

# An approach to reduce tobacco use among TB patients

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 23/05/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 23/05/2019	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Tuberculosis (TB) and tobacco use are two public health concerns and independently pose considerable threats to global health. In 2011, nearly 6 million people died from tobacco use globally and tobacco use is responsible for 16% and 7% of annual deaths among men and women, respectively. Smoking is an established risk factor for developing TB, exacerbating TB, and dying from TB. Compared with people who have never smoked, smokers have twice the risk of TB infection. Globally, more than 20% of TB cases are attributable to smoking, so there is a critical need to reduce TB prevalence through tobacco cessation. Tobacco cessation increases adherence to treatment and the chances of getting treated among those with TB. However, tobacco cessation activities have not been integrated into routine TB treatment. The aim of this study is to use mHealth solutions to integrate tobacco control into TB programmes to reduce tobacco use and improve TB treatment outcomes in Uganda. The primary objective is to support TB patients to quit tobacco use. The secondary objectives are: a) to train health workers on mHealth solutions for TB-tobacco integration; b) to assess the time that participants take to quit tobacco use; c) to support TB patients to adhere to TB treatment.

### Who can participate?

Patients with TB within the study sites, who have been treated for less than two months, are residing within the catchment area of the study site, have not been on treatment before, and are at least 18 years of age.

### What does the study involve?

Participants are randomly allocated to one of two groups. One group receives text messages on tobacco cessation and TB treatment adherence and the other group receives only text messages on TB treatment adherence. Participants receive text messages for 4 months. Tobacco use cessation, knowledge on tobacco cessation among healthcare workers, time to quit tobacco use and TB adherence are all measured.

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

The possible benefit is getting reminders on the tobacco cessation which increases likelihood for good outcomes for TB patients.

Where is the study run from?  
23 hospitals and health centres in Uganda

When is the study starting and how long is it expected to run for?  
February 2017 to October 2020

Who is funding the study?  
The study is being funded by USAID through the National Academy of Sciences and Partnerships for Enhanced Engagement in Research (PEER)

Who is the main contact?  
Elizeus Rutebemberwa  
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## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
Nil known

## Study information

**Scientific Title**  
mHealth for TB-Tobacco: an approach to reduce tobacco use among TB patients

**Acronym**

mHealth TB-Tobacco

**Study objectives**

Using SMS messages encouraging patients with tuberculosis who use tobacco will not make them stop using tobacco.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 01/10/2018, Makerere University School of Public Health Higher Degrees Ethics and Research Committee (PO Box 7072, Kampala, Uganda; Tel: +256 (0)393291397; Email: wtusiime@musph.ac.ug), Number 487

**Study design**

Randomized controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Prevention

**Participant information sheet****Health condition(s) or problem(s) studied**

Tobacco use cessation

**Interventions**

The study is a randomised controlled trial. The study will target 634 TB patients; 317 in the intervention arm and 317 in the control arm randomized at the individual level using block randomization by the SMS provider. Participants in the intervention arm will be supported with text messages on tobacco cessation for 4 months. The control arm will receive SMS messages focusing on adherence to TB treatment but not those on tobacco cessation. However, the routine treatment for TB will continue as usual. The primary outcome is tobacco use cessation. Secondary outcomes include improved knowledge on tobacco cessation among healthcare workers, time to quit tobacco use and TB adherence. The study will take place in 24 health facilities in the country including the 13 regional referral hospitals, other 5 general hospitals in the country and the 6 health facilities in Kampala City where TB treatment is offered.

Analysis for the primary outcome smoking cessation will be done by comparing non-intervention and intervention participants. Adherence, defined as the extent to which patients follow the instructions they are given for prescribed treatments, will be measured using a checklist asking the health worker for the adherence level for the patient at the end of four months. Health

workers routinely measure adherence by looking at the pills which the patient would have taken compared to the chart filled. Patients routinely fill a chart as they take pills and also come with the empty packets showing how many pills they have taken. Those who would have consumed 90% of the expected number of pills are taken to have had adherence. Since this is a measure that is routinely taken, the researchers will get it from the health workers for that particular participant using a checklist.

### **Intervention Type**

Behavioural

### **Primary outcome measure**

Tobacco cessation measured by the presence of cotinine in urine at baseline and non-presence of cotinine in urine at cessation within four months of follow-up from baseline

### **Secondary outcome measures**

1. Time to cessation measured from the baseline to the time the participant says s/he has ceased using tobacco and confirmed by cotinine test
2. Adherence to TB treatment measured using a checklist asking the health worker for the adherence level for the patient at the end of 4 months
3. The number of cigarettes smoked per day measured using a questionnaire at baseline and after 4 months of intervention. This will only be in those who have not ceased using tobacco after four months of intervention

### **Overall study start date**

01/02/2017

### **Completion date**

30/10/2020

## **Eligibility**

### **Key inclusion criteria**

1. Aged over 18 years
2. Uses tobacco
3. On laboratory-confirmed TB treatment within the first two months
4. Has a mobile phone and is able to receive SMS messages on it
5. Has consented to the study

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

**Target number of participants**

634

**Key exclusion criteria**

1. Inpatients
2. Visitors to the health facility
3. Terminal illness like cancer
4. Mental or cognitive problems
5. Absconded on TB treatment before

**Date of first enrolment**

20/05/2019

**Date of final enrolment**

20/06/2020

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

Uganda

**Study participating centre**

**Referral hospitals in Uganda, government facilities in Kampala and four general hospitals of Rakai, Mityana, Buluba and Angal**

Makerere University

College of Health Sciences

Department of Health Policy, Planning and Management

Kampala

Uganda

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**Sponsor information****Organisation**

USAID

**Sponsor details**

The National Academies of Sciences, Engineering, and Medicine

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+1 (0)202 334 2000

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**Sponsor type**

Research organisation

**Website**

<http://sites.nationalacademies.org/pga/peer/index.htm>

**ROR**

<https://ror.org/01n6e6j62>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Partnerships for Enhanced Engagement in Research

## **Results and Publications**

**Publication and dissemination plan**

The protocol is not published yet but it is with the IRB of Makerere University School of Public Health. Contact person for IRB is wtusiime@musph.ac.ug. Publications will be done once the data is out. Dissemination will be done to the Ministry of Health.

**Intention to publish date**

31/12/2020

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

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

**IPD sharing plan summary**

Data sharing statement to be made available at a later date