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Holistic impact of Nikshay Mitra on TB patient outcomes in India: An observational study from a tertiary care center

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Abstract

Background: Under the Pradhan Mantri TB Mukt Bharat Abhiyan, the Indian government introduced the Nikshay Mitra Yojana. This program focuses on mobilizing community volunteers to provide social and logistical support to TB patients. This can include treatment adherence monitoring, nutritional assistance & social support.Aim of the study is to evaluate the outcome of Nikshay Mitra Yojana under NTEP in Agra. ***Objective:*** Study was done with the objective is to assess the effectiveness of Nikshay Mitra Yojana in terms of Treatment Outcome, Nutritional status, Quality of Life and Psychological wellbeing of patients.***Material and Methods:*** This study was an observational & prospective study conducted at the department of Respiratory Medicine at S.N. Medical College, Agra. We selected newly diagnosed Drug Sensitive Pulmonary Tuberculosis patients enrolled under Nikshay Portal from 01 Nov 2022 to 31 Dec 2022.After applying the exclusion and inclusion criteria, we got 135 cases and 120 cases (2 deaths;13 patients loss to follow up) were followed up till the end of treatment to observe the outcome of Nikshay Mitra Yojana.***Result:*** Out of 120 patients, 60 patients were availing the benefits of Nikshay Mitra Yojana and enrolled under group1, while 60 were not availing the benefits of Yojana enrolled under group2. There was statistically significant improvement in nutritional status of patients. Treatment success (Treatment completed + Cured) was 96.6% in group1 and 81.6% in group2. Quality of life assessed by SGRQ score had significantly improved in the Nikshay Mitra group and psychological well being assessed by WHO-5 Well Being Index improved at the end of treatment (overall independent t-test $p<0.001$). ***Conclusion:*** Nikshay Mitra had positive impact on nutritional status, Quality of life, Psychological well being of patient and significant improvement in treatment success rate.

Keywords: Pulmonary tuberculosis, Nikshay Mitra, treatment outcome.

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INTRODUCTION

India is home to the most deadly TB burden. TB is the most deadly infectious disease and has a public health impact that is comparable to that of COVID-19. In fact, TB has approximately five times more deaths than COVID-19. According to the World Health Organization's Global TB Report 2025, close to 25% of the global TB burden comes from India. Notably, around 2.7 million new cases of TB are estimated to have occurred in 2024 in India.[1] Furthermore, according to the TB report, the incidence rate of TB in India is approximately 187 per 100,000 population. In spite of the substantial decline in TB incidence by 21% since 2015, which is quite promising, India stands a long way away from its national target. This target is for 2025 for a TB incidence of 44 cases per 100,000 population.[2]

Most noteworthy, it is an undoubtedly nasty disease that causes a multi-dimensional burden. This burden is physical, but at the same time also psychological, social, and economic. Furthermore, this burden is mostly on vulnerable populations in low- and middle-income settings.According to a statement made by the WHO (World Health Organization) undernutrition seems to be the most important modifiable risk factor for TB. It together with the provision of adequate nutrition must be included in any effective TB management strategy. Research has shown that severe undernutrition at treatment onset (BMI <16 kg/m^2) is independently associated with over twofold higher the risk of an unfavorable treatment outcome which includes treatment failure death relapse[3]. Also, failing to achieve weight gain during the intensive phase of treatment has a four- to five-fold higher mortality rate As a result, the improvement of treatment outcome in TB patients must address the nutritional deficits.Keeping this in mind, the Government of India has initiated multiple patient-support interventions under National TB Elimination Programme (NTEP). Among them is the 'Nikshay Poshan Yojana' (500 Rs/month direct benefit transfer to TB patients).[2] However, the financial and social needs of TB patients are often more

than what the benefit of eating schemes alone provide. To address this disparity, 'Pradhan Mantri TB Mukt Bharat Abhiyan' (PMTBMBA) was launched by Hon'ble President of India on 9th September 2022.[4] Under this Initiative, Community Stakeholders called 'Nikshay Mitras' will voluntarily adopt TB patients and provide them with nutritional, additional diagnostic, and vocational support for a minimum duration of six months and a maximum of three years.[5] The Nikshay Mitra scheme works on the Nikshay 2.0 portal and is showing good initial results.[5]

As per the India TB Report 2024, the treatment success rate among TB patients supported by a Nikshay Mitra was 95%, versus 90% for those without support.[6] The weight gain was also greater, at a mean of 4.2 kg vs. 3.8 kg in non-beneficiaries. A cohort study conducted in the Haridwar district of Uttarakhand found a treatment success rate of 94% among 304 TB patients provided support through a CSR-NGO mix model under the Nikshay Mitra scheme. There were no deaths or loss to follow-up. However, field studies have pointed to implementation problems. These include stigma related to the disease, donor retention issues, supply disruptions, and breaches of confidentiality of beneficiaries.[7]

The Nikshay Mitra scheme has not been studied for its total impact like on nutritional or psychological or on treatment related outcome especially in tertiary care centers in large observational studies despite some good evidence. The present study was therefore designed to assess the total impact of Nikshay Mitra support on TB patients' at a tertiary care centre which will help in policy and programming

MATERIALS AND METHODS

It was an observational and prospective study conducted on 135 active newly diagnosed Drug Sensitive Pulmonary Tuberculosis patients registered in Nikshay portal from 01 Nov 2022 to 31 Dec 2022. After applying the exclusion and inclusion criteria, we got 135 cases and 120 cases (2 deaths;13 patients loss to follow up) were followed up till the end of treatment toobserve the outcome of Nikshay Mitra Yojana. Out of 120 patients, 60 patients were availing the benefits of Nikshay Mitra Yojana and enrolled under group1, while 60 were not availing the benefits of Nikshay Mitra Yojana enrolled under group2.

Inclusion Criteria

- Patients of newly diagnosed drug sensitive pulmonary tuberculosis patients who were more than 18 years of age included in our study.
- Patients must be registered in Nikshay portal.
- Patients must be registered in Nikshay Mitra yojana by giving OTP based consent or written consent.
- Patients must be resident of Agra.
- All patients giving written informed consent to participate in our study.

Exclusion Criteria

- Patients not giving consent to participate in our study.
- Patients with comorbidity (HIV, HEP-B HEP-C Diabetes mellitus, hypertensives and with any other immunocompromised state).
- Known cases of drug resistant pulmonary tuberculosis patients.
- Healed pulmonary tuberculosis.
- Extrapulmonary and Disseminated tuberculosis patients.
- Pregnant and Breastfeeding females.
- Patients were not resident of Agra.
- Unstable and seriously ill patients with severe comorbidities such as end stage chronic renal failure, hepatic disease, malignancy, coronary artery disease.

A detailed evaluation of enrolled patients included detailed history (including previous ATT history, Tubercular Contact history, Allergy history, Atopy history, Medical Illness history, thorough clinical examination, Weight & height, BMI (Kg/m2), Waist Circumference, Hip Circumference, Waist Hip Ratio. Complete blood count with hemoglobin & platelets count. Liver function test with serum Albumin level, Blood urea and S. Creatinine to assess renal function, Blood sugar to screen for Diabetes Mellitus, UPT (for all women of childbearing age), Chest X ray. HIV testing and counselling. Sputum smear for AFB by ZN staining method, CBNAAT.

Statistical analysis of data

Data were entered in Microsoft Excel and analyzed using statistical software SPSS version.The continuous variables were evaluated by mean (standard deviation) or range value when required. The quantitative data were presented as the mean ± SD and as median with 25th and 75th percentiles (interquartile range). For comparison of the mean between the two groups, analysis by Student t-test was used. A p-value of < 0.05 or 0.001 was considered to be statistically significant

RESULTS

Over a period of six months, 120 pulmonary tuberculosis patients were enrolled in the study, which comprised 70% male and 30% female. Most of them were from rural and lower socio-economic background. Patients were divided in a 1:1 ratio into Group 1 (n=60, availing benefit of Pradhan Mantri TB Mukt Bharat Yojana) and Group 2 (n=60, not availing benefit of any scheme).

The two groups didn't have statistically significant differences for any of the baseline variables, including BMI (16.68 ± 1.77 vs. 16.18 ± 1.24, p=0.080), hemoglobin (9.33 ± 1.62 vs. 8.79 ± 1.37, p=0.054), serum albumin (3.04 ± 0.42 vs. 2.90 ± 0.42, p=0.061), SGRQ Total Score (38.40 ± 9.11 vs. 38.26 ± 4.97, p=0.918) and WHO-5 Index (5.50 ± 3.13 vs. 5.40 ± 2.33, p=0.843). This provided a good basis for valid inter-group comparison.

Table 1: Baseline Parity at Treatment Initiation

Variable	Group 1 (Mean ± SD)	Group 2 (Mean ± SD)	P-Value
BMI	16.68 ± 1.77	16.18 ± 1.24	0.080
W/H Ratio	0.778 ± 0.047	0.789 ± 0.039	0.182
Hemoglobin	9.33 ± 1.62	8.79 ± 1.37	0.054
Serum Albumin	3.04 ± 0.42	2.90 ± 0.42	0.061
SGRQ Total Score	38.40 ± 9.11	38.26 ± 4.97	0.918
WHO-5 Index	5.50 ± 3.13	5.40 ± 2.33	0.843

The nutritional parameters of Group 1 showed extremely significant improvement at the end of 6 months. In group one, the BMI of females increased from 16.10 to 19.90 kg/m². While in group two, it increased from 15.40 to 16.60 kg/m² (p<0.001). The male BMI in the intervention group improved from 17.10 to 20.40 kg/m2 while that in the control group improved from 16.40 to 17.60 kg/m2 (p<0.001) There were significantly higher hemoglobin levels of the females and the males in comparison to the previous and final levels 8.54→12.50 versus 7.67→9.61 g/dl, both p< 0.001 and 9.79→13.50 versus 9.10→10.80 g/dl, both p< 0.001. In Group 1, serum albumin improved from 3.04 to 3.71 g/dL. This was in contrast with Group 2, whose levels remained at 2.90 to 3.10 g/dL (p=0.0014).

Table 2: Changes in Nutritional Parameters (Baseline vs. 6 Months)

Parameter	Group 1 (Initial → 6 Mo)	Group 2 (Initial → 6 Mo)	P-Value
BMI (Female)	16.10 → 19.90	15.40 → 16.60	< 0.001
BMI (Male)	17.10 → 20.40	16.40 → 17.60	< 0.001
Hb (Female)	8.54 → 12.50	7.67 → 9.61	< 0.001
Hb (Male)	9.79 → 13.50	9.10 → 10.80	< 0.001
Serum Albumin	3.04 → 3.71	2.90 → 3.10	0.0014

Table 3: Shift in Categorical Nutritional Status

Status Indicator	Group 1 (Baseline)	Group 1 (6 Months)	Group 2 (Baseline)	Group 2 (6 Months)
Normal BMI	21.67%	71.67%	3.33%	16.67%
Underweight BMI	78.33%	18.33%	96.67%	83.33%
No Anemia	1.67%	76.67%	0.00%	13.33%
Moderate/Severe Anemia	85.00%	5.00%	98.33%	70.00%
Normal Serum Albumin	11.70%	60.00%	8.30%	11.70%

The percentage of patients with normal BMI increased from 21.67% to 71.67% in Group 1 (G1) whereas there was a minimal increase in Group 2 (G2) from 3.33% to 16.67%. A strikingly high resolution of anemia was observed. The proportion of patients with no anemia increased from 1.67% to 76.67% in Group 1, whereas in Group 2, it increased 0% to only 13.33%. The proportion of patients with normal serum albumin increased from 11.70 % to 60.00% in Group 1, whereas in Group 2, it remained relatively unchanged (8.30% to 11.70%).

Table 4: Clinical and Treatment Outcomes (At 6 Months)

Outcome	Group 1 (n=60)	Group 2 (n=60)	P-Value
Microbiologically Confirmed	44 (73.3%)	39 (65.0%)	0.327
Treatment Success (Cured + Completed)	58 (96.6%)	49 (81.6%)	0.0087
Treatment Failure	2 (3.3%)	11 (18.3%)	0.0084
Lost to Follow-up	1 (1.6%)	12 (20.0%)	-
Died	0 (0.0%)	2 (3.3%)	-

Microbiological confirmation rates were similar (73.3% vs. 65.0%, p=0.327) but treatment success rate was significantly higher in Group 1 (96.6% vs. 81.6% Group 2, p=0.0087). Group 1 had a lower rate of treatment failure (3.3% vs. 18.3%; p<0.0084). Loss to follow-up was significantly lower in group 1 (1.6% v 20.0%) and no deaths occurred in group 1 while 2 deaths (3.3%) occurred in group 2. Quality of life and mental well-being (table 5).

Table 5: Quality of Life & Psychological Well-Being

Assessment Tool	Group 1 (Baseline → 6 Mo)	Group 2 (Baseline → 6 Mo)	P-Value
SGRQ Symptom Score	83.16 → 17.25	81.70 → 28.78	< 0.001
SGRQ Activity Score	26.80 → 11.63	27.74 → 15.31	< 0.001
SGRQ Impact Score	31.49 → 11.65	29.54 → 15.92	< 0.001
SGRQ Total Score	38.41 → 13.30	38.27 → 20.17	< 0.001
WHO-5 Index	5.50 → 16.38	5.40 → 9.40	< 0.001

Both groups started with extremely low quality of life. After six months, the SGRQ indication total score reduced from 38.41 to 13.30 (the symptoms improved greatly) in Group 1 as compared to Group 2 (from 38.27 to 20.17, p<0.001). The World Health Organization Well-Being Index (WHO-5) significantly improved from 5.50 to 16.38 over 3 days in group 1 (with nutritional and financial support). In contrast, WHO-5 did not significantly improve in group 2 (with only nutritional one) (5.4-9.4) (p<0.001)

DISCUSSION

The baseline nutritional status of patients in this study, with mean BMI values <18.5 kg/m2 and near-universal moderate to severe anemia, closely matches the established epidemiological burden of TB in poor settings within India.

India has the highest burden of TB cases and deaths globally, and undernutrition is the single most modifiable risk factor for the incidence of TB and poor treatment outcomes.[8] Malnutrition and TB are known to have a bi-directional relationship. Undernutrition affects cellular immunity ; active TB, in turn, accelerates the process of catabolism, suppresses appetite, causes malabsorption etc.[9]

Thus, it forms a vicious cycle, which ATT cannot overcome. The World Health Organization Guideline on Nutritional Care and Support for Tuberculosis Patients recognizes this pathophysiological association and calls for the incorporation of nutritional evaluation and assistance in the national tuberculosis programme.[10]The substantial increase in BMI in Group 1, approximately 3–4 kg/m² over 6 months against just ~1 kg/m² in Group 2, mirrors findings from the landmark RATIONS (Reducing Activation of Tuberculosis by Improvement of Nutritional Status) trial by Gupta et al.[11] Thus, nutrition-supplementation (1200 kcal and 52 g protein/day) was found to significantly improve body weight and nutritional status in TB patients receiving ATT in a trial in Jharkhand, India.

According to an earlier review by the WHO, TB patients receiving food supplements in the course of treatment consistently gained more weight than those not receiving the supplements, although this was heterogeneous across settings. A recent research by Devarajulu RS et al. [12] further confirmed that among the TB patients put on retreatment regimens, there were significant BMI improvement resulting in reduced treatment failure due to nutritional supplementation. The researchers note an inverse, log-linear relation of incidence of tuberculosis (TB) to body mass index (BMI).[13] McQuaid et al.[14] note that the higher the BMI, better the treatment outcome at the population level.The clinical significance of Group 1's serum albumin increase from 3.04 to 3.71 g/dL with virtually no change in Group 2 (2.90 to 3.10 g/dL). In a retrospective study, Liu et al.[15] noted that a significant increase in serum albumin early during ATT was reliably associated with a good response, while static albumin levels despite treatment predicted treatment failure. According to a recent study of the dynamics of BMI and serum albumin in patients with tuberculosis, only patients who received sufficient calorie and protein intake showed a significant improvement in nutrition at intensive phase of treatment.[16] The mean rise in hemoglobin in group 1 in both sexes (female 8.54→12.50 g/dL; male 9.79→13.50 g/dL) corroborates the reversal of anemia of chronic inflammation and iron deficiency anemia after nutritional rehabilitation followed by ATT as reported from Sub-Saharan Africa.[17]The treatment success rate for Group 1 was 96.6% compared to 81.6% for Group 2 (p=0.0087). This rate is comparable to and greater than the national program rates.

In the study conducted by Engoru S et al [18] to examine the impact of malnutrition on unsuccessful treatment of TB, malnourished patients had a significantly higher rate of treatment failure, death and loss to follow-up. The loss-to-follow-up rate was 19.4% among malnourished patients in the study by Engoru S et al [18] which is similar to the rate of 20.0% seen in Group 2 of the present study. The food support intervention conducted by Sinclair et al.[19] among patients below the poverty line in India similarly found that food support was significantly associated with a reduced risk of overall unsuccessful TB treatment outcome including loss to follow-up. The almost complete eradication of loss to follow-up in Group 1 (1.6%) is particularly noteworthy: Storla et al. [20] cite socioeconomic obstacles (including lack of transport cost and food insecurity) as the main causes of TB treatment non-adherence and loss to follow-up; these are precisely the

obstacles that the Yojana scheme seeks to address. A study conducted by researchers namely Vita D et al. [21] showed that nutritional support can also effectively improve the treatment adherence of TB patients. It helps in understanding that when both financial and nutritional incentives are provided, they reduce the opportunity cost of treatment attendance. The fact that two deaths occurred only in Group 2, while no deaths were observed in Group 1, is consistent with what Bhargava et al.[22] found, which is that TB patients with low BMI are at significantly higher risk for death. However, the small absolute numbers in this study precludes us from making any stern conclusions.The researchers observed that the SGRQ Total Score in Group 1 decreased from 38.41 to 13.30. Group 2 showed a decrease from 38.27 to 20.17 ($p<0.001$). In a study on quality of life among TB patients from South India, Rajeswari et al [23] found similar improvement of SGRQ with treatment, but those attaining better nutritional and microbiological response had steeper improvement.

A recent narrative review on health-related quality of life of TB patients confirmed that socio-economic status, nutritional status and treatment compliance are the strongest predictors of post-treatment SGRQ improvement which is consistent with the pattern of differential improvement seen between the groups in the present study.[24] The WHO-5 Index improvement was a lot better in Group 1 where it improved from 5.50 to 16.38 as compared to Group 2 where it improved by only 5.40 to 9.40 ($p<0.001$). This is of major public health significance. At baseline, WHO-5 score <13 suggests probable depression and both groups started in this range. After 6 months of treatment, group 1 reached the psychologically well range, while group 2 remained impaired. A study by Nasiri et al[25] on self-care education and quality of life in patients with TB noted that structured support interventions raised the quality of life scores in several domains.

It further reaffirmed that the psychosocial aspect of TB is strongly modulated by perception of adequacy of external support.The multi-dimensional benefit seen – nutritional recovery, higher treatment success, lower loss to follow-up and better mental health – provides strong evidence in favour of Pradhan Mantri TB Mukt Bharat Abhiyaan being a programme level intervention. Rao et al.[26] assessed PMTBMBA that revealed coverage of nutritional support under PMTBMBA was associated with improved outcome and increased uptake of the Ni-kshay Mitra scheme by people with TB. The financial support provided by the Ni-Kshay Poshan Yojana has seen increasing incremental strengthening, with a recent enhancement in the amount of monthly nutritional allowance. This is a policy shift that was necessitated on the basis of evidence from such studies as ours. The intervention is estimated at approximately US$167 per disability-adjusted life year saved, according to the cost-effectiveness modelling by McQuaid et al.[15] Structured nutritional support is therefore one of the most cost-effective TB elimination strategies in high-burden settings. This was a single-center study with a relatively small sample of 120 patients, which may limit generalizability to other geographic and demographic settings. Independent quantification of dietary intake was not performed, making it difficult to precisely isolate the effect of nutritional supplementation from other components of the Yojana scheme, such as financial assistance and counseling. Follow-up was limited to the 6-month treatment duration; post-treatment relapse rates and sustained nutritional and quality of life outcomes could not be assessed.

CONCLUSION

Drug sensitive Pulmonary Tuberculosis patients with Nikshay Mitra had remarkable treatment success rate of 96.6% and no mortality was observed. Positive impact was observed among patients in terms of nutritional status as evidenced by significant improvement in BMI and waist hip circumference ratio. These results underscore the success of involving Nikshay Mitra as support partners for TB patients, showcasing the benefits of the Pradhan Mantri TB Mukt Bharat Abhiyan. The combined effort of corporate backing, NGO support, and government supervision has established a comprehensive system that tackles both the medical and socio-economic dimensions of TB care.

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