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Supplementary appendix

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Supplementary appendix

Addressing undernutrition as a comorbidity in Tuberculosis: Outcomes in a programmatic cohort nested within the RATIONS trial in Jharkhand, India

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A. Supplementary methods

Trial setting:

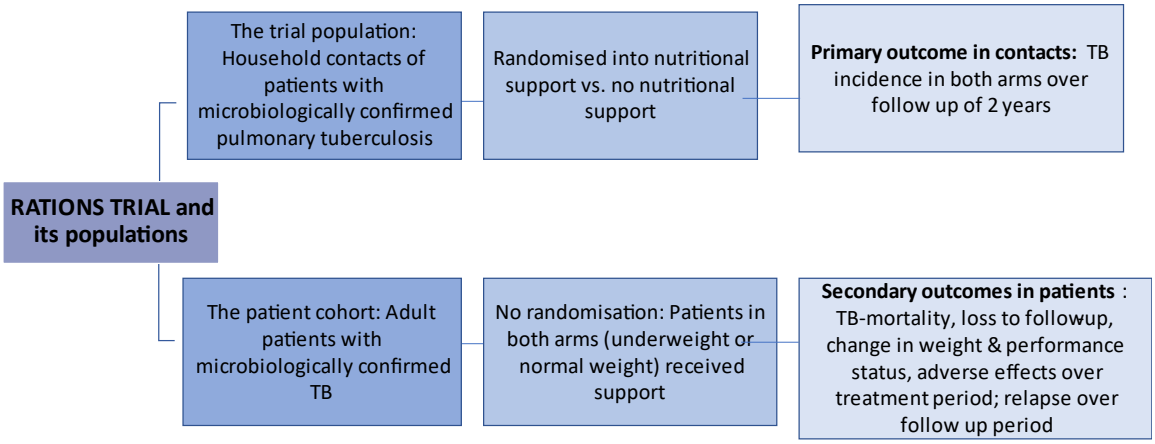
Jharkhand is the 16th largest state in India with an area of 79,714 km^2 with an estimated population of 33 million in 2011 Census.[1] The State is divided into 24 districts, and had a projection of increase in population to 38 million by 2021. As per census 2011, the Scheduled Caste (SC) and Scheduled Tribe (ST) population is 3·9 million (12·1%) and 8·6 million (26·2%), respectively. The sex ratio at birth (923 females for every 1000 males) is higher than the national average. The crude birth and death rates were 22·3 and 5·3 respectively in 2019. The literacy rate in men and women was 76·8% and 55·4% respectively in 2011. The infant mortality rate is 27 per 1000 live births, the maternal mortality ratio is 71 per 1000, while the life expectancy in Jharkhand was estimated to be 69·1 years in 2017-18.

Table S1: Objectives of the RATIONS Study, and the outcome variables

Objective	Outcome variables	Index	HHC
Primary Objective			
Effect of household nutritional supplementation in reducing TB incidence among HHC of patients with microbiologically confirmed PTB	Difference in number of incident cases of active TB (all forms) detected by active case finding over a follow-up period of two years in intervention and control arms		✓
Secondary Objectives			
Effect of nutritional supplementation on anthropometric indicators over 6 months	Anthropometric indicators such as weight and BMI	✓	✓
Non-TB infectious morbidity and mortality in HHC in both the arms	Malaria, diarrhoea, lower respiratory tract infection, hospitalization with fever of any cause, or death with fever of any cause <15 days in duration		✓
Adherence to anti-TB therapy	Proportion completing the therapy successfully	✓	
Mortality during treatment	Proportion of index cases who died during treatment	✓	
Adverse effects	Severe adverse effects with TB drugs	✓	
Recurrence of TB within 2 years after cure	Relapse rate of microbiologically confirmed TB	✓	
Performance status	Change in ECOG scale at 6 months compared to baseline	✓	

HHC: household contact; PTB: pulmonary tuberculosis; MDR: multi-drug resistant tuberculosis; ECOG: modified eastern co-operative oncology group; BMI: Body mass index

Figure S1: RATIONS trial and its populations



Legend for Figure S1: RATIONS: Reducing Activation of Tuberculosis Through Improvement of Nutritional Status; NTEP: National Tuberculosis Elimination Programme

Table S2: Key indicators of Jharkhand related to the Sustainable Development Goals (SDGs)[2]

Indicators	
Forest cover (%)	29·62
Population below poverty line (%)	36·96
Multidimensional Poverty Index Head count ratio (%)	46·5
Households covered by health scheme/insurance (%)	13·3
Households living in kachcha/mud houses (%)	6·6
Monthly per capita out-of-pocket expenditure on health (%)	11
Physicians, nurses, and midwives per 10,000 population	4
Rural population getting drinking water within premises through piped water supply (%)	35·49
Regular wage/salaried employees in non-agriculture sector, without social security benefits (%)	60·50
Population in the lowest two wealth quintiles (%)	68
Beneficiaries under National Food Security Act (%)	77·8
Children under 5 years who are underweight (%)	42·9
Children under 5 years who are stunted (%)	36·2
Pregnant women (15-49 years) who are anaemic (%)	62·6
Adolescents (10–19 years) who are anaemic (%)	34
Maternal Mortality Ratio (per 1,00,000 live births)	71
Under 5 mortality rate (per 1,000 live births)	34
Children (9-11 months) fully immunized (%)	94
Notification rate of Tuberculosis per 1,00,000 population	146
HIV incidence per 1,000 uninfected population	0·04

Table S3: Key indicators of the four districts where the RATIONS trial was implemented[3]

		West Singbhum		Saraikela Kharsawan		East Singbhum			Ranchi		
	Indicators	Rural	Total	Rural	Total	Urban	Rural	Total	Urban	Rural	Total
1	Households with an improved drinking water source (%)	64·0	68·9	72·2	80·7	96·0	83·1	90·2	92·3	62·3	75·0
2	Households using improved sanitation facility (%)	10·3	16·1	9·3	27·0	71·0	8·9	43·4	66·2	17·0	37·8
3	Households using clean fuel for cooking (%)	2·4	10·0	4·1	24·9	69·1	4·4	40·4	75·8	12·1	39·1
4	Households with any member covered by health insurance (%)	3·3	4·7	9·0	10·5	20·5	18·8	19·8	8·6	4·9	6·5
5	Women who are literate (%)	43·0	49·8	52·7	60·0	83·4	54·6	71·4	85·5	62·4	73·0
6	Men who are literate (%)	64·0	69·6	78·6	78·2	94·7	73·2	84·9	90·2	81·6	85·5
7	Children under 5 years who are stunted (height for age) (%)	62·9	59·4	47·1	45·1	28·2	50·2	39·3	24·0	51·9	40·7
8	Children under 5 years who are wasted (weight for height) (%)	37·9	37·5	24·2	23·3	33·0	48·0	40·6	25·1	28·6	27·2
10	Children under 5 years who are underweight (weight for age) (%)	67·5	66·9	56·0	52·6	36·6	62·6	49·8	32·1	51·7	43·8
11	Women with BMI below normal (BMI < 18·5 kg/m^2) (%)	34·4	32·4	41·3	34·8	14·7	28·0	20·2	18·7	37·9	29·1
12	Men with BMI below normal (BMI < 18·5 kg/m^2) (%)	23·9	25·3	29·1	23·9	13·6	16·4	14·8	20·8	32·3	27·3
13	Children age 6-59 months who are anaemic (< 11·0 g/dl) (%)	84·2	83·8	82·4	81·9	59·4	73·7	66·5	49·5	74·1	64·8
14	All women age 15-49 years who are anaemic (%)	75·4	72·8	83·4	78·8	60·6	74·8	66·6	53·1	73·8	64·5
15	Men age 15-49 years who are anaemic (<13·0 g/dl) (%)	36·3	30·6	43·7	38·7	29·6	41·4	35·0	12·4	39·3	27·6

Table S4: Inclusion and Exclusion criteria of participants in the RATIONS trial [4]

Participant type	Inclusion Criteria	Exclusion criteria
Index cases	Patients ≥18 years with microbiologically confirmed pulmonary TB	No household contacts Time interval between initiation of treatment and enrolment is >14days
Household contacts	Persons living in the same house, eating from same kitchen as index case for ≥ one night or for frequent or extended periods during the day during the 3 months before diagnosis in index case	Current smear or GeneXpert or Line Probe Essay or culture confirmed TB Clinically diagnosed pulmonary or extra-pulmonary TB and currently on treatment

Table S5: List of household assets possessed and their approximate cost in the RATIONS trial

Number	Asset	Approximate cost
1.	Cot or bed	2000
2.	Chair	750
3.	Table	1500
4.	Pressure-cooker	1500
5.	Electricity connection	500
6.	Fan	1500
7.	Radio/tape recorder	1500
8.	TV	10000
9.	A watch or a clock	750
10.	Telephone/mobile	5000
11.	Bicycle	6000
12.	Motorcycle	60000
13.	Fridge	15000
14.	Computer or tablet	20000
15.	Vehicle (car/truck, etc)	600000
16.	Lift pump	75000
17.	Goat	8000
18.	Cow	30000
19.	Ox	25000
20.	Buffalo	40000
21.	Hen	250
22.	Duck	300
23.	Pig	5000

Table S6: Number of missing values of variables measured in baseline evaluation of patients in RATIONS trial

Variable	No. of missing values
Baseline weight, n (%)	15 (0·5%)
Baseline height, n (%)	20 (0·8%)
Baseline BMI, n (%)	20 (0·8%)
Baseline SpO2, n (%)	3 (0·1%)
Blood pressure, n (%)	47 (1·7%)
Hemoglobin, n (%)	66 (2·4%)

Table S7: Details of nutritional support to participants in the RATIONS trial [4]

	Intervention arm	Control arm
Index case*	Nutritional counselling along with 5 kg of rice, 3 kg roasted Bengal gram powder (locally called as *sattu*), 1·5 kg of milk powder, 500 ml vegetable oil, and one RDA of micronutrient	Nutritional counselling along with 5 kg of rice, 3 kg roasted Bengal gram powder (locally called as *sattu*), 1·5 kg of milk powder, 500 ml vegetable oil, and one RDA of micronutrient
Household contact[§]	Nutritional counselling along with 5 kg rice, 1·5kg pulses (split pigeon peas), and one RDA of micronutrient per person (Half of this amount for children less than 10 years)	Nutritional counselling and the usual food assistance available to eligible households through public distribution system

RDA = Recommended Dietary Allowance; * Quantity is per person per month and approximately 1200 Kcal of energy and 52 gm proteins per day; § Quantity is per person per month and approximately 750 Kcal of energy and 23 gm of proteins per day.

Definitions of outcomes in patients according to the National Tuberculosis Elimination Programme

Programmatic definitions of outcomes in patients with microbiologically confirmed TB according to National Tuberculosis Elimination Programme (previously Revised National Tuberculosis Control Programme).[5]

a) Cured: Patients with microbiologically confirmed PTB who were smear negative/culture at end of treatment.

b) Treatment completed: A patient who completed treatment without evidence of failure or clinical deterioration but with no record of negative smear or culture at the end of treatment either because it was not done or was not available.

c) Treatment success: Patients who were either cured or who completed treatment.

d) Treatment failure: A patient whose specimen is positive by smear or culture at end of treatment.

e) Lost to follow up: A patient whose treatment was interrupted for one or more consecutive month or more

f) Treatment regimen changed: A TB patient who is on first line regimen and has been diagnosed as having DR-TB and switched to drug resistant TB regimen prior to being declared failed.

g) Death: A patient who has died during the course of anti-TB treatment.

Lost to follow-up, withdrawal from study and withdrawal from intervention

a) All attempts (including telephonic contact) were made to retain follow-up in case of temporary migration with an in-person visit on their return. Participants were termed as lost to follow-up if in-person or telephonic contact was not made for ≥2 months in the intervention period or for ≥6 months in the follow-up period. All participants lost to follow-up were approached for an end of study evaluation to ascertain information on the primary and relevant secondary outcomes.

b) The reasons for discontinuation of study intervention were recorded, but these participants remained in the study and underwent protocol-specified follow-up procedures. However, if the participant also explicitly withdrew consent for follow-up and collection of additional information in addition to discontinuation of consumption of study intervention, the withdrawal of consent was recorded, and only the data collected prior to withdrawal of consent was used in the study.

c) Study participants were free to withdraw at any time during the trial. The reasons for the withdrawal were documented, which may include refusal of follow-up, lost to follow-up, participant request, or death. Unless the participants withdrew consent for further follow-up, attempts were made to ascertain outcomes.

Table S8: Eastern Co-operative Oncology Group (ECOG) scale for functional assessment

ECOG categories	Additional description	Category
Able to carry out normal activity without restriction	No physical restriction	0
Unable to do physically strenuous activity, but ambulatory and able to carry out light work	Able to walk around the neighbourhood, but unable to do any income-generating work	1
Ambulatory and capable of all self-care, but unable to carry out any work; up and about <50% of waking hours	Able to walk around the house and backyard	2
Capable of only limited self-care; confined to bed or chair >50% of waking hours	Able to go to the bathroom,	3
Completely disabled; cannot carry out any self-care; totally confined to bed or chair	Unable to go to the bathroom	4

For some analysis, we also dichotomized the ECOG categories into poor performance status (ECOG categories 3 and 4) and better performance status (ECOG categories 0,1, and 2)

Table S9: Classification of nutritional status as per body mass index (BMI)[6,7]

Classification	Body mass index (BMI) in kg/m^2
Extremely severe underweight	< 14·00
Severe underweight	<16·00
Moderate underweight	16·00 – 16·9
Mild underweight	17·00 – 18·4
Normal range	18·50 – 24·9
Pre-obese	25-29·9
Obese Class I	30·0 – 34·9
Obese Class II	35·0 – 39·9
Obese Class III	>40·00

Table S10: Classification of anemia as per WHO cut-offs of hemoglobin levels (g/dl)[8]

Group	No Anemia	Mild	Moderate	Severe
Non-pregnant women (>15 years)	≥12	11-11·9	8-10·9	<8
Pregnant Women	≥11	10-10·9	7-9·9	<7
Men	≥13	11-12·9	8-10·9	<8

Table S11: Composition of micronutrient supplement pill provided with the food-basket

Micronutrient	
Vitamin A	5000 IU
Vitamin D3	400 IU
Vitamin E	15 mg
Vitamin B1	5 mg
Vitamin B2	5 mg
Nicotinamide (Vitamin B3)	45 mg
D-panthenol	5mg
Vitamin B6	2 mg
Vitamin C	75 mg
Folic Acid	1000 mcg
Vitamin B12	5 mcg
Dibasic Calcium phosphate	70mg
Copper sulphate	0·1 mg
Manganese sulphate monohydrate	0·01 mg
Zinc sulphate monohydrate	28·7 mg
Potassium iodide	0·025 mg
Magnesium oxide	0·15 mg

IU: International Units; mcg: micrograms; the only commercial preparation containing both fat soluble and water-soluble vitamins had levels of vitamin A, B-Vitamins (B1, B3, B12) folate higher than the recommended daily allowance, and hence the pill was taken every alternate day

Criteria for referral or red-flag features for field workers

1. Systolic BP < 90 mm Hg
2. Arterial oxygen saturation < 94
3. Body mass index < 16 kg/m^2 along with presence of edema.
4. Body mass index < 14 kg/m^2
5. Inability to stand without support (ECOG-4)

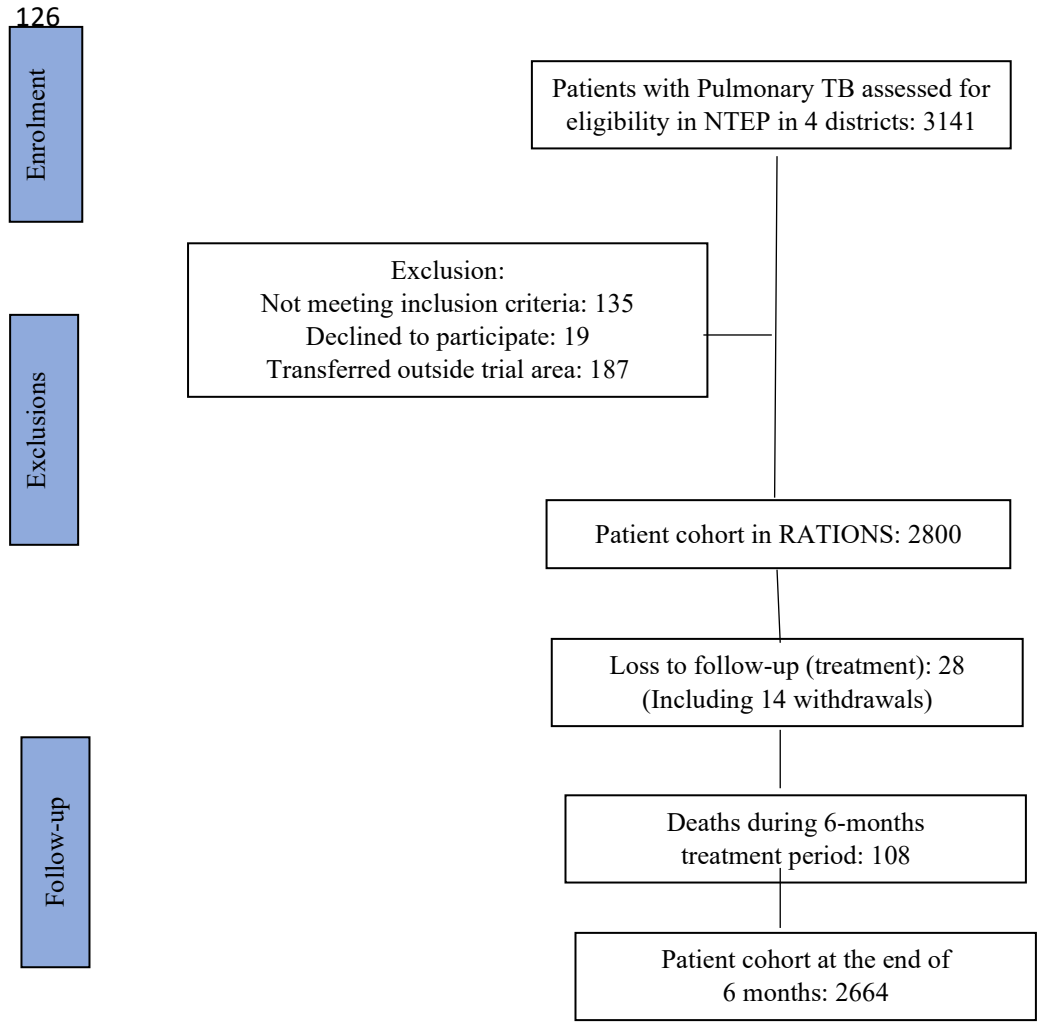
B. Supplementary results

Table S12: Occupational status of patients in the RATIONS trial

Occupational status	n (%)
Unemployed	176 (5·79)
M**G**NREGS, paid labor, sell forest product and ride rickshaw or cart	1619 (53·24)
Sell milk, vegetables, livestock, and small-scale trade	260 (8·55)
Making and selling of baskets, tailoring, making selling of alcohol and tobacco	41 (1·35)
Remittance, pensions, employment in mines, contract, and permanent job	202 (6·64)
Medium and large-scale trade, income from land	30 (0·99)
Student	204 (6·71)
Housewife	465 (15·29)
Not applicable	44 (1·45)
Total^	3041 (100)

***MGNREGS**: Mahatma Gandhi National Rural Employment Guarantee Scheme; ^ Due to multiple occupations, the number does not add up to 2800

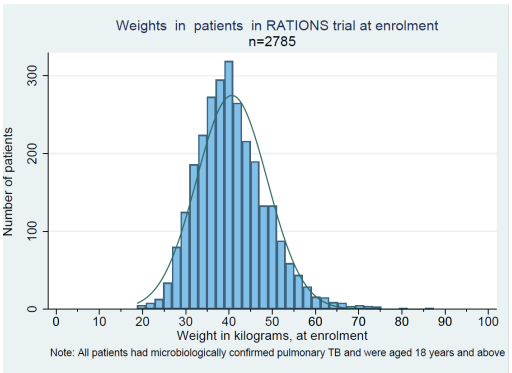
Figure S2: Patient Cohort in RATIONS trial:



Legend for figure 2: NTEP is National Tuberculosis Elimination Programme

Figure S3: Histogram of weights (A) and BMI (B) of patients at enrolment in the RATIONS trial

A



B

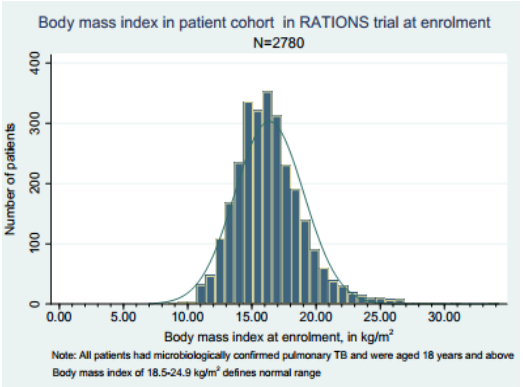


Figure S4: Histogram of Hemoglobin level of patients in the RATIONS trial

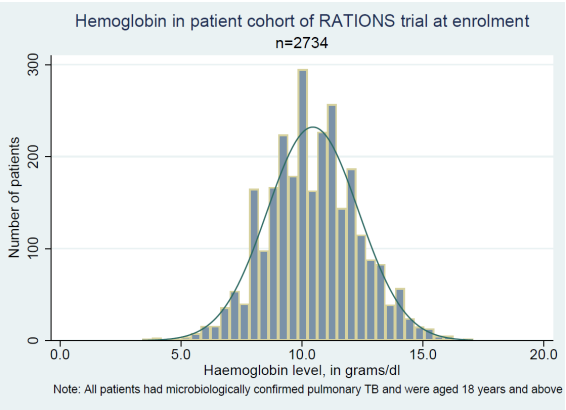


Table S13: Changes in weight in patients stratified by trial arms in the RATIONS trial at 6-months

	Men (n=1850)			Women (n=776)		
Weight changes	Control (n=916)	Intervention (n=934)	p value	Control (n=403)	Intervention (n=373)	p value
Baseline weight; mean (SD)	42·64 (7·47)	42·98 (7·89)	0·3388	36·42 (7·66)	36·03 (6·60)	0·45*
Weight at 6 months, mean (SD)	47·33 (7·10)	48·52 (7·80)	0·0006	40·69 (7·29)	40·62 (6·65)	0·89*
Weight gain, mean (SD)	4·69 (3·41)	5·54 (3·27)	<0·0001	4·26 (2·84)	4·58 (2·97)	0·12*
Weight gain, median (IQR)	4·3(2·4, 6·6)	5·2(3·3, 7·4)	<0·0001	4·0(2·3, 5·9)	4·5(2·8, 6·4)	0.047^
Weight gain (range)	-5·2, 22·3	-6, 23·5		-3·2, 13·65	-4·25, 15·45	
Percent weight gain, mean (SD)	11·81 (9·53)	13·66 (9·16)	<0·0001	12·7 (9·80)	13·42 (9·71)	0·31*

SD: Standard deviation; IQR: Inter-quartile range; *Student's t-test; ^ Mann Whitney test

Table S14: BMI/nutritional status at 6 months of patients stratified by trial arms in the RATIONS trial

	Men (n=1848)			Women (776)		
BMI	Control (n=915)	Intervention (n=933)	p value	Control (n=403)	Intervention (n=373)	p value
Baseline BMI, mean (SD)	16·5 (2·5)	16·6 (2·6)	0·52^	16·2 (3·0)	16·2 (2·7)	0·80^
BMI at 6 months, mean (SD)	18·3 (2·4)	18·7 (2·5)	0·0005^	18·1 (2·8)	18·2 (2·8)	0·63^
BMI categories at 6 months						
Obese/Overweight, n (%)	8 (0·9%)	20 (2·1%)		10 (2·5%)	7 (1·9%)	
Normal, n (%)	399 (43·6%)	446 (47·7%)		152 (37·7%)	147 (39·4%)	
Underweight, n (%)	508 (55·5%)	468 (50·2%)		241 (59·8%)	219 (58·7%)	
Mild underweight, n (%)	236 (25·8%)	236 (25·3%)	0·03$	99 (24·6%)	97 (26·0%)	0·78$
Moderate underweight, n (%)	131 (14·3%)	116 (12·4%)		62 (15·4%)	52 (13·9%)	
Severe underweight, n (%)	118 (12·9%)	105 (11·3%)		68 (16·9%)	56 (15·0%)	
Extremely severe underweight, n (%)	23 (2·5%)	11 (1·2%)		12 (3·0%)	14 (3·8%)	

BMI: body mass index; ^ Student's t-test; $ Chi-square test; Underweight: BMI< 18·5 kg/m^2; Mild underweight: BMI 17·0-18·4 kg/m^2; Moderate underweight: BMI 16·0-16·9 kg/m^2; Severe underweight: 14·0-15·9 kg/m^2; Extremely severe underweight: BMI <14·0 kg/m^2

Table S15: ECOG in patients at 6 months stratified by trial arms in the RATIONS trial

	Men			Women		
ECOG category at 6 months	Control (n=923)	Intervention (n=944)	p value^	Control (n=406)	Intervention (n=378)	p value^
Category 0, n (%)	715 (77·4%)	715 (75·7%)		294 (72·4%)	276 (73·0%)	
Category 1, n (%)	167 (18·1%)	210 (22·3%)		93 (22·9%)	88 (23·3%)	
Category 2, n (%)	31 (3·4%)	16 (1·7%)	0·01	16 (3·9%)	11 (2·9%)	0·86
Category 3, n (%)	8 (0·9%)	2 (0·2%)		1 (0·2%)	2 (0·5%)	
Category 4, n (%0	2 (0·2%)	1 (0·1%)		2 (0·5%)	1 (0·3%)	

ECOG – Eastern Co-operative Oncology Group; ^ Chi-square test
For further explanation of ECOG categories, refer to table S8

Table S16: BMI categories of patients at baseline and at six months support in RATIONS trial

	BMI (kg/m^2) after 6 months of nutritional support							
Baseline BMI (kg/m^2)	<14	≥14-15·99	>16·0-16·99	≥17·0- 18·49	≥18·5-24·99	≥25·0-29·99	≥30·00	Total
<14	55	198	86	74	17	0	0	430 (16·4)
≥ 14-15·99	5	134	226	303	145	0	0	813 (31·0)
>16·0-16·99	0	11	40	201	182	0	0	434 (16·5)
≥17·0- 18·49	0	4	9	87	375	0	0	475 (18·1)
≥18·5-24·99	0	0	0	3	422	21	0	446 (17·0)
≥25·0-29·99	0	0	0	0	2	20	2	24 (0·9)
≥30·00	0	0	0	0	0	0	2	2 (0·1)
	60 (2·3)	347 (13·2)	361 (13·8)	668 (25·5)	1143 (43·6)	41 (1·6)	4 (0·2)	2624

Table S17: Weight gain stratified by BMI categories in patients in RATIONS

BMI category at baseline n=2620	Weight gain in kg, mean (SD)	Weight gain in kg, median (IQR)
BMI < 14 kg/m^2, n=430	6·7 (3·7)	6·3 (4·2, 9·1)
BMI 14·0-15·9 kg/m^2, n=813	5·4 (3·1)	5·1 (3·3, 7·3)
BMI 16·0-16·9 kg/m^2, n=430	4·5 (2·8)	4·6 (2·6, 6·1)
BMI 17·0-18·4 kg/m^2, n=475	4·2 (2·9)	3·9 (2·5, 5·8)
BMI 18·5-24·9 kg/m^2, n=446	3·7 (2·9)	3·5 (2·1, 5·4)
BMI ≥ 25·0 kg/m^2, n=26	2·4 (3·5)	2·2 (0·7, 4·0)

Table S18: Case fatality ratio in patients enrolled in the RATIONS study stratified by ECOG categories

ECOG	**Deaths, no of patients**	**Case fatality ratio (95% CI)**
Category 0	0/79	None
Category 1	19/1202	1·6 (0·9–2.5)
Category 2	33/1194	2·8 (0·5–3·9)
Category 3	34/271	12·6 (2·0–17·1)
Category 4	22/54	40·7 (6·7–55·0)

ECOG: modified Eastern Co-operative Oncology Group; CI: Confidence Interval

For explanation of ECOG categories refer to table S8

Table S19: Case fatality ratio in patients enrolled in the RATIONS study stratified by weight categories

Weight category (kg)	**Deaths**	**CFR (95% CI)**
18-24·9	5/27	18·5 (6·3–38·1)
25-29·9	19/172	11·1 (6·8–16·7)
30-34·9	54/1211	4·5 (3·4–5·8)
35-39·9	22/1233	1·8 (1·1–2·7)
40-54·9	2/129	1·6 (0·2–5·5)
55-69·9	0/13	0%
≥70 kg	0/2	0%

CI: Confidence Interval; Weights were missing in 6 patients in whom weight measurements were not possible

Table S20: Case fatality ratio in patients enrolled in the RATIONS study stratified by BMI categories

Nutritional categories using BMI	Deaths	CFR (95% CI)
Extremely severe undernutrition (<14 kg/m^2)	42/480	8·8 (6·4–11·6)
Severe undernutrition (14-15·9 kg/m^2)	31/869	3·6 (2·4–5·0)
Moderate undernutrition (16·0-16·9 kg/m^2)	16/455	3·5 (2·0–5·6)
Mild undernutrition (BMI 17·0-18·4 kg/m^2)	2/485	0·4 (0·05–1·5)
Normal BMI (18·5-24·9 kg/m^2)	7/459	1·5 (0·6–3·1)
Overweight (25·0-29·9 kg/m^2)	1/27	3·7 (0·09–19·0)
Obesity (≥ 30·0 kg/m^2)	0/2	--

BMI: Body mass index; CI: Confidence Interval; BMIs were missing in 9 patients in whom height measurements were not possible

Table S21: Characteristics of patients who survived and died in the RATIONS study

Characteristics	Survived (n=2692)	Died (n=108)
Age: mean (SD)	40·0 (14·43)	47·2 (14·63)
Gender: male, n (%)	1898 (70·5 %)	81 (75%)
Caste (ST), n (%)	1818 (67·5%)	78 (72·2%)
Being PDS beneficiary, n (%)	2261 (84·0%)	95 (88·0%)
Diabetes, n (%)	124 (4·61%)	15 (13·9%)
Alcohol use, n (%)	1337 (49·7%)	68 (63·0%)
MDR-TB, n (%)	38 (3·0%)	None
Smoker, n (%)	969 (36·0%)	52 (48·2%)
Weight at diagnosis (mean, SD)		
Men, mean (SD)	42·8 (7·7)	37·3 (8·1)
Women, mean (SD)	36·3 (7·2)	30·8 (5·8)
Height at diagnosis (mean, SD)		
Men, mean (SD)	159 (6·6)	160.9(6·3)
Women, mean(SD)	148·6(7·7)	149·4(5·9)
Stunting, n (%)	1435 (53·5)	63 (63·6)
BMI, mean (SD)	16·4 (2·7)	14·7 (2·9)
Men	16·5 (2·6)	14·7 (3·1)
Women	16·2 (2·9)	14·3 (2·5)
Weight gain in 1 month, median (IQR)	1·1 (0·45, 2·0)	0·6 (-0·4, 1·3)
Weight gain in 2 months, median (IQR)	2·2 (1·2, 3·6)	0·9 (-0·2, 2·6)
Systolic BP (median, IQR)	109 (98, 121)	100 (90, 115)
Diastolic BP (median, IQR)	78 (71, 85)	73 (64, 80)
SpO2 (median, IQR)	97 (95, 98)	95 (94, 97)
Grade of sputum microscopy		
Scanty to 1+ (n=910)	875 (45·1)	35 (42·7)
2+ to 3+ (n=1115)	1068 (54·9)	47 (57·3)
Performance status using ECOG, n (%)		
Better (Category 0-2)	2423 (90·0)	52 (48·2)
Poor (Category 3-4)	269 (10·0)	56 (51·8)

ECOG: modified Eastern Co-operative Oncology Group, refer to table S8 for further details; SD: Standard Deviation; ST: Scheduled tribes ; SpO2: Oxygen saturation; BMI: Body mass index

Table S22: Association between nutritional status at baseline and weight gain and TB-mortality

Characteristics of the patients	Patients who survived the treatment period	Patients who died during treatment	P value
Underweight (BMI<18·5 kg/m^2), n (%)	2291 (82·1%)	91 (91·9%)	0·011$^{@}$
Not underweight (BMI≥18·5 kg/m^2), n (%)	481 (17·9%)	8 (8·1%)	
Body weight at baseline in underweight patients (BMI<18·5 kg/m^2, mean (SD)	38·5 (6·0)	34·5 (6·2)	<0·0001§
Body weight at baseline in patients who were not underweight (BMI≥18·5 kg/m^2 , mean (SD)	51·8 (7·4)	52·0 (8·2)*	0·93§
Mean BMI (SD) at baseline in those who were underweight	14·1 (1·9)	15·5 (1·7)	<0·0001§
MUAC at baseline in those with missing BMI, median (IQR), n=20$^{\#}$	17·3 (16·1, 18)	14·1 (14, 15·6)	0·0074$^{!}$
Weight gain in kg in 1 month those underweight at baseline, median (IQR),	1·10 (0·5, 2·05)	0·63 (-0·28, 1·32)	0.0001$^{!}$
Weight gain in kg in 2 months in those underweight at baseline, median (IQR),	2·3 (1·3, 3·75)	1·05 (-1·91, 2·60)	0·0002$^{!}$

*5 out of these 8 patients had diabetes; #:9 of these died; $^{@}$: chi-squared test § t-test; $^{!}$: Mann-Whitney U test done due to non-normal distribution of some data

Table S23: Unadjusted and Adjusted Incidence Rate Ratios for TB-mortality during treatment

Covariate	Unadjusted IRR, 95% Cis	Adjusted IRR, 95% CIs
Male sex	1·24 (0·83, 1·85)	
Scheduled Tribes	Ref	Ref
Scheduled Castes	0·66 (0·26, 1·66)	0·92 (0·37, 2·26)
Other Backward Classes	0·84 (0·53, 1·34)	0·88 (0·51, 1·52)
Others	1·03 (0·40, 2·68)	2·22 (0·68, 7·27)
Log asset cost	0·87 (0·73, 1·03)	1·00 (0·84, 1·20)
Arm of trial	1·5 (0·98, 2·30)	1·50 (0·95, 2·38)
Sputum grade scanty	Ref	Ref
Sputum grade 1+	1·21 (0·71, 2·01)	1·52 (0·93, 2·51)
Sputum grade 2+	0·96 (0·52, 1·78)	0·83 (0·45, 1·49)
Sputum grade 3+	1·84 (1·00, 3·37)	1·29 (0·79, 2·11)
Cough duration	1·02 (1·01, 1·04)	1·01 (0·99, 1·03)
Tobacco use	0·62 (0·43, 0·90)	0·69 (0·43, 1·10)

Alcohol use	1·70 (1·05, 2·60)	1·70 (1·05, 2·60)
Family history of TB in past	0·29 (0·14, 0·60)	0·35 (0·18, 0·66)
Weight in kg at baseline	0·91 (0·88, 0·88)	0·95 (0·90, 0·99)
Hemoglobin	0·72 (0·62, 0·84)	0·86 (0·73, 1·00)
Eastern Co-operative Oncology Group (ECOG) category	Ref (ECOG 0-2)	Ref (ECOG 0-2)
ECOG categories (3-4)/poor performance status	9·52 (5·26, 17·22)	5·33 (2·90, 9·80)
Diabetes status	3·22 (1·77, 5·88)	3·30 (1·64, 6·66)

IRR: Incidence Rate Ratio; CI: Confidence Intervals

Table S24: Adverse drug reactions in patients enrolled in the RATIONS study

Adverse effect	**Percent patients with adverse effect**
Joint pain	1259 (45·0%)
Further loss of appetite	589 (21%)
Itching	520 (18·6%)
Abdominal pain	485 (17·3%)
Tingling sensation in limbs	343 (12·3%)
Vomiting and nausea	311 (11·1%)
Rash	259 (9.3%)
Drug induced hepatitis diagnosed by a physician	8 (0·3%)

Table S25: Association between severe anemia and TB-mortality in patients in the RATIONS trial

Characteristic	Patients who survived, n=2668	Patients who died, n=66*
Severe anemia present, n (%)	193 (7·2%)	12 (18·2%)
Severe anemia absent, n (%)	2475 (92·8%)	54 (81·8%)

Severe anemia is hemoglobin < 8 g/dl; 66 missing values of hemoglobin at baseline: 42 values of hemoglobin in patients who died (39%), and 24 (0.9%) in those who survived; p value=0·001 by chi-squared test

C. Supplementary discussion

Reference Indian man and woman in terms of weight and height to provide a perspective on the anthropometry of patient cohort of RATIONS trial:

In 2020, the National Institute of Nutrition proposed reference body weights for Indian men and women in the age group of 19-39 years.[9] This reference weights were based on the median weights of the population which had heights in the range of 95th percentile of heights of adults in the National Nutrition Monitoring Bureau's Urban survey of 2016, with body mass index in the range of 18·5-22·9 kg/m^2. This reference weight for an Indian man and woman was suggested as 65 kg and 55 kg respectively. In contrast, the weights observed in adult men and women with PTB enrolled in the trial were more than 20kg less. This points towards low baseline weights that were worsened due to the disease.

D. References to supplementary appendix

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