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Randomized Control Trial on the Effect of Health Education on Health Related Quality of Life Among Tuberculosis Patients in Kenya

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Abstract: Although health education is incorporated in tuberculosis treatment in Kenya, its role in improving quality of life of the patient is unknown. The main objective of the study was to determine effect of health education on the health related quality of life of tuberculosis patients in Kenya. To achieve this goal the health education program was designed using the PRECEDE-PROCEED model of study. Randomized controlled trial design with pre- and post-test assessments was adopted. The study was conducted between September 2019 and February 2020 in Nairobi and Murang'a Counties. A sample size of 450 patients was calculated with 373 meeting the eligibility criteria. Before introducing health education the patients were assigned into experimental and control groups. Health education was administered to the experimental group but no such intervention was given to the control group. After six months the two groups were compared. A standard questionnaire was used to collect demographic data while data on health related quality of life adopted EQ-5D-5L and EQ-VAS instruments. MANOVA was used to analyze domains of health and scores on the test of perceived poor health. 15% of the changes in the domains of health were accounted for by health education while 39.3% of changes in health scores were attributed to health education. The study concluded that improved knowledge on TB by patients as a result of health education enhanced the health related quality of life. It was recommended that the health education model be adapted in other health facilities providing tuberculosis services in Kenya.

Keywords: Experimental and Control Groups, Health Education Intervention, Health Related Quality of Life, Tuberculosis Patient

1. Introduction

Despite being a curable disease, tuberculosis (TB) is still a major global public health concern. Although effective anti-tuberculosis agents have been available for over thirty years, the incidence rate of the disease is still increasing [1]. Studies demonstrate that as compared with the general population, tuberculosis patients report decline in their physical and mental wellbeing as well as lower quality of life due to long term treatment and side effects of TB drugs. [2]. Health related quality of life is an individual's overall health over time. It is a multi-dimensional concept related to physical, mental, emotional and social functioning associated with illness [3].

At present much of the attention within tuberculosis management is spent on microbiological cure but its impact on health related quality of life from the patient's perspective is undervalued. For better treatment outcomes, a systematic review suggested that the effects of the directly observed treatment, short-course strategy can be strengthened through

combination with other interventions such as provision of health education [4].

The instruments that were used to evaluate health related quality of life were the EQ-5D and EQ-VAS instruments. The EQ-5D measures the outcomes of health on five domains of health namely: mobility, self- care, usual activities, pain/discomfort, and anxiety/depression. On the other hand EQ-VAS is a self-evaluation tool with scores ranging from 0-100%. A score of 0 is equivalent to death and a score of 100% indicates the patient is in their best possible health. In some cases the self-evaluation score is indicated as 0-1 with 0 being death and 1 being perfect health [5].

A Study done in Malaysia by Noor *et al* (2019) evaluating the impact of tuberculosis treatment and education on health related quality of life (HRQoL) of smear positive pulmonary tuberculosis (PTB) patients concluded that while health related quality of life improved with the treatment, the scores on component summary measures showed compromised physical and mental health at the end of their treatment [6]. A similar study by Iqbal *et al* (2015) was conducted in Pakistan to evaluate the importance of health education in improving health related quality of life among pulmonary tuberculosis patients under the supervision of registered hospital pharmacists. The study concluded that health related quality of life was significantly improved in the interventional group after the pharmaceutical-led interventional program [7]. Louw (2016) in a study in South Africa to evaluate patient's-reported health related quality of life in pulmonary tuberculosis observed impaired physical, mental and psycho-social health domains at start of treatment. Health related quality of life improved significantly during the course of standard tuberculosis treatment, over the period of study. The greatest improvement (95%) was observed in mental health. Younger patients with higher education and who were employed had a better health related quality of life [8]. Adewole et al (2018) in a study whose aim was to evaluate the variation in health related quality of life in pulmonary tuberculosis patients during the intensive phase of treatment found that the overall health related quality of life scores at enrolment was 43.18 (SD 17.2) and 60.22 (SD19.83) at the end of two months. Mean change was 17.04, $P<0.001$. The least change was on the emotional well-being domain (Mean change=4.24, $P=0.05$ [9].

In yet another study by Macrony (2016) across five European countries whose aim was to gain insight into the complication of tuberculosis from the perspective of the patient, the average score was found to be 0.69 lower than that of healthy population. The mean values were higher (0.76) in the absence of complications [10]. Sreenharshike et al (2014) in a study in India established that lack of knowledge regarding tuberculosis infection and its treatment contributed to feelings of helplessness and anxiety. With the health education intervention the self-reported improvement was high 78%, ($P<0.001$) against 50% ($P<0.001$) for the control group. Further, there was positive health behavior modification and participants with reported improved scores in the heath related quality of life [11].

The aim of the present study was to establish the effect of health education in promoting health related quality of life among tuberculosis patients in Kenya. The expected study outcomes were to ascertain the difference in health conditions between interventional and control groups both in the ten domains using the EQ-5D-5L and the European Quality Visual Analogue Scale (EQ-VAS) instruments [12]. The objectives were achieved by assessing baseline (pre-test) and end-line (post-test) data for both the experimental and control groups. Only the experimental group had an intervention administered to them i.e. the health education program. Health education programs are geared towards imparting knowledge to an individual or/community for them to take action towards improvement of their own health.

Health education was administered to patients in the experimental group twice a month for six months when the patients went for their drug rations [13]. The teaching sessions took 10-15 minutes per patient. The program was conducted by both members of the research team and the TB clinic staff members. It included home visits in addition to the health education administered when patients went for their drug rations.

2. Methods

The Consolidated Standards of Reporting Trials (CONSORT) checklist (supplementary files) and flow diagram (figure 1) were used in reporting the results from this analysis.

2.1. Study Design

The study adopted the Randomized Controlled Trial Design with pre-and post-test data assessments. The identified TB clinics were selected randomly. Patients were recruited from the TB attendance and treatment registers. Thereafter, they were assigned to experimental and control groups on a 1:1 ratio. The pre-test was conducted on the two groups to establish baseline data for the patients. Health education intervention was then introduced to the experimental group. No such intervention was given to the control group. Both groups were again assessed after the study period (post-test).

2.2. Eligibility Criteria of Participants

To qualify for inclusion in the study, the patient had to be an adult (18 years and above) and under Directly Observed Treatment, Short-Course Strategy. Further, the patient should have been registered in the TB treatment register for at least two weeks. The study excluded patients who were underage, those diagnosed with Multiple Drug Resistant TB (MDR-TB) and HIV as well as those who were participating in other intervention studies.

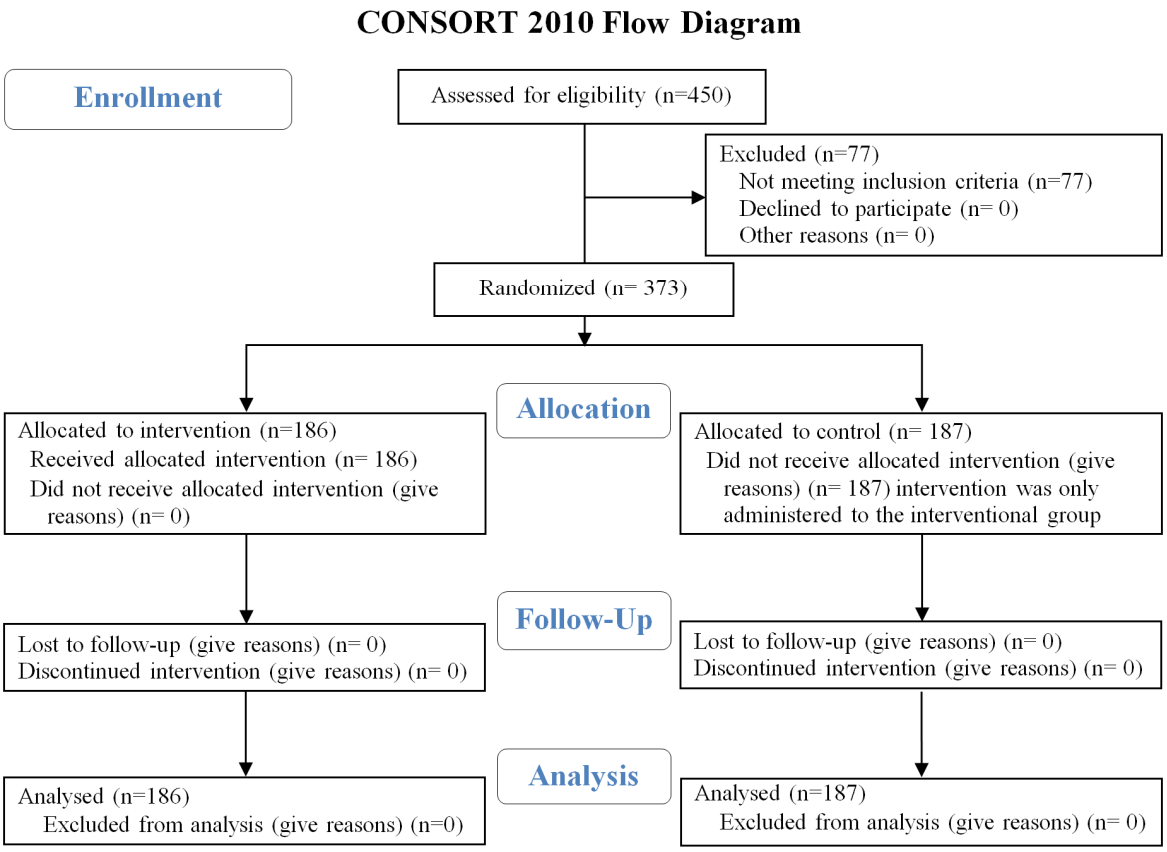

Figure 1. *Consort flow diagram.*

2.3. Study Setting and Population

The study was carried out in the Republic of Kenya because it is among the high TB burden countries with a prevalence rate of 558 people per 100,000 population. In Kenya, TB is managed under the national tuberculosis, leprosy and lung disease program under the ministry of health. Treatment services are free and available to patients in all public health facilities [14]. The study targeted 4,149 tuberculosis patients who attended TB clinics in the public health facilities.

2.4. Sample Size Determination and Sampling Technique

Sample size was determined by using the Lemeshow & Hosmer (1990) formula for sample size determination:

$$n = \frac{\left(Z\frac{\alpha}{2} + Z\beta\right)^2 * p1(1-p1) + p2(1-p2)}{(p1-p2)^2}$$

Where Zα/2 is the critical value of the normal distribution=1.96

Zβ is the critical value of the normal distribution=1.26

P1 and p2 are the expected sample proportions of the two groups.

p1=85% (0.85) proportion of TB patients who are adherent according to previously reported result under normal TB treatment strategy (DOTS),

And by hypothesizing p2=95% (0.95) and considering 95% Confidence Interval, 80% power, 5% margin of error and equal sample size for each group, then the sample size will be 137 for each group.

To overcome the design effect we assumed design effect 1.5. The sample size was then: 137 x 1.5=205.

10% (20) of the sample will be added to take care of mortality, transfers and possible withdrawals.

Total sample size (225) for each group.

Total sample size for the two groups (450)

Interventional group (225) and control group (225).

A sample size of 450 patients was determined; 225 were allotted to the experimental group and 225 in the control group. The study adopted the multi-stage sampling. Random sampling was used to select the hospitals, health centers and dispensaries (2 hospitals, 5 health centers and 7 dispensaries). Random sampling proportionate to TB patients' population was adopted in selecting the study patients.

2.5. Patients' Recruitment

TB patients were identified through the attendance and treatment registers in the selected health facilities and then recruited with the help of the clinical staff in those facilities. The potential participants were then provided with detailed explanation about the study objectives. After assurance of confidentiality those willing to participate in the study were asked to sign the Informed Consent Form (supplementary files).

2.6. Data Collection

The European Quality EQ-5D-5L (EuroQol 5-dimension, 5-Level) and EQ-VAS (EuroQol Visual Analogue Scale) instruments were used to collect data on health related quality of life. Both are standard instruments used in the collection of data for health related quality of life. The EQ-5D-5L instrument is used to assess patient's health related quality of life in five domains of health namely; mobility, self- care, usual activities, pain/discomfort and anxiety/depression. Patients indicate their health related quality of life on a scale of 1-5 with 1 being the best possible health and 5 being the worst possible health. The EQ-5D-5L instrument used in this study had five additional levels namely sleep, memory/concentration, fatigue/energy, seeing/hearing and contact with others.

The EQ-VAS is an instrument used for self-assessment where patients indicate their perceived health related quality of life on a scale from 0-100%.

A standard questionnaire was used to collect data on the social-demographic characteristics of the patients in the following key areas: name of health facility, TB case, date registered, age, sex, residence, TB supporter, and contact details of the patient. All the data collection instruments are available in the supplementary file.

2.7. Ethical Considerations

Permission was sought and granted (Supplementary files) from Kenyatta National Hospital, University of Nairobi Ethics Review Committee and National Commission for Science, Technology and Innovation (NACOSTI). The participant's consent was voluntary, free of any coercion, intimidation or inflated promise of benefits from participation. Care was taken to ensure that the consent form was administered by someone who did not hold authority over the participant. Anonymity, confidentiality, secrecy and privacy were safeguarded with regard to information about treatment, medical records and drugs for the patient.

2.8. The Health Education Program (PRECEDE-PROCEED) Model

The health education program for the study was modeled within the PRECEDE-PROCEED program. The PRECEDE-PROCEED is a framework for assessing health and quality of life needs, and for designing, implementing and evaluating health promotion and other public health programs to meet those needs. The health education activities that were carried out coincided with the time the patient was seeking treatment. The health education interaction was twice a month and took (10-15) minutes on average for 6+ months. Health education was administered by both the research team and the TB clinic staff members both in the clinic when patients went for their drug ration and through home visits. Health information was in form of teaching, questions and answers, interview, discussion and scenario analysis. Education materials consisted of interactive tools including pictures and cards with topics for discussion on basic issues about tuberculosis (Supplementary files).

The components of the health education provided essential facts about the disease, diagnosis and treatment, potential barriers to treatment adherence, possible adverse effects of the medication, provision of support through counseling and encouragement of social support from family and friends. Support and encouragement for the TB patients was provided by family, friends and hospital staff.

2.9. Statistical Methods

Both descriptive and inferential statistics were used in analyzing data. SPSS v.20© and Microsoft Excel© were used to support the analysis. Patient's social-demographic characteristics were summarized using descriptive statistics and presented in tables showing frequencies and percentages.

Testing for the effects of the health education intervention was done both within the groups and between the groups. Within the groups testing was achieved using mean change and percentage increases or decreases between the pre- and post-test results for each group. Descriptive statistics was used to achieve the within groups testing and statistical significance was also calculated to determine if the improvements within the groups were significant.

Inferential statistics on the other hand were used to test for differences between the groups; i.e. between the pre-test values of the experimental and control groups and between the post-test values of the experimental and control groups. Because all patients in the study were already undergoing treatment, it was naturally expected that their quality of life would improve due to medication. The inferential tests used determined if the health education intervention caused more improvement in the patients who received the intervention as compared to those who did not receive it. Statistical significance was evaluated at $P<0.05$ (two-tailed).

2.9.1. MANOVA

Multivariate Analysis of Variance (MANOVA) was the main test used to establish the effects of the health education on the patient's health related quality of life. The null hypotheses in each of the objectives were tested using Wilk's Λ followed by Analysis of Variance (ANOVA) tests for each of the variables. Levene's test for equality of variances was used for assumption testing to determine existing variances in the pre and post-test phases. The MANOVA variables were grouped into independent and dependent variables. The groups i.e. the experimental and control groups were the independent variables/fixed factors. The pre-test and post-test scores were the dependent variables as indicated in the sample in the supplementary files.

MANOVA tested for variances in the means between the two groups. Levene's test for equality of variances tested separately the pre-test and post-test values between the two groups to determine if there were any statistically significant differences. Wilk's lambda tested for the effect of the health education intervention using F values and partial eta squared (η^2) which showed the percentage effect of the intervention on the observed changes. Finally

ANOVA tests between groups for both the pre- and post-test phases were conducted and presented in F values, P values and partial eta squared. The F values indicated whether the experimental group had greater improvement than the control group.

MANOVA was used to analyze the data collected from both the EQ-5D-5L and EQ-VAS instruments. For the EQ-5D-5L instruments, the responses were on a scale of 1-5 for the first five domains and 1-3 for the next five domains. In both cases, a response of 1 indicated that the patient had the best possible health while a response of 5 or 3 respectively indicated that the patient had the worst possible health. Data was analyzed as was indicated by the responses as categorical variables. For the EQ-VAS instrument, responses ranged from 0-100 and were analyzed as indicated in the responses as continuous variables.

2.9.2. Paired Sample T-Test

Paired Sample T-Test was used to determine if the differences in means between the experimental and control groups in the pre and post-test phases were significant. The paired sample t-test was used to test for differences in between groups as opposed to within groups.

2.9.3. Poisson Log-linear Regression

Poisson log-linear regression was used to test for associations between patients' socio-demographic characteristics and perceived heath related quality of life (EQ-VAS scores). The EQ-VAS scores were modeled as the dependent variable while the socio-demographic information was used as factors and covariates in the case of age. The goodness of fit deviance was used for assumption testing to determine whether the results were accurate. Deviations between 0.8-1.2 were considered accurate with anything above or below considered as too much deviation to be accurate.

2.10. Assumptions, Limitations and Generalization of the Study

The study assumed that all TB patients who were recorded in the counties' public health facilities and who participated in the study gave the correct information about their demographic characteristics, treatment and treatment outcomes. Due to the health state of the patients, there were the possibilities of bias in the information they provided. To build confidence in patients and for better health education outcomes the researcher worked closely with the TB clinic managers and the community health volunteers in the respective health facilities.

This was a Randomized Controlled Trial Design (RCT). RCT was chosen because confounders are analyzed, anticipated and accounted for by researchers while allocating study participants into different groups thus minimizing selection bias [15]. The study participants were randomly allocated to the experimental and control groups as evenly as possible taking into account all potential confounding factors. This was evidenced by the lack of significant differences in the demographic characteristics of patients as is presented in Table 1.

The study participants were patients attending public health facilities in Kenya which attend to patients with similar characteristics. Thus the participants had similar demographic characteristics viz. sex, ethnicity, diagnosis, age and treatment amongst others. The similarity of patient characteristics as well as the public health facilities setting allow for the results to be generalized.

3. Results

Although 450 patients were identified and recruited for the study, only 373 were included in the study. The remaining 77 did not meet the eligibility criteria due to being underage, having MDR-TB and HIV. Of the 373 patients, 186 were in the experimental group and 187 were in the control group both at the beginning and at the end. Health education was administered to patients who were already enrolled in the TB program during their visits to the clinics. Thus, there was no dropout in the study. The study was concluded after six months at the end of standard treatment which all patients in the review were undertaking.

The majority (63%) of respondents were male while 37% were female. Most of the respondents (17.4%) were aged between 25-29 years, followed by 15.6% of respondents aged 30-34 years. Those with primary and secondary school levels of education were 32.5% and 41.8% respectively. Most of the respondents were household heads (61.7%) and were married (55.5%). Majority of the respondents were employed in the informal sector (33.8%) or unemployed (30%). Statistical comparison between the experimental and control groups for each of the socio-demographic characteristics showed no significant differences between the groups as indicated by the *P*-values (Table 1).

Table 1. *Demographic Characteristics of TB Patients.*

Variable	Experimental	Control	Total	(*P* value)
Sex				
Male	126 (67.7%)	109 (58.3%)	235 (63%)	
Female	60 (32.3%)	78 (41.7%)	138 (37%)	0.997
Total	186	187	373	
Age Range				
Below 20 years	5 (2.7%)	9 (4.8%)	14 (3.8%)	
20-24 years	19 (10.2%)	29 (15.5%)	48 (12.9%)	0.367
25-29 years	37 (19.9%)	28 (15%)	65 (17.4%)	
30-34 years	31 (16.7%)	27 (14.4%)	58 (15.6%)	

Variable	Experimental	Control	Total	(*P* value)
35-39 years	30 (16.1%)	21 (11.2%)	51 (13.7%)	
40-44 years	25 (13.4%)	28 (15%)	53 (14.2%)	
45-49 years	19 (10.2%)	15 (8%)	34 (9.1%)	
≥50 years	20 (10.8%)	30 (16.1%)	50 (13.3%)	
Total	186	187	373	
Level of education				
No schooling	14 (7.5%)	14 (7.5%)	28 (7.5%)	
Primary school	61 (32.8%)	60 (32.1%)	121 (32.5%)	
Secondary school	78 (41.9%)	78 (41.7%)	156 (41.8%)	0.455
Tertiary institutions	33 (17.8%)	35 (18.7%)	68 (18.2%)	
Total	186	187	373	
Marital Status				
Single	68 (36.6%)	71 (38%)	139 (37.3%)	
Married	105 (56.4%)	102 (54.5%)	207 (55.5%)	
Divorced	7 (3.8%)	6 (3.2%)	13 (3.5%)	0.203
Separated	6 (3.2%)	8 (4.3%)	14 (3.7%)	
Total	186	187	373	
Primary occupation				
Agriculture	20 (10.8%)	27 (14.4%)	47 (12.6%)	
Formal sector	17 (9.1%)	18 (9.6%)	35 (9.4%)	
Informal sector	63 (33.9%)	63 (33.7%)	126 (33.8%)	
Security agencies	16 (8.6%)	5 (2.7%)	21 (5.6%)	0.255
students	13 (7%)	19 (10.2%)	32 (8.6%)	
Unemployed	57 (30.7%)	55 (29.4%)	112 (30%)	
Total	186	187	373	

3.1. Domains of Health (EQ-5D-5L)

The EQ-5D-5L instrument (with five additional domains) was used to measure the outcomes of health on ten domains of health namely: mobility, self- care, usual activities, pain/discomfort, anxiety/depression, sleep, memory/concentration, fatigue/energy, seeing/hearing and contact with others.

The patients were asked to indicate their quality of life on the aforementioned domains of health in five levels for the first five domains (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) and in three levels for the remaining five domains (sleep, memory/concentration, fatigue/energy, seeing/hearing and contact with others).

A response of 1 indicated that the patient had no problem in that domain (for all ten domains) and a response of 5 indicated that the patient had severe problems in the domain for the first five domains. For the remaining five domains, a response of 3 indicated severe problems (Questionnaire, supplementary files).

Frequencies and percentages were calculated for the ten domains which were categorized into 'No problems' for a response of 1 and 'Problems' for responses 2, 3, 4 and 5.

In the experimental group, 'contact with others' had the highest frequency for 'no problems', 148 (79.6%), in the pre-test phase while 'pain/discomfort' had the lowest frequency for 'no problems', 65 (34.9%). In the post-test phase, 'contact with others' had the highest frequency for 'no problems', 183 (98.4%) and 'fatigue/energy' had the lowest frequency for 'no problems', 139 (74.7%).

In the control group, 'contact with others' had highest frequency, 145 (77.5%) and 'pain/discomfort' had the lowest frequency for 'no problems', 53 (28.3%) in the pre-test phase. In the post-test phase, 'contact with others' had the highest frequency for 'no problems', 175 (93.6%) and 'pain/discomfort' had the lowest frequency for 'no problems', 120 (64.2%); (Table 2).

Table 2. *Frequencies and percentages for EQ-5D-5L.*

Dimension		Experimental group			Control group		
		Pre-test N (%)	Post-test N (%)	P value	Pre-test N (%)	Post-test N (%)	P value
Mobility	No problems	120 (64.5%)	175 (94.1%)	<0.001	117 (62.6%)	152 (81.3%)	<0.001
	Problems	66 (35.5%)	11 (5.9%)		70 (37.4%)	35 (18.7%)	
	Total	186	186		187	187	
Self-care	No problems	101 (54.3%)	162 (87.1%)	<0.001	96 (51.3%)	134 (71.7%)	<0.001
	Problems	85 (45.7%)	24 (12.9%)		91 (48.7%)	53 (28.3%)	
	Total	186	186		187	187	
Usual activities	No problems	74 (39.8%)	154 (82.8%)	<0.001	63 (33.7%)	120 (64.2%)	<0.001
	Problems	112 (60.2%)	32 (17.2%)		124 (66.3%)	67 (35.8%)	
	Total	186	186		187	187	
Pain/discomfort	No problems	65 (34.9%)	143 (76.9%)	<0.001	53 (28.3%)	120 (64.2%)	<0.001
	Problems	121 (65.1%)	43 (23.1%)		134 (71.7%)	67 (35.8%)	
	Total	186	186		187	187	

Dimension		Experimental group			Control group		
		Pre-test N (%)	Post-test N (%)	P value	Pre-test N (%)	Post-test N (%)	P value
Anxiety/depression	No problems	88 (47.3%)	156 (83.9%)	<0.001	80 (42.8%)	131 (70%)	<0.001
	Problems	98 (52.7%)	30 (16.1%)		117 (57.2%)	56 (30%)	
	Total	186	186		187	187	
Sleep	No problems	92 (49.5%)	159 (85.5%)	<0.001	84 (44.9%)	141 (75.4%)	<0.001
	Problems	94 (50.5%)	27 (14.5%)		103 (55.1%)	46 (24.6%)	
	Total	186	186		187	187	
Memory/concentration	No problems	114 (61.3%)	160 (86%)	<0.001	105 (56.1%)	145 (77.5%)	<0.001
	Problems	72 (38.7%)	26 (14%)		82 (43.9%)	42 (22.5%)	
	Total	186	186		187	187	
Fatigue/energy	No problems	79 (42.5%)	139 (74.7%)	<0.001	70 (37.4%)	131 (70.1%)	<0.001
	Problems	107 (57.5%)	47 (25.3%)		117 (62.6%)	56 (29.9%)	
	Total	186	186		187	187	
Seeing/hearing	No problems	134 (72%)	169 (90.9%)	<0.001	129 (69%)	161 (86.1%)	<0.001
	Problems	52 (28%)	17 (9.1%)		58 (31%)	26 (13.9%)	
	Total	186	186		187	187	
Contact with others	No problems	148 (79.6%)	183 (98.4%)	<0.001	145 (77.5%)	175 (93.6%)	<0.001
	Problems	38 (20.4%)	3 (1.6%)		42 (22.5%)	12 (6.4%)	
	Total	186	186		187	187	

Mean and standard deviation were also calculated to ascertain the differences between the pre-test and post-test phase through mean changes. Mean was calculated from a scale of 0-1 with 0 indicating poor health and corresponding to a response of 5 or 3 in the EQ-5D instrument and 1 indicating good health and corresponding to a response of 1 on the EQ-5D instrument.

In the experimental group, in the pre-test phase, patients indicated that they had the best health related quality of life in the 'contact with others', 0.957 (SD 0.095) and the worst in 'pain/discomfort', 0.779 (SD 0.198). The highest mean change at the end of the treatment period was recorded for 'pain/discomfort' (mean change=0.161, *P*=0.000) while 'contact with others' recorded the least mean change (mean change=0.039, *P*=0.000).

In the control group, in the pre-test phase, patients indicated that they had the best health related quality of life in 'contact with others', 0.948 (SD 0.105) and the worst in 'pain/discomfort', 0.761 (SD 0.184). The highest mean change at the end of the treatment period was recorded for 'pain/discomfort' (mean change=0.133, *P*=0.000) while 'contact with others' recorded the least mean change (mean change=0.040, *P*=0.000) (Table 3).

Table 3. *Mean changes in domains of health.*

Variable	Experimental group				Control group			
	Pre-test Mean (SD)	Post-test Mean (SD)	Mean change	p value	Pre-test Mean (SD)	Post-test Mean (SD)	Mean change	p value
Mobility	0.893 (0.16)	0.985 (0.59)	0.093	<0.001	0.878 (0.179)	0.949 (0.111)	0.071	<0.001
Self-care	0.854 (0.177)	0.966 (0.089)	0.113	<0.001	0.832 (0.194)	0.918 (0.139)	0.086	<0.001
Usual activities	0.815 (0.179)	0.953 (0.108)	0.138	<0.001	0.773 (0.197)	0.895 (0.156)	0.122	<0.001
Pain/discomfort	0.779 (0.198)	0.940 (0.114)	0.161	<0.001	0.761 (0.184)	0.894 (0.155)	0.133	<0.001
Anxiety/depression	0.843 (0.166)	0.960 (0.092)	0.117	<0.001	0.814 (0.193)	0.919 (0.128)	0.105	<0.001
Sleep	0.860 (0.149)	0.964 (0.088)	0.104	<0.001	0.844 (0.153)	0.937 (0.115)	0.093	<0.001
Memory/concentration	0.902 (0.128)	0.967 (0.084)	0.065	<0.001	0.886 (0.135)	0.947 (0.103)	0.061	<0.001
Fatigue/energy	0.847 (0.14)	0.937 (0.109)	0.090	<0.001	0.817 (15.87)	0.925 (0.118)	0.108	<0.001
Seeing/hearing	0.927 (0.12)	0.977 (0.072)	0.050	<0.001	0.915 (0.132)	0.965 (0.091)	0.050	<0.001
Contact with others	0.957 (0.095)	0.996 (0.322)	0.039	<0.001	0.948 (0.105)	0.988 (0.055)	0.040	<0.001

3.1.1. Urban Facilities

In urban health facilities, in the pre-test phase, patients in the experimental group indicated that they had the best health related quality of life in the dimension 'contact with others', 0.972 (SD 0.079) and the worst health related quality of life in the domain 'pain/discomfort', 0.790 (SD 0.203). The highest mean change at the end of the treatment period was recorded for the domain 'pain/discomfort' (mean change=0.141, p=0.000) while 'seeing/hearing' (mean change=0.022, p=0.000) and 'contact with others' (mean change=0.022, p=0.000) recorded the least mean changes.

In the control group, in the pre-test phase, patients indicated that they had the best health related quality of life in the domain 'contact with others', 0.965 (SD 0.092) and the worst health related quality of life in the domain 'pain/discomfort', 0.768 (SD 0.191). The highest mean change at the end of the treatment period was recorded for the domain 'pain/discomfort' (mean change=0.107, p=0.000). 'Contact with others' recorded the least mean change (mean change=0.022, p=0.004) (Table 4).

Table 4. *Mean changes in domains of health in urban patients.*

Urban facilities	Experimental group				Control group			
Variable	**Pre-test Mean (SD)**	**Post-test Mean (SD)**	**Mean change**	**p value**	**Pre-test Mean (SD)**	**Post-test Mean (SD)**	**Mean change**	**p value**
Mobility	0.904 (0.1524)	0.983 (0.624)	0.079	<0.001	0.887 (0.177)	0.939 (0.119)	0.052	<0.001
Self-care	0.881 (0.165)	0.964 (0.093)	0.083	<0.001	0.849 (0.198)	0.913 (0.145)	0.060	<0.001
Usual activities	0.826 (0.180)	0.945 (0.115)	0.119	<0.001	0.778 (0.205)	0.877 (0.164)	0.099	<0.001
Pain/discomfort	0.790 (0.203)	0.937 (0.116)	0.141	<0.001	0.768 (0.191)	0.875 (0.163)	0.107	<0.001
Anxiety/depression	0.869 (0.155)	0.964 (0.089)	0.094	<0.001	0.836 (0.19)	0.911 (0.133)	0.075	<0.001
Sleep	0.874 (0.152)	0.965 (0.087)	0.091	<0.001	0.859 (0.159)	0.933 (0.119)	0.074	<0.001
Memory/concentration	0.920 (0.121)	0.970 (0.082)	0.050	<0.001	0.903 (0.132)	0.948 (0.102)	0.045	<0.001
Fatigue/energy	0.859 (0.143)	0.950 (0.10)	0.091	<0.001	0.826 (0.165)	0.926 (0.118)	0.100	<0.001
Seeing/hearing	0.957 (0.099)	0.979 (0.070)	0.022	<0.001	0.939 (0.125)	0.966 (0.091)	0.027	<0.001
Contact with others	0.972 (0.079)	0.995 (0.036)	0.022	<0.001	0.965 (0.092)	0.987 (0.057)	0.022	0.004

Table 5. *Domains of health in rural patients.*

Rural facilities	Experimental group				Control group			
Variable	**Pre-test Mean (SD)**	**Post-test Mean (SD)**	**Mean change**	**p value**	**Pre-test Mean (SD)**	**Post-test Mean (SD)**	**Mean change**	**P value**
Mobility	0.843 (0.183)	0.993 (0.042)	0.150	<0.001	0.838 (0.183)	0.993 (0.043)	0.154	<0.001
Self-care	0.736 (0.181)	0.979 (0.071)	0.243	<0.001	0.757 (0.157)	0.941 (0.108)	0.184	<0.001
Usual activities	0.766 (0.164)	0. 986 (0.059)	0.220	<0.001	0.750 (0.151)	0.978 (0.072)	0.228	<0.001
Pain/discomfort	0.729 (0.165)	0.950 (0.101)	0.221	<0.001	0.728 (0.143)	0.978 (0.072)	0.250	<0.001
Anxiety/depression	0.729 (0.165)	0.943 (0.107)	0.214	<0.001	0.715 (0.180)	0.969 (0.097)	0.254	<0.001
Sleep	0.800 (0.118)	0.957 (0.096)	0.157	<0.001	0.779 (0.102)	0.956 (0.967)	0.177	<0.001
Memory/concentration	0.829 (0.132)	0.957 (0.096)	0.129	<0.001	0.810 (0.124)	0.941 (0.108)	0.131	<0.001
Fatigue/energy	0.793 (0.113)	0.879 (0.127)	0.086	<0.001	0.779 (0.119)	0.919 (0.119)	0.140	<0.001
Seeing/hearing	0.80 (0.118)	0.971 (0.081)	0.171	<0.001	0.810 (0.108)	0.963 (0.09)	0.153	<0.001
Contact with others	0.890 (0.126)	100 (0.00)	0.110	<0.001	0.871 (0.127)	0.992 (0.044)	0.121	<0.001

3.1.2. Rural Facilities

In the rural health facilities, in the pre-test phase, patients in the experimental group indicated that they had the best health related quality of life in the dimension 'contact with others', 0.890 (SD 0.126) and the worst health related quality of life in the domains: 'pain/discomfort', 0.729 (SD 0.165), and 'anxiety/depression', 0.729 (SD 0.165). The highest mean change at the end of the treatment period was recorded for the domain 'self-care' (mean change=0.243, p=0.000) while 'fatigue/energy' recorded the least mean change (mean change=0.086, p=0.000).

In the control group, in the pre-test phase, patients indicated that they had the best health related quality of life in the dimension 'contact with others', 0.871 (SD 0.127) and the worst health related quality of life in the domain 'anxiety/depression', 0.715 (SD 0.180). The highest mean change at the end of the treatment period was recorded for the domain 'anxiety/depression' (mean change=0.254, p=0.000). 'Contact with others' recorded the least mean change (mean change=0.121, p=0.000) (Table 5).

3.2. T-Test

Paired sample T-test was carried out between group means for each domain of health in both the pre-test and post-test phases to determine if there were significant differences between groups. The results showed that the differences in the means for the domains of health between the experimental and control groups at the beginning of the study were insignificant except for the domain 'usual activities' (p=0.039). In the post-test however, the differences between the experimental and control groups were significant for most domains except the domains 'fatigue/energy' (p=0.340) and 'seeing/hearing' (p=0.171) indicating that the intervention used had an effect on the health related quality of life of patients (Table 6).

3.3. MANOVA

MANOVA was used to ascertain the effects of health education intervention on quality of life. MANOVA tested for differences between the groups in both the pre-test and post-test phases. The two groups were modeled as the fixed factor while the pre-test and post-test results were modeled as the dependent variables. Wilk's Λ test had an F value of 2.969, $P<0.001$ and partial η^2 was 0.150 indicating that 15% of the observed differences were due to health education. Levene's test of equality of variances had insignificant P values in the pre-test phase indicating that there were no statistically significant differences between the experimental and control groups in the pre-test phase. In the post-test phase however, the P values were less than 0.05 for all the variables indicating that the variances between the experimental and control groups were

statistically significant which could be attributed to the health education intervention. The ANOVA results were statistically insignificant between the experimental and control groups in the pre-test phase. In the post-test phase however, the *P* values indicated statistically significant differences between the experimental and control group (except for the domains 'fatigue/energy', 'seeing/hearing' and 'contact with others'). This was evidence that the health education intervention had an impact on the quality of life of patients (Table 7).

Table 6. *Paired-Sample T-Test Results.*

Domains	Pre-test			Post-test		
	Experimental (Mean)	Control (Mean)	P value	Experimental (Mean)	Control (Mean)	P value
Mobility	0.893	0.878	0.431	0.985	0.949	<0.001
Self-care	0.854	0.832	0.263	0.966	0.918	<0.001
Usual activities	0.815	0.773	0.039	0.953	0.895	<0.001
Pain/discomfort	0.779	0.761	0.396	0.940	0.894	0.001
Anxiety/depression	0.843	0.814	0.113	0.960	0.919	0.001
Sleep	0.860	0.844	0.345	0.964	0.937	0.013
Memory/concentration	0.902	0.886	0.169	0.967	0.947	0.043
Fatigue/energy	0.847	0.817	0.073	0.937	0.925	0.340
Seeing/hearing	0.927	0.915	0.354	0.977	0.965	0.171
Contact with others	0.957	0.948	0.447	0.996	0.988	0.032

Note: the differences in means in the pre-test phase can be partially attributed to unequal sample sizes.

Table 7. *Multivariate Analysis of Variance for the EQ-5D-5L Domains of Health.*

Variable (EQ-5D-5L)	Levene's test		ANOVA			Experimental	Control
	F	*P*	F	*P*	Partial η^2	Mean (SD)	Mean (SD)
Mobility (pre-test)	3.065	0.081	0.961	0.328	0.003	0.893 (0.16)	0.878 (0.179)
Mobility (post-test)	71.496	0.000	15.702	0.000	0.042	0.985 (0.59)	0.949 (0.111)
Self-care (pre-test)	1.475	0.225	0.860	0.354	0.002	0.854 (0.177))	0.832 (0.194)
Self-care (post-test)	55.915	0.000	13.931	0.000	0.038	0.966 (0.894)	0.918 (0.139)
Usual activities (pre-test)	0.001	0.970	6.953	0.009	0.019	0.815 (0.179)	0.773 (0.197)
Usual activities (post-test)	64.935	0.000	21.928	0.000	0.058	0.953 (0.108)	0.895 (0.156)
Pain/discomfort (pre-test)	2.365	0.125	1.490	0.223	0.004	0.779 (0.198)	0.761 (0.184)
Pain/discomfort (post-test)	35.813	0.000	10.836	0.001	0.030	0.940 (0.114)	0.894 (0.155)
Anxiety/depression (pre-test)	0.843	0.359	2.940	0.087	0.008	0.843 (0.166)	0.814 (0.193)
Anxiety/depression (post-test)	51.793	0.000	12.597	0.000	0.034	0.960 (0.922)	0.919 (0.128)
Sleep (pre-test)	0.004	0.948	1.321	0.251	0.004	0.860 (0.149)	0.844 (0.153)
Sleep (post-test)	25.330	0.000	6.061	0.014	0.017	0.964 (0.883)	0.937 (0.115)
Memory (pre-test)	3.470	0.063	1.386	0.240	0.004	0.902 (0.128)	0.886 (0.135)
Memory (post-test)	14.669	0.000	3.562	0.050	0.010	0.967 (0.844)	0.947 (0.103)
Fatigue/energy (pre-test)	0.583	0.446	2.813	0.094	0.008	0.847 (0.14)	0.817 (15.87)
Fatigue/energy (post-test)	4.866	0.028	1.131	0.288	0.003	0.937 (0.109)	0.925 (0.118)
Seeing/hearing (pre-test)	3.784	0.053	0.880	0.349	0.002	0.927 (0.12)	0.915 (0.132)
Seeing/hearing (post-test)	7.728	0.006	1.874	0.172	0.005	0.977 (0.722)	0.965 (0.907)
Contact with others (pre-test)	5.271	0.022	1.259	0.253	0.004	0.957 (0.95)	0.948 (0.105)
Contact with others (post-test)	12.452	0.000	3.010	0.084	0.008	0.996 (0.322)	0.988 (0.545)

3.4. Test of Perceived Poor Health Among the Urban and Rural TB Patients

Using the European Quality Visual Analogue Scale (EQ-VAS), the patients self-rated their health at pre-test and post-test phases. The scores range from 0-100%. A score of 0 is equivalent to death and a score of 100% indicates the patient is in their best possible health. The scores were classified into five groups as recommended by the EuroQol group (the creators of both the EQ-5D and EQ-VAS instruments). The five groups were 0-20%, 21-40%, 41-60%, 61-80% and 81-100%. The higher the patient score, the higher their perceived health related quality of life [16].

In the experimental group and in the pre-test phase, majority of the patients (66.1%) had health scores between 61-80%, while the category between 0-20% had no patients. 14.5% patients between 81-100%. In the post-test phase, majority of the patients (54.8%) scored between 61-80% followed by 43.1% scoring between 81-100% which indicated an increase of 28.6% from the pre-test phase.

In the control group, in the pre-test phase, majority of the patients (61%) scored between 61-80%, while only 1.1% had between 0-20%. 10.1% scored between 81-100%. In the post-test phase, the majority of the patients (64.7%) had between 61-80%. 16.6% patients scored between 81-100% indicating a 6.5% improvement in this category (Figure 2).

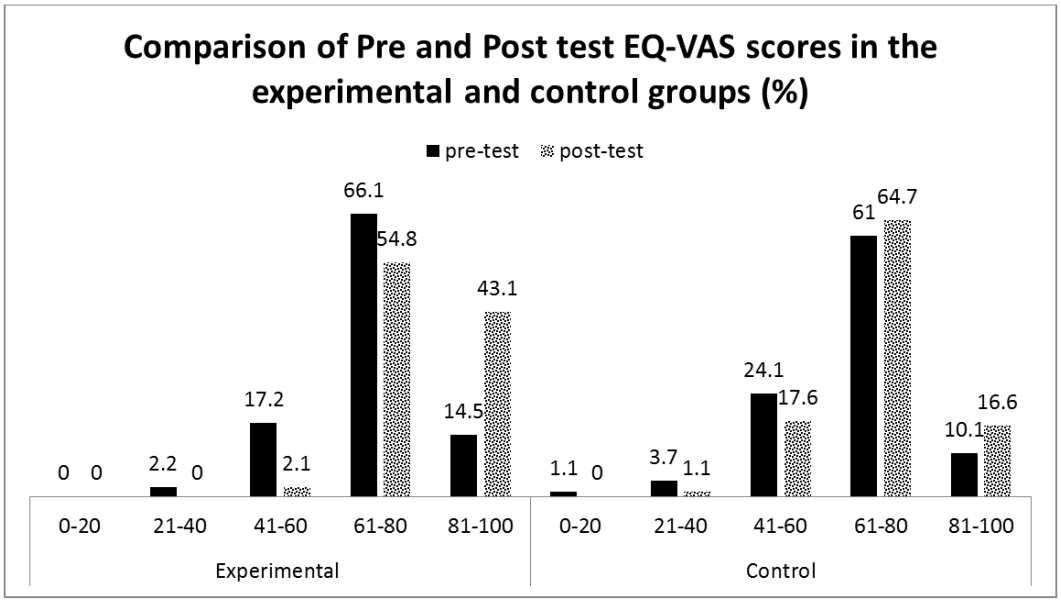

Figure 2. *EQ-VAS scores of patients in the experimental and control groups.*

3.4.1. Urban and Rural Facilities

In the urban facilities, in the experimental group, majority (70.2%) of the patients were between 61-80% in the pre-test phase followed by 17.3% who scored between 81-100%. In the post-test phase, majority (51%) of the patients scored between 61-80% followed by 49% who had between 81-100% indicating a 31.7% increase in the category.

In the control group, majority (64.7%) of the patients scored between 61-80% in the pre-test phase and 12.7% scoring between 81-100%. In the post-test phase, majority (66.7%) had between 61-80% followed by 18.9% who scored between 81-100% indicating a 6.2% increase (Figure 3).

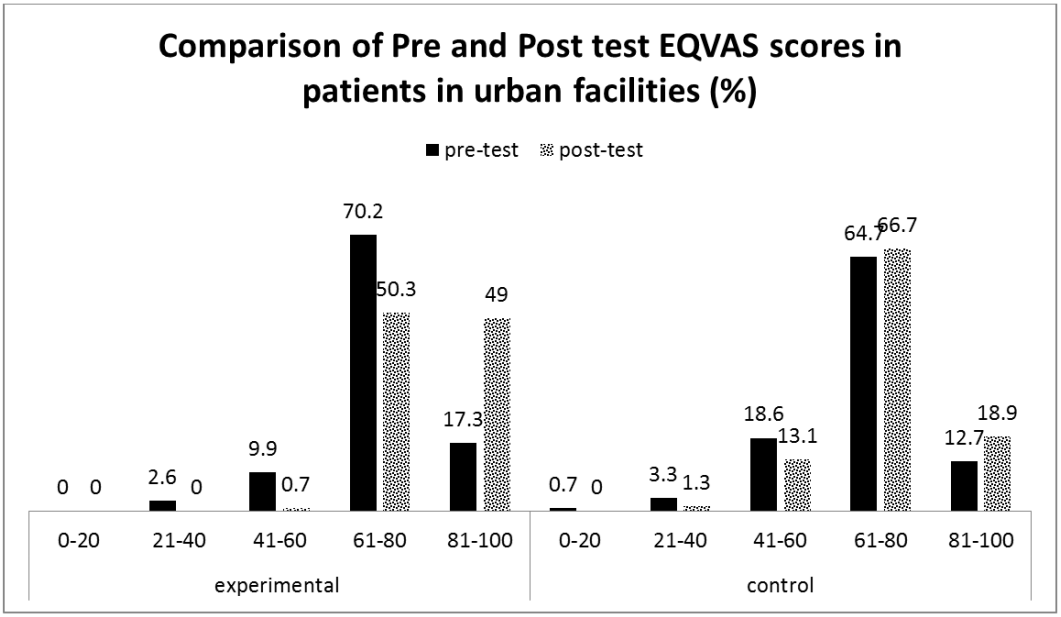

Figure 3. *EQ-VAS scores of patients in the experimental and control groups in urban facilities.*

In the rural facilities, in the experimental group, there was a tie between the scores 41-60% and 61-80% which had 48.6% patients each in the pre-test phase. There were only 2.8% patients who scored between 81-100%. In the post-test phase, majority (74.3%) of the patients scored between 61-80% followed by 17.1% who scored between 81-100% indicating an increase of 14.3%.

In the control group, most patients (47.1%) had between 41-60% in the pre-test phase. There were no patients who scoring between 81-100%. In the post-test phase, majority (55.9%) scored between 61-80%. There were 5.9% of patients scoring between 81-100% indicating an improvement in this category (Figure 4).

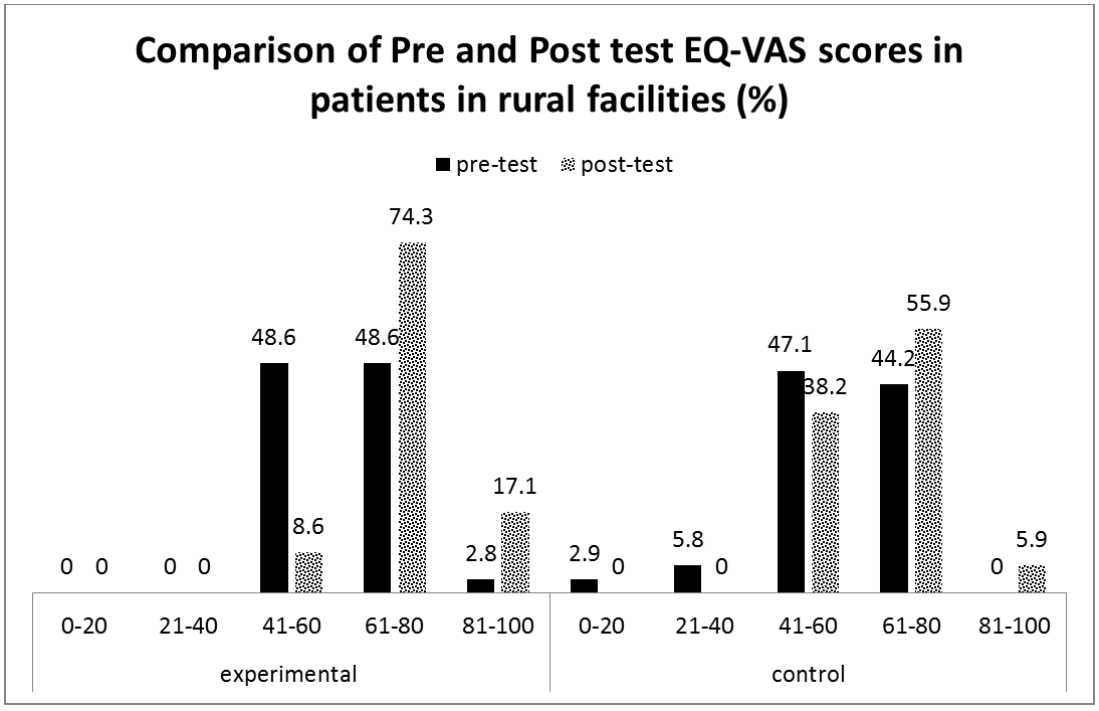

Figure 4. *EQ-VAS scores of patients in the experimental and control groups in rural facilities.*

3.4.2. Mean Change

The experimental group had a mean change of 9.95% and the control group had a mean change of 5.45% indicating more improvement in the experimental group. In the urban patients the perceived health related quality of life (PHRQoL) mean increased by 10.34% for the experimental group and by 3.98% in the control group. In the rural patients the PHRQoL increased by 9.41% in the experimental group and by 7.4% in the control group (Table 8).

Table 8. *Mean changes in the perceived poor health scores in urban and rural patients.*

Variable	Experimental				Control			
	Pre-test Mean (%) (SD)	Post-test Mean (%) (SD)	Mean change (%)	p value	Pre-test Mean (%) (SD)	Post-test Mean (%) (SD)	Mean change (%)	p value
PHRQoL (overall)	**67.45 (6.96)**	**77.4 (6.25)**	**9.95**	**0.000**	**62.82 (8.64)**	**68.27 (6.9)**	**5.45**	**0.000**
Urban and Rural facilities								
PHRQoL (Urban)	70.29 (8.49)	80.63 (7.54)	10.34	0.000	65.28 (8.01)	69.26 (7.17)	3.98	0.003
PHRQoL (Rural)	63.68 (5.77)	73.09 (3.02)	9.41	0.001	59.54 (9.58)	66.94 (8.2)	7.4	0.002

3.4.3. MANOVA

MANOVA was used to ascertain the effects of health education on perceived health related quality of life. MANOVA tested for differences between the groups in both the pre-test and post-test phases. The two groups were modeled as the independent variables/fixed factor while the pre-test and post-test results were modeled as the dependent variables (see supplementary file for sample data model). Wilk's Λ test had an F value of 119.211, $P<0.001$ and partial η^2 was 0.393 indicating 39.3% of the observed differences were due to health education. The *P* values for Levene's test of equality of Variances were insignificant in both pre and post-test phases. The ANOVA F values showed a large difference between the pre-test (F=12.176) and post-test (F=85.201) after the intervention which was statistically significant (Table 9).

Table 9. *Multivariate analysis of variance for the EQ-VAS test of perceived poor health.*

Variable (EQ-VAS)	Levene's test		ANOVA			Experimental	Control
	F	*P*	F	*P*	Partial η^2	Mean (SD)	Mean (SD)
Perceived health related quality of life (pre-test)	0.208	0.648	12.176	0.001	0.032	67.45 (6.96)	62.82 (8.64)
Perceived health related quality of life (post-test)	2.880	0.091	85.201	<0.001	0.188	77.4 (6.25)	68.27 (6.9)

3.5. Associations Between Socio-demographic Factors and Perceived Poor Health

The association between socio-demographic factors (age, gender, level of education, marital status and primary occupation) and perceived health related quality of life in both the pre-test and post-test was assessed using Poisson log-linear regression. The EQ-VAS scores were the dependent variable gender, level of education, marital status and primary occupation were all factors. Age was modeled as a covariate since it was a continuous variable like the scores. Goodness of fit was used for assumption testing. The goodness of fit deviation for the regression results in the pre-test phase for the experimental group was 2.947 while in the control group, the deviation was 3.217. Thus, the pre-test associations were not sufficiently accurate in either group due to too much deviation.

Regarding the post-test in the experimental group, only the 'no schooling' education level (OR 1.106; 95% CI: 1.017, 1.204) and occupation in the informal sector (OR 1.069; 95% CI: 1.021, 1.119) were significantly associated with perceived health related quality of life. The goodness of fit deviation was 1.127. Thus the post-test results for the experimental group were considered accurate because the deviations were within the acceptable range of 0.8-1.2. The goodness of fit deviation for the post-test in the control group was 2.222. Thus the results were considered inaccurate due to too much deviation. The difference between the experimental and control group post-test results were as a result of the health education program which improved the patients' perceived health related quality of life thus reducing the deviations in patient scores in the experimental group (Tables 10 & 11).

Table 10. *Associations between Socio-demographic Factors and PHRQOL in the experimental group using Poisson regression.*

Experimental group				
Variable	**Pre-test**		**Post-test**	
	OR (95% CI)	**P value**	**OR (95% CI)**	**P value**
Age	0.998 (0.996, 1.000)	0.043	0.998 (0.997, 1.000)	0.072
Gender				
Male	1.016 (0.975, 1.059)	0.437	1.001 (0.963, 1.040)	0.961
Female	1	-	1	-
Education				
No schooling	1.136 (1.038, 1.243)	0.006	1.106 (1.017, 1.204)	0.019
Primary school	1.022 (0.962, 1.087)	0.475	1.045 (0.987, 1.106)	0.133
Secondary school	1.040 (0.982, 1.101)	0.180	1.047 (0.992, 1.104)	0.093
Tertiary institutions	1	-	1	-
Marital Status				
Single	0.961 (0.860, 1.075)	0.491	0.984 (0.887, 1.091)	0.753
Married	0.954 (0.53, 1.066)	0.403	0.945 (0.853, 1.048)	0.284
Divorced	0.862 (0.746, 0.996)	0.044	0.938 (0.818, 1.075)	0.355
Separated	1	-	1	-
Occupation				
Agriculture	1.012 (0.944, 1.085)	0.746	0.991 (0.929, 1.057)	0.781
Formal Sector	1.102 (1.027, 1.182)	0.007	1.050 (0.983, 1.122)	0.148
Informal sector	1.110 (1.056, 1.166)	0.000	1.069 (1.021, 1.119)	0.004
Security Agencies	1.100 (1.014, 1.193)	0.021	1.057 (0.979, 1.140)	0.154
Students	0.923 (0.842, 1.011)	0.085	0.963 (0.886, 1.046)	0.367
Unemployed	1	-	1	-

Table 11. *Associations between Socio-demographic Factors and PHRQOL in the control group using Poisson regression.*

Control Group				
Variable	**Pre-test**		**Post-test**	
	OR (95% CI)	**P value**	**OR (95% CI)**	**P value**
Age	1.001 (0.999, 1.003)	0.247	1.001 (0.999, 1.003)	0.224
Gender				
Male	0.999 (0.958, 1.042)	0.962	0.998 (0.958, 1.039)	0.918
Female	1	-	1	
Education				
No schooling	1.003 (0.910, 1.006)	0.946	1.026 (0.933, 1.127)	0.599
Primary school	1.026 (0.964, 1.092)	0.413	1.060 (0.998, 1.125)	0.057
Secondary school	1.074 (1.015, 1.136)	0.013	1.083 (1.025, 1.143)	0.04
Tertiary institutions	1	-	1	-
Marital status				
Single	1.049 (0.944, 1.166)	0.372	1.017 (0.920, 1.124)	0.745
Married	1.147 (1.035, 1.270)	0.009	1.118 (1.005, 1.221)	0.038
Divorced	0.963 (0.829, 1.120)	0.627	1.032 (0.897, 1.188)	0.660
Separated	1	-	1	-
Occupation				

Control Group				
Variable	Pre-test		Post-test	
	OR (95% CI)	P value	OR (95% CI)	P value
Agriculture	0.863 (0.805, 0.925)	<0.001	0.931 (0.872, 0.995)	0.034
Formal sector	0.975 (0.902, 1.054)	0.517	0.991 (0.919, 1.069)	0.823
Informal sector	0.997 (0.944, 1.053)	0.912	1.008 (0.956, 1.061)	0.776
Security agencies	1.075 (0.959, 1.205)	0.214	1.065 (0.952, 1.191)	0.271
Students	1.079 (1.002, 1.162)	0.044	1.084 (1.008, 1.165)	0.029
Unemployed	1	-	1	-

4. Discussion

From the study, there was marked improvement after health education intervention in the domains 'pain/discomfort', 'anxiety/depression', 'usual activities', 'sleep' and 'mobility'. This was similar to the findings by Louw (2016) who noted significant improvement in the physical, mental and psycho-social domains of health after treatment [8].

The experimental group had improvement in more domains of health compared to the control group. These findings agree with the findings by Iqbal et al (2016) who observed that health related quality of life was significantly improved in the interventional group after a pharmaceutical-led interventional program [7]. The perceived health related quality of life mean in the post-test was 77.4% in the experimental group and 68.27% in the control group. These findings are consistent with the study by Noor (2019) that established that with health education intervention the self-reported improvement was higher in the experimental group (78%) against 50% for the control group [6].

Urban patients had more improvement in EQ-VAS scores compared to rural patients. Improved scores in the urban patients could have been as a result of easy access to health facilities by the TB patients which was not the case for the rural patients. There are clear disparities in health services delivery systems which seem to favor the urban settings [15].

5. Conclusion

Health education was found to have an effect on the health related quality of life among patients. The patients who were subjected to the health education intervention registered higher scores on both the EQ-5D-5L and EQ-VAS instruments than those who were not subjected to the health education intervention.

It was recommended that the health education program should be adapted by health care workers in the treatment of tuberculosis patients in Kenya. Perceived health related quality of life should be adopted as a measure of effectiveness of health education program in tuberculosis treatment.

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Abbreviations

ANOVA- Analysis of variance
EuroQol=European Quality of life
EQ-5D-5L- European quality with five domains of health and five levels in each domain
EQ-VAS- European quality visual analogue scale
HRQoL- Health related quality of life
MANOVA- Multivariate analysis of variance
OR- Odds ratio
PHRQoL- Perceived health related quality of life
TB: Tuberculosis

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