

# POST-TB centre for assessment and research excellence

<b>Submission date</b> 31/07/2025	<b>Recruitment status</b> Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 07/08/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 07/08/2025	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Millions of people around the world have survived tuberculosis (TB), but many still face serious health, emotional, and financial challenges even after treatment ends. In countries like South Africa and Cambodia, where TB is common and resources are limited, there is very little support for people after TB treatment. This study aims to improve care for TB survivors by understanding their needs and creating better support systems. Researchers will work with TB survivors, healthcare providers, and communities to develop tools, care packages, and a centre of excellence for post-TB care.

### Who can participate?

People who have finished TB treatment and those who provide post-TB care are invited to take part in the study.

### What does the study involve?

Participants will help researchers understand the physical, emotional, and financial effects of TB after treatment. This may include medical check-ups, interviews, and surveys. The study will also explore what kind of care and support TB survivors need and how best to provide it in places with limited resources.

### What are the possible benefits and risks of participating?

Participants may benefit from thorough health assessments and help connecting with health and social services. The risks are similar to those of standard medical tests, and all procedures will be carried out by trained professionals under medical supervision.

### Where is the study run from?

The study is led jointly by the London School of Hygiene and Tropical Medicine in the UK and Stellenbosch University in South Africa.

### When is the study starting and how long is it expected to run for?

August 2024 to August 2028.

Who is funding the study?  
National Institute for Health and Care Research (NIHR) in the UK.

Who is the main contact?  
Prof Rein Houben – Rein.Houben@lshtm.ac.uk  
Prof Brian Allwood – brianallwood@sun.ac.za

**Study website**  
<https://www.posttbcare.com/care/index>

## Contact information

**Type(s)**  
Public, Scientific, Principal Investigator

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
NIHR156644

## Study information

**Scientific Title**  
NIHR Global Health Research Group on post-tuberculosis care in high TB burden settings

**Acronym**  
POST-TB CARE

## **Study objectives**

Aim: To improve post-TB care in high-burden, resource-limited settings

Objective 1: Develop an operational multidimensional assessment tool, which can quantify impairment in TB survivors to accurately assess post-TB care needs.

Objective 2: Design an effective, appropriate, and sustainable post-TB care package for resource-limited settings, using principles of good clinical governance.

Objective 3: Create a knowledge sharing and advocacy platform for post-TB in high-burden TB settings.

Objective 4: Develop a multi-disciplinary centre of excellence for post-TB research, care, and community engagement in South Africa to enable sustainable, collaborative south-south and north-south research partnerships in post-TB.

## **Ethics approval required**

Ethics approval required

## **Ethics approval(s)**

Approved 03/07/2025, LSHTM Ethics Committee (Keppel Street, London, WC1E 7HT, United Kingdom; +44 20 76368636; ethics@lshtm.ac.uk), ref: 31414

## **Study design**

Multi-centre observational cohort study

## **Primary study design**

Observational

## **Secondary study design**

Cohort study

## **Study setting(s)**

Hospital

## **Study type(s)**

Diagnostic, Quality of life, Screening

## **Participant information sheet**

## **Health condition(s) or problem(s) studied**

Post-tuberculosis disease

## **Interventions**

To address Objective 1 (post-TB care needs assessment) and Objective 2 (post-TB care package) our Target Populations are TB survivors and post-TB care providers from South Africa and Cambodia, Settings where a high burden of post-TB care need (estimated 1 in 20 individuals are TB survivors), while facing limited human resources and near absent access to advanced medical tests). For Objective 1 (assessment) we will recruit a cohort of TB survivors and repeat the assessments over a period of 12 months to monitor changes in 1) post-TB care needs and 2) the association between reference standard and operational tools

Data collection for Objective 1 will include repeated radiological, physiological and cardiopulmonary function assessment, as well as extended questionnaires to assess psychosocial and economic post-TB impairment, and how these change over 12 months. For objective 2 we will conduct qualitative interviews and Discrete Choice Experiments (DCE). Data

analysis for data collected in work package 1 will include ROC curves/C-statistic and regression approaches, while predictive modelling will be used to identify a short list of the most informative questions for psychosocial and economic post TB assessment in these populations. Qualitative data from work package 2 will be analysed using deductive thematic analytic approaches, while DCEs will be analysed using Multinomial Logit and Latent Class models. To address Objective 3 (Knowledge sharing and advocacy platform) we will convene online and in-person meetings, targeting post-TB communities from high-burden settings across the world. Objective 4 (develop centre of excellence in post-TB research) we will strengthen the human and material infrastructure.

## **Intervention Type**

Other

## **Primary outcome measure**

Objective 1: Post-TB Care Assessment

1. Severity of biological impairment is measured using radiological imaging (e.g. chest X-ray or CT), spirometry, and cardiopulmonary exercise testing over 12 months
2. Severity of psychosocial impairment is measured using extended questionnaires including validated mental health and quality of life scales (e.g. PHQ-9, GAD-7, WHOQOL-BREF) over 12 months
3. Severity of economic impairment is measured using structured economic impact questionnaires (e.g. household income, employment status, healthcare expenditure) over 12 months
4. Predictive accuracy of the operational assessment tool is measured using ROC curves and C-statistics comparing tool outputs to reference standard assessments over 12 months
5. Informative items for psychosocial and economic assessment are identified using predictive modelling of questionnaire responses over 12 months

Objective 2: Post-TB Care Package

6. Patient preferences for post-TB care are measured using qualitative interviews and Discrete Choice Experiments
7. Provider preferences for post-TB care are measured using qualitative interviews and Discrete Choice Experiments
8. Acceptability and feasibility of post-TB care package is measured using thematic analysis of qualitative interview data from patients and providers
9. Preference heterogeneity in post-TB care is measured using Multinomial Logit and Latent Class models applied to Discrete Choice Experiment data

## **Secondary outcome measures**

There are no secondary outcome measures

## **Overall study start date**

01/08/2024

## **Completion date**

31/08/2028

## **Eligibility**

### **Key inclusion criteria**

1. Completed TB treatment, or
2. Providing care for TB patients

**Participant type(s)**

Patient, Health professional, Service user

**Age group**

Adult

**Lower age limit**

15 Years

**Upper age limit**

99 Years

**Sex**

Both

**Target number of participants**

600

**Key exclusion criteria**

Current TB

**Date of first enrolment**

03/08/2025

**Date of final enrolment**

30/08/2026

## **Locations**

**Countries of recruitment**

Cambodia

South Africa

**Study participating centre**

**Stellenbosch University**

Cape Town

South Africa

7602

**Study participating centre**

**KHANA**

Phnom Penh

Cambodia  
P.O. Box 2311

## Sponsor information

### Organisation

London School of Hygiene & Tropical Medicine

### Sponsor details

Keppel Street  
London  
England  
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ethics@lshtm.ac.uk

### Sponsor type

University/education

### Website

<http://www.lshtm.ac.uk/>

### ROR

<https://ror.org/00a0jsq62>

## Funder(s)

### Funder type

Government

### Funder Name

National Institute for Health and Care Research

### Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

## Location

United Kingdom

# Results and Publications

## Publication and dissemination plan

All results will be published in open access journals, and findings will be disseminated.

## Intention to publish date

01/08/2028

## Individual participant data (IPD) sharing plan

The datasets generated during the current study will be stored in a non-publicly available repository. Enquiries for use are welcome, and should be directed to the study leads.

## IPD sharing plan summary

Stored in non-publicly available repository, Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>			31/07/2025	No	Yes