

Effectiveness of the DOTS Program in Enhancing Management of Pulmonary Tuberculosis: A Systematic Review

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ABSTRACT

Background: The Directly Observed Therapy Short-Course (DOTS) program is a key strategy for managing pulmonary tuberculosis (PTB) by ensuring treatment adherence and improving patient outcomes. The effectiveness of the DOTS program in improving management of PTB patients was evaluated through a systematic review.

Methods: A systematic review methodology was employed to identify and analyze relevant studies published between 2019 and 2024, focusing on the effectiveness of interventions for tuberculosis management. The review utilized seven major databases—ScienceDirect, Scopus, ProQuest, EBSCOhost, Sage Journals, Taylor & Francis, and PubMed—searched with a well-defined strategy and Boolean operators to ensure comprehensive coverage of the literature. Studies were selected based on established inclusion and exclusion criteria. For quality appraisal, the Joanna Briggs Institute (JBI) checklist was used to assess quasi-experimental studies, while the ROBVIS tool was applied to evaluate the risk of bias in randomized controlled trials. The review adhered to the Synthesis Without Meta-Analysis (SWiM) guidelines for data analysis to ensure a transparent and structured synthesis of findings. Additionally, the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist was utilized to guide the final appraisal and reporting of the selected articles.

Results: Three studies (quasi-experimental and RCT) conducted in Uganda and India, with intervention durations ranging from 6 to 8 months, demonstrated significant improvements in pulmonary tuberculosis (PTB) treatment outcomes. The studies, reviewed from a pool of 13,495 articles, exhibited an overall low risk of bias. Strategies such as DOTS and herbal adjuncts like *Rudanti* (*Capparis moonii*) were effective in enhancing treatment efficacy, alleviating drug-induced hepatotoxicity, and improving symptom relief. Also, the integration of digital adherence technologies (DATs), such as 99DOTS, has shown great promise in boosting treatment compliance through mobile-based solutions.

Conclusion: The DOTS program has significantly improved TB management by ensuring treatment adherence, reducing drug resistance, and achieving high cure rates. Despite challenges like resource demands and logistical issues, it remains a cornerstone in TB control. Innovations such as digital adherence tools and adjunct therapies are enhancing its impact which provide solutions for better patient outcomes and broader TB eradication efforts.

Keywords: Tuberculosis (TB) Management; TB-DOTS Program; Treatment Effectiveness; Systematic Review

INTRODUCTION

Tuberculosis (TB), caused by the bacterium *Mycobacterium tuberculosis*, remains a critical global health challenge, affecting both the lungs and other organs. It is primarily transmitted through airborne droplets when infected individuals exhale, cough, or sneeze. Although only about 10% of those infected with *M. tuberculosis* develop active TB during their lifetime, the disease continues to be a leading cause of preventable deaths worldwide, particularly among low- and middle-income populations (Batista et al., 2020; Laws et al., 2022). Effective control measures within healthcare settings are essential for reducing TB-related morbidity, mortality, and transmission (Olmo-Fontán, 2022; Yue et al., 2021).

Despite being both preventable and curable, TB remains the leading infectious cause of death globally. A significant barrier to TB elimination is poor adherence to treatment regimens, which contributes to prolonged infectiousness, the emergence of multidrug-resistant TB (MDR-TB), and poor treatment outcomes (Nezenega et al., 2020). Recognizing the need for structured supervision of treatment, the World Health Organization (WHO) introduced the Directly Observed Therapy Short-Course (DOTS) strategy in the 1990. In this strategy, healthcare workers or trained observers directly supervise patients as they take their medication, ensuring adherence and monitoring progress (Berger et al., 2020; Idoko & Adeyemi, 2022).

The DOTS strategy has been instrumental in improving TB treatment outcomes and remains the global standard for TB care (Ereso et al., 2021). However, its implementation presents notable challenges. DOTS is time-consuming, resource-intensive, and logistically demanding—issues that are particularly pronounced in resource-limited settings or for patients residing in remote areas (Al-Sahafi et al., 2021). These challenges underscore the need for more flexible and patient-centered approaches that can either complement or replace direct observation while maintaining high adherence levels.

The widespread adoption of mobile phones in countries with high TB burdens has created new opportunities to address the limitations of DOTS through digital adherence technologies (DATs). Innovations such as SMS reminders, video-observed therapy (VOT), and medication event reminder monitors offer promising methods to enhance treatment adherence. These technologies aim to alleviate the logistical burdens of DOTS while offering greater convenience to patients (Kafie et al., 2024). However, the WHO has provided only conditional recommendations for DATs due to limited and inconsistent evidence regarding their effectiveness. Studies evaluating DATs have produced mixed results, with varying levels of patient engagement and inconsistent impacts on treatment outcomes (Zary et al., 2024).

Given the varied findings from existing studies and the evolving landscape of TB treatment adherence strategies, a systematic review is necessary to comprehensively evaluate the effectiveness of the DOTS program. This review will synthesize current evidence, identify gaps in the literature, and provide insights into best practices and future directions for improving TB management globally.

METHODOLOGY

Study Design

This study is a systematic review about the effectiveness of the TB Dots program in improving the management of PTB patients. Primarily, this study is anchored on the concept of establishing PICO. Formulation of the research inquiry, the inquiry as stated in this study: “How effective is the TB Dots program in improving the management of PTB patients?”. It is presented in the table below.

Table 1. Description of PICO

Element	Description
P(People/Participants)	PTB Patients
I (Intervention)	Effectiveness of TB Dots program
C (Comparison)	Conventional program
O (Outcomes)	Improve Management of PTB patient

Search Methods

This study has been done through visiting the five-research data bases, such as ProQuest (4,646), Science Direct (129), PubMed (20), Sage Journal (11), and Taylor and Francis (6). The search strategy employed in this study was through the use of Boolean operators (AND, OR) for combining keywords and phrases. Quotation marks (""") were employed for exact phrase searching, and parenthesis () was used for grouping similar concepts. The keywords used were: ("Pulmonary Tuberculosis" or "PTB") AND (TB DOTS Program).

Inclusion and Exclusion Criteria

The inclusion criteria for this study are: (1) studies focusing on pulmonary tuberculosis patients; (2) articles published in Scopus or ISI indexed journals; (3) publications from the years 2014 to 2024; (4) studies employing research designs such as randomized controlled trials; and (5) articles written in English. Conversely, the exclusion criteria include: (1) articles sourced from unreliable websites; (2) surveys, case reports, protocols, reviews, and studies with unidentified authors; (3) articles that are inaccessible for download or lack full access; and (4) articles not written in English.

Screening of Articles

The screening process involved all authors of this study, including M.A.A. Hayudini, H.K. Pangandaman, S.A. Mai-Alauya, R.D.R. Macarambon, S.P. Macalaba, N.A. Ali, N.P. Mukattil, F.C.L. Tandih, M.A. Jupakkal, N.M. Joe, and M.S. Abdulhan. The authors played a major role in several stages of the process. First, relevant keywords were identified from the five selected databases. Next, the titles and abstracts were screened to assess their relevance based on the inclusion criteria. Full-text availability was then evaluated to confirm alignment with the study's requirements. In cases of disagreement among the reviewers, the senior researchers, M.A.A. Hayudini, H.K. Pangandaman, S.P. Macalaba, and N.P. Mukattil collaborated to resolve discrepancies and ensure the accuracy and consistency of the screening process. This reconciliation step was designed to promote reliable and consistent decision-making.

Data Extraction

Eight articles that met the inclusion criteria were selected for data extraction. Reviewers utilized a grid synthesis format to systematically extract key information, including author details, publication year, country, objectives, study design, healthcare setting, intervention model, duration, and results relevant to the effectiveness of the DOTS program in managing pulmonary tuberculosis. The extracted data were compiled and summarized in a table (Table 2) for comprehensive analysis and comparison.

Quality assessment of selected articles:

To assess the quality of the included studies, the researchers employed critical appraisal tools from two reputable sources: the Joanna Briggs Institute (JBI) for quasi-experimental studies and the Critical Appraisal Skills Programme (CASP) for randomized controlled trials (RCTs). The JBI critical appraisal checklist for quasi-experimental research is available at <https://jbi.global/criticalappraisal-tools> and has been rigorously peer-reviewed and endorsed by the JBI Scientific Committee. For evaluating the quality of RCTs, the Risk of Bias Visualization (ROBVIS) checklist was used, which can be accessed at <https://www.riskofbias.info/welcome/robvis-visualizationtool> (Table 3). ROBVIS provides a comprehensive framework for assessing the risk of bias in RCTs, ensuring a detailed evaluation of study design, execution, and reporting. The critical appraisal process was carried out by all of the authors involved following the established guidelines from JBI and ROBVIS.

Risk of bias:

For quasi-experimental designs, the risk of bias in individual studies was assessed using a cutoff approach. Studies were categorized as having a low risk of bias if they scored "yes" for 70% or more of the appraisal questions, a moderate risk if they scored "yes" for 50 to 69% of the questions, and a high risk if the "yes" scores were below 50% (21). Among the articles reviewed, one was classified as a moderate risk (Table 4). Regarding RCTs, the risk of bias assessment was conducted using the Cochrane collaboration tool (22). Among the two articles focusing on RCT designs, one study had a low risk of bias, and one had a high risk of bias (Table 3).

DATA ANALYSIS

The authors applied the Synthesis Without Meta-analysis (SWiM) guidelines to structure their data analysis. These guidelines were used to synthesize quantitative data on intervention effects and were presented across nine reporting items.

The first item focused on categorizing the included studies into relevant sections, such as authors and publication year, country, objectives, study design, setting, intervention model, duration, results, and components of the TB DOTS program that contribute to improving the management of PTB patients. The analysis of the studies addressed critical elements, including study design, intervention methods, assessment tools, and the effects of the interventions.

The findings were systematically organized in a comparative table (Table 2), facilitating a clear evaluation of similarities and differences in the reported outcomes across the studies. This structured approach provided a comprehensive overview of the evidence on the effectiveness of the TB DOTS program in enhancing PTB patient management.

Table 2. Data extraction of the selected studies

No.	Authors, years of Publication, and country	Design	Setting	Intervention Model	Duration	Result	Components of TB Dots program in Improving Management of PTB patient
1.	Crowder et al., 2020, Uganda	RCT	18 TB treatment units in Uganda	99DOTS: Digital Adherence Technology for TB medication adherence	8 months	Improved TB treatment adherence by leveraging SMS reminders, IVR check-ins, and toll-free calls.	Strengthened adherence monitoring by combining technology-based supervision with DOTS principles, ensuring improved patient compliance and engagement.
2.	Nagar et al., 2022, India	RCT	OPD and IPD, S.S. Hospital, Varanasi	Adjunct therapy: DOTS plus Rudanti powder (5g twice daily)	6 months	Adjunct Rudanti therapy led to better symptom relief, improved BMI, and reduced hepatotoxicity	Leveraged DOTS by adding adjunct therapy (Rudanti), improving outcomes while retaining DOTS principles like patient follow-ups, symptom monitoring, and medication supervision.
3.	Tyagi and Balusamy, 2022, India	Quasi-experimental	DOTS centers in Bareilly and Shahjahanpur districts	Sensitization program focusing on TB infection prevention and control	6 months	Knowledge and practice regarding TB prevention improved significantly post-sensitization.	Enhanced community-level impact of DOTS by integrating health education and training, reinforcing infection prevention at DOTS centers for comprehensive TB control.

Table 3: ROBVIS risk of bias tool for RCT

Authors and Year	Sample Size	Bias arising from the randomization process	Bias due to deviations from intended interventions	Bias due to missing outcome data	Bias in measurement of the outcome	Bias in selection of the reported result	Overall
Crowder et al., 2020	1,890	+	+	-	+	-	+
Lalit Nagar et al., 2022	100	-	+	+	-	+	-

Note: (+) indicates a low risk of bias, (-) indicates a high risk of bias, (?) shows unclear risk of bias

Table 4. Risk of bias assessment for quasi experimental design

Authors and year [sample responders]	JBI Assessment tools										Interpretation
	Q1a	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	%Yes	
Tyagi & Balusamy, 2022 (TB patients, n=80)	No	Yes	No	Yes	No	Yes	Yes	Yes	No	55.60%	moderate risk of bias
<p>Notes:</p> <p>a Q1 – Q9 indicate questions 1 to 9 based on the JBI risk assessment</p> <p>b The risk of bias was ranked as high when the study reached up to 49% of “yes” scores, moderate when the study reached from 50 to 69% of “yes” scores, and low when the study reached more than 70% of “yes” scores</p> <p>c Not means “Unclear”</p>											

RESULTS

Characteristics of the selected studies

A total of eight articles were included in the final review. Initially, researchers identified 13,495 articles from seven databases. After applying exclusion criteria—such as publication year, article type, subject area, and open access status—4,812 articles were removed. The remaining 8,683 articles were screened based on their titles and abstracts, reducing the selection to 168 articles for further evaluation. Additional exclusions were made based on the inclusion criteria, resulting in a final subset for full-text assessment. After thoroughly reviewing the eligibility and incorporating relevant studies from reference lists, eight articles were selected for inclusion in the review.

Among the reviewed articles, two were from India and one from Uganda. One study was conducted at a TB treatment unit, while another took place in a DOTS center and a hospital setting. The interventions employed a variety of innovative approaches: three studies implemented structured educational programs, two utilized digital adherence technologies, and one incorporated an herbal adjunct therapy. The intervention duration in two studies was six months, while one lasted eight months. Overall, the reviewed studies reported notable improvements in knowledge, adherence to treatment protocols, and clinical outcomes. For instance, digital adherence technology enhanced medication compliance, herbal therapy demonstrated an additive effect in managing pulmonary TB, and educational programs effectively increased patient awareness while reducing behaviors associated with TB transmission.

Participants and study setting

The participants in this study were adults with drug-susceptible pulmonary TB. The participants of the two studies were pulmonary TB patients (90 control and 90 experimental). The highest number of participants in the quasi-experimental studies was 100 pulmonary TB patients (50 control, 50 test group), with 80 as the lowest. The

number of participants in the RCT studies (see Table 3) was higher than in quasi-experimental studies (Table 4).

Characteristics of the intervention and components of the TB Dots Program

The interventions varied in focus, duration, implementation challenges, and scalability. The sensitization program centered on patient education and behavior change, while the digital adherence technology emphasized technological solutions for monitoring and adherence. Rudanti therapy introduced a complementary medical approach. Both the sensitization program and Rudanti therapy were implemented over defined durations of six months, whereas the digital adherence intervention followed a stepped-wedge rollout across eight months. Implementation challenges differed, with digital technology requiring robust infrastructure and training, while the sensitization program and herbal therapy relied more on healthcare provider expertise. In terms of scalability, digital adherence technology showed the highest potential due to its ability to integrate with existing health systems, whereas the other two interventions required greater contextual adaptation.

Contribution of TB DOTs program in the development of TB Treatment

The reviewed studies highlighted various components of the TB DOTS program that contribute to the enhancement of TB treatment by integrating innovative approaches to patient adherence, symptom management, and community engagement.

The integration of digital adherence technologies, such as SMS reminders, IVR check-ins, and toll-free calls, has played a crucial role in strengthening patient compliance and engagement. The combination of technology-based supervision with DOTS principles has not only improved treatment adherence but also equipped healthcare providers with valuable skills in remote monitoring and technology-assisted patient management.

Incorporating adjunct therapies, such as Rudanti powder alongside the DOTS program, has demonstrated positive outcomes, including improved symptom relief, better BMI management, and reduced hepatotoxicity. This approach has fostered clinical decision-making skills among healthcare providers by requiring them to assess the compatibility of adjunct therapies with standard TB treatments. Moreover, it has reinforced patient monitoring practices, medication supervision, and symptom management to optimize treatment outcomes.

Community sensitization programs have further contributed to TB management by enhancing patient knowledge and adherence behaviors. These programs have strengthened community-level engagement and provided healthcare providers with the necessary skills to educate patients, conduct awareness campaigns, and implement effective infection control measures. The emphasis on health education and training has reinforced practitioners' ability to foster behavioral change and ensure comprehensive TB management within communities.

Collectively, these studies underscore the multifaceted approach of the TB DOTS program, integrating technology, adjunct therapies, and community-focused interventions to enhance treatment adherence, symptom management, and public health outcomes.

DISCUSSION

This systematic review aims to evaluate the effectiveness of various interventions within the TB DOTS program in enhancing TB treatment adherence and management. The review focused on interventions such as digital adherence technology, adjunct therapies, and community sensitization programs, all designed to improve patient compliance, symptom management, and community engagement in TB care. Eight studies were included in this review, highlighting the contributions of these interventions to TB treatment outcomes.

The findings reveal that digital adherence technology, such as 99DOTS, has significantly improved patient adherence by leveraging SMS reminders, IVR check-ins, and toll-free calls (Crowder et al., 2020; Pangandaman, 2024). Integrating technology with DOTS principles has strengthened adherence monitoring and enhanced patient compliance and engagement. Additionally, healthcare providers have acquired valuable skills in utilizing digital platforms for remote patient monitoring and management, further improving the effectiveness of TB treatment (Tyagi & Balusamy, 2022). Similar findings have emphasized the role of digital technologies in improving medication adherence, although challenges such as limited technological literacy and infrastructure constraints remain significant barriers (Colon et al., 2020; Hoval & Nevase, 2024).

Another significant finding pertains to using adjunct therapies, such as Rudanti powder, alongside the DOTS program. The inclusion of this herbal therapy has shown promising results, including better symptom relief, improved BMI, and reduced hepatotoxicity (Nagar et al., 2020). This intervention has enhanced clinical decision-making among healthcare providers by requiring them to assess and monitor adjunct therapies in conjunction with standard TB treatment protocols, ensuring comprehensive patient care (Abdulmalik & Pangandaman, 2024; Crowder et al., 2020). However, it has been suggested that while adjunct therapies can provide additional benefits, their efficacy varies depending on patient demographics and adherence to prescribed regimens (Al-Sahafi et al., 2021; Salve & Pangandaman, 2024).

Community sensitization programs have also played a vital role in improving TB management by enhancing patient knowledge and promoting adherence behaviors (Tyagi & Balusamy, 2022). These programs have

contributed to increased awareness of TB prevention and control, reinforced patient education, and strengthened infection control practices at the community level. Healthcare providers have benefited from these programs by developing improved communication skills and the ability to implement effective health education strategies (Crowder et al., 2020). This aligns with findings that highlight the importance of community involvement in achieving sustainable TB control outcomes (Haldane et al., 2019; Sejie & Mahomed, 2023).

The quality assessment of the included studies indicated that most randomized controlled trials had a low risk of bias, while the quasi-experimental studies demonstrated a moderate risk of bias. Factors such as unclear blinding and incomplete outcome data were observed in some studies, which should be considered when interpreting the findings. Despite these limitations, the results provide valuable insights into the multifaceted approaches of the TB DOTS program in enhancing TB treatment adherence and patient outcomes.

Conducting a systematic review on the effectiveness of interventions within the TB DOTS program is crucial for consolidating existing evidence, identifying gaps, and informing future research and policy decisions. A systematic review provides a comprehensive synthesis of the available literature, offering healthcare professionals, policymakers, and researchers valuable insights into the most effective strategies for enhancing TB treatment adherence and management. By analyzing multiple studies, this review highlights trends, strengths, and limitations of different interventions, enabling a more evidence-based approach to TB control efforts. Additionally, systematic reviews help to standardize treatment protocols, improve healthcare delivery, and facilitate resource allocation in regions with high TB burden.

CONCLUSION

In conclusion, the integration of digital adherence technologies, adjunct therapies, and community sensitization programs has significantly enhanced TB management by addressing critical challenges such as patient compliance, symptom monitoring, and public health outreach. These interventions have demonstrated their potential to improve treatment adherence and overall patient outcomes, reinforcing the importance of multifaceted approaches in TB control. The systematic review of the present study has provided valuable insights into the effectiveness of these strategies, highlighting the strengths and areas for improvement in their implementation. It has also underscored the need for continued efforts to refine these interventions to ensure their sustainability and scalability across diverse healthcare settings. Future research should focus on long-term evaluations, cost-effectiveness analyses, and the adaptability of these interventions to various resource-limited environments to further optimize TB management.

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Conflict of Interest

The authors declared no conflict of interest.

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