Original article

USAGE OF N-TB MOBILE APPLICATION TO EVALUATE THE NUTRITIONAL STATUS OF PULMONARY TB PATIENTS ENROLLED UNDER NIKSHAY POSHAN YOJANA SCHEME AT RAMANAGARA DISTRICT, KARNATAKA – A CROSS SECTIONAL STUDY

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ABSTRACT

Introduction: Tuberculosis affects millions of people every year, and India is among the 30 countries with the highest TB burden as identified by the WHO, accounting for 87% of worldwide cases. The significant role of nutrition in the treatment of TB has been well established. Various strategies and innovations have been introduced globally to combat TB, hastening the process towards its elimination. One such measure taken by the Indian government is the Nikshay Poshan Yojana (NPY) program, which provides nutritional assistance to individuals affected by TB.

Methodology: A cross sectional study with objectives to assess the nutritional status of TB patients using N-TB application and to determine the factors associated with utilization pattern of Nikshay Poshan Yojana was conducted for a period of 6 Months from August 1st 2021 to January 31st 2022. A total of 270 patients with pulmonary TB were selected according to PPPS from 5 different Talukas/ tuberculosis units (TUs) of Ramanagara district who had received incentives for all 6 months of their treatment period and information was collected using a predesigned, pretested and semi-structured questionnaire.

Results: Among 270 study subjects, 143 were underweight at the time of diagnosis. Among 143 underweight study subjects at the time of diagnosis, 31.5% (45) attained normal BMI, and 1.4% (2) became overweight, while the majority 67.1% (96) remained underweight at the end of 6 months of treatment. It was found that there was statistically significant association between nutritional status at the end of 6 months and age group, gender, marital status and presence of co-morbidity.

Conclusion: Most of the individuals who took part in the study utilized NPY scheme according to its intended purpose. It is crucial to provide nutritional support promptly through NPY before completion of treatment to gain a better understanding of the improved nutritional status. Regular nutritional evaluations and counselling for TB patients would also enhance positive treatment outcomes.

Key words: Tuberculosis, Nutrition, BMI, NPY, Treatment Outcome

INTRODUCTION

Although tuberculosis is a curable and preventable disease, it remains one of the top 10 leading causes of death globally, exacerbated by the emergence of COVID-19. India has the highest percentage of global TB cases (26%), with a commitment from Government of India to eliminate the disease by 2025. [1,2] Pulmonary tuberculosis is the commonest type of TB, comprising 72% of all cases in India and 68% in Karnataka. [3] Under nutrition is a risk factor for conversion of latent TB infection into active TB disease, are exacerbating malnutrition and WHO recognizes this causal link between under nutrition and TB. [7], estimating 2.2 million cases attributable to under nutrition alone; [4,5] Nutritional supplementation has shown positive outcomes for TB patients, with higher cure rates and better outcomes. [6] India has launched the Nikshay Poshan Yojana (NPY) scheme under the National Tuberculosis Elimination Programme (NTEP) in 2018 to provide cash benefits to all TB patients for the complete treatment period. [4,5,6,7] The Nutrition TB (N-TB) mobile application was also launched during the period to simplify nutritional assessment, counselling, and care of TB patients. The "N-TB" is a mobile-based application that has been endorsed by the NTEP and World Health Organisation, India to assess the nutritional status of patients under the programme. In addition to calculating BMI, the app has the capability to categorize the severity of under nutrition, simplifying the process of triage and guiding clinical decisions based on BMI. The app also provides information on the recommended body weight corresponding to a BMI as well as the daily caloric and protein intake for underweight patients with active TB. Moreover, the app offers dietary counselling for TB patients, guidance on major food groups, and emphasizes the importance of an adequate and balanced diet using locally available foods to support the nutritional recovery of TB patients. These additional features are provided within the N-TB application, benefiting patients with TB. [8] However, there are limited studies on the utilization of nutrition support and assessment of nutritional status of TB patients in Karnataka, India. Therefore, we conducted a study with an aim to determine the proportion of pulmonary TB patients who utilized the NPY scheme, assess their nutritional status using the N-TB mobile application, and determine the factors associated with utilization and spending patterns of the cash benefit received.

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METHODOLOGY

The study was a cross-sectional investigation carried out in Ramanagara district with a population of 1.4 million, located in the southern state of India, Karnataka. The district comprises five Tuberculosis Units (TUs) which are the programmatic management unit under NTEP, namely Ramanagara, Harohalli, Channapattana, Kanakpura, and Magadi. The study spanned a six-month period from August 2021 to January 2022. The participants were patients diagnosed with pulmonary tuberculosis, who had completed six months of treatment and resided in the Ramanagara district. Only notified pulmonary TB patients who had used at least one incentive of NPY scheme in the 2020 financial year (April 2020 to March 2021) were included in the study. Patients who were not willing to participate, unable to comprehend or respond, paediatric pulmonary TB patients, pregnant and lactating mothers, Drug Resistance Tuberculosis (DRTB) patients, and extra pulmonary TB patients were excluded from the study. The selection of pulmonary TB cases was based on the duration of treatment, which was six months. Furthermore, the N-TB application is intended for adults only, and the body mass index cannot be considered during pregnancy and lactation. Finally, DRTB and extra pulmonary TB patients were excluded because the duration of treatment and DBT benefit varies for these patients.

Sources of data: The proforma was utilized to directly collect primary data using software EpiCollect 5, from patients through interviews, while secondary data on patient information related to DBT was obtained from the NIKSHAY portal and treatment cards of TB patients. Prior to data collection, the participants were provided with an explanation of the study's nature and purpose, and written informed consent was obtained. from them.

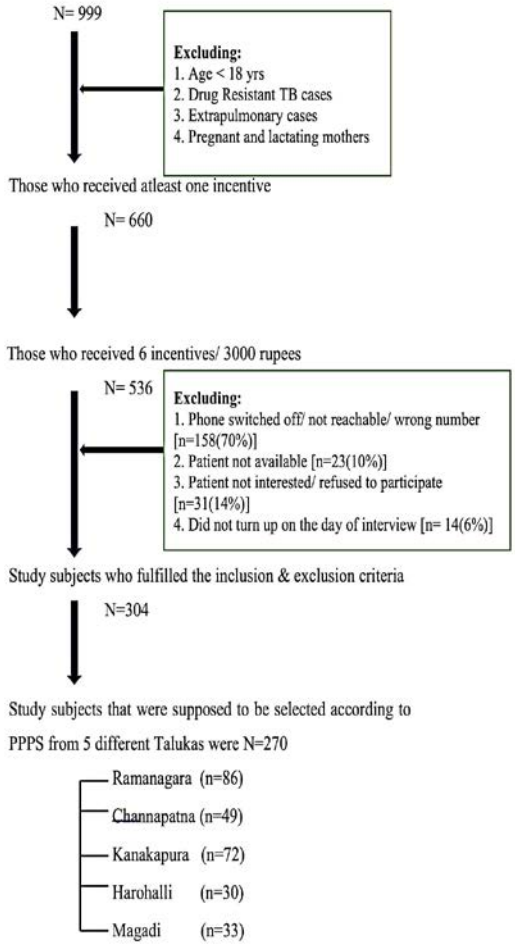

Figure 1: Case Selection Process: Total Number of Patients Enrolled in NIKSHAY from April 2020 to March 2021

Data collection tool:

To collect information from the study participants, a semi-structured questionnaire, which was predesigned and pretested, was used. The questionnaire was piloted among 30 subjects attending the out patient department of pulmonary medicine at our institution. The questionnaire comprised six sections aimed at collecting details related to socio-demographic factors, TB diagnostic and treatment, as well as nutritional incentives. To ensure content validity, the questionnaire was shared with subject-matter experts who were requested to provide feedback on how well each question measures the construct in question. The feedback received was analysed to determine the effectiveness of each question. Pretesting was conducted by subject experts, which involved pilot study, translation, and back translation.

Sample size:

The sample size was calculated using data from the research study conducted by Bharat Kumar HP et al., which showed a 42.2% utilization for NPY.[4] Considering a power of 80%, a confidence interval of 95%, a relative precision of 15% and a design effort of 1, we arrived at an estimated sample size of 270.

The following formula was used to calculate the sample size:$n=Z^2\ pq/d^2$ where,

Z = relative deviate (1.96 at 95% confidence)
p = prevalence (42.2)
q = 100-p=100-42.2 = 57.8
d = Absolute precision =15%
The sample size (n) obtained was 245.
Considering a non-response rate of 10% the total calculated sample size was 245+25=270.

Anthropometric measurements:

Patient weight details at the time of TB diagnosis were obtained from their TB cards. For 85% of the participants, height details were also available in the TB cards. For the remaining participants, height measurements were obtained at the time of the interview. The N-TB mobile app was used to calculate BMI at three different time points: at the time of diagnosis, at the end of 6 months of treatment, and at the time of the interview, using weight and height details collected from the participants by following standard protocol.

S. N.	Attribute measured	Instrument used
1.	Weight (kilograms)	Analogue weighing scale (Samso)
2.	Height (centimetres)	Portable Staturemeter

Statistical analysis: The collected data was entered into a Microsoft Excel worksheet and compiled. Statistical software SPSS 20.0 was utilized for data analysis. The Shapiro-Wilk test was used to assess the normality of the data. The descriptive statistics, including mean, standard

deviation (SD), and percentages, were computed to analyze the data. Chi-square test was utilized to determine the association between the attributes. The Wilcoxon signed-rank test was employed to assess significant changes in variables resulting from the intervention. Furthermore, Friedman's test was applied to examine the progression of BMI from the time of diagnosis to the time of the interview.

Ethical issues: We obtained approval from the institutional ethical committee with the IEC No. CDSIMER/MR./0022/IEC/2021. The permission for the conduct of the study was obtained from district and state tuberculosis office.

RESULTS

The study involved 270 individuals who completed all six instalments of NPY. Most of these individuals (21.1%) fell within the age group of 51-60 years, with a median age of 48 years and an interquartile range of 36-60 years. Of the respondents, 72.2% were male and 92.6% were Hindu. Additionally, 42.6% were illiterate, 21.5% had a high school education, and 40.4% were agricultural laborers. In terms of socioeconomic status, 36.7% belonged to Class IV according to modified BG Prasad Classification of socioeconomic status. Among the study subjects, 35.6% had at least one comorbidity, with diabetes being the most common (29.2%). Smoking and alcohol use were reported in 15.2% and 7.8% of the study subjects, respectively. A previous history of TB was seen in 15.2% of the participants, while 18.1% had a family member with a history of TB.

Many of the study subjects (99.6%) were diagnosed at public labs, with the majority (98.9%) diagnosed using the CBNAAT (Cartridge Based Nucleic Acid Amplification Test) method. Of the study subjects, 5.2% reported experiencing severe side effects, with vomiting being the most common (78.6%). Additionally, 87.0% of the study subjects had received at least one dose of the COVID vaccine. Details about the nutritional incentives received by the study subjects are presented in **Table 1**, while BMI at the time of diagnosis and at the end of 6 months is shown in **Table 2**.

Table 1: Information on the nutritional incentives provided to the participants in the study

Aware about Nikshay Poshana Yojana	**n (%)**
Yes	77 (28.5)
No	193 (71.5)
Total	270 (100)
Source of Awareness about NPY	**n (%)**
STS (Senior TB Supervisor)	45 (58.4)
TBHV (TB Health Visitor)	17 (22.1)
ASHA	11 (14.3)
MO (Medical Officers)	4 (5.2)
Total	77 (100)
Details of the money received	**n (%)**
Received in the First installment	265 (98.1)
Received in the Second installment	260 (96.3)
Received in the Third installment	254 (94.1)
Received in the Fourth installment	226 (83.7)
Received in the Fifth installment	206 (76.3)
Received in the Sixth installment	169 (62.6)
Nutritional incentives during the six months of time	**n (%)**
Fully Received (Rs.3000)	194 (71.9)
Partially Received (≤ Rs.2500)	76 (28.1)
Total	270 (100)

Name of Tuberculosis Unit	**n (%)**
Ramanagara	86 (31.9)
Kanakapura	72 (26.7)
Channapatna	49 (18.1)
Magadi	33 (12.2)
Harohalli	30 (11.1)
Total	270 (100)
Fully Received within 6 months	n (%)
Ramanagara	68 (79.1)
Kanakapura	44 (61.1)
Channapatna	43 (87.8)
Magadi	22 (66.7)
Harohalli	17 (56.7)
Utilization Pattern	n (%)
Nutritional Purposes	240 (88.9)
Medicines	30 (11.1)
Total	270 (100)

Table 2: Body Mass Index (BMI) measured both during diagnosis and after 6 months			
BMI at the time of Diagnosis	**BMI at the end of 6 months**		
	Underweight (99, 36.7%)	**Normal weight (140, 51.9%)**	**Overweight (31, 11.5%)**
	n (%)	n (%)	n (%)
Underweight (143, 53.0%)	96 (67.1)	45 (31.5)	2 (1.4)
Normal weight (113, 41.9%)	3 (2.7)	95 (84.1)	15 (13.3)
Overweight (14, 5.2%)	0 (0)	0 (0)	14 (100)

Of the 143 study subjects who were underweight at the time of diagnosis, 31.5% gained normal BMI, and 1.4% became overweight at the end of the 6th month. Majority of these subjects (67.1%) remained underweight.

Table 3. shows that several factors, including age group, gender, family size, socio-economic status, previous history of TB, family history of TB, alcohol use, smoking, diet, the interval between onset of symptoms and initiation of TB treatment, treatment interruption, follow-up visits, awareness about NPY, and history of side effects had an odds ratio of more than 1, indicating a higher impact on BMI status.

The mean BMI at the time of diagnosis was 18.6±3.7kg, while the mean BMI after the 6th month was 20.2±3.8 kg. The mean change in BMI was 1.54±1.77kg, with a median change in BMI of 1.3 and an interquartile range of 0.8 to 2.0. At the end of the 6th month, 3.7% of study subjects reported no change in BMI, 5.2% reported a decrease in BMI, and 91.1% reported an increase in BMI.

Table 3: Odds ratios depicting the factors associated with underweight and normal/overweight						
BMI	**Underweight (99)**	**Normal and Overweight (171)**	**Odds ratio**	**95 % CI**	**z statistic**	**p-value**
Age-Group (Years)	**N (%)**	**N (%)**				
≤48	63 (63.6)	76 (44.4)	2.1875	1.3154 to 3.6377	3.017	0.0026
>48	36 (36.4)	95 (55.6)				
Marital Status						
Married	77 (77.8)	155 (90.6)	0.3613	0.1795 to 0.7272	2.852	0.0043
Unmarried	22 (22.2)	16 (9.4)				
Co-morbidity						
Yes	18 (18.2)	78 (45.6)	0.265	0.1465 to 0.4793	4.391	< 0.0001
No	81 (81.8)	93 (54.4)				
Diabetes Mellitus						
Yes	11 (11.1)	71 (41.5)	0.176	0.0877 to 0.3534	4.886	< 0.0001
No	88 (88.9)	100 (58.5)				
No	98 (99.0)	168 (98.2)				
Previous History of TB						
Yes	21 (21.2)	20 (11.7)	2.0327	1.0395 to 3.9748	2.073	0.0381
No	78 (78.8)	151 (88.3)				
Family History of TB						
Yes	27 (27.3)	22 (12.9)	2.5398	1.3536 to 4.7654	2.903	0.0037
No	72 (72.7)	149 (87.1)				

Table 4: Comparison of BMI after receiving the Nikshay Poshana Yojana among the study subjects								
	Descriptive Statistics			Paired Differences				
BMI	**Mean**	**SD**	**Median**	**Mean**	**SD**	**Median**	**Q1**	**Q3**
At Diagnosis	18.6	3.7	18.2	1.54	1.77	1.3	0.8	2.0
After 6th Month	20.2	3.8	19.6					
BMI at 6th-Month	**n (%)**	**Mean Rank**		**Sum of Ranks**		**Wilcoxon Signed Ranks Test**	**p-value**	
Decreased	14 (5.2)	148.0		2072.0		-12.274	0.000 (< 0.05)	
Increased	246 (91.1)	129.5		31856.0				
Constant	10 (3.7)							

Table 4 depicts these findings. The Shapiro-Wilk test was used to test the normality of BMI data, which was found to be <0.05 at all three time points, indicating non-normality.

Applying the Wilcoxon signed-rank test showed that Z = -12.274 and p < 0.05, indicating a statistically significant change in BMI at the end of 6 months of treatment. The median with Inter quartile range (IQR) at the time of diagnosis was 18.2 (16.0-21.2), after the 6th month was 19.6 (17.3-22.7), and at the time of the interview was 20.9 (18.0-23.9) with mean rank 1.21, 2.28, 2.51 respectively. The BMI showed a significant difference across three time points, including the time of diagnosis, the end of 6 months of treatment, and the time of the interview. This difference was confirmed by Friedman's chi-square test (χ^2 = 274.12, p < 0.05). A Box and Whisker plot representing this difference is presented in **Figure 2**.

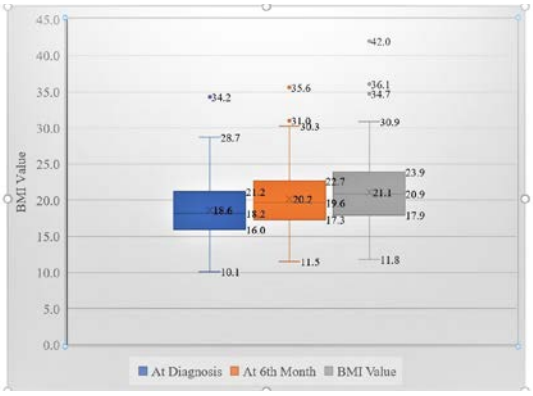

Figure 2: Box and Whisker plot showing the mean, median with inter quartile range values of the BMI at the time of diagnosis, at the end of 6 months and at the time of interview

DISCUSSION

The findings of our study indicate that a majority of individuals, approximately 21.1%, fell within the age group of 51-60, which is consistent with the results reported by J. Begam et al., where 44% of the respondents were male [9]. Furthermore, our study revealed that a significant majority (85%) of the cases were newly diagnosed, a finding similar to the study conducted by M.P. Poornima et al., where 94% of the cases were newly diagnosed. Interestingly, our study also showed that 99.6% of the participants received their diagnosis at public healthcare facilities, while other studies have reported that around 50% of patients seek public health care for TB diagnosis [10]. This disparity in findings could be attributed to the fact that the National Tuberculosis Elimination Program (NTEP) provides free screening, diagnostic, and treatment services for all TB patients, resulting in higher rates of diagnosis in the public sector. Additionally, potential factors contributing to this difference may include underreporting or reduced participation from private practitioners, as well as variations in the study populations. Another noteworthy finding was that approximately 52.9% of the study subjects were underweight at the time of diagnosis, which aligns with the findings reported by Bhargava A et al. [8].

Regarding awareness of the Nikshay Poshan Yojana (NPY) scheme, our study revealed that only 28.5% of the participants were aware of it. Among those who were aware, the primary sources of information were Senior Treatment Supervisors

(58.4%), followed by Tuberculosis Health Visitors (22.1%), Accredited Social Health Activists (14.3%), and medical officers (5.2%). This low awareness rate of the NPY scheme in our study could be attributed to the participants' unfamiliarity with the scheme's name. However, all participants were aware of the Rs. 500 cash incentive provided by the NTEP through Direct Benefit Transfer (DBT) for each month of TB treatment until completion. In contrast, a study conducted by J. Begum et al. reported that 91.5% of beneficiaries were aware of the cash incentive offered by the Nikshay Poshan Yojana, with healthcare workers being the primary source of information (84.3%), followed by neighbours (3.6%), friends and family (2.4%), and media (1.2%) (9). Another study identified television as the main source of information on tuberculosis [11].

Regarding the incentives received, our study found that 98.1% of the participants received the first instalment during the treatment period, which is higher compared to studies conducted by Rohit A et al. and Patel BH et al., where 78.5% and 42.2% received the first instalment during treatment, respectively [4,12]. However, in our study, 28.1% of the subjects did not receive the complete amount of money during the 6-month treatment period. This contrasts with a study by Kumar R et al., which reported that 47.3% of the study subjects did not receive any incentive during treatment [6]. Among those who received the incentives in our study, 72% received them on time, and the majority (89%) utilized the funds for nutritional purposes. Similarly, in a study by Rohit A et al., 76% of the participants spent the money on buying food for nutrition, while the remaining 24% used it for personal and family needs [4,12].

In terms of the association between Body Mass Index (BMI) and participants' characteristics, our study demonstrated a statistically significant difference in BMI from the time of diagnosis to the time of the interview. Additionally, age, gender, and marital status were found to have a statistically significant association with BMI. However, we did not find a statistically significant association between BMI and other demographic details, which is consistent with the findings of a study conducted by J. Begum et al. [9].

A retrospective cohort study by J.D. Dave and M.P. Rupani aimed to determine the association between non-receipt of Direct Benefit Transfer (DBT) and unfavourable treatment outcomes. They found that 15% of patients were tobacco smokers, 5% consumed alcohol, 4% were HIV positive, and 9% had diabetes. Similar result were found in our study: 15.2% of participants smoked tobacco, 7.8% consume alcohol, and 1% were HIV positive, with the exception of diabeticsm, who made up 29.2% of the sample [13].

Challenges identified in the study conducted by J. Begum et al. included patient illiteracy and ignorance, the stigma attached to the disease, non-cooperation of patients, and a lack of effective follow-up [9]. Similarly, in our study, non-cooperation from patients and the fear of stigmatization were identified as main challenges. However, building trust among patients and implementing effective Behaviour Change Communication involving NTEP staff were recognized as strategies to overcome these challenges.

CONCLUSION

We conclude that the majority of the study participants utilized the NPY scheme as per the proposed purpose of the program. But, few of them received the final incentive of NPY after the completion of treatment, which compromised the intended purpose.

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CONFLICT OF INTEREST

None

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LIMITATION

The patient will start gaining weight as soon as he is started on Anti Tubercular Treatment with increase in his/her appetite. Therefore scientifically, the weight gain cannot be attributed solely to the incentives provided through the NPY scheme.

The N-TB application, which was used for our study, was based on the WHO classification of BMI and it was not specific to the South Asian standards.

RECOMMENDATION

Nutritional incentives should be disbursed on time at regular intervals to the TB patients for it to be impactful, otherwise it will defeat the purpose of the program. If we invest in nutrition, we can have a better outcome and end TB by 2035.

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