

**ADDIS ABABA UNIVERSITY
COLLEGE OF HEALTH SCIENCES
SCHOOL OF PUBLIC HEALTH**



**Health Related Quality of Life among Diabetes Patients with Diabetic
Peripheral Neuropathic Pain in Zewditu Memorial Hospital and St. Paul
Hospital Millennium Medical Collage Addis Ababa: A Facility Based
Comparative Cross-sectional Study, 2017**

By: - Hiwot Degu (BSc)

**Thesis Submitted to School of Graduate Studies of Addis Ababa University in Partial
Fulfillment for Degree of Masters in Public Health**

**November 2017
Addis Ababa, Ethiopia**

Acknowledgment

- My sincere and deepest gratitude goes to my advisors Dr. Ayele Belachew, MS Abigia Wondimagegnehu and Dr. Yared Mamushet for giving me a timely comment. constructive advice and support from proposal preparation to the end of thesis writing.
- I would also like to extends special thanks to AAU SPH Instructors for their insightful comments whenever I want asked them
- I would also like to thanks my fellow students for the stimulating discussion and encouragement throughout our thesis
- Finally, I appreciate greatly and profoundly the support, love and endurance given by my beloved family.

Dedication

This paper is dedicated to my mother. She is a type II diabetes mellitus patient suffering with DPNP condition and one of my inspiration to study on this topic.

Abbreviations/Acronyms

A. A	Addis Ababa
BMI	Body Mass Index
BP	Body Pain
DM	Diabetes Mellitus
DN4	Douleur Neuropathique 4
DPN	Diabetic peripheral neuropathy
DPNP	Diabetic peripheral Neuropathic Pain
DSQOL	Diabetes Specific Quality of Life Scale
EH	Emotional Health
GH	General Health
HRQOL	Health related quality of life
IDF	International Diabetic Federation
MH	Mental Health
PH	Physical Health
RP	Rolle of Physical
SF	Social Functioning
SF -36	Short Form of 36 Questionnaire
SPHMMC	St. Paul Hospital Millennium Medical Collage
QOL	Quality of Life
VT	Vitality
VAS	Visual Analogue Scale
WHO	World Health Organization
ZMH	Zewditu Memorial Hospital

Table of Contents	
Acknowledgment	i
Abbreviations/Acronyms	v
Chapter One: Introduction	1
1.1 Background	1
1.2. Statement of the Problem	4
1.3. Significance of the Study	5
Chapter Two: Literature Review.....	6
2.1. Diabetes Mellitus Illness Profile	6
2.2. Measuring Quality of life	7
2.3 Impact of DM and Neuropathic Pain on HRQoL.....	9
2.4. Conceptual Framework	11
Chapter: Three Objectives	12
3.1. General Objective.....	12
3.2. Specific Objectives.....	12
Chapter Four: Methods	13
4.1 Study Design	13
4.2. Study Area and Period.....	13
4.3. Source Population.....	13
4.4. Study Population	13
4.5. Study Unit.....	13
4.6. Inclusion Criteria.....	13
4.7. Exclusion criteria.....	14
4.8. Sample size.....	14
4.9. Sampling Procedures	15
4.10. Data Collection Procedure and Instruments	16
4.11. Terms Definitions	17
4.12. Data Quality Management.....	19
4.13. Procedure for Data Processing and Data Analysis	20
4.14. Ethical Considerations.....	20
4.15. Dissemination of the Results	20

Chapter Five: Results	21
5.1. Socio-Demographic Characteristics of the Study Participants	21
5.2. Diabetes Related Characteristic of the Participants.....	23
.....	25
5.3 Mean scores and mean differences of SF36 HRQoL between with and without DPNP type II DM Patients	26
5.4. Visual Analogue Score (VAS) and HRQoL Correlation	28
5.6. Multivariate Analysis of Variance (MANOVA)	29
Chapter Six: Discussion	31
Chapter Seven: Strength and limitation of the Study.....	35
7.1. Strength of the Study	35
7.2. Limitations of the Study	35
Chapter Eight: Conclusion and Recommendation	36
8.1. Conclusion.....	36
8.2. Recommendations	37
References	38
Annex I. Information sheet and consent form (Amharic version)	43
Annex II. Information Sheet and Consent Form (English version)	45
Annex III Questionnaires	47

List of Figures

Figure 1: Conceptual Framework	11
Figure 2: Duration of Diabetes Mellitus	23
Figure 3: Body Mass index Composition.....	24
Figure 4: Diabetes Mellitus Related Complication.....	25
Figure 5: Mean Score and Mean Differences of HRQoL.....	27
Figure 6: Visual Analogue Score and HRQoL Correlation.....	28

List of Tables

Table 1: Socio-Demographic Characteristics of the Study Subjects.....	22
Table 2: Mean Score and Mean Differences of HRQoL.....	26
Table 4: Multivariate Analysis of Variances for Demographic Data	30
Table 5: Multivariate Analysis of Variances for Medical Related Data.....	30

Abstract

Background

Diabetic polyneuropathy is one of the commonest long-term complications of diabetes. The pain of diabetic peripheral neuropathy could affect the day to day activities of patients and could be troublesome to them. This study required to examine the influence of Diabetic Peripheral Neuropathic Pain on the health related quality of life of type II diabetes patients in our study settings.

Objectives: To describe the health related quality of life among type II diabetes patients suffering from diabetic peripheral neuropathic pain in two hospitals (Zewditu Memorial Hospital and St. Paulo Hospital Millennium Medical Collage) in Addis Ababa, Ethiopia 2017 G.C

Methods: Facility based comparative cross sectional study was conducted among sample of 220 type II diabetes patients with and without Diabetic Peripheral Neuropathic Pain, who are under the follow up care in Zewditu Memorial Hospital and St. Paul Hospital Millennium Medical Collage Addis Ababa. SF-36 questionnaire was used to collect data on health related quality of life. IBM SPSS statistics version 2015 software was used to analysis, mean score, mean score differences, multivariate analysis of variances and correlation score.

Results: The study subjects with Diabetic Peripheral Neuropathic Pain have lower health related quality of life (in all eight domains and two components summary report of SF 36) comparing to those group without Diabetic Peripheral Neuropathic Pain. The mean score difference in all the eight dimensions and both Physical and Mental Health Summary scores of the SF-36 was statistically significant with p-value 0.000

Conclusion: The presence or absence of diabetic peripheral neuropathic pain was found to influence health related quality of life mean score among type II diabetes patients. The domains that were more influenced among SF 36 health related quality of life are role of functioning and emotion. We recommend health care providers to give due attention to painful peripheral neuropathy associated quality of life in diabetic patients.

Chapter One: Introduction

1.1 Background

Diabetes mellitus (DM) is one of the most common chronic diseases that involve people of all ages and races in approximately all countries. The prevalence of DM continues to increase mainly due to the changes in lifestyles resulting in physical inactivity, and increased obesity. DM is a group of metabolic diseases characterized by high blood sugar (glucose) level, it is classified under three major groups, namely, type I, type II, and gestational diabetes. World Health Organization (WHO) defined DM as 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 (1).

Globally, 415 million people or 6 % of adults are estimated to have diabetes, among this 90% of them are type II DM and 80% live in Low- and Middle-income countries (LMICs). If these trends continue, by 2035, about 592 million people, or one adult in 10 will have diabetes (2). In Africa about 19.8 million adults were estimated have diabetes. Africa's most populous countries have the highest numbers of people with diabetes, including: Nigeria (3.9 million), South Africa (2.6 million), Ethiopia (1.9 million), Tanzania (1.7 million)(2). In 2015 the total number of excess deaths attributable to diabetes worldwide was estimated to be 3.96 million in the age group 20–79 years, 6.8% of global (all ages) mortality. Diabetes accounted for 6% of deaths in adults in the African Region, to 15.7% in the North American Region.(2). According to International Diabetes Federation (IDF) 2015 report concerning Ethiopia, in 2015, among the total adult 45,979,000 population 1333,200 adults have DM, while undiagnosed cases of DM estimated to be 951,300. As well as the number of deaths in adults due to DM were 23,145. And also a DM treatment has costed 45\$ (USD) per person.

Type II DM is a multidimensional health problem with consequences of Chronicity and complications like disability, decreased health-related quality of life and premature death. WHO estimates that 90 percent of people around the world who suffer from diabetes suffer from type II diabetes. More than eight of every 10 diabetes-related deaths occur in low- and middle-income countries. WHO anticipates that worldwide deaths attributable to diabetes will double by 2030.

Adults ages 40 to 59 comprise the world's age group with the highest diabetes rates, although this is expected to shift to adults ages 60 to 79 by 2030(2). Most of the chronic illness therapeutic success is measured by disease free, overall survival and control major physical symptom while this factor is play a primary role on this evaluation effort have been made to assess the extent to which the chronic disease and their treatment affect patient's functional psychological and social health and overall sense of well-being or quality of life (QOL)(3, 4). The WHO defines Quality of Life (QOL) as an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns (5). It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, personal beliefs and their relationship to significant features of their environment. Although clinicians and competent professionals may evaluate severity of the disease and degree of deterioration, their opinion of the patients' quality of life may not match with personal view of the patients. There is a great impact of psychosocial and cultural factors on the personal view of the patient.

Type II DM leads to many complications include micro vascular (nephropathy, retinopathy, and neuropathy) and macro vascular (stroke, myocardial infarction, and coronary artery disease) with co morbidities leads to a substantial decrease in the patients' quality of life as well as socio-economic implications(6-9). QoL evaluation has emerged as an important outcome measure for chronic disease management. It is increasingly recognized that in diabetes psychosocial factors have an important impact on self-care, acceptance of therapeutic regimens and treatment success. Metabolic measures like glycemic control are poorly correlated with quality of life necessitating separate assessment. In turn, management models for diabetes that include strategies to identify and enhance patient's health-related quality of life issues have the potential to improve compliance and hence their metabolic status. Quality of life is an individual perception and each particular subset of patients differs in their perception of quality of life influenced by their ethnicity, culture, education, income, the recognition of the patient important (versus disease-oriented) and patient reported areas of well-being led to the introduction of a technical term: health-related quality of life(10). Therefore, measuring HRQoL is important, as they predict the individual's capacity to manage his disease and maintain long-term health and well-being and it is also increasingly recognized as an important health outcome in its own right, representing the ultimate goal of all health interventions.

One of the commonest complication of DM is diabetic peripheral neuropathy (DPN) which is a well-known microvascular complication of type II diabetes mellitus attributed to chronic hyperglycemia, and is defined as the presence of peripheral nerve dysfunction in diabetics after exclusion of other causes(11). DPN leads to further infections, increasing the risk of foot ulcers and non-traumatic amputations. Estimates of foot infections in type II diabetes mellitus range from a lifetime risk of 4–7% annually(12). Peripheral neuropathy may be asymptomatic or symptomatic, when symptoms are present, they may be negative or positive, Negative symptoms include loss of sensation and loss of strength, while positive symptoms include pricking or pain. Up to 11% of patients with DPN may be affected by diabetic peripheral neuropathic pain (DPNP). As it defined by the International Association for the Study of Pain (IASP), pain arising as a direct consequence of abnormalities in the peripheral somatosensory system in people with diabetes. Clinically, DPNP is characterized by pain of insidious onset, which is described as burning, shooting or aching. It may be accompanied by allodynia, hyperalgesia and numbness, with symptoms often worsening at night, such neuropathic pain often causes difficulties falling asleep, sleep disturbances caused by pain, burning sensations and itching. The loss of sleep often leads to anxiety and depression, so many patients enter a vicious cycle of sleep deprivation. Sleep deprivation in return results in lack of energy, strongly influencing patient's ability to function through decreased motility and dependence on others in everyday functioning, (13, 14). For these reasons, it's a major public health problem, especially for developing country like ours it can be one of hindering factor to decreased income generating activities and overall productivity.

Today measuring or diagnosing neuropathic pain is a phenomenon for research or for clinical purpose and there are several neuropathic pain detecting techniques and tools, like Michigan Neuropathy Screening Instrument, Neuropathic Pain Scale, Leeds Assessment of Neuropathic Symptoms and Signs ,Neuropathic Pain Questionnaire, Neuropathic Pain Symptom Inventory, Douleur Neuropathique 4 questions (DN4), pain DETECT, Pain Quality Assessment Scale, and the Short-Form McGill Pain Questionnaire (11, 15-17).

1.2. Statement of the Problem

As more and more people become sedentary and towners, non-communicable like diabetes are becoming more prevalent. DM can have a profound effect on one's quality of life in terms of social and psychological wellbeing as well as physical ill-health and it is one of the most psychologically debilitating of the chronic diseases (18, 19). Consequently, a diabetic peripheral neuropathy prevalence rate as high as 50% (11) has been reported in the literatures, but there are considerable differences across studies (7, 11, 20, 21), which may be due to methodological differences and the lack of consensus on its diagnostic criteria. Data related to the prevalence of DPNP are even more sparse and variable. A significant proportion (10–20%) of type II diabetic patients with DPN requires treatment for severe painful symptoms that develop over time(11, 22).

Older age, long diabetes duration and poor glycaemic control are well-established risk factors for DPN and are possibly also associated with DPNP (23). Clinically, it characterized by pain of insidious onset, which is described as burning, shooting or aching. DPNP responds poorly to conventional analgesics such as nonsteroidal anti-inflammatory drugs (NSAIDs) and may lead to sleep disturbance and depression, and may interfere with daily activities. Consequently, DPNP is associated with significant deterioration in patients' health related quality-of-life due to painful symptoms leading to disability.

1.3. Significance of the Study

DPNP is the commonest and most affecting in day to day activities among DM type II patients, which is might be another economic and social burden for developing country like ours. Although many studies around the world has shown that impact of diabetes on quality of life in terms of social, psychological and physical well-being, comparatively there is lesser studies on how DPNP is affecting HRQOL by itself alone(21). When we come to our country also, to our knowledge there is no study looking for the HRQoL in DPNP. Since we have a different life standard from developed countries we can't fully rely on their findings regarding quality of life. So, this study required to reveal the extent of to DPNP affect the HRQoL of diabetic type II patients and strive to put further recommendation and intervention depending on the outcome of the study.

Chapter Two: Literature Review

2.1. Diabetes Mellitus Illness Profile

Globally, 415 million people, or 8.3% of adults, are estimated to have diabetes. About 80% live in low- and middle-income countries and if these trends continue, by 2035, about 592 million people, or one adult in 10 will have diabetes. In Africa about 19.8 million adults were estimated have diabetes and regional prevalence of 4.9% and Africa's most populous countries have the highest numbers of people with diabetes, including: Nigeria (3.9 million), South Africa (2.6 million), Ethiopia (1.9 million), Tanzania (1.7 million) and the extrapolated prevalence of DM in Africa in 2013 was 4.36 % (24) Reportedly, 34,262 patients out of 1.8 million DM cases died in Ethiopia in 2013. It is also known that a large number of people remain undiagnosed, with estimated number of undiagnosed cases reported to be 1.39 million people in 2013 (24).

Type II diabetes mellitus is the most common form of DM worldwide, accounting for more than 90 % of case. Peripheral neuropathy mainly involves type II DM, which remains asymptomatic over a long period of time in many cases and is only diagnosed once the associated complications appear. The most common neuropathies are symmetrical generalized polyneuropathy, especially the distal symmetric polyneuropathy or sensorimotor, called peripheral diabetic neuropathy, followed by the autonomic, sensory-acute; and focal and multifocal, less frequent, more than half of all individuals with diabetes exhibit one or more microvascular complications, including diabetic nephropathy (DN), diabetic peripheral neuropathy (DPN), or diabetic retinopathy (DR), which have a serious negative impact on the quality of life of patients. DPN is a well-known microvascular complication of type II DM. DPN is attributed to chronic hyperglycemia and is defined as the presence of peripheral nerve dysfunction in individuals with diabetes after the exclusion of other causes DPN is associated with infections and is directly associated with increased risk for foot ulceration and nontraumatic amputation (25). The estimates of foot infections in type II DM patients range from a risk of 4% to 7% annually, the symptoms of DPN are intermittent and include persistent limb pain with a tingling or burning sensation, among others. DPN is one of the most debilitating factors for patients. Neuropathic pain can be defined as abnormal pain sensation in peripheral or central nervous system following injuries It is caused by dysfunctions in the peripheral or central nervous system without peripheral nociceptive stimulation.6,7 Neuropathic pain syndromes represent a group of highly heterogeneous clinical

conditions The prevalence of DPN ranges from 30% to 90%. Patients might also develop hypoesthesia or paresthesia with numbness or an “electric shock” sensation (11) A significant proportion (10–20%) of type 2 diabetic patients with DPN requires treatment for severe painful symptoms that develop over time. Older age, long diabetes duration and poor glycaemic control are well-established risk factors for DPN and also are possibly associated with DPN-P (11, 12, 21, 26). Other previously reported coexisting factors are patients’ gender, height, insulin therapy, smoking status, alcohol consumption, high body mass index (BMI), elevated systolic blood pressure, presence of peripheral vascular disease, retinopathy, nephropathy and hypercholesterolemia (17, 27, 28).

2.2. Measuring Quality of life

Nowadays it’s approved that the medical outcome can’t described fully by measurement of clinical outcome and clinical indicators alone Not only many factors such as pain, apprehension, financial situation have influence on health related status but also subjective well-being has effects on individual’s health(29). Measuring QOL changes usually involves imploring peoples’ self-reported feelings, behaviors and attitudes through interviewing or evaluating responses to questionnaires. The instruments and techniques used to assess quality of life vary depending to the type of the respondents, then setting of the evaluation and the type of questionnaire used. Quality of life, in general, can be measured with generic or disease - specific instruments. The Diabetes Specific Quality of Life Scale (DSQOL) is a reliable and valid measure of diabetes specific quality of life. The scale is able to distinguish between patients with different treatment and dietary regimens and to detect social inequities, which comprised 64 items on individual treatment goals (10 items), satisfaction with treatment success (10 items), and diabetes-related distress (44 items) Use of the DSQOLS for assessment of individual treatment goals as defined by the patients may be helpful to identify motivational deficits and to tailor individual treatment strategies(30). However, DSQOL questionnaire is not validated for Ethiopia and we couldn’t use it for the current study.

Out of many generic health related quality of measuring questionnaire, the SF-36 is the most commonly used health status measure in the world today. The SF-36 derived from the work of the Rand Corporation of Santa Monica during the 1970s. Rand's Health Insurance Experiment compared the impact of alternative health insurance systems on health status and utilization. The

outcome measures developed for the study have been widely used and several are described in this book. They were subsequently refined and used in Rand's Medical Outcomes Study (MOS), which focused more narrowly on care for chronic medical and psychiatric conditions (31).

The SF36 questionnaire contains 36 questions measuring health across eight different dimensions, physical functioning (PF), role limitation because of physical health (RP), social functioning (SF), vitality (VT), bodily pain (BP), mental health (MH), role limitation because of emotional problems (RE) and general health (GH). Responses to each question within a dimension are combined to generate a score from 0 to 100, where 100 indicates "good health"(32-36). Thus, the SF-36 generates a profile of HRQoL outcomes.

Furthermore, there are several tools to measure HRQOL. Examples include The WHOQOL (World Health Organization Quality of Life) questionnaire, QWB-SA (Quality of Well-Being Questionnaire), Euro QoL (European Quality of Life) or EQ-5D (Euro-QOL 5-Dimensions), DQLCTQ-R (Diabetes Quality of Life Clinical Trials Questionnaire Revised), ADDQOL (Audit of Diabetes Dependent QOL) instrument. Diabetes QOL life measuring instruments exist both with generic and specific likewise there are many diabetic neuropathies specific instruments (37) The Peripheral Neuropathy Quality of Life Instrument (PN-QOL-97). Vickrey, Hays and Beckstrand also developed a questionnaire to evaluate peripheral neuropathy. The instrument was formed from items from the Rand, a widely used HRQoL PROM measure (Hays & Morales, 2001), and responses from focus group material, and evaluated in 80 patients at 3 and 6 month follow up evaluations in a clinical setting. The instrument was re-evaluated, and in the process, pared down from 162 items to 97 items during the study through examination of construct validity, reliability, and comparisons to HRQOL measures. Findings resulted in strong associations between the instrument's results and reported diabetic neuropathy (DN) symptoms and support for reliability and validity for use in adults with DN. The revisions ultimately arrived at an instrument that is made of two base components, a physical component and a mental component, both of which are scored through a complex set of calculations provided by the author(38).

2.3 Impact of DM and Neuropathic Pain on HRQoL

Diabetic polyneuropathy, both in its painful and non-painful form, significantly influences the patients' quality of life. The study of Van Acker K1 et al,(39) showed that neuropathic pain can be identified with inexpensive and easy-to-use screening tools. Despite its profound impact on QOL, DPN- with neuropathic pain remains undertreated. On their finding, the prevalence of DPN was 43% (95% CI 40.1-45.9), and was higher in type 2 (50.8%) than in type 1 (25.6%) diabetic patients. The prevalence of painful DPN was 14% (95% CI 12.1-16.2) which, again, was higher in type 2 (17.9%) than in type 1 (5.8%) patients. This prevalence both increased with age and diabetes duration. Nephropathy, obesity, low HDL cholesterol and high triglyceride levels were independently associated with DPN and/or painful DPN. Physical and mental components of QOL were significantly altered by painful DPN, but not DPN. Multivariate analyses of QoL scores revealed that DPN-P independently affected both the physical and mental QoL, even after adjusting for pain intensity. In addition, changes in physical QoL were associated with age and BMI, while a poorer mental QoL was associated with female gender, smoking, BMI and diabetes duration. DPN alone had no statistically significant effect on either physical or mental QoL scores (39).

The study done in Korea by Sang Soo Kim et.al about prevalence and its risk factors of painful peripheral diabetes neuropathy and its association with quality of life showed that PDPN was independently associated with age, female gender, fasting plasma glucose, hypertension, and previous cerebrovascular events. All pain severity and interference measures were higher in patients with painful DPN than in non-painful DPN patients, and patients with Painful DPN reported more impaired sleep and lower EQ-5D and VAS scores The study done in Croatia, including 80 patients that with neuropathic pain and 80 patients with DPN, but without neuropathic. after they neuropathic symptoms and signs assessed by Visual analogue scale (VAS) and Leeds assessment of (LANSS) they used SF-36 standardized questionnaire for assessment of the quality of life and BDI questionnaire for assessment of depression and found that Subjects in group Painful had statistically significantly lower values compared to group non neuropathic pain DPN in all 8 dimensions and both summary values of the SF-36 scale. They ascribe the extremely low results of all parameters of SF-36 scale in group to painful diabetic polyneuropathy with its complications. The patients without painful DPN showed higher average values in all dimension compared to without painful DPN, but also somewhat higher quality of life compared to general

population of Croatia in 4 of 8 dimensions, namely vitality (VT), social functioning (SF), role-emotional (RE) and mental health (MH), which was unexpected result. Clinically, the most pronounced differences between two groups were noted in sleeping disorders and problems regarding micturition and defecation, which were significantly more expressed in group with DPN. The similar situation was with walking distance and color-doppler sonography of carotid arteries, which were significantly worse in group with neuropathic pain. Consequently, subjects in group diabetic neuropathic pain were more medicated than the patients in group without diabetic neuropathic pain, particularly with tramadol, antiepileptic and antidepressants(40).The study done by Etlik Mh et.al in turkey Ankara 2015, on Effects of Pain and Disability on Quality of Life in Patients with Diabetic Polyneuropathy found that effects of neuropathic complaints on QoL a statistically significant decrease in the in patients with pain (41). The study done in South Africa by Andrew Jacovides et.al by EQ-5D questionnaire, Mean_ SD and DSIS scores were 0.84_0.16 and 0.83_1.90, respectively, in participants without DPNP versus 0.64_0.25 and 3.62_2.96, respectively, in those with DPNP. Their assessment of HRQOL by EQ-5D subscale showed that, there was a statistically significant negative correlation between pain and physical functioning, physical role limitation, social functioning, and pain domains (21).

2.4. Conceptual Framework

Theoretical model derived from literature review that directly and indirectly related to major variables of the study which is health related quality of life. Diagrammatically illustrated as follows:

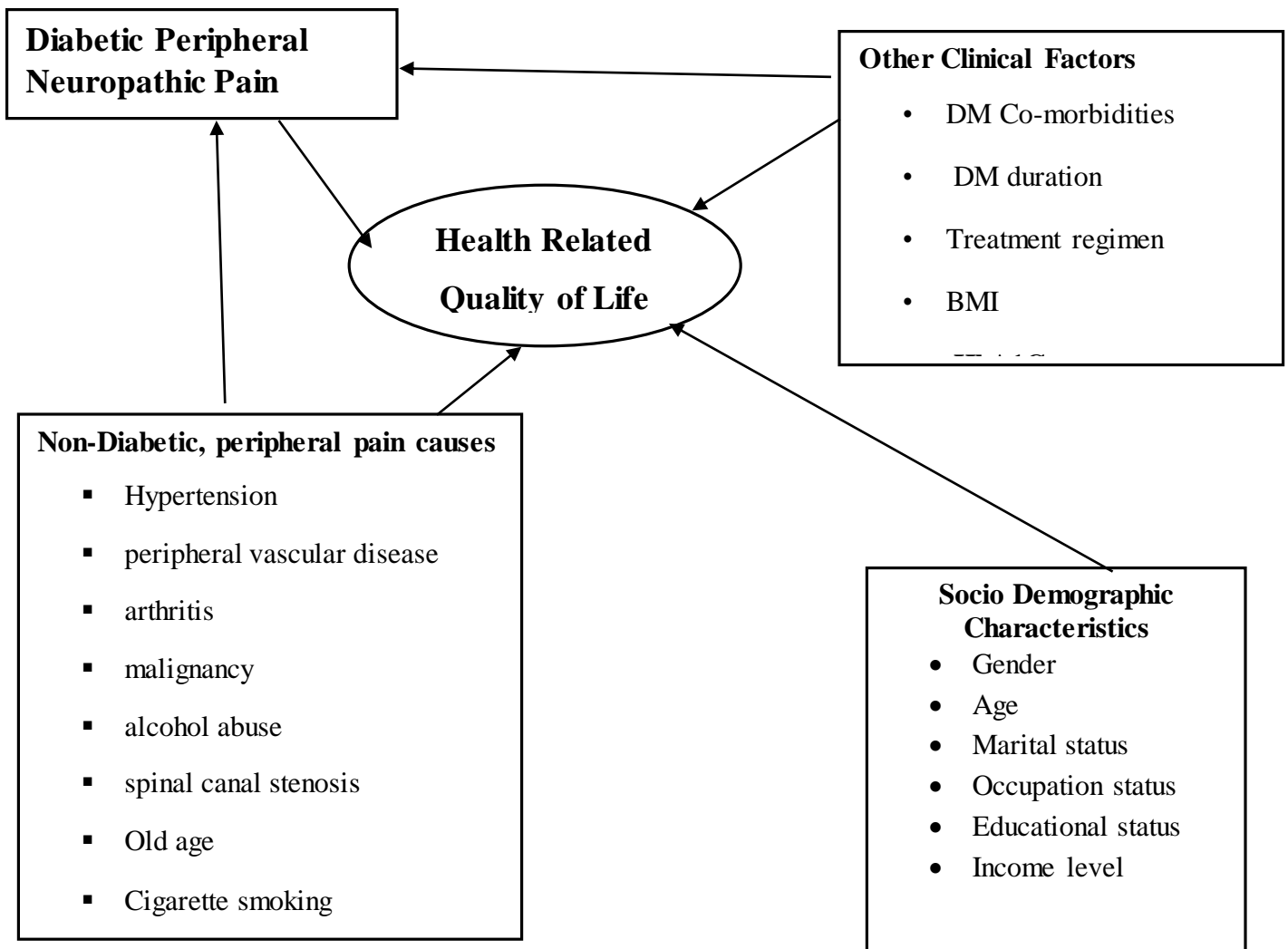


Figure 1. Conceptual Framework illustration of connections between the dependent and independent variables

Chapter: Three Objectives

3.1. General Objective

To compare Health Related Quality of Life among Type II DM patients with and Without DPNP, in Zewditu Memorial Hospital and St. Paul Hospital Millennium Medical Collage, Addis Ababa_2017

3.2. Specific Objectives

- To identify the quality of life domain that more influenced by the diabetic peripheral neuropathic pain

- To determine health related quality of life by the intensity of pain among patients with diabetic peripheral neuropathic pain.

Chapter Four: Methods

In this chapter, the study design, sample selection, study area and population of this study are discussed, followed by data collection and SF-36 questionnaire discussion as well as procedure for data processing and data analysis. Lastly, the ethical considerations and thesis dissemination were elaborated.

4.1 Study Design

An institution based comparative cross-sectional study design is used to conduct the present study.

4.2. Study Area and Period

Three hospitals in A.A, 2017, namely, Tikur Anbesa Specialize Hospital (TASH), St. Paul Hospital Millennium Medical Collage (SPHMMC) and Zewditu Memorial (ZMH) were purposely selected to be the study areas. These aim of these hospitals were selected due to the high flow of DM patients and their suitability to this research. Among three purposively selected public hospitals, two public hospitals were selected by lottery method, (i.e., St. Paul Hospital Millennium Medical Collage and Zewditu Memorial Hospital) and then the study was conducted.

4.3. Source Population

All type II diabetes patients who visits Zewditu Memorial Hospital and St. Paul Hospital Millennium Medical Collage A.A, hospitals in Addis Ababa.

4.4. Study Population

All type II diabetes patients who visited and Zewditu Memorial Hospital and St. Paul Hospital Millennium Medical Collage during the study period.

4.5. Study Unit

All type II diabetes patients who visited Zewditu Memorial Hospital and St. Paul Hospital Millennium Medical Collage during the study period and eligible of inclusion criteria.

4.6. Inclusion Criteria

- Type II DM patients diagnosed through WHO criteria
- Type II DM patients aged between 18 years and 65 years
- Type II DM patients No admissions in past 3 months

4.7. Exclusion criteria

- Patients who have known serious clinical diseases, like cancer, asthma etc.
- Patients who have history of substance abuse, e.g. alcohol, and drugs
- Patients who have disabilities unrelated to DM
- Patients who displayed a gross mental health condition during data collection

4.8. Sample size

The sample size was determined assuming a normally distributed independent means. For this study, the HRQoL mean scores of HRQoL found from previous study and which was done in South Africa by Andrew Jacovides et.al (21) used for sample size determination. STATA version 13 software used for sample size calculation

Formula of Sample Sizes Determination for Two Independent means, continuous outcome.

$$n = \frac{2\sigma^2 (Z_{\beta} + Z_{\alpha/2})^2}{d^2}$$

n = sample size

$z_{\alpha/2}$ = Critical value at 95 % level of significance

$z_{1-\beta}$ = standard normal distribution value corresponding to power 0.2

σ^2 = the population variance difference in means)

d = difference wanted to be detected

Data entered in STATA 2013 software

Alpha = 0.05

Power = 0.8

Mean 1 = 0.84

Mean 2 = 0.64

SD = 0.5

r = ratio of exposed to non-exposed =1

α =Type one error (0.05)

$z_{\alpha/2}$ = Critical value at 95 % level of significance

$z_{1-\beta}$ = standard normal distribution value corresponding to power 0.2

Output of STATA 2013

N =200

Per each group =100

By adding 10 % non-response rate

Total sample size 220

4.9. Sampling Procedures

A systematic random sampling technique (selecting patients with every four k interval) was used to select study subjects out of all type II DM patients who visited outpatient departments of Zewditu Memorial hospital and St. Paulos referral hospital at the time of the study.

The study subjects sample size allocation for two hospitals (Zewditu Memorial hospital and St. Paulos referral hospital) was done using proportional sample size allocation formula.

$$ni = n \frac{Ni}{N}$$

ni= Sample size per hospital

n = Total sample size

Ni = Total population of DM patients per hospital (annually)

N = Total population of DM Zewditu Memorial hospital and St. Paulos referral hospitals (annually)

Since annual DM patients flow of Zewditu Memorial hospital is 4800 and St. Paulos referral hospital's is 1714, the final sample allocation was 162 for Zewditu Memorial hospital and 58 for St, Paulos Referral hospital.

4.10. Data Collection Procedure and Instruments

After the study subjects who fulfilled the inclusion criteria recruited in to the study, DPNP was evaluated through interview and physical examination using a standard neuropathic pain detecting tool which is 90 percent specific and 85 percent sensitive (i.e. Douleur Neuropathique 4 questions (DN4)). Additionally, for study subjects who have DPNP, pain intensity was measured by visual analogue scale (VAS) score, that was marked by the patients themselves. The VAS scoring of 0 shows no pain whereas 10 shows unbearable pain.

Patient's card was reviewed for co-morbidities, HbA1c, lipid profile and DM complication recording. Additionally, study subjects were scaled for their weight and height to BMI calculation and also patients were asked about drug adherence and the information about duration DM, which the duration of DM considered by the first time patients knew they had Diabetes. Finally, the BSc nurses interviewed both groups (those with and without DPNP) using SF 36 questionnaire, that was validated and translated for Ethiopia by two validation studies (42, 43).

The SF-36 questionnaire was selected for its capability to evaluate both the physical and psychological components of quality of life, and also some articles recommended it for the quality of life studies related to neuropathy (33, 35). The SF-36 questionnaire assesses eight dimensions of health related quality of life, which relate to the physical and mental components of the individual's health perception. Specifically, the domains 'physical functioning' (10 items), 'role-physical' which means role limitation due to physical health problems (4 items), 'bodily pain' (2 items), and 'general health' (5 items) are more related to the physical component, whereas the domains 'vitality/energy' (4 items), 'social functioning' (2 items), 'role-emotional' which means role limitations due to emotional problems (3 items), and general 'mental health' (5 items) are more related to the psychological component. Possible scores for each domain range from 0 (corresponding to the worst possible state) to 100 (corresponding to the best possible state). These eight domains can be grouped into two summary scores: the 'physical component summary' (PCS) evaluates the patients' perception of limitations or disabilities in self-care, physical, social and role activities, the presence of bodily pain and fatigue. The 'mental component summary' (MCS) score evaluates the feelings of psychological distress, social and role disability because of emotional problems. The scales (Vitality, General Health, and Social Functioning) can be considered either

physical or mental components. On many articles, it's recommended that it's better to use the two summary measures than using the eight scales in statistical analysis of the SF-36 as it reduces the number of statistical comparison tests(30, 31, 34, 35).

4.11. Terms Definitions

Quality of Life (QoL)

Quality of life can be defined as, the state of contentment in a conscious individual due to his other satisfaction in physiological, psychological, social and spiritual aspects of life According to WHO, Quality of life is defined as individual's perceptions of their position in life in the context of the culture and value systems in which they live and in relation to them goals, expectations, standards and concerns (10).

Health Related Quality of Life (HRQoL)score

First the score for each domain was calculated by summing up each item under each domain then each raw scale score was transformed to 0-100 scale by using the formula.

$$\text{Transformed scale} = \left[\frac{\text{Actual raw score} - \text{lowest possible score}}{\text{Possible raw score range}} \right] \times 100$$

Then HRQoL was calculated by summing up each transformed score by dividing into eight domains as well as physical component summary and mental component summary were calculated after factor analysis based on 1993 Ware JE et.al. SF-36 Health Survey Manual and Interpretation Guideline (33).

Neuropathic Pain

Neuropathic pain is a complex, chronic pain state that usually is accompanied by tissue injury with neuropathic pain, the nerve fibers themselves may be damaged, dysfunctional or injured. These damaged nerve fibers send incorrect signals to other pain center. Based on DN4 neuropathic pain assessment standard questionnaire which includes physical examination and interview. Neuropathic pain determined if the pain score is 4 or higher than the pain is likely to be neuropathic pain but if the pain score is less than 4 then the pain is less likely to be neuropathic pain (44).

Substance Abuse

Meanwhile, is when a person consumes alcohol or addictive drugs regularly, despite the fact that it causes issues in their life. The issues caused by abuse may be related to their job, their personal life, or even their safety (45).

Independent Variables

- Diabetic peripheral neuropathic pain
- Gender,
- Age
- Marital status,
- Educational status
- Income
- BMI
- Occupation.
- Duration of diabetes mellitus
- Type of the regime
- Diabetes Complication
- HbA1C

Dependent Variables

➤ **Physical Function (PF)**

Extent to which health limits physical activities such as walking, self-care, climbing stairs, lifting and exercises

➤ **Role Physical (RF)**

Extent to which physical health interferes with work including accomplishing less and difficulties in performing activities

➤ **Body Pain (BP)**

Intensity of pain and its effect on work

➤ **General Health (GH)**

Personal evaluation of health, including current health and health outlook

➤ **Vitality (VT)**

Feeling energetic versus feeling tired and worn out

➤ **Social Functioning (SF)**

Extent to which physical health or emotional problems interfere with social activities

➤ **Role Emotional (RE)**

Extent to which emotional problems interfere with work including decreased time spent on activities, accomplishing less

➤ **Mental Health (MH)**

General mental health, including depression, anxiety, behavioral-emotional control

➤ **Physical Health Component Summary (PCS)**

Includes physical functioning, role limitations due to physical health problems, bodily pain, and general health perception.

➤ **Mental Health Component Summary (MCS)**

Includes social functioning, role limitations due to emotional problems, mental health and vitality.

4.12. Data Quality Management

A two days of training on data collection technique was given to data collectors (4 clinical BSc nurses). The training was focused on acquainting interviewers with the questionnaire and giving them the opportunity to practice using it. During data collection the principal investigator has been conducting a site supervision. The principal investigator reviewed and checked the collected data for completeness before entering the data. For the data consistency, the cleaning process was done by running simple frequency after data entry. Data which is not consistent was checked by referring the hard copy questionnaire.

4.13. Procedure for Data Processing and Data Analysis

The principal investigator cleaned and entered data into Epi-Data version 3.1 then exported to IBM SPSS Statistics version 2015 software for analysis. Mean, percentage and frequency analysis was carried out to for demographics and clinical characteristics of 220 study subjects. The Chi square test and ANOVA test was done to check similarity between two comparative groups (with and without DPNP) in terms of demographic and clinical characteristics.

For HRQoL result analysis, the mean scores and mean differences was calculated and results summarized and presented by tables and charts. Correlation score analysis was also carried out to see the effect of pain intensity on HRQoL among with DPNP group. Additionally, after statistical assumption of multivariate analysis of variance (MANOVA) tested and the data fixed by log transform, to fulfil the normal distribution assumption of the MANOVA, the analysis was carried out considering physical health component summary PCS scale and mental health component summary MCS scale as outcome variable.

4.14. Ethical Considerations

The thesis proposal was submitted to the Research Ethical Committee (REC) of the school and Institutional Review Board (IRB) of Addis Ababa University, college of Health Sciences for approval. Following the approval by IRB, Official letter of co-operation was written to concerned bodies by the School of Public Health AAU, then the data collection allowed by the hospitals after submission of official letter from AAU SPH and the thesis proposal. Since the study was conducted through physical examination, review of medical records and interview, the study subjects were informed and written consent was obtained from each study participants and Confidentiality and anonymity of the participants had kept. Participants was also informed that participation will be on voluntary basis and they can stop or leave the participation at any time if they are not comfortable about the questionnaire or over all study.

4.15. Dissemination of the Results

The final report of this thesis will be submitted to the school of public health, Addis Ababa University. And also the study findings will be disseminated to the Addis Ababa regional health bureau and respective health facilities. Moreover, efforts will be made to publish the findings in medical journal.

Chapter Five: Results

5.1. Socio-Demographic Characteristics of the Study Participants

A total of 220 type II diabetes patients who had follow-up in DM clinics of Zewditu Memorial hospital (n= 162) and St. Paul Hospital Millennium Medical Collage (n= 58) were involved in the study. The response rate was 100% for, physical examination, interviewing, and weight and height measurement. Among the total respondents, 132 (60%) were females). As for age 132(60 %) of them were >50 years old. For marital status, 74%(164) were married. 62(28.2%) were high school completed, 75 (34%) were unemployed and 152(69.1%) Orthodox Christian by religion.

The chi square test was done to compare the similarity of socio demographic characteristics between comparative study groups (DPNP and without DPNP) and the result showed that the two groups are not significantly different by age, sex (gender), educational statuses, religion, income, marital statuses, and occupation at P value greater than 0.05. For instances gender (sex) distribution in both group is similar with p. value of 0.41, educational statuses p value of 0.53, income statuses p value 0.30. The result is summarized in table 1.

Table 1: Socio-Demographic Characteristics of Type II DM in Zewditu Memorial Hospital and St. Paul Hospital Millennium Medical Collage Addis Ababa, Ethiopia _2017

Variables	Total n=220 (%)	With DPNP n=110 (%)	Without DPNP (n=110) (%)	P- value
Sex				
Male	88(40)	47(42.7%)	41(37)	.491
Female	132(60)	63(57.3)	69(62.7)	
Age (Mean +SD)	50.4±9.9	52.7±9.3	47.4±10.6	.281
Educational Status				
Illiterate	36(16.4)	21(19.1)	15(13.6)	.527
Read and write only	31 (14.1)	16(14.5)	15(13.6)	
Primary school completed	52(23.6)	27(24.5)	25(22.7)	
Secondary school completed	62(28.2)	31(28.2)	31(28.2)	
College completed	39(17.7)	15(13.6)	24(21.8)	
Marital status				
Single	24(10.9)	10(9.1)	14(12.7)	.585
Married	164 (74.6)	81(73.6)	83(75.5)	
Divorced	16 (7.3)	9(8.2)	7(6.4)	
Widow	16 (7.3)	10(9.1)	6(5.5)	
Religion				
Orthodox	152(69.1)	78(70.9)	74(67.3)	0.82
Muslim	35 (15.9)	16(14.5)	19(17.3)	
Protestant	33 (15)	16(14.5)	17(15.5)	
Occupation				
Unemployed	75(34.1)	43(39.1)	32(29.1)	.201
Governmental org. employed	30 (13.6)	13(11.8)	17(15.5)	
Private org. employed	54 (24.6)	27(24.5)	27(24.5)	
Self employed	39(17.7)	14(12.7)	25(22.7)	
Retired	22 (10)	13(11.8)	9(8.2)	
Income (mean &SD)	1322±1180	1409.5±1303	1402.3±1251.65	.453

5.2. Diabetes Related Characteristic of the Participants

The DM related clinical characteristics (type of drug regimen, blood cholesterol, adherence, HbA1c, DM complications) were recorded from the study subject's patient card. However, patient's height and weight were measured right away during this study. The Analysis of variance (ANOVA) test for similarity between two groups (with and without DPNP) showed that the two groups are not significantly different for total cholesterol at p-value of 0.246 and for BMI at p-value of 0.615. Whereas the two groups are significantly different for duration of DM at p-value of 0.05 and HbA1c at p-value of 0.03

Among 220 type II DM patients 196 of the participants (88.7%) are adherent for the oral hypoglycemia drugs and insulin that prescribed by their respective physician, while 24 (10.9 percents) are non-adherent. Regarding cholesterol, the mean total cholesterol for 220 patients was 213(\pm 28.2) mg/dL, while for with DPNP group 220 \pm 26.2mg/dL and 205 \pm 28.7mg/dL for without DPNP.

DM Duration

Figure 2. showing duration of DM (the time since the patients knew they have DM) classified by four groups. The percent of the patients those who have DM duration of 1-5 years, 6-10 years, 11-15 years are almost equal (30%, 30.5% and 25.9%) however, percentage of patients who have above 15 years of DM duration are comparatively smaller (13.6%). Total mean duration for 220 patients was 9.6 \pm 5.5. respectively, 11.2 \pm 5.2 for with DPNP and 7.5 \pm 5.4 for without DPNP patients.

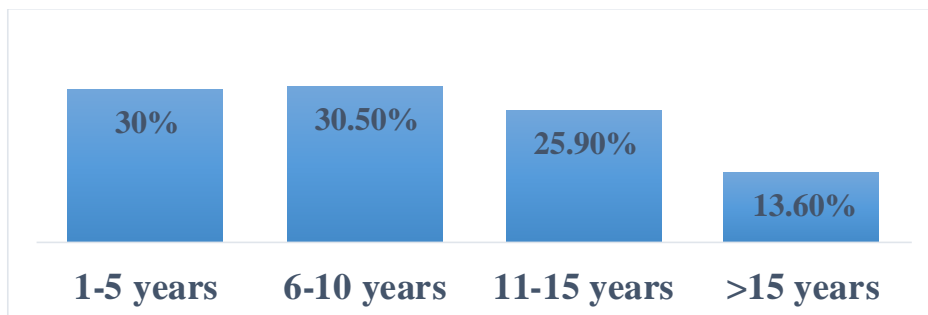


Figure 2. Duration of DM among 220 Type II DM Patients in ZMH and SPHMMC, Addis Ababa, Ethiopia, 2017.

Hemoglobin A1c (HbA1c)

HbA1c indicates the status of long term diabetes control. The total mean score of HbA1c for 220 was 9.13 ± 2.8 mmol. Respectively, for with DPNP patients 10.4 ± 2.6 mmol and 7.5 ± 2.7 mmol for without DPNP patients. By classifying according to HbA1c from normal to very high, 30 percent of the patients have HbA1c < 7 mmol, 49 percent of them fall in the range of HbA1c 7-11mmol, while 21 percent have HbA1c > 11 mmol.

Body Mass Index (BMI) Measurement

By standard classification of BMI, majority of them (49%) were overweight, while those with normal BMI range are 34 percent. The total mean score of BMI for 220 patients was 25.9 ± 3.7 , while 26.4 ± 3.7 for with DPNP patients and 25.2 ± 3.5 for without DPNP patients.

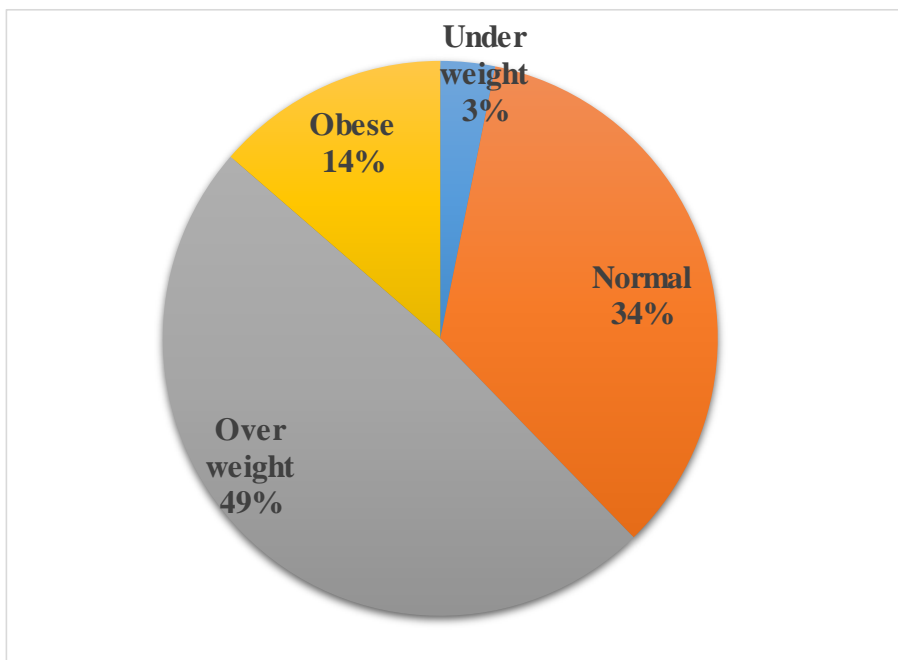


Figure 3. Body Mass Index composition among Type II DM 220 Patients in ZMH and SPHMMC, Addis Ababa, Ethiopia, 2017

DM complication

Six types of DM related complications were recorded from the study subjects' patients card reports. Among 220 type II DM patients, the total number of patients who have one or more DM complication was 144 (65.5 percent). Those who have foot ulcer was 3 patients, heart disease 8 patients, retinopathy 19 patients, nephropathy 30 patients, hypertension 34 patients and neuropathy 120 patients. Figure 4. Showing that DM complication according to their study groups (with and without DPNP)

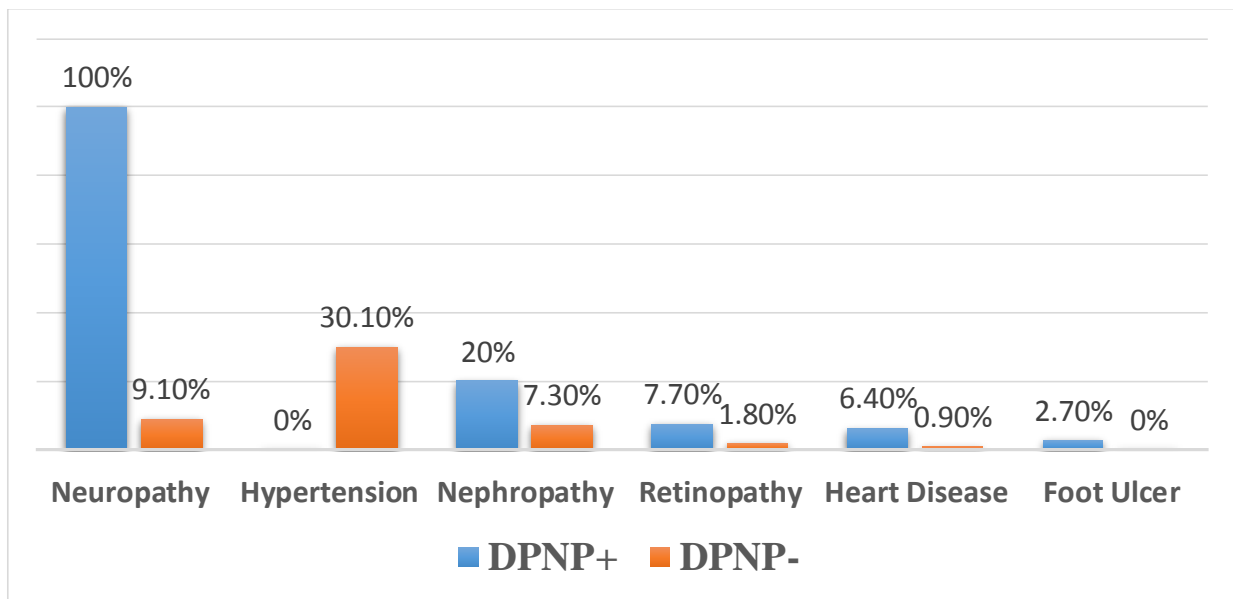


Figure 4. DM Comorbidity (Complications) Distribution among Type II Diabetes Patients (with DPNP (blue) and without DPNP (red)) in ZMH and SPHMMC, Addis Ababa, Ethiopia, 2017

5.3 Mean scores and mean differences of SF36 HRQoL between with and without DPNP type II DM Patients

Table 2. Mean Score and mean difference of SF36 HRQoL Domains and Two Summary Scales among with and without DPNP Type II diabetic patients, in ZMH and SPHMMC, Addis Ababa, Ethiopia, 2017.

HRQoL Domains		Mean & SD			Independent Samples Test t-test for Equality of Means		
SF36 HRQoL	Without DPNP n=110	With DPNP n=110	Total N=220	Mean Difference	95% Confidence interval		Sig. (2-tailed)
					Lower	Upper	
PF	72.3±22.3	42±19.1	57.2±25.7	30.3	24.6	35.8	.000
RP	60.9±36.3	21.8±28.2	41.4±37.8	39.1	30.5	47.7	.000
BP	70.3±36.3	45.6±15.5	57.9±20.4	24.8	20.5	29.1	.000
GH	66±17.3	39.9±16.5	52.9±21.5	26.1	21.5	30.7	.000
VT	64.8±16.2	46.3±13.1	55.6±17.3	18.5	14.6	22.4	.000
SF	74.7±13.8	57±19	65.3±18.3	17.6	13.2	22	.000
RE	60.3±42.7	22±33.3	41.2±42.7	38.3	28.0	48.4	.000
MH	67.6±17.3	48.9±15.1	58.3±18.7	18.7	14.4	23	.000
PCS	47.4±7.7	36±7	41.7±9.3	11.4	9.4	13	.000
MCS	37.3±13.6	22.6±11.6	30±14.6	14.7	11.4	18.1	.000

The HRQoL mean score differences between two study groups (with DPNP and without DPNP) was statistically significant (p-value 0.000) in all SF-36 eight domains and two summary scores. The PCS mean difference was 11.4 which includes physical functioning, role limitations due to physical health problems, bodily pain, and general health perception and the MCS mean difference was 14.7 which includes social functioning, role limitations due to emotional problems, mental health and vitality.

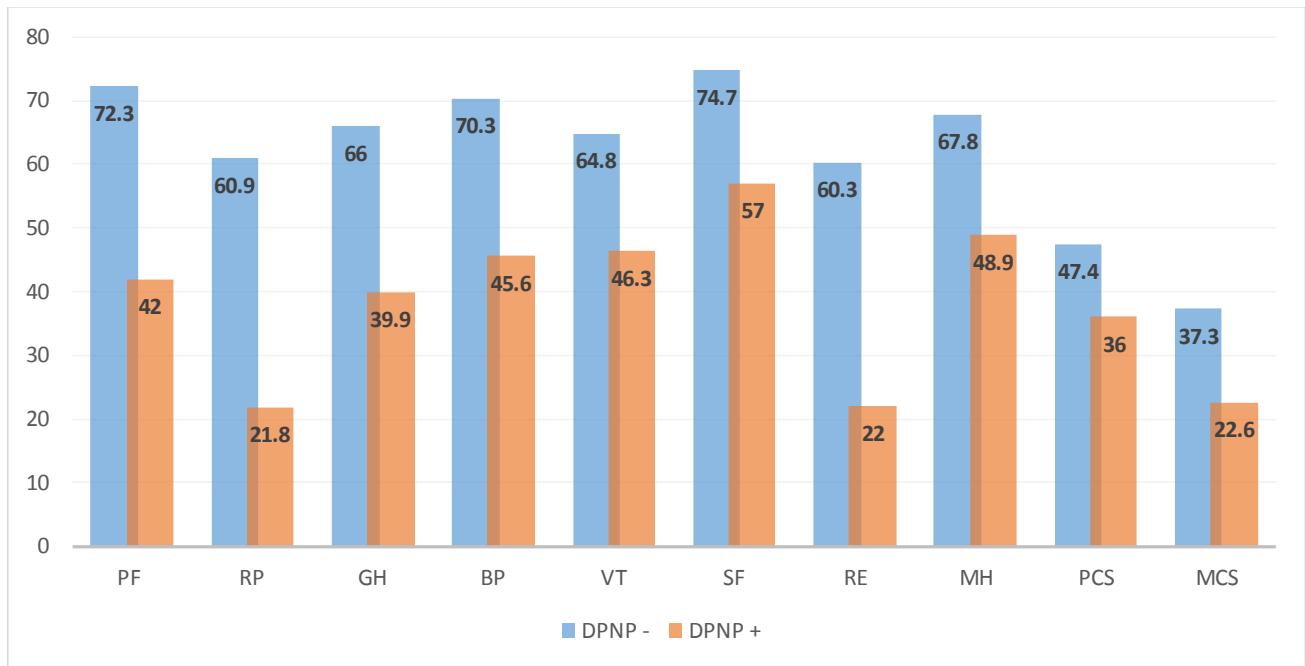


Figure 5. Mean score and mean difference of SF36 HRQoL domains and two summary scales among with and without DPNP Type II DM patients ZMH and SPHMMC, Addis Ababa, Ethiopia_2017.

The mean of the dimensions of SF-36 scale among DM type II study participants, with DPNP (red) and without DPNP (blue). Physical functioning (PF); Role-physical (RP); Bodily pain (BP); General health (GH); Vitality (VT); Social functioning (SF); Mental Health (MH); Role-emotional (RE), Physical Component Summary (PCS) and mental Health Summary (MCS).

5.4. Visual Analogue Score (VAS) and HRQoL Correlation

Participants with DPNP patients (110 study subjects) were assessed for pain intensity by Visual analogue scale (VAS), which the VAS scored by the participants themselves. The score of 0 shows that no pain while 10 shows unbearable pain. A mean score of VAS was $6.54 \pm .95$ with minimum score of 5 and maximum score 9. The Pearson correlation analysis of VAS score and HRQoL SF36 domains showed that a statistically significant negative correlation between the intensity of pain and HRQoL (i.e. the HRQoL decreases when the pain intensity of the patients increases).

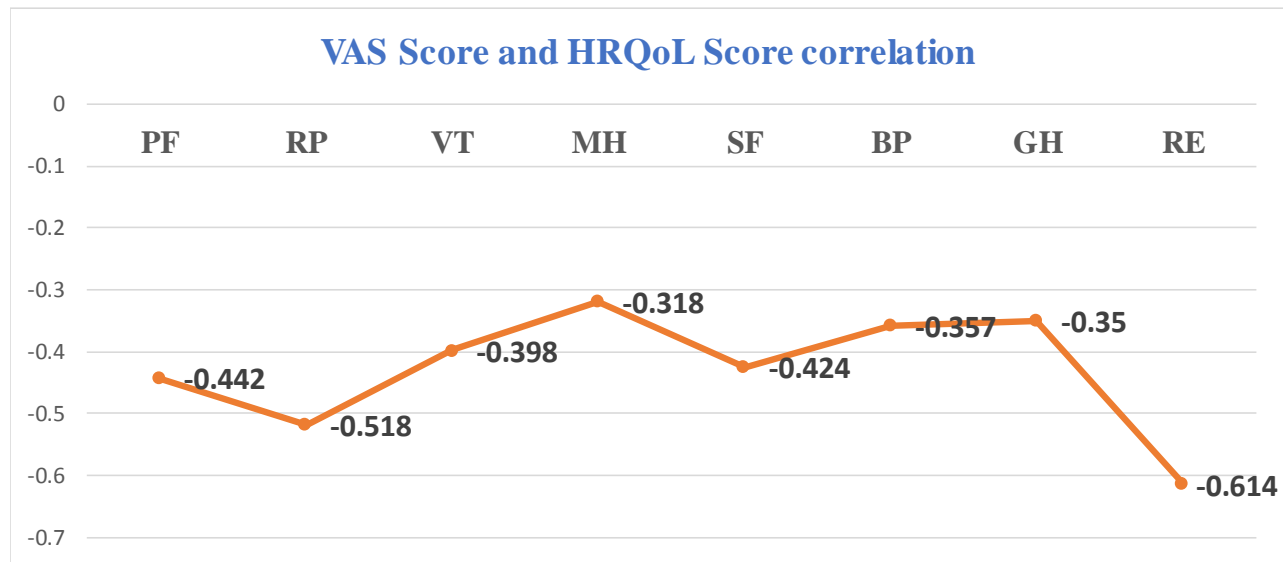


Figure. 6. Correlation between VAS score and SF 36 HRQoL 8 Domains Outcome among Type II DM Patients with DPNP in ZMH and SPHMMC, Addis Ababa, Ethiopia, 2017

Correlation between VAS score and SF 36 HRQoL 8 domains among DM type II study participants. Physical functioning (PF); Role-physical (RP); Bodily pain (BP); General health (GH); Vitality (VT); Social functioning (SF); Mental Health (MH); Role-emotional (RE), Physical Component Summary (PCS) and mental Health Summary (MCS).

5.6. Multivariate Analysis of Variance (MANOVA)

This section reports on the findings from a multivariate Analysis of Variance (MANOVA) for total 220 samples. The MANOVA analysis carried for demographic and clinical conditions variables on their influence on HRQoL considering physical health component summary scale and mental health component summary scale as HRQoL outcome.

The result showed that, from demographic data, only age has a statistically significant influence on both mental health component and physical health component summaries. While significance level of age for physical component summary was p-value 0.001, whereas for mental health component summary the p-value was 0.045, those age group of 51-60 and 61-65 have significantly (p-value <0.05) lower HRQoL score comparing to those age group of 20-50.

From clinical conditions, DPNP and DM related complication were significant in both physical component summary and mental health summary. The post-hoc test for DPNP and DM complication couldn't be performed due to both are only consists two categories in per variable. In additional to DM related complication and DPNP, DM duration and HbA1C were a statistically significant influence on physical health component summary but insignificant for mental health component summary. DM duration found to be statistically significant (p-value 0.001) on influencing on score of HRQoL. Those <5 years' duration diabetes type II patients has statistically significantly higher mean score comparing to with those a diabetes duration of and 6-10, 11-15 and >15 years DM duration. But there is no statistically significant HRQoL (physical health and mental health summary mean scores) differences among the DM duration of group of 6-10, 11-15 years and >15 years of duration. Another statistically significant variable of clinical related condition was HbA1c score which was significant at p-value of 0.039, while mental health component summary score remains insignificant.

Table 4. Multivariate Analysis of Variance Test for Demographic Data Influence on HRQoL (Type II diabetic patients) in ZMH and SPHMMC, Addis Ababa, Ethiopia, 2017

HRQoL		Age	Gender	Marital status	Educational Status	Occupation Status	Income
PCS	F	5.33	3.464	0.414	1.234	0.094	1
	P-value	0.001	0.067	0.743	0.304	0.984	0.397
MCS	F	2.57	0.482	0.442	1.516	0.82	2.34
	P-value	0.045	0.49	0.724	0.206	0.517	0.08

Table 5. Multivariate Analysis of Variance Test for Medical Related Data Influence on HRQoL (Type II diabetic patients) in in ZMH and SPHMMC, Addis Ababa, Ethiopia, 2017

HRQoL		DPNP	DM Complication	DM Duration	H ebA1C	Types of Regimen	BMI
PCS	F	7.449	6.612	4.142	3.336	1.645	1.777
	P-value	0.007	0.011	0.008	0.039	0.197	0.155
MCS	F	13.363	7.465	1.596	1.012	0.184	0.496
	P-value	0.000	0.007	0.194	0.367	0.832	0.685

Chapter Six: Discussion

This research was designed to investigate health related quality of life among type II DM patients comparing those with and without diabetic peripheral neuropathic pain, in two public hospitals which are found in Addis Ababa Ethiopia, namely Zewditu Memorial Hospital and St. Paul Hospital Millennium. The response rate was 100% for physical examination, interviewing, weight and height measurement. Among the total respondents, 132 (60%) were females. The two comparative group were similar in terms of all sociodemographic variables. For DM related clinical variable also, they are also similar except for duration of DM and HbA1C.

6.1. Result of HRQoL for Total 220 Type II DM Patients

Irrespective of their diabetic peripheral neuropathic pain statuses, the highest HRQoL domain score in current study among total type II DM patients was social functioning (65.3 ± 18.8). The reason of that social functioning domain score comparatively higher than the rest domains might be explained by the norm of social life style in Ethiopia, that someone obligated in to social life engagement even though she/he is sick or highly busy with their life. The lowest domain mean scores were role of emotion (41.2 ± 42.7) and Role of physical (41.4 ± 37.8), this finding is almost similar with the cross sectional study was done among type II DM patients in UAE, 2011 (41). The rest SF36 HRQoL domain scores were clear-cut which are, physical functioning 57.2 ± 25.7 , Vitality 55.6 ± 17.3 , Mental health 58.3 ± 18.7 , Social functioning, body pain 57.9 ± 20.4 , General health 52.9 ± 21.5 . The two summary scales, PCS (41 ± 9.3) and MCS (30 ± 14.6), this findings are low comparing with non-diabetes HRQoL studies done in Ethiopia but approximate with DM related HRQoL studies done in others countries(46-48).

6.2. HRQoL Result Comparison between two Groups (with and without DPNP) Type II DM Patients

While comparing two current study groups (with DPNP and without DPNP patients), in all SF36 eight domains and two component summary reports, we could find a statistically significant mean score differences among two comparative groups. Those with DPNP group scored the lower mean score in all eight domains and two summary scores of SF36 HRQoL tool. The highest scored HRQoL domain by those with diabetic peripheral pain was a mental health

domain which is 48.9 ± 15 whereas the lowest score of this group was role of physical which is 21.8 ± 28.2 , this score is almost similar with the cross sectional study done in Croatia by Dermanovic Dobrota et.al, comparing 80 with diabetic polyneuropathy pain patients and 80 without diabetic polyneuropathy pain patients, which the score of role of physical for the painful group the mean was 13.4 (40). In addition, the current mean score finding of role of physical score supported by the study done in South Africa by Andrew Jacovides et.al. (21). For without DPNP group their highest scored mean domains were social functioning (74.7 ± 13.4), physical functioning (72.3 ± 22.3) and body pain (70.3 ± 16.3) while their lowest of all domains are role of emotion (60.3 ± 42.7) and role of physical (60.9 ± 36.3). Both physical component summary and mental health summary more affected by with DPNP group even though those without pain group also has low score comparing to the two validation studies done in Ethiopia (42, 43). This dissimilarity might be due to the two validation studies were done on different population, while one was on general population and the other was among people on highly active HIV/AIDS antiretroviral therapy. The highest mean difference between two groups (with and without DPNP) were recorded among domains of role of physical and emotion with mean differences of 39.1 for role of physical and 38.3 for role of emotion score. Whereas the lowest mean difference was recorded by domain of social functioning which was 17.6.

6.3. HRQoL Result by the Neuropathic Pain Intensity among with DPNP Type II DM 110 Patients

Depending on DPNP intensity, the Pearson correlation analysis of VAS score and HRQoL score showed that a statistically significant (p . value $\leq .001$) negative correlation in all domain of SF36. That HRQoL scores more decreased when the intensity of the pain increases. This finding was supported by the two studies done in Turkey and German involving participants from different European countries (47, 49)

6.4. HRQoL Results by Sociodemographic Factors among 220 Type II DM Patients

When we see HRQoL based on socio demography statuses, older age has negative influence on all of HRQoL domains. A multiple analysis of variance showed that the age variable has statistically significant negative effect on both mental health component and physical health component summaries. For physical component summary the p -value was 0.001 while for mental

health component summary the was p-value 0.045. For in between group comparison the post hoc test was performed which showed that, those age group of 51-60 and 61-65 have statistically significantly (p-value <0.05) lower HRQoL score comparing to those age group of 20-50. In our study we found that Those older group has lowest mean score of than those younger age group physical functioning 39.4 ± 20.7 , role of physical $16 \pm$ vitality 49.3 ± 14 mental health 50.7 ± 15.7 social functioning 57 ± 19.5 body pain 48.8 ± 17.5 general health perception 41 ± 19.6 as well as role of emotion 18.2 ± 31 mean score were score by them while youngers those less than 60 have scored better mean as this finding parallel to the study done in Turkey by Nurten Olmez YD et.al (47).

In our study gender has not showed a significant effect on score HRQoL Life but other parallel studies have found that gender has effect on HRQoL score (19, 40). Regarding educational statuses we found that high school and above have better mean scores of HRQoL comparing to those are elementary school ,read and write only and illiterates, this finding supported by quality of studies done on diabetes in Argentina, Croatia, Kenya and Saudi Arabia(6, 8, 19, 46, 48). Related to occupation statuses, the governmental organization and the self-employed group has a better domains mean scores amongst the occupation group. Particularly on physical functioning, social functioning and also a body pain domain. This finding supported by earlier studies that indicating stable working enviroment and job security, like self employed and governmental work employed improves HRQoL among DM type II patients (19, 48).

Another socio economic charactestics is marital statuses. Those unmarried/ singles category have scored a betterHRQoL mean score. This might be most of the single who are included in this study are youngest of the all the study participants. due to that they could have a high chance to be newly diagnosed for DM type II and have lesser DM complications comparing to alder ages.

6.5. HRQoL Results by Clinical Characterstics among 220 Type II DM Patients

From DM related clinical characteristics, the main independent variable (DPNP) has a statistically significant influence on both summary scores (MCS= p-value 0.000 and PCS p- value 0.007), DM duration and DM complication have statistically significant influence on HRQoL. Those <5 years' duration DM type II patients has higher mean score comparing to with those a

DM duration of and 6-10,11-15 and >15 years. But there is no significant health related quality of life (physical health and mental health summary mean scores) score differences among the DM duration of group of 6-10, 11-15 years and >15 years of duration.

When we come to the HbA1c quantity influence to HRQoL, despite the fact the HbA1c report taken from patient records was not the recent data but HbA1c is a crucial in order to show glycemic control and indication to complication prevention among DM patients. However, HbA1C was another statistically significant DM related clinical variable which influenced a physical component summary with (p-value of 0.039), while mental health component summary score remains statistically insignificant. As confirmed in our study, previous studies revealed that prolonged disease duration and poor glycemic control are the significant factors over worsening poor HRQoL in DM patients (15, 20, 48).

BMI was another clinical related characteristics variable measured its influence on HRQoL. Though others studies found a significant negative relationship between BMI and quality of life scores(8, 48), in current study it didn't showed a statistically significant influence on scores of HRQoL. When we see based on the regimen or the medication they are following, those who are taking oral hypoglycemia have a better HRQoL score than those who are on insulin. Even though insulin known to be improving the health status and quality of life among type II patients, but this study didn't much. Despite the fact, this might be clarified the due to type II DM patients starts insulin after they treated by oral hypoglycemia for long time and developed oral hypoglycemia resistance which is indirectly related to long time DM duration and DM complication those known factors for lowering HRQoL among DM patients.

Chapter Seven: Strength and limitation of the Study

7.1. Strength of the Study

- As far as our knowledge, this study is the first in Ethiopia which studied health related quality of life among type II with and without DPNP patients.
- This study used a standard HRQoL questionnaire (SF 36) which was validated for our country

7.2. Limitations of the Study

- Lack of separate room for physical diagnosis and patient interview in hospitals.
- This research didn't include its own laboratory diagnosis. Since some variables (i.e. DM complication, HbA1c...) were to be recorded from patient's card, they were old, incomplete or absent which was a problem for the progress of the research.

Chapter Eight: Conclusion and Recommendation

8.1. Conclusion

- DPNP is a major factor and distressful condition that influenced health related quality of life among type II diabetes patients.
- Those without DPNP type II DM patients have a better health related quality of life comparing to with those with DPNP patients.
- DPNP has more negative influence on health related quality of life when the intensity of the pain increases.
- DPNP has a negative impact on the patients physical functioning, role of emotion, role of physical, which encompasses doing daily activities, self-care, income generating, social activities and emotional well-being.
- Additionally, an older age, long duration of DM, high HbA1c level, and DM complication have a negative influence (exacerbating) on health related quality of life, this finding supported by some others international studies too.

8.2. Recommendations

This study has suggestion for both practice and future areas of research.

- We recommend that an intervention to improve HRQoL among DPNP patients by strict diagnosis, pain management care and also vital to improve the health related quality life.
- Encouraging clinicians to well identify patients with painful peripheral neuropathy in diabetic population via questioning all complaints and to make further investigations if needed.
- Since our finding showed that DM Relate complication, uncontrolled diabetes (high HbA1c) is worsening in the reducing of HRQoL, early diagnoses and management of DM is a crucial.
- Besides currently it's approved that the medical outcome cannot described fully by measurement of clinical outcome and clinical indicators alone such as pain, apprehension, financial situation has influence on health related status but also subjective well-being has effects on individual's but there is a scarcity of health related quality of life studies among diabetes patient in Ethiopia. So, further researches of HRQoL among DM patients is should be encouraged
- For the future studies we recommended that when a DM related HRQoL research planned to be done, it's better to plan a full budget that can covers a physical and clinical investigations than relying on secondary records.
- Since there is no a validated DM specific HRQoL questionnaires in our set up (Ethiopia), we recommend that a validation studies to be done on diabetic specific HRQoL questionnaires.

References

1. WHO. Definition, diagnosis and classification of diabetes Mellitus and complications. WHO/NCD/992.
2. International Diabetes Federation. diabetes atlas in IDF Atlas of DM ,7th,Editor.2015.
3. Nigatu T. Epidemiology, complications and management of diabetes in Ethiopia: A systematic review. *Journal of diabetes investigation*. 2012;4:174–80.
4. International Diabetes Federation. diabetes atlas in IDF Atlas of DM ,6th,Editor 2013.
5. Nazir SuR, Hassali MA, Saleem F, Bashir S, Hashmi F, Aljadhey H. A cross-sectional assessment of health-related quality of life among type 2 diabetic patients in Pakistan. *Journal of Pharmacy & Bioallied Sciences*. India: Medknow Publications & Media Pvt Ltd; 2016. p. 64-8.
6. Rui Wang, Yanfang Zhao, Xiaoyan Yanet. et.al Health related quality of life measured by SF-36: a population-based study in Shanghai, China. *BMC Public Health*. 2008;2(292).
7. WHOQOL Group; (WHOQOL). development and general psychometric properties. *Soc Sci Med* 46:1998; 569-83.
8. Schlenk EA, Erlen JA, Dunbar-Jacob J, McDowell J, Engberg S, Sereika SM, et al. Health-related quality of life in chronic disorders: a comparison across studies using the MOS SF-36. *Quality of Life Research*. 1997;7(1):57-65.
9. Abbashar Hussein, A.Sidig Omer el-Adil , Ahmmed Hamad, et.al. The prevalence of neurological complications among Adult Sudanese diabetic patients. *Sudanese Journal of Public Health*. 2009;4(3):331-4.
10. Tessa Peasgood AB, Peter Mansell, Jackie Elliott, Hasan Basarir, Jen Kruger. The Impact of Diabetes-Related Complications on Preference-Based Measures of Health-Related Quality of Life in Adults with Type I Diabetes. Original Article. August 31, 2016:1-14.
11. Yerra VGA, Aparna; Komirishetty, Prashanth ; Kumar, Ashutosh. Neuroinflammation and Oxidative Stress in Diabetic Neuropathy: Futuristic Strategies Based on These Targets. *International Journal of Endocrinology*. 2014:10.
12. Francis Guillemin. Cross-cultural Adaptation of health related quality of life measures: literature review and proposed guidelines. *J Clin epidemiology*. 1993; 46:1417-32.

13. Solomon Tesfaye. Painful diabetic peripheral neuropathy: consensus recommendations on diagnosis, assessment and management. *Diabetes Metab Res Rev* 2011;27:629–38.
14. Khaled Kasim a, Morsy Amar a, Abdel Aziz El Sadek, Said Abdel Gawad b. Peripheral neuropathy in type-II diabetic patients attending diabetic clinics in Al-Azhar University Hospitals, Egypt. *International Journal of Diabetes Mellitus* 2 (2010) 20–23.
15. Mark Davies, Rhys Williams, Ann Taylor, The Prevalence, Severity, and Impact of Painful Diabetic Peripheral Neuropathy in Type 2 Diabetes. *Diabetes Care* 2006;29:1518–22.
16. Aaron I. Vinik Rem, Braxton D. Mitchell, Roy Freeman,. Diabetic Autonomic Neuropathy. *Diabetes care.* 2003;26(5):1553–79.
17. Georgios Lyrakos N1 EH, Dimitrios Damigos3, Athanasia Papazafiropoulou K4, Stavros Bousboulas5, Chrysanthi Batistaki6. Predictors of health-related quality of life in Diabetic Neuropathy type II diabetic patients in Greece. *Health Science Journal.* 2013;Volume 7:327-41.
18. Kolawole Mosaku; Babatope Kolawole; Celestine Mume; Rosemary Ikem. Depression, Anxiety and Quality of Life among Diabetic Patients: A Comparative Study. *Journal of the National Medical Association,* . (2008):73-8.
19. G. Cruccua b, P. Anandc, N. Attald, L. Garcia-Larreaa,e, M. Haanpa`a` a,f, E. Jøruma,g, J. Serraa,h, Jensena aTS. EFNS guidelines on neuropathic pain assessment. *European Journal of Neurology.* 2004;11:153–62.
20. Ana Spasić1 RVR, 2,3, Aleksandra Catić Đorđević1,, Nikola Stefanović1 TC, 4. Quality of Life in Type 2 Diabetic Patients. 2014;31(3):193-200.
21. Genga E.K, Otieno C.F, Ogola E.N Maritim M.C. Assessment of the Perceived Quality of Life of Non insulin Dependent Diabetic patients attending the Diabetes Clinic in Kenyatta National Hospital. *IOSR Journal Of Pharmacy.* March 2014;4(3):15-21.
22. S.J Benbow Mewiam. Diabetic peripheral neuropathy and quality of life. *QJ Med.* 1998(91):733-7.
23. Andrew Jacovides1 MB, Larry A Distiller3, et.al. An Epidemiological Study to Assess the Prevalence of Diabetic Peripheral Neuropathic Pain Among adults with Diabetes Attending Private and Institutional Outpatient Clinics in South Africa. *International Medical Journal.* 2014;42(4):018–1028.
24. Francisco LJWaS. Neurologic Complications of Diabetes. *California Medicine.*14-20.

25. AJM. B. Management of diabetic peripheral neuropathy. . Clin Diabetes. 2005;23:9-15.
26. Dipika Bansal KG, Harini Muthyala, Hari Prasad Esam, Ramya Nayakallu, Anil Bhansali. Prevalence and risk factors of development of peripheral diabetic neuropathy in type2 diabetes mellitus in a tertiary care setting. journal of diabetes investigation.5:714–21.
27. Abdul Hamid Zargar, Bashir Ahmad Laway, Shariq Rashid Masoodi, Nissar Ahmad Shah Profile of Neurological Problems in Diabetes Mellitus: Retrospective Analysis of Data From 1294 Patients. Health Administrator 2009 :95-106
28. Andréa D Bertoldi¹, Giovanny França¹, André Carraro, et.al. Epidemiology, management, complications and costs associated with type 2 diabetes in Brazil: a comprehensive literature review. Globalization and Health. (9:62):1-12.
29. Seung-Hyun Ko B-YC. Diabetic Peripheral Neuropathy in Type 2 Diabetes Mellitus in Korea. Diabetes & Metabolism Journal 2233-6087.
30. Bowden A aF-RJ. Systematic and and Critical Review of the Process of Translation and Adaptation of Generic Health Related Quality of life Measures in Africa ,Asia,Easern Europe,the Middle east,South America. Soc Sci Med2003. 2003(Oct;57):1289-306.
31. Stanislava Yordanova VP, Guenka Petrova, Milen Dimitrov, et.al. Comparison of health-related qualityof-life measurement instruments in diabetic patients. Biotechnology & Biotechnological Equipment.28: (4):769-74,.
32. Rand Corporation and John E. Ware Jr., revised 1996. The Short Form SF 36 Health survey.
33. Liliane Lins and Fernando Martins Carvalho. SF-36 total score as a single measure of health-related quality of life: Scoping review. SAGE Open Medicine. 2016;4:1-12.
34. Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Medical Care. 1992;30.
35. Brazier JE, Harper R, Jones NMB, O'Cathain A, Thomas KJ, Usherwood T, et al. Validating the SF-36 health survey questionnaire: new outcome measure for primary care. British Medical Journal. 1992;305.
36. Ware JE, Snow KK, Kosinski M, Gandek B. SF-36 Health Survey Manual and Interpretation Guide. Boston, MA: The Health Institute, New England Medical Centre; 1993.
37. Manuals for SF-36 (Accessed 19-12-2012).

38. Walters SJ. Sample size and power estimation for studies with health related quality of life outcomes: a comparison of four methods using the SF-36. *Biomedical Journal*. 2004;2(26).
39. Brown JJ, University OD. *Neuropathy Detection, Quality of Life Tools & Treatment for Type 2 Diabetes*. Human Movement Sciences Theses & Dissertations. 2016.
40. K. Van AckerD. Bouhassira, D. De Bacquer, et.al. Prevalence and impact on quality of life of peripheral neuropathy with or without neuropathic pain in type 1 and type 2 diabetic patients attending hospital outpatients clinics. *Diabetes & Metabolism Journal*. 2008:206–13.
41. Dermanovic Dobrota V, Hrabac P, Skegro D, Smiljanic R, Dobrota S, Prkacin I, et al. The impact of neuropathic pain and other comorbidities on the quality of life in patients with diabetes. *Health and Quality of Life Outcomes*. 2014;12:171.
42. Khaled J. Issa¹ YI, Nasir Ali¹, Abdulla Haroon¹, Mohammed Waseem¹, Noor Aldin¹, Shatha Al-, Sharbatti² RBS, Elsheba Matthew². The effect of diabetes mellitus on quality of life. *Sudanese Journal of Public Health*. January 2014;9(1):4852.
43. Derege Kebede, Teshome Shibire et.al. Health related quality of life (SF-36) survey in Butajira, rural Ethiopia: Normative data and evaluation of reliability and validity. *Ethio Med J*. 2004:289-97.
44. Kebede Abera. Quality of life of people living with HIV/AIDS and on highly active antiretroviral therapy in Ethiopia. *African Journal of AIDS Research*. 2014;9:1,0:31-40.
45. Ian Gilron RB, Troels Jensen. *Neuropathic Pain: Principles of Diagnosis and Treatment*. *Mayo Clinic Proceedings*. 2015;90:532-45.
46. Peter W. Vik TC, Amy Jarchow et.al. Cognitive impairment in substance abuse. *Psychiatry* 2004;27:97–109.
47. Rui V. Duarte; Lazaros Andronis; Mathieu Lenders; et.al Quality of life increases in patients with painful diabetic neuropathy following treatment with spinal cord stimulation. *Quality of Life Research*, . 2016;25:1771–7
48. Nurten Olmez YD, Hulusi Kececi. Effects of Pain and Disability on Quality of Life in Patients with Diabetic Polyneuropathy. *Neuroscience & Medicine*. 4 September 2015:2015, 6, 98-106.
49. Andres Pichon-Riviere VI, Andrea Beratarrechea, Andrea Alcaraz, Carolina Carrara. Quality of life in type 2 diabetes mellitus patients requiring insulin treatment in Buenos Aires, Argentina: a cross-sectional study. *Int J Health Policy Manag*. 2015;7:475–80.

50. Duarte1 RV, Andronis L, Lenders, Cecile C. Quality of life increases in patients with painful diabetic neuropathy following treatment with spinal cord stimulation. cross mark. 2016 25:1771–1777 DOI 10.1007/s11136-015-1211-4).

Annex I. Information sheet and consent form (Amharic version)

የምርምር/ጥናት/ማብራሪያና የስምምነት መግለጫ ቅጽ

1. መግቢያ

እኔ ----- ህይወት ደጉ በተባለች ተመራማሪ በስኳር ህመምተኞች የኑሮ ሁኔታ እና ተዛማጅነት ባላቸው ጉዳዮች ዙሪያ ለማወቅ በተዘጋጀ ጥናት ላይ መረጃ ሰብሳቢ ሠራተኛ ስሆን ይህንንም ጥናት ለማሳካት የእርስዎ ቅንነት የተሞላበት ተሳትፎ ወሳኝነት አለው። የዚህ የምርምር ማብራሪያና የስምምነት ቅጽ ዓላማ አሁን እርስዎ አንዲሳተፉበት የምንጠይቀውን የምርምር ጥናት ምንነት ማብራራት ነው። በዚህ የምርምር ፕሮጀክት ለመሳተፍ ከመወሰንዎ በፊት ይህንን የማብራሪያ ቅጽ በጥንቃቄ በማንበብ ጥያቄዎች ካሉዎት ይጠይቁ። በተጨማሪም በጥናቱ መሳተፍ ከጀመሩ በኋላ በማንኛውም ጊዜ ጥያቄዎች ካሉዎት መጠየቅ ይችላሉ።

2. የምርምር ፕሮጀክቱ ዓላማ:- የአይነት 2 ስኳርና የስኳር የነርቭ ህመምተኞች የኑሮ ሁኔታ እና ተዛማጅነት ባላቸው ጉዳዮች ዙሪያ ለማጥናት የተዘጋጀ ነው።

3. የአስራር ሂደት:- ይህንን ጥናት ዓላማ የተፈለገው ግብ እንዲመታና በጥናቱ መሠረት የሚለዩ የተለያዩ ችግሮችን በመንግሥትና በሌሎች ድጋፍ ሰጪ ድርጅቶች አካላት ትብብር አማካኝነት በጥናቱ የተደረሰባቸውን ችግሮች ለመፍታት እርስዎ እንዲሳተፉ ተጋብዘዋል። በዚህ ጥናት ውስጥ ለመሳተፍ ከተስማሙ ስምምነቱን በደንብ መረዳትና እንዲሁም መፈረም ይገባዎታል። ይህ ጥናት አራት መለኪያዎችን አካቷል፡ የሰውነት ምረመራ (Physical Diagnose) ፣ የክብደትና የቁመት ልኬት፣ የህክምና መዝገብን ማንበብ ሲሆኑ፤ ከዚያ በመቀጠል ለጥናቱ በተዘገጀው መጠይቅ መሰረት ፣ ለሚጠየቁት ጥያቄ መልስ እንዲመልሱ ፈቃደኝነትዎን እንጠይቃለን። በዚህ ጥናት ሲሳተፉ የሚሠጡት መልስም ሆነ የሚገኘው ውጤት በምስጢር ይጠበቃል።

4. ሊከሰቱ የሚችሉ ስጋቶችና ምቹት መጓደሎች:- በዚህ ጥናት መሳተፍዎ ምናልባት ጊዜዎን ሊሻማብዎ ይችላሉ። ነገር ግን የጥናቱ ውጤት ወደፊት ከሚሠጠው ጥቅም አንጻር ይህን ያህል አይደለም። በዚህ ጥናት በመሳተፍዎ ምንም ዓይነት ስጋት (ችግር) አያጋጥምዎትም።

5. ጥቅሞች:- በዚህ ጥናት በመሳተፍዎ የተለየ ጥቅም አያገኙም። ነገር ግን የርስዎ በጥናቱ መሳተፍዎ ለጥናቱ መሳካት በጥናቱ በተለያዩ ችግሮች መፍትሄ ሲሰጥ እርስዎ እና ሌሎች ታማሚዎች ተጠቃሚ ይሆናሉ።

6. ማካካሻ:- በዚህ ጥናት በመሳተፍዎ ምንም ዓይነት ማካካሻ አይሠጥዎትም። ነገር ግን በጥናቱ በመሳተፍዎ ምስጋናችን ከፍተኛ ነው።

7. ምስጢር ስለመጠበቅ:- ከዚህ ጥናት የሚገኝ መረጃ በሙሉ በምስጢራዊነት ይጠበቃል። ለዚህ ጥናት የሚሠበሰቡ እርስዎን የሚመለከት መረጃ በማህደር የሚቀመጥ ሲሆን ማህደሩም በስምዎ ሳይሆን በተለየ ኮድ ሲቀመጥ ኮዱ ከዋናው ተመራማሪ ውጭ ለማንም አይገለጽም።

8. በጥናቱ ያለመሳተፍ ወይም ራስን የማግለል መብት፡-በጥናቱ ላለመሳተፍ ከፈለጉ በዚህ ጥናት ያለመሳተፍ ወይም ከአንድ በላይ ወይም ሁሉንም ጥያቄዎች አለመመለስ ይችላሉ። በዚህ ጥናት ባለመሳተፍዎ ወይም በከፊልም ሆነ በሙሉ ጥያቄዎችን ባለመመለስዎ ማንኛውንም አገልግሎት ከማግኘት አይከለከሉም።

9. ከጥናቱ ጋ በተያያዘ ማንኛውም ጥያቄ ሆነ ቅሬታ ካሉት በዚህ አድራሻ ሊያገኙን ይችላሉ። ስም ህይወት ደንስልክ 0913112490 ኢ.ሜል hiwotdegu055@gmail.com

ከላይ በዝርዝር የተሰጡትን መረጃዎች እና ቅጹን አንብቤዋለሁ ወይም ልረዳ በምችለዋለሁ መልኩ በ መረጃ ሰብሳቢዬ ተነባላችኋል። ስለሆነም በ ጥናቱ ላይ ስለመሳተፍ የሚከተለውን ወስኛለሁ

1. ተስማምቻለሁ _____

2. አልተስማማሁም _____

ይህንንም በፊርማዎ አረጋግጣሁ _____

የመረጃ ሰብሳቢዬ ስም _____ ፊርማ _____

መረጃዬ የተሰጠበት ቀን _____

የመረጃ ተቆጣጣሪ ስም _____ ፊርማ _____

Annex II. Information Sheet and Consent Form (English version)

Dear respondent my name is _____ I am here to collect data for a study which entitled with “Impact of Diabetics Peripheral Neuropathic Pain On Health Related Quality of Life. It is conducted by Hiwot Degu who is a Masters of Public Health (MPH) student in Addis Ababa University, the research consists of 4 phases which are, physical examination, weight and height scaling, patient card reviewing and an interview. The physical examination requires whether you have diabetic peripheral neuropathic pain, weight and height scaling needs for body mass index (BMI) calculation additionally your patient card will be reviewed to evaluate co morbidities, finally interview explores about your quality of life in 60-90 minutes to be completed. As a study participant you will be benefited when the result is utilized. The study will be carried out in the form of interview and do not cause any harm to you. The result will be displayed in general form not in individual. To achieve the study, your honest and genuine participation by responding to the question prepared is very important and highly appreciated. You have also a right to continue or to discontinue as a participant and there is no any influence that insists you to participate unless you are volunteer.

We will proceed to the interview after you understand the following points

Objective of the study: To assess “Impact of Diabetics Peripheral Neuropathic Pain On Health Related Quality of Life among diabetes type II patients in Addis Ababa public hospitals, Ethiopia.

Benefit: The information generated from the study help policy makers and program planning, to improve

QOL and will enable health care providers to implement other care beyond metabolic control.

Harm: The participants do not have any harm by participating to the study

Alternatives to participation: You do not have to take part in this research if you do not wish to do so. Your participation/ non-participation, or refusal to respond to the questions will have no effect now or in the future on services that you or any member of your family may receive from

any service providers. In between, you have the right to terminate from the study by any reason, related to the study or personal reason.

Confidentiality: We would like to assure you that the privacy will strictly be maintained throughout. Your responses to any of the questions will not be given to anyone else and no reports of the study will

ever identify you. If a report of the results will be published, only Information about the total group will

appear.

Persons to contact: If you have any question you can contact the investigator at the following address and you may ask at any time you want.

Hiwot Degu

Tel: +251-093112490

E-mail: hiwotdegu055@gmail.com

I have read the document stated above or it has been read to me by the data collector as I can understand all conditions stated above. Therefore, I have decided to:

1. Agree _____
2. Disagree _____ on participation of the study

And I confirmed it by signature _____

Name of the interviewer: _____ Sign. _____ Date of interview _____

Name of the supervisor: _____ Sign. _____ Date _____

Thank You for willingness to participate

Annex III Questionnaires

Part 1. Socio demographic characteristics

1. gender? Male Female
2. Age? _____ years
3. What is the highest level of education you received?
None at all
Write and read only
Primary School
High School
College
4. What is your religion?
Orthodox
Muslim
Protestant
Others(specify)_____
5. What is your marital status?
Single Separated Married Divorced Widowed
6. What is your occupation?
Unemployed self-employed NGO Governmental organization
Others(specify)_____
7. How much money do you earn on monthly basis? _____Ethiopian birr.
8. How long have you had diabetes? _____ in years.

Part 2. Factors that affect quality of life

9. Which drug regimen you are following currently for your diabetes?

Oral anti diabetic medication only

Insulin only

Insulin and oral anti diabetic medication

Only following dietary plan as recommended

Others(specify)_____

10. From patient records/ patient card/ physical diagnosis

Hypertension Diabetic Nephropathy Diabetic Neuropathy

Diabetic Retinopathy Diabetic foot ulcer Diabetic related heart disease

Others(specify)_____

Biochemical

HbA1C_____

RBS_____

FBS_____

Lipid profile

Cholesterol _____

TG _____

HDL _____

LDL_____

Others (specify)_____

11.From assessment

Weight _____kg

Height _____meters

Body mass index _____kg/m²

For DPNP group

VAS score _____

Part 3. The question section that shows your health in general. as answer these, please consider All your health problem

SF-36 Questionnaires/ English Version

Please answer the 36 questions of the Health Survey completely, honestly, and without interruptions.

S.N	Question	Answer	Code
GENERAL HEALTH			
01	In general, would you say your health is:	<p>Excellent 01</p> <p>Very Good 02</p> <p>Good 03</p> <p>Fair 04</p> <p>Poor 05</p>	
02	Compared to one year ago, how would you rate your health in general now?	<p>Much better now than one year ago 01</p> <p>Somewhat better now than one year ago 02</p> <p>About the same 03</p> <p>Somewhat worse now than one year ago 04</p> <p>Much worse than one year ago 05</p>	
LIMITATIONS OF ACTIVITIES			
The following items are about activities you might do during a typical day. Does your health now limit you in these? activities? If so, how much?			
03	Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	<p>Yes, limited a Lot 01</p> <p>Yes, limited a Little 02</p> <p>No, Not Limited at all 03</p>	
04	Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	<p>Yes, limited a Lot 01</p> <p>Yes, limited a Little 02</p> <p>No, Not Limited at all 03</p>	

05	Lifting or carrying groceries	Yes, limited a Lot 01 Yes, limited a Little 02 No, Not Limited at all 03	
06	Climbing several flights of stairs	Yes, limited a Lot 01 Yes, limited a Little 02 No, Not Limited at all 03	
07	Climbing one flight of stairs	Yes, limited a Lot 01 Yes, limited a Little 02 No, Not Limited at all 03	
08	Bending, kneeling, or stooping	Yes, limited a Lot 01 Yes, limited a Little 02 No, Not Limited at all 03	
09	Walking more than a mile	Yes, limited a Lot 01 Yes, limited a Little 02 No, Not Limited at all 03	
10	Walking several blocks	Yes, limited a Lot 01 Yes, limited a Little 02 No, Not Limited at all 03	
11	Walking one block	Yes, limited a Lot 01 Yes, limited a Little 02 No, Not Limited at all 03	
12	Bathing or dressing yourself	Yes, limited a Lot 01 Yes, limited a Little 02 No, Not Limited at all 03	

PHYSICAL HEALTH PROBLEMS:

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

13	Cut down the amount of time you spent on work or other activities	Yes 01 No 02	
14	Accomplished less than you would like	Yes 01 No 02	
15	Were limited in the kind of work or other activities	Yes 01 No 02	
16	Had difficulty performing the work or other activities (for example, it took extra effort)	Yes 01 No 02	

EMOTIONAL HEALTH PROBLEMS:

During the past 4 weeks, 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)?

17	Cut down the amount of time you spent on work or other activities	Yes 01 No 02	
18	Accomplished less than you would like	Yes 01 No 02	
19	Didn't do work or other activities as carefully as usual	Yes 01 No 02	

SOCIAL ACTIVITIES:

20	Emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all 01 Slightly 02 Moderately 03 Severe 04 Very Severe 05	
-----------	---	---	--

PAIN

21	How much bodily pain have you had during the past 4 weeks?	None 01 Very Mild 02 Mild 03 Moderate 04 Severe 05 Very Severe 06	
22	22. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all 01 A little bit 02 Moderately 03 Quite a bit 04 Extremely 05	

ENERGY AND EMOTIONS:

These questions are about how you feel and how things have been with you during the last 4 weeks. For each question, please give the answer that comes closest to the way you have been feeling.

23	Did you feel full of pep?	All of the time 01 Most of the time 02 A good Bit of the Time 03 Some of the time 04 A little bit of the time 05 <input type="checkbox"/> None of the Time 06	
24	Have you been a very nervous person	All of the time 01 Most of the time 02 A good Bit of the Time 03 Some of the time 04 A little bit of the time 05 <input type="checkbox"/> None of the Time 06	

25	Have you felt so down in the dumps that nothing could cheer you up?	<p style="text-align: right;">All of the time 01</p> <p style="text-align: right;">Most of the time 02</p> <p style="text-align: right;">A good Bit of the Time 03</p> <p style="text-align: right;">Some of the time 04</p> <p style="text-align: right;">A little bit of the time 05</p> <p style="text-align: right;"><input type="checkbox"/>None of the Time 06</p>	
26	Have you felt calm and peaceful?	<p style="text-align: right;">All of the time 01</p> <p style="text-align: right;">Most of the time 02</p> <p style="text-align: right;">A good Bit of the Time 03</p> <p style="text-align: right;">Some of the time 04</p> <p style="text-align: right;">A little bit of the time 05</p> <p style="text-align: right;"><input type="checkbox"/>None of the Time 06</p>	
27	Did you have a lot of energy?	<p style="text-align: right;">All of the time 01</p> <p style="text-align: right;">Most of the time 02</p> <p style="text-align: right;">A good Bit of the Time 03</p> <p style="text-align: right;">Some of the time 04</p> <p style="text-align: right;">A little bit of the time 05</p> <p style="text-align: right;"><input type="checkbox"/>None of the Time 06</p>	
28	Have you felt downhearted and blue?	<p style="text-align: right;">All of the time 01</p> <p style="text-align: right;">Most of the time 02</p> <p style="text-align: right;">A good Bit of the Time 03</p> <p style="text-align: right;">Some of the time 04</p> <p style="text-align: right;">A little bit of the time 05</p> <p style="text-align: right;"><input type="checkbox"/>None of the Time 06</p>	
29	Did you feel worn out?	<p style="text-align: right;">All of the time 01</p> <p style="text-align: right;">Most of the time 02</p> <p style="text-align: right;">A good Bit of the Time 03</p> <p style="text-align: right;">Some of the time 04</p>	

		<p>A little bit of the time 05</p> <p><input type="checkbox"/>None of the Time 06</p>	
30	Have you been a happy person?	<p>All of the time 01</p> <p>Most of the time 02</p> <p>A good Bit of the Time 03</p> <p>Some of the time 04</p> <p>A little bit of the time 05</p> <p>None of the Time 06</p>	
31	Did you feel tired?	<p>All of the time 01</p> <p>Most of the time 02</p> <p>A good Bit of the Time 03</p> <p>Some of the time 04</p> <p>A little bit of the time 05</p> <p>None of the Time 06</p>	
SOCIAL ACTIVITIES			
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 with friends, relatives, etc.)?	<p>All of the time 01</p> <p>Most of the time 02</p> <p>A good Bit of the Time 03</p> <p>Some of the time 04</p> <p>A little bit of the time 05</p> <p><input type="checkbox"/>None of the Time 06</p>	
GENERAL HEALTH			
How true or false is each of the following statements for you?			
33	I seem to get sick a little easier than other people	<p>Definitely true 01</p> <p>Mostly true 02</p> <p>Don't know 03</p> <p>Mostly false 04</p> <p>Definitely false 05</p>	

34	I am as healthy as anybody I know	Definitely true 01 Mostly true 02 Don't know 03 Mostly false 04 Definitely false 05	
35	I expect my health to get worse	Definitely true 01 Mostly true 02 Don't know 03 Mostly false 04 Definitely false 05	
36	My health is excellent	Definitely true 01 Mostly true 02 Don't know 03 Mostly false 04 Definitely false 05	

ክፍል አንድ - ማህበራዊ እና ስነ ህዝብ መረጃ መጠይቅ

1. ያታ? ወንድ ሴት 2. እድሜ? _____ መለያ ቁ-----

3. የትምህርት ደረጃ

ያልተማረ

መፃፍና ማንብብ ብቻ

አንደኛ ደረጃን ያጠናቀቀ

ሁለተኛ ደረጃን ት/ቤት ያጠናቀቀ

የኮሌጅ ት/ትቤት ያጠናቀቀ

4. ሐይማኖት ?

ኦርቶዶክስ ሙሴሊም ፕሮቴስታንት ሌላ (ይገለፅ) _____

5. የጋብቻ ሁኔታ ?

ያገባ ያላገባ የፈታ በሞት የተለየ

6. የስራ ሁኔታ?

ስራ የሌለው የመንግስት ሰራተኛ የግል ድርጅት ሰራተኛ ነገዴ ጡረተኛ

ሌላ (ይገለፅ) _____

7. የወር ገቢ መጠን? _____ የኢትዮጵያ ብር

8. የሥኳር በሽታ እንዳለብዎት ካወቁ ምን ያህል አመት ሆኗት:: -----አመት

ክፍል ሁለት- የስኳር ህመምን ጥሩ የኑሮ ሁኔታ እንዳይኖሩ የሚያደርጋቸው ሁኔታዎች

9. ለስኳር በሽታ ከሚሰጡ መድሃኒቶች መካከል የትኛዎቹን በተከታታይ ይወስዳሉ;

የሚዋጡትን ብቻ

ኢንሱሊንን ብቻ

የሚዋጡትን እና ኢንሱሊን

አመጋገብ እና እንቅስቃሴ በማከናወን ብቻ

ሌላ (ይገለፅ) _____

10. ባለፉት ሰባት ቀናት ውስጥ የታዛዘሎትን የስኳር መድሀኒት ለምን ያህል ጊዜ ወስደዋል?

አንድ ሁለት ሶስት አራት አምስት ስድስት ሰባት

11. ባለፉት ሰባት ቀናት ውስጥ የታዛዘሎትን ኢንሱሊን ለምን ያህል ጊዜ ተወግተዋል? (ለኢንሱሊን ተጠቃሚዎች)

አንድ ሁለት ሶስት አራት አምስት ስድስት ሰባት

12. ባለፉት ሰባት ቀናት ውስጥ የታዛዘሎትን የስኳር እንክብል ለምን ያህል ጊዜ ወስደዋል? (ለስኳር እንክብል ተጠቃሚዎች)

አንድ ሁለት ሶስት አራት አምስት ስድስት ሰባት

SF-36 Questionnaires/ Amharic Version

እባኩን የሚከተሉትን 36 የጥናት ጥያቄዎችን በሙሉ በታማኝነት መልሶን ይስጡን

መለ/ተ.ቁ	ጥያቄ	መልስ	ኮድ
አጠቃላይ ጤንነት			
01	ጤንነትዎ በአጠቃላይ ሲታይ ምን ይመስላል?	እጅግ በጣም ጥሩ ነው 01 በጣም ጥሩ ነው 02 ጥሩ ነው 03 ደህና ነው 04 መጥፎ ነው 05	
02	ካለፈው አመት ጋር ሲነፃፀር በአጠቃላይ ጤንነትዎ ምን ደረጃ ላይ ነው ይላሉ?	ካለፈው አመት በጣም የተሻለ ነው 01 ካለፈው አመት በተወሰነ መልኩ የተሻለ ነው 02 ካለፈው አመት ልዩነት የለውም 03 ካለፈው አመት ጋር ሲወዳደር ተባብሷል 04 ካለፈው አመት ከነበረው ጋር ሲወዳደር በጣም ተባብሷል 05	
የእንቅስቃሴ መገደብ			
የሚቀጥሉት ጥያቄዎች መሉ ጤነኛ በነበሩበት ጊዜ የሚያከናውናቸው አሁን የጤናዎ ሁኔታ እነዚህ ተግባራት ማከናዎን አግደዎታል፤ ከሆነ፤ ምን ያህል?			
03	ከባድ እንቅስቃሴዎች እንደ ሩጫ፤ ከባድ እቃ ማንሳት፤ አድካሚ ሰፖርታዊ እንቅስቃሴዎች ማድረግ?	አዎ ብዙ ገደቦኛል 01 አዎ ትንሽ ገደቦኛል 02 አይቻልም 03	
04	መካከለኛ እንቅስቃሴዎች ጠረጴዛ መንቀሳቀስ፤ ቤት ማፅዳት ፡ ወዘተ...?	አዎ ብዙ ገደቦኛል 01 አዎ ትንሽ ገደቦኛል 02 አይቻልም 03	
05	አሰቤዛ ከገበያ ገዝቶ መሸከም ወይም ማነሳት ከገብያ	አዎ ብዙ ገደቦኛል 01 አዎ ትንሽ ገደቦኛል 02 አይቻልም 03	

06	ብዙ የፎቅ ደረጃ (ከቤድ ያለ ዳገት ወይም አቀበት) መውጣት	አዎ ብዙ ገድቦኛል 01 አዎ ትንሽ ገድቦኛል 02 አይ በጭራሽ አልገደብኝም 03
07	አንድ የፎቅ ደረጃ (ቀለል ያለ ዳገት) መውጣት	አዎ ብዙ ገድቦኛል 01 አዎ ትንሽ ገድቦኛል 02 አይ በጭራሽ አልገደብኝም 03
08	ጎንበስ፣ ቁጢጥ ማለት፣ በትንሹ ጎንበስ ማለት	አዎ ብዙ ገድቦኛል 01 አዎ ትንሽ ገድቦኛል 02 አይ በጭራሽ አልገደብኝም 03
09	ከ 1.6 ኪ.ሜ በላይ መጓዝ (1600 እርምጃ)	አዎ ብዙ ገድቦኛል 01 አዎ ትንሽ ገድቦኛል 02 አይ በጭራሽ አልገደብኝም 03
10	ከቤትዎ ራቅ ወዳላ ቤት መሄድ(የ 1 ጠጠር ውርወራ ያህል)	አዎ ብዙ ገድቦኛል 01 አዎ ትንሽ ገድቦኛል 02 አይ በጭራሽ አልገደብኝም 03
11	ከቤትዎ አጠገብ ወዳላ ቤት መሄድ	አዎ ብዙ ገድቦኛል 01 አዎ ትንሽ ገድቦኛል 02 አይ በጭራሽ አልገደብኝም 03
12	እራሶን ትለው ገላዎን መታጠብና ልብስ መልበስ?	አዎ ብዙ ገድቦኛል 01 አዎ ትንሽ ገድቦኛል 02 አይ በጭራሽ አልገደብኝም 03

የአካል የጤና ትግር

ባለፈው 1 ወር ጊዜ ውስጥ በአካላዊ ጤናዎ መታወክ ምክንያት በስራዎና በዕለት ተለት እንቅስቃሴዎት ላይ የሚቀጥሉት ችግሮች ገጥመዎታል?

13	በስራዎ ወይን በሌላ እንቅስቃሴ ላይ የሚያሳልፉትን ጊዜ ቀንሷል?	አዎ 01 አይ 02
14	ከሚፈልጉት በታች አከናውነዋል?	አዎ 01 አይ 02

15	በተወሰኑ ስራና ሆነ በእንቅስቃሴ ጌታ ነው የሚያከናውኑት		አዎ 01 አይ 02
16	ስራዎችን የተለመዱ እንቅስቃሴዎችን ለማከናወን ተቸግረዋል ማለትም ተጨማሪ ጉልበት ይጠይቅታል?		አዎ 01 አይ 02
17	ስራዎች ላይ ወይም እንቅስቃሴ ላይ የሚያሳልፉት ጊዜ ቀንሷል?		አዎ 01 አይ 02
18	መስራት ከሚፋልጉት በታች አከናውነዋል?		አዎ 01 አይ 02
19	ስራዎችን እንደወትሮ በጥንቃቄ አላከናወንኩም?		አዎ 01 አይ 02
ማህበራዊ እንቅስቃሴ			
20	ባለፉት 4 ሳምንታት ውስጥ የስነልቦና ጫና ከማህበራዊ እንቅስቃሴዎች ገደብዎታል፤ ከቤተሰብ፤ ከጋደኝነት፤ ጉርብትና ወይም ከቡድን እንቅስቃሴዎች?		በፍፁም 01 በትንሹ 02 በመካከለኛው 03 በጣም 04 እጅግ በጣም 05
ህመም			
21	ባለፉት 4 ሳምንታት ውስጥ ምን ያህል ጊዜ የሰውነት ህመም አጋጥሞታል ?		በፍፁም 01 በጣም በትንሹ 02 በትንሹ 03 በመካከለኛው 04 ከቡድን ያለ 05 እጅግ በጣም ከባድ 06
22	ባለፉት 4 ሳምንታት ውስጥ የአካል ህመም ምን ያህል ጊዜ ከቤትና ከውጭ ስራ አስተጓግሎታል		በፍፁም 01 በትንሹ 02 በመካከለኛው 03

		ከባድ ያለ 04 እጅግ በጣም ከባድ 05	
ጉልበትና ስሜታዊነት			
የሚቀጥሉት ጥያቄዎች በለፉት 4 ሳምንታት ውስጥ በራስዎ ዙርያ ምን ሲሰማዎት እንደነበረ የሚሳዩ ናቸው እባኩን ከነበሩበት ሁኔታ ጋር ተቀራራቢ የሆነውን መልስ ይምረጡ			
23	በለፉት 4 ሳምንታት ውስጥ ሙሉ አቅም ይሰማዎታል?	ሁል ጊዜ 01 አብዛኛውን ጊዜ 02 ብዙ ጊዜ 03 አንዳንዴ 04 ጥቂት ጊዜ 05 በጭራሽ 06	
24	ፈርተው /ተጨናንቀው ነበር	ሁል ጊዜ 01 አብዛኛውን ጊዜ 02 ብዙ ጊዜ 03 አንዳንዴ 04 ጥቂት ጊዜ 05 በጭራሽ 06	
25	ከባድ የድብርት ስሜት ተሰምቶት ነበር ምንም አላስደሰት እስከሚሉት ?	ሁል ጊዜ 01 አብዛኛውን ጊዜ 02 ብዙ ጊዜ 03 አንዳንዴ 04 ጥቂት ጊዜ 05 በጭራሽ 06	
26	በለፉት 4 ሳምንታት ውስጥ መረጋጋትና ሰላማዊነት ተሰምቶት ነበር?	ሁል ጊዜ 01 አብዛኛውን ጊዜ 02 ብዙ ጊዜ 03 አንዳንዴ 04 ጥቂት ጊዜ 05	

			በጭራሽ 06
27	በለፉት 4 ሳምንታት ውስጥ ብዙ ጉልበት /ጥንካሬ ተሰምቶት ነበር ?		ሁል ጊዜ 01 አብዛኛውን ጊዜ 02 ብዙ ጊዜ 03 አንዳንዴ 04 ጥቂት ጊዜ 05 በጭራሽ 06
28	በለፉት 4 ሳምንታት ውስጥ ድብርትና ተስፋ መቁረጥ ተሰምቶት ነበር?		ሁል ጊዜ 01 አብዛኛውን ጊዜ 02 ብዙ ጊዜ 03 አንዳንዴ 04 ጥቂት ጊዜ 05 በጭራሽ 06
29	የመኖር ተስፋዎ ያበቃለት መስሎት ነበር?		ሁል ጊዜ 01 አብዛኛውን ጊዜ 02 ብዙ ጊዜ 03 አንዳንዴ 04 ጥቂት ጊዜ 05 በጭራሽ 06
30	ደስተኛ ሰው ነበሩ?		ሁል ጊዜ 01 አብዛኛውን ጊዜ 02 ብዙ ጊዜ 03 አንዳንዴ 04 ጥቂት ጊዜ 05 በጭራሽ 06
31	ድካም ይሰማዎት ነበር?		ሁል ጊዜ 01 አብዛኛውን ጊዜ 02

			ብዙ ጊዜ 03 አንዳንዴ 04 ጥቂት ገዜ 05 በጭራሽ 06
የማህበራዊ ህይወት እንቅስቃሴ			
32	ባለፉት 4 ሳምንታት ውስጥ ምን ያህል ጊዜ የአካላዊ ወይንም ስነ-ልቦና ችግሮችዎ ማህበራዊ ህይወቶችን አስተጓግለዋል? (ለምሳሌ ጓደኛ መጎብኘት፣ ቤተሰብ መጎብኘት ወዘተ...)		ሁል ጊዜ 01 አብዛኛውን ጊዜ 02 ብዙ ጊዜ 03 አንዳንዴ 04 ጥቂት ገዜ 05 በጭራሽ 06
አጠቃላይ ጤና			
የሚቀትሉት ጥቂዎች ለእርሶ ምን ያህል እውነት ወይንም ሐሰት ናቸው?			
33	ከሌሎች ሰዎች ይልቅ በቀላሉ የምታመም ይመስለኛል		በርግጥም እውነት 01 በአመዘኛ እውነት 02 አላውቅም 03 በአመዘኛውሽት 04 በፍፁም ወሽት 05
34	እንደሚታዩት ሰዎች ሁሉ ጤነኛ ነኝ		በርግጥም እውነት 01 በአመዘኛ እውነት 02 አላውቅም 03 በአመዘኛውሽት 04 በፍፁም ወሽት 05
35	ጤንነቴ ሁኔታ ይባባሳል ብዬ ጠብቃለሁ		በርግጥም እውነት 01 በአመዘኛ እውነት 02 አላውቅም 03 በአመዘኛውሽት 04 በፍፁም ወሽት 05

36	ጤንነቱ እጅግ በጣም ጥሩ ነው	<p>በርግጥም እውነት 01</p> <p>በአመዘኙ እውነት 02</p> <p>አላውቅም 03</p> <p>በአመዘኙ ውሸት 04</p> <p>በፍፁም ውሸት 05</p>	
----	--------------------	--	--