Cureus
Part of SPRINGER NATURE

Open Access Original Article

Completion of Tuberculosis Preventive Therapy Among Household Contacts of Pulmonary Tuberculosis Patients in Lucknow, India: A Prospective Observational Study

Review began 10/22/2026
Review ended 10/26/2026
Published 11/06/2026

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DOI: 10.7759/cureus.119223

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Abstract

Background: Tuberculosis preventive therapy (TPT) protects eligible household contacts from developing active tuberculosis, but only if they complete the course. This study assessed completion of a six-month TPT regimen among household contacts in Lucknow, India, and the factors associated with it.

Methods: A community-based observational study was conducted from August 2023 to January 2024 among 407 household contacts identified through two randomly selected tuberculosis units of Lucknow district. Contacts of patients with pulmonary tuberculosis who had been started on TPT by the programme, after active tuberculosis was ruled out, were enrolled at home visits and followed up to the end of their course. Data were collected with a pretested, interviewer-administered questionnaire developed by the investigators. Completion of the prescribed TPT course was verified at the end of the course using TPT cards and an interview with a tablet count, and associations were tested using the chi-square test.

Results: Of the 407 contacts, 345 (84.8%; 95% CI 81.0-87.9) completed TPT. At the initial assessment, 351 (86.2%) reported taking their medicines regularly. Completion was 94.9% (333/351) among regular users and 21.4% (12/56) among irregular users ($p < 0.001$). Completion also differed by caste ($p = 0.012$) and family type ($p = 0.024$). Among the 62 (15.2%) non-completers, the commonest reasons were non-adherence or other personal reasons, 22 (35.5%); adverse effects or advice to stop treatment, 14 (22.6%); and travel or migration, 8 (12.9%).

Conclusion: Most contacts completed the six-month course. Contacts who reported irregular intake at the initial assessment were much less likely to complete treatment. Checking for missed doses early, assessing adverse symptoms, and making arrangements for contacts who migrate may help reduce non-completion.

Categories: Pharmacology, Epidemiology/Public Health, Internal Medicine
Keywords: adherence, household contacts, preventive therapy, treatment completion, tuberculosis

Introduction

Tuberculosis (TB) is still among the leading infectious causes of death in the world. An estimated 10.8 million people fell ill with TB in 2023, and India contributed 26% of these cases [1]. About a quarter of the global population is thought to have latent TB infection, from which most new cases will arise in the future [2]. Household contacts of pulmonary TB patients are at particular risk. In low- and middle-income countries, active TB has been found in about 3% and latent infection in about half of such contacts [3], and WHO considers them a priority group for preventive treatment [4].

TPT is given to eligible contacts once active disease has been ruled out. A Cochrane review found that isoniazid preventive therapy lowered the risk of active TB by about 60% in people without HIV infection [5]. In 2021, India's National TB Elimination Programme extended TPT from children under five years to household contacts of all ages [6]. Starting treatment, however, is only the first step [7]. Contacts have to keep taking the medicines for the full duration and need support when side effects or other difficulties come up [6]. A systematic review of the latent TB care cascade showed losses at every stage, from identification of contacts to completion of treatment [8].

It is not easy to continue a preventive course when one feels well. Doses may be missed because of side effects, doubts about why treatment is needed, travel, work, or gaps in follow-up [9]. Completion rates reported from Indian programme settings range widely, from about 40% to 77% [10-14], and the reasons for stopping vary from place to place [11,13,14]. Uttar Pradesh reports the highest number of TB patients among

Indian states [15], but there is little community-based information on TPT completion among household contacts in Lucknow. Such local information can help tuberculosis units decide where contacts need more support.

The objectives of this study were (i) to estimate the proportion of household contacts of pulmonary TB patients who completed six months of TPT in two tuberculosis units of Lucknow district, (ii) to find out the socio-demographic and programme factors associated with completion, and (iii) to describe the reasons for non-completion.

Materials And Methods

Study design, setting, and period

This community-based observational study was conducted in Lucknow district, Uttar Pradesh, from August 2023 to January 2024, as a Short-Term Research Project (2023-24) funded by the Tuberculosis Association of India. Follow-up of enrolled contacts continued, until the last enrolled contact reached the end of the course. Two of the 28 tuberculosis units in the district were selected randomly. The study was a descriptive observational study with follow-up. Contacts were enrolled while they were taking TPT, so at enrolment they were at different points of their course. Each contact was then followed until the course ended, so the primary outcome, completion, was always observed after treatment had ended. Programme records were used to confirm the start date and the outcome. The study is reported in line with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines [16], and the completed checklist is provided as a supplementary file.

Participant recruitment, eligibility screening and follow-up

Index patients were patients with pulmonary tuberculosis notified from the two selected tuberculosis units who had been started on treatment in the six months before data collection began. They were listed from the tuberculosis unit register, and all listed patients were approached.

The investigators visited the home of each included index patient. A household contact was defined as a person who shared the same enclosed living space with the index patient for one or more nights, or for frequent or extended daytime periods, during the three months before the start of the index patient's treatment [6]. All household contacts were listed and assessed for eligibility. Contacts were eligible if TPT had been prescribed for them by the programme after active tuberculosis had been ruled out, and if they (or, for participants under 18 years, a parent or guardian) gave written informed consent. Contacts with active tuberculosis or a contraindication to TPT were excluded.

Inclusion criteria: (i) household contact of an index patient with pulmonary tuberculosis notified from the two selected tuberculosis units during the study period; (ii) TPT prescribed by the programme after active tuberculosis had been ruled out; and (iii) written informed consent from the contact or, for those under 18 years, from a parent or guardian.

Exclusion criteria: (i) active tuberculosis; (ii) a contraindication to TPT (acute or chronic hepatitis, regular heavy alcohol use, peripheral neuropathy, or hypersensitivity to TPT drugs); (iii) not available at home after three visits; and (iv) refusal of consent.

Each enrolled contact was interviewed at the first home visit (the initial assessment) and was then followed up by home visit or telephone call (monthly) until six months after the date of starting TPT, or until treatment was stopped, whichever came first. Contacts who could not be reached were were classified as not completed.

TPT eligibility, exclusion of active tuberculosis, and regimens

TPT was initiated with the support of the National TB Elimination Programme (NTEP). Under the national guidelines [6], the list of notified index patients is taken from Ni-kshay, and health workers enumerate household contacts through a home visit or telephone call and record them in the Prevent TB India application. Each contact is screened for symptoms of tuberculosis. The doctor at the health facility, including the community health officer at a health and wellness centre, assesses eligibility, rules out active disease, checks for contraindications, and initiates TPT. Before starting, the contact or caregiver is counselled about tuberculosis infection, the regimen and its duration, possible side effects, the importance of completing the course, and what to do if symptoms of tuberculosis or drug toxicity appear. Contacts are then followed up through scheduled visits and drug refills, with symptom screening at every contact with a health worker [6].

TPT was prescribed and dispensed by the programme, not by the investigators, according to the national guidelines [6]. Before TPT was started, every contact was screened for current cough, fever, weight loss, and night sweats. Contacts with any of these symptoms were investigated for tuberculosis and were given TPT only if active disease was excluded. In contacts aged five years and above, a chest X-ray was done where

available, and the absence of symptoms together with a normal chest X-ray was taken to rule out active tuberculosis [6].

Age-specific eligibility followed the same guidelines. Contacts aged under five years were given TPT once active tuberculosis had been ruled out, without a test for tuberculosis infection. Contacts aged five years and above were offered a tuberculin skin test (TST) or interferon-gamma release assay (IGRA) where available and were given TPT if the test was positive or not available [6]. Contacts with acute or chronic hepatitis, regular heavy alcohol use, signs of peripheral neuropathy, or known hypersensitivity to TPT drugs were not given TPT [6].

The investigation done before TPT was taken from the TPT card and grouped as chest X-ray or "others". A chest X-ray had been done in 382 contacts. The "others" group (n = 25) consisted of contacts in whom active tuberculosis was ruled out without a chest X-ray, by symptom screening and clinical examination alone.

The regimen given was as per NTEP guidelines. The dates of diagnosis of the index patient and of starting TPT were recorded for each contact from the TPT card. Doses were taken at home once daily, and a parent or caregiver gave the doses to children. At each refill visit, the health facility staff screened the contact for symptoms of tuberculosis and adverse effects, counselled the contact on adherence, and recorded the doses issued on the TPT card [6].

Monitoring for isoniazid hepatotoxicity. In line with the national guidelines, baseline liver function tests are not required routinely but are advised for people with risk factors such as a history of liver disease, regular alcohol use, HIV infection, or pregnancy and the postpartum period. TPT is stopped if jaundice or symptoms of hepatitis develop, or if ALT/AST is at least five times the upper limit of normal, or at least three times with symptoms [6].

Sample size

The sample size was calculated with the formula $n = Z^2pq/d^2$, where Z = 1.96 for a 95% confidence level, p = expected completion of 40% [10], q = 1 − p = 60%, and d = absolute precision of 5%. This gave $n = (1.96^2 \times 0.40 \times 0.60)/0.05^2 \approx 369$. After adding 10% for non-response and loss to follow-up, the required sample size was 406. A total of 407 contacts were finally included.

Study team and data collection

Data were collected by the investigators. The Senior Treatment Supervisor (STS) of each tuberculosis unit helped identify index patients from the register and arranged the first home visit. At this visit, the interviewer listed the household contacts, explained the study, and obtained consent. Each contact (or the caregiver of a child) was then interviewed face to face in Hindi, and the investigation done before TPT, the regimen and the TPT start date were copied from the TPT card. At follow-up, the interviewer asked about intake, adverse effects and reasons for stopping, checked the TPT card, and counted the remaining tablets.

Data collection tool and outcomes

A pretested, semi-structured, interviewer-administered questionnaire was used. It was developed by the investigators for this study, based on the national guidelines for programmatic management of TPT [6], and has not been published before. The complete questionnaire is given in Appendix 1. Information was collected on demographic details, socio-economic status, relationship with the index patient, the investigation done before starting TPT, and treatment. At the initial assessment, each participant (or the parent or guardian of a child) was asked whether he or she was taking TPT regularly. Regular intake was defined as no prescribed dose missed in the preceding two weeks. The primary outcome was completion of six months of TPT. For those who did not complete treatment, the reason was noted in the participant's own words. Two investigators independently grouped these reasons into the eight categories shown in Table *4*. "Comorbidity/concurrent treatment" meant that TPT was stopped because of another illness or its treatment.

Definition and verification of completion. TPT was considered completed when the contact had taken the full prescribed course of TPT, as recorded on the TPT card, in line with the national guidelines [6]. A contact who did not meet this definition for any reason, including stopping because of adverse effects, migration, refusal, active tuberculosis or death, or never starting the prescribed TPT, was classified as not completed. Completion was verified at the end of the course from (i) the TPT card and (ii) an interview with the contact or caregiver, with a count of the remaining tablets. Contacts whose outcome could not be confirmed were counted as not completed, so all 407 contacts had an outcome in the analysis.

Socio-economic status was assessed with the modified B. G. Prasad classification [17]. Per capita monthly income cut-offs were updated for the study period using the All-India Consumer Price Index for Industrial Workers [18], and participants were placed in classes I (upper) to V (lower).

Statistical analysis

Data were entered and analysed in IBM SPSS Statistics for Windows, version 22 (IBM Corp., Armonk, NY). Categorical variables are presented as frequencies and percentages, n (%). The completion rate was calculated using all 407 contacts as the denominator (an intention-to-treat approach, so the three contacts for whom prescribed TPT was never started were counted as not completed), and reasons for non-completion are shown as n (%) of the 62 non-completers.

The outcome was coded as completed or not completed. Its association with age group, gender, religion, caste, marital status, family type, socio-economic class, residence, investigation before TPT, and self-reported regular intake at the initial assessment was tested using Pearson's chi-square test, with Yates' continuity correction for 2 × 2 tables. Completion rates are given with 95% confidence intervals (CIs), calculated by the Wilson method. Unadjusted odds ratios (ORs) with 95% CIs were calculated against a reference category for gender, caste, family type, evaluation before TPT and self-reported regular intake, and for children under 15 years versus contacts aged 15 years and above. The chi-square test for linear trend was used for age group, and Fisher's exact test was used to confirm 2 × 2 comparisons with expected cell counts below five. Results for socio-economic class and age group, which had small expected counts in some cells, should be read with caution. A two-tailed p-value below 0.05 was taken as significant. Only bivariate (unadjusted) analysis was done; multivariable analysis was not performed.

Ethics and quality assurance

The study was approved by the Institutional Ethics Committee of Dr Ram Manohar Lohia Institute of Medical Sciences, Lucknow (RC-910). Written informed consent was obtained from adult participants. For participants under 18 years, written consent was obtained from a parent or guardian, and assent from children aged 7-17 years. Permission to access the TPT records of the two tuberculosis units was obtained from the District TB Officer. Data were copied from programme records only for consenting contacts; names were replaced by study codes, and the data were stored on a password-protected computer accessible only to the investigators. Confidentiality of data was maintained. For quality control, 10% (n = 41) of the filled questionnaires were rechecked.

Results

There were 207 (50.9%) males and 200 (49.1%) females. The largest age group was 25-44 years, 125 (30.7%), followed by 5-14 years, 99 (24.3%). Most participants lived in urban areas, 285 (70.0%), and were in nuclear families, 317 (77.9%). By the modified B. G. Prasad classification [16,17], 263 (64.6%) belonged to class V (Table *1*).

Characteristic	Category	n (%)
Age group (years)	<5	22 (5.4)
	5-14	99 (24.3)
	15-24	89 (21.9)
	25-44	125 (30.7)
	45-59	53 (13.0)
	≥60	19 (4.7)
Gender	Male	207 (50.9)
	Female	200 (49.1)
Religion	Hindu	298 (73.2)
	Muslim	109 (26.8)
Caste	Scheduled caste	127 (31.2)
	Other backward caste (OBC)	174 (42.8)
	Others	106 (26.0)
Marital status	Married	188 (46.2)
	Unmarried	219 (53.8)
Family type	Nuclear	317 (77.9)
	Joint	90 (22.1)
Socio-economic class (modified B. G. Prasad)	I	0 (0.0)
	II	5 (1.2)
	III	36 (8.8)
	IV	103 (25.3)
	V	263 (64.6)
Residence	Urban	285 (70.0)
	Rural	122 (30.0)

TABLE 1: Participant characteristics (N = 407)

The most common educational level was primary school, 122 (30.0%), and the largest occupational group was housewives, 103 (25.3%). Sons, 67 (16.5%), and brothers, 55 (13.5%), were the relations of the index patient most often recorded (Table *2*).

Characteristic	Category	n (%)
Educational status	Primary school	122 (30.0)
	Illiterate (not valid for child <7 years)	76 (18.7)
	Middle school	68 (16.7)
	Secondary school	65 (16.0)
	Graduate and above	42 (10.3)
	Others	29 (7.1)
	Illiterate	5 (1.2)
Occupation	Housewife	103 (25.3)
	Others	99 (24.3)
	Unemployed	93 (22.9)
	Self-employed	81 (19.9)
	Private employee	29 (7.1)
	Government employee	2 (0.5)
Relation to index patient	Others	73 (17.9)
	Son	67 (16.5)
	Brother	55 (13.5)
	Mother	46 (11.3)
	Daughter	43 (10.6)
	Father	37 (9.1)
	Wife	36 (8.8)
	Sister	35 (8.6)
	Husband	15 (3.7)

TABLE 2: Socio-demographic profile

Illiterate (not valid for child <7 years)" refers to children aged under 7 years, for whom literacy status is not applicable. "Illiterate" refers to participants aged 7 years and above, including adults, who cannot read and write with understanding in any language.

At the initial assessment, 351 (86.2%) contacts reported taking their medicines regularly, and 56 (13.8%) reported irregular intake. At six months, 345 (84.8%; 95% CI 81.0-87.9) had completed TPT, and 62 (15.2%) had not (Figure *1*).

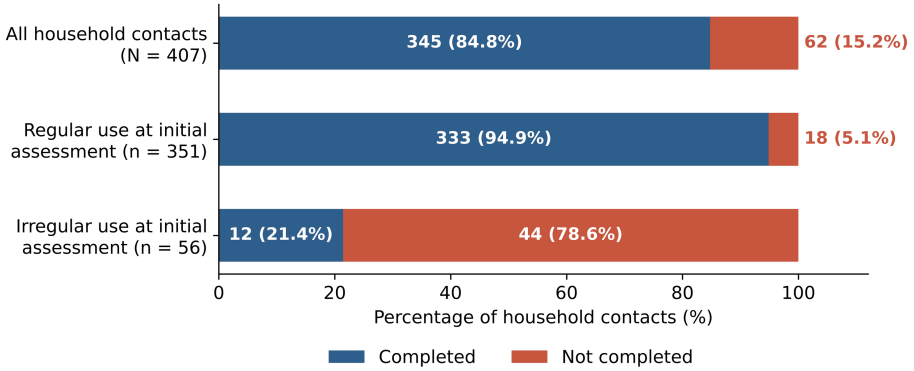


FIGURE 1: Medication completion among participants

Completion was very different in these two groups. Of the 351 contacts reporting regular intake, 333 (94.9%) completed treatment, compared with 12 (21.4%) of the 56 reporting irregular intake ($p < 0.001$) (Figure *1*, Table *3*). Of the contacts who had a chest X-ray before TPT, 333 (87.2%) of 382 completed treatment, compared with 12 (48.0%) of 25 who were evaluated by other methods ($p < 0.001$) (Table *3*). Age group, gender, religion, marital status, socio-economic class, and residence were not significantly associated with completion ($p > 0.05$) (Table *3*).

Variable	Category	Total, N	Completed, n (%)	Not completed, n (%)	p-value
Age group (years)	<5	22	20 (90.9)	2 (9.1)	0.24
	5-14	99	89 (89.9)	10 (10.1)	
	15-24	89	70 (78.7)	19 (21.3)	
	25-44	125	108 (86.4)	17 (13.6)	
	45-59	53	42 (79.2)	11 (20.8)	
	≥60	19	16 (84.2)	3 (15.8)	
Gender	Male	207	177 (85.5)	30 (14.5)	0.776
	Female	200	168 (84.0)	32 (16.0)	
Religion	Hindu	298	254 (85.2)	44 (14.8)	0.78
	Muslim	109	91 (83.5)	18 (16.5)	
Caste	Other backward caste (OBC)	174	137 (78.7)	37 (21.3)	0.012*
	Scheduled caste	127	112 (88.2)	15 (11.8)	
	Others	106	96 (90.6)	10 (9.4)	
Marital status	Married	188	155 (82.4)	33 (17.6)	0.285
	Unmarried	219	190 (86.8)	29 (13.2)	
Family type	Nuclear	317	276 (87.1)	41 (12.9)	0.024*
	Joint	90	69 (76.7)	21 (23.3)	
Socio-economic class (modified B. G. Prasad)	II	5	5 (100.0)	0 (0.0)	0.445
	III	36	29 (80.6)	7 (19.4)	
	IV	103	91 (88.3)	12 (11.7)	
	V	263	220 (83.7)	43 (16.3)	
Residence	Urban	285	238 (83.5)	47 (16.5)	0.353
	Rural	122	107 (87.7)	15 (12.3)	
Evaluation before TPT	Chest X-ray	382	333 (87.2)	49 (12.8)	<0.001*
	Others	25	12 (48.0)	13 (52.0)	
Regular medication use at initial assessment	Yes	351	333 (94.9)	18 (5.1)	<0.001*
	No	56	12 (21.4)	44 (78.6)	

TABLE 3: Factors associated with completion of six-month tuberculosis preventive therapy among household contacts (N = 407)

Percentages are row percentages. p values from Pearson's chi-square test (Yates' continuity correction for 2 × 2 tables). *Statistically significant at p < 0.05. TPT: tuberculosis preventive therapy.

Completion differed by caste (p = 0.012). It was 78.7% (137/174) in the other backward caste group, 88.2% (112/127) in the scheduled caste group, and 90.6% (96/106) in the "others" group. Contacts from nuclear families completed treatment more often, 276 (87.1%) of 317, than those from joint families, 69 (76.7%) of 90 (p = 0.024) (Table 3).

Completion did not differ significantly by age group (p = 0.240; chi-square for trend p = 0.191). It was 90.1% (109/121) in children under 15 years and 82.5% (236/286) in contacts aged 15 years and above (OR 1.92, 95%

CI 0.99-3.76; p = 0.073). Completion was similar in males, 85.5% (177/207), and females, 84.0% (168/200) (OR for females 0.89, 95% CI 0.52-1.53; p = 0.776). Compared with the other backward caste group, the odds of completion were higher in the scheduled caste group (OR 2.02, 95% CI 1.05-3.86) and the "others" caste group (OR 2.59, 95% CI 1.23-5.47). Contacts from joint families had lower odds of completion than those from nuclear families (OR 0.49, 95% CI 0.27-0.88). The odds of non-completion were 67.8 times higher (95% CI 30.6-150.2) among contacts reporting irregular intake at the initial assessment, and the odds of completion were lower in the "others" testing group than in the chest X-ray group (OR 0.14, 95% CI 0.06-0.31; Fisher's exact p < 0.001). The "others" group consisted of contacts screened by symptoms and clinical examination alone, without a chest X-ray.

Various reasons were given by the 62 non-completers (Table *4*). Non-adherence or other personal reasons accounted for 22 (35.5%), adverse effects or medical advice to stop for 14 (22.6%), and migration, travel, or change of residence for 8 (12.9%). Five (8.1%) contacts felt that treatment was not needed or refused it, and another five (8.1%) stopped because the family refused. Three (4.8%) stopped because of another illness or treatment, and three (4.8%) were recorded as "TPT prescribed but not initiated." These three contacts were eligible and enrolled, but TPT was never started for them. They were kept in the denominator and counted as not completed; if they are excluded, completion is 345 of 404 (85.4%). Two (3.2%) contacts developed active tuberculosis during follow-up.

Categorised reason	n (%)
Non-compliance/other personal reasons	22 (35.5)
Adverse effects/medical advice to stop	14 (22.6)
Migration/travel/change of residence	8 (12.9)
Perceived lack of need/refusal	5 (8.1)
Family refusal	5 (8.1)
Comorbidity/concurrent treatment	3 (4.8)
TPT prescribed but not initiated	3 (4.8)
Developed active TB	2 (3.2)

TABLE 4: Reasons for non-completion of tuberculosis preventive therapy (n = 62)

Percentages are calculated among the 62 non-completers.

Discussion

In this study, 345 (84.8%) of 407 household contacts completed six months of TPT. This is higher than in several recent Indian studies. Mukherjee et al. found a completion rate of 69.3% in Murshidabad district, West Bengal [11], and Samudyatha et al. reported 77% in a rural district of Karnataka [12]. Kumar et al. reported 66.5% in rural Delhi [13]. In western Uttar Pradesh, Singh et al. found 55.3%, with 40.9% of contacts lost to follow-up [14]. Ghoshal Mukherjee et al. observed that only 40% of child contacts who started isoniazid completed the course [10]. Since our study covered only two tuberculosis units, the higher rate may partly reflect the follow-up practices in these units. Losses at each step from identification to completion of treatment have also been described in a systematic review of the latent TB care cascade [8].

Regular intake reported at the initial assessment was strongly associated with completion: 333 (94.9%) of 351 regular users completed treatment, compared with 12 (21.4%) of 56 irregular users. Singh et al. similarly found regular follow-up to be significantly associated with completion [14]. Asking contacts about missed doses early in the course may help health workers pick out those who need extra counselling or a clinical review. This association does not, however, prove cause and effect.

The reasons for non-completion were broadly similar to those in other studies. In our study, 14 (22.6%) of the 62 non-completers stopped because of adverse effects or on medical advice. Side effects and the long duration of isoniazid treatment were also reported as barriers in Delhi [19]. Migration or travel explained 8 (12.9%) cases in our study and 21.7% in Murshidabad [11]. Perceived lack of need or refusal was less common in our study, 5 (8.1%), than in Murshidabad (50.7%) [11], rural Delhi (36.5%) [13] and western Uttar Pradesh (41.9%) [14]. In rural Delhi, the most common reason was the non-availability of medicines (50.8%) [13], which was not reported by any participant in our study. Contacts who stop because of side effects need clinical evaluation, and those who migrate should be linked to a health facility where they move. Contacts without symptoms may need better counselling about why preventive treatment is given.

The length of the regimen may also affect completion. In rural Delhi, 93.9% completed the isoniazid-rifapentine regimen compared with 60.6% on isoniazid alone [13]. In a randomised trial by Sterling et al., completion was higher with three months of weekly rifapentine and isoniazid than with nine months of isoniazid (82.1% vs 69.0%) [20]. Greater use of shorter regimens under the national programme [6] might therefore improve completion, although regimens were not compared in this study.

Completion also varied with caste and family type. Singh et al. reported that education, occupation and socio-economic status were associated with completion [14], whereas socio-economic class was not significantly associated with completion in our study. As only unadjusted comparisons were made, these associations may be due to confounding. In the same way, higher completion among contacts who had a chest X-ray does not mean that the X-ray itself improved adherence. Contacts in the “others” group were screened by symptoms and clinical examination alone, and the two groups may also have differed in age or access to health facilities.

This study has several strengths. It was community-based, and contacts were interviewed in their homes. The tuberculosis units were selected randomly, and the sample size was calculated in advance and reached. All 407 enrolled contacts were followed to a final outcome, and completion was checked against programme records and tablet counts as well as interviews.

This study has certain limitations. Intake at the initial assessment was self-reported. Contacts were enrolled at different points of their course rather than at the start of TPT, so the study did not observe the whole course prospectively for every contact. Because index patients diagnosed up to six months earlier were included, some contacts were already well into their course when first interviewed, which may have strengthened the association between early regular intake and completion. Completion was verified from programme records and interviews rather than by an objective measure such as urine isoniazid testing. Adverse effects were self-reported, and liver function tests were not done routinely, so mild or symptomless rises in liver enzymes may have been missed. Only unadjusted bivariate analysis was done, so the associations with caste, family type and the investigation done before TPT may be due to confounding. The commonest reason for non-completion grouped non-adherence together with other personal reasons. Lastly, findings from two tuberculosis units may not apply to the whole district.

Conclusions

Most household contacts in the two tuberculosis units completed the six-month course of preventive therapy, which suggests that good completion is possible within routine programme conditions. Irregular intake reported early in the course was the strongest indicator that a contact would not complete treatment. This is easy to ask about during home visits or follow-up calls, and health workers can use it to decide which contacts need closer counselling, review of side effects and follow-up.

Most of the reasons for stopping treatment, such as side effects, migration, and the feeling that a healthy person does not need medicines, can be dealt with within the existing programme. Timely clinical review of symptoms, including asking about symptoms of liver injury at every visit and referring contacts with such symptoms for liver function tests, linking migrating contacts to a nearby health facility, and explaining to contacts why preventive treatment matters would help. Adding a simple check for missed doses to routine contact follow-up may further improve completion. Wider use of shorter regimens is also worth considering, although this study did not evaluate it. Larger studies from more sites, with objective measures of adherence and adjusted analysis, are needed to confirm these findings.

Appendices

Questionnaire

1. Name

2. Age

3. Gender

a) Male

b) Female

c) Other

4.Religion

a) Hindu

b) Muslim

c) Other

5. Caste

a) Scheduled caste

b) Scheduled tribe

c) Other backward caste (OBC)

d) Others

6. Marital status

a) Married

b) Unmarried

7. Occupation

a) Government employee

b) Private employee

c) Self employed

d) Unemployed

e) Housewife

f) Others

8. Education status

a) Illiterate

b) Primary school

c) Middle school

d) Secondary school

e) Graduate and above

9. Type of family

a) Nuclear

b) Joint

c) Others

10. Socio-economic status (modified BG Prasad May 2022)

a) I

b) II

c) III

d) IV

e) V

11. Per capita income (in rupees)

a) ⩾8480

b) 4240-8479

c) 2544-4239

d) 1272-2543

e) <1272

12. Members in your family:.....

13. Residence

a) Rural

b) Urban

14. Date of index case diagnosis: .....

15. Relation with index case

a) Brother

b) Sister

c) Wife

d) Husband

e) Other

16. Testing before starting TPT

a) Tuberculin Skin Test (TST)

b) Interferon-Gamma Release Assay (IGRA)

c) Chest X-ray

d) Others

17. Date of starting TPT

18. Regular on medications

a) Yes

b) No

19. Days in the past 2 weeks prescribed doses not taken

a) <14

b) >14

20. If No, then

a) Due to the adverse effect of drug (Gastrointestinal, Central nervous system, Rash/acne, Hepatotoxicity, Tiredness)

b) Due to any other reasons

21. Contacted to doctor regarding these adverse effects

a) Yes

b) No

Additional Information

Author Contributions

All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the work.

Concept and design: Amit Kaushik, CM Singh, Chhaya Singh, Sandeep Kumar

Drafting of the manuscript: Amit Kaushik, Chhaya Singh, Sandeep Kumar

Critical review of the manuscript for important intellectual content: CM Singh, Shikhar Singh

Acquisition, analysis, or interpretation of data: Shikhar Singh

Disclosures

Human subjects: Informed consent for treatment and open access publication was obtained or waived by all participants in this study. Dr. Ram Manohar Lohia Institute of Medical Sciences Ethics Committee issued approval RC-910. **Animal subjects:** All authors have confirmed that this study did not involve animal subjects or tissue. **Conflicts of interest:** In compliance with the ICMJE uniform disclosure form, all authors declare the following: **Payment/services info:** Amit Kaushik and Sandeep Kumar declare that this study was supported by a grant from the Tuberculosis Association of India, New Delhi, under the Short-Term Research Project 2023-24. **Financial relationships:** All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work. **Other relationships:** All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

Acknowledgements

We thank the District TB Officer, Lucknow, the Senior Treatment Supervisors, Senior Treatment Laboratory Supervisors, and other National Tuberculosis Elimination Programme staff of the respective tuberculosis units for their help in identifying index patients and accessing tuberculosis preventive therapy records. We also thank all participants and their families.

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