## PEER REVIEW HISTORY



## ARTICLE DETAILS

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| **TITLE (PROVISIONAL)** | The RATIONS (Reducing Activation of Tuberculosis by Improvement of Nutritional Status) study: A cluster 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, Jharkhand, India |
| **AUTHORS** | Bhargava, Anurag; Bhargava, Madhavi; Velayutham, Banurekha; Thiruvengadam, Kannan; Watson, Basilea; Kulkarni, Bharati; Singh, Manjula; Dayal, Rakesh; Pathak, Rajeev; Mitra, Anindya; Rade, Kiran; Sachdeva, KS |

## VERSION 1 – REVIEW

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| **REVIEWER** | Pranay Sinha,<br>Boston Medical Center, Infectious Diseases |
| **REVIEW RETURNED** | 12-Feb-2021 |

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| **GENERAL COMMENTS** | Although the association between undernutrition and TB has been known for decades, the causal pathways have been quesitioned. Does undernutrition increase risk for TB or does TB cause weight lose through hypercatabolism and a hypothesized anabolic block. Given that the global population-attributable fraction of TB is 21% (more than twice that of HIV), it is bewildering why nutritional care has not been more robustly integrated into TB care and why nutritional policy has not been wielded to further TB elimination efforts. Part of the problem is that there has been a lack of a substantive randomized study that can inform policymakers. The RATIONS study as described here has the potential to fill the vacuum. |

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| **REVIEWER** | Simon Tiberi<br>Barts Health NHS Trust, Infection |
| **REVIEW RETURNED** | 15-Feb-2021 |

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| **GENERAL COMMENTS** | 'The RATIONS (Reducing Activation of Tuberculosis by Improvement of Nutritional<br>Status) study: A cluster randomized trial of nutritional support (food rations) to reduce<br>TB-incidence in household contacts of patients with microbiologically confirmed<br>pulmonary tuberculosis in communities with a high prevalence of under nutrition,<br>Jharkhand, India' is a very important trial in one of the countries most affected by tuberculosis. The authors have demonstrated in their well known and cited published works that under nutrition is a challenge to health and a risk factor to TB reactivation and worse |

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| | outcomes.<br><br>It would be a shame in my humble opinion to embark on such an incredible project and possibly miss some details that would not burden the study but make it a benchmark for future studies in this field.<br>Important points would be mentioning and possibly capturing ESPEN 2015 criteria and GLIM 2018 criteria for malnutrition criteria and the definition of malnutrition and it's 4 domains A-D Espen domains i.e. A intake, B body composition, c cognitive.<br>Define malnutrition, i.e. ESPEN definition is 'a state resulting from lack of intake or uptake of nutrition that leads to altered body composition (decreased fat free mass) and body cell mass leading to diminished physical and mental function and impaired clincial outcome from disease (Cederholm T et al. ESPEN guidelines. Clin Nutr 2017).<br>BMI cut off point for malnutrition should be offered.<br>Consider questionnaire for self reported diet quality and food frequency questionnaire, also consider the PG-SGA questionnaire as this is one of the few instruments that covers all domains of the definition of malnutriton.<br>will albumin, Hb, Hct, globulin, iron fixation capacity levels be taken?<br>will a mini nutritional assessment be performed?<br>will you calculate percent ideal body weight?<br>will you measure cognitive function during the study?<br>will other pathologies, intestinal parasites be considered? will this have an impact on your study? |

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| **REVIEWER** | Lies Ter Beek<br>University Medical Center Groningen |
| **REVIEW RETURNED** | 21-Feb-2021 |

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| **GENERAL COMMENTS** | I think this study has a good possibility to enhance our knowledge of the way nutrition may impact TB. I do have some remarks.<br>1) To promote more uniform use of nutrition-related scientific terminology I would recommend to use the term ‘malnutrition’ rather than undernutrition.<br>2) In the Introduction it would improve clarity if the authors defined malnutrition in the beginning. E.g. “a state resulting from lack of intake or uptake of nutrition that leads to altered body composition (decreased fat-free mass) and body cell mass leading to diminished physical and mental function and impaired clinical outcome from disease” Cederholm T, Barazzoni R, Austin P, et al. ESPEN guidelines on definitions and terminology of clinical nutrition. Clin Nutr. 2017;36(1):49-64. doi:10.1016/j.clnu.2016.09.004<br>3) For the assessment of malnutrition in this study BMI is used. However, since 2018 there are consensus diagnostic criteria for malnutrition: the ‘GLIM criteria’, please take notice and incorporate, or at least discuss these: Cederholm T, Jensen GL, Correia MITD, et al. GLIM criteria for the diagnosis of malnutrition - A consensus report from the global clinical nutrition community. Clin Nutr. 2019;38(1):1-9. doi:10.1016/j.clnu.2018.08.002<br><br>Abstract<br>Line 31/32: 52 proteins, please add: 52 grams of protein<br>Line 31/32: supplying 1200 calories and 52 grams of protein, please add: per day<br>Line 34/35: supplying 750 calories and 23 grams of protein per day<br><br>Strength and limitations |

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| | I suggest to add as a limitation: the nutritonal intervention is standardized and there has been no individual needs-assessment, therefore the extent to which the intervention meets individual requirements is unknown.<br><br>Introduction<br>• Line 54: it is stated under Objectives that effects on 'anthropometric indicators' will be evaluated, I would suggest to describe this as evaluation of the effect on malnutrition (preferrably measured by GLIM criteria or otherwise by BMI). In other words: you want to know whether people are less malnourished, which you measure in a certain way. You have to distinguish between the construct (malnutrition) and the method (GLIM or BMI) you use to measure it. Furthermore, I would suggest to move this from secondary outcome measures to the primary outcome measures since it is the main topic of the study: you aim to lower the number of activations in HHC by improving their nutritional status (stated as such also in the title of the protocol).<br>• In the Introduction I would like to see a reference for the statement that Jharkhand is a region/community with a high prevalence of malnutrition.<br><br>Criteria for discontinuation or withdrawal of study participants<br>Line 29-31: Please clarify 'Other reasons for discontinuation are non-consumption of rations, non-availability for follow-up and development of active disease (in HHC)' If the aim of the study is to improve the nutritional status, and certain participants do not eat the rations, then I would very much like to know who these people are (hallmarks) and what causes them not to eat the rations. Why remove them from the study? These are people you will learn a lot from, I would say. And in addition, if you remove participants that are not compliant, where exactly do you draw the line? |

**VERSION 1 – AUTHOR RESPONSE**

| Reviewer 1 | |
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| Although the association between undernutrition and TB has been known for decades, the causal pathways have been questioned. Does undernutrition increase risk for TB or does TB cause weight lose through hypercatabolism and a hypothesized anabolic block. Given that the global population-attributable fraction of TB is 21% (more than twice that of HIV), it is bewildering why nutritional care has not been more robustly integrated into TB care and why nutritional policy has not been wielded to further TB elimination efforts. Part of the problem is that there has been a lack of a substantive randomized study | We thank the reviewer for his comments on the relevance of this trial for TB care and control. |

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| that can inform policymakers. The RATIONS study as described here has the potential to fill the vacuum. | |
| Reviewer 2 | |
| 'The RATIONS (Reducing Activation of Tuberculosis by Improvement of Nutritional Status) study: A cluster 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 under nutrition, Jharkhand, India' is a very important trial in one of the countries most affected by tuberculosis. The authors have demonstrated in their well known and cited published works that under nutrition is a challenge to health and a risk factor to TB reactivation and worse outcomes. | We thank the reviewer for his appreciation. |
| It would be a shame in my humble opinion to embark on such an incredible project and possibly miss some details that would not burden the study but make it a benchmark for future studies in this field. | We are pleased to note the reviewer's views on the importance of the project. It would have been desirable to have more detailed assessments as part of this project but this is a large trial (more than 13,000 participants) in a real world setting in a health system with low-resources, involving marginalised populations living in a challenging terrain, with constraints of budgets and manpower. However given the relevance of some of the additional information that the reviewers have referred to, we are conducting sub-studies which will provide information on energy intakes, dietary diversity, micronutrient status, body composition, muscle and immune function.<br><br>We hope that the context in which this trial is being conducted is understood. Jharkhand is one of India's poorest states with the most challenging social, economic and health indicators. Two thirds of our patient population belong to the indigenous communities which are marginalised. Nearly 40% of our patients are illiterate. In the districts where we are working 60-80% of the population are officially below the poverty line. The terrain is challenging, in view of the large forest cover, absence of proper roads to every village. The distance from one treatment unit in Ranchi to another in East Singhbhum is more than 250 km.Our project staff negotiate mud tracks, have crossed flowing streams on their motorcycles, and even encountered elephants on the |

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| | way. Patients live in villages with no coverage of mobile networks, and a trip of 20 km to a forest village may turn out infructuous because the patient who has recovered has gone to the forest. The health system has many challenges of access, and resources. There are only 2 medical colleges or tertiary care institutions in a state which has the population approximately similar to that of Canada. The district hospital is the only facility where the CB-NAAT or radiology is available. The availability of specialists like physicians, paediatricians is a problem. There are no dieticians in the public health system and there is no equipment to measure body composition at any level. |
| Important points would be mentioning and possibly capturing ESPEN 2015 criteria and GLIM 2018 criteria for malnutrition criteria and the definition of malnutrition and it's 4 domains A-D Espen domains i.e. A intake, B body composition, c cognitive. | We thank the reviewer for the reference to the ESPEN and GLIM criteria which represents an attempt by the clinical nutrition community to evolve a consensus on the criteria for malnutrition. We have now referred to the ESPEN 2015 consensus statement and the GLIM criteria in our introduction.<br><br>However it must be pointed out that the definitions used in these documents are context-specific and cannot be applied across settings. The GLIM statement is also clearly a work in progress, as in a recent article on the GLIM criteria by the same group of experts it was admitted that these criteria need validation and reliability testing and they are currently based on only expert opinion. *(de van der Schueren MAE, Keller H, Cederholm T, Barazzoni R, Compher C, Correia M, et al. Global Leadership Initiative on Malnutrition (GLIM): Guidance on validation of the operational criteria for the diagnosis of protein-energy malnutrition in adults. Clin Nutr. 2020;39(9):2872-80.)*<br><br>The BMI cut-offs currently recommended by the WHO and CDC for the diagnosis of malnutrition and gradation of its severity are based on their relation to outcomes in population based studies. The criteria for diagnosis of malnutrition on the basis of low BMI alone in the ESPN 2015 statement (for the diagnosis of malnutrition) is in agreement with the WHO and the CDC definition of underweight. We have mentioned this on page 9 and referenced the ESPEN 2015 document.<br><br>However ESPEN 2015 has also suggested an alternative criterion for diagnosis of malnutrition based on a combination of weight loss in combination with age-dependent cut-offs of reduced BMI ( < 20 kg/$m^2$ in age <70 years and < 22 kg/$m^2$) OR reduced fat-free mass index ( according to gender dependent cut-offs) which we cannot apply in our setting. The cut-offs based on fat-free mass assume the availability of techniques like Dual Energy X-ray Absorptiometry and Bioelectric impedance which are not available |

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| | in low-resource settings.<br><br>Another major departure in the GLIM 2018 criteria from other guidelines are the differential thresholds for diagnosis of malnutrition based on age and geographical regions and the thresholds proposed for grading its severity,<br><br>The value considered low BMI for Asians is 18.5 kg/$m^2$ for those below 70 years of age while for those Asians above 70 it is 20 kg/$m^2$, while in the case of other populations these thresholds are < 20 kg/$m^2$ and < 22 kg/$m^2$ respectively.<br><br>The GLIM 2018 suggests <18.5 kg/$m^2$ also as the threshold for diagnosis of severe malnutrition is also 18.5 kg/$m^2$. This is a major recommendation contrary to other international guidelines of grading severity of undernutrition. As already stated, this threshold represents expert opinion and awaits validation in cohort studies. If we adopt GLIM criteria, as 90% of Indian patients with TB would be reclassified as having severe undernutrition as they have a BMI < 18.5 kg/$m^2$ The grading of severity of undernutrition according to the WHO and CDC suggests a BMI < 16 kg/$m^2$ as indicating severe underweight. For this reason we cannot adopt the GLIM criteria in our study, but at the time of analysis of results we can refer to the GLIM thresholds and their relation to outcomes.<br><br>We agree that to assess the 4 domains of malnutrition would have been ideal but this would have been feasible if this trial was a smaller one and being conducted in health facilities with access to trained manpower. However in a large field based trial with limited human resources it is not possible to assess these 4 domains. |
| BMI cut off point for malnutrition should be offered. | We have added this on page 5 of the manuscript. We have also mentioned the cut-offs for the different categories of underweight on page 10 of the manuscript |
| Consider questionnaire for self reported diet quality and food frequency questionnaire, also consider the PG-SGA questionnaire as this is one of the few instruments that covers all domains of the definition of malnutriton. | We have stated earlier, the challenges and the context in which this trial is being conducted. It is not feasible to administer questionnaire for self-reported dietary quality and food frequency to the over ≈13,000 participants in this study. We are capturing dietary intakes and diversity and body composition in a sub-study on a smaller sample of patients and contacts.<br><br>We may point out that this information is available in surveys like the National Family Health Survey which have shown poor dietary diversity in these populations.<br><br>Regarding the PG-SGA, we agree that the Patient generated-subjective global assessment (PG-SGA) covers domains of |

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| | weight loss, food intake, symptoms and activities and function. However 2 factors will render administration and scoring of PG-SGA difficult in our trial. These are illiteracy in our patient population, and the absence of past records of weight (self-measured or measured in a health facility), which will render scoring of weight loss impossible. |
| will albumin, Hb, Hct, globulin, iron fixation capacity levels be taken? | Hemoglobin is being offered to all patients at the field level with a HemoCue device at the time of enrolment to rule out anemia. Those with anemia are being referred to the health system for further evaluation.<br><br>Regarding measurement of a visceral protein like albumin according to the ESPEN 2015 paper, inflammation is today considered the major reason for reduced serum levels of visceral proteins. Thus, visceral proteins should not be used for either screening or diagnosis of malnutrition. Harrison's Principles of Internal Medicine also states that although albumin is often done in cases of suspected malnutrition it lacks sensitivity or specificity for diagnosis of malnutrition. |
| will a mini nutritional assessment be performed? | While MNA is not being performed in the elderly, information on appetite, performance status ( including descriptors of mobility) and body mass index is being recorded :<br><br>Calf circumference measurements are not feasible in this large trial. |
| will you calculate percent ideal body weight? | We shall be doing it in the final analysis. |
| will you measure cognitive function during the study? | No we are measuring cognitive function in this study. |
| will other pathologies, intestinal parasites be considered? will this have an impact on your study? | No we are not assessing for intestinal parasites like intestinal protozoa or helminths. In a large randomized control trial like this one, all the known and unknown confounders including helminthic co-infection are likely to be equally distributed in the two arms. |
| Reviewer 3 | |
| I think this study has a good possibility to enhance our knowledge of the way nutrition may impact TB | Thank you for your appreciation. |
| To promote more uniform use of nutrition-related scientific terminology I would recommend to use the term 'malnutrition' rather than undernutrition. | We would like to clarify that the articles related to both ESPEN 2015 and GLIM 2018 have specifically mentioned "undernutrition" interchangeably with malnutrition. In fact in the ESPEN 2015 consensus statement the experts deliberated on which of the 2 two terms should be used. The article states "the general perception of the group was that malnutrition and undernutrition is about equally used in the scientific literature and in clinical practice, with a slight |

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| | preponderance for malnutrition. A potential problem with the term malnutrition is that it literally covers all deviating nutritional state. In a consensus poll, malnutrition had a slight preponderance with 53% of the votes as compared to 47% in favor of undernutrition. Due to this uncertain result the consensus group doesn't advocate any specific term, but has chosen to use malnutrition for this paper."<br><br>It may be pointed out that the important Lancet series on maternal and child nutrition uses the term "undernutrition" rather than "malnutrition."<br><br>In the past, malnutrition was used only in the sense of deficiency of calories, proteins and this was termed as protein-calorie/protein energy malnutrition. The ESPEN 2015 criteria and GLIM 2018 criteria define malnutrition in this sense. However with the emergence of overweight and obesity, the term malnutrition is also being used as a broader umbrella term including both undernutrition as well as overnutrition. For example according to WHO malnutrition refers to "deficiencies, excesses, or imbalances in a person's intake of energy and/or nutrients. This term therefore encompasses undernutrition (wasting, stunting and underweight), micronutrient-related malnutrition and overweight and obesity." (https://www.who.int/news-room/fact-sheets/detail/malnutrition)<br><br>By using the term undernutrition rather than malnutrition in this trial we are being explicit that we are referring to the deficiency of intake of energy and nutrients and not to their excess, or imbalance. |
| In the Introduction it would improve clarity if the authors defined malnutrition in the beginning. E.g. "a state resulting from lack of intake or uptake of nutrition that leads to altered body composition (decreased fat-free mass) and body cell mass leading to diminished physical and mental function and impaired clinical outcome from disease" Cederholm T, Barazzoni R, Austin P, et al. ESPEN guidelines on definitions and terminology of clinical nutrition. Clin Nutr. 2017;36(1):49-64. doi:10.1016/j.clnu.2016.09.004 | We have now defined undernutrition in the beginning of the manuscript.<br><br>The definition in the 2017 ESPEN guidelines (in fact from a 2012 textbook on Clinical Nutrition) defines malnutrition in terms of altered body composition (decreased fat-free mass) and body cell mass.<br><br>This definition is of greater relevance to settings where body composition measurements are routinely done to supplement anthropometric indicators. Body composition measurements in low resource settings like India are the exception. As we are not measuring body composition in all patients, such a definition is not operational in the context of this trial. |
| For the assessment of malnutrition in this study BMI is used. However, since 2018 there are consensus diagnostic criteria for malnutrition: the | |

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| 'GLIM criteria', please take notice and incorporate, or at least discuss these: Cederholm T, Jensen GL, Correia MITD, et al. GLIM criteria for the diagnosis of malnutrition - A consensus report from the global clinical nutrition community. Clin Nutr. 2019;38(1):1-9. doi:10.1016/j.clnu.2018.08.002 | |
| Line 31/32: 52 proteins, please add: 52 grams of protein | Thanks for pointing this out. It has been corrected. |
| Line 31/32: supplying 1200 calories and 52 grams of protein, please add: per day | Thanks for pointing this out. It has been corrected. |
| Line 34/35: supplying 750 calories and 23 grams of protein per day | Thanks for pointing this out. It has been corrected. |
| Strength and limitations<br>I suggest to add as a limitation: the nutritonal intervention is standardized and there has been no individual needs-assessment, therefore the extent to which the intervention meets individual requirements is unknown. | We thank the reviewer for pointing this out. It has been added to the section on limitations. |
| • Line 54: it is stated under Objectives that effects on 'anthropometric indicators' will be evaluated, I would suggest to describe this as evaluation of the effect on malnutrition (preferrably measured by GLIM criteria or otherwise by BMI). In other words: you want to know whether people are less malnourished, which you measure in a certain way. You have to distinguish between the construct (malnutrition) and the method (GLIM or BMI) you use to measure it.<br>Furthermore, I would suggest to move this from secondary outcome measures to the primary outcome measures | Please see our response to reviewer 2. We are in a position only to measure weight and height in all patients and contacts and body composition only in a very small sub-sample of patients.<br><br>We have now defined undernutrition in the introduction as suggested and also referred to the ESPEN consensus statement and the GLIM criteria.<br><br>The BMI cut off of < 18.5 kg/$m^2$ is aligned with the definition of underweight according to the WHO, as well as the ESPEN consensus definition of malnutrition and the GLIM criteria. We have already expressed our inability regarding using definitions based on assessment of body composition as well our reservations about the grading of severity of undernutrition according to GLIM criteria.<br><br>The primary outcome of reduced TB incidence in HHC was used to |

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| since it is the main topic of the study: you aim to lower the number of activations in HHC by improving their nutritional status (stated as such also in the title of the protocol). | determine the sample size in the RATIONS trial, based on an estimated effect size of 50% reduction in TB incidence in HHC given the nutritional intervention.<br><br>Improvement of nutritional status in HHCs given food rations would be expected but the translation of the food rations into protection from progression of latent to active TB would be of greater interest and relevance. So we are considering improving nutritional status as a means to an end (a secondary outcome) rather than end (primary outcome) in itself. We were also uncertain whether nutritional supplementation in a population with involved in moderate-heavy manual labour for income and has a high prevalence of deficiency in intake in energy and proteins, would necessarily translate into weight gain and improved nutritional status.<br><br>In a population like Jharkhand, which has deficient intake of proteins, higher protein intake and improved immune function may not necessarily be accompanied by improvement in nutritional status as measured by weight and BMI. On the other hand, improved weights if they occur primarily as a result of increased fat mass may not translate into improved immunity. So we have chosen TB incidence as the outcome measure of primary importance and that of improved nutritional status as the secondary outcome in this trial |
| In the Introduction I would like to see a reference for the statement that Jharkhand is a region/community with a high prevalence of malnutrition. | We have added a reference based on the National Family Health Survey findings in the introduction. The state has the highest levels of underweight (47.8%), wasting (29.0%), and the second highest level of stunting (45.3%) in children under six years of age in India. According to the National Family Health Survey (2015-6) more than two of out of every five (41%) of adult rural women in Jharkhand had a body mass index of less than 18.5 kg/$m^2$, who also had the highest prevalence of anemia in adult women in India(65.9%) |
| Criteria for discontinuation or withdrawal of study participants<br>Line 29-31: Please clarify 'Other reasons for discontinuation are non-consumption of rations, non-availability for follow-up and development of active disease (in HHC)' If the aim of the study is to improve the nutritional status, and certain participants do not eat the rations, then I would very much like to know who these people | We thank the reviewer for pointing out the ambiguity in this section and have reworked this paragraph on page 12.<br><br>We are removing non consumptions of rations as an investigator based criterion for withdrawal from this study and we shall clarify this in an amendment to the Institutional Ethics Committee. We have not had any withdrawal of patients or contacts from the trial due to this reason so far.<br><br>The protocol has a case record forms which do record reasons for non-intake of rations. As a further measure of ascertainment of the reasons, we shall include some of participants who discontinued |

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| are (hallmarks) and what causes them not to eat the rations. Why remove them from the study? These are people you will learn a lot from, I would say. And in addition, if you remove participants that are not compliant, where exactly do you draw the line? | consumption of the rations, in the qualitative sub-study of the perceptions, experiences related to the intervention.<br><br>We shall therefore not be removing these patients from the data and unless the patient withdraws consent completely, we shall continue the follow up of these participants to record the primary outcomes in contacts and the index cases.<br><br>We shall be conducting an intention to treat analysis which will analyse the contacts according to the arm to which they were randomised regardless of their consumption of rations. |

**VERSION 2 – REVIEW**

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| **REVIEWER** | Simon Tiberi<br>Barts Health NHS Trust, Infection |
| **REVIEW RETURNED** | 31-Mar-2021 |

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| **GENERAL COMMENTS** | Thank you for resubmitting the revision for “ |

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| **REVIEWER** | Lies Ter Beek<br>University Medical Center Groningen |
| **REVIEW RETURNED** | 18-Apr-2021 |

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| **GENERAL COMMENTS** | Review of study protocol The RATIONS (Reducing Activation of Tuberculosis by Improvement of Nutritional Status) study: A cluster 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, Jharkhand, India<br><br>Review of the track changes version of this article<br><br>Overall I am satisfied with the amendments made by the authors and I congratulate them on their work. I do have some remarks.<br>Line 15/16 of page 5: ‘The body mass index cut-off for underweight proposed by WHO<br>of < 18.5 kg/m2 for populations,10 has also been accepted as a criterion for clinical diagnosis of malnutrition/undernutrition in a recent consensus statement.11’<br>Reference 11 states clearly that: ‘WHO advocates BMI <18.5 kg/m2 as a general cut-off for underweight. This cut-off is justified at a public health population level, whereas its relevance for clinical and care settings may be questioned’. Which is one of the reasons the GLIM criteria have been developed. However, I do think that since the RATIONS is a study in HHC and not in patients the use of BMI can be supported.<br><br>Line 13/14 of page 6: Small correction needed: which has the a high prevalence ?<br>Line 22 of page 6: I do not see the relevance of mentioning anemia prevalence? Why mention anemia and any other possible lab |

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| | outcome? Please support this with an explanation or, even better, just leave this out.<br><br>Line 38/39 of page 6: I would recommend to alter 'anthropometric indicators' into 'undernutrition'. As mentioned before: you want to measure an effect on the nutritional status of people, not on the way you measure it. |

**VERSION 2 – AUTHOR RESPONSE**

| Reviewer 3 | |
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| Overall I am satisfied with the amendments made by the authors and I congratulate them on their work. | We thank the reviewer for his appreciation. |
| Line 15/16 of page 5: 'The body mass index cut-off for underweight proposed by WHO of < 18.5 kg/m2 for populations,10 has also been accepted as a criterion for clinical diagnosis of malnutrition/undernutrition in a recent consensus statement.11' Reference 11 states clearly that: 'WHO advocates BMI <18.5 kg/m2 as a general cut-off for underweight. This cut-off is justified at a public health population level, whereas its relevance for clinical and care settings may be questioned'. Which is one of the reasons the GLIM criteria have been developed. However, I do think that since the RATIONS is a study in HHC and not in patients the use of BMI can be supported. | We thank the reviewer for agreeing with our revision which references the GLIM consensus statement as well. |
| Line 13/14 of page 6: Small correction needed: which has the a high prevalence ? | We have deleted the word "the" |
| Line 22 of page 6: I do not see the relevance of mentioning anemia prevalence? Why mention anemia and any other possible lab outcome? Please | We have modified the sentence which now reads,<br><br>"Similarly, more than two of out of every five (41%) of adult rural women in Jharkhand had a body mass index of less than 18.5 $kg/m^2$, and had the highest prevalence of anemia in adult women in |

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| support this with an explanation or, even better, just leave this out. | India,(65.9%), which is largely related to nutritional deficiencies of iron and folic acid."<br><br>Anemia can be due to a variety of causes but in India the widespread anemia in women of reproductive age group, pre-school children and adolescents is largely due to deficient intake of micronutrients like iron and folic acid. This is the reason that we mentioned anemia prevalence following the prevalence of low BMI. The National Nutritional Anemia Prophylaxis programme was launched in 1970 followed in 2013 by the Weekly Iron and Folic acid Supplementation Programme. |
| Line 38/39 of page 6: I would recommend to alter 'anthropometric indicators' into 'undernutrition'. As mentioned before: you want to measure an effect on the nutritional status of people, not on the way you measure it. | The household contacts can fall into various categories based on their weight (underweight, normal, overweight). Therefore we shall be recording the changes in anthropometric indicators in all contacts, rather than only in those who are underweight.<br><br>Also, the words pointed out appear in the section on objectives of the trial which have been approved by the Expert committee of the ICMR, and the Institutional Ethics Committee. |