

# Effectiveness and cost-effectiveness of an mHealth intervention (mTB-Tobacco) for smoking cessation in people with tuberculosis

<b>Submission date</b> 29/08/2023	<b>Recruitment status</b> Recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 11/09/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 19/03/2025	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Quit 4 TB Trial is a research study on tobacco smoking among tuberculosis (TB) patients. TB is an infectious disease caused by bacteria that usually attacks the lungs but can also affect any part of the body, including bone, brain and nervous system. It is spread when a person inhales tiny droplets from the coughs or sneezes of an infected person. Tobacco smoking is bad for health, particularly for those with TB. If TB patients continue to smoke during their treatment they may not recover from it. Quit 4 TB trial is aimed to test how best to get TB patients to stop smoking and to successfully complete TB treatment. However, tobacco smoking is highly addictive and smokers find it difficult to give up. Researchers have designed a mTB-Tobacco programme in which we will send motivational and informative short message service (SMS) messages throughout a patient's TB treatment.

### Who can participate?

Patients aged at least 15 years with drug-sensitive pulmonary TB in the last 4 weeks who currently smoke tobacco on a daily basis or have only stopped or reduced smoking (less than daily) since being diagnosed with TB

### What does the study involve?

Each participating clinic will be randomly allocated into a group by chance. Patients who attend the health centre that is allocated to the mTB-Tobacco group will be given access to the mHealth smoking cessation package. mHealth is a general term for the use of mobile devices (e.g. mobile phones and other wireless technology) in medical care and public health services. mTB-Tobacco programme delivers SMS messages via mobile phones to TB patients. Participants in this group must have access to a personal mobile phone to receive SMS content. The researchers will send a total of 134 SMS messages over a period of 6 months to help them quit smoking and complete their TB treatment effectively. In the first 2 months, the frequency of messages would be 4 to 5 messages per day, in the next two months the frequency would reduce to 1 or 2 messages per day and in the last 2 months there would be 1 message sent per week. Patients who attend the health centre that is allocated to standard usual care will receive education leaflets from TB health professionals.

What are the possible benefits and risks of participating?

Participants will be provided with some advice on how to quit smoking and successfully complete TB treatment. There are no potential risks/harms associated with taking part in this study.

Where is the study run from?

1. ARK Foundation (Bangladesh)
2. The Initiative (Pakistan)
3. University of Edinburgh (UK)

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

June 2022 to March 2026

Who is funding the study?

The NIHR Global Health Research Unit on Respiratory Health (RESPIRE) (UK)

Who is the main contact?

1. Dr Amina Khan, aminakhan67@gmail.com
2. Prof. Rumana Huque, rumanah14@yahoo.com

### **Study website**

<https://www.ed.ac.uk/usher/respire/research/preventable-risk-factors/current/quit4tb>

## **Contact information**

### **Type(s)**

Principal Investigator

### **Contact name**

Prof Kamran Siddiqi

### **ORCID ID**

<https://orcid.org/0000-0003-1529-7778>

### **Contact details**

The Hull York Medical School  
University of York  
York  
United Kingdom  
YO10 5DD  
+44 (0)1904 321335  
[kamran.siddiqi@york.ac.uk](mailto:kamran.siddiqi@york.ac.uk)

### **Type(s)**

Principal Investigator

### **Contact name**

Prof Rumana Huque

### **Contact details**

AKR Foundation  
Suite C-3 & C-4  
House #06  
Road # 109  
Gulshan-2, Dhaka-1212  
Dhaka  
Bangladesh  
1212  
+88 (0)2 55069866  
Rumana@arkfoundationbd.org

**Type(s)**

Principal Investigator

**Contact name**

Dr Amina Khan

**Contact details**

The Initiative,  
Main Office  
Orange Grove Farm, Main Korung Rd  
Banigala  
Islamabad  
Pakistan  
44000  
+92 (0)51 8732651  
amina.khan@theinitiative.org.pk

**Type(s)**

Scientific

**Contact name**

Dr Maham Zahid

**ORCID ID**

<http://orcid.org/0000-0003-2878-0435>

**Contact details**

The Initiative  
103 Iqbal Heights  
Korang Road  
Bani Gala  
Islamabad  
Pakistan  
-  
+923425091321  
zahidmaham487@gmail.com

**Type(s)**

Scientific

**Contact name**

Dr Ai Keow Lim

**ORCID ID**

<http://orcid.org/0000-0002-3189-0558>

**Contact details**

Usher Institute  
The University of Edinburgh  
Room 216B  
Doorway 3, Teviot Place  
Edinburgh  
United Kingdom  
EH8 9AG  
+44 (0)131 6509452  
[ak.lim@ed.ac.uk](mailto:ak.lim@ed.ac.uk)

## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

AC22139

## Study information

**Scientific Title**

A mHealth intervention (mTB-Tobacco) for smoking cessation in people with tuberculosis: a two-stage adaptive design, multi-country randomised controlled trial

**Acronym**

Quit 4 TB Trial

**Study objectives**

mTB Tobacco is more effective and cost effective than usual care. mTB Tobacco is as effective and cost effective as face-to-face behavioural support.

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

Approved 26/04/2023, Edinburgh Medical School Research Ethics Committee (EMREC) (University of Edinburgh, Edinburgh, EH16 4TJ, United Kingdom; +44 (0)131 242 7441; [emrec@ed.ac.uk](mailto:emrec@ed.ac.uk)), ref: EMREC-RESPIRE-23-01

## **Study design**

Two-stage adaptive design multi-country randomized controlled trial

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Hospital, Medical and other records

## **Study type(s)**

Prevention, Quality of life, Efficacy

## **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**

Smoking cessation in people with tuberculosis

## **Interventions**

Current interventions as of 19/03/2025:

This trial is a clustered RCT where health facilities will be randomly allocated to the different trial arms. The health facilities (clusters) would be randomised 2:2:1 to mTB-Tobacco (intervention A), face-to-face (intervention B), or standard care (Control). An independent statistician who will be blinded to centres, will identify and use computer-generated random-number lists to generate the allocation sequence. The allocation will be based on using minimisation to ensure balance across the groups on the average number of TB patients seen per month and geographical location (Bangladesh and Pakistan).

Using an adaptive design, the researchers will conduct a multi-centre, cluster randomized, controlled trial consisting of four phases. Phase 1 involves consultation with Patients and Public Involvement (PPI) group about the study processes. PPI members will also review and provide feedback on the participant facing materials. Phase 2 is the pilot study. In Phase 3 (superiority trial), which will last for 12 months (6 months recruitments and 6 months follow-ups), the researchers will compare mTB-Tobacco (intervention A) with usual care (control). In Phase 4 (non-inferiority trial), which will last for another 12 months (6 months recruitment and 6 months follow-ups), the researchers will compare mTB-Tobacco (intervention A) with face-to-face behavioural support (intervention B).

### **mTB-TOBACCO (INTERVENTION A)**

The mTB-Tobacco programme (intervention A) is designed to send short message service (SMS) content with two distinct areas of intervention. The first tries to instil behaviour change in patients to quit the habit of tobacco use and the second includes a combination of supportive motivational and informative messages through the period of TB treatment. The overall outcome is that a person is able to both successfully quit tobacco consumption and complete TB treatment.

### FACE-2-FACE BEHAVIOURAL SUPPORT (INTERVENTION B)

This consists of an adapted version of a pre-developed and proven effective intervention to help people to quit smoking and smokeless tobacco use.<sup>10</sup> This consists of two face-to-face sessions delivered at day 0 and day 5 (+2) and which last 10 and 5 minutes respectively. The sessions will be structured using an educational flipbook; the session on day 0 will be aimed at encouraging tobacco users to see themselves as non-users and set a plan for a quit date five days later; with a session on the quit date (day 5) to review progress. Further encouragement and support (if needed) will be offered at a subsequent visit at week 5.

### STANDARDISED USUAL CARE

The TB health professionals will be provided with patient education leaflets to be given out to all patients allocated to the respective trial arm. Leaflets for patients and others in the house contain information on the harmful effects of tobacco and advice on stopping its use.

---

### Previous interventions:

This trial is a clustered RCT where health facilities will be randomly allocated to the different trial arms. The health facilities (clusters) would be randomised 2:2:1 to mTB-Tobacco (intervention A), face-to-face (intervention B), or standard care (Control). An independent statistician who will be blinded to centres, will identify and use computer-generated random-number lists to generate the allocation sequence. The allocation will be based on using minimisation to ensure balance across the groups on the average number of TB patients seen per month and geographical location (Bangladesh and Pakistan).

Using an adaptive design, the researchers will conduct a multi-centre, cluster randomized, controlled trial consisting of two phases. In Phase 1 (superiority trial), which will last for 12 months (6 months recruitments and 6 months follow-ups), the researchers will compare mTB-Tobacco (intervention A) with usual care (control). In Phase 2 (non-inferiority trial), which will last for another 12 months (6 months recruitment and 6 months follow-ups), the researchers will compare mTB-Tobacco (intervention A) with face-to-face behavioural support (intervention B).

### mTB-TOBACCO (INTERVENTION A)

The mTB-Tobacco programme (intervention A) is designed to send short message service (SMS) content with two distinct areas of intervention. The first tries to instil behaviour change in patients to quit the habit of tobacco use and the second includes a combination of supportive motivational and informative messages through the period of TB treatment. The overall outcome is that a person is able to both successfully quit tobacco consumption and complete TB treatment.

### FACE-2-FACE BEHAVIOURAL SUPPORT (INTERVENTION B)

This consists of an adapted version of a pre-developed and proven effective intervention to help people to quit smoking and smokeless tobacco use.<sup>10</sup> This consists of two face-to-face sessions delivered at day 0 and day 5 (+2) and which last 10 and 5 minutes respectively. The sessions will be structured using an educational flipbook; the session on day 0 will be aimed at encouraging tobacco users to see themselves as non-users and set a plan for a quit date five days later; with a session on the quit date (day 5) to review progress. Further encouragement and support (if needed) will be offered at a subsequent visit at week 5.

### STANDARDISED USUAL CARE

The TB health professionals will be provided with patient education leaflets to be given out to

all patients allocated to the respective trial arm. Leaflets for patients and others in the house contain information on the harmful effects of tobacco and advice on stopping its use.

## **Intervention Type**

Mixed

## **Primary outcome measure**

Biochemically verified continuous abstinence at 6 months post-randomisation. Abstinence is defined as self-report of not having used more than 5 cigarettes, bidis, or water pipe sessions since the quit date, verified biochemically by a breath carbon monoxide (CO) reading of less than 10 ppm at month 6.

## **Secondary outcome measures**

1. Point abstinence, defined as a self-report of not using tobacco in the previous 7 days, assessed at week 9 and month 6
2. Adherence to TB treatment: all registered TB patients' medication logs (for anti-TB medication) are recorded on the 'Treatment Support Card'; a copy of this card would be requested from the TB paramedic by the RA at Week 9 and Month 6 and attached with the patient case report form
3. TB Programme outcomes: the proportion of treatment success (including cured and completed treatment), treatment failure, defaulted and died will be recorded from the TB register (TB03) at month 6. The definitions of these outcomes are as follows:
  - 3.1. Cured: A patient who was initially smear-positive and who was smear-negative in the last month of treatment (at month 6) and on at least one previous occasion
  - 3.2. Completed treatment: A patient who completed treatment (at month 6) but did not meet the criteria for cure or failure
  - 3.3.. Treatment failure: A patient who was initially smear-positive and who remained smear-positive at month 6 or later during treatment
  - 3.4.. Defaulted: A patient whose treatment was interrupted for 2 consecutive months or more
  - 3.5. Died: A patient who died from any cause during treatment
  - 3.6.. Relapse: A patient who was previously treated for TB, was declared cured or treatment completed at the end of his most recent course of treatment, and is now diagnosed with a recurrent episode of TB (either a true relapse or a new episode of TB caused by reinfection)

## **Overall study start date**

01/06/2022

## **Completion date**

31/03/2026

# **Eligibility**

## **Key inclusion criteria**

1. Age at least 15 years (counted as adult TB patients in Bangladesh and Pakistan)
2. Willing and able to provide written informed consent
3. Diagnosed with drug-sensitive pulmonary TB (smear positive or negative) in the last 4 weeks
4. Currently smokes tobacco on a daily basis or has only stopped or reduced smoking (less than daily) since being diagnosed with TB
5. Willing to quit tobacco use
6. Access to personal mobile phone

**Participant type(s)**

Patient

**Age group**

Mixed

**Lower age limit**

15 Years

**Sex**

Both

**Target number of participants**

Phase 3 (superiority trial): 1080 TB smoker patients; Phase 4 (non-superiority trial): 1620 TB smoker patients

**Key exclusion criteria**

1. Less than 15 years of age
2. Retreatment TB, multidrug-resistant (MDR) TB, miliary or extrapulmonary TB
3. Currently using any pharmacotherapy for tobacco dependence
4. Unwilling or unable to provide written informed consent

**Date of first enrolment**

01/09/2023

**Date of final enrolment**

30/09/2025

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

Bangladesh

Pakistan

**Study participating centre****Ark Foundation**

Suite C3-4, House, 6 Rd 109

Dhaka

Bangladesh

1212

**Study participating centre****The Initiative**

Orange Grove Farm

Main Korung Road

Malpur



Bani Gala  
Islamabad  
Pakistan  
44000

## Sponsor information

### Organisation

University of Edinburgh

### Sponsor details

Royal Infirmary of Edinburgh Site:  
Research & Development Management Suite  
The Queen's Medical Research Institute  
47 Little France Crescent  
Edinburgh  
Scotland  
United Kingdom  
EH16 4TJ  
+44 (0)131 242 3330  
resgov@accord.scot

### Sponsor type

University/education

### Website

<http://www.ed.ac.uk/home>

### ROR

<https://ror.org/01nrxf90>

## 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

**Publication and dissemination plan**

The results of the trial will be published in international journals and presented at national and international meetings in both TB care and Tobacco Control. A lay summary of results will be distributed to local TB care networks.

**Intention to publish date**  
31/03/2027

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

De-identified datasets generated during and/or analysed during the current study will be stored in secure, password-protected DataVault / DataShare (to be decided at a later date) at the University of Edinburgh for a minimum of 10 years following the end of the study. DataShare is an open-access repository for anonymised data, which means that all non-identifiable data is freely available. DataVault is a secure repository for sensitive information which can only be accessed by approved researchers who have undergone a rigorous application and review process.

**IPD sharing plan summary**  
Stored in publicly available repository

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol (preprint)</a>		10/12/2024	10/01/2025	No	No
<a href="#">Protocol article</a>		25/02/2025	26/02/2025	Yes	No