gender						
Male	66 (71.0)	27 (29.0)	Ref		Ref	
Female	47 (56.0)	37 (44.0)	0.52 (0.279 – 0.967)	0.04	0.43 (0.21 – 0.86)	0.02
Ethnicity						
Malay	105 (64.1)	59 (35.9)	0.445 (0.49 – 4.074)	0.473	0.73 (0.07 – 7.80)	0.79
Chinese	2 (40.0)	3 (60.0)	0.167 (0.01 – 2.821)	0.214	0.09 (0.004 – 1.87)	0.12
Indian	2 (66.7)	1 (33.3)	0.5 (0.19 – 12.9)	0.676	0.58 (0.02 – 17.08)	0.75
Others	4 (80.0)	1 (20.0)	Ref		Ref	
Occupation						
Unemployed	14 (73.7)	5 (26.3)	Ref		Ref	
Pensioner	1 (50.0)	1 (50.0)	0.36 (0.19 – 6.85)	0.50	0.4 (0.02 – 8.16)	0.55
Self employed	1 (100.0)	0 (0.0)	5.8 × 10 ⁸ (0.00 – 0.00)	1.00	6.5 × 10 ⁸ (0.00 – 0.00)	1.00
Government	78 (59.1)	54 (40.9)	0.52 (0.18 – 1.52)	0.23	0.54 (0.18 – 1.68)	0.29
Private	19 (82.6)	4 (17.4)	1.70 (0.38 – 7.49)	0.49	2.04 (0.43 – 9.71)	0.37
Level of education						
No formal / Primary	1 (100.0)	0 (0.0)	Ref		Exclude	
Secondary	29 (74.4)	10 (25.6)	0.0 (0.00 – 0.00)	1.00		
Tertiary	83 (60.6)	54 (39.4)	0.0 (0.00 – 0.00)	1.00		
Knowledge						
Good	64 (68.1)	30 (31.9)	1.48 (0.80 – 2.74)	0.21	1.9 (0.95 – 3.82)	0.07
Poor	49 (59.1)	34 (40.9)	Ref		Ref	

determined that gender was the only significant factor. Specifically, female patients had 0.43 lower odds of accepting TPT for latent TB compared to male participants (95% CI: 0.21-0.86, P: 0.02) (Table 6). Other sociodemographic factors examined did not show statistically significant associations with TPT acceptance in this study.

DISCUSSION

This study found that 63.8% of the 177 surveyed patients agreed to undergo TPT. However, other studies have reported different acceptance rates for TPT, indicating that acceptance rates may vary due to different socio-demographic factors and clinic capabilities across the study populations.⁸⁻⁹

The most common barriers to TPT acceptance identified in this study were fear of medication side effects, long waiting time, and stigma, which align with the findings of a systematic search by Liu et al⁸. Similarly, a Swedish study also reported that medication adverse side effects were a significant barrier to treatment acceptance and completion.¹⁰

Among the socio-demographic factors, older patients, males, individuals from other ethnic groups, self-employed individuals, and those with lower education levels showed a higher acceptance rates of TPT, akin similar to findings of a study by Musaazi which also showed that older aged individuals tend to be more receptive to treatment with TPT.¹¹ Although good knowledge about latent TB did not significantly influence the decision to undergo preventive therapy in this study, it is important to note that health literacy may influence how knowledge affects treatment attitudes across different study populations. A study by Colson et al showed good knowledge as one of the predictors to treatment acceptance.⁹ However, based on our study, good knowledge does not significantly improve the acceptance of treatment. This difference may be due to constraints of our healthcare providers in providing education to the patients with TPT due to human resource and time constraint.

The study's finding that female participants had lower odds of accepting TPT is consistent with the results of a study by Colson et al, which showed that men were more likely to accept TPT than women.⁹ The reasons behind this difference are not

clear, but other studies have suggested that men may have greater belief in tuberculosis treatment, while women may experience more tuberculosis-related stigma compared to men.¹²⁻¹³ Further research may be needed to explore these gender-related differences and consider potential adjustments in clinical approaches for women with latent TB infection who require preventive treatment.

By identifying facilitators and barriers to TPT acceptance, a more robust and targeted public health interventions such as increased mass media campaign to promote the benefits of TPT usage and risk of not using it, and policy initiatives aimed at improving LTBI management in Malaysia can be implemented including the use of reminder systems for those who initially reject the usage of TPT.

It is hoped by completion of this and other similar studies, the adherence of healthcare providers in managing LTBI and prescribing treatment for it will be improved, in line with the recommendation of the Malaysian Clinical Practice Guideline of Tuberculosis.¹

Strengths and limitations of the study

Strengths

This study has several advantages. The prevalence of TPT acceptance and other health characteristics can help to assess disease burden in a specific population and this information can assist healthcare planners and policymakers in allocating resources effectively and devising targeted interventions to combat TB in the region.

As one of the few quantitative studies on LTBI and TPT acceptance, this research enriches the existing body of knowledge in this area. Future researchers can build upon these findings and conduct further investigations to deepen their understanding of latent TB infection and optimize treatment strategies for the affected patients.

Conducting the study in urban settings offers unique perspectives on TPT acceptance among urban populations with latent TB infection. Since urban areas may present distinct challenges and opportunities related to healthcare access and attitudes toward treatment, the findings can help tailor interventions and policies to better serve this specific demographic profile.

Limitations

This study has certain limitations. Cross-sectional studies possess limited capability in establishing causality, thereby precluding determination of causal relationships between independent and dependent variables.

Another limitation lies in selection bias, wherein certain individuals from the latent tuberculosis (TB) population may be more likely to be included in the study sample due to the restricted number of study sites. The study exclusively comprises urban residents, potentially limiting its representation for the entire LTBI population.

Additionally, the relatively small sample size may impede the detection of significant differences in the outcomes. Consequently, the results and conclusions may be subject to bias and lack generalizability to broader populations.

In addition, the sampling method used in this study was convenience sampling. This sampling method was used because of time constraint and limited names in tuberculosis registry. The researchers will try to recruit more centers to ensure the use of a more robust sampling method to ensure representativeness of the population in future studies.

Recommendation for clinical practice

To enhance the management and outcome of LTBI within the population, there is a need to provide patients with increased encouragement and education to accept latent TB treatment. Raising awareness of LTBI among the population can be

effectively achieved through regular health talks, targeted advertisements, and educational campaigns on social media platforms.¹⁴ By engaging in these awareness-raising efforts, healthcare professionals can foster greater acceptance of latent TB treatment through greater knowledge sharing, leading to improved health outcomes, policy support and a reduction in the burden of LTBI.¹⁵

Recommendation for research

The study was limited to only two health clinics in Putrajaya district. To ensure more robust and accurate data, future research should extend its scope to encompass a broader range of urban and rural regions across Malaysia. This broader representation would enhance the generalizability and reliability of the study's findings.

CONCLUSIONS

The acceptance rate of TPT for LTBI was observed to be relatively low, at 63.8%. This suggests that the rate of initiating treatment might be even lower. Acceptance of TPT was found to be influenced by various factors, including the socio-demographic characteristics of the patients, particularly being male. The identification of facilitators, barriers, and associated factors of acceptance of TPT provides valuable insights that can be utilized to enhance patient education regarding the advantages of TPT. By addressing these factors, healthcare providers can better promote the acceptance of TPT among individuals with LTBI.

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