

Factors Associated with Acceptability of Tuberculosis Preventive Therapy among Household Contacts of Pulmonary TB Patients in Delhi

Dr. Aditi Bakshi
MPH-IS, Cohort 1
Roll No- 001

IIHMR University Supervisor :

Dr. Nutan Prabha Jain, Professor
SD Gupta School of Public Health
IIHMR University, Jaipur, India

Organization Supervisor:

Dr. KK Chopra
Consultant/ Ex-Director
New Delhi Tuberculosis Centre
State TB Training & Demonstration Centre

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Introduction

01

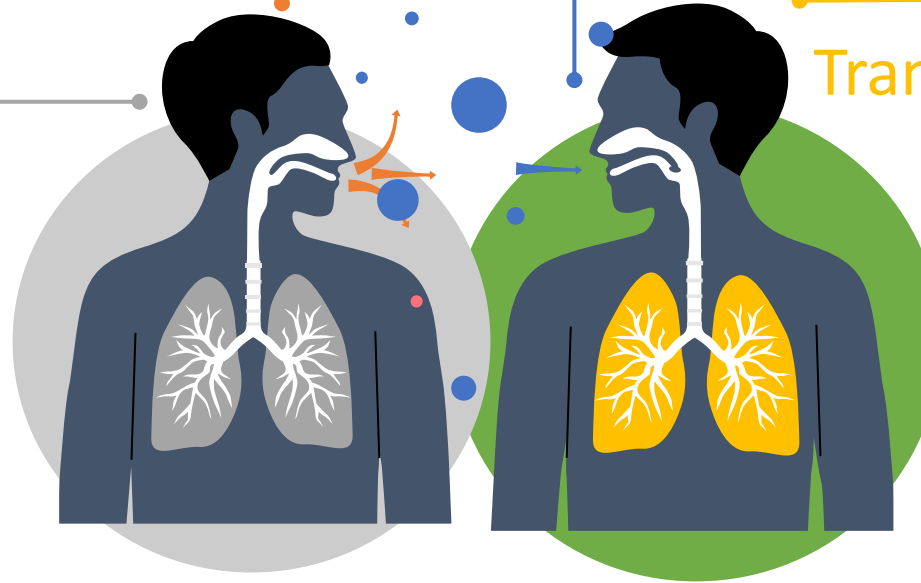
What is TB?

It is contagious disease caused by the bacillus *Mycobacterium tuberculosis*, primarily impacting the lungs. It is transmitted through the air when individuals who are infected cough, sneeze, or spit (WHO Facts, 2024).

02

Forms of TB

TB can take different forms- from subclinical (TB Infection) with no symptoms to clinical with active symptoms (TB Disease). TB can be both pulmonary and extrapulmonary.



Latent to TB

03

Clinical symptoms may not manifest in every TB-infected person unless the infection progresses to an active state.

04

Transition from TBI to TB Disease

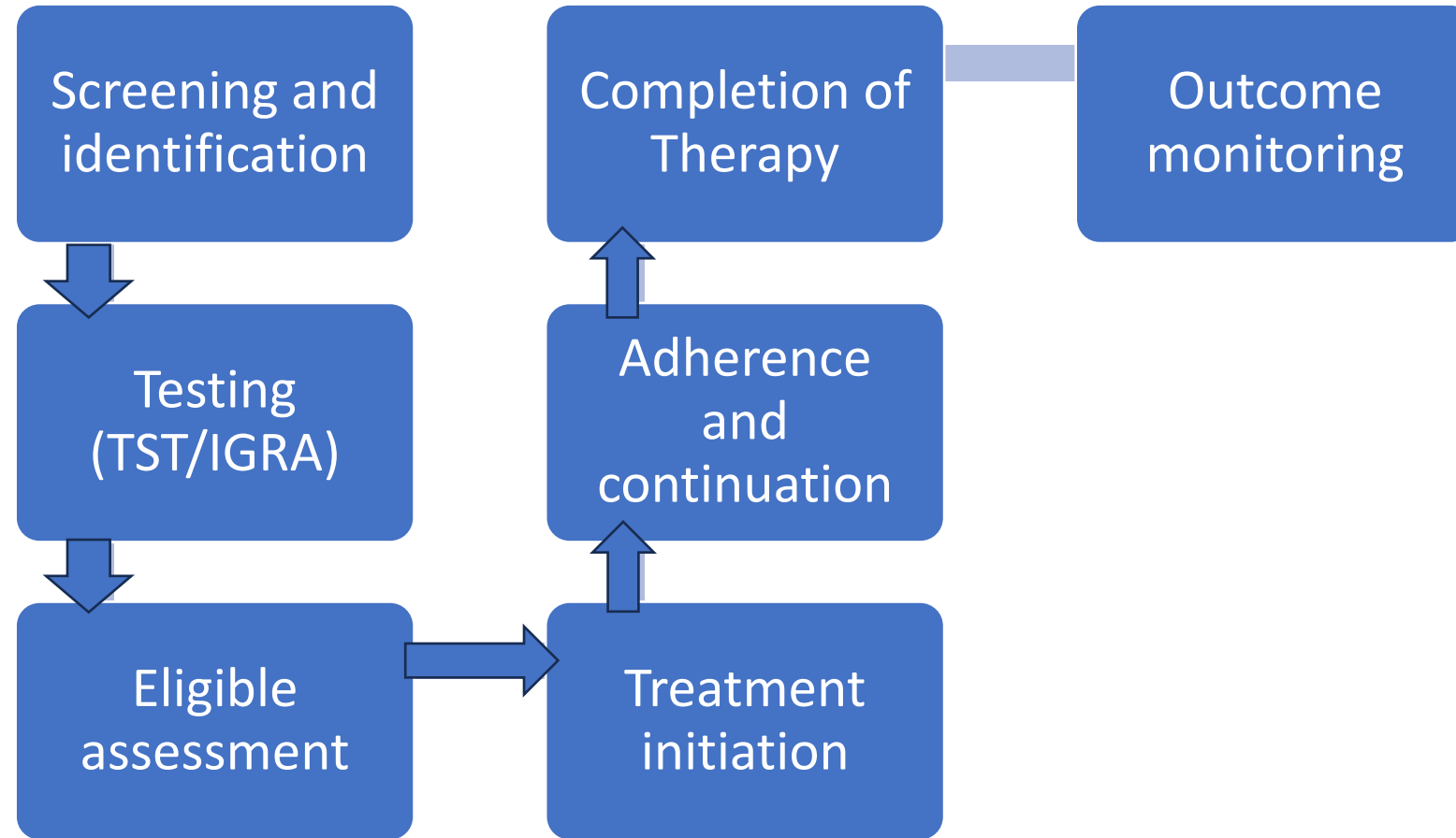
Factors such as inadequate nutrition, insufficient ventilation, smoking, and other immunodeficiency diseases contribute to it

TB Statistics- Global, SEAR, and India

Region/Metric	TB Incidence (per 100,000)	TB Prevalence (per 100,000)	TB Mortality (per 100,000)	TB DALY (Million)	TBI Statistic
Global	134	316	16.5 (2023)	122	23.67%
SEAR	45% of Global Cases	Data not Available, Heavily Burdened	37 (2021)	55 (45% of Global)	24.46%
India	171	316	23 (2022)	15	31.2% (NaTPS)

Source: Global TB Report, 2023, Global Health Exchange Data, Lancet, and Global Burden of Disease, 2021, WHO

Cascade of Care (WHO)



Problem Statement

Despite the high prevalence of TB in India, only 22% of eligible Household contacts (HHCs) are undergoing TB Preventive Treatment (TPT).

Factors influencing the acceptability of TPT among HHCs in India are not well understood.

The gap hinders efforts to improve adherence and completion rates.

Understanding enablers and barriers to TPT acceptability is crucial for its success.

Research Questions

What are the potential factors that influence the acceptance and rejection of TPT among HHCs of microbiologically confirmed drug-susceptible pulmonary tuberculosis (DS PTB) patients?

How do the identified factors affect the TPT engagement?

What could be alternative evidence-based strategies to enhance treatment uptake?

Objectives of the Study

Primary Objectives

- To investigate factors influencing the acceptance and rejection of TPT among HHCs of microbiologically confirmed DS PTB patients, and
- To understand how these factors affect the initiation, continuation, and completion of TPT among HHCs across different subgroups.

Secondary Objectives

1. To examine the relationship between socio-demographic factors, socioeconomic factors, social stigma related to tuberculosis, knowledge about tuberculosis and TPT and accessibility to TPT services with the acceptability of TPT among HHCs.
2. To study key enabling and hindering factors associated with acceptability of TPT among HHCs of PTB patients
3. To suggest evidence-based recommendations to enhance the acceptability and uptake of TPT among HHCs.

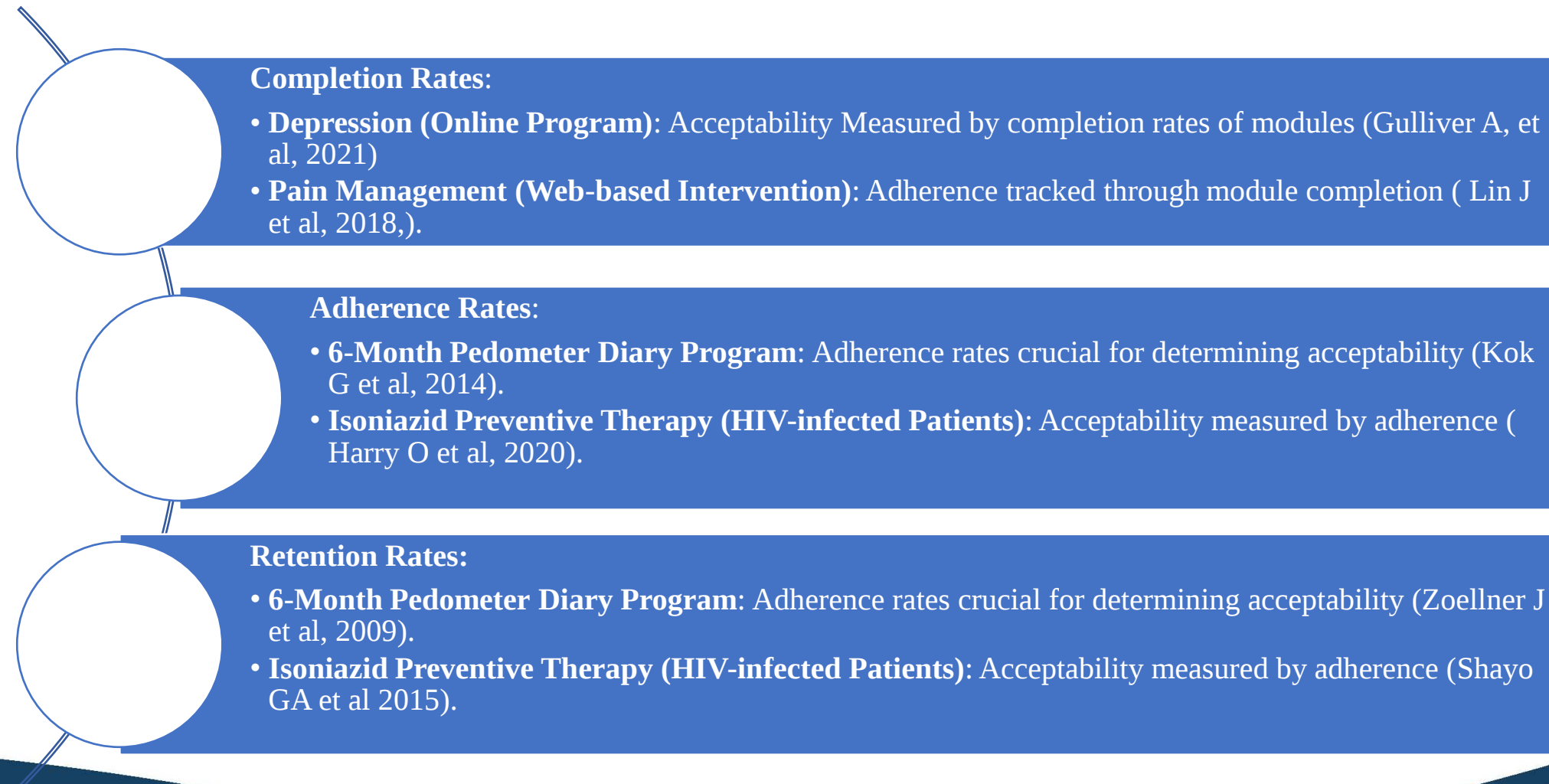
Literature Review: A Snapshot

Year of Study	Title	Author(s) and Reference/Link	Key Objectives	Key Points of Methodology	Key Results
2024	Situation Analysis of Early Implementation of Programmatic Management of Tuberculosis Preventive Treatment among Household Contacts of Pulmonary TB Patients in Delhi India	Alvi Y, Philip S, Anand T, Chinnakali P, Islam F, Singla N, et al. Tropical Medicine and Infectious Disease. 2024 Jan;9(1):24.	To analyze the early implementation of programmatic management of TB preventive treatment among household contacts in Delhi	Situation analysis of early implementation practices	Detailed the early implementation outcomes and identified barriers in programmatic management of TB preventive treatment
2023	Community-based referral for tuberculosis preventive therapy is effective for treatment completion	Shenoi SV et al. (PLOS Global Public Health)	To evaluate the effectiveness of community-based referral for TB preventive therapy	Prospective cohort study	Found that community-based referral significantly improved treatment completion rates
2023	Acceptability of Isoniazid Preventative Therapy for Tuberculosis among Healthcare Workers in Gaborone, Botswana	Milton T	To assess the acceptability of isoniazid preventive therapy among healthcare workers in Botswana	Survey and interviews with healthcare workers	Found high acceptability, but concerns about side effects and workload were noted
2023	Healthcare worker perceived barriers and facilitators to implementing a tuberculosis preventive therapy program in rural South Africa: a content analysis using the consolidated framework for implementation research	Brittney J. van de Water, Michael Wilson, Karl le Roux, Ben Gaunt, Sarah Gimbel, Norma C. Ware	To identify barriers and facilitators to TB contact investigations and TPT management in rural Eastern Cape, South Africa	Semi-structured interviews	Identified barriers and facilitators with the help of consolidated framework of implementation research
2023	Feasibility, enablers, and challenges of using timeliness metrics for household contact tracing and TB preventive therapy in Pakistan	Jamil B, Nair D, Thekkur P, Laeeq N, Adil A, Khogali M, et al.	To assess the feasibility, enablers, and challenges of implementing 7-1-7 metric for screening and management of household contacts of index patients with bacteriologically confirmed pulmonary TB in Karachi city, Pakistan	Explanatory mixed methods study	7-1-7 timeliness metrics was found out to be feasible and useful

Continued

2023	Test and Treat Model for Tuberculosis Preventive Treatment among Household Contacts of Pulmonary Tuberculosis Patients in Selected Districts of Maharashtra: A Mixed-Methods Study on Care Cascade Timeliness and Early Implementation Challenges (Project Axshya)	Mahajan P, Soundappan K, Singla N, Mehta K, Nuken A, Thekkur P, et al. Tropical Medicine and Infectious Disease. 2023 Dec 23;9(1):7.	To evaluate the test and treat model for TB preventive treatment among household contacts in Maharashtra	Mixed-methods study assessing care cascade timeliness and implementation challenges	Identified timeliness issues and early implementation challenges in the test and treat model for TB prevention
2023	Implementation of Tuberculosis Preventive Therapy with INH-Rifapentine (3HP) for Latent Tuberculosis Infection Management in Household Tuberculosis Contacts in India: A Prospective Study	Sharma N, Bakshi R, Basu S, Zode M, Arora R, Khanna A. Tropical Medicine & International Health. 2023;28(12):890–900	To assess the implementation of INH-Rifapentine therapy for managing latent TB infection among HHCs in India	Prospective study on HHCs receiving INH-Rifapentine therapy	Highlighted the effectiveness and challenges in the implementation of INH-Rifapentine therapy for TB prevention
2022	They do not have symptoms – why do they need to take medicines? Challenges in Tuberculosis Preventive Treatment among Children in Cambodia: A Qualitative Study	An Y et al. (BMC Pulmonary Medicine)	To explore challenges in TB preventive treatment among children in Cambodia	Qualitative interviews with caregivers and health workers	Identified key challenges including a lack of understanding of latent TB and the need for preventive treatment
2022	Acceptability of Community-Based Tuberculosis Preventive Treatment for People Living with HIV in Zimbabwe	Msukwa MK et al. (Healthcare)	To assess the acceptability of community-based TB preventive treatment among people living with HIV	Qualitative study	Found high acceptability but identified barriers like stigma and lack of awareness
2018	Latent Tuberculosis Infection: Updated and Consolidated Guidelines for Programmatic Management	World Health Organization. Available from: NCBI	Update and consolidate guidelines for the management of latent tuberculosis infection	Comprehensive review and consolidation of existing guidelines	Updated recommendations for latent TB infection management
2015	Acceptability and Adherence to Isoniazid Preventive Therapy in HIV-Infected Patients Clinically Screened for Latent Tuberculosis in Dar es Salaam, Tanzania	Shayo GA, Moshire C, Aboud S, et al. BMC Infect Dis. 2015 Aug 26;15(1):368	To assess the acceptability and adherence to isoniazid preventive therapy in HIV patients	Adherence measured through therapy completion rates; acceptability evaluated via patient feedback	High acceptability and adherence were observed among participants

Quantifying Acceptability in Health Intervention



Completion Rates:

- **Depression (Online Program):** Acceptability Measured by completion rates of modules (Gulliver A, et al, 2021)
- **Pain Management (Web-based Intervention):** Adherence tracked through module completion (Lin J et al, 2018,).

Adherence Rates:

- **6-Month Pedometer Diary Program:** Adherence rates crucial for determining acceptability (Kok G et al, 2014).
- **Isoniazid Preventive Therapy (HIV-infected Patients):** Acceptability measured by adherence (Harry O et al, 2020).

Retention Rates:

- **6-Month Pedometer Diary Program:** Adherence rates crucial for determining acceptability (Zoellner J et al, 2009).
- **Isoniazid Preventive Therapy (HIV-infected Patients):** Acceptability measured by adherence (Shayo GA et al 2015).

Theoretical Framework of Acceptability (TFA)

Affective attitude	Burden	Ethicality	Intervention coherence	Opportunity costs	Perceived effectiveness	Self-efficacy
•How an individual feels about the intervention	•Perceived amount of effort required to participate in the intervention	•Extent to which the intervention is a good fit with an individual's value system	•Extent to which the participants understands the intervention and how it works	•Extent to which benefits, profits, or values must be given up to engage in the intervention	•Extent to which the intervention is perceived as likely to achieve its purpose	•Participant confidence that they can perform behaviours required to participate in the intervention

Prospective acceptability
Prior to participating in the intervention

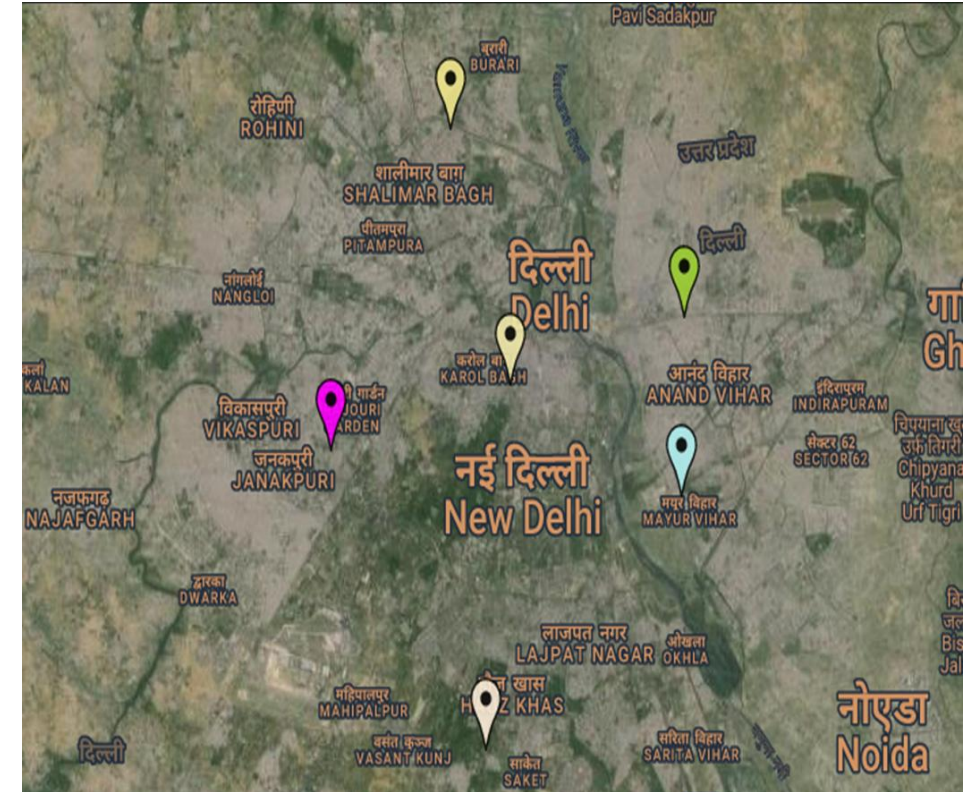
Concurrent acceptability
Whilst participating in the intervention

Retrospective acceptability
After participating in the intervention

Methodology

Study design and study setting

- Descriptive cross-sectional approach
- Time period- January 2023 to May 2024
- High burden districts of Delhi were chosen strategically for the study.
- Study setting
 - Shahdara Chest Clinic, Shahdara District*
 - DDU Chest Clinic, West Delhi*
 - Jhandewalan Chest Clinic, Central Delhi*
 - BJRM Hospital, Jahangir Puri, North Delhi*
 - Patparganj Chest Clinic, East Delhi*
 - National Institute for TB and Research and Development, Mehrauli (NITRD), South Delhi*



Pink: DDU Chest Clinic, Yellow [top] : BJRM Hospital, Yellow [middle]: Jhandewalan Chest Clinic, White : NITRD, Mehrauli, Green: Shahdara Chest Clinic, Blue: Patparganj Chest Clinic

Study Population

HHCs of bacteriologically confirmed DS PTB patients enrolled in the Ni-kshay portal who underwent TB treatment between 1st January 2023- 31st May 2024. All HHCs who were initiated during this period, and who met the inclusion criteria were enrolled in the study.

Inclusion Criteria

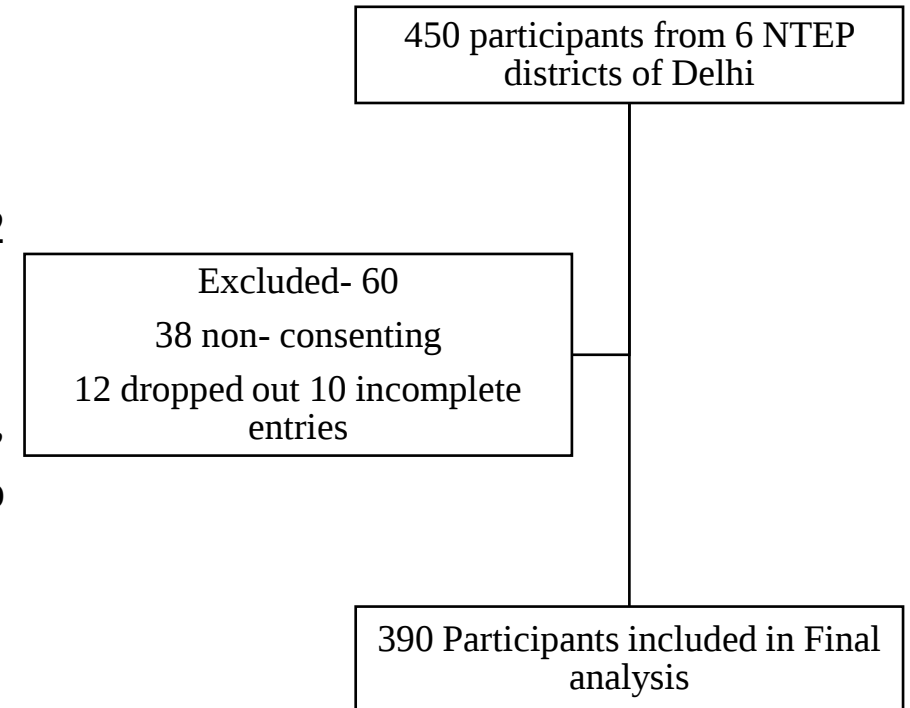
- **Age Requirement**
- **Risk-based Preference**

Exclusion Criteria-

- **Age Restriction**
- **Non-Initiation on TPT**
- **Non-Consenting Individuals**
- **Bedridden Status**
- **Non-Availability**

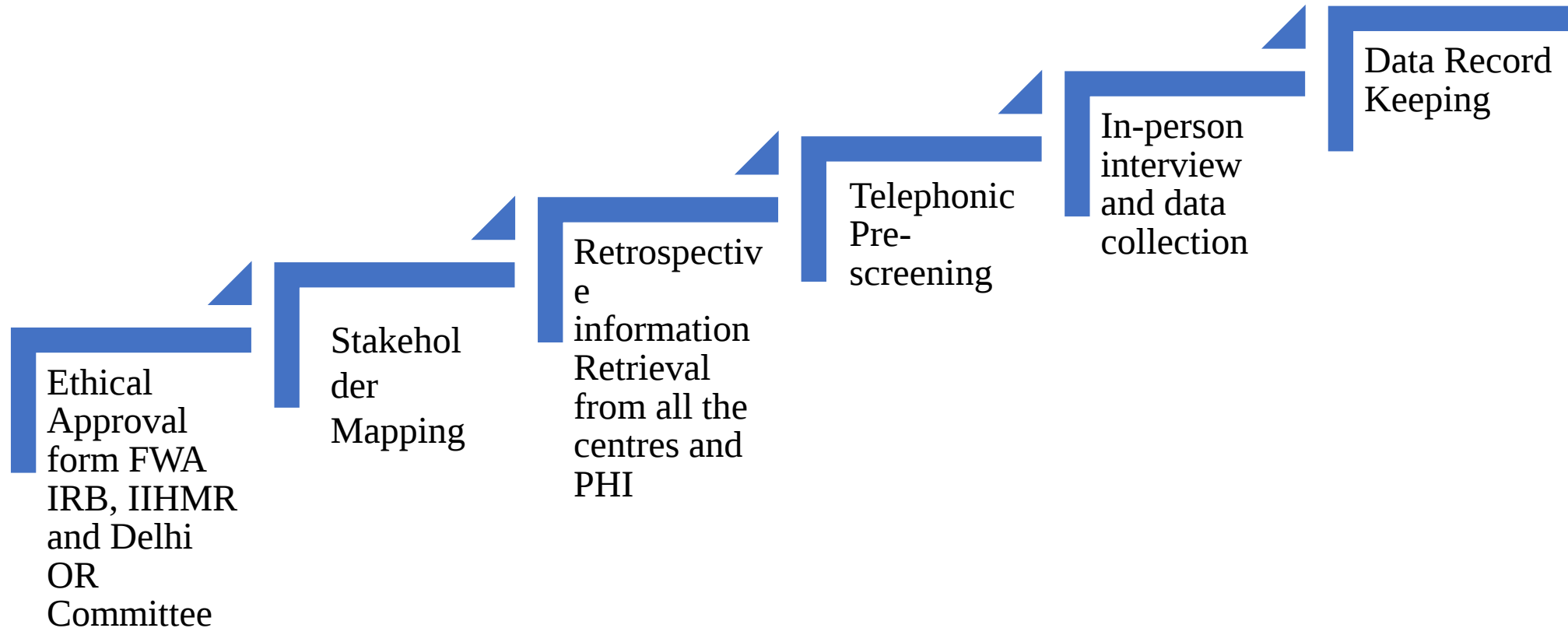
Sampling and Sample Size

- Systematic random sampling, with an interval of 2 means every second HHC, aged 18 years and older who met inclusion criteria
- The sample size was calculated using the following formula: $N_0 = \frac{z^2 \cdot P(1-P)}{(d-P)^2}$
- where:- Z is the Z-score corresponding to a 95% confidence interval, which is 1.96.; P is the assumed population proportion, set at 50% to ensure maximum sample size.; d is the margin of error, set at 5%.
- Sample size = 385
- Considering a non- response rate of 15%, adjusted sample size is 450



Final Sample Derivation

Data Collection Methods



Data collection tool and their reliability

- *Structured Interview schedule and consent forms developed*
- *Translated into local language Hindi,*
- *Pre-tested for reliability*
- *Finalized under the guidance of the CTD and State TB Cell*

Reliability Statistics	n (%)	No. of Items	Value
Cronbach's Alpha	382 (97.9)	67	.703

Data Analysis

- Descriptive Analysis using distribution of frequencies and percentages
- Bivariate Analysis using Chi Square to find association among variables

- Chi square formula- $\chi^2 = \sum (O_i - E_i)^2 / E_i$

Where:

O_i = observed frequency in each category

E_i = expected frequency in each category

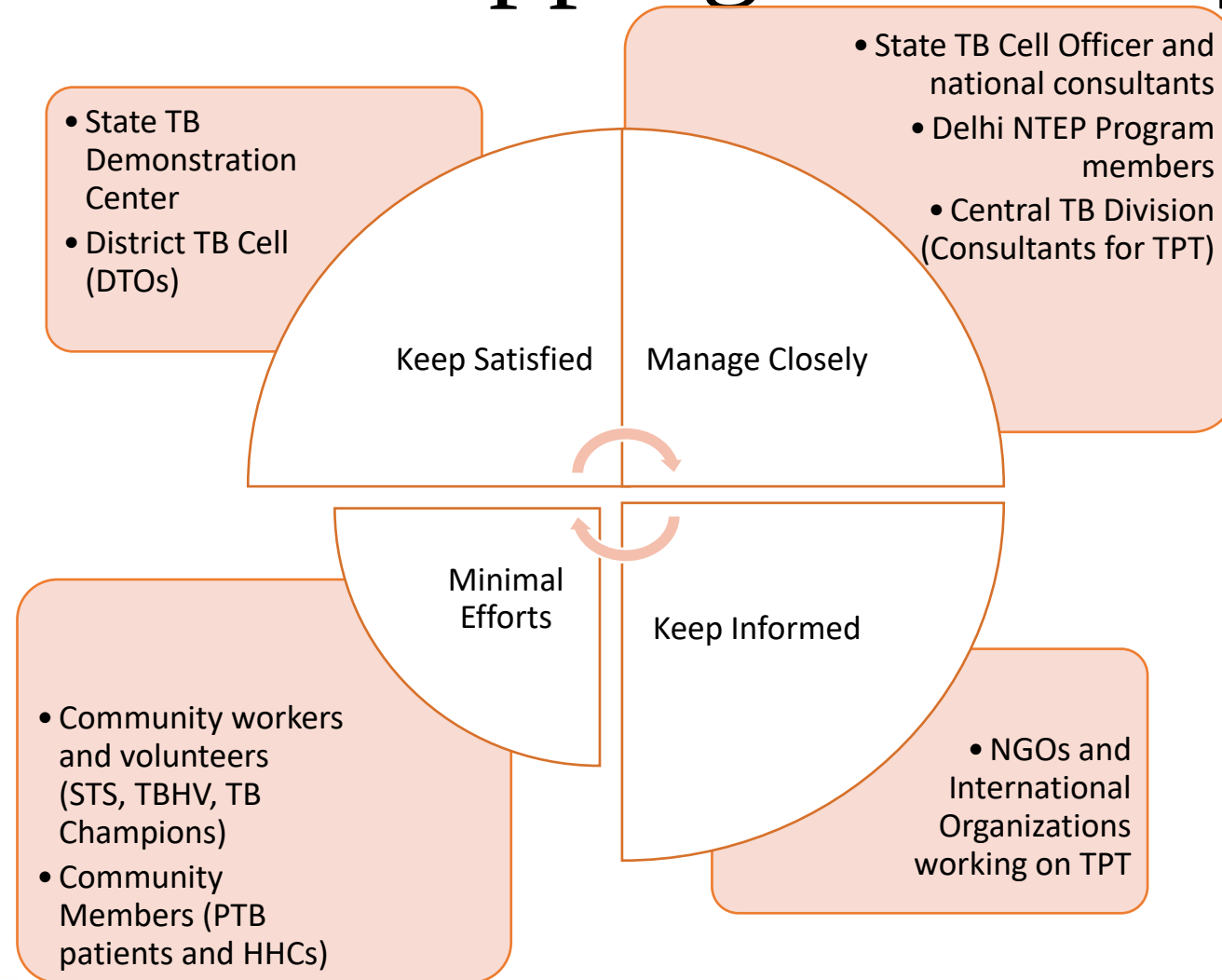
- Net response rate= 87% (390 of 450)

Background characteristics (Age)	TPT Initiated and on Continued		TPT Initiated and Dropped	TPT Completed
18-44 Years				
45-74 Years				
P value				
Significance (Insignificant/significant)				

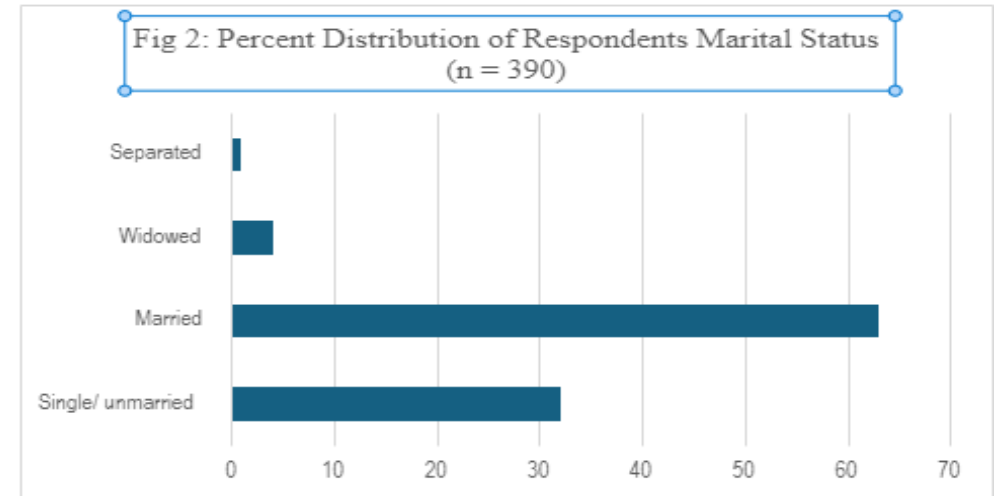
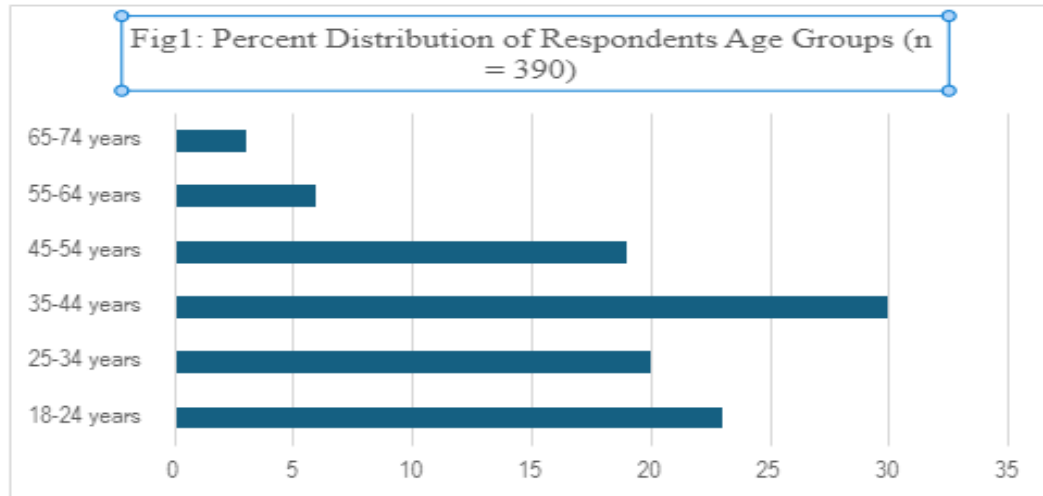
Dummy Table

Results

Stakeholder Mapping and Analysis



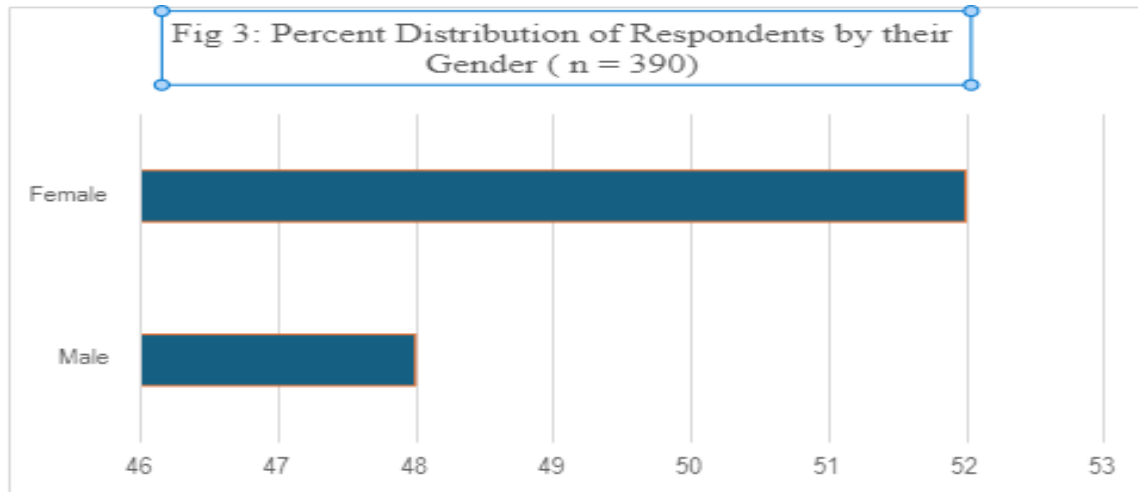
Demographic Profile (n = 390)



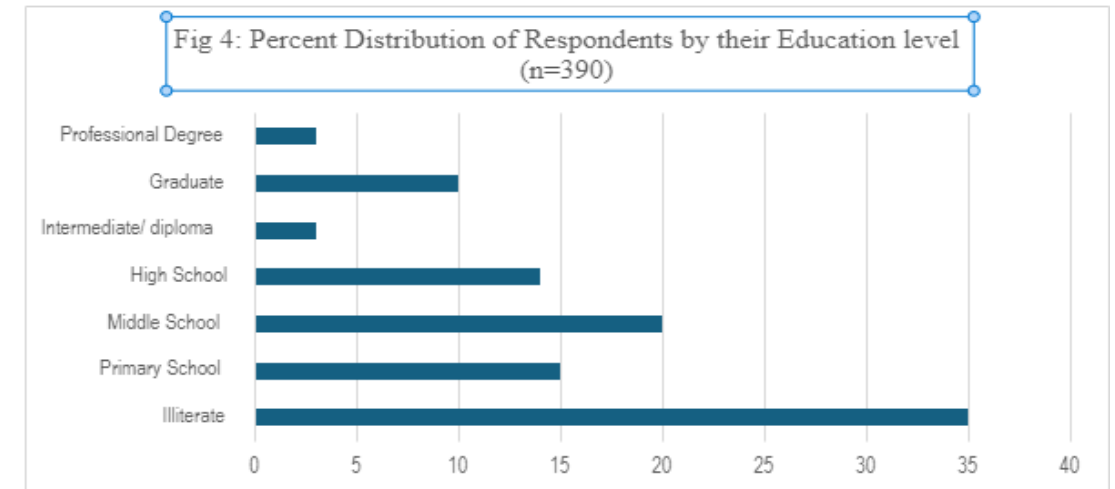
The mean age of the group was 37 years $\pm$ 12.6 years!

About 72% of the respondents were up to the age of group of 35- 44 years

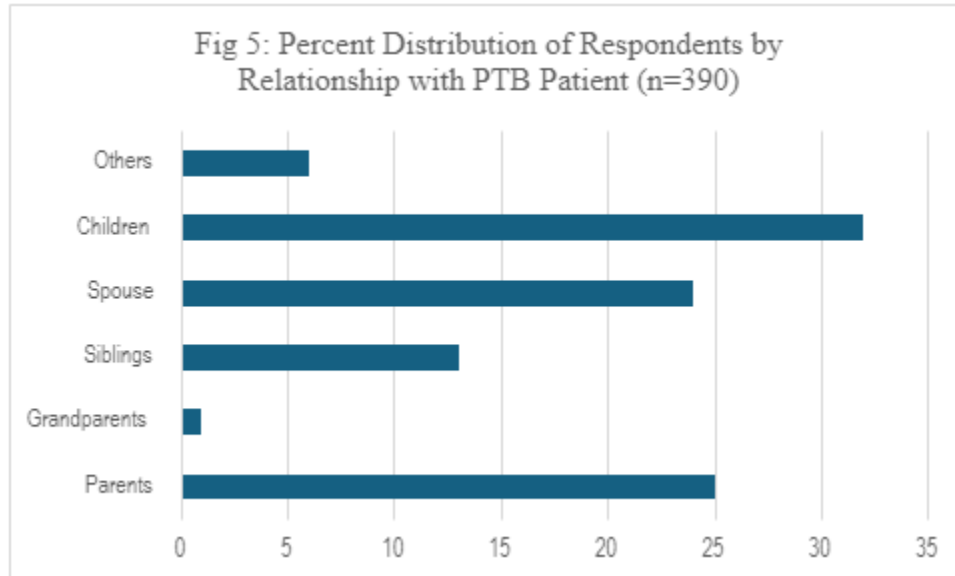
About 63.3% are married; and 31.5% are single



About 52% Women; and 48% men



About 35.4% of the respondents were illiterate
only 2.8% had completed professional degree



Nearly 31.7% were children of PTB patients, 24.9% were parents and 23.9% were spouse.

Clinical Characteristics (n = 390)

Clinical Characteristics	Subcategory	n	% (CI)
1. BMI	Underweight	58	14.9 (11.37-18.43)
2. Comorbidities	Diabetes	23	6.0 (3.64-8.36)
	Rheumatoid Arthritis	5	1.3 (0.18-2.42)
	Tobacco consumers	16	4.2 (22.21-6.19)
	Other immune deficient diseases	10	2.6 (1.02-4.18)
3. No. of HHCs	0-5	299	76.6 (72.40-80.80)
	5-9	79	20.2 (16.22-24.18)
	10 and above	12	3.1 (1.38-4.82)

- Nearly 14.9% participants were underweight
- Only 6% had Diabetes and 4.2% were tobacco consumers
- 76.6% PTB patients had HHCs between 0-5 and 20.2% had between 5-9 HHCs

Continued

Clinical Characteristics	Subcategory	n	% (CI)
4. No. of bedrooms	0-3	372	95.4 (93.32-97.48)
	4-7	17	4.4 (2.36-6.44)
5. Separate Bedrooms of the PTB		210	53.8 (48.85-58.75)
2. Total number of weeks PTB patients took the treatment for	< 8 weeks	100	25.6 (21.27-29.93)
	> 8 weeks	290	74.4 (70.07-78.73)

- Nearly 95% participants had 0-3 bedrooms in their houses
- Nearly 54% of individuals had separate bedroom from PTB patients
- Approximately 74% of participant's PTB relative had completed >8 weeks of treatment (completed IP Phase)

Sociodemographic Characteristics and Acceptability of TPT (n =390)

Background characteristics	TPT Initiated and Continued, n (%)	TPT Initiated but Dropped, n (%)	TPT Completed, n (%)
Religion			
Hindu	80 (20.6)	18 (4.9)	44 (11.3)
Other than Hindus	158 (40.6)	71 (18.3)	147 (37.8)
p value	0.518	0.009**	0.000***
Significance	Insignificant	< 0.05 significant	< 0.01 significant

- Religion was found to be statistically significant to higher dropouts in other religions
- However, it was also significant with higher completion in other religions as well

Continued

Background characteristics	TPT Initiated and Continued, n (%)	TPT Initiated but Dropped, n (%)	TPT Completed, n (%)
Place of Birth			
Delhi	149 (38.2)	56 (14.4)	109 (27.9)
Others	90 (23.1)	34 (8.7)	83 (21.3)
p value	0.067*	0.441	0.442
Significance	<0.10 Significant	Insignificant	Insignificant

- Place of birth was also found to be statistically significant to TPT adherence.
- Those who resided in Delhi had a higher adherence rate (38.2%) than no residents of Delhi

Continued

Background characteristics	TPT Initiated and Continued, n (%)	TPT Initiated but Dropped, n (%)	TPT Completed, n (%)
Duration of Stay at the current address			
More than 5 years	7 (1.8)	10 (2.6)	11 (2.8)
Less than 5 years	144 (36.9)	290 (74.4)	181 (46.4)
P value	0.988	0.028*	0.302
Significance	Insignificant	P < 0.05 Significant	Insignificant

- Duration of stay at current address was also found to be statistically significant with higher dropouts.
- Those who stayed for less than 5 years at the current address has higher dropout rate (74.4%).

Continued

Background characteristics (Age)	TPT Initiated and Continued, n (%)	TPT Initiated but Dropped, n (%)	TPT Completed, n (%)
Type of Residence			
Rural	43 (11)	41 (10.5)	33 (8.5)
Urban	196 (50.3)	49 (12.6)	159 (40.8)
P value	0.000***	0.000***	0.018**
Significance	P < 0.01 Insignificant	P < 0.01 Insignificant	P < 0.05 Insignificant

- Type of Residence was found to be statistically significant with all the three parameters
- Those residing in urban areas had higher adherence (50.3%) and completion (40.8%).
- Moreover, urban residents had higher dropouts as well however the difference between the two is very marginal

Continued

Background characteristics (Age)	TPT Initiated and Continued, n (%)	TPT Initiated but Dropped, n (%)	TPT Completed, n (%)
Type of Living arrangement			
Nuclear Family	207 (53.1)	77 (19.7)	161 (41.3)
Joint Family	32 (8.2%)	13 (3.3)	31 (7.9)
P value	0.013**	0.433	0.594
Significance	P < 0.05 Significant	Insignificant	Insignificant
Family Size			
0-8 Members	234 (60.2)	86 (22.1)	186 (47.8)
9-17 Members	4 (1)	3 (0.8)	6 (1.5)
P value	0.011**	0.895	0.62
Significance	P < 0.05 Significant	Insignificant	Insignificant

- Type of living arrangement was found to be statistically significant with higher adherence.
- Those living in nuclear families has higher rates of continuation (53.1%, p = 0.013)
- Similarly, family size was also found to be statistically significant with higher adherence
- Those with a smaller family size had higher adherence rate than those living in nuclear families

Socioeconomic Status and Acceptability of TPT

Background characteristics	TPT Initiated and Continued, n (%)	TPT Initiated but Dropped, n (%)	TPT Completed, n (%)
Occupation of the participant			
Low skilled Occupation	204 (52.3)	78 (20)	161 (41.3)
High Skilled Occupation	35 (9)	12 (3.1)	31 (7.9)
p value	0.077	0.736	0.023**
	Insignificant	Insignificant	< 0.05 significant

- Occupation was also found to be statistically significant with higher completion rates.
- Those who were engaged in highly skilled occupation had higher completion rate (41.3%).

Continued

Background characteristics	TPT Initiated and Continued, n (%)	TPT Initiated but Dropped, n (%)	TPT Completed, n (%)
Household Income			
Below Poverty Levels	92 (23.6)	74 (19)	98 (25.1)
Above Poverty Levels	147 (37.7)	16 (4.1)	94 (24.1)
p value	0.002**	0.000***	0.012**
	P < 0.05 significant	P < 0.01 significant	< 0.05 significant

- Household income was also found to be statistically significant with all three parameters.
- Those who APL status had higher adherence (37.7%) and completion as well (25.1%), and those with BPL status had higher dropouts (19%).

Stigma of the Disease and Acceptability of TPT (n = 390)

Background characteristics	TPT Initiated and Continued, n (%)	TPT Initiated but Dropped, n (%)	TPT Completed, n (%)
Neighbour awareness of TB Patient			
Not Aware	98 (25.1)	21 (5.4)	67 (17.2)
Aware	141 (36.2)	69 (17.7)	125 (32.1)
p value	0.118	0.001**	0.221
Significance	Insignificant	< 0.05 significant	Insignificant

- Neighbours awareness of TB patient was found to be statistically significant to higher dropouts.
- Participants whose neighbour were aware of TB status had higher dropout rates (17.7%).

Continued

Background characteristics	TPT Initiated and Continued, n (%)	TPT Initiated but Dropped, n (%)	TPT Completed, n (%)
Stigma from Neighbours			
No	25 (6.4)	22 (5.7)	22 (5.7)
Yes	214 (55)	68 (17.5)	169 (43.4)
p value	0.3	0.000***	0.13
Significance	Insignificant	< 0.05 significant	Insignificant

- Stigma from neighbours was found to be statistically significant to higher dropouts.
- Participants who's faced stigma from neighbours had higher dropout rate (17.5%)

Continued

Background characteristics	TPT Initiated and Continued, n (%)	TPT Initiated but Dropped, n (%)	TPT Completed, n (%)
Hesitation to Tell Neighbours			
No	39 (10)	22 (5.6)	42 (10.8)
Yes	200 (51.3)	68 (17.4)	150 (38.5)
P value	0.015**	0.434	0.006**
Significance	P < 0.05, significant	Insignificant	P < 0.05, significant

- Those who hesitated to tell neighbors had higher adherence (51.3%) and completion rates (38.5%)

Continued

Background characteristics	TPT Initiated and Continued, n (%)	TPT Initiated but Dropped, n (%)	TPT Completed, n (%)
Reason for Hesitation			
Fear of Discrimination	39 (10)	22 (5.6)	42 (10.8)
Feel it is unnecessary to discuss	182 (46.7)	67 (17.2)	144 (36.9)
Others	18 (4.6)	1 (0.3)	6 (1.5)
P value	0.006**	0.083	0.129
Significance	P < 0.05, significant	Insignificant	Insignificant

- Those who hesitated to discuss with neighbors because they felt unnecessary to discuss their condition had higher adherence (46.7%)

Knowledge about TB and TPT and Acceptability of TPT (n= 390)

Background characteristics	TPT Initiated and Continued, n (%)	TPT Initiated but Dropped, n (%)	TPT Completed, n (%)
Symptoms of TB			
Incorrect	162 (41.5)	66 (16.9)	108 (27.7)
Correct	77 (19.7)	24 (6.2)	84 (21.5)
P value	0.030**	0.029**	0.003**
Significance	P < 0.05, significant	P < 0.05, significant	P < 0.05, significant

- Those who had incorrect knowledge regarding TB symptoms had higher adherence rate (41.5%) and completion rate (27.7%)
- However, those who had incorrect knowledge had higher dropout rates as well (16.9%).

Background characteristics	TPT Initiated and Continued, n (%)	TPT Initiated but Dropped, n (%)	TPT Completed, n (%)
Transmission of TB			
Incorrect	42 (10.8)	7 (1.8)	12 (3.1)
Correct	197 (50.5)	83 (21.3)	180 (46.2)
P value	0.023**	0.042**	0.000***
Significance	P < 0.05, significant	P < 0.05, significant	P < 0.01, significant

- Those who had correct knowledge regarding transmission of TB had higher adherence rate (50.5%) and completion rate (46.2%)
- However, those who had correct knowledge also had higher dropout rates (21.3%).

Background characteristics	TPT Initiated and Continued, n (%)	TPT Initiated but Dropped, n (%)	TPT Completed, n (%)
Cost of TB and TPT Services			
Incorrect	7 (1.8)	3 (0.8)	8 (2.1)
Correct	232 (59.5)	87 (22.3)	184 (47.2)
P value	0.025**	0.44	0.524
Significance	P < 0.05, significant	Insignificant	Insignificant

- Those who had correct knowledge regarding cost of TB and TPT services had higher adherence rate (59.5%)

Background characteristics	TPT Initiated and Continued, n (%)	TPT Initiated but Dropped, n (%)	TPT Completed, n (%)
Duration of TPT Regimen			
Incorrect	152 (39)	49 (12.6)	76 (19.5)
Correct	87 (22.3)	41 (10.5)	116 (29.7)
P value	0.014**	0.348	0.000***
Significance	P < 0.05, significant	Insignificant	P < 0.01, significant

- Those who had correct knowledge regarding transmission of TB had higher adherence rate (50.5%) and completion rate (46.2%)
- However, those who had correct knowledge also had higher dropout rates (21.3%).

Background characteristics	TPT Initiated and Continued, n (%)	TPT Initiated but Dropped, n (%)	TPT Completed, n (%)
Advantages of TPT			
Incorrect	41 (10.5)	13 (3.3)	47 (12.1)
Correct	198 (50.8)	77 (19.7)	145 (37.2)
P value	0.025**	0.44	0.524
Significance	P < 0.05, significant	Insignificant	Insignificant

- Those who had correct knowledge regarding advantages of TPT had higher adherence rate (50.8%)

Accessibility to TPT and Acceptability of TPT (n = 390)

Background characteristics	TPT Initiated and Continued, n (%)	TPT Initiated but Dropped, n (%)	TPT Completed, n (%)
Geographical accessibility			
Mode of Transport			
Walking	112 (28.7)	34 (8.7)	89 (22.8)
Private	46 (11.8)	16 (4.1)	23 (5.9)
Public	81 (20.8)	40 (10.3)	80 (20.5)
p value	0.502	0.104	0.004**
Significance	Insignificant	< 0.05 significant	< 0.01 significant
Time taken to reach DOTS Centre			
<10 minutes	105 (26.9)	31 (7.9)	82 (21)
>10 minutes	134 (34.4)	59 (15.1)	110 (28.2)
p value	0.551	0.020**	0.344
Significance	Insignificant	< 0.05 significant	Insignificant

- Those who had preferred walking to DOTS centre had higher completion rates (22.8%) followed by people who used public transport (20.5%)
- Participants that took more than 10 minutes to reach DOTS had higher dropout rates (15.1%)

Background characteristics	TPT Initiated and Continued, n (%)	TPT Initiated but Dropped, n (%)	TPT Completed, n (%)
Financial accessibility			
Cost of Services			
Not Free of Cost	7 (1.8)	3 (0.8)	8 (2.1)
Free of Cost	232 (59.5)	87 (22.3)	184 (47.2)
p value	0.025**	0.44	0.524
Significance	< 0.05 significant	Insignificant	Insignificant

Background characteristics	TPT Initiated and Continued, n (%)	TPT Initiated but Dropped, n (%)	TPT Completed, n (%)
Organizational Accessibility			
Number of times participant met the physician			
1-2 times	146 (37.4)	38 (9.7)	120 (30.8)
3-4 times	67 (17.2)	31 (7.9)	53 (13.6)
More than 5 times	26 (6.7)	21 (5.4)	19 (4.9)
P value	0.088	0.000***	0.605
Significance	Insignificant	< 0.01 significant	Insignificant

- Those who accessed free of cost services had higher adherence rate (59.5%).
- Participants who met the physicians 1-2 times only had higher dropout rate (9.7%).

Background characteristics	TPT Initiated and Continued, n (%)	TPT Initiated but Dropped, n (%)	TPT Completed, n (%)
Informational accessibility			
Healthcare literacy by healthcare workers on TBI			
No	37 (5.1)	9 (2.3)	19 (4.9)
Yes	134 (34.4)	55 (14.1)	138 (35.4)
Partially	68 (17.4)	26 (6.7)	35 (9)
P value	0.012**	0.228	0.000***
Significance	< 0.05 significant	Insignificant	< 0.01 significant

- Those who were given literacy on TBI by healthcare workers had higher adherence (34.4%) as well as completion rate (35.4%).

Background characteristics	TPT Initiated and Continued, n (%)	TPT Initiated but Dropped, n (%)	TPT Completed, n (%)
Healthcare literacy by healthcare workers on Potential Risk of TB			
No	94 (24.1)	13 (3.3)	41 (10.5)
Yes	111 (28.5)	65 (16.7)	139 (35.6)
Partially	34 (8.7)	12 (3.1)	12 (3.1)
P value	0.000***	0.000***	0.000***
Significance	< 0.01 significant	< 0.01 significant	< 0.01 significant

- Participants who were properly given health literacy on potential risks of TB had higher adherence (28.5%), dropout (16.7%) as well as completion rates (35.6)

Background characteristics	TPT Initiated and Continued, n (%)	TPT Initiated but Dropped, n (%)	TPT Completed, n (%)
Healthcare literacy by healthcare workers on Preventive Measures			
No	37 (9.5)	12 (3.1)	25 (6.4)
Yes	150 (38.5)	63 (16.2)	145 (37.2)
Partially	52 (13.3)	15 (3.8)	22 (5.6)
P value	0.204	0.575	0.000***
Significance	Insignificant	Insignificant	< 0.01 significant

- Those who were given proper literacy on preventive measures by healthcare workers had higher completion rates (37.2%).

Background characteristics	TPT Initiated and Continued, n (%)	TPT Initiated but Dropped, n (%)	TPT Completed, n (%)
Healthcare literacy by healthcare workers on Importance of TPT			
No	58 (14.9)	17 (4.4)	30 (23.1)
Yes	101 (26)	54 (13.9)	126 (32.4)
Partially	79 (20.3)	19 (4.9)	35 (9)
P value	0.001**	0.069	0.000***
Significance	< 0.01 significant	Insignificant	< 0.01 significant

- Participants who were properly given health literacy on importance of TPT had higher adherence (26%) as well as completion rates (32.4%).

Key Enabling Factors

- Perceived advantage of TPT- Prevents from TB Disease
- Perceived Drivers (Severity of the disease and doctor's advice)
- Healthcare literacy by HCW on importance of TPT
- Patients' involvement
- Availability of Physician
- Perceived Effectiveness of intervention
- Self-efficacy – restarted medicine after a break

Key Hindering Factors

- Perceived Disadvantage (found it of no use, side effects, development of TB Disease)
- Negative Reinforcement (felt forced to take medicine)
- Poor self-efficacy (inability to clear doubts, dropped TPT after breaks)

Discussion

Factors	Findings from Previous Studies	Findings from This Study
Socio-demographic Factors	- Age, gender, and marital status were significantly associated with TPT completion rates(Sharma N, Bakshi, et al, van de Water BJ et al, 2023, Phyo Htut P, 2024). - Family size and structure weren't significantly discussed in prior studies.	- No significant association between age, gender, or marital status and TPT completion. - Religion and residence type were significant, with non-Hindus showing higher dropout and completion rates. - Urban residents and those with shorter stays at their current address were more likely to adhere. - Nuclear families and smaller family sizes were associated with higher TPT initiation and continuation.
Socioeconomic Factors	- Higher socioeconomic status, particularly household income, was linked to better acceptability of healthcare interventions (Yuan Y et al, 2023, Egesimba G). - Income level was positively associated with treatment adherence.	- Income and occupation were significantly associated with TPT completion. - Low-skilled occupations and those above the poverty line had higher completion rates. Interestingly, BPL participants had higher completion rates than APL participants.

Factors	Findings from Previous Studies	Findings from This Study
Disease-related Stigma	Studies from Bangladesh and elsewhere indicated that TB stigma leads to higher dropout rates (Sultana N, 2023, Samudyatha UC et al, 2023).	Consistent with previous studies, stigma led to higher dropout rates. However, those who hesitated to disclose their status to neighbors showed higher initiation and continuation.
Knowledge about TB and TPT	Limited knowledge was identified as a barrier in studies from Zimbabwe and other countries (Msukwa MK et al, 2023, Yuan Y et al, 2023).	Higher knowledge about TB and TPT was strongly associated with initiation, continuation, and completion. Even participants with incorrect knowledge showed higher initiation rates.
Accessibility Factors	Studies identified distance to healthcare facilities, transport, and wage loss as barriers to TPT adherence (Mahajan P, et al, 2023).	Like previous findings, geographical accessibility, especially distance from healthcare centres, impacted TPT dropout rates. Solutions like mobile clinics or transport subsidies could help.

Enabling Factors	Findings from Previous Studies	Findings from this study
Perceived Advantage of TPT	Perceived efficacy and prevention of TB were key factors for higher initiation and continuation rates (Milton T, 2021).	Patients recognized that TPT prevents TB, leading to better adherence and continuation of treatment.
Perceived Drivers	Disease severity and healthcare professional advice strongly influenced patient decisions (Yuan Y et al, 2023).	Severity of the disease and physician advice were critical motivators for TPT initiation and continuation.
Healthcare Literacy by HCW	Studies show that proper health education by healthcare workers improved knowledge and adherence to TPT (Msukwa MK, 2023, Yuan Y, et al, 2023).	Healthcare literacy provided by HCWs on the importance of TPT significantly improved adherence.
Patient Involvement	Studies from various contexts show that active patient involvement in decision-making processes improves treatment adherence (Egesimba G, 2023).	Higher patient involvement in decision-making processes correlated with better initiation and completion rates.

Enabling Factors	Findings from Previous Studies	Findings from this study
Availability of Physician	• Accessibility to healthcare professionals and regular follow-ups were identified as enablers in studies related to chronic diseases (Mahajan P et al, 2023)	• Regular access to physicians was found to be important for maintaining confidence in TPT adherence and continuation.
Perceived Effectiveness of Intervention	• Perceived efficacy of the intervention was linked to better treatment adherence in various studies (Milton T, 2021, Egesimba G, 2023).	• Belief in TPT's effectiveness in preventing TB was associated with higher initiation, continuation, and completion rates.
Self-efficacy	• Self-efficacy (confidence in self-managing treatment) positively impacted adherence in previous studies (Milton T, 2021, Egesimba G, 2023).	• Patients who restarted TPT after breaks exhibited higher self-efficacy and continued treatment.
Healthcare Accessibility	• Accessibility to healthcare services and transport options were significant enablers in several studies, ensuring better adherence (Mahajan P et al, 2023).	• Free services and better access to healthcare facilities were associated with higher adherence rates in this study.

Hindering Factors	Findings from Previous Studies	Findings from this study
Perceived Disadvantage of TPT	Side effects, skepticism about efficacy, and fear of developing TB were commonly cited barriers in previous studies (An Y et al, 2023).	Some participants perceived TPT as ineffective or experienced side effects, contributing to higher dropout rates.
Negative Reinforcement	Coercion into taking treatment negatively impacted adherence in TB and other chronic illness treatments (An Y et al, 2023).	Feeling forced to take TPT led to lower initiation and continuation rates.
Poor Self-efficacy	Lack of confidence in managing treatment, inability to resolve doubts, or non-compliance after breaks were observed in studies related to TB and chronic diseases (An Y et al, 2023).	Patients who were unable to resolve their doubts or dropped out after breaks demonstrated poor self-efficacy and were less likely to complete TPT.
Cultural and Religious Factors	Cultural barriers, including religion and beliefs, impacted adherence in TB treatment in prior studies from regions such as Bangladesh (Samudyatha UC et al, 2023, , Sultana N, 2024).	Religion significantly influenced adherence, with non-Hindus showing higher dropout and completion rates.

Hindering Factors	Findings from Previous Studies	Findings from this study
Income and Occupation	Previous studies indicated that higher household income and occupation type were associated with better treatment adherence (Yuan Y et al, 2023, Egesimba G, 2023).	Participants with low-skilled occupations and higher income showed better completion rates. Interestingly, BPL participants had higher completion rates than APL, possibly due to greater perceived necessity.
Stigma Related to TB	TB-related stigma led to higher dropout rates, especially in communities where TB is highly stigmatized, as observed in studies from Bangladesh and other countries (Samudyatha UC et al, 2023 , Sultana N, 2024).	Participants who experienced stigma from neighbours exhibited higher dropout rates, while those hesitant to disclose their TB status to neighbours showed higher initiation and continuation.

Hindering Factors	Findings from Previous Studies	Findings from this study
Geographical and Financial Barriers	Accessibility challenges like distance, time, wage loss, and transport costs were barriers to TB treatment adherence, as observed in various studies (Mahajan P et al, 2023).	Geographical distance to DOTS centres was a major barrier to TPT adherence, and participants traveling longer distances were more likely to drop out. Financial barriers also played a role, with free services enhancing adherence rates.
Cultural and Religious Factors	Cultural barriers, including religion and beliefs, impacted adherence in TB treatment in prior studies from regions such as Bangladesh (Samudyatha UC et al, 2023 Sultana N, 2024).	Religion significantly influenced adherence, with non-Hindus showing higher dropout and completion rates.

Recommendations

Culturally Tailored Health Education and Stigma Reduction

Develop Context-Specific Programs for TPT implementation

Promote Holistic Conversations with patients incorporating mental and social well being

Revise Health Education Efforts for the patients as well the TBHV on updated knowledge

Targeted Support for Rural and Mobile Populations

Introduce mobile clinics for rural populations by the district/block

Enhance Health Education in Rural Population with more focused intervention incorporating actions like development of materials in local language or including reinforcing activities

Family-Centric Approaches

Tailor Support to Family Structure

Implement Family Counseling

Financial Support Mechanisms

Provide non-monetary support- introduce ration schemes for TPT users as well

Implement Door-to-Door Interventions to dispense TPT by CHW/ASHAs

Increase Follow-Up Frequency

Establish Regular Follow-Up Visits- plan in such a way that it can be integrated with ration dispensation (weekly)

Integrate Follow-Ups for HHCs taking TPT into TB Programs

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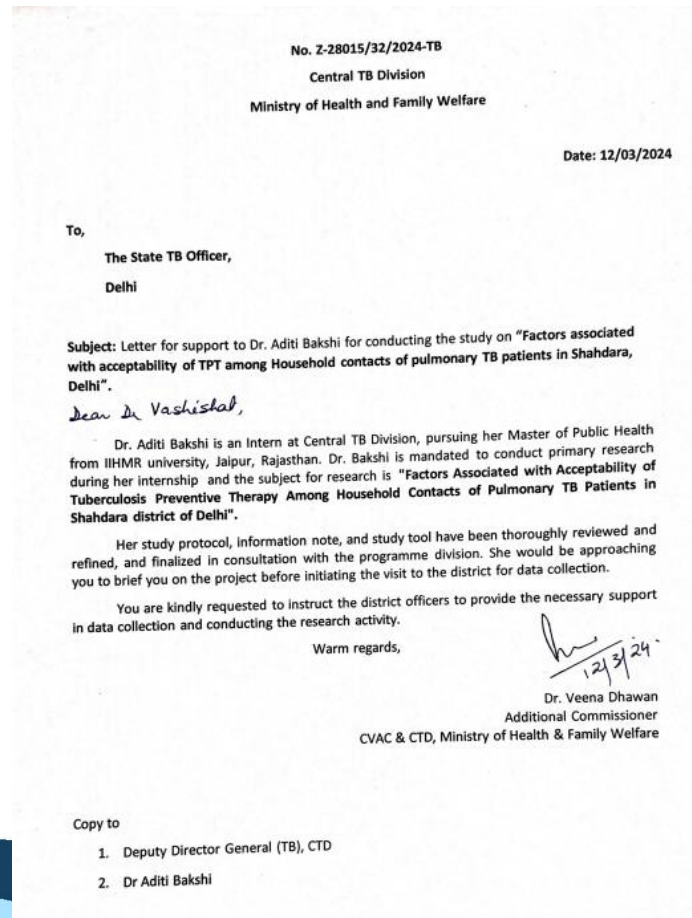
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Approval from the Central TB division and Delhi State TB Cell



Aditi bakshi <aditibakshi2407@gmail.com>

Fwd: Request for expedited approval and Data Collection

Wed, May 29, 2024 at 8:20 PM

STO Delhi <stodl@mtcp.org>

To: Aditi bakshi <aditibakshi2407@gmail.com>

Cc: DTO Shahdara <dtodshd@mtcp.org>, tanmaya talukdar <8talukdar@gmail.com>, Dr Veena Dhawan <dhawanv@mtcp.org>, "Dr. Hardik Solanki" <solankih@mtcp.org>, Arvind Kumar <arvind.kumar@theunion.org>, dlconsultants <dlconsultants@mtcp.org>

Dear Ms Aditi Bakshi

With reference to the data collection for the research study on 'Factors associated with acceptability of Tuberculosis Preventive Therapy among Household Contacts of Pulmonary TB Patients: A Study in Shahdara District'. The Research Protocol along with the submitted documents were circulated to Delhi State OR Committee members for their suggestions/Comments/Approval. The OR Committee members have given approval for data collection for the above mentioned Research Study. Kindly contact DTO Chest Clinic Shahdara for the relevant data.

You are required to submit the findings of the Research Protocol with the DTO Chest Clinic Shahdara with a copy to the State TB Office.

Regards
Dr B.K.Vashishat
SPO-NTEP

----- Forwarded message -----

From: Dr Veena Dhawan <dhawanv@mtcp.org>

Date: Tue, 7 May 2024 at 20:23

Subject: Fwd: Request for expedited approval and Data Collection

To: STO Delhi <stodl@mtcp.org>

Cc: DLconsultants <dlconsultants@mtcp.org>, Dr Rajendra P Joshi <ddgtb@mtcp.org>, Aditi bakshi <aditibakshi2407@gmail.com>, Dr. Hardik Solanki <solankih@mtcp.org>, Arvind Kumar <arvind.kumar@theunion.org>

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Approval from IRB of the University

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Protection of Human Subjects**
IORG0007355 OMB No. 0990-0279 IRB 00008833
Approved for use through June 30, 2025
Date: June 18, 2024

**Indian Institute of Health
Management Research (IIHMR)**
J. Prabhakar Marg, Sanganer, Jaipur -
320011, India Phone: +91-141-2924090
Fax: +91-141-2924078, ihmr@iihmr.edu.in

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Jaipur
Dr Rajeshwari Gupta
Retd Professor (Ob&G)

Serial No. of Institutional Review Board	June 2024	01
1	Project Title Factors Associated with Acceptability of Tuberculosis Preventive Therapy Among Household Contacts of Pulmonary TB patients: A Study in Shahdara District	
2	Name of Researcher Dr Aditi Bakshi	
3	Date of Submission to the IRB 0 7 0 4 2 0 2 4	
4	Date of Submission to the Agency	
5	Review Category of the Proposal	
	Expedited Review	
	Full Review	
	Exemption from Review	
6	Date of Review 2 2 0 4 2 0 2 4	
7	Reviewer's Name Dr M L Jain, Dr Anoop Khanna, Dr Vinod S V, Mr Umesh Saraswat, Ms Kamaljeet Yadav, Dr Seema Mehta	
8	Reviewer's Feedback (Please tick the following, if you are satisfied)	
8.1	Respect for person	
8.2	Fair subject selection	
8.3	Informed consent	
8.4	Maintaining privacy	
8.5	Maintaining confidentiality	
9	Final Comment	
	Approved without suggestions	
	Approved with suggestions	
	Sent back for revision and re-submission	
	Not approved	
10	Suggestions	
	The suggestions are incorporated in close supervision and guidance of the Central TB Division / State and District TB officers team	
	Signature	

18/6/24



THANK YOU