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Electronic monitors for improving tuberculosis patients' treatment adherence in China

Submission date
15/07/2023

Recruitment status
No longer recruiting

Registration date
29/07/2023

Overall study status
Ongoing

Last Edited
28/07/2023

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Treatment non-adherence poses a serious risk to survival and hinders the improvement of tuberculosis (TB) control effectiveness in Inner Mongolia, China. To improve treatment adherence and health outcomes in Inner Mongolia, this study aims to maximize the impact of an electronic monitor and smartphone app (EM program) by developing interventions that optimize the EM program, putting it into practice and evaluating it, and developing scale-up activities of the optimized EM program.
To represent the east, central, and western regions of Inner Mongolia, China, the study will be carried out in the cities of Chifeng, Hohhot, and Baotou. The researchers chose these study locations based on the extent to which the EM program has been implemented, the region, the size of the population, the traffic situation, and the program's representativeness. Primary care facilities (such as community health centers and township hospitals) will use the intervention. Facilities that are part of the intervention will run the optimized EM program, and those that are not will run the standard EM program.

Who can participate?
Patients who have been diagnosed in the TB dispensary following national and international care guidelines and who are beginning a typical 6-month short course of chemotherapy in community health centers or township hospitals. TB patients must satisfy the following requirements to be considered eligible: aged 15 years or over; no speech, mental, visual, auditory, or other communication impairments; and no family member residing in the same household who has already been enrolled in the study.

What does the study involve?
Six new pulmonary TB patients (two in each district) will be randomly allocated into the intervention or control groups as pilot cases. The feasibility and acceptability of the intervention will then be evaluated after 2 weeks of observation. A revision of the implementation plan will be made in light of the results of the pilot study.
Primary care facilities (such as community health centers and township hospitals) will use the intervention. Facilities that are part of the intervention will run the optimized EM program, and those that are not will run the standard EM program. Community health centers and township hospitals had to sign up for the electronic monitors in accordance with the current EM program.

Beyond holding the TB medication, the electronic monitors served two purposes. First, they used human voice recordings to remind patients to take their medication on time. Second, they linked a computer with a mobile app to send the history of patient adherence to a cloud-based server

What are the possible benefits and risks of participating?
This study aims to maximize the impact of an electronic monitor and smartphone app (EM program) by developing interventions that optimize the EM program, putting it into practice and evaluating it, and developing scale-up activities of the optimized EM program. All patients receive standard treatment and the management strategy following the national TB guideline. There will have no potential harm to the participants.

Where is the study run from?
1. The National Natural Science Foundation of China
2. The Natural Science Foundation of Inner Mongolia

When is the study starting and how long is it expected to run for?
March 2020 to December 2025

Who is funding the study?
1. The National Natural Science Foundation of China
2. The Natural Science Foundation of Inner Mongolia

Who is the main contact?
Prof. Min Su, sumin1227@126.com

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
Grant number: 72204128 (The National Natural Science Foundation of China), Optimal Mechanism and Impact Evaluation of the Tuberculosis Management Model via Electronic Monitors and a Mobile App in Primary Care Facilities in Frontier Ethnic Regions

Study information

Scientific Title
Improving tuberculosis (TB) patients' treatment adherence via optimized electronic monitors in China: a pragmatic parallel cluster-randomized trial

Study objectives
This study will generate a context-sensitive, evidence-based implementation strategy for electronic monitor (EM) program optimization in collaboration with the Chinese Center for Disease Control and Prevention and Inner Mongolia Center for Disease Control and Prevention, with the goal of enhancing the reach, effectiveness, adoption, implementation, and maintenance of the EM program in Inner Mongolia from a multidisciplinary research perspective.

By maximizing the EM program's implementation, the overall objective is to improve the treatment adherence and health outcomes of TB patients. The study's specific goals include:
1. To identify the barriers and facilitators of implementing an EM program that aims to improve TB patients' treatment adherence and health outcomes in Inner Mongolia, China
2. To co-produce context-sensitive, and evidence-based interventions that optimize the EM program, and implement the optimized interventions, and evaluate the implementation strategies regarding acceptability, cost-effectiveness, and long-term effects in remote areas of China.
3. To develop strategic options for the scalability and generalizability of the optimized interventions.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/03/2020, The Xi'an Jiaotong University Health Science Center's Ethics Committee (No. 28 West Xianning Road, Xi'an, 710049, China; +86 (0)15891725861; fanxj112@xjtu.edu.cn), ref: 2020-119

Study design
Interventional prospective unblinded multicenter pragmatic individual randomized controlled trial

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Pulmonary tuberculosis

Interventions
After recruitment, randomization will be conducted using the computer random list generated by STATA 15.0 software. A 1:1 ratio of patients will be randomly assigned to the intervention group or the control group. Sealed envelopes containing the group numbers will be kept by the research manager, who is not directly involved in participant recruitment or follow-up. The research designer will keep the group assignment results until the end of the data analysis period.

Primary care facilities (such as community health centers and township hospitals) will use the EM program. Facilities that are part of the intervention will run the optimized EM program, and those that are not will run the standard EM program. Community health centers and township hospitals had to sign up for the electronic monitors in accordance with the current EM program. Beyond holding the TB medication, the electronic monitors served two purposes. First, they used human voice recordings to remind patients to take their medication on time. Second, they linked a computer with a mobile app to send the history of patient adherence to a cloud-based server. The researchers will incorporate ERIC-based implementation strategies into the current EM program to create an optimized EM program.

The total duration of intervention: 20 months
Follow-up: 27 months

Intervention Type
Mixed

Primary outcome measure
Treatment adherence calculated from monthly level data for each patient indicating the number of doses taken per month. The researchers will identify treatment adherence ≥80% as high adherence, otherwise it is non-adherence. Treatment adherence is measured every month during the study period.

Secondary outcome measures
Measured at baseline, 6, 12, 18, 24, 30, and 36 months:
1. Treatment completion rate, as defined by the WHO standard definitions: a TB patient who finished treatment without having evidence of treatment failure, but who did not have negative sputum smear or culture results in at least one prior instance or in the final month of treatment, either because the tests were not conducted or the results were not available

2. Loss to follow-up rate, as defined by the WHO standard definitions: a TB patient who did not initiate treatment or whose treatment was interrupted for two consecutive months or more
3. Treatment failure, as defined by the WHO standard definitions: a TB patient who received treatment and had positive results from a sputum smear or culture at month five or later
4. Death, as defined by the WHO standard definitions: a TB patient who passed away before starting treatment or while receiving it, for any reason

Based on the RE-AIM framework, the impact of the optimized EM program is also assessed in comparison to standard care for the subsequent secondary outcome measures at baseline, 6, 12, 18, 24, 30, and 36 months:
5. Reach: the quantity and percentage of TB patients who participate in the medication e-monitoring program, as well as their motivations for doing so
6. Effectiveness: the effects of the improved e-monitoring program on TB treatment outcomes, treatment adherence, and financial outcomes
7. Adoption: the number of TB patients enrolled in the optimized e-monitoring program, the number of primary care providers enrolled in the optimized e-monitoring program, and the acceptance level of the optimized e-monitoring program among directors from primary care facilities and CDC
8. Implementation:
8.1. Fidelity: the extent to which the optimized e-monitoring program is implemented as per the original protocol
8.2. Feasibility: the extent to which the optimized e-monitoring program can be implemented in a specific setting
8.3. Outer context: macro-level external factors including social, funding, and leadership
8.4. Inner context: micro-level internal factors including CDC partnership, programmatic staff, feedback, primary care facility, and individual level
9. Maintenance:
9.1. Sustainability of effectiveness: views on maintaining effectiveness from policymakers, directors of CDC and primary care facilities, healthcare providers, and TB patients
9.2. Stakeholders' satisfaction: satisfaction with the effectiveness and implementation strategy of the optimized e-monitoring program among policymakers, directors of CDC and primary care facilities, health care providers, and TB patients
9.3. Financial sustainability: views on funding and return on investment from policymakers and directors of CDC and primary care facilities
9.4. Institutionalization of interventions: core components that are transferable and require local adaptation for replication in other settings

Data source:
Inner Mongolia Center for Disease Control and Prevention will regularly gather patient data, such as name, age, gender, education, occupation, diagnosis, and treatment results. The results of sputum smears performed at baseline, 6, 12, 18, 24, 30, and 36 months, as well as treatment completion, loss to follow-up, treatment failed, and death will be recorded as routinely tracked treatment outcomes.

In terms of the implementation outcomes, a semi-structured interview will be used to gather the data. Each sampling site will host in-depth interviews. The researchers will consult the managers and staff at each site to determine which employees are best suited for an interview. They will obtain informed consent forms. At each site, interviews will take place over the phone or in person and last for 60 to 90 minutes. The researchers will take notes and record the interviews. Two researchers will independently code the recordings and notes. Additionally, two researchers will conduct the analysis independently at each stage of coding, indexing, and interpreting and come to a consensus in the event of any disagreement. The policy documents,

institution reports, and project meeting notes will also be used throughout the study to identify implementation challenges and opportunities, improve the program, and give site staff feedback. The qualitative analysis program NVivo 12.0 will be used to examine all interview data.

Overall study start date
20/03/2020

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. The study sample will consist of patients who have been diagnosed in the TB dispensary following national and international care guidelines and who are beginning a typical 6-month short course of chemotherapy in community health centers or township hospitals.
2. TB patients must satisfy the following requirements to be considered eligible:
2.1. Aged 15 years or over
2.2. No speech, mental, visual, auditory, or other communication impairments
2.3. No family member residing in the same household who has already been enrolled in the trial

Participant type(s)
Patient

Age group
Mixed

Lower age limit
15 Years

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Patients' age is less than 15 years old
2. Have communication impairments, such as speech, mental, visual, auditory, etc
3. Having any family member residing in the same household who has already been enrolled in the trial

Date of first enrolment
01/11/2023

Date of final enrolment
01/02/2025

Locations

Countries of recruitment
China

Study participating centre
Primary care facilities (such as community health centers and township hospitals) in Chifeng
Chifeng
China
024000

Study participating centre
Primary care facilities (such as community health centers and township hospitals) in Hohhot
Hohhot
China
010000

Study participating centre
Primary care facilities (such as community health centers and township hospitals) in Baotoun
Baotou
China
014000

Sponsor information

Organisation
National Natural Science Foundation of China

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Sponsor type
Research organisation

Website
http://www.nsfc.gov.cn/publish/portal1/

ROR

https://ror.org/01h0zpd94

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Natural Science Foundation of Inner Mongolia

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Sponsor type
Research organisation

Funder(s)

Funder type
Research organisation

Funder Name
National Natural Science Foundation of China

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, , NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Funder Name
Natural Science Foundation of Inner Mongolia

Alternative Name(s)

Inner Mongolian Natural Science Foundation, Inner Mongolia Provincial Natural Science Foundation, Natural Science Foundation of Inner Mongolia, Inner Mongolia Natural Science Foundation of China, Inner Mongolia Natural Science Foundation

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

Publication and dissemination plan
This study will be done over a 28-month period, with a 3-month preparation and pilot phase, a 15-month participate recruitment phase, with a 6/7-momth treatment phase for all patients, and a 3-month data analysis and write-up stage. A 12-month follow-up study of all participates will be conducted after they end treatment under the optimized EM program to look at the treatment outcomes, and implementation strategies between the treatment arms. Results of the follow-up study will be reported in a separate paper from the trial results.

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan
The anonymized patient-level data and statistical code generated during and/or analyzed during the current study will be available upon reasonable request to Prof. Min Su (sumin1227@126.com) or Prof. Xiaolin Wei (xiaolin.wei@utoronto.ca) after all papers of this study have been published and within 5 years after the trial ended. The data can only be used for research and shared with research organizations/qualified researchers. Consent for data use will be obtained during patient recruitment. A confidential agreement has to be signed between the applicant and the local CDC before data sharing according to local policy requirements.

IPD sharing plan summary
Available on request