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POST-TB centre for assessment and research excellence

Submission date	Recruitment status	[_] Prospectively registered
31/07/2025	Recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/08/2025	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
07/08/2025	Infections and Infestations	[X] 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

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Rein Houben

ORCID ID
https://orcid.org/0000-0003-4132-7467

Contact details
Keppel Street
London
United Kingdom
WC1E 7HT
+44 (0)20 7636 8636
rein.houben@lshtm.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Diagnostic, Quality of life, Screening

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(s)
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

Key secondary outcome(s))
There are no secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
15 years

Upper age limit

99 years

Sex
All

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

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

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?
Participant information sheet			31/07/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes