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Spirometry screening for post-tuberculosis lung disease among adolescents and adults in Mozambique

Submission date
12/09/2024

Recruitment status
No longer recruiting

Registration date
16/09/2024

Overall study status
Completed

Last Edited
14/10/2024

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Despite receiving adequate treatment, many tuberculosis (TB) survivors are left with post-tuberculosis complications, possibly due to lung tissue damage incurred during the active period of the disease. Current TB programs worldwide deliver quality care throughout the course of active TB treatment, yet often fail to provide organized follow-up once treatment ends. Post-tuberculosis lung disease (PTLD) is a prominent, yet underrecognized cause of chronic lung disease, managed similarly to chronic respiratory diseases with pharmacotherapy and/or personalized pulmonary rehabilitation interventions. Basic pulmonary rehabilitation packages for people finishing TB treatment are still lacking in low- and middle-income countries (LMICs). This study offers a protocol to evaluate the implementation of spirometry and symptom screening for PTLD among people who have completed TB treatment in a rural district in Mozambique.

Who can participate?
Patients aged ≥15 years of age enrolled in the NTCP at CHC with a GeneXpert-positive sputum

What does the study involve?
This study involves spirometry and symptom screening amongst those recently considered cured of TB to determine the prevalence of PTLD. All participants enrolled in the study will receive this intervention at baseline (upon enrollment) and at six-month follow-up. Using spirometry, Forced expiratory volume in one second (FEV1) and Forced Vital Capacity (FVC) will be measured in all participants.

What are the possible benefits and risks of participating?
This study will not likely benefit participants directly, but the knowledge gained from this study will be used to assist decision makers in determining a course of action for increasing spirometry screening coverage, optimizing the intervention's impact, and translating our findings into evidence-based programming. There are no risks associated with participating in this study.

Where is the study run from?
Tulane University

When is the study starting and how long is it expected to run for?
February 2023 to June 2025

Who is funding the study?
Fogarty International Center

Who is the main contact?
Prof Troy Moon, tmoon2@tulane.edu

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Prof Troy D. Moon

ORCID ID
https://orcid.org/0000-0002-1637-829X

Contact details
Tulane University School of Public Health and Tropical Medicine
Tidewater Building
1440 Canal St. Suite 2316
New Orleans
United States of America
70112
+1 5048623412
tmoon2@tulane.edu

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
TW009745

Study information

Scientific Title

Implementation of spirometry screening for post-tuberculosis lung disease (PTLD) among adolescents and adults enrolled within the National Tuberculosis Control Program of Carmelo Hospital in Chókwè District, Mozambique: A hybrid type III effectiveness-implementation study protocol

Study objectives
Adaptations in the tuberculosis care and treatment care cascade that consider local, real-world inputs, will result in greater uptake in spirometry screening and subsequent treatment amongst persons recently completing tuberculosis treatment.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 14/05/2024, Comité Nacional de Bioética para Saúde, CNBS (Ministry of Health, 2nd floor, Eduardo Mondlane Avenue #1008, Maputo, 00000, Mozambique; +258 82 406 6350; cnbsmocambique@gmail.com), ref: 285/CNBS/2024

2. Approved 30/11/2023, Tulane University Human Research Protection Office (1440 Canal Street, suite 1851, New Orleans, 70112, United States of America; +1 504 988-2665 ; irbmain@tulane.edu), ref: 2023-1198

Study design
Hybrid type III effectiveness-implementation design

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic, Screening, Efficacy

Participant information sheet
Not available in web format

Health condition(s) or problem(s) studied
Pulmonary lung function screening (spirometry) in persons completing 6 months of treatment for active TB

Interventions
This study involves pulmonary lung function screening (spirometry) in persons completing 6 months of treatment for active TB.

To document the prevalence of PTLD in patients enrolled at Carmelo Hospital (CHC), a prospective observational study will be conducted to introduce spirometry and symptom

screening within the National TB Control Program (NTCP) at baseline (completion of six-months of TB treatment) and six months after completion of TB treatment. Patient enrollment into the spirometry screening program will continue for approximately three months following study initiation. Enrolled participants will complete standardized respiratory symptoms and quality of life questionnaires at each visit. Spirometry will be performed at each visit using spirometers that meet the International Organization for Standardization (IOS) standards.

For the qualitative portion of the study, a total of approximately 16-19 semi-structured key-informant interviews will be conducted that will include a minimum of two participants at the central level of the NTCP in Maputo (Mozambique's capital city), two administrators of CHC, and one administrator at each of three selected peripheral health facilities. In addition, the study involves interviews with the three clinicians (1 physician, 1 medical technician, and 1 nurse) responsible for implementing the spirometry screening program at CHC, as well as all clinicians responsible for treating TB at each of the three selected peripheral health facilities (it is estimated there will be between two to three clinicians at each of the three health facilities).

Intervention Type
Procedure/Surgery

Primary outcome measure
Prevalence of post-tuberculosis lung disease amongst persons completing 6 months of treatment for active TB measured using spirometry and symptom screening at baseline (completion of 6 months of TB treatment) and at 6 months after completion of TB treatment.

Secondary outcome measures
Site-, provider-, and individual-level determinants that either promote or inhibit the successful adoption, implementation, and maintenance of the spirometry screening program will be measured using semi-structured key-informant interviews evaluating constructs from the Consolidated Framework for Implementation Research (CFIR), including perceptions about the intervention characteristics (e.g., facilitators, potential challenges, eligibility, and cost); outer setting factors influencing use (e.g., perception of patient needs and resources, demand creation, commitment); inner setting factors impacting uptake and fidelity to the intervention (e.g., resources needed, workload, standard operating procedures, infrastructure); characteristics of individuals (e.g., knowledge, competency, belief it can be done with quality); and process factors of implementation (e.g., fidelity, execution, and evaluation) within each health facility. These interviews will be performed after the completion of the spirometry portion of the study

Overall study start date
13/02/2023

Completion date
30/06/2025

Eligibility

Key inclusion criteria
Primary outcome:
1. Aged ≥15 years of age
2. Enrolled in the National TB Control Program (NTCP) at Carmelo Hospital (CHC) with a

GeneXpert-positive sputum
3. Completed six months of TB treatment and considered TB-cured
4. Ability to understand and comply with study procedures

Semi-structured key-informant interviews:
1. Participants at the central level of the NTCP in Maputo (Mozambique's capital city)
2. Administrators of CHC and at each of the three selected peripheral health facilities
3. Clinicians (physician, medical technician, and nurse) responsible for implementing the spirometry screening program at CHC, as well as all clinicians responsible for treating TB at each of the three selected peripheral health facilities

Participant type(s)
Patient, Health professional

Age group
Mixed

Lower age limit
15 Years

Upper age limit
99 Years

Sex
Both

Target number of participants
115

Total final enrolment
115

Key exclusion criteria
1. Less than 15 years of age
2. Active respiratory symptoms at the time of screening that are indicative of a new acute respiratory illness

Date of first enrolment
01/08/2024

Date of final enrolment
30/11/2024

Locations

Countries of recruitment
Mozambique

Study participating centre

Carmelo Hospital of Chokwe
Chokwe
Mozambique
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Sponsor information

Organisation
Tulane University

Sponsor details
1440 Canal Street
New Orleans
United States of America
70112
+1 504.988.1147
ResearchCompliance@tulane.edu

Sponsor type
University/education

Website
https://tulane.edu/

ROR
https://ror.org/04vmvtb21

Funder(s)

Funder type
Research organisation

Funder Name
Fogarty International Center

Alternative Name(s)
Fogarty, Fogarty at NIH, John E. Fogarty International Center, John Edward Fogarty International Center, NIH John F. Fogarty International Center, NIH's Fogarty International Center, NIH Fogarty International Center, Fogarty International Center at NIH, Fogarty International Center, U.S. National Institutes of Health (NIH), Fogarty International Center AT THE NATIONAL INSTITUTES OF HEALTH, FIC

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal and through presentations at both domestic and international scientific conferences. The study findings will also be disseminated locally to stakeholders at CHC; the three selected peripheral health facilities: Centro de Saúde da Cidade, Centro de Saúde de Chalucuane, and Centro de Saúde Urbano; and to the NTCP/Ministry of Health and stakeholders in Maputo.

Intention to publish date
01/07/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be stored in a publicly available repository (Open Science Framework, https://osf.io/)

De-identified participant spirometry results; data will become available by June 30, 2025, and will continue to be available for 5 years from that date.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		10/10/2024	14/10/2024	Yes	No