Role of clinical pharmacist to improve tubercular patient's compliance referred to NTEP centre attached to a tertiary care hospital: a randomised controlled study

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In the Faculty of Pharmacy

By

Dr. Bandaru Yeswanth Raja Pharm D

(Registration No: KLEU/Ph.D./2020-21/DO1220036)

Under the Guidance of

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NOVEMBER 2024

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Dr. Bandaru Yeswanth Raja

ABSTRACT

Introduction and background: India stands one of the highest burdens of tuberculosis (TB) cases worldwide. Delays in diagnosis and lack of adherence to anti-TB drug regimens are common challenges observed among TB patients. Identifying these gaps and raising awareness about TB infection are crucial steps toward achieving the goal of a 'Global end TB strategy' by 2030. Therefore, this study aims to assess and evaluate the clinical pharmacist counselling and improve the medication compliance of TB patients regarding the management of TB.

Aim: To assess the impact of clinical pharmacist counselling in improving tubercular patients' compliance referred to the NTEP centre at tertiary care hospital and follow up them in completion of anti-TB treatment in the primary health care centres.

Methods: A Randomized controlled study carried out among TB patients. Patients were interviewed the with different materials at the baseline. In test group using patient information leaflets and personal patient counselling was given under the clinical pharmacist whereas in control group usual care was given by other health care team. Then two follow ups were done after every three months with the same set of tools in both groups.

Results: At baseline, this study revealed significant gaps in medication adherence, knowledge, attitude, perception, and quality of life among TB patients. Follow-up scores demonstrated highly significant improvements in the test group compared to the control group after pharmacist intervention. During treatment, drug-related problems and common adverse drug reactions (ADRs) were also noted. Educating patients through pharmacist counseling significantly enhances their success in completing anti-TB treatment.

Conclusion: This study concludes that clinical pharmacists play a crucial role in pharmaceutical patient care, significantly contributing to understanding and improving the management of TB

Keywords: - Tuberculosis, Drug related problems, Adverse drug reactions, Antitubercular drugs, clinical pharmacist.

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LIST OF ABBREVIATIONS

SR NO	ABBREVIATION	FULL FORM
1	TB	Tuberculosis
2	WHO	World Health Organization
3	MDR/RR-TB	Multidrug-resistant or rifampicin-resistant TB
4	HIV	Human Immunodeficiency Virus
5	NTP	National TB Programme
6	BCG	Bacille Calmette-Guerin
7	SIDA	Swedish International Development Agency
8	RNTCP	Revised National Tuberculosis Program
9	NTEP	National Tuberculosis Elimination Program
10	NSP	National Strategic Plan
11	DOTS	Directly Observed Treatment Short-Courses
12	FDC	Fixed-Dose Combination
13	LMICs	low- and middle-income countries
14	HRQOL	Health-related quality of life
15	PHCs	Primary Healthcare Centres
16	UHCs	Urban Healthcare Centres
17	ICF	Informed Consent Form
18	CTRI	Clinical trials registry of India

19	IEC	Institutional Ethics Committee
20	ATT	Antitubercular therapy
21	SNOSE	Sequentially Numbered Opaque Sealed Envelopes
22	RCT	Randomized controlled trial
23	PIS	Patient Information Sheet
24	LAR	Legally Authorized Representative
25	PILs	Patient information leaflets
26	FRE	Flesch Reading Ease
27	BALD	Baker Able Leaflet Design
28	SES	Socioeconomic Status
29	SD	Standard Deviation
30	MAATT	Medication Adherence Assessment for Tuberculosis Treatment
31	PCNE	Pharmaceutical Care Network Europe
32	FACIT- TS	Functional Assessment of Chronic Illness Therapy - Treatment Satisfaction
33	FACIT- SWiP	Functional Assessment of Chronic Illness Therapy - Satisfaction With Pharmacist
34	HCPs	Healthcare professionals
35	SPSS	Statistical Package for the Social Sciences
36	DRPs	Drugs related Problems
37	ADRs	Adverse Drug Reactions

38	GI	Gastrointestinal
39	KAP	Knowledge, Attitude and Perception/Practice
40	SF-36	Short Form-36
41	TBIC	TB infection control
42	BMI	Body Mass Index
43	WHO-UMC	World health organization- Uppsala monitoring center
44	IPA	Indian Pharmaceutical Association

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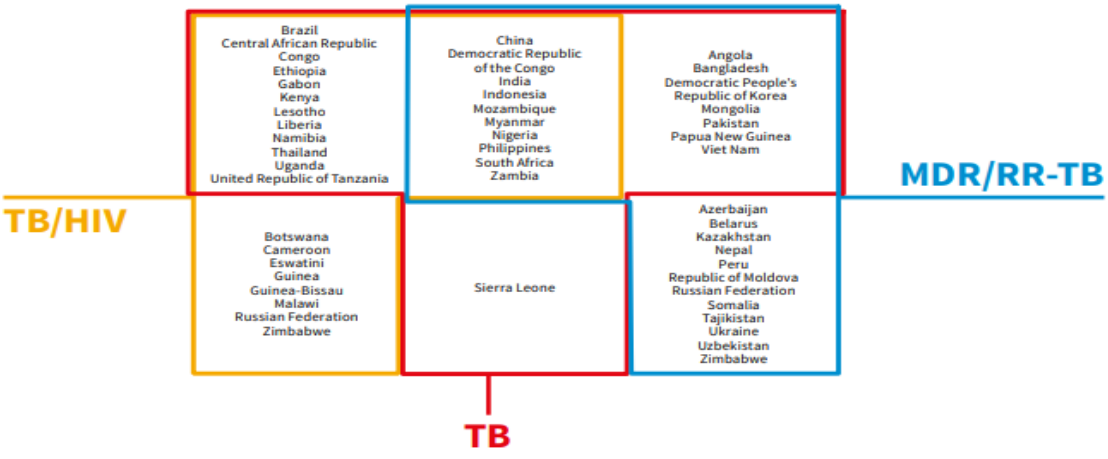
1. INTRODUCTION

1.1 Background: Tuberculosis (TB), Global burden, and India.

Tuberculosis (TB) is an infectious disease condition caused by the bacterium Mycobacterium tuberculosis. It is transmitted through the air when a person with the infection coughs, sneezes, or spits, thereby releasing the bacteria into the environment where it can be inhaled by others.[1] The disease primarily targets the lungs (known as pulmonary TB) but can also affect other parts of the body such as the meninges, kidneys, lymph nodes, small intestine, spine, and skin (known as extrapulmonary TB).[2] Individuals suffering from TB may experience symptoms like a chronic cough (which may produce blood), chest discomfort, weakness, fatigue, significant weight loss, decreased appetite, fevers, and night sweats. These symptoms emerge when the infection transitions to an active state, compressing the immune system in our body.[3]

The World Health Organization (WHO) has identified TB as a major cause of mortality from a single infectious agent, highlighting that the disease is predominantly treatable and preventable. In 2019, it was estimated that out of the 10 million individuals who developed TB, about 2.9 million were either not diagnosed or their cases were not reported to the WHO.[4] Moreover, 87% of new TB cases in 2019 were concentrated in 30 countries with a high burden of the disease. Of these, eight countries — India, Indonesia, China, the Philippines, Pakistan, Nigeria, Bangladesh, and South Africa — collectively accounted for two-thirds of the global total. These 30 nations are also recognized for their significant burden of TB, TB associated with HIV, and multidrug-resistant or rifampicin-resistant TB (MDR/RR-TB).[5]

Fig. 1: TB high-burden countries by WHO for the period 2021–2025, and their areas of overlap.



1.2 Global burden of TB.

TB remains one of the deadliest infectious diseases across the world. It's believed that Mycobacterium tuberculosis, the bacteria responsible for TB, has infected about a third of the global population, making it one of the most widespread diseases. Annually, it's responsible for around 1.3 million deaths, including 167,000 among individuals living with Human Immunodeficiency Virus (HIV).[6] According to data from the WHO in 2016, India reported the highest number of TB cases globally, with an estimated 2.79 million people affected out of a global total of 10 million cases.[7] By 2022, the number of people diagnosed with TB increased to approximately 10.6 million, with the eight countries reporting at least 100,000 cases each contributing to the majority of new incidents as shown in Fig 3.

The WHO's End TB Strategy aims for a dramatic decrease in tuberculosis cases and fatalities, targeting a 90% drop in incidence and a 95% reduction in deaths by 2035. Furthermore, a declaration by the United Nations General Assembly in September 2018, during the High-Level Meeting on combating Tuberculosis, set forth a goal to diagnose and treat 40 million individuals with TB by 2022.[8] To reach these strong objectives, it's crucial to implement effective measures that enhance the detection and initiation of treatment for those affected by TB.

Fig. 2: Global TB report 2023

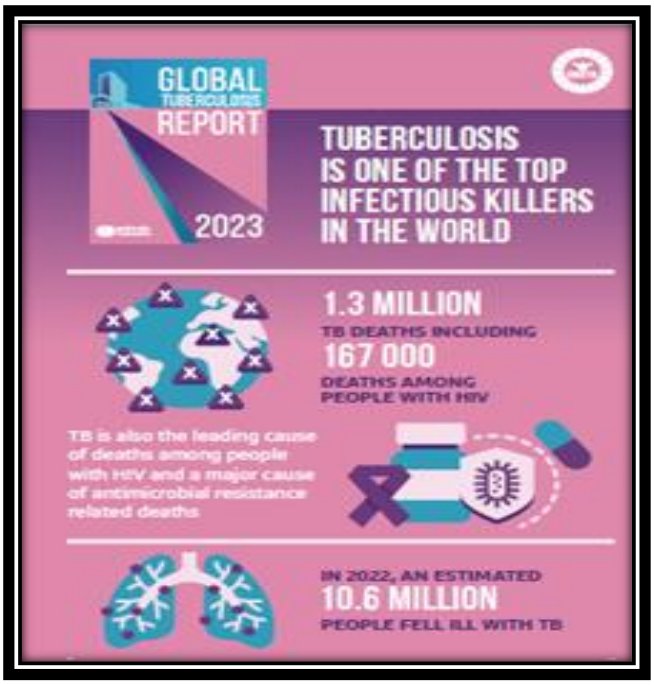
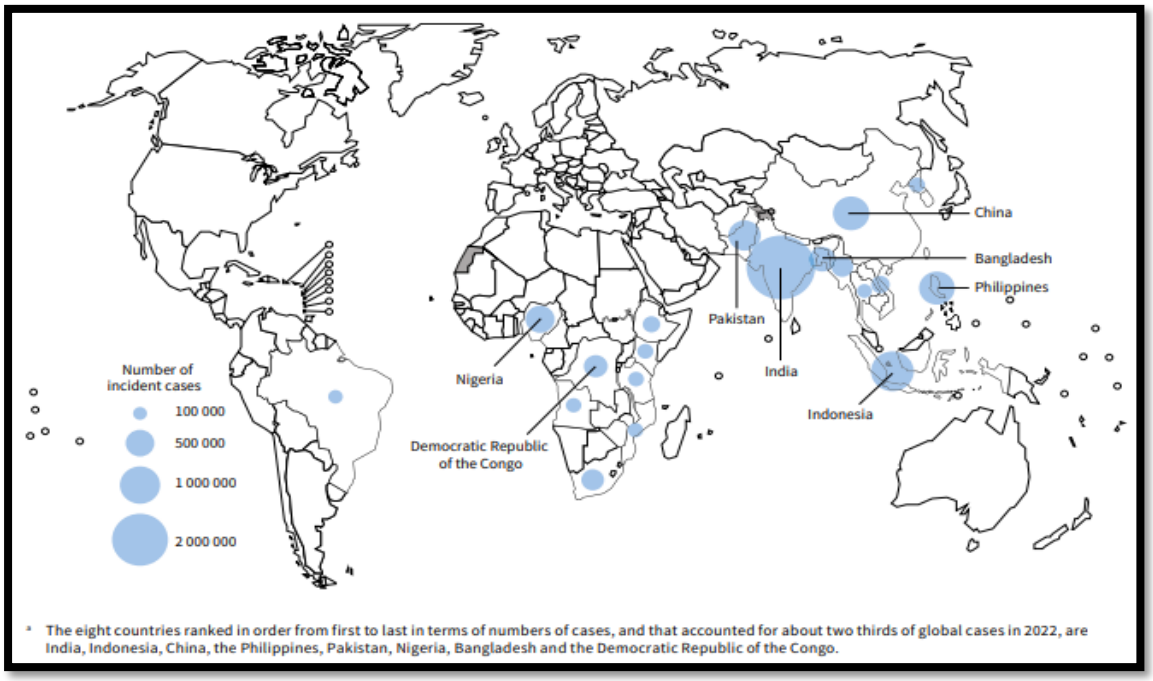
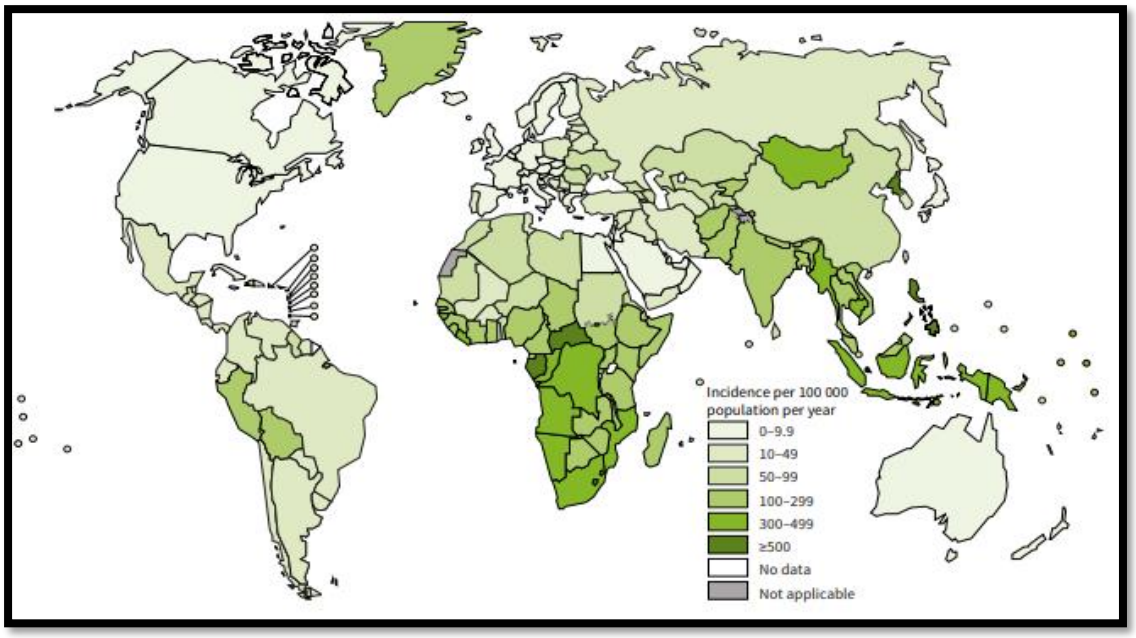


Fig. 3: Estimated incidence of TB cases, noting that eight high-burden countries each reported at least 100,000 new TB cases.



The intensity of TB outbreaks across different nations, measured by the annual number of new and recurring TB cases per 100,000 people, shows significant variation, ranging from fewer than 10 to over 500 cases per 100,000 individuals each year.[9]

Fig. 4: Estimated TB incidence rates,2022



1.3 TB burden India.

India was among the leading countries contributing to the majority (60%) of the worldwide reduction in TB notifications during 2020 and 2021, with all these countries reporting levels above those of 2019 by 2022. TB continued to be the second most common cause of death from a single infectious agent in 2022, following Coronavirus disease 19 (COVID-19). According to the WHO global TB report of 2023, India reported 2.8 million TB cases and 33,100 TB-related deaths from its 1.4 billion population in 2022. The incidence rate saw a decline of 16% between 2015 and 2022. Out of the 2.3 million new and relapse TB cases reported, 75% were of pulmonary TB among both new and relapsed cases, with men accounting for 58% of these cases compared to 37% among women.[9] In 2021, Karnataka has notified the cases of 57,309 in public sector with 82.1%. of success rate and death rate was 8.2%. In private sector the notified cases were 12,096, success rate was 84.7% and death rate 4.3%. Overall, the state estimated prevalence to notification ratio of TB is 4.08 whereas the national average stands at 2.84.[10]

1.4 RNTCP, DOTS, NSP (2017-2025).

The Government of India initiated the National TB Programme (NTP) in 1962, employing a District TB Centre model that encompassed Bacille Calmette-Guerin (BCG) vaccination and TB treatment. By 1978, BCG vaccination was transferred to the Expanded Programme on Immunisation. A comprehensive review of the NTP was conducted jointly by the Government of India, the WHO, and the Swedish International Development Agency (SIDA) in 1992. In 1997, the Indian government commenced widespread implementation of the Revised National Tuberculosis Program (RNTCP), which was later expanded nationwide by March 2006. In 2019, the RNTCP was renamed as the National Tuberculosis Elimination Program (NTEP).[11]

The National Strategic Plan (NSP) for TB elimination 2017–25 serves as a framework, focusing on four core strategies: "Detect, Treat, Prevent, and Build". It directs the efforts of various stakeholders, including national and state governments, development partners, civil society organizations, international agencies, research institutions, the private sector, and others involved in TB elimination in India. Directly Observed Treatment Short-Courses (DOTS) represent a practical and effective approach for TB diagnosis, treatment, and monitoring. Each of the five components of DOTS—political and administrative commitment, case detection primarily through microscopic examination of patient sputum, standardized short-course chemotherapy

administered under direct observation, ensuring an adequate supply of high-quality drugs, and systematic monitoring and responsibility for each diagnosed patient—is crucial for achieving success.[12]

Table 1: Treatment regimen with Fixed-Dose Combination (FDC) administered on a daily basis.[13]

Drug dosages for first line anti- TB drugs

Drugs	Adult	Children	Maximum in children
Isoniazid	5 mg/kg daily (4 to 6 mg/kg)	10 mg/kg daily (7-15 mg/kg)	300 mg
Rifampicin	10 mg/kg daily (8-12 mg/kg)	15 mg/kg daily (10-20 mg/kg)	600 mg
Pyrazinamide	25 mg/kg daily (20- 30 mg)	35 mg/kg daily (30-40 mg/kg)	2000 mg
Ethambutol**	15 mg/kg daily (12-18 mg/kg)	20 mg/kg daily (15-25 mg/kg)	1500 mg
Streptomycin*	15 mg/kg daily (15-20 mg/kg)	20 mg/kg daily (15-20 mg/kg)	1000 mg

*Streptomycin is administered only in certain situations, likeTB meningitis or if any first line drug need to be replaced due to ADR as per weight of the patient

** Ethambutol is given separately for children to monitor ophthalmic ADR.

Daily Dose Schedule for Adults (as per weight bands)

Weight category	**Number of tablets (FDCs)**		
	Intensive phase HRZE	**Continuation phase HRE**	
	75/150/400/275	**75/150/275**	
25-34 kg	2	2	
35-49 kg	3	3	
50-64 kg	4	4	
65-75 kg	5	5	
>75 kg	6	6	

During treatment if the weight of the patient increases by more than 5 kg and crosses the next weight band category then patient should be given the next higher weight band FDC drugs.

1.5 Clinical Pharmacist role in the management of TB control and care.

Clinical pharmacists play a crucial role and act as an integral part of the health care team. They dedicate to improve the standard of pharmaceutical care by offering essential support services to both health care professionals and patients. The treatment of tuberculosis patients necessitates a comprehensive, team-based approach by a multi-disciplinary team. They act as one of the essential members in the health care team because of their ready availability, clinical pharmacists hold a unique position to facilitate suitable interaction and collaboration between patients and physicians, ensuring the effectiveness of treatment. As vital members of the healthcare team, clinical pharmacists engage at various stages in the value chain for TB management and prevention.[14]

These specialized pharmacists focus lies in optimizing medication use, with particular attention to accurate dosing, monitoring drug efficacy and safety, identifying potential drug interactions and adverse reactions, and educating both patients and their care givers. Furthermore, they aim to ensure the economic viability of treatment plans to secure the best possible outcomes for patients. Clinical pharmacists work across diverse health care settings, applying their in-depth knowledge of medications and disease management to administer medication therapy collaboratively within a multidisciplinary team.[15] This research study will delineate the responsibilities and potential extent of practice of a clinical pharmacist in managing, treating and improving the compliance among tuberculosis patients in NTEP programme and aiming towards the global objective strategy of ending TB by 2035.

1.6 Justification of the Study

- India, the second most populous country globally, represents a quarter of the world's annual TB incidence. Each year, approximately two million individuals in India develops the TB, with three lakhs dying to the disease due to insufficient counseling, adherence, and nutrition.
- Over the past decade, the RNTCP has treated more than 15 million patients and saved an additional three million lives.
- According to the Stop TB Partnership's Global Plan to End TB (2018–2022), approximately US$ 8.6 billion was deemed necessary for TB prevention, diagnostic, and treatment services in 128 low- and middle-income countries

(LMICs) in 2018 including India, with a projected increase to US$ 15 billion by 2022. Additionally, an extra US$ 2 billion per year was estimated to be required for TB research.

- In India, there have been limited studies conducted on the treatment of TB patients who were either taking or not taking anti-tubercular drug regimens. In contrast to Western countries, such studies are limited in India.
- The majority of patients were lost to follow-up because of inadequate guidance or education and were unaware of the treatment strategies required to complete their anti-tubercular drug regimens.
- Therefore, to address these challenges, it is essential for healthcare providers to offer comprehensive guidance to ensure adherence, monitoring, and prevention of TB among affected patients. This study aims to provide evidence for enhancing the role of clinical pharmacists in TB management.

1.7 Research hypothesis:

❖ Null hypothesis (H_0) – There is no statistically significant difference between clinical pharmacist managed TB treatment and usual standard care among test and control group.

❖ Alternative hypothesis (H_1) – There is statistically significant difference between clinical pharmacist managed TB treatment and usual standard care among test and control group.

1.8 Study objectives:

1.8.1 Primary objectives:

1. To assess the impact of clinical pharmacist counselling, patient education and to improve the medication adherence among tubercular patients.

2. To assess the knowledge, attitude and perception towards tuberculosis by using standard validated questionnaire among tubercular patients.

1.8.2 Secondary objectives:

1. To assess the health-related quality of life (HRQoL) and improve quality of life among tubercular patients.

2. To prepare and validate the patient information leaflet on tuberculosis and to assess the patient challenges that were faced during treatment time.

3. To assess the knowledge, attitude and practice towards tuberculosis by using standard validated questionnaire among health care providers and to synergize them the importance of elimination of tuberculosis.

2. REVIEW OF LITERATURE

- **Saranya P, Swathi S., et al.,** (2016) were carried out an interventional study to assess the effectiveness of structured and standardized education for tuberculosis (TB) patients. The intervention, designed after an initial evaluation of patients' knowledge, attitude, and practice (KAP) towards TB, focused on educating them about the disease, medication, diet, and lifestyle modifications. Post-intervention results demonstrated a significant improvement in patients' KAP, leading to better adherence to antitubercular therapy (ATT). This improved adherence played a key role in reducing the risk of drug resistance. The study highlights the essential role of patient education in enhancing treatment compliance and combating drug-resistant TB.[16]
- **Minlan Xu, Urban Markström, et al.,** (2017) were reported a study involving 358 rural TB patients, selected through multi-stage randomized sampling, to evaluate the reliability and validity of the Chinese version of the Morisky Medication Adherence Scale (C-MMAS-8) and assess adherence levels. Data were collected through interviewer-administered questionnaires. The study confirmed the C-MMAS-8 as a reliable and valid instrument for measuring medication adherence. Factors contributing to low adherence were analysed using Pearson's chi-square test and multiple logistic regression, offering valuable insights into adherence behaviours within this population.[17]
- **Addisu AG, Megbaru Debalkie, et al.,** (2018) were conducted an institution-based cross-sectional study from April 15 to May 30, 2017, utilizing systematic sampling to select tuberculosis (TB) patients from Arba Minch governmental health institutions. The study employed a semi-structured questionnaire and the Morisky Medication Adherence Scale-8 (MMAS-8). The findings revealed a high prevalence of non-adherence to anti-TB medications. Key factors contributing to non-adherence included extended waiting times at health facilities, the distance patients needed to travel, and medication side effects.[18]
- **Vedavathi Hanumaiah, Dharani Devangi Ranganath, and Nataraja Kakkuppi** (2019) were reported a cross-sectional study at the district TB centre at SIMS, Shimoga, involving interviews with pulmonary TB patients. Adherence was assessed using the Morisky Medication Adherence Scale-8 (MMAS-8). The study found a high prevalence of non-adherence, particularly among patients in the

continuous phase of TB treatment. The study highlight the critical need for ongoing and effective health education for patients and their families about the adverse effects and the importance of strict adherence to the treatment regimen to achieve a complete cure.[19]

- **Chau Quy Ngo, Toshie Manabe, et al.,** (2019) were carried out a cross-sectional study at a national tertiary and general hospital in Hanoi, Vietnam, using a KAP survey to assess TB infection control practices among healthcare professionals, including physicians, nurses, and other staff. The study revealed significant gaps in knowledge, particularly regarding the use of N95 respirators for self-protection and the immediate isolation of patients with (suspected) TB. It underscores the critical need for early recognition of (suspected) TB cases to prevent transmission. The authors recommend that healthcare professionals rely on scientific sources for TB-related knowledge and adopt appropriate infection control measures to reduce the risk of nosocomial TB.[20]
- **Ajith Kumar G and Saranya P,** (2019) together reported a study involving 382 healthcare workers from the chest and tuberculosis departments of government hospitals and directly observed treatment short course (DOTS) clinics. Participants were selected from 500 healthcare workers approached, all of whom provided informed consent. A structured and validated questionnaire was administered by the principal investigator to assess their KAP towards tuberculosis. The findings revealed that over 80% of respondents demonstrated good KAP, though areas for improvement were identified. The study emphasizes the potential of structured, periodic training to further enhance the TB-related KAP of healthcare workers.[21]
- **Shahriar Salehitalia, Kobra Nooriana, et al.,** (2019) were carried out a descriptive-analytic cross-sectional study involving 71 tuberculosis patients, selected using a census method. Data were collected through a questionnaire comprising two sections: demographic information and the standard 36-Item Short Form Health Survey (SF-36). The study revealed that prolonged tuberculosis treatment had a significant adverse impact on patients quality of life, with social and mental health domains being particularly affected.[22]
- **AS Moriarty, GM Louwagie, et al.,** (2019) were conducted a prospective, multicentre, two-arm individual randomized controlled trial across three provinces in South Africa. The study evaluated the effectiveness and cost-effectiveness of the ProLife programme, a multifaceted behavioural intervention. This program

incorporated Motivational Interviewing (MI) techniques delivered by lay health workers, complemented by follow-up SMS reminders. The ProLife programme aimed to address harmful lifestyle behaviors and enhance tuberculosis (TB) treatment outcomes, offering an innovative approach to improving patient care and adherence.[23]

- **Shaik Salma, Abdul A Siddiqua, et al.,** (2019) were conducted a prospective observational study involving 278 participants, comprising 139 TB patients and 139 healthy volunteers. Data were collected using a structured questionnaire covering socio-demographic characteristics, lifestyle factors, and co-morbid conditions associated with TB. Quality of life (QOL) was assessed using the WHO-QOL BREF questionnaire, while medication adherence was evaluated with the MMAS-8. The study found that patients with higher adherence to anti-tubercular therapy reported better QOL. Furthermore, risk factors such as age, education, locality, dietary habits, income, smoking, and alcoholism were independently associated with TB, underscoring their influence on disease outcomes and the importance of addressing these factors in TB management.[24]
- **Sumona Datta, Robert H. Gilman, et al.,** (2020) were carried out a case–control study with a nested prospective cohort from July 13, 2016, to February 24, 2018, across 15 desert shantytowns and 17 urban communities in Callao, Peru, selected for their high TB notification rates. Participants were followed up until November 8, 2019. The study employed the EUROHIS-QOL eight-item questionnaire to evaluate various quality of life domains, including health, energy levels, activities of daily living (ADL), self-perception, relationships, financial status, and living conditions. The findings revealed that TB significantly reduced psychosocioeconomic QOL, which improved with successful treatment. Moreover, lower QOL scores were associated with poorer treatment outcomes. This concise questionnaire provided valuable insights into the multifaceted needs of TB patients, highlighting its potential to inform patient-centered care strategies and improve treatment outcomes.[25]
- **Omowunmi Aibana, Emily Dauria et al.,** (2020) were reported a study involving sixty adults who underwent treatment for drug-sensitive TB between June 2012 and August 2015. The interviews were structured around WHO's framework for barriers to adherence to long-term therapies and included inquiries into patient preferences

and motivators related to treatment adherence. The findings underscored significant barriers to TB treatment adherence within this population and proposed targeted interventions to address the high rates of poor treatment outcomes observed in Ukraine.[26]

- **Rajesh K Yadav, Hari P Kaphle, et al.,** (2021) were carried out a cross-sectional study with 180 TB patients enrolled in the DOTS program and undergoing treatment for at least 60 days. The WHOQOL-BREF tool was used to assess QOL, while the MMAS-8 measured medication adherence. The QOL scores ranged from 10.75 to 89.25, with a mean of 55.96 ± 14.65. The study found that 79.4% of participants adhered to their medication regimen, and those with higher adherence reported better QOL. It emphasized the importance of addressing the needs of TB patients with co-infections and highlighted the critical role of supportive healthcare interactions and counseling in sustaining medication adherence and improving overall QOL.[27]
- **Munazzah Orooj, Bhavna Sharma, et al.,** (2021) were conducted a cross-sectional study among 250 pulmonary tuberculosis patients at a tertiary DOTS center. The study employed the Morisky Medication Adherence Scale (MMAS) and the St. George's Respiratory Questionnaire (SGRQ) to evaluate medication adherence and HRQOL, respectively. The findings revealed a decline in medication adherence rates among TB patients during the COVID-19 pandemic. A positive correlation was observed between SGRQ scores and adherence, indicating that better adherence was associated with improved HRQOL. The study highlighted the significant challenges faced by TB patients during the pandemic, including reduced quality of life and adherence to treatment, emphasizing the need for targeted support and interventions to sustain treatment adherence and enhance HRQOL.[28]
- **Wondimagegn Wondimu, Tewodros Yosef, et al.,** (2021) were surveyed an institution-based cross-sectional study from September 1 to 30, 2019, involving eligible health professionals at a hospital. The study found that 70.2% (95% CI: 63.8%–76.6%) of participants demonstrated good knowledge, and 78.3% (95% CI: 72.3%–84%) exhibited a positive attitude toward tuberculosis infection control (TBIC). Key factors influencing knowledge levels included profession, job location, and prior TBIC training. While the findings indicate satisfactory knowledge and attitudes among participants, the study underscores the need for

ongoing efforts to strengthen TBIC practices and align with the objectives of the End TB strategy.[29]

- **SS Valloto Dalazoana, BM Alcântara Gabardo, et al.,** (2021) were carried out a mixed-methods study, combining descriptive qualitative and quantitative approaches, to explore the experiences of primary-care professionals in nine municipalities of Paraná State, Brazil. The study revealed significant challenges faced by these professionals, including lack of patient commitment to treatment (48.3%), limited access to basic health clinics (31.4%), and logistical difficulties in reaching patients (8.8%). Additional concerns included inadequate staffing (4.1%) and substance use among patients (3.9%). The findings emphasized the need to enhance healthcare providers' knowledge about Directly Observed Therapy (DOT) and stressed the importance of fostering strong relationships with patients and their families. The study highlighted the critical role of health teams in ensuring treatment adherence and addressing these systemic challenges.[30]
- **DS Rachmawati, Nursalam, et al.,** (2021) were employed an analytical observational design with a cross-sectional approach involving 73 randomly selected respondents out of 89 pulmonary TB patients. They utilized a questionnaire and applied Partial Least Square Structural Equation Modeling (PLS-SEM) for data analysis. The study found that both subjective well-being (SWB) and quality of life (QoL) models were adequately fitted based on R2 and Q2 values. Patient-related factors were identified as dominant influencers of SWB, whereas family-related factors had the most significant impact on QoL. These findings suggest a foundational model for future research aiming to enhance care strategies for pulmonary tuberculosis patients and their families, thereby improving overall quality of life and patient acceptance of their health conditions.[31]
- **Zohra Bhatti, Amer Hayat Khan, et al.,** (2021) were carried out a cross sectional study using a validated structured tool among TB patients aged 18 years and older. The study utilized descriptive statistics to summarize the socio-demographic characteristics and levels of knowledge, attitudes, and practices related to tuberculosis (TB). To analyse differences across demographic groups, the Kruskal-Wallis H test was applied. Among the 337 participants, 231 (68.5%) were male and 106 (31.5%) female, with a mean age of 46.5 ± 17.1 years. The study found significant differences between males and females in TB knowledge and practices

related to age. Patients with an educational background of 12 years or more demonstrated notably better knowledge about TB.[32]

- **Wudalem Amare, MS Teshome, et al.,** (2021) were conducted a cross-sectional study across 76 TB follow-up clinics. The study findings indicated that 68.7% of patients had a high level of knowledge about tuberculosis, while 31.3% scored low. Among governmental employees, only 16.7% demonstrated high knowledge levels. Regarding attitudes, 67.3% of patients displayed a positive overall attitude, while 32.7% had low attitudes. In terms of practices, 56.7% exhibited high overall practices, whereas 43.3% showed low practices. The study highlighted a general deficiency in patients' perception of TB knowledge and attitudes, emphasizing the need for targeted health education and awareness initiatives to improve understanding and treatment adherence.[33]
- **Anja Vigenschow, Jean Ronald Edoa, et al.,** (2021) were surveyed a KAP study among healthcare workers in 20 healthcare facilities across all levels in the Moyen-Ogooué province, Gabon. The study revealed that 40.8% of participants demonstrated intermediate knowledge about tuberculosis, 28.2% exhibited good knowledge, and 21.4% had poor knowledge. While healthcare workers generally displayed positive attitudes towards tuberculosis infection control, the findings underscored a significant need for enhanced infection control training, particularly for less trained staff such as assistant nurses. This emphasizes the importance of targeted training programs to strengthen healthcare workers' preparedness and improve tuberculosis control practices.[34]
- **MY Essar, KJ Rezayee, et al.,** (2022) were conducted a cross-sectional descriptive study among residents of Kabul, Afghanistan, who visited adult outpatient departments in public hospitals between January 1 and March 20, 2022. The study included 829 participants, of whom 54.3% were male and 45.7% female, with a median age of 28 years, and 63.3% were married. The majority were unemployed (75.5%), yet 54% reported a monthly income exceeding 3,000 Afghanis, reflecting a reliance on family support. The study findings revealed that 87.7% of participants possessed good knowledge about TB, while 96.5% demonstrated positive attitudes toward TB treatment and control. Poor practices related to TB prevention were reported by only a few participants. These results indicate that outpatient attendees in Kabul have a strong foundation of knowledge, attitudes, and practices regarding

TB, supporting ongoing efforts to enhance TB awareness and control in the region.[35]

- **Goedele L, Mona K, Neo KM, et al.,** (2022) were carried out a multicenter randomized controlled study involving 574 adults undergoing treatment for drug-sensitive pulmonary TB who were either tobacco smokers or reported harmful/hazardous alcohol use. Participants were randomized in a 1:1 ratio to receive either the ProLife intervention (n=283) or usual care (n=291). The study found no significant difference in TB treatment success rates between the intervention group (67.8%) and the control group. Furthermore, the ProLife intervention showed no evidence of effectiveness in achieving continuous smoking abstinence at 3- and 6-month follow-ups. In summary, the ProLife intervention did not improve TB treatment outcomes according to the study results.[36]
- **Louisa Quarcoopome, Eric Tornu, et al.,** (2022) were carried out a descriptive cross-sectional survey to evaluate the quality of life among 250 individuals with TB across four public health facilities. Using the WHO QOL Brief Questionnaire, the study assessed physical, psychological, social, and environmental domains. The findings revealed that sociodemographic factors, including marital and employment status, significantly influenced all four domains. Additionally, the site of TB infection (pulmonary or extra pulmonary) and the treatment phase affected the physical, psychological, and social domains. Other determinants, such as sex, education level, and average monthly income, were also found to impact quality of life. The study concluded that individuals with TB experience a diminished quality of life, largely shaped by their socioeconomic conditions. These findings highlight the critical need for strategies aimed at monitoring and enhancing quality of life throughout TB treatment and management.[37]
- **AA Touré, AS Magassouba, et al.,** (2022) were reported a study from Conakry, Guinea, to evaluate HRQoL among TB patients receiving treatment at 11 health centers. Using validated tools and logistic regression analysis, the study identified factors contributing to HRQoL deterioration. Among the 439 participants, 44% reported experiencing pain, while 31% reported anxiety. Key factors associated with lower HRQoL included larger household sizes and greater distances to health centers. Qualitative interviews highlighted additional challenges, such as nutritional and financial hardships exacerbated by the COVID-19 pandemic, alongside perceptions of insufficient government assistance. The findings underscore the

urgent need for targeted interventions, including nutritional and psychological support, to improve the well-being of TB patients. Such measures are especially critical for individuals facing travel restrictions, which restrict TB care to access, limit employment opportunities, and exacerbate financial strain.[38]

- **Phiman T, Paleeratana W, et al.,** (2022) were conducted a study at Choke Chai Community Hospital in North-eastern Thailand from 2016 to 2018. The study included 332 newly diagnosed TB patients from the hospital's TB clinics, with the majority being new cases (94%) and a smaller proportion (6%) comprising patients returning due to treatment discontinuation, relapse, or disease recurrence. The sample consisted of 68.7% males and 31.3% females, with an average age of 52.7 years. Most participants were married (60.5%), employed (68.6%), and had low incomes (66.6%). A significant portion had chronic diseases (73%), consumed alcohol (31.7%), or smoked (85.7%). Approximately half of the pulmonary TB patients experienced treatment delays, which were strongly associated with being over 50 years old ($p < 0.001$). The study highlighted that pulmonary tuberculosis adversely affects patients' QoL, particularly in those facing treatment delays.[39]
- **Anas HA Abu-Humaidan, Alaa Tarazi, et al.,** (2022) were carried out a cross-sectional study from May to June 2022 focusing on Jordanian university students. The survey included 602 participants, with the majority being female (60.8%), in their first three years of university (84.4%), and from healthcare-related fields of study (57.0%). The results revealed a median knowledge score of 27 out of 51, highlighting gaps, particularly in understanding TB treatment and transmission. Attitudes towards TB patients were generally positive, with a median score of 6 out of 9, reflecting minimal social stigma. Regarding TB-related practices, the median score was 6 out of 8, with most students showing appropriate actions if they suspected infection. However, 41.0% expressed uncertainty about the importance of masks in preventing airborne diseases. These findings highlight the need for targeted educational initiatives to enhance TB knowledge and practices, particularly among students in non-healthcare fields.[40]
- **EA Hammouda, WF Gobran, RM Tawfeek et al.,** (2023) were carried out a cross-sectional study in chest clinics and main chest hospitals in Alexandria, Egypt. The study included 180 participants, of whom 74.4% were male, 54.4% were married, 60.0% were aged 18–40 years, 83.3% lived in urban areas, 31.7% were illiterate, 69.5% reported insufficient income, and 10.0% had multidrug-resistant TB. The

results revealed that TB patients had significantly lower QoL scores compared to the TB-free population across all domains—physical, psychological, social, and environmental ($P < 0.0001$). Notably, patients aged 18–30 years had the highest environmental domain scores among all age groups ($P = 0.021$). The study concluded that TB significantly impacts QoL, with the physical and psychological domains being the most affected. These findings highlight the urgent need for strategies to improve the QoL of TB patients, enhancing their treatment adherence and overall well-being.[41]

- **Farman Ullah Khan et al.,** (2023) were carried out a randomized, controlled prospective study at a TB control center in Pakistan, comparing usual care with pharmaceutical care interventions. Patients in the intervention group experienced a significant improvement in EQ-5D-3L health utility scores ($p < 0.001$), increasing from a baseline mean ± SD of 0.40 ± 0.36 to 0.89 ± 0.09 after six months of treatment. In contrast, the control group showed improvement from 0.42 ± 0.35 to 0.78 ± 0.27. Although no statistically significant associations were found between intervention variables and health-related quality of life (HRQoL), the study highlighted the substantial enhancement in HRQoL achieved through pharmacist-led, patient-centered care interventions. The findings advocate for the integration of clinical pharmacists into interdisciplinary teams for managing TB patients to optimize treatment outcomes.[42]
- **S Kaaffah, IY Kusuma, et al.,** (2023) were conducted an online survey in 34 provinces in Indonesia. The study included 3,205 participants, of whom 56.4%, 91%, and 38% demonstrated high levels of KAP regarding TB, respectively. Independent determinants of high knowledge scores included being aged 26–35 years, marital status, and salary. High attitude and perception scores were independently associated with factors such as residence in a village (adjusted odds ratio: 0.76 [95% CI: 0.59–0.98]) and occupation as a civil servant (adjusted odds ratio: 1.53 [95% CI: 1.09–2.13]), respectively. The study highlighted that while most Indonesians exhibit high knowledge and positive attitudes toward TB, there remains significant scope for improving perceptions. Targeted health education initiatives are essential to raise public awareness and contribute to reducing Indonesia's TB burden. [43]

3. MATERIALS AND METHODS

A. Impact of clinical pharmacist on medication adherence among tuberculosis patients

3.1 Study Site: This study was conducted at KLE's Dr. Prabhakar Kore Hospital and MRC, NTEP centre (tertiary care hospital), Nehru Nagar, Belagavi, 2- Primary Healthcare Centres (PHCs) and 2- Urban Healthcare Centres (UHCs) at Belagavi district of Karnataka.

3.2 Study population: The intended population for this study includes, patients diagnosed with pulmonary tuberculosis who were undergoing treatment with first-line anti-tuberculosis drugs or FDC therapy under the supervision of physicians.

3.3 Study Design: The study design was randomised controlled study where the subjects were randomized into two groups i.e. interventional group and control group.

3.4Study period:

One year six months

3.5 Sample Size:

$$n = \frac{Z1-\alpha/2\ SD2}{(20\%\ \text{of}\ SD)2} \times 1.1$$

95% Confidential interval

20% Alliable error

10% attraction

n = 105.644 equivalent to **106**

3.6 Participant selection: Information regarding the target population were pulmonary tuberculosis patients. Those who satisfy the eligibility criteria were recruited.

3.7 Eligibility Criteria:

3.7.1 Inclusion Criteria:

- Patient of age ≥ 18 years of age with either sex.
- Patients newly diagnosed as positive for (pulmonary) Koch's.

- Patient referred to NTEP centre, visiting outpatient departments of respiratory medicine and general medicine of KLEs Dr. Prabhakar Kore Hospital & MRC.
- Patients should be capable of reading and comprehending the Informed Consent Form (ICF) in any of the following languages: English, Kannada, Marathi, and Hindi.

3.7.2 Exclusion Criteria:

- Patients with extra pulmonary TB.
- Patients with MDR to TB treatment.
- Patients who are having complicated health related problems.
- Special population like paediatrics, pregnant and lactating women.
- Patients not willing to participate.
- Patients interfere with loss to follow up.

3.8 Administrative and Ethical considerations:

3.8.1 Hospital Authority: Formal permission was taken from Director, Medical superintendent, Head of the department of respiratory medicine and community medicine of KLE's Dr. Prabakar Kore hospital, Belagavi, Karnataka.

3.8.2 Ethical consideration: The study was taken approval from KAHER, Belagavi of human ethics committee with Reg no: KAHER/EC/21-22/020.

3.8.3 CTRI registration: The study had been registered in clinical trials registry of India (CTRI) registration with Reg no: CTRI/2021/11/038142.

3.9 Study Procedure

This randomized controlled study was carried (conducted) at respiratory medicine outpatient and inpatient departments, KLE's Dr, Prabhakar Kore Hospital and research Centre, Belagavi.

3.9.1 Participants screening, selection & recruitment

1. Information on eligible participants were gathered from both the outpatient and inpatient departments of respiratory medicine, focusing on patients diagnosed with pulmonary tuberculosis and those undergoing antitubercular therapy (ATT). Following the procurement of Ethical Clearance from the Institutional Ethics Committee (IEC), individuals meeting the inclusion criteria were selected from the screened patients.

2. The individuals who willingly agreed to participate in the study were approached, and an informed consent form was provided to them.

3. Individual signature were obtained from the consenting subjects, and they were subsequently enrolled in the study. The enrolled participants were then randomized into case and control groups using the SNOSE method.

3.9.2 Randomization of the Participants:

A single-blinded randomized controlled trial (RCT) was carried out and implemented in our study. The randomization process involved two parallel arms in a 1:1 ratio using Sequentially Numbered Opaque Sealed Envelopes (SNOSE). One arm received usual care (Control) while the other received pharmaceutical care intervention (Test). The process of randomization was performed using a computer-based Research Randomizer, done by the investigator (clinical pharmacist). The envelopes were kept in the confidential and securely stored. Participants were then randomly assigned by opening the sealed envelopes in front of the pharmacist. The test group participants were given pharmaceutical care intervention under a clinical pharmacist in a separate room at TB centre in the tertiary care hospital and control group with usual care under other health care professionals. The clinical pharmacist conducting the trial served as the primary contact for participants during the study, remaining blinded to the initial outcome assessment to minimize bias.

3.9.3 Informed consent process:

The Informed Consent Form (ICF)/ Patient Information Sheet (PIS) were created in three languages: English, Kannada and Marathi, to accommodate the preferences and linguistic needs of the patients. Patients were offered the forms in either Kannada or Marathi, based on their preference, to ensure comprehension and comfort. Upon enrolment, the participants received a concise overview of the study and were invited to participate voluntarily. In instances where a participant's consent could not be directly obtained, consent was sought from their Legally Authorized Representative (LAR), ensuring that the participant's rights were respected. The participants thoroughly informed about the study's significance, objectives, potential benefits, and risks. They were also briefed on the duration of the study, the procedures for monitoring their health, the strict confidentiality measures in place, the process of randomization, and their freedom to withdraw from the study at any point without consequence. To

verify understanding, participants comprehension of the study details was assessed, and any queries or concerns they had been duly addressed. Based agreeing to participate in the study, participants signed two copies of the ICF; one copy was handed to the participant for their records, while the other was retained by the investigator (clinical pharmacist) for official documentation [Annexure III]. Additionally, participants were provided with a copy of the PIS for their reference [Annexure IV].

3.9.4 Data collection process:

The data for the study was gathered using a well-structured data collection form [Annexure V]. Each aspect of the patient's case profile was thoroughly examined, verified, and then documented. The information entered into the data collection forms encompassed various categories including socio-demographic particulars, past medical and medication records, family medical history, social habits, findings from examinations (both general and systemic), as well as results from both parametric and non-parametric investigations. Additionally, diagnoses, prescribed medications, and other relevant study outcomes were recorded during the monitoring phase for both the control and intervention groups.

3.9.5 Control group participants: (Usual clinical care)

The participants under the control group were only received the anti-tubercular therapy treatment and management under the supervision of the physicians and other health care professionals at a tertiary care hospital, without any involvement from pharmacist intervention. Their progress was monitored, assessed, and evaluated for various study outcomes starting from the baseline of the 1st month, followed by follow-ups at the 3rd and 6th months. These assessments were conducted at various healthcare centers, including two PHCs, two UHCs, and the tertiary care hospital (KLE Hospital) located in the Belagavi district.

3.9.6 Test group participants: (Pharmaceutical care intervention)

The participants in the test group were received the treatment and management for tuberculosis, guided by physicians and other health care professionals, with the specialized pharmaceutical care intervention from a clinical pharmacist in a private setting at the NTEP centre within a tertiary care hospital. The progress of these participants was closely monitored, assessed, and evaluated for several study outcomes

starting at the baseline of 1st month, to follow-ups at the 3rd and 6th months. These assessments were conducted at various healthcare centers, including two PHCs, two UHCs, and the tertiary care hospital (KLE Hospital) located in the Belagavi district.

3.9.7 Developing and validation of patient information leaflets (PILs):

The patient information leaflets were developed according to WHO and NTEP guidelines, and were validated by an expert team comprising four respiratory medicine physicians, three pharmacists, and one lay member. The PILs were initially created in English, later were translated into local languages of Kannada and Marathi to accommodate a wider audience. To assess readability, we utilized the Flesch Reading Ease (FRE) scale, which ranges from 0 to 100. A score below 60 indicates difficulty in reading, while a score above 60 signifies ease of comprehension. Our PILs achieved an average FRE score of 78, indicating they were easily understandable and readable. The design and layout of the PILs were evaluated using the Baker Able Leaflet Design (BALD) score, which considers factors such as line length, spacing, font size and type, indentation, inclusion of pictures/logos, colour usage, and paper texture. The mean BALD score obtained for our PILs was 25, indicating they were effectively designed for readability and understanding. The PILs encompassed concise yet comprehensive information of TB and its transmission, signs and symptoms, risk factors, treatment, management, precautions, dietary recommendations, lifestyle modifications, and contact details of investigators. These PILs were subsequently implemented and distributed in three languages as part of our pharmaceutical care intervention to educate and counsel the participants in the test group of our study [Annexure XVI].

3.10 Intervention tools used by clinical pharmacist in both Test and control groups:

***Modified Kuppuswamy's Socioeconomic Status (SES) Scale 2019 [Annexure VI]*:** Monthly income of the family was assessed based on a scoring system ranging from 3 to 29, taking into account factors such as the education level and occupation of the family head. This categorizes the community into five groups: "Lower," "Upper lower," "Lower middle," "Upper-middle," and "Upper."

Fagerstrom test for nicotine dependence (smoking and smokeless tobacco users) [Annexure VII]: The six components of questionnaire was assessed to check the nicotine dependence. The score obtained was measured based on the level of

dependence (6: High dependence, 4-6: Moderate dependence and less than 6: low dependence).

Medication Adherence Assessment for Tuberculosis Treatment (MAATT) [Annexure X]: A self-validated questionnaire consists of 8 questions were administered to the participants to assess the medication adherence of TB treatment. The reliability and validity of this questionnaire were evaluated by expert members from our institution (Cronbach's alpha i.e., $\alpha \geq 0.9$). The questionnaire measures the various factors affecting the medication adherence, such as forgetfulness, travel, concerns about treatment inconvenience, and health condition control. Scores on the MAATT questionnaire range from 0 to 8. A score below 4 indicates inadequate adherence, while a score above 4 indicates satisfactory adherence.

PCNE classification for drug related problems V9.1 [Annexure VIII]: The PCNE classification system was used to identify drug-related problems and their causes during treatment. This classification comprises three main domains for problems, nine main domains for causes, and five main domains for Planned Interventions. Additionally, there are three primary domains for the level of acceptance of interventions and four primary domains for the status of the problem.

Knowledge, Attitude, and Perception Questionnaire [Annexure XII]: The questionnaire was developed and validated based on the modified WHO TB questionnaire to test the TB knowledge and awareness, attitude and stigma, and perception of participants. The reliability was found to be good (Cronbach's alpha i.e., $\alpha \geq 0.83$). The Questionnaires consisted of four sections.

i. **First section:** Consisted of health seeking behaviour of the participant of the patient visiting clinic for their health problems and how often visits to health centre.
ii. **Second section:** Consisted ('Yes', 'No' & 'Don't know') of Knowledge of participant related to TB infection and control awareness of TB transmission, TB symptoms.
iii. **Third section:** Consisted ('Strongly disagree', 'Disagree', 'Neither agree nor disagree', 'Agree' & 'Strongly agree') of 'Attitude and stigma of participants (ATT therapy, side effects, TB care, continuation of treatment, disease condition disclosure to family members).

iv. **Fourth section:** Consisted ('Yes', 'No' & 'Don't know') of perception towards TB of participants (TB cure, expenditure in TB, mental illness, information about TB).

Health-related QoL (SF-36) [Annexure XI]: The SF 36 questions were organized, scored, and weighted to create two indices that provide understanding into both mental and physical functioning and overall health-related quality of life.

FACIT- Treatment Satisfaction – General (TS-G) [Annexure XIV]: The initial two items on the scale were assessed using a five-point scale (0 = a lot worse to 4 = a lot better), the following three items used a four-point scale (0 = No, not at all to 3 = Yes, completely), the next two items were evaluated with a three-point scale (0 = No, 1 = May be, 2 = Yes) and the final item was rated on a five-point scale (0 = poor to 4 = Excellent). Feedback on participants satisfaction with the overall treatment was documented.

FACIT- Satisfaction With Pharmacist (SWiP) [Annexure XIII]: The seven components of the Pharmacist Satisfaction (SWiP) scale were evaluated using a five-point Likert scale (0 = not at all to 4 = very much). Feedback from the test group of TB patients regarding their interactions with clinical pharmacists was recorded.

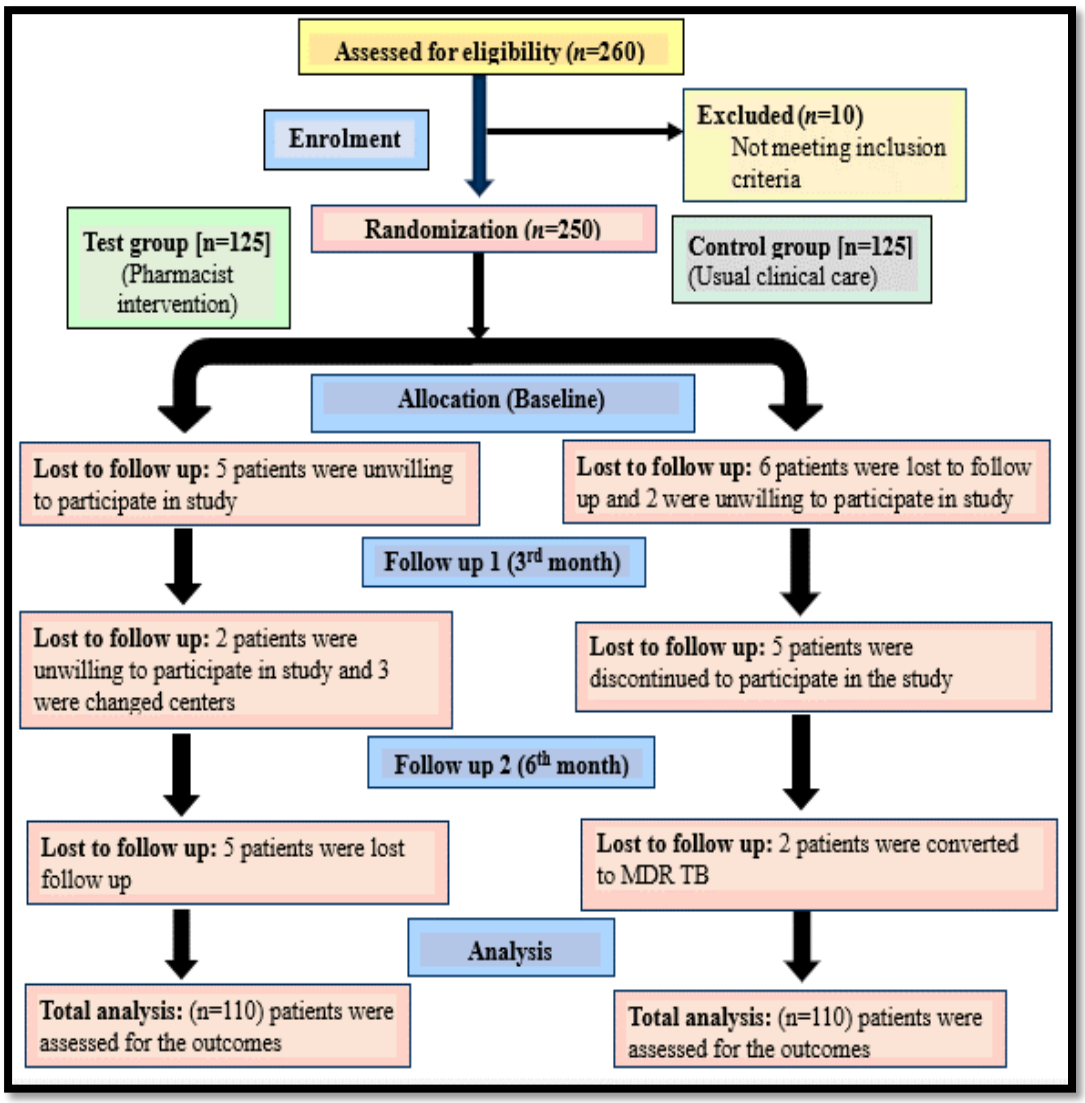
3.11 Study Materials:

1. Informed Consent Forms (ICF).
2. Patient Information Sheets (PIS)
3. Patient Information Leaflets (PILs).
4. Modified WHO KAP Questionnaire.
5. Data collection forms.
6. Modified Kuppuswamy's Socioeconomic Status (SES) Scale 2019.
7. Fagerstrom test for nicotine dependence.
8. Medication adherence assessment for TB treatment (MAATT) scale.
9. PCNE classification for drug related problems (Version 9.1).
10. ADR assessment tools (ADRs causality - WHO-UMC scale, Naranjo's scale, ADRs severity - Modified Hartwig Siegel scale & ADRs preventability – Modified Schumock and Thronton scale).
11. 36-item short form survey (SF-36) for health-related QoL.

12. FACIT-TS-G -- Functional Assessment of Chronic Illness Therapy - Treatment Satisfaction – General (Version 4).
13. FACIT-SWiP – Functional Assessment of Chronic Illness Therapy - Satisfaction with Pharmacist (Version 4).

3.12 Consort flow chart of study procedure in TB patients

Fig 5: The schematic consort flow chart representation of TB patients



B. Assessment of KAP towards tuberculosis among health care professionals.

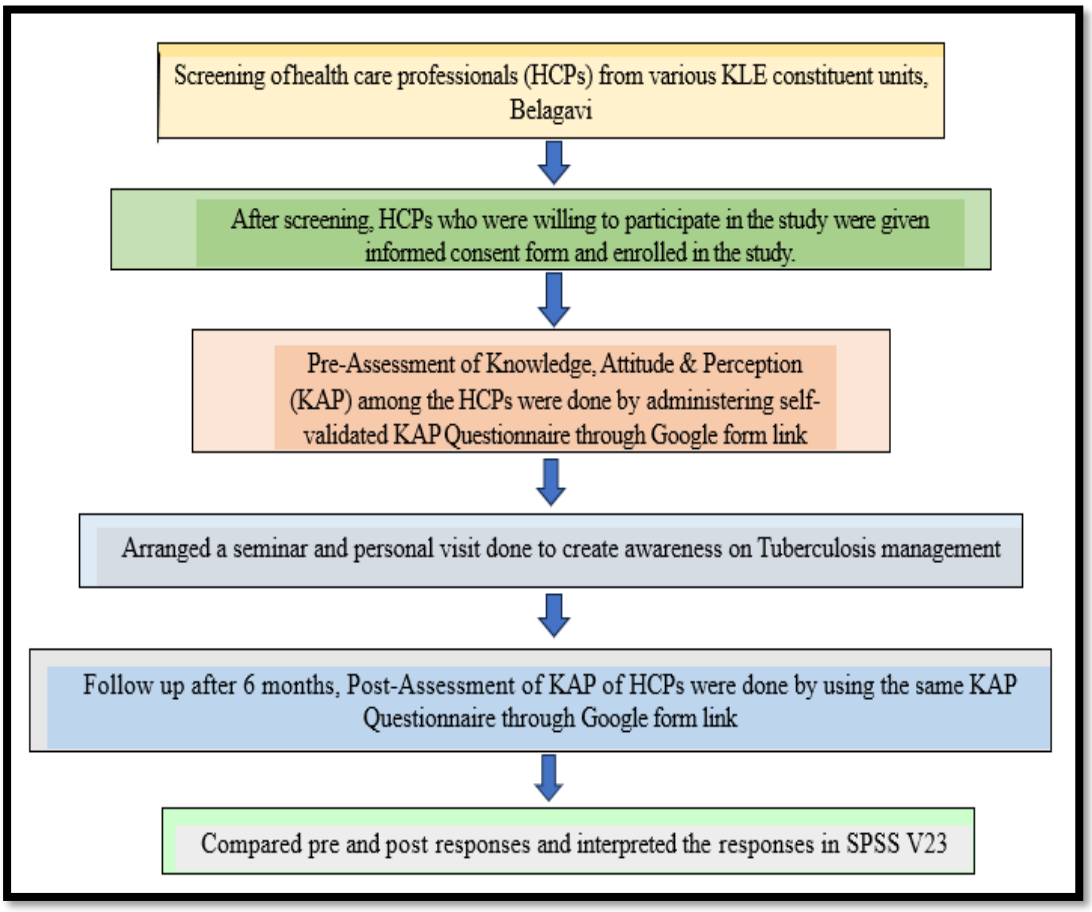
A self-designed and validated Knowledge, Attitude, and Perception (KAP) questionnaire was developed and distributed to healthcare professionals across various constituent units of KLE institutions. Due to their busy schedule the questionnaire was developed in Google form and the link was circulated to the health care professionals through WhatsApp platform.

Knowledge, Attitude, and Perception Questionnaire for healthcare professionals (HCPs) [Annexure XV]: The questionnaire was developed and validated based on the modified WHO TB questionnaire and various sources to test the TB knowledge, attitude, and perception of participants. The reliability was found to be good (Cronbach's alpha i.e., $\alpha \geq 0.89$). The Questionnaires consisted of four sections.

i. **First section:** Consisted of the general information on participants willingness and socio demographic details.
ii. **Second section:** Consisted (5-point Likert scale options 'Strongly disagree', 'Disagree', 'Neither agree nor disagree', 'Agree' & 'Strongly agree') of Knowledge of participant related to TB infection and control awareness of TB transmission, TB symptoms.
iii. **Third section:** Consisted (5-point Likert scale options 'Strongly disagree', 'Disagree', 'Neither agree nor disagree', 'Agree' & 'Strongly agree') of Attitude of participants (prevention of TB transmission, screening, TB care, sputum examination, periodic education).
iv. **Fourth section:** Consisted (5-point Likert scale options 'Strongly disagree', 'Disagree', 'Neither agree nor disagree', 'Agree' & 'Strongly agree') of practice towards TB patients (isolation rooms, ventilation, mask wear in approaching patient, nutritional information on treating TB patients).

3.13 Flow chart of study procedure among health care professionals

Fig 6: The schematic consort flow chart representation of HCPs



3.14 Study outcome measures:

3.14.1 Primary outcomes:

1. To improve the medication adherence on the TB medication within the timeline and evaluate the impact of clinical pharmacist among tuberculosis patients
2. To evaluate the drug related problems during the period of treatment and identify if any ADRs/side effects occurred during the treatment.
3. To educate and improve the knowledge, attitude and perception towards TB management among the patients.

3.14.2 Secondary outcomes:

4. To evaluate the effectiveness of counseling provided by clinical pharmacists in the implementation of Patient Information Leaflets (PILs).
5. To evaluate TB patients' compliance with managing physical, mental, and overall health concerns, aiming to enhance their quality of life.

6. To collaborate with medical practitioners and other healthcare professionals to support the WHO's objective of TB elimination by 2035, strengthening their involvement in the process.

3.15 Data Analysis:

The data analysis was performed in alignment with the study objectives and the hypotheses tested. Both descriptive and inferential statistical techniques were applied to examine the collected data. Descriptive statistics, including frequency, mean, standard deviation, and mean percentage, were used to offer a detailed summary of the data. For inferential statistics, the chi-square test, Mann-Whitney U test, t-test, and Karl Pearson's correlation coefficient were utilized to identify significant associations and differences among the groups. A significance level of $p<0.05$ was established to determine statistical significance.

4. RESULTS

A. Impact of clinical pharmacist on improving medication compliance among tuberculosis patients.

4.1 Socio Demographic details:

A total of 250 patients were randomly allocated into test and control groups. Among them, 30 patients were lost to follow-up by the end of the second follow-up (6th month). Therefore, we assessed a total of 220 patients (110 in the test group and 110 in the control group) for the study outcomes. Regarding background information, the majority of participants were males in both the test and control groups (53.64% in the test group and 55.45% in the control group), and most belonged to the 26-35 years age group (57.27% in the test group and 60% in the control group). Approximately 83.64% of participants in both groups were literate, and the majority resided in urban areas (52.73% in the test group and 55.45% in the control group) compared to rural areas (47.27% in the test group and 44.55% in the control group). The majority identified as Hindu (84.55% in the test group and 78.18% in the control group), followed by Muslims (9.09% in the test group and 16.36% in the control group), with other religions such as Christian, Jainism and Buddhism making up a smaller percentage (6.36% in the test group and 5.45% in the control group). In terms of marital status, the majority were married (70% in the test group and 78.18% in the control group). Regarding BMI, most participants were either underweight (41.82% in the test group and 48.18% in the control group) or of healthy weight (58% in the test group and 51.82% in the control group). In terms of occupation, the majority were employed (31.82% in the test group and 24.55% in the control group), followed by farmers (28.18% in the test group and 15.45% in the control group), housewives (12.73% in the test group and 21.82% in the control group), unemployed individuals (13.64% in the test group and 27.27% in the control group), and daily labourers (13.64% in the test group and 10.91% in the control group). Socioeconomically, the majority belonged to the lower middle class (31.82% in the test group and 39.09% in the control group), followed by the upper lower and upper middle-class groups. [Table 2]

Table 2: Comparison of control group and test group with Socio-demographic profile of TB patients

Socio-demographic profile	Test (n=110)	(%)	Control (n=110)	(%)
Age groups				
15-25 years	13	(11.82)	11	(10.00)
26-35 years	63	(57.27)	66	(60.00)
36-45 years	34	(30.91)	33	(30.00)
Gender				
Female	51	(46.36)	49	(44.55)
Male	59	(53.64)	61	(55.45)
Literacy				
Illiterate	18	(16.36)	18	(16.36)
Literate	92	(83.64)	92	(83.64)
Residency				
Rural	52	(47.27)	49	(44.55)
Urban	58	(52.73)	61	(55.45)
Religion				
Hindu	93	(84.55)	86	(78.18)
Muslim	10	(9.09)	18	(16.36)
Others	7	(6.36)	6	(5.45)
Marital status				
Unmarried	33	(30.00)	24	(21.82)
Married	77	(70.00)	86	(78.18)
BMI				
Underweight	46	(41.82)	53	(48.18)
Healthy weight	64	(58.18)	57	(51.82)
Occupation				
Daily labourer	15	(13.64)	12	(10.91)
Farmer	31	(28.18)	17	(15.45)
Housewife	14	(12.73)	24	(21.82)
Unemployed	15	(13.64)	30	(27.27)
Employee	35	(31.82)	27	(24.55)
Socioeconomic Status				
Upper	3	(2.73)	4	(3.64)
Upper middle	23	(20.91)	16	(14.55)
Lower middle	35	(31.82)	43	(39.09)
Upper lower	35	(31.82)	29	(26.36)
Lower	14	(12.73)	18	(16.36)
Total	110	100.0	110	100.0

In this study, the majority of participants were newly diagnosed with TB were undergoing treatment with ATT medication (59.09% in the test group and 55.45% in the control group). Regarding social history, most were non-alcoholic or non-smokers (45.45% in the test group and 50% in the control group), while a minority were smokers (21.82% in the test group and 23.64% in the control group) or engaged in smokeless tobacco use (23.64% in the test group and 17.27% in the control group). The majority of participants did not have any comorbidities; only a few had hypertension (5.45% in both the test and control groups) and diabetes (2.73% in the test group and 3.64% in the control group). [Table 3]

Table 3: Comparison of control group and test group with TB drug treatment, social history and comorbidities of TB patients.

Socio-demographic profile	Test (n=110)	(%)	Control (n=110)	(%)
TB drug treatment				
FDC	45	(40.91)	49	(44.55)
ATT	65	(59.09)	61	(55.45)
Social History				
Smoker	24	(21.82)	26	(23.64)
Smokeless tobacco	26	(23.64)	19	(17.27)
Alcohol	0	(0.00)	3	(2.73)
Alcoholic with smoking	10	(9.09)	7	(6.36)
Non-alcoholic/smoker	50	(45.45)	55	(50.00)
Comorbidities				
Hypertension	6	(5.45)	6	(5.45)
Diabetes	3	(2.73)	4	(3.64)
No comorbidities	101	(91.82)	100	(90.91)
Total	110	100.0	110	100.0

4.2 Identifying the nicotine dependence level among smoking and smokeless tobacco chewing based on fagerstrom test.

Among the 220 patients, 50 were smokers and 45 were users of smokeless tobacco, all of whom were screened to evaluate nicotine dependence. We assessed the Nicotine dependence for both smoking and smokeless tobacco chewing based on fagerstrom test for smoking and Modified fagerstrom test for smokeless tobacco users. The fagerstrom test determines the risk of nicotine dependence in patients who consume tobacco, categorizing them into four levels: low dependence, low to

moderate dependence, moderate dependence, and high dependence. In our study we found that low dependence of nicotine (74%) followed by low to moderate (22%) and moderate dependence (4%) of nicotine among smoking patients as shown in figure 7. In other hand we found that high dependence (77.78%) of nicotine consuming followed by low to moderate dependence (22.22%) of nicotine consuming among smokeless tobacco consuming patients as shown in figure 8.

Fig. 7: Fagerstrom test for nicotine dependence among smoking patients

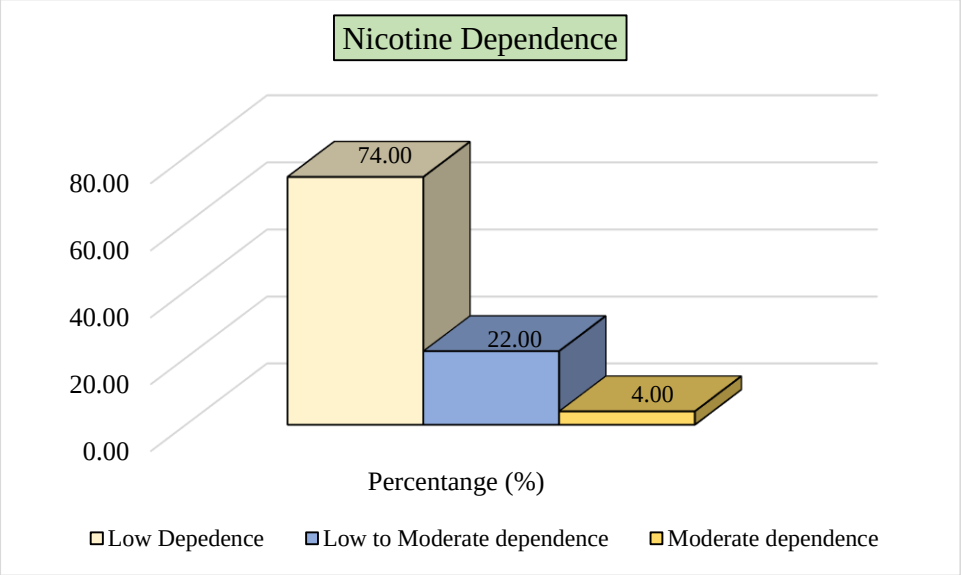
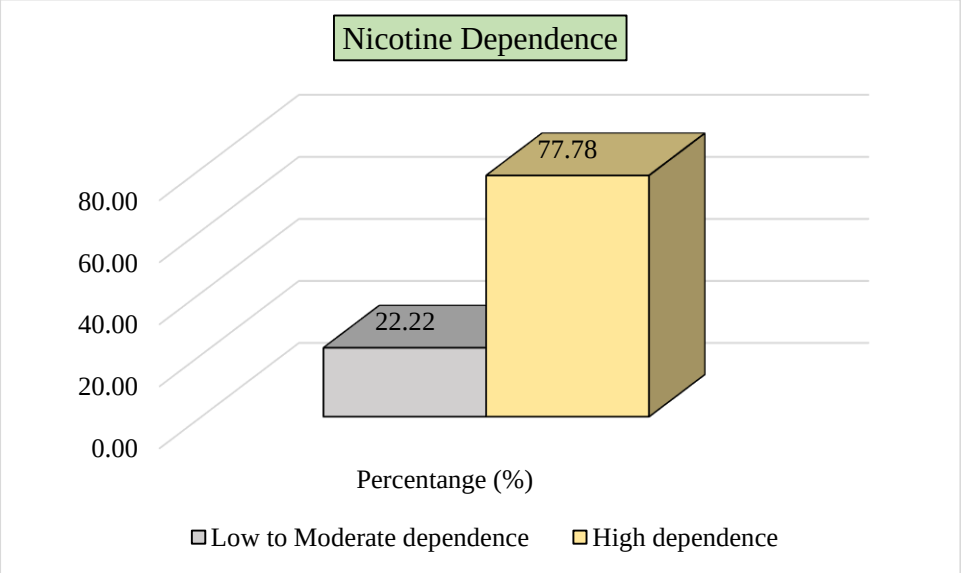


Fig. 8: Modified Fagerstrom test for nicotine dependence among smokeless tobacco patients



4.3 Identification of Drug Related Problems (DRPs) and its related causes:

By using the PCNE classification (V9.1), our analysis identified drug-related problems (DRPs) in both the test and control groups. Specifically, 3 (1.36%) patients experienced suboptimal drug treatment effects, 42 (19.09%) had untreated symptoms or indications impacting treatment effectiveness, 129 (58.64%) possibly encountered adverse drug events related to treatment safety, and 46 (20.91%) had unclear problems or complaints attributed to other factors, as detailed in Table 3. The causes of DRPs observed among both test and control groups in this study included multiple drug prescriptions for a single indication in 4 (1.82%) patients, excessively high doses in 10 (4.55%), overly long treatment durations in 57 (25.91%), patient non-adherence to prescribed dosages or complete non-usage in 24 (10.91%), improper timing or dosing intervals in 56 (25.45%), and issues related to medication reconciliation during patient transfers in 69 (31.36%) patients, as shown in Table 4.

4.4 Acceptance of the Intervention proposals, planned interventions & status of the DRPs:

In our interventional study, we introduced pharmacist-led interventions to the test group from the start. Out of 110 patients in the test group, 94 (85.45%) fully embraced and implemented the pharmacist's interventions, 14 (12.73%) accepted the interventions but implemented them only partially, and 2 (1.82%) agreed to the interventions but the extent of implementation was unclear, as depicted in figure 7. Regarding the planned interventions for the test group, drug counseling was provided to 83 patients (75.45%), written information was given to 12 patients (10.91%) who had hearing impairments, and family member counseling was conducted for 15 individuals (13.64%), as detailed in figure 8. By the end of the six-month follow-up period, we observed that drug-related problems had been completely resolved for 74 (67.27%) of the patients in the test group, while 36 (32.73%) still had partially resolved issues.

Table 4: Detailed drug related problems (PCNE)

THE PROBLEMS								
PRIMARY DOMAIN	**CODE**	**PROBLEM**	**FREQUENCY (N=220)**		**PERCENT (%)**	**TOTAL (N=220)**		**TOTAL (%)**
			Test	**Control**	**Test**	**Control**		
1. Treatment effectiveness	P1.2	Effect of drug treatment not optimal	3	0	2.73	0	3	1.36
	P1.3	Untreated symptoms or indication	16	26	14.55	23.64	42	19.09
2. Treatment Safety	P2.1	Adverse drug event(possibly) occurring	57	72	51.82	65.45	129	58.64
3. Other	P3.2	Unclear problem/ complaint. Further clarification necessary	34	12	30.91	10.91	46	20.91
TOTAL			110	110	100	100	220	100

Table 5: Causes for drug related problems (PCNE)

THE CAUSES								
PRIMARY DOMAIN	**CODE**	**CAUSE**	**FREQUENCY (N=220)**		**PERCENT (%)**		**TOTAL (N=220)**	**TOTAL (%)**
			Test	**Control**	**Test**	**Control**		
1. Drug selection	C1.6	Too many different drugs/active ingredients prescribed for indication	2	2	1.82	1.82	4	1.82
2. Dose selection	C3.2	Drug dose of a single active ingredient too high	6	4	5.45	3.64	10	4.55
3. Treatment duration	C4.2	Duration of treatment too long	30	27	27.27	24.55	57	25.91
4. Patient related	C7.1	Patient intentionally uses/takes less drug than prescribed or does not take the drug at all for whatever reason	16	8	14.55	7.27	24	10.91
	C7.7	Inappropriate timing or dosing intervals	27	29	24.55	26.36	56	25.45
5. Patient transfer related	C8.1	Medication reconciliation problem	29	40	26.36	36.36	69	31.36
TOTAL			110	110	100	100	220	100

Fig. 9: The planned interventions

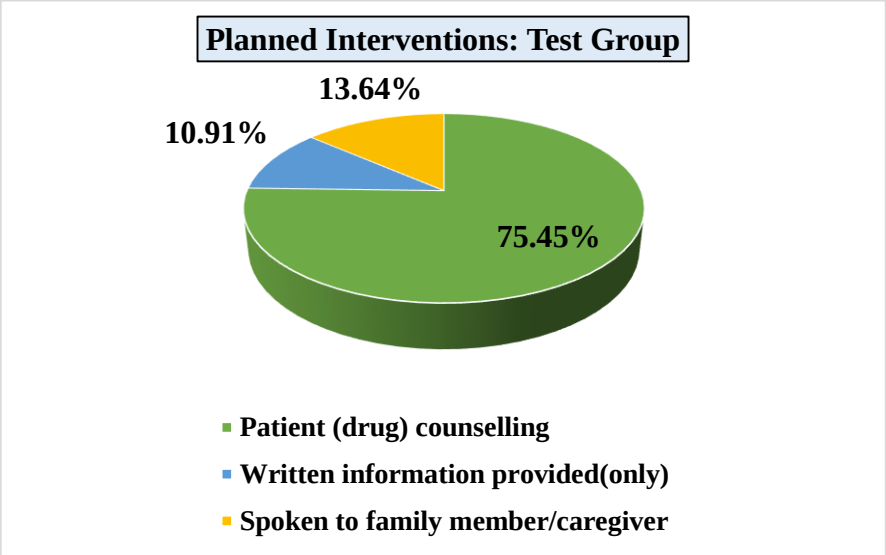
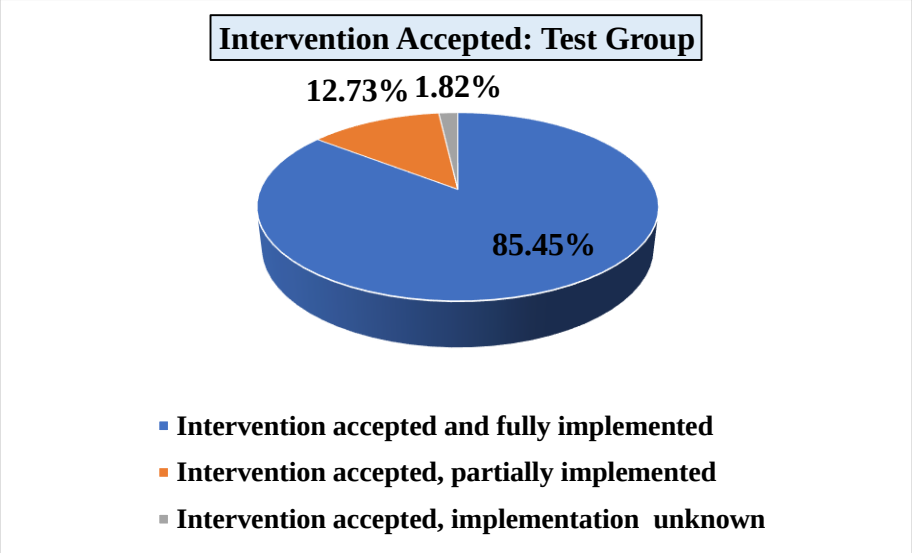


Fig. 10: Acceptance of the intervention proposals



4.5 Evaluation of Adverse drug reactions (ADRs) observed in the participants:

In our study, the majority of ADRs, accounting for 95.85%, occurred during the intensive phase of treatment, while only 4.15% appeared in the continuation phase across both the test and control groups. About half of the ADRs manifested within the first week of treatment initiation. The most frequent ADRs involved gastrointestinal issues such as nausea, vomiting, abdominal pain, and headaches. The commonly observed ADRs in our study related to Isoniazid included Hepatotoxicity (4.55%),

Peripheral neuritis (5%), GI disturbance (68.18%), and Skin rashes (2.73%), as depicted in Table 6.

Table 6: Comparison of test group and control group with presence of ADR status in Isoniazid category

Isoniazid	Test group	%	Control group	%	Total	%	Chi-square	p-value
Hepatotoxicity								
Absent	104	94.55	106	96.36	210	95.45	0.4190	0.5170
Present	6	5.45	4	3.64	10	4.55		
Peripheral neuritis								
Absent	103	93.64	106	96.36	209	95.00	0.8610	0.3530
Present	7	6.36	4	3.64	11	5.00		
GI disturbance								
Absent	33	30.00	37	33.64	70	31.82	0.3350	0.5630
Present	77	70.00	73	66.36	150	68.18		
Skin rashes								
Absent	106	96.36	108	98.18	214	97.27	0.6850	0.4080
Present	4	3.64	2	1.82	6	2.73		
Total	110	100.00	110	100.00	220	100.00		

*p<0.05

The commonly observed ADRs in our study related to Rifampicin included Orange/Red Colour Urine (100%), Abdominal Pain (23.64%), Flu-Like Syndrome (7.73%), and Nausea/Vomiting (20%), as demonstrated in table 7.

Table 7: Comparison of test group and control group with presence of ADR status in Rifampicin category

Rifampicin	Test group	%	Control group	%	Total	%	Chi-square	p-value
Orange/Red Colour Urine								
Absent	0	0.00	0	0.00	0	0.00	0.0000	1.0000
Present	110	100.0	110	100.0	220	100.0		
Abdominal Pain								
Absent	85	77.27	83	75.45	168	76.36	0.1010	0.7510
Present	25	22.73	27	24.55	52	23.64		
Flu Like Syndrome								

Absent	99	90.00	104	94.55	203	92.27	1.5940	0.2070
Present	11	10.00	6	5.45	17	7.73		
Nausea/Vomiting								
Absent	81	73.64	95	86.36	176	80.00	5.5680	0.0180 *
Present	29	26.36	15	13.64	44	20.00		
Total	110	100.0	110	100.0	220	100.0		

*p<0.05

The commonly observed ADRs in our study related to Pyrazinamide included Arthralgia (1.82%), Hepatotoxicity (4.55%), Malaise (3.18%), Anorexia (1.36%), and Nausea/vomiting (20%), as depicted in Table 8.

Table 8: Comparison of test group and control group with presence of ADR status in Pyrazinamide category

Pyrazinamide	Test group	%	Control group	%	Total	%	Chi-square	p-value
Arthralgia								
Absent	108	98.18	108	98.18	216	98.18	0.0000	1.0000
Present	2	1.82	2	1.82	4	1.82		
Hepatotoxicity								
Absent	104	94.55	106	96.36	210	95.45	0.4190	0.5170
Present	6	5.45	4	3.64	10	4.55		
Malaise								
Absent	106	96.36	107	97.27	213	96.82	0.1480	0.7010
Present	4	3.64	3	2.73	7	3.18		
Anorexia								
Absent	109	99.09	108	98.18	217	98.64	-	1.0000
Present	1	0.91	2	1.82	3	1.36		
Nausea/vomiting								
Absent	81	73.64	95	86.36	176	80.00	5.5680	0.0180*
Present	29	26.36	15	13.64	44	20.00		
Total	110	100.00	110	100.00	220	100.00		

*p<0.05

The commonly observed ADRs in our study associated with the Ethambutol were Ocular side effects (1.36%), Optic neuritis (0.91%), Pruritis (5%), GI disturbance (68.18%), and Headache (20.45%) as shown in Table 9.

Table 9: Comparison of test group and control group with presence of ADR status in Ethambutol category

Ethambutol	Test group	%	Control group	%	Total	%	Chi-square	p-value
Ocular side effects								
Absent	109	99.09	108	98.18	217	98.64	-	1.0000
Present	1	0.91	2	1.82	3	1.36		
Optic neuritis								
Absent	110	100.00	108	98.18	218	99.09	-	0.4983
Present	0	0.00	2	1.82	2	0.91		
Pruritis								
Absent	103	93.64	106	96.36	209	95.00	0.8610	0.3530
Present	7	6.36	4	3.64	11	5.00		
GI disturbance								
Absent	33	30.00	37	33.64	70	31.82	0.3350	0.5630
Present	77	70.00	73	66.36	150	68.18		
Headache								
Absent	83	75.45	92	83.64	175	79.55	2.2630	0.1330
Present	27	24.55	18	16.36	45	20.45		
Total	110	100.00	110	100.00	220	100.00		

*$p<0.05$

4.6 Assessment of ADRs severity, causality and preventability by different scales.

We evaluated out the severity of ADRs using the modified Hartwig and Siegal scale. In our findings, 102 (92.73%) ADRs in the test group and 106 (96.36%) in the control group were categorized as mild (Level 1 and 2), while 8 (7.27%) in the test and 4 (3.64%) in the control were moderate (Level 3 and 4). There were no ADRs classified as severe. The severity findings of ADRs by using modified Hartwig and Siegal scale is shown in Table 10.

Table 10: Severity of ADRs by using Modified Hartwig Siegel scale

SNo	Hartwig Siegel scale	Test (n)	Control (n)	Test (%)	Control (%)
1	Mild	102	106	92.73	96.36
2	Moderate	8	4	7.27	3.64

By using the Naranjo algorithm for causality assessment, 102 (92.73%) ADRs in the test group and 105 (95.45%) in the control were deemed possible, and 8 (7.27%) in the test and 5 (4.55%) in the control were probable. There were no definite ADRs recorded. The causality findings of ADRs by using Naranjo's scale is shown in Table 11.

Table 11: Causality of ADRs by using Naranjo's Scale

SNo	Naranjo scale	Test (n)	Control (n)	Test (%)	Control (%)
1	Possible	102	105	92.73	95.45
2	Probable	8	5	7.27	4.55

Additionally, we used the WHO-UMC scale for causality assessment, we found 98 (89.09%) ADRs in the test group and 99 (90%) in the control were noted as possible, and 12 (10.91%) in the test and 11 (10%) in the control were probable/likely. There were no certain/unclassified/unlikely/assessable ADRs recorded. The causality findings of ADRs by using WHO-UMC scale is shown in Table 12.

Table 12: Causality of ADRs by using WHO-UMC scale

SNo	WHO-UMC scale	Test (n)	Control (n)	Test (%)	Control (%)
1	Possible	98	99	89.09	90
2	Probable/Likely	12	11	10.91	10

According to the Schumock and Thornton preventability assessment scale, 95 (86.36%) ADRs in the test group and 102 (92.73%) in the control group were classified as definitely preventable, with 15 (13.64%) in the test and 8 (7.27%) in the control categorized as probably preventable. None of the ADRs were classified as not preventable. The Preventability of ADRs by using Modified Schumock and Thornton Scale is shown in table 13.

Table 13: Preventability of ADRs by using Modified Schumock and Thornton Scale

Sno	Schumock and Thorton scale	Test (n)	Control (n)	Test (%)	Control (%)
1	Definitely Preventable	95	102	86.36	92.73
2	Probably Preventable	15	8	13.64	7.27

4.7 Assessment and evaluation of medication adherence of TB patients using MAATT questionnaire.

Ensuring patient adherence to their prescribed treatment regimen is a vital responsibility of clinical pharmacists by keeping records and offering guidance on medication usage and dosage. Medication adherence is particularly critical in infectious diseases such as TB, where discontinuation of medication can result in the development of MDR-TB. In our study, we employed a self-validated questionnaire known as the Medication Adherence Assessment for Tuberculosis Treatment (MAATT) scale, proven to be the most reliable method for assessing medication adherence among TB patients.

We conducted a comparison of the Baseline (1st month), Follow-up 1 (3rd month), and Follow-up 2 (6th-month) time points of the MAATT scale using both independent T-tests between the groups and dependent T-tests within the groups. Our analysis revealed that the mean scores of MAATT for all time points were subjected to an independent t-test to determine the significance of the data and understand variations. The overall mean medication adherence score of patients increased progressively from the baseline of the 1st month (4.57 ± 0.63) to (6.16 ± 1.11) at Follow-up 1 (3rd month) and (7.33 ± 0.94) at Follow-up 2 (6th month) among patients in the control group, indicating an enhancement in medication adherence among those receiving usual clinical care. Conversely, the overall mean medication adherence score of patients increased from the baseline of the 1st month (4.55 ± 0.70) to (6.77 ± 0.90) at Follow-up 1 (3rd month) and (7.85 ± 0.45) at Follow-up 2 (6th month) among patients in the test group who received intervention under clinical pharmacist supervision. Moreover, a significant increase in mean scores was observed in the test group compared to the control group. The most notable effect on adherence

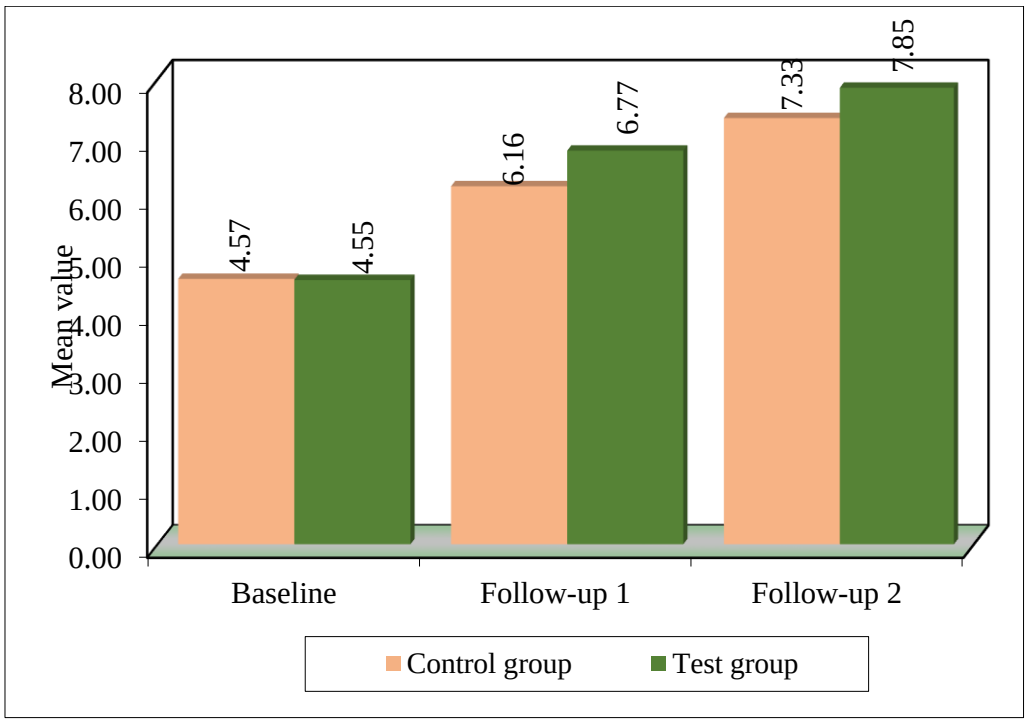
was observed between the baseline of the 1st month and the 6th month, as indicated by the t-values. The differences in medication adherence scores between the time points were found to be statistically significant (p=0.0001) as shown in table 14 and figure 11.

Table 14: Comparison of control group and test group with MAATT at different treatment times by independent t test

Times	Control group		Test group		t-value	p-value
	Mean	Std.Dev.	Mean	Std.Dev.		
Baseline	4.57	0.63	4.55	0.70	0.3045	0.7610
Follow-up 1	6.16	1.11	6.77	0.90	-4.4725	0.0001*
Follow-up 2	7.33	0.94	7.85	0.45	-5.2103	0.0001*

*p<0.05

Fig. 11: Graph showing the comparison of control group and test group with MAATT at different treatment times by independent t test



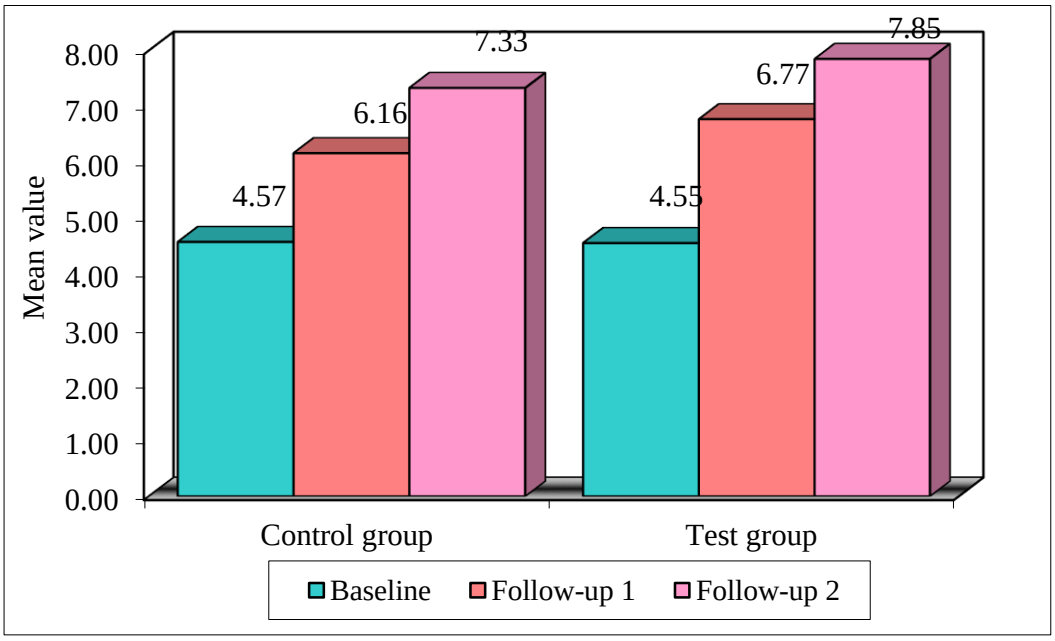
We observed that the mean difference scores of MAATT within the groups for all time points were analyzed using dependent T-tests to establish the significance of the data and understand variation. The overall mean difference scores of patients increased from the baseline of the 1st month to follow-up 1 of the 3rd month (-1.59 ± 1.27), with a percentage change of -34.79. From the baseline of the 1st month to follow-up 2 of the 6th month, the overall mean difference scores increased (-2.75 ± 1.09), with a percentage change of -60.24. Additionally, from follow-up 1 of the 3rd month to follow-up 2 of the 6th month, the overall mean difference scores increased (-1.16 ± 1.14), with a percentage change of -18.88. These findings indicates an increase in medication adherence from the baseline of 1st month to follow-up 2 of the 6th month among the control group patients who received usual clinical care. Similarly, in the test group, the overall mean difference scores of patients increased from the baseline of the 1st month to follow-up 1 of the 3rd month (-2.23 ± 0.99), with a percentage change of -49. From the baseline of the 1st month to Follow-up 2 of the 6th month, the overall mean difference scores increased (-3.30 ± 0.84), with a percentage change of -72.60. Moreover, from follow-up 1 of the 3rd month to follow-up 2 of the 6th month, the overall mean difference scores increased (-1.07 ± 0.89), with a percentage change of -15.84. These findings indicates an increase in medication adherence from the baseline of 1st month to follow-up 2 of the 6th month among the test group patients who received pharmaceutical care under the clinical pharmacist. The maximum effect on adherence was noted for the period between the 1st month and the 6th month, as indicated by the t-values. The difference in medication adherence scores between the time points was statistically significant (p=0.0001) as shown in table 15 and figure12.

Table 15: Comparison of different treatment times with MAATT in control group and test group by dependent t test

Groups	Times	Mean	SD	Mean Diff.	SD Diff.	% of change	t-value	p-value
Control group	Baseline	4.57	0.63					
	Follow-up 1	6.16	1.11	-1.59	1.27	-34.79	-13.1839	0.0001*
	Baseline	4.57	0.63					
	Follow-up 2	7.33	0.94	-2.75	1.09	-60.24	-26.6209	0.0001*
	Follow-up 1	6.16	1.11					
	Follow-up 2	7.33	0.94	-1.16	1.14	-18.88	-10.7284	0.0001*
Test group	Baseline	4.55	0.70					
	Follow-up 1	6.77	0.90	-2.23	0.99	-49.00	-23.5422	0.0001*
	Baseline	4.55	0.70					
	Follow-up 2	7.85	0.45	-3.30	0.84	-72.60	-41.1525	0.0001*
	Follow-up 1	6.77	0.90					
	Follow-up 2	7.85	0.45	-1.07	0.89	-15.84	-12.7094	0.0001*

*p<0.05

Fig. 12: Graph showing the comparison of different treatment times with MAATT in control group and test group



4.8 Assessment and evaluation of knowledge, attitude and perception among the tuberculosis patients

Regarding health seeking behaviour we assessed that about 97.27% of the patients in both test and control group patients that they usually go to private clinic whenever they feel sick or to treat a general health problem and only 2.73% patients of both groups prefer for government clinic or hospital. About 84.55% in both groups at once in a month generally seek health care at a clinic or hospital, 14.55% in both groups the patients seeks at least twice a year or more to the healthcare clinic or hospital followed by only 0.91% patients in both groups seeks once per year to the healthcare clinic or hospital. The comparison of both control and test groups with Health-seeking behaviour of TB patients was mentioned at table 16.

Table 16: Comparison of control group and test group with Health-seeking behaviour of TB patients

Health-seeking behaviour	**Control group**	**%**	**Test group**	**%**	**Total**	**%**
Where do you usually go if you are sick, or to treat a general health problem?						
Private clinic	107	97.27	107	97.27	214	97.27
Government clinic or hospital	3	2.73	3	2.73	6	2.73
How often do you generally seek health care at a clinic or hospital?						
Once in a month	93	84.55	93	84.55	186	84.55
Twice a year or more	16	14.55	16	14.55	32	14.55
Once per year	1	0.91	1	0.91	2	0.91
Total	110	100.0	110	100.0	220	100.0

4.8.1 TB knowledge and awareness:

During the assessment and evaluation of knowledge and awareness regarding tuberculosis (TB), patients underwent interviews concerning various aspects of the disease, including its severity, signs and symptoms, modes of transmission, preventive measures, and its occurrence across different age demographics. The questionnaire administered in three treatment times i.e., baseline, follow up 1 and follow up 2. By using the Mann Whitney U-test in each item, both the control and test

groups initially demonstrated low levels of knowledge and awareness. For Q1, the control group had a mean rank of 110.6 and the test group had a mean rank of 110.4, resulting in non-significant differences (U-value = 6043, Z-value = 0.0138, p-value = 0.9890). However, in follow-up 1, the control group exhibited a mean rank of 126.7 and the test group 94.3, with a significant improvement observed (U-value = 4268.0, Z-value = 3.7739, p-value = 0.0002). This trend continued in follow-up 2, where the control group's mean rank decreased to 84.0 and the test group's increased to 137.0, indicating highly significant improvement (U-value = 3135.0, Z-value = -6.1740, p-value = 0.0001). Similarly, for Q2, the control group initially had a mean rank of 94.8 and the test group 126.2 (U-value = 4323.5, Z-value = -3.6563, p-value = 0.0003), with significant improvement observed in follow-up 1 (U-value = 5076.0, Z-value = 2.0622, p-value = 0.0392) and highly significant improvement in follow-up 2 (U-value = 3080.0, Z-value = -6.2905, p-value = 0.0001). The pattern persisted across Q3, Q4, and Q5, with varying degrees of significance in improvement observed in follow-up assessments for both groups as shown in table 17.

Table 17: Comparison of control group and test group with responses of patient in each item of TB knowledge and awareness at different treatment times by using Mann Whitney U-test

Questions	**Treatment times**	**Control group**	**Test group**	**U-value**	**Z-value**	**P-value**
		Mean rank	Mean rank			
Q1	Baseline	110.6	110.4	6043.0	0.0138	0.9890
	Follow up 1	126.7	94.3	4268.0	3.7739	0.0002*
	Follow up 2	84.0	137.0	3135.0	-6.1740	0.0001*
Q2	Baseline	94.8	126.2	4323.5	-3.6563	0.0003*
	Follow up 1	119.4	101.6	5076.0	2.0622	0.0392*
	Follow up 2	83.5	137.5	3080.0	-6.2905	0.0001*
Q3	Baseline	110.2	110.8	6014.0	-0.0752	0.9401
	Follow up 1	159.1	61.9	708.5	11.3142	0.0001*
	Follow up 2	104.5	116.5	5390.0	-1.3971	0.1624
Q4	Baseline	93.5	127.5	4180.0	-3.9603	0.0001*
	Follow up 1	120.5	100.5	4949.5	2.3302	0.0198*
	Follow up 2	86.5	134.5	3410.0	-5.5914	0.0001*
Q5	Baseline	110.1	110.9	6005.0	-0.0943	0.9249
	Follow up 1	121.9	99.1	4796.5	2.6543	0.0079*
	Follow up 2	57.2	163.8	191.5	-12.409	0.0001*

*$p<0.05$

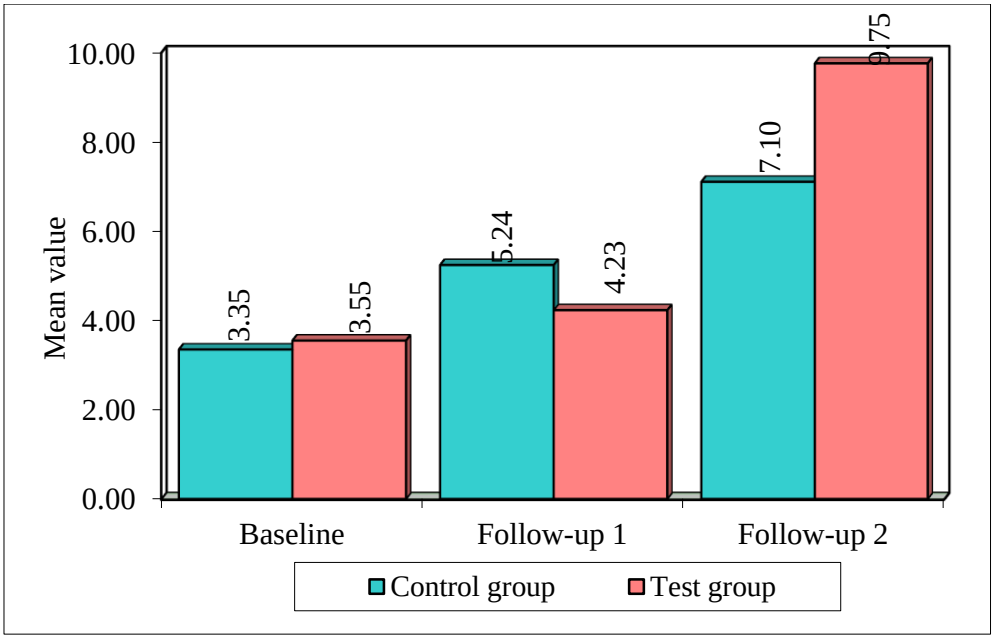
In addition, an independent t-test was conducted to assess the levels of knowledge and awareness at baseline for both the control and test groups. Initially, both groups exhibited low scores, with the control group averaging 3.35 ± 0.92 and the test group averaging 3.55 ± 1.55. The resulting t-value was -1.1104, suggesting no significant difference between the groups (p-value = 0.2681). However, during follow-up 1, a notable divergence emerged. The control group's mean score rose to 5.24 ± 0.99, whereas the test group's mean score was 4.23 ± 1.00. This yielded a t-value of 7.5326, with a highly significant p-value of 0.0001, indicating substantial improvement. This trend persisted into follow-up 2, where the control group's mean score increased to 7.10 ± 1.10 and the test group's to 9.75 ± 0.98. The resulting t-value was -18.9101, with a p-value of 0.0001, demonstrating highly significant improvement. These findings are illustrated in the accompanying table 18 and figure 13.

Table 18: Comparison of control group and test group with TB knowledge and awareness scores at different treatment times by independent t test

Times	**Control group**		**Test group**		**t-value**	**p-value**
	Mean	**Std.Dev.**	**Mean**	**Std.Dev.**		
Baseline	3.35	0.92	3.55	1.55	-1.1104	0.2681
Follow-up 1	5.24	0.99	4.23	1.00	7.5326	0.0001*
Follow-up 2	7.10	1.10	9.75	0.98	-18.9101	0.0001*

*p<0.05

Fig. 13: Graph showing the comparison of control group and test group with TB knowledge and awareness scores at different treatment times by independent t test



4.8.2 TB attitude and Stigma:

During the assessment and evaluation of attitudes and stigma surrounding TB, patients were interviewed regarding several aspects including adherence to ATT therapy, reporting of side effects, the decision to continue anti-TB treatment in the event of side effects, disclosure of their condition to family members, and continuation of anti-TB treatment upon reduction of signs and symptoms. By using the Mann Whitney U-test, we analysed the levels of attitude and stigma among both the control and test groups at baseline and during follow-up assessments. Initially, both groups demonstrated low levels of attitude and stigma, with no significant differences observed in their mean ranks for Q1 to Q5 (U-value = 6050, Z-value = 0.0011, p-value = 0.9992). However, significant improvements were evident during follow-up assessments. In follow-up 1, there was a slight decrease in the control group's mean rank to 110.4 and a slight increase in the test group's mean rank to 110.6, though the differences were not significant (U-value = 6040.0, Z-value = -0.0201, p-value = 0.9839). Notably, in follow-up 2, both groups exhibited highly significant improvements. For instance, in Q2, the control group's mean rank decreased to 57.5 and the test group's increased to 163.5, indicating significant enhancement (U-value = 216.0, Z-value = -12.3575, p-value = 0.0001). This pattern persisted across all the questions (Q1 to Q5), with both groups demonstrating highly significant improvements in attitude and stigma levels during follow-up assessments as shown in Table 19.

Table 19: Comparison of control group and test group with responses of patient in each item of TB attitude and stigma at different treatment times by using Mann Whitney U-test.

Questions	**Treatment times**	**Control group**	**Test group**	**U-value**	**Z-value**	**P-value**
		Mean rank	Mean rank			
Q1	Baseline	110.5	110.5	6050.0	0.0011	0.9992
	Follow up 1	110.4	110.6	6040.0	-0.0201	0.9839
	Follow up 2	81.1	139.9	2815.0	-6.8519	0.0001*
Q2	Baseline	110.5	110.5	6050.0	0.0011	0.9992
	Follow up 1	81.2	139.8	2828.0	-6.8243	0.0001*
	Follow up 2	57.5	163.5	216.0	-12.3575	0.0001*

Q3	Baseline	110.5	110.5	6050.0	0.0011	0.9992
	Follow up 1	90.0	131.0	3799.0	-4.7674	0.0001*
	Follow up 2	59.4	161.6	426.0	-11.9127	0.0001*
Q4	Baseline	110.5	110.5	6050.0	0.0011	0.9992
	Follow up 1	92.4	128.6	4059.0	-4.2166	0.0001*
	Follow up 2	77.7	143.3	2442.0	-7.6420	0.0001*
Q5	Baseline	110.5	110.5	6050.0	0.0011	0.9992
	Follow up 1	89.4	131.6	3731.0	-4.9114	0.0001*
	Follow up 2	64.5	156.5	993.5	-10.7105	0.0001*

*p<0.05

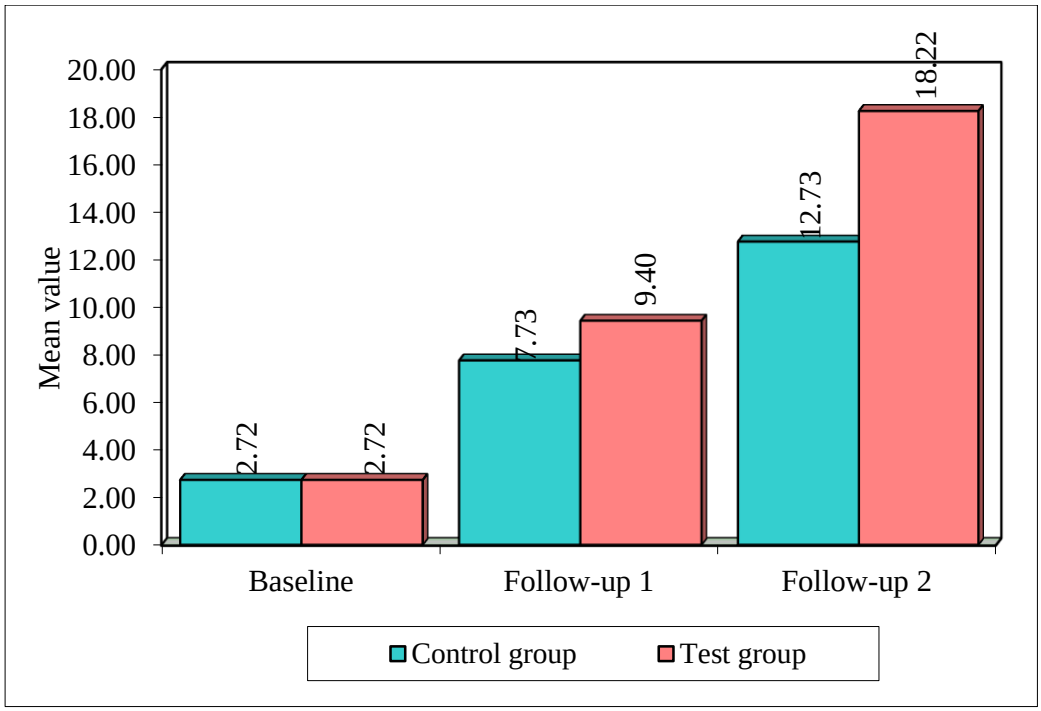
In addition, by using independent t-test, both the control and test groups initially displayed low levels of attitude and stigma. At baseline, the mean scores for both groups were identical, with the control group averaging 2.72 ± 1.44 and the test group averaging 2.72 ± 1.44, resulting in a t-value of 0.0 and a non-significant p-value of 1.0, indicating no significant difference between the groups. However, during follow-up 1, substantial improvements were observed. The mean score for the control group increased to 7.73 ± 1.31, while for the test group, it rose to 9.40 ± 1.10, resulting in a t-value of -10.2356 and a highly significant p-value of 0.0001. Moreover, in follow-up 2, these improvements continued. The control group's mean score further increased to 12.73 ± 1.31, while the test group's mean score significantly rose to 18.22 ± 1.07, resulting in a remarkable t-value of -34.0073 and a highly significant p-value of 0.0001. These findings are illustrated in the accompanying table 20 and figure 14.

Table 20: Comparison of control group and test group with TB attitude and stigma scores at different treatment times by independent t test

Times	**Control group**		**Test group**		**t-value**	**p-value**
	Mean	**Std.Dev.**	**Mean**	**Std.Dev.**		
Baseline	2.72	1.44	2.72	1.44	0.0000	1.0000
Follow-up 1	7.73	1.31	9.40	1.10	-10.2356	0.0001*
Follow-up 2	12.73	1.31	18.22	1.07	-34.0073	0.0001*

*p<0.05

Fig. 14: Graph showing the comparison of control group and test group with TB attitude and stigma scores at different treatment times



4.8.3 Perception on TB:

During the assessment and evaluation of perceptions towards TB, patients were interviewed regarding various aspects including the possibility of cure, expenses related to treatment and diagnosis, mental well-being, and willingness to share TB-related issues and information. By using the Mann Whitney U-test, both the control and test groups initially exhibited low levels of attitude and stigma. At baseline, there were no significant differences between the groups for all questions (Q1 to Q5), as evidenced by similar mean ranks and non-significant p-values. However, significant improvements were observed during follow-up assessments. For example, in follow-up 1, there was a substantial increase in attitude and stigma scores for both groups, with highly significant differences evident in mean ranks and p-values across all questions. Similarly, in follow-up 2, further enhancements were noted in both groups. Despite some variations in mean ranks, highly significant improvements were still evident across all questions, indicating a sustained positive trend in attitude and stigma levels for both the control and test groups. These findings are illustrated in the following table 21.

Table 21: Comparison of control group and test group with responses of patient in each item of Perception on TB at different treatment times by using Mann Whitney U-test.

Questions	Treatment times	Control group	Test group	U-value	Z-value	P-value
		Mean rank	Mean rank			
Q1	Baseline	110.5	110.5	6050.0	0.0011	0.9992
	Follow up 1	131.2	89.8	3772.5	4.8235	0.0001*
	Follow up 2	101.0	120.0	5003.0	-2.2169	0.0266*
Q2	Baseline	110.5	110.5	6050.0	0.0011	0.9992
	Follow up 1	138.5	82.5	2970.0	6.5235	0.0001*
	Follow up 2	91.0	130.0	3905.0	-4.5428	0.0001*
Q3	Baseline	110.5	110.5	6050.0	0.0011	0.9992
	Follow up 1	103.5	117.5	5280.0	-1.6301	0.1031
	Follow up 2	84.0	137.0	3135.0	-6.1740	0.0001*
Q4	Baseline	114.9	106.1	5564.0	1.0285	0.3037
	Follow up 1	97.0	124.0	4562.0	-3.1511	0.0016*
	Follow up 2	110.5	130.5	3050.0	-5.7535	0.0001*
Q5	Baseline	110.5	110.5	6050.0	0.0011	0.9992
	Follow up 1	81.5	139.5	2860.0	-6.7565	0.0001*
	Follow up 2	91.0	130.0	3905.0	-4.5428	0.0001*

*$p<0.05$

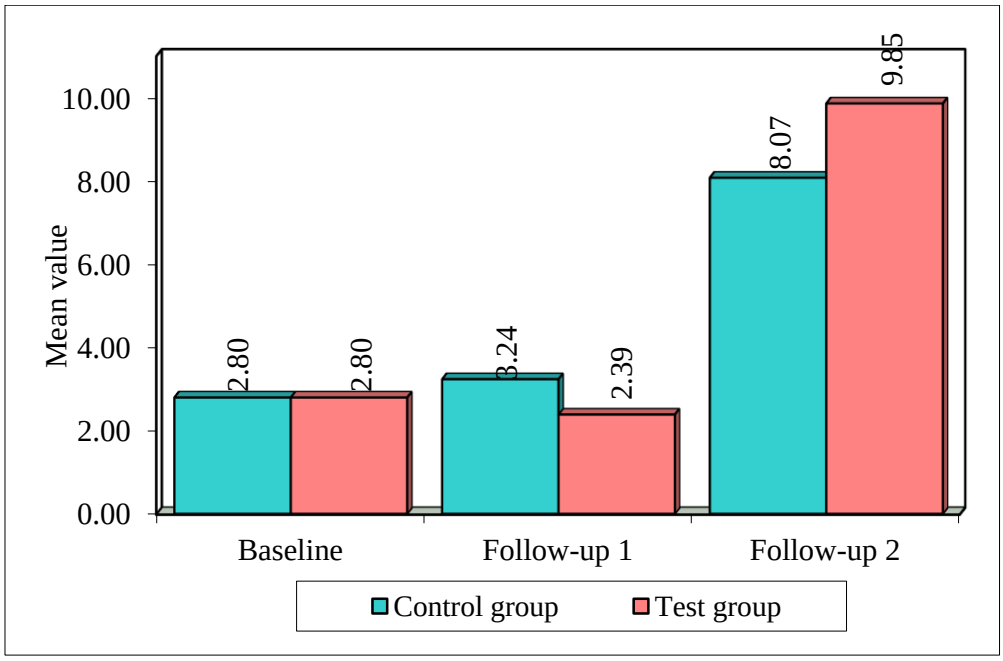
In addition, by using the independent t-test, both the control and test groups initially exhibited low perception towards TB at baseline, with mean scores of 2.80 ± 1.43 for both groups and a non-significant t-value of 0.0 and p-value of 1.0. However, significant improvements were observed during follow-up assessments. In the first follow-up, the control group's mean perception score increased to 3.24 ± 1.45, while the test group's mean score decreased to 2.39 ± 1.82, resulting in a t-value of 3.8176 and a highly significant p-value of 0.0001. Furthermore, in the second follow-up, substantial enhancements were noted in both groups. The control group's mean perception score rose to 8.07 ± 1.39, and the test group's mean score increased to 9.85 ± 0.76, resulting in a remarkable t-value of -11.7635 and a highly significant p-value of 0.0001, indicating significant improvement. These findings are illustrated in the accompanying Table 22 and figure 15.

Table 22: Comparison of control group and test group with TB Perception scores at different treatment times by independent t test

Times	Control group		Test group		t-value	p-value
	Mean	Std.Dev.	Mean	Std.Dev.		
Baseline	2.80	1.43	2.80	1.43	0.0000	1.0000
Follow-up 1	3.24	1.45	2.39	1.82	3.8176	0.0001*
Follow-up 2	8.07	1.39	9.85	0.76	-11.7635	0.0001*

*p<0.05

Fig 15: Graph showing the comparison of control group and test group with TB Perception scores at different treatment times.



4.9 Comparison of 1st month, 3rd month and 6th-month time points with SF-36 and its component scores by independent t-test.

The mean of the scores was calculated for both the overall questionnaire and its individual categories, assessing nine parameters related to physical, emotional, and social well-being. Differences were evaluated using independent t-tests. Data were collected at three distinct time points for both the control and test groups: Baseline (1st month), Follow-up 1 (3rd month), and at the end Follow-up 2 (6th month).

The overall HRQOL mean scores were lower at baseline (1st month) in both the control group (7.48 ± 5.35) and the test group (12.80 ± 6.6). However, after six months of treatment, there was a notable increase in HRQOL mean scores compared to the first month, with the control group (70.19 ± 10.25) and the test group (96.31 ±

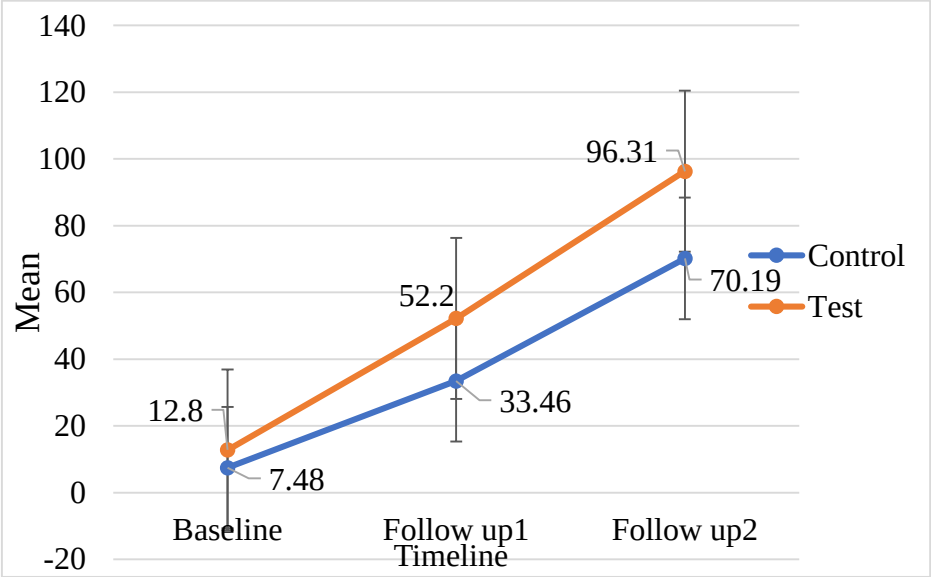
4.39). The comparison of control group and test group with HRQOL at different treatment times by independent t test was shown in table 23 and figure 16.

Table 23: Comparison of control group and test group with HRQOL at different treatment times by independent t test

Times	Control group		Test group		t-value	p-value
	Mean	Std.Dev.	Mean	Std.Dev.		
Baseline	7.48	5.35	12.80	6.63	-6.5495	0.0001*
Follow-up 1	33.46	8.42	52.20	8.25	-16.6665	0.0001*
Follow-up 2	70.19	10.25	96.31	4.39	-24.5791	0.0001*

*p<0.05

Fig. 16: Graph showing the comparison of control group and test group with HRQOL at different treatment times by independent t test



The mean scores for the nine parameters related to mental, social and physical wellbeing were improved after Follow up 2 (6 months) of treatment as compared to 1st month. At the baseline of 1st month, almost every parameter in both control and test groups, there was low QOL. Especially the physical functioning mean scores were 10.45±20.43 in control and 13.18±22.13 in the test group, energy/fatigue mean scores were 4.55±11.64 in control and 5.18±22.13 in the test group, emotional well-being mean scores were 36.00±12.65 in control and 38.73±12.73 in the test group, social functioning mean scores were 10.23±12.35 in control and 13.18±15.68 in the test group and general health mean scores were 6.59±11.41 in control and 15.45±13.72 in the test group. The difference between the mean scores of the two

data of each parameter of the SF-36 questionnaire was statistically significant as indicated by the p-value. (0.0001) as show in Table 24. At the end of the study (up to one year), 46 (92%) of the 50 patients are cured from the tuberculosis and remaining 4 (8%) were lost to follow-up after the completion of six months treatment. The reduction in scores could be attributed to several other additional factors such as social isolation and/or side effects of Anti-TB medications that negatively affected health.

Table 24: Comparison of 1st month, 3 months and 6 months' time points with SF-36 and its component scores by independent t-test.

Parameters	**Times**	**Control group**		**Test group**		**t-value**	**p-value**
		Mean	**Std. Dev.**	**Mean**	**Std. Dev.**		
Physical functioning	Baseline	10.45	20.43	13.18	22.13	-0.9498	0.3433
	Follow-up 1	47.27	13.27	55.45	18.36	-3.7889	0.0002*
	Follow-up 2	72.27	24.96	98.18	9.40	-10.1864	0.0001*
Role limitations due to physical health	Baseline	5.45	22.81	15.45	36.31	-2.4457	0.0153
	Follow-up 1	20.91	40.85	61.82	48.81	-6.7413	0.0001*
	Follow-up 2	45.45	50.02	96.36	18.81	-9.9916	0.0001*
Role limitations due to emotional problems	Baseline	1.82	13.42	7.27	26.09	-1.9500	0.0525
	Follow-up 1	10.91	31.32	47.27	50.15	-6.4500	0.0001*
	Follow-up 2	38.18	48.81	95.45	20.93	-11.3118	0.0001*
Role limitations due to emotional problems	Baseline	1.82	13.42	7.27	26.09	-1.9500	0.0525
	Follow-up 1	10.91	31.32	47.27	50.15	-6.4500	0.0001*
	Follow-up 2	38.18	48.81	95.45	20.93	-11.3118	0.0001*
Energy/fatigue	Baseline	4.55	11.64	5.18	12.73	-2.0740	0.0158
	Follow-up 1	81.82	11.35	94.91	8.75	-9.5807	0.0001*
	Follow-up 2	27.64	11.16	37.09	14.03	-5.5294	0.0001*
Emotional well-being	Baseline	36.00	12.65	38.73	13.35	-1.5554	0.1213
	Follow-up 1	85.09	10.98	96.91	7.26	-9.4135	0.0001*
	Follow-up 2	44.36	11.29	51.82	10.94	-4.9730	0.0001*
Social functioning	Baseline	10.23	12.35	16.36	15.68	-3.2248	0.0015
	Follow-up 1	45.45	13.62	62.95	12.55	-9.9096	0.0001*
	Follow-up 2	79.77	13.75	97.05	8.11	-11.3468	0.0001*
Pain	Baseline	10.18	11.41	15.45	13.72	-3.0984	0.0022
	Follow-up 1	31.27	14.21	44.18	14.36	-6.7009	0.0001*
	Follow-up 2	79.09	14.93	95.45	8.42	-10.0108	0.0001*

General health	Baseline	6.59	11.07	12.50	12.56	-3.7029	0.0003
	Follow-up 1	35.91	12.46	44.55	10.37	-5.5883	0.0001*
	Follow-up 2	77.27	14.97	96.82	8.37	-11.9514	0.0001*
Health change	Baseline	1.36	15.70	6.82	11.19	-4.5565	0.0025
	Follow-up 1	24.55	12.20	49.55	11.22	-15.8168	0.0001*
	Follow-up 2	72.73	19.02	95.68	9.49	-11.3253	0.0001*

*$p<0.05$

4.10 Assessment of patient's satisfaction on overall health care professionals using [functional assessment of chronic illness therapy - treatment satisfaction - general (FACIT TS G)] method.

FACIT – treatment satisfaction general questionnaire was used to determine the overall impression of TB patients towards health care professionals and tertiary care over a period of six months. This questionnaire includes eight elements. The first two elements are rated on a five-point scale ranging from "a lot worse" (0) to "a lot better" (4); the next three items use a four-point scale from "No, not at all" (0) to "Yes, completely" (3); the following two items are evaluated using a three-point scale from "No" (0) to "Yes" (2); and the final item is assessed on a five-point scale from "poor" (0) to "excellent" (4). The mean scores from these elements were analyzed using a Mann-Whitney U test to determine the impact of the training provided on how patients were approached by healthcare providers.

Patients reported satisfaction across most elements of the FACIT scale, except for TS3 and TS7. TS3, which assesses the physician's evaluation of the treatment's effects, showed no significant difference with a p-value of 0.7451. TS7, regarding the likelihood of choosing the same treatment again, also showed no significant difference, with a p-value of 0.9081. For the other elements, there was a notable improvement in how healthcare professionals interacted with patients and treated from TB. The improvement calculated was statistically significant as indicated by the p-value of 0.0001 ($p<0.001$). The results obtained from the FACIT TS G scale have been tabulated in Table 25.

Table 25: Comparison of control group and test group with response of each item of FACIT TS G by Mann-Whitney U test

Items	Control group			Test group			U-value	Z-value	P-value
	Mean	SD	Mean rank	Mean	SD	Mean rank			
TS1	2.8	0.7	81.7	3.5	0.6	139.3	2886.0	-6.7015	0.0001*
TS2	2.4	0.6	74.9	3.3	0.7	146.1	2132.5	-8.2977	0.0001*
TS3	1.8	0.7	111.9	1.5	0.8	109.1	5896.0	0.3252	0.7451
TS4	1.3	0.5	90.5	1.7	0.6	130.5	3852.0	-4.6551	0.0001*
TS5	1.9	0.6	83.6	2.5	0.5	137.4	3096.0	-6.2566	0.0001*
TS6	1.4	0.5	82.0	1.9	0.3	139.0	2915.0	-6.6400	0.0001*
TS7	1.9	0.8	110.0	1.9	0.7	111.0	5995.0	-0.1155	0.9081
TS8	2.0	0.9	65.0	3.6	0.5	156.0	1045.0	-10.6014	0.0001*

*p<0.05

We have also assessed FACIT TS G mean scores between control group and test group with independent t test as shown in Table 25. We found mean score in test group (20.23 ± 1.74) compared to control group (15.49 ± 1.74) with t value obtained (-21.9002) and improvement was shown statistically significance difference with P value 0.0001 (p<0.0001).

Table 26: Comparison of control group and test group with FACIT TS G scores by independent t test

Groups	Mean	SD	SE	t-value	P-value
Control group	15.49	1.74	0.17	-21.9002	0.0001*
Test group	20.23	1.46	0.14		

*p<0.05

4.11 Assessment of patient's satisfaction with clinical pharmacist using (functional assessment of chronic illness therapy (FACIT-SWiP) method.

FACIT – Satisfaction with Pharmacist (Version 4) questionnaire was used to determine the overall impression of test group TB patients towards clinical pharmacist. The seven elements on the Pharmacist Satisfaction (SWiP) scale were graded on a Likert scale of five points (0 = not at all to 4 = very much) at 1st month, 3rd month and 6th month of training. The mean of the scores obtained therein was analyzed by a dependent t-test to understand the effect of the training imparted in this study on patient approach.

Results of scores obtained from the FACIT scale have been tabulating in Table 26. The effect was more pronounced in the period between 1st and 6th month with the mean being 4.90± 2.16 in the 1st month, the difference in mean being 25.98±1.78 at 6th month (t= -79.0734). Between the 1st and 3rd month, the difference in mean was calculated to be 15.68±2.79, which is low, as reflected in the t value of -36.7368. The % effect was also found to be highest between the 1st and 6th months. The difference in mean scores indicates that there was an overall improvement in the interaction of clinical pharmacist with the patients among the test group. The improvement calculated was statistically significant as indicated by the p-value of 0.0001 ($p<0.05$).

Table 27: Comparison of test group with FACIT-SWiP scores at different time points by dependent t test

Times	**Mean**	**SD**	**Mean Diff.**	**SD Diff.**	**%of change**	**t-value**	**p-value**
Baseline	4.90	2.16					
Follow-up 1	15.68	2.79	-10.78	3.08	-220.04	-36.7368	0.0001*
Baseline	4.90	2.16					
Follow-up 2	25.98	1.78	-21.08	2.80	-430.24	-79.0734	0.0001*
Follow-up 1	15.68	2.79					
Follow-up 2	25.98	1.78	-10.30	2.74	-65.68	-39.3594	0.0001*

*$p<0.05$

4.12 Patient counseling photos

B. Assessment and evaluation of KAP towards tuberculosis among health care professionals.

A Knowledge, Attitude, and Practice (KAP) questionnaire, specifically created and validated for this study, was distributed among healthcare professionals at different KLE institutions. To accommodate their busy schedules, the questionnaire was created using Google Forms, and the link was shared with healthcare professionals via WhatsApp. Additionally, some healthcare professionals were personally interviewed at their institutions or workplaces. After 6 months of gap, we have conducted a day training programme for HCPs on world pharmacists' day with the help of District Tuberculosis Office of Belagavi and collaborative with Indian Pharmaceutical Association (IPA) Belagavi branch and some of the HCPs were conducted on World Tuberculosis Day with the help of PHC Medical officer.

4.13 Sociodemographic details of HCPs

A total of 300 health care professionals from various units of KLE institutions across the Belagavi city of were enrolled into the study, but only 240 of them agreed to participate in the study for pre and post-tests. After enrolling them, the HCPs population of 35.02% (84) were males and 64.98% (156) were female. The age group of HCPs population were 28.27% (68) in between 15-20 years, 64.98% (156) in between 21-25 years and 6.75% (16) in ≥26 years with the mean 21.81 and SD 2.11. The most working site of the HCPs were belonging to general medicine 56.54% (134), community medicine 8.44% (21), medical laboratory 15.61% (37), respiratory medicine 15.61% (39), and followed by clinical research 3.80% (9). In qualification based, most of the HCPs were Undergraduate qualified 80.17% (191) and followed by Postgraduate 19.83% (49). The profession wise level of the majority HCPs were the Physicians 35.02% (86), nurse 27.85% (66), pharmacist 15.61 (37). Medical laboratory technicians 18.14% (43) and clinical research were about 3.38% (8). The majority of the HCPs were having were not working yet as they were doing internship and training yet but some them having working experience of 1-5 years 10.12% (26) and less than l year were 10.97% (27). The demographics profile of the HCPs population is characterised in table 28.

Table 28: Demographic profile of respondents

Demographic profile	No of respondents (N)	Frequency of respondents (%)
Gender		
Male	84	35.02
Female	156	64.98
Age groups		
15-20 years	68	28.27
21-25 years	156	64.98
>=26 years	16	6.75
Profession		
Clinical research (CRC/CRA)	8	3.38
Medical laboratory technician	43	18.14
Nurse	66	27.85
Pharmacist	37	15.61
Physician	86	35.02
Working site		
Clinical research	9	3.80
Community medicine	21	8.44
General medicine	134	56.54
Laboratory	36	15.61
Respiratory medicine	39	15.61
Educational level		
Undergraduate	191	80.17
Postgraduate	49	19.83
Working experience		
>5 years	27	10.97
1-5 years	26	10.12
<1 year	187	78.90
Total	240	100.00

4.14 Training and awareness program on World Pharmacist Day and World TB Day.

After the initial survey of 6 months, we invited the HCPs from various areas to attend the half day training and awareness programs on World Pharmacist Day and similarly on World TB Day. As per NTEP guidelines and WHO guidelines training module are focused and assessed Knowledge, Attitude, and Practice for HCPs. Half-day training programs includes followings:

1. Global and Indian scenario of Tuberculosis.
2. Essential comprehension of Tuberculosis and TB drug resistance.
3. Understanding NTEP and DOTS Strategy.
4. Referring TB patients to NTEP.
5. Treatment supporter of NTEP.
6. Follow up of TB Patients.
7. Tuberculosis patient counseling tips.
8. National strategic plan 2017-25 to eradicate TB.
9. WHO end TB strategy by 2035.
10. Evaluating the post-test KAP of HCPs in TB control and care.

4.14.1 The training and awareness program was conducted on World Pharmacist Day according to our Secondary objective to support the World Health Organization's objective of TB elimination by 2035.

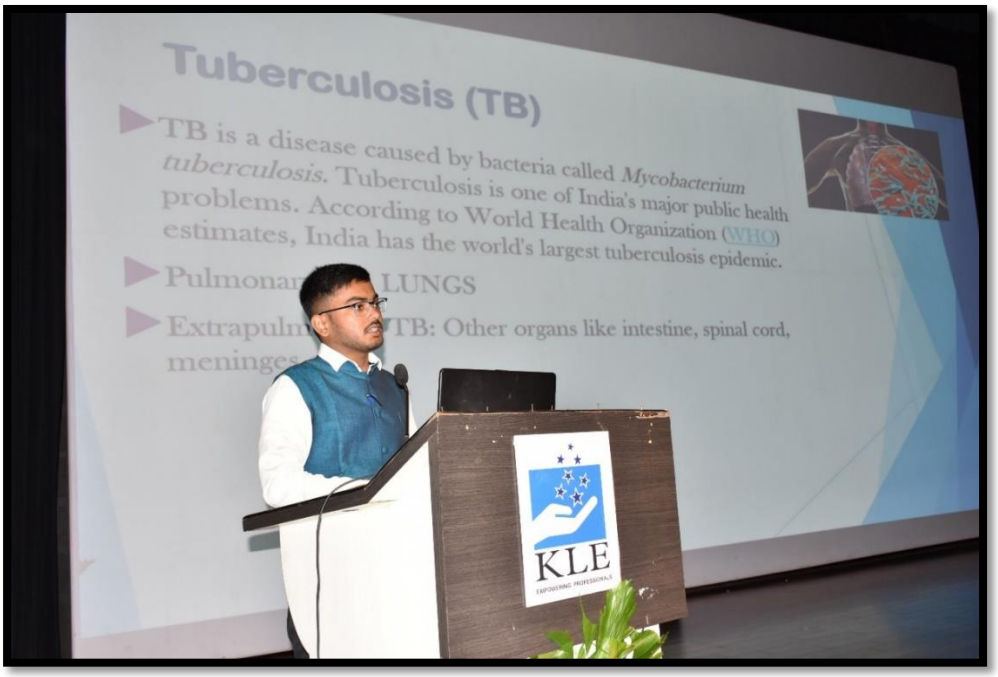
4.14.2 Inauguration of training

4.14.3 Prof. (Dr.) M S Ganachari, Head, Department of Pharmacy Practice, KLE College of Pharmacy, overviewed the training program.

4.14.4 Dr. Anil Korabu District TB officer discussed about various measures initiated by the Government to eradicate tuberculosis disease.

4.14.5 Deepak N Gaikwad, Deputy Drug Controller, Delivered training on Schedule H and Schedule H1 and documentation process of Anti-TB drugs.

4.14.6 Being Research scholar delivered the awareness on TB management with entitled topic "Role of health care professionals in the management of tuberculosis"



4.14.7 Participant's group photo

4.14.8 The training and awareness program was conducted on 24th march 2022, World TB Day with theme of "Invest to end TB: Save lives".

Inauguration function was done by Chief Guest given by **Dr. Aniket,** asst professor & medical officer, Dept of community medicine, J. N. Medical College, Belagavi.

As a research scholar I had delivered a speech on awareness of TB and its medical management.

4.15 Knowledge wise response

We have interviewed the knowledge wise ten questions to HCPs regarding to TB infection and control awareness of TB transmission, TB symptoms. In the pre-test of Q1, 9 respondents (3.80%) strongly disagreed, 11 (4.64%) disagreed, 6 (2.11%) neither disagreed nor agreed, 108 (45.15%) agreed, and 106 (44.30%) strongly agreed. In the post-test, no respondents strongly disagreed or disagreed, 8 (3.38%) neither disagreed nor agreed, 110 (45.57%) agreed, and 122 (51.05%) strongly agreed. This pattern continues for each question (Q2-Q10), showing how respondents' responses shifted from pre-test to post-test. For instance, in question Q6, there's a notable increase in the number of respondents selecting "Strongly agree" in the post-test compared to the pre-test, indicating a positive change in their knowledge following the pharmacist intervention as shown in Table 29.

Table 29: Comparison of pre-test and post-test knowledge wise responses of HCPs.

SN	Items	Category	Knowledge wise response Pre & Post-test N (%)				
			Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly agree
1	Q1	Pre	9 (3.80)	11 (4.64)	6 (2.11)	108 (45.15)	106 (44.30)
		Post	0 (0)	0 (0)	8 (3.38)	110 (45.57)	122 (51.05)
2	Q2	Pre	10 (3.38)	4 (1.69)	2 (0.42)	129 (54.43)	95 (40.08)
		Post	0 (0)	0 (0)	21 (34.61)	114 (12.30)	102 (1.53)
3	Q3	Pre	6 (1.69)	13 (5.06)	6 (2.53)	126 (53.16)	89 (37.55)
		Post	0 (0)	0 (0)	22 (8.86)	126 (52.32)	92 (38.82)
4	Q4	Pre	4 (1.69)	5 (1.69)	9 (3.38)	150 (63.29)	72 (29.96)
		Post	0 (0)	0 (0)	25 (10.13)	140 (59.07)	75 (30.80)
5	Q5	Pre	8 (2.53)	12 (4.64)	14 (5.06)	156 (65.40)	53 (22.36)
		Post	0 (0)	0 (0)	27 (10.55)	154 (64.98)	59 (24.47)
6	Q6	Pre	23 (8.86)	79 (33.33)	26 (9.70)	87 (36.29)	28 (11.81)
		Post	0 (0)	0 (0)	27 (10.97)	9 (3.80)	204 (85.23)
7	Q7	Pre	9 (3.38)	10 (4.22)	9 (3.38)	155 (64.98)	57 (24.05)
		Post	0 (0)	0 (0)	26 (10.55)	148 (62.45)	66 (27.00)
8	Q8	Pre	7 (2.53)	9 (3.80)	37 (15.19)	155 (65.40)	32 (13.08)
		Post	0 (0)	0 (0)	25 (10.13)	177 (74.26)	36 (15.61)

9	**Q9**	Pre	5 (2.11)	11 (4.22)	41 (16.46)	147 (62.03	36 (15.19)
		Post	0 (0)	0 (0)	19 (6.75)	177 (74.68)	44 (18.57)
10	**Q10**	Pre	6 (2.53)	10 (3.80)	9 (3.38)	141 (59.07)	74 (31.22)
		Post	0 (0)	0 (0)	19 (7.59)	142 (59.92)	79 (32.49)

4.16 Attitude wise response

Similarly, we have interviewed the attitude wise ten questions to HCPs regarding to prevention of TB transmission, screening, TB care, testing sputum examination, periodic education for HCPs. In the pre-test Q11, 4 respondents (1.69%) strongly disagreed, 4 (1.69%) disagreed, 2 (0.84%) neither agreed nor disagreed, 124 (52.32%) agreed, and 103 (43.46%) strongly agreed. In the post-test, no respondents strongly disagreed or disagreed, 17 (7.17%) neither agreed nor disagreed, 104 (43.88%) agreed, and 116 (48.95%) strongly agreed. This pattern continues for each question (Q12-Q20), showing how respondents' attitudes shifted from pre-test to post-test. For instance, in question Q13, there's a significant increase in the number of respondents selecting "Strongly agree" in the post-test compared to the pre-test, indicating a positive change in their attitudes following the pharmacist intervention as shown in Table 30.

Table 30: Comparison of pre-test and post-test attitude wise responses of HCPs.

SN	**Items**	**Category**	**Attitude wise response Pre & Post-test N (%)**				
			Strongly Disagree	**Disagree**	**Neither Agree or Disagree**	**Agree**	**Strongly agree**
1	**Q11**	Pre	4 (1.69)	4 (1.69)	3 (0.84)	126 (52.32)	103 (43.46)
		Post	0 (0)	0 (0)	18 (7.17)	106 (43.88)	116 (48.95)
2	**Q12**	Pre	6 (2.11)	6 (2.11)	7 (2.53)	149 (62.87)	72 (30.38)
		Post	0 (0)	0 (0)	24 (9.70)	121 (50.21)	95 (40.08)
3	**Q13**	Pre	13 (5.06)	46 (18.57)	31 (13.08)	117 (49.37)	33 (13.92)
		Post	0 (0)	0 (0)	35 (13.92)	45 (18.57)	160 (67.51)
4	**Q14**	Pre	2 (0.84)	17 (6.33)	31 (12.66)	161 (67.93)	29 (12.24)
		Post	0 (0)	0 (0)	39 (15.61)	169 (70.89)	32 (13.50)
5	**Q15**	Pre	5 (1.27)	6 (2.11)	10 (4.22)	143 (60.34)	76 (32.07)

		Post	0 (0)	0 (0)	89 (36.71)	136 (56.96)	15 (6.33)
6	**Q16**	Pre	4 (1.69)	12 (5.06)	42 (17.72)	145 (60.34)	37 (15.19)
		Post	0 (0)	0 (0)	50 (21.10)	168 (70.04)	22 (8.86)
7	**Q17**	Pre	3 (1.27)	17 (7.17)	49 (20.68)	147 (61.60)	24 (9.28)
		Post	0 (0)	0 (0)	33 (13.08)	175 (73.42)	32 (13.50)
8	**Q18**	Pre	3 (1.27)	9 (3.80)	12 (5.06)	166 (68.78)	50 (21.10)
		Post	0 (0)	0 (0)	52 (21.94)	159 (66.67)	29 (11.39)
9	**Q19**	Pre	2 (0.84)	7 (2.95)	16 (6.75)	169 (70.46)	46 (18.99)
		Post	0 (0)	0 (0)	46 (19.41)	171 (70.89)	23 (9.70)
10	**Q20**	Pre	3 (1.27)	3 (1.27)	11 (3.80)	138 (58.23)	85 (35.44)
		Post	0 (0)	0 (0)	18 (7.17)	119 (50.21)	103 (42.62)

4.17 Practice wise response

Finally, we have interviewed the practice wise five questions to HCPs regarding to keeping TB patients in isolation rooms, ventilation, mask wear in approaching patient, nutritional information on treating TB patients. In the pre-test of Q21, 2 respondents (0.84%) strongly disagreed, 22 (9.28%) disagreed, 18 (7.59%) neither agreed nor disagreed, 137 (57.81%) agreed, and 58 (24.47%) strongly agreed. In the post-test, no respondents strongly disagreed, 16 (6.75%) neither agreed nor disagreed, 149 (62.87%) agreed, and 72 (30.38%) strongly agreed. This pattern continues for each question (Q22-Q25), showing how respondents' practices shifted from pre-test to post-test. For instance, in question Q23, there's an increase in the number of respondents selecting "Neither agree nor disagree" in the post-test compared to the pre-test, indicating a change in their practices following the pharmacist intervention as shown in Table 31.

Table 31: Comparison of pre-test and post-test practice wise responses of HCPs.

SN	Items	Category	Practice wise response Pre & Post-test N (%)				
			Strongly Disagree	**Disagree**	**Neither Agree or Disagree**	**Agree**	**Strongly agree**
1	**Q21**	Pre	2 (0.84)	24 (9.28)	18 (7.59)	138 (57.81)	58 (24.47)
		Post	0 (0)	0 (0)	16 (6.75)	152 (62.87)	72 (30.38)
2	**Q22**	Pre	4 (1.69)	15 (5.49)	23 (9.28)	158 (66.67)	40 (16.88)
		Post	0 (0)	0 (0)	33 (13.08)	169 (69.62)	38 (17.30)
3	**Q23**	Pre	1 (0.42)	7 (2.53)	19 (7.17)	161 (67.93)	52 (21.94)
		Post	0 (0)	0 (0)	64 (26.58)	149 (62.45)	64 (26.58)
4	**Q24**	Pre	2 (0.84)	1 (0.42)	9 (3.38)	124 (51.48)	104 (43.88)
		Post	0 (0)	0 (0)	25 (9.70)	96 (40.51)	119 (49.79)
5	**Q25**	Pre	2 (0.84)	6 (2.53)	15 (5.49)	146 (61.60)	71 (29.54)
		Post	0 (0)	0 (0)	26 (10.55)	128 (53.16)	86 (36.29)

4.18 Comparison of pre-test and post-test knowledge, attitude and practice scores by Wilcoxon matched pairs test

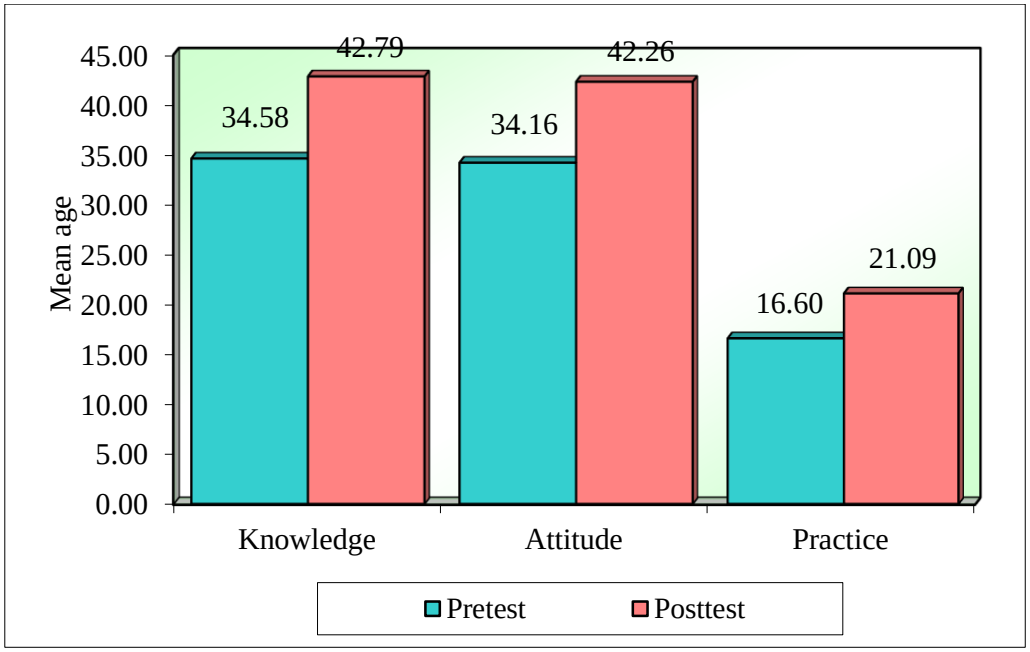
In our study we compared the pre-test and post-test knowledge, attitude and practice scores by using Wilcoxon matched pairs test, we found that knowledge variable mean and standard difference was -8.21, 6.95 with percentage of change -23.74, z value was 12.2946 with significant p value 0.0001. The attitude variable mean and standard difference was -8.10, 8.65 with percentage of change -23.72, z value was 11.7342 with significant p value 0.0001. The practice variable mean and standard difference was -4.49, 5.52 with percentage of change -27.04, z value was 9.9941 with significant p value 0.0001. The results of pre-test and post-test knowledge, attitude and practice scores by Wilcoxon matched pairs test was show in table 32 and figure 14.

Table 32: Comparison of pre-test and post-test knowledge, attitude and practice scores by Wilcoxon matched pairs test

Variable	Time point	Mean	SD	Mean Diff.	SD Diff.	% of change	Z-value	p-value
Knowledge	Pre-test	34.58	4.87	-8.21	6.95	-23.74	12.2946	0.0001*
	Post-test	42.79	4.03					
Attitude	Pre-test	34.16	6.60	-8.10	8.65	-23.72	11.7342	0.0001*
	Post-test	42.26	3.83					
Practice	Pre-test	16.60	4.00	-4.49	5.52	-27.04	9.9941	0.0001*
	Post-test	21.09	2.36					

*p<0.05

Fig. 17: Comparison of pre-test and post-test knowledge, attitude and practice scores



4.19 Correlations among pre-test knowledge, pre-test attitude and pre-test practice scores by Karl Pearson's correlation coefficient.

In our study, we assessed the pre-test relationship between knowledge, attitude and practice of HCPs towards TB control and management was evaluated by Karl Pearson's correlation coefficient to analyze how one variable affects the other. The results have been given in Table 21. The strongest correlation was observed to be between scores for attitude and practice (r= 0.8462, t=24.3438, p=0.0001*), followed by the moderate positive correlation between scores for "knowledge and attitude"

(r=0.4628, t=8.0027, p=0.0001*) and the weak positive correlation was found between "Knowledge and Practice" (r=0.3451, t=5.6366, p=0.0001*).

Table 33: Correlations among pre-test knowledge, pre-test attitude and pre-test practice scores by Karl Pearson's correlation coefficient

Correlations between	r-value	t-value	p-value
Knowledge and attitude	0.4628	8.0027	0.0001*
Knowledge and Practice	0.3451	5.6366	0.0001*
Attitude and Practice	0.8462	24.3438	0.0001*

*p<0.05

4.20 Correlations among post-test knowledge, post-test attitude and post-test practice scores by Karl Pearson's correlation coefficient.

Simultaneously we evaluated the post-test relationship between knowledge, attitude and practice of HCPs towards TB control and management" by Karl Pearson's correlation coefficient to analyze how one variable affects the other. The results have been given in Table 21. The strongest positive correlation was observed to be between scores for "knowledge and attitude" (r= 0.7969, t=20.2192, p=0.0001*), followed by between scores for "attitude and practice" (r=0.7185, t=15.8363, p=0.0001*) and the moderate positive correlation was found between "Knowledge and Practice" (r=0.6765, t=14.0805, p=0.0001*).

In both pre-test and post-test cases, since the p-values were <0.05, statistical significance was strong and this could be due to the good sample size of the study (n=220).

Table 34: Correlations among post-test knowledge, post-test attitude and post-test practice scores by Karl Pearson's correlation coefficient

Correlations between	r-value	t-value	p-value
Knowledge and attitude	0.7969	20.2192	0.0001*
Knowledge and Practice	0.6765	14.0805	0.0001*
Attitude and Practice	0.7185	15.8363	0.0001*

*p<0.05

5. DISCUSSION

A. Impact of clinical pharmacist on improving medication compliance among tuberculosis patients.

5.1 Clinical pharmacist led pharmaceutical care intervention among TB patients

This study aimed to assess and evaluate the compliance of medication related problems, impact of treatment compliance issues that affected on the quality of life, making comprehension of anti-TB drugs therapy and improving the medication adherence during the course of six months of TB treatment. There were several studies have been conducted across various countries in past decade that evaluated and assessed the level of adherence to WHO guidelines for treating TB patients with anti TB drugs by medical practitioners and others health care professionals, in which pharmacists' involvement were found to be less in the management of TB. Consequently, this study was structured to illuminate pharmacists' overall outlook on delivering pharmaceutical care services for TB control. Through the literature review, it became apparent that pharmacists were the main point of contact for various patient groups, including those with tuberculosis.

In the current scenario, clinical pharmacists are emerging as most accessible primary healthcare providers worldwide, and they are becoming the part of integral healthcare professionals in India. Despite the inclusion of pharmacists in the Public-Private Partnership program under the NTEP in India, their awareness and training provided by the central TB centre for roles such as DOTs provider, drug safety & effectiveness detection, and counsellor were found insufficient.[44] The NTEP program offers effective methods for establishing the connection between disease transmission and infection to initiate TB prophylaxis. Assessments of training and educational efforts conducted by pharmacists in nations dealing with significant TB burdens indicate that significance of understanding the TB can alter the approach of high-risk groups towards TB prevention.[45]

5.2 Determining the risk factors among TB patients

This study was undertaken with the main objective of evaluating and engaging the TB patients in the management of TB and also to understand their relevance in completing the anti-TB drugs within the given duration of time period under

pharmaceutical care given by the clinical pharmacist. Of 220 participants were involved in this study, it was observed that the majority of them were males, consisting of 53.64% in the test group and 55.45% in the control group, while females were about 46.36% and 44.55% in the respective groups (Table 2). These similar findings have been noticed in various other studies, suggesting a greater risk to infection among males compared to females. [46,47,49]

The study predominantly had the adults aged between 26-35 years, half of from rural setup, and were married (Table 2), who exhibited a higher susceptibility to infection compared to both the elderly and children, aligning with findings from previous other studies. [48,49] Additionally, our study unveiled a significant prevalence of TB among patients who use smokeless tobacco or are smokers (Table 3), reflecting the finding from a study conducted by Fei et al., which highlighted the association between TB and smoking habits, including smokeless tobacco.[47] Moreover, our study revealed a lower number of patients without comorbidities compared to those with comorbid conditions (Table 3), which contrasts with findings from another study indicating a higher incidence among patients without comorbidities.[48]

As per to the modified Kuppuswamy modified SES scale of 2019 (Table 2), most of the patients' belonged to the lower-middle & upper-lower socioeconomic sections, with monthly incomes ranging from Rs 10,000 to Rs 20,000 and Rs 8,000 to Rs 14,000, respectively. This places a significant financial burden on families to afford TB treatment out of pocket. Furthermore, approximately 70% of patients were either unemployed, daily wage labourers, farmers, or housewives (Table 2). Since many patients work in the informal sector, often in manual or blue-collar jobs, their likelihood of contracting TB in the workplace is higher, as indicated by the Kuppuswamy scale of 2019. There have been many reports highlighting a strong relationship between ambient air pollution and the incidence of TB.[50] In this regard a clinical pharmacist will play a vital role in educating TB patients and the general population about various risk factors and the transmission of the disease.

5.3 Evaluation of anti-TB Drugs related Problems (DRPs) and common Adverse Drug Reactions (ADRs)

Clinical pharmacists play an indispensable role in ensuring the proper use of anti-TB medications by identifying and managing various DRPs that occur during the

treatment. According to PCNE-DRP (V9.1) classification, a DRP is an event or circumstance associated with drug therapy that could potentially or actually disrupt the desired health outcomes. Typically, the standard treatment for newly diagnosed TB patients includes a six-month course of first-line anti-TB medication.[51] This prolonged treatment period, increases the likelihood of encountering DRPs, which can lead to treatment discontinuation and affect the overall quality of life.

In this present study highlights the importance of interventions led by clinical pharmacists to effectively address these DRPs. Similar findings to our study have been observed in other studies, which also emphasize the benefits of timely interventions in managing DRPs.[52,53] Our study specifically investigates DRPs among TB patients at a NTEP centre in a tertiary care hospital, with follow-ups visits at PHC centres in community sectors. Most importantly, this study is among the few in India that systematically examine interventions addressing DRPs in TB patients using the PCNE classification, and evaluates ADRs associated with TB treatment.

In our study, out of 220 patients,129 cases (58.64%) were observed as potentially adverse events, followed by 46 cases (20.91%) with unclear issues/complaints, 42 cases (19.09%) involving untreated symptoms or conditions, and only 3 cases (1.36%) where the drug treatment effect was suboptimal (Table 4). However, a study by Tharanon V et al. identified various types of DRPs, including issues related to drug indications, excessively high or low dosages, drug interactions, and patient not receiving their medications.[54]

In our study, the main reasons for DRPs were identified as medication reconciliation issues (31.36%), excessively long treatment durations (25.91%), and improper timing or dosing intervals (25.45%) (Table 5). These results were attributed to the anti-TB drug treatment protocol, which requires patients to undergo at least six months of therapy and to refill their prescriptions weekly or monthly. Fauna Herawati et al. also observed a similar pattern, noted that TB patients often struggle with adherence when they were admitted or transferred to different healthcare facilities, leading to discontinuation of treatment.[55]

In our study, gastrointestinal (GI) disturbances were the most common ADRs observed with all four anti-TB medications. While in other study highlights the gastritis as the predominant ADR during anti-TB medication.[56] Our study indicated low

occurrences of hepatotoxicity, peripheral neuritis, flu, skin rashes, and malaise. The observation of orange/red-coloured urine among all patients was attributed to a common ADR associated with Rifampicin. A higher frequency of ADRs was noted during the intensive phase (95.96%) compared to the continuation phase (5.04%), aligning with findings from other study suggesting a higher incidence of ADRs in the initial months of TB treatment.[57] Despite these ADRs, our study found that the overall therapeutic outcome was not affected.

In the current study, among the reported ADRs, 102 cases (92.73%) in the test group and 106 cases (96.36%) in the control group were classified as mild (Level 1 and 2) based on the modified Hartwig and Siegal scale. Additionally, 8 cases (7.27%) in the test group and 4 cases (3.64%) in the control group were categorized as moderate (Level 3 and 4) (Table 10). Generally, mild ADRs do not warrant any alterations in treatment, while moderate ADRs may require adjustments to the suspected drug dose or discontinuation of the drug. Regarding causality assessment using the Naranjo algorithm, the majority of ADRs, 102 cases (92.73%) in the test group and 105 cases (95.45%) in the control group, were deemed possible. Only 8 cases (7.27%) in the test group and 5 cases (4.55%) in the control group were classified as probable (Table 11).

Additionally, by using WHO-UMC scale, we found 98 (89.09%) ADRs in the test group and 99 (90%) in the control were noted as possible, and 12 (10.91%) in the test and 11 (10%) in the control were probable/likely (Table 12). It's important to note that the study did not conduct rechallenge tests to confirm the causative agent, and there were no laboratory investigations to determine drug concentrations in tissues or body fluids. As a result, no reported ADRs were categorized as definite in this study. We also checked for preventability of ADRs with Schumock and Thornton preventability assessment scale, we found that 95 (86.36%) ADRs in the test group and 102 (92.73%) in the control group were classified as definitely preventable, with 15 (13.64%) in the test and 8 (7.27%) in the control categorized as probably preventable. None of the ADRs were classified as not preventable (Table 13).

5.4 Evaluation of Knowledge, Attitude and Perception (KAP) among TB patients

During the requirement of participants in our study, we surveyed the patients for health seeking behaviour in visiting hospital/clinics and we observed that most of the patients of about 97.27% in both groups approached the private health facility for

their tuberculosis symptoms (Table 16). Similar study conducted by Uplekar et al. found that in the Pune city, 60% of individuals with chest symptoms first approached a private provider and in another study by the same author, it was found to be 86%.[58] In this study 84.55% patients in both groups oftenly visit at least once in month to clinics/hospital as they have to refill the prescription or consult the physician for any discomfort or problems that arises during the treatment.

In our study, initial evaluations of TB knowledge and awareness revealed that only few of the participants understood the severity of TB, the cough as a transmission route, and the occurrence of TB across different age groups (Table 17,18) (Fig 13). However, following interventions by clinical pharmacists, there was a marked improvement in knowledge among the test group patients. In contrast, a study by Sabir et al. in Rawalpindi found that participants had limited understanding of TB causes and transmission methods.[59] The reason for the large variation may be due to our study conducted out in both urban and rural areas patients. Meanwhile, a study by Mohamed et al. in a rural area of Sudan found that only 1.9% of participants were aware of the causes of TB.[60]

In our study, initially at the baseline, more than a quarter of participants displayed low attitude and significant stigma associated with TB (Table 19, 20) (Fig 14). However, following interventions by clinical pharmacist, there was a notable improvement in attitudes among those in the test group. This contrasts with findings from a study by Mweemba et al. in Zambia, where 80% of participants held a positive attitude towards TB.[61] Furthermore, our study found observed that 49.1% of participants were willing to disclose their TB status to family members and support isolation measures for infected individuals, indicating ongoing discrimination against TB patients in our community. While the commitment to continue anti-TB medication even after symptoms subsided was generally positive, only a few participants reported experiencing side effects.

In our study, we observed that many participants held a negative perception regarding the curability of TB and perceived the treatment and diagnostic processes in India as costly (Table 21, 22) (Fig 15). However, according to the Central TB Division, between 80-85% of patients complete their treatment successfully, with all diagnostic and treatment services provided free of charge under the NTEP programme.[62] This

prolong gaps in attitudes and perceptions could be reduced through targeted interventions and more uniform health service distribution across all areas. Several studies have demonstrated that TB awareness increases significantly when educational programs are implemented.[63.64,65] Therefore, we assert the clinical pharmacist had an important role within NTEP programme by educating and informing TB patients about their health and disease condition.

5.5 Improving Medication adherence and health related quality of life (HRQoL)

The main outcomes of conducting this study under clinical pharmacist were to improve medication adherence, enhance satisfaction, and enhancing the quality of life of patients. In developing countries such as India, adherence to medical regimes has been estimated to be as low as 40%.[66] As in India, most of the TB patients were lost follow up/discontinue the anti-TB drug treatment due improper guidance, lack of moral support and financial economic support. In our study, many TB patients were receiving treatment from private practitioners and exhibited irregular adherence to anti-tuberculosis therapy (ATT) as they did not consistently follow up with their physicians. Some of them were referred to PHCs and UHCs in their respective areas, where they were placed on FDC treatment under the supervision of medical officers. To ensure compliance and address issues arising during treatment, clinical pharmacist played a significant in healthcare provision, helping TB patients adhere to and complete their treatment regimen.

At the initial of 1st month, scores for medical adherence were generally low for most questionnaire items, particularly related to forgetting medications and other challenges. The overall p-value was not significant among both groups (Table 14) (Fig 11). However, after six months of clinical pharmacist involvement in providing pharmaceutical care to the test group, all TB patients in this group achieved 100% adherence to their medication regimens, showing a significant improvement from the first month. This indicates that with proper counselling and education awareness, patients can significantly improve their adherence to recommended medications and dosages. Meanwhile, the control group, which received usual care, also showed better adherence but not to the same extent as the test group with pharmacist intervention. In a study conducted by Kassahun et al., reported that the majority (58%) of patients cited

forgetfulness, followed by 17.3% mentioning traveling away from home without pills, as major reasons for non-adherence to TB treatment.[67]

Another essential outcome of our study was the improvement in HRQoL, as many complex factors associated with TB treatment significantly impact patients' quality of life. To assess HRQoL, we used the Short Form 36 (SF-36) questionnaire, which evaluates physical, emotional, social, functional, and general health conditions across 10 domains. The intervention group, which received clinical pharmacist services, showed a marked improvement in HRQoL over six months of follow-up visits compared to the usual care group (Table 23, 24) (Fig 16). Similar findings were reported in previous studies by Mishra et al., Ali et al., and Saleem et al.[68,69,70] The improvement in HRQoL observed in our study can be attributed to patient-centred pharmaceutical care, which likely helped patients alleviate their symptoms and enhance their ability to adhere to anti-TB treatment. Our study's results support the argument that empowering patients through focused, patient-centred care positively impacts HRQoL. In a study by UK Rangaswamy et al., collaborative intervention between community and clinical pharmacists significantly improved outcomes in pulmonary TB patients, enhancing compliance and quality of life through specialized pharmaceutical care services.[71]

By the end of the study (up to one and half year), 220 (88%) of the 250 patients were cured from the tuberculosis, while the remaining 30 (12%) were lost to follow-up from baseline to end of the six-month treatment in both groups. Final overall satisfaction feedback from both groups of patients regarding their interactions with HCPs, treatment in the hospital and hospital facilities was collected using FACIT TS G item scores (Table 25, 26). The results indicated satisfaction with all items except for evaluating drug effects taken by physicians and choosing again TB treatment again, where patients expressed disagreement. In contrast, satisfaction among the test group patients (who received pharmacist intervention) was assessed using the FACIT-SWiP questionnaire. The service provided by clinical pharmacists received high satisfaction ratings, as indicated by the negligible difference between the first month and the third and sixth months of FACIT scores (Table 27). Thus, we successfully delivered improved outcomes in pulmonary TB patients through the clinical pharmacist's pharmaceutical care services.

B. Assessment and evaluation of KAP towards tuberculosis among health care professionals.

The WHO's recommends that every medical institution should ensure that graduates possesses the necessary knowledge, skills, and attitudes for managing tuberculosis in both individual patients and the community. The knowledge, attitude and practices of healthcare workers are critical for effective tuberculosis infection control. In pretest of our study, we collected the demographic and responses, we found the average age of participants was between 21-25 years, similar to the demographic in Demissiegizaw et al.[72] The majority of the participants were female (64.98%), which aligns with findings from other study but is lower than the 71% reported by Pathak et al., 2016. Most participants were Physicians 69%, comparable to the 66% recorded by Pathak et al.[73] Additionally, 27.85% were nurses, 18.14% were medical laboratory technicians, and 15.61% were pharmacists. A significant portion of them were undergraduates (80.17%), while only 19.83%. were postgraduates. The overall qualifications of the study population was deemed adequate for healthcare workers managing TB patients. Most participants (78.90%) had of at least 1year of professional experience, with 10.97% having >5 years and 10.12% having between 1-5years. (Table 28)

After analysing data from the pretest survey of HCPs, we invited all HCPs to participate in a training program six months later. The programs, titled "Role of Healthcare Professionals in the Management of Tuberculosis," was conducted by the Department of Pharmacy Practice at KLE College of Pharmacy, in association with the India Pharmaceutical Association (IPA), Belagavi chapter, and in collaboration with the District TB Control Centre and the regional office of the Deputy Drugs Controller. This training aligned with the secondary objective of our study, which was to evaluate and improve the knowledge, attitudes and practices of HCPs regarding tuberculosis, emphasizing the importance of TB elimination. The HCPs from various constituent units of KLE institutions attended the program, which featured sessions led by distinguished officers from the District Tuberculosis centre and the regional office of the Deputy Drugs controller. We conducted two programs: one on World Pharmacist Day at the KLE Convention Centre in Dr. H.B. Rajashekhar Hall, and another on World Tuberculosis Day at a PHC centre in collaboration with the Department of Community Medicine.

The training revealed that, prior to the sessions, healthcare providers had poor knowledge regarding TB spread, the use of masks, and transmission (Table 29). However, six months after the training, knowledge scores on TB had improved to over 99% among all participating HCPs. This study highlights the initial knowledge levels about TB among various HCPs in the region and can inform future training programs. Similarly, a study by Naidoo et al. in South Africa demonstrated that training programs significantly enhance HCPs knowledge levels.[74] It was observed that well-trained HCPs with university degrees possessed good to excellent knowledge about TB, though they comprise a small fraction of the workforce in regional healthcare facilities. Almost two-thirds of the respondents were undergraduates, who had notably lower knowledge levels. In conclusion, as TB knowledge continues to evolve, it is crucial to provide updated TB training to all levels of HCPs. Our study emphasizes the importance of tailored TB training programs focused on HCPs with lower professional degrees to improve the overall competency of the healthcare staff.

In this study, the attitudes of HCPs towards TB patients are identified as crucial factors in enhancing patients' health-seeking behaviours, adherence to prescribed treatment regimens, treatment outcomes, and preventing the development of drug resistance (Table 30). Initially, our data indicated that while HCPs generally had positive attitudes towards working with TB patients, some negative attitudes were observed in the pretest. However, post-training, there was a notable improvement in their attitudes towards patients. These improvements were mainly related to TB transmission prevention, screening, TB care, sputum testing, periodic education for HCPs, and various aspects of TB management and treatment. Despite many HCPs expressing concern about nosocomial TB transmission, they also believed their personal risk of acquiring TB from patients was very low. Factors influencing HCPs attitudes included suboptimal knowledge about TB, its transmission and treatment, personal experiences, the stigma associated with the disease, and concerns about infection.[75] Most respondents recognized the need for better regional TB control and viewed TB as a significant public health threat. This high level of awareness among HCPs about the seriousness of TB in their region provides a strong foundation for the implementation of new TB infection control (TBIC) policies and training programs.

In this study, about half of the HCPs reported that they would wear a mask when dealing with a coughing patient and emphasized the importance of isolating TB patients and ensuring proper ventilation (Table 31). However, due to the unavailability of appropriate respirators and ventilation systems in most facilities, HCPs were mainly referring to surgical masks. A study from Uganda revealed that only a third of HCPs knew that surgical masks do not provide adequate protection against TB transmission.[76] Consequently, our training program not only clarified when mask use is appropriate but also identified which types of masks are most suitable for patients and attending HCPs. Due to limited resources in primary healthcare settings, such as dispensaries, this lack of appropriate protective measures is unsurprising. Additionally, there may be concerns about stigmatizing patients. Despite the cost-effectiveness and high efficiency of natural ventilation compared to mechanical ventilation,[77] only about two-thirds of the respondents reported opening doors and windows when dealing with an infectious TB patient, indicating a general lack of awareness about environmental control measures.

TB is often associated with more severe malnutrition than other chronic illnesses. An Indian study found that the nutritional status of TB patients was worse than that of patients with leprosy.[78] In our training program, we highlighted the importance of the Nikshay Poshan Yojana, which provides nutritional support to TB patients. This initiative offers a monthly financial incentive of Rs 500/- per month to each notified TB patient undergoing anti-TB treatment, through Direct Benefit Transfer. In pretest of this study, nonetheless a significant proportion of the HCPs demonstrated overall adequate knowledge about TB and the National NTEP, with no notable differences in knowledge, attitude and practices scores among the HCPs was studied. Despite this, it's important to address the identified knowledge, attitude and practice gaps regarding at-risk groups, symptoms and examination, and the current TB epidemiology in India.

During the training programmes, below were the valuable statements and commitments shared by the respective dignitaries:

"Deputy drugs controller*: We are dedicated to provide the necessary resources and support to healthcare professionals and pharmacists to ensure effective management and treatment of TB. By expanding our efforts into rural areas and facilitating access to essential anti-TB medications, we aim to strengthen our National Tuberculosis Elimination Program and move closer to a TB-free future."*

"District tuberculosis officer: *We are implementing comprehensive strategies that include early detection, effective treatment, and continuous education about TB. Our goal is to enhance collaboration with healthcare providers, pharmacists, and local organizations to ensure that every patient has access to the necessary resources and support. Together, we can achieve a TB-free district and contribute to the national effort to eliminate this disease."*

"PHC Medical Officer: *Our healthcare team is committed to implementing best practices and innovative approaches to combat TB, providing comprehensive care to those affected. By working closely with patients, their families, and the community, we strive to increase awareness, reduce stigma, and ultimately eliminate TB from our region. Together, we can achieve a future free from tuberculosis."*

*"**Private practitioners:*** *We are committed to providing high-quality care and support to our patients. We believe that early diagnosis, effective treatment, and patient education are essential in the fight against TB. We work closely with public health authorities and community organizations to ensure that our patients have access to the resources they need. Together, through coordinated efforts and continuous education, we can eliminate TB and improve the health and well-being of our community."*

"Pharmacists: *Through collaboration with other healthcare professionals. We are committed to ensuring that every TB patient receives comprehensive care. We are interested to upgrade the knowledge in other areas also by continuing pharmacy education."*

From our study we observed that effective TB management of patients requires a multidisciplinary healthcare team (HCPs) approach, pharmacists playing a crucial role at various stages of TB control. In the present study, Pharmacists proved the significance in contributing to TB treatment by identifying various DRPs and monitoring ADRs. Their involvement is essential for enhancing treatment adherence, assessing risk factors, managing disease control and prevention, and improving the safety and efficacy of TB treatment. Therefore, the provision of pharmaceutical care services in TB management, overseen by pharmacists, is a vital component in controlling and preventing TB.

6. SUMMARY

Tuberculosis, a chronic bacterial infection, primarily affecting the lungs but can also target other body parts. It spreads through the air when an infected person coughs, sneezes, or spits, releasing bacteria that others can inhale. Symptoms of active TB include a chronic cough (sometimes with blood), chest pain, fatigue, weight loss, reduced appetite, fevers, and night sweats. The WHO identifies TB as a major cause of death from a single infectious agent, noting that it is mostly treatable and preventable. In 2019, approximately 10 million people developed TB, with 2.9 million cases either undiagnosed or unreported. Annually, TB causes approximately 1.3 million deaths, including 167,000 among HIV-positive individuals around the world. In 2016, India had the highest number of TB cases, with 2.79 million out of a global 10 million. By 2022, the number of diagnosed TB cases rose to 10.6 million, with eight countries reporting at least 100,000 cases each.

The WHO's End TB Strategy aims to reduce TB incidence by 90% and deaths by 95% by 2035. The UN's 2018 declaration set a goal to diagnose and treat 40 million people with TB by 2022. Achieving these goals requires effective measures to enhance TB detection and treatment initiation. India played a significant role in the global reduction of TB notifications during 2020 and 2021, contributing to 60% of the worldwide decrease. In 2022, TB was the second leading cause of death from a single infectious agent, after COVID-19. According to the WHO's 2023 global TB report, India reported 2.8 million TB cases and 33,100 TB-related deaths from its 1.4 billion population in 2022. The incidence rate declined by 16% between 2015 and 2022. Of the 2.3 million new and relapse TB cases reported, 75% were pulmonary TB, with men accounting for 58% and women 37%.

India's NTP began in 1962, focusing on BCG vaccination and TB treatment. After a comprehensive review in 1992, the RNTCP was launched in 1997 and expanded nationwide by 2006. In 2019, RNTCP was renamed the NTEP. The National Strategic Plan (NSP) for TB elimination 2017–2025 focuses on four core strategies: "Detect, Treat, Prevent, and Build." The DOTS strategy includes political and administrative commitment, case detection via sputum microscopy, standardized chemotherapy,

ensuring a supply of high-quality drugs, and systematic patient monitoring, all crucial for successful TB elimination.

Clinical pharmacists play a crucial role in the healthcare team, particularly in managing TB patients. They improve pharmaceutical care by supporting healthcare professionals and patients, ensuring effective treatment through a multidisciplinary approach. Their availability enables them to facilitate interaction and collaboration between patients and physicians. Clinical pharmacists optimize medication use by focusing on accurate dosing, monitoring drug efficacy and safety. Working in diverse healthcare settings, clinical pharmacists apply their expertise in medication and disease management collaboratively within a multidisciplinary team. This research study will outline the responsibilities and potential extent of practice of clinical pharmacists in managing, treating, and improving compliance among TB patients in the NTEP. The study aims to contribute to the global objective of ending TB by 2035.

A single-blinded RCT study was conducted with two parallel arms: usual care (Control) and pharmaceutical care intervention (Test). Participants were randomized using SNOSE and assigned to either group by the clinical pharmacist. The test group received pharmaceutical care in a separate room at a TB centre, while the control group received usual care from other healthcare professionals. The clinical pharmacist, blinded to initial outcomes, served as the primary contact for participants. ICFs and PIS were provided in English, Kannada, and Marathi. Patients chose their preferred language for comprehension. Consent was obtained directly from participants or their LAR. Participants were informed about the study's purpose, benefits, risks, procedures, confidentiality, randomization process, and their right to withdraw at any time. Understanding was verified, and any questions were addressed. Participants signed two copies of the ICF, keeping one and returning the other to the investigator. They also received a copy of the PIS.

Data was gathered using a structured form, covering socio-demographics, medical history, social habits, examination findings, and investigation results. Diagnoses, medications, and study outcomes were recorded for both groups. In control, Participants received anti-tubercular therapy and management from physicians and healthcare professionals without pharmacist intervention. Progress was monitored and assessed at baseline (1st month), 3rd month, and 6th month at various healthcare

centers, including two PHCs, two UHCs, and KLE Hospital in Belagavi district. In test, participants received TB treatment and management with additional pharmaceutical care intervention from a clinical pharmacist in a private setting at the NTEP centre within a tertiary care hospital. Their progress was monitored and assessed at the same intervals and locations as the control group.

In this study of 220 participants, the majority were males (53.64% in the test group, 55.45% in the control group) and adults aged between 26-35 years. About half were from rural areas, and most were married. A higher number of participants had comorbid conditions compared to those without, and most belonged to lower-middle and upper-lower socioeconomic sections. To evaluate the effectiveness of TB treatment and overall patient outcomes, data was collected and statistically analysed using various tools, including PCNE DRPs, a self-prepared KAP questionnaire, MAATT, FACIT-SWiP & TS, and the SF-36 questionnaire. Our study on DRPs among TB patients at an NTEP centre in a tertiary care hospital, with follow-up visits at PHC centers, involved 220 patients. Among them, 58.64% experienced potentially adverse events, 20.91% had unclear issues or complaints, and 19.09% had untreated symptoms or conditions. Suboptimal drug treatment effects were reported in only 1.36% of cases. Major DRPs included medication reconciliation issues (31.36%), excessively long treatment durations (25.91%), and improper timing or dosing intervals (25.45%). Gastrointestinal disturbances were the most common ADRs observed across all anti-TB medications, with low incidences of other ADRs such as hepatotoxicity, peripheral neuritis, flu, skin rashes, and malaise. The observation of orange/red-coloured urine in all patients was attributed to Rifampicin's common ADR.

In our study on health-seeking behaviour and patient perceptions among TB patients at an NTEP centre, we found that a significant majority (97.27%) initially sought care at private health facilities for TB symptoms. About 84.55% of patients visited clinics or hospitals monthly for prescription refills or consultations. Initially, there was limited awareness among participants regarding TB severity, transmission routes like coughing, and its prevalence across age groups. However, interventions by clinical pharmacists led to noticeable improvements in knowledge and attitudes among the test group. Initially, over a quarter of participants had stigma and negative perceptions about TB's curability and the costliness of treatment and diagnostics in

India, despite these services being free under the NTEP program. Addressing these gaps through targeted interventions and equitable healthcare distribution could help improve attitudes and perceptions towards TB management.

In our study focusing on pulmonary TB patients, initial adherence to medication regimens was low, especially concerning forgetting medications and other challenges, with no significant difference between groups initially. However, after six months of clinical pharmacist involvement, the test group achieved 100% adherence, a marked improvement. Quality of life, assessed via SF-36, showed substantial enhancements in the intervention group compared to usual care over the same period. Ultimately, 88% of the 250 patients were cured, while 12% were lost to follow-up. Satisfaction feedback from both groups highlighted overall positive experiences with healthcare professionals and hospital facilities, though some concerns were noted about physician communication regarding drug effects and treatment choices. Conversely, the test group, benefiting from pharmacist interventions, expressed consistently high satisfaction with services throughout the study, affirming the positive impact of pharmaceutical care on TB treatment outcomes.

In other hand, we assessed the knowledge, attitude and practices of HCPs who are critical for effective tuberculosis infection control. In pretest of our study, we collected the demographic and responses, we found the average age of participants was between 21-25 years. The majority of the participants were female (64.98%). Most participants were Physicians 69%. Additionally, 27.85% were nurses, 18.14% were medical laboratory technicians, and 15.61% were pharmacists. A significant portion of them were undergraduates (80.17%), while only 19.83%. were postgraduates. The overall qualifications of the study population was deemed adequate for healthcare workers managing TB patients. Most participants (78.90%) had of at least 1year of professional experience, with 10.97% having >5 years and 10.12% having between 1-5years.

After analysing data from the pretest survey of HCPs, initial assessments of healthcare HCPs regarding TB knowledge showed significant gaps in understanding TB spread, mask usage, and transmission. Following our training programs conducted on World Pharmacist Day at KLE Convention Centre and World Tuberculosis Day at a PHC centre, facilitated by the Department of Pharmacy Practice at KLE College of

Pharmacy, there was a remarkable improvement in TB-related knowledge among participating HCPs. Our study underscores the critical role of ongoing training programs in improving HCPs understanding and management of TB within community healthcare settings.

While well-trained HCPs with university degrees demonstrated strong knowledge about TB, they constituted a minority in regional healthcare facilities. The majority of respondents, primarily undergraduates, exhibited lower levels of TB knowledge. Attitudes among HCPs towards TB patients were identified as pivotal in influencing health-seeking behaviours, treatment adherence, and overall outcomes, including preventing drug resistance. Initial assessments revealed mixed attitudes, but post-training, significant improvements were noted, particularly regarding TB transmission prevention, screening, care, and treatment management. The study highlighted challenges such as the use of appropriate masks and ventilation systems, often limited by resource constraints in primary healthcare settings. Effective training not only clarified mask usage but also addressed environmental control measures to mitigate TB transmission risks, despite prevalent concerns about stigmatization and resource availability.

From our study emphasizes the critical role of pharmacists in multidisciplinary healthcare teams for effective TB management. Pharmacists are pivotal in identifying DRPs, monitoring ADRs. and enhancing treatment adherence. Their involvement contributes significantly to managing disease control, assessing risk factors, and improving the safety and efficacy of TB treatment. Providing pharmaceutical care services under pharmacists' oversight is essential for comprehensive TB management, highlighting their crucial role in controlling and preventing TB through integrated healthcare approaches.

7. CONCLUSION

This study appears to be one of the first pharmaceutical care interventional study carried out among TB patients of tertiary care hospital referred to primary health care sectors and the critical role of clinical pharmacist's in enhancing the TB care through targeted interventions. Our findings demonstrate that clinical pharmacist-led initiatives significantly improve patient outcomes, medication adherence, knowledge, attitude, perceptions and overall treatment success rates as the association of results were calculated and found to be statistically significant (P value: 0.0001*). By providing patient education through PILs, medication management, and direct support through personal visits and tele-communications, pharmacists can effectively bridge gaps in TB care, leading to higher cure rates and reduced instances of treatment failure or relapse. Continued research and investment in pharmacist-driven models are essential to sustaining and enhancing these positive impacts on TB management. The patient-centred approach significantly contribute to the effective management of TB, suggesting that healthcare systems should prioritize and integrate pharmaceutical care services to improve TB treatment success rates.

The study also highlighted the critical role clinical pharmacist's play in optimizing TB treatment through several key contributions:

i. **Improved Medication Adherence and HRQoL:** Pharmacist-led interventions, such as patient counseling and education on medication management, significantly enhanced adherence to TB treatment regimens and increased good quality of life. This was evident in the higher rates of completed therapy and reduced instances of missed doses among patients.

ii. **Increased Knowledge and Awareness:** Training and collaboration with clinical pharmacist increased healthcare professionals' knowledge and awareness about TB treatment protocols, updated WHO & NTEP guidelines, national strategy plans, and side effect management. This multidisciplinary approach led to more informed decision-making and better patient care.

iii. **Reduction in DRPs and ADRs:** Pharmacists' expertise in pharmacotherapy contributed to the early identification and management of DRPs and ADRs, thereby minimizing the incidence of drug-related complications and improving patient safety.

iv. **Enhanced Treatment Outcomes:** The involvement of clinical pharmacist's resulted in improved clinical outcomes for TB patients. This included higher rates of

sputum conversion indicating quicker reduction in infectiousness and bacterial load, faster time to cure, and reduced treatment failures, suggesting that pharmacist interventions effectively support the clinical management of TB.

Overall, the study underscores the value of integrating clinical pharmacists into the TB treatment team. Their specialized knowledge and skills enhance the quality of care provided to TB patients, leading to better health outcomes and more efficient healthcare delivery.

7.1 LIMITATION OF THE STUDY

The study was confined to a single tertiary care hospital and a limited number of PHC Centers within the Belagavi region. The study exclusively recruited Pulmonary Tuberculosis patients. The standard practices of private practitioners in their individual clinics were not documented in the study. Due to the limited time patients stayed, interactions with the clinical pharmacist for patient counseling were minimal. Additionally, TB patients seeking treatment in the private sector faced social stigma. The training was conducted for only 240 healthcare professionals who were interested in improving their KAP.

7.2 FUTURE PERSPECTIVES

In future, the study could be extended in many tertiary care district hospitals and the super specialty hospitals also because a greater number of patients are available in those areas. The compulsory continuing education and training programs should be made mandatory to every healthcare practitioner who are working in the field of tuberculosis to upgrade their knowledge and contribute to eradicating tuberculosis in India.

We recommend a continuous support and education, addressing potential barriers to adherence and providing ongoing patient support as pharmacists helps in sustaining the benefits of initial treatment, leading to a reduction in treatment failures and relapse rates. We suggest that pharmacist interventions are not only cost-effective and but also crucial in advising healthcare practitioners and patients about FDC treatment provided at free of cost under NTEP program, leading to reduced healthcare costs through better resource utilization, fewer hospitalizations, and improved treatment adherence and outcomes.

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ANNEXURE – I - ETHICAL CLEARANCE LETTER

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Formerly known as KLE University)
(Deemed-to-be-University established u/s 3 of the UGC Act, 1956)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
JNMC Campus, Nehru Nagar, Belagavi-590 010, Karnataka State, India
☎: 0831-2444444 FAX: 0831-2493777 Web: http://www.kledeemeduniversity.edu.in E-mail: info@kledeemeduniversity.edu.in

Ref.No.KAHER/EC/21-22/ 020 29th July 2021

To,
Mr. Bandaru Yeswanth Raja
Full time Ph.D. Research Scholar,
2020-21Batch, Faculty of Pharmacy,
KAHER, Belagavi.

Dear Research Scholar,

The KAHER Ethics Committee on Human Subjects for Ph.D. Research Project met on **the 7th and 8th June, 2021** to consider your application for approval of the research project **"Role of clinical pharmacist to improve tubercular patient's compliance referred to NTEP centre attached to a tertiary care hospital :A randomised controlled study"**

As there are no ethical issues involved in your proposed research project, the committee has provided approval for this research project.

You are requested to report to Ethical Committee of the following:

1. Any deviation from or change of the protocol.
2. Any changes in study documents.

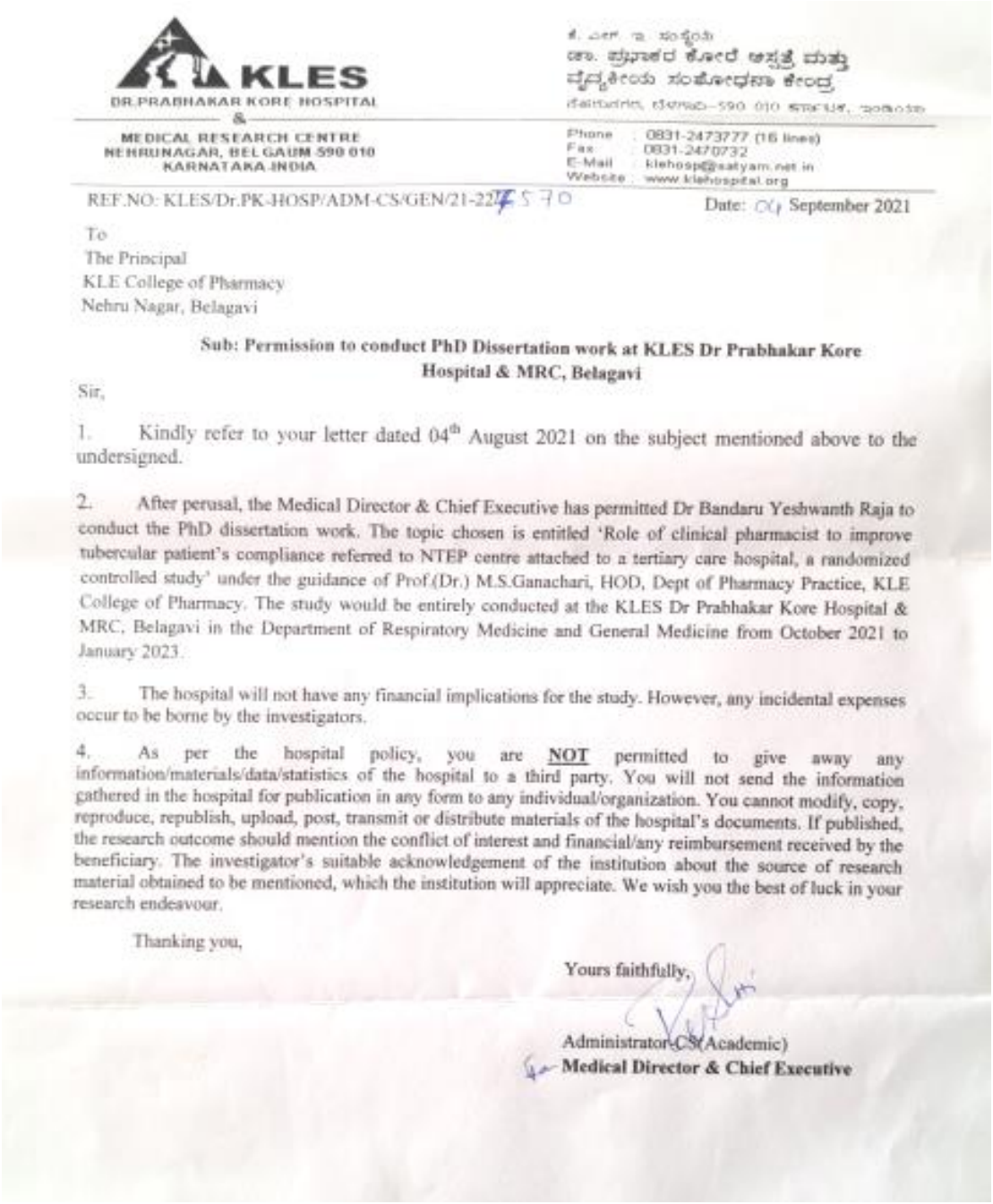
(Dr. Sheetal U. Harakuni)
Member-Secretary
Ethical Committee (Human) for Ph. D. Research
KAHER, Belagavi.

(Dr. B.C. Kotintot)
Chairman
Ethical Committee (Human) for Ph. D. Research
KAHER, Belagavi.

CC to:

- Special Officer to Hon. Vice Chancellor, KAHER, Belagavi
- The Registrar, KAHER, Belagavi.
- The Director Research Foundation, KAHER, Belagavi.
- The Director Academic Affairs, KAHER, Belagavi.

ANNEXURE – II - PERMISSION LETTERS



KLES
DR.PRABHAKAR KORE HOSPITAL
&
MEDICAL RESEARCH CENTRE
NEHRUNAGAR, BELGAUM 590 010
KARNATAKA INDIA

ಕೆ. ಎಲ್. ಇ. ಸಂಸ್ಥೆಯ
ಡಾ. ಪ್ರಭಾಕರ ಕೋರೆ ಆಸ್ಪತ್ರೆ ಮತ್ತು
ವೈದ್ಯಕೀಯ ಸಂಶೋಧನಾ ಕೇಂದ್ರ
ನೆಹರುನಗರ, ಬೆಳಗಾವಿ-590 010 ಕರ್ನಾಟಕ, ಭಾರತ

Phone : 0831-2473777 (16 lines)
Fax : 0831-2470732
E-Mail : klehosp@satyam.net.in
Website : www.klehospital.org

REF.NO: KLES/Dr.PK-HOSP/ADM-CS/GEN/21-22/ 5 7 0 Date: 06 September 2021

To
The Principal
KLE College of Pharmacy
Nehru Nagar, Belagavi

Sub: Permission to conduct PhD Dissertation work at KLES Dr Prabhakar Kore Hospital & MRC, Belagavi

Sir,

1. Kindly refer to your letter dated 04th August 2021 on the subject mentioned above to the undersigned.

2. After perusal, the Medical Director & Chief Executive has permitted Dr Bandaru Yeshwanth Raja to conduct the PhD dissertation work. The topic chosen is entitled 'Role of clinical pharmacist to improve tubercular patient's compliance referred to NTEP centre attached to a tertiary care hospital, a randomized controlled study' under the guidance of Prof.(Dr.) M.S.Ganachari, HOD, Dept of Pharmacy Practice, KLE College of Pharmacy. The study would be entirely conducted at the KLES Dr Prabhakar Kore Hospital & MRC, Belagavi in the Department of Respiratory Medicine and General Medicine from October 2021 to January 2023.

3. The hospital will not have any financial implications for the study. However, any incidental expenses occur to be borne by the investigators.

4. As per the hospital policy, you are **NOT** permitted to give away any information/materials/data/statistics of the hospital to a third party. You will not send the information gathered in the hospital for publication in any form to any individual/organization. You cannot modify, copy, reproduce, republish, upload, post, transmit or distribute materials of the hospital's documents. If published, the research outcome should mention the conflict of interest and financial/any reimbursement received by the beneficiary. The investigator's suitable acknowledgement of the institution about the source of research material obtained to be mentioned, which the institution will appreciate. We wish you the best of luck in your research endeavour.

Thanking you,

Yours faithfully,

Administrator-CS(Academic)
for **Medical Director & Chief Executive**

Date:26/08/2021

To
Medical Superintendent
KLEs Dr. Prabhakar Kore Charitable Hospital
Nehrunagar, Belagavi – 590010

Through,
Principal,
KLE College of Pharmacy,
Nehrunagar, Belagavi – 590010

Sub: Application for permission to conduct Ph. D dissertation work in the department of Respiratory medicine and General medicinein KLEs Dr. Prabhakar Kore Charitable Hospital, Belagavi -590010

Respected Sir,

With respect to the above cited subject, Dr. Bandaru Yeswanth Raja, full time research scholar of Doctor of Philosophy (Ph. D) in pharmacy, under the guidance of Prof. (Dr.) M. S. Ganachari, would like to take your permission to conduct Ph. D dissertation work from October 2021 to January 2023 in the department of Respiratory medicine and General medicine in KLEs Dr. Prabhakar Kore Hospital & MRC. A copy of ethical approval has been attached for your reference. The detail of the project is mentioned below:

Title: Role of clinical pharmacist to improve tubercular patient's compliance referred to NTEP centre attached to a tertiary care hospital: a randomised controlled study.

Kindly permit the same and do the needful

Thanking you,

Yours sincerely,

Research Guide
Prof. (Dr.) M. S. Ganachari
Head of the Department
Dept. of Pharmacy Practice
KLE College of Pharmacy,
Nehrunagar, Belagavi - 590010

Principal
KLE College of Pharmacy,
Nehrunagar, Belagavi - 590010

PRINCIPAL
KLE College of Pharmacy
BELAGAVI - 10.

CC to: HOD, Department of Respiratory medicine and General medicine, KLEs Dr. Prabhakar Kore Charitable Hospital, Nehru Nagar, Belagavi

ANNEXURE – III - INFORMED CONSENT FORM

(ENGLISH, KANNADA, MARATHI)

Informed consent form (English)

Subject Name: -…… **Date of Birth: -**……

Age: -……... **Gender: -**…….

Please read the following before putting your signature

1) I confirm that, have read and understood/have been explained about the information in the participant(patient) information sheet concerning this study. My questions concerning this study have been answered by Dr. B. Yeswanth Raja

2) I understand that my participation is voluntary in the study and I am free to withdraw at any time, without giving any reason and without my medical care/legal rights being affected.

3) I understood and permit the above researcher/Ethics committee/regulatory authorities to look into my health records, both for current study and further research that may be conducted in relation to it even if i stop taking part in the study.

4) I understand that my identity will be confidential and will not be revealed in any information related to scientific purpose or published.

5) I agree not to restrict the use of any of my information or results that arises from this study provided, such a use is only for scientific purpose.

6) I have been given a copy of the information sheet and consent form to keep; by signing this form, I have not given up my legal rights.

7) I agree to take part in the study

Participant's Name **Signature/thumb impression**

Name of the Impartial witness **Signature/ thumb impression**

Name of the investigator: Dr. B. Yeswanth Raja **Signature**

Informed consent form Kannada

ಮಾಹಿತಿಯುತ ಸಮ್ಮತಿ ನಮೂನೆ

ವಿಷಯ ಹೆಸರು:-…… ಹುಟ್ಟಿದ ದಿನ:-……

ವಯಸ್ಸು:-…….. ಲಿಂಗ:-……..

ನಿಮ್ಮ ಸಹಿಯನ್ನು ಹಾಕುವ ಮೊದಲು ದಯವಿಟ್ಟು ಈ ಕೆಳಗಿನವುಗಳನ್ನು ಓದಿ

1) ಈ ಅಧ್ಯಯನಕ್ಕೆ ಸಂಬಂಧಿಸಿದ ಸ್ಪರ್ಧಿ (ರೋಗಿ) ಮಾಹಿತಿ ಹಾಳೆಯಲ್ಲಿನ ಮಾಹಿತಿಯ ಬಗ್ಗೆ ಓದಿದ್ದೇನೆ ಮತ್ತು ಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನೆ/ ವಿವರಿಸಲಾಗಿದೆ ಎಂದು ನಾನು ದೃಢೀಕರಿಸುತ್ತೇನೆ. ಈ ಅಧ್ಯಯನಕ್ಕೆ ಸಂಬಂಧಿಸಿದ ನನ್ನ ಪ್ರಶ್ನೆಗಳಿಗೆ ಡಾ. ಬಿ. ಯಶವಂತ ರಾಜಾ ಉತ್ತರಿಸಿದ್ದಾರೆ.

2) ಅಧ್ಯಯನದಲ್ಲಿ ನನ್ನ ಪಾಲ್ಗೊಳ್ಳುವಿಕೆ ಸ್ವಯಂಪ್ರೇರಿತವಾಗಿದೆ ಎಂದು ನಾನು ಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನೆ ಮತ್ತು ಯಾವುದೇ ಕಾರಣವನ್ನು ನೀಡದೇ ಮತ್ತು ನನ್ನ ವೈದ್ಯಕೀಯ ಆರೈಕೆ / ಕಾನೂನು ಹಕ್ಕುಗಳ ಮೇಲೆ ಪರಿಣಾಮ ಬೀರದೆ ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಹಿಂತೆಗೆದುಕೊಳ್ಳಲು ನಾನು ಸ್ವತಂತ್ರನಾಗಿದ್ದೇನೆ.

3) ನಾನು ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವುದನ್ನು ನಿಲ್ಲಿಸಿದರೂ ಸಹ ಅದಕ್ಕೆ ಸಂಬಂಧಿಸಿದಂತೆ ನಡೆಸಬಹುದಾದ ಪ್ರಸ್ತುತ ಅಧ್ಯಯನ ಮತ್ತು ಹೆಚ್ಚಿನ ಸಂಶೋಧನೆಗಾಗಿ ನನ್ನ ಆರೋಗ್ಯ ದಾಖಲೆಗಳನ್ನು ಪರಿಶೀಲಿಸಲು ಮೇಲಿನ ಸಂಶೋಧಕ / ನೈತಿಕ ಸಮಿತಿ / ನಿಯಂತ್ರಣ ಪ್ರಾಧಿಕಾರಗಳನ್ನು ಅರ್ಥಮಾಡಿಕೊಂಡೆ ಮತ್ತು ಅನುಮತಿಸುತ್ತೇನೆ.

4) ನನ್ನ ಗುರುತು ಗೌಪ್ಯವಾಗಿರುತ್ತದೆ ಮತ್ತು ವೈಜ್ಞಾನಿಕ ಉದ್ದೇಶ ಅಥವಾ ಪ್ರಕಟಿತ ಯಾವುದೇ ಮಾಹಿತಿಯಲ್ಲಿ ಬಹಿರಂಗಪಡಿಸಲಾಗುವುದಿಲ್ಲ ಎಂದು ನಾನು ಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನೆ.

5) ಈ ಅಧ್ಯಯನದಿಂದ ಉದ್ಭವಿಸುವ ನನ್ನ ಯಾವುದೇ ಮಾಹಿತಿ ಅಥವಾ ಫಲಿತಾಂಶಗಳ ಬಳಕೆಯನ್ನು ನಿರ್ಬಂಧಿಸದಿರಲು ನಾನು ಒಪ್ಪುತ್ತೇನೆ, ಅಂತಹ ಬಳಕೆಯು ವೈಜ್ಞಾನಿಕ ಉದ್ದೇಶಕ್ಕಾಗಿ ಮಾತ್ರ.

6) ಈ ನಮೂನೆಗೆ ಸಹಿ ಹಾಕುವ ಮೂಲಕ, ನನ್ನ ಕಾನೂನು ಹಕ್ಕುಗಳನ್ನು ಬಿಟ್ಟುಕೊಟ್ಟಿಲ್ಲ ಎಂದು ಮಾಹಿತಿ ಹಾಳೆ ಮತ್ತು ಸಮ್ಮತಿ ನಮೂನೆಯ ಪ್ರತಿಯನ್ನು ನನಗೆ ನೀಡಲಾಗಿದೆ.

7) ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನಾನು ಒಪ್ಪುತ್ತೇನೆ

ಸ್ಪರ್ಧಿಯ ಹೆಸರು: ಸಹಿ/ ಹೆಬ್ಬೆರಳು ಗುರುತು:

ನಿಷ್ಪಕ್ಷಪಾತ ಸಾಕ್ಷಿಯ ಹೆಸರು; ಸಹಿ/ ಹೆಬ್ಬೆರಳು ಗುರುತು:

ತನಿಖಾಧಿಕಾರಿಯ ಹೆಸರು: ಡಾ. ಬಿ. ಯಶವಂತ ರಾಜಾ ಸಹಿ:

Informed consent form (Marathi)

सूचित संमती फॉर्म

रुग्णाचे नाव: -_____ जन्मतारीख: - _____

वय: - _____ लिंग: - _____

कृपया आपली स्वाक्षरी करण्यापूर्वी खालील गोष्टी वाचा.

१) मी याची पुष्टी करतो की या अभ्यासासंबंधित सहभागी (रुग्ण) माहिती पत्रकामधील माहिती वाचली व समजली आहे / समजली आहे / समजली आहे. या अभ्यासासंबंधित माझ्या प्रश्नांची उत्तरे डॉ. बी. येसवंत राजा यांनी दिली आहेत.

२) मला समजले आहे की माझा सहभाग अभ्यासामध्ये ऐच्छिक आहे आणि कोणतेही कारण न देता आणि माझ्या वैद्यकीय सेवा / कायदेशीर अधिकारांवर परिणाम होत नसल्यामुळे मी कधीही माघार घेऊ शकतो.

३) वरील संशोधक / नीतिशास्त्र समिती / नियामक अधिकाऱ्यांना मी सध्याच्या अभ्यासानुसार माझ्या आरोग्याच्या नोंदी तपासण्यासाठी समजून घेऊन परवानगी दिली आहे आणि मी अभ्यासात भाग घेणे बंद केले तरीही त्याच्याशी संबंधित असे आणखी संशोधन केले जाऊ शकते.

४) मला समजले आहे की माझी ओळख गोपनीय असेल आणि वैज्ञानिक हेतूशी संबंधित किंवा प्रकाशित कोणत्याही माहितीमध्ये प्रकट केली जाणार नाही.

५) माझ्या अभ्यासानुसार दिलेल्या माहितीचा किंवा परिणामांचा वापर मर्यादित न ठेवण्यासाठी मी सहमत आहे, प्रदान केलेल्या अभ्यासामुळे असा उपयोग केवळ वैज्ञानिक हेतूसाठी आहे.

६) या माहितीवर स्वाक्षरी करुन मी माझे कायदेशीर अधिकार सोडलेले नाही, याची माहिती पत्रक व संमती फॉर्मची प्रत मला देण्यात आली आहे.

७) मी अभ्यासात भाग घेण्यास सहमत आहे.

सहभागीचे नाव_____ स्वाक्षरी / अंगठ्याचा ठसा_____

निष्पक्ष साक्षीदाराचे नाव _____स्वाक्षरी / अंगठ्याचा ठसा _____

अन्वेषकांचेनाव: डॉ. बी. येसवंत राजा. स्वाक्षरी_____

ANNEXURE – IV - PATIENT INFORMATION SHEET

(ENGLISH, KANNADA, MARATHI)

Patient Information Sheet (English):

Background:

You/Your relative are being requested to take part in this study of Significance of Clinical Pharmacy Services in the Management of pulmonary tuberculosis patients. Please take your time to read this document and make your decision. You may choose to discuss this study with your friends, family, family doctor and your study doctor. Make sure that all your questions are answered before agreeing to take part in this study. If you decide to take part in this study, I need your co-operation.

Why is this study being done?

The study is being done to evaluate the role of clinical pharmacy services in improving medication adherence, lifestyle modifications, quality of life, knowledge, attitude and practices on tuberculosis treatment regimen and hospital revisiting's.

How many subjects will take part in the study?

Patients visiting in the respiratory medicine OPs/ admitting IPs wards, NTEP centre of KLE hospitals and PHCs/UHCs of Belgaum with Pulmonary tuberculosis will be enrolled in the study. Approximately 200 subjects will take part in the study.

How long will I be in the study?

You will be enrolled in the study for 2years.

What is involved in the study?

Tests and procedures: Your/ Patient participation in this study is done by collecting sputum sample, 4ml of blood which will be withdrawn from the antecubital vein of the forearm and X-ray.

Study schedule: The study duration will be for 2years.

What are the risks of the study?

Risks of blood withdrawal. It is possible you/patient may have mild pain or bruising where the needle enters the vein when blood sample are taken. There will be no other significant adverse effects associated with drawing of blood. All routine aseptic precaution will be taken while drawing of blood.

Are there benefits in taking part in the study?

People taking part in the study may or may not have any direct benefit. The long-term benefits may include overall improvement in health, medication adherence and quality of life.

What other choices are there?

If you decide not to participate in this study. It will not affect your standard treatment. Please talk to your investigator, if you have any questions about the benefits and risks of this study.

What about privacy?

Confidentiality will be maintained throughout the study. Your identity will not be disclosed. The tests done will not be used for any purpose other than described above. If the study is published in a medical journal or scientific publication for further advancement of sciences and your identity will not be disclosed.

What are my medical costs?

No extra cost will be added to your treatment cost due to your participation in this study. All the study related costs would be borne by the investigator.

Compensation: No compensation will be given for participation in this study. Any problems arising during the blood drawing or due to the blood drawn, proper medical care will be given by your doctor.

What are my rights as participant?

Taking part in this study is voluntary. You may choose not to take part in this study, or you may choose to leave the study at any time. The quality of your medical care will not change if you decide not to take part in this study or if you decide to leave the study early.

Whom do I call if I have questions or problems?

Dr. Bandaru Yeswanth Raja, Pharm.D, Research scholar, Department of Pharmacy Practice, KLE College of Pharmacy, KAHER, Belagavi, Phone No. 9490650260

Patient Information Sheet (Kannada):

ಅಧ್ಯಯನದ ಶೀರ್ಷಿಕೆ:

ತೃತೀಯ ಆರೈಕೆ ಆಸ್ಪತ್ರೆಯಲ್ಲಿ ಆರ್ ಎನ್ ಟಿಇಪಿ ಕೇಂದ್ರಕ್ಕೆ ಉಲ್ಲೇಖಿಸಲಾದ ಕ್ಷಯ ರೋಗಿಗಳ ಅನುಸರಣೆಯನ್ನು ಸುಧಾರಿಸಲು ಕ್ಲಿನಿಕಲ್ ಫಾರ್ಮಾಸಿಸ್ಟ್ ಪಾತ್ರ.

ತನಿಖಾಧಿಕಾರಿಗಳು:

ಡಾ. ಬಂಡಾರು ಯಶವಂತ ರಾಜಾ, ಫಾರ್ಮ್ ಡಿ, (ಸಂಶೋಧನಾ ವಿದ್ಯಾರ್ಥಿ)

ಡಾ. ಮೀ ಎಸ್. ಗಣಾಚಾರಿ, ಎಂ. ಫಾರ್ಮ್, ಪಿಎಚ್ ಡಿ, ಪ್ರೊಫೆಸರ್, ಎಚ್ ಒಡಿ, ಫಾರ್ಮಸಿ ಅಭ್ಯಾಸ ವಿಭಾಗ, ಕೆಎಲ್ಇ ಕಾಲೇಜ್ ಆಫ್ ಫಾರ್ಮಸಿ.

ಡಾ., ಪ್ರೊಫೆಸರ್ ಮತ್ತು ಉಸಿರಾಟದ ಔಷಧ ವಿಭಾಗ,

ಡಾ., ಎಚ್ ಒಡಿ, ಹೃದಯ ರಕ್ತನಾಳ ಮತ್ತು ಎದೆಶಸ್ತ್ರಚಿಕಿತ್ಸೆ ಮತ್ತು ಕೆಎಲ್ಇ ಆಸ್ಪತ್ರೆ ಕಹರ್, ಬೆಳಗಾವಿ-590010, ಬೆಳಗಾವಿ ಜಿಲ್ಲೆ, ಕರ್ನಾಟಕ, ಭಾರತ

ಹಿನ್ನೆಲೆ:

ಶ್ವಾಸಕೋಶದ ಕ್ಷಯ ರೋಗಿಗಳ ನಿರ್ವಹಣೆಯಲ್ಲಿ ಕ್ಲಿನಿಕಲ್ ಫಾರ್ಮಸಿ ಸೇವೆಗಳ ಪ್ರಾಮುಖ್ಯತೆಯ ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನಿಮ್ಮನ್ನು/ನಿಮ್ಮ ಸಂಬಂಧಿಯನ್ನು ವಿನಂತಿಸಲಾಗುತ್ತಿದೆ. ದಯವಿಟ್ಟು ಈ ದಾಖಲೆಯನ್ನು ಓದಲು ಮತ್ತು ನಿಮ್ಮ ನಿರ್ಧಾರವನ್ನು ತೆಗೆದುಕೊಳ್ಳಲು ನಿಮ್ಮ ಸಮಯವನ್ನು ತೆಗೆದುಕೊಳ್ಳಿ. ಈ ಅಧ್ಯಯನವನ್ನು ನಿಮ್ಮ ಸ್ನೇಹಿತರು, ಕುಟುಂಬ, ಕುಟುಂಬ ವೈದ್ಯರು ಮತ್ತು ನಿಮ್ಮ ಅಧ್ಯಯನ ವೈದ್ಯರೊಂದಿಗೆ ಚರ್ಚಿಸಲು ನೀವು ಆಯ್ಕೆ ಮಾಡಬಹುದು. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಒಪ್ಪುವ ಮೊದಲು ನಿಮ್ಮ ಎಲ್ಲಾ ಪ್ರಶ್ನೆಗಳಿಗೆ ಉತ್ತರಿಸಲಾಗಿದೆ ಎಂದು ಖಚಿತಪಡಿಸಿಕೊಳ್ಳಿ. ನೀವು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನಿರ್ಧರಿಸಿದರೆ, ನನಗೆ ನಿಮ್ಮ ಸಹಕಾರ ಬೇಕು.

ಈ ಅಧ್ಯಯನವನ್ನು ಏಕೆ ಮಾಡಲಾಗುತ್ತಿದೆ?

ಔಷಧೋಪಚಾರದ ಅನುಸರಣೆ, ಜೀವನಶೈಲಿ ಮಾರ್ಪಾಡುಗಳು, ಜೀವನದ ಗುಣಮಟ್ಟ, ಜ್ಞಾನ, ವರ್ತನೆ ಮತ್ತು ಕ್ಷಯ ಚಿಕಿತ್ಸಾ ಕ್ರಮ ಮತ್ತು ಆಸ್ಪತ್ರೆಯ ಮರುಭೇಟಿಯ ಅಭ್ಯಾಸಗಳನ್ನು ಸುಧಾರಿಸುವಲ್ಲಿ ಕ್ಲಿನಿಕಲ್ ಫಾರ್ಮಸಿ ಸೇವೆಗಳ ಪಾತ್ರವನ್ನು ಮೌಲ್ಯಮಾಪನ ಮಾಡಲು ಈ ಅಧ್ಯಯನವನ್ನು ಮಾಡಲಾಗುತ್ತಿದೆ.

ಅಧ್ಯಯನದಲ್ಲಿ ಎಷ್ಟು ವಿಷಯಗಳು ಭಾಗವಹಿಸುತ್ತವೆ?

ಉಸಿರಾಟದ ಔಷಧ ಒಪಿಗಳು/ ಐಪಿಎಸ್ ವಾರ್ಡ್ ಗಳಿಗೆ ಭೇಟಿ ನೀಡುವ ರೋಗಿಗಳು, ಕೆಎಲ್ ಇ ಆಸ್ಪತ್ರೆಗಳ ಆರ್ ಎನ್ ಟಿಇಪಿ ಕೇಂದ್ರ ಮತ್ತು ಶ್ವಾಸಕೋಶದ ಕ್ಷಯ ಹೊಂದಿರುವ ಬೆಳಗಾವಿಯ ಪಿಎಚ್ ಸಿಗಳು/ಯುಎಚ್ ಸಿಗಳನ್ನು ಅಧ್ಯಯನದಲ್ಲಿ ದಾಖಲಿಸಲಾಗುವುದು. ಸುಮಾರು 200 ಪ್ರಯೋಗಾರ್ಥಿಗಳು ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲಿದ್ದಾರೆ.

ನಾನು ಎಷ್ಟು ದಿನ ಅಧ್ಯಯನದಲ್ಲಿ ರುತ್ತೇನೆ?

ನೀವು 2 ವರ್ಷಗಳ ಕಾಲ ಅಧ್ಯಯನಕ್ಕೆ ದಾಖಲಾಗುತ್ತೀರಿ.

ಅಧ್ಯಯನದಲ್ಲಿ ಏನು ಭಾಗಿಯಾಗಿದೆ?

ಪರೀಕ್ಷೆಗಳು ಮತ್ತು ಕಾರ್ಯವಿಧಾನಗಳು: ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನಿಮ್ಮ / ರೋಗಿಯ ಪಾಲ್ಗೊಳ್ಳುವಿಕೆಯನ್ನು ಕಫದ ಮಾದರಿ, 4 ಮಿಲೀ ರಕ್ತವನ್ನು ಸಂಗ್ರಹಿಸುವ ಮೂಲಕ ಮಾಡಲಾಗುತ್ತದೆ, ಇದನ್ನು ಮುಂಗೈ ಮತ್ತು ಎಕ್ಸ್-ರೇಯ ಪೂರ್ವಾಗ್ರಹರಕ್ತನಾಳದಿಂದ ಹಿಂತೆಗೆದುಕೊಳ್ಳಲಾಗುತ್ತದೆ.

ಅಧ್ಯಯನ ವೇಳಾಪಟ್ಟಿ: ಅಧ್ಯಯನದ ಅವಧಿ 2 ವರ್ಷಗಳವರೆಗೆ ಇರುತ್ತದೆ.

ಅಧ್ಯಯನದ ಅಪಾಯಗಳು ಯಾವುವು?

ರಕ್ತ ಹಿಂತೆಗೆದುಕೊಳ್ಳುವ ಅಪಾಯಗಳು. ರಕ್ತದ ಮಾದರಿಯನ್ನು ತೆಗೆದುಕೊಂಡಾಗ ಸೂಜಿಯು ರಕ್ತನಾಳವನ್ನು ಪ್ರವೇಶಿಸುವಲ್ಲಿ ನೀವು/ರೋಗಿಗೆ ಸೌಮ್ಯ ನೋವು ಅಥವಾ ಜಜ್ಜುಗಾಯವಾಗುವ ಸಾಧ್ಯತೆಯಿದೆ. ರಕ್ತದ ರೇಖಾಚಿತ್ರ ಕ್ಕೆ ಸಂಬಂಧಿಸಿದ ಇತರ ಯಾವುದೇ ಗಮನಾರ್ಹ ಪ್ರತಿಕೂಲ ಪರಿಣಾಮಗಳು ಇರುವುದಿಲ್ಲ. ರಕ್ತವನ್ನು ತೆಗೆದುಕೊಳ್ಳುವಾಗ ಎಲ್ಲಾ ವಾಡಿಕೆಯ ಅಸೆಪ್ಟಿಕ್ ಮುನ್ನೆಚ್ಚರಿಕೆಗಳನ್ನು ತೆಗೆದುಕೊಳ್ಳಲಾಗುತ್ತದೆ.

ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳುವುದರಿಂದ ಪ್ರಯೋಜನಗಳಿವೆಯೇ?

ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳುವ ಜನರಿಗೆ ಯಾವುದೇ ನೇರ ಪ್ರಯೋಜನಇರಬಹುದು ಅಥವಾ ಇಲ್ಲದಿರಬಹುದು. ದೀರ್ಘಕಾಲೀನ ಪ್ರಯೋಜನಗಳು ಆರೋಗ್ಯದಲ್ಲಿ ಒಟ್ಟಾರೆ ಸುಧಾರಣೆ, ಔಷಧೋಪಚಾರದ ಅನುಸರಣೆ ಮತ್ತು ಜೀವನದ ಗುಣಮಟ್ಟವನ್ನು ಒಳಗೊಂಡಿರಬಹುದು.

ಇತರ ಯಾವ ಆಯ್ಕೆಗಳಿವೆ?

ನೀವು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸದಿರಲು ನಿರ್ಧರಿಸಿದರೆ. ಇದು ನಿಮ್ಮ ಪ್ರಮಾಣಿತ ಚಿಕಿತ್ಸೆಯ ಮೇಲೆ ಪರಿಣಾಮ ಬೀರುವುದಿಲ್ಲ. ಈ ಅಧ್ಯಯನದ ಪ್ರಯೋಜನಗಳು ಮತ್ತು ಅಪಾಯಗಳ ಬಗ್ಗೆ ನಿಮಗೆ ಯಾವುದೇ ಪ್ರಶ್ನೆಗಳಿದ್ದರೆ ದಯವಿಟ್ಟು ನಿಮ್ಮ ತನಿಖಾಧಿಕಾರಿಯ ಜೊತೆ ಮಾತನಾಡಿ.

ಗೌಪ್ಯತೆಯ ಬಗ್ಗೆ ಏನು?

ಅಧ್ಯಯನದುದ್ದಕ್ಕೂ ಗೌಪ್ಯತೆಯನ್ನು ಕಾಪಾಡಿಕೊಳ್ಳಲಾಗುವುದು. ನಿಮ್ಮ ಗುರುತನ್ನು ಬಹಿರಂಗಪಡಿಸಲಾಗುವುದಿಲ್ಲ. ಮಾಡಿದ ಪರೀಕ್ಷೆಗಳನ್ನು ಮೇಲೆ ವಿವರಿಸಿರುವುದಕ್ಕಿಂತ ಬೇರೆ ಯಾವುದೇ ಉದ್ದೇಶಕ್ಕಾಗಿ ಬಳಸಲಾಗುವುದಿಲ್ಲ. ವಿಜ್ಞಾನಗಳ ಹೆಚ್ಚಿನ ಪ್ರಗತಿಗಾಗಿ ಅಧ್ಯಯನವನ್ನು ವೈದ್ಯಕೀಯ ನಿಯತಕಾಲಿಕ ಅಥವಾ ವೈಜ್ಞಾನಿಕ ಪ್ರಕಾಶನದಲ್ಲಿ ಪ್ರಕಟಿಸಿದರೆ ಮತ್ತು ನಿಮ್ಮ ಗುರುತನ್ನು ಬಹಿರಂಗಪಡಿಸಲಾಗುವುದಿಲ್ಲ.

ನನ್ನ ವೈದ್ಯಕೀಯ ವೆಚ್ಚಗಳು ಯಾವುವು?

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನೀವು ಭಾಗವಹಿಸುವುದರಿಂದ ನಿಮ್ಮ ಚಿಕಿತ್ಸಾ ವೆಚ್ಚಕ್ಕೆ ಯಾವುದೇ ಹೆಚ್ಚುವರಿ ವೆಚ್ಚವನ್ನು ಸೇರಿಸಲಾಗುವುದಿಲ್ಲ. ಅಧ್ಯಯನಕ್ಕೆ ಸಂಬಂಧಿಸಿದ ಎಲ್ಲಾ ವೆಚ್ಚಗಳನ್ನು ತನಿಖಾಧಿಕಾರಿಯು ಭರಿಸುತ್ತಾನೆ.

ಪರಿಹಾರ: ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಯಾವುದೇ ಪರಿಹಾರವನ್ನು ನೀಡಲಾಗುವುದಿಲ್ಲ. ರಕ್ತ ತೆಗೆಯುವ ಾಗ ಅಥವಾ ರಕ್ತ ತೆಗೆದುಕೊಳ್ಳುವುದರಿಂದ ಉಂಟಾಗುವ ಯಾವುದೇ ಸಮಸ್ಯೆಗಳು, ನಿಮ್ಮ ವೈದ್ಯರು ಸರಿಯಾದ ವೈದ್ಯಕೀಯ ಆರೈಕೆಯನ್ನು ಮಾಡುತ್ತಾರೆ.

ಭಾಗಿದಾರನಾಗಿ ನನ್ನ ಹಕ್ಕುಗಳು ಯಾವುವು?

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳುವುದು ಸ್ವಯಂಪ್ರೇರಿತವಾಗಿದೆ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳದಿರಲು ನೀವು ಆಯ್ಕೆ ಮಾಡಬಹುದು, ಅಥವಾ ನೀವು ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಅಧ್ಯಯನವನ್ನು ತೊರೆಯಲು ಆಯ್ಕೆ ಮಾಡಬಹುದು. ನೀವು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸದಿರಲು ನಿರ್ಧರಿಸಿದರೆ ಅಥವಾ ನೀವು ಅಧ್ಯಯನವನ್ನು ಬೇಗನೆ ಬಿಡಲು ನಿರ್ಧರಿಸಿದರೆ ನಿಮ್ಮ ವೈದ್ಯಕೀಯ ಆರೈಕೆಯ ಗುಣಮಟ್ಟಬದಲಾಗುವುದಿಲ್ಲ.

ನನಗೆ ಪ್ರಶ್ನೆಗಳು ಅಥವಾ ಸಮಸ್ಯೆಗಳಿದ್ದರೆ ನಾನು ಯಾರನ್ನು ಕರೆಯುತ್ತೇನೆ?

ಡಾ. ಬಂಡಾರು ಯಶವಂತ ರಾಜಾ, ಫಾರ್ಮ್.ಡಿ, ಸಂಶೋಧನಾ ವಿದ್ವಾಂಸ, ಫಾರ್ಮಸಿ ಅಭ್ಯಾಸ ವಿಭಾಗ, ಕೆಎಲ್ಇ ಕಾಲೇಜ್ ಆಫ್ ಫಾರ್ಮಸಿ, ಕೆಎಎಚ್ಇಆರ್, ಬೆಳಗಾವಿ, ದೂರವಾಣಿ ಸಂಖ್ಯೆ 9490650260

Patient Information Sheet (Marathi):

अभ्यासाचे शीर्षक:

क्षयरोगाच्या रूग्णांचे अनुपालन सुधारण्यासाठी क्लिनिकल फार्मासिस्टची भूमिका, तृतीयक काळजी रुग्णालयात आरएनटीईपी केंद्रात संदर्भित.

अन्वेषक:

डॉ. बंडारू येसवंथ राजा, फार्म डी, (संशोधन अभ्यासक)

डॉ. एस. एस. गणाचारी, एम. फार्म, पीएचडी, प्रोफेसर, एचओडी, फार्मसी प्रॅक्टिस विभाग, केएलई कॉलेज ऑफ फार्मसी.

प्राध्यापक आणि श्वसन औषध विभागातील डॉक्टर.

डॉ. एचओडी, हृदय व रक्तवाहिन्यासंबंधी विभाग आणि थोरॅसिक सर्जरी आणि केएलई हॉस्पिटल काहेर, बेलागाव-590010, बेळगाव जिल्हा, कर्नाटक, भारत.

पार्श्वभूमी:

आपणास / आपल्या नातेवाईकांना पल्मनरी क्षय रोगाच्या व्यवस्थापनात क्लिनिकल फार्मेसी सर्व्हिस चे महत्त्व या अभ्यासात भाग घेण्याची विनंती केली जात आहे. कृपया हा दस्तऐवज वाचण्यासाठी आपण आपला वेळ घ्या आणि नंतर निर्णय घ्या. आपण या अभ्यासाबद्दल आपले मित्र, कुटुंब, कौटुंबिक डॉक्टर आणि आपल्या अभ्यास डॉक्टरांशी चर्चा करणे निवडू शकता. या अभ्यासात भाग घेण्यास सहमती देण्यापूर्वी आपल्या सर्व प्रश्नांची उत्तरे दिली असल्याची खात्री करा. आपण या अभ्यासामध्ये भाग घेण्याचे ठरविल्यास, मला आपल्या सहकार्याची आवश्यकता आहे.

ही अभ्यासिका का केली जात आहे?

औषधोपचारांचे पालन, जीवनशैलीत बदल, जीवनशैली, ज्ञान, दृष्टीकोन सुधारण्यासाठी क्लिनिकल फार्मसी सेवांच्या भूमिकेचे मूल्यांकन करण्यासाठी हा अभ्यास केला जात आहे आणि क्षयरोग उपचार पथ्ये आणि रूग्णालयाच्या पुनरावृत्तीच्या पद्धती सुधारण्यासाठी.

बरेच रुग्ण अभ्यासात भाग कसा घेतील?

श्वासोच्छवासाच्या औषधांचे ओपी / प्रवेश घेणारे आयपी वॉर्ड, केएलई रुग्णालयांचे आरएनटीईपी केंद्र आणि पल्मोनरी क्षय रोग असलेल्या बेळगावच्या पीएचसी / यूएचसीमध्ये अभ्यास करणाऱ्या रुग्णांची अभ्यासामध्ये नोंदणी केली जाईल. सुमारे 200 रुग्ण अभ्यासात भाग घेतील.

मी अभ्यासात किती काळ राहू?

आपण 2 वर्षांच्या अभ्यासामध्ये प्रवेश घ्याल.

अभ्यासात काय समाविष्ट आहे?

<u>चाचण्या आणि कार्यपद्धती:</u>

या अभ्यासात आपला / रुग्णाचा थुंकीचा नमुना गोळा केला जातो, रक्त 4 मिलीलीटर, जो सखल आणि क्ष-किरणांच्या एन्टीक्युबिटल नसातून काढून घेतला जाईल.

<u>अभ्यासाचे वेळापत्रक:</u>

अभ्यासाचा कालावधी 2 वर्षांचा असेल.

अभ्यासाचे धोके काय आहेत?

रक्त जमा करण्याचे धोके. जेव्हा रक्तचा नमुना घेतला जातो तेव्हा आपल्यात / रूग्णाला हलकी वेदना किंवा जखम होण्याची शक्यता आहे जिथे सुई शिरामध्ये प्रवेश करते. रक्ताच्या रेखांकनाशी संबंधित इतर कोणतेही महत्त्वपूर्ण दुष्परिणाम होणार नाहीत. रक्ताचे रेखांकन करताना सर्व नियमित असेप्टिक खबरदारी घेतली जाईल.

अभ्यासात भाग घेण्यामध्ये काय फायदे आहेत?

अभ्यासामध्ये भाग घेत असलेल्या लोकांना त्याचा थेट फायदा कदाचित नसू शकतो. दीर्घकालीन फायद्यांमध्ये आरोग्य, औषधाचे पालन आणि जीवनशैली मध्ये एकंदर सुधारणा समाविष्ट असू शकते.

इतर निवडी तिथे काय आहेत?

आपण या अभ्यासामध्ये भाग न घेण्याचे ठरविल्यास. हे आपल्या प्रमाणित उपचारांवर परिणाम करणार नाही. या अभ्यासाचे फायदे आणि जोखीम याबद्दल आपल्याकडे काही प्रश्न असल्यास कृपया आपल्या अन्वेषकांशी बोला.

गोपनीयता काय आहे?

संपूर्ण अभ्यासात गोपनीयता राखली जाईल. तुमची ओळख जाहीर केली जाणार नाही. केलेल्या चाचण्या वर वर्णन केल्याखेरीज इतर कोणत्याही हेतूसाठी वापरल्या जाणार नाहीत. हा अभ्यास विज्ञानांच्या पुढील प्रगतीसाठी वैद्यकीय जर्नलमध्ये किंवा वैज्ञानिक प्रकाशनात प्रकाशित झाल्यास आपली ओळख उघड केली जाणार नाही.

माझे वैद्यकीय खर्च काय आहेत?

या अभ्यासात सहभागामुळे आपल्या उपचार खर्चामध्ये कोणतीही अतिरिक्त किंमत जोडली जाणार नाही. अभ्यासाशी संबंधित सर्व खर्च अन्वेषक तपासून घेतील.

भरपाई:

या अभ्यासामध्ये भाग घेण्यासाठी कोणतीही भरपाई दिली जाणार नाही. रक्ताच्या रेखांकनादरम्यान किंवा रक्त काढल्यामुळे उद्भवणारी कोणतीही समस्या असल्यास आपल्या डॉक्टरांकडून योग्य वैद्यकीय सेवा दिली जाईल.

भागीदार म्हणून माझे हक्क काय आहेत?

या अभ्यासामध्ये भाग घेणे ऐच्छिक आहे. आपण या अभ्यासामध्ये भाग न घेण्याची निवड करू शकता किंवा आपण कधीही अभ्यास सोडून देऊ शकता. आपण या अभ्यासामध्ये भाग न घेण्याचा निर्णय घेतल्यास किंवा आपण लवकर अभ्यास सोडून देण्याचा निर्णय घेतल्यास आपल्या वैद्यकीय सेवेची गुणवत्ता बदलणार नाही.

मला प्रश्न किंवा समस्या असल्यास मी कोणाशी बोलू?

डॉ. बंडारू येसवंथ राजा, फार्म.डी, संशोधन अभ्यासक, फार्मसी प्रॅक्टिस विभाग, केएलई कॉलेज ऑफ फार्मसी, काहेर बेळगाव, फोन नंबर 9490650260

ANNEXURE – V - DATA COLLECTION FORM

Name: **IP No./OP No.:**

Age: **Height:** **Weight:** **BMI:**

Gender: **Occupation:** **DOA:**

Address:

Phone no: **Gmail:**

Past medical history:

Past medication history:

Name of the Drug	Dose	Frequency	Route	Started Date	Stopped Date

Family history:

Social history:

Smoker	Alcoholic	Food Habits

Chief complaints:

Vital Signs:

Temp:	**Pulse Rate:**
Blood Pressure:	**Respiration Rate:**
SPO_2:	

Systemic Examination:

Laboratory Investigations:

Hematology	Value			Normal Range
	Day	Day	Day	
Hb				M – (13- 17 g /dl) F – (12 – 15 g/dl)
RBC				M – (4.5 – 5.5 million cells /cumm) F – (3.8 -4.8 Millon cells/cum)
PCV				M- (40-50%) F- (36-46%)
MCV				83 – 101 f L

MCH				27 – 32 p g
MCHC				31.5 – 34.5 g/dl
WBC				4000 – 11000 Cells/ cu .mm
Neutrophils				40 – 80 %
Lymphocyte				20 – 40 %
Monocyte				2 – 10 %
Eosinophil				1-4%
Platelet				1,50,000 – 4,00,000 cells/cu.mm
ESR				M (0 – 10 mm / hr) F (0 – 20 mm / hr)
CRP				<1.0 mg//L
Ferritin				M (24-285 ug/L) F (12-270 ug/L)

Remarks:

Tuberculin test:

Sputum Smear test:

Special investigations:

Final diagnosis:

Medications:

Name of the Drug	**Dose**	**Frequency**	**Route**	**Started Date**	**Stopped Date**

Discharge medications:

Remarks:

Signature of Physician

(If Necessary)

Signature of the Pharmacist:

ANNEXURE – VI - Modified Kuppuswamy's Socioeconomic Status (SES) Scale 2019

Education of head of family			Score
Professional degree			7
Graduate or postgraduate			6
Intermediate or post high school diploma			5
High school certificate			4
Middle school certificate			3
Primary school certificate			2
Illiterate			1
Occupation of head of family			
Professional (white collar)			10
Semi-professional			6
Clerical, shop-owner/farm			5
Skilled worker			4
Semi-skilled worker			3
Unskilled worker			2
Unemployed			1
Monthly income of family			
In 2001 (Base year)	**In 2017 (January 2017 CPI)**	**In 2019 (February 2019 CPI)**	**Score**
≥15,197	≥41,430	≥52,734	12
7,595-15,196	20,715-41,429	26,355-52,733	10
5,694-7,594	15,536-20,714	19,759-26,354	6
3,793-5,693	10,357-15,535	13,161-19,758	4
2,273-3,792	6,214-10,356	7,887-13,160	3
761-2,272	2,092-6,213	2,641-7,886	2
≤760	≤2,091	≤2,640	1
Socioeconomic class			**Total score**
I	Upper		26-29
II	Upper middle		16-25
III	Lower middle		11-15
IV	Upper lower		5-10
V	Lower		01-04

ANNEXURE – VII – Fagerstrom test

Fagerstrom test for smoking	**Modified Fagerstrom test for smokeless tobacco users**
How soon after you wake up do you smoke your first cigarette/bidi? Within 5 minutes 3 6 to 30 minutes 2 31 to 60 minutes 1 More than 60 minutes 0	How soon after you wake up do you use your first dip/chew? Within 5 minutes 3 6 to 30 minutes 2 31 to 60 minutes 1 After 60 minutes 0
Do you find it difficult to refrain from smoking in places where it is forbidden? Yes 1 No 0	How often do you intentionally swallow tobacco juice? Always 2 Sometimes 1 Never 0
Which cigarette/bidi would you hate to give up most? The first one in the morning 1 All others 0	Which tobacco chew would you hate to give up most? The first one in the morning 1 All others 0
How many cigarettes/bidis do you smoke per day? 10 or less 0 11-20 1 21-30 2 or more 3	How many cans/pouches of tobacco do you use per week? More than 3 2 1-3 1 Less than 1 0
Do you smoke more frequently in the first hours after waking up than during the rest of the day? Yes 1 No 0	Do you chew tobacco more frequently in the first hours after waking up than during the rest of the day? Yes 1 No 0
Do you smoke when you are so ill that you are in bed most of the day? Yes 1 No 0	Do you chew tobacco when you are so ill that you are in bed most of the day? Yes 1 No 0
Total score:	Total score:

Level of dependence:

6: high, 4-6: moderate, less than 6: low

ANNEXURE – VIII – PCNE CLASSIFICATION V9.1

The Problems

Primary Domain	Code V9.1	Problem
1.Treatment effectiveness There is a (potential) problem with the (lack of) effect of the pharmacotherapy.	**P1.1**	No effect of drug treatment despite correct use
	P1.2	Effect of drug treatment not optimal
	P1.3	Untreated symptoms or indication
2. Treatment safety Patient suffers, or could suffer, from an adverse drug event. *N.B. If there is no specific cause, skip Causes coding.*	**P2.1**	Adverse drug event (possibly) occurring
3. Other	**P3.1**	Unnecessary drug-treatment
	P3.2	*Unclear problem/complaint. Further clarification necessary (please use as escape only)*

The Causes (including possible causes for potential problems)

[N.B. One problem can have more causes]

	Primary Domain	Code V9.1	Cause
Prescribing & drug selection	**1. Drug selection** The cause of the (potential) DRP is related to the selection of the drug (by patient or health professional)	**C1.1**	Inappropriate drug according to guidelines/formulary
		C1.2	No indication for drug
		C1.3	Inappropriate combination of drugs, or drugs and herbal medications, or drugs and dietary supplements
		C1.4	Inappropriate duplication of therapeutic group or active ingredient
		C1.5	No or incomplete drug treatment in spite of existing indication
		C1.6	Too many different drugs/active ingredients prescribed for indication
	2. Drug form The cause of the DRP is related to the selection of the drug form	**C2.1**	Inappropriate drug form/formulation (for this patient)
	3. Dose selection The cause of the DRP is related to the selection of the dose or dosage	**C3.1**	Drug dose too low
		C3.2	Drug dose of a single active ingredient too high
		C3.3	Dosage regimen not frequent enough
		C3.4	Dosage regimen too frequent
		C3.5	Dose timing instructions wrong, unclear or missing
	4. Treatment duration The cause of the DRP is related to the duration of treatment	**C4.1**	Duration of treatment too short
		C4.2	Duration of treatment too long
Disp	**5. Dispensing** The cause of the DRP is related to the logistics of the prescribing and dispensing process	**C5.1**	Prescribed drug not available
		C5.2	Necessary information not provided or incorrect advice provided
		C5.3	Wrong drug, strength or dosage advised (OTC)
		C5.4	Wrong drug or strength dispensed
Use	**6. Drug use process** The cause of the DRP is related to the way the patient gets the drug administered ***by a health professional or other carer***, despite proper dosage instructions (on label/list)	**C6.1**	Inappropriate timing of administration or dosing intervals by a health professional
		C6.2	Drug under-administered by a health professional
		C6.3	Drug over-administered by a health professional
		C6.4	Drug not administered at all by a health professional
		C6.5	Wrong drug administered by a health professional
		C6.6	Drug administered via wrong route by a health professional
	7. Patient related The cause of the DRP is related to the patient and his behaviour (intentional or non-intentional)	**C7.1**	Patient intentionally uses/takes less drug than prescribed or does not take the drug at all for whatever reason
		C7.2	Patient uses/takes more drug than prescribed
		C7.3	Patient abuses drug (unregulated overuse)
		C7.4	Patient decides to use unnecessary drug
		C7.5	Patient takes food that interacts
		C7.6	Patient stores drug inappropriately
		C7.7	Inappropriate timing or dosing intervals

		C7.9	Patient physically unable to use drug/form as directed
		C7.10	Patient unable to understand instructions properly
Seamless	**8. Patient transfer related** The cause of the DRP can be related to the transfer of patients between primary, secondary and tertiary care, or transfer within one care institution.	**C8.1**	Medication reconciliation problem
	9. Other	**C9.1**	No or inappropriate outcome monitoring (incl. TDM)
		C9.2	Other cause; specify
		C9.3	No obvious cause

The Planned Interventions

N.B. One problem can lead to more interventions

Primary Domain	Code V9.1	Intervention
No intervention	**I0.1**	No Intervention
1. At prescriber level	**I1.1**	Prescriber informed only
	I1.2	Prescriber asked for information
	I1.3	Intervention proposed to prescriber
	I1.4	Intervention discussed with prescriber
2. At patient level	**I2.1**	Patient (drug) counselling
	I2.2	Written information provided (only)
	I2.3	Patient referred to prescriber
	I2.4	Spoken to family member/caregiver
3. At drug level	**I3.1**	Drug changed to …
	I3.2	Dosage changed to …
	I3.3	Formulation changed to …
	I3.4	Instructions for use changed to …
	I3.5	Drug paused or stopped
	I3.6	Drug started
4. Other intervention or activity	**I4.1**	Other intervention (specify)
	I4.2	Side effect reported to authorities

Acceptance of the Intervention proposals

N.B. One status of acceptance per intervention proposal

Primary domain	Code 9.1	Implementation
1. Intervention accepted (by prescriber or patient)	**A1.1**	Intervention accepted and fully implemented
	A1.2	Intervention accepted, partially implemented
	A1.3	Intervention accepted but not implemented
	A1.4	Intervention accepted, implementation unknown
2. Intervention not accepted (by prescriber or patient)	**A2.1**	Intervention not accepted: not feasible
	A2.2	Intervention not accepted: no agreement
	A2.3	Intervention not accepted: other reason (specify)
	A2.4	Intervention not accepted: unknown reason
3. Other (no information on acceptance)	**A3.1**	Intervention proposed, acceptance unknown
	A3.2	Intervention not proposed

Status of the DRP

N.B. This domain depicts the outcome of the intervention. One problem (or the combination of interventions) can only lead to one level of solving the problem

Primary Domain	Code V9.1	Outcome of intervention
0. Not known	**O0.1**	Problem status unknown
1. Solved	**O1.1**	Problem totally solved
2. Partially solved	**O2.1**	Problem partially solved
3. Not solved	**O3.1**	Problem not solved, lack of cooperation of patient
	O3.2	Problem not solved, lack of cooperation of prescriber
	O3.3	Problem not solved, intervention not effective
	O3.4	No need or possibility to solve problem

ANNEXURE – IX a –Naranjo Scale

Naranjo Adverse Drug Reaction Probability Scale				
Question	Yes	No	Do Not Know	Score
1. Are there previous *conclusive* reports on this reaction?	+1	0	0	
2. Did the adverse event appear after the suspected drug was administered?	+2	-1	0	
3. Did the adverse reaction improve when the drug was discontinued or a *specific* antagonist was administered?	+1	0	0	
4. Did the adverse event reappear when the drug was re-administered?	+2	-1	0	
5. Are there alternative causes (other than the drug) that could on their own have caused the reaction?	-1	+2	0	
6. Did the reaction reappear when a placebo was given?	-1	+1	0	
7. Was the drug detected in blood (or other fluids) in concentrations known to be toxic?	+1	0	0	
8. Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	+1	0	0	
9. Did the patient have a similar reaction to the same or similar drugs in *any* previous exposure?	+1	0	0	
10. Was the adverse event confirmed by any objective evidence?	+1	0	0	
TOTAL SCORE:				

Modified from: Naranjo CA et al. A method for estimating the probability of adverse drug reactions. Clin Pharmacol Ther 1981; 30: 239-245.

b –WHO-UMC scale

Causality term	Assessment criteria (all points should be reasonably complied)
Certain	• Event or laboratory test abnormality, with plausible time relationship to drug intake • Cannot be explained by disease or other drugs • Response to withdrawal plausible (pharmacologically, pathologically) • Event definitive pharmacologically or phenomenologically (ie, an objective and specific medical disorder or a recognized pharmacologic phenomenon) • Rechallenge satisfactory, if necessary
Probable/ likely	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Unlikely to be attributed to disease or other drugs • Response to withdrawal clinically reasonable • Rechallenge not required
Possible	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Could also be explained by disease or other drugs • Information on drug withdrawal may be lacking or unclear
Unlikely	• Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) • Disease or other drugs provide plausible explanation
Conditional/ unclassified	• Event or laboratory test abnormality • More data for proper assessment needed, or • Additional data under examination
Unassessable/ unclassifiable	• Report suggesting an adverse reaction • Cannot be judged because information is insufficient or contradictory • Data cannot be supplemented or verified

c – Modified Schumock and Thornton scale

Definitely Preventable
1. Was there a history of allergy or previous reactions to the drug?
2. Was the drug involved inappropriate for the patient's clinical condition?
3. Was the dose, route or frequency of administration inappropriate for the patient's age, weight or disease state?
4. Was a toxic serum drug concentration (or laboratory monitoring test) documented?
5. Was there a known treatment for the Adverse Drug Reaction?
Probably Preventable
6. Was required Therapeutic drug monitoring or other necessary laboratory tests not performed?
7. Was a drug interaction involved in the ADR?
8. Was poor compliance involved in the ADR?
9. Were preventative measures not prescribed or administered to the patient?
Not preventable
If all above criteria not fulfilled

d – Modified Hartwig and Siegel scale

Level 1	An ADR occurred but required no change in treatment with the suspected drug
Level 2	The ADR required that treatment with the suspected drug be held, discontinued, or otherwise changed. No antidote or other treatment requirement was required. No increase in length of stay (LOS)
Level 3	The ADR required that treatment with the suspected drug be held, discontinued, or otherwise changed. AND/ OR An Antidote or other treatment was required. No increase in LOS
Level 4	Any Level 3 ADR which increases length of stay by at least 1 day. OR The ADR was the reason for the admission
Level 5	Any Level 4 ADR which requires intensive medical care
Level 6	The adverse reaction caused permanent harm to the patient
Level 7	The adverse reaction either directly or indirectly led to the death of the patient

ADR: adverse drug reaction.
Mild = Levels 1 and 2; moderate = Levels 3 and 4; severe = Levels 5, 6 and 7.

ANNEXURE – X – Medication Adherence Assessment for Tuberculosis Treatment (MAATT)

Ensuring proper medication adherence is crucial for the successful treatment of tuberculosis. This questionnaire assesses various factors affecting medication adherence, such as forgetfulness, travel, concerns about treatment hassles, and health condition control. By understanding these aspects, healthcare providers can offer tailored support to improve adherence and overall treatment outcomes. Please provide your response to each question based on your personal experiences with your medications. Keep in mind that there are no correct or incorrect answers. (Please indicate your choice by circling the appropriate option below).

Forgetting Medications	1.	Do you occasionally find yourself forgetting to take your TB medication?	YES	NO
	2.	Considering the past two weeks, were there any occasions when you skipped taking your TB medication?	YES	NO
Stopping Treatment	3.	Have you ever decreased or discontinued taking your TB medication without consulting your doctor, because you felt worse while on them?	YES	NO
	4.	Do you ever discontinue your TB medication when you believe that your health condition is managed?	YES	NO
Travel and Medication	5.	Did you take your TB medication yesterday?	YES	NO
	6.	Do you occasionally neglect to bring your TB medication when traveling or leaving home?	YES	NO
Challenges and Hassles	7.	Does the requirement of taking TB medication daily ever pose difficulties for you in following your treatment plan?	YES	NO
	8.	How often do you experience difficulties in remembering to take all of your TB medication?	Never/rarely Once in a while Sometimes Usually All the time	4 3 2 1 0
		Total score		

ANNEXURE – XI – SF 36 questionnaire

1. In general, would you say your health is:	
Excellent	1
Very good	2
Good	3
Fair	4
Poor	5
2. Compared to one year ago,	
Much better now than one year ago	1
Somewhat better now than one year ago	2
About the same	3
Somewhat worse now than one year ago	4
Much worse now than one year ago	5

3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?
(Circle One Number on Each Line)

	Yes, Limited a Lot (1)	**Yes, Limited a Little (2)**	**No, Not limited at All (3)**
a. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
b. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
c. Lifting or carrying groceries	1	2	3
d. Climbing **several** flights of stairs	1	2	3
e. Climbing **one** flight of stairs	1	2	3
f. Bending, kneeling, or stooping	1	2	3

g. Walking **more than a mile**	1	2	3
h. Walking **several blocks**	1	2	3
i. Walking **one block**	1	2	3
j. Bathing or dressing yourself	1	2	3

4. During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?
(Circle One Number on Each Line)

	Yes (1)	**No (2)**
a. Cut down the amount of time you spent on work or other activities	1	2
b. **Accomplished less** than you would like	1	2
c. Were limited in the **kind** of work or other activities	1	2
d. Had **difficulty** performing the work or other activities (for example, it took extra effort)	1	2

5. During the **past 4 weeks,** have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?
(Circle One Number on Each Line)

	Yes	**No**
a. Cut down the amount of time you spent on work or other activities	1	2
b. **Accomplished less** than you would like	1	2
c. Didn't do work or other activities as **carefully** as usual	1	2

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	
Not at all	1
Slightly	2
Moderately	3
Quite a bit	4
Extremely	5

7. How much bodily pain have you had during the past 4 weeks?	
None	1
Very mild	2
Mild	3
Moderate	4
Severe	5
Very severe	6
8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	
Not at all	1
A little bit	2
Moderately	3
Quite a bit	4
Extremely	5

These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling. **(Circle One Number on Each Line)**

9. How much of the time during the **past 4 weeks** . . .

	All of the Time	**Most of the Time**	**A Good Bit of the Time**	**Some of the Time**	**A Little of the Time**	**None of the Time**
a. Did you feel full of pep?	1	2	3	4	5	6
b. Have you been a very nervous person?	1	2	3	4	5	6
c. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
d. Have you felt calm and peaceful?	1	2	3	4	5	6
e. Did you have a lot of energy?	1	2	3	4	5	6

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
f. Have you felt downhearted and blue?	1	2	3	4	5	6
g. Did you feel worn out?	1	2	3	4	5	6
h. Have you been a happy person?	1	2	3	4	5	6
i. Did you feel tired?	1	2	3	4	5	6

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)? (Circle One Number)	
All of the time	1
Most of the time	2
Some of the time	3
A little of the time	4
None of the time	5

11. How TRUE or FALSE is each of the following statements for you. (Circle One Number on Each Line)

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
a. I seem to get sick a little easier than other people	1	2	3	4	5
b. I am as healthy as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

ANNEXURE – XII –Modified WHO TB questionnaire for assessing TB knowledge and awareness, attitude and stigma, perception (KAP)

Sno	
I.	**Health-seeking behaviour**
1	Where do you usually go if you are sick, or to treat a general health problem?
	Private clinic
	Government clinic or hospital
	Traditional or homeopathic healer
	Clinic run by a nongovernmental organization
	Other
2	How often do you generally seek health care at a clinic or hospital?
	Once in a month
	Twice a year or more
	Once per year
II.	**TB knowledge and awareness**
3	In your opinion, Is TB is a serious disease?
	Yes
	No
	Don’t know
4	Is cough, chest pain, fever and weight loss are the signs and symptoms of TB?
	Yes
	No
	Don’t know
5	Is TB is transmitted through the air while a person coughs or sneezes?
	Yes
	No
	Don’t know
6	In your opinion, TB can be prevented by avoiding shaking hands?
	Yes
	No
	Don’t know
7	In your opinion, all age group can be infected with TB?
	Yes
	No
	Don’t know
III.	**TB attitude and stigma**
8	Do you like to take ATT therapy?
	Strongly disagree
	Disagree
	Neither agree nor disagree
	Agree
	Strongly agree
9	Would you report side effects during the therapy?
	Strongly disagree
	Disagree
	Neither agree nor disagree
	Agree
	Strongly agree
10	Would you like to continue the treatment even side effects occurs?

	Strongly disagree
	Disagree
	Neither agree nor disagree
	Agree
	Strongly agree
11	Are you embrassed to disclose your condition to your family members?
	Strongly disagree
	Disagree
	Neither agree nor disagree
	Agree
	Strongly agree
12	Would you like to continue the treatment even the signs and symptoms were reduced?
	Strongly disagree
	Disagree
	Neither agree nor disagree
	Agree
	Strongly agree
IV.	**TB Perception**
13	Can TB cured?
	Yes
	No
	Don't know
14	Do you think getting TB diagnosis and treatment is expensive in our country?
	Yes
	No
	Don't know
15	Do you think taking TB treatment for six months will affect you mentally?
	Yes
	No
	Don't know
16	Do you fear to share your TB related problems?
	Yes
	No
	Don't know
17	Do you feel well informed about TB?
	Yes
	No
	Don't know

ANNEXURE – XIII – FACIT- Satisfaction with Pharmacist (SWiP)

Below is a list of statements that other people with your illness have said are important. **Please circle or mark one number per line to indicate your response as it applies to the <u>past 7 days</u>.**

		Not at all	A little bit	Some-what	Quite a bit	Very much
SWiP1	My pharmacist advises me on the proper use of my medicines	0	1	2	3	4
SWiP2	My pharmacist advises me on the adverse (side) effects of my medicines	0	1	2	3	4
SWiP3	I have confidence in my pharmacist(s)	0	1	2	3	4
SWiP4	My pharmacist is available to answer my questions	0	1	2	3	4
SWiP5	My pharmacist helps with the arrangements necessary to obtain my medicines	0	1	2	3	4
SWiP6	My pharmacist is aware of my treatment-related needs	0	1	2	3	4
SWiP7	My pharmacist responds to my treatment-related needs	0	1	2	3	4

ANNEXURE – XIV – FACIT- Treatment Satisfaction – General (TS-G)

Please mark one answer for each of the following questions.

		A lot worse	A little worse	About the same	A little better	A lot better
TS1	Compared to what you expected, how do you rate the effectiveness of the treatment so far?	0	1	2	3	4
TS2	Compared to what you expected, how do you rate the side effects of treatment so far?	0	1	2	3	4

		No, not at all	Yes, to some extent	Yes, for the most part	Yes, completely
TS3	Did your doctor(s) help you evaluate the effects of your treatment so far?.....	0	1	2	3
TS4	Do you feel you received the treatment that was right for you?	0	1	2	3
TS5	Are you satisfied with the effects of this treatment so far?	0	1	2	3

		No	Maybe	Yes
TS6	Would you recommend this treatment to others with your illness?.....	0	1	2
TS7	Would you choose this treatment again?.....	0	1	2

		Poor	Fair	Good	Very Good	Excellent
TS8	How do you rate this treatment overall?	0	1	2	3	4

Thank you! Do you have any comments? _____

ANNEXURE – XV – Knowledge, Attitude and Practice questionnaire for HCPs.

Health care Professional information

1.Profession

i.Physician

a) Resident
b) Consultant
c) Specialist
d) General practitioner
e) Other (Please specify): _____

ii.Pharmacist

a) Hospital Pharmacist
b) Clinical Pharmacist
c) Community Pharmacist

iii.Nurse

iv.Asha worker

v.Others (Please specify): _____

2.Age

i.<18
ii.20-30
iii.30-40
iv.40-50
v.50-60
vi.>60

3.Sex

i.Male
ii.Female
iii.Others

4.Site of working

i.Respiratory medicine
ii.General medicine
iii.Community medicine
iv.Others: _____

5.Educational level

i.Diploma
ii.BSc degree
iii.Undergraduate
iv.Postgraduate
v.Research scholar
vi.Others (Please specify): _____

6.Staff category (if staff)

i.Teaching staff
ii.Hospital staff
iii.Others (Please specify): _____

7.Working experience

i.<1 year
ii.1-5 year
iii.5-10 years
iv.>10 years

Knowledge

1. Is tuberculosis transmitted by droplet spread?
   i. Strongly disagree
   ii. Disagree
   iii. Neither agree nor disagree
   iv. Agree
   v. Strongly agree

2. Cough and chest pain are the most common symptoms of pulmonary TB?
   i. Strongly disagree
   ii. Disagree
   iii. Neither agree nor disagree
   iv. Agree
   v. Strongly agree

3. Do you think separating TB suspected patient should be kept away from the rest of the patients will help in preventing of spread of TB?
   i. Strongly disagree
   ii. Disagree
   iii. Neither agree nor disagree
   iv. Agree
   v. Strongly agree

4. Do you think wearing surgical mask/respirator can protect the health worker from TB?
   i. Strongly disagree
   ii. Disagree
   iii. Neither agree nor disagree
   iv. Agree
   v. Strongly agree

5. Do you think regular screening of health workers for TB is one of TBIC measures?
   i. Strongly disagree
   ii. Disagree
   iii. Neither agree nor disagree
   iv. Agree
   v. Strongly agree

6. Do you think TB cannot be transmitted from person to person by blood contact?
   i. Strongly disagree
   ii. Disagree
   iii. Neither agree nor disagree
   iv. Agree
   v. Strongly agree

7. Do you think Sputum microscopy is the most effective tool for the diagnosis of TB?
   i. Strongly disagree
   ii. Disagree
   iii. Neither agree nor disagree
   iv. Agree
   v. Strongly agree

8. When TB treatment not properly administered MDR-TB occurs?
   i. Strongly disagree
   ii. Disagree
   iii. Neither agree nor disagree
   iv. Agree
   v. Strongly agree

9. Is Mycobacterium bacillus resistant to at least isoniazid and rifampicin in multi drug resistance TB?
   i. Strongly disagree
   ii. Disagree
   iii. Neither agree nor disagree
   iv. Agree
   v. Strongly agree

10. Is BCG vaccination being protective against for TB?

i.Strongly disagree
ii.Disagree
iii.Neither agree nor disagree
iv.Agree
v.Strongly agree

Attitude

11. Do you think educating the TB patients about prevention of TB transmission will help in control of TB?

i.Strongly disagree
ii.Disagree
iii.Neither agree nor disagree
iv.Agree
v.Strongly agree

12. Do you think the family members of TB patient has to be screened for TB infection?

i.Strongly disagree
ii.Disagree
iii.Neither agree nor disagree
iv.Agree
v.Strongly agree

13. Do you think starting TB treatment is a better option for a TB patient before diagnosis is confirmed if a suspected TB patient?

i.Strongly disagree
ii.Disagree
iii.Neither agree nor disagree
iv.Agree
v.Strongly agree

14. Is it necessary should the sputum examination for category one patients has to be repeated?

i.Strongly disagree
ii.Disagree
iii.Neither agree nor disagree
iv.Agree
v.Strongly agree

15. Do you think that counselling the patient towards TB and its treatment, improve patient medication adherence?

i.Strongly disagree
ii.Disagree
iii.Neither agree nor disagree
iv.Agree
v.Strongly agree

16. Do you think MDR-TB arises due to medication non adherence?

i.Strongly disagree
ii.Disagree
iii.Neither agree nor disagree
iv.Agree
v.Strongly agree

17. Do you think patient medication nonadherence is due to adverse effects of tubercular therapy?

i.Strongly disagree
ii.Disagree
iii.Neither agree nor disagree
iv.Agree
v.Strongly agree

18. Do you think health care workers require screening for latent/active TB infection period?

i.Strongly disagree
ii.Disagree
iii.Neither agree nor disagree
iv.Agree
v.Strongly agree

19. Do you think the staff who have evidence of LTB should receive prevention treatment?

i.Strongly disagree
ii.Disagree
iii.Neither agree nor disagree
iv.Agree
v.Strongly agree

20. Do you think health care workers require periodic education towards TB and its infection control?

i.Strongly disagree
ii.Disagree
iii.Neither agree nor disagree
iv.Agree
v.Strongly agree

Practice:

21. Do you think always keeping the active TB patients in isolated room is good practice?

i.Strongly disagree
ii.Disagree
iii.Neither agree nor disagree
iv.Agree
v.Strongly agree

22. Do you recommend TB patients room to open windows whenever possible to increase natural ventilation?

i.Strongly disagree
ii.Disagree
iii.Neither agree nor disagree
iv.Agree
v.Strongly agree

23. Do you think following TB treatment guideline to treat positive TB patient will give correct treatment timeline course?

i.Strongly disagree
ii.Disagree
iii.Neither agree nor disagree
iv.Agree
v.Strongly agree

24. Do you use a mask when approaching TB suspected patient for your prevention?

i.Strongly disagree
ii.Disagree
iii.Neither agree nor disagree
iv.Agree
v.Strongly agree

25. Do you think educating about nutrition diet intake on TB suspected patients will help in completion of treatment?

i.Strongly disagree
ii.Disagree
iii.Neither agree nor disagree
iv.Agree
v.Strongly agree

ANNEXURE – XVI – PATIENT INFORMATION LEAFLET (PIL)

a. English

Do's

- Maintaining good health and immune system is most important with calorie dense food.
- High intake of protein rich foods such as eggs, legumes, peas, meat, beans, dry fruits etc.
- Intake of food rich in Vitamin A, C and E such as carrots, spinach, green leafy vegetables.
- Intake of food rich in B complex.
- Intake of food rich in zinc such as fish, sea foods, poultry, leafy vegetables.
- Take all the medications for the full prescribed period on regular basis.
- Cover your mouth when coughing or sneezing.
- Always wear a mask and maintain distance with another person whenever you are communicating.
- Regular wash your hands with disinfectant soaps or use alcohol sanitizers on your hands.
- Always sleep in ventilation area where free air flow is available in the room.

Don't

- Avoid smoking and reduce intake of alcohol consumption.
- Avoid chewing of tobacco products such as ~~ghutka, kaini, zarda~~
- Don't split sputum on the roads, hospital premises, public areas instead use wash rooms.
- Don't stop anti TB medications before your physician discontinues them.
- Avoid eating of spicy foods, junk foods and semi cooked foods.

TB is CURABLE & PREVENTABLE

Wishing you a Faster healthy recovery

For any information please contact:

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HEALTHY CARE FOR YOU, BREATH FREE!

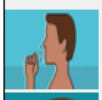
TUBERCULOSIS
WHAT IT IS?
SIGNS &SYMPTOMS?
RISK FACTORS?
RECOMMENDATIONS

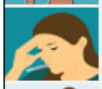
TUBERCULOSIS: GET THE FACTS!

WHAT IS TUBERCULOSIS?

Tuberculosis (TB) is caused by a bacterium (germ) called *Mycobacterium tuberculosis*. TB usually affects lungs but can affect other parts of the body including the glands, bones and rarely the brain. Diagnosis of pulmonary TB is made on sputum sample sent for microbiological testing and chest x-ray.

SIGNS AND SYMPTOMS

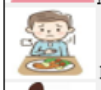

Cough that lasts for 3weeks


Fever


Fatigue


Weight loss


Night sweats


Loss of appetite


Chest Pain

HOW DOES TB TRANSFER?

TB usually spread in the air when a person is active TB disease of the lungs or throat coughs or sneezes.

RISK FACTORS


Malnutrition


Smoking


Consuming tobacco products


Alcohol consumption


Low immunity


Chronic kidney disease


Diabetes mellitus


HIV/AIDS

Antituberculosis Medications

Taking anti tubercular drugs are very important. At least 6 months, you have to take the complete antitubercular drugs even if you feel better to kill all the TB germs in your body.

1. **Isoniazid (INH)/(H)**
2. **Rifampicin (RFM)/(R)**
3. **Pyrazinamide (PZA)/(Z)**
4. **Ethambutol (ETM)/(E)**

Side effects

Only a few people will develop side effects which should be reported to your doctor or nurse or pharmacist.

- Nausea or vomiting
- Orange or red colour urine/sweat/sputum
- Rash or itch
- Vision changes
- Joint pain
- Stomach ache

b. Kannada

ಮಾಡು

- ಹೆಚ್ಚಿನ ಕ್ಯಾಲೋರಿ ಆಹಾರದೊಂದಿಗೆ ಉತ್ತಮ ಆರೋಗ್ಯ ಮತ್ತು ಪ್ರತಿರಕ್ಷಣಾ ವ್ಯವಸ್ಥೆಯನ್ನು ಕಾಪಾಡಿಕೊಳ್ಳುವುದು ಅತ್ಯಂತ ಮುಖ್ಯವಾಗಿದೆ.
- ಪ್ರೋಟೀನ್ ಭರಿತ ಆಹಾರಗಳಾದ ದೋಟ್ಟೆ, ಕಾಳುಗಳು, ಬಟಾಣಿ, ಮಾಂಸ, ಬೀನ್ಸ್, ಒಣ ಹಣ್ಣುಗಳು ಇತ್ಯಾದಿಗಳ ಹೆಚ್ಚಿನ ಸೇವನೆ.
- ವಿಟಮಿನ್ ಎ, ಸಿ ಮತ್ತು ಇ ಸಮೃದ್ಧವಾಗಿರುವ ಕ್ಯಾರೆಟ್, ಹಾಲಕ, ಹುರುಳಿ ಎಲೆಗಳ ತರಕಾರಿಗಳ ಸೇವನೆ.
- ಬಿ ಕಾಂಪ್ಲೆಕ್ಸ್ ಭರಿತ ಆಹಾರ ಸೇವನೆ.
- ಮೀನು, ಸಮುದ್ರ ಆಹಾರಗಳು, ಕೋಳಿ, ಎಲೆಗಳ ತರಕಾರಿಗಳಂತಹ ಸತುವು ಸಮೃದ್ಧವಾಗಿರುವ ಆಹಾರವನ್ನು ಸೇವಿಸುವುದು.
- ನಿಯಮಿತವಾಗಿ ಸಂಪೂರ್ಣ ನಿಗದಿತ ಅವಧಿಗೆ ಎಲ್ಲಾ ಔಷಧಿಗಳನ್ನು ತೆಗೆದುಕೊಳ್ಳಿ.
- ಕೆಮ್ಮುವಾಗ ಅಥವಾ ಸೀನುವಾಗ ನಿಮ್ಮ ಬಾಯಿಯನ್ನು ಮುಚ್ಚಿಕೊಳ್ಳಿ.
- ನೀವು ಸಂದರ್ಶನ ಮಾಡುವಾಗ ಯಾವಾಗಲೂ ಮಾಸ್ಕ್ ಧರಿಸಿ ಮತ್ತು ಇನ್ನೊಬ್ಬ ವ್ಯಕ್ತಿಯೊಂದಿಗೆ ಅಂತರವನ್ನು ಕಾಯ್ದುಕೊಳ್ಳಿ.
- ನಿಯಮಿತವಾಗಿ ನಿಮ್ಮ ಕೈಗಳನ್ನು ಸೋಂಕುನಿವಾರಕ ಸಾಬೂನಿನಿಂದ ತೊಳೆಯಿರಿ ಅಥವಾ ನಿಮ್ಮ ಕೈಯಲ್ಲಿ ಆಲ್ಕೋಹಾಲ್ ಸ್ಯಾನಿಟೈಸರ್ ಬಳಸಿ.
- ಕೋಣೆಯಲ್ಲಿ ಉಚಿತ ಗಾಳಿಯ ಹರಿವು ಲಭ್ಯವಿರುವ ಜಾತಾಯನ ಪ್ರದೇಶದಲ್ಲಿ ಯಾವಾಗಲೂ ಮಲಗಿಕೊಳ್ಳಿ.

ಮಾಡಬೇಡಾ

- ಧೂಮಪಾನವನ್ನು ತಪ್ಪಿಸಿ ಮತ್ತು ಆಲ್ಕೋಹಾಲ್ ಸೇವನೆಯನ್ನು ಕಡಿಮೆ ಮಾಡಿ.
- ತಂಬಾಕು ಉತ್ಪನ್ನಗಳಾದ ಗುಟ್ಕಾ, ಖೈನಿ, ಜರ್ದಾ ಜಗಿಯುವುದನ್ನು ತಪ್ಪಿಸಿ
- ರಶ್ತೆ, ಆಸ್ಪತ್ರೆ ಆವರಣ, ಸಾರ್ವಜನಿಕ ಪ್ರದೇಶಗಳಲ್ಲಿ ಕಫ ಉಗುಳಬೇಡಿ ಬದಲಿಗೆ ಟಾಕ್ ರೂಂ ಬಳಸಿ.
- ನಿಮ್ಮ ವೈದ್ಯರು ಆವುಗಳನ್ನು ನಿಲ್ಲಿಸಲು ಹೇಳುವ ಮೊದಲು ಟಿಬಿ ವಿರೋಧಿ ಔಷಧಿಗಳನ್ನು ನಿಲ್ಲಿಸಬೇಡಿ.
- ಮಸಾಲೆಯುಕ್ತ ಆಹಾರಗಳು, ಜಂಕ್ ಆಹಾರಗಳು ಮತ್ತು ಅರೆ ಬೇಯಿಸಿದ ಆಹಾರವನ್ನು ಸೇವಿಸುವುದನ್ನು ತಪ್ಪಿಸಿ.

ಕ್ಷಯರೋಗವನ್ನು ತಡೆಗಟ್ಟಬಹುದು
ಮತ್ತು ಗುಣಪಡಿಸಬಹುದು!

ನೀವು ಆರೋಗ್ಯವಂತರಾಗಿ ಜೀತರಿಸಿಕೊಳ್ಳಲಿ
ಎಂದು ಹಾರೈಸುತ್ತೇನೆ

ಯಾವುದೇ ಮಾಹಿತಿಗಾಗಿ ಸಂಪರ್ಕಿಸಿ:
ಡಾ.ಬಂಡಾರು ಯಶವಂತರಾಜ, ಫಾರ್ಮ ಡಿ
ಸಂಶೋಧನಾ ವಿದ್ವಾಂಸ,
ಫಾರ್ಮಸಿ ಅಭ್ಯಾಸ ವಿಭಾಗ,
ಕೆಎಲ್ಇ ಕಾಲೇಜ್ ಆಫ್ ಫಾರ್ಮಸಿ,
ಕೆಎಲ್ಇ ಅಕಾಡೆಮಿ ಆಫ್ ಹೈಯರ್ ಎಜುಕೇಶನ್ ಅಂಡ್ ರಿಸರ್ಚ್ ಬೆಳಗಾವಿ 590010
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KLES
DR. PRABHAKAR KORE HOSPITAL & MEDICAL RESEARCH CENTRE
NEHRU NAGAR, BELAGAVI-590010

ನಮ್ಮಿಂದ ನಿಮ್ಮ ಆರೋಗ್ಯ ರಕ್ಷಣೆ, ಮುಕ್ತವಾಗಿ ಉಸಿರಾಡಿ!

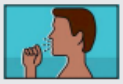
ಕ್ಷಯರೋಗ
ಕ್ಷಯರೋಗ ಎಂದರೇನು?
ರೋಗ ಸೂಚನೆ ಹಾಗೂ ಲಕ್ಷಣಗಳು
ಅಪಾಯದ ಅಂಶಗಳು
ಶಿಫಾರಸುಗಳು

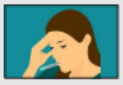
ಕ್ಷಯರೋಗ:
ವಾಸ್ತವಿಕತೆಯನ್ನುತಿಳಿಯಿರಿ!

ಕ್ಷಯರೋಗ ಎಂದರೇನು?

ಕ್ಷಯರೋಗ (ಟಿಬಿ) ಮೈಕೋಬ್ಯಾಕ್ಟೀರಿಯಂ ಟ್ಯೂಬರ್ಕ್ಯುಲೋಸಿಸ್ ಎಂಬ ಬ್ಯಾಕ್ಟೀರಿಯಾದಿಂದ (ಸೂಕ್ಷ್ಮಜೀವಿ) ಉಂಟಾಗುತ್ತದೆ. ಟಿಬಿ ಸಾಮಾನ್ಯವಾಗಿ ಶ್ವಾಸಕೋಶದ ಮೇಲೆ ಪರಿಣಾಮ ಬೀರುತ್ತದೆ ಆದರೆ ಗ್ರಂಥಿಗಳು, ಮೂಳೆಗಳು ಮತ್ತು ಅಪರೂಪವಾಗಿ ಮೆದುಳು ಸೇರಿದಂತೆ ದೇಹದ ಇತರ ಭಾಗಗಳ ಮೇಲೆ ಪರಿಣಾಮ ಬೀರಬಹುದು. ಪಲ್ಮನರಿ ಟಿಬಿಯ ರೋಗನಿರ್ಣಯವನ್ನು ಸೂಕ್ಷ್ಮ ಜೀವವಿಜ್ಞಾನದ ಪರೀಕ್ಷೆ ಮತ್ತು ಎದೆಯ ಕ್ಷ-ಕಿರಣಕ್ಕಾಗಿ ಕಳುಹಿಸಲಾದ ಕಫ

ರೋಗ ಸೂಚನೆ ಹಾಗೂ ಲಕ್ಷಣಗಳು


ಮೂರು ವಾರಗಳಿಗಿಂತ ಹೆಚ್ಚು ಕೆಮ್ಮಿನ ಉಪಸ್ಥಿತಿ


ಜ್ವರ


ಆಯಾಸ


ತೂಕ ಇಳಿಕೆ


ರಾತ್ರಿ ಬೆವರುವಿಕೆ


ಹಸಿವಿಲ್ಲದಿರುವುದು


ಎದೆ ನೋವು

ಟಿಬಿ ಪರ್ಣಾವಣೆ ಹೇಗೆ?

ಶ್ವಾಸಕೋಶಗಳು ಅಥವಾ ಗಂಟಲಿನ ಸಕ್ರಿಯ ಟಿಬಿ ಕಾಯಿಲೆ ಹೊಂದಿರುವ ವ್ಯಕ್ತಿಯು ಕೆಮ್ಮುವಾಗ ಮತ್ತು ಸೀನುವಾಗ ಸಾಮಾನ್ಯವಾಗಿ ಕ್ಷಯರೋಗ ಗಾಳಿಯಲ್ಲಿ ಹರಡುತ್ತದೆ.

ಅಪಾಯದ ಅಂಶಗಳು

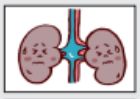

ಅಪೌಷ್ಟಿಕತೆ


ಧೂಮಪಾನ


ತಂಬಾಕು ಉತ್ಪನ್ನಗಳನ್ನು ಸೇವಿಸುವುದು


ಮದ್ಯ ಸೇವನೆ


ಕುಂದಿದ ರೋಗ ನಿರೋಧಕ ಶಕ್ತಿ


ದೀರ್ಘಕಾಲದ ಮೂತ್ರಪಿಂಡ ಕಾಯಿಲೆ


ಮಧುಮೇಹ


ಎಚ್ಐವಿ/ಏಡ್ಸ್

ಆಂಟಿಟ್ಯೂಬರ್ಕ್ಯುಲರ್ ಔಷಧಿಗಳು

ಕ್ಷಯ ರೋಗ ನಿವಾರಣೆಯ ಔಷಧಿಗಳನ್ನು ತೆಗೆದುಕೊಳ್ಳುವುದು ಬಹಳ ಮುಖ್ಯವಾಗಿದೆ. ನಿಮ್ಮ ದೇಹದಲ್ಲಿರುವ ಎಲ್ಲಾ ಟಿಬಿ ಸೂಕ್ಷ್ಮಾಣುಗಳನ್ನು ಕೊಲ್ಲಲು ನೀವು ಉತ್ತಮವಾಗಿದ್ದರೂ ಸಹ, ಕನಿಷ್ಠ 6 ತಿಂಗಳುಗಳವರೆಗೆ, ನೀವು ಸಂಪೂರ್ಣ ಕ್ಷಯ ರೋಗ ನಿವಾರಣೆಯ ಔಷಧಿಗಳನ್ನು ತೆಗೆದುಕೊಳ್ಳಬೇಕು.

1. ಐಸೋನಿಯಾಜಿಡ್ (INH)/(H)
2. ರಿಫಾಂಪಿಸಿನ್ (RFM)/(R)
3. ಪಿರಾಜಿನಮೈಡ್ (PZA)/(Z)
4. ಎಥಾಂಬುಟಾಲ್ (ETM)/(E)

ಅಡ್ಡ ಪರಿಣಾಮಗಳು

ನಿಮ್ಮ ವೈದ್ಯರು ಅಥವಾ ನರ್ಸ್ ಅಥವಾ ಔಷಧಿಕಾರರಿಗೆ ವರದಿ ಮಾಡಬೇಕಾದ ಅಡ್ಡಪರಿಣಾಮಗಳಿಂದ ಕೆಲವೇ ಜನರು ಬಳಲುತ್ತಾರೆ.

- ವಾಕರಿಕೆ ಅಥವಾ ವಾಂತಿ
- ಕಿತ್ತಳೆ ಅಥವಾ ಕೆಂಪು ಬಣ್ಣದ ಮೂತ್ರ/ಬೆವರು/ಕಫ
- ದದ್ದು ಅಥವಾ ತುರಿಕೆ
- ದೃಷ್ಟಿ ಬದಲಾವಣೆಗಳು
- ಕೀಲು ನೋವು
- ಹೊಟ್ಟೆ ನೋವು

c. Marathi

करा

- उच्च कॅलरी आहारासह चांगले आरोग्य आणि रोगप्रतिकारक शक्ती राखणे अत्यंत महत्वाचे आहे.
- अंडी, शेंगा, मटार, मांस, सोयाबीन, सुकामेवा इत्यादी प्रथिनेयुक्त पदार्थांचे जास्त सेवन.
- व्हिटॅमिन ए, सी आणि अ समृद्ध अन्न जसे की गाजर, पालक, हिरव्या पाले भाज्या घ्या.
- बी कॉम्प्लेक्सने समृद्ध असलेले अन्न घ्या.
- मासे, समुद्री खाद्यपदार्थ, कुक्कुटपालन, पालेभाजी यासारखे झिंक समृद्ध असलेले अन्न घ्या.
- संपूर्ण विहित कालावधीसाठी सर्व औषधे नियमितपणे घ्या.
- खोकताना किंवा शिंकताना तोंड झाका.
- दुसरी व्यक्ती तुमच्याशी संवाद साधत असताना नेहमी मास्क घाला आणि अंतर राखा.
- आपले हात नियमितपणे जंतुनाशक साबणाने धुवा किंवा अल्कोहोल सॅनिटायझर वापरा.
- नेहमी वायुवीजन क्षेत्रामध्ये झोपा जेथे खोलीत मुक्त वायु प्रवाह उपलब्ध आहे.

करू नका

- धूम्रपान टाळा आणि दारूचे सेवन कमी करा.
- घुटका, कैनी, जर्दा यांसारखे तंबाखूजन्य पदार्थ चघळणे टाळा
- रस्त्यावर, हॉस्पिटलच्या आवारात आणि सार्वजनिक ठिकाणी थुंकण्याऐवजी शौचालयाचा वापर करा
- तुमच्या डॉक्टरांनी थांबवण्यास सांगण्यापूर्वी क्षयरोगविरोधी औषधे थांबवू नका.
- मसालेदार पदार्थ, जंक फूड आणि अर्धवट शिजवलेले पदार्थ खाणे टाळा.

क्षयरोग टाळता येतो आणि बरा होतो!

मी तुम्हाला निरोगी पुनर्प्राप्तीसाठी शुभेच्छा देतो

कोणत्याही माहितीसाठी कृपया संपर्क साधा:
डॉ. बंडारू यशवंत राजा, फार्म डी
संशोधन अभ्यासक,
फार्मसी प्रॅक्टिस विभाग,
केएलई कॉलेज ऑफ फार्मसी,
केएलई अकादमी ऑफ हायर एज्युकेशन अँड
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KLES
DR. PRABHAKAR KORE HOSPITAL
&
MEDICAL RESEARCH CENTRE
NEHRU NAGAR, BELAGAVI-590010

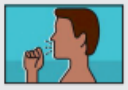
तुमच्यासाठी आरोग्यदायी काळजी,
मोकळा श्वास घ्या!

क्षयरोग
हे काय आहे?
चिन्हे आणि लक्षणे?
जोखीम घटक?
शिफारसी
क्षयरोग:
तथ्ये मिळवा!

क्षयरोग म्हणजे काय?

क्षयरोग (टीबी) हा मायकोबॅक्टेरियम ट्यूबरक्युलोसिस नावाच्या जिवाणूमुळे होतो. टीबी सहसा फुप्फुसांवर परिणाम करतो परंतु ग्रंथी, हाडे आणि क्वचितच मेंदूसह शरीराच्या इतर भागांवर परिणाम करू शकतो. फुप्फुसीय क्षयरोगाचे निदान मायक्रोबायोलॉजिकल चाचणी आणि छातीचा एक्स-रे साठी पाठवलेल्या थुंकीच्या नमुन्यावर केले जाते.

चिन्हे आणि लक्षणे?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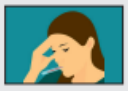

ताप


थकवा


वजन कमी होणे


रात्री घाम येणे


भूक न लागणे


छाती दुखणे

क्षयरोग संक्रमण कसे होते?

क्षयरोग सामान्यतः हवेत पसरतो जेव्हा एखादी व्यक्ती फुप्फुसाचा किंवा घशाचा क्षयरोग सक्रिय असतो किंवा खोकतो किंवा शिंकतो.

जोखीम घटक

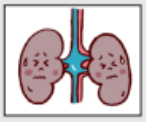

कुपोषण


धुम्रपान


तंबाखूजन्य पदार्थांचे सेवन


दारूचे सेवन


कमी प्रतिकारशक्ती


जुनाट मूत्रपिंडआजार


मधुमेह


एचआयव्ही/एड्स

क्षयरोग प्रतिबंधक औषधे

क्षयविरोधी औषधे घेणे खूप महत्वाचे आहे. तुमच्या शरीरातील सर्व क्षयरोगाचे जंतू मारण्यासाठी तुम्हाला बरे वाटले तरी कमीत कमी 6 महिने संपूर्ण क्षयरोगप्रतिबंधक औषधे घ्यावी लागतील.

1. आयसोनियाझिड (INH)/(H)
2. रिफाम्पिसिन (RFM)/(R)
3. पायराझिनामाइड (PZA)/(Z)
4. इथम्बुटोल (ETM)/(E)

दुष्परिणाम

फक्त काही लोकांनाच दुष्परिणाम होतील ज्यांची तक्रार तुमच्या डॉक्टरांना किंवा नर्सला किंवा फार्मासिस्टला करावी.

- मळमळ किंवा उलट्या
- केशरी किंवा लाल रंगाचा लघवी/घाम/थुंक
- पुरळ किंवा खाज सुटणे
- दृष्टी बदलणे
- सांधे दुखी
- पोटदुखी

ANNEXURE – XVII – PUBLICATIONS

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https://www.jyoungpharm.org

Original Article

Assessment and Evaluation of Knowledge, Attitude and Perception among Pulmonary Tuberculosis Patients in Belagavi Region

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ABSTRACT

Background: India is among the highest burden of Tuberculosis (TB) cases across the world. Delaying the diagnosis and treatment adherence towards anti TB drugs were common causes observed among the TB patients. There is a need to identify the gaps and provide the awareness about the TB infection, which will help to achieve a 'TB free India' by 2025. Therefore, we aim to assess and evaluate the Knowledge, Attitude and Perception (KAP) among TB patients regarding the management of TB. **Materials and Methods:** A Randomized controlled study was conducted among TB patients. A Self-prepared and validated KAP questionnaire was developed using World Health Organization (WHO) recommendations for TB KAP studies and interviewed the patients at the baseline. In test group by using patient information leaflets and counselling were given under the clinical pharmacist whereas in control group usual care was given by other health care team. Then two follow ups were done after every three months by using same set of questionnaires in both groups. **Results:** A total of 250 participants were enrolled, among 220 were recruited in which majority of them belongs to 26-35 age group in both test 63 (57.27%) and control 66 (60%). In health seeking behaviour, most of them usually go to private clinic compared to government clinic or hospital. In response to TB knowledge and awareness, attitude with stigma and perception at baseline found to be low but at the end of sixth month the parameters were improved among both test and control group. The test group had shown better improved KAP than the control group. **Conclusion:** Majority of the participants had inadequate levels of KAP at baseline but got improved in post follow ups among both test and control groups. Test group had shown more improvement compared to control group. Thus, indicating the importance of clinical pharmacist intervention in improving the KAP among TB patients.

Keywords: Tuberculosis, Knowledge, Attitude, Perception, Antitubercular drugs.

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INTRODUCTION

Tuberculosis (TB) had come to epidemic extent in many countries including India.[1] India has more new cases of TB each year than any other country and has the highest burden of TB, contributing one-fifth to the global burden.[2] Among different types, pulmonary TB is one of the leading causes of death in adults followed by MDR TB and HIV/AIDs with TB as it leads every 3 min two people die in our country with TB.[3] To combat tuberculosis, in 1962 India's National Tuberculosis Control Program was launched, later renamed to Revised National Tuberculosis Control Programme (RNTCP) and then National Tuberculosis Elimination Programme (NTEP).[4] The aim of this program is to reduce TB mortality and morbidity as well as TB transmission until TB is no longer a major concern for public health.[5]

The NTEP program uses DOTS (Directly Observed Treatment, Short course) to achieve this goal. To successfully complete the program, it is important that patients have basic and correct knowledge about the disease.[6] Since 1970, Knowledge, Attitude and Perception (KAP) research has become the main intervention strategy to fight Tuberculosis (TB) worldwide.[7] Several studies have shown that KAP levels in individuals are associated with effective disease management, response to medical treatment, and improvement in their own health.[8-11] Lower levels of KAP were considered one of the key factors for poor health, ineffective use of health care services, low screening rates, and inadequate preventive behaviour.[12-14] Even in many Indian states have shown evidences in this regard.

Clinical pharmacist's plays a critical role in clinical settings to improve patient compliance and outcomes. Since many years, pharmacists are involved in patient care and raising awareness

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about maintenance of good healthcare systems.[15] They also have responsibility to involve in national strategy plan in elimination of TB from India by 2025. The common causes that were observed among the TB patients were the diagnosis delay and drug adherence towards anti TB drugs.[16] There is a need to identify the gaps, reasons and provide the awareness about the TB infection, which will help to achieve of a 'TB free India' by 2025.[17] Clinical pharmacist through pharmaceutical care services can educate the TB patients on the basic awareness of KAP might improve in achieving the treatment outcomes.[18] Therefore, we aim to study the Knowledge, Attitude and Perception (KAP) among the TB patients in different follow up times in the region of Belagavi of Karnataka state in India.

MATERIALS AND METHODS

Study design and settings

A single-blind randomized controlled study was carried out in a tertiary-care hospital TB center and four Primary Health Care (PHC) centers in the district of Belagavi, Karnataka state in India. The study was carried out between September 2021 to March 2023 on TB patients who were visiting the TB center in tertiary care hospital and followed up back in PHCs. The randomization was performed by two parallel arms divided in a ratio of 1:1 ratio by a simple envelope technique as usual care group (Control) and the pharmaceutical care intervention group (Test). The envelopes were opened in front of pharmacist and study participant were assigned. The test group participants were given pharmaceutical care intervention under a clinical pharmacist in a separate room at TB center in the hospital and control group with usual care under other health care professionals. The clinical pharmacist was the primary person of contact if any problem arises during the study.

Designing and development of questionnaire

A self-framed and validated KAP questionnaire was developed by using World Health Organization (WHO) recommendations for TB KAP studies[19] and were interviewed for both test and controls from baseline to follow ups. The questionnaire consisted of yes or no or don't know type questions and others was developed using 5-point Likert scale. The questionnaire was divided into five sections covering demographic information, health-seeking behaviour, TB knowledge and awareness, TB attitude and stigma and perception on TB. In prior to conduct the main study a pilot study was conducted as the questionnaire got validated from the faculty members of KLE college of pharmacy and reliability was found to be good (Cronbach's alpha i.e., $\alpha \geq 0.83$).

Development and validation of Patient Information Leaflets (PILs)

In accordance to WHO and NTEP guidelines, patient information leaflets (PILs) for educating and counselling were prepared in English, Kannada and Marathi languages. A team of respiratory medicine physicians (n=4), pharmacists (n=3), and lay person (n=1) reviewed the leaflets. The readability of the patient information leaflet was assessed using the Flesch Reading Ease (FRE) formula. The FRE scale value ranges from 0 to 100. If the value was less than 60, the leaflet will be difficult to read. The average FRE score is 78, indicating that it was easy to read and understand. The layout and design of the PILs was evaluated using with mean Baker Able Leaflet Design (BALD) score. The values were calculated depending on line length, line spacing, font type and size, indentation, colours, pictures, paper texture etc. The mean BALD score was found to be 25, confirming that the patients were able to read and understand the PILs. The PILs consists of regarding TB and its complications, signs and symptoms, risk factors, ATT drug information, life style changes and modifications.

Study participants

Participants above 18 years old, new diagnosed pulmonary TB and taking self-administered TB treatment both Antitubercular Treatment (ATT) and Fixed Dose Combination therapy (FDC) from private practitioners were included. Participants with extrapulmonary TB, having more than one comorbidity, and not willing to participate were excluded from the study. Participants were explained about the study through subject information sheets and Informed Consent Forms (ICF) was obtained after enrolling into the study.

Data collection

The Participants were interviewed with data collection form which includes demographic details such as age, gender, marital status, religion, area, education level, working experience etc. The participants who were enrolled at the baseline were follow-up for two regular intervals, one at third and final sixth month of TB treatment.

Statistical Analysis

The statistical analysis was carried out by using Microsoft Excel spread sheet and later entered into SPSS V23.0 (IBM, USA). Descriptive analysis was utilized and expressed in frequency, percentage, Mean±SD, and by using independent t test. Tabulations and Bar graphs were used to display the data. The level of significance was kept to be less than 0.05.

Ethical considerations

From the Institutional Ethical Clearance (IEC) for human subjects committee at KLE academy of higher education and research, Belagavi, Karnataka, India, the study was approved with approval number: KAHER/EC/21-22/020.

The consort flow chart representation of materials and methods was shown in Figure 1.

RESULTS

Socio Demographic details

In our study, according to eligibility 250 participants were allocated and were randomised into test and control groups. Almost 20 patients were lost follow up at the end of follow up 2 (6th month). We assessed the KAP of a total number of 220 patients (n=110 test and n=110 control). As far as background information was concerned, majority of the patients were males in both test and control (53.64% in test and 55.45% in control) and majority belonged to the 26-35 years of age group (57.27% in test and 60% in control). Around 83.64% of the patients in both groups were literate and most of them were living in urban residential area compared to rural area in both groups. The marital status was found that majority of them got married (70% in test and 78.18% in control). The socioeconomic status of the patients found that majority were belong to lower middle (31.82% in test and 39.09% in control) followed by upper lower and upper middle-class groups. Most of the patients who were newly diagnosed for TB were taking ATT medication (59.09% in test and 55.45% in control). The social history of the patients found that most of them were Non-alcoholic or smokers (45.45% in test and 50% in control) but there were few smokers (21.82% in test and 23.64% in control) and smokeless tobacco chewing (23.64% in test and 17.27% in control). Majority of the patients were not having any comorbidities only few of them had hypertension (5.45% in control and test) and diabetes (2.73% in test and 3.64% in control) [Table 1].

Health-Seeking behaviour

Regarding health seeking behaviour we assessed that about 97.27% of the patients in both test and control group patients that

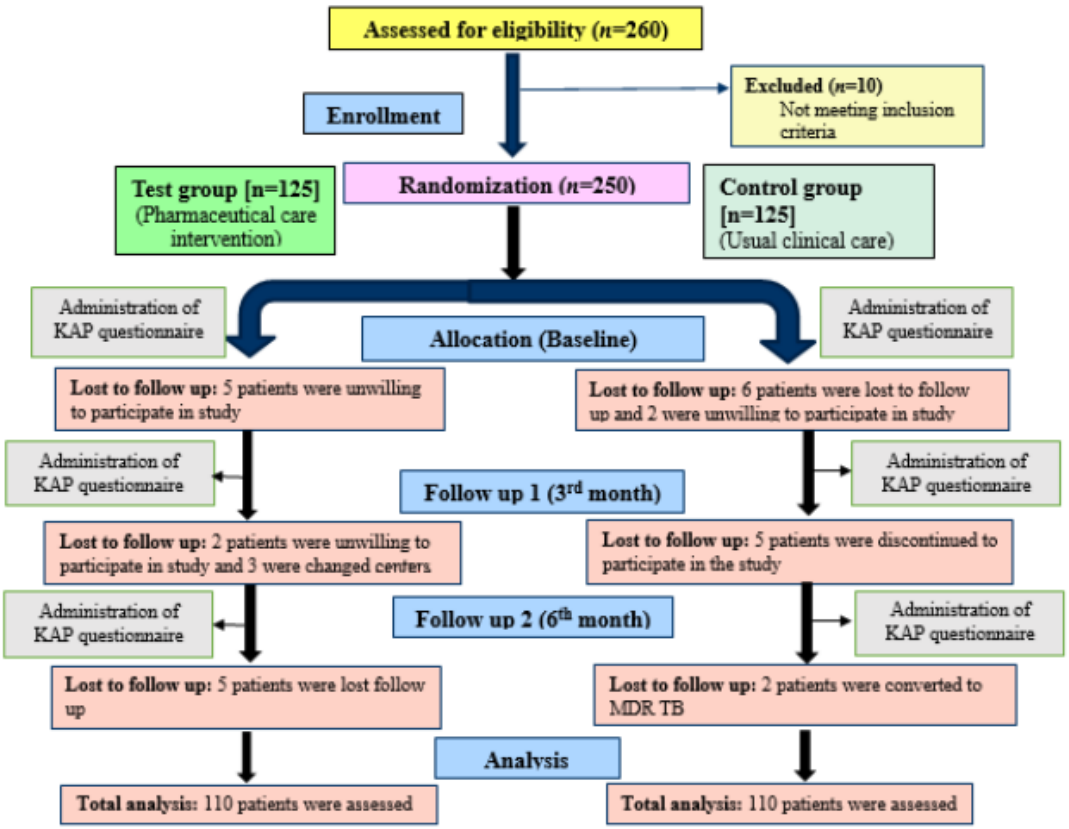

Figure 1: The consort flow chart representation of materials and methods.

Table 1: Comparison of control group and test group with Socio-demographic profile of TB patients.

Socio-demographic profile	Test (*n*=110)	(%)	Control (*n*=110)	(%)
Age groups				
15-25	13	(11.82)	11	(10.00)
26-35	63	(57.27)	66	(60.00)
36-45	34	(30.91)	33	(30.00)
Gender				
Female	51	(46.36)	49	(44.55)
Male	59	(53.64)	61	(55.45)
Literacy				
Illiterate	18	(16.36)	18	(16.36)
Literate	92	(83.64)	92	(83.64)
Residency				
Rural	52	(47.27)	49	(44.55)
Urban	58	(52.73)	61	(55.45)
Marital status				
Unmarried	33	(30.00)	24	(21.82)
Married	77	(70.00)	86	(78.18)
Socioeconomic Status				
Upper	3	(2.73)	4	(3.64)
Upper middle	23	(20.91)	16	(14.55)
Lower middle	35	(31.82)	43	(39.09)
Upper lower	35	(31.82)	29	(26.36)
Lower	14	(12.73)	18	(16.36)
TB drug treatment				
FDC	45	(40.91)	49	(44.55)
ATT	65	(59.09)	61	(55.45)
Social History				
Smoker	24	(21.82)	26	(23.64)
Smokeless tobacco	26	(23.64)	19	(17.27)
Alcohol	0	(0.00)	3	(2.73)
Alcoholic with smoking	10	(9.09)	7	(6.36)
Non-alcoholic/smoker	50	(45.45)	55	(50.00)
Comorbidities				
Hypertension	6	(5.45)	6	(5.45)
Diabetes	3	(2.73)	4	(3.64)
No comorbidities	101	(91.82)	100	(90.91)
Total	110	100.0	110	100.0

they usually go to private clinic whenever they feel sick or to treat a general health problem and only 2.73% patients of both groups prefer for government clinic or hospital. About 84.55% in both groups at once in a month generally seek health care at a clinic or hospital, 14.55% in both groups the patients seek at least twice a year or more to the healthcare clinic or hospital followed by only 0.91% patients in both groups seeks once per year to the healthcare clinic or hospital. The comparison of both control and test groups with Health-seeking behaviour of TB patients was mentioned at Table 2.

TB knowledge and awareness

On assessment and evaluation of knowledge and awareness on TB, patients were interviewed about seriousness of the disease, signs

and symptoms, TB transmission, prevention, and occurrence among all age groups. The questionnaire administered in three treatment times i.e., baseline, follow up 1 and follow up 2. By using independent t test, at baseline both control and test groups has shown low knowledge and awareness, in which control group mean score 3.35±0.92 and test group mean score 3.55±1.55 with *t*-value -1.1104 and *p*-value 0.2681. In follow-up 1 control group mean score 5.24±0.99 and test group mean score 4.23±1.00 with *t*-value 7.5326 and *p*-value 0.0001. In follow-up 2 controls group mean score 7.10±1.10 and test group mean score 9.75±0.98 with *t*-value -18.9101 and *p*-value 0.0001 which had shown highly significant improvement [Figure 2].

TB attitude and Stigma

On assessment and evaluation of attitude and stigma towards TB, patients were interviewed about ATT therapy, reporting side effects, continuation of anti TB treatment when side effects occur, disclosing condition to family members and continuation of anti TB treatment when signs and symptoms were reduced. By using independent t test, at baseline both control and test groups has shown low attitude and stigma, in which control group mean score 2.72±1.44 and test group mean score 2.72±1.44 with t-value 0.0 and *p*-value 1.0. In follow-up 1 control group mean score 7.73±1.31 and test group mean score 9.40±1.10 with *t*-value -10.2356 and *p*-value 0.0001. In follow-up 2 controls group mean score 12.73±1.31 and test group mean score 18.22±1.07 with *t*-value -34.0073 and *p*-value 0.0001 which had shown highly significant improvement [Figure 3].

Perception on TB

On assessment and evaluation of perception towards TB, patients were interviewed about cure, treatment and diagnosis expense, mental stability, sharing TB related problems and information about TB. By using independent t test, at baseline both control and test groups has shown low perception towards TB, in which control group mean score 2.80±1.43 and test group mean score 2.80±1.43 with *t*-value 0.0 and *p*-value 1.0. In follow-up 1 control group mean score 3.24±1.45 and test group mean score 2.39±1.82 with *t*-value 3.8176 and *p*-value 0.0001. In follow-up 2 controls group mean score 8.07±1.39 and test group mean score 9.85±0.76 with *t*-value -11.7635 and *p*-value 0.0001 which had shown highly significant improvement [Figure 4].

DISCUSSION

At present, clinical pharmacists are most accessible primary healthcare providers in India. Despite the addition of pharmacists in Public-Private Partnership programme under NTEP in India, for being a DOT provider, case finder, counsellor, the awareness and training the pharmacist by central TB center was found inadequate in India.[20] The NTEP program provides effective ways to establish the link between disease transmission and infection to initiate TB prophylaxis. Training and education interventions delivered by pharmacists have been evaluated in other countries with high TB burdens and suggest that increased knowledge about TB can change the way High-risk groups approach TB prevention.[21]

In our study, males were outnumbered than females by constituting more than 50% of the total sample among both test

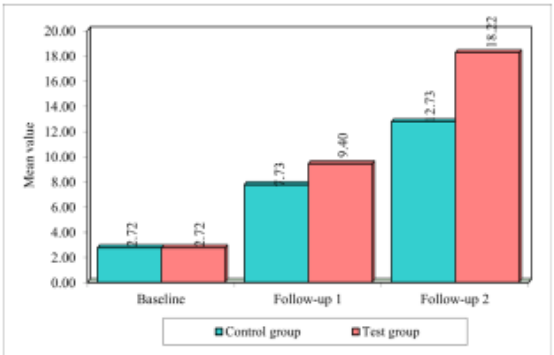

Figure 3: Comparison of control group and test group with TB attitude and stigma scores at different treatment times.

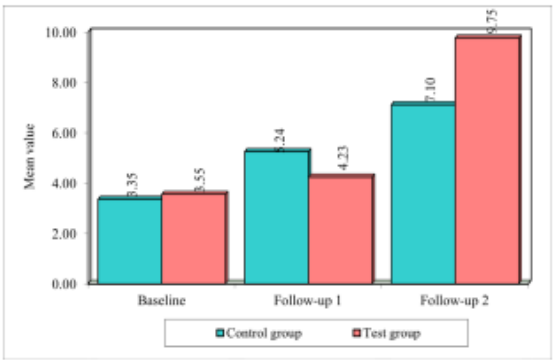

Figure 2: Comparison of control group and test group with TB knowledge and awareness scores at different treatment times.

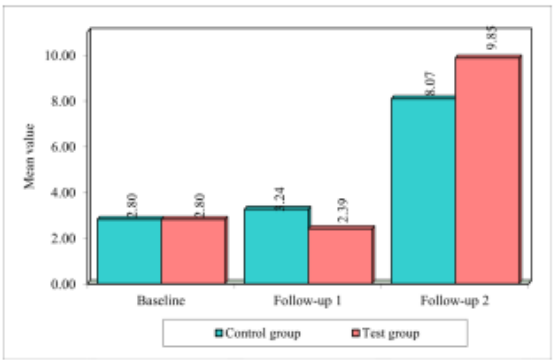

Figure 4: Comparison of control group and test group with TB Perception scores at different treatment times.

Table 2: Comparison of control group and test group with Health-seeking behaviour of TB patients.

Health-seeking behaviour	Control group	%	Test group	%	Total	%
Where do you usually go if you are sick, or to treat a general health problem?						
Private clinic	107	97.27	107	97.27	214	97.27
Government clinic or hospital	3	2.73	3	2.73	6	2.73
How often do you generally seek health care at a clinic or hospital?						
Once in a month.	93	84.55	93	84.55	186	84.55
Twice a year or more.	16	14.55	16	14.55	32	14.55
Once per year.	1	0.91	1	0.91	2	0.91
Total	110	100.0	110	100.0	220	100.0

and control. The maximum number of participants were at the working age group 26-35 (57.27% in test and 60% in control). Similar results were reported by Vani *et al*., (2015) marking a higher incidence rate of TB from 25 to 35 years of age, the rate gradually decreases.[22] In our study most of the patients of about 97.27% approached the private health facility for their tuberculosis symptoms. Similar study conducted by Uplekar *et al*. found that in the Pune city, 60% of individuals with chest symptoms first approached a private provider and in another study by the same author, it was found to be 86%.[23,24]

In our study, while assessing TB knowledge and awareness at baseline we found that only few participants knew that a seriousness of the TB disease, only few knew that cough was the mode of transmission and were unknown of TB occurrence among different age groups but after pharmacist intervention we found significant improvement among test group patients. In a study by Sabir *et al*. in Rawalpindi, it was found that the participants had little known knowledge about the causes of TB and the mode of transmission.[25] The reason for this large difference may be because our study was carried out in both urban and rural areas. However, another study conducted in Sudan rural area by Mohamed *et al*. showed that only 1.9% of the participants knew the cause of TB.[26]

In our study we found that more than a quarter of participants had low attitude and found high stigma regarding TB in the baseline and after pharmacist intervention we found significant improvement in test group patients. In a study conducted by Mweemba *et al*. in Zambia showed that 80% of participants had a positive attitude towards TB.[27] Our study also observed that 49.1% of the participants agreed to disclose TB to family members and isolate TB patients. This shows that TB patients are still discriminated against in our society. Although the attitude to continue taking anti-TB drugs even when symptoms declined was good, only few of them reports the side effects.

In our study while we found, most of them have negative perception opinion in curing and were thought expensive with treatment and diagnosis available in India. According to Central TB division, it was reported that 80-85% of patients were successfully treated; all diagnostic tests and treatment expenses were available free under NTEP programme.[28] This extension gap in attitude and perception can be reduced with appropriate interventions and equitable distribution of health services in all regions. Several studies have shown that knowledge about TB increases by conducting awareness interventional programs.[29-31] Hence, we believe the role of clinical pharmacist plays an important role with NTEP programme in providing and educating the TB patients to know about their disease condition.

CONCLUSION

We conclude majority of the patients in both control and test groups were having lack of knowledge and awareness, low attitude and perception on TB at the baseline. After intervention from a clinical pharmacist and usual care from health care team, we found significant improvement among TB patients. Test group patients have shown greater improvement than control group. It was shown that clinical pharmacist adequate counselling and education of patients Played an important role aspect in reducing the stigma, the impact of social consequences of TB and completion of anti TB treatment within duration of period. Thus, the clinical pharmacists have a significant role in the national strategy plan in elimination of TB from India by 2025.

LIMITATIONS

The findings are limited to only one tertiary care hospital and four PHC centres only in Belagavi. So, the results cannot be fully extrapolated for general population. Moreover, patients attending government hospitals are expected to have a relatively greater awareness on health issues.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

TB: Tuberculosis; **WHO:** World Health Organisation; **MDR-TB:** Multi drug-resistance tuberculosis; **HIV:** Human immunodeficiency virus; **AIDs:** Acquired immunodeficiency syndrome; **KAP:** Knowledge, attitude and perception; **RNTCP:** Revised National Tuberculosis Control Programme; **NTEP:** National Tuberculosis Elimination Program; **IEC:** Institutional Ethical Clearance; **PHC:** Primary Health Care centre; **PILs:** Patient Information Leaflets; **FRE:** Flesch Reading Ease; **BALD:** Baker Able Leaflet Design; **ATT:** Antitubercular treatment; **FDC:** Fixed Dose Combination therapy; **ICF:** Informed consent forms.

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Research Article

Identification and Evaluation of Drug-Related Problems to First Line Therapy of Antitubercular Drugs among the Pulmonary Tuberculosis Patients in a Tertiary Care Hospital- A Randomised Controlled Study

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ABSTRACT

The standard treatment involves first-line antitubercular therapy for treating pulmonary tuberculosis (TB) in treating pulmonary tuberculosis (TB). This treatment is associated with many drug-related problems (DRPs) and adverse drug reactions (ADRs). A single-blind, randomized, controlled study was conducted on 250 patients to identify and evaluate the DRPs and ADRs among newly diagnosed pulmonary TB patients in a tertiary care hospital. The patients were classified as the usual care group (Control) and pharmaceutical care intervention group (Test). At the end of the follow-up study, the DRPs were assessed using PCNE classification V9.1. The causality assessment of ADRs was done with the Naranjo algorithm, the severity assessment was carried with a modified Hartwig and Siegel scale and the preventability of ADRs was assessed with a modified Schumock and Thornton scale. The statistical percentage analysis was done using Microsoft Excel 2019. Of 250 participants, 88% had DRPs and developed one or more ADRs. The DRPs of adverse drug event (possibly) occurring, unclear problem/complaint, duration of treatment too long, medication reconciliation problem and inappropriate timing or dosing intervals were found to be more. Around 94.55% of ADRs were mild, and 5.45% were moderate. The causality of ADRs around 94.09% were possible and 5.92% were probable, while the preventability of ADRs found around 89.55% definitely preventable and 10.45% were probably preventable. The study concludes the importance of clinical pharmacists in pharmaceutical patient care will contribute to understanding different DRPs and ADRs in managing TB.

INTRODUCTION

Tuberculosis (TB) remains a significant global health challenge, ranking among the deadliest infectious diseases.[1] The first-line treatment regimens for treating active TB encompass isoniazid (INH/H), rifampicin (RMP/R), ethambutol (EMB/E), and pyrazinamide (PZA/Z).[2] However, the prolonged use of these drugs in TB patients often results in medical issues and side effects, potentially leading to non-adherence. These adverse effects range from minor, such as abdominal pain, epigastric discomfort, nausea, vomiting, peripheral neuritis, itching, and joint pain, to major complications like hepatitis, seizures, jaundice, and optic neuritis. It is essential to note that while minor reactions do not necessitate discontinuation of antitubercular drugs, they can be managed by employing alternative medications to mitigate the adverse effects. Conversely, major adverse effects require the withholding or withdrawal of drug therapy for the well-being of the patient.[3]

Pharmaceutical care involves the clinical provision of medication therapy, focusing on identifying, resolving, and preventing drug-related problems (DRPs).[4] These problems encompass issues related to indications, safety, efficacy, and compliance, and addressing them is crucial for

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delivering suitable treatment and preventing medication non-adherence. The delivery of pharmaceutical care is entrusted to a clinically trained pharmacist, proficient in pharmacotherapeutic oversight. The primary objective of these pharmacists is to attain well-defined therapeutic goals, including curing ailments, stabilizing disease processes, preventing diseases, and alleviating symptoms. Collaborating with other healthcare professionals, these pharmacists enhance patients' quality of life.[5]

Unresolved DRPs and ADRs can result in significant morbidity and impact TB treatment regimens.[6] Many patients experience a loss of follow-up upon discharge from the hospital, leading to therapy discontinuation, frequent changes in drug regimens, and insufficient patient counseling and education. These factors may contribute to the occurrence of DRPs or ADRs and unnecessary healthcare utilization. In this context, monitoring TB patients through a healthcare team is crucial to ensure treatment completion. In the current scenario, the comprehensive provision of pharmaceutical care by pharmacists is vital. This approach includes offering sufficient patient counseling to enhance medication compliance, positively influencing morbidity outcomes, detecting adverse events, correcting medication errors, promoting medication adherence, and ultimately contributing to an improved quality of life.[7,8] Therefore, the objective of the current study is to identify and assess DRPs and ADRs in individuals undergoing first-line therapy with antitubercular drugs through the implementation of pharmaceutical care.

Materials and Methods

Study Design and Settings

A randomized, controlled study with a single-blind design was conducted among tuberculosis (TB) patients visiting a tertiary-care teaching hospital in the Belagavi district of Karnataka state, India. The study spanned for 18 months, commenced in September 2021, and was completed in March 2023. Randomization was achieved through the use of a simple envelope method, resulting in two parallel branches (1:1 ratio): the usual care group (Control) and the pharmaceutical care intervention group (Test). The study participants opened the envelopes containing the group assignments in the presence of a clinical pharmacist. Participants in the test group received pharmaceutical care interventions administered by the clinical pharmacist in a designated room at the TB center within the hospital. On the other hand, the control group received standard care from other healthcare professionals within the usual care room in the hospital.

Study Participants

The study included individuals aged 18 years and above who were newly diagnosed with pulmonary tuberculosis (TB) and undergoing self-administered TB treatment, encompassing both antitubercular treatment (ATT) and fixed-dose combination therapy (FDC), obtained from private practitioners. Exclusion criteria comprised individuals below 18 years of age, those diagnosed with extrapulmonary TB, individuals with more than one comorbidity, and those unwilling to participate in the study. The participants were provided information about the study through a subject information sheet, and their consent was obtained after enrolling them.

Data Collection and Statistical Analysis

The participants underwent interviews using a data collection form that collected demographic details, including age, gender, marital status, religion, area, education level, and working experience. In adherence to the eligibility criteria, patients who did not meet the inclusion criteria were excluded. Through a single-blind randomization technique, the included patients were randomized into two groups: the test group (with pharmacist intervention) and the control group (with clinical care). Two regular intervals of participant follow-up followed enrollment at baseline. The first follow-up occurred at the third month, and the second follow-up occurred three months after the first follow-up. Data were collected and documented after the second follow-up. Statistical analysis was carried out using Microsoft Excel spreadsheet 2019. Descriptive statistics, such as frequencies and percentages, were calculated for the necessary data. Data visualization techniques were employed, including tabulations, bar graphs, and pie charts. The schematic consort flow chart outlining the materials and methods is depicted in Fig. 1.

The patient medication compliance, which are DRPs and ADRs was identified and evaluated. The DRPs were categorized using the Pharmaceutical Care Network

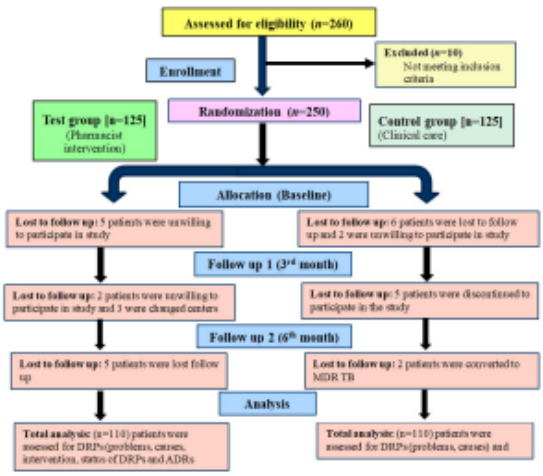

Fig. 1: The schematic consort flow chart representation of materials and methods

Europe's classification system (PCNE version 9.1).[9] The causality assessment of ADRs was conducted using the Naranjo algorithm, followed by the evaluation of severity using the modified Hartwig and Siegel scale. The preventability assessment was also performed using the modified Schumock and Thornton scale.[10-12]

The study received approval from the Institutional Ethical Clearance (IEC) for human subjects under the reference number KAHER/EC/21-22/020, dated July 29, 2021, from KLE Academy of Higher Education and Research in Belagavi, India.

RESULTS

Socio Demographic Details

In our study, a total of 250 patients were allocated and randomized into test and control groups. 30 patients were lost follow-up at the end of follow-up 2 (6th month). We assessed a total number of 220 patients (n = 110 test & n = 110 control) DRPs and ADRs. As far as background information was concerned, the majority of the participants were males in both test and control (53.64% in test and 55.45% in control) and the majority belonged to the 26 to 35 years of age group (57.27% in test and 60% in control). Around 83.64% of the participants in both groups were literate and most were living in urban residential areas compared to rural areas in both groups. The marital status of the participants found that the majority of them got married (70% in test and 78.18% in the control). The participants' socioeconomic status found that the majority belonged to the lower middle (31.82% in test and 39.09% in control) followed by upper-lower and upper-middle-class groups. Most of the participants who were newly diagnosed for TB were taking ATT medication (59.09% in test and 55.45% in control). The social history of the participants found that most of them were non-alcoholic or smokers (45.45% in test and 50%in control) but there were few smokers (21.82% in the test and 23.64% in control) and smokeless tobacco chewing (23.64% in test and 17.27% in control). The majority of the participants were not have any comorbidities only a few of them had hypertension (5.45% in control and test) and diabetes (2.73% in test and 3.64% in control) (Table 1).

Table 1: Comparison of control group and test group with socio-demographic profile of TB patients

Socio-demographic profile	*Test (n = 110)*	*(%)*	*Control (n = 110)*	*(%)*
Age groups				
15–25	13	(11.82)	11	(10.00)
26–35	63	(57.27)	66	(60.00)
36–45	34	(30.91)	33	(30.00)
Gender				
Female	51	(46.36)	49	(44.55)
Male	59	(53.64)	61	(55.45)
Literacy				
Illiterate	18	(16.36)	18	(16.36)
Literate	92	(83.64)	92	(83.64)
Residency				
Rural	52	(47.27)	49	(44.55)
Urban	58	(52.73)	61	(55.45)
Marital status				
Unmarried	33	(30.00)	24	(21.82)
Married	77	(70.00)	86	(78.18)
Socioeconomic status				
Upper	3	(2.73)	4	(3.64)
Upper middle	23	(20.91)	16	(14.55)
Lower middle	35	(31.82)	43	(39.09)
Upper lower	35	(31.82)	29	(26.36)
Lower	14	(12.73)	18	(16.36)
TB drug treatment				
FDC	45	(40.91)	49	(44.55)
ATT	65	(59.09)	61	(55.45)
Social history				
Smoker	24	(21.82)	26	(23.64)
Smokeless tobacco	26	(23.64)	19	(17.27)
Alcohol	0	(0.00)	3	(2.73)
Alcoholic with smoking	10	(9.09)	7	(6.36)
Non-alcoholic/smoker	50	(45.45)	55	(50.00)
Comorbidities				
Hypertension	6	(5.45)	6	(5.45)
Diabetes	3	(2.73)	4	(3.64)
No comorbidities	101	(91.82)	100	(90.91)
Total	110	100.0	110	100.0

Type of Drug Related Problems Identified

According to PCNE classification (V9.1), current study findings on drug related problems (DRPs) were identified among both test and control groups. We found that 03 (1.36%) patients were due to suboptimal drug treatment effects, while 42 (19.09%) patients had untreated symptoms or disease indication affecting treatment effectiveness. Adverse drug events potentially occurring were noted in 129 (58.64%) of patients, indicating concerns about treatment safety. Additionally, 46 (20.91%) of patients presented with unclear complaints or problems possibly arising from external factors (Table 2). The current study also identified various causes of DRPs among both test and control groups. These were due to polypharmacy which were unnecessarily prescribed in 4 (1.82%) patients, therapeutic duplication (excessively high doses of single active ingredients) were administered in 10 (4.55%) patients, complexity in dosage/treatment regimen

Table 2: Detailed drug related problems (PCNE)

The problems								
Primary domain	*Code*	*Problem*	*Frequency (N = 220)*		*Percentage (%)*		*Total (N = 220)*	*Total (%)*
			Test	*Control*	*Test*	*Control*		
1. Treatment effectiveness	P1.2	Effect of drug treatment not optimal	3	0	2.73	0	3	1.36
	P1.3	Untreated symptoms or indication	16	26	14.55	23.64	42	19.09
2. Treatment safety	P2.1	Adverse drug event (possibly) occuring	57	72	51.82	65.45	129	58.64
3. Other	P3.2	Unclear problem/complaint. Further clarification necessary	34	12	30.91	10.91	46	20.91

Table 3: The causes for drug related problems (PCNE)

The causes								
Primary domain	*Code*	*Cause*	*Frequency (n = 220)*		*Percentage (%)*		*Total (N = 220)*	*Total (%)*
			Test	*Control*	*Test*	*Control*		
1. Drug selection	C1.6	Too many different drugs/active ingredients prescribed for indication	2	2	1.82	1.82	4	1.82
2. Dose selection	C3.2	Drug dose of a single active ingredient too high	6	4	5.45	3.64	10	4.55
3. Treatment duration	C4.2	Duration of treatment too long	30	27	27.27	24.55	57	25.91
4. Patient related	C7.1	Patient intentionally uses/takes less drug than prescribed or does not take the drug at all for whatever reason	16	8	14.55	7.27	24	10.91
	C7.7	Inappropriate timing or dosing intervals	27	29	24.55	26.36	56	25.45
5. Patient transfer related	C8.1	Medication reconciliation problem	29	40	26.36	36.36	69	31.36
Total			110	110	100	100	220	100

(longer duration of treatment) found in 57 (25.91%) patients, patient non-compliance (low dosage of prescribed drug intake or does not take the drug) was found among 24 (10.91%) patients, dosing timings or intervals were inappropriately administered among 56 (25.45%) patients and lack of transition care where the patients shift from hospital care to primary health care centres (medication reconciliation problem) were found among 69 (31.36%) patients (Table 3).

Acceptance of the Intervention Proposals, Planned Interventions & Status of the DRPs

As our study was an interventional RCT trial, we have implemented the interventional proposal to test group from the baseline. Among 110 patients in the test group, 94 (85.45%) patients were accepted pharmacist intervention and fully implemented it, 14 (12.73%) patients were accepted intervention but partially implemented, only 2 (1.82) patients accepted intervention but implementation of pharmaceutical care services was unknown (Fig. 2). Regarding the planned interventions, the test group was given with patient (drug) counseling on 83 (75.45%) patients, written information of provided on 12 (10.91%) patients who were unable to listen and on 15 (13.64%) counselling was given to family members (Fig. 3). After the follow-up, 2 (6th month), at the end of the study, We found 74 (67.27%) patients in the test group the DRPs were totally solved and 36 (32.73%) patients the DRPs were partially solved.

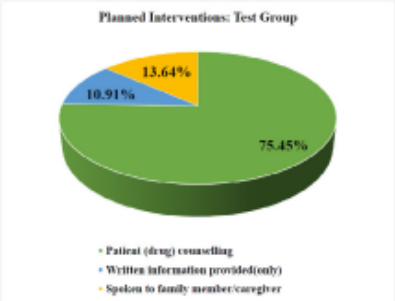

Fig. 2: The planned interventions

Table 4: Common adverse drug reactions observed in both test and control groups.

Drugs	*Common ADRs*	*Test (n = 110)*	*(%)*	*Control (n = 110)*	*(%)*
Isoniazid	Hepatotoxicity	6	(5.45)	4	(3.64)
	Peripheral neuritis	7	(6.36)	4	(3.64)
	GI disturbance	77	(70)	73	(66.36)
	Skin rashes	4	(3.64)	2	(1.82)
Rifampicin	Orange/red color urine	110	(100)	110	(100)
	Abdominal pain	25	(22.73)	27	(24.55)
	flu-like syndrome	11	(10)	6	(5.45)
	Nausea/vomiting	29	(26.36)	15	(13.64)
	Arthralgia	2	(1.82)	2	(1.82)
Pyrazinamide	Hepatotoxicity	6	(5.45)	4	(3.64)
	Malaise	4	(3.64)	3	(2.73)
	Anorexia	1	(0.91)	2	(1.82)
	Nausea/vomiting	29	(26.36)	15	(13.64)
Ethambutol	Ocular side effects	1	(0.91)	2	(1.82)
	Optic neuritis	0	(0)	2	(1.82)
	Pruritis	7	(6.36)	4	(3.64)
	GI disturbance	77	(70)	73	(66.36)
	Headache	27	(24.55)	18	(16.36)

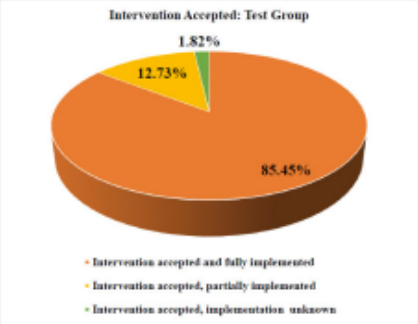

Fig. 3: Acceptance of the intervention proposals

Adverse Drug Reactions Assessment

Most adverse drug reactions (ADRs) (95.85%) occurred in the intensive phase, while only 4.15% occurred in the continuation phase in both test and control groups. Around 50% of ADRs occurred in the 1st week of treatment in the baseline. The majority of them were common ADRs, which were related to gastrointestinal disturbance, nausea or vomiting, abdominal pain, headache etc. The common ADRs that were observed in both test and control groups with four antitubercular drugs are listed in Table 4.

We have assessed the severity of ADRs by using a modified Hartwig and Siegal scale, and found that 102 (92.73%) in test and 106 (96.36%) in the control group of the ADRs classified as mild (Level 1 and 2), 8 (7.27%) in test and 4 (3.64%) in control as moderate (Level 3 and 4). None of the ADRs were classified as severe. According to the Naranjo algorithm causality assessment, 102 (92.73%) in the test and 105(95.45%) in the control group of the ADRs were classified as possible, 8 (7.27%) in the test and 5 (4.55%) in the control as probable. No ADRs were classified as definite. According to Schumock and Thorton preventability assessment scale, 95 (86.36%) in test and 102 (92.73%) in the control group of the ADRs were classified as definitely preventable, 15 (13.64%) in test and 8 (7.27%) in control as probably preventable. No ADRs were classified as not preventable.

Discussion

Pharmacists play a crucial role in ensuring the appropriate use of medications by identifying and addressing DRPs. As per the PCNE-DRP (V9.1) classification, a DRP is defined as an event or circumstance related to drug therapy that either actually or potentially interferes with the desired health outcomes. The standard treatment duration for newly diagnosed TB patients involves a six-month regimen with first-line antitubercular drugs.[13] During this extended therapy period, the potential for DRPs arises, posing a risk of treatment withdrawal and impacting the overall quality of life. Our present study underscores the significance of clinical pharmacist-led interventions in efficiently identifying and addressing DRPs. Similar findings were found from various studies that emphasize the positive impact of timely interventions in managing DRPs.[14-16]

This study specifically evaluates DRPs among TB patients attending the National Tuberculosis Elimination Program (NTEP) center at a tertiary care hospital, with subsequent follow-ups conducted at primary health care centers. Importantly, this study stands out as one of the few in India that systematically analyzes interventions targeting DRPs in TB patients, utilizing the PCNE classification, and assesses ADRs related to TB treatment.

In the current study involving 220 participants, it was observed that the majority were males, constituting 53.64% in the test group and 55.45% in the control group, while females accounted for 46.36 and 44.55% in the test and control groups, respectively. This similar finding was seen in several other studies, indicating a higher risk of infection among males. [17,18] The study predominantly included adults aged 26 to 35 years, who had high risk of infection compared to the elderly and children, consistent with findings from other studies.[19,20] Furthermore, the present study revealed a notable prevalence of smokeless tobacco and smoker patients affected by TB, mirroring similar findings in other study, which highlighted the association between TB patients and smoking and smokeless tobacco habits.[20] Additionally, our study reported fewer patients without comorbidities compared to those with comorbidities, differing from another study that indicated a higher incidence.[21]

In our study, a total of 129 cases (58.64%) were identified as adverse events possibly occurring, followed by 46 cases (20.91%) with unclear problems/complaints, 42 cases (19.09%) related to untreated symptoms or indications, and only 3 cases (1.36%) where the effect of drug treatment was not optimal among the 220 patients. However, in the study by Tharanon V *et al.* revealed different categories of DRPs, including drug problems related to indications, excessively high or low drug doses, drug interactions, and patient failure to receive medication.[22] In our current study, the primary causes of DRPs were identified as medication reconciliation problems (31.36%), duration of treatment too long (25.91%), and inappropriate timing or dosing intervals (25.45%). These findings were attributed to the antitubercular drug treatment strategy, requiring patients to undergo a minimum 6-month therapy and refill their prescriptions weekly or monthly. Fauna Herawati *et al.* reported a similar trend, where TB patients faced challenges in adherence when admitted or transferred to different healthcare institutions, leading to treatment loss.[23]

Regarding ADRs, gastrointestinal disturbances were the most prevalent in our study. While in other study highlights gastritis as the most common ADR during anti-TB medication.[24] Our study reported low occurrences of hepatotoxicity, peripheral neuritis, flu, skin rashes, and malaise. The observation of orange/red-colored urine among all patients was attributed to a normal ADR associated with rifampicin. A higher frequency of ADRs was noted during the intensive phase (95.96%) compared to the continuation phase (5.04%), consistent with other studies indicating a higher incidence of ADRs in the early months of TB treatment.[25,26] our study did not affect the overall therapeutic outcome despite these ADRs.

In the current study, among the reported ADRs, 102 cases (92.73%) in the test group and 106 cases (96.36%) in the control group were categorized as mild (Level 1 and 2) on the modified Hartwig and Siegal scale. Additionally, 8 cases (7.27%) in the test group and 4 cases (3.64%) in the control group were classified as moderate (Level 3 and 4). Mild ADRs typically do not necessitate any changes in treatment, while moderate ADRs may require adjustments to the suspected drug dose or discontinuation of the drug. Regarding causality assessment using the Naranjo algorithm, the majority of ADRs, 102 cases (92.73%) in the test group and 105 cases (95.45%) in the control group, were classified as possible. Only 8 cases (7.27%) in the test group and 5 cases (4.55%) in the control group were categorized as probable. It's essential to note that the study did not conduct rechallenge tests to establish the causative agent, and there were no laboratory investigations to determine drug concentrations in tissues or body fluids. As a result, no reported ADRs were categorized as definite in this study.

The effective management of TB patients necessitates a multidisciplinary healthcare professional team strategy. Pharmacists play a vital role within such teams and can contribute at various stages in the value chain for TB control. The current study indicates that pharmacists significantly contribute to TB treatment by identifying DRPs and monitoring ADRs. This involvement proves instrumental in enhancing treatment adherence, assessing risk factors, managing disease control and prevention, and enhancing the safety and efficacy of TB treatment. Therefore, the provision of pharmaceutical care services in TB management, under the supervision of pharmacists, is a crucial element in contributing to controlling and preventing TB disease.

CONCLUSION

This study appears to be first pharmaceutical care interventional study conducted on tuberculosis patients in India through a clinical pharmacist. A thorough understanding of the various DRPs and ADRs helped in effective TB management. Additionally, this study contributes to the assessment of the safe usage of antitubercular drugs, as the ADRs identified align with those previously reported in the literature. A noteworthy outcome of the study is the high acceptance and implementation of planned pharmacist interventions and recommendations among the test group patients. Furthermore, pharmaceutical care intervention in the test group resulted in resolving and improving DRP status. This study's findingshow that pharmaceutical care services' impactes in treating tuberculosis promotes better healthcare outcomes.

ACKNOWLEDGMENT

We would show our extreme gratitude to the Associate Professor & in charge of NTEP centre, Dr. Jyothi Hattiholi of KLE hospital, Belagavi, Karnataka who supported us in collecting cases in the hospital. We would like to acknowledge all patients who were participated and responded to our study.

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ANNEXURE – XVIII – PRESS RELEASE

ಬೆಳಗಾವಿಯ ಕೆಎಲ್ಇ ಶತಮಾನೋತ್ಸವ ಭವನದಲ್ಲಿ ವಿಶ್ವ ಫಾರ್ಮಸಿಸ್ಟ್ ದಿನ ಸಮಾರಂಭಕ್ಕೆ ಗಣ್ಯರು ಚಾಲನೆ ನೀಡಿದರು.

ವಿಶ್ವ ಫಾರ್ಮಸಿಸ್ಟ್ ದಿನಾಚರಣೆ

ಬೆಳಗಾವಿ: ಕೆಎಲ್ಇ ಕಾಲೇಜ್ ಆಫ್ ಫಾರ್ಮಸಿ, ಜಿಲ್ಲಾ ಕ್ಷಯ ರೋಗ ಕೇಂದ್ರ ಮತ್ತು ಜಿಲ್ಲಾ ಔಷಧ ನಿಯಂತ್ರಣ ಇಲಾಖೆ ಸಹಯೋಗದಲ್ಲಿ ಸೋಮವಾರ ಕೆಎಲ್ಇ ಶತಮಾನೋತ್ಸವ ಭವನದಲ್ಲಿ ವಿಶ್ವ ಫಾರ್ಮಸಿಸ್ಟ್ ದಿನ ಆಚರಿಸಲಾಯಿತು.

ಮುಖ್ಯ ಅತಿಥಿಯಾಗಿ ಪಾಲ್ಗೊಂಡಿದ್ದ ಔಷಧ ನಿಯಂತ್ರಣಾಧಿಕಾರಿ ದೀಪಕ ಗಾಯಕವಾಡ, ಸಮಾಜ ಸೇವೆಯಲ್ಲಿ ಫಾರ್ಮಸಿಸ್ಟ್ ಪಾತ್ರದ ಕುರಿತು ತಿಳಿಸಿದರು. ಅಧ್ಯಕ್ಷತೆ ವಹಿಸಿದ್ದ ಕೆಎಲ್ಇ ಫಾರ್ಮಸಿ ಕಾಲೇಜಿನ ಪ್ರಾಂಶುಪಾಲ ಪ್ರೊ.ಡಾ. ಸುನೀಲ ಜಲಾಲಪುರೆ, ಕೋವಿಡ್ ಸಾಂಕ್ರಾಮಿಕ ಸಂದರ್ಭದಲ್ಲಿ ಫಾರ್ಮಸಿಸ್ಟ್‌ಗಳ ಸೇವೆ ಶ್ಲಾಘಿಸಿದರು. ಜಿಲ್ಲಾಕ್ಷಯ ರೋಗ ನಿಯಂತ್ರಣಾಧಿಕಾರಿ ಡಾ.ಅನಿಲ್, ಕಾಹೆರ್ ಡೆಪ್ಯುಟಿ ರಿಜಿಸ್ಟ್ರಾರ್ ಡಾ. ಎಂ.ಎಸ್.ಗಣಾಚಾರಿ ಮಾತನಾಡಿದರು. 30 ವರ್ಷಗಳಿಂದ ಸೇವೆ ಸಲ್ಲಿಸುತ್ತಿರುವ ಬೆಳಗಾವಿ ಜಿಲ್ಲೆಯ 11 ಫಾರ್ಮಾಸಿಸ್ಟ್‌ಗಳನ್ನು ಹಾಗೂ ಡಾ. ಸುನೀಲ ಜಲಾಲಪುರೆ ಅವರನ್ನು ಕಾರ್ಯಕ್ರಮದಲ್ಲಿ ಸನ್ಮಾನಿಸಲಾಯಿತು. ಈ ವೇಳೆ ಸಹಾಯಕ ಔಷಧ ನಿಯಂತ್ರಕ ಮಲ್ಲಿಕಾರ್ಜುನ ಕೆ.ಎಸ್., ಅಜಯ ಮುದಗಲ್, ಕೆ.ವಿ.ಮನೋಹರ್, ರಘು ರಾಮ್ ಇತರರು ಇದ್ದರು. ಡಾ. ವಿನೋದ ಎಸ್. ಮಣ್ಣೂರ ಸ್ವಾಗತಿಸಿದರು. ಡಾ.ಅಂಜನಾ ಪರಿಚಯಿಸಿದರು. ಶಶಿಕಲಾ ವಾಲಿ ವಂದಿಸಿದರು.

केएलई फार्मसी कॉलेजतर्फे क्षयरोग जागृती शिबिर

डिफार्मसी, क्लिनिकल रिसर्चच्या विद्यार्थ्यांकडून नाटिका सादर

प्रतिनिधी
बेळगाव

केएलई कॉलेज ऑफ फार्मसी व जे. एन. मेडिकल कॉलेजच्या कम्युनिटी मेडिसीन विभागाच्या वतीने जागतिक क्षयरोग दिनानिमित्त क्षयरोग जागरूकता कार्यक्रमाचे आयोजन करण्यात आले होते. साहाय्यक प्राध्यापक डॉ. अनिकेत यांच्या हस्ते या कार्यक्रमाचे उद्घाटन करण्यात आले.

डॉ. अनिकेत यांनी राष्ट्रीय क्षयरोग निर्मूलन कार्यक्रमाचे महत्व उपस्थित रुग्ण, आशा कार्यकर्त्या, अंगणवाडी कर्मचारी, एएनएम आणि इतर प्राध्यापक सदस्यांना सांगितले. क्षयरोगाचे उपचार आणि प्रतिबंधात्मक उपचाराबद्दल त्यांनी माहिती दिली. कॉलेज ऑफ फार्मसीचे प्राचार्य डॉ. सुनिल जलालपुरे व डॉ. एम. एस. गणाचारी यांनी या कार्यक्रमासाठी परिश्रम घेतले.

दीप प्रज्वलन करताना आरोग्य कर्मचारी. बाजूला केएलई फार्मसीचे प्राध्यापक.

डॉ. बी. यशवंतराजा यांनी क्षयरोगाबद्दल जागरूकता आणि वैद्यकीय व्यवस्थापन याविषयी माहिती दिली. डिफार्मसी व क्लिनिकल रिसर्चच्या विद्यार्थ्यांनी यावर आधारित एक नाटिका सादर केली.

यावेळी डॉ. एम. बी. पाटील, प्रा. शशिकला वाली, गीतांजली सालीमठ यांच्यासह विद्यार्थी व रुक्मिणीनगर येथील प्राथमिक आरोग्य केंद्राचे कर्मचारी उपस्थित होते.

ಭಾನುವಾರ,27 ಮಾರ್ಚ್ 2022 ನಮ್ಮ ಬೆಳಗಾವಿ III

ವಿಶ್ವ ಕ್ಷಯ ರೋಗ ದಿನಾಚರಣೆ ಪ್ರಯುಕ್ತ ಕೆಎಲ್ಇ ಸಂಸ್ಥೆಯ ಫಾರ್ಮಸಿ ಮಹಾವಿದ್ಯಾಲಯ ಹಾಗೂ ಜೆಎನ್ಎಂಸಿ ಸಮುದಾಯ ವೈದ್ಯಕೀಯ ವಿಭಾಗದ ವತಿಯಿಂದ ಜಾಗೃತಿ ಕಾರ್ಯಕ್ರಮ ಜರುಗಿತು. ಜೆಎನ್ಎಂಸಿ ಸಹಾಯಕ ಪ್ರಾಧ್ಯಾಪಕ ಡಾ. ಅನಿಕೇತ, ಫಾರ್ಮಸಿ ವಿಭಾಗದ ಮುಖ್ಯಸ್ಥ, ಡೆಪ್ಯೂಟಿ ರಿಜಿಸ್ಟ್ರಾರ್ ಡಾ. ಎಂ.ಎಸ್.ಗಣಾಚಾರಿ, ಪ್ರಾಚಾರ್ಯ ಡಾ. ಸುನೀಲ ಜಲಾಲಪುರೆ, ಡಾ. ಬಿ. ಯಶವಂತರಾಜ, ಸಹ ಪ್ರಾಧ್ಯಾಪಕಿಯರಾದ ಶಶಿಕಲಾ ವಾಲಿ, ಗೀತಾಂಜಲಿ ಸಾಲಿಮಠ ಸೇರಿದಂತೆ ಇನ್ನಿತರರು ಇದ್ದರು.

ANNEXURE – XIX – GRANT APPROVAL
NTEP Financial assistance 2022-2023

GOVERNMENT OF KARNATAKA
HEALTH & FAMILY WELFARE SERVICE
OFFICE OF THE JOINT DIRECTOR (TB), LADY WILLINGDON STATE TB CENTRE, 2nd FLOOR,
AROGYA SOUDHA, 1st CROSS, MAGADI ROAD, BENGALURU-560023

No: LWSTC/NTEP/PPM/64/2022-23 Date: 17/10/2022

Minutes of State OR Committee meeting held on 22nd September 2022 at State TB Office, Arogya Soudha, Bengaluru

The state OR committee meeting was held at the State TB Office, Arogya Soudha, Bengaluru on 22nd September 2022 and the esteemed OR committee members had attended the meeting physically and virtually. The list of OR committee members who were present during the meeting is listed in Annexure 1.

The following are the points and decisions taken during the meeting:

(1) The state had received 25 (twenty-five) post-graduate thesis on the area of tuberculosis from various medical colleges of Karnataka and MPH/PhD thesis from institutes affiliated to medical colleges. The committee had obtained priory approval from Central TB Division (CTD) to fund thesis for non-medical PG courses. However, as per the CTD directives, it was envisaged that the medical college PG thesis should always be prioritised under any circumstances. The OR committee recommended all the thesis for funding. (Annexure 2)
(2) The three multicentric OR studies which were supposed to be undertaken discussed during the last State OR committee meeting were dropped as few administrative issues were foreseen.
(3) The state had received 20 Operational Research Protocols from various medical colleges and one dental college across the state. The protocols were reviewed by internal and external experts. Based on the merits and discussions, the committee selected eight (8) proposals for funding from the programme (Annexure 3). The select Principal and one Co-Investigator shall mandatorily undergo 'State level protocol development workshop' at National TB Institute, Bengaluru from 7th – 11th November 2022.
(4) The three approved protocols which were selected in the previous OR cycles and had not received funding shall we included in the current financial year.

The meeting ended with vote of thanks.

Annexure I

1. Dr Sharath BN, Chair, State OR Committee, Karnataka
2. Dr Anil S, State TB Officer, Member Secretary
3. Dr Ashok Dorle, Member (Virtual mode)
4. Dr Raveendra Reddy, Member (Virtual mode)
5. Dr Ravichandra, Member (Virtual mode)
6. Dr Ashwini, Member (Virtual mode)
7. Dr Akshay, Member (Virtual mode)
8. Dr Shazia Anjum, Ex-officio member

Joint Director (TB)

16	Dr Bandaru Yeswanth Raja	Role of clinical pharmacist to improve tubercular patient's compliance referred to NTEP centre attached to a tertiary care hospital: a randomised controlled study	Doctor of Philosophy (Ph.D.)	KLE College of Pharmacy, JNMC Campus, Belagavi	2020

ANNEXURE – XX – CERTIFICATES OF PRESENTATION

JSS ACADEMY OF HIGHER EDUCATION & RESEARCH
(DEEMED TO BE UNIVERSITY) MYSURU

PharmaNEST'3.E

Operant Pharmacy Federation

International Conference on Professional Development and Advanced Training in Artificial Intelligence driven drug design, discovery and development

Jointly Organized By:
JSS Academy of Higher Education & Research, Mysuru & Operant Pharmacy Federation

Certificate of Award

This is to certify that

Dr. BANDARU YESWANTH RAJA, KLE COLLEGE OF PHARMACY, BELGAVI

has participated in Oral Presentation competition and awarded **First Prize** in PharmaNEST'3.E International Conference held at JSS College of Pharmacy, Ooty, The Nilgiris, Tamil Nadu on 14 - 15 October, 2022.

Dr. SP Dhanabal	Dr. R. Kalirajan	Vikram Choudhary	Dr. S. Jubie
Convener, PharmaNEST 3.E	Organizing Secretary, PharmaNEST 3.E	Chairman, PharmaNEST 3.E	Chairman, SSC, PharmaNEST 3.E

NATCON 2022

77th National Conference of Tuberculosis & Chest Diseases

27TH FEB 28TH FEB 01ST MAR 2023 | JAYPEE PALACE HOTEL & CONVENTION CENTRE, AGRA, UTTAR PRADESH

Conference Theme : Back to the Basics and Beyond in TB Elimination

Organised By : Department of Tuberculosis & Respiratory Diseases, S.N. Medical College, Agra in association with UP TB Association & The Union, South East Asia Region under the aegis of Tuberculosis association of India

Certificate

This is to certify that

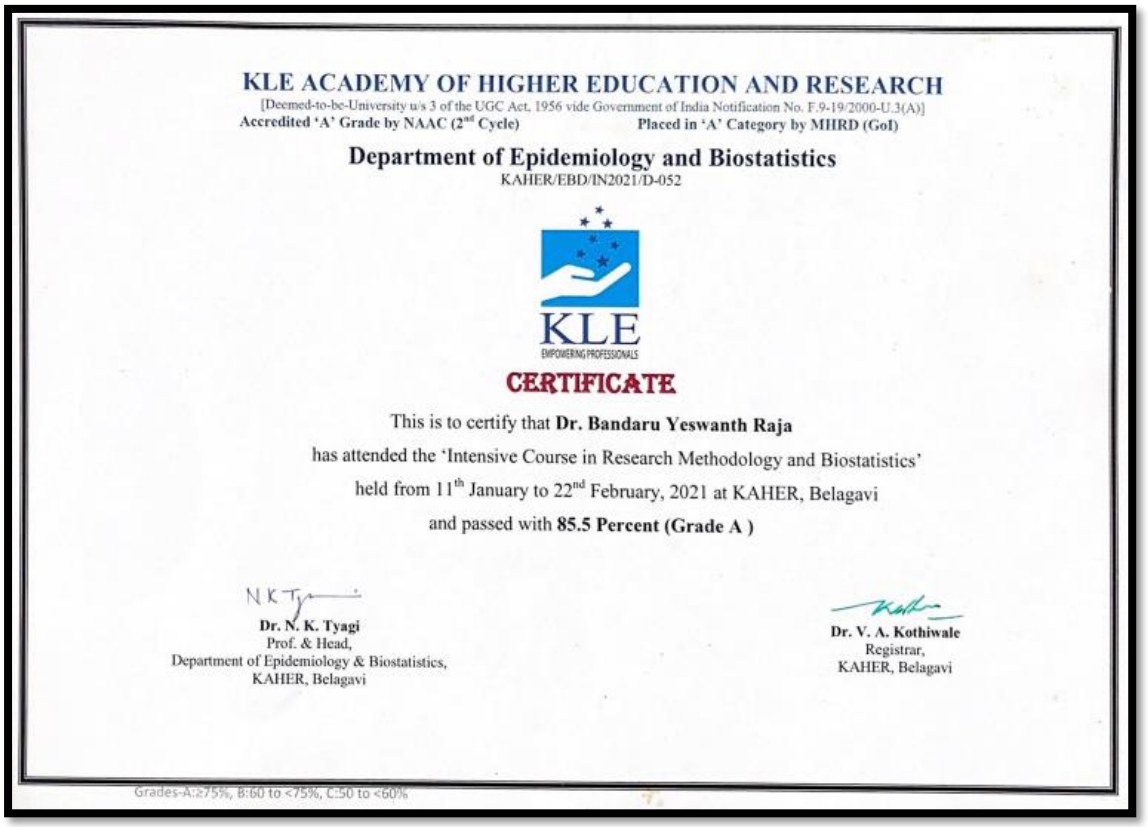
DR. BANDARU YESWANTHRAJA

has awarded..Second....Prize in the **Best Research Paper Session (Oral)** during **NATCON 2022 AGRA**

held on 27th February, 28th February & 01st March 2023 at JAYPEE Palace Hotel & Convention Centre, Agra, Uttar Pradesh, India

Dr. B. Wesley	Dr. Santosh Kumar	Dr. Gajendra Vikram Singh	Dr. V.K. Arora	Dr. Surya Kant
President	Organising Chairman	Organising Secretary	Chairperson, Tuberculosis Association of India	Chairman, Scientific Committee

ANNEXURE – XXI – Trainings undergone



KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH

[Deemed-to-be-University u/s 3 of the UGC Act, 1956 vide Government of India Notification No. F.9-19/2000-U.3(A)]

Accredited 'A' Grade by NAAC (2nd Cycle) Placed in 'A' Category by MHRD (GoI)

Department of Epidemiology and Biostatistics

KAHER/EBD/IN2021/D-052

KLE

EMPOWERING PROFESSIONALS

CERTIFICATE

This is to certify that **Dr. Bandaru Yeswanth Raja**

has attended the 'Intensive Course in Research Methodology and Biostatistics'

held from 11th January to 22nd February, 2021 at KAHER, Belagavi

and passed with **85.5 Percent (Grade A)**

Dr. N. K. Tyagi
Prof. & Head,
Department of Epidemiology & Biostatistics,
KAHER, Belagavi

Dr. V. A. Kothiwale
Registrar,
KAHER, Belagavi

Grades-A:≥75%, B:60 to <75%, C:50 to <60%

NPTEL Online Certification

(Funded by the Ministry of HRD, Govt. of India)

This certificate is awarded to

DR BANDARU YESWANTH RAJA

for successfully completing the course

Health Research Fundamentals

(ICMR-NIE e-Certificate course: NIeCer 101)

with a score of **65** %

Online Assignments	22.92/25	Proctored Exam	42.43/75

Total number of candidates certified in this course: **852**

Dr. Manoj Murhekar
Scientist 'G' & Director
ICMR-National Institute of Epidemiology, Chennai

Prof. Balram Bhargava
Secretary to Govt. of India, Dept. of Health Research
& Director-General, Indian Council of Medical Research

Prof. Andrew Thangaraj
NPTEL, Coordinator
IIT Madras

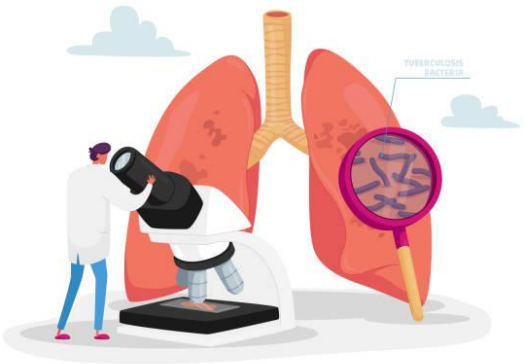
icmr NIE

Jan-Mar 2021
(8 week course)

swayam

Introduction

Review of Literature



Methodology

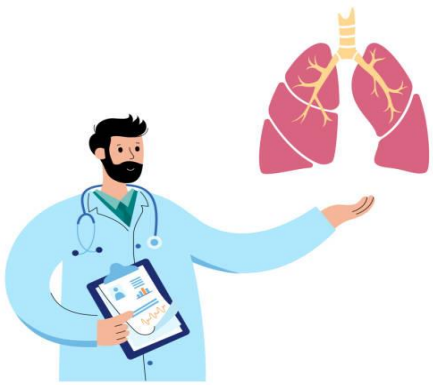
Results

Discussion

Conclusion

Summary

Bibliography



Annexures