

RATIONS (Reducing Activation of Tuberculosis by Improvement Of Nutritional Status) study:

A randomized trial of nutritional support (food rations) to reduce TB incidence in household contacts of patients with microbiologically confirmed pulmonary tuberculosis in communities with a high prevalence of undernutrition

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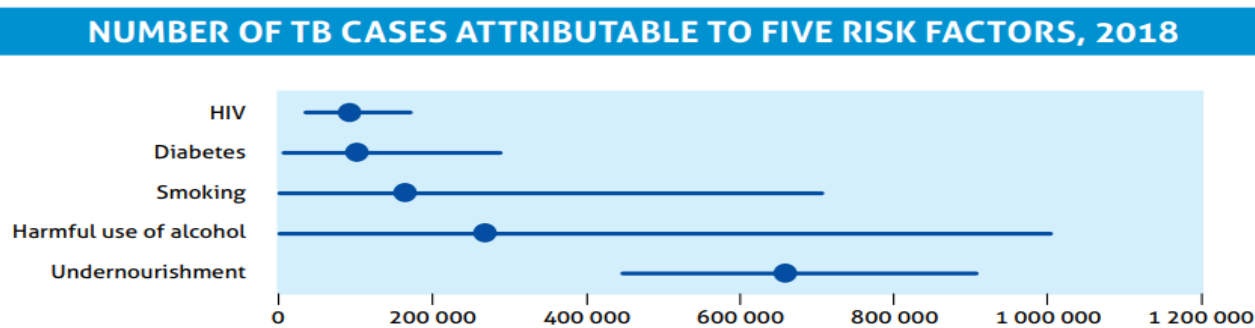
Enrollment and approved timeline

Start date of trial: 14th May 2019.; **Start of Enrolment :** 15th August 2019

- Targeted no. of index cases: 2800 adult patients with microbiologically confirmed PTB, in 28 TUs in 4 districts of Jharkhand
- Enrollment achieved : 100% by January 2021
- Targeted number of contacts: 11,200 based on a family size of 4
- Number of contacts enrolled: 10,345
- Timeline of enrollment approved: 12 months
- Time to achievement of enrollment : 18 months because of COVID-19 induced disruption
- Approved duration: Till May 2022

Introduction

- Malnutrition : Major driver of TB epidemic in India, more than all other factors combined.



Global TB report 2019. WHO

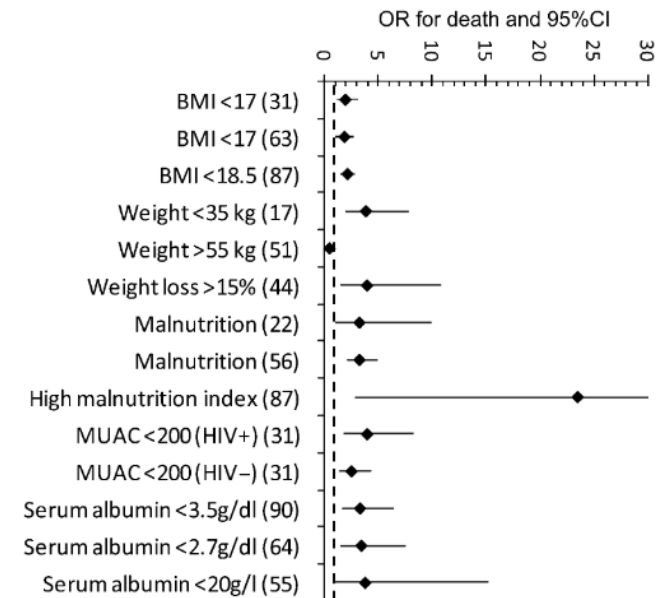
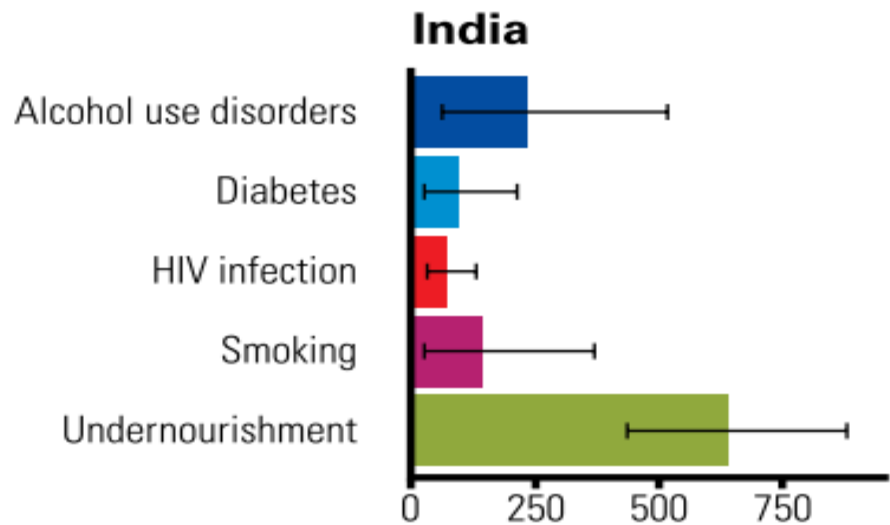
- Malnutrition in TB patients is frequent, severe and lethal.
- Total no. of trials of food support: 4. No. of patients: 567
- **Largest trial** of food support to improve patient outcomes: >1900 enrolled so far
- **First trial** globally to aim prevention of TB by nutrition.

RATIONALE

TABLE 8.4

Global estimates of the number of TB cases attributable to selected risk factors

RISK FACTOR	RELATIVE RISK (UNCERTAINTY INTERVAL)		EXPOSED (MILLIONS)	POPULATION ATTRIBUTABLE FRACTION (%)	ATTRIBUTABLE TB CASES (MILLIONS, UNCERTAINTY INTERVAL)	
Alcohol use disorders	3.3	2.1–5.2	288	8.1	0.72	0.30–1.3
Diabetes	1.5	1.3–1.8	489	3.1	0.35	0.14–0.65
HIV infection	18	15–21	38	7.7	0.76	0.68–0.86
Smoking	1.6	1.2–2.1	1 040	7.1	0.70	0.23–1.4
Undernourishment	3.2	3.1–3.3	812	19	2.2	1.5–3.1



Source: Global TB report 2020; Waitt CJ. IJTL2011;15(7):87185.

Objectives

Primary objective:

To achieve 50% reduction in rates of TB in contacts by improving their nutritional status.

Secondary outcomes (*in patients*):

To improve nutritional status

To improve adherence to treatment/Loss to follow up.

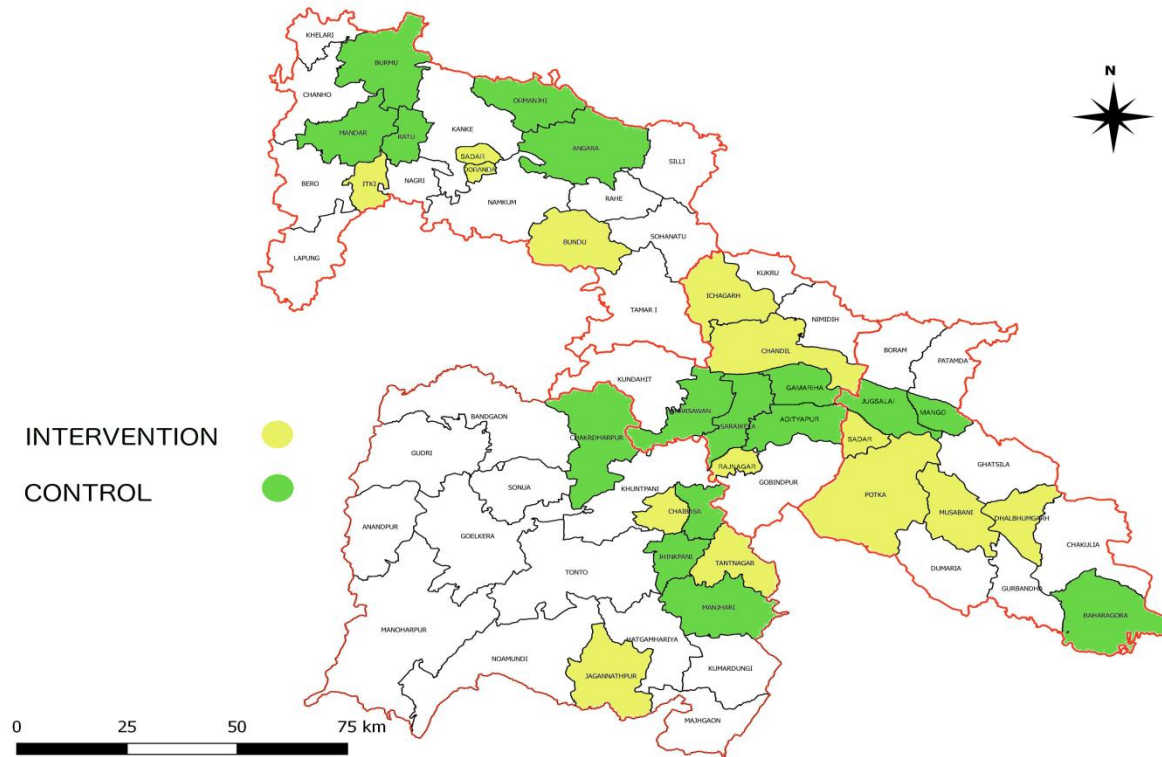
To reduce TB deaths

To improve performance status following treatment

To reduce disease recurrence

Secondary outcomes (*in contacts*):

To improve nutritional status, to reduce frequency of non-TB infections.



- 28 TUs in 4 districts of Jharkhand
- 2800 microbiologically confirmed pulm. TB + @12,600 contacts
- Food support & multivitamins to household + patient Vs. food support + multivitamin to patient alone

Intervention and control arm

Study arms	Description
Intervention arm	<ul style="list-style-type: none"><li data-bbox="480 311 2127 468">• Nutritional assessment + dietary advice+ Nutritional support (patient <i>and the family</i> for 6 months) <p data-bbox="480 521 2204 678">Patient: 5 Kg Rice + 3 Kg Sattu + 1.5 Kg milk powder + 500 ml Oil + multivitamins (1193 Kcal + 32-38 gm prot)</p> <p data-bbox="480 731 2218 888">Family: 5 Kg Rice +1.5 Kg Daal + Multivitamins (750 Kcal + 23 g prot)</p>
Control arm	<ul style="list-style-type: none"><li data-bbox="480 925 2218 1082">• Nutritional assessment + dietary advice + food support for patient <i>alone</i> for 6 months<li data-bbox="480 1135 2172 1292">• Patient: 5 Kg Rice + 3 Kg Sattu + 1.5 Kg milk powder+ 500 ml Oil + multivitamins<li data-bbox="480 1345 1984 1416">• Family: Nutritional assessment + dietary advice





Protocol

Open access

Protocol

BMJ Open The RATIONS (Reducing Activation of Tuberculosis by Improvement of Nutritional Status) study: a cluster randomised trial of nutritional support (food rations) to reduce TB incidence in household contacts of patients with microbiologically confirmed pulmonary tuberculosis in communities with a high prevalence of undernutrition, Jharkhand, India

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ABSTRACT

Introduction India has the largest burden of cases and deaths related to tuberculosis (TB). Undernutrition is the leading risk factor accounting for TB incidence, while

Strengths and limitations of the study

▶ The Reducing Activation of Tuberculosis by Improvement of Nutritional Status study is the first

Food delivery and follow up in a difficult terrain. This is not desktop research !



Field experiences



The journey of an orphan tribal boy aged 18 years: baseline weight : 26.4 kg . BMI: 10.7 kg/m²



Current weight : 42.2 kg .
BMI: 17.1 kg/m²



Making the poorest of India stand on their feet again, with care and dignity



Empowering patients to become productive again: Improvement in a single month



Supportive supervision



Stock register supervision



Hemoglobin testing and weight measurement in the field



Height and blood pressure measurement



