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

Submission date 12/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/11/2005	**Overall study status** Completed	
Last Edited 28/10/2009	**Condition category** Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00192556

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure

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).

Secondary outcome measures
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

Overall study start date
01/04/2005

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
270

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)

Sponsor details
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Sponsor type
Other

Website
http://www.who.int

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Results article	results	26/10/2009		Yes	No