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Impact and cost-effectiveness of integrated care and results-based financing intervention on adherence among pulmonary tuberculosis patients in Georgia

Submission date
11/12/2018

Recruitment status
No longer recruiting

Registration date
14/01/2019

Overall study status
Completed

Last Edited
06/09/2022

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
In Georgia, health care staff dealing with tuberculosis (TB) receive very minimal salaries and work in isolation from one another. Because of this, TB patients may not find it easy to remain on treatment, despite how vital this treatment is to them being cured. Georgia is particularly struggling with retaining drug-resistant patients on treatment; this is a risk for the country overall. Researchers will study how a new way of delivering health care services affects the health of TB patients in Georgia.

This new way of care delivery means that health care providers are asked to work together in teams to look after the health of TB patients. Provider roles are re-defined to ensure health services are integrated and focused on the patient. To reward providers for this extra work, bonus payments are made to clinics and providers depending on the number of patients that are still on treatment and the quality of care that patients receive.

The purpose of researching this new way of doing things – including via a trial and other methods – is to find a way to deliver care services for TB patients which is effective, pragmatic and value-for-money both in the short and longer term. TB care providers are very important to this and therefore we want to find out what they find acceptable and whether this new way of doing things is helpful.

Who can participate?
Health facilities in Georgia, meeting specific inclusion criteria relating to their routine patient load and also current treatment outcomes, can participate. We have excluded participation of health care facilities which are already performing very well, or those facilities where less than 20 new patients present per year.

The trial will recruit pulmonary tuberculosis patients (both drug-sensitive and drug-resistant) provided they are over 18 and have been referred for outpatient TB management, suffer from no significant other conditions and have not been hospitalized for longer than two months.

What does the study involve?
The study is a 'cluster randomized clinical trial' – that means that we randomly assign this new type of care to some of the health care facilities in Georgia (the intervention arm). The other facilities serve as a comparison group and continue to do things as they have done so far (the control arm).

In health facilities which have been randomly allocated to the intervention arm, health care providers will be trained on integrated tuberculosis management; additionally, providers will be made aware that they will receive bonus payments depending on the quality and quantity of care they provide. This means that their quality of care (e.g. patient communication) will be observed by an independent third party and that their quantity of care – i.e. the number of patients still on treatment for TB during each quarter – will be monitored. If providers offer high quality care and also retain patients on treatment, they receive a higher bonus payment. In facilities allocated to the control arm, providers will continue to offer health services as usual.

At the end of this trial, CIF and QMU colleagues will compare how many patients have remained on treatment in both groups. Colleagues from ITM will look at how this new way of doing things has changed services and how providers and patients have responded; colleagues at LSHTM will also determine whether the new way provides value for money for the country.

What are the possible benefits and risks of participating?
There are no benefits or risks anticipated for patients participating in this trial; their clinical care consists of exactly the same elements, however the general management of tuberculosis and the way providers interact with patients may change in the intervention arm. Health facilities participating in the trial will benefit from increased financial resources depending on their performance – if quality of care and the number of patients that are on treatment is high, facilities and staff therein receive bonuses. There are no risks of participating.

Where is the study run from?
The project involves partners from Curatio International Foundation (CIF) in Georgia, Queen Margaret University, Edinburgh (QMU), the Institute of Tropical Medicine, Antwerp (ITM) and the London School of Hygiene and Tropical Medicine (LSHTM). CIF is responsible for running the study with support from all other institutions.

When is the study starting and how long is it expected to run for?
The study is expected to start February 2019 and will run for 2 years.

Who is funding the study?
Results4TB is a research project funded by the Medical Research Council UK.

Who is the main contact?
Maia Uchaneishvili- Project Manager
Ivdity Chikovani- Co- Investigator

Contact information

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Additional identifiers

Protocol serial number
Results4TB_20180327_version_1

Study information

Scientific Title
Cluster randomized trial of an integrated care and results-based financing intervention to improve adherence among patients with drug-susceptible and drug-resistant tuberculosis in Georgia

Acronym
Results4TB

Study objectives
For DS-TB patients, the trialists hypothesize the intervention will lead to a 6% reduction in Lost to Follow Up (LFU); for DR-TB patients, they theorize a likely effect of 12%.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 07/08/2020:
1. National Center for Disease Control and Public Health Institutional Review Board, 04/05/2018, ref. 2018-019, continuation ref: 2019-017, continuation ref: 2020-024
2. Observational / Interventions Research Ethics Committee of London School of Hygiene and Tropical Medicines, 26/10/2018, ref. 15756.
3. The ethical review board at Queen Mary's University, Edinburgh, 17/05/2018, ref: REP0172
4. University of Antwerp Ethical Committee, 07/2018, ref. 18/25/303.

Previous ethics approval:
1. National Center for Disease Control and Public Health Institutional Review Board, 04/05/2018, ref. 2018-019
2. Observational / Interventions Research Ethics Committee of London School of Hygiene and Tropical Medicines, 26/10/2018, ref. 15756.
3. The ethical review board at Queen Mary's University, Edinburgh, 17/05/2018, ref: REP0172
4. University of Antwerp Ethical Committee, 07/2018, ref. 18/25/303.

Study design
Pragmatic cluster randomised controlled superiority trial with two parallel groups

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Drug-susceptible and drug-resistant pulmonary tuberculosis

Interventions

Pragmatic cluster randomised controlled superiority trial with two parallel groups, fixed number of clusters of unequal size and a primary endpoint of adherence to outpatient TB treatment of patients with drug sensitive and drug resistant pulmonary TB. A clustered design – featuring health facilities as clusters was chosen as facilities represent the ideal frame to disburse performance related payments to TB providers. Randomization will be stratified according to facility size and clusters will be allocated to intervention and control arms on a 1:1 ratio.

The intervention is defined as a package of interventions, including Results Based Financing (RBF) of healthcare providers, aimed to reduce lost to follow-up and to improve TB treatment success in patients with DS-TB.
Two models of intervention packages are proposed considering the current set-up of TB services at the outpatient level:
1. Intervention package in TB units administratively integrated into Primary Health Care (semi-urban areas)
2. Intervention package in TB units administratively NOT integrated into Primary Health Care - so-called specialized TB services (urban areas)
The intervention aims to create a better relationship between a patient with TB and providers through adopting a Patient-Centred Care approach, which should result in engaging the patient in the decision-making process and in better trust, better management of co-morbidities and side effects to TB drugs, which in turn contribute to better adherence to treatment.
Performance-based payments will be based on the TB unit performance measured by a specific indicator (adherence to treatment) reported on a quarterly basis.
The bonus payment to a TB unit considers the number of patients with TB; distribution onwards to team members is based on their contribution and basic salary.

Intervention package designed for TB units integrated with primary health care centres in semi-urban areas
Under the intervention, patients with TB will receive an integrated, multidisciplinary treatment at the PHC level. An integrated team composed by a TB doctor, a TB nurse (or rural nurse for rural patients) and a family doctor will be established.
The package includes:
1. Defining roles and responsibilities of health care providers involved in a TB case management (including a TB doctor, a family doctor, a DOT nurse, a nurse) within the scope of their professional competencies; (see Appendix 3)
2. Introducing new tools such as a treatment plan for patient and instruments for monitoring, a facility managers' guideline on implementing the intervention;
3. Training on principles of integrated care, for all members of a TB team and on managing side effects of TB treatment, for family doctors and TB doctors;
4. Paying bonuses (incentive payments) to a team based on outcomes (adherence to treatment).

Intervention package tailored to specialized TB services in urban areas
Under current model the team is composed of a TB doctor and a TB nurse. The intervention package involves:
1. Introduction of new tools such as a case management plan, instruments for monitoring, a facility managers' guideline on implementing the intervention
2. Training for TB doctors to manage side effects
3. Payment of performance based incentives to the team
In both models the facility manager has a role in the intervention package. The manager will be responsible for enabling the work of the team (such as contracting, creating job descriptions, supervision on the bonus distribution among the team etc) and ensuring a supportive

environment for providing patient-centred care. The total bonus payment for the facility includes the manager's and the institution's share.

The control arm is comprised of health facilities offering care under standard conditions. The control group will comprise health facilities (i.e. clusters) not implementing the intervention and managing TB as per standard (current) treatment protocols and processes. Randomization is stratified according to facility size and clusters will be allocated to intervention and control arms on a 1:1 ratio.

We use constrained randomization techniques (implemented in STATA 15) to ensure that eligible facilities are randomized to control vs. intervention arms. Randomization takes into account the type of facility to be randomized (i.e. integrated service model vs. specialist model) and further variables of relevance. (number of TB doctors and nurses and their relevant salaries; baseline drug-resistant and drug-sensitive patient loads and loss-to follow up; facility location (urban or semi) and facility ownership (private public)).

The intervention will start alongside the trial in February 2019 and is expected to end in February 2021 (2 years of implementation). Patient outcomes will be ascertained from routine health system data (at facility level, TB relevant patient forms will be consulted; nationally, we plan to consult the TB registry). No formal patient follow-up is planned beyond the period of the trial or intervention implementation.

Intervention Type
Other

Primary outcome(s)
1. Loss to follow-up of patients with DS-TB or DR-TB, defined as the difference between the two intervention arms in the proportion of patients who did not start treatment or whose treatment was interrupted for 2 consecutive months or more. The trial will collect and compare loss to follow-up as follows:
1.1. Loss-to-follow-up for patients with pulmonary DS-TB at 3 months
1.2. Loss-to-follow-up for patients with pulmonary DS-TB at 6 months
1.3. Loss-to-follow-up for patients with pulmonary DR-TB at 3 months
1.4. Loss-to-follow-up for patients with pulmonary DR-TB at 6 months
1.5. Loss-to-follow-up for patients with pulmonary DR-TB at 9 months
1.6. Loss-to-follow-up for patients with pulmonary DR-TB at 12 months
1.7. Loss-to-follow-up for patients with pulmonary DR-TB at 15 months
1.8. Loss-to-follow-up for patients with pulmonary DR-TB at 18 months
1.9. Loss-to-follow-up for patients with pulmonary DR-TB at 21 months

Key secondary outcome(s))
1.1. Secondary outcome: treatment success rate among patients with DS-TB, defined as per WHO 2014, calculated as the difference in the proportion of patients classed as successfully treated between trial arms annually or bi-annually.
1.2. Adherence to TB treatment among patients with DS-TB and DR-TB, defined as difference between intervention and control arm in the proportion of patients who remained on treatment six months after the treatment was initiated (regardless where the treatment was initiated, outpatient or inpatient).
The trial will collect and compare adherence outcomes as follows:
1.2.1. Adherence to DOT for patients with pulmonary DS-TB after 3 months
1.2.2. Adherence to DOT for patients with pulmonary DS-TB at 6 months

1.2.3. Adherence to DOT for patients with pulmonary DR-TB at 6 months
1.2.4. Adherence to DOT for patients with pulmonary DR-TB at 9 months
1.2.5. Adherence to DOT for patients with pulmonary DR-TB at 12 months
1.2.6. Adherence to DOT for patients with pulmonary DR-TB at 15 months
1.2.7. Adherence to DOT for patients with pulmonary DR-TB at 18 months
1.2.8. Adherence to DOT for patients with pulmonary DR-TB at 21 months
1.2.9. Adherence to DOT for patients with pulmonary DR-TB at 24 months

The definition of adherence to DOT for patients with pulmonary DS-TB is as follows:
1. From the start of the treatment up to the treatment completion, not more than one missing day per month if patient visits a facility 8-12 –times during a month to fulfil DOT (DOT is performed 2 or 3 days per week. Every other day patient receives drugs at home)
2. From the start of the treatment up to the treatment completion, no single missing day per month if patient visits a facility 4 – times during a month to fulfil DOT (some patients visit a facility only once a week for DOT and take drugs for home-taking)

The definition of adherence to DOT for patients with pulmonary DR-TB is as follows:
1. From the start of the treatment, not more than three missing days per month (DOT is performed 26 days per month - 6 days a week except Sunday)

Completion date
01/07/2021

Eligibility

Key inclusion criteria
1. Aged ≥18
2. All new or previously treated patients with pulmonary TB
3. Assigned to outpatient TB treatment not more than one month prior to enrolment in the study; This restriction (not more than one month treatment) does not refer to patients whose most recent treatment outcome was failure and who were assigned to a new treatment regimen
4. Assigned to outpatient TB treatment at outpatient facility or at home (through DOT) according to the national TB treatment guidelines
5. TB diagnosis established by a direct sputum smear microscopy, culture or Gene Xpert MTB/RIF (bacteriologically confirmed case), OR TB diagnosis established by an X-ray, histological or morphological changes (clinically diagnosed case)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
1153

Key exclusion criteria
1. TB outpatient treatment started more than one month prior to enrolment in the study
2. Patients with extra-pulmonary TB
3. Patients with DS-TB with more than two months of hospitalisation or patients with DR-TB with more than 6 months of hospitalisation
4. Patients known at the start of treatment to require the treatment longer than it is recommended by the Georgian TB Management Guidelines for the appropriate type of TB
5. Custody patients
6. Patients involved in other clinical studies related to TB treatment
7. Patients with intention to leave the place within next 6 months

Date of first enrolment
24/05/2019

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
Georgia

Study participating centre
Curatio International Foundation
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Sponsor information

Organisation
Curatio International Foundation

ROR
https://ror.org/00hcdm003

Funder(s)

Funder type

Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

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
Economic and Social Research Council

Alternative Name(s)
Economic and Social Research Council (ESRC), ESRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the Co-investigator Dr. Ivdity Chikovani email: i.chikovani@curatio.com . Clinical trial data including patient characteristics and outcomes will be available 2 years post trial completion to researchers or practitioners in the field, upon reasonable request. Data may be used for confirmatory analyses and meta-analyses by encrypted file sharing. Consent was obtained from participants and only completely anonymized datasets will be available.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	realist evaluation protocol	14/04/2019		Yes	No
Protocol article	protocol	28/08/2019	30/08/2019	Yes	No
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