Master's thesis

NTNU
Norwegian University of Science and Technology
Faculty of Medicine and Health Sciences
Department of Public Health and Nursing

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Glycemic control and its association with medication adherence among type 2 diabetes mellitus patients in Nepal

A hospital based cross-sectional study in Dhulikhel Hospital, Nepal

Master's thesis in Public Health specializing in Global Health
Supervisor: Bård Eirik Kulseng
Trondheim, June 2017

NTNU (Top) and Dhulikhel Hospital (Bottom)

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ABSTRACT

Title

Glycemic control and its association with medication adherence among type 2 diabetes mellitus patients: A hospital based cross-sectional study in Dhulikhel Hospital, Nepal

Background

Diabetes is a medical condition characterized by high sugar level in blood caused due to impaired insulin production or function. It is steadily increasing everywhere around the world resulting in 1.5 million deaths due to diabetes in 2012 as per WHO report in 2016. The high mortality rate is due to a number of life-threatening health problems caused by uncontrolled glycemia. Medication adherence, among other factors such as diet control, exercise and life-style modification, is one of the necessary pre-conditions to have good glycemic control and therefore, to reduce burden of diabetes.

Objectives

The primary objectives of this study were (i) to determine the status of glycemic control, (ii) to determine the status of medication adherence for diabetes medicines and (iii) to identify the association between glycemic control and medication adherence. Secondary objectives were to identify the associated factors of medication adherence on diabetes medicines and to identify the association between attendance of diabetes counseling and medication adherence for both formally educated and not formally educated type 2 diabetes mellitus (DM) patients.

Methods

A hospital based cross sectional study was conducted at laboratory department of Dhulikhel Hospital among the patients visiting for their regular Fasting Blood Sugar (FBS) test from September to December 2016. Inclusion criteria were (i) type 2 DM patients (ii) under diabetes medication from at least past three months (iii) aged ≥18 years. Patients with FBS < 7 mmol/litre and glycated haemoglobin (HbA1c) < 7% were categorized as good glycemic control. The medication adherence was measured with Nepali version of 8 item Morisky Medication Adherence Scale (MMAS-8) (© 2007 Donald E. Morisky). Multivariate linear regression was applied to assess the association of glycemic control (FBS and HbA1c) and

medication adherence and multivariate logistic regression to identify the associated factors of medication adherence of diabetes medicines. Both of them were adjusted for sociodemographic and clinical characteristics.

Results

A total of 343 eligible cases were recruited for the study. Mean age of respondents was 55.8 years, 54.2% were male and 49% belonged to Newar ethnicity. Average FBS was 147.9 (SD: 57.3) mg/dl [8.2 (SD: 3.2) mmol/L] and average HbA1c among 198 participants was 7.8 (SD: 1.8) %. Only 42% had good FBS control while 37.4% had good HbA1c control despite of having high mean MMAS-8 (© 2007 Donald E. Morisky) score of 7.4 (SD: 1) with 60.9% high adherence (score =8), 31.8% moderate adherence (score ≥6 and <8) and 7.3% low adherence (score <6). There was statistically significant association between FBS and medication adherence [β: -14.32 (95% CI: -28.47,-0.16), p=0.047] but no such association between HbA1c and medication adherence. High medication adherence was found to be significantly associated with formal education [AOR: 2.43 (95%CI: 1.34, 4.39), p=0.003] and attendance of diabetes counseling [AOR: 1.76 (95% CI: 1.02, 3.04), p=0.04]. There was no significant interaction between education and attendance of diabetes counseling [95% CI: 0.49, 4.25, p=0.51] in relation to medication adherence.

Conclusion

The glycemic control among the sample representing Nepalese type 2 DM population was not good though the proportion of high medication adherence was high. There was statistically significant association of glycemia (FBS) with high medication adherence. In addition, high medication adherence was statistically significant with formal education and attendance of diabetes counseling. For all the patients with formal or no formal education, medication adherence had significant association with attendance of diabetes counseling. Hence, we encourage that higher number of type 2 DM patients should take part in counseling program and constant training should be given to health care professionals to conduct diabetes counseling.

Key words

FBS, Glycemic control, HbA1c, Medication Adherence, Diabetes Counseling

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I have obtained written permission from copyright owners for any excerpts from copyrighted works that are included and have credited the sources in the Article or the Supplemental Materials. I would like to acknowledge Dr. Donald E. Morisky for giving me the license of Morisky Medication Adherence Scale – 8 (MMAS-8) (© 2007 Donald E. Morisky) and its official Nepali translated version and waiving me the fees to use in my thesis study. Without this scale, the study would not have been possible.

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Pushpanjali Shakya

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LIST OF ABBREVIATIONS

ADA	-	American Diabetes Association
AOR	-	Adjusted Odds Ratio
β	-	Beta coefficient
BP	-	Blood Pressure
BMI	-	Body Mass Index
COR	-	Crude Odds Ratio
DM	-	Diabetes Mellitus
DCCT	-	Diabetes Control and Complications Trial
FBS	-	Fasting Blood Sugar
GDP	-	Gross Domestic Product
HbA1c	-	Glycated Hemoglobin
HPLC	-	High Performance Light Chromatography
IDF	-	International Diabetes Federation
IQR	-	Interquartile Range
Kcal	-	Kilo calorie
MARS	-	Medication Adherence Report Scale
MET	-	Metabolic Equivalent
mg/dl	-	milligram per decilitre
MMAS-8	-	Morisky Medication Adherence Scale-8 (© 2007 Donald E. Morisky)
mmHg	-	millimeter of mercury
mmol/L	-	millimole per litre
NCD	-	Non Communicable Disease
NGSP	-	National Glycohemoglobin Standarization Program
NRs	-	Nepali Rupees
ODK	-	Open Data Kit
OGTT	-	Oral Glucose Tolerance Test
OPD	-	Out-Patient Department
SLC	-	School Leaving Certificate
USD	-	US Dollars
USDA	-	United States Department of Agriculture
WC	-	Waist Circumference

1 INTRODUCTION

1. 1 General Background of Nepal

Nepal, the land of Mount Everest and birthplace of Lord Buddha, is a developing landlocked country in South Asia situated between China and India. It has population of 28.03 million, mostly based in agriculture, with annual per capita Gross Domestic Product (GDP) of 761.59 US Dollar (USD) in 2015 (1), literacy rate of 65.9% (1) and average life expectancy at birth of 68 years (2).

Being a mountainous country with 8 out of 10 highest peaks in the world, Nepal faces a number of developmental challenges. The geography is rugged, economic growth is very slow and there is high level of social and political disturbances. Furthermore, the country is prone to natural disasters like earthquake, flood and landslides. Poverty is very high with more than 25% of the population living below the national poverty line (3). However, the country is making progress by reducing the percentage of people living on less than 1.25 USD a day from 53 percent in 2003-04 to 25 percent in 2010-11 (4).

Health care system in Nepal is rudimentary and troubled with problems such as insufficient workforce, low quality infrastructure, inadequate financing among others. There are 102 government hospitals and 301 private hospitals with 16,854 doctors and 33,293 nurses (1). Maternal, neonatal and nutritional problems followed by infectious diseases are positioned in top-most list of burden of disease in 2012 in Nepal (2). Cardiovascular disease and diabetes constitute the third highest reason after them creating a double burden of disease in Nepal (2).

1. 2 Burden of Diabetes

Diabetes is a medical condition characterized by chronic hyperglycemia in which the glucose metabolism is impaired because insulin secreted by pancreas gland is either inadequate or does not function properly (5). Global prevalence of diabetes (defined as those having a fasting plasma glucose value of greater than or equal to 7.0 mmol/L or on medication for diabetes/ raised blood glucose) was 422 million (8.5%) among adults aged over 18 years in 2014 and is rapidly increasing in low and middle income countries (6). South East Asia has covered second largest prevalence of diabetes comprising 96 million (8.6%) (6). The age

standardized prevalence of diabetes among adults of range 20 to 79 years of Nepal was estimated to be 4.9% in 2013 (7). The age standardized numbers of diabetes in urban and rural settings in Nepal were 315,710 and 191,010 respectively in 2013 (7). Though, nationwide prevalence surveys for diabetes have never been done yet, a field survey conducted from 1999 to 2001 among 20 years or older in five urban (n=1237) and two rural populations (n=604) of Nepal reported 14.6% and 2.5% prevalence of diabetes (a fasting plasma glucose ≥7 mmol/L) respectively (8). A meta-analysis done for prevalence of diabetes in Nepal from 2000 to 2014 found the pooled prevalence of type 2 diabetes as 8.5% (ranging from 1.4% to 19%) with the diagnostic method of Fasting Blood Sugar (FBS), urine and Oral Glucose Tolerance Test (OGTT) in both urban and/or rural settings (9). As per the diabetes country profiles 2016, the prevalence of diabetes in Nepal was found to be 9.1% (10).

World Health Organization (WHO) estimates high blood glucose as the third highest risk factor for global premature mortality (11). In 2012, 2.2 million deaths were caused by diabetes and high blood sugar, while 1.5 million deaths were directly caused by diabetes (6). In Nepal, the death proportion among all ages due to diabetes was 3% as per the diabetes country profiles 2016 (10). Hence, diabetes is becoming a major non-communicable public health problem even in low income country like Nepal (6).

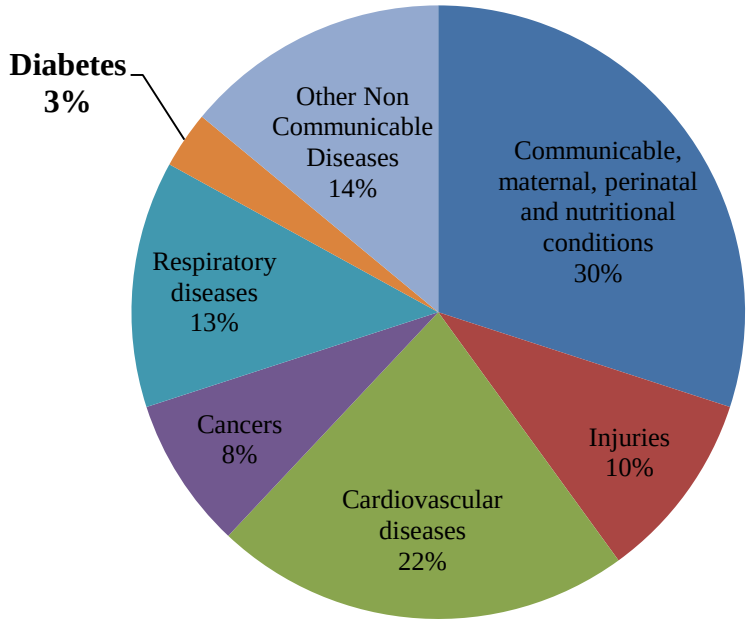


Fig 1: Proportion mortality in Nepal (%)

The high mortality rate is due to a number of life-threatening health problems caused by high blood sugar level affecting heart, blood vessels, eyes, kidneys and nerves (12). These complications along with diabetes have placed a large financial burden on individuals and their families, and subsequently countries and their national health care system (12). Therefore, for a country like Nepal with low gross national income per capita (2420 USD), diabetes has imposed a major economic burden (13).

1. 3 Glycemic control and Medication Adherence

If glycated haemoglobin (HbA1c) level in blood is less than 7%, or FBS is less than 126 mg/dl [7 mmol/L], then the glycemic control is considered to be good or near normal (14). Sustained glycemic control is important to prevent the development of acute and chronic complication of diabetes (15) and thereby prevent the deterioration of quality of life. The regular contact with health care system improves glycemic control (13). Similarly, medication for diabetes is equally important to have good glycemic control (16). Therefore, WHO has included Diabetes Mellitus (DM) medication such as Metformin, Glycazide, Insulin injection (Soluble) and Intermediate acting insulin in the list of essential medicines (12, 17) which should be available and accessible to all the people with diabetes (18). In context of Nepal, despite the WHO recommendation, they are not available and accessible (19) because of their high financial cost. DM medications constituted 58.93% of the total cost (NRs. 1156.15 equivalent to 16.17 USD) per prescription per person in Nepal (20). Additionally, the medication adherence is not satisfactory even when they are available. Consequently, poor medication adherence leads to poor glycemic control (13, 21). However, there can be several other factors that contribute to poor glycemia, such as socio-demographic factors (age, race, occupation, financial difficulties) (22), lack of family support (22), longer diabetes duration, taking insulin therapy (13), existing diabetes complications (22) which can hinder in determining the true association of glycemic control and medication adherence. Therefore, more studies on relation of glycemic control and medication adherence controlling the confounders should be conducted to generate the true association between them, as medication adherence is the key component for diabetes management.

The review of literatures showed various methods or scales to measure medication adherence like six item self-administered questionnaire (22), self-reported adherence on Medication Adherence Report Scale (MARS) (23), four item Morisky Medication Adherence Scale

(MMAS-4) (24, 25) and eight item Morisky Medication Adherence Scale (MMAS-8) (13, 26). However, in context of Nepal, the information about adherence on diabetes medicines is rarely found and none of the studies have used any of the international standard tools. But, there was an observational cross-sectional hospital based study, done among 95 type 2 DM patients showing the relation of glycemic control and medication adherence (27), which had used only two questions to measure adherence on diabetes medicines. It showed that 38% were not adherent to Oral Hypoglycemic Agents (OHAs) while 25% had discontinued the medicines at least once and there was no association between glycemic control and medication adherence (p=0.936).

1. 4 Rationale of the study

It is important to study the association of glycemic control and medicine adherence in a bigger population in Nepal to sufficiently power the study and to measure the adherence in more valid and reliable way to downsize the measurement error. This study could give some baseline information related to glycemic control and medication adherence and their associated factors. This can contribute in understanding what constitutes good adherence and good glycemic control. The study will also be helpful for the policy makers and stakeholders to initiate evidence based planning for the management of diabetes in Nepal.

1. 5 Objectives

The primary objectives of the study were:

1. To determine the status of glycemic control among type 2 DM patients
2. To determine the level of adherence to OHA and Insulin therapy
3. To identify the association of glycemic control with the level of medication adherence (OHA or Insulin)

The secondary objectives of the study were:

- To identify the associated factors of medication adherence on diabetes medicines among type 2 DM patients
- To identify the relation of medication adherence with diabetic counseling and its interaction with education level of the patients

Null Hypothesis:

There is no association between glycemic control and medication adherence among type 2 DM patients.

Alternate Hypothesis:

There is significant association between glycemic control and medication adherence among type 2 DM patients.

1. 6 Conceptual Framework

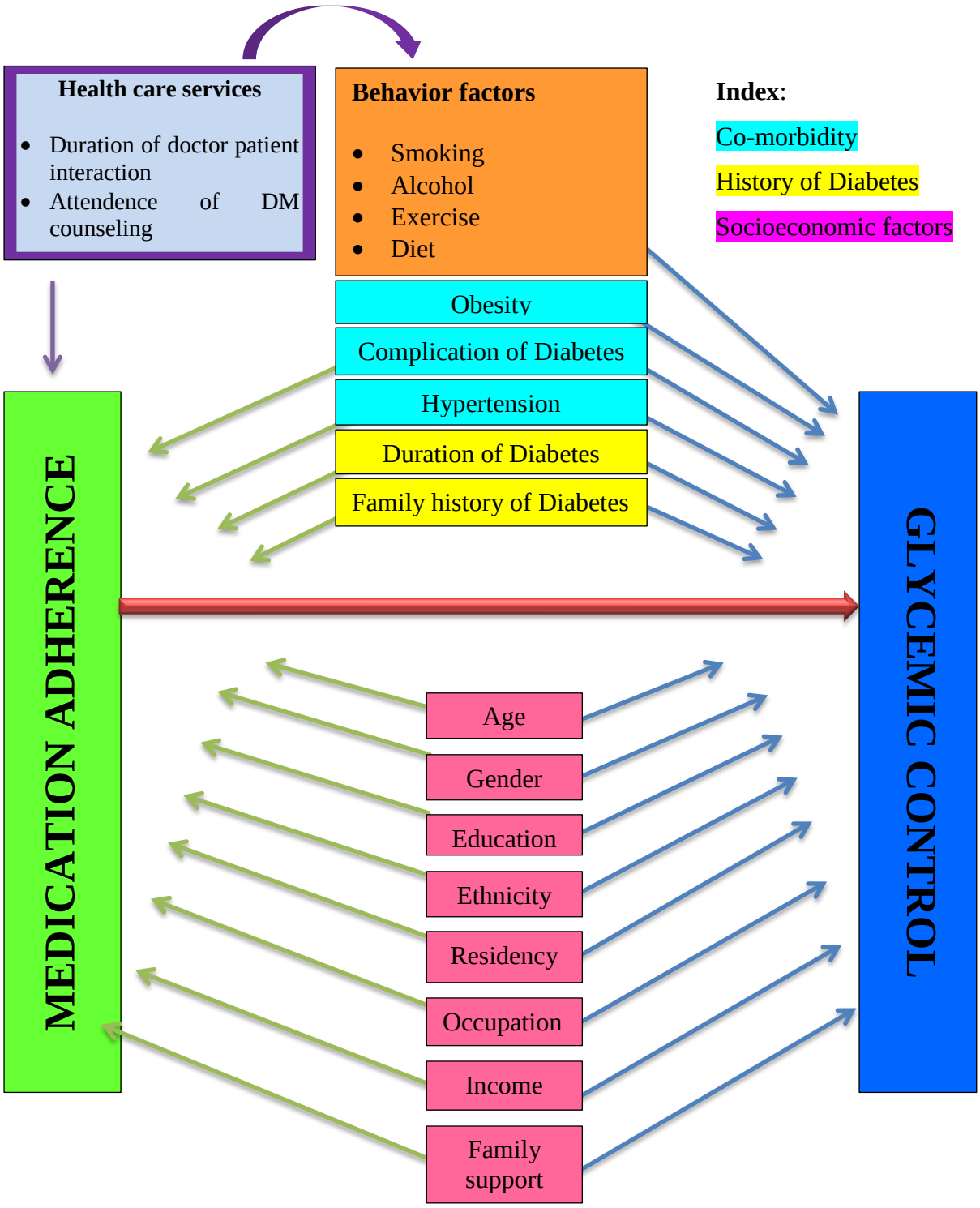


Fig 2: Conceptual framework

2 METHODOLOGY

2. 1 Study design and study site

A hospital based cross sectional study was conducted in Dhulikhel Hospital using consecutive sampling technique. Dhulikhel Hospital was tertiary care hospital located at center of Kavrepalanchowk district covering the population of approximately 1.9 million people from Kavrepalanchowk, Sindhupalchowk, Dolakha, Sindhuli, Ramechhap, Bhaktapur and other surrounding districts. The hospital had good flow of type 2 DM patients. It also had Diabetic Counseling Program run by the nurses. As per the Annual Nursing Report 2016 of Dhulikhel Hospital, 164 diabetes counseling sessions were conducted; total 397 diabetes patients and 133 family members had attended counseling program and 73 diabetes patients had attended insulin therapy sessions in the year 2016.

2. 2 Study population

All type 2 DM patients who had visited laboratory department of Dhulikhel Hospital to have their regular FBS test from September to December 2016 were contacted. Patients meeting following criteria were included in the study:

- Participants being 18 years or older
- Participants who had diagnosed type 2 DM
- Participants who had been prescribed for DM medication (oral or insulin) at least for the past 3 months

Patients with following criteria were excluded from the study:

- People with type 1 diabetes
- People with gestational diabetes
- Recently diagnosed diabetes cases with or without medication prescription for less than three months
- Critically ill patients

All eligible type 2 DM patients were recruited until required sample size of 343 was achieved. The sample size was calculated using Fleiss with Continuity correction method (28) using the data of the study done in Israel [Two-sided confidence level (CI): 95%, Power

(1-Beta or & chance of detecting): 80%, Ratio of Unexposed to Exposed in sample = 1.15, Percent of Unexposed with outcome = 77.8%, Percent of exposed with outcome = 89.6%, adding 10% of calculated sample size] (29).

2. 3 Data collection procedure

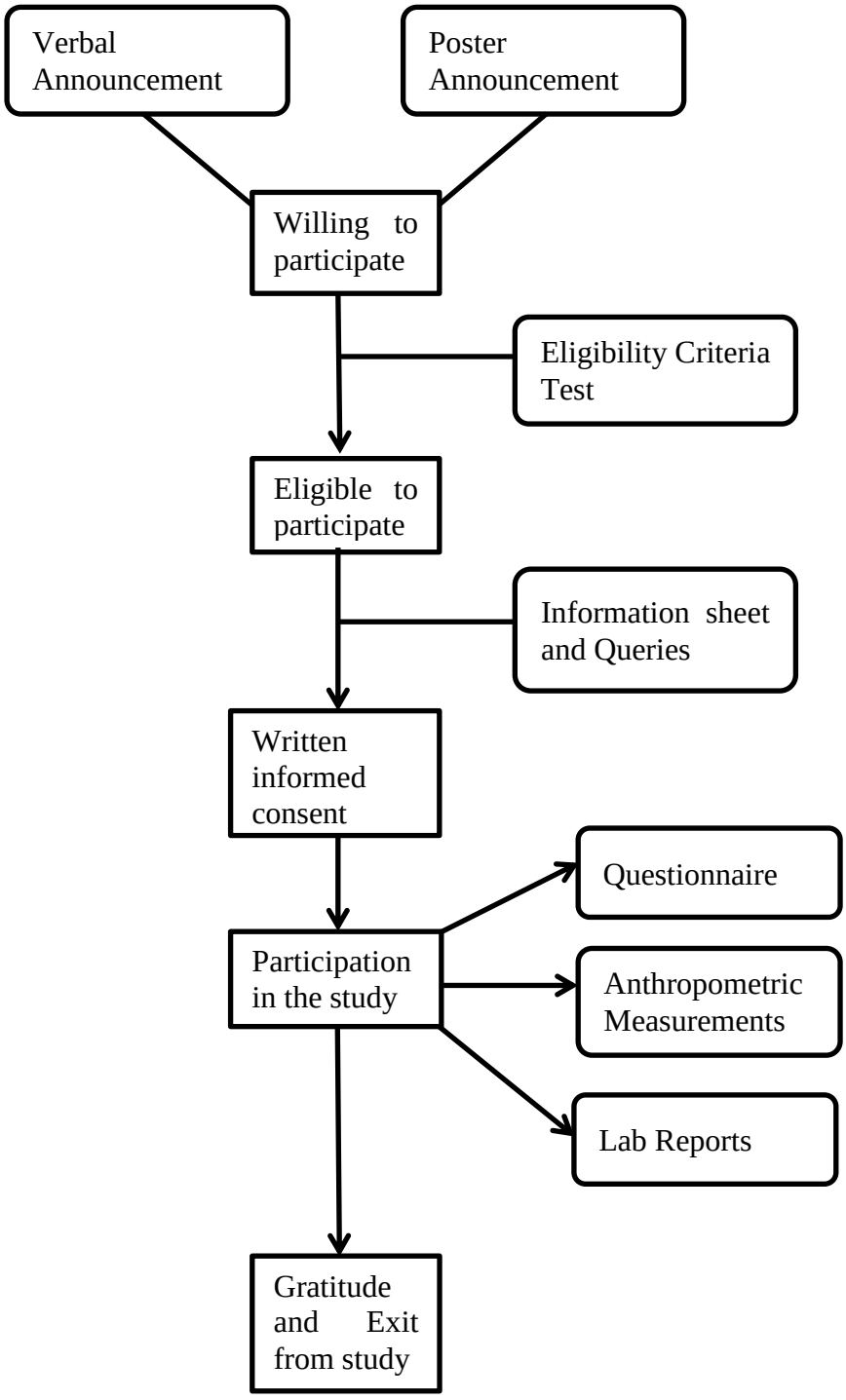


Fig 3: Data collection procedure

Multi-colored flex with description of study in Nepali language was posted near-by the laboratory department to let the participants know about study. Periodic announcements were also made verbally to have voluntary participation of the eligible candidates. Those who came in contact were explained the purpose of the study and their willingness to participate was determined. When verbal consent was received, detail information sheet was handed over or read out to them. Finally, signature or finger-prints were taken for written informed consent. A separate record sheet was maintained for the purpose of research only, containing code number of the participants, their hospital registration number, contact details and date of data collection along with some remarks.

Pre-test was done among 10 participants. Changes to the research tools were made accordingly. Competent research assistants were recruited and full training was given to the research assistants to get involved in the data collection process.

2. 4 Research Tools and Equipment

Questionnaire was used as the primary research tool for the study. First information on types of diabetes mellitus, hospital registration number and diabetes medication from the patients' Out-Patient Department (OPD) Card were recorded. Then pre-tested questionnaire was asked face to face using Nepali language (National language of Nepal) to the participants. The answers were entered in electronic version in a tablet with Android Operating System using the Open Data Kit (ODK) software[1] .

The questionnaire was divided into five parts as shown in the chart in the next page:

[1] For further details, please visit https://opendatakit.org/ and http://www.kobotoolbox.org/

Questionnaire Chart

Parts	Variables	Unit of measurement
Socio-demographic characteristics	Age Gender Education Ethnicity Residency Occupation Annual Household per capita Income Family Support for medication	Years Male / Female Non-formal / up to SLC/ Above SLC Brahmin / Newars / Others Rural / Urban Housewife / Business / Agriculture / Office (Professional) / Unemployed / Other occupation NRs per year Yes / No
Clinical History	Duration of diabetes Duration of medication intake Immediate family members with diabetes History of Hypertension History of current antihypertensive medication History of diabetes complication Time given by doctors Diabetes counseling Types of diabetes medication	Years / Months Years / Months Yes / No Yes / No Yes / No Yes / No Minutes per visit Yes / No OHA / Insulin / Both
Behavioral Factors	Pack years of smoking Smoking Drinking Alcohol Exercise 24 hour diet recall Diabetes plate model Regular sleep Sleep duration	Pack years Never / Former / Current Drinks per week Metabolic Equivalent (METs) Minutes per week Total calorie intake per day Yes / No Yes / No Hours per day
Medication Adherence	8 item Morisky Medication Adherence Scale (MMAS-8) (© 2007 Donald E. Morisky)	0-8
Anthropometric measurements	Weight Height Hip circumference Waist circumference Blood Pressure	Kilogram (kg) Centimeter (cm) Centimeter (cm) Centimeter (cm) mmHg

Anthropometric measurements were taken using standardized techniques and calibrated equipment. Weight (in kg) was taken in light indoor clothing without shoe using Analog Weighing Scale (Camri weighing scale). Height (in cm) was measured using a height scale (Prestige R height scale); hip circumference was measured using a plastic tape around the widest portion of the buttocks, with the tape parallel to the floor; and waist (in cm) was measured by placing a plastic tape horizontally, passing the umbilicus (midway between the 12th rib and the iliac crest on the midaxillary line). Blood pressure of the participants was measured in resting position using 'A and D' digital blood pressure measurement instrument (30). Three blood pressure measurements were taken (30) and average was used for the study.

FBS was carried out following a minimum of 8 hours' fasting by trained laboratory technician from Haematology department following aseptic techniques as part of patients' regular test. The reports of FBS of all 343 participants were collected from the Biochemistry department of Dhulikhel Hospital using the hospital registration number of the participants. In addition to FBS, among the participants within 343 sample size, reports of HbA1c tests that were done within last three months or up to three months from the date of data collection were also collected. The hospital laboratory department measured HbA1c by the NycoCard Reader and its reagent carried out using Point of care Testing (POCT) (14) device (NycoCard™ READER - AXIS-SHIELD) till 24th October 2016. It was previously recognized by Diabetes Control and Complications Trial (DCCT) and National Glycohemoglobin Standarization Program (NGSP). Later, DCCT aligned HbA1c test, High Performance Liquid Chromatography (HPLC) (31) was done from 25th October 2016.

All data collected from questionnaire, anthropometric measurements and lab reports were first entered into the ODK software, checked for the complete information and transferred from the tablet to the computer. Data were first extracted into excel file and was imported into SPSS for analysis. All data were secured by password and were accessible only to the researcher.

2. 5 Data analysis

Data analysis was conducted using SPSS version 22. Appropriate categories were created for different variables in the study.

Glycemic Status

Glycemic status was measured using FBS and HbA1c data. FBS was categorized as good FBS control if it was less than 7 mmol/L and poor FBS control if FBS ≥7 mmol/L (14). Similarly, for HbA1c, the cutoff point of ≥7% was used.

Morisky Medication Adherence Scale[2]

The eight item Morisky Medication Adherence Scale [MMAS-8 (© 2007 Donald E. Morisky)] (32-34) was used for the study to measure the medication adherence of diabetes medicines of type 2 DM patients. License was obtained from Dr. Morisky to use both English version as well as officially translated Nepali version of the scale.

The MMAS-8 (© 2007 Donald E. Morisky) score was calculated as per the instruction provided by the owner in the license contract. If total score was equal to 8, it was categorized as "High Adherence", the score greater than or equal to 6 but less than 8 was categorized as "Moderate Adherence" and the score less than 6 was categorized as "Low Adherence". Only two categories of "High Adherence" (score=8) and "Moderate/Low Adherence" (score< 8) were used in multivariate linear regression to identify the association of glycemic control & medication adherence and also in multivariate logistic regression to identify the associated factors of medication adherence because very few cases were reported in Low adherence category.

Hypertension

Hypertension was defined as those with systolic Blood Pressure (BP) ≥ 140 mmHg or diastolic BP ≥ 90 mmHg (35) or with self-reported history of hypertension or with self-reported intake of antihypertensive medications.

[2] *Use of the ©MMAS is protected by US copyright laws. Permission for use is required. A license agreement is available from: Donald E. Morisky, MMAS Research LLC, 16636 159th Place SE, Renton WA 98058; dmorisky@gmail.com.*

Smoking status

Smoking status was categorized into three categories as never smoker (who had never attempted cigarette smoking till the data collection date), former smoker [those who had left smoking for at least past 6 months (36)] and current smoker (those who smoked cigarette or *Bidi* till the date of data collection). A pack year of smoking was calculated using following formula:

$$Packed\ years\ of\ smoking\ = \frac{Number\ of\ cigarattes\ consumed\ per\ day}{20}\ X\ \text{Duration of smoking in years}$$

Bidi (small, thin, hand rolled cigarettes wrapped in a leaf) (37) was included in the total pack years of smoking because it was found to be common local variety of smoking.

Alcohol drinking

Alcohol consumption was measured in grams of pure alcohol per day where one alcoholic drink-equivalent was described as containing 14 g (0.6 fl oz) of pure alcohol (38). Alcohol guideline in Dietary Guidelines for Americans 2015-2020 was used as reference to calculate the amount of grams of pure alcohol in different alcoholic drinks. They were:

- 12 fluid ounces (approximately 357.84 ml) of regular beer consisted of 5% alcohol
- 5 fluid ounces (approx. 147.85 ml) of wine consisted of 12% alcohol
- 1.5 fluid ounces (approx. 44.35 ml) of a proof distilled spirits like rum consisted of 40% alcohol (39)

Diet: 24 hours diet recall

Participants were asked to recall their diet for past 24 hours prior to data collection to obtain the information about diet. The information contained types of food, amount of food and ingredients used to cook the food. Self-reported serving size based on diagram made by Belgium Food Composition which was also used in Dhulikhel Heart Study after edition to suit the Nepali context was used to record the amount of food. The diagram consisted of serving size of 0.5, 1, 1.5 and 2 from which patients had to indicate the amount closest to their consumption in past 24 hours. The serving size was later converted into grams of food on basis of the Belgium Food Composition Chart while those not found in the chart were measured by the researcher. Finally, gram of food was converted into kilo calorie (kcal) using Food Composition Table for Nepal (40), guideline from United States Department of

Agriculture (USDA) (41) and Norwegian food database (42). The sum of the total calorie per day was then obtained for the analysis of food variable in the study.

Diabetic plate model is the food portion distribution with carbohydrate (rice, rice flakes, bread, potato, pasta, etc.) one-fourth of the plate; protein (pulses, lentils, meat, fish, egg, milk, etc.) one fourth of the plate; and vegetables (cauliflower, broccoli, spinach, green leafy vegetables, etc.) & fruits (apple, banana, orange, etc.) half of the plate (43).

Fig 4: Diabetes plate model[3]

Physical activity

Physical activity was analyzed using continuous data of Metabolic Equivalent (METs) minutes per week as recommended by WHO. MET is the ratio of metabolic rate during working time relative to metabolic rate during resting time (44). One MET is defined as the energy cost of sitting quietly, and is equivalent to a calorie consumption of 1 kcal/kg/hour (44). It was estimated that the metabolic rate in moderate and vigorous activity is 4 times and 8 times higher than metabolic rate in resting time respectively. Therefore, moderate activity was multiplied by 4 while vigorous activity was multiplied by 8. Total physical activity METs minutes per week was derived by the sum of total METs of activity for each setting. WHO recommendation on physical activity for health of achieving at least 600 MET mins per week (44) was used as cut-off point.

Annual household per capita income

In the current study, only 234 cases provided information about annual household per capita income which reduced the power for the study. Hence, missing indicator for this variable was

[3] Researcher's own creation during diabetes counseling in 2012

used in the model. However, the values in the model (not shown in the tables) did not give sensible meaning in relation to glycemic control and medication adherence.

2. 6 Statistical analysis

a. Descriptive Statistics

Mean and standard deviation were used for descriptive analysis of normally distributed continuous variables whereas median and interquartile range were used for continuous variables with skewed distribution. Frequency and percentage were used for the descriptive analysis of categorical variables.

b. Analytical Models

Models	Description
Model 1	Bivariate analyses were done to identify the association of glycemic control and medication adherence with each predictor variable.
Model 2	Multivariate analyses were done adjusting for socio-demographic variables (age, education, occupation and annual household per capita income).
Model 3	Multivariate analyses were done adjusting for socio-demographic variables (age, education, occupation and annual household per capita income) and clinical characteristics (medicine intake duration, attendance of diabetes counseling and types of diabetes medicines).
Multivariate linear regression model	Both models 1 and 2 were run by multivariate linear regression to identify the association of glycemic control (FBS and HbA1c) [continous data] with medication adherence (High adherence and moderate/low adherence) (Table 4.1 and 4.2). Beta coefficient (β) was used to estimate the change in outcome variable (glycemia) with every unit change in the exposure (medication adherence).
Multivariate logistic regression model	Both models 1 and 2 were run separately by multivariate logistic regresssion to identify the associated factors of medication adherence (High adherence and moderate/low adherence) (Table 5). Adjusted Odds Ratio (AOR) was used to estimate the effect of factors on medicine adherence.

Model 4 was also conducted with the similar variables as in Model 3 to identify the interaction between education of the participants and attendance of diabetes counseling (not shown in the table 5) in relation to medication adherence. Natural logarithm was done for medicine intake duration to adjust in the both regression models due to its skewed distribution.

2. 7 Ethical statement

The research protocol was approved by Regional Committee for Medical and Health Research Ethics (REK), Norway; Nepal Health Research Council (NHRC) and Institutional Review Committee, Kathmandu University School of Medical Sciences (IRC/ KUSMS), Nepal. In addition, written permission was obtained from the Hospital Director to use the laboratory department of Dhulikhel Hospital. Participants were recruited on a voluntary basis after providing full information about the research and obtaining written informed consent.

3 RESULTS

3. 1 Socio-demographic characteristics

A total of 343 eligible participants were recruited with consecutive sampling technique. The socio-demographic characteristics of 186 male and 157 female in the study sample are shown in Table 1. The mean age was 55.8 (SD: 11.5) years and nearly half of study participants were of Newar ethnicity (49%). Most of the study participants (89.4%) were from urban residence and 89.8% were currently married. More males were educated than females. Most of the female participants were housewife (62.4%) while most of male participants (34.4%) were engaged in business. The median annual household per capita income was 1167.8 USD (Table 1).

3. 2 Life-style characteristics

Table 2 presents the life style characteristics of the study sample. Half of the study participants were smokers. Males participants comprising 22.7% were current smokers compared to 11.5% of females. The mean pack years of smoking was 4.4 (SD: 33.4). The mean number of alcohol drinks per week was 8 (SD: 45.26) for males and 0.2 (SD: 1.1) for females. The mean total calorie intake per day was 1502.8 (SD: 519.9) kcal. The average calorie intake for women was lower than men. Most of the study participants (95.9%) reported that they did not follow diabetic plate model. The mean sleep duration of the participants was 7.3 (SD: 1) hours. Thirty three percent of males and 44.6% of females reported to have physical activity less than WHO recommendation i.e. less than 600 METs min per week. Fifty seven percent of participants were overweight or obese. Sixty percent of females had substantially increased central obesity compared to 11.8% males.

3. 3 Clinical characteristics

The clinical characteristics of the study participants are shown in Table 3, stratified by gender. More than half of study participants (58%) had poor FBS control. More females had poor FBS control compared to males. The results based on gender were similar for HbA1c criteria. Most of the study participants (84.3%) were under only Oral Hypoglycemic Agents (OHA). The median duration of medicine intake of the study sample was 3 (IQR: 1, 6) years. The mean of MMAS-8 (© 2007 Donald E. Morisky) score was 7.4 (SD: 1). Number of

participants with high, moderate and low adherence were 60.9%, 31.8% and 7.3 % respectively. Most of the male participants (76.3%) paid for their medicine themselves compared to only 18.5% of female participants. Some participants (14.9%) reported that their immediate family members have diabetes. More than half (58%) had not received any diabetes counseling. The mean time duration for doctor patient interaction was 8.6 (SD: 4.9) minutes. Almost half of the participants (47.5%) had hypertension and 8.5% reported to have diabetes related complication

Table 1: Socio-Demographic Characteristics

Characteristics	Male (n=186)		Female (n=157)		Total (n=343)	
	n	(%)	n	(%)	n	(%)
Age, years mean (SD)	57.1 ± 11.4		54.3 ± 11.4		55.8 ± 11.5	
Ethnicity						
Newar	91	(48.9)	77	(49.0)	168	(49.0)
Brahmin/ Chhetri	68	(36.6)	60	(38.2)	128	(37.3)
Other	27	(14.5)	20	(12.7)	47	(13.7)
Marital Status						
Currently married	179	(96.2)	129	(82.2)	308	(89.8)
Not currently married	7	(3.8)	28	(17.8)	35	(10.2)
Education						
No formal education	28	(15.1)	100	(63.7)	128	(37.3)
School Leaving Certificate (SLC)	112	(60.2)	49	(31.2)	161	(46.9)
Above SLC	46	(24.7)	8	(5.1)	54	(15.7)
Occupation						
Housewife	0	(0.0)	98	(62.4)	98	(28.6)
Business	64	(34.4)	11	(7.0)	75	(21.9)
Agriculture	44	(23.7)	30	(19.1)	74	(21.6)
Office (Professional)	29	(15.6)	5	(3.2)	34	(9.9)
Unemployed	19	(10.2)	5	(3.2)	24	(7.0)
Other occupation	30	(16.1)	8	(5.1)	38	(11.1)
Residency*						
Urban	164	(90.6)	132	(88)	296	(89.4)
Rural	17	(9.4)	18	(12.0)	35	(10.6)
Annual Household Per Capita Income, USD#**						
Median	1025.9		1167.7		1167.8	
(IQR)	(700.6, 1751.6)		(700.6, 1780.8)		(700.6, 1751.6)	

*n = 331,** n = 234

**# Income was considered as self-reported cash income. Converted into USD @ 102.76 (Exchange rate derived from nrb.org.np accessed on 16/04/17)

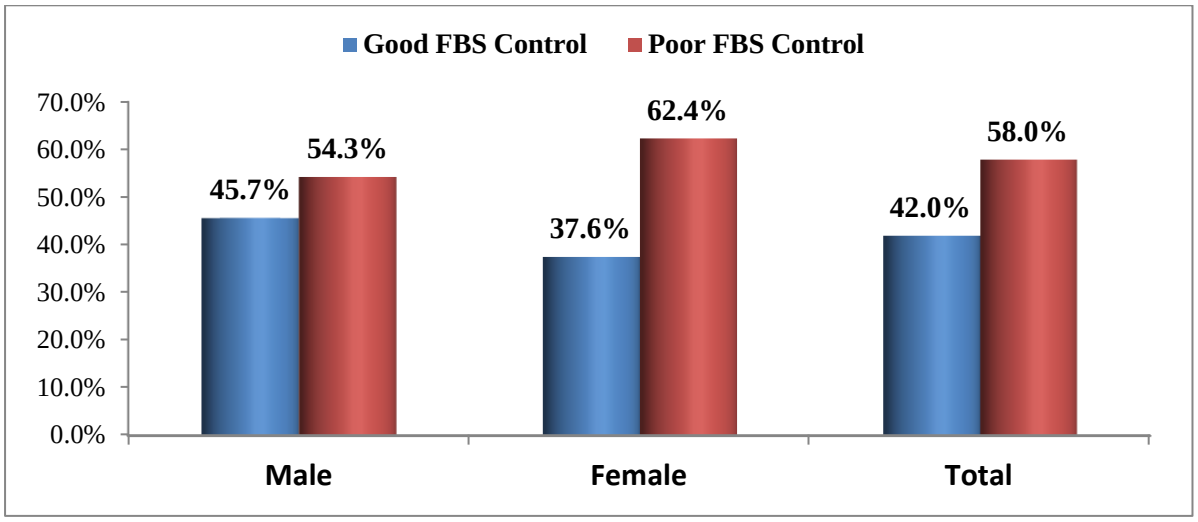
Table 2: Life Style Characteristics

Characteristics	Male (n=186) n (%)	Female (n=157) n (%)	Total (n=343) n (%)
Smoking Status			
Never smoked	56 (30.3)	115 (73.2)	171 (50.0)
Former smoker	87 (47)	24 (15.3)	111 (32.5)
Current smoker	42 (22.7)	18 (11.5)	60 (17.5)
Smoking Quantity, Pack Years Mean (SD)	9.4 ± 17.7	2.4 ± 7.4	4.4 ± 33.4
Alcohol, Drinks per week Mean (SD)	8 ± 45.26	0.2 ± 1.1	14.7 ± 21.4
Diabetic Plate Model*			
Not Followed	177 (95.2)	152 (96.8)	329 (95.9)
Followed	9 (4.8)	5 (3.2)	14 (4.1)
Diet, calorie per day Mean (SD)	1599.4 ± 572.8	1388.4 ± 423.2	1502.8 ± 519.9
Sleep Duration, hours Mean (SD)	7.2 ± 1.0	7.4 ± 1.0	7.3 ± 1.0
Physical Activity, MET min per week			
Less than 600	62 (33.3)	70 (44.6)	132 (38.5)
Equal to 600 or more	124 (66.7)	87 (55.4)	211 (61.5)
Physical Activity, MET min per week Median (IQR)	840 (420, 2670)	840 (260, 1680)	840 (360, 2240)
BMI, kg/m2			
Mean (SD)	25.3 ± 3	26.2 ± 4	25.7 ± 3.5
Underweight (<18.5)	3 (1.6)	2 (1.3)	5 (1.5)
Normal weight (≥18.5<25)	83 (44.6)	60 (38.2)	143 (41.7)
Overweight (≥25<30)	85 (45.7)	72 (45.9)	157 (45.8)
Obesity (≥30)	15 (8.1)	23 (14.6)	38 (11.1)
Waist circumference, cm			
Mean (SD)	95.1 ± 7.9	91.9 ± 10.7	93.6 ± 9.4
Obese**	22 (11.8)	95 (60.5)	117 (34.1)
Not obese	164 (88.2)	62 (39.5)	226 (65.9)

* Food portion distribution with carbohydrate (rice, rice flakes, bread, potato, pasta, etc.) one-fourth of the plate; protein (pulses, lentils, meat, fish, egg, milk, etc.) one fourth of the plate; and vegetables (cauliflower, broccoli, spinach, green leafy vegetables, etc.) & fruits (apple, banana, orange, etc.) half of the plate [shown in Figure 4].

** Waist circumference > 102 cm for male and >88 cm for female.

Status of glycemic control (FBS)

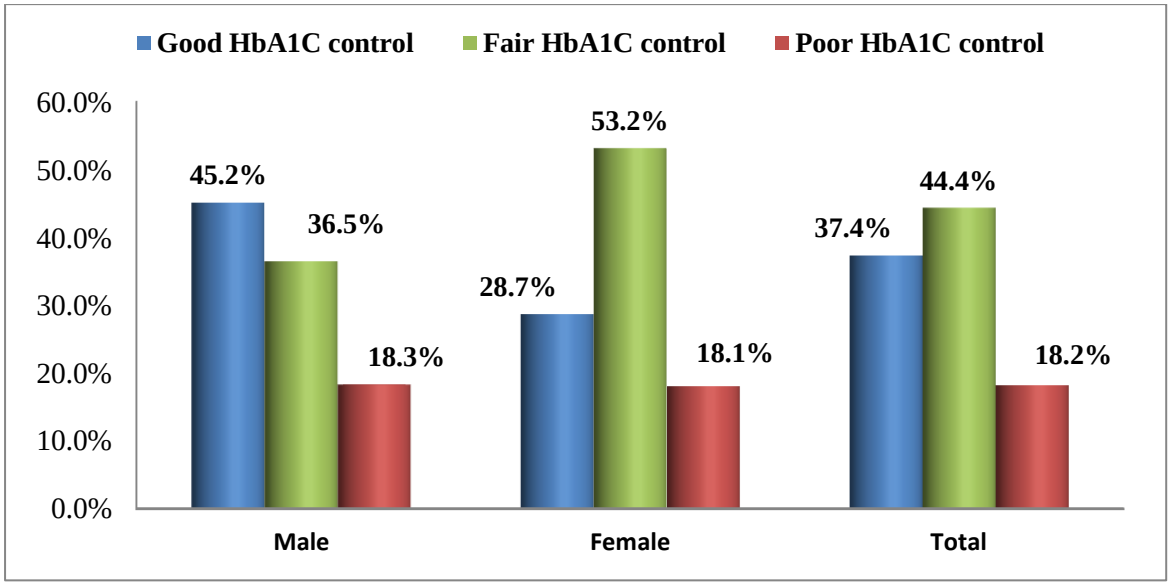


Poor FBS control *≥ 7 mmol/L*
Good FBS control *< 7 mmol/L*

n *:343*
Total male *:186*
Total female *:157*

Fig 5: Status of FBS

Status of glycemic control (HbA1c)

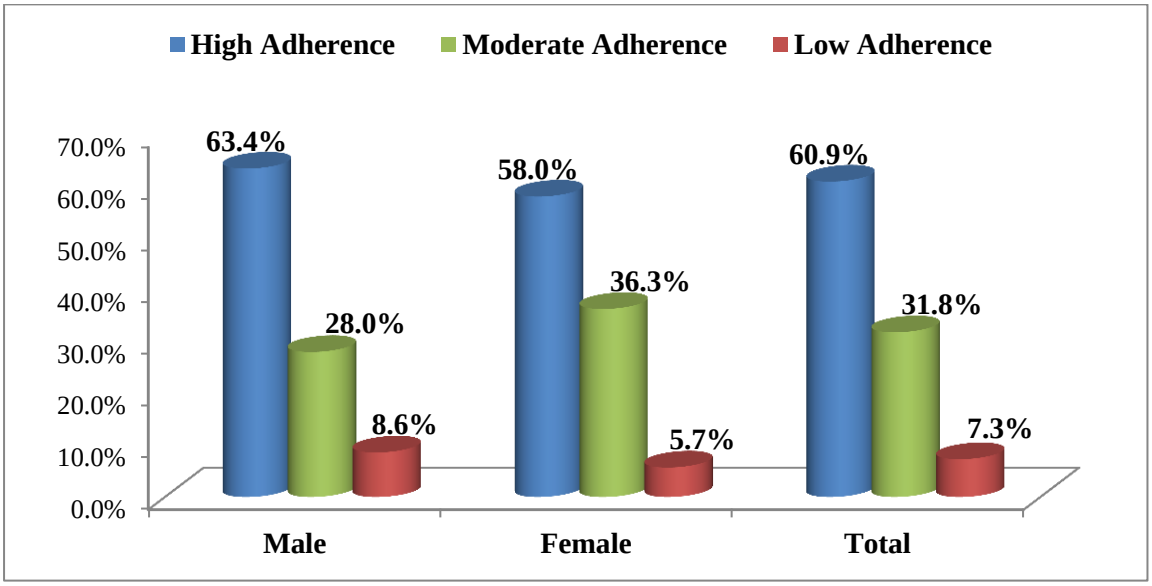


Good HbA1c control *<7%*
Fair HbA1c control *≥7%≤9%*
Poor HbA1c control *>9%*

n *:198*
Total Male *:104*
Total Female *:94*

Fig 6: Status of HbA1c

Status of medication adherence



Morisky medication adherence score (MMAS-8) (© 2007 Donald E. Morisky)

High:	*8*	*n*	*:343*
Moderate:	*≥6 to <8*	*Total male*	*:186*
Low :	*<6*	*Total female*	*:157*

Fig 7: Status of medication adherence[4]

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Table 3: Clinical Characteristics

Characteristics	Male (n=186)		Female (n=157)		Total (n=343)	
	n	%	n	%	n	%
FBS, mean (SD)						
mg/dl	145.2 ± 57.7		151.1 ± 56.8		147.9 ± 57.3	
mmol/L	8.1 ± 3.2		8.4 ± 3.2		8.2 ± 3.2	
HbA1c, %, mean (SD)*	7.6 ± 1.8		7.9 ± 1.7		7.8 ± 1.8	
Status of HbA1c control*						
Good control (HbA1c>=7%)	47	(45.2)	27	(28.7)	74.0	(37.4)
Poor control (HbA1c<7%)	57	(54.8)	67	(71.3)	124	(62.6)
Types of diabetes medicines						
OHA	153	(82.3)	136	(86.6)	289	(84.3)
OHA and Insulin	22	(11.8)	16	(10.2)	38	(11.1)
Insulin only	11	(5.9)	5	(3.2)	16	(4.7)
Medicine intake, years Median (IQR)	3 (1, 6)		2.5 (1, 6)		3 (1,6)	
MMAS-8 (© 2007 Donald E. Morisky)* Mean (SD)**	7.4 ± 0.9		7.3 ± 1		7.4 ± 1	
Financial support for diabetes medicine**						
Self	132	(76.3)	27	(18.5)	159	(49.8)
Family member	41	(23.7)	119	(81.5)	160	(50.2)
Immediate family member with diabetes						
Yes	29	(15.6)	22	(14)	51	(14.9)
No	157	(84.4)	135	(86)	292	(85.1)
Attendance diabetes counselling						
Yes	74	(39.8)	70	(44.6)	144	(42)
No	112	(60.2)	87	(55.4)	199	(58)
Duration of doctor-patient interaction, minutes Mean (SD)	8.8 ± 5.7		8.3 ± 3.9		8.6 ± 4.9	
Hypertension						
Yes	100	(53.8)	63	(40.1)	163	(47.5)
No	86	(46.2)	94	(59.9)	180	(52.5)
Self-reported chronic complications						
Yes	20	(10.8)	9	(5.8)	29	(8.5)
No	165	(89.2)	147	(94.2)	312	(91.5)

n =198, **n =319, * Use of the ©MMAS is protected by US copyright laws. Permission for use is required. A license agreement is available from: Donald E. Morisky, MMAS Research LLC, 16636 159th Place SE, Renton WA 98058; dmorisky@gmail.com.*

3. 4 Association of FBS and HbA1c with medication adherence

In multivariate linear regression model (Model 3, Table 4.1 and Table 4.2) adjusted for socio-demographic characteristics and clinical characteristics, there was statistically significant association of FBS with medication adherence [β:-14.32 (-28.47,-0.16) p=0.047] (Table 4.1) but no statistically significant association of HbA1c with medication adherence [β: -0.33 (-0.88, 0.23) p= 0.17] (Table 4.2).

The estimated decrease in FBS was 14.32 mg/dl and in HbA1c was 0.33% when patients obtained high adherence in comparison to moderate/low adherence. Both FBS and HbA1c were also found to be significantly associated with age (Model 3, Table 4.1 and Table 4.2). For every annual increase in age, FBS was estimated to decrease by 0.79 mg/dl and HbA1c by 0.03%. Further, FBS was significantly associated with medicine intake duration with estimated increase by 11.69 mg/dl as the medicine intake duration doubled. FBS was significantly associated with types of diabetes medicines only in bivariate analysis (Model 1, Table 4.1), but not in multivariate analysis (Model 3, Table 4.1). However, there was significant association of HbA1c and types of diabetes medicines in models 1 and 3 (Table 4.2). The HbA1c was estimated to increase by 1.24% if insulin or insulin & OHA were taken rather than taking only OHA.

3. 5 Associated factors of medication adherence

In multivariate logistic regression model (Model 3, Table 5) adjusted for socio-demographic characteristics and clinical characteristics, medication adherence was significantly associated with education and attendance of diabetes counseling. The medication adherence was significantly associated with education and attendance of diabetes counseling in bivariate analysis as well (Model 1, Table 5). The odds of medication adherence seemed to increase by 2.4 times and 1.7 times with obtaining formal education and attending diabetes counseling respectively (Model 3, Table 5). The odds of medication adherence decreased by 9% if medication intake duration doubled, though the association with medication intake duration was not statistically significant [AOR=0.91 (95% CI: 0.73, 1.13) p=0.41]. There was no significant interaction between education and attendance of diabetes counseling in relation to medication adherence [(95% CI: 0.49, 4.25), p=0.51)] [Model 4, not shown in the table].

Table 4.1: Association between Glycemic Control (FBS) and Medication Adherence***

Characteristics	Model 1			Model 2*			Model 3**		
	Bivariate analysis (n=343)			Adjusted for socio demographic variables (n=343)			Adjusted for socio demographic & clinical history (n=343)		
	Beta	**95% CI**	**p-value**	**Beta**	**95% CI**	**p-value**	**Beta**	**95% CI**	**p-value**
Medication adherence***									
Moderate/Low adherence (<8)	Ref			Ref			Ref		
High adherence (=8)	-10.73	(-23.16, 1.70)	0.09	-14.29	(-28.82, 0.24)	0.05	-14.32	(-28.47, -0.16)	0.047
Age, years	-0.33	(-0.86, 0.21)	0.23	-0.43	(-0.98, 0.12)	0.23	-0.79	(-1.36, -0.24)	0.006
Education									
No formal education	Ref			Ref			Ref		
Formal education	-4.11	(-16.69, 8.48)	0.52	-3.52	(-17.92, 10.88)	0.63	-7.42	(-21.44, 6.61)	0.29
Occupation									
Unemployed	Ref			Ref			Ref		
Employed	-2.40	(-15.12,10.32)	0.71	-2.86	(-16.98, 11.25)	0.69	0.58	(-13.19, 14.35)	0.93
Medicine intake duration, Years (nat. log)	10.20	(5.38, 15.02)	0.000	-	-	-	11.69	(6.51, 16.86)	0.000
Attendance of diabetes counseling									
No	Ref						Ref		
Yes	5.88	(-6.45, 18.21)	0.35	-	-	-	-1.77	(-14.35, 10.81)	0.78
Types of Diabetes medicines									
Only OHA	Ref						Ref		
Insulin or Insulin with OHA	20.34	(3.76, 36.93)	0.02	-	-	-	15.94	(-0.78, 32.66)	0.06

Dependent Variable: FBS mg/dl *** *Use of the ©MMAS is protected by US copyright laws. Permission for use is required. A license agreement is available from: Donald E. Morisky, MMAS Research LLC, 16636 159th Place SE, Renton WA 98058; dmorisky@gmail.com.*

Table 4.2: Association between Glycemic Control (HbA1c) and Medication Adherence***

Characteristics	Model 1			Model 2*			Model 3**		
	Bivariate analysis (n=198)			Adjusted for socio demographic variables (n=198)			Adjusted for socio demographic and clinical history (n=198)		
	Beta	**95% CI**	**p-value**	**Beta**	**95% CI**	**p-value**	**Beta**	**95% CI**	**p-value**
Medication adherence***									
Moderate/Low adherence (<8)	Ref			Ref			Ref		
High adherence (=8)	-0.06	(-0.56, 0.44)	0.82	-0.21	(-0.79,0 .36)	0.47	-0.33	(-0.88, 0.23)	0.17
Age, years	-0.02	(-0.04, 0.00)	0.06	-0.03	(-0.05, 0.00)	0.03	-0.03	(-0.05, -0.01)	0.008
Education									
No formal education	Ref			Ref			Ref		
Formal education	-0.15	(-0.67, 0.37)	0.56	-0.20	(-0.76, 0.37)	0.49	-0.25	(-0.79,0 .29)	0.37
Occupation									
Unemployed	Ref			Ref			Ref		
Employed	-0.23	(-0.75, 0.29)	0.38	-0.29	(-0.84, 0.25)	0.29	-0.33	(-0.85, 0.19)	0.21
Medicine intake duration, Years (nat. log)	0.10	(-0.09, 0.29)	0.29	-	-	-	0.13	(-0.07, 0.32)	0.19
Attendance diabetes counseling									
No	Ref						Ref		
Yes	0.55	(0.06, 1.05)	0.03	-	-	-	0.26	(-0.24, 0.76)	0.31
Diabetes medicine types									
Only OHA	Ref						Ref		
Insulin or Insulin with OHA	1.34	(0.70, 1.98)	0.00	-	-	-	1.24	(0.58,1.91)	0.000

Dependent Variable: HbA1c in % **** Use of the ©MMAS is protected by US copyright laws. Permission for use is required. A license agreement is available from: Donald E. Morisky, MMAS Research LLC, 16636 159th Place SE, Renton WA 98058; dmorisky@gmail.com.*

Table 5: Associated Factors of Medication Adherence***

Characteristics	Model 1			Model 2*			Model 3**		
	Bivariate analysis (n=343)			Adjusted for sociodemographic variables (n=343)			Adjusted for socio demo & clinical history (n=343)		
	OR	95% CI	p-value	OR	95% CI	p-value	OR	95% CI	p-value
Age, years	0.99	(0.97, 1.01)	0.28	0.99	(0.97, 1.01)	0.40	0.99	(0.97, 1.02)	0.73
Education									
No formal education	Ref			Ref			Ref		
Formal education	2.43	(1.55, 3.81)	0.000	2.36	(1.32, 4.23)	0.00	2.43	(1.34, 4.39)	0.003
Occupation									
Unemployed	Ref			Ref			Ref		
Employed	1.19	(0.76, 1.88)	0.44	0.71	(0.39, 1.29)	0.26	0.70	(0.38, 1.29)	0.25
Medicine intake duration, Years (nat.log)	1.00	(0.95, 1.04)	0.85	-	-	-	0.91	(0.73, 1.13)	0.41
Attendance diabetes counseling									
No	Ref						Ref		
Yes	1.78	(1.14, 2.79)	0.01	-	-	-	1.76	(1.02, 3.04)	0.04
Diabetes medicine types									
Only OHA	Ref						Ref		
Insulin or Insulin with OHA	1.34	(0.73, 2.47)	0.35	-	-	-	1.28	(0.60,2.73)	0.52

Dependent Variable: Medication Adherence (High adherence and Moderate/Low adherence)

* *Model 2 has been adjusted for socio-demographic characteristics (Age, education, occupation and annual household per capita income).*

** *Model 3 has been adjusted for socio-demographic characteristic and clinical characteristics (Age, education, occupation, annual household per capita income, medicine intake duration (natural log), duration of doctor patient interaction, attendance of DM counselling and types of diabetes medicines).*

4 DISCUSSION

The current study showed that mean FBS was 147.9 mg/dl (8.2 mmol/L) and mean HbA1c was 7.8%. High medication adherence was obtained among 60.9% of total participants. FBS had statistical significant association with medication adherence while HbA1c did not have such association. Medication adherence was significantly associated with education and attendance of diabetes counseling but the latter two independent variables did not have any significant interaction in relation to medication adherence.

It was a hospital based study done among type 2 DM patients visiting hospital for their regular FBS checkup. It was therefore more likely that participants of this study were concerned for their health and they were motivated to take the medicines to control their glycemia. The scenario could have been different if the study was done in community set up in terms of both exposure (medication adherence) and outcome (glycemic control).

Sample obtained for FBS was 343 while it was only 198 for HbA1c because FBS was more common and cheaper (approx. NRs. 80, equivalent to 0.77 USD) blood sugar test than HbA1c (approx. NRs. 750, equivalent to 7.25 USD) in Nepal. Hundred and one cases of HbA1c were analysed by POCT method till 24th of October, 2016 and 97 cases by HPLC method from 25th October, 2016 because the HbA1c test procedure was upgraded in the laboratory department of Dhulikhel Hospital in the middle of the current study. On average, HPLC method showed 0.34% lower HbA1c results than POCT method among 20 randomly selected cases. However, detail study on their difference was not evaluated in this study. Therefore, smaller sample size and inconsistent HbA1c test method had reduced the power of analysis and constrained further discussion in HbA1c. One of the impacts of sample size was the wider range of confidence interval in some of the results. The lower number in the reference group could also have affected the confidence interval.

MMAS-8 (© 2007 Donald E. Morisky) was used in this study for adherence on diabetes medicines. This scale was initially developed for antihypertensive medication adherence (32) and had also been used in Nepal for the same (Dhulikhel Heart Study). Therefore, officially translated Nepali version of MMAS-8 (© 2007 Donald E. Morisky) was available. There were studies which used MMAS-8 for medication adherence of diabetes medicines as well

(13, 26) in global context. But, it has not been used for diabetes medicine in Nepal yet as per the knowledge of the researcher. Most studies had used MMAS-8 to measure adherence for OHA only (26) while in some studies MMAS-4 scale were used to measure the adherence for both OHA and Insulin (24, 25). In the current study, the adherence had been measured for both OHA and Insulin using MMAS-8 (© 2007 Donald E. Morisky).

In the current study, nearly half of study participants were of Newar ethnicity (49%) because the study site Dhulikhel Hospital was located within the community mostly covered by Newars. Since, Dhulikhel is semi-urban residential area, most of the study participants (89.4%) reported from urban residence. The patriarchal society in Nepal might have influence more males (96.2%) to be currently married than females (82.2%). It is more common to have multiple marriages by a man if his spouse is dead in context of Nepal. More males were educated than females. Most of the female participants were housewife (62.4%) while most of male participants (34.4%) were engaged in business. Most of the male participants (76.3%) paid for their medicine themselves compared to only 18.5% of female participants. Males had better glycemic control and better medication adherence than females in the study. All these results can also be the impact of patriarchal society in Nepal. The median annual household per capita income was 1167.8 USD. Some participants hesitated to answer the question related to their income. This could have affected annual household per capita income in the current study.

4. 1 Status of Glycemic Control

Mean glycemia among type 2 DM patients in this study was high in terms of both FBS (147.9 mg/dl) and HbA1c (7.8%) compared to the recommended glycemia by ADA guideline (14). FBS was comparable with one other study done in Nepal that showed mean FBS of 132 mg/dl (n=95) but HbA1c in the current study was higher than HbA1c in that study with mean HbA1c of 6.8% (n=41) (27). In addition, 62.6% had poor HbA1c control in the current study compared to only 34% in the other study in Nepal (27). The variation in sample sizes might explain the differences in the result of these two studies. Mean HbA1c in current study was similar to that in Ethiopia (13) but was higher than that in China (26), France (22) and USA (45) and lower than that in UK (23). The differences in income, education, diet pattern, lifestyle behaviors and health organizations might have accounted for this variability.

Very high number (95.9%) of the study participants had not followed diabetic plate model which might also explain high glycemia in the study sample. It could be further explained by common dietary pattern of Nepalese population consisting of rice, lentils and vegetables *(Bhaat, Dal, Tarkari)* in proportion of 2:1:1 respectively two times a day instead of following diabetic plate model as shown in the figure 4. The mean calorie intake (1502.8 ± 519.9 kcal) was lower than that found by one another study in Nepal (46) and both were insufficient than estimated requirement of 2250 kcal/person/day (46, 47). The finding was unusual in the current study because participants might have consciously reduced their diet in past 24 hours of their blood test in order to get good control over glycemia. Other reason could be participants did not convey the correct information about their diet either due to recall bias or fear of being judged by the researcher.

4. 2 Status of Medication Adherence

Mean MMAS-8 (© 2007 Donald E. Morisky) score for both OHA and insulin was 7.4 (SD: 1) in the current study which was better than the study done in China with mean MMAS-8 score of 6.79 (SD: 1.37) for OHA only (26). The difference could be because study in China measured adherence only for OHA while the current study measured adherence for both OHA and insulin. It is more likely that patients with only OHA tend to forget to take their medicines compared to the patients who need to put on injection before their meal. It was also evident in the current study that patients taking insulin only or insulin with OHA had better medication adherence [AOR: 1.28 (0.60, 2.73), p=0.52] than those taking only OHA (Model 3, Table 5). High proportion (60.9%) had high adherence to diabetes medication (score=8) in the current study. This rate was similar to the findings of previous study done in Nepal (n=95), though that study did not use MMAS-8 (27). Similarly, 92.7% of the participants had optimal adherence (score≥6) including high adherence in the current study. This was far higher than findings of China (n = 565) where it was 67.8% (26). The difference can be explained by similar reasons above related to adherence to OHA and insulin. However, since both the studies were done in clinical set ups, it was more likely that patients coming in health care centers adhere more on their medication due to their concern for health resulting in better medication adherence. In addition, people in Nepal believe strongly in their doctors & their prescribed medicines and therefore adhere to their medication more than adhering to the balance diet (following diabetic plate model) and regular exercise.

The pattern of distribution of adherence found in Ethiopian study (13) using MMAS-8 were 47.32% with high adherence, 23.03% with moderate adherence and 11.07% with low adherence. This percentage of high adherence was 13.6% lower than the obtained proportion of high adherence of 60.9% in the current study. Though, both Ethiopia and Nepal are low income countries, medication adherence was found to be better in the current study than above Ethiopian study.

MMAS-4 and 6 item questionnaires were used to measure diabetes medicine adherence in some studies instead of MMAS-8. In Ethiopia (n=288), the another study that used MMAS-4, showed that status of medication adherence was 85.1% (24) while in France (n=3637) that used 6 item self-administered medication adherence scale, the status was 39% for good adherence, 49% for medium adherence and 12% for poor adherence (22). The difference in measurement scale, study size and population characteristics could account for the variability in the findings.

4. 3 Association of Glycemic Control and Medication Adherence

There was significant association of FBS with medication adherence [β:-14.32 (-28.47,-0.16) p=0.047]. The estimated decrease in FBS was 14.32 mg/dl among highly adherent compared with those having moderate/low adherence. This was in contrast with the study in Nepal that did not show any association between them (p=0.936) (27). The smaller sample size (n=95) in the previous study including participants from lab, emergency, OPD, In-patient departments could have impacted on the result. Those patients coming in emergency and getting admitted in the in-patient departments were more likely to have higher glycemia possibly due to infection and other complication. In some conditions, some emergency patients may also have hypoglycemia. The current study recruited only those type 2 DM patients who come for their regular FBS test. Additionally, the previous study did not use any standard methods of measuring medication adherence, which could have also resulted in the differences obtained in these two studies. Similarly, use of chi-square test for statistical analysis in the previous study did not control effect of confounders to identify the association of glycemic control and medication adherence (27).

There was no significant association of HbA1c with medication adherence [β: -0.33 (-0.88, 0.23) p= 0.17] in the current study. This was in contrast to the study done in China [β: -0.095,

(-0.164, -0.026), p=0.007] (26), the only study using MMAS-8 and same statistical tool of multivariate linear regression as in the current study to identify the association between glycemic control and medication adherence. The exposure (medication adherence) was assigned continuous data in that study (26), while it was assigned categorical data in the current study. The study size and population characteristics might have influenced the difference in the result of these two studies. Study done in UK (23) using MARS also did not find any association (p=0.05) between glycemic control and medication adherence on diabetes medicines while study done in USA (25) using MMAS-4 and in Ethiopia (13) using MMAS-8 with multivariate logistic regression found significant association between them with p-value <0.001 and AOR: 3.19 (1.76, 5.80) respectively.

4. 4 Associated Factors

For every annual increase in age, both FBS and HbA1c were estimated to decrease by 0.79 mg/dl (p = 0.006) and 0.03% (p = 0.008) respectively (Model 3, Table 4.1 and 4.2). This was in contrast to other study that showed FBS to increase by 2 mg/dl per decade (48). The reason for decreasing glycemia as age increases need to be studied further. Medication adherence, on the other hand, was not significantly associated with age (p=0.73) (Model 3, Table 5) but had tendency to decrease by 0.1% per year, which is in line with the study done in Nepal (27). Age related memory problem and age related agitation to take the medicines could be reasons for this result. However, the result was contradicted with the finding in French study (22) which showed age less than 45 years to be more likely to have poor adherence (OR=5.2).

Education, another confounder, did not have significant association with FBS (p=0.29) but had significant association with medication adherence [AOR: 2.43 (95% CI: 1.34, 4.39), p=0.003). Respondents with formal education were 2.43 times more likely to be highly adherent than respondents without formal education. Higher education might have helped the patients to understand more about diabetes and its complication and therefore making them more adhere to their medication. The result obtained in the current study was similar to the results of Ethiopia (24), which showed statistically significant association with educational level [Grade 1-6th , AOR: 5.25 (1.19-23.12) and Certificate and above, AOR 14.27 (3.0-67.82)] but was contrast to the study done in Nepal (27) which did not show any significant association between medication adherence and education.

There was no significant association of occupation with FBS (p=0.93) [Model 3, Table 4.1] or medication adherence (p=0.25) [Model 3, Table 5] in the current study. There was a tendency to increase FBS by 0.58 mg/dl among those employed than unemployed. Employed patients are more likely to spend their money on unhealthy foods. For medication adherence, employed patients were likely to be less adherent, which was similar to the French study (22) because employed patients were more likely to forget to take medicines as they get engaged in their work (22).

Medicine intake duration was significantly associated with FBS [β: 11.69 (6.51, 16.86), p=0.000)] (Model 3, Table 4.1) but not with medication adherence [AOR: 0.91 (0.73, 1.13), p=0.409] (Model 3, Table 5). As the medicine intake duration doubled, FBS increased by 11.69 mg/dl while medication adherence tended to decrease by nearly 10%. As medication intake duration extended, the duration of diabetes was also extended increasing the possibility for complication leading to high glycemia.

Type 2 DM patients preferred OHA to insulin injection because oral tablets were easy to carry and convenient to take. Conventional insulin therapy was mostly applied than intensive insulin therapy in Nepalese population of type 2 DM patients. Firstly, most of the elderly type 2 DM patients were not literate and cannot recognize the number in the syringe or cartridge of the insulin. Secondly, there was still lack of proper formal teaching on insulin therapy to adjust the dose of insulin themselves. Thirdly, devices which were mandatory to apply intensive insulin therapy like glucometer and its stripes are expensive to use multiple times a day. Finally, insulin pumps and other recent technology were rarely available in Nepal.

In the current study, diabetes medicines had no significant association with FBS [β: 15.94 (95% CI: -0.78, 32.66), p=0.06] (Model 3, Table 4.1) and medication adherence [AOR: 1.28, (95% CI: 0.60, 2.73), p=0.52] (Model 3, Table 5), but had significant association with HbA1c [β: 1.24 (95% CI: 0.58, 1.91), p=0.000] (Model 3, Table 4.2). This was similar to the study done in Ethiopia (24) [COR : 0.74 (0.32, 1.70)]. The tendency of increase in FBS in the current study was 15.94 mg/dl and 1.24% in HbA1c among those patients under insulin only or both insulin and OHA in comparison with patients under OHA only. This could be because insulin therapy or the combination of insulin and OHA are mostly used for patients with high glycemia. Similarly, the patients under insulin only or insulin with OHA were 1.28 times more likely to be highly adherent than among those with only OHA. Insulin therapy is more

challenging for patients and therefore they tend to be more adherent on insulin alone or with OHA.

Participants were asked if they got financial support for paying diabetes medicines from the family members. The proportion of the payment made by the patients themselves and family members was similar with about 50% each. However, the current study did not analyse the association of family support and medication adherence, though one of the studies (45) showed non supportive behaviours from family to be associated with poor adherence to diabetes medication ($p<0.001$) and subsequently higher HbA1c ($p =0.03$). However, the definition of family support (doing exercise with the patient and eating together with patient) was different in that study than in the current study (paying for diabetes medication). There was also no significant association between medication adherence and family support in the previous study done in Nepal (27).

4. 5 Diabetes Counseling

Diabetes counseling for the patients could help them to manage their glycemia by adhering to diet, exercise and medication. In the current study, it was found that medication adherence was significantly associated with attendance of diabetes counseling [AOR: 1.76 (1.02, 3.04), p=0.04)] (Model 3, Table 5). Patients attending diabetes counseling had 1.76 times higher level of medication adherence. Although, attending diabetes counseling increased high medication adherence, it did not result in significant decrease in FBS [β: -1.77 (95% CI: -14.35, 10.81); p=0.78] (Model 3, Table 4.1). It was more likely that patients with higher glycemia might have attended diabetes counseling with special recommendation from their doctors in order to control their glycemia and prevent further consequences of hyperglycemia. Since both education of the patients and attendence of diabetes counseling had significant association with medication adherence, an interaction model was run (not shown in Table 5) to identify the true association of medication adherence and attendence of diabetes counseling. The result did not show any significant interaction between them [95% CI 0.49, 4.25 (p=0.51)] in relation to medication adherence. This highlighted the importance of attending diabetes counseling for both formally educated and not formally educated patients in terms of better adherence on diabetes medicines.

5 STRENGTH

- The sample size was sufficient to infer the information about glycemic control and medication adherence.
- The confounders were controlled to identify the true association between glycemic control and medication adherence.
- Blood tests were measured with high quality control mechanism in the laboratory of Dhulikhel Hospital.
- Medication adherence was measured with standardized tool eight item Morisky Medication Adherence Scale (MMAS-8) (© 2007 Donald E. Morisky).
- License for Nepali translated version of Morisky Scale (© 2007 Donald E. Morisky) was obtained.
- Open data kit (ODK) software was used to collect the data ensuring the complete information of the participants and minimizing the time and effort for data entry.
- Anthropometric measurements (height, weight, waist circumference, hip circumference and blood pressure) were measured using standardized procedures and instruments. They were not self-reported.
- WHO recommended standard questionnaire were used for measurement of physical activity.

6 LIMITATION

- The recruitment and retention of research assistants was difficult as this was the small project. This made difference in having consistency in the quality of data collection.
- The answers for medication adherence were subjective.
- HbA1c test was done by POCT till 24th October and DCCT aligned HbA1c from 25th October 2016 onwards.
- Some of the results of the study should be considered cautiously due to wider confidence interval.
- There is a possibility of other variables acting as a confounder for the obtained result.
- Generalization cannot be done to the overall type 2 diabetes patients as the study was done in hospital, which did not represent every other characteristics of Nepalese type 2 DM population.

7 IMPLICATION

The current study gives the overall picture of glycemic status of type 2 DM patients visiting a tertiary care hospital in Nepal. It also showed that 18.2% of the study sample had HbA1c more than 9%. It is well documented that higher HbA1c increases the risk of complication of diabetes. To reduce the number of patients with high risk of complication, we should improve our health care system for diabetes management. In addition to the regular OPD visits and blood checkups, the patients should undergo diabetes counseling programs. Provision of counseling services to diabetes patients gives comprehensive care to the patients. Since, only 42% of the study population had attended diabetes counseling, we should encourage more patients to attend counseling and also emphasize its importance to make them adhere on their medication. This is also supported by findings of our study which showed significant association of counseling on medication adherence. Our study also showed that patients with formal education as without formal education profit from learning more about diabetes and importance of its better treatment by attending diabetes counseling. The demand of diabetes counseling can be met by increasing the number of healthcare personnel like diabetic nurses who can answer to this need.

8 RECOMMENDATION

- Further studies can be done in a community set up addressing glycemic control, medication adherence and value of diabetes counseling.
- More extensive studies can be done with more reliable HbA1c figures on glycemic control.
- Further researches can be done with objectively measured medication adherence.
- Further studies using qualitative method addressing associated factors of glycemic control and medication adherence can be done to add up the meaning to the quantitative data.

9 CONCLUSION

The overall glycemia of the study population of the current study was higher than the recommended glycemia by ADA guideline. However, the level of medication adherence was good among the participants. There was statistically significant association of better glycemic control (FBS) and high medication adherence in the study. Medication adherence was significantly associated with formal education and attendance of diabetes counseling. In addition, for all the patients with formal or no formal education, medication adherence had significant association with attendance of diabetes counseling. Hence, we encourage that higher number of type 2 DM patients take part in counseling programs and we emphasize the provision of proper training to health care professionals to conduct diabetes counseling.

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11 ANNEX: INFORMED CONSENT

Request for participation in Diabetes Research Project

"Glycemic control and its association with medication adherence among Type-2 diabetes patients: A hospital based cross-sectional study in Nepal"

Background and purpose

This is a request for you to participate in a research study about diabetes. Participation in this study is completely voluntary. The study intends to find out whether the way you take your diabetes medicines has any impact on your blood sugar level. You are eligible for this study if (i) you are generally healthy adult diabetes patient (above 18 years) and (ii) you have been taking diabetes medicine at least since last three months.

This study is a part of Masters' Thesis under Master of Science in Public Health specializing in Global Health in NTNU, Norway. St. Olavs Hospital, Norway is responsible for this study.

It has been approved by the Regional Committee for Medical Research Ethics (REC, Norway), Nepal Health Research Council (NHRC, Nepal) and Kathmandu University-Institutional Review Committee (KU-IRC, Nepal).

What does the study entail?

In this study, 343 diabetes patients like you who are visiting biochemistry department of Dhulikhel Hospital for their regular blood sugar test will be recruited.

If you wish to participate in this study, you need to give consent for filling out the questionnaire; taking measurements of your blood pressure, height, weight, waist & hip circumference and using your blood test results. If you give consent for participation, first, few questions will be asked that include (i) information about you and your family such as age, sex, address, etc. (ii) information about your diabetes such as since when did you have diabetes, list of medicines you take, etc. (iii) the ways you take care of diabetes such as regular exercise, food, etc. Then, your blood pressure, height, weight, waist and hip circumference will be measured. The whole process will take about 40 minutes. Finally, if you give consent to use your blood test results, on the basis of your hospital ID number;

authorized health personnel of Biochemistry Laboratory Department will provide us with your recent FBS (blood test for sugar level done under empty stomach) and HbA1c test (blood test for sugar level done every 3 months).

If you do not give permission to allow health personnel from biochemistry department to give your fasting blood test and HbA1c results to us or if you do not want to answer the questions or if you do not want your measurements be taken, you can freely choose not to participate in the study.

If any of your measurements are beyond the normal range, you will be recommended to visit the concerned doctor of the hospital.

Potential advantages and disadvantages

Advantages: You will get the measurement of blood pressure, weight, height, waist circumference and hip circumference on the spot. You will also get a free diabetes friendly light morning snacks.

Disadvantage: You have to give me your valuable time which you could have used for economic or leisure activities. You might be delayed to return to your home or work from hospital. If you have not eaten breakfast yourself or taken the morning snacks provided by us before the study begins, you might feel sweaty, weak, shaky, dizzy, etc. because of dropping down of sugar in your blood. Please do inform us immediately if you feel any discomfort. In such case, the study will be stopped immediately and appropriate precaution will be taken.

What will happen to the information about you?

Your information collected from this study will only be used for the study purpose. All the data will be processed without name, identity number or other directly recognisable type of information. A code number links you to your data. Only authorised project personnel will have access to the code.

It will not be possible to identify you when the study findings are published.

Voluntary Participation

Participation in the study is completely voluntary. You can decide to take part or not to take part in this study with your own consent without any compulsion. You may also withdraw your consent to participate in the study at any time and without stating any particular reason. This will not have any consequences for your further treatment. If you wish to participate, you need to sign or mark your fingerprint in the declaration of consent on the final page. Even if you agree to participate at this time, you may later withdraw your consent anytime. This will not affect your future treatment in any way. If you have any further questions regarding this study, or want to contact us, you may contact us:

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Privacy

Information that is registered about you are (i) answers that you provide for the questions (ii) measurements of height, weight, etc. taken during the study and (iii) your blood test results. All your information will be coded so that it is not possible to identify you. These de-identified data will be stored in USB drive accessible only to researchers and will not be disclosed to anyone. The drive will be stored in a locked shelf at researcher's office. After the completion of data collection, all the de-identified data that is recorded about you, along with the USB drive, will be taken from Nepal to NTNU, Norway safely for further works by the research team themselves. Project data will be stored safely and responsibly for 5 years after completion of the study for audit purposes.

Right to access and right to delete your data

If you agree to participate in the study, you can ask us any time about your registered information. If you find any mistakes on that data, you can ask us to correct them. If you withdraw from the study, you can demand that the collected data are deleted, unless the data have already been used for analyses or publications.

Funding

The study is funded by Department of Public Health and General Practice of NTNU as a part of master thesis.

Insurance

There will not be any insurance schemes for the research participants of this study.

Information about the outcome of the study

You can ask for information about the outcome of the study from Dhulikhel Hospital after completion of the study.

Consent for participation in the study

I am willing to participate in the study.

(Signed by the project participant, date)

OR

(Finger prints of project participant, date)

I confirm that I have given information about the study.

(Signed, role in the study, date)

(Note: This informed consent has been translated in Nepali language which is given below.)

12 ANNEX: INFORMED CONSENT IN NEPALI

अनुसन्धानात्मक अध्ययनमा सहभागिताको लागि अनुरोध

"मधुमेहका विरामीहरुमा रगतमा चिनीको मात्राको नियन्त्रण तथा यसको औषधि सेवनको निरन्तरतासंगको सम्बन्ध : नेपालको एक अस्पतालमा आधारित अध्ययन"

पृष्ठभूमि तथा उद्देश्य

हामी तपाईंलाई मधुमेह सम्बन्धि अनुसन्धानात्मक अध्ययनमा सहभागि हुनका लागि अनुरोध गर्दछौं । यस अध्ययनमा पूर्ण रुपले स्वैच्छिक सहभागिता जनाउन सक्नुहुन्छ । यस अध्ययनको उद्देश्य मधुमेह भएका व्यक्तिहरुको रगतमा रहेको चिनीको मात्रा र विरामीहरुले सेवन गर्ने औषधिको निरन्तरताबीचको सम्बन्ध के छ भन्ने पत्ता लगाउनु हो । तपाईं एक स्वस्थ वयस्क (१८ वर्ष उमेर पुगेको) मधुमेहका विरामी भएको र डाक्टरले तपाईंलाई कम्तीमा पनि गत तीन महिनादेखि मधुमेहको औषधि सेवन गरिरहनुभएको हुनुहुन्छ भने तपाईं यस अध्ययनमा सहभागिता जनाउन योग्य हुनुहुन्छ ।

नर्वेको नर्वेजियन यूनिभर्सिटि अफ साइन्स् यन्ड टेक्नोलोजी (NTNU) मा मास्टर अफ साइन्स् इन् पब्लीक हेल्थ (ग्लोबल हेल्थ) भन्ने विषयको अन्तिम वर्षको थेसिस् अन्तर्गत नर्वेको सेन्ट ओलाभस् अस्पतालको जिम्मेवारीमा यस अध्ययन गरिएको हो ।

यस अध्ययनलाई नर्वेको रेक एवं नेपालको नेपाल स्वास्थ्य अध्ययन परिषद् र काठमाडौं विश्वविद्यालय संस्थागत समिक्षा कमिटिले अनुमति प्रदान गरेको छ ।

यस अध्ययनमा के के गरिन्छ ?

यस अध्ययनमा यस धुलिखेल अस्पतालको बायो केमिस्ट्रि विभागमा नियमति रगत (खाली पेटमा गरिने रगतमा चिनीको मात्रा र तीन महिनामा एक पटक गरिने HbA1C) जचाउन आउनु भएका तपाईं जस्ता ३४३ जना दोश्रो प्रकारको मधुमेहका विरामीहरुलाई समावेश गरिने छ ।

यदि तपाईंलाई यस अध्ययनमा सहभागिता जनाउन चाहनुहुन्छ भने तपाईंले हामीलाई एक प्रश्नावलीको उत्तर दिन, तपाईंको रक्त चाप, उचाई, तौल र कम्मर र पटेको गोलाई नाप्न र तपाईंको रगत जाँचको नतिजा प्रयोग गर्न तपाईंको सहमतिको आवश्यकता हुन्छ । तपाईंले सहमति जनाएमा तपाईंलाई केही प्रश्नहरु सोधिनेछ जस अन्तर्गत (क) तपाईं र तपाईंको परिवारको बारेमा जानकारीहरु पर्दछन् जस्तै उमेर, लिङ्ग, ठेगाना, आदि र (ख)

तपाईंको मधुमेह र यसको हेरचाह सम्बन्धि प्रश्नहरु जस्तै तपाईंलाई कहिले देखि यो रोग लाग्यो, कुन कुन औषधि सेवन गर्नुहुन्छ, नियमित व्यायाम र खानपिन, आदिका प्रश्नहरु पर्दछन् । त्यसपछि तपाईंको रक्त चाप, उचाई, तौल र कम्मर र पटेको गोलाई पनि नापिनेछ । यी सबै प्रक्रियाहरु गर्न करिब ४० मिनेट लाग्नेछ । अन्तमा तपाईंले तपाईंको अस्पताल दर्ता नम्बर प्रयोग गरी तपाईंको रगत जाँचको नतिजा प्रयोग गर्न अनुमति दिएमा अस्पतालको प्रयोगशालाका अधिकार प्राप्त व्यक्तिबाट तपाईंको दुई वटा रगत परिक्षणका नतिजा (१) खालि पेटमा लिइएको रगतमा भएको चिनीको मात्रा तथा (२) एच.बी.ए.वान.सि ९ज्दब्ज्ञ्ऋ० को नतिजा संकलन गरिनेछ ।

यदि तपाईंले अस्पतालको प्रयोगशालाका अधिकार प्राप्त व्यक्तिलाई आफ्नो रगत जाँचको नतिजा प्रयोग गर्न अनुमति नदिएमा वा तपाईंलाई सोधिने प्रश्नहरुको उत्तर दिन इच्छा नभएमा वा तपाईंको रक्त चाप, उचाई, तौल र कम्मर र पटेको गोलाई नाप्न सहमति नभएमा, तपाईंले कति पनि नहिच्किच्याइ सजिलै यस अध्ययनलाई छोड्न सक्नुहुन्छ ।

यदि तपाईंको नाप तौल आदि विवरण तथा रगत परिक्षणका नतिजाहरु असामान्य भएमा तपाईलाई सम्बन्धित डाक्टरलाई भेट्न सल्लाह दिइनेछ ।

यस अध्ययनका के के फाइदाहरु छन् ?

तपाईंले तत्काल आफ्नो रक्त चाप, तौल, उचाई, कम्मरको गोलाई र पेटको गोलाई सम्बन्धि जानकारी प्राप्त गर्न सक्नु हुनेछ । तपाईंलाई निशुल्क विहानको हल्का नास्ता पनि दिइनेछ ।

यसका केही बेफाइदाहरु छन् की ?

तपाईंको केही अमूल्य समय हामीलाई दिनुपर्नेछ जुन तपाईंले अन्य काममा दिन सक्नुहुन्थयो । तपाईंलाई अस्पतालबाट घर फर्कन ढिलो हुनसक्छ । यदि तपाईंले यस अध्ययनमा भाग लिने क्रममा बिहानको नास्ता नखाई भोको पेटमा बस्नुभएमा तपाईंलाई पसिना आउने, कम्जोरी महसुस हुने, काम्ने वा रिङ्गाटा लाग्ने इत्यादि जस्ता अनुभुति हुनसक्छ । यदि तपाईंलाई केही त्यस्ता अप्ठेरा अवस्था भएमा हामीलाई तुरुन्तै खबर गर्नुहोस् र तपाईंको स्वास्थ्यलाई हानी नपुऱ्याउन हामी चाँडो भन्दा चाँडो सावधानी अपनाउनेछौं ।

तपाईंले दिनु भएको रगत परिक्षणको नतिजा र सोधिएका प्रश्नका उत्तरहरुलाई के गरिन्छ ?

तपाईंले दिनु भएका सम्पूर्ण सूचनाहरु माथि उल्लेख गरिएको उद्देश्य (मधुमेहको अध्ययन गर्ने) बाहेक अन्य प्रायोजनका लागि प्रयोग हुने छैन । सबै सूचनाहरुमा काम गर्दा तपाईंको नाम, हस्पितल दर्ता नं वा अन्य कुनै पनि माध्यमबाट तपाईंको व्यक्तिगत पहिचान खुल्ने वा इंगित गर्ने गरि प्रयोग गरिने छैन ।

तपाईंसम्बन्धि सम्पूर्ण जानकारीहरु कोडको माध्यमद्वारा गोप्य राखिनेछ र अधिकार प्राप्त कर्मचारीहरुलाई मात्र उक्त कोडको जानकारी हुनेछ । अध्ययन समाप्त भएपश्चात यस अध्ययनको नतिजा प्रकाशन गर्दा तपाईंको व्यक्तिगत परिचय खुल्न सम्भव छैन ।

स्वैच्छिक सहभागिता

यस अध्ययनमा सहभागिता पूर्ण रुपमा स्वैच्छिक हुनेछ । तपाईंले आफ्नो अनुकुलता अनुरुप यस अध्ययनमा सहभागी हुने वा नहुने निर्णय गर्न सक्नुहुन्छ । तपाईंले अध्ययनको बीचमा बिना केही कारण खुलाई आफ्नो सहभागिता छोड्न पनि सक्नु हुनेछ । यस अध्ययनमा भाग लिएको वा नलिएको आधारमा तपाईंको उपचार तथा तपाईंलाई अस्पताल, रक्त परिक्षणशाला वा सम्बन्धित कर्मचारीहरुले हाल दिइरहेको वा भविष्यमा दिने सेवा सुविधामा केही असर पर्नेछैन । यदि तपाईं यस अध्ययनमा सहभागिता जनाउन चाहनुहुन्छ भने कृपया अन्तिम पृष्ठमा सहमतिको सूचना जनाई आफ्नो दस्तखत गर्नुहोस् वा औंठाको छाप लगाउनुहोस् । यदि तपाईं अहिले सहमति जनाई पछि उक्त सहमति फिर्ता लिन चाहेमा पनि सहमति फिर्ता लिन सक्नुहुनेछ । सहमति फिर्ता लिन हामीलाई सम्पर्क गर्नुहोस् । सहमति फिर्ता लिएको अवस्थामा पनि तपाईंको उपचारमा केही असर पर्नेछैन । यदि तपाईंलाई यस अध्ययनको विषयमा केही जानकारी प्राप्त गर्नुछ वा अन्य विषयमा सम्पर्क गर्नु छ भने सम्पर्क गर्नका लागि हाम्रो ठेगान :

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गोपनियता

तपाईसंग सम्बन्धित निम्न जानकारीहरु रजिष्टर गरिएको हुन्छ (क) तपाईंले दिनुभएका प्रश्नका उत्तरहरु ख) नाप तौल आदि विवरणहरु र ग) प्रायोगशालाबाट प्राप्त रगत परिक्षणको नतिजा । यी सबै जानकारीहरु तपाईंको परिचय नखुल्ने गरी कोडको माध्यमबाट रेकर्ड कायम गरिएको हुन्छ । उक्त कोडको माध्यमबाट राखिएका जानकारीहरु अध्ययनकर्ताको टोलीले पेन ड्राइभमा राख्नेछ र अन्य कसैलाई पनि उपलब्ध गराइने छैन । उक्त पेन ड्राइभ सुरक्षित ठाउँमा ताला लगाइएको दराज भित्र राखिनेछ । यस जानकारी संकलन पश्चात उक्त कोडको माध्यमबाट राखिएका जानकारीहरु भएका पेन ड्राइभ अध्ययनकर्ता स्वयंले नै सुरक्षाका साथ नेपालबाट नर्वे लगी थप अध्ययन गरिनेछ । भविष्यमा गर्न सकिने अध्ययनको परिक्षणका लागि सबै जानकारीहरु सुरक्षित र जिम्मेवारपूर्वक पाँच वर्षसम्म राखिनेछ ।

सूचना प्राप्त गर्ने तथा हटाउने अधिकार

यस अध्ययनमा सभागिता जनाउन सहमति दिनु भए तपाईलाई आफूसंग सम्बन्धित के कस्ता सूचनाहरु रजिष्टर गरिएको छ सोको बारेमा जानकारी प्राप्त गर्ने अधिकार रहनेछ । साथै ती सूचनाहरुमा केही गल्ती भए ती गल्तीहरु सच्याउन पनि अधिकार रहनेछ । यदि तपाईं यस अध्ययनबाट आफ्नो सहमति फिर्ता लिनु हुन्छ भने आफ्ना सबै सूचनाहरु हटाउने अधिकार पनि हुनेछ । तर यदि ती सूचनाहरु विश्लेषण तथा वैज्ञानिक लेख प्रकाशनका लागि प्रयोग भइसकेको अवस्थामा भने तपाईंको सूचना हटाउन मिल्ने छैन।

प्रायोजन

यस अध्ययनलाई स्नातकोत्तर अध्ययनको थेसिस्का लागि एनटीएनयू (NTNU) अन्तर्गत सार्वजनिक स्वास्थ्य तथा सामान्य चिकित्सा विभागबाट आर्थिक सहयोग प्राप्त भएको छ ।

बीमा

यस अध्ययनमा सहभागिता जनाए बापत कुनै पनि प्रकारको बीमा गरिएको छैन ।

अध्ययन समाप्ति पश्चात नतिजाबारे जानकारी

अध्ययन समाप्ति पश्चात यसको नतिजाको बारेमा तपाईले धुलिखेल अस्पतालबाट जानकारी प्राप्त गर्न सक्नुहुनेछ।

अध्ययनमा सहभागिताको लागि सहमति पत्र

म यस अध्ययनमा सहभागिता जनाउन सहमत छु ।

.....

(सहभागिको हस्ताक्षर र मिति)

वा

.....

(सहभागिको औंठाको छाप र मिति)

मैले यस अध्ययनमा सूचना दिएको छु भनी प्रमाणित गर्दछु ।

.....

(हस्ताक्षर, अध्ययनमा भूमिका र मिति)

13 ANNEX: ENGLISH QUESTIONNAIRE

A. Code number:

B. Geographical information

1. District
   a. Kavrepalanchowk c. Bhaktapur e. Lalitpur
   b. Sindhupalchowk d. Kathmandu f. Others …….
2. Municipality/ VDC Name ……
3. Is this municipality or VDC? a) Municipality b) VDC

C. Socio demographic data:

1. Sex (Observe): (a) Male (b) Female (c) Other
2. What is your age? (Completed years) _____ years
3. What is your ethnic group?
   a. Brahmin
   b. Chettri (Thakuri/ Sanyasi)
   c. Newar
   d. Janajati (Magar/Tamang/Rai/Limbu)
   e. Madhesi (Shah/Tharu/Jha)
   f. Dalit (Kami/ Damai/ Sarki /Gaaine/ Baadi)
   g. Others
4. What is your marital status?
   a. Never married
   b. Currently married
   c. Separated
   d. Widowed
   e. Cohabiting
   f. Refused
   g. Divorced
   h. Other
5. Are you literate? (a) Formal Education (b) Informal Education (c) Illiterate
6. Do you have formal education? (a) Yes (b) No
7. What is the highest level of formal education you have ever completed?
   a. Under SLC
   b. SLC
   c. Intermediate/High School
   d. Bachelors
   e. Masters
   f. PhD
   g. Others
8. What is your occupation?
   (a) Agriculture
   (b) Animal husbandry
   (c) Business
   (d) Office
   (e) Student
   (f) Housewife
   (g) Driver
   (k) Other
9. Whom do you live with? a) living with family b) living alone
10. What is the monthly income of your family? _____ NRs
11. How many of your family members including yourself earn for your family? _____
12. How many of your family members share the income? _____
13. Who pays for your diabetes medication?
    a. Self b. Family member c. Refused
14. Does any of your family members accompany you to visit doctor for the follow up?
    a. Yes b. No
15. Does any of your family members remind you to take medication? Yes No

D. Geographical accessibility:

1. Where do you usually go for your diabetes management?
   (a) Dhulikhel hospital (b) PHCC (c) Other
2. How do you normally travel to the nearest health center?
   (a) On foot (b) Bicycle (c) Motorcycle
   (d) Motor (e) Other
3. How long does it take you to travel to the health center in minutes for your typical mode of transport? ____ mins
4. How much do you spend for the transportation for one way? ____ NRs

E. Information about DM

1. Since how long have you known to be suffering from diabetes? ..... (months/ years)
2. How long ago you were first advised to take medicine for Diabetes? ..... (mth/ years)
3. How long ago did you start taking medicine? .....

F. Family history of Diabetes

1. Who else have DM in your family who live together?
   a. None
   b. Grand father
   c. Grand mother
   d. Grand father in law
   e. Grand mother in law
   f. Father
   g. Mother
   h. Father in law
   i. Mother in law
   j. Husband
   k. Wife
   l. Brother
   m. Sister
   n. Brother in law
   o. Sister in law
   p. Son
   q. Daughter
   r. Uncle
   s. Aunty
   t. Other
2. How many of your immediate blood relatives have diabetes? _____

G. Information related to hypertension

1. Do you have high blood pressure? (a) Yes (b) No (c) Don't Know
2. Currently, are you under anti-hypertensive medicine? (a) Yes (b) No

H. Medicine intake history

1. Which of the following medicines are prescribed by doctor or health worker for you?

	Name of the medicine	Yes/ No	Dose 1	Dose 2	Frequency (per day)	When started Year | Month
Oral hypoglycemic agents	Acarbose					
	Glibenclamide					
	Glicazide					
	Glipizide					
	Glimepiride					
	Metformin					
Insulin	Rapic acting					
	Regular					
	Intermediate acting					
	Long acting					
	Very long acting					
	Mixed					

I. Morisky Medication Adherence Scale-8[5] (© 2007 Donald E. Morisky) (Diabetes medication: Oral hypoglycemic agent and insulin injection)

1. Do you sometimes forget to take your medicine of diabetes?
2. Over the past 2 weeks, were there any days when you did not take your medicine of diabetes?
3. Have you ever cut back or stopped taking your medication without telling your doctor because you felt worse when you took it?
4. When you travel or leave home, do you sometimes forget to bring along your medications?
5. Did you take your medicine of diabetes yesterday?
6. When you feel like your blood sugar is under control, do you sometimes stop taking your medicine?
7. Do you ever feel hassled about sticking to your treatment plan?
8. How often do you have difficulty remembering to take all your medication of diabetes?

J. Behaviour towards medication

1. Which of the following are related to missing your medicine?
   a) It is too expensive to take it regularly.
   b) I get side effects (from the medicine) if I take regularly.
   c) I am afraid that if I take it regularly I might be dependent on the medicine and would need to take life.
   d) I do not have any symptoms of the disease and hence do not feel like I need to take it every day. I take it only when I get symptoms (like headache, dizziness)
   e) My friends or family members suggested not to take it regularly.
   f) I started alternative medicines (e.g., herbal, homeopathy, etc) and decided to be irregular with the medicine.
   g) I did not know (I was not told) that I had to take medicine regularly.
   h) I do not believe that the medicine will help to control my disease. So I don't mind taking it irregularly.
   i) The medicines are not easily available.
   j) I lost trust on my health care provider and thus miss taking the medicine.
   k) Other

K. Health care services

1. How much time on an average do your doctors give you per visit in out patient department for diabetes? ..... minutes
2. Have you attended any counseling sessions of Diabetes? (a) Yes (b) No
   a. Where did you attend the counselling?
      (a) Dhulikhel Hospital (b) Other hospital
      (c) Community Program (d) Private Clinics (e) Others
   b. Do you find diabetes counselling session effective? (a) Yes (b) No

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L. Information about Smoking:

1. Have you ever smoked cigarettes? (a) Yes (b) No
   a. Do you still smoke cigarettes? (a) Yes (b) No
      i. If yes, how long have you been smoking? _____ Days/ months/ years
      ii. What is average number of cigarattes do you usually smoke? _ per day/ week/ mth/yr
      iii. What type of cigaratte do you usually smoke?
         a) Filter cigarrettes b) Non-filter cigarrettes c) Both d) Don't know
   b. If no, how long have you left smoking? ……. Years/month
      i. How long had you smoked? _____ Days/ months/ years
      ii. What was average number of cigarattes you usually smoked? _ per day/ week/ mth/yr
2. Other than cigaratte, do you use any other type of tobacco? (a) Yes (b) No
3. Have you ever tried to quit smoking? (a) Yes (b) No

M. Alcohol Drinking

1. Have you ever drunk raksi? (a) Yes (b) No (c) Refused
   a. Do you still drink raksi? (a) Yes (b) No (c) Refused
      i. If yes, since how long have you been drinking? ___ day/month/year
      ii. How many days do you drink in a typical month? ____
      iii. How many glasses do you drink in one day? ___ ml
      iv. What is the maximum number of drinks in one occasion you had in the past month?
   b. If no, how long ago had you left drinking alcohol? ____ years/month
      i. How long had you drunk raksi? ___ day/month/year
      ii. How many days did you drink in a typical month? ____
      iii. How many glasses did you drink in one day? ___ ml
      iv. What was the maximum number of drinks in one occasion you had in typical month?
2. Do you drink any other alcoholic drink than raksi at present time? (a) Yes (b) No
   a. Which of the following alcoholic drinks other than raksi do you drink?

i. beer	vi. nigar	xi. rum
ii. wine	vii. rakshi	xii. vodka
iii. jaad	viii. slotyang	xiii. sherry
iv. chyang	ix. whiskey	xiv. champagne
v. tongba	x. brandy	xv. other

   b. If yes, since how long have you been drinking? ___ day/month/year
   c. How many days do you drink in a typical month? ____
   d. How many glasses do you drink in one day? ___ ml
   e. What is the maximum number of drinks in one occasion you had in the past month?
3. In the past five years, has your alcohol intake increased, decreased or remained the same?
   (a) No (b) Increased intake (c) Decreased intake

N. Information about Food:

1. How many times do you usually eat in a day? _____ (per day)
2. Do you follow diabetic plate model for your main meal? (a) Yes (b) No
   (Show the picture of diabetic plate model) (c) No Information
3. Do you take small frequent meals? (a) Yes (b) No
   (Explaining to participant what small frequent meal is.) (c) No information
4. Do you take sugary foods (sugar/ sweets/ chocolate/ juice /cold drinks)?
   (a) Yes (b) No (c) No information
   a) How often do you take sugary foods?
      (a) Always (b) Sometimes (c) Occasionally

O. 24 hours diet recall

1. What did you eat yesterday? Please give detail list and amount of all foods you ate.

Time (when)	Place (where)	Food name (what)	Amount (how much)

P. Information about Sleep

1. Do you have regular routine for your sleep? (a) Yes (b) No (c) No information
2. How long do you sleep usually? _____ hours
3. Do you wake up at night? (a) Yes (b) No (c) No information
    a. How many times do you wake up at night? ____

Q. Information about Physical activity

*(In answering the following questions 'vigorous-intensity activities' are activities that require hard physical effort and cause large increases in breathing or heart rate (*that causes large increase in breathing or heart rate like carrying or lifting heavy loads, digging or construction work, etc.. for at least 10 minutes continuously*), 'moderate-intensity activities' are activities that require moderate physical effort and cause small increases in breathing or heart rate.* that causes small increases in breathing or heart rate such as brisk walking or carrying light loads] for at least 10 minutes continuously*)*

a. Activity at work

1. Does your work involve vigorous-intensity activity that causes large increase in breathing or heart rate like carrying or lifting heavy loads, digging or construction work, etc.. for at least 10 minutes continuously? (a) Yes (b) No
    a. If Yes, In a typical week, on how many days do you do vigorous- intensity activities as part of your work? ___ (days/ month/year)
    b. How much time do you spend doing vigorous-intensity activities at work on a typical day? ___ (minutes/ hour)
    c. In a typical year, how many months are you involved in this activity? ___
2. Does your work involve moderate-intensity activity that causes small increases in breathing or heart rate such as brisk walking [or carrying light loads] for at least 10 minutes continuously? (a) Yes (b) No
    a. In a typical week, on how many days do you do moderate- intensity activities as part of your work? ___ (days/month/year)
    b. How much time do you spend doing moderate-intensity activities at work on a typical day? ___ (mins/ hour)
    c. In a typical year, how many months are you involved in this activity? ___

b. Travel to and from places

(The next questions exclude the physical activities at work that you have already mentioned. Now I would like to ask you about the usual way you travel to and from places. For example to work, for shopping, to market, to place of worship)

1. Do you walk or use a bicycle (pedal cycle) for at least 10 minutes continuously to get to and from places? (a) Yes (b) No
    a. If yes, in a typical week, on how many days do you walk or bicycle for at least 10 minutes continuously to get to and from places? ___ (days/ month/year)
    b. How much time do you spend walking or bicycling for travel on a typical day? ___ (mins/ hour)

C. Recreational activities

1. Do you do any vigorous-intensity sports, fitness or recreational (leisure) activities that cause large increases in breathing or heart rate like [running or football,] for at least 10 minutes continuously? (a) Yes (b) No
    a. If yes, in a typical week, on how many days do you do vigorous-intensity sports, fitness or recreational (leisure) activities? ___ (days/ month/year)
    b. How much time do you spend during vigorous-intensity sports, fitness or recreational activities on a typical day? ___ (minutes/ hour)
    c. In a typical year, how many months do you do vigorous-intensity sports, fitness or recreational activities? ___ months
2. Do you do any moderate-intensity sports, fitness or recreational (leisure) activities that causes a small increase in breathing or heart rate such as brisk walking,(cycling, swimming, volleyball) for at least 10 minutes continuously? (a) Yes (b) No
    a. If yes, in a typical week, on how many days do you do moderate-intensity sports, fitness or recreational (leisure) activities? ___ (days/ month/year)
    b. How much time do you spend doing moderate-intensity sports, fitness or recreational (leisure) activities on a typical day? ___ (minutes/ hour)
    c. In a typical year, how many months do you do moderate-intensity sports, fitness or recreational activities? ___ months

Q. Sedentary behavior

1. How much time do you usually spend sitting or reclining on a typical day? ___ (mins)

R. Complications of DM

1. Have you been suffering from any chronic complications (a) Yes (b) No
    a. Type ____
    b. When did it start? ____

S. Anthropometric measurements

1. Height : …… cm
2. Weight : ……kg
3. Waist circumference : ……cm
4. Hip circumference : …….cm
5. Blood pressure : ……mmHg
    a) BP1 ------- -------
    b) BP2 ------- -------
    c) BP3 ------- -------

T. Blood Test Measurements

1. FBS : ___ mg/dl
2. HbA1c : ___ %

Thank you.

----- This is the end of the interview. -----

(Questionnaire in Nepali language is in the following page)

14 ANNEX: NEPALI QUESTIONNAIRE

नेपाली प्रश्नपत्र

क. कोड नं

ख) भौगोलिक विवरण

1. जिल्ला
   १) काभ्रेपलाञ्चोक २) सिन्धुपाल्चोक ३) भक्तपुर
   ४) काठमाडौं ५)ललितपुर ६) अन्य
2. नगरपालिका / गा.बि.स. को नाम : .....
3. यो नगरपालिका हो कि वडा हो ? १) नगरपालिका २) गा.बि. स.

ग) सामाजिक जनसांख्यिक विवरण

1. लिङ्ग (हेरेर लेख्नुहोस्) १) पुरुष २) महिला ३) अन्य
2. तपाईंको उमेर कति हो ? (पूरा भएको वर्ष) .....
3. तपाँई कुन जातिमा पर्नु हुन्छ ?
   १) बाहुन २) क्षेत्री/ठकुरी/सन्यासी ३) नेवार
   ४) जनजाति (मगर/तामाङ्ग/राई/लिम्बु/ शेर्पा/भोटे)
   ५) दलित (कामी/दमाई/सार्की/गाईने/बाडी) ६) अन्य
4. तपाँईको वैवाहिक स्थिति के हो ?
   १) अविवाहित २) हाल विवाहित
   ३) विवाहित तर छुटेर बसेको ४) विधवा
   ५) अविवाहित तर छुटेर बसेको ६) भन्न चाहन्न
   ७) पारपाचुके भएको ८) अन्य
5. के तपाई साक्षर हुनु हुन्छ ? १) छु २) छैन
6. के तपाइको औपचारिक शिक्षा छ ? १) छ २) छैन
7. तपाईले सबै भन्दा उच्च शिक्षा हासिल गर्नु भएको कति हो ?
   १) SLC भन्दा कम २) SLC
   ३) उच्च माध्यमिक बिद्यालय ४) स्नातक
   ५) स्नातकोतर ६) PhD
8. तपाईको पेशा के हो ?
   १) व्यवसायिक २) सेवा ३) शीपयुक्त मजदूर
   ४) शीप नभएको मजदूर ५) कृषि ६) विद्यार्थी
   ७) गृहणी ८) सेना / पुलिस ९) अन्य
9. तपाईं को संग बस्नु हुन्छ ? १) परिवार संग २) एक्लै
10. तपाइको परिवारको मासिक आम्दानी कति हो ? ..... नेरू
11. तपाइको परिवारमा कति जनाले परिवारको लागि कमाउनु हुन्छ ? .....
12. भएको आम्दानी परिवारको कति जनालाई खर्च हुन्छ? .....
13. तपाइको मधुमेहको औषधिको लागि कसले पैसा दिनु हुन्छ ?
    १) स्वयेम आफै २) परिवार को सदस्य ३) भन्न चाहन्न
14. डाक्टरसंग भेट्न जाँदा तपाईसंग परिवारका सदस्यहरु पनि साथमा आउनुहुन्छ? १) छ २) छैन
15. तपाइलाई औसधि सेवन गर्नको लागि परिवारका सदस्यहरुले सम्झाइदिनुहुन्छ? १) छ २) छैन

घ) भौगोलिक पहुँच

1. तपाइ मधुमेहको उपचारको लागि प्राय कुन ठाउँमा जानु हुन्छ ?
   १) धुलिखेल अस्पताल २) प्राथमिक स्वास्थ्य उपचार केन्द्र ३) अन्य .....
2. तपाई नजिकको स्वास्थ्य केन्द्र सम्म कसरि जानु हुन्छ ?
   १) हिड्ने २) साईकल ३) मोटरसाईकल ४) गाडी ५) अन्य
3. तपाइलाई स्वास्थ्य केन्द्र सम्म पुग्न मिनेटमा कति समय लाग्छ ? ..... मिनेट
4. तपाई एकतर्फी यातायातको लागि कति खर्च गर्नु हुन्छ ? ..... नेरू

ङ) मधुमेह सम्बन्धि सुचनाहरु

1. तपाइलाई मधुमेह लागेको कति वर्ष भयो ? ----------
   (महिना/वर्ष)
2. तपाइलाई सर्वप्रथम मधुमेह को लागि औसधि खानु भनी कहिले भनेको हो? ---------
   (महिना/वर्ष)
3. तपाइले औसधि सुरु गर्नु भएको कति भयो? ----------

च) मधुमेहको पारिवारिक इतिहास

1. तपाइको परिवार मा अरु कसलाई मधुमेह छ ?
   १) छैन २) हजुरबुबा ३)हजुरआमा ४) सासु ५) ससुरा ६)बुबा ७) आमा

छ) उच्चरक्तचाप सम्बन्धि जानकारी

1. के तपाईलाई उच्चरक्तचाप छ? १) छ २) छैन ३) थाहा छैन
2. हाल उच्च रक्तचापको औसधि सेवन गर्नु हुन्छ ? १) गर्छु २) गर्दिन

ज) औसधि सेवन को इतिहास

1. तपाईलाई डाक्टर वा स्वास्थ्यकर्मीले गत तीन महिना मा कुन कुन औसधि दिनु भएको छ?

		औसधिको नाम	छ/ छैन	मात्रा	मात्राको किसिम	पटक (प्रति दिन)	औसधि दिनु को कारण	कहिले देखि सुरु गर्नु भयो?
मधुमेहको लागि औसधिहरु	Oral hypoglycemic agents	Acarbose						
		Glibenclamide						
		Glicazide						
		Glipizide						
		Glimepiride						
		Metformin						
	Insulin	Rapic acting						
		Regular						
		Intermediate acting						
		Long acting						
		Very long acting						
		Mixed						

झ) औसधि प्रयोगको नियमितता मापन स्केल (मधुमेह औसधि : मौखिक खाने र इन्सुलिन इन्जेक्सन)[6] (© 2007 Donald E. Morisky)

1. के तपाईले कहिलेकाही आफ्नो मधुमेहको औसधि खान बिर्सिनु हुन्छ ?
2. मानिसहरुले कहिलेकाही औसधि प्रयोग गर्न छुताउछन, त्यसमा बिर्सिने बानी बाहेक अरु धेरै कारणहरु छन | गत दुइ हप्ताको विचार गर्दा, कुनै त्यस्ता दिनहरु थिए जब तपाईले आफ्नो औसधि खान छुटाउनु भएको थियो ?
3. तपाईले कहिल्यै डाक्टरलाई नभनिकन औसधिको मात्रा घटाउनु वा खान छोड्नु भएको छ किनकि तपाईले त्यो औसधि खादा झन् खराब महसुश गर्नुभएको थियो ?
4. के तपाई यात्रामा जाँदा वा घर छाडेर जादा आफ्नो औसधि साथमा लान बिर्सिनु भएको छ ?

5. के तपाईले मधुमेहको औसधि हिजो खानु भयो ?
6. जब तपाईलाई आफ्नो रगतमा चीनीको मात्रा ठिक्क भएको महसुश हुन्छ, के तपाई ले कहिलेकाही औसधि लिन बन्द गर्नु हुन्छ?
7. दैनिक औसधि सेवन गर्दा कोहि मान्छेहरुलाई अफ्ठ्यारो महसुश हुने गर्छ | के तपाईलाई कहिल्यै आफ्नो मधुमेह नियन्त्रण गर्न उपचार गर्ने योजना प्रति दिक्क लाग्छ ?
8. तपाई लाई सम्पूर्ण औसधि सम्झेर खान कति गार्हो लाग्छ ? (कृपया तपाइको प्रतिक्रियामा गोलो लगाउनुहोस्)

ञ) औसधि तर्फको व्यवहार

1. तल दियिएका मध्ये कुन कारण तपाइको औसधि लिन छुट्ने संग सम्बन्धित छन ?
   a. सधै औषधि खादा धेरै नै खर्च हुने भएकोले
   b. सधै औषधि खादा मलाई अरु नराम्रो असर हरु पर्न थाल्यो.
   c. सधै खादा फेरी सधै नै खानु पर्ने हुन्छ र जीवनभर खानु पर्छ भन्ने डर ले
   d. मलाई रोग सम्बन्धि केहि संकेत/समस्याहरु देखिएको छैन. त्यसैले सधै खन्न. जुन बेला अलि संकेत/समस्या हरु देखिन्छ (जस्तै: रिंगटा लाग्ने, टाउको दुख्ने,आदि), त्यहि बेला मात्र खान्छु.
   e. मेरा साथीहरु र नातेदार हरुले सधै नखाने सल्लाह दिए, मेरा परिवारले सधै नखाने सल्लाह दिए..
   f. मैले अरु नै उपचार सुरु गरे (जस्तै:होमिओपैथि, आयुर्वेदिक, आदि) र औषधि कहिलेकाहीं मात्र खाने निधो गरे.
   g. मलाई थाहा नै थिएन (मलाई भनिएको थिएन) कि मलाई औसधि नियमित खानु पर्छ भनि .
   h. मलाई औषधि ले प्रेसर कम गर्छ भन्ने बिस्वासै लाग्दैन. त्यसैले कहिले कहिँ नाखादा केहि फरक पर्दैन जस्तो लाग्छ.
   i. औषधि पाउनै एकदम गार्हो भएकोले
   j. मलाई मेरो डाक्टर/स्वस्थ कर्मी हरु प्रति बिस्वासै लाग्न छाड्यो र त्यसैले औसधि सधै खान त्यति ध्यान दिन्न.
   k. अन्य

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ट) स्वास्थ्य उपचार सेवाहरु

1. मधुमेहको लागि बहिरंग विभागमा तपाइलाई प्रत्येक जाँचमा डाक्टरले औसतमा कति समय दिनु हुन्छ ? ..... मिनेट
2. अस्पतालमा मधुमेह सम्बन्धि कुनै प्रशिक्षण कक्षामा बस्नु भएको छ? १) छ २) छैन
    a. तपाईले कुन ठाउँमा उक्त प्रशिक्षण लिनु भएको हो ?
        १) धुलिखेल अस्पताल २) अन्य अस्पताल ३) सामुदायिक कार्यक्रम
        ४) निजि क्लिनिक ५) अन्य
3. के तपाईलाई तिनीहरु प्रभावकारी लाग्छन? १) छ २) छैन

ठ) धूमपान सम्बन्धि जानकारी

1. के तपाई कहिल्यै धूमपान गर्नु भएको थियो ? १) थिए २) थिएन
    a. के तपाई अहिले पनि धुमपान गर्नु हुन्छ ? १) गर्छु २) गर्दिन
        i. यदि गर्नु हुन्छ भने कति समय देखि धुम्रपान गर्दै हुनु हुन्छ ? ..... दिन/महिना/बर्ष
        ii. तपाइले औसतमा कति वोटा चुरोट खानु हुन्छ? ..... प्रति दिन / हप्ता /महिना/ बर्ष
        iii. तपाई प्राय कुन प्रकार को चुरोट खानु हुन्छ?
            १) फिल्टर गरेको चुरोट २) फिल्टर नगरेको चुरोट ३) दुवै ४) थाहा छैन
    b. यदि गर्नु हुन्न भने धुम्रपान छाड्नु भएको कति भयो ?..... दिन/महिना/बर्ष
        i. छोड्न अगाडी तपाईले कति समय सम्म धुम्रपान गर्नु भयो ? ..... दिन/महिना/बर्ष
        ii. तपाइले औसतमा कति वोटा चुरोट खानु हुन्थ्यो? ..... प्रति दिन/ हप्ता /महिना/ बर्ष
2. चुरोट बाहेक तपाई अन्य प्रकार को धुमपान गर्नु हुन्थ्यो?
3. तपाईले कहिले चुरोट छोड्ने प्रयास गर्नु भाको थियो ?

द) मादकपदार्थ सेवन

1. तपाई कहिल्यै रक्सी खानु भएको छ ? १) छ २) छैन ३) भन्न चाहन्न
    a. तपाई अहिले पनि रक्सी खानु हुन्छ? १) छ २) छैन ३) भन्न चाहन्न
        i. यदि खानु हुन्छ भने तपाईले कति समयदेखि खादै हुनु हुन्छ ? ..... दिन/ महिना / बर्ष
        ii. कुनै महिनामा कति दिन जति खानु हुन्छ ? .....
        iii. कुनै एक दिन मा कति मात्रा खानु हुन्छ? ..... मि.लि.
        iv. गएको महिनामा सब भन्दा धेरै खानु भएको कति पटक हो ? .....
    b. यदि खानु हुन्न भने तपाईले कति समयदेखि छाड्नुभयो ? ..... दिन / महिना / बर्ष
        i. कुनै महिनामा कति दिन जति खानु हुन्थ्यो ? .....
        ii. कुनै एक दिन मा कति मात्रा खानु हुन्थ्यो? ..... मि.लि.
        iii. औसतमा एक महिनामा सब भन्दा धेरै खानु भएको कति पटक हो ? .....
2. रक्सी बाहेक अन्य कुनै मादक पदार्थ खानु हुन्छ? १) खान्छु २) खादिन
    a. खानु हुन्छ भने निम्न मध्ये कुन मादक पदार्थ खानु हुन्छ?
        १) जाँड २) छयांग ३) तुंबा ४) निगार ५)बियर ६)सोल्त्यांग
        ७) व्हिस्की ८) ब्रान्डी ९) रम १०) भोड्का ११) शेर्री १२) अन्य
    b. यदि खानु हुन्छ भने तपाईले कति समयदेखि खादै हुनु हुन्छ ? ..... दिन / महिना / बर्ष
        i. कुनै महिनामा कति दिन जति खानु हुन्छ ? .....
        ii. कुनै एक दिन मा कति मात्रा खानु हुन्छ? ..... मि.लि.
        iii. गएको महिनामा सब भन्दा धेरै खानु भएको कति पटक हो ? .....
3. गएको पाँच वर्षमा तपाईको मादकपदार्थको मात्रा बढेको छ वा घटेको छ वा उस्तै रहेको छ ?
    १) उस्तै छ २) बढेको छ ३) घटेको छ

ध) खाना सम्बन्धि जानकारी

1. तपाई दिनको कति पटक खानु हुन्छ? (पटक खाना)
2. के तपाई आफ्नो खानको लागि मधुमेहको खाना प्लेट मोडेल प्रयोग गर्नु हुन्छ ? (मधुमेहको खाना प्लेट मोडेलको चित्र देखाउने) १) गर्छु २) गर्दिन ३) थाहा छैन
3. के तपाई थोरै तर धेरै पटक खाने गर्नु हुन्छ ? (बिरामी लै थोरै तर धेरै पटक खानको बारेमा बताउने) १) गर्छु २) गर्दिन ३) थाहा भएन
4. के तपाई गुलियो खान खानु हुन्छ? (चिनी, मिठाई, चोक्लेट, जुस, चिसो पेयपदार्थ) ? १) खान्छु २) खादिन ३) थाहा छैन

a. तपाई कति समयमा गुलियो खान खानु हुन्छ? १) सधै २) अक्सर ३) कहिले कहिँ

२४ घन्टाको खानकि सम्झिने

1. तपाईले हिजो के खानु भयो? कृपया बिस्तृत विवरण तथा खानको मात्रा पनि दिनु होला

समय (कहिले)	स्थान (कहाँ)	खानाको नाम (के)	मात्रा (कति)

न) सुताई बारे जानकारी

1. के तपाइको नियमित सुत्ने नियम छ? १) छ २) छैन ३) थाहा भएन
2. कति लामो समय सम्म सुत्नु हुन्छ? ..... घण्टा
3. तपाई राति पनि बिउझिनु हुन्छ? १) छ २) छैन ३) थाहा भएन
    a. तपाई राति कति पटक बिउझिनु हुन्छ ? .....

त) शारीरिक क्रियाकलापबारे जानकारी

(तल दिएका प्रश्नहरुको उत्तर दिने बेलामा मा कडा क्रियाकलाप भन्नाले धेरै शारीरिक मिहेनत पर्ने तथा स्वास प्रश्वासमा वा मुटुको चालमा ठुलो वृद्धि हुने क्रियाकलापहरुलाई जनाउछ .(जस्तै १० मिनेट भन्दा बढी सम्म गह्रौ भारि बोक्ने, जमिन खन्ने वा निर्मसंग सम्बन्धित कामहरु, आदि)). मध्यम क्रियाकलाप भन्नाले ठिक्कको शारीरिक क्रियाकलाप तथा श्वास प्रश्वासमा मध्यम प्रभाव पर्ने क्रियाकलापहरुलाई जनौदछ जस्तै छिट्टो छिट्टो हिड्ने वा हल्का समान बोकेर कम्तिमा १० मिनेट सम्म निरन्तर हिड्ने .)

अ) कार्यस्थलका क्रियाकलाप

1. के तपाईको काम मा कडा क्रियाकलापहरु पर्दछन् जसले गर्दा तपाइको श्वासप्रश्वासमा ठुलो बृधि हुन्छ वा मुटुको चाल बढ्न जान्छ जस्तै १० मिनेट भन्दा बढी सम्म गह्रौ भारि बोक्ने, जमिन खन्ने वा निर्मानसंग सम्बन्धित कामहरु, आदि ? १)छ २) छैन
    a. यदि छ भने कुनै एक हप्तामा कति दिन तपाई कडा क्रियाकलाप गर्नु हुन्छ? (दिनको संख्या) ..... दिन
    b. तपाई कडा क्रियाकलापमा प्रति दिन कति समय खर्चिनु हुन्छ? ..... मिनेट/ घण्टा
    c. कुनै एक बर्षमा तपाई यस्तो क्रियाकलापमा कति महिना लाग्नु हुन्छ? ..... महिना
2. के तपाईको काम मा मध्यम क्रियाकलापहरु पर्दछन् जसले गर्दा तपाइको श्वासप्रश्वासमा हल्का बृधि हुन्छ वा मुटुको चाल हल्का बढ्न जान्छ जस्तै छिट्टो छिट्टो हिड्ने वा हल्का समान बोकेर कम्तिमा १० मिनेट सम्म निरन्तर हिड्ने, आदि ? १)छ २) छैन
    a. यदि छ भने कुनै एक हप्तामा कति दिन तपाई मध्यम क्रियाकलाप गर्नु हुन्छ? (दिनको संख्या) ..... दिन
    b. तपाई मध्यम क्रियाकलापमा प्रति दिन कति समय खर्चिनु हुन्छ? ..... मिनेट/ घण्टा
    c. कुनै एक बर्षमा तपाई यस्तो क्रियाकलापमा कति महिना लाग्नु हुन्छ? ..... महिना

आ) एक ठाउँबाट अर्को ठाउँ आउने जाने यातायात

(अबको प्रश्नहरुले तपाईको शारीरिक काम सम्बन्धि कुराहरुसंग सम्बन्धित छैनन किनभने तिनीहरु माथिनै उत्तर दिसक्नु भएको छ . अब मा तपाईलाई नियमित यातायात तथा हिडडुल सम्बन्धि प्रस्नहरु गर्नेछु . जस्तै काममा जाँदा, पसल जाँदा, बजार जाँदा, मन्दिर जाँदा, आदि)

1. के तपाई यातायातका लागि कम्तिमा १० मिनेट सम्म हिड्ने वा साइकल चलाउने गर्नु हुन्छ?
   १) गर्छु २) गर्दिन
   a. यदि गर्नु हुन्छ भने कुनै एक हप्तामा कति दिन तपाईले निरन्तर कम्तिमा १० मिनेट सम्म हिड्ने वा साइकल चलाउने गर्नु हुन्छ? ..... दिन/महिना/बर्ष
   b. कुनै एक दिन मा तपाई कति समय हिडेर वा साइकल चलाएर बिताउनु हुन्छ? ..... मि/ घण्टा

थ) मनोरन्जनात्मक क्रियाकलाप

1. के तपाई कम्तिमा १० मिनेट सम्म निरन्तर कुनै कडा खेलकुद तथा मनोरन्जनात्मक क्रियाकल्पहरु गर्नु हुन्छ जस्तै फुटबल, दौड आदि जसले गर्दा स्वासप्रस्वासमा ठुलो बृधि हुन्छ वा मुटुको चाल मा ठुलो बृधि हुन्छ? १) गर्छु २) गर्दिन
   a. यदि छ भने कुनै एक हप्तामा कति दिन तपाई कडा खेलकुद तथा मनोरन्जनात्मक क्रियाकलाप गर्नु हुन्छ? (दिनको संख्या) ..... दिन
   b. तपाई कडा खेलकुद तथा मनोरन्जनात्मक क्रियाकलापमा प्रति दिन कति समय खर्चिनु हुन्छ? ..... मिनेट/ घण्टा
   c. कुनै एक बर्षमा तपाई यस्तो क्रियाकलापमा कति महिना लाग्नु हुन्छ? ..... महिना
2. के तपाई कम्तिमा १० मिनेट सम्म निरन्तर मध्यम खेलकुद तथा मनोरन्जनात्मक क्रियाकलापहरु गर्नु हुन्छ जसले गर्दा तपाइको श्वासप्रश्वासमा हल्का बृधि हुन्छ वा मुटुको चाल हल्का बढ्न जान्छ जस्तै छिट्टो छिट्टो हिड्ने, साइकल चलाउने, पौडी खेल्ने, भलिबल खेल्ने, आदि? १)छ २) छैन
   a. यदि छ भने कुनै एक हप्तामा कति दिन तपाई मध्यम खेलकुद तथा मनोरन्जनात्मक क्रियाकलाप गर्नु हुन्छ? (दिनको संख्या) ..... दिन
   b. तपाई मध्यम खेलकुद तथा क्रियाकलापमा प्रति दिन कति समय खर्चिनु हुन्छ? .....मि/ घण्टा
   c. कुनै एक बर्षमा तपाई यस्तो क्रियाकलापमा कति महिना लाग्नु हुन्छ? ..... महिना

द) निस्क्रिय जीवनशैली

1. तपाई कुनै दिन कति समय बसेर वा ढल्केर बस्नु हुन्छ? ..... मिनेट/घण्टा

ध) मधुमेहको जटिलताहरु

1. के तपाई मधुमेहको जटिल समस्याहरुबाट पनि पिडित हुनु हुन्छ? १) छु २) छैन
   a. छ भने, कुन प्रकारको ? .....
   b. कहिले देखि सुरु भएको हो? .....

न) शारीरिक नाप जांचहरु

1. उचाई : ..... से.मि.
2. तौल : ..... के.जि.
3. कम्मरको गोलाई : ..... से.मि.
4. पेटको गोलाई : ..... से.मि.
5. रक्तचाप : ..... एम.एम.एच. जि.

   रक्तचाप १ ..... रक्तचाप २ ..... रक्तचाप ३ .....

त) रक्त परिक्षण नतिजा

खाली पेटको जाँच : ___ mg/dl HbA1C : ___ %

धन्यबाद

15 ANNEX: WORK PLAN

Activities	**Months**														
	Second semester					**Third semester**					**Fourth semester**				
	Jan	Feb	Mar	Apr	May	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May
Extensive literature/documents review and detail research tool preparation															
Master thesis protocol preparation															
Master thesis protocol submission															
Piloting of the research tools and communication to the concerned authorities for research															
Data collection from Dhulikhel Hospital															
Data entry															
Workshop on Advanced Epidemiology and Statistics															
Preliminary data analysis															
Preliminary report preparation															
Final report publication and dissemination															