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A trial comparing digital tools to help tuberculosis patients complete their treatment in India

Submission date
13/08/2026

Recruitment status
No longer recruiting

Registration date
19/08/2026

Overall study status
Completed

Last Edited
18/08/2026

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Tuberculosis (TB) is a common infectious disease caused by bacteria that primarily affects the lungs. It affects millions of people each year, with India accounting for a quarter of all TB cases worldwide. Standard treatment is 6 months of daily tablets, but many patients struggle to take them every day. Digital tools are widely used to help patients remember to their tablets and alert health workers to support those patients who have missed their doses. However, there is limited evidence on how well these tools work. This study compares two such commonly used tools, a daily toll-free calling system and a smart pill-box, against a simpler monthly check-in (refill monitoring), to see which best helps patients take their tablets regularly and successfully complete treatment.

Who can participate?
Patients aged 18 years and over with pulmonary TB that responds to standard first-line rifampicin-based treatment

What does the study involve?
Participants are randomly placed into one of three groups, with an equal chance of each:
1. Toll-free calling: call a free number daily after taking tablets
2. Smart pillbox: an alarm-fitted electronic pill-box that logs each opening
3. Refill monitoring (comparison group): call a free number whenever prescription is refilled, typically every month

All groups get the same free tablets, counselling at treatment initiation and follow-up: a phone call if a signal is missed for 3 days, a home visit if missed for 7 days, plus counselling and troubleshooting, if required. Additionally, each participant gets up to three urine tests at random points during treatment. At the end of 6 months, each participant's outcome is recorded based on a survey, and a sputum test.
A separate part of the study looks at why each tool works or doesn't, by interviewing some participants and health workers about their experience. The study also tracks the cost of running each approach.

What are the possible benefits and risks of participating?
Everyone receives the same free treatment and same follow-up support, so any problems can be identified and addressed sooner. Participants also receive free sputum and urine testing as part of the study. There are no notable risks, as the study only adds monitoring and counselling to usual TB care. Participants can switch home visits to phone calls, request a different time or place for follow-up, or decline current or future follow-ups if they find them inconvenient.

Where is the study run from?
Indian School of Business

When is the study starting and how long is it expected to run for?
July 2025 to October 2026

Who is funding the study?
Bill & Melinda Gates Foundation (USA)

Who is the main contact?
Prof. Sarang Deo, sarang_deo@isb.edu

Contact information

Type(s)
Principal investigator, Public, Scientific

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Study information

Scientific Title
Effectiveness of digital adherence technologies on treatment outcome and adherence among drug-susceptible tuberculosis patients in India

Study objectives
The primary objective is to evaluate the relative impact of two digital adherence management strategies - toll-free calling (99DLite) and smart pillboxes (medication event reminder-monitor [MERM]) - on TB treatment adherence and outcomes, as compared to refill monitoring.

There are two sub-studies nested within this trial with the following objectives:
1. To assess the behavioral mechanisms through which each DAT strategy influences adherence

and outcomes
2. To assess the relative programmatic costs and cost-effectiveness of each DAT strategy

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 11/11/2024, Institutional Ethics Committee, Dayanand Medical College & Hospital (Civil Lines, Ludhiana, 141001, India; +91 (0)161 468 7501; ethics.dmch@gmail.com), ref: 2024-993

2. Approved 01/03/2022, Institutional Review Board, Indian School of Business (Gachibowli, Hyderabad, 500111, India; +91 (0)40 2300 7000; irbassist@isb.edu), ref: 2022-09

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Tuberculosis (TB)

Interventions
This is a three-arm non-blinded, parallel-grouped, patient randomised trial with individual-level randomisation and a 1:1:1 allocation ratio, stratified by HCW and facility type (public vs private). Participants are randomised to one of three adherence management strategies: (1) toll-free calling (99DLite), (2) smart pillboxes (MERM), or (3) control group refill monitoring.

All participants receive counselling at treatment initiation. Free first-line fixed-dose combination (FDC) therapy treatment is supplied at the diagnosing facility, per prescribed refill frequency.

Intervention arm 1 – 99DLite:
Participants receive a medication container labelled with a toll-free number and are oriented to call daily to confirm dose intake. Missed calls for 3 consecutive days trigger a follow-up phone call; 7 consecutive days trigger a home visit.

Intervention arm 2 – MERM:
Participants receive an electronic pillbox with an audio-visual alarm set to their preferred dose time; opening the lid automatically logs the dose daily. A missed signal for 3 consecutive days triggers a follow-up call; 7 consecutive days triggers a home visit.

Control arm – Refill Monitoring:
Participants receive a toll-free number on their initial prescription and are oriented to call at time of prescription refill (expected monthly). A missed call within 3 days of the refill due date triggers a follow-up call; 7 days triggers a home visit.

Follow-ups for all three arms include adherence counselling, personalised counselling on treatment challenges, and troubleshooting, if any.

Intervention Type
Mixed

Primary outcome(s)
1. Unfavourable treatment outcome measured using a binary variable (1 = unfavourable, else 0), defined per Indian National TB Elimination Programme as any of: treatment failure, death, loss to follow-up, switch to drug resistant regimen, or not evaluated, measured using culture results and patient interviews at the end of the 6-month treatment

Key secondary outcome(s)
1. Medication non-adherence measured using a binary variable (1 = negative, else 0) based on the proportion of urine tests negative for isoniazid metabolites using the Arkansas colorimetric method at up to three randomly assigned urine tests during 6-month treatment regimen

Completion date
19/10/2026

Eligibility

Key inclusion criteria
1. Notified in the national TB platform, Nikshay, in participating study sites
2. Aged 18 years or older
3. Diagnosed with pulmonary tuberculosis
4. Microbiologically confirmed by a nucleic acid amplification test (NAAT) with rifampicin sensitivity
5. Initiated on free first-line treatment with fixed-dose combination (FDC) therapy
6. Plans to reside in the study district for the treatment duration period
7. Has daily access to a mobile phone (own or a family member's)

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
1081

Key exclusion criteria
1. Extrapulmonary tuberculosis without pulmonary involvement
2. Mycobacterium tuberculosis (MTB) not detected on NAAT, or diagnosed with rifampicin-resistant or multidrug-resistant tuberculosis (RR-TB/MDR-TB) at enrolment
3. More than 25 days into treatment at the time of enrolment
4. Plans to migrate to a different district during the treatment duration period
5. Was part of similar digital adherence technology (DAT) interventions in prior programs
6. Has a household member concurrently enrolled in a DAT intervention
7. Unable or unwilling to provide informed consent
8. Follow-up not feasible due to inaccessible locations (e.g., prisons)

Date of first enrolment
02/07/2025

Date of final enrolment
31/03/2026

Locations

Countries of recruitment
India

Sponsor information

Organisation
Indian School of Business

ROR
https://ror.org/027t6ka17

Funder(s)

Funder type

Funder Name
Bill and Melinda Gates Foundation

Alternative Name(s)
Bill & Melinda Gates Foundation, Gates Foundation, Gates Learning Foundation, William H. Gates Foundation, BMGF, B&MGF, GF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon reasonable request

IPD sharing plan summary
Available on request