

**HEALTH RELATED QUALITY OF LIFE AND ITS ASSOCIATED
FACTORS AMONG TYPE 2 DIABETES MELLITUS PATIENTS
ATTENDING PUBLIC HOSPITALS AT HARARI REGION,
EASTERN ETHIOPIA**

MSc THESIS

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**Health Related Quality of Life and Its Associated Factors among Type 2
Diabetes Mellitus Patients Attending Public Hospitals at Harari Region,
Eastern Ethiopia**

**A Thesis Submitted to School of Graduate Studies College of Health and
Medical Sciences, Haramaya University**

**In a Partial Fulfillment of the Requirements for the Degree of
Master in Adult Health Nursing Specialty**

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ACRONYMS AND ABBREVIATIONS

ADA	American Diabetic Association
BMI	Body Mass Index
BSC	Bachelor of Science
DM	Diabetes Mellitus
EQ 5D 3L	Euro Quality of Life 5 Dimensions 3 Level
HFSUH	Hiwot Fana Specialized University Hospital
HRQOL	Health-Related Quality of Life
HU	Haramaya University
GDM	Gestational Diabetes Mellitus
IDF	International Diabetes Federation
IHRERC	Institutional Health Research Ethics Review Committee
JH	Jugal Hospital
MSC	Masters of Science
OR	Odds Ratio
QoL	Quality of Life
SD	Standard deviation
UK	United Kingdom
US	United States
VAS	Visual Analogue Scale
WHO	World Health Organization
WHOQOL-BREF	World Health Organization Quality of Life

ABSTRACT

Background: Diabetes mellitus is a complex chronic disease requiring continuous medical care and multifactorial risk reduction strategies beyond glycemic control. Continuous patient self-management, education, and support are essential to prevent acute complications and reduce the risk of long-term complications. In Ethiopia, even though several studies have assessed health-related quality of life among type 2 diabetes patients. But, still lack well-established utility values for diabetes patients based on different health states of the disease and there is a paucity of studies that employ societal preference and health-related quality of life. Albeit, it is not uncovered in the study area.

Objective: To assess health-related quality of life and its associated factors among type 2 diabetes mellitus patients attending public hospitals at Harari region, Eastern Ethiopia,

Methods: An institution-based cross-sectional study design was employed, from June 15 - July 15, 2021. The simple random sampling technique was used to selecting the participants. Health-related quality of life was assessed by using Euro quality of life 5-dimension 3 level questionnaires, valued by a general reference population of Zimbabwe tariff, since no value set in Ethiopia. EpiData version 3.1 was used for data entry and Stata version 16 was used for analysis. Multivariate linear regression was used to identify factors associated with health-related quality of life. P-value less than 0.05 was considered statically significant and strength of association was measured by coefficient with 95% CI.

Result: A total of 414 patients participated in this study, overall mean health-related quality of life of the study participants was 0.714 (± 0.20). Age group above and equal to 65 years old ($B = -0.005$), female ($B = -0.067$), being unemployed ($B = -0.034$), widowed ($B = -0.083$), and presence of complication ($B = -0.058$) were inversely associated with overall health-related quality of life ($p < 0.05$).

Conclusion: The overall health-related quality of life among type 2 diabetic patients was 0.714. Old age, female gender, being unemployed, being widowed, and presence of complications, were inversely associated with health-related quality of life. Special attention should be given to the elderly, female, unemployed, and patients who develop a complication.

Keywords: Diabetes, Euro quality of life 5-dimension 3 level, Health-related quality of life, Quality of life, Type 2 diabetes

1. INTRODUCTION

1.1. Background

Diabetes mellitus (DM) is a metabolic disorder of multiple etiology characterized by chronic hyperglycemia with disturbances of carbohydrate, fat, and protein metabolism resulting from defects in insulin secretion, insulin action, or both (WHO, 2016). It occurs either when the pancreas fails to produce sufficient insulin which type 1 diabetes or when the body cannot effectively use the produced insulin which is called type 2 diabetes (WHO, 2016; Shaw *et al.*, 2010).

Diabetes is a complex, chronic illness requiring continuous medical care with multifactorial risk reduction strategies beyond glycemic control (ADA, 2020). Ongoing patient self-management education and support are critical to preventing acute complications and reducing the risk of long-term complications (ADA, 2020)

Globally, 463 million people or (9.3%) of adults are diabetic patients, among this 90% of them are type 2 DM and 80% live in Low and Middle-income countries (LMICs), with higher prevalence in urban (10.8%) than rural (7.2%) areas and high-income (10.4%) than low-income countries (4.0%) (IDF, 2019). According to the IDF Africa region report in 2019, about 19.4 million adults were estimated to have diabetes, representing a regional prevalence of 3.9%. It also reports 1.9 million people of Ethiopia have diabetes with a 4.36% national prevalence of diabetes (IDF, 2019).

Globally 11.8% of all age's mortality, in Africa 6.8% of adult's deaths, and North American Region 13.7% was due to diabetes (Saeedi *et al.*, 2020). WHO estimates that Type 2 diabetes accounts for 90% of all diabetes (WHO, 2016). It is a common condition and a serious global multidimensional health problem with consequences of chronicity and complications like disability, decreased health-related quality of life (HRQOL), and premature death (Zhang *et al.*, 2010; IDF, 2019).

World Health Organization defines the quality of life as an “individual's perception of their position in life in the context of the culture and value systems in which they live and concerning their goals, expectations, standards and concern”(WHO, 1998). Health-related quality of life (HRQOL) refers to the physical, psychological, and social domains of health that are influenced

by a person's experiences, beliefs, expectations, and perceptions; therefore, healthcare providers should strive to understand the physical, emotional, and social impact of chronic diseases such as DM (WHO, 1998;Kim, 2014).

Most successful treatments for chronic illness are measured by overall survival and control of major physical symptoms. These factors are crucial to evaluate how much chronic disease and their treatment affect a patient's overall sense of wellbeing and/or quality of life (QoL) (Sneeuw *et al.*, 2002). Diabetes is chronic disease with an impact on health status and quality of life(Boyle *et al.*, 2001)

Therefore, measuring health-related quality of life (HRQOL) is important, because they predict the individual's capacity to manage the disease and maintain long-term health and well-being. It is also increasingly recognized as an important health outcome in its own right, representing the ultimate goal of all health interventions.

1.2. Statement of problem

Diabetes is a major health issue that has reached alarming levels: today, nearly half a billion people are living with diabetes worldwide. It is one of the fastest-growing global health emergencies currently (IDF, 2019).

Diabetes mellitus negatively influences HRQOL. This negative influence affects many aspects of a person's life, including the psychological impact, dietary restrictions, changes in social life, symptoms of an inadequate metabolic system, chronic complications, and lifelong infirmities (Aschalew *et al.*, 2020; Sreedevi *et al.*, 2016; Al Hayek *et al.*, 2014b).

The study was done in Botswana (Rwegerera *et al.*, 2019) and Felege Hiwont Referral Hospital, Ethiopia (Reba *et al.*, 2018), indicating that diabetic patients have poor HRQOL. Poor HRQOL was associated with the presence of complications, duration of disease, old age, and female (Zurita-Cruz *et al.*, 2018). A cross-sectional study conducted in Belgravia, also shows that more than half of the study participants had poor QOL in older age, obesity, longer duration of DM (Raghavendra *et al.*, 2017).

Poor health-related quality of life leads the patients to trouble participating actively in the social and economic life of the community. Patients with poor quality of life may have restricted social life, difficulty in the accomplishment of roles, school or work absence, poor sleep, increased hospital visits, hospitalizations, and worsening of glycemic control (Imayama *et al.*, 2011)

Studies also indicated that the HRQOL of patients with DM is decreased by different domains of QoL such as role limitation, emotional disturbances, pain, and fatigability. Besides these factors like socio-demographics and economic status, behavioral, clinical, and social-related factors also affect HRQOL (Wegeberg *et al.*, 2019; Gredig and Bartelsen-Raemy, 2017). Depression was also the major determinant factor in HRQOL concerning physical and psychological domains in developed and low-income countries (Gebremedhin *et al.*, 2019a; Jing *et al.*, 2018).

Type 2 Diabetes Mellitus has many effects on the well-being of a person, assessment of quality of life is crucial since it predicts the individual's capacity to manage the disease, maintain long-term well-being and increasingly recognized as an important health outcome (Singh and Bradley, 2006).

According to American Diabetes Association recommendations, HRQOL monitoring is a key measure for effective management and improved clinical outcomes with the recommendation that providers monitor the burden of treatment and life conditions of patients when prescribing treatments (ADA, 2020). Despite these recommendations, glucose levels are poorly controlled and the HRQOL of patients is still not well studied (Al-Shehri, 2014;Saleh *et al.*, 2014).

Diabetes mellitus negatively affects health-related quality of life. This health-related quality of life in diabetic patients is related to a complication of DM, duration of DM, level of education, age, and female gender (Sreedevi *et al.*, 2016).

In Ethiopia, even though programs have been launched regarding chronic disease management, prevention, screening, diagnosis, treatment and care, little is emphasized on factors that affecting HRQOL among patients. National Guideline on major non-communicable diseases lacks the specific areas of HRQOL dimension which is affected by the disease. The existing articles and reviews have tried to indicate the epidemiology, complications, therapies, comparisons of treatments, and health strategies but the data regarding contributing factors of HRQOL and how much it is affected by the condition is scarce (FMOH, 2016).

In Ethiopia, several studies have assessed HRQoL of type 2 DM patients using the WHOQOL. However, there is a paucity of studies that employ tools such as the EQ-5D that incorporate societal preference and provide effective means to assess the impact of the disease across different health states. As a result, health care decision-makers in Ethiopia still lack well-established utility values for DM patients based on different health states of the disease. To this effect, the current study aimed to assess HRQoL and determine health state utility values and factors that influence the values among type 2 DM patients attending public hospitals of Harari Region, Eastern Ethiopia.

1.3. Significance of study

This study will be helpful for further identification of determinants of HRQOL among individuals with type 2 diabetes. This will be a guide to form targeted intervention strategies to improve outcomes for this population group and will assist health care professionals to have an understanding of factors related to HRQOL. This also enables them to manage diabetes appropriately and study will be helpful to implement effective strategies that would lead the patient to an optimum level of functioning. The potential findings of this study will help policymakers, program planning bodies, and service providers to evaluate the quality of existing policies, treatment strategies, programs, and treatment guidelines and to improve or change it to attain optimum level of functioning and help as a baseline for future studies. Finally, since there is limited research at the country level, this study can be used as a resource for other studies in this regard.

1.4. Objective

1.4.1. General objective

To assess health-related quality of life and its associated factors among type 2 diabetes mellitus patients attending public hospitals at Harari Region, Eastern Ethiopia, June 15- July 15, 2021.

1.4.2. Specific objective

1. To assess health-related quality of life among type 2 diabetes mellitus patients attending public hospitals at Harari Region, Eastern Ethiopia.
2. To identify factors associated with health-related quality of life among type 2 diabetes mellitus patients attending public hospitals at Harari Region, Eastern Ethiopia.

2. LITERATURE REVIEW

2.1. Introduction

Health-related quality of life is an important outcome for persons with type 2 diabetes, as it has been used to evaluate the impact of the disease and its treatment on individuals and health care costs. The disease itself can harm the quality of life. Several factors have been identified as predictors of HRQOL and diabetes-related quality of life in type 2 diabetes, including older age, female sex, number of diabetic complications, presence of comorbidities, and insulin use (Wexler *et al.*, 2006). HRQOL provides a multidimensional perspective that encompasses a patient's physical, emotional, and social functioning (IDF, 2019).

Literature are searched from international databases (PubMed, Medline, Web of Science, CINAHL, Scopus, and ERIC) through the following search terms: [“diabetes” AND “quality of life” AND “health-related quality of life” AND “type 2 DM”]. Moreover, Google was also used for extra publications.

Diabetes mellitus negatively affects health-related quality of life. This health-related quality of life in diabetic patients is related to a complication of DM, duration of DM, level of education, age, and female gender.

2.2. Health-related quality of life among type 2 DM patients

According to a cross-sectional study in Portugal, the HRQOL score was 0.6772 in the EQ-5D-3L within the dimensions of mobility, self-care, and usual activities, more than 70% of the sample scored at level 1 (no problems). In the dimensions of pain/discomfort and anxiety/depression, more than 50% of the participants scored at level 2 (some problems) (Cardoso *et al.*, 2016).

A study conducted in the largest governmental diabetes center in South of Iran, the mean and median of EQ-5D-3L index of patients were 0.75 ± 0.006 and 0.72 ± 0.20 , respectively. (Zare *et al.*, 2020). Another study conducted in Iran also shows that the mean EQ-5D score was 0.70 (Javanbakht *et al.*, 2012). The survey conducted in Norway on both types of diabetes patients shows that health-related quality of life of EQ5D index for type 2 diabetes patients was 0.73 (Solli *et al.*, 2010)

A descriptive cross-sectional study conducted from July to December 2015 in India, suggests that patients with type 2 diabetes have a poor quality of life with reporting EQ 5D levels 1 to 5 by dimensions. Self-care was reported at level 1 by 86.8% while pain/discomfort scored lowest at 46.6% for level 1 (Parik and Patel, 2019). The study carried out in I revealed that the overall EQ-5D index score was 0.77 (0.75–0.79) the highest percentage of self-reported health problems was in the pain/discomfort dimension (61%) (Arifin *et al.*, 2019).

Other cross-sectional studies conducted in Bangladesh from January to June 2018, suggest that more than half of the study participants (53.4%) were ranked as “average” HRQOL. Overall, 64% of respondents had a “problem” at least in one of the dimensions of the EQ-5D-5L. Among the five dimensions, the highest reported “problem” was 79.8% for anxiety/depression, 77.7% for pain/discomfort, and 60.1% for mobility (Barua *et al.*, 2021).

A cross-sectional study conducted from November 2017 to April 2018 in Saudi Arabia among 378 patients with Type 2 diabetes mellitus result shows that moderate health-related quality of life, as reported by the mean index score of 0.808 with more than a quarter of patients with severe-extreme health state in some or all domains. Among the respondents, 88%, 51%, 50%, 43%, and 31% were agreed as having no problem in terms of self-care, anxiety or depression, usual activities, mobility, and pain or discomfort respectively (Alshayban and Joseph, 2020b). Another study conducted in Jordan shows that the mean of the total EQ-5D score was 0.724 and 0.675 (SD = 0.14) (Jarab *et al.*, 2019; Jarab *et al.*, 2021)

A cross-sectional study conducted on 147 diabetes patients attending the University of Nigeria Teaching Hospital, Enugu State, Nigeria shows that the mean health-related quality of life of respondents as was 0.72 ± 0.13 (Adibe *et al.*, 2018). In another cross-sectional study in southeastern Nigeria also the mean index was 0.78

2.3. Factors associated with HRQOL among type 2 DM patients

2.3.1. Socio-demographic characteristics

A study conducted in the United Arab Emirates shows that three factors significantly influenced the total HRQOL was the presence of diabetes complications, duration of diabetes, and marital status (Bani-Issa, 2011). Other study conducted in Saudi Arab also shows that male gender,

high monthly income, having no diabetes-related complications were prone to have a higher index score compared to the corresponding contrary group (Alshayban and Joseph, 2020a)

A cross-sectional study conducted in Portugal, suggesting that the EQ-5D-3L observed higher mean scores in the age group of 30-49 years than in the other age groups, with these differences being statistically significant ($p < 0.01$). Divorced/separated individuals had the highest mean score in the EQ-5D-3L and this difference was statistically significant ($p < 0.01$) (Cardoso *et al.*, 2016).

A cross-sectional study was conducted to evaluate QoL among Iranian type 2 diabetes patients in Ahvaz, Iran. Numerous demographic and psychosocial determinants affect the QoL of diabetic patients. Some socio-demographic variables associated with QoL in diabetes patients parallel those in the general population. Specifically, men seem to report better QoL than women; It was stated that women with diabetes appeared to have more depression and anxiety, worse HRQOL, and lower scores for general and mental well-being than men, and their anxiety scores (Mohammadi *et al.*, 2016). Similarly, in a study conducted in the largest governmental diabetes center in the South of Iran, the median of EQ5D in men was significantly higher ($p = 0.006$) in comparison to women (0.725 versus 0.710). ($p = 0.108$) (Zare *et al.*, 2020). A national survey conducted in Iran has also reported a significant association between employment and HRQOL of patients with type 2 DM (Javanbakht *et al.*, 2012)

A descriptive study conducted in India suggests that age, male gender, uncontrolled disease, and presence of comorbidities can worsen QOL further. Self-care was reported at level 1 by 86.8% while pain/discomfort scored lowest at 46.6% for level 1. Mobility, self-care, usual activities, and pain/discomfort were most affected in the age group 71 years and above with 61.4%, 80.7%, 61.4%, and 36.9% reporting level 1, respectively. Anxiety/depression affected the age group 18–30 years most with 42% reporting at level 1 that is no problem (Parik and Patel, 2019).

Another cross-sectional study carried out in Indonesia shows that male participants had a higher EQ-5D index score compared to females, and the highest percentage of self-reported health problems was in the pain/ discomfort dimension (61%). Factors identified as being significantly associated with lower HRQOL EQ-5D index scores, not undergoing T2DM therapy, and being a housewife (Arifin *et al.*, 2019).

According to a study carried out in Bangladesh, patients with type 2 diabetes have a poor quality of life as measured by EQ 5D 5L. Age, male gender, income, and the presence of comorbidities can worsen it further (Barua *et al.*, 2021). Another study conducted in Jordan shows that identified women gender ($\beta = -0.252$; $P < 0.01$), number of medications ($\beta = -0.423$; $P < 0.01$), and insulin therapy ($\beta = -0.205$; $P < 0.05$) as being significantly associated with poor HRQoL (Jarab *et al.*, 2021).

Another study conducted In Egypt regarding different studied variables showed that QoL was significantly affected by sex. Females had worse QoL than males ($p = 0.004$) and the total mean QoL score for males was significantly better than females (25.2 ± 7.3 vs. 29.1 ± 9.5 , respectively) with $p = 0.004$ (Hassan *et al.*, 2017).

The study done in Uganda indicate the health-related quality of life of patients is 0.87 and 0.82 lower in the dimension of role limitation and physical endurance in patients aged 50-59 as compared to patients less than 50 (Nyanzi *et al.*, 2014)

The study done in Botswana indicate that the determinants were female gender and older age which was worse physical composite scores. Besides, the musculoskeletal disease was associated with worse mental composite scores. On the other hand, an increased number of diabetic complications was associated with worse scores for both physical and mental composite scores (Rwegerera *et al.*, 2019).

In another cross-sectional study conducted in Felege Hiwot Referral Hospital, North West Ethiopia the HRQOL of patients diagnosed with type 2 DM is affected by their marital status, occupation and duration of DM, and presence of DM complication (Reba *et al.*, 2018). A similar study conducted in Mizan Tepi Ethiopia shows that age, complication, and BMI were inversely associated with overall HRQOL (Gebremedhin *et al.*, 2019b). Another study conducted in Nekemte specialized hospital shows that age, male gender, BMI, absence of complication was associated with health-related quality of life (Feyisa *et al.*, 2020)

2.3.2. Clinical factors

A study conducted in Ontario, Canada 2016, indicated among 1143 participants reduction in HRQOL is associated with diabetic complications and the duration of therapy. Based on the OLS model, reductions in HRQL were associated with duration of diabetes (-0.0015 , $SE =$

0.0006), 6 experiencing a myocardial infarction (MI) (-0.059, SE= 0.017), amputation (-0.063, SE = 0.059), stroke (-0.046)(O'Reilly *et al.*, 2016).

Studies that have examined the effect of diabetes mellitus on health-related quality of life in Indian patients with complication shows that HRQOL of patients was significantly lower in diabetes with DR when compared with those without DR with the maximum effect seen on general health, general vision, and mental health. Quality of life decreased as the duration of retinopathy and severity of retinopathy increased ($p < 0.001$) (Pereira *et al.*, 2017).

A cross-sectional study was conducted among 283 type 2 DM patients during June 2011 and September 2012 at a major tertiary hospital in Riyadh, Saudi Arabia. This shows that there was a negative association between diabetes duration and HRQOL. The longer duration of diabetes is associated with poor HRQOL. It also revealed that a significantly better HRQOL among insulin-treated patients than oral hypoglycemic drugs-treated patients. Besides, the combination of insulin and oral hypoglycemic drugs treated patients had better HRQOL than those treated with insulin alone (Al Hayek *et al.*, 2014a).

According to a cross-sectional survey conducted in Vietnam, results from the regression model indicated that those suffering from diabetes complications were more likely to report lower HRQOL (Tran Kien *et al.*, 2021). Another Study that has examined the effect of type 2 diabetes mellitus on health-related quality of life in Mulago, Uganda a sample of 219 patients shows that diabetic complications have an association in lowering the quality of life in diabetic patients as compared with non-diabetic patients. Health-related quality of life of patients is 0.87 and 0.82 lower in the dimension of role limitation and physical endurance in patients aged 50-59 as compared to patients less than 50 (Nyanzi *et al.*, 2014).

2.3.3. Health service factors

Cross-sectional study conducted in six European countries, shows that HRQOL indices decrease with increasing travel time/kilometer to the provider and increasing waiting time in a health facility (Konerding *et al.*, 2017)

Cross-sectional study conducted in Bangladesh, majority number of diabetic patients' traveling distance and time were only 0-5 km and 0-30 min to get to service, however, they had to spend half-day at the hospital. It might happen because of fixed timing for visiting doctors, collecting

the specimen, overcrowded hospital services, and the growing number of diabetes patients. This shows the longer the traveling and waiting time affect health-related quality of life(Siddique *et al.*, 2017)

2.4. Conceptual framework

The conceptual framework that will be used directly and indirectly related to major variables of the study is health-related quality of life derived from different literature reviews (Reenen *et al.*, 2018; Spasić *et al.*, 2014; Green *et al.*, 2005).

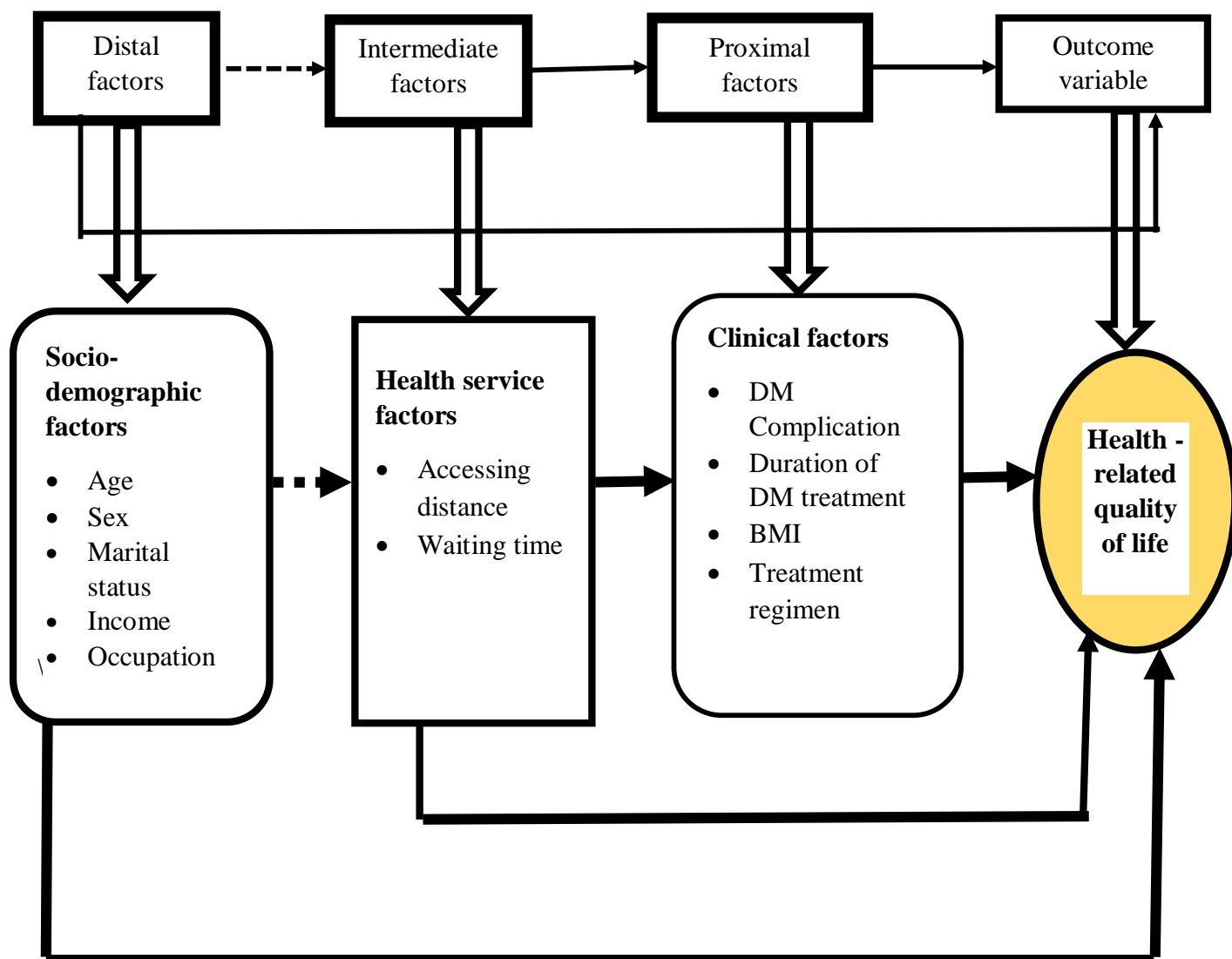


Figure 1. Schematic representation of conceptual framework for possible associated factors that affect health related quality of life among type 2 diabetes mellitus patients attending public hospitals at Harari region, Eastern Ethiopia, 2021.

3. MATERIALS AND METHODS

3.1. Study Area and Period

This study was conducted at two public hospitals, Hiwot Fana Specialized University Hospital and Jugal Hospital, in Harar town from June 15 – July 15, 2021. Harar town is the capital city of the Harari region located 526 km away from Addis Ababa with an estimated area of 334 square kilometers and according to the population projection report total population of the town is 246,000 (CSA, 2017). In the town, there are 45 health facilities (34 health posts, 8 health centers, 3 hospitals).

Hiwot Fana Specialized University Hospital was established during Italian territory (1928-1933). It was named Chaffee hospital but now the hospital is a teaching hospital under Haramaya University. There are a total of 285 types 2 DM patients who were active on follow-up in HFSUH. In JH there are 250 types 2 DM patients who were active on follow-up. The total catchment population is expected to be 5.8million of whom 2.85 million are females and 2.95 million are male population (HFSUH, 2019). It serves the population of the Harari region, Somali region, Dire Dawa administration, and East Hararghe region.

3.2. Study design

Institution-based cross-sectional study was conducted.

3.3. Population

3.3.1. Source of populations

All type 2 diabetic patients who visit public hospitals in Harari regional state.

3.3.2. Study population

Patients with type 2 diabetes mellitus who attended follow-up at Hiwot Fana specialized comprehensive hospital and Jugal hospital during the study period.

3.4. Inclusion and Exclusion criteria

3.4.1. Inclusion criteria

The patient who has been clinically diagnosed for type 2 diabetes mellitus, age 18 years and above and those attending follow-up at HFSUH and JH.

3.4.2. Exclusion criteria

- ✓ Patients who were unable to communicate due to serious medical and psychiatric illness during data collection.
- ✓ Newly diagnosed in the last three month , the mother with GDM

3.5. Sample Size determination and sampling technique

3.5.1. Sample size determination

The sample size was calculated by using a single mean formula, by considering the following assumptions: mean and standard deviation overall HRQOL of among type 2 DM patients was 52.6 ± 12.1 (Reba *et al.*, 2018), the margin of error was decided to be 1.2 and 95% ($z\alpha/2 = 1.96$) confidence interval (CI) with 10% non-response rate and computed as follows.

Overall HRQOL SD = ± 12.1

$$n = \frac{(z \alpha/2)^2 * s^2}{E^2} = \frac{(1.96)^2 \times (12.1)^2}{1.44} = 562.5 = 391$$

Then by adding a 10% non-response rate the final sample size becomes 430.

Where: n =minimum required to sample for the study.

Z = standard normal distribution ($z=1.96$) with confidence interval of 95%.

S = standard deviation (SD= 12.1) (Reba *et al.*, 2018)

E= is tolerable margin of error (E= 1.2)

For the second specific objective (to identify the factors associated with health-related quality of life). Sample size can be calculated using single mean formula (table 1).

Table 1. Sample size determination for a study on factors associated with health-related quality of life among type 2 DM patients attending public hospitals at Harar Region, Eastern Ethiopia, 2021.

Factors	$z\alpha/2$	SD	E	final sample size	Reference
Age	1.96	9.84	1.14	315	(Gebremedhin <i>et al.</i> , 2019a)
BMI	1.96	3.7	0.43	312	(Gebremedhin <i>et al.</i> , 2019a)
Complication	1.96	P (34.1%)	0.05	380	(Gebremedhin <i>et al.</i> , 2019a)
Income	1.96	6.5	1	162	(Reba <i>et al.</i> , 2018)

Finally, sample size calculated for objective one was taken (430) as a final sample size

3.6. Sampling procedure

A simple random sampling technique was used by using registration book as sampling frame to select study subjects out of all type 2 DM patients attending treatment units at Hiwot Fana specialized University hospital (HFSUH) and Jugal hospital (JH) at the time of the study. The study subjects sample size allocation for two hospitals (Hiwot Fana specialized University hospital (HFSUH) and Jugal hospital (JH)) was done using the proportional sample size allocation formula.

$$n_i = n \frac{N_i}{N}$$

n_i = Sample size per hospital

n = Total sample size

N_i = Total population of DM patients per hospital

N = Total population of type 2 DM at Hiwot Fana specialized University hospital (HFSUH) and Jugal hospital (JH)

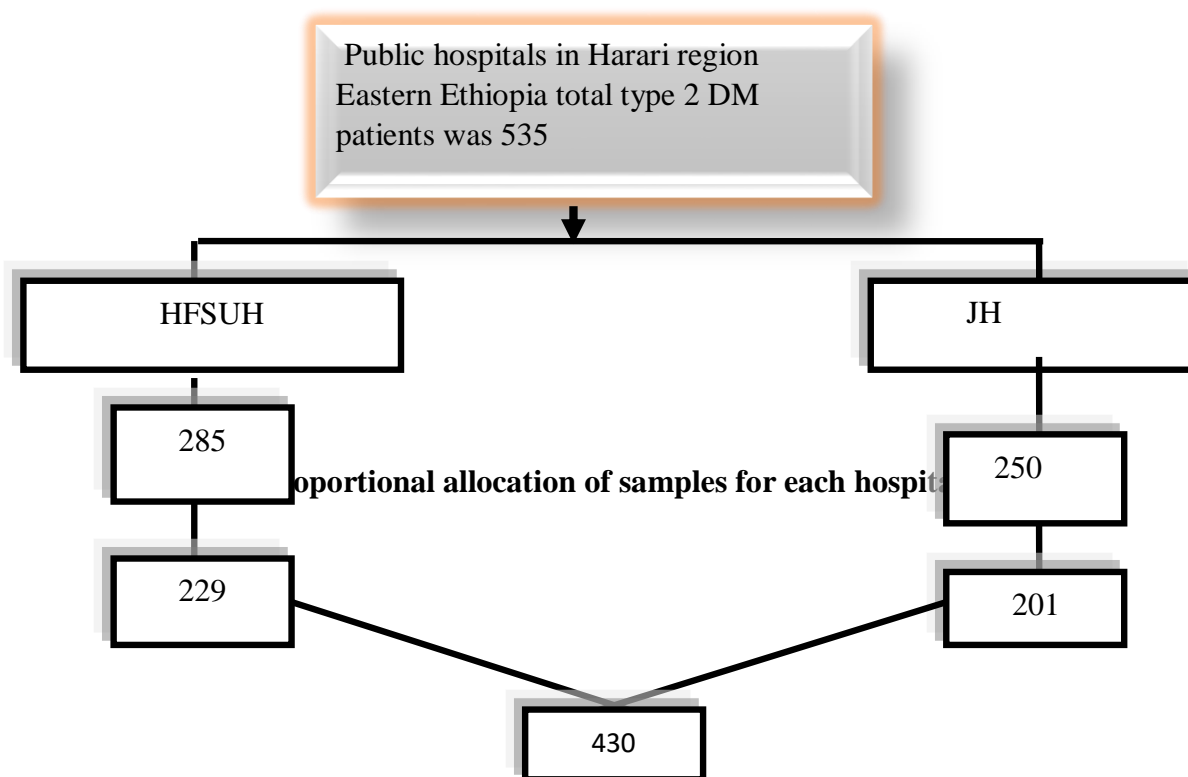


Figure 2. Sampling procedure for health-related quality of life and its associated factors among type 2 diabetes mellitus patients attending at public hospitals of Harari region, Eastern Ethiopia, 2021.

3.7. Data Collection Methods

3.7.1. Data collection instrument

A structured questionnaire consisting of socio-demographic and clinical characteristics was used. The health-related quality of life was determined using the EQ-5D-3L. EQ-5D involves patients self-reporting on their health status from five perspectives: mobility (MO), self-care (SC), usual activities (UA), pain/discomfort (P/D), and anxiety/depression (A/D). Each perspective has “no problems”, “some or moderate problems” and “extreme problems” constituting a three-level scale, which scores from 1 (no problem) to 3 (extreme problems). Responses of the EQ-5D were presented separately for each perspective in terms of a profile (EQ-5D profile) and converted into a weighted index (EQ-5D index) using the population preference scores of Zimbabwe since EQ-5D 3L has seldom been used in Ethiopia and there is no value set. The questionnaire was adopted from a validated instrument of the EQ 5D 3L tool (Reenen *et al.*, 2018). The English version questionnaire was translated to Amharic and Afan Oromo (local language). Data were collected using an interviewer-administered questionnaire.

3.7.2. Data Collectors and Supervisors

Interviewer-administered structured questionnaires were collected by two-diploma nurses and two BSc nurses and supervised by two BSc nurses who fluently speak both Afan Oromo and Amharic languages.

3.7.3. Data Collection Procedures

The data was collected through face-to-face interviews by using the structured and semi-structured questionnaire which was translated from the English version to the Amharic and Afan Oromo version. Some of the clinical information was corroborated from patient records. All consecutive eligible patients were recruited into the study.

3.8. Study Variable

3.8.1. Dependent variable:

Health-related quality of life

3.8.2. Independent variable:

Socio-demographic (age, sex, marital status, educational status, and income level); Clinical factors (disease duration, DM complication, BMI, and duration of therapy) and Health service factors (accessing distance, waiting time for service)

3.9. Operational definition of terms

Health-related quality of life; The values for each dimension according to the Zimbabwe general population health states time trade off by the EQ 5D 3L calculated. The mean utility was calculated by the multiplicative assumption theory according to the next formula.

$$1- (U)X = 1 - \sum_{j=1}^n K_{juj}(x_j)$$

Body mass index (BMI): is calculated as weight in kilogram divided by height meter square. BMI is categorized as BMI Weight Status below 18.5 Underweight, 18.5 – 24.9 normal, 25.0 – 29.9 Overweight and 30.0 and Above Obese.

3.10. Data Quality control

The questionnaire was translated to Amharic and Afan Oromo languages and translated back to English again to ensure its consistency. The training was given to data collectors and facilitators /supervisors by the principal investigator about how to use of questionnaire, the ethical principle of confidentiality, and data management before data collection. The pre-test was done on 5% of the sample size, at Bisidimo primary hospital. Results were not included in the result of the finding. Based on the finding of the pretest data, the questionnaire was checked for its clarity, simplicity, and understandability. The data collectors were supervised daily and the filled questionnaires were checked daily by the supervisors and principal investigator for completeness.

3.11. Data Processing and Analysis

Each questionnaire was checked for completeness and consistency by principal investigators and supervisors. Then data was cleaned, coded, and double entered by using EpiData version 3.1, and Stata version 16 was used for analysis. Descriptive statics of numeric variables were presented in means and standard deviations. Categorical variables were presented using frequency and percentage. The HRQoL utility scores (index values) were calculated using the Zimbabwean value set data due to the lack of utility score data for the Ethiopian population. Simple and multivariable linear regression was performed to identify factors associated by using

the overall index mean as the dependent variable. Only variables responsible for significant variation ($p < 0.25$) in the simple linear regression analyses were included in multivariate linear regression. For the goodness of model fit, all linear regression assumptions, adjusted R-squared, residual plots (p-p, q-q), SEs, and outliers were considered. Multicollinearity was checked and the maximum variable inflation factor reported was 1.54, which indicates that there was no multicollinearity threat. A p-value less than 0.05 was considered as an independently associated factor.

3.12. Ethical Considerations

Ethical issues were approved by Haramaya University College of health and medical sciences Institutional health research ethical review committee (IHRERC) and a formal permission letter was obtained and it was taken to the selected public hospitals before data collection. Before interviewing the questionnaires, the objectives and advantages of the study were clearly explained to the participants, and informed voluntary written and signed consent was obtained. Confidentiality was ensured throughout the accomplishment of the study. Participants were informed that their participation is voluntary that they could withdraw from the study at any time if they wish to do so. All the information given by the respondents was used for research purposes only. On top of that, to keep the anonymity of study participants, code numbers rather than personal identifiers were used. Finally, the questionnaires were kept locked after data entry had been completed. During the data collection period, all the guide line of COVID-19 prevention was applied.

3.14. Information Disseminations

The finding of this study was submitted and presented to the college of health and medical sciences, Haramaya University. After having approval from the IHRERC, it will be communicated to concerned bodies through reports. Also, the study findings will be disseminated to the regional health bureau, respective health facility, and for both HFSUH and JH. The findings also will be presented in various workshops and conferences and all possible efforts will be made to publish the findings in peer-reviewed journals. Attempts will be made to publish the on reputable national or international journal.

4. RESULTS

4.1 Socio-demographic characteristic of respondents

From a total sample of 430 study participants, 414 participated in the study, giving a response rate of 96%. About half of the participants (50.5%) were females and the mean age was (56.6 ± 10.4) years. Most of the participants (79.5%) were living in urban and about (98, 23.7%) participants were retired on occupation. A little over half (213, 51.45%) of the study participants were married. The average estimated monthly income was 2500 Ethiopian birr (table 2).

Table 2. Basic Socio-demographic characteristics of type 2 DM patients attending public hospitals at Harari region, Eastern Ethiopia, 2021(n=414)

Variable	category	Frequency	Percentage
Age (mean \pm SD) in years		56.6 \pm 10.37	
Sex	Male	205	49.5
	Female	209	50.5
Residence	Urban	329	79.5
	Rural	85	20.5
Marital status	Single	51	12.32
	Married	213	51.45
	Widowed	72	17.39
	Divorced /Separated	78	18.84
Occupation	Unemployed	77	18.6
	Gov't and NGO Employed	66	15.94
	Merchant	46	11.11
	Private	70	16.91
	Farmer	57	13.77
	Retired	98	23.67
Average monthly income (media with 50 th IQR)		2500	

4.2. Diabetes and health service-related characteristics of the participants

Nearly half of (46.38%) the participants were on oral anti diabetics' medication, duration of the therapy of the study participants median was 6 years. About half of the participants (50%) reported developing complications. About (30.68%) of type two diabetic patients had traveled 2.5-5 kilometers to access the health service facilities. To get service patients waiting time median were 2 hrs. By standard classification of BMI, more than half of them (54%) were normal, while those with overweight BMI range are 29.5 percent. (Table 3)

Table 3. Diabetes and health service-related characteristics of type 2 DM patients attending public hospitals at Harari region, Eastern Ethiopia, 2021 (n= 414).

Characteristic	Categories	Frequency	Percent
Current treatment	Oral	192	46.38
	Injection	75	18.12
	Both oral and injection	147	35.51
DM complication	Yes	207	50.0
	No	207	50.0
Distance health facilities in Kms.	1- 2.5	104	25.6
	2.5- 5	127	30.68
	5 - 7.5	92	22.22
	>7.5	89	21.5
BMI	Underweight	33	7.79
	Normal	223	53.86
	Overweight	122	29.47
	Obese	36	8.7
Duration of therapy (median 50 th IQR) in year		6	
Waiting time (median, 50 th IQR) in hr.		2	

DM complication

Six types of DM-related complications were recorded from the study subject's medical record. Among 414 type2 DM patients, the total number of patients who have DM complications was 207 (50 %). A little more than half of the participants (52.7%) were reported hypertension. (Figure 4).

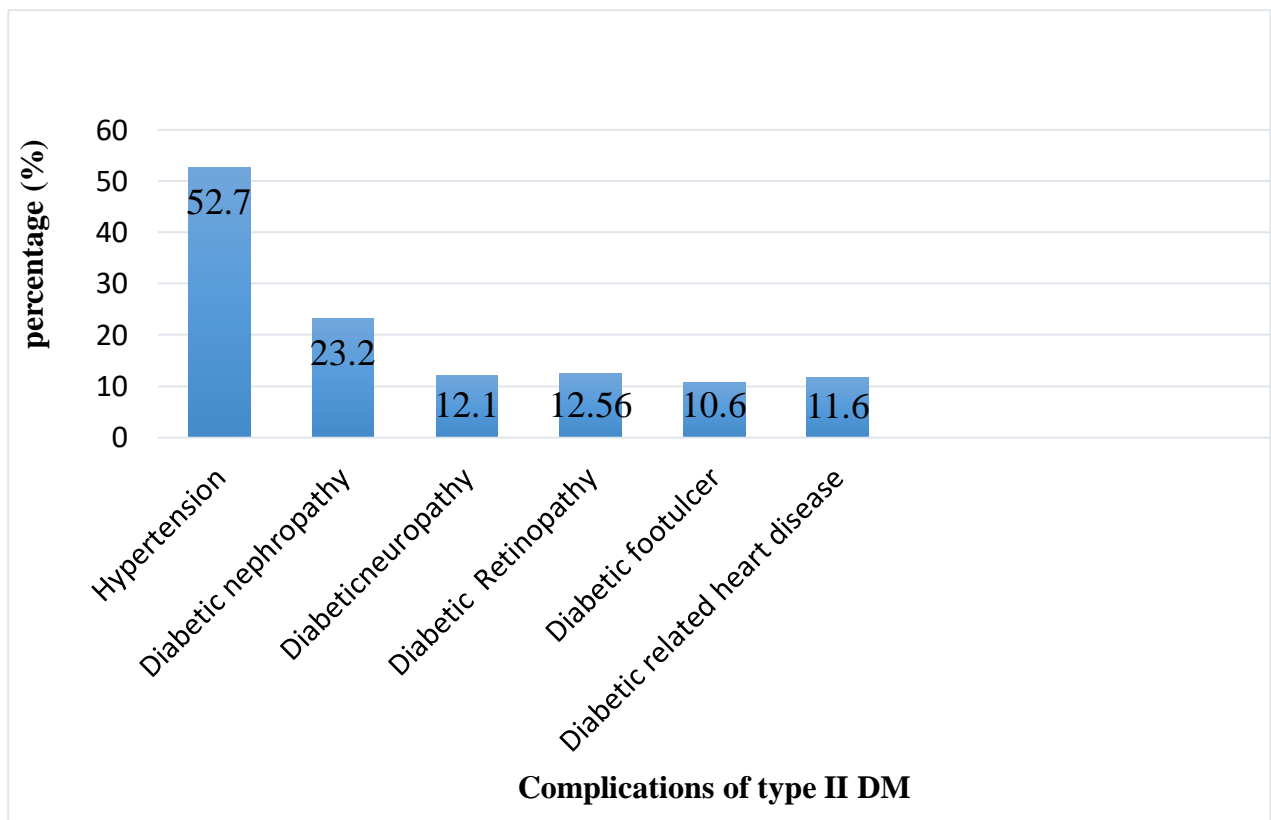
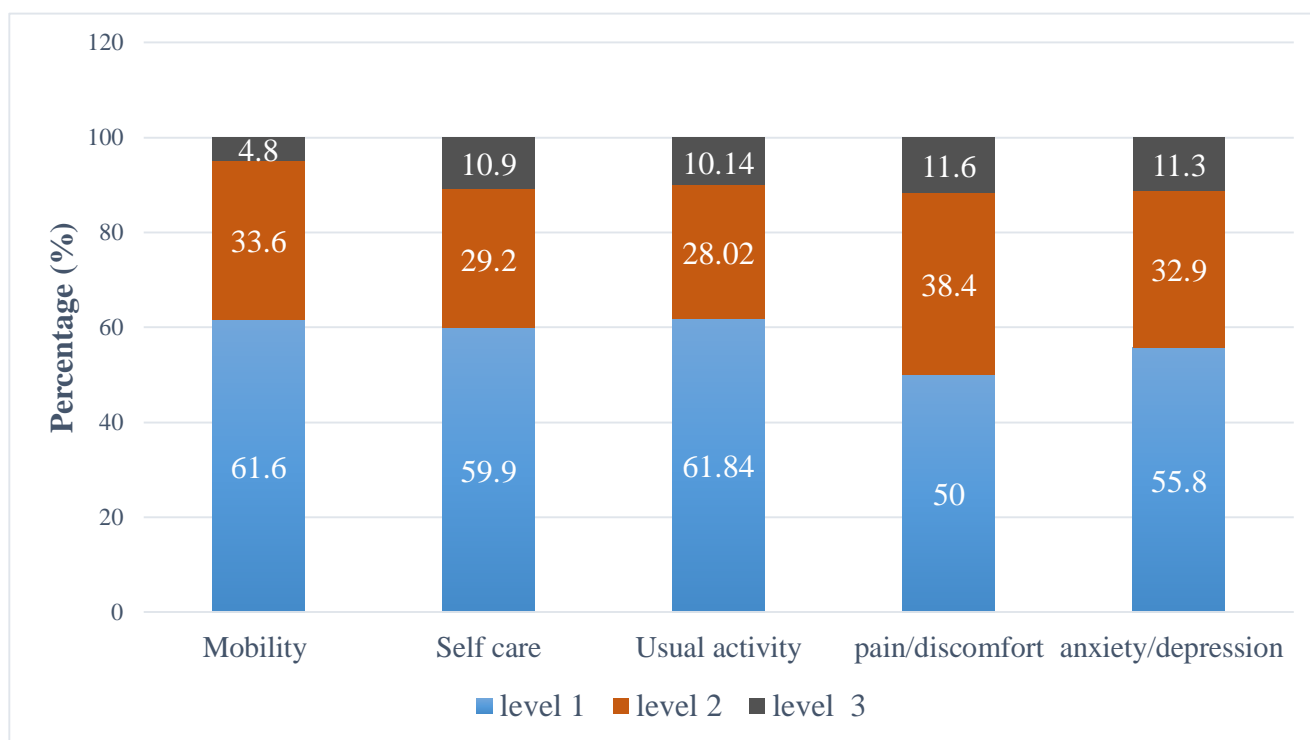


Figure 3. Diabetes complications distribution among type 2 DM patients' public hospitals at Harari Region, Eastern Ethiopia, 2021(n=414).

4.3. Health-related quality of life among participants using EQ-5D utility scores

The study population had reported an average HRQOL EQ5D utility score of 0.714 (\pm 0.201). The frequency distributions of the problems within the health-related quality of life dimensions for individual patients had assessed. In the mobility dimension, most of the patients report level 1(no problem) (61.6%) and on the self-care dimension also most (59.9%) of the patients reported no problem. Participants also reported on pain/ discomfort dimension some and extreme problem higher (38.4%) and (11.6%), respectively than another dimension. (Figure 4).



Level 1 = no problem, level 2 = some problem and level 3 = extreme problem

Figure 4: The frequency distributions of problems within the health-related quality of life dimensions among type 2 DM patients attending public hospitals at Harari Region Eastern Ethiopia, 2021(n=414).

4.4. Factor associated with HRQOL among type 2 diabetes patients

4.4.1. Simple linear regression analysis

From factors entered age, sex, residence, marital status, occupation, income, and marital status, occupation, waiting time, complication, treatment regimens, and BMI were significantly associated. (Table 4)

Table 4. Simple linear regression analysis on factors associated with health-related quality of life among type 2 diabetic patients attending public hospitals at Harari region, Eastern Ethiopia, 2021. (n =414)

Variable	Category	HRQol Mean	B	95% CI
Age in years ^c		0.714	- 0.006	(- 0.007, - 0.004)*
Sex	Male	0.748	1	1
	Female	0.681	-0.067	(-0.106, - 0.029)*
Residence	Urban	0.720	1	1
	Rural	0.690	-0.030	(-0.018, - 0.078)*
Marital status	Single	0.768	1	1
	Married	0.739	-0.029	(-0.237, - 0.098)
	Widowed	0.633	-0.134	(-0.206, - 0.064)*
	Divorced /Separated	0.683	-0.085	(-0.154, - 0.015)*
Occupation	Employed	0.728	1	1
	Unemployed	0.709	-0.019	(-0.084, -0.046)
	Merchant	0.779	0.070	(0.005, 0.145)
	Self –employed	0.727	-0.018	(-0.049, 0.085)
	Farmer	0.740	0.031	(-0.039, 0.102)
	Retired	0.650	-0.059	(-0.122, - 0.003)*
Distance of health facility	1-2.5km	0.709	1	1
	2.5-5	0.727	0.018	(-0.034, 0.070)
	5-7.5	0.723	0.014	(-0.043, 0.0702)
	>7.5	0.692	-0.017	(-0.074, - 0.040)
DM complication	Yes	0.673	-0.082	(-0.120, - 0.043)*
	No	0.214	1	1
Current treatment	Oral	0.734	1	1
	Injection	0.737	0.003	(-0.051, 0.056)
	Both oral and injection	0.675	-0.060	(-0.103, -0.017)*
BMI	Normal	0.740	1	1
	Underweight	0.673	-0.067	(0.140, 0.006,)*
	Overweight	0.681	-0.059	(-0.103, -0.015)*
	Obese	0.703	-0.037	(-0.107, 0.034)
Duration of therapy type 2 DM		0.741	0.002	(-0.002, 0.005)
Waiting time, hr.		0.741	0.018	(0.007, 0.043)*
Average monthly income		0.714	0.004	(0.006, 0.025)*

Dependent variable = overall health-related quality of life * =p value <0.25,

4.4.2. Multivariable linear regression analysis

Multivariable linear regression analysis declared that old age, female, widowed marital status, unemployed and complication had inverse association with health-related quality of life. As age increased by one year, patients HRQOL decreased by 0.005 while keeping the effect of other variables constant [$B = -0.005$, 95% CI (-0.006, - 0.003)]. Female had on average 0.067 lower HRQOL as compared with male keeping effect of other variables constant [$B = -0.067$, 95% CI (-0.105, -0.029)]. Being widowed was on average 0.083 lower health-related quality of life as compared with single keeping effect of other variables [$B = -0.083$, 95% CI (-0.151, -0.014)]. Being unemployed would likely lower health-related quality of life by 0.034 when compared to employed keeping effect another variable constant [$B = -0.034$, 95% CI (-0.104, -0.037)]. Participants who have complications were on average 0.046 lower health-related quality of life as compared with those patients who have no complication keeping the effect of other variables constant [$B = -0.058$, 95% CI (-0.097, -0.020)]. (Table 5)

Table 5. Multiple linear regression analysis on factors associated with health-related quality of life among type 2 diabetic patients attending public hospitals at Harari region, Eastern Ethiopia, 2021. (n=414)

Variable	Category	HRQOL Mean	B	95% CI
Age in years ^c		0.714	- 0.005	(-0.006, - 0.003)**
Sex	Male	0.748	1	1
	Female	0.681	-0.067	(-0.105, -0.029)**
Residence	Urban	0.720		
	Rural	0.690	-0.042	(-0.091, 0.006)
Marital status	Single	0.768	1	1
	Married	0.739	-0.017	(-0.075, 0.041)
	Widowed	0.633	-0.083	(-0.151, -0.014)**
	Divorced / Separated	0.683	-0.044	(0.111, 0.023)
Occupation	Employed	0.728	1	1
	Unemployed	0.709	-0.034	(-0.104, -0.037)**
	Merchant	0.779	-0.035	(-0.037, 0.106)
	Self –employed	0.727	-0.003	(-0.061, 0.067)
	Farmer	0.740	-0.025	(-0.043, 0.093)
	Retired	0.650	-0.022	(-0.090, 0.047)
monthly ^c income		0.714	0.005	(0.006, 0.002)
Waiting time, hr. ^c		0.174	0.024	(- 0.003 , 0.048)
DM complication	Yes	0.673	-0.058	(-0.097, -0.020)**
	No	0.214	1	1
Current treatment	Oral	0.734	1	1
	Injection	0.737	0.035	(-0.015, 0.085)
	Both oral and injection	0.675	-0.014	(-0.067, -0.039)
BMI	Normal	0.740	1	1
	Underweight	0.673	-0.035	(-0.104, 0.034)
	Overweight	0.681	-0.027	(-0.069, 0.016)
	Obese	0.703	-0.012	(-0.056, 0.081)
Constant			1.007	(0.865, 1.149)

Dependent variable = overall health related quality of life $R^2 = 21.6\%$,

**= p value < 0.05, taken as statistically significant.

C = continuous variables

5. DISCUSSION

The findings of this study show that the overall average HRQOL score was 0.714 (\pm 0.204) in patients with type 2 diabetes mellitus. Old age, women, unemployed, widowed, and the presence of complications were inversely associated with health-related quality of life, while high-income levels show a positive association.

This finding showed that the average score was relatively low relative to the norms of the Zimbabwean population on which the value set was based. The results indicate that type 2 diabetic patients in the study estimated their health to be below that of the general population of Zimbabwe, which was 0.842. The observed variations may have been expected as the Zimbabwean study used the general population, which was not necessarily sick, while this study used type 2 diabetic patients. Regional differences in socio-economic and health care systems may play an important role. In developing and resource-limited countries such as Ethiopia, some people with diabetes remain undiagnosed until complications occur. Thus, such delays in seeking medical care, in large part because of limited income and ignorance, can harm the quality of life of these individuals (Jelsma *et al.*, 2003; Janssen and Szende, 2014).

The finding of this study was also compared with the previous studies which used the EQ 5D 3L scale to determine HRQOL among type 2 DM patients. A study conducted in Enugu State, Nigeria (Adibe *et al.*, 2018), South Iran (Zare *et al.*, 2020), Jordan (Jarab *et al.*, 2019), Norway (Solli *et al.*, 2010), which was consistent with the finding of this study and this may be due to the poor socio-economic status, sociocultural status of the study populations.

The finding of HRQOL score in this study was slightly higher than study conducted in Portugal (Cardoso *et al.*, 2016), Jordana (Jarab *et al.*, 2021), Korea (Choi *et al.*, 2011), Saudi Arabia (Alshayban and Joseph, 2020b) and Indonesia (Arifin *et al.*, 2019). This difference may be due to socio-demographic, sampling technique, sample size, sociocultural difference, and tool level use by others.

This study shows that age has an inverse association with HRQOL, this shows that HRQOL decrease when age increase with one unit, In line with this finding, studies conducted in Ethiopia (Reba *et al.*, 2018), Mizan Tepi (Gebremedhin *et al.*, 2019b), Nekemte Specialized Hospital (Feyisa *et al.*, 2020), Nigeria (Ekwunife *et al.*, 2016), India (Parik and Patel, 2019), Bangladeshi

(Barua *et al.*, 2021), Uganda(Nyanzi *et al.*, 2014), Botswana (Rwegerera *et al.*, 2019) and Iran (Didarloo and Alizadeh, 2016) revealed that age was inversely associated with HRQOL. Such findings may reflect that younger people are more likely to enjoy better health than the elderly. This might be because of the biological alteration of the patients as they got older and older, increasing cell degeneration, decreasing the immunity system, decreasing muscular fitness, increasing muscular atrophy and increasing cognitive impairment.

The finding of the study also shows that being a female patient has an inverse relationship with HRQOL, which was consistent with studies conducted in Iran (Mohammadi *et al.*, 2016), Portugal (Cardoso *et al.*, 2016), India ((Parik and Patel, 2019), Pakistan (Hassali *et al.*, 2016), China (Jin *et al.*, 2018), Spain (Mata-Cases *et al.*, 2016;) and EQ-5D-5L (Corrêa *et al.*, 2017; Rodríguez-Almagro *et al.*, 2018), Saudi Arabia (Alshayban and Joseph, 2020) and Jordana (Jarab *et al.*, 2021). A review of gender differences in diabetic patients found that male patients were less depressed and anxious and overall living more effectively with the disease than females (Siddiqui *et al.*, 2013).

Patients with type 2 diabetes who are widowed had also lower QOL than those who are single. This relationship between marital status and QOL is also observed in previous studies conducted among type 2 DM patients in Ethiopia (Reba *et al.*, 2018) and Iran (Gholami *et al.*, 2013). The possible explanation for the finding is that being widowed may increase social isolation by the population, feeling lonely, and lack of confidence in the community, family health instability and economic crisis.

Unemployed type 2 diabetes patients had lower HRQOL as compared with those patients who are employed. A study conducted in Ethiopia also shows unemployment affect HRQOL (Reba *et al.*, 2018), a national survey conducted in Iran has also reported a significant association between employment and HRQOL of patients with type 2 DM (Javanbakht *et al.*, 2012). Possible explanation Patient who are not employed will develop stress and they could be psychological and emotionally disturbed.

The current study has also observed an inverse association between the presence of complications and HRQOL among DM patients. It has demonstrated that patients with type 2 DM who have developed any DM complication have worse QOL. The negative effect of DM complication on HRQOL of patients with DM has been reported in previous studies also,

Ethiopia (Reba *et al.*, 2018) (Gebremedhin *et al.*, 2019b), Uganda (Nyanzi *et al.*, 2014), United Arab Emirates (Bani-Issa, 2011), China (Zhang *et al.*, 2020), Saudi Arab (Alshayban and Joseph, 2020a) and Vietnam (Tran Kien *et al.*, 2021). This is may be due to patients who develop complications would live under the double crisis, they felt unhappy of being patient with diabetes and they would be under the psychological, physical, emotional, social and spiritual pain.

6. STRENGTH AND LIMITATION OF THE STUDY

6.1. Strength of the study

The study tries to get adequate information from a representative sample and the data collected was primary data direct from the patient interviews. The study also uses an international standard tool for data collection. Also, this study considered the outcome variable as continuous, which might minimize misclassification bias.

6.2. Limitations of the study

Because this was a cross-sectional study, the observed associations were not necessarily causal and it has to be noted that the data was collected using an interviewer-administered questionnaire which may make the finding prone to interviewee bias and. The data was collected at a point period and fluctuations are likely to occur if HRQOL is measured at multiple points in time.

7. CONCLUSION AND RECOMMENDATION

7.1. Conclusion

The overall health-related quality of life among type 2 diabetic patients was low. Old age, female gender, unemployed occupation, being widowed, and complications were inversely associated with health-related quality of life.

7.2 Recommendation

For decision/policy makers

- It will be better if the government gives special attention to elderly DM patients by establishing mechanisms to support them in improving their quality of life.
- Diabetes self-management Education (DSME) should be given on diabetes management which enhance the patients' knowledge and motivate them to engage in to self-care practices, timely monitoring their blood glucose level to reduce the risk of developing the complications.
- Special attention should be given to DM patients to break the cycle of low occupational status through creating job opportunities that to reduce the financial stress of DM patients

For health care providers

- It is known that education has the power for changing the overall qualities of life, personalities, and attitudes of a given society. Just to improve the quality of life of DM patients, educational programs should be designed and offered to DM patients in the focus of improvement of understanding self-care and management of DM, risk minimization, glycemic control, lifestyle modification, and perception of self-worth.
- The health care team for diabetics should not be only disease-centered; the QOL of the diabetic patient should always be regularly assessed and improved accordingly.

For researcher

- This study is a point study it could be better if researchers conduct the full quality of life assessment at 6 weeks, 2 months, 4 months, and 12 months for better estimation of QoL.

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9. ANNEXES

Annex I. Information Sheet and Informed Voluntary Consent Form

Annex IA: For the Head of the Institution

My name is _____. I am working as a data collector for the study being conducted by Ayalnesh Mechal who is studying for her master's degree at Haramaya University, Collage of Health and Medical sciences. I kindly request you to lend me your attention to explain you about the study and your institution being selected as study setting.

The study title: Health related quality of life and its associated factors among type 2 diabetes mellitus patients attending at public hospitals of Harari region, Eastern Ethiopia, 2021.

Purpose of the study: to assess health related quality of life and its associated factors among type 2 Diabetes Mellitus patients attending in-patient and out-patient treatment units at public hospitals of Harari region, eastern Ethiopia, June 1-July 15, 2021 .Moreover, the aim of this study is to write a thesis as a partial requirement for the fulfillment of master's degree in Adult Health Nursing Specialty for principal investigator.

Procedure and duration: I will be interviewing the patient using a questionnaire to provide me with pertinent data that is helpful for the study. There are 3 parts of questions to answer where I will fill the questionnaire by interviewing the patient. The interview on each patient will take about 30 minutes.

Risks and benefits: the risk of being participant in this study is minimal, but only taking few minutes from the participants time. There would not be any direct payment for participating in this study. But the findings from this research may reveal important information which will benefit you and other diabetes mellitus patient in the future by identifying factors associated with health related quality of life.

Confidentiality: the information that will be provided will be kept confidential. There will be no information that will identify the participants in particular. The finding of this study will be general for the study community and will not reflect anything particular of individual person. The questionnaires will be coded to exclude showing names. No reference will be made in oral or written reports that could link participants to the research.

Rights: participation for this study is fully voluntary. The participants have the right to declare to participate or not in this study. If they decided to participate, they have the right to withdraw from the study at any time and this will not label them for any loss of benefit which they otherwise are entitled. They do not have to answer any question that they do not want to answer.

Contact address: if there are any questions or enquires any time about the study or procedures, please contact in this address.

The principal investigator: Ayalnesh Mechal

Mobil phone: +251-984-88-19-69

Email address: Ayalneshmechal@gmail.com

Institutional health research ethics review committee (IHRERC):

Office phone: +251254662011, P.O.B: 235, Harar.

Declaration of informed voluntary consent:

I have read the participant information sheet. I have clearly understood the purpose of the research, the procedures. The risks and benefits, issues of confidentiality, the rights of participating and the contact address for any quires. I have been given the opportunity to ask questions for things that may have been unclear. I was informed that participants have the right to withdraw from the study at any time or not to answer any question that they do not want. I am also informed that the university have the right to stop this study from being conducted if any misdeeds and unethical procedures are observed during the data collection process in the hospital's premises. Therefore, I declare my voluntary consent on behalf of university management to allow this study to be conducted in the university with my initials (signature).

Name and signature of head of the institution _____

Signature of data collector _____

Thank you for your cooperation!

Annex IB: For patient Participant

My name is _____, I am working as data collector for the study being conducted in this hospital with Ayalnesh Mechal who is studying her master's degree at Haramaya University collage of Health and Medical sciences. I kindly request you to lend me attention to explain you about the study.

The study title: Health related quality of life and its associated factors among type 2 diabetes mellitus patients attending at public hospitals of Harari region, eastern Ethiopia, June 15 –July 15, 2021.

Purpose of the study: to assess health related quality of life and its associated factors among type 2 Diabetes mellitus patients attending in-patient and out-patient treatment units at public hospitals of Harari region, eastern Ethiopia, June 15-July 15, 2021. Moreover, the aim of this study is to write a thesis as a partial requirement for the fulfillment of master's degree in Adult Health Nursing Specialty for principal investigator.

Procedure and duration: I will be interviewing you using a questionnaire to provide me with pertinent data that is helpful for the study. There are 3 parts of questions to answer where I will fill the questionnaire by interviewing you. The interview will take about 30 minutes, so I kindly request you to spare me this time for the interview.

Risks and benefits: the risk of being participant in this study is minimal, but only taking few minutes from the participants time. There would not be any direct payment for participating in this study. But the findings from this research may reveal important information for the local health planners.

Confidentiality: the information that will be provided will be kept confidential. There will be no information that will identify the participants in particular. The finding of this study will be general for the study community and will not reflect anything particular of individual person. The questionnaires will be coded to exclude showing names. No reference will be made in oral or written reports that could link participants to the research.

Rights: participation for this study is fully voluntary. The participants have the right to declare to participate or not in this study. If they decided to participate, they have the right to withdrawn

from the study at any time and this will not label them for any loss of benefit which they otherwise are entitled. They do not have to answer any question that they do not want to answer.

Contact address: if there are any questions or enquires any time about the study or procedures, please contact in this address.

The principal investigator: Ayalnesh Mechal

Mobil phone: +251-984-88-19-69

Email address: Ayalneshmechal@gmail.com

Institutional health research ethics review committee (IHRERC)

Office phone: +251254662011, P.O.B: 235, Harar.

Declaration of informed voluntary consent:

I have read the participant information sheet. I have clearly understood the purpose of the research, the procedures. The risks and benefits, issues of confidentiality, the rights of participating and the contact address for any quires. I have been given the opportunity to ask questions for things that may have been unclear. I was informed that participants have the right to withdraw from the study at any time or not to answer any question that they do not want. I am also informed that the hospitals have the right to stop this study from being conducted if any misdeeds and unethical procedures are observed during the data collection process in the hospitals premises. Therefore, I declare my voluntary consent on behalf of hospitals management to allow this study to be conducted in the hospital with my initials (signature).

Signature of participant _____

Signature of data collector _____

Thank you for your cooperation

Annex 2. Questionnaire

Part I: socio- demographic and clinical characteristic

All questionnaires are complete anonymously. We would appreciate it if you answer all the questions and answer as honestly as possible. Please circle on the number you select that best answers and give responses on give space for others question with blank space. Kindly make only one Selection unless otherwise instructed.

S.no	Question	Response
101	Age	_____ (in year)
102	Sex	1. Male 2. Female
103	Residence	1. Urban 2. Rural
104	What is your Marital status	1. Single 4. Divorced 2. Married 5. Separated 3. Widowed
105	What is your Occupation	1. Government employee 2. Non- governmental employee 3. Merchant 4. private 5. Farmer 6. Retired 7. Other (specify) _____
106	Average monthly income	_____
107	How far do you travel to access the health service?	_____ Kms _____ Hrs.
108	For how long you wait to get a service after you reach health service centre	_____ min/hr.
109	Mode of treatment taken	1. Oral 2. Injection 3.Both
110	Duration of therapy	_____ (year)
111	Height Weight	_____ cm _____ kg

112	Presence of diabetic Complication	1. Yes (specify) _____ 2. No
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Part 2. EQ 5D 3L English version for assessing health related quality of life

For the questions below select the numbers which express your today's health state for each question, the number above the question is as response for each choice

s.no	Question	1	2	3
201	Mobility	No any problem in mobility	some problem in walking	confined to bed
202	Self-care (Washing , dressing , eating , toileting)	No problems with self-care	some problems washing or dressing myself	unable to wash or dress myself
203	Usual activities (No any problem to perform	Some problems to perform activities	Un able to perform my usual activities
204	Pain/ discomfort	No any pain	Some pain/discomfort	Extreme pain/ discomfort
205	Anxiety / depression	Not anxious or depressed	Moderately anxious or depressed	Extremely anxious or depressed

Annex IB: For patient Participant (Amharic version)

አባሪ IB ለታካሚ ተሳታፊ

ስሜ _____ ነው ፣ በዚህ ሆስፒታል ውስጥ በሀራማያ ዩኒቨርሲቲ የጤና እና ሜዲካል ሳይንስ ኮሌጅ የሁለተኛ ዲግሪን ከምታጠናው አያልነሽ መቻል ጋር በዚህ ሆስፒታል ለሚካሄደው ጥናት የመረጃ ሰብሳቢ ሆኑ እየሰራሁ ነው ። ስለ ጥናቱ እንደገልጽልዎትኩረት እንድትሰጡኝ በአክብሮት እጠይቃለሁ ።

የጥናቱ ርዕስ- የስኳር ህመምተኞች የኑሮ ሁኔታ እና ተዛማጅነት ያላቸው ጉዳዮች ዙሪያ በምስራቅ ኢትዮጵያ ሐረሪ ክልል በሚገኙ የህዝብ ሆስፒታሎች ውስጥ ተመላላሽ ታካሚ ለማጥናት የተዘጋጀ ነው ሰኔ 1- ሐምሌ 30 ፣ 2021

የጥናቱ ጥቅም - በዚህ ጥናት በመሳተፍዎ የተለየ ጥቅም አያገኙም። ነገር ግን የርሶዎ በጥናቱ መሳተፍዎ ለጥናቱ መሳካት በጥናቱ በተለያዩ ችግሮች መፍትሄ ሲሰጥ እረስዎ እና ሌሎች ታማሚዎች ተጠቃሚ ይሆናሉ።

የአሠራር ሂደት እና የቆይታ ጊዜ - ለጥናቱ ጠቃሚ የሆኑ መረጃዎችን እንዲያቀርቡልኝ መጠይቅ ተጠቅሜ ቃለ መጠይቅ አደርግልዎታለሁ ። መጠይቁን የምሞላበትን ለመመለስ 3 የጥያቄዎች ክፍሎች አሉ። ቃለመጠይቁ 30 ደቂቃ ያህል ይወስዳል ፣ ስለዚህ ለቃለ መጠይቁ በዚህ ጊዜ እንድታቆዩኝ በትህትና እጠይቃለሁ ።

አደጋዎች እና ጥቅሞች-በዚህ ጥናት ውስጥ ተሳታፊ መሆን አደጋ የለውም ፣ ግን ከጊዜዎ ጥቂት ደቂቃዎችን ብቻ ይወስዳል ። በዚህ ጥናት ውስጥ ለመሳተፍ ቀጥተኛ ክፍያ አይኖርም ። ነገር ግን የዚህ ምርምር ግኝት ለአካባቢው የጤና እቅድ አውጪዎች ጠቃሚ መረጃን ሊያሳይ ይችላል ።

ሚስጥራዊነት-የሚቀርበው መረጃ በሚስጥራዊነት ይቀመጣል ። በተለይም ተሳታፊዎችን ለይቶ የሚያሳውቅ መረጃ አይኖርም ። የዚህ ጥናት ግኝት ለጥናቱ ማህበረሰብ አጠቃላይ ይሆናል እናም የግለሰቦችን የተለየ ነገር የሚያንፀባርቅ አይሆንም ። መጠይቆቹ ስሞችን ከማሳየት እንዲለዩ ኮድ ይደረግባቸዋል ። ተሳታፊዎችን ከምርምር ጋር ሊያገናኝ የሚችል በቃል ወይም በፅሁፍ ሪፖርቶች ውስጥ ማጣቀሻ አይሰጥም ።

መብቶች-የዚህ ጥናት ተሳትፎ ሙሉ በሙሉ በፈቃደኝነት የተመሰረተ ሲሆን በዚህ ጥናት ውስጥ ለመሳተፍ ወይም ላለመሳተፍ መብት አለዎት። ለመሳተፍ ከወሰኑ በማንኛውም ጊዜ ከጥናቱ የመውጣት መብት አላቸው እናም ይህ በሌላ መንገድ ሊያገኙዎቸው በሚችሉት የጥቅም ኪሳራ አይለያቸውም። መመለስ የማይፈልጉትን ማንኛውንም ጥያቄ ለመመለስ አይገደዱም

አድራሻ- ስለ ጥናቱ ወይም ስለ አሠራሩ በማንኛውም ጊዜ ጥያቄዎች ካሉ እባክዎ በዚህ አድራሻ ያነጋግሩ።

ዋና ተመራማሪ አያልነሽ መቻል

የሞባይል ስልክ: + 251-984-88-19-69

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የተቋማት የጤና ጥናት ሥነምግባር ግምገማ ኮሚቴ (አይኤች አር ሲ)

የቢሮ ስልክ +251254662011 ፣ ፖስታ 235 ፣ ሀረር።

በመረጃ የተደገፈ ፈቃደኝነት መግለጫ

የተሳታፊውን የመረጃ ወረቀት አንብቤያለሁ። የምርምር ዓላማውን፣ አሰራሮቹን በግልፅ ተረድቻለሁ። አደጋዎች እና ጥቅሞች፣ የምስጢር ጉዳዮች፣ የተሳትፎ መብቶች እና ለማንኛውም ፍላጎት የግንኙነት አድራሻ። ግልጽ ባልሆኑ ጉዳዮች ላይ ጥያቄዎችን ለመጠየቅ እድሉ ተሰጥቶኛል። በማንኛውም ጊዜ ከጥናቱ የመውጣት ወይም የማይፈልጉትን ማንኛውንም ጥያቄ የመመለስ መብት እንዳላቸው ተነግሮኛል። በሆስፒታሎች ቅጥር ግቢ ውስጥ በመረጃ አሰባሰብ ሂደት ውስጥ ምንም አይነት ጥፋቶች እና ስነምግባር የጎደለው አካሄዶች ከታዩ ሆስፒታሎቹ ይህንን ጥናት እንዳያካሂዱ የማድረግ መብት እንዳላቸውም ተነግሮኛል። ስለሆነም ይህ ጥናት በሆስፒታሎች የመጀመሪያ ፊደሎች (ፊርማዬ) እንዲከናወን በሆስፒታሎች አስተዳደር ስም የውዴታ ፈቃዴን አሳውቃለሁ

የተሳታፊ ፊርማ _____

የመረጃ ሰብሳቢ ፊርማ _____

ለትብብርዎ እናመሰግናለን

አባሪ 2. መጠይቅ (አማረኛ)

ክፍል I: ማህበራዊ-ስነ-ህዝብ እና ክሊኒካዊ ባህሪ መጠይቅ

በጥያቄው ውስጥ የተሻሉ መልሶችን እባክዎ በመረጡት ቁጥር ላይ ያክብቡ ::

S.no	ጥያቄ	መልስ
101	ዕድሜ	_____
102	ፆታ	1. ወንድ 2. ሴት
103	መኖሪያ ቤት	1. ከተማ 2. ገጠር
104	የጋብቻ ሁኔታ	1. ያላገባ 4. የፈታ 2. ያገባ 5. ተለያይቷል 3. በሞት የተለየ
105	ሥራ	1. የመንግስት ሰራተኛ 2. መንግስታዊ ያልሆነ ሰራተኛ 3. ነጋዴ 4. ተማሪ 5. ገበሬ 6. ሌላ (ይግለጹ) _____
106	አማካይ ወርሃዊ ገቢ	_____
107	የጤና አገልግሎቱን ለማግኘት ምን ያህል ርቀት ይጓዛሉ?	_____ Kms _____ Hrs.
108	የጤና አገልግሎት ማዕከል ከደረሱ በኋላ አገልግሎት ለማግኘት ለምን ያህል ጊዜ ይጠብቃሉ	_____ min/hr.
109	የሕክምና ዓይነት	1. የሚዋጥ 2. መርፌ 3. ሁለቱም
110	የሕክምና ጊዜ	_____ (አመት))
111	ቁመት ክብደት	_____ ሴ.ሜ. _____ ኪግ

112	ከስኳር በሽታ መኖር ጋር የተያያዘ ልላ የጤና እክል አለ	3. አዉ (ይግለጹ) _____ 4. አይ
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ክፍል 2. ከጤና ጋር የተያያዘ የኑሮ ሁኔታ መጠይቅ

ከዚህ በታች በእያንዳንዱ ቡድን ውስጥ አንድ ቁጥርን በማክበብ እባክዎን ዛሬ የትኛው መግለጫ ጥናዎን በተሻለ ሁኔታ እንደሚገልጹ ያመልክቱ ፡

1. እንቅስቃሴ	የመራመድ ችግር የለብኝም	1
	መጠነኛ የሆነ የመራመድ ችግር አለብኝ	2
	ምንም መራመድ አልቸልም	3
2. ራስንመንከባከብ	ለመታጠብም ሆነ ለመልበስ ምንም ችግር የለብኝም	1
	ለመታጠብም ሆነ ለመልበስ መጠነኛ ችግር አለብኝ	2
	ራሴ ልታጠብም ሆነ ልለብስ አልቸልም	3
3. መደበኛ ተግባራት	መደበኛ ተግባራቶቼን ያለምንም ችግር አከናውናለሁ	1
	መደበኛ ተግባራቶቼን ለማከናወን መጠነኛ ችግር አለብኝ	2
	መደበኛ ተግባራቶቼን ለማከናወን አልቸልም	3
4. የሕመምስሜት/ምቹትማጣት	የሕመም ስሜትም ሆነ የምቹት ማጣት ስሜት የለኝም	
	መጠነኛ የሕመም ስሜት ወይም የምቹት ማጣት ስሜት አለኝ	
	የከፋ የሕመምስሜት ወይም የምቹት ማጣት ስሜት አለኝ	
5. 5. ጭንቀት/ድብርት	ጭንቀትም ሆነ ድብርት የለብኝም	1
	መጠነኛ ጭንቀት ወይም ድብርት አለብኝ	2
	እጅግ ከባድ ጭንቀት ወይም ድብርት አለብኝ	3

Annex IB: Dhukkubsattoota hirmaattotaaf (Afaan oromoo)

Ani maqaan koo _____Jedhama. Ani kanan dhufeef, Koollejj saayins Fayyaa, Yuniversit Haramayatti barattuu digir lammaffaa kan taate Ayaallesh Machaal waraqaa qo'annoo ishee hospital kanatti waan dalagduuf, odeeffannoo funaanufi. Waa'ee qorannoo kanaa akka isin2nf ibsuuf, akka xiyyeeffannoo naaf kennitan2 dh2fama wal2n isin gaafadha.

Mata duree qoranichaa: Qulqulinaa jireenyaa fayyaan wlaqabaatu fi wantoota kanaan wajjin walqabatan/Sababa tahuu dandayan irratti namoota dhibee sukkaraa gosa 2ffaa kutaa c2sani yaalamu fi deedebe'an2 yalamu dhufan Hospitaloota uumataa naannoo Harar2 keessati argamanirratti qorranna taasifamudha, Baha Itiyoophiyaa,.

Kaayyoon qoranichaa: kayoon qoranna kanaa Qulqulinaa jireenyaa fayyaa wlaqabaatu fi wantoota kanaan wajjin walqabatan/Sababa tahuu dandayan irratti namoota dhibee sukkaraa gosa 2ffaa kutaa c2sani yaalamu fi deedebe'an2 yalamu dhufan Hospitaloota uumataa naannoo Harar2 keessati argamanirratti qorranna taasifamudha, Baha Itiyoophiyaa, Akkasumas, Qorataaf qoraannoo eebaa digr2 lammafaa Nars2 gaa'eessotaa fayyaa ittin xummuruf oola.

Akkaataa adeemsa qoranicha:-Gaafiwwan qorannoof tahuu danda'an isin gaafatmu. Gaafiwwan kutaa 3 qabuu. Kana deebisuuf tilmaamaan daqiiqa 30 fudhata. Kanaaf irra deebi'e yeroo keessan akka naaf kennitan kabajaan isin gaafadha.

M2dhaa fi faayidaa: Qorannoo kana irratti hirmaachuu keessan2n m2dhaan isin irra gahu tokkollen hin jiru, yeroo gabaabduu isin jalaa fudhatu malee. Yeroo amma qoranno kana irratti hirmachu keessan2n faayidaan argatan hin jiru,garuu qoranna kana irra odeeffannon argamu qaamolee dhimmi ilaaluuf karoora akka irratti baafatan2f faayidaa guddaa qaba.

Ic2t2;-Odeeffanno kennitan hundaaf ic2t2n isaa kan eegamuu fi wanti maqaa keessan ibsu tokkolleen hin jiru.kanaaf bu'aan qoranno argamu dhunfaan oso hin taane akka wal2 galaatti kan ibsamuudha.

Mirga Hirmaataa;-Qoranno kana irratti hirmachuu yookan dhisuuf mirga guutuu qabdu. Yoo hin barbaadin yeroo barbaadanitti qoranicha addaan kuttani dhisu Uni dandeessu. Gaaafi deebisu hin barbaanne dh2su dandeessu.

Teessoo:-Waa'ee qoranichaa irratti gaaf2 tahan hunda ykn waan isin yaadessu yoo jiraate teesso armaan gad2 kanaan yeroo barbaadanitti argachu ni dandeessu.

Abbaa qorannoo Maqaa:- **Ayaallesh Machaal** Lakk. Mob. +251-984-88-19-69

Email address – Ayalneshmechal@gmail.com

Haramaya University Lakk. wajjira- **0254662011** or Lakk.posta- 235, Harar. Kanaan bilbiluun argachu dandeessan.

Wal2 galtee:-waa'een haala himaanna qoranno erga naaf dubbifame booda kaayyoon qoranna, bu'aan qoranna, m2dhaan qorannoon qabu, haalli eegumsa , mirgi hirmaachu fi hirmachu dh2suu fi tessoon naaf ibsame jira. Gaaf2 yoon qabaadhe gaafachuuf carraan naaf kenname jira, gidduttis dh2su yoon barbaade yeroon barbaadetti hirmaachu dh2su akkan dandahu gat2 deebisuu kan hin barbaachifne tahuu mirga guutu akkaan qabu ergan hubadhe booda fedhinnaa guutuun qorannoo kana irratti hirmaachuu kanin murtesse tahu kiyya maqaa fi mallattoo kiyyaanin mirkaneessa.

Maqaa fi mallattoo odeeffanno kennaa_____Guyyaa_____

Maqaa fi mallattoo odeeffanno sassaaba_____Guyyaa_____

Galatooma!!!

Kutaa I: Haala jireenya hawaasummaa fi haalaa fayyummaa

Maaloo lakkoofsa isa sirr2dha jettee filattetti maruun deebisi. Lakkoofsa tokko qofa filachuu dandeessa.

lakk	Gaaff2	Deeb2
101	Umr2
102	Saala	1. Dh2ra 2. Dhaala
103	Iddo jireenya	1. Magaalaa 2. Baadiyaa
104	Haala cidhaa	1. kan hinfune/an hin heerume 2. kan fudhee/kan heerume 3. kan duhan adda bahe 4. kan wal h2kan 5. addan bahaniru
105	Hoji	1. Hojaata motumma 2. Hoj2 dhunfaa 3. Daldalaa 4. Barataa 5. Qonnan bulaa 6. kan biro
106	Gal2 jihaan argaatan
107	Tajaajila fayyaa aragachuf fagenyaa hagam deemtu?Km
108	Tajaajila fayyaa aragachuf ergaa gessani amam turtu?daq/sahat2n
109	Gosaa yaala argaatan	1. kan liqifamu 2. kan waranamuu 3. lachuu
110	Yeroon yaala amam turee? waggan
111	Dheerina UlfaatinacentimetiraanKg
112	Dhukuba sukkaran jirachuu waj2n walqabate rakkini fayyaa biro jiru?	1. Eyyee (ibsa) 2. lakk2

Kutaa 2 -Akka dhaabata faaya adunyaati qulqullina jireenya

Lakkoofsawaan Kannen armaan gad2 saanduqaa keessati argaman keessa tokkoti maarun sadarkaa faayan keessan irraatti argamu agarsisaa

1. Soch2	Rakkinaa deemsa hin qabu	1
	Amma tokko Rakkinaa deemsa nan qaba	2
	Waan tokkole deemu hin danda'u	3
2. Ofkununsuu	Dhiqaachufis tahee wayyaa uffaachuuf rakkoo tokkole hin qabu	1
	Dhiqaachufis tahee wayyaa uffaachuuf rakkoo murasan qaba	2
	Of2koon dhiqachufis tahee uffaachuuf hin dandahu	3
3.hoj2lee guyya guyyan hojjetamu	Hojjechuuf huma na rakkisu.	1
	Hojjechuuf xiqqoo na rakkisa.	2
	Hojjechuu hin danda'u.	3
4.dhukkubb2/ Sitti toluu dhabu.	Dhukkubb2 hin qabu	1
	Xiqqoo dhukkubb2 qaba/natti tolaa hin jiru.	2
	Dhukkubb2 cimaa qaba/ natti tolaa hin jiru.	3
5.Dhiphachuu/joonja'uu	ani hin dhiphadhu/ hinjoonja'u	1
	Xiqqooshee nan dhiphadha/nan joonja,a	2
	baayyeen/garmaleen dhiphadha/joonja'a	3

Annex 2I. Curriculum vitae

Personal Information

Name: Ayalnesh Mechal Bireda

Sex: Female

Age: 26

Date of birth: Mar 24, 1995

Place of birth: Jijiga, Somali region, Ethiopia.

Nationality: Ethiopian

Contact Address: +251-984-88-19-69.

E-mail: Ayalneshmechal@gmail.com.

Work Experience

- ☐ Oct 2018 to Oct 2019 Instructor at Wachemo University CMHS Department of Nursing.

Educational background

Level of education	University	year	Awards
Higher education	Jimma University	2015-2018	BSc in nursing
Preparatory	Jijiga preparatory and secondary school	2013-2014	Grade 11-12
Secondary school	Saint Joseph School	2011-2012	Grade 9-10
Elementary school	Saint Michael Primary School	2003-2010	Grade 1-8

Qualification

- ☐ I have graduated from Jimma University in Generic BSc Nursing at 2018 with CGPA 3.85.

Language Skills

Language	Amharic	English
Speaking	Excellent	Excellent
Listening	Excellent	Excellent
Reading	Excellent	Excellent
Writing	Excellent	Excellent

Hobbies

Reading various books.

Listening various music.

Searching web site information.

Playing games and watching movies.

References

- Mr. Admasu Belay (BScN, MScN A), Lecturer at Jimma University, Ethiopia.
- Mr. Eyoale Abate (BScN, MScN), Lecturer at wachemo University, Ethiopia.

