Effectiveness of electronic reminders to improve medication adherence in tuberculosis patients: a cluster-randomised trial

DOI

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Data Creators

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Data Description

An anonymised dataset of 4,292 TB patients who gave informed consent to participate in a pragmatic, cluster-randomised trial of 36 districts/counties (clusters) within the provinces of Heilongjiang, Jiangsu, Hunan, and Chongqing, China between June 2011 and March 2012. Dataset contains variables on stratified randomisation and cluster code, socio-demographic information, TB treatment outcomes, adherence outcomes, medication monitor problems, mobile phone problems, and the type of patient treatment management initiated (if at all).

Methods

A pragmatic, cluster-randomised trial of 36 districts/counties (clusters) within the provinces of Heilongjiang, Jiangsu, Hunan, and Chongqing, China. Clusters were randomised to one of four case-management approaches using stratification and restriction. The four arms were standard of care (control), or receiving adherence reminders from (i) text messages, (ii) an electronic medication monitor or (iii) both. See paper for more details on the intervention definitions. TB patients in these clusters were recruited at the start of treatment and followed up for six months. The primary outcome was the percentage of patient-months on TB treatment where at least 20% of doses were missed as measured by pill count and failure to open the medication monitor. Secondary outcomes included additional adherence measures and standard treatment outcome measures. Interventions were not masked to study staff and patients.

From June 2011- March 2012 a total of 4,292 TB patients gave informed consent. Of these, 61 were reassessed as not having TB by their managing doctor and 58 were switched to a different treatment model within the first month (due to hospitalisation or travel) and were therefore excluded from all analyses. Therefore, 4,173 patients were eligible for the analysis.

Spatial Coverage

Data were captured in 36 districts/counties (clusters) within the provinces of Heilongjiang, Jiangsu, Hunan, and Chongqing, China

Temporal Coverage

Data were collected between 1 June 2011 and September 2012.

Species:

Human population

Privacy:

Patients are identified by a unique study number. External identifiers have been removed.

Ethics

The study was approved by the ethics committees of China Center Disease Control (201008) and the London School of Hygiene and Tropical Medicine (5704).

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Keywords

tuberculosis treatment, electronic reminders, China, adherence

Language of written material

English

Project Information

Project

Use of Innovative Tools and Delivery Approaches to Improve TB Control in China: Community Randomised Trial of Mobile Text Messaging and Medication Monitor Adherence Measures.

Funder/Sponsor

Bill & Melinda Gates Foundation.

Grant Number

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Trial registration: http://www.isrctn.com/ISRCTN46846388

Associated Roles

Role	Forename	Surname	Faculty / Dept	Institution
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Research Centre/Group

- LSHTM TB Centre
- MRC Tropical Epidemiology Group

Participating Institutions

- National Center for TB Control and Prevention, China Center for Disease Control, Beijing, China
- London School of Hygiene & Tropical Medicine, UK,
- Jiangsu Provincial Center for Disease Control and Prevention, Nanjing, Jiangsu, China,
- Chongqing Provincial TB dispensary, Chongqing, China,
- Heilongjiang Provincial TB dispensary, Harbin, Heilongjiang, China,
- Hunan Provincial TB dispensary, Changsha, Hunan, China,
- China-Gates Foundation TB Project National Program Management Office, China
- CDC, Beijing, China, Dafeng County Center for Disease Control and Prevention in Jiangsu province, Dafeng, Jiangsu, China,
- The Bill & Melinda Gates Foundation Beijing Office, Beijing, China

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File Description

Title	Filename	File type	Description
China CRT dataset	ChinaCRT_dataset.csv	Comma Separated Values	An anonymised dataset of 4,292 TB patients who gave informed consent to participate in a pragmatic, cluster-randomised trial. Each row represents a study participant. The unique identifier is "studynumber". Variables in the data set are grouped as follows: 1. Randomisation arm, variables used in stratified randomisation, cluster code 2. Socio-demographic variables measured at study enrolment 3. TB treatment outcomes 4. Adherence outcomes (based on electronic data from the medication monitor and pill count) 5. Medication monitor problems 6. Mobile phone problems 7. Whether intensive management or directly observed therapy was initiated (intervention arm only)
China CRT Data Dictionary	ChinaCRT_datadictionary.txt	ASCII text	The data dictionary is formatted as one line per variable, each line of which is split into three sections with the pipe "|" character. I.e. variable name|variable description|value labels