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Supplementary appendix

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Supplementary appendix

Title: Nutritional supplementation to prevent TB incidence in household-contacts of patients with pulmonary tuberculosis: Results from the RATIONS, a field-based open-label cluster-randomized controlled trial in Jharkhand, India.

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A. Amendments in the protocol:

Amendments in September 2019 (Enrolment started on 16th August, 2019)

1. The title originally had household contacts of patients with “smear positive” pulmonary tuberculosis patients. This was amended in September 2019 to “microbiologically confirmed” patients considering the increasing availability and use of Cartridge based nucleic acid amplification tests (CB-NAAT) like GeneXpert MTB/RIF assay (Cepheid, Sunnyvale, CA, USA) and TrueNat (Molbio Diagnostics/Bigtec Labs, Goa/Bengaluru, India)
2. Definition of household-contact: Initially a household-contact was defined as a person any age living in the same house as the index patient for one or more nights or for frequent or extended periods during the day with the index case for at least three months prior to the diagnosis. To this a phrase, “eating from the same kitchen as the index patient” was added as in rural Jharkhand, several families related by birth may live in the same compound but may not be in close contact with the patient. Hence, we revised the definition of household as a unit where members eat from the same kitchen.
3. Enrolment of participants: Screening, evaluation and enrolment of household-contacts was originally mentioned as “within 2 weeks from the diagnosis of the index patient”. This was modified to “2 weeks from the initiation of treatment of the index patient” because often the patients are diagnosed in a different TU or at a larger hospital and transferred out or referred to the closest tuberculosis unit after diagnosis. This can result in some delay. Since the time of initiation of treatment rather than the time of diagnosis determines the infectivity, this was as the cut-off for eligibility of enrolment.
4. Intervention: We considered groundnut as part of the food basket as had been recommended in the Guidance Document on Nutritional Care and Support for patients with Tuberculosis in India.¹ However, on quality check before the first dispatch in the trial, we found some larvae suggestive of “Bruchid of groundnut”. Aflatoxicosis was also a concern in view of humidity. After consulting experts from National Institute of Nutrition, Hyderabad and National Center for Excellence and Advanced Research in Diets (NCEARD), New Delhi, we replaced it with “Sattu” a flour from roasted Bengal gram that is a popular food item in Jharkhand. The protein content of Sattu is close to groundnut; however, the calorie content is less due to less invisible fat. To approximate the calorie content of the food basket to the original ground-nut based rations, we decided to add 500ml Soyabean oil.
5. Change of one Tuberculosis Unit: Originally, Manoharpur TU was included in the intervention arm. However, on the first visit, we found that it was very inaccessible and may be very difficult to monitor patients as well as evaluate the household-contacts. No participant was enrolled for more than 2 weeks, and we decided to replace it with Jagannathpur TU. It had similar case-load and demography, and although it was in a hard-to-reach part of the state, it had better accessibility than Manoharpur.

Amendment in October 2021

Originally for the study duration, follow-up period for the index patient and household contacts was up to 24 months after enrolment of the index case. Due to COVID-19 pandemic related disruption, the enrolment of the 2800 patients was completed in January 2021 instead of August 2020. The funding agency approved a no-cost extension of the trial till 13 August, 2022.

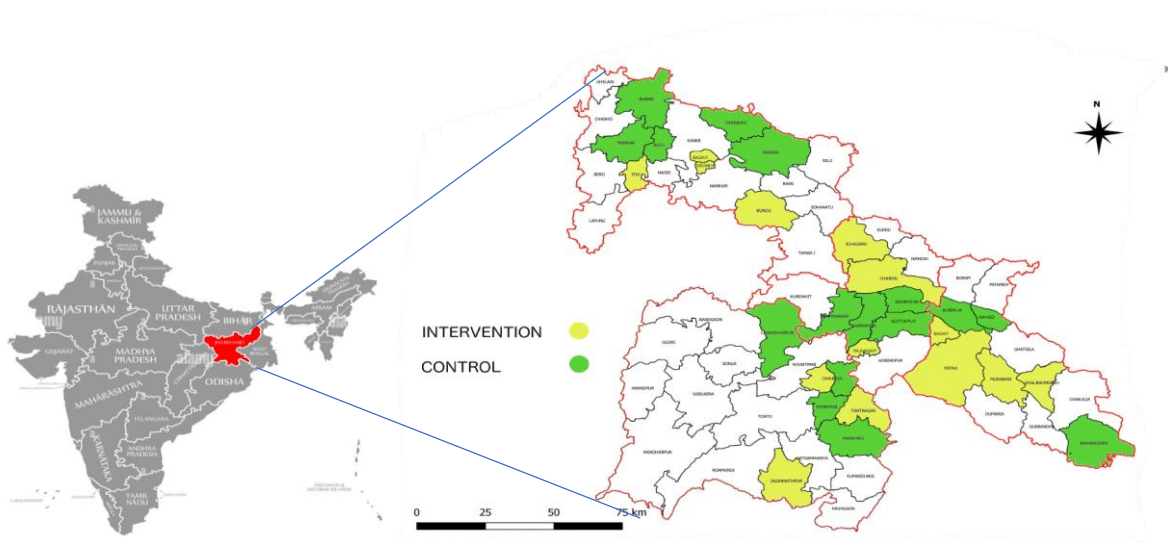
In view of these circumstances that precluded 2 years follow up of all household contacts, as well as disruptions caused by the COVID-19 pandemic we decided to amend the protocol from a common follow-up period to a common closeout period design.² The common closeout period was from May 1-July 31, 2022. The common closeout period allowed us to maximize the detection of incident cases in the household-contacts where those who were enrolled early in the trial would be followed-up beyond 24 months (upto a maximum of 33 months) and those enrolled after August 2020, would be followed-up for up to a minimum of 18 months. In contact studies, it has been seen that the higher risk of TB incidence in the household contacts is not limited to the first 2 years of exposure but is substantial even in year 3 in low and middle income countries.³

B. Supplementary section on trial setting

- i. Districts and Tuberculosis Units (TUs) included in the RATIONS trial in Jharkhand:
The four districts included were: Saraikela-Kharsawan, West Singhbhum, East Singhbhum, Ranchi.

The 28 TUs that were eligible and were randomized are as per Table S1. The administrative division of the district is in terms of blocks, for which population and demographic information is available in census data. However, the TB units did not always conform to the administrative blocks and sometime one TU was serving even 2-3 administrative blocks. Also, some blocks like Chaibasa had more than 1 TU. Therefore, information of the population and demography specific to the TU are not available for all. The information related to the active case finding, peripheral health institutions, designated microscopy centres and availability of investigations in each TU is current as of 2021, the percentages related to demographic features are based on Census – 2011.⁴ According to the Indian Constitution, certain population groups have been officially designated scheduled castes (SC) and scheduled tribes (ST) and considered as disadvantaged socioeconomic groups. Figure S1 depicts the trial district and the TUs in the intervention and control arms

Figure S1: Map of the four districts of Jharkhand included in the RATONS trial



1 **Table SI: Important characteristics of tuberculosis units in the RATIONS trial**

	TU	Arm of trial	Population	Literacy (%)	ST%	SC%	Urban pop%	ACF	PHIs	DMC	CBNAAT	Xray-facilities
1.	DTC-Saraikela	Control	93759	57.6	42.9	6.9	22	539	15	1	3	1
2.	Rajnagar	Intervention	136600	53.9	52.7	2.1	0	255	6	1	2	2
3.	Chandil	Intervention	157949	66.7	30.2	4.9	30.4	209	8	2	1	1
4.	Adityapur	Control	349065	70.6	13.9	5.1	99.9	272	8	4	1	0
5.	Gamharia	Control	309072	66.5	20.8	5.7	61.5	335	10	2	2	1
6.	Kharswan	Control	88642	65.3	39.9	7.7	0	152	13	2	1	1
7.	Ichagarh	Intervention	83099	61.0	32.3	7.6	0	241	10	3	1	1
8.	Angarha+Ratu	Control	112759	64.9	55.1	7.9	29	124	15	2	1	1
9.	Bundu	Intervention	82975	68.7	48.1	7.2	25.4	273	21	2	2	2
10.	Doranda	Intervention	597044	75.9	20.6	5.0	100	332	19	3	2	2
11.	Itki	Intervention	50058	73.6	48.4	1.4	100	800	14	2	3	1
12.	Mandar +Burmu	Control	218474	66.1	54.9	4.9	0	207	21	3	3	2
13.	Ormanjhi	Control	94137	67.5	35.8	4.2	5.5	124	12	2	1	2
14.	Sadar	Intervention	437178	78.2	18.4	4.0	100	2843	17	4	3	2
15.	Jagannathpur	Intervention	99169	60.7	59.6	5.4	12	265	12	1	1	0
16.	DTC Chaibasa*	Urban: Intervention Rural: Control	69565	86.9	25.7	6.5	100	775	14	2	2	1
17.	Chakradharpur	Control	56531	85.8	15.3	8.8	100	564	12	2	2	0
18.	Jhinkpani	Control	53792	58.2	59.8	5.3	24.3	204	11	2	1	0
19.	Manjhari	Control	68450	47.8	76.8	1.4	0	193	9	1	1	0
20.	Tantnagar	Intervention	63910	58.6	76.4	1.2	100	121	12	1	0	0
21.	Dhalbhumgarh	Intervention	61932	62.8	54.4	4.1	0	268	21	2	2	0
22.	Sadar	Intervention	631364	64.1	52.5	9.4	100	451	11	3	3	3
23.	Musaboni	Intervention	107084	71	46.4	5.5	46.3	289	29	2	1	1
24.	Mango	Control	223805	85.8	6.1	0.2	100	300	9	1	1	0
25.	Bahragora	Control	153051	64.5	35.9	6.8	0	300	14	2	1	2
26.	Jugsalai	Control	49660	84.4	3.3	0.5	100	512	11	1	2	2
27.	Potka	Intervention	199612	64.1	52.5	3.9	5.3	251	24	2	1	2

TU: Tuberculosis Unit; ST: Scheduled Tribes; SC: Scheduled Castes; ACF: Annualised case finding (in 2022); PHI: Peripheral Health Institutions, these are all primary, secondary and tertiary care facilities where National TB Elimination Programme is implemented; DMC: Designated Microscopy Centres; CBNAAT: Cartridge Based Nucleic Acid Amplification Test; DTC: District TB Centre; * The DTC Chaibasa has an urban TU that was randomized to the intervention arm and a rural TU that was randomised to the control arm.

ii. TB situation in Jharkhand, important highlights from India TB Report 2022 ⁵

- TB notification in Jharkhand: The details of notifications as per India TB Report 2022 are given in the table below.
- Tribal TB: The number of districts mapped as tribal districts (partly or wholly) were 15 and the net (this is after accounting for transferred in and out between facility, districts, states) tribal patients notified was 28102, the highest among all Indian states. Of these 27157 (96.6%) were initiated on treatment.
- The TB-mortality in Jharkhand was 1144 (4%) in male patients and 424 (3%) in female patients.
- Tuberculosis Preventive Treatment (TPT) in under-five (July to Dec 2021): Of 4283 under-five household contacts of microbiologically confirmed PTB patients, 3223 (75%) were screened for TB, 112 (3%) were symptomatic of TB of which 103 (92%) were evaluated for TB, 98 (95%) were diagnosed with TB and 95 (97%) were started on treatment. Thus 4185 were eligible for TPT and of these 1213 (29%) were started on treatment. In case of other age-groups (July to Dec 2021), of 15098 eligible for TPT, 2161 (14%) were initiated on TPT.

Important TB related information from Jharkhand in 2021	
TB notification	52,179; 130/100,000
Proportion that underwent CBNAAT/TrueNAT	19.6%
Notification from government facilities	87/100,000
Percentage new cases	47,948 (91.9%)
Percentage previously treated	3450 (6.6%)
Drug resistant	781 (1.5%)
Pulmonary TB	43885 (84%)
Extrapulmonary TB	8294 (16%)
Bacteriologically confirmed TB	22,897 (44%)
Diagnosed using microscopy	27%
Diagnosed using molecular tests	17%
Total paediatric cases notified	2716 (5.2%)
Paediatric cases notified in public sector	1159 (42.7%)
Paediatric cases notified in private sector	1557 (57.3)
Percentage initiated on treatment in public sector	95%
Percentage initiated on treatment in private sector	100%

iii. Risk factors of TB in Jharkhand as per NFHS-5.⁶

- Undernutrition at population level: Prevalence of women (15-49 years) that had BMI <18.5kg/m² was 26.2% (17.3% in urban; 29.2% in rural), and the same in men was 17.1% (12.1% in urban; 18.9% in rural). In case of under-five children, the prevalence of stunting was 39.5% (26.8% in urban; 42.3% in rural), wasting was 22.4% (23% in urban; 22.3% in rural), underweight was 39.4% (30.0% in urban; 41.4% in rural). Anemia was prevalent in 65.3% non-pregnant women, 29.6% men, and 67.5% under-five children.
- Proportion of women who had either high blood sugar level (141-160 mg/dl), or very high blood sugar level (>160 mg/dl) or were taking some medication to control blood sugar was 10.2 in women (12.5% in urban; 9.5% in rural) and 14.1% in men (15.8% in urban; 13.4% in rural).
- HIV testing was dropped in NFHS-5, but as per NFHS-4, the prevalence was 0.15% during NFHS-4 (2015-2016)
- Tobacco was used by almost half (49%) men and 2% women as per NFHS-5. Tobacco products mostly used by men are khaini (39%), cigarettes (15%), gutkha or paan masala with tobacco (12%), and paan with tobacco (5%). These are all local variations of tobacco products commonly used in India. Among women and men, the use of any form of tobacco is higher in rural areas (3% for women and 52% for men) than in urban areas (2% for women and 40% for men).
- In Jharkhand, among adults aged 15-49, a negligible proportion (3%) of women and two-fifth (40%) of men drink alcohol. Among men, consumption is higher in rural areas than in urban areas (42% versus 35%). Most men who drink alcohol drink it about once a week (43%) or less than once a week (29%), and 28 percent drink almost every day.
- BCG vaccination coverage was 95% in Jharkhand (93% in urban areas and 95.4% in rural areas)

iv. COVID-19 situation in Jharkhand⁷

The trial had a significant overlap with the COVID-19 pandemic. Although it did not get stalled, some components got affected, such as: some families were given food rations for two months in advance, heights became difficult as transport got affected and stadiometers could not be carried at times, diagnostics in the NTEP were disrupted, patients and families were hesitant to have any contact with the health personnel coming to their houses due to fear of spread of infection to name a few. Our own staff were also affected, although we facilitated their vaccination as soon as it was available. We also conducted multiple training sessions on COVID-19 pandemic and infection prevention.

As per the updates till December 2022, there were a total of 442567 cases in Jharkhand and 5331 deaths recorded. With respect to the time period that overlapped with the trial, the first wave was from July 2020 and reached maximum in August end and early September and then reduced by November 2020. The second wave was from March 2021, peaked by the end of April and continued till June 2021.

Figure S2: Snapshot of COVID-19 pandemic in Jharkhand from the COVID-19 dashboard

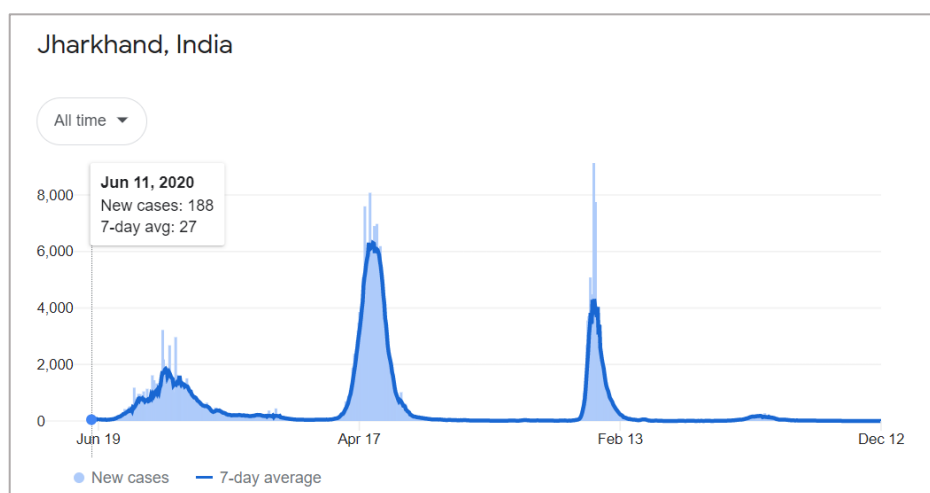
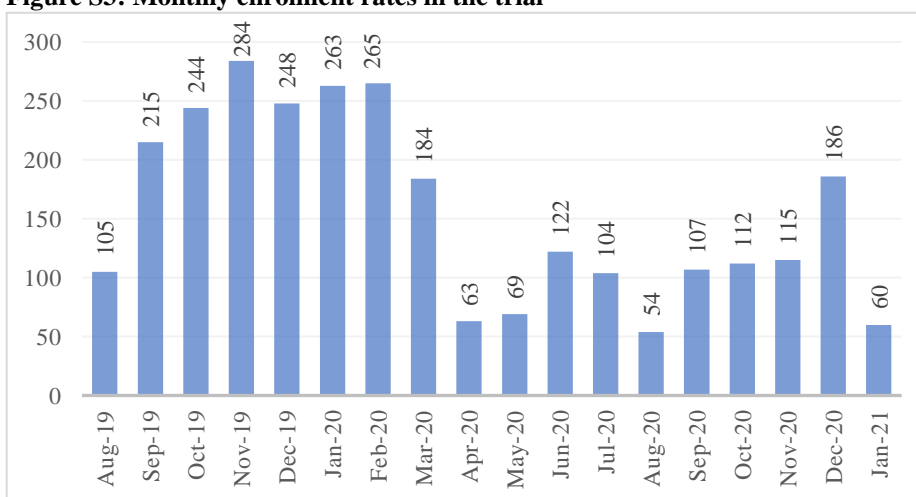


Figure S3: Monthly enrolment rates in the trial



C. Supplementary Methods:

Trial team: The field team consisted of a supervisory technical team of one project director, two project consultants, and one research associate along with 56 field-staff, two data-entry operators, two phlebotomists, and one laboratory technician (for sub-studies). There were two field-staff for each cluster for the first two years and one for the last year. The field-staff collected data in electronic form in a hand-held device, delivered the intervention, screened and advised the household-contacts for seeking further evaluation; they were not involved in the ascertainment of outcomes. For two districts (28 field-staff), one project consultant oversaw the work-flow, supervised the sub-depots, ration purchase forecasting, liaising with the program staff and trouble shooting. There was one project director in the Ranchi trial office who

co-ordinated with the two project consultants and the investigators. There were bimonthly field monitoring visits by the investigators, interrupted for some time during the COVID-19 pandemic.

The trial had a 6- member Data Safety Management Board and a 11-member Advisory committee.

D. Supplementary Results:

Table S2: Comparison of selected characteristics of households and household-contacts

Characteristic	Control arm	Intervention arm
Number of household-contacts per TU, median (IQR)	336 (288.3, 395)	426 (316.5, 456)
Age of household contacts in years, median (IQR)	21.0 (11, 36.1)	22.0 (11, 37.0)
Asset sum [*] , median (IQR)	5.9 (4.8, 7.7)	6.3 (5.3, 6.9)
Asset cost in INR, median (IQR)	32498.8 (23315, 54260.9)	35613 (29747.3, 50783.2)
Proportion of all contacts underweight [§] at baseline, n (%)	1517/4724 (32.1 %)	2026/5621 (36.0 %)
Baseline weight of adult men in kg, median (IQR)	50.7 (45.9, 57.6)	51.3 (45.6, 57.7)
Baseline BMI of adult men in kg, median (IQR)	19.8 (18.2, 22.0)	19.7 (17.9, 22.0)
Baseline weight of adult women in kg, median (IQR)	42.9 (38.3, 48.8)	42.4 (38.0, 48.2)
Baseline BMI of adult women in kg, median (IQR)	19.3 (17.4, 21.6)	19.0 (17.4, 21.4)

* Asset sum is indicative of number of assets [§] Underweight in all household-contacts is defined by the presence of the composite indicator of BMI<18.5 in adults, weight-for-age z scores<-2SD in children ≤5years, and BMI-for-age z-scores<-2SD for ages 6-17 years; TU: Tuberculosis Unit; INR: Indian National Rupee; IQR: Interquartile range

Table S3: List of household assets and their approximate costs assessing the asset cost ⁸

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

Assets were listed in consultation with local non-governmental organization Ekjut that is working since many years in Jharkhand

Table S4: Cost of food basket for the index patient and the household-contacts in the RATIONS trial

Food Item	Quantity/month basket for patient	Quantity/month for household-contact	Cost/month in INR (USD) for patient	Cost/month in INR (USD) for each household-contact [#]
Rice	5 Kg	5 kg	150	150
Sattu ^{**}	3 Kg	--	270	--
Milk powder	1.5 Kg	--	500	--
Vegetable Oil	500 ml	--	45	--
Micronutrient [*]	12 capsules	12 capsules	15	15
Split pigeon peas	--	1.5 kg	--	125
			980 (13.9 USD) [^]	290 (4.1 USD) [^]

*For children (≤10 year) we had a syrup preparation; ** Sattu is roasted Bengal gram flour that is used locally in various sweet and savoury recipes; [#]The basket was half this quantity for children (≤10 year); [^]The delivery cost for each was INR 100 (USD ~1.5) and the USD conversion is the average in 2019 of INR 1 = 0.0142 USD when the project started

Table S5: 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

Table S6: Baseline characteristics of the index patients with microbiologically confirmed pulmonary tuberculosis

Characteristic		Control (n=1400)	Intervention (n=1400)	Total
Sputum smear result (n=2025)	Sputum scanty /1+	532 (38.0)	378 (27.0)	910
	Sputum 2+/3+	539 (38.5)	576 (41.1)	1115
Sputum CBNAAT	CBNAAT positive*	329 (23.5)	446 (31.9)	775
ECOG categories	ECOG Category 3, 4 (poor performance)	156 (11.1)	169 (12.1)	325
	ECOG category 0-2 (better performance)	1244 (88.9)	1231 (87.9)	2475
Nutritional status [§]	Severe underweight (<16 kg/m ²)	664 (47.6)	683 (49.3)	1347
	Mild to moderate underweight (16 – 18.5 kg/m ²)	479 (34.3)	465 (33.6)	944
	> 18.5 kg/m ² #	252 (18.1)	237 (17.1)	489
Recurrent TB	History of TB in past	145 (10.4)	117 (8.4)	262

ECOG: modified Eastern Co-operative Oncology Group; CBNAAT: Cartridge based nucleic acid amplification tests; ECOG categories: 0: No physical restriction; 1: No strenuous activity; 2: Self-care possible but cannot work and is up <50% of waking hours; 3: Self-care only, confined to bed/chair >50% of waking hours; 4: No ability to carry out self-care, confined to bed/chair (for additional description please refer to appendix); * Basis for diagnosis (as it may have been done in those that were also sputum positive); [§] Weights were available 1397 patients in control arm and 1388 in intervention arm; # overweight/obese in control arm were 12 and 17 in intervention arm; p-value for sputum grade is <0.0001; CBNAAT is 0.245; ECOG: 0.443; BMI: 0.471; Past TB: 0.069; There were 26/520 (5%) patients with Rif resistance in control arm and 12/738 (1.6) in intervention arm; p-value is 0.001

Table S7: Characteristics of the patients in those households that had incident TB compared to those without incident TB

Characteristics		Index patient that had HHC with incident TB	Index patient with no HHC with incident TB	P value
Characteristics of index patients with TB (204) **	Males	126 (61.8)	1853 (71.4)	0.004
	Females	78 (38.2)	743 (28.6)	
	Sputum 1+	72 (47.1)	839 (44.8)	
	Sputum 2+, sputum 3+	81 (52.9)	1033 (55.2)	0.263
	ECOG Category 3, 4 (poor performance)	22 (10.8)	303 (11.7)	
	ECOG category 0-2 (better performance)	182 (89.2)	2293 (88.3)	0.703
	Median BMI	15.9 (14.4, 17.4)	16.1 (14.6, 17.9)	0.0274
All 218	Deaths in index	5 (2.5%)	103 (4.0%)	0.284

HHC: Household-contacts; ECOG: Eastern Co-operative Oncology Score; BMI: Body Mass Index *This number excludes those who died, lost to follow-up or withdrew from the study; ** Out of 218 incident cases, 25 were contributed by 11 index cases, therefore the total index cases that contributed to incident TB were 204

Table S8: Nutritional status of household-contacts less than 18 years of age in the RATIONS trial

Nutritional status indicator		Control	Intervention	p-value
Under-five children (0 – 60 months)				
WAZ Mean (SD)	Boys	-1.84 (1.5)	-1.93 (1.30)	0.5423
	Girls	-1.82 (1.44)	-1.89 (1.43)	0.5685
HAZ Mean (SD)	Boys	-1.74 (2.19)	-1.56 (1.93)	0.2618
	Girls	-1.70 (1.77)	-1.38 (1.53)	0.3202
6 – 18 years adolescents (61 – 215 months)				
WAZ Mean (SD)	Boys	-1.8 (1.25)	-1.81 (1.24)	0.9246
	Girls	-1.66 (1.22)	-1.61 (1.19)	0.6286
BAZ Mean (SD)	Boys	-1.28 (1.17)	-1.44 (1.17)	0.0076
	Girls	-1.05 (1.1)	-1.2 (1.12)	0.0097
HAZ Mean (SD)	Boys	-1.64 (1.39)	-1.57 (1.32)	0.3100
	Girls	-1.64 (1.27)	-1.68 (1.24)	0.5414

WAZ: weight-for-age z-score; HAZ: height-for-age z-score; BAZ: BMI-for-age z-score; WAZ is calculated only for 61-120 months as post that age, pubertal growth is differential and does not allow for this measure

Table S9: Secondary outcomes in household-contacts at the end of 6-months intervention period

	Control arm	Intervention arm	Total	P value
Diarrhea	83	87	170	0.16
Lower respiratory tract infections	5	1	6	0.624
Malaria	13	2	15	0.685
Hospitalisation related to infections	2	2	4	0.862
Deaths during 6 months related to acute infection*	4	3	7	0.267

*A total 34 deaths occurred in the intervention period, 17 in each arm, out of a total of 127 deaths over the entire follow up period.

Table S10: Comparison of the characteristics at the time of enrolment of the household-contacts who did or did not develop incident TB in the RATIONS trial

Characteristics		Household-contacts with incident TB (n = 218)	Household-contacts with no incident TB (n = 9393)	P value (Chi-squared for proportions and Mann Whitney for medians)
Age	Median age	33.2 (20.0, 50.0)	21.0 (10.9, 35.9)	<0.0001
Sex	Male	122 (56.0)	4221 (55.1)	
	Female	96 (44.0)	5172 (44.9)	0.001
Caste	ST	157 (72.0)	6519 (69.4)	
	SC	19 (8.7)	719 (7.7)	
	OBC	30 (13.8)	1624 (17.3)	
	Others	12 (5.5)	531 (5.6)	0.558
Tobacco use	Users (n=818)	40/(18.4)	778 (8.3)	
	Non-users (8793)	178 (81.6)	8615 (91.7)	<0.0001
Alcohol use	Users	66 (30.3)	1275 (13.6)	
	Non-users	152 (69.7)	8118 (86.4)	<0.0001
BCG scar	Present	110 (50.5)	5515 (58.7)	
	Absent	108 (49.5)	3878 (41.3)	0.014
Nutrition	Median BMI, IQR (n, adults=5567)	17.9 (16.1, 19.9)	19.4 (17.7, 21.8)	<0.0001
	Underweight in adults	108/176 (61.6)	1952/5391 (36.2)	<0.0001
	Median weight, IQR	42.9 (38.2, 49.2)	46.3 (40.3, 53.1)	<0.0001
	Underweight under-fives	5/10 (50)	544/1136 (47.9)	0.4474
	Thinness in 6–17-year-olds	11/30 (36.7)	723/2988 (24.2)	0.0562
	% weight gain (all ages)	2.6 (0.6-1)	4.2 (1.4, 8.6)	0.0002

ST: Scheduled tribes; SC: Scheduled castes; OBC: Other backward classes; BMI: body mass index;

There were 11 families where two or more cases were detected in HHC or in other words, there were three or more cases in at least 11 families during follow-up. With 31 co-prevalent cases, 31 families had at least two cases at baseline assessment. The rest of the 193 incident cases came from 193 families. Therefore, there were 235/2800 families (8.4%) had either co-prevalent or incident TB during the study period.

Note on study power in view of shortened follow up of certain households:

The shorter duration of follow up in light of the delayed enrolment caused by the COVID pandemic would have been expected to decrease the study power. However, the power calculation made several other assumptions which also have bearing on this question.

Sample size calculations took clustering at the TU and household level into account. We assumed that families would have an average size of 5 and an Intraclass correlation coefficient (ICC) of 0.2 within households for the outcome – leading to a design effect of 1.8. Instead, the average household size was 3.7 and the Intra-cluster correlation coefficient at household level was just 0.0036 – leading to a design effect of 1.01.

We assumed that the average TU size would be 400 with an Intraclass correlation coefficient at cluster level of 0.01 – leading to a design effect of 5. We found instead, that our average TU size was 368 and the ICC was 0.0018 – leading to a design effect of 1.66.

Thus, overall, we believe the trial was adequately powered.

Table S11: Weight loss in household contacts in RATIONS trial and the association with nutritional status at baseline

	Control arm (n=4321)		Intervention arm (n=5429)	
	Weight loss present (n=678)	Weight loss absent (n=3643)	Weight loss present (n=528)	Weight loss absent (n=4901)
Underweight at baseline (n=3360)	183/1382(13.2%)	1199/1382(86.2%)	122/1978(6.2%)	1856/1978(93.8%)
Normal/overweight at baseline (n=6390)	495/2939(16.8%)	2444/2939(83.2%)	406/3451(11.8%)	3045/3451(88.2%)

Overall weight loss occurred in 1206/9750 (12.7%) contacts. In the control arm weight loss occurred in 678/4321 (15.7%) contacts and in 528/5429 (9.7%) contacts in the intervention arm ($p<0.0001$). Most of the weight loss occurred in those who were normal/overweight at enrolment. The occurrence of weight loss in some of the contacts impacted on the overall weight gain seen in the trial.

Table S12: BMI at baseline and at the end of 6 months in adult household contacts in the control arm

Baseline BMI in the adults in the control arm	BMI after 6 months of nutritional supplementation in adults in the control arm (n=2463)					Total
	<16 kg/m ²	>16.0-16.99 kg/m ²	≥17.0- 18.49 kg/m ²	≥18.5-24.99 kg/m ²	≥25.0 kg/m ²	
<16 kg/m ²	130	66	14	1	0	211 (8.6)
>16.0-16.99 kg/m ²	14	91	93	8	0	206 (8.4)
≥17.0- 18.49 kg/m ²	4	23	280	138	0	677 (21.1)
≥18.5-24.99 kg/m ²	0	0	34	1611	74	1719 (57.0)
≥25.0 kg/m ²	0	0	0	6	237	243 (8.0)
	148 (6.0)	180 (7.3)	561 (17.5)	2001 (62.4)	311 (9.7)	2463 (100.0)

In the control arm, in adult contacts with severe undernutrition and moderate undernutrition at baseline, 81/211(38%) and 101/206 (49%) respectively improved to lesser severity of undernutrition, while in those with mild undernutrition at baseline, 138/677 (31%) attained BMI of normal range despite being in the arm where only the patient was given a 10 kg food basket and they were not receiving any food supplementation.

Table S13: BMI at baseline and at the end of 6 months in adult household contacts in the intervention arm

	BMI after 6 months of nutritional supplementation in adults in the intervention arm (n=3204)					
Baseline BMI in the adults in the control arm	<16 kg/m ²	>16.0-16.99 kg/m ²	≥17.0-18.49 kg/m ²	≥18.5-24.99 kg/m ²	≥25.0 kg/m ²	Total
<16 kg/m ²	127	85	40	4	0	256(8.0)
>16.0-16.99 kg/m ²	5	96	177	31	0	309(8.6)
≥17.0-18.49 kg/m ²	0	18	310	341	0	677(21.1)
≥18.5-24.99 kg/m ²	0	0	34	1611	74	1719(57.0)
≥25.0 kg/m ²	0	0	0	6	237	243(8.0)
	132(4.1)	199(6.2)	561 (17.5)	2001(62.5)	311(9.7)	3204(100.0)

In the intervention arm where the patients as well as the contacts received in adult contacts with severe, moderate undernutrition at baseline, improvement to lesser severity of undernutrition occurred with 129/256 (50%), 208/309 (67%) of contacts while in those with mild undernutrition, 341/677(52%) became normal.

Analysis of intervention effect stratified by age and nutritional status.

The intervention effect was positive only in adults. In terms of nutritional status, the intervention effect approached statistical significance. We estimated the Incidence rate ratios (IRRs) in the age groups further stratified by nutritional status. The results are as follows.

IRRs in the underweight:

0-5 yrs. old: 1.03 (p value not significant)

6-17 years old: 1.56 (p value not significant)

18+ years old: 0.67 (95% CI: 0.5, 0.96)

IRRs in the normal/ overweight:

0-5 yrs. old: 1.64 (p value not significant)

6-17: 0.56 (p value not significant)

18+ years old: 0.32 (95% CI: 0.18, 0.6)

It appears likely from this analysis that the overall lack of statistically significant effect in the underweight contacts was due to lack of statistically effect in the 0-17 years age group (underpowered due to small number of events in this age group) while the effect was significant in both underweight and normal/overweight adult contacts in the intervention arm.

Analysis of intervention effect stratified by districts:

We included district in the adjusted model to account for the differences in the districts and found that there was no difference in the results.

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