

Participant information sheet: control arm

**COMMUNITY TRIAL OF NEW METHODS IN TUBERCULOSIS TREATMENT
MANAGEMENT**

Health education

1. Tuberculosis is curable under standard treatment management with more than 6 months' treatment.
2. Taking medicine regularly is very important for cure the disease. Due to irregular medication or interruption of the course, drug-resistant TB is developed among a number of patients.
3. The symptoms of TB will be disappeared after being treated with anti-TB drugs. However, before conversion to the sputum smear negative, patients would not speak aloud, cough, and sneeze among the public.

Brief introduction of the new treatment management

1. DOT require patients to go to village clinic for taking TB drugs every two days, but it would cost more and result in inconvenience for doctors and patients.
2. Now, we use an electronic medication box to assist patients' treatment management.
3. Electronic medication box is FREE for patients who are enrolled in the study.
4. The electronic medication box we provided is only used for containing TB drugs. Please keep the box from water, children and fire.
5. Patients will return to the TB dispensary for monthly re-fills and for when to give spit specimens at 2, 5 and 6 months following start of TB treatment.
6. TB patients in other districts/counties are receiving other methods to improve TB adherence. We will then compare treatment adherence amongst patients from districts/counties receiving the other methods to improve TB adherence with patients receiving standard of care.

INFORMED CONSENT FOR COMMUNITY TRIAL OF NEW METHOD IN TUBERCULOSIS STANDARD
TREATMENT MANAGEMENT

(CONTROL ARM)

Dear patients,

Tuberculosis is curable under standard treatment management. However, due to irregular medication or interruption of the course, drug-resistant TB is developed among a number of patients. This makes their condition worse and results in the occurrence of incurable tuberculosis. To ensure medication is taken timely and treatment adherence is good, National Center for Tuberculosis Control and Prevention, China CDC, is conducting a community trial of new methods in tuberculosis treatment management

We are doing the research study and would like to invite you to take part. You will receive an electronic medication box, and your treatment management is conducted with the use of the facility. All information collected during the course of this study will be kept securely and confidentially. Your name and contact details will only be available to study staff, and will be stored electronically, completely separately from the other information.

Your decision to take part or not will not affect your health care. You can decide to stop taking part in the study at any time, without giving a reason. If you have any question on the study, you can enquire your doctor.

If you decide to take part, we will ask you to sign on a consent form.

National Center for Tuberculosis Control and Prevention, China CDC

I, _____ (insert name) have read the patient information sheet and understand my participation is voluntary and I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

hereby, state that I am willing to take part in the study and accept the use of electronic medicine box in the treatment management.

Patients Signature: _____ Date: _____

I have accurately informed the subjects of this document to the patients/recipients. He/she has accurately read informed consent and has the opportunity to raise question. I, hereby, guarantee that he/she sign this informed consent based on the voluntary principles.

Doctors (Name of Person taking consent) Signature: _____ Date: _____

Participant information sheet: cell phone arm

**COMMUNITY TRIAL OF NEW METHODS IN TUBERCULOSIS TREATMENT
MANAGEMENT**

Health education

4. Tuberculosis is curable under standard treatment management with more than 6 months' treatment.
5. Taking medicine regularly is very important for cure the disease. Due to irregular medication or interruption of the course, drug-resistant TB is developed among a number of patients.
6. The symptoms of TB will be disappeared after being treated with anti-TB drugs. However, before conversion to the sputum smear negative, patients would not speak aloud, cough, and sneeze among the public.

Brief introduction of the new treatment management

7. DOT require patients to go to village clinic for taking TB drugs every two days, but it would cost more and result in inconvenience for doctors and patients.
8. Now, we use new method with SMS and electronic medication box to conduct patients' treatment management.
9. Electronic medication box is FREE for patients who are enrolled in the study.
10. If patient has not a cell phone, we will provide a free one for him/her who is enrolled in the study.
11. Patients will return to the TB dispensary for monthly re-fills and for when to give spit specimens at 2, 5 and 6 months following start of TB treatment.
12. TB patients in other districts/counties are receiving standard of care or other methods to improve TB adherence. We will then compare treatment adherence amongst patients from districts/counties receiving the cell phone to improve TB adherence with patients receiving standard of care. We will also compare adherence amongst patients from districts/counties receiving the other methods with patients receiving standard of care.

What is the treatment management of cell phone?

1. To send SMS to remind patients for taking medicine on time
 - a) According to patients' requirement, Doctor /study member will set the time when patient receives the SMS by cell phone. SMS text is "please take the medication on time" and is the same for each reminder. Once receiving the SMS of reminding, patients should take medicines and make a reply with cell phone.
 - b) Up to three SMS reminders are sent to the patient on the day of medication, depending on whether the patient replies or not. These reminders are sent at the agreed time medication is to be taken and subsequently at 12noon and 6pm if no reply is received.

- c) The patient is expected to reply by SMS with or without text. Once a reply has been received the reminders stop for that day.
- 2. To send SMS to remind patients of the monthly dispensing visit
SMS reminder sent 4,3,2,1 days before the scheduled monthly follow-up visit.
- 3. Other issues of using cell phone for treatment management
 - a) To keep cell phone working, avoid cell phone out of power, recharge fee timely;
 - b) If taking medication in advanced, patient still need to reply the SMS by cell phone;
 - c) If any question and problem with cell phone, please contact your doctor or study member ASAP.
 - d) We will provide an electronic medication box which is only used for containing TB drugs. Please keep the box from water, children and fire.

INFORMED CONSENT FOR COMMUNITY TRIAL OF NEW METHOD IN TUBERCULOSIS STANDARD
TREATMENT MANAGEMENT
(MOBILE PONHE ARM)

Dear patients,

Tuberculosis is curable under standard treatment management. However, due to irregular medication or interruption of the course, drug-resistant TB is developed among a number of patients. This makes their condition worse and results in the occurrence of incurable tuberculosis. To ensure medication is taken timely and treatment adherence is good, National Center for Tuberculosis Control and Prevention, China CDC, is conducting a community trial of new methods in tuberculosis treatment management

We are doing the research study and would like to invite you to take part. You will receive a cell phone and an electronic medication box, and your treatment management is conducted with the use of the facilities. All information collected during the course of this study will be kept securely and confidentially. Your name and contact details will only be available to study staff, and will be stored electronically, completely separately from the other information.

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hereby, state that I am willing to take part in the study and accept the use of electronic medicine box in the treatment management.

Patients Signature: _____ Date: _____

I have accurately informed the subjects of this document to the patients/recipients. He/she has accurately read informed consent and has the opportunity to raise question. I, hereby, guarantee that he/she sign this informed consent based on the voluntary principles.

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COMMUNITY TRIAL OF NEW METHODS IN TUBERCULOSIS TREATMENT MANAGEMENT

Health education

7. Tuberculosis is curable under standard treatment management with more than 6 months' treatment.
8. Taking medicine regularly is very important for cure the disease. Due to irregular medication or interruption of the course, drug-resistant TB is developed among a number of patients.
9. The symptoms of TB will be disappeared after being treated with anti-TB drugs. However, before conversion to the sputum smear negative, patients would not speak aloud, cough, and sneeze among the public.

Brief introduction of the new treatment management

13. DOT require patients to go to village clinic for taking TB drugs every two days, but it would cost more and result in inconvenience for doctors and patients.
14. Now, we use new method with an electronic medication box to conduct patients' treatment management.
15. Electronic medication box is **FREE** for patients who are enrolled in the study.
16. Patients will return to the TB dispensary for monthly re-fills and for when to give spit specimens at 2, 5 and 6 months following start of TB treatment.
17. TB patients in other districts/counties are receiving standard of care or other methods to improve TB adherence. We will then compare treatment adherence amongst patients from districts/counties receiving the electronic medication box to improve TB adherence with patients receiving standard of care. We will also compare adherence amongst patients from districts/counties receiving the other methods with patients receiving standard of care.

What is the treatment management of electronic medication box?

1. To remind patients for taking medicine with human voice or music
 - a) According to patients' requirement, Doctor /study member will set an agreed time when the box remind patient to take medication in first time.
 - b) If the box is not opened at that time there is up to eight further reminders (bleep), taking place at 5, 20, 30 minutes, 1 hour, 2 hour, 4 hour, 6 hour and 8 hour after 30 minutes of the agreed time if the medication box is not opened.
 - c) Patients should open the box and take medication when receiving reminder at once. Once the box has been opened the reminders stop for that day.
 - d) The box will ask patient to close the box with human voice of "close the box" if the box keeps open beyond 15 seconds.

2. To remind patients of the monthly dispensing visit
Medication box reminder (human voice) 4,3,2,1 days before the scheduled monthly follow-up visit.
3. Other issues of using electronic box for treatment management
 - a) To keep the box working, avoid it out of power;
 - b) To keep the box from water, children and fire;
 - c) Do not open the box frequently, especially in non-taking medication day.
 - d) If opening the box in advanced, patient still need to reply the SMS by cell phone;
 - e) If any question and problem with the box happened, please contact your doctor or study member ASAP.

INFORMED CONSENT FOR COMMUNITY TRIAL OF NEW METHOD IN TUBERCULOSIS STANDARD
TREATMENT MANAGEMENT
(MEDICATION MONITOR ARM)

Dear patients,

Tuberculosis is curable under standard treatment management. However, due to irregular medication or interruption of the course, drug-resistant TB is developed among a number of patients. This makes their condition worse and results in the occurrence of incurable tuberculosis. To ensure medication is taken timely and treatment adherence is good, National Center for Tuberculosis Control and Prevention, China CDC, is conducting a community trial of new methods in tuberculosis treatment management

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National Center for Tuberculosis Control and Prevention, China CDC

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hereby, state that I am willing to take part in the study and accept the use of electronic medicine box in the treatment management.

Patients Signature: _____ Date: _____

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Doctors (Name of Person taking consent) Signature: _____ Date: _____

Participant information sheet: **electronic medication box and cell phone arm**

COMMUNITY TRIAL OF NEW METHODS IN TUBERCULOSIS TREATMENT MANAGEMENT

Health education

10. Tuberculosis is curable under standard treatment management with more than 6 months' treatment.
11. Taking medicine regularly is very important for cure the disease. Due to irregular medication or interruption of the course, drug-resistant TB is developed among a number of patients.
12. The symptoms of TB will be disappeared after being treated with anti-TB drugs. However, before conversion to the sputum smear negative, patients would not speak aloud, cough, and sneeze among the public.

Brief introduction of the new treatment management

18. DOT require patients to go to village clinic for taking TB drugs every two days, but it would cost more and result in inconvenience for doctors and patients.
19. Now, we use new method with SMS and electronic medication box to conduct patients' treatment management.
20. Electronic medication box is FREE for patients who are enrolled in the study.
21. If patient has not a cell phone, we will provide a free one for him/her who is enrolled in the study.
22. Patients will return to the TB dispensary for monthly re-fills and for when to give spit specimens at 2, 5 and 6 months following start of TB treatment.
23. TB patients in other districts/counties are receiving standard of care or other methods to improve TB adherence. We will then compare treatment adherence amongst patients from districts/counties receiving the cell phone and the electronic medication box to improve TB adherence with patients receiving standard of care. We will also compare adherence amongst patients from districts/counties receiving the other methods with patients receiving standard of care.

What is the treatment management of cell phone?

2. To send SMS to remind patients for taking medicine on time
 - b) According to patients' requirement, Doctor /study member will set the time when patient receives the SMS by cell phone. SMS text is "please take the medication on time" and is the same for each reminder. Once receiving the SMS of reminding, patients should take medicines and make a reply with cell phone.
 - c) Up to three SMS reminders are sent to the patient on the day of medication, depending on whether the patient replies or not. These reminders are sent at the agreed time medication is to be taken and subsequently at 12noon and 6pm if no

reply is received.

- d) The patient is expected to reply by SMS with or without text. Once a reply has been received the reminders stop for that day.
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 - c) If any question and problem with cell phone, please contact your doctor or study member ASAP.

What is the treatment management of electronic medication box?

- 3. To remind patients for taking medicine with human voice or music
 - e) The first time of electronic box reminding patients is after 30 minutes of an agreed time of receiving first SMS.
 - f) If the box is not opened at that time there is up to eight further reminders (bleep), taking place at 5, 20, 30 minutes, 1 hour, 2 hour, 4 hour, 6 hour and 8 hour after 30 minutes of the agreed time if the medication box is not opened.
 - g) Patients should open the box and take medication when receiving reminder at once. Once the box has been opened the reminders stop for that day.
 - h) The box will ask patient to close the box with human voice of "close the box" if the box keeps open beyond 15 seconds.
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INFORMED CONSENT FOR COMMUNITY TRIAL OF NEW METHOD IN TUBERCULOSIS STANDARD
TREATMENT MANAGEMENT

(MOBILE PONHE+ MEDICATION MONITOR ARM)

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