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

Submission date
29/08/2023

Recruitment status
No longer recruiting

Registration date
11/09/2023

Overall study status
Ongoing

Last Edited
06/01/2026

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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 April 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

Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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), ref: EMREC-RESPIRE-23-01

Study design
Two-stage adaptive design multi-country randomized controlled trial

Primary study design

Interventional

Study type(s)
Efficacy, Prevention, Quality of life

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.10 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)
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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(s)
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.

Key secondary outcome(s))

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. 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)

Completion date
29/04/2026

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
15 years

Upper age limit
99 years

Sex

All

Total final enrolment
2860

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
29/10/2025

Locations

Countries of recruitment
Bangladesh

Pakistan

Study participating centre
Ark Foundation
Suite C3-4, House, 6 Rd 109
Dhaka
Bangladesh
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Study participating centre
The Initiative
Orange Grove Farm
Main Korung Road
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44000

Sponsor information

Organisation
University of Edinburgh

ROR
https://ror.org/01nrxwf90

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

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?
Results article		22/12/2025	06/01/2026	Yes	No
Protocol article		25/02/2025	26/02/2025	Yes	No

Protocol (preprint)	10/12/2024	10/01/2025	No	No
Study website	11/11/2025	11/11/2025	No	Yes