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Community trial of new methods in tuberculosis treatment management

Submission date
28/05/2011

Recruitment status
No longer recruiting

Registration date
21/07/2011

Overall study status
Completed

Last Edited
16/09/2015

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims:
Tuberculosis (TB) is a bacterial infection that mainly affects the lungs. China has the second largest number of TB cases in the world, next only to India. New technology such as medication monitoring and mobile phone text messaging may provide a good opportunity for improving the treatment of TB . The aim of this study to find out whether mobile text messaging and medication monitoring can improve adherence to TB medication and the outcomes of TB treatment.

Who can participate?
Newly registered TB patients aged 18 and over from 36 districts/counties in four provinces (Chongqing, Hubei, Jiangsu and Heilongjiang) in China.

What does the study involve?
The 36 districts/counties are randomly allocated to one of four groups. In the first group patients are provided with mobile phones. On medication intake days patients are sent a short message service (SMS) to remind them to take their medication. They respond with a brief message when they have taken their medication. Doctors in the TB dispensary collect the SMS feedback from patients to assess how many doses are missed in a month. Based on the number of missed doses, there will be additional visits from the township/village doctor. In the second group patients are provided with a medication monitor box with reminding functions. This tool is used to remind patients to take their tuberculosis medication and also records drug intake. Doctors at the TB dispensary collect the drug intake record from the medication monitor monthly to assess how many doses are missed in a month. Based on the number of missed doses, there will be additional visits from the township/village doctor. In the third group patients are provided with both the mobile phone and the medication monitor box to remind them to take their medication and to record drug intake. The drug intake record from the medication monitor and SMS from patients are collected monthly, and the number of doses missed in a month is calculated using the drug intake record of the medication monitor. Based on the number of missed doses, there will be additional visits from the township/village doctor. In the fourth group patients are managed based on the current standard of care.

What are the possible benefits and risks of participating?
There are no major risks in taking part in the study.

Where is the study run from?
36 districts/counties in four provinces (Chongqing, Hubei, Jiangsu and Heilongjiang) in China.

When is the study starting and how long is it expected to run for?
June 2011 to August 2012.

Who is funding the study?
The Bill and Melinda Gates Foundation (USA).

Who is the main contact?
Shiwen Jiang
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
51914

Study information

Scientific Title
Cluster randomized trial of using mobile text messaging and a medication monitor in tuberculosis (TB) case management

Study objectives
Innovative approaches for enhancing TB patient treatment management such as mobile text messaging and medication monitor can improve adherence to TB medication and outcomes of TB treatment

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethical Review Committee of China CDC. 12/07/2010, ref: 201008
2. London School of Hygiene and Topical Medicine Ethics Committee, 23/06/2010, ref: 5704

Study design
Cluster randomized non-blinded controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Tuberculosis

Interventions
This is a cluster randomised non blinded trial. Clusters are defined as a county or district. This is a four armed trial, three intervention arms and one control arm:
1. Mobile phone
Patients are provided with mobile phones as a reminding tool to take their tuberculosis medication. On medication intake days patients are sent a SMS to remind them to take their medication. They respond with a brief message when medication is taken. Doctors in TB dispensary collect the SMS feedback from patients to assess how many doses are missed in a month. Based on the missed doses, additional intervention and incentive mechanisms are implemented such as visits from the township/village doctor and incentives per visit given to the township/village doctor.
2. Medication monitor
Patients are provided with a medication monitor box with reminding functions. This tool is used to remind patients to their tuberculosis medication and also records drug intake. Doctors at the TB dispensary collect the drug intake record from medication monitor monthly to assess that how many doses are missed in a month. Based on the missed doses, additional intervention and incentive mechanism are implemented as described in the mobile phone intervention (1)
3. Mobile phone and medication monitor
Patients are provided with both the mobile phone and medication monitor box with reminding function for as tools for communication, reminding and recording drug intake. The drugs intake record from medication monitor and SMS from patients are collected monthly, and the number of doses missed in a month is calculated using the drug intake record of the medication monitor. Based on the missed doses, additional intervention and incentive mechanism are implemented as described in the mobile phone intervention (1)
4. Control
Patients are managed based on the current standard of care.

All patients will be followed up to the end of tuberculosis treatment.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The mean proportion of months a patient has at least 3 doses missed (this is based on pill count data from the medication monitor box)

Key secondary outcome(s))
1. The mean proportion of months a patient has at least 7 doses missed
2. The mean proportion of overall missed doses
3. Proportion of patients defined as non-adherent (at least 10% of doses missed)
4. Proportion of patients defaulting during TB treatment
5. Proportion of smear positive TB cases who become smear negative at 2 months
6. The proportion of patients with treatment outcome of cure or completed treatment

Completion date
31/08/2012

Eligibility

Key inclusion criteria
1. TB patients, smear-positive or smear-negative, recruited from the study clusters (county /district)
2. Willing to participate in the study
3. Conscious without any mental disease
4. Conscious without any visual, auditory or language impairment
5. At least 18 years old
6. Patient or family member is able to read a short message service (SMS)/ text and use medication monitor after training

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Does not meet inclusion criteria
2. Patients with tuberculosis pleurisy
3. Patients with no sputum smear data at tuberculosis diagnosis

Date of first enrolment
01/06/2011

Date of final enrolment
31/08/2012

Locations

Countries of recruitment
China

Study participating centre
China Center for Disease Control and Prevention
Beijing
China
102206

Sponsor information

Organisation
China Center for Disease Control and Prevention (China)

ROR
https://ror.org/04wktzw65

Funder(s)

Funder type
Charity

Funder Name
Bill and Melinda Gates Foundation (Grant ref: 51914)

Alternative Name(s)
Bill & Melinda Gates Foundation, Gates Foundation, Gates Learning Foundation, William H. Gates Foundation, BMGF, B&MGF, GF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/09/2015		Yes	No