

**(Reducing Activation of Tuberculosis by  
Improvement Of Nutritional Status)**

# **RATIONS Trial**

**Supported by the India TB Research Consortium - ICMR**

Impact of nutrition in reducing TB incidence in household contacts of PTB patients in communities with high undernutrition

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# Study population of the RATIONS trial

## RATIONS TRIAL and its populations

**10345 Household contacts** followed for 2 years of Primary outcome: TB incidence in both arms

**2800 Patients** received food baskets for 6 months **and** followed up for secondary outcomes: TB-mortality, LTFU, drug-induced side-effects, activity levels

**Control group: 4724** household contacts were on usual diet

**Intervention group: 5621** contacts received food baskets + multivitamins for 6 months

## Objectives

### Primary Objective

Difference in incident TB cases in Household Contacts in both groups in 24 month of follow-up

### Secondary Objectives

- TB mortality
- Changes in weight, BMI
- Loss to follow-up
- Severe adverse effects to TB drugs
- Change in functional status



#### Monthly food basket in Intervention Arm

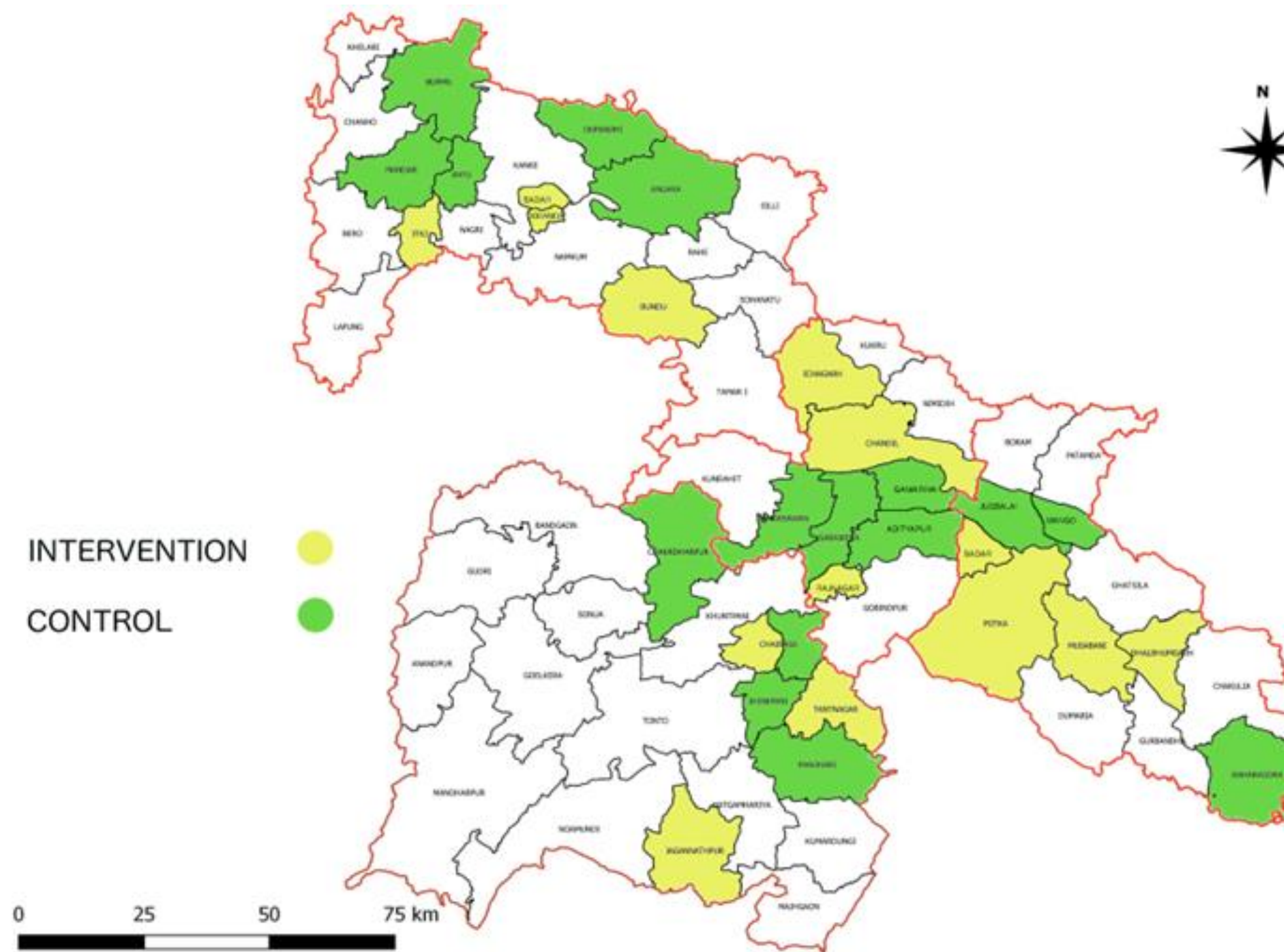
5 kg Rice,  
1.5 kg split pigeon peas  
Micronutrient pills



#### Monthly Food Basket both the arms:

5 kg Rice, 1.5 kg Milk Powder, 3 kg Roasted Chickpea flour, 500 ml Oil  
Micronutrient pills

# Trial setting: Jharkhand (The land of trees)



- 24 districts, predominantly rural
- Indigenous communities (STs): 28%
- High levels of undernutrition & poverty (36.9%)
- Case notification rate: 130/100,000
- 28 TB units in 4 districts: Ranchi, Seraikela Kharsawan, East Singhbhum, West Singhbhum

## Trial Timeline

**Start date of trial: 14<sup>th</sup> May 2019**

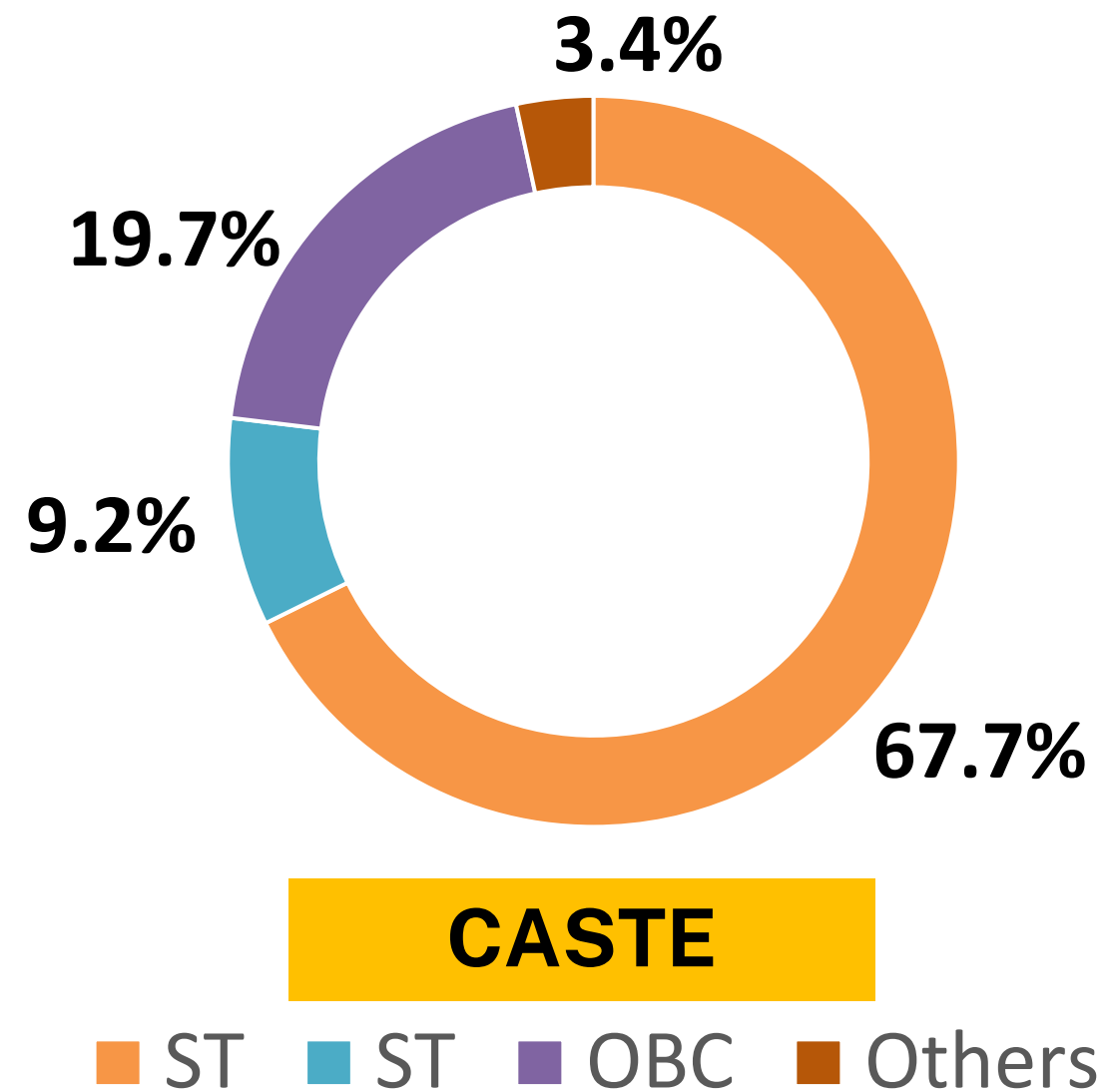
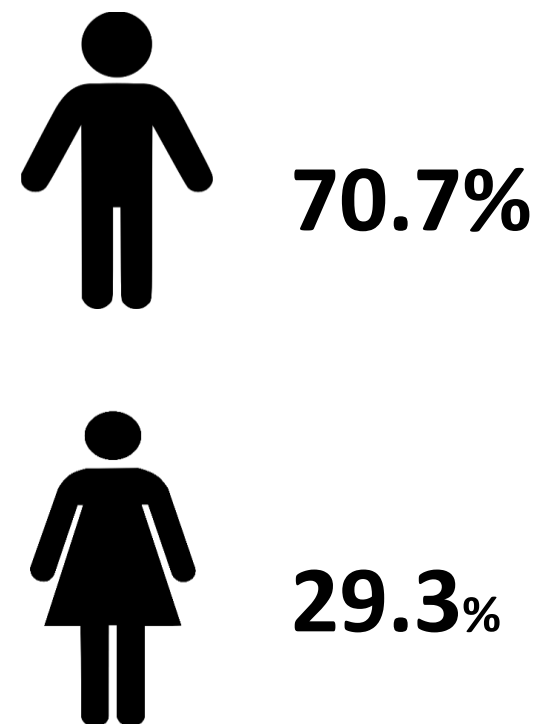
**Start of Enrolment : 16<sup>th</sup> Aug 2019**

**Trial duration: 3 years**

**End date: 13<sup>th</sup> August 2022**

# Baseline characteristics of patients with TB (Index case)

- People with Diabetes – **5%**
- History of TB in family members – **14%**
- History of Tobacco use – **36.5%**
- History of Alcohol use – **50.2%**
- MDR: **3%**
- HIV: **0.3%**
- Severely underweight (BMI<16 kg/m<sup>2</sup>): **48.6%**
- Hypotension – **10.4%**
- Hypoxia: **9%**
- Anemia: **88%**
- Severe anemia: **7.5%**



Activity levels by ECOG at **baseline**

Able to do normal work: **3%**

Limited activity or bed bound: **12 %**

# Baseline characteristics of household contacts

- People who had access to PDS: **85%**
- Tobacco consumption: **9%**
- Alcohol consumption: **14%**
- Presence of BCG Scar: **70%**
- Tuberculosis preventive treatment: **16%**



Children <5 years: **11%**  
Children 6-17 years: **30%**



Adults: **59%**

## Prevalence of Underweight in Household contacts at enrolment

	Control	Intervention
Adults	<b>35%</b>	<b>39%</b>
Children	<b>47%</b>	<b>49%</b>
Adolescents	<b>21%</b>	<b>27%</b>

# Outcomes in contacts of the RATIONS trial

## PRIMARY OUTCOME

### Overall TB Incidence:

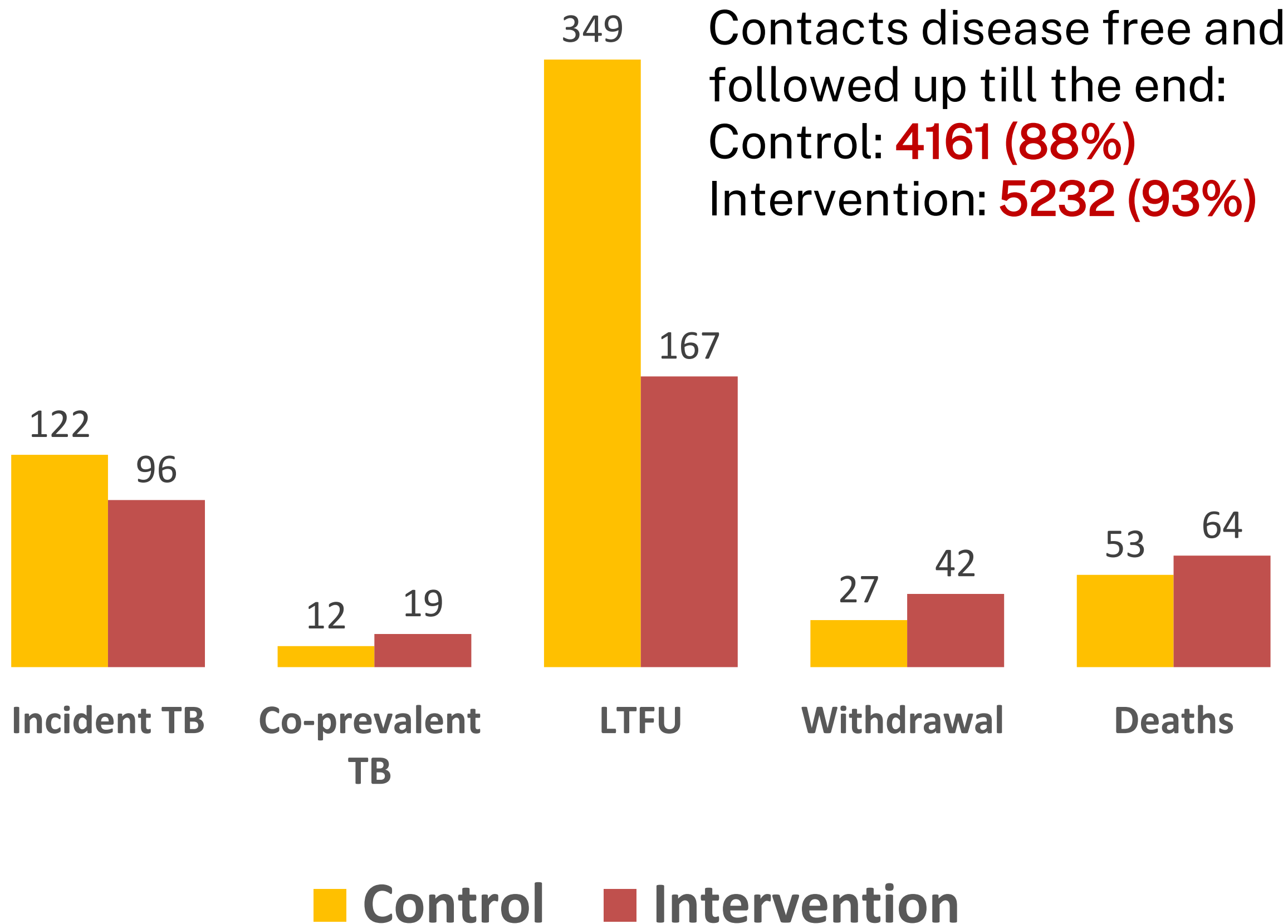
- **218/10,345** contacts over 21,869 person years of follow up

### By Arms:

- **96/5621 (1.7%)**: Intervention
- **122/4724 (2.6%)**: Control

Adjusted Incidence rate ratio (all forms of TB): **0.61 (39% reduction in incidence)**

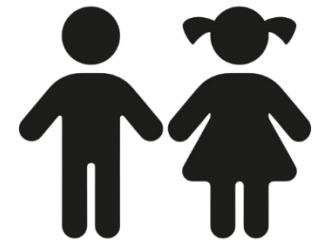
Adjusted incidence rate ratio of pulmonary TB: **0.52 (48% reduction in incidence)**



# Characteristics of incident TB in household contacts

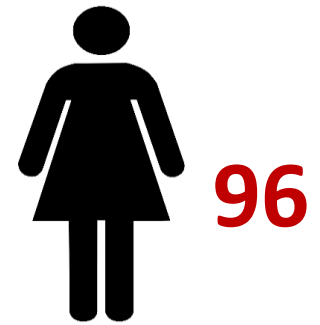


122



<5 years): **11**

6-17 years: **30**



96



Adults: **177**

## TYPES OF INCIDENT TB IN CONTACTS

- Microbiologically confirmed: **153**  
Control: **91**; Intervention: **62**
- Clinically diagnosed PTB (adults): **38**
- Extrapulmonary: **6**
- Clinically diagnosed (children): **21**

## Average weight gain in household contacts (kilograms)

### INTERVENTION ARM

- Adults (18-59): **1.6**
- Adults (>60): 1.1 (men) & 1.3 (women)
- Children (<5) 1.4 (boys), 1.5 (girls)
- Children (>5) 1.9 (boys); 2 (girls)

### CONTROL ARM

- Adults (18-59): **0.8**
- Adults (>60): 0.6 kgs
- Children (<5): 1.4 (boys), 1.3 (girls)
- Children (>5) 1.5 (boys); 1.6 (girls)

# Treatment outcomes in 2800 patients at 6 months

**Treatment success: 94%**

- Cure: **49%**
- Treatment completed: **45%**
- Weight gain in patients: **4.6 kg**

**Unfavorable outcomes: 5%**

- Death during treatment: **3.9 %**
- Treatment failure: **0.3 %**
- Loss to follow-up: **0.9 %**

## Predicting and preventing TB deaths

- Most deaths occurred at home
- Most deaths occurred within first 2 months (median: 46 days)
- Low body weight, poor performance status and diabetes: major predictors of death
- **5%** weight gain in first two months reduced the risk of death by **60% (Adjusted Hazard ratio: 0.39)**



# Impact of nutritional support on TB mortality

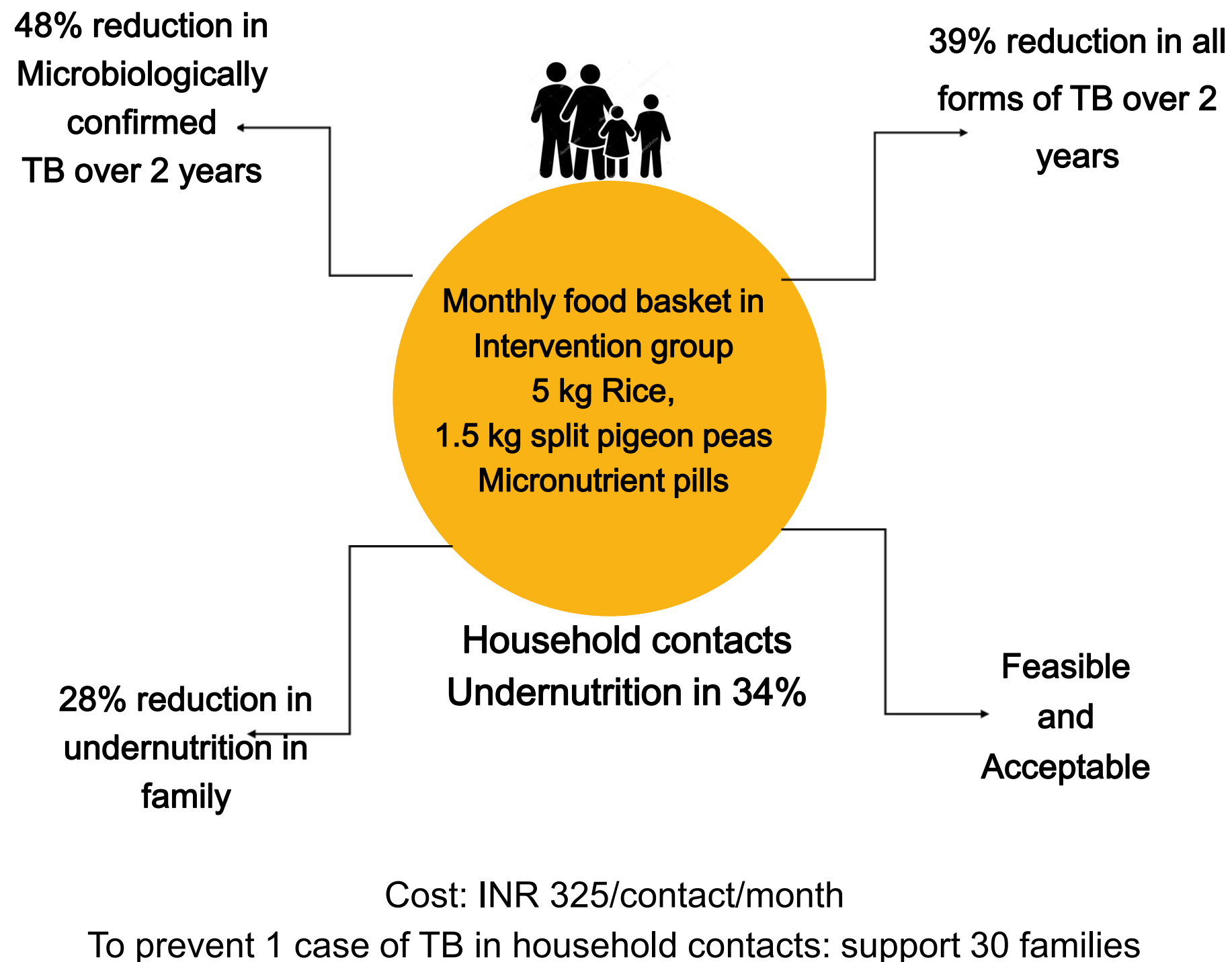
Activity levels by ECOG at <b>baseline</b>	Activity levels by ECOG at <b>6 months</b>
Able to do normal work: <b>3%</b>	Able to do normal work: <b>75 %</b>
Limited activity or bed bound: <b>12 %</b>	Limited activity or bed bound: <b>0.7 %</b>

## Impact of nutrition support in TB-deaths and comparison to other cohorts

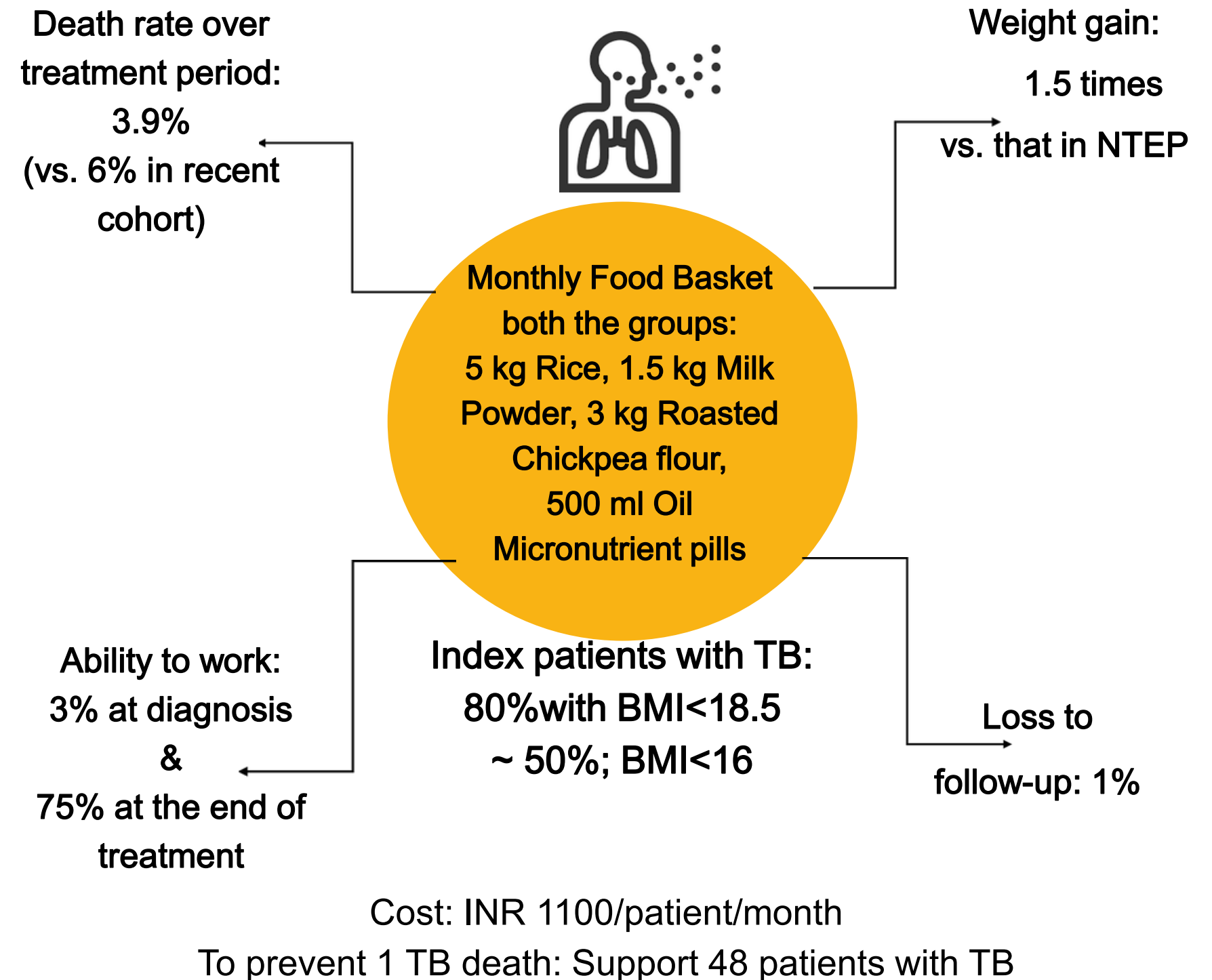
- The overall mortality of the RATIONS trial was **3.9%**
- Significantly lower than the mortality rate of **5.9%** in the comparison cohorts
- In those <35 kg: it was **half** that of comparison cohort

# Evidence from the RATIONS Trial in Jharkhand, India

## Food as a tool for TB prevention



## Food for better outcomes in patients with TB



# Conclusion

Reduced rates of TB incidence (all forms) by 39%

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Reduced rates of confirmed TB by 48%

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Lower death rate

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Increased weight gain

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Higher treatment success rate

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Better ability to go back to work

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Insights for comprehensive integrated TB care for mortality reduction