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An approach to reduce tobacco use among TB patients

Submission date
14/05/2019

Recruitment status
No longer recruiting

Registration date
23/05/2019

Overall study status
Completed

Last Edited
23/05/2019

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 group. One group receives text messages on tobacco cessation and TB treatment adherence and 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Prevention

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
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Sponsor information

Organisation
USAID

ROR
https://ror.org/01n6e6j62

Funder(s)

Funder type
Research organisation

Funder Name
Partnerships for Enhanced Engagement in Research

Results and Publications

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