

# Exploring physical activity levels of adults living with tuberculosis in Kyrgyzstan

<b>Submission date</b> 28/08/2019	<b>Recruitment status</b> Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/09/2019	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 08/07/2022	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

There is a wealth of literature demonstrating the benefits of physical activity, including reduced risk of heart disease, stroke, cancer, depression and dementia. It has been shown that adults with lung disease have reduced physical activity levels and higher stationary time compared to those without lung disease. However, this data has come from high income countries.

Chronic lung disease in low and middle income countries is highly prevalent and often associated with fumes from cooking on open stoves, air pollution and infections such as tuberculosis (TB). Data on physical activity and stationary time on adults living with TB in Kyrgyzstan is scarce. Due to the importance of physical activity, the objective of this trial is to measure the physical activity levels and stationary time of adults living with TB in Kyrgyzstan. The information gathered will help guide future physical activity interventions.

### Who can participate?

People over 18 years old who suffer from tuberculosis

### What does the study involve?

Participants will wear a small device (accelerometer) to measure their activity levels for seven days.

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

Benefits of participation are to contribute to informing new knowledge of the physical activity levels of patients with post-TB lung disease in Kyrgyzstan. There are no risks to participation.

### Where is the study run from?

National Center of Cardiology and Internal Medicine, Kyrgyzstan

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

September 2019 to March 2021

### Who is funding the study?

National Institute for Health Research (NIHR), UK

Who is the main contact?

Dr Mark Orme

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## Contact information

### Type(s)

Public

### Contact name

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## Additional identifiers

### EudraCT/CTIS number

Nil known

**IRAS number**

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

Version 1

## **Study information**

### **Scientific Title**

A cross sectional study examining physical activity levels and stationary time in adults living with tuberculosis: Global RECHARGE Kyrgyzstan

### **Acronym**

Global RECHARGE Kyrgyzstan (Physical activity)

### **Study objectives**

Data is lacking surrounding the physical activity levels and stationary time of adults living with tuberculosis in Kyrgyzstan

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Current ethics approval as of 23/10/2019:

1. Approved 22/07/2019, Ethics Committee, National Centre of Cardiology and Internal Medicine (3 Togolok Moldo str, 720040, Bishkek, Kyrgyz Republic), ref: Protocol #17
2. Approved 16/09/2019, University of Leicester Ethics Committee (The University of Leicester, University Road, Leicester, LE1 7RH, United Kingdom; +44 (0)1162522522; ethicsapp@leicester.ac.uk), ref: 22293

Previous ethics approval:

1. Approved 22/07/2019, Ethics Committee, National Centre of Cardiology and Internal Medicine (3 Togolok Moldo str, 720040, Bishkek, Kyrgyz Republic), ref: Protocol #17
2. Approval pending, University of Leicester Ethics Committee (The University of Leicester, University Road, Leicester, LE1 7RH, United Kingdom; ethicsapp@leicester.ac.uk), ref:

### **Study design**

Observational cross sectional study

### **Primary study design**

Observational

### **Secondary study design**

Cross sectional study

### **Study setting(s)**

Hospital

**Study type(s)**

Quality of life

**Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

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

Tuberculosis

**Interventions**

Patients will be identified from the City TB Hospital, NCCIM and family medical centres jointly by the TB doctors and the rehabilitation team. Eligible patients will be informed verbally about the study by their clinician and they will be provided with a typed Patient Information Sheet written in their own language, and invited to take part in the study. They will be provided with an opportunity to ask questions, and if willing to take part in the study, they will be asked to provide written informed consent.

Physical activity and stationary time will be assessed using a tri-axial accelerometer (Actigraph GT3x).

Participants will be asked to wear the monitor during waking hours for seven consecutive days. Demographics will be recorded.

**Intervention Type**

Other

**Primary outcome measure**

Volume and patterns of physical activity and stationary time measured using an accelerometer over seven consecutive days.

**Secondary outcome measures**

1. Seasonal effects on activity (measured by accelerometer) assessed by stratifying the year into months and seasons (Spring, Summer, Autumn, Winter)
2. Bouts of activity (measured by accelerometer)

**Overall study start date**

01/04/2018

**Completion date**

31/03/2021

**Reason abandoned (if study stopped)**

This study was terminated before it began due to the impact of the COVID-19 pandemic on timelines and resources

**Eligibility****Key inclusion criteria**

1. Aged  $\geq 18$  years;
2. Definite diagnosis of a TB-negative patients with PTBLD lung disease

3. Previous TB treatment or finished treatment
4. Medical Research Council dyspnoea score grade 2 or higher

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

80

**Key exclusion criteria**

1. Comorbidities such as severe or unstable cardiovascular, other internal diseases and locomotor difficulties that preclude exercise
2. Malignant disease such as lung cancer
3. Evidence of active TB on Chest X-ray or sputum tests within 1 month of assessment
4. Unable or unwilling to provide informed consent

**Date of first enrolment**

01/05/2020

**Date of final enrolment**

30/04/2021

**Locations****Countries of recruitment**

Kyrgyzstan

**Study participating centre**

**National Center of Cardiology and Internal Medicine**

3 Togolok Moldo Street

Bishkek

Kyrgyzstan

720040

**Sponsor information**

**Organisation**

University of Leicester

**Sponsor details**

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**Sponsor type**

University/education

**Website**

<https://le.ac.uk/>

**ROR**

<https://ror.org/04h699437>

**Funder(s)****Funder type**

Government

**Funder Name**

National Institute for Health Research

**Results and Publications****Publication and dissemination plan**

It is anticipated that the results from this study will be published in international journals and presented locally, nationally and internationally at appropriate meetings and conferences. All data that will be collected is anticipated to be published.

**Intention to publish date**

31/03/2021

**Individual participant data (IPD) sharing plan**

The current data sharing plans for this study are unknown and will be available at a later date

**IPD sharing plan summary**

Data sharing statement to be made available at a later date