



ST. PAUL'S HOSPITAL MILLENNIUM MEDICAL COLLEGE
SPECIALITY STUDY PROGRAM

**ASSESSMENT OF HEALTH-RELATED QUALITY OF LIFE AND
ITS ASSOCIATED FACTORS AMONG MULTI DRUG-
RESISTANT TUBERCULOSIS TREATED PATIENTS ON
FOLLOW UP AT ST. PETER'S SPECIALIZED HOSPITAL AND
ALERT HOSPITAL ADDIS ABABA, ETHIOPIA**

Investigator: Dr. Esrom Hagos (MD, internal medicine resident)

A research paper submitted to the department of internal medicine, St. Paul Hospital Millennium Medical College presented in partial fulfillment of the requirements for the certificate of specialty in internal medicine

OCTOBER, 2022

ADDIS ABABA, ETHIOPIA

ST. PAUL'S HOSPITAL MILLENNIUM MEDICAL COLLEGE

SPECIALITY STUDY PROGRAM

DEPARTMENT OF INTERNAL MEDICINE

**ASSESSMENT OF HEALTH-RELATED QUALITY OF LIFE AND
ITS ASSOCIATED FACTORS AMONG MULTI DRUG-
RESISTANT TUBERCULOSIS TREATED PATIENTS ON
FOLLOW UP AT ST. PETER'S SPECIALIZED HOSPITAL AND
ALERT HOSPITAL, ADDIS ABABA, ETHIOPIA**

Investigator: Dr. Esrom Hagos (MD, Internal Medicine Resident)

Advisors: DR Anteneh Getachew (MD Assistant Professor of Internal
Medicine)

Mr. Takele Gezahegn (MPH Assistant Professor)

OCTOBER, 2022

ADDIS ABABA, ETHIOPIA

Acknowledgments

First, I would like to express my deepest gratitude to the Department of Internal Medicine, St. Paul's Hospital Millennium Medical College for giving me the educational opportunity and allowing me to use its resources and Department of Public Health for assigning me a public health advisor to guide me in the making of this research paper. I would also like to give my sincere thanks to my team of research advisors, Dr. Anteneh Getachew and Mr. Takele Gezahegn who tirelessly worked to make sure I acquire the knowledge, skill and understanding needed to carry out this study. I also want to forward my gratefulness and appreciation to the data collectors for their tireless work and commitment to make this paper a reality. Finally i would also like to give my sincere thanks to the study participants for their willingness in participating in this study by sacrificing their valuable time.

Table of Contents

Acknowledgments	ii
List of tables.....	IV
List of figures	IV
List of Abbreviations and Acronyms.....	V
Abstract	VI
1. Introduction.....	1
1.1. Background of the study	1
1.2. Statement of the Problem.....	3
1.3. Significance of the Study	4
2. Literature Review	5
2.1. Burden of MDR-TB.....	5
2.2. HRQoL among Patients on MDR-TB drug treatment.....	5
2.3. Factors associated with HRQoL among patients on MDR-TB drug treatment.....	8
2.4. Conceptual framework.....	9
3. Objectives of the study.....	10
3.1. General Objectives	10
3.2. Specific Objectives.....	10
4. Methods and Materials	11
4.1. Study Setting and period	11
4.2. Study Design	12
4.3. Population	12
4.4. Eligibility criteria	13
4.5. Sample Size Determination and Sampling Technique.....	14
4.6. Study Variables.....	15
4.7. Operational Definitions and Measurement	15
4.8. Data Collection Method, Tool and Procedures	16
4.9 Data Quality control	16
4.10. Data processing and analyses.....	17
4.11. Ethical Considerations	17
4.12 Plan for dissemination of results.....	17
5. Result.....	18

Socio demographic characteristics of respondents	18
Treatment related characteristics of the patients	20
Health related quality of life (HRQoL) in MDR-TB treated patients.....	21
Factors associated with physical impairment or affected PCS.....	22
Factors associated with risk of depression or affected MCS.....	24
6. Discussion	26
7. Conclusion and recommendations.....	29
7.1 Conclusions.....	29
7.2 Recommendations.....	29
8. References	30
Annexes	34
Annex 1: An informed consent sheet	34
Annex 2: English version Data Collection tool	35
Annex 3. Amharic version Data collection tool	40
Declaration	44

List of tables

Table 1 Socio demographic characteristics of MDR-T B treated patients at ALERT and St. Peter hospital and St. Peter hospital. Addis Ababa, Ethiopia March 2020- March 2022 GC.....	19
Table 2 Treatment related characteristics of MDR-TB treated patients at ALERT and St. Peter hospital and St. Peter hospital. Addis Ababa, Ethiopia March 2020- March 2022 GC.....	20
Table 3 Health related quality of life SF 36 domain scores and component summary score of patients who completed MDR-TB treatment at St. Peter and ALERT hospital Addis Ababa, Ethiopia March 2020 - March 2022 GC.....	21
Table 4 Health related quality of life physical and mental component summary scores Frequency and Percentage of patients who completed MDR-TB treatment at St. Peter and ALERT hospital Addis Ababa, Ethiopia March 2020- March 2022 GC	21
Table 5 Factors associated with affected PCS score physical impairment among patients who completed treatment for MDR-TB patients at ALERT and St. Peter hospital. Addis Ababa, Ethiopia March 2020- March 2022 GC	23
Table 6 Factors associated with affected MCS score or at risk of depression among patients who completed treatment for MDR-TB patients at ALERT and St. Peter hospital. Addis Ababa, Ethiopia March 2020- March 2022 GC	25

List of figures

Figure 1 Conceptual framework showing the possible factors associated with HRQoL adopted from different literatures done previously	9
---	---

List of Abbreviations and Acronyms

ALERT- All Africa Leprosy, Tuberculosis and Rehabilitation Training Centre

BP-Bodily pain

GH-General health

HIV- Human immunodeficiency virus

HRQoL-Health related quality of life

K10-Kessler Psychological Distress Scale

MCS-Mental component summary

MDR- Multi drug resistant

MH-Mental health

NBS -Norm based scale

PCS- Physical component summary

PF-Physical functioning

PHQ- Patient health questioner

QOL-Quality of life

RE-Role-emotional

RP-Role-physical

RR- Rifampin resistant

SF-Social functioning

SF 36- Short form 36

SPHMMC- St. Paul's Hospital Millennium Medical College

TB- Tuberculosis

VAS- Visual analog scale

VT-Vitality

WHOQoL- World Health Organization Quality of Life

Abstract

Background: Multidrug-resistant tuberculosis has become a major public health problem, especially in developing countries. Despite the considerable attention given to traditional microbiological and clinical indicators, the effect of Multidrug-resistant tuberculosis on the Health related quality of life of patients has not been well investigated in Ethiopia.

Objectives: The primary objective of the study is to assess health-related quality of life and the factors associated with it in patients who have completed treatment for Multidrug-resistant tuberculosis at St. Peter's specialized hospital and ALERT hospital Addis Ababa, Ethiopia.

Method: A hospital based cross-sectional study was done to assess health-related quality of life among patients who had completed Multidrug-resistant tuberculosis treatment at St Peter's specialized hospital and ALERT hospital. The 36-Item Short Form Survey (SF-36), a health related quality of life assessment tool was used to measure the dependent variables. The data was analyzed using Statistical Package for Service Solution Version 27 (SPSS 27). A Physical component summary (PCS) score of less than 54.1 and mental component summary (MCS) score of less than 49.5 on SF-36 Survey was considered to be suggestive of function Impairment and at risk of depression respectively. Bivariate and multivariate analysis between health-related quality of life and the independent variables was performed.

Result: A total of 187 patients were interviewed, out of which 55.1% and 67.4 % had a mean PCS and MCS scores below population based normative scores respectively. Retroviral infections, type of anti-TB regimen, duration after completing treatment were predictive of affected MCS score.

Conclusion & recommendations: This study showed that MDR-TB has a substantial impact on patients health related quality of life. Therefore interventional programs to enhance HRQoL should be implemented at various stages treatment and also post treatment for MDR-TB patients

1. Introduction

1.1. Background of the study

Tuberculosis (TB) is a communicable disease which is one of the top 10 causes of death worldwide and the leading cause of death from a single infectious agent. About 30 high TB burden countries account for almost 90% of those who fall sick with TB each year. TB is a disease of poverty, and economic distress, vulnerability, marginalization, stigma and discrimination are often faced by people affected by TB. Globally, an estimated 10.0 million people fell ill with TB in 2019, a number that has been declining very slowly in recent years(1). Multidrug-resistant tuberculosis (MDR-TB) is Tuberculosis that is resistant to at least against Rifampicin and Isoniazid treatment the two most potent anti TB drugs. As compared to drug susceptible TB treatment is more prolonged, expensive and regimens are more toxic. MDR TB is also has a more potent sources of infection for others with high rates of treatment failure(2).

Drug-resistant TB continues to be a public health threat. Globally close to half a million people developed rifampicin-resistant TB (RR-TB), of which 78% had multidrug-resistant TB (MDR-TB) in 2019. The three countries with the largest share of the global burden were India (27%), China (14%) and the Russian Federation (8%). Globally in 2019, 3.3% of new TB cases and 17.7% of previously treated cases had MDR/RR-TB. The highest proportions (>50% in previously treated cases) were in countries of the former Soviet Union(3).

The annual incidence of TB in 2016 was around 177 per 100,000 which still put Ethiopia among the 30 countries with high burden of TB and DR-TB for years to come. Though exact estimation of the level of DR-TB is missing, it is estimated that around 2.7% of New TB cases and 14% previously treated TB cases suffer from DR-TB(4).

The term “quality of life” is defined as the subjective perception of satisfaction or happiness with life in domains of importance to the individual. Because many factors other than health can affect quality of life, outcomes of disease and treatment generally are evaluated under the more restricted concept and term “health-related

quality of life” (HRQoL).Health-related quality of life is defined as the subjective perception of the impact of health status, including disease and treatment, on physical, psychological, and social functioning and well-being(5).

Clinicians and public health officials have used HRQoL and well-being to measure the effects of chronic illness, treatments and short and long-term disabilities. Currently a number of institutions working on health have included the evaluation and improvement of HRQoL and well-being as a public health priority(6).

The World Health Organization Quality of Life Assessment (WHOQoL), Medical Outcomes Study 36-Item Short Form (SF-36), and 12-Item Short-Form Health Survey (SF-12) are among the most widely used instruments for assessing HRQoL(7).

1.2. Statement of the Problem

Multi drug resistant Tuberculosis has become a significant public health problem worldwide and Ethiopia is among the high burden countries affected by MDR-TB. According to the 2019 WHO estimate, the global treatment success rate of MDR/RR-TB was only 56%(8).

Patients with MDR- TB are not only affected by the diseases clinical impact but also by different psychosocial and economic problems as well. The symptoms and clinical burden of the disease often extend beyond the duration of treatment as a result of complications. The treatment itself is also associated with several side effects(9). Therefor MDR- TB has a huge impact on the overall well-being which can even exceed the physical impact of the illness.

The disease influences all QOL domains and substantially adds to patients morbidity, and these complex and multidimensional interactions pose challenges in accurately quantifying impairment in QOL(10). However currently the MDR-TB care mainly gives emphasis on clinical and microbiological aspect of the disease and its impact on patients HRQoL has been given little attention. Economic distress, vulnerability, marginalization, stigma and discrimination are often faced by people affected by MDR TB.

Many of the studies conducted in our setting focus only on clinical and microbiological outcomes. A few studies in Ethiopia have assessed the Health Related Quality of Life (HRQoL) among TB patients. Most conducted studies on MDR-TB patients focus on HRQoL before and during treatment with little emphasis given to HRQoL post treatment. To our knowledge, no study has directly assessed HRQoL after treatment completion for MDR TB alone .There are gaps in additional interventions such as a multidisciplinary rehabilitation and psychosocial support.

1.3. Significance of the Study

Available data are suggestive of high levels of poor quality of life among MDR TB patients. In Ethiopia, there are only a few of published papers about HRQoL among MDR TB patients which were limited by the use of a non-standardized data collection tool and focusing on TB confection with other diseases(11). Understanding the degree of HRQoL is an important aspect in intervention programs to enhance HRQoL. Assessment of HRQoL will serve as an essential source, for further studies. The gravity of the problem will be substantiated by this study. The outcome of the study can be used as a basis for evidence based guidelines to be published by the Federal Ministry of Health (FMOH), St Peters Specialized Hospital, ALERT Hospital, other TB/MDR TB treatment centers and also other stakeholders.

2. Literature Review

2.1. Burden of MDR-TB

Worldwide Tuberculosis (TB) is one of the leading infectious diseases with the highest case fatality rate(12).Globally in 2019, 61% of people with bacteriologically confirmed TB were tested for rifampicin resistance, up from 51% in 2017 and 7% in 2012.Coverage of testing was 59% for new and 81% for previously treated TB patients. A global total of 206,030 people with MDR/RR-TB were detected and notified in 2019, a 10% increase from 186 883 in 2018, and 177,099 people were enrolled in treatment, up from 156,205 in 2018(1).

A hospital based retrospective study in Ethiopia to assess the pattern of anti-TB drug resistance showed that among 376 culture positive for *M. tuberculosis* one hundred and two (27.1%) were susceptible to all of the four first line anti-TB drugs -Isoniazid (INH), Rifampicin (RIF), Ethambutol (ETB) & Streptomycin (STM). While 274 (72.9%) were resistant to at least one drug(13).

2.2. HRQoL among Patients on MDR-TB drug treatment

Most previously conducted studies have focused on clinical or programmatic outcomes among MDR-TB and only a handful of researches have tried to assess post-MDR-TB treatment HRQOL.

An Indian Study conducted in Mumbai in two DR TB treatment centers with the aim of assessing HRQoL and associated factors among DR-TB patients used a mixed-methods design: a quantitative cross-sectional questionnaire ([WHOQoL-BREF]); and qualitative in-depth interviews for purposively selected patients between April and November 2016. In this study a total of Ninety-five patients completed WHOQoL- BREF of which 12 were interviewed. In this article the most affected domains were the psychological and physical health domains with a mean scores of 56.2 and 56.5 respectively out of a maximum of 100 score. The social relations and environmental domains mean scores were respectively 68.6 and 60.3 (14).

A similar prospective cohort study conducted in four of the five main MDR-TB canthers in Yemen also tried to evaluate the HRQoL during and after treatment and predictors of HRQoL score differences. In this study the authors used the SF-36 V2

tool which consists of eight scales that measure eight domains of HRQoL, namely physical functioning (PF) , role-physical (RP) , bodily pain (BP), general health(GH) , vitality functioning (VF) , social functioning (SF) role-emotional(RE) and mental health(MH) categorized into two groups referred to as physical component summary (PCS) and mental component summary (MCS).Based on the tool used in this study a total normal base score (NBS) of < 47 reflects impairment of functions, whereas a mental component summary (MCS) score of < 43 indicates a risk of depression. At the beginning of treatment, the mean scores for all health domains were < 47 NBS points with subsequent increase in all eight health domains at completion of treatment. The peculiar finding in this article is the low HRQoL scores obtained for all health domains and a high depression status in patients even after 1 year of completing therapy (15).

Another study which was conducted in Johannesburg South Africa assessed HRQoL in patients who are on treatment for DR TB and also included the role of Treatment induced adverse events on HRQoL from February 2015 to January 2018. In this study the authors enrolled 149 DR-TB patients and used SF-36 questionnaire for data on HRQoL. Self-reported AEs were collected by trained interviewers through face-to-face interviews. The findings from this study showed that SF-36 domains and summary scores (MCS and PCS) were lower in those who reported an AE compared to those who did not, and both were lower than healthy adults(16).

A study in Namibia examined a total of 36 patients who completed treatment for MDR TB using the Short Form-8™ (SF-8) questionnaire consisting of eight Likert-type questions and assessed for adverse events as well as patients' perceived HRQoL. This study revealed that Patients who completed treatment for MDR-TB scored moderately low on their HRQoL (17).

When comparing Drug-Susceptible to that of Multidrug-Resistant Tuberculosis in terms of HRQoL, MDR-TB patients had a worse health-related quality of life as compared to Drug-Susceptible Tuberculosis which was evident in a study conducted in Eritrea. In this study a total of 92 patients (46 MDR-TB, 46 DS-TB) were enrolled and data was collected using the WHOQoL-BREF questionnaire. This study concluded that HRQoL was impaired in both groups, but MDR-TB patients had a worse HRQoL(18).

Information on the impact of MDR TB with regards to HRQoL is extremely limited in our country. Only a couple of papers have been published.

A prospective observational study which was conducted at 14 primary health-care centers in south central (Silti and Gurage zones) and northern Ethiopia (Bahir Dar zone) among newly diagnosed tuberculosis patients tried to assess the association between comorbid depression and tuberculosis treatment outcomes, quality of life and disability. A total of 648 patients were examined between December 2014 and July 2016 at treatment initiation and after 2 and 6 months. The investigators in this study used a Patient Health Questionnaire (PHQ-9) to assess depression, a 12-item WHO Disability Assessment Schedule version 2.0 to assess Disability and a Visual Analogue Scale (VAS) scored from zero for worst imaginable to 10 for best imaginable to assess HRQoL. Even though the study had adequate sample size the authors excluded patients who were diagnosed with MDR TB and Quality of life was assessed using a non-standardized tool with a single question of “How would you rate your health related quality of life?” (19).

Another study conducted in Ethiopia tried to assess the HRQoL and Associated factors among HIV mono-infected and tuberculosis (TB) and HIV co-infected patients in public health facilities in the town of Dessie. It was a comparative facility-based cross-sectional study which was conducted from February to May 2019, enrolling a total of 434 HIV mono infected and 143 TB/ HIV co-infected patients. The Authors measured HRQOL using the WHO quality of life HIV instrument in terms of physical, psychological, level of independence, social relationships, environmental and spiritual health domains. Kessler-10 (K10) depression scale was used to assess depressive symptoms (11). The study revealed that the TB/HIV co-infected patients had poor health related quality of life in all domains compared with HIV mono-infected patients. Besides, depression and stigma were more prevalent among co-infected patients. Although this study is useful in addressing the impact of TB/HIV co-infection with regards to HRQOL, it doesn't give information on the sole burden of TB/MDR-TB on HRQOL by their self.

2.3. Factors associated with HRQoL among patients on MDR-TB drug treatment

Health related quality of life among patients on MDR-TB drug treatment can be influenced by several patient, disease, and treatment-related factors. In one study Length of sickness prior to the diagnosis of MDR-TB and female gender was associated with a compromised physical and mental health(10).

Adverse events during the early months of treatment may be responsible for reducing HRQoL which was evident in the study conducted in Johannesburg(16).On the contrary the occurrence of adverse events did not lead to lower HRQoL scores upon treatment completion in a similar study carried out in Namibia(17).Untreated depression in people with tuberculosis was also shown to be associated with worse treatment outcomes, poor quality of life and greater disability(19). Among many other factors Social support was one of the main factors that positively affected HRQoL. On the other hand Loss of jobs due to TB adversely affected HRQoL mainly in terms of social relations and environmental domains(14).Past TB treatment history, anti-HIV treatments, being unmarried, and having symptoms of alcohol use disorder were associated with psychological distress which impacts HRQoL(20).

2.4. Conceptual framework

Health related quality of life in MDR-TB patients is affected by multiple variables. Stigma and isolation after MDR-TB diagnosis, illicit drug use and patients socio demographic characteristics can affect health related quality of life after MDR-TB treatment. Patients HIV infection status and the anti-TB regimen used and its duration can also affect the quality of life. The conceptual framework is depicted in the figure below.

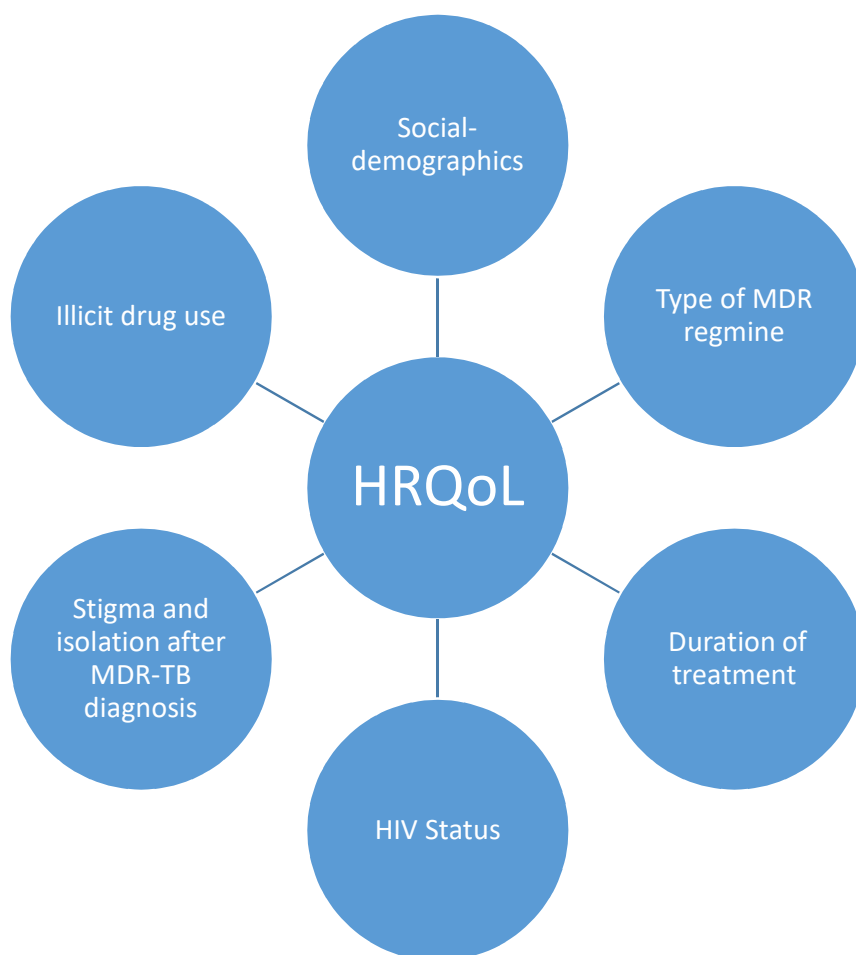


Figure 1 Conceptual framework showing the possible factors associated with HRQoL adopted from different literatures done previously(11)(10).

3. Objectives of the study

3.1. General Objectives

The main aim of this study was to assess post treatment HRQoL and its associated factors among Multi drug resistant tuberculosis patients treated at St. Peter's Specialized Hospital and ALERT Hospital Addis Ababa, Ethiopia from November 2021 to July 2022.

3.2. Specific Objectives

1. To determine the level of post-treatment health related quality of life among MDR-TB patients treated at St. Peter's Specialized Hospital and ALERT Hospital.
2. To identify the factors affecting post MDR-TB treatment HRQoL at St. Peter's Specialized Hospital and ALERT Hospital.

4. Methods and Materials

4.1. Study Setting and period

The study was conducted at St. Peter's Specialized Hospital and ALERT Hospital.

St. Peter's Specialized Hospital established in 1953 is the largest TB referral center in the country. It is a governmental hospital under Ethiopian federal ministry of health found in the capital Addis Ababa. It is located in Gulele sub city around Shiromeda. The hospital provides various services especially in multidrug resistance tuberculosis diagnosis and treatment. There are around 703 healthcare professionals in the hospital consist of doctors, nurses, midwives, pharmacists, anesthetists, laboratory technicians, health officers and radiographers. The hospital gives serves to a catchment area consisting of around 5 million people in different internal medicine, surgical, pediatrics, and gynecology and obstetrics specialties. It also gives services in dermatology and psychiatry departments. Within the internal medicine department it has a TB/MDR TB unite. The MDR TB unit has two MDR-TB follow up clinics and a ward for inpatient management. The MDR-TB ward consists of 34 beds. Around 121 MDR-TB patients were treated in the last three fiscal years. There were also 21 new MDR-TB patients which were enrolled from June 2020 to July 2020(13).

ALERT Hospital which was established in 1934 is the highest Level of Referral Hospital for Leprosy and is also a WHO recognized international Leprosy training Centers. ALERT hospital also provides specialized health care for TB, dermatology, ophthalmology, orthopedic, General and reconstructive surgery. It is a governmental hospital under Ethiopian federal ministry of health found in the capital Addis Ababa. ALERT Hospital consists of 11 health centers under its catchment area. Tuberculosis Center was established as a center to provide service to MDR – TB patients on March 2011 G.C. The MDR TB unit has a staff consisting of one Internist, three general practitioners, one pharmacy professional, 7 nurses, one phlebotomist, 2 cleaner, 1 social worker 1 IT service provider and 1 runner. As of March 30 2017 416 MDR-TB patients were enrolled. Around 144 patients have completed treatment and 109 are currently on follow up(21).

The study period was from January 2022 to March 2022.

4.2. Study Design

A multi centered hospital-based, cross- sectional study was used

4.3. Population

4.3.1 Source Population

The source population was all patients who are on follow-up after completing treatment for MDR-TB at St. Peter's specialized hospital and ALERT hospital.

4.3.2 Study Population

The study population were patients who have been treated for MDR- TB at St. Peter's hospital and ALERT hospital, who fulfill the inclusion criteria during the study period.

4.3.3 Study unit

Post treatment MDR- TB patients were the study unit

4.3.4 Sampling frame

The sampling frame was all patients who have completed Treatment for MDR- TB from MDR- TB registration book

4.4. Eligibility criteria

4.4.1 Inclusion Criteria

Those patients willing and able to give informed consent to participate in the study and those who were 18 years of age and above, who completed treatment for MDR-TB at St Peter's hospital and ALERT Hospital.

4.4.2 Exclusion Criteria

Patients who did not complete treatment were excluded from this study.

4.5. Sample Size Determination and Sampling Technique

4.5.1. Sample Size Determination

Sample size Determination for single population proportion.

$$N_0 = \frac{Z_{1/2}^2 P (1 - p)}{d^2}$$

Z=1.96 corresponding to 95% confidence interval n=sample size

α =degree of accuracy

p=proportion taken as 50% that is 0.5(assuming population proportion to be 50%, as there are no related studies in Ethiopia)

d= degree of precision within in 5%

$$N_0 = \frac{1.96^2 (0.5 \times 0.5)}{(0.05)^2}$$

Hence, sample size determination using the finite population correction factor will be:

$n = n_0 N / n_0 + (N-1)$, where n is the corrected sample size, n_0 is the sample size determined from the single proportion formula and N represents the finite.

The corrected sample size is approximately 136

Considering a 10% non-response rate, the final sample size will be 150

There were a combined number of 210 patients who fulfill the inclusion criteria who were registered with contact information (telephone number) in the MDR- TB register data base and log book in both hospitals.

4.5.2. Sampling Technique

Given the small number of patients a universal sampling technique was applied and all 210 patients were included in the study. Out of the 210 patients we were able to contact and interview 187 patients, 131 from St Peters hospital and 56 from ALERT hospital.

4.6. Study Variables

Dependent variable

- ❖ Health related quality of life post MDR-TB treatment.(PCS score affected(< 54.1) not affected(≥ 54.1) and MCS score affected(< 49.5) not affected(≥ 49.5)

Independent variables

- ❖ **Socio-demographic variables:** Age, sex, marital status, level of education, residence, occupation, and average monthly income
- ❖ HIV Status
- ❖ MDR-TB regimen
- ❖ Illicit drug use(Chewing khat, Smoking, Alcohol intake)
- ❖ Duration after completion of treatment

4.7. Operational Definitions and Measurement

Affected health related quality of life (HRQoL): A score less than of 54.1 in PCS suggests function Impairment and a score of less than 49.5 in the MCS score suggests at risk of being depressedes (22).

Multi-drug resistant tuberculosis (MDR-TB): Tuberculosis that is resistant to at least Rifampicin and Isoniazid.

Multi-drug resistant tuberculosis(MDR-TB)Treatment completed: treatment completed according to national recommendation without evidence of failure but no record that three or more consecutive cultures taken at least 30 days apart are negative after the intensive phase(4) .

Standardized short term: A course of MDR TB treatment lasting 9-12 month consisting of drugs such as Isoniazide, Pyrazinamide, Ethambutol, Moxifloxacin, Gatifloxacin and Kanamycin(4).

All oral long regimen: A course of MDR TB treatment lasting for 18-20 month with no discrete intensive and continuation phase, consisting of drugs such as Delamanid, Linezolid, Bedaquiline(4).

Previous long regimen: A course of MDR TB treatment lasting 20 month with drugs such as Pyrazinamide, Capreomycin, Levofloxacin, Prothionamide, Ethionamide and Cycloserine(4).

Individualized regimen: A course of MDR TB treatment lasting 20 month, designed based on the patient's most recent drug sensitivity test results and history of previous drug use and/or exposure(4).

4.8. Data Collection Method, Tool and Procedures

Data was collected using a structured interviewer administered questionnaire using phone interview. Patient's phone numbers and other information were obtained from MDR TB Data base for ALERT hospital and MDR TB registration log book for St. Peter's specialized hospital. The interview was conducted by two general practitioners working at MDR TB clinic from March to July 2022 GC .The data collectors were compensated per number of patients they interviewed. A translated (from English to Amharic) and validated Amharic version of SF-36V2 which is a HRQOL measuring tool was used for data collection. The Amharic version of the SF-36 has been shown to have content acceptability and is a valid instrument to measure HRQoL on previous study's conducted on TB and leprosy (23).

The SF-36v2 has 36 questions consisting of eight scales that measure eight domains of HRQoL namely

- ❖ Physical functioning (PF) ten items Qs (3 4 5 6 7 8 9 10 11 12)
- ❖ Role-physical (RP) four items Qs (13 14 15 16)
- ❖ Bodily pain (BP) two items Qs(21 22)
- ❖ General health (GH) five items Qs (1 33 34 35 36)
- ❖ Vitality (VT) four items Qs (23 27 29 31)
- ❖ Social functioning (SF) two items Qs(20 32)
- ❖ Role-emotional (RE) three items Qs(17 18 19)
- ❖ Mental health (MH) five items Qs (24 25 26 28 30)

These eight domains are categorized into two groups referred to as physical component summary (PCS) and mental component summary (MCS).PF, RP and BP scales are strongly correlated with PCS, whereas MH, RE and SF scales are correlated with MCS.VT and GH are moderately correlated with both PCS and MCS(22). Data was scored using the RAND 36-Item Health Survey technique and calculated using free online Ortho Toolkit calculator (24) (25) .

4.9 Data Quality control

The questionnaire was pre-tested in 5% of the total sample size to avoid any confusion during actual data collection period. Training was given for data collectors. During data collection, principal investigator checked data for its completeness and missing information at each point. Furthermore, data was checked during entry into the computer before analysis.

4.10. Data processing and analyses

Data was analyzed using the Statistical Package of Social Sciences (SPSS) version 25.0 computer software. Descriptive analysis such as frequencies and mean were done. Bivariate analysis between dependent and independent variables was performed using binary logistic regression. Variables found to have association with the dependent variable (p-value up to 0.2) were then entered in to multivariate logistic regression models for further analysis and Hosmer and Lemeshow's goodness-of-fit test was done and variables having P- value <0.05 were considered as significantly associated with the dependent variable. The degree of association between dependent and independent variables was expressed by using odds ratio with 95% confidence interval. The data was summarized and presented by use of tables and texts.

4.11. Ethical Considerations

Permission and ethical clearance was obtained from the Institutional Review Board of SPHMMC, St Peter's specialized hospital and ALERT hospital. Verbal informed consent was obtained from each study participant after being introduced to the purpose of the study and informed about their rights to interrupt the interview at any time. Confidentiality was maintained by concealing patient's names at all levels of the study and reporting the findings in aggregate.

4.12 Plan for dissemination of results

The research findings will be presented and defended to the department of internal medicine, SPHMMC and submitted to the department of public health. In addition, the research report will be archived in the main Library of SPHMMC. The outcome of the study will be presented at different seminar, research symposium and conferences. It will also be submitted to Federal Ministry of Health (FMOH), St Peters Specialized Hospital, ALERT hospital, SPHMMC and other TB/MDR-TB treatment centers to help compliment upcoming TB/MDR TB treatment guidelines. All attempts will be made to publish the findings of this study on peer reviewed reputable local and international journal.

5. Result

Socio demographic characteristics of respondents

Out of 210 patients who have completed treatment for MDR TB and had documented contact information (telephone number) on TB registration data base and log book 187 patients were telephoned and interviewed making the response rate 89 %. The remaining 11% either did not answer their phone or their phone number was not working. The age distribution of the respondents is normally distributed. The mean (SD) age of respondents in the study was 31.48 (± 10.98) years. The maximum and minimum age of respondents was 18 and 74 years respectively. Nearly three-fourth of the respondents were between the age group of 20-39. Over half (53.5%) of the respondents were male. In regards to marital status more than half (54.0%) were single. While 74(39.6%) of the respondent have a maximum educational achievement of secondary education, 23(12.3%) did not attend any formal education. 156(83.4%) of the respondents lives in urban area. Majorities (41.7%) of the respondents are engaged in private works but 61 (32.6%) of the respondents do not have any formal work. HIV-infection was identified only in 24 (12.8%) of the patients.

Table 1 Socio demographic characteristics of MDR-T B treated patients at ALERT and St. Peter hospital and St. Peter hospital. Addis Ababa, Ethiopia March 2020- March 2022 GC

Variables		Frequency	Percentage
10-years age groups			
	10-19	15	8.0
	20-29	83	44.4
	30-39	54	28.9
	40-49	20	10.7
	50-59	10	5.3
	60-69	4	2.1
	70-79	1	0.5
Sex			
	Male	100	53.5
	Female	87	46.5
Marital status			
	Single	101	54.0
	Married	73	39.0
	Divorced	5	2.7
	Widowed	8	4.3
Educational status			
	No formal education	23	12.3
	Primary education	51	27.3
	Secondary education	74	39.6
	College level education and above	39	20.9
Monthly Income			
	1500 ETB and less	63	23.8
	1501-3500 ETB	89	33.6
	3501-5500 ETB	71	26.8
	Above 5500 ETB	42	15.8
Place of residency			
	Urban	156	83.4
	Rural	31	16.6
Occupation			
	Private works	78	41.7
	Government Employee	38	20.3
	Farmer or labor work	10	5.3
	No formal work	61	32.6
HIV Status			
	HIV Positive	24	12.8
	HIV Negative	163	87.2

Treatment related characteristics of the patients

Duration of time since TB infection diagnosed was more than one year in all of the patients. Above half (53.5%) of the respondents took the previous long regimen as their anti-TB regimen. It has been more than one year after completion of anti-TB regimen in 162 (86.6%) of the respondent. Only 27 (14.4%) of the respondent reported that they took some form of illicit drugs.

Table 2 Treatment related characteristics of MDR-TB treated patients at ALERT and St. Peter hospital and St. Peter hospital. Addis Ababa, Ethiopia March 2020- March 2022 GC

Variables		Frequency	Percentage
Time since completion of anti-TB			
	Less than 1 year	25	13.4
	More than 1 year	162	86.6
Anti-TB regimen			
	Standardized short term	33	17.6
	All oral long regimen	41	21.9
	Individualized	13	7.0
	Previous long regimen	100	53.5
Illicit drug use			
	Yes	27	14.4
	No	160	85.6

Health related quality of life (HRQoL) in MDR-TB treated patients

The mean (SD) scores of HRQoL domain are presented in the table below. The SF 36 HRQoL domains and component summary scores were normally distributed with Body pain (86.2) and social functioning (80.42) having the highest mean scores followed by physical functioning (73.75). Mental Health and Vitality had the lowest scores with 56.89 and 56.93 respectively. The overall Physical Component summary score and mental component summary scores were 46.40 and 39.98 respectively. Functional impairment was identified in 103 (55.1%) of the patients who completed MDR TB treatment. Similarly, 126 (67.4%) of MDR TB patients have affected MCS score and are at risk of depression.

Table 3 Health related quality of life SF 36 domain scores and component summary score of patients who completed MDR-TB treatment at St. Peter and ALERT hospital Addis Ababa, Ethiopia March 2020 - March 2022 GC

	Overall				Alert hospital		St. peter hospital	
Variables	Mean	SD	Min	Max	Mean	SD	Mean	SD
Physical functioning (PF)	73.57	25.48	10	100	73	26.7	73.6	25.1
Role-physical (RP)	65.47	43.50	0.00	100.00	66.4	42.6	65.1	43.9
Body Pain (BP)	86.20	23.33	.00	100.00	84.3	25.4	86.9	22.5
General Health (GH)	66.75	23.15	10.0	100.00	69.3	24.1	65.8	22.7
Vitality (VT)	56.93	17.38	15.0	100.0	57.2	16.7	56.8	17.6
Social functioning	80.42	24.47	12.50	100.00	81.9	21.7	79.8	25.4
Role-emotional (RE)	67.09	42.57	.00	100.0	66.4	41.8	67.3	42.9
Mental Health	56.89	17.22	20.0	100.0	55.7	17.1	56.9	17.3
Physical Component summary (PCS)	46.40	13.80	10.18	62.69	47.4	12.3	46.0	14.3
Mental component summary (MCS)	39.98	13.46	13.19	59.31	39.8	12.8	40.0	13.7

Table 4 Health related quality of life physical and mental component summary scores Frequency and Percentage of patients who completed MDR-TB treatment at St. Peter and ALERT hospital Addis Ababa, Ethiopia March 2020- March 2022 GC

Variables	Frequency	Percentage
Physical component Score (PCS)		
Not affected or no functional impairment	84	44.9
Affected or functional impairment	103	55.1
Mental component score(MCS)		
Not affected or not at risk of depression	61	32.6
Affected or at risk of depression	126	67.4

Factors associated with physical impairment or affected PCS

On Bivariate analysis of factors associated with physical component summary score, time since completion of anti-TB was found to have a statistically significant association. Patients with duration of more than 1 year after completion of anti TB were 2.45 times more likely to have affected PC score .Other variables including sex, place of residence, marital status, educational level, RVI status, illicit drug use and anti-TB regimen did not show statistically significant association. But on multivariate model controlling for variables that have p-value less than 0.2, did not show a statistically significant association between time since completion of anti-TB and PCS. The following variables were included in the multivariate model: place of residency, marital status, occupation, RVI status, and illicit drug use and anti-TB regimen.

Table 5 Factors associated with affected PCS score physical impairment among patients who completed treatment for MDR-TB patients at ALERT and St. Peter hospital. Addis Ababa, Ethiopia March 2020- March 2022 GC

Variables	PCS Affected		COR (95% CI)	P-value	AOR (95% CI)	P-value
	No	Yes				
Time since completion of anti-TB						
Less than 1 year	16 (64.0%)	9(36.0%)				
More than 1 year	68(42.0%)	94(58.0%)	2.45(1.02-5.89)	.044	3.18(0.98-10.30)	.054
Sex						
Male	42(42.0%)	58(58.0%)				
Female	42(48.3%)	45(51.7%)	.776(.435-1.383)	.390		
Place of residence						
Urban	75(48.1%)	81(51.9%)	1.00			
Rural	9 (29.0%)	22(71.0%)	2.263(.980-5.22)	.056		
Marital status						
Married	25(34.2%)	48(65.8%)	1.00			
Single	55(54.5%)	46(45.5%)	.436(.234-.811)	.090		
Divorced	2(40.0%)	3(60.0%)	.781(.122-4.98)	.794		
Widowed	2(25.0%)	6(75.0%)	1.56(.294-8.31)	.604		
Educational Level						
No formal education	7(30.4%)	16(69.6%)	1.00			
Primary education	19(37.3%)	32(62.7%)	.737(.257-2.11)	.570		
Secondary education	37(50.0%)	37(50.0%)	.438(.161-1.18)	.105		
College level education	21(53.8%)	18(46.2%)	.375(.126-1.11)	.077		
Occupation						
Private work	39(50.0%)	39(50.0%)	1.00			
Government work	18(47.4%)	20(52.6%)	1.11(.511-2.41)	.790		
Farmer or labor work	3(30.0%)	7(70.0%)	2.33(.56-9.68)	.243		
No formal work	24(39.3%)	37(60.7%)	1.54(.78-3.04)	.211		

Table 6 Factors associated with affected PCS score physical impairment among patients who completed treatment for MDR-TB patients at ALERT and St. Peter hospital. Addis Ababa, Ethiopia March 2020- March 2022 GC (continued)

Variables	PCS Affected		COR (95% CI)	P-value	AOR (95% CI)	p-value
	No	Yes				
HIV Infection status						
HIV positive	8(33.3%)	16(66.7%)	1.00			
HIV Negative	76(46.6%)	87(53.4%)	.572(.232-1.41)	.226		
Anti-TB regimen						
Standardized short term	18(54.5%)	15(45.5%)	1.00			
All oral long regimen	14(34.1%)	27(65.9%)	2.31(.90-5.93)	.081		
Individualized	4(30.8%)	9(69.2%)	2.70(.69-10.54)	.153		
Previous long regimen	48(48.0%)	52(52.0%)	1.30(.590-2.86)	.515		
Illicit drug use						
Yes	6(22.2%)	21(77.8%)	1.00			
No	55(34.4%)	105(65.6%)	.819(.35-1.87)	.637		

Factors associated with risk of depression or affected MCS

On Bivariate analysis HIV infection status, Time since completion of anti-TB and the type of anti-TB regimen taken showed statistically significance association.

To conduct multi-variate logistic regression, variables that have a p-value less than 0.2 on Bivariate analysis were included in the model. The multivariate model includes the following variables: HIV infection status, Time since completion of anti-TB, type of anti-TB regimen, place of residency, marital status, occupation and illicit drug use.

Based on multivariate analysis HIV infection status, time since completion of anti-TB and the type of anti-TB regimen used were found to have a statistically significant association with mental component score (MCS). HIV positive patients are 4.6 times more likely to have an affected MCS than HIV negative patients. Patients who elapsed more than 1 year after completion of anti-TB also are 6.5 times more likely to have an affected MCS. Patients who received all oral long regimen anti-TB are 7.5 times more likely to have an affected MCS than patient who took the standard short-term regimen.

Table 7 Factors associated with affected MCS score or at risk of depression among patients who completed treatment for MDR-TB patients at ALERT and St. Peter hospital. Addis Ababa, Ethiopia March 2020- March 2022 GC

Variables	MCS Affected		COR (95% CI)	P-value	AOR (95% CI)	P-value
	No	Yes				
Sex						
Male	29(29.0%)	71(71.0%)				
Female	32(36.8%)	55(63.2%)	.702(.380-1.29))	.258		
Place of residence						
Urban	54(34.6%)	102(65.4%)	1.00			
Rural	7(22.6%)	24(77.4%)	1.18(.735-4.48)	.196		
Marital status						
Married	19 (26.0%)	54(74.0%)	1.00			
Single	40(39.6%)	61(60.4%)	.537(.27-1.03))	.063		
Divorced	1(20.0%)	4(80.0%)	1.40(.14-13.39)	.766		
Widowed	1(12.5%)	7(87.5%)	2.46(.284-21.34)	.413		
Educational Level						
No formal education	4 (17.4%)	19(82.6%)	1.00			
Primary education	15(29.4%)	36(70.6%)	.505(.147-1.73)	.279		
Secondary education	28(37.8%)	46(62.2%)	.346(.107-1.12)	.077		
College level education	14(35.9%)	25(64.1%)	.376(.107-1.32)	.128		
Occupation						
Private work	27(34.6%)	51(65.4%)	1.00			
Government work	8(21.1%)	30(78.9%)	1.98(.80-4.96)	.139		
Farmer or labor work	2(20.0%)	8(80.0%)	2.11(.42-10.68)	.363		
No formal work	24(39.3%)	37(60.7%)	.816(.408-1.63)	.566		
HIV Infection status						
HIV positive	3(12.5%)	21(87.5%)	3.86(1.10-13.51)	.034	4.69(1.12-19.62)	.034
HIV negative	58 (35.6%)	105(64.4%)	1.00			
Time since completion of anti-TB						
Less than 1 year	14(56.0%)	11(44.0%)	1.00			
More than 1 year	47(29.0%)	115(71.0%)	3.11(1.31-7.35)	.010	6.56(1.72-25.02)	.006
Anti-TB regimen						
Standardized short term	18(54.5%)	15(45.5%)	1.00			
All oral long regimen	6(14.6%)	35(85.4%)	7.00(2.32-21.12)	.001	7.55(2.10-27.03)	.002
Individualized	2(15.4%)	11(84.6%)	6.60(1.26-34.54)	.025	5.14(0.82-31.84)	.079
Previous long regimen	35(35.0%)	65(65.0%)	2.23(1.00-4.96)	.049	1.49(0.50-4.40)	.472
Illicit drug use						
Yes	11(40.7%)	16(59.3%)	1.00			
No	73(45.6%)	87(54.4%)	.54(.208-1.43))	.218		

6. Discussion

The main purpose of this study is to provide the much needed data about the post MDR-TB treatment HRQoL status of patients. The impact of MDR- TB is not just limited to its clinical aspect but also by different psychosocial and economic problems as well. To the best of our knowledge, this is the first study which evaluated the impact of MDR-TB post treatment on patients HRQoL in the country.

On initial evaluation, we observed that Vitality and Mental Health of the study participants were the two most affected health domains. This indicated that patients had loss of energy, were fatigued and had low mood or nervousness. This might be because of chronic and destructive nature of MDR-TB, and pro- longed therapy with the fear of disease relapse and stigmatization. Domains such as bodily pain were relatively more preserved. The HRQoL summary scores were found to be generally well below population based norms of this country (NBS scores) as well as US and other country's general population norms(16). This study has also shown that comparatively the MCS score were lower than the PCS score Which is an indication of more mental distress rather than the physical problems which is also evident in other similar studies This finding was also comparable with studies on drug susceptible TB conducted elsewhere (26).

Even though the PCS scores were well below population based norms in our study, significant associations were not identified with the independent variables. On the contrary HIV infected patients had a low PCS summary score than those without HIV infection in similar studies conducted using a similar HRQoL measuring tool (16).

This study identified a high prevalence of depression risk (MCS < 49.5 NBS points) among majority of the study participants. A high prevalence of depression has similarly been reported among patients with MDR-TB in related studies. The high proportion of patients at risk of depression may be attributed to prior treatment failures, knowledge of suffering from a debilitating form of TB and psychiatric side-effects related to the use of some of the anti TB drugs. The relatively longer period of treatment, social stigma, inadequate social support could have also contributed to the comparatively worse mental health among this group of patients.

This study has shown that patients who were on standard short-course regimen were better off in terms of their MCS score, but had similar PCS summary score implying lesser risk of depression as compared to other regimens especially those with prolonged duration like the all oral long regimen. This might be explained by the fact that patients on short-course regimen are less prone to drug

related adverse events which might translate to relative better mental well-being. Other studies which mainly focused on drug adverse events while patients are on treatment showed that patients on an individualized regimen had a better mental wellbeing summary score, than those who were on a standard long- or short-course regimen (16) . This can be explained with the fact that drug related adverse mental wellbeing while on treatment might not translate to long term adverse mental well-being and that prolonged duration of treatment might actually be more important in terms of risk of depression in the long term.

Compared to HIV negative patients, MCS scores for HIV positive patients were significantly lower. This is not surprising considering the fact that previous studies have shown the impact of RVI on mental well-being and risk off depression(11). In contrary to other studies longer time after completion of treatment didn't reduce the risk of depression in fact the risk of depression was found to be higher in this study in Patients who elapsed more than 1 year after completion Treatment. The discrepancy might be due to the fact that the additive effect of the psychosocial and economical burden will still be in existence even long after treatment completion in a low income country like Ethiopia.

Sex, smoking, residence, marital status and illicit drug use did not show statistically significant interaction with affected MCS scores. This is also in contrary to other studies which have shown to predict lower MCS score .This discrepancy might be explained by the socio demographic and culture difference in the study participants as well as by the difference in the sample of the study participants (15).

Strength of the study

The major strength of the study is that it was a multicenter study conducted in the two MDR-TB treatment centers which are the only treatment centers in the capital.

Limitations of this study

- 1, Data was collected through the phone due to the fact that small amount of patients were coming for follow up because of the current effect of COVID 19 pandemic and phone interviews have high non response rate are one dimensional only using verbal communication unlike as face to face interview where additional information can be obtained .
- 2, Given the small number of the sample size interpretation might be impaired.
- 3, Post TB complications of patients which could affect their physical and psychosocial health were not assessed.

7. Conclusion and recommendations

7.1 Conclusions

This study revealed that 55.1% and 67.4 % of the study participant's had a mean PCS and MCS scores below population based normative scores respectively. Retroviral status, type of anti-TB regimen, duration after completing treatment was statistically significantly associated with the mean MCS score.

7.2 Recommendations

For MDR TB treatment centers in the country

Work should be done to improve the HRQoL after treatment by following up patients with MDR-TB. Interventional programs with multi-disciplinary engagement involving psychologists and psychiatrist can provide psychotherapy and also create peer-to-peer support groups .Early screening and management of depression and also its risk factors should be given emphasis. Support in terms of material, food and housing can be provided by involving various stake holders to those highly affected patients.

For physicians and other health care providers

Physicians and health care providers should keep in mind the non-clinical burdens of MDR TB and should incorporate rehabilitation and psychotherapy services in every step of the treatment process.

For fellow researchers

Further prospective and analytic studies should be conducted to identify early target areas of intervention which could change the HRQOL outcome for the better in the long-term.

Further validation and development of tools with population NBS should be conducted to asses HRQOL in TB and also in other chronic illnesses.

For Federal Ministry of health

Policies and guidelines regarding MDR-TB comprehensive care should be revised with further attention on the non-clinical aspect of the disease. Additional MDR TB treatment centers should be established to limit the burden of the very few centers giving service currently.

8. References

1. World Health Organization. Who, 2020. J Chem Inf Model. 2013;53(9):1689–99.
2. Ozer EK, Goktas MT, Toker A, Pehlivan S, Bariskaner H, Ugurluoglu C, et al. Thymoquinone protects against the sepsis induced mortality, mesenteric hypoperfusion, aortic dysfunction and multiple organ damage in rats. Vol. 69, Pharmacological Reports. 2017. 683–690 p.
3. Executive summary. Am J Public Health. 1991;81(SUPPL.):9–10.
4. Structures MB. No Federal Democratic Republic of Ethiopia MoH, “National guideline for TB, DR-TB and leprosy in Ethiopia,” Federal Democratic Republic of Ethiopia MoH, Addis Ababa, Ethiopia, 6 edition, 2018.
5. Leidy NK, Revicki DA, Genesté B. Recommendations for Evaluating the Validity of Quality of Life Claims for Labeling and Promotion. Value Heal [Internet]. 1999;2(2):113–27. Available from: <http://dx.doi.org/10.1046/j.1524-4733.1999.02210.x>
6. Foundation Health. Healthy People 2020. Foundation Health Measure Report: Health-Related Quality of Life and Well-Being. Found Heal Meas Rep [Internet]. 2010;(November):1–6. Available from: <http://www.healthypeople.gov/sites/default/files/HRQoLWBFullReport.pdf>
7. Pequeno NPF, Pequeno NPF, Cabral NL de A, Marchioni DM, Lima SCVC, Lyra C de O. Quality of life assessment instruments for adults: a systematic review of population-based studies. Health Qual Life Outcomes. 2020;18(1):1–13.
8. Alemu A, Bitew ZW, Worku T, Gamtesa DF, Alebel A. Predictors of mortality in patients with drug-resistant tuberculosis: A systematic review and meta-analysis. PLoS One [Internet]. 2021;16(6June):1–24. Available from: <http://dx.doi.org/10.1371/journal.pone.0253848>
9. Girum T, Muktar E, Lentiro K, Wondiye H, Shewangizaw M, Muluneh MA, et al.

Epidemiology of multidrug-resistant tuberculosis (MDR-TB) in Ethiopia: A systematic review and meta-analysis of the prevalence, determinants and treatment outcome. *Trop Dis Travel Med Vaccines*. 2018;2021(1):1–12.

10. Aggarwal AN. Quality of life with tuberculosis. *J Clin Tuberc Other Mycobact Dis* [Internet]. 2019;17:100121. Available from: <https://doi.org/10.1016/j.jctube.2019.100121>
11. Hailu T, Yitayal M, Yazachew L. Health-related quality of life and associated factors among adult HIV mono-infected and TB/HIV co-infected patients in public health facilities in northeast Ethiopia: A comparative cross-sectional study. *Patient Prefer Adherence*. 2020;14:1873–87.
12. Simbwa BN, Katamba A, Katana EB, Laker EAO, Nabatanzi S, Sendaula E, et al. The burden of drug resistant tuberculosis in a predominantly nomadic population in Uganda: a mixed methods study. *BMC Infect Dis* [Internet]. 2021;21(1):1–11. Available from: <https://doi.org/10.1186/s12879-021-06675-7>
13. Abate D, Taye B, Abseno M, Biadgilign S. Epidemiology of anti-tuberculosis drug resistance patterns and trends in tuberculosis referral hospital in Addis Ababa, Ethiopia. *BMC Res Notes*. 2012;5(X).
14. Laxmeshwar C, Stewart AG, Dalal A, Kumar AMV, Kalaiselvi S, Das M, et al. Beyond ‘cure’ and ‘treatment success’: Quality of life of patients with multidrug-resistant tuberculosis. *Int J Tuberc Lung Dis*. 2019;23(1):73–81.
15. Jaber AAS, Ibrahim B. Calidad de vida relacionada con la salud de pacientes con tuberculosis multirresistente en Yemen: estudio prospectivo. *Health Qual Life Outcomes* [Internet]. 2019;17(1):142. Available from: <https://hqlo.biomedcentral.com/articles/10.1186/s12955-019-1211-0>
16. Sineke T, Evans D, Schnippel K, Van Aswegen H, Berhanu R, Musakwa N, et al. The impact of adverse events on health-related quality of life among patients receiving treatment for drug-resistant tuberculosis in Johannesburg, South Africa. *Health Qual Life Outcomes*. 2019;17(1).

17. Sagwa EL, Ruswa N, Mavhunga F, Rennie T, Leufkens HG, Mantel-Teeuwisse AK. Adverse events and patients' perceived health-related quality of life at the end of multidrug-resistant tuberculosis treatment in Namibia. *Patient Prefer Adherence*. 2016;10:2369–77.
18. Araia ZZ, Mesfin AB, Mebrahtu AH, Tewelde AG, Tewelde AT, Ngusbrhan Kidane S. Health-Related Quality of Life in Tuberculosis Patients in Eritrea: Comparison Among Drug-Susceptible and Rifampicin/Multidrug-Resistant Tuberculosis Patients. *Patient Relat Outcome Meas*. 2021;Volume 12:205–12.
19. Ambaw F, Mayston R, Hanlon C, Medhin G, Alem A. Untreated depression and tuberculosis treatment outcomes, quality of life and disability, Ethiopia. *Bull World Health Organ*. 2018;96(4):243–55.
20. Tola HH, Shojaeizadeh D, Garmaroudi G, Tol A, Yekaninejad MS, Ejeta LT, et al. Psychological distress and its effect on tuberculosis treatment outcomes in Ethiopia. *Glob Health Action*. 2015;8(1).
21. Shimeles E, Enquselassie F, Tilahun M, Mekonnen A, Wondimagegn G, Hailu T, et al. <https://alertethiopia.org/about-alert/>. *Open J Respir Dis*. 2019;09(01):1–17.
22. Ware JE, Snow KK, Kosinski M, Gandek B. SF-36 Health Survey Manual and Interpretation Guide. Bost New Engl Med Cent [Internet]. 1993; Available from: <http://www.mendeley.com/catalog/sf-36-health-survey-manual-interpretation-guide/>
23. Lambert SM, Walker SL, Nicholls PG, Lockwood DNJ. Validating an Amharic Version of the 36-item Short Form Health Survey (SF-36) in Individuals With Leprosy in Ethiopia . 2021;1–17.
24. Functioning M. The RAND 36-Item Health Survey The RAND 36-Item Health Survey. *Heal (San Fr*. 1992;91–7.
25. [orthotoolkit.com](https://orthotoolkit.com/sf-36/) [Internet]. Available from: <https://orthotoolkit.com/sf-36/>
26. Ahmad N, Javaid A, Sulaiman SAS, Basit A, Afridi AK, Jaber AAS, et al. Effects of

multidrug resistant tuberculosis treatment on patients' health related quality of life:
Results from a follow up study. PLoS One. 2016;11(7):1–16.

Annexes

Annex 1: An informed consent sheet

መድሐኒት የተለማመደ የፀረ ቲቢ ሕክምና የተከታተሉ ታካሚዎች ከጤና ጋር ተያያዥ የሆነ የኑሮ ደረጃን የሚለካ ጥናት ለጥናቱ ተሳታፊዎች የሚሰጥ መረጃና መጠይቅ

ዋና ተመራማሪ:

1. ዶ/ር ኤስሮም ሀጎስ (የውስጥ ደዌ ሬዚደንት)

ቅዱስ ጳውሎስ ሆስፒታል ሚሌኒየም ሜዲካል ኮሌጅ፤ አዲስ አበባ ፤ ኢትዮጵያ

ስልክቁጥር:- 0913628654

Email:- esrombabu@gmail.com

ምርምሩ ውስጥ የሚሳተፉ ተቋማት

የቅዱስ ጳውሎስ ሆስፒታል ሚሌኒየም ሜዲካል ኮሌጅ

የቅዱስ ጴጥሮስ ሆስፒታል

አለርት ሆስፒታል

ውድ የጥናቱ ተሳታፊዎች፣ የዚህ ጥናት አላማ በቅዱስጴጥሮስ ሆስፒታል እና አለርት ሆስፒታል መድሐኒት የተለማመደ የፀረቲቢ ሕክምና የተከታተሉ ታካሚዎች ከጤና ጋር ተያያዥ የሆነ የኑሮ ደረጃን ማጥናት ነው። እድሜያቸው ከ18 ዓመት በላይ ያሉ እናበጥናቱ ለመሳተፍ ፍላጎት ያላቸው በዚህ ጥናት መሳተፍ ይችላሉ።

በመጀመርያ በጥናቱ ለመሳተፍ ፍቃደኛ መሆንዎን እንጠይቃለን። በጥናቱ ለመሳተፍ ፍቃደኛ ከሆኑ ብቻ ጥናቱ ላይ እንዲሳተፉ እናደርጋለን። በጥናቱ ላይ ለመሳተፍ ፍቃደኛ ከሆኑ ከህክምና መዝገብ ላይ አስፈላጊ መረጃዎችን እንወስዳለን። ከዚህ መጠይቅ የሚገኘው መረጃ ለመመረቂያ ፅሁፌ እንደግብዐት ሆኖ ያገለግላል።

በዚህ ጥናት ላይ በመሳተፍዎ የሚደርስበት ምንም አይነት ጉዳት የለም። የህመምዎ መረጃ የህክምና ካርድዎ ላይ ይመዘገባል። ለመረጃዉ ደህንነት ሲባል ስምዎ የመረጃ ቋት ላይ አይጻፍም። ከርስዎ የምናገኘውን መረጃ ከተመራማሪውና ከሃኪሙ በስተቀር ለማንም አሳልፈን አንሰጥም። መረጃውን ለሌላ ተመራማሪዎች ለመስጠት አስፈላጊ ሆኖከተገኘ የተቋሙን ህግና ደንብ በተከተለ መልኩ ይሆናል።

ስለ ጥናቱ ማንኛውም አይነት ጥያቄ ካለዎት የጥናቱን ተመራማሪዎች ማናገር ይችላሉ።

በዚህም መሠረት በዚህ ጥናት ላይ እንዲሳተፉ በአክብሮት እንጋብዝዎታለን።

Annex 2: English version Data Collection tool

Socio-demographic and treatment related characteristics		
Age		
Sex	1. Male 2. Female	
Residency	1. Urban 2. Rural	
Marital status	1. Married 2. Single 3. Divorced 4. Widowed	
Level of education	1, Don't know how to read or write 2, Can read and write 3, Primary education 4, Secondary education 5, College level education	
Average monthly House hold in came		
Occupation	1,Private work 2, Government employee 3,Farmer 4, Non-government work 5, Unemployed 6,Student 7,Merchant 8, Daily laborer	
RVI Status	1, HIV negative 2, HIV positive	
MDR-TB regimen	1, Standardized short term 2, All oral long regimen 3, Individualized. 4, Previous long regimen	
Duration post MDR-TB treatment	1, More than one year 2, Less than one year	
How long since known infection with MDR TB	1, More than one year 2, Less than one year	
Illicit drug use	1,smoking 2,Alchol 3,khat	

SF-36 QUESTIONNAIRE

1. In general, would you say your health is?

Excellent (1)	Very Good (2)	Good (3)	Fair (4)	Poor (5)
------------------	------------------	-------------	-------------	-------------

2. Compared to one year ago, how would you rate your health in general now?

Much better now than one year ago (1)	Somewhat better now than one year ago (2)	About the same as one year ago (3)	Somewhat worse now than one year ago (4)	Much worse now than one year ago (5)
---	---	---	---	--

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much: (circle one number on each line)

	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
3. Vigorous activities, such as running, lifting heavy objects participating in strenuous sports	1	2	3
4. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
5. Lifting or carrying groceries	1	2	3
6. Climbing several flights of stairs	1	2	3
7. Climbing one flight of stairs	1	2	3
8. Bending, kneeling, or stooping	1	2	3
9. Walking more than a mile	1	2	3
10. Walking several hundred yards	1	2	3
11. Walking one hundred yards	1	2	3
12. Bathing or dressing yourself	1	2	3

During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health? (Circle one number on each line)_

	All the time	Most of the time	Some of the time	A little of the time	None of the time
13. Cut down on the amount of time you spend on work or other activities	1	2	3	4	5
14. Accomplished less than you would like	1	2	3	4	5
15. Were limited in the kind of work or other activities	1	2	3	4	5
16. Had difficulty performing the work or other activities (for example, it took extra effort)	1	2	3	4	5

During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)? (Circle one number on each line)

	All the time	Most of the time	Some of the time	A little of the time	None of the time
17. Cut down on the amount of time you spend on work or other activities	1	2	3	4	5
18. Accomplished less than you would like	1	2	3	4	5
19. Did work or activities less carefully than usual	1	2	3	4	5

20. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your social activities with family, friends, neighbours, or groups? (Circle one)

Not at all (1)	Slightly (2)	Moderately (3)	Quite a bit (4)	Extremely (5)
-------------------	-----------------	-------------------	--------------------	------------------

21. How much bodily pain have you had during the past 4 weeks? (Circle one)

None (1)	Very Mild (2)	Mild (3)	Moderate (4)	Severe (5)	Very Severe (6)
-------------	------------------	-------------	-----------------	---------------	--------------------

22. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)? (Circle one)

Not at all (1)	Slightly (2)	Moderately (3)	Quite a bit (4)	Extremely (5)
-------------------	-----------------	-------------------	--------------------	------------------

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks... (Circle one number on each line)

	All the time	Most of the time	Some of the time	A little of the time	None of the time
23. Did you feel full of life?	1	2	3	4	5
24. Have you been very nervous?	1	2	3	4	5
25. Have you felt so down in the dumps nothing could cheer you up?	1	2	3	4	5
26. Have you felt calm and peaceful?	1	2	3	4	5
27. Did you have a lot of energy?	1	2	3	4	5
28. Have you felt downhearted and depressed?	1	2	3	4	5
29. Did you feel worn out?	1	2	3	4	5
30. Have you been happy?	1	2	3	4	5
31. Did you feel tired?	1	2	3	4	5

32. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

All of the Time (1)	Most of the Time (2)	Some of the Time (3)	A Little of the Time (4)	None of the Time (5)
------------------------	-------------------------	-------------------------	-----------------------------	-------------------------

How TRUE or FALSE is each of the following statements for you? (Circle one number on each line)

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
33. I seem to get sick a little easier than other people	1	2	3	4	5
34. I am as healthy as anybody I know	1	2	3	4	5
35. I expect my health to get worse	1	2	3	4	5
36. My health is excellent	1	2	3	4	5

Annex 3. Amharic version Data collection tool

ጥያቄ	Coding categories
1.ጾታ	1.ወንድ 2.ሴት
2.እድሜ	
3.የመኖሪያ ቦታ	1.ከተማ 2.ገጠር
4.የጋብቻሁኔታ	1.ያገባ/ች 2.ያላገባ/ች 3.የፈታ/ች 4. የሞተበት/በት
5.የትምህርትደረጃ	1.ማንበብ እና መፅሐፍ የማይችል/ት 2.ማንበብ እና መፅሐፍ የሚችል/ት 3.የመጀመሪያ ደረጃ 4.ሁለተኛ ደረጃ 5.ድፕሎማ ወይም ከዛ በላይ
6.ወርሐዊአማካይየቤትገቢ?	
7.የሥራሁኔታ?	1.የግልስራ 2.የመንግስትሰራተኛ 3.ገበሬ 4.መንግስታዊያልሆነስራ 5. የቤት እመቤት 6. ተማሪ 7. የንግድ ስራ
8.ኤች.አይ.ቪ የምርመራ ውጤት ምን ይመስላል?	1.ሻይረሱ በደሜ ውስጥ አለ 2.ሻይረስ በደሜ ውስጥ የለም
9. የሳንባ ነቀርሳ በሽታ ከተያዙ ምን ያህል ጊዜ ሆኖታል	1.ከ አንድ አመት በታች 2.ከ አንድ አመት በላይ
10. የሳንባነቀርሳ በሽታ መድሃኒት ከቸረሱ ምን ያህል ጊዜ ሆኖታል	1.ከ አንድ አመት በታች 2.ከ አንድ አመት በላይ
11 የሳንባነቀርሳ በሽታ መድሃኒት አይነት	
12.ከተጠቀሱት እጾች ውስጥ የትኞቹን በተከታታይነት ተጠቅመዋል?	1.ሲጋራ 2.አልኮል መጠጦች 3. ጫት

ክፍል ሁሉት :- ለለፋት አራት ሳምንታት ከጤና ጋር ተያያዥ የሆኑ የኑሮ ደረጃን የሚዳስሱ ጥያቄዎች

ከዚህ በታች ለተዘረዘሩት ጥያቄዎች ለእያዳዱ አንድ መልስ ይመልሱ፡፡

1. ጠቅላላ አድርገው፤ ሲመለከቱት የጤንነት ሁኔታ ምን ይመስላል?

1. እጅግ በጣም ጥሩ ነዉ 4. ለክፉ አይሰጥም
2. በጣም ጥሩ ነዉ 5. መጥፎ ነዉ
3. ጥሩ ነዉ

2. ከባለፈዉ አመት ጋር ሲያስተያየት የአሁኑ ጤና ሁኔታዎ እንዴት ይገለጻል?

1. ከአምና እጅግ በጣም ይሻላል 5. ከአምና እጅግ በጣም ብሶብኛል
2. በተወሰነ መልኩ ይሻላል
3. ተመሳሳይ ነዉ/ለዉጥ የለዉም
4. በተወሰነ መልኩ ከአምና ብሶብኛል

ከዚህ በታች ለተዘረዘሩት ትጥያቄዎች በየቀኑ የሚያደርጓቸዉ ናቸዉ ተብሎ ይገመታል፡፡ የአሁኑ የጤና ሁኔታህ/ሽ እነዚህን እንዳታደርጋ(ግያ)ቸዉ ይከለክላል? መልሱ አዎ ከሆነ፤ መጠኑን እንዴት ትገልጻለህ/ሽ?

		አዎ በጣም አቅቶኛል	በመጠኑ አቅቶኛል	አይ፣ ያቃተኝ ነገር የለ
3.	ከበድያ ሉ እንቁስቃሴዎች ለምሳሌ መሮጥ፣ ከባድ እቃወችን ማንሳትና ከበድያ ሉ ስፖርቶችን መስራት ያቅቶታል?			
4	መጠነኛ ክብደት ያላቸዉን እንቁስቃሴዎች ማድረግ ለምሳሌ፤ ጠረጴዛ/ወንበር/የቤት ቁሳቁስ/ከቦታ ወደቦታ ማንቀሳቀስ እና ቀለል ያሉ ስፖርቶችን ማከናወን ያቅቶታል?			
5	አነስ ያለ ክብደት ያላቸዉን እቃ ማንሳት/መሸከም ለምሳሌ፤ አስቤዛዎችን፤ ቀለል ያሉ የቤት እቃዎችን ከቦታ ወደቦታ ማንቀሳቀስ ያቅቶታል?			
6	ብዙ ደረጃወችን መዉጣት ወይም ተራራማ በታዎችን መዉጣት ያቅቶታል?			
7	አንድ ደረጃ መዉጣት ወይም አነስ ያሉ ከፍታዎች መዉጣት ይቅታል?			
8	መታጠፍ፣ መንበርከክ፣ ማጎንበስ ያቅቶታል?			
9	ከሁለት ኪሎ ሜትር በላይ መራመድ			
10	ብዙ መንደሮችን በእግሮ መሄድ ያቅቶታል?			
11	ከአንድ መንደር ወደላላ አንድ መንደር በእግሮ መሄድ ያቅቶታል?			
12	ራሱን ችለዉ ገላውትን መታጠብ ወይም ልብስ መልበስ ያቅቶታል?			

ባለፉት 4 ሳምንታት ውስጥ ከዚህ በታች ከተዘረዘሩት ችግሮች ውስጥ በአካላዊ ጤና ምክኒያት በሥራዎ ወይም የየጎረቤት ተግባሮች ላይ ያጋጠሙ ችግሮች አሉ?

- 13. በስራ ወይም በሌላ እንቅስቃሴ የሚጠቀሙትን ሰዓት ሽራር፣ደወል/ቆራርጠዋል? 1.አዎ 2. አይደለም
- 14. መስራት ከሚፈልጉት በታች ነው ያከናውኑት? 1. አዎ 2. አይደለም
- 15. አንዳንድ ሥራወችን እንዳይሰሩ ገድቦታል? 1. አዎ 2. አይደለም
- 16. ስራዎን መስራት ከብዶታል ወይም ተጨማሪ አቅም ጠይቆታል? 1. አዎ 2. አይደለም

ባለፉት 4 ሳምንታት ውስጥ በስነልቦና ማለትም በድብርት ወይም በብስጭት ምክንያት በስራ ቦታ አልያም በተለመደው ለተቀን እንቅስቃሴ ላይ ከነዚህ ውስጥ ያጋጠሙት ችግር አሉ?

- 17. በስራ ወይም በሌላ እንቅስቃሴ የምትጠቀሙትን ሰዓት ቆራርጠዋል? 1. አዎ 2. አይደለም
- 18. መስራት ከሚፈልጉት በታች ነው ያከናውኑት? 1. አዎ 2. አይደለም
- 19. ስራዎን እንደሌላ ግዜ በጥንቃቄ አልስሩም? 1. አዎ 2. አይደለም

20. ባለፉት 4 ሳምንታት በምንያህል የአካል ወይም የስነ-ልቦና ችግሮች በማህበራዊ እንቅስቃሴ ላይ ከቤተሰብ፣ ከጎደኛዎ፣ ከጎረቤቶ ወይም ከሌሎች ጋር ባሎት ግንኙነት ላይ ተጽኖ አሳድሮታል?

- 1. ምንም ተጽኖ አላሳደረብኝም
- 2. በትንሹ
- 3. በመጠኑ
- 4. በከፍተኛ ሁኔታ
- 5. በጣም በከፍተኛ ሁኔታ

21. ባለፉት 4 ሳምንታት ምንያህል የሰውነት ህመም አጋጥሞታል?

- 1. ምንም አላጋጠመኝም
- 2. በጣም በትንሹ
- 3. በትንሹ
- 4. በመጠኑ
- 5. በከፍተኛ ሁኔታ
- 6. በጣም በከፍተኛ ሁኔታ

22. ባለፉት 4 ሳምንታት ውስጥ በሰውነት ውስጥ የሚሰማዎ ህመም ሥራዎ ላይ ምንያህል ተጽኖ ነበረዉ?

- 1. ምንም ተጽኖ አልነበረዉም
- 2. በትንሹ
- 3. በመጠኑ
- 4. በከፍተኛ ሁኔታ
- 5. በጣም በከፍተኛ ሁኔታ

ከዚህ በታች የተዘረዘሩት ጥያቄዎች ባለፉት 4 ሳምንታት እንዴት ይሰማዎት እና ነገሮች እንዴት እንደነበሩ የሚጠይቁናቸዉ።

እባኩን ከታች ከተዘረዘሩት አማራጮች መካከል ከአርሶ ሁኔታ ጋር የሚቀራረበዉን አንዱን ይመልሱ

ባለፉት 4 ሳምንታት ምንያህል ጊዜ

ተ.ቁ	ጥያቄ	ሁልጊዜ	በአብዛኛዉጊዜ	በተዋሰነጊዜ	አንዳንድጊዜ	በጣምትንሽጊዜ	በጭራሽ
23	ከመጠን ያለፈ/እጅግ ከፍተኛ ደስታ ተሰምቶታል?						
24	ብስጩ ሆነዎ ታውቃሉ?						
25	ምንም ነገር አይስደስተኝም ብለዉ የበታችኝነት ስሜት ተሰምቶታል?						
26	የተረጋጋና ሰላማዊ ስሜት ተሰምቶታል ይውቃል?						
27	ብዙአቅም(ጉልበት) አሎት?						
28	ሀዘንና ጭንቀት/የመተከዝስሜት ተሰምቶታል ይውቃል?						
29	እንደማይጠቅም ሰው ተሰምቶታል ይውቃል						
30	ደስተኛ ሰው ነበሩ?						
31	ድካም ተሰምቶታል ይውቃል?						

32. ባለፉት 4 ሳምንታት ውስጥ ምን ያህል ጊዜ የአካላዊ ጤና ችግር ወይም የ ስነ-ልቦና መረብ ሽ በማህበራዊ እንቅስቃሴዎች ላይ ለምሳሌ በቤተሰብ፣ በጓደኞች፣ በጎረቤቶች እንድሁም ከሌሎች ጋር ያሉት ግኑኝነት ላይ ተጽኖ አድርጎበታል?

1. ሁል ጊዜ
2. በአብዛኛዉ ጊዜ
3. አንዳንድ ጊዜ
4. በጣም ብዙ ጊዜ
5. በጭራሽ/ምንም

ከዚ በታች የተዘረዘሩት ጥያቄዎች ለእርሶ ምን ያህል እውነት ወይንም ሃሰት ናቸው፡፡

ተ.ቁ	ጥያቄ	በትክክል እውነት	በአብዛኛ ውሳኔ እውነት	አላውቅም	በአብዛኛ ውሳኔ ሃሰት	በትክክል ሃሰት
33.	ከሌላ ሰው ይልቅ በቀላሉ ለሌላ					
34	እንደማንኛዉም ሰው ጤናኛ ነኝ					
35	የጤናዬ ሁኔታ እየተባባሰ					
36	ጤናዬ እጅግ በጣም ጥሩ ነዉ					

መረጃ ስብሰቢዉ ስምና ፈርማ-----አመሰግናለሁ!!!

Declaration

I the undersigned resident that this thesis is my original work, in partial fulfillment of the requirement for certificate of specialty in internal medicine. I also declare that it has never been presented in this or any higher institution and all the resources and materials used in the research work have duly acknowledged.

Name of the Resident: Dr. Esrom Hagos

Signature: _____

Date: _____

Approval of Advisors

Name of Public Health Advisor: Takele Gezahegn (MPH, Assistant Professor)

Signature: _____

Date: _____

Name of Clinical Advisor: Dr. Anteneh Getachew (MD Assistant Professor of Internal Medicine)

Signature: _____

Date: _____