Effectiveness of psychosocial counseling on Treatment Adherence among patients with a new tuberculosis diagnosis in primary care: A study protocol of a quasi-experimental trial

Abstract

Introduction: Newly diagnosed TB patients frequently experience psychological distress, stigma, and concerns regarding treatment duration, side effects, and social consequences, which may negatively affect adherence. Psychosocial counseling has been proposed as a patient-centered strategy to address these challenges; however, evidence regarding its effectiveness among newly diagnosed TB patients in primary care settings remains limited. This study aims to evaluate the effectiveness of a psychosocial counseling intervention in improving treatment adherence and psychosocial outcomes among newly diagnosed TB patients receiving care in primary health care centers. **Methods and Analysis:** This study will employ a two-arm quasi-experimental design conducted in 10 primary health care centers (PHCs) in Semarang City, Indonesia. Five PHCs will be allocated to the intervention group and five PHCs to the control group to minimize contamination. A total of 108 newly diagnosed pulmonary TB patients will be recruited. Participants in the intervention group will receive a structured psychosocial counseling program in addition to standard TB care, while participants in the control group will receive standard TB care alone. Data will be collected at baseline (T0), immediately after the intervention (T1), and two months after treatment initiation (T2). The primary outcome is treatment adherence during the intensive phase of treatment. Secondary outcomes include psychological distress, TB-related stigma, TB knowledge, and treatment self-efficacy. Data will be analyzed using descriptive statistics, mixed-design analysis of variance, chi-square tests, and multivariable logistic regression. **Ethics and Dissemination** Ethical approval has been obtained from the Ethics Committee of the Faculty of Public Health, Diponegoro University (304/EA/KEPK-FKM/2026). Written informed consent will be obtained from all participants prior to enrollment. Study findings will be disseminated through peer-reviewed scientific journals. **Trial Registration Number: xxxxxx**

Keywords: tuberculosis, psychosocial counseling, treatment adherence, stigma, psychological distress, primary health care, quasi-experimental study,

Introduction

Tuberculosis (TB) continues as a major global threat to public health. In 2024, TB is estimated to have infected more than 10 million people in 2024, and 1.23 million died. Indonesia accounts for 10% of the cases, becoming the second-highest country with a TB burden after India (25%)[1]. Despite ongoing efforts to strengthen TB control, treatment adherence remains a major challenge in Indonesia. Poor adherence to anti-tuberculosis treatment contributes to treatment failure, disease recurrence, and the emergence of drug-resistant tuberculosis. Indonesia remains among

the countries with the highest burden of multidrug-resistant tuberculosis (MDR-TB), with 7.3% accounted for global cases in 2024 [1]. Although 73% of patients initiated treatment, only 55% completed the treatment course, indicating substantial gaps in treatment retention and continuity of care [2].

The challenges of TB treatment extend beyond clinical and pharmacological factors. Patients newly diagnosed with TB frequently experience psychological distress, including fear, anxiety, stigma, social isolation, and concerns about treatment duration and side effects [3–5]. Studies found that psychological distress affects nearly half of TB patients, with a pooled prevalence of 47.5% reported [6]. Anxiety is also common, affecting approximately 32.5% of patients, while depression has been reported in about 45.2% of individuals undergoing TB treatment [7,8]. Furthermore, TB-related stigma remains a significant psychosocial burden, contributing to social withdrawal, delayed health-seeking behavior, and poor treatment adherence.

The standard treatment regimen that requires at least six months of continuous medication demands substantial behavioral commitment and social support. These psychosocial burdens may negatively affect patients' motivation, self-efficacy, and treatment adherence, which compromises treatment outcomes. Previous studies have demonstrated that psychosocial factors substantially influence TB treatment outcomes. Depression has been associated with an increased risk of negative treatment outcomes, including loss to follow-up and mortality. A systematic review reported that patients with depressive symptoms had 8.7 times fold higher odds of loss to follow-up during treatment [9]. In addition, perceived stigma and inadequate social support have been consistently identified as barriers to treatment adherence and retention in care [10,11]. Therefore, addressing psychosocial factors is an essential component of comprehensive TB care.

Psychosocial counseling has been recognized as a promising strategy to support individuals coping with chronic illnesses by enhancing emotional well-being, strengthening coping mechanisms, and promoting health-related behaviors [12,13]. In the context of tuberculosis, counseling interventions may help patients understand their disease, manage treatment-related concerns, reduce stigma, and build confidence to complete treatment [14]. Despite growing recognition of the importance of patient-centered care, evidence regarding the effectiveness of psychosocial counseling for newly diagnosed TB patients in primary care settings remains limited, particularly in low- and middle-income countries such as Indonesia. Evaluating such interventions is therefore important for informing evidence-based strategies to improve treatment adherence and patient outcomes. This study aims to evaluate the effectiveness of a psychosocial counseling intervention among newly diagnosed tuberculosis patients receiving treatment in primary care compared with standard care. The intervention is guided by the Health Belief Model (HBM) and Social Cognitive Theory (SCT), which suggest that treatment adherence is influenced by patients' perceptions of

disease severity and susceptibility, perceived benefits and barriers to treatment, self-efficacy, and social support. These theoretical constructs are incorporated into the counseling sessions to enhance patients' understanding of tuberculosis, strengthen coping strategies, reduce stigma-related concerns, and improve confidence in completing treatment.

Methods

Study design and setting

This study will employ a two-arm quasi-experimental design to evaluate the effectiveness of a psychosocial counseling intervention among newly diagnosed TB patients receiving treatment in primary care settings [15]. The study will be conducted over 2 months in 10 primary health care centers (PHCs) in Semarang City, Central Java, Indonesia. The participating PHCs will be selected based on having the highest TB case notifications in the city.

To minimize contamination between participants, five PHCs will be randomly assigned to the intervention group and five PHCs to the control group. Cluster allocation at the PHC level is intended to reduce the likelihood of interaction between participants receiving different treatments within the same facility. Participants in the intervention group will receive a structured psychosocial counseling program in addition to standard TB care, while participants in the control group will receive standard TB care in accordance with the Indonesian National TB Program guidelines.

The study will focus on the first two months of anti-TB treatment, corresponding to the intensive phase of treatment. This period was selected because patients commonly encounter medication-related side effects, psychological distress associated with a new diagnosis, concerns regarding stigma and discrimination, and challenges in establishing adherence to a daily medication regimen. Early psychosocial support during this phase may help patients adapt to treatment and improve adherence [16].

Data collection will be conducted at three time points. Baseline assessment (T0) will be conducted after participants have received and acknowledged their TB diagnosis, but before the psychosocial counseling intervention is delivered. Following the baseline assessment, participants in the intervention group will be given time to process their diagnosis and initial emotional responses before participating in the counseling session. An immediate post-intervention assessment (T1) will be conducted upon completion of the counseling session to evaluate short-term changes in psychosocial outcomes. A follow-up assessment (T2) will be performed two months after treatment initiation to assess treatment adherence and the sustained effects of the intervention during the intensive phase of TB treatment.

Study participants

The study population will consist of newly diagnosed TB patients receiving treatment at the selected PHCs during the study period. Eligible participants will be adults aged 18 years and older with a newly confirmed diagnosis of pulmonary tuberculosis who are scheduled to initiate anti-tuberculosis treatment at the participating PHCs. All participants will be provided written informed consent before enrollment.

Patients will be excluded if they are diagnosed with multidrug-resistant tuberculosis (MDR-TB), have severe cognitive impairment or psychiatric disorders that may affect their ability to participate in counseling sessions and study assessments, or have serious medical conditions requiring hospitalization at the time of recruitment. Patients who are unable to complete the follow-up assessment or who plan to relocate outside the study area during the study period will also be excluded.

Participants will be recruited consecutively from each participating PHC until the required sample size is achieved. All eligible patients attending the selected PHCs during the recruitment period will be invited to participate. Participants in both study groups will continue to receive routine TB treatment and follow-up services throughout the study period, regardless of their group allocation.

Sample size

The sample size was calculated using G*Power version 3.1 software. The calculation was based on a previous counseling intervention study among patients with newly diagnosed drug-sensitive tuberculosis that reported treatment adherence rates of 85.7% in the intervention group and 67.5% in the control group [17]. Assuming a two-sided significance level of 0.05 and 80% power, the minimum required sample size was estimated at 82 participants (41 per group). To account for a potential attrition rate of 30% during the two-month follow-up period, the sample size was increased to 108 participants. Therefore, a total of 108 participants, comprising 54 participants in the intervention group and 54 participants in the control group, will be recruited for the study. Figure 1. Showed the flow of participants' recruitment and follow-up.

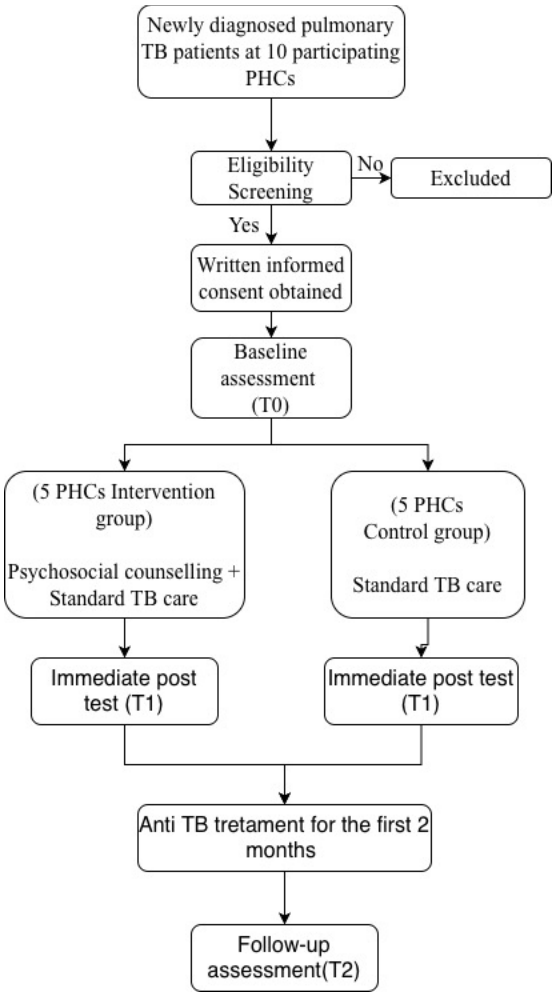


Figure 1. Flow of the recruitment and follow-up of participants

Intervention

The intervention in this study is a structured psychosocial counseling program developed for newly diagnosed TB patients receiving care in primary health care settings. The counseling is designed to facilitate psychological adjustment following a TB diagnosis, improve understanding of the disease and its treatment, reduce TB-related stigma, strengthen coping strategies, and promote treatment adherence during the intensive phase of anti-tuberculosis treatment.

The intervention is delivered individually in a face-to-face format by trained counselors holding at least a bachelor's degree in public health who have received specific training on the counseling protocol and TB patient support. A standardized counseling manual is used to ensure consistency in intervention delivery across all intervention groups. Counseling is provided after the baseline assessment and before initiation of anti-tuberculosis treatment. Each session is conducted in a private counseling room and lasts approximately 30–45 minutes. The counseling session consists of five components as shown in Table 1. The intervention is informed by the HBM and SCT. These

theoretical frameworks guide the development of counseling activities aimed at increasing perceived benefits of treatment, reducing perceived barriers, strengthening self-efficacy, and promoting self-regulation of medication-taking behaviors. Participants in the control group receive standard TB care according to the Indonesian National TB Program guidelines without the structured psychosocial counseling intervention.

Table 1. Components of the psychosocial counseling intervention

Counselling Component	HBM Construct	SCT Construct	Activities and content
Emotional assessment and psychological support	Perceived barriers	Emotional coping responses	Explore feelings and concerns related to diagnosis; identify sources of emotional distress; validate emotions and normalize reactions to diagnosis
TB education	Perceived susceptibility, perceived severity, perceived benefits	Behavioral capability	Explain causes, symptoms, transmission, prevention, treatment, and prognosis of TB; address misconceptions and misinformation
Treatment preparation and side-effect management	Perceived benefits, perceived barriers	Outcome expectations, self-regulation	Discuss treatment duration, importance of adherence, mechanism of treatment, common side effects, and management strategies
Stigma reduction and coping strategies	Perceived barriers, cues to action	Self-efficacy, observational learning, social support	Address self-stigma and community stigma; promote self-acceptance; discuss coping mechanisms and social support resources
Adherence planning	Cues to action, perceived benefits	Self-efficacy, self-regulation, goal setting	Develop individualized medication-taking plan; identify barriers and solutions; introduce treatment adherence card for self-monitoring

Measures

The study outcomes will be determined through analysis of responses obtained from self-administered questionnaires and treatment adherence records. The primary outcome is treatment adherence during the intensive phase of anti-TB treatment. Secondary outcomes include psychological distress, tuberculosis-related stigma, tuberculosis knowledge, coping ability, and treatment self-efficacy.

Treatment adherence will be assessed at the two-month follow-up using treatment records maintained by the primary health care centers and a treatment adherence card completed by

participants throughout the intensive treatment phase. Adherence will be defined as the extent to which participants follow the prescribed anti-TB treatment regimen during the first two months of therapy. Psychological distress will be assessed using the Depression Anxiety Stress Scale-21 (DASS-21). The DASS-21 is a validated self-report instrument consisting of 21 items divided into three subscales measuring depression, anxiety, and stress. Each subscale contains seven items scored on a four-point Likert scale ranging from 0 ("Did not apply to me at all") to 3 ("Applied to me very much or most of the time"). Scores for each subscale are summed and multiplied by two, with higher scores indicating greater psychological distress [18].

TB-related stigma will be measured using a validated TB stigma scale. The instrument assesses perceived stigma, internalized stigma, and experienced stigma associated with tuberculosis. Participants respond to each item using a Likert-scale format, with higher scores indicating greater levels of TB-related stigma [19]. TB knowledge will be assessed using a structured questionnaire developed based on the Indonesian National TB Program guidelines and the counseling module used in this study. The questionnaire includes items related to TB transmission, symptoms, prevention, treatment, medication adherence, and treatment side effects. Higher scores indicate better knowledge regarding tuberculosis and its treatment. Treatment self-efficacy will be measured using a validated self-efficacy scale adapted for tuberculosis treatment. The instrument assesses participants' confidence in their ability to adhere to medication schedules, manage treatment-related challenges, and complete the full course of treatment. Higher scores indicate greater treatment self-efficacy [20].

Data will be collected at three time points: baseline (T0), immediately after the counseling intervention (T1), and two months after treatment initiation (T2). Sociodemographic and clinical information, including age, sex, educational level, occupation, marital status, and relevant clinical characteristics, will be collected at baseline. The outcome measures and timing of assessment are summarized in Table 2.

Table 2. Outcome measures and assessment schedule

Outcome Measure	Instrument	T0	T1	T2
Sociodemographic and clinical characteristics	Structured questionnaire	✓	–	–
TB knowledge	TB knowledge questionnaire	✓	✓	✓
Psychological distress	DASS-21	✓	✓	✓
TB-related stigma	TB stigma scale	✓	✓	✓
Treatment self-efficacy	Self-efficacy scale	✓	✓	✓
Treatment adherence	Adherence card and treatment records	–	–	✓

Procedures

Newly diagnosed pulmonary TB patients attending the participating primary health care centers will be screened for eligibility by healthcare personnel. Eligible patients will receive information about the study and provide written informed consent before participation. Following consent, participants will complete the baseline assessment (T0). Baseline assessment will be conducted after participants have received their TB diagnosis and before initiation of anti-tuberculosis treatment. Participants in the intervention PHCs will subsequently receive the psychosocial counseling intervention delivered by trained counselors. Immediately after completion of the counseling session, participants will complete the post-intervention assessment (T1) to evaluate short-term changes in psychosocial outcomes. Participants in the control group T1 will be assessed after finishing the standard of care procedure on the same day.

Participants in both intervention and control groups will then initiate anti-tuberculosis treatment according to the Indonesian National TB Program guidelines. Throughout the two-month intensive treatment phase, all participants will continue receiving routine TB care and follow-up services provided by their respective PHCs. At the end of the intensive phase, participants will complete the follow-up assessment (T2), which will evaluate treatment adherence, knowledge, self-efficacy, and psychosocial outcomes. Reasons for withdrawal, loss to follow-up, and incomplete assessments will be documented throughout the study.

Planned statistical analysis

Data will be analyzed using IBM SPSS Statistics version 29.0.1.0. Descriptive statistics will be used to summarize participants' sociodemographic and clinical characteristics. Continuous variables will be presented as means and standard deviations or medians and interquartile ranges, depending on the distribution of the data. Categorical variables will be presented as frequencies and percentages. Baseline characteristics between intervention and control groups will be compared using independent-samples t-tests or Mann–Whitney U tests for continuous variables and chi-square tests or Fisher's exact tests for categorical variables.

Changes in psychosocial outcomes over time will be analyzed using repeated-measures analysis. A mixed-design analysis of variance (ANOVA) will be used to examine differences between groups (intervention vs control), across time points (T0, T1, and T2), and the interaction between group and time. When assumptions for parametric analyses are not met, appropriate non-parametric alternatives will be applied.

Treatment adherence at the end of the intensive phase (T2) will be compared between groups using chi-square tests. Multivariable logistic regression analyses will be conducted to assess the effect of the psychosocial counseling intervention on treatment adherence while adjusting for potential confounding variables, including age, sex, educational level, marital status, household income, comorbidities, baseline psychological distress, baseline TB-related stigma, and treatment

self-efficacy. Statistical significance will be set at $p < 0.05$ for all analyses. Missing data will be examined and managed using appropriate statistical methods based on the extent and pattern of missingness.

Ethical Consideration

Ethical approval for this study has been obtained from the Ethics Committee of the Faculty of Public Health, Diponegoro University (304/EA/KEPK-FKM/2026).The study will be conducted in accordance with the ethical principles outlined in the Declaration of Helsinki and applicable national regulations governing research involving human participants.

Written informed consent will be obtained from all participants before enrollment. Participants will be informed about the study objectives, procedures, potential benefits, and potential risks. They will be informed that participation is voluntary and that they have the right to decline to answer any question or withdraw from the study at any time without affecting their access to TB treatment or other healthcare services. All participant information will be treated as strictly confidential and used solely for research purposes. Personal identifiers will be removed from study datasets, and only authorized members of the research team will have access to the data. No identifiable participant information will be disclosed in any publication or presentation arising from this study.

The potential benefits of participation include receiving additional psychosocial support during the early phase of TB treatment and contributing to the development of evidence-based interventions to improve treatment adherence and psychological well-being among TB patients. The risks associated with participation are considered minimal and are primarily related to possible emotional discomfort when discussing personal experiences, psychological distress, or stigma associated with TB. Participants who exhibit significant psychological distress during the study will be referred to appropriate healthcare professionals or mental health services for further assessment and support. Participants may withdraw from the study at any time without penalty.

Dissemination

The findings of this study will be disseminated through publication in peer-reviewed scientific journals related to public health, tuberculosis control, behavioral health, and health promotion. Study findings may also be shared with local health authorities and primary health care centers to support the implementation of psychosocial interventions for TB patients. Participant confidentiality will be maintained in all dissemination activities. Requests for access to de-identified study data for legitimate research purposes may be considered by the research team following completion of the study and publication of the primary results, subject to applicable ethical and institutional requirements.

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