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Exploring physical activity levels of adults living with tuberculosis in Kyrgyzstan

Submission date 28/08/2019	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/09/2019	**Overall study status** Stopped	
Last Edited 08/07/2022	**Condition category** Respiratory	

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

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 ≥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
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Sponsor information

Organisation
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Sponsor type
University/education

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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