

# Nutrition Supplement Improves Treatment Outcome among Adults on the Retreatment Regimen for Tuberculosis; A Two Arm Stepped Wedge Phased Implementation Study

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## Abstract

**Background:** Loss to follow-up and noncompliance to anti-tuberculosis treatment (ATT) are the main causes of recurrence of tuberculosis (TB). In this study, we aim to investigate the effect of nutritional supplements as a treatment enhancer to help patients with pulmonary TB (PTB) on a retreatment regimen to complete ATT, reduce loss to follow-up, and thus increase favorable outcomes in a programmatic setting. **Methods:** In this prospective community interventional study conducted under NTEP program in the Vellore district of Tamil Nadu during 2017–2019, PTB patients on a retreatment regimen were given a nutritional supplement. The supplement, given fortnightly as a 500 gm pack of enriched flour, was distributed to all the tuberculin units of Vellore in a phased manner. The flour consisted of finger millet (ragi), rice flakes, groundnuts, and roasted Bengal gram with advice to cook and consume 30 gm per day with milk or hot water. ATT was given as per the National Program guidelines. Phased implementation of the supplement was performed in the tuberculosis unit, while the others were considered as control groups. **Results:** We enrolled 415 adult PTB patients on a retreatment regimen. Of them, 284 (68%) patients received the nutritional supplement, and 131 (32%) did not receive the nutritional supplement. There was a 28% significant decrease in unfavorable outcomes among the intervention group (adjusted risk ratio [aRR] –0.72 (0.57–0.90) when compared to the control arm. There was also a significant increase in weight and mid-arm circumference over the follow-up period of 14 months in the intervention arm. There was a significant improvement in social relationships and environmental domains in quality of life among the intervention group. **Conclusion:** In a program setting, nutritional supplement not only increases weight but also act as treatment enhancers. This improves treatment completion and reduces unfavorable outcomes among retreatment patients.

**Keywords:** India, NTEP, nutritional, RNTCP, treatment failure

## INTRODUCTION

Globally in 2023, it has been estimated that nearly 10.6 million people fell ill with tuberculosis disease (TB).<sup>[1]</sup> India is the largest contributor to the global burden of TB and accounts for 30% of global TB deaths.<sup>[2]</sup> India has planned to meet the global targets of TB Elimination and launched the National Strategic Plan to eliminate TB by 2025.<sup>[3]</sup> Apart from routine management, India is taking additional steps like active case finding of TB, research and implementation of newer diagnostic tests, and direct benefit transfer of money to the patients to improve notification and treatment.<sup>[4,5]</sup> One of the major challenges in reaching this goal is the treatment of

patients with recurrence of pulmonary TB (PTB) who generally have poor treatment outcomes, high loss to follow-up rate, and pose a huge public health risk by transmitting the infection

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in the community.<sup>[6,7]</sup> Malnutrition, poor socio-economic condition, illiteracy, and alcoholism are associated with this loss to follow-up and poor outcome. Ensuring the nutritional support and motivation of these patients is, therefore, the key in sustaining them in the treatment program.<sup>[7,8]</sup> With this background, we proposed to study the effect of providing nutrition supplements along with anti-tuberculosis therapy as an enhancer to treatment outcomes among adults with pulmonary TB, started on a retreatment regimen in a district of south India.

## METHODS

This was a prospective study done under programmatic setting in a phased implementation manner [Stepped wedge design – Figure 1].<sup>[9]</sup> Stepped wedge design (phased implementation) is particularly useful when it is not feasible to provide the intervention to every individual/community at once. The intervention was rolled out sequentially to the trial participants (either as individuals or clusters of individuals) over a number of time periods. Subsequently, at regular intervals (the “steps”), one cluster (Or a group of clusters) was randomized to cross from the control to the intervention under evaluation. The order in which the different individuals or clusters receive the intervention was determined at random, and, by the end of the random allocation, all individuals or groups have received the intervention. Each step consists of one quarter (3 months). First, we started the intervention with one TU, while the other TUs were treated as controls. After 3 months, the next TU was given the supplement along with the first, while other TUs were treated as controls. Gradually over the study period, other TUs were recruited to give the supplement every 3 months, until all TUs were given the supplement. The study participants were recruited during the period of 2017 to 2019 from seven tuberculosis units (TUs) in Vellore District, India. Pulmonary TB patients on retreatment regimen due to relapse, failure, and loss to follow-up were included in this study. Inclusion criteria were age  $\geq 18$  years; started on retreatment regimen; who were willing to sign an informed consent form; willing to adhere to follow-up schedule and study procedures; and willing to home visit by study staff. Exclusion criteria were new smear-positive PTB;

extra-pulmonary tb; moribund state/uncontrolled type II diabetes mellitus/renal failure/multidrug-resistant TB; was allergic to pulses/nuts, was unable to receive the nutrition supplement; was unable to attend study center or comply with treatment or follow-up; has alcohol dependence as assessed by WHO’s Modified AUDIT scale which is likely to interfere with treatment adherence.

After getting written informed consent, medical, personal, and family history were collected. A brief physical examination and anthropometrics were recorded. St George Respiratory Questionnaire and World Health Organisation Quality of Life Short Form (WHOQOL-BREF) questionnaire were used to assess the quality of life.<sup>[10,11]</sup> Field staff supplied 500 grams of nutrition mixture once in 15 days for eight months in the intervention group. The nutrition mixture was locally prepared raw flour. Every 30 grams of the flour consisted of finger millet (Ragi) flour 10 grams, rice flakes 5 grams, ground nuts 10 grams, and roasted chickpea (Bengal gram) 5 grams which are equivalent to 128 Kcal. Two packets were supplied to the patient every fortnightly for eight months, with an instruction to consume 30 gm every day in the form of rice gruel or pancake (kanji or porridge or dosa). Nutrition packets were supplied to the patient by the study staff at the study center. Enrolled participants were followed once a month till the end of treatment (8 months) and at 3<sup>rd</sup> and 6<sup>th</sup> months during the post-treatment period. Participants were motivated to be regular with treatment and adherence to the nutrition supplement. The study staff conducted surprise check, and during this visit, the staff ensured that the frequency and regularity of intake of the supplement by the patient by checking the nutrition supplement packets along with the anti-tuberculosis treatment (ATT) pill count. Results of sputum smear for acid-fast bacilli (AFB) at baseline/pre-treatment, end of 3<sup>rd</sup> month (IP), and end of treatment were collected from the treatment cards of the National Tuberculosis Elimination Program (NTEP). The treatment outcome was either favorable which included bacteriological cure and/or treatment completion or unfavorable that included death, incomplete treatment, and bacteriological failure. Data was entered in Epidata software Version 3.1. and analyzed using STATA software Version 15.1. (StataCorp., Texas, USA).<sup>[12]</sup> The Chi-square test was used to assess the association of categorical

**Figure 1: Schematic representation of the study design and the number of participants recruited in each quarter in the nutrition supplementation study among participants on TB – retreatment in the Vellore District of Tamil Nadu, India from 2019 to 2020**

Tuberculosis Units	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Quarter 5	Quarter 6	Quarter 7	Quarter 8
TU 1	5	5	9	6	10	7	13	12
TU 2	4	6	8	5	6	13	12	13
TU 3	3	5	5	7	12	11	13	14
TU 4	1	5	6	5	7	8	11	14
TU 5	2	4	5	7	6	10	10	15
TU 6	3	2	3	7	6	7	8	13
TU 7	4	2	4	6	7	5	6	12

Intervention group in gray color, control group in white color

variables with the groups, and the Mann-Whitney test was used to assess the differences in the continuous variables between the groups. A simple and multiple Poisson regression analysis was performed to identify the factors associated with the TB treatment outcomes. The adjusted risk ratio was calculated after adjusting for the covariates and design effect. This study was approved by the Institute Ethics Committee (RefNo: 2016011).

## RESULTS

In this study, we enrolled 415 adults on retreatment for pulmonary TB, of whom 284 (68%) received and 131 (32%) did not receive the nutritional supplement. Among both groups, the mean age of the participants was 45 (33–52), the majority were males (80%), about 4% were known to have hypertension, and 18% were known to be diabetic [Table 1]. Among the control group, the favorable treatment outcome was 74 (56%), and the unfavorable treatment outcome was 57 (44%). In the intervention group, the favorable treatment outcome was 192 (68%), and the unfavorable treatment outcome was 32% [Figure 2].

There was a 28% significant decrease in unfavorable outcomes among the intervention group ( $n = 92$ , 32%) when compared to the control group ( $n = 57$ , 44%) (crude risk ratio – 0.75 (0.58–0.96), adjusted risk ratio (aRR) – 0.72 (0.57–0.90),  $P < 0.05$ , after adjusting for related and significant variables. Apart from nutrition intervention, younger age [0.99 (0.98–0.99)], male sex [2.67 (1.77–4.02)], poor general condition [2.12 (1.43–3.13)], and underweight [0.96 (0.94–0.97)] were associated with unfavorable outcomes. Baseline characteristics between the control intervention group are shown in Table 1. Risk factors adjusted against unfavorable outcomes are shown in Table 2. There was also a significant increase in weight and mid-arm circumference, quality of life, social relationship, and environmental domains among the intervention group over the follow-up period of 14 months [Table 3]. However, there was no significant change in the overall score in quality of life as well as lung health between the intervention and control groups.

## DISCUSSION

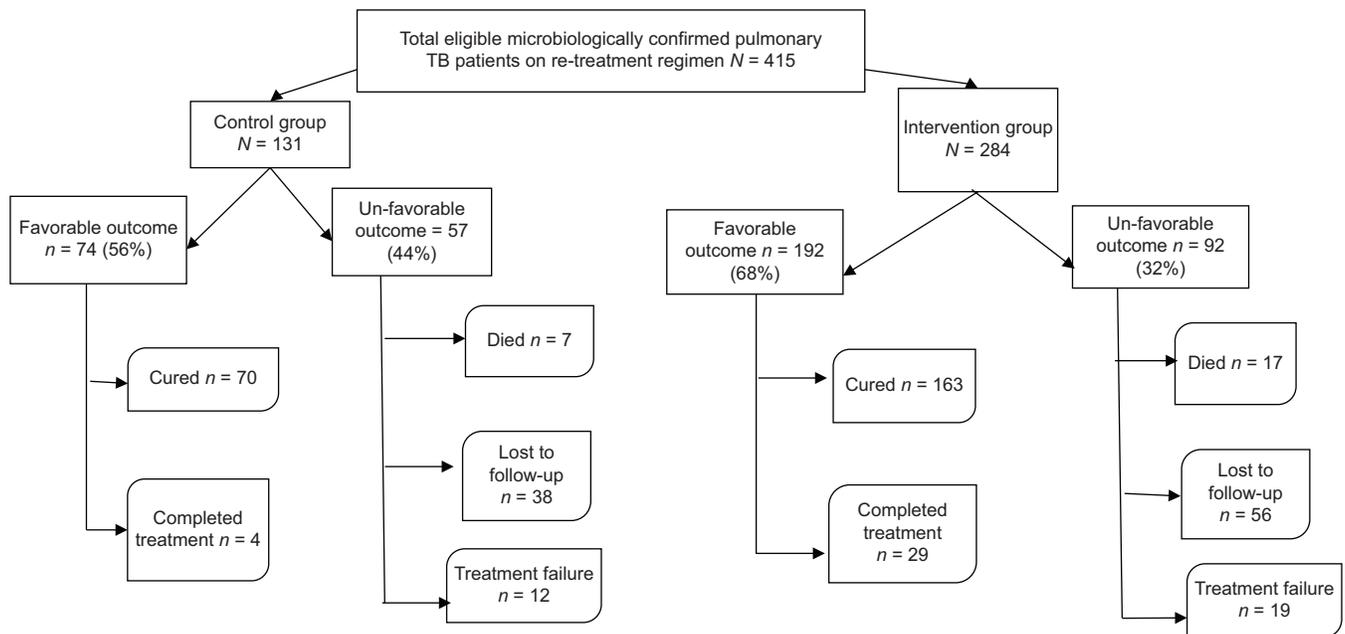
Many countries have eliminated TB well before the advent of drugs by improving the living conditions and the nutritional status of the population, while India is still struggling even with newer drugs and advanced diagnostics.<sup>[13]</sup> Recently conducted National TB Prevalence Survey of India has shown that 27% of pulmonary TB cases in the community is due to recurrence of TB disease.<sup>[14]</sup>

The major finding in our study was that there was a 28% decrease in unfavorable outcomes in the intervention group when compared to the control group [aRR 0.72 (0.57–0.90),  $P < 0.05$ ]. One of the retrospective cohort studies conducted in West Bengal among patients with new and retreatment PTB has shown that there was a 50% reduction in unfavorable outcomes in the group which received nutritional support.<sup>[15]</sup> A recent RATIONS study with nutritional support for the PTB patients

**Table 1: Baseline characteristics and key outcome of study participants in both control and intervention arm of nutrition supplementation study among participants on TB retreatment in the Vellore District of Tamil Nadu, India from 2019 to 2020**

Factors	Control (131)	Intervention (284)	P
Age			
Median (IQR)	45 (34–52)	44.5 (33–52)	0.465
Gender			
Female	25 (19%)	61 (21%)	0.605
Male	106 (81%)	223 (79%)	
Marital Status			
Single	17 (13%)	41 (14%)	0.762
Married	114 (87%)	243 (86%)	
Education			
Illiterate	49 (37%)	151 (53%)	0.003
Literate	82 (63%)	133 (47%)	
Occupation			
Unemployed	10 (8%)	38 (13%)	0.100
Employed	121 (92%)	246 (87%)	
General Condition			
Good	120 (92%)	277 (98%)	0.009
Poor	11 (8%)	7 (2%)	
Alcohol			
No	69 (53%)	148 (52%)	>0.950
Yes	62 (47%)	136 (48%)	
Hypertension			
No	127 (97%)	272 (96%)	0.785
Yes	4 (3%)	12 (4%)	
Diabetes			
No	107 (82%)	233 (82%)	>0.950
Yes	24 (18%)	51 (18%)	
Anemia			
No	107 (82%)	210 (74%)	0.106
Yes	24 (18%)	74 (26%)	
Haemoptysis			
No	113 (86%)	235 (83%)	0.393
Yes	18 (14%)	49 (17%)	
Weight (Kg)	45 (40–52)	45 (39–53)	>0.950
Loss of weight			
No	42 (32%)	69 (24%)	0.121
Yes	89 (68%)	215 (86%)	
Loss of appetite			
No	50 (38%)	101 (36%)	0.661
Yes	81 (62%)	183 (64%)	
Previous TB treatment			
No	1 (1%)	7 (2%)	0.445
Yes	130 (99%)	277 (98%)	
Outcome			
Favorable*	74 (56%)	192 (68%)	0.036
Unfavorable	57 (44%)	92 (32%)	
Outcome (Specific)			
Bact. cure	70 (54%)	163 (57%)	0.029
Rx complete	4 (3%)	29 (10%)	
Death	7 (5%)	17 (6%)	
Incomplete Rx	38 (29%)	56 (20%)	
Bact. Fail/Rec.	12 (9%)	19 (7%)	

\*Favorable outcome includes bacteriological cure or treatment complete, Rec-recurrence



**Figure 2:** Consort diagram for the nutrition supplementation study among participants on TB – retreatment in the Vellore District of Tamil Nadu, India from 2019 to 2020

**Table 2: Risk factors associated with the unfavorable outcome among the study participants on retreatment for Tuberculosis in the Vellore District of Tamil Nadu, India from 2019 to 2020**

	Favorable (266)	Unfavorable (149)	RR [95% CI]	P	aRR [95% CI]	P
ARM						
Control	74 (56%)	57 (44%)	Ref.		Ref.	
Intervention	192 (68%)	92 (32%)	0.74 (0.58–0.96)	0.025	0.72 (0.57–0.90)	0.004
Age (mean (IQR))						
↑	45 (35–55)	41 (32–49)	0.99 (0.98–1.01)	0.058	0.99 (0.98–0.99)	0.003
Gender						
Female	68 (79%)	18 (21%)	Ref.		Ref.	
Male	198 (60%)	131 (40%)	1.90 (1.24–2.93)	0.004	2.67 (1.77–4.02)	<0.001
General condition						
Good	259 (65%)	138 (35%)	Ref.		Ref.	
Poor	7 (39%)	11 (61%)	1.76 (1.19–2.60)	0.005	2.12 (1.43–3.13)	<0.001
Weight (Kg)						
↑	46 (40–54)	43 (38–51)	0.98 (0.96–0.99)	<0.001	0.96 (0.94–0.97)	<0.001
Diabetes						
No	209 (61%)	131 (39%)	Ref.		Ref.	
Yes	57 (76%)	18 (24%)	0.62 (0.41–0.95)	0.029	0.90 (0.59–1.38)	0.629

RR – Risk ratio; aRR – Adjusted risk ratio; ↑ indicates that the value was continuous, and the reference was the lower value in the observation

in Jharkhand has revealed a reduction in mortality among PTB patients with weight gain at two months.<sup>[16]</sup> The same study on household contacts of pulmonary TB patients (family members of TB patients) also demonstrated that nutrition intervention has significantly reduced the newer incidence of all forms of TB by 49%.<sup>[17]</sup> All these findings reiterated the importance of nutrition supplementation for the patients and their family members.

Apart from this major finding, our study also demonstrated that the unfavorable TB outcome is associated with lower age, male sex, poor general condition, and decrease in weight.<sup>[18]</sup> The

association of the male sex with unfavorable TB outcomes was already reported in the previous studies; however, the detailed analysis showed that this association was due to poor adherence among male patients.<sup>[19]</sup> A similar finding was noticed in MDR patients where the unfavorable outcome was associated with male sex and underweight.<sup>[20]</sup>

Findings from this study have shown significant improvement with favorable outcomes, increase in weight, mid-arm circumference, and waist circumference in the intervention group when compared to the control group in long term 14 months of follow-up after treatment. This finding is

**Table 3: Comparisons over 14 months of follow-up in the nutrition supplementation study among participants on TB – retreatment in the Vellore District of Tamil Nadu, India from 2019 to 2020**

	Mean (SD)		Absolute change and (%) from baseline		P value between group*
	Control	Intervention	Control	Intervention	
Weight (Kg)	49.7 (11.9)	48.3 (10.2)	0.12 (0.23)	0.45 (0.9)	0.002
Body Mass Index	18.9 (4.2)	18.6 (3.5)	0.08 (0.46)	0.19 (0.94)	0.131
Mid-arm circumference (cm)	23.1 (3.9)	23.5 (3.4)	0.21 (0.73)	0.28 (0.99)	0.014
Waist circumference (cm)	72.1 (10.6)	71 (10.6)	0.18 (0.79)	0.14 (0.65)	0.025
WHO BREF quality of life					
BREF physical	50.7 (12.9)	49.3 (14.6)	3.29 (6.16)	7.56 (14.11)	0.128
BREF psychological	53.8 (14.6)	52.4 (15.0)	5.43 (12.0)	6.71 (14.36)	0.182
BREF social relationship	37.8 (18.6)	42.1 (17.8)	4.68 (19.66)	4.79 (18.25)	<0.001
BREF environment	51.9 (13.2)	55.8 (13.8)	3.00 (5.80)	4.55 (8.04)	<0.001
BREF overall	48.5 (12.7)	49.9 (12.8)	4.10 (7.33)	5.90 (10.28)	0.116
St George Respiratory Questionnaire					
SGRQ symptoms	36.7 (24)	34.6 (22.6)	-9.2 (-3.22)	-13.85 (-8.26)	0.166
SGRQ activity	51.1 (27)	54.1 (32.7)	-10.53 (-6.83)	-14.46 (-9.86)	0.151
SGRQ impact	30.7 (27.6)	32.8 (27.1)	-12.25 (13.41)	-14.83 (-6.58)	0.245
SGRQ overall	37.9 (23)	39.6 (25.2)	-11.22 (6.6)	-14.55 (28.31)	0.304

\*difference in difference analysis, BREF – WHO BREF Quality of life questionnaire, SGRQ – St George Respiratory Questionnaire, Kg – Kilogram, cm – centimetres

again reiterated by the recent studies where nutrition has improved the TB treatment outcome and other anthropometric parameters.<sup>[16,17]</sup>

Improvement in the quality of life in terms of social relationships and environmental conditions was observed in the intervention group in our study. Prospective studies have shown that there was an improvement in the quality of life over time, especially environmental domain.<sup>[21,22]</sup> In our study apart from improvement in the quality of life within the intervention and control, domains related to social relationships and environmental conditions were shown significant improvement in the intervention group.

However, no difference in the respiratory health was observed between the two groups. Studies have shown there will be an improvement in respiratory health over the time of treatment.<sup>[23]</sup> In our study, also there was an improvement in respiratory health in both groups. Even though the intervention group had better improvement in respiratory health, the difference was not statistically significant [Table 3].

Management of patients with TB recurrence is always a challenge in a pragmatic setting. To attain the national targets of the NTEP, there is an urgent need to consider the patients under retreatment regimen as a special population and address their issues. There is a need for vigorous follow-up of these patients to address their medical, nutritional and social issues and to motivate them or enable them to drug adherence.<sup>[24]</sup> Incentives, nutritional supplements, and early intervention in the retrieval of these patients will improve the outcome in this group.<sup>[25]</sup> Existing nutrition supplement activities (Ni-Kshay Poshan Yojana and Pradhan Mantri TB Mukh Bharat Abhiyan) in the National Program to be strengthened.<sup>[26]</sup>

This study has many strengths. First, this is a community-based intervention trial demonstrating the intervention effectiveness on treatment outcomes as well as the implementation effectiveness of a locally available and acceptable nutritional supplement. Second, this has been done in a pragmatic setting, which will help the program managers to have a better insight while implementing nutritional interventions. Third, this study targeted pulmonary TB patients under a retreatment regimen, who have a higher propensity for relapse, failure and loss of follow-up, which will eventually lead to poor outcomes and a high risk of infection transmission in the community. Fourth, this study has not only shown a reduction in unfavorable outcomes but also a better treatment completion rate.

A few challenges faced during the conduct of the study included a tight schedule of monthly follow-up of all the cases and difficulties in the supply chain of nutrition powder every fortnight with limited manpower. These could be reduced and a feasible model may be adopted in the field setting optimizing manpower management while implementing in a wider population under the programmatic setting. This study can be replicated in similar settings of high TB burden in middle- and low-income countries.

## CONCLUSION

To conclude, in a pragmatic setting, nutritional supplement not only increases body weight but also act as a treatment enhancer/enabler and reduce the unfavorable outcomes among patients on retreatment regimens for recurrent PTB.

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Nil.

## Conflicts of interest

There are no conflicts of interest.

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