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Exploring factors influencing the health-related quality of life of tuberculosis patients: a WHOQOL-BREF-based study

Surabhi Panduranga Kodical,¹ Rishabh Roy,² Deekshitha Shetty,¹ Nandakumar UP,¹ Rajesh V,³ Sharad Chand,⁴ Reshma Kolar,⁵ Praneetha Jain¹

¹Department of Pharmacy Practice, NGSM Institute of Pharmaceutical Sciences (NGSMIPS), Nitte (Deemed to be University), Mangalore; ²Department of Pharmacy Practice, KLE College of Pharmacy-Bangalore (a constituent unit of KAHER, Belagavi), Bangalore; ³Department of Respiratory Medicine, Yenepoya Medical College Hospital, Mangaluru; ⁴Department of Pharmacy Practice, School of Health Sciences and Technology, Dr. Vishwanath Karad MIT World Peace University, Pune, Maharashtra; ⁵Department of Community Medicine, KS Hegde Medical Academy (KSHEMA), Nitte (Deemed to be University), Mangalore, India

Correspondence: Nandakumar UP, Department of Pharmacy Practice, NGSM Institute of Pharmaceutical Sciences, Nitte University, Mangalore. Tel.: +91-9633023062. E-mail: nandakumarvtkv@gmail.com,

Contributions: SPK, RR, DDS, NUP, study concept, literature review, data collection, preparation of report, preparation of draft; NUP, RV, RK, study design, data collection, data validation, clinical monitoring, clinical supervision, statistical analysis, preparation of report; SC, PJ, study concept, study design, study coordination, study supervision, drafting manuscript; NUP, RV, SC, preparation of manuscript. All authors read and approved manuscript.

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Abstract

As a chronic illness, tuberculosis is known to negatively affect patients' day-to-day functioning. Therefore, evaluating all aspects of their health is imperative to improve their quality of life. The current study was conducted to assess the quality of life of patients receiving tuberculosis therapy and to identify the associated risk factors. A prospective, cross-sectional study of six months was planned and conducted in 66 Mycobacterium tuberculosis-infected patients who justified the pre-defined inclusion criteria. All pertinent data about the patients were collected in a precisely created data collection form. Further, the brief version of the World Health Organization Quality of Life Questionnaire was used to evaluate the patients' quality of life. Of the 66 patients who were enrolled, 42 (63.6%) were male, and 14 (21.2%) belonged to the age group of 61-70 years. The domains of physical, psychological, social relationships, and environment had mean scores of 46.76±20.15 standard deviation (SD), 55.02±16.12 SD, 54.83±13.91 SD, and 64.92±14.59 SD, respectively. All four quality-of-life domains were found to have statistically significant associations with a variety of sociodemographic and treatment-related variables. This study gives healthcare practitioners an insight into the need to evaluate patients' health-related quality of life, particularly for individuals with chronic illnesses.

Key words: cross-sectional, quality of life, tuberculosis, WHOQOL-BREF.

Introduction

Tuberculosis (TB) is a chronic, infectious, and communicable disease caused by Mycobacterium tuberculosis, a rod-shaped bacillus which can either produce a latent infection or an active progressive disease and if left untreated or inadequately treated, it can cause tissue degradation and in due course, death [1]. The reactivation of dormant bacilli is higher among cases of Human immunodeficiency virus infection/ Acquired Immune Deficiency Syndrome (HIV/AIDS), diabetes mellitus, malnutrition, alcohol consumption and tobacco smoking. According to the World Health Organisation (WHO) global tuberculosis report 2023, an estimated 10.6 million people worldwide contracted TB, with 5.8 million being men, 3.5 million women, and 1.3 million children. The TB incidence rate increased by 3.9% between 2020 and 2022, reversing a trend of about 2% annual declines over the past two decades. Globally, TB caused an estimated 1.30 million deaths in 2022. This represents a slight decrease from the estimated 1.4 million deaths in 2020 and 2021, nearly returning to 2019 levels. However, India is still one of eight countries responsible for more than two-thirds of the global TB burden [2]. The India TB report 2023 states that the year 2022 witnessed a 13% increase in the incident TB cases in comparison to that of 2021, attaining a record high notification of 24.2 lakh cases [3]. Approximately 85% of *M. tuberculosis* infected patients can be successfully treated with a six-month medication regimen consisting of two months of intensive phase and four to seven months of continuous phase [4].

As per WHO, an individual's perception of their physical and mental health, as well as their psychological, economic, spiritual, and social well-being is collectively referred to as their quality of life (QOL). The chronicity, severity of disease and the associated side effects of the anti-tubercular therapy may adversely affect a patient's quality of life [5,6]. As a result, they usually experience negative impacts on their physical, social, and psychological well-being [7,8]. In the present study, WHOQOL-BREF instrument, which is a shorter version of WHOQOL-100 is used to assess the influence of tuberculosis and its treatment on various domains of the patient's health [9]. Since achieving a better quality of life is one of the major therapy objectives, it is important to address all these domains of health. This has led to the realization among all the health care professionals that the physical aspects of the diseases can never alone be considered for obtaining the most effective therapeutic outcome, especially in chronic disease conditions [10,11]. Therefore, the current study was planned and conducted to evaluate the *M. Tuberculosis* patient's quality of life, receiving drug therapy and to determine the factors associated with that.

Materials and Methods

Study design, sample size calculation and data collection

A cross-sectional study was conducted prospectively over a six-month period, spanning from October 2021 to March 2022. This study was planned and executed at the departments of general medicine and pulmonary medicine of a tertiary care teaching hospital, centrally located in the district of Dakshina Kannada, Karnataka, India. Both inpatients and out-patients, regardless of gender, who were above 18 years of age and receiving treatment for either pulmonary or extrapulmonary tuberculosis were included. Patients who were pregnant, critically ill, or those who declined to provide consent were excluded from the study. Prior to commencement of the study, necessary approval was taken from the Institutional Ethics Committee (IEC) (Reference number-NGSMIPS/IEC/18/2021). Additionally, the study was also registered with the Clinical Trials Registry-India (CTRI) (Registration number- REF/2021/11/049088).

The required sample size was determined to be 66 using nMaster software version 2, with a consideration of a standard deviation of 8.27 as reported by Salehitali S et al.[12], and a margin of error of 2 at 5% level of significance.

An appropriately constructed data collection form was used to collect sociodemographic, clinical and treatment related information as well as other pertinent data on the patients' course of care. The WHOQOL-BREF questionnaire used to assess the quality of life, consists of a total of 7 items pertaining to the physical domain, 6 items on psychological, 3 items on social relationship and 8 items on the environment domain. In addition to these domains, two additional items are evaluated independently: question 1 asks about a person's overall perception of quality of life, and question 2 asks about a person's overall health perception. The WHOQOL-BREF questionnaire has five-point ordinal answer scales, with each item having a range of 1 to 5. Following a linear transformation, the total raw scores for each domain were converted to a 0–100 scale, using the WHOQOL-BREF scoring manual.

Statistical analysis

All the data of the tuberculosis patients were analysed using descriptive and inferential statistics using SPSS software version 28.0. Quantitative data were presented as Mean \pm SD, while qualitative data were represented by frequency and percentage. The scores of various domains of QOL of the patients were summarized as mean \pm S.D. Factors significantly associated with the patients' quality of life were identified using univariate followed by multivariable linear regression analysis.

Results

Socio-demographic characteristics of patients enrolled

Out of 66 patients enrolled in the study, 42 (63.6%) were found to be male and 24 (36.4%) were female with the mean age of 49.24 ± 16.82 years. In addition, the highest number of respondents were found to be within the age group of 61-70 years, 14 (21.2%), followed by 41-50 years, 13 (19.7%). In terms of place of residence, 39 (59.1%) were found to be urban residents, whereas 27 (40.9%) were found to be from rural backgrounds. About the diagnosis of the present patient population, 39 (59.1%) were diagnosed with extrapulmonary tuberculosis, whereas 27 (40.9%) were diagnosed with extrapulmonary tuberculosis. Most subjects were prescribed with more than 10 drugs, 24 (36.3%). The details are described in Table 1.

Distribution of patients based on perception of their QOL

A majority of the total respondents had an average perception of quality of life, 28 (42.4%), followed by patients with a good perception, 21 (31.8%). 11 (16.6%) patients had bad perception and 3 (4.6%) patients each had very bad and very good perception.

Distribution of patients based on perception of their general health

Out of the 66 patients enrolled in the study, highest number of patients were found to be dissatisfied with their health, 26 (39.4%), followed by which there were patients who had an average perception of their health, 19 (28.8%). A total of 14 (21.2%) were found to be very dissatisfied and only 7(10.6%) were found to be satisfied. None of the patients were very satisfied.

Quality of life of the patients

The average scores for the domains of physical, psychological, social relationship, and environment were 46.76 ± 20.15 SD, 55.02 ± 16.12 SD, 54.83 ± 13.91 SD, and 64.92 ± 14.59 SD, respectively. The highest domain score was found to be of environment, whereas the lowest score was of the physical.

Factors associated with domains of quality of life

Physical domain

The physical domain score was considered as the dependent variable and the independent variables for the univariate linear regression analysis included gender, age group, domiciliary status, body mass index (BMI) categories, level of education, status of

employment, socioeconomic class, marital status, social habits, comorbid conditions, diagnosis, treatment regimen, number of fixed drug combination (FDC) tablets in directly observed treatment short course (DOTS) therapy, and total number of prescribed drugs. Extrapulmonary tuberculosis (B= -10.06; 95% Cl= -19.90, -0.22; p value= 0.04) and >10 number of drugs prescribed (B= -18.15, 95% Cl= -30.31, -5.99; p value= 0.004) were significantly associated with lower physical domain scores. Following this, a multivariate linear regression analysis was carried out using the same dependent variable, whereas diagnosis and total number of drugs prescribed were taken as independent variables. In comparison with the reference category, extrapulmonary tuberculosis (B= -10.27; 95% Cl= -19.59, -0.94; p value=0.031) and >10 number of drugs prescribed (B= -18.21, 95% Cl= -30.01, -6.40; p value=0.003) were found significantly associated with lower physical domain scores.

Psychological domain

The psychological domain score was considered as the dependent variable and the independent variables for the univariate linear regression analysis included gender, age group, domiciliary status, BMI categories, level of education, status of employment, socioeconomic class, marital status, social habits, comorbid conditions, diagnosis, treatment regimen, number of FDC tablets in DOTS therapy, and total number of prescribed drugs. Patients educated till high school (B= -12.16; 95% Cl= -22.89, -1.43; p value= 0.027) and chronic liver disease as comorbidity (B= -36.56; 95% Cl= -67.97, -5.16; p value= 0.023) were significantly associated with lower psychological domain scores. After this, a multivariate linear regression analysis was carried out using the same dependent variable, whereas level of education and chronic liver disease as comorbidity were taken as independent variables. Compared to the reference category, patients educated till high school were significantly associated with lower scores of psychological domains (B= -10.58; 95% Cl= -21.19, 0.02; p value= 0.04). The results are summarized in Table 3.

Social relationship domain

The social relationship domain score was considered as the dependent variable and the independent variables for the univariate linear regression analysis included gender, age group, domiciliary status, BMI categories, level of education, status of employment, socioeconomic class, marital status, social habits, comorbid conditions, diagnosis, treatment regimen, number of FDC tablets in DOTS therapy, and total number of

prescribed drugs. Patients belonging to overweight category of BMI (B= -10.95; 95%Cl= -20.09, -1.81; p value= 0.020) and those who were unmarried (B= -8.46; 95%Cl= - 16.66, -0.26; p value= 0.043) were significantly associated with lower social relationship domain scores. Following this, a multivariate linear regression analysis was carried out using the same dependent variable, whereas BMI and marital status were taken as independent variables. Patients who were unmarried scores (B= -11.82; 95%Cl= -22.06, -1.59; p value= 0.024) and those belonging to the overweight category of BMI (B= - 11.72; 95%Cl= -20.72, -2.72; p value= 0.012) were significantly associated with lower social relationship domain. The results are summarized in Table 4.

Environment domain

The environment domain score was considered as the dependent variable and the independent variables for the univariate linear regression analysis included gender, age group, domiciliary status, BMI categories, level of education, status of employment, socioeconomic class, marital status, social habits, comorbid conditions, diagnosis, treatment regimen, number of FDC tablets in DOTS therapy, and total number of prescribed drugs. Patients educated till high school (B= -14.77; 95%Cl= -23.62, -5.92; p value= 0.001) and chronic liver disease as comorbidity (B= -34.44; 95%Cl= -62.78, -6.10; p value= 0.018) were significantly associated with lower environment domain scores. Following this, a multivariate linear regression analysis was carried out using the same dependent variable, whereas level of education and chronic liver disease as comorbidity were taken as independent variables. Patients educated till high school (B= -14.77; 95%Cl= -23.62, -5.92; p value= 0.001) and chronic liver disease as comorbidity were taken as independent variables. Patients educated till high school (B= -14.77; 95%Cl= -23.62, -5.92; p value= 0.001) and chronic liver disease as comorbidity were taken as independent variables. Patients educated till high school (B= -14.77; 95%Cl= -23.62, -5.92; p value= 0.001) and chronic liver disease as comorbidity (B= -34.44; 95%Cl= -62.78, -6.10; p value= 0.018) were significantly associated with lower environment domain scores. The results are summarized in Table 5.

Discussion

The present research assessed the quality of life and its associated factors in tuberculosis patients at a tertiary care teaching hospital. According to the study findings, males were more prevalent than females. This aspect of the result was found similar to a study carried out by Sartika I *et al.*, 2019, in which they observed a higher number of males (58%) over females (42%) [13]. According to various scientific literatures, it is evidenced that the males are more prone to the disease when compared to their counterpart. However, in contradiction, Malik M *et al.*, 2018, observed dominance of females (53.4%) over males (46.6%) [14]. The mean age of the patient population was found to be

49.24±16.82 SD, which was found comparable with the research conducted by Salehitali S et al., 2019, which had the mean age of their population as 51.11±21.25 SD [12]. In the current study, patients from urban areas were found more in number than their counterpart. A study performed by Salehitali S et al., 2019 showed similar results as 76.6% of their patient population comprised of urban residents [12]. In contradiction, a study carried out by Gao XF et al., 2015 had 83.3% of their patients belonging to the rural backgrounds, as it was conducted among migrant population from 3 provinces in China which consisted majorly of the countryside inhabitants, whereas the present study was carried out in a tertiary care teaching hospital located within the urban limits [15]. Most of the patients were found belonging to the healthy BMI category of 18.5-24.9. This aspect was found comparable to results of Juliasih NN et al., 2020, in which 55.4% of the patients were in the same category [16]. Out of the total patient population, majority had high school level of education. This result was found comparable with a study performed by Malik M et al., 2018 in which 39.5% of the patients had the same level of education [14]. On the contrary, a study conducted in Lahore, Pakistan by Atif A et al., 2014 found that 67.91% of their participants were illiterate [17]. However, the current study had only 2 subjects from the illiterate category, which could generally be attributed to the higher literacy rate of the southern part of India. Majority of the patients presented in the current study were employed, which was found similar to a study conducted by Atif M et al., 2014 showing 80.6% of their patients being employed [17].

On evaluation of socio-economic status of patients in the present study, a majority were found belonging to the lower middle class. This observation was in line with the study carried out by Banerjee S *et al.*, 2019 showing 35% of their population belonging to the same class [18]. In contrast, a study by Iti JL et al., 2019, found 28.81%, constituting the highest number of their patients within the upper middle class [19]. Being a charitable hospital, patients of all sectors especially those of lower socio-economic backgrounds prefer the present study site for their treatment needs. This could be a possible explanation for the higher number of lower middle-class patients being included in the present study. Although most of the patients enrolled in the current study had no social habits, around 15% of the total sample enrolled had the habit of alcohol consumption, marking it as the major social habit, outweighing smoking and substance use. However, people who had the habit of smoking were found to be only 9.09%. A study conducted by Dujaili JA *et al.*, 2015 had made a highly contradicting observation as almost half of their enrolled patients were smokers [20]. Among the total patient population enrolled in the present study, it was noticed that there were equal number of patients with and

without any comorbidities. Juliasih NN *et al.*, 2020 conducted a study with similar objectives and found that 36.3% of their subjects had the presence of at least one comorbid condition [16]. Having known that the possibility of acquiring comorbidities increases with increasing age of patients in general, the difference in the number of patients in this context can be related to the lesser number of middle aged and elderly patients presented in their study. In the present study, majority were found to be diagnosed with extrapulmonary tuberculosis. On the contrary, research by Salehitali S *et al.*, 2019 showed that 60.9% of their patients suffered from pulmonary tuberculosis [12].

Previous research has demonstrated that tuberculosis impacts a patient's physical, emotional, and social well-being. The findings of the present study also prove the same as the highest mean score among all domains of quality of life was only 64.92 out of 100. As tuberculosis is chronic and infectious in nature, it is certain that various aspects of the physical health of the patients, quantified in terms of daily activities, mobility, work capacity, energy and sleep would remain compromised. Previous studies also have shown that psychological disturbances upon diagnosis of the disease, including anxiety, depression, disturbed sleep, fear of isolation, etc., among the patients could impose a negative impact on all domains of health. A contradicting observation to the present result was made by Dires A et al., 2021 which showed a lower domain score ranging from 39.79 (social relationship) to 46.67 (psychological) [21]. A study conducted by Deribew et al., in Ethiopia presented very low scores in comparison to the present results, ranging from 11.8 (environment) to 14.9 (psychological) [22]. A plausible explanation for the lower scores of domains in the latter study could be attributed to the presence of HIV co-infected subjects among the study population. Thus, in general the variation in the domain values of similar studies could be attributed to the differences in the patient, disease and treatment specific characteristics.

In the present study, extrapulmonary tuberculosis and prescription of >10 drugs were found to be significantly associated with the physical domain. The higher number of medications among patients could be due to the severity of the disease or the presence of coexisting health conditions. However, managing multiple conditions simultaneously could result in poorer physical domain scores. Additionally, the location and extend of extrapulmonary tuberculosis could impair the physical functioning of the patients, contributing to lower physical domain scores. High school level of education was found to be a statistically significant factor affecting the psychological domain. Patients who have completed higher levels of education, may have better health knowledge and awareness, which can help them better understand their condition, and cope with the psychological impact of the disease. This explains the higher quality of life among graduates in the present study. In the domain of social relationships, over-weight BMI and unmarried status were the significant factors. When combined with the stigma already associated with body weight, overweight TB patients may experience double the burden of discrimination, which could lead to social exclusion and diminished social interactions, which can impact social quality of life. Similarly, unmarried TB patients may not have the same level of emotional support as that of married individuals, contributing to reduced social quality of life. High school level of education and presence of chronic liver disease as a comorbidity were significantly associated with the environment domain. Individuals with chronic liver disease and TB often require regular medical appointments, monitoring, and follow-up care. This ongoing need for medical attention can consume a significant amount of their time and energy, leading to a heightened focus on their health status and treatment. They may feel more restricted or limited in their ability to engage with their surroundings, potentially reducing their overall environmental quality of life. Moreover, higher education is often associated with increased access to resources, including financial stability, better access to healthcare facilities, which justifies significantly higher environment domain scores among the graduates in the present study.

When compared to the results of the present study, Dires A *et al.*, 2021 showed different set of factors associated with the domains of quality of life. They found non-adherence and pulmonary tuberculosis to have a significant association with the physical domain, whereas comorbidity, non-adherence and pulmonary tuberculosis were found to be significantly associated in the psychological domain [21]. In the social relationship domain, pulmonary tuberculosis, non- adherence, and the occupation of farming were the significant factors. The environment domain was found to be significantly associated with pulmonary tuberculosis, occupation of farming and non-adherence.

The present study provides a very detailed assessment of factors significantly affecting the quality of life of tuberculosis patients. However, the limited sample size might possibly impact the generalisability of the obtained results.

Conclusions

The present study evaluated the quality of life and the factors associated with it among patients with either pulmonary or extrapulmonary tuberculosis. The mean score of the domains of physical, psychological, social relationship, and environment were 46.76 \pm

20.15 SD, 55.02 ± 16.12 SD, 54.83 ± 13.91 SD, and 64.92 ± 14.59 SD, respectively. Extrapulmonary tuberculosis and prescribing of >10 drugs were the factors found to have significant association with the physical domain of quality of life, whereas high school level of education was found to be significantly associated with the psychological domain. In the domain of social relationships, over-weight BMI and unmarried status were the significant factors. Level of education of high school and presence of chronic liver disease as a comorbid condition were the significant factors affecting the environment domain.

The present study would provide an insight to the healthcare professionals on the relevance of assessing health-related quality of life of all patients, especially those suffering from chronic disorders. Also, the study emphasises on the importance of a shift of focus of patient care on to the overall improvement of the various dimensions of health, rather than being only disease focused.

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Variables	
Condex	Frequency (%)
Male	42(03.0)
Ago group (in vooro)	24(30.4)
Age group (in years)	10 (15 2)
10-50	
<u>31-40</u>	$\frac{12(10.2)}{12(10.7)}$
41-50	$\frac{13(19.7)}{11(10.7)}$
51-60	$\frac{11(10.7)}{14(21.2)}$
> 70	(21.2)
$\frac{2}{10}$	0(9.1)
Age III years (Mean ± 5.D)	49.24±10.02
	27(40.0)
Ilrhan	27(40.3)
PML categories	59(59.1)
Lindonwoight (<18.5)	10 (28 8)
Healthy $(18.5, 24.0)$	
$\frac{116a101}{2524.9}$	
$\frac{\text{Obero}\left(23-29.9\right)}{\text{Obero}\left(23-29.9\right)}$	2(10.2)
Lovel of education	2 (3:0)
Illiterate	2 (3 00
Primary	8 (12 1)
Higher primary	7 (10.6)
High school	20(303)
Higher secondary	
Craduato	15(13.7)
Status of employment	10 (24.2)
Employed	42 (63 6)
	24(364)
Socioeconomic class	21(30:1)
Upper	2 (3 0)
Upper Middle	24(364)
Lower Middle	
Upper Lower	6 (9 1)
lower	
Marital status	1 (1.3)
Unmarried	14 (21.20
Married	46 (69.7)
Widowed/Divorced	6 (9 1)
Social habits	0 (311)
Alcohol	7 (10.6)
Smoking	3 (4 5)
Tobacco	3 (4 5)
Alcohol + Smoking	3 (4 5)
No substance use	50 (75.8)
Comorbid conditions	
Diabetes Mellitus	19 (28.8)
Hypertension	13 (19.7)
Ischemic heart disease	2 (3.0)
Seizure	2 (3.0)
Anaemia	4 (6.1)
Chronic liver disease	1 (1.5)

Table 1. Attributes of patients with tuberculosis (sample size=66).

Thyroid disorder	4 (6.1)				
Kidney disease	7 (10.6)				
Diagnosis					
Extrapulmonary Tuberculosis	39 (59.1)				
Pulmonary Tuberculosis	27 (40.9)				
Treatment regimen					
DOTS (NTEP)	50 (75.8)				
Private Regimen	16 (24.2)				
Number of FDC tablets					
2	3 (6.0)				
3	14 (28.0)				
4	26 (52.0)				
5	4 (8.0)				
6	3 (6.0)				
Total number of drugs prescribed					
0-3	3 (4.5)				
4-6	17 (25.8)				
7-9	22 (33.3)				
>10	24 (36.3)				

Table 2.	Results	of m	ultivariate	linear	regression	analysis	examining	potential	factors	linked	to t	ihe
physical	domain	•			C	,	U	•				

Variables	В	95% CI	P value				
Diagnosis							
Pulmonary	Ref	Ref	Ref				
tuberculosis							
Extrapulmonary	-10.27	-19.59, -0.94	0.031*				
tuberculosis*							
Total number of drugs	prescribed						
0-3	0.021	-23.30, 23.34	0.999				
4-6	Ref	Ref	Ref				
7-9	-11.13	-23.15, 0.88	0.069				
>10	-18.21	-30.01, -6.40	0.003*				
Constant	63.15	52.59, 73.72	0.000				

B, unstandardized coefficient; CI, confidence interval; *statistically significant.

Table 3.	Results	of multivariate	linear	regression	analysis	examining	potential	factors	linked	to 1	the
psycholo	ogical do	omain.		-		-	-				

Variables	В	95% Cl	P values					
Level of education								
Illiterate	1.43	-22.01, 24.88	0.903					
Primary	-7.93	-21.47, 5.60	0.245					
Higher primary	-2.92	-17.08, 11.25	0.682					
High school	-10.58	-21.19, 0.02	0.04*					
Higher secondary	-5.75	-17.43, 5.92	0.328					
Graduate	Ref	Ref	Ref					
Comorbid condition- Chronic Liver Disease								
Absent	Ref	Ref	Ref					
Present	-31.47	-63.55, 0.60	0.054					
Constant	61.06	53.24, 68.88	0.000					

B, unstandardized coefficient; CI, confidence interval; *statistically significant.

Table 4. Results of multivariate linear regression analysis examining potential factors linked to the social relationship domain.

Variables	В	95% Cl	P values			
BMI categories						
Underweight (<18.5)	-4.02	-11.58, 3.54	0.291			
Healthy (18.5-24.9)	Reference	Reference	Reference			
Overweight (25-29.9)	-11.72	-20.72, -2.72	0.012*			
Obese (>30)	4.42	-14.31, 23.16	0.638			
Marital Status						
Unmarried	-11.82	-22.06, -1.59	0.024*			
Married	Ref	Ref	Ref			
Widowed/Divorced	-10.33	-21.55, 0.88	0.070			
Constant	70.58	62.81, 78.34	0.000			

B, unstandardized coefficient; CI, confidence interval; *statistically significant.

Table 5. Results of multivariate linear regression analysis examining potential factors linked to the environment domain.

Variables	В	95% CI	P values				
Level of education							
Illiterate	3.86	-15.19, 22.92	0.686				
Primary	-6.33	-17.45, 4.78	0.259				
Higher primary	5.51	-6.19, 17.21	0.350				
High school	-12.43	-21.71, -3.16	0.009*				
Higher secondary	-4.01	-13.50, 5.47	0.400				
Graduate	Ref	Ref	Ref				
Comorbid condition- Chronic Liver Disease							
Absent	Ref	Ref	Ref				
Present	-30.0	-56.13, -3.89	0.025*				
Constant	73.45	64.99, 81.91	0.000				

B, unstandardized coefficient; CI, confidence interval; *statistically significant.