

# The Food Incentives for Tuberculosis Treatment Compliance study in Dili, East Timor (FITTCET)

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| <b>Submission date</b><br>12/09/2005   | <b>Recruitment status</b><br>No longer recruiting        | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>25/11/2005 | <b>Overall study status</b><br>Completed                 | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>28/10/2009       | <b>Condition category</b><br>Infections and Infestations | <input type="checkbox"/> Statistical analysis plan   |
|  |  | <input checked="" type="checkbox"/> Results          |
|  |  | <input type="checkbox"/> Individual participant data |

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**ClinicalTrials.gov (NCT)**  
NCT00192556

**Protocol serial number**  
A30746

## Study information

**Scientific Title**

**Acronym**

FITTCET

**Study objectives**

Food incentives are an achievable, effective method of encouraging full adherence to Directly Observed Treatment-Short Course Programme (DOTS) and thus improved treatment outcomes in Dili, Timor-Leste.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Full ethics approval received on the 17th March 2005.

**Study design**

Randomised trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

Tuberculosis

**Interventions**

Patients enrolled will be randomised to receive either the food intervention or nutritional advice and followed for duration of treatment (eight months)

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

The proportion of patients who successfully complete the eight month course of TB treatment and achieve cure in each group (treatment success) and the proportion of patients who do not complete treatment or have persistent disease (treatment failure).

**Key secondary outcome(s)**

1. The proportion of clinic visits compared with expected, measured weekly for first 2 months then monthly for next 6 months
2. Response to treatment measures:
  - 2.1. Symptoms (cough, sputum, fever), measured at 4, 8, 24 and 32 weeks
  - 2.2. Changes in weight and Body Mass Index (BMI), measured at 4, 8, 24 and 32 weeks
  - 2.3. Sputum clearance, measured at at 8 weeks
  - 2.4. Nutritional markers, measured at 4, 8, 24 and 32 weeks

**Completion date**

30/06/2006

## Eligibility

**Key inclusion criteria**

Adult Tuberculosis (TB) patients diagnosed at one of the participating clinics during the study period will be eligible for enrolment if they are:

1. 18 years of age or older
2. Diagnosed to have tuberculosis (sputum smear positive or smear negative or extrapulmonary TB) using the standard National Tuberculosis Programme (NTP) definition for this diagnosis
3. Have never received more than one month of anti-tuberculosis treatment in the past
4. Not pregnant
5. Voluntarily accept to be involved in this study

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

Does not comply with inclusion criteria.

**Date of first enrolment**

01/04/2005

**Date of final enrolment**

30/06/2006

## Locations

**Countries of recruitment**

Switzerland

Timor-Leste

**Study participating centre**

**20, Avenue Appia**  
Geneva-27  
Switzerland  
CH-1211

## Sponsor information

### Organisation

UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR)

### ROR

<https://ror.org/01f80g185>

## Funder(s)

### Funder type

Other

### Funder Name

United Nations Children's Fund (UNICEF)

### Funder Name

United Nations Development Programme (UNDP)

### Funder Name

World Bank

### Funder Name

World Health Organization (WHO) - Special Programme for Research and Training in Tropical Diseases (TDR)

## Results and Publications

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 26/10/2009   |            | Yes            | No              |