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PREVENT TB: Improving determinants of TB cure, prevention & diagnosis

Submission date
09/06/2016

Recruitment status
No longer recruiting

Registration date
19/10/2016

Overall study status
Completed

Last Edited
19/03/2021

Condition category
Respiratory

[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
Tuberculosis (TB) is a common, infectious condition caused by a bacterial infection. It is generally spread by breathing in tiny droplets released into the air by an infected person coughing or sneezing. TB usually affects the lungs (pulmonary TB), but it can also affect other areas of the body such as the bones, brain and kidneys. TB infections are estimated to cause around 10 million cases of active TB disease and 1.5 million deaths every year. Poverty, including associated undernutrition (deficiency of calories, protein, and/or one or more essential nutrients), is known to increase TB risk. Furthermore, TB worsens poverty by increasing expenses and reducing income. Poverty also impairs access to TB care and this mismatch between need for and access to TB care undermines TB control and worsens poverty. Poverty also impacts TB-related knowledge, wellbeing and marginalisation that increase the risk of adverse TB outcomes. The World Health Organisation's "End TB" strategy has recently formally included socioeconomic (social and financial) support as a key part of the global response to TB. However, there is very little published evidence to inform policy makers about what social and/or economic support would be most effective to strengthen TB control and how they should be used. The aim of this study is to evaluate the effectiveness of a socioeconomic support package for TB-affected households.

Who can participate?
Patients starting TB treatment in participating communities, and their household members.

What does the study involve?
All patients with TB and their household members in the 32 participating communities receive the standard care provided free of charge by the Peruvian National TB Program. This includes treatment for all patients, and testing and preventive therapy for their household members. These 32 communities are randomly allocated to one of two groups. Those in the first group (16 'comparison' communities) receive only the Peruvian National TB Program standard care. Those in the second group (16 'supported' communities) are additionally offered for the duration of their treatment a socioeconomic support package, led by recovering patients (who are termed peer mentors), for two years. This involves a combination of social support made up of household visits and TB clubs providing information and peer support, and economic support made up of cash transfers as incentives and enablers, covering the household's average TB-

related costs. Participants in both groups are followed up after six and 18 months in order to assess cure rate, case-finding rate and prevention.
At the same time as the study is taking place, the research team are also looking at TB risk factors, by comparing patients with TB to other healthy people living nearby; lab tests and other predictors of TB cure; lab tests and approaches for testing people for TB; and lab tests and approaches for predicting TB risk in patient's household members.

What are the possible benefits and risks of participating?
All participants benefit from having time to speak with the study health care professionals. Patients with TB are free to use this time to discuss any questions or concerns that they may have about their diagnosis and TB treatment. Participating also benefits both the patient with TB and the Peruvian TB control program by offering rapid, extensive, state-of-the-art testing to confirm TB and also test for multi-drug resistant TB (a form of TB that does not respond to normal drug treatment), which is not available to most patients. All patient participants at the time of recruitment are offered testing and if positive for TB will also be tested for drug-resistant TB. Patients and their household members recruited in the 'supported' communities are offered the socioeconomic support package. For this group (which constitutes approximately half of the participants) this is a considerable potential benefit because socioeconomic support may increase rightful access to TB care. There are no notable risks involved with participating in this study.

Where is the study run from?
The study is run by Innovation for Health and Development (IFHAD) and takes place in shantytowns on the outskirts of cities and urban communities in Callao (Peru)

When is the study starting and how long is it expected to run for?
October 2012 to October 2021

Who is funding the study?
1. Wellcome Trust, grant numbernumbers: 105788/Z/14/Z and 201251/Z/16/Z (UK)
2. Medical Research Council Joint Global Health Trials scheme (UK)
3. Department for International Development (UK)
4. World Bank Group (USA)
5. Bill and Melinda Gates Foundation (UK)
6. Innovation for Health and Development (IFHAD) (UK)

Who is the main contact?
Professor Carlton Evans

Contact information

Type(s)
Public

Contact name
Prof Carlton Evans

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32

Additional identifiers

Protocol serial number
Imperial College London number 14IC2191

Study information

Scientific Title
PREVENT TB: Improving determinants of TB cure, prevention and diagnosis with a Community Randomised Evaluation of a Socioeconomic Intervention to Prevent TB (CRESIPT)

Acronym
PREVENT TB, CRESIPT

Study objectives
Socioeconomic support increases TB cure, case-finding and prevention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The Peruvian Ministry of Health DIRESA Callao ethics committee, 20/04/2016, ref: 790-2014-DG
2. The non-governmental organization Asociacion Benefica PRISMA, Peru Research Ethics Committee, Lima, 21/04/2016, ref: CE0970.16
3. Imperial College London Research Ethics Committee, 09/05/2016, ref: 14IC2191

The protocol has also been approved by:
4. The London School of Hygiene and Tropical Medicine Research Ethics Committee, 26/05/2016, ref: 11625
5. Universidad Peruana Cayetano Heredia, Lima, Peru Research Ethics Committee, 02/05/2016, ref: 231-11-16

Study design
Interventional community randomised evaluation study

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied

Tuberculosis

Interventions
Communities (clusters) are allocated to be 'supported' (n=16) or 'comparison' (n=16) in a 1:1 ratio by restricted randomisation. The principal restriction variables are: average case notification rates per cluster; average cluster-level percentage registered to receive national health insurance; average cluster-level percentage of TB cases lost to follow-up; and average cluster-level percentage of TB cases resistant to any drugs.

All communities: Patients with TB and their household members in all 32 communities (16 supported and 16 comparison) will receive the standard care provided free of charge by the Peruvian National TB Program. This includes treatment and MDR-TB testing for all patients, and TB testing and preventive therapy for their household members.

Supported communities: Patients with TB and their household members in the 16 supported communities will additionally be offered for the duration of their treatment a socioeconomic support package led by recovering patients who are termed peer mentors. This trial intervention will consist of integrated:1. Social support constituting household visits and TB clubs providing information and peer support; and2. Economic support constituting cash transfers as incentives and enablers, defraying household's average TB-related costs.

Comparison communities: Patients with TB and their household members in the 16 comparison communities will be recruited but will receive no trial intervention.

Participants in both the 'supported' and 'comparison' communities are followed up approximately 6 months and 18 months after they initiate TB treatment. The 18 month follow up includes a prevalence survey for all patients and their household members to screen for TB recurrence and prevalent TB.

Intervention Type
Behavioural

Primary outcome(s)
1. “Cure TB long-term.” A composite adverse treatment outcome* in patients with TB, as measured through reviewing TB program records when patient treatment ends, and follow-up constituting an interview for self-reported incident TB and a prevalence survey to test for laboratory proven prevalent TB 18 months after recruitment
* The composite adverse treatment outcome is defined as any of: death attributed to TB at any time or death from any cause during TB treatment; loss to follow-up during treatment as defined by the TB program (treatment ‘abandoned’ for ≥30 days); treatment failure as defined by the TB program; or TB recurrence defined as any repeat TB diagnosis after recruitment
Patients who at follow-up are still adhering to ongoing TB treatment (e.g. during prolonged treatment for MDR TB) and have not developed any of these adverse treatment outcomes are considered not to have had an adverse outcome and are included in the analysis. Patients whose TB treatment outcome is unknown are excluded e.g. because their treatment was transferred elsewhere.

2. “Find TB in those at high risk.” TB diagnosis in the household members of patients with TB during the first 8 weeks from when the patient with TB commenced treatment is measured by reviewing TB program records when patient treatment ends, and follow-up constituting an interview for self-reported incident TB 18 months after recruitment

3. “Prevent TB in patient households.” TB diagnosis in the household members of patients with TB at any time from 8 weeks after the patient with TB commenced treatment is measured by reviewing TB program records when patient treatment ends, and follow-up constituting an interview for self-reported incident TB and a prevalence survey to test for laboratory proven prevalent TB 18 months after recruitment

Key secondary outcome(s))
Secondary outcome measures 1 and 2 are measured at recruitment and compared with repeat measurement approximately 6 months after recruitment. Secondary outcome 3 is measured approximately 6-months after recruitment.

1. "Social empowerment" aiming to improve TB-related:
1.1. Knowledge gaps, measured using a questionnaire designed for the purpose of this study
1.2. Wellbeing, measured using the WHO EUROHISQOL-8 tool and Beck Depression Inventory
1.3. Marginalisation, measured using the World Bank SASCAT-derived social capital and EMIC stigma questionnaires

2. "Economic empowerment" aiming to improve TB-related:
2.1. Impoverishment, measured through the household composite poverty and dissaving score
2.2. Nutrition, measured through patient anthropometry and questionnaire-based food insecurity score
2.3. Costs, measured using a questionnaire evaluating net costs and catastrophic costs after subtracting cash transfers

3. "Empowering equitable access" to TB program care aiming to improve:
3.1. Patient adherence, measured using TB program records as the proportion of patient treatment doses missed
3.2. Screening, measured using TB program records as the proportion of household members of patients with TB who do not complete TB screening
3.3. Preventive therapy, measured using TB program records as the number of weeks of TB preventive therapy taken by the household members of patients with TB.

Exploratory outcome:
“Control TB”: Changes in community case notification rates defined as a numerator of all TB cases notified by the NTP divided by a denominator of community population size is estimated by the regional ministry of health (based on the national census data) calculated for each community per 100,000 person years. All cases diagnosed only in the prevalence survey 18 months after recruitment are excluded from the numerator in order to calculate an estimate of notification rates in a “real-world” setting.

Completion date
30/06/2022

Eligibility

Key inclusion criteria
All patients living in the 32 communities participating in the study who are commencing or have within the past 6 weeks commenced TB treatment at National TB Program health posts, and their household members, who are able and willing to give informed written consent/assent to participate in this trial, including completing the recruitment questionnaire and recruitment household visit.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
All

Sex
All

Key exclusion criteria
Patients who were taking a previous course of TB treatment and then experienced an adverse TB treatment outcome that occurred after the trial start date.

Date of first enrolment
21/10/2016

Date of final enrolment
21/04/2020

Locations

Countries of recruitment
Peru

Study participating centre
Innovation for Health and Development (IFHAD)
Prisma Headquarters
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Sponsor information

Organisation
Imperial College London

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Funder Name
Medical Research Council Joint Global Health Trials scheme

Funder Name
Department for International Development

Alternative Name(s)
Department for International Development, UK, DFID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
World Bank Group

Alternative Name(s)

World Bank, The World Bank, Grupo Banco Mundial, Groupe Banque Mondiale, , Группа Всемирного банка, WBG

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United States of America

Funder Name
Bill and Melinda Gates Foundation

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

Funder Name
Innovation For Health And Development, Imperial College Healthcare Charity, UK

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes