

Exploring physical activity levels of adults living with tuberculosis in Kyrgyzstan

Submission date 28/08/2019	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2019	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 08/07/2022	Condition category 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?

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Contact information

Type(s)

Public

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Quality of life

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(s)

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

Key secondary outcome(s)

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)

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 ≥ 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

ROR

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

Funder(s)**Funder type**

Government

Funder Name

Results and Publications

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