Prevalence of risk factors for development of angiopathy of lower extremities in Type 2 Diabetes patients: a mixed methods study

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by

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Acknowledgments`

Abstract

Introduction: Diabetes Mellitus is one of the most common non-communicable diseases in the world and it is reaching epidemic proportions worldwide. Complications affecting the lower extremities are among the most common manifestations of diabetes; it was reported that 15% of diabetes patients eventually suffer from foot ulceration during their lifetime. About 60% of all lower extremity amputations in the United States are performed on persons with diabetes. According to the WHO, diabetes morbidity and mortality in Armenia have been steadily increasing over the past decade. Chronic diseases accounted for 90% of all deaths in 2002, and 6% of all deaths resulted from diabetes.

Objectives: To identify the prevalence of risk factors leading to the development of angiopathy of lower extremities in Type 2 diabetes patients aged 40 years and older and to make recommendations to reduce diabetes foot complications.

Methods: This study utilized a mixed methods approach with a case-control study conducted in Hospital and Polyclinic of Police, with 197 cases and 197 controls, and 22 in-depth interviews with family members of diabetes patients. The case control study collected data using telephone interviews.

Results: The analysis of the quantitative research showed that the risk of having diabetic angiopathy of lower extremities increased with one year increase in duration of the disease (OR=1.14; 95% CI: 1.03; 1.25), with one-unit increase in BMI (OR=1.20; 95% CI: 1.08; 1.34), and with smoking one more cigarette per day (dose-response relationship) (OR=1.11; 95% CI: 1.07; 1.17). There was statistically significant association between diabetic angiopathy of lower extremities and poor self-monitoring of blood glucose level (OR=2.78; 95% CI: 1.51; 7.83) and presence of hypertension (OR=6.10; 95% CI: 2.26; 22.44). The odds of diabetic angiopathy of lower extemities was 10 times higher (OR=10.20; 95% CI: 2.61; 30.51) among those diabetes patients who did not check feet on a regular basis from the moment they were diagnosed with diabetes.

In-depth interviews revealed a low level of knowledge of diabetes patients' family members regarding the diabetes management, diabetes complications and their prevention. Many respondents found that health professionals provided little information to persons diagnosed with diabetes, making it difficult for those persons to understand how to manage diabetes. Most of the respondents often quoted financial issues as the cause of poor patients' compliance with medication and diet.

Conclusion: This mixed methods study showed that multiple factors and mechanisms contribute to the development of diabetic angiopathy of lower extremities in Type 2 diabetes patients. Poor foot self-checking following the diagnosis of diabetes, poor blood glucose control, current smoking level, presence of hypertension, BMI, and duration of the disease were predictive risk factors for antipathy of lower extremes in Type 2 diabetes patients. The role of health care providers was reported to be essential, particularly as patients seemed to need more information and guidance regarding the diabetes management.

1. Introduction/Literature review

Diabetes Mellitus is one of the most common non-communicable diseases in the world and it is reaching epidemic proportions worldwide (1). According to the World Health Organization diabetes is characterized by chronic elevation of the concentration of glucose in the blood and by disturbance of carbohydrate, lipid and protein metabolism that is associated with absolute or relative deficiencies in insulin action or insulin secretion (1; 3). There are three main types of diabetes:

Type 1 Diabetes (Insulin-Dependent Diabetes Mellitus) typically occurs in childhood or adolescence and is characterized by the inability of the pancreas to produce insulin (6). It accounts for 5-10% of all diagnosed cases of diabetes (6). Risk factors for Type 1 diabetes may be genetic or environmental. There is no known way to prevent Type 1 Diabetes (4; 6).

Type 2 Diabetes (Non-Insulin-Dependent Diabetes Mellitus) typically begins after age 35-40, as a result of insulin resistance, when the cells do not use insulin properly, and the pancreas gradually loses its ability to produce insulin (4). Type 2 diabetes accounts for 90-95% of all diagnosed diabetes (4; 6).

Gestational diabetes is a form of glucose intolerance that appears during pregnancy. Some evidence indicates that women who have had gestational diabetes have 40%-50% chance of developing diabetes in the next 5–10 years (4; 6).

Diabetes Mellitus is considered as a serious public health problem, posing a significant burden in mortality, morbidity and cost (7). It is a serious public health problem with important socio-economic consequences (1). Diabetes affects all dimensions of a person's life; diabetes patients usually experience depression that could be an obstacle to adaptating healthy lifestyle (2).

The global burden of diabetes, estimated to rise from 171 million people in 2000 to 366 million people by 2030, brings with it a substantial increase in the prevalence of

complications (1). Around 3.2 million deaths every year are attributable to complications of diabetes; six deaths every minute (8). About 1.6 million new cases of diabetes were diagnosed in people aged 20 years or older in 2007 (9).

In 2007, in the United States of America (US), 23.6 million Americans or about 8.0% of the population suffered from diabetes, 76.0% of them were diagnosed, and 24.0% - were undiagnosed (7; 9). The majority of people with diabetes are 60 years of age and over (6).

Like other chronic conditions, diabetes causes lots of problems not only for patients, but also for family members due to hospitalizations and financial costs, disabilities, and lifestyle changes. Overall, the direct health care costs of diabetes range from 2.5% to 15.0% of annual health care budgets, depending on local diabetes prevalence and sophistication of the treatment (8). For example, diabetes costs the US $132 billion each year, including $92 billion in medical costs and $40 billion in costs related to disability and work loss (10).

In middle-income countries the majority of people with diabetes are in the 45-64 age category, and the majority of people with diabetes in high-income countries are over 65 years of age (1).

The incidence of Type 2 diabetes is slightly higher in women than in men and it increases with increasing age (11). Studies showed that the mortality rate from medical causes in diabetics under age 45 is eight times greater than that for the age and sex-matched general population (12). Type 2 diabetes is an epidemic in industrialized societies and is strongly associated with obesity (13).

The main risk factors for developing Type 2 diabetes are: family history, being overweight and having sedentary lifestyle (6). Several studies found that higher levels of habitual physical activity are associated with significantly lower subsequent mortality in Type 2 diabetes patients (14). Therefore, regular exercise programs had a statistically and clinically significant beneficial effect on glycemic control in Type 2 diabetes patients (14;

15). The US Center for Disease Control and Prevention has published the new recommendations that health-related benefits could increase from a minimum of 30 minutes of moderate physical activity, such as brisk walk or bicycling at a regular pace on most days of the week (16).

Support within the family would influence family food choice and physical activity behaviors (17). About 95% of Type 2 diabetes care is composed of patients' self-management of the disease and support of the family members (17; 18). Hispanic adults in the US with Type 2 diabetes mentioned attitudes, perceptions, and preferences of their family members as considerable barriers to making changes in their diet and exercise patterns recommended by their physicians (19).

Support from family and friends are especially predictive of better self-management of diabetes patients (20). Several studies found that family behavior and attitude can support patients' psychosocial adaptation to the illness and subsequently a patients' willingness to implement diabetes-management (self-care) strategies (17; 18). Adherence to treatment in diabetes patients could also be associated with their trust in traditional medicine, education level, and socio-economic level of patients (22).

In uncontrolled diabetes, glucose and lipids remain in the bloodstream, which over time can harm the blood vessels, kidney, heart, eyes, and other body systems (4; 5). Problems that result from this harm are called complications, which can be fatal or disabling. Diabetes complications include diabetic retinopathy, blindness, nephropathy, ischemic heart disease, macro- and microangiopathy of lower extremities, gangrene, amputation, neuropathy, and stroke. Adults with diabetes have 2-4 times higher risk developing stroke and heart disease than those without diabetes (10).

Diabetes is the leading cause of kidney failure, accounting for 44% of new cases in the US in 2004; more than 44,000 people with diabetes begin kidney dialysis each year (9).

Approximately 60% - 70% of Americans with diabetes have mild to severe forms of nervous system damage (10). Several studies found that men with diabetes are 2 times as likely to experience erectile dysfunction as men without diabetes (10).

Almost every person who has a diagnosis of diabetes is afraid of the manifestations of diabetes angiopathy of the lower extremities such as foot ulceration, sepsis, and amputation (23; 24). Complications affecting the lower extremities are among the most common manifestations of diabetes; it was reported that 15% of diabetes patients eventually suffer from foot ulceration during their lifetime (28).

The main cause of hospitalization of diabetes patients with angiopathy of the lower extremities is infection of foot ulcers (23). About 60% of all lower extremity amputations in the United States are performed on persons with diabetes (23). At the same time, about half of these amputations could be prevented through regular foot examinations and diabetes patient education (23; 24). Type 2 diabetes patients can get foot complications even soon after diagnosis of diabetes, because they might have diabetes for a long time without knowing (24; 77).

Several studies found that men with diabetes are 2 times as likely to develop diabetes foot complication compared to women with diabetes due to behavioral and physiological peculiarities (10; 25).

There are two types of diabetic angiopathy: macroangiopathy and microangiopathy. In macroangiopathy, blood clots and lipids stick to the large blood vessel walls and block the flow of blood. Macroangiopathy may cause development of ischemic heart disease, stroke and peripheral vascular diseases that contribute to the development of diabetic foot ulcers and risk of amputation (5; 25; 26).

In microangiopathy, the walls of the smaller blood vessels (capillars) become so fragile that they bleed. It causes a decrease of blood flow through blood clot formation as

well as stenosis that lead to local tissue ischemia, necrosis, foot ulceration and gangrene which in turn may require an amputation (5; 25; 26) (see Appendix 1).

Microangiopathy may also cause peripheral neuropathy, retinopathy and blindness as well as diabetic nephropathy. Diabetes microvascular complications are also strongly associated with cardiovascular disease (5; 25; 26).

The major risk factors for developing diabetic macroangiopathy of the lower extremities are the following: presence of hypertension, smoking, obesity, hyperlipidemia, poor blood glucose control, and family history of diabetes (26; 27). The major risk factors for developing diabetic microangiopathy of lower extremities are: loss of protective sensation (the ability to feel normal sensation in feet due to diabetes), poor blood glucose control, noncompliance with treatment, having diabetes more than 10 years, and history of previous foot ulceration (23; 26).

All patients with diabetes should be screened regularly for loss of protective sensation to prevent further development of foot ulceration (23; 24). Diabetes patients should adopt a daily routine of checking and caring for their feet to prevent injury to the feet (23; 24). Several studies found that strict monitoring of blood glucose level is very important in preventing microangiopathy of lower extremities in Type 2 diabetes patients (29).

Literature suggests that taller diabetic patients are at higher risk of peripheral sensory loss than shorter diabetic patients and thus may be at increased risk of lower-extremity ulcers and amputation (30). People with diabetes are commonly overweight and that nearly doubles the risk of developing diabetic angiopathy of lower extremities and other diabetes complications (31).

Alcohol consumption is confirmed as one of the strongest predictors for the development of diabetes foot ulceration, especially heavy alcohol consumption (more than 3 drinks per day) (32; 34). Alcohol use is associated with key self-care behaviors that are

important for the health of patients with diabetes (33; 35). Research indicates that smoking is a predictor of both foot complications and mortality in Type 2 diabetes patients (32; 36; 37; 56).

Nearly 40% of Type 2 diabetes patients diagnosed with angiopathy of lower extremities have coexisting hypertension (27; 38). Hypertension contributes to the presence of diabetic complications such as angiopathy of lower extremities, nephropathy, neuropathy, and cardio-vascular disease (38; 39). Several studies found that a reduction in systolic blood pressure of 10 mm Hg was associated with 13% reduction in risk of developing diabetic microangiopathy (27; 39, 40).

1.1 Situation in Armenia

Diabetes Mellitus is a great public heath problem in Armenia. According to WHO, diabetes is third behind cancer and cardio- vascular diseases as causes of death, and has been steadily increasing over the past decade in Armenia (41; 42). Chronic diseases accounted for 90% of all deaths in 2002, and 6% of all deaths resulted from diabetes (41). In 2004, the percentage of people in Armenia aged 20 years and above with diabetes was approximately 4.7-5.7% (43). According to WHO, there were about 120,000 diabetics in Armenia in 2000 (44). However, specialists think the real number of diabetics exceeds the official numbers approximately 2 times (45).

Over the past 15-20 years the morbidity and mortality rates of diabetes have been increasing. If in 1990 the death rate due to diabetes was 13.96 per 100, 000 population, in 2003 it was 53.19 per 100,000 population (46). The disparity between the death rate due to diabetes in Armenia and the US in 2002 was very striking: about 3 times higher (73) (see Appendix 2).

Currently, diabetes patients in Armenia are covered by the Basic Benefit Package and receive free medication at the polyclinic-ambulatory institutions (47; 48). According to the

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state resolution № 396 of June 8, 1999, provision of pharmaceutical drugs to socially vulnerable groups of population and groups with special diseases such as diabetes is performed free of charge for the patient (49). However, there is a lack of available funds for health care and availability of pharmaceutical supply could be an issue (50; 51).

 People covered by the Basic Benefits Package should receive free pharmaceuticals in case of inpatient treatment. However, due to insufficient state funds even those patients pay informally out-of pocket (49).

1.2 The main aims of the study were:

- To identify the prevalence of risk factors leading to development of angiopathy of lower extremities in Type 2 diabetes patients aged 40 years and over

- To assess the awareness and knowledge of Type 2 diabetes patients regarding the risk factors of diabetic angiopathy of lower extremities

- To identify awareness level of diabetes patients' family members (primary care takers) of risk factors for development of diabetic angiopathy of lower extremities

- To reveal the problems related to Type 2 diabetes management from the standpoint of diabetes patients' family members

- To make recommendations for reducing diabetes foot complications

2. Methods

This was a mixed methods study (qualitative and quantitative) conducted in the Polyclinic and Hospital of Police in Yerevan.

2.1 Qualitative study

Despite the fact that diabetes is the third cause of mortality in Armenia, no qualitative research was conducted in Armenia to reveal the public perceptions of diabetes. To fill this gap, the qualitative component of this study aimed to examine the perception of diabetes management by family members of patients, because families play a significant role in supporting diabetes patients in self-management of their disease.

The research question of the qualitative component of the study was:

- What are the knowledge and attitude of Type 2 diabetes patients' family members regarding diabetes management, diabetes complications and their prevention?

2.1.1 Target population

In-depth interviews were conducted with Type 2 diabetes patients' family members (primary care takers). The sample needed to achieve saturation was estimated to be 22 interviews: 11 informants were family members of diabetes patients with angiopathy of lower extremities, and another 11 informants were family members of diabetes patients without angopathy of lower extremities.

2.1.2 The study instrument

The student-investigator developed a semi-structured in-depth interview guide in English on the basis of an interview guide used in a similar study, which aimed to identify knowledge and perception of diabetes in general population (35). It was translated into Armenian, pre-tested and revised accordingly. The in-depth interview guide had 8 open-ended questions and it took about 20 minutes to administer it.

The student-investigator transcribed all the in-depth interviews and analyzed them. Analysis began by coding the collected data. Then codes were emerged into categories

which in turn summed up into themes that were determined according to concepts and issue the respondents emphasized repeatedly. These themes are illustrated with appropriate quotations in the text boxes.

2.2 Quantitative study

The research questions of the quantitative component of the study were:

- What is the prevalence of risk factors for the development of angiopathy of lower extremities in Type 2 diabetes patients aged 40 years and older, and being treated at the Polyclinic and Hospital of Police in Yerevan, Armenia?

- Is there an association between self-monitoring of blood glucose level, duration of the disease, smoking level, daily alcohol consumption, BMI, foot self-examinations and presence of hypertension and angiopathy of lower extremities in Type 2 diabetes patients?

A case-control study was conducted in the Polyclinic and Hospital of Police in Yerevan to answer the research questions.

2.2.1 Study population

The target population included all Type 2 diabetes patients aged 40 years and older and being treated at the Polyclinic and Hospital of Police in Yerevan from January of 2006 to January of 2009.

Cases were defined as Type 2 diabetes patients aged 40 years and older with clinically and instrumentally confirmed diagnosis of angiopathy of lower extremities and being treated at the Police Polyclinic and Hospital in Yerevan.

Controls were defined as Type 2 diabetes patients aged 40 years and older without angiopathy of lower extremities and being treated at the same health facilities.

Inclusion criteria were:

- Having Type 2 diabetes

- Age 40 years and older

- Being treated at the Hospital or Polyclinic of Police from January of 2006 to January of 2009

- Resident status for Armenia

Exclusion criteria were:

- Having Type 1 diabetes

- Poor knowledge of Armenian language

- Not being in Armenia

2.2.2 Variables

The main variables of this study are listed in Table 1.

The dependent (outcome) variable is diabetic angiopathy of lower extremities. Independent variables are BMI, self-monitoring of blood glucose level, adherence to treatment, following proper diet, physical activity level, current smoking level, daily alcohol consumption, family history of having diabetes (in at least one person with diabetes generation - parents or grandparents), duration of the disease, foot self-examinations following the diagnosis of diabetes, foot examinations by physician, presence of hypertension and knowledge level regarding diabetes self-management (21; 26; 38; 39; 40). The intervening variables are age, gender, level of education, socio- economic status, employment status, marital status, job type, and place of residence (1; 11).

The student-investigator came up with categories for BMI, hypertension status, current smoking level, and daily alcohol consumption using WHO recommendations (33; 52;

53; 55; 57; 74). Physical activity was categorized according to guidelines for data processing and analysis of the International Physical Activity questionnaire (IPAQ) (55).

(see Table 1).

2.2.3 Sampling methodology

A mixed sampling methodology was used to choose the study population. The Polyclinic and Hospital of Police were chosen by convenience. The reason for choosing these health facilities was that the Polyclinic and Hospital of Police are unique health facilities in Armenia, because they serve all police officers from Armenia, both Yerevan and the marzes. The student-investigator had access to these health facilities.

This study used simple random sampling methodology to choose the participants of the study. The sampling frame was enumerated lists of Type 2 diabetes patients registered in the Polyclinic and Hospital of Police in Yerevan from January of 2006 to January of 2009.

2.2.4 Sample size

Sample size calculation was performed based on the formula for case-control designs taking into consideration preliminary estimates of proportion exposed in cases and controls (57):

$$n = \frac{\left\{ z_{1-\alpha/2} \sqrt{2P(1-P)} + z_{1-\beta} \sqrt{P_1(1-P_1) + P_2(1-P_2)} \right\}^2}{(P_1 - P_2)^2}$$, where

P_1 = proportion exposed in cases,

P_2 = proportion exposed in controls, and

$P = P_1 + P_2 / 2$

The sample size calculation was done assuming equal number of cases and controls with the level of significance $\alpha = 0.05$ and power $= 0.8$. The proportion of diabetes patients

with foot complications who poorly control their blood glucose level was estimated as 60% (28; 58), the proportion of diabetes patients without foot complications who poorly control their blood glucose level was estimated as 42% (59), and an odds ratio of 1.8 was considered (60; 61; 62). Using these estimates, the sample size was calculated to be 197 cases and 197 controls. The expected response rate was 90%; therefore, the actual sample size was calculated to be 217 cases and 217 controls.

2.2.5 Study instrument

The study instrument for the quantitative part of this study was an interviewer-administered questionnaire. The questionnaire had 59 questions and consisted of four main sections: general socio-demographic information, knowledge about diabetes, behavioral characteristics and diabetes management.

Questions 6, 9-11, 14-20, 33, 35-36, 38, 41, 45, 48, 49, 50, 51-57, 60-62 were based on the instrument for Kaiser Permanente Diabetes Study of Northern California (63). Questions 12, 26, 31, 34 and 35 were based on the instrument for the National Survey of people with diabetes (64). Questions 21-24 related to physical activities were based on the International Physical Activity Questionnaire (IPAQ) (65). Questions 4 and 56 were coming from the instrument for Household Health Survey conducted in Armenia (66).

Questions 27-30 were based on the Medication Adherence Scale (MAS) or Morisky scale (67). The MAS consists of four items, which address reasons of non-adherence such as forgetfulness, carelessness, or stopping medications because they feel better or worse. The lower the MAS score is the better adherence to medication.

The student-investigator developed the questionnaire in English and then translated into Armenian. Pre-testing of the translated instrument with 15 people was conducted by phone interviews. Appropriate changes were made after pre-testing. The phone interviews

lasted for about 20 minutes. Appendix 3 provides information related to procedures for contact and recontact as well as the journal form filled after each interview.

Only residential telephones were eligible for this survey, which were telephones located in a residence and used primarily for private, non-business purposes. The selection of phone interview technique was due to financial and time constraints.

2.2.6 Data analysis

Data were entered into SPSS 11 for Windows and checked for accuracy through range and spot checking. After cleaning and recoding procedures, the study used STATA 10.0 statistical package for statistical analyses. Differences in distribution between cases and controls for categorical variables were tested using the chi-squared test. Differences in proportions were evaluated using the z-test or chi-squared test.

Differences in means of continuous variables were assessed using the independent t-test. The Fisher's Exact test was used for variables with small frequencies (76). Simple logistic regression was used to assess the relationship between each of the independent variables and diabetic angiopathy of lower extremities.

All covariates identified as statistically significant in the bivariate analysis ($p<0.05$) were included in a multiple logistic regression analysis. Categorical data were converted into "dummy" variables to be used in regression analysis. However, the original continuous variables were used for the logistic regression analysis.

The student-investigator applied multiple logistic regression models to control for potential confounders and explore possible interactions between different statistically significant risk factors. In epidemiological terms confounding occurs only if a potential confounding variable affects disease risk (diabetic angiopathy of lower extremities) and is associated with exposure (risk factor) even among controls and is not in the causal pathway

between disease (diabetic angiopathy of lower extremities) and exposure (risk factor) (75). Study applied Variance Inflation Factor (VIF) method for detecting the severity of colinearity for variables in the final model.

The Likelihood Ratio test helped with the model building to obtain the most parsimonious model. The model goodness-of-fit was evaluated by Hosmer-Lemeshow chi-square test statistics (57).

2.3 Ethical considerations

The American University of Armenia Departmental Institutional Review Board approved the protocol of this study before starting the fieldwork. The oral consent form included a description of the nature of the research, the risks and benefits of being included in the research, and that the participation was voluntary (see Appendix 4).

3. Results

3.1 Qualitative study

The respondents were females of mean age 47 ranging from 23 to 62. More than half of the 22 respondents had completed school education (46.5%) or professional technical education (23.7%). Most of the respondents were not currently employed (82.8%). Twenty-one out of 22 respondents were spouses of diabetes patients, and only one participant was the daughter of a patient.

3.1.1 Knowledge about diabetes

Most respondents never recognized symptoms of diabetes before diagnosis. The majority mentioned that their relatives with diabetes were mostly diagnosed by chance. They mentioned dry mouth, frequent urination, frequent eating, itching, sleep disturbance, decline

in memory, and anxiety as the main symptoms of diabetes. Many respondents stated that there was no cure for diabetes. Many respondents expressed fear against severe complications of diabetes and felt that diabetes was a potential threat to life of their relatives. Almost all respondents mentioned stress or fear and genetic predisposition as the main cause of diabetes. A few respondents mentioned consuming too much sugar as the main cause of diabetes. Not going to doctors was often mentioned as the barrier to early detection, especially in Armenian men. Several respondents felt that a lot of people did not want to know that they had diabetes, particularly because it would put a burden on the family.

"Diabetes is incurable and burdensome disease."

"Diabetes is a terrible disease accompanied by a difficult life style."

"Diabetes is worse than cancer with dead end. I put it higher than cancer. Because it is long term. It's a slow process of dying. You are not able to do anything."

"Diabetes is when you're always sleepy and wanting to eat all the time."

"I do not know anything regarding my husband's disease. Thankfully, I don't suffer from diabetes."

"Diabetes can be either hereditary or acquirable. Stress and genetics play an essential role in the development of diabetes."

3.1.2 Impact of diabetes on family life

The diagnosis of diabetes was shocking news for most of the respondents. Most of the primary care takers were ready to help their relatives struggle with the disease. Many respondents mentioned that all family members were eating the same type of food; however, the preparation was different most of the time. Most respondents stated that it was too

difficult to live with a diabetes patient; many of them pointed out that all family members felt sorry for their relatives with diabetes.

Almost all participants mentioned that it became too difficult to communicate with their husband after being diagnosed with diabetes. They mentioned that diabetic patients were anxious, and this mood would transfer to the whole family. Many respondents talked about constant fear for their family members, especially their children, of the probability of developing diabetes. One of the common concerns was about the way of communicating the news about this diagnosis to the patient: they would get depressed if directly told about it. The participants suggested that physicians should first discuss it with the wife of the patient.

"Living with diabetes patient is too difficult. My husband thinks about his disease too much: it makes him anxious. His anxiety affects negatively both me and my children."

"His disease has changed the life style of our family. The communication with my husband becomes too difficult now, all members of our family feel sorry for him."

"It is necessary to control whether or not he follows the diet or takes the medication on time. Diabetes patients do not want to accept the fact that they are ill."

"I was shocked when I learned that my husband had diabetes."

"I am afraid that our children can have diabetes in the future."

3.1.3 Diet and exercise

Many respondents stated that following proper diet is very important in diabetes treatment. However, many respondents noticed that their relatives with diabetes did not carefully follow the diet. Furthermore, they mentioned that following the diet sometimes becomes impossible due to financial constraints of family. They stated that food that was allowed to diabetes patient was really expensive. Some respondents mentioned that they

excluded sweets from the family's food ration. They categorized food into two groups "healthy food" and "unhealthy food."   "Unhealthy food" included: "sugar, sweets, cakes, greasy food, butter, baked chicken, fried food, grape, pork and barbecue." "Healthy food" included "vegetables, boiled meat or chicken, some fruits, green and herbal tea, green bean, oil, potatoes and lemon."

Most respondents did not know even about the necessity and positive effects of exercising for diabetes patients. Although endocrinologists explained about necessity of appropriate physical activity, several respondents stated that exercising could be harmful for their relatives with diabetes. Some respondents gave physical constraints as an excuse for not exercising. They were sure that walking every day was enough for their relatives with diabetes and there was no need to exercise. Only a few of the respondents mentioned that they understood the importance of physical activity for their relatives with diabetes; they mentioned that they read about it a lot. However, they added that they were not able to persuade their relatives with diabetes to exercise.

"Our endocrinologist has explained that following the diet plays a very important role in diabetes treatment."

"I know that diabetes patient should not stay hungry. Diabetes patients should eat 4-5 times a day but in small portions. I think that sweet food is the enemy of diabetes patients. I am avoiding preparing cakes; my husband likes sweets very much."

"Following the diet depends on the financial status of the family. We should buy meat, chicken, special fruits as well as vegetables, which are too expensive."

"I have never heard that doing exercises is helpful for diabetes patient. I don't even know if physical activity is good or bad for him."

"He was exercising before development of foot complications, now it is impossible. My

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husband does not have enough time to exercise."

3.1.4 Diabetic monitoring

Several respondents mentioned blood glucose control as a main part of diabetic monitoring. However, they mentioned that their relatives with diabetes did not regularly test blood sugar level. They pointed out that their relatives' endocrinologist said that there was no need to check blood sugar level frequently if the patient felt well so the patient did not to get "obsessed" with it.

Most of the respondents mentioned about several methods of treatment of diabetes such as traditional or medical treatment, non-traditional treatment and following a diet. Most of the respondents often quoted financial issues as the cause of poor patients' compliance with both medical treatment and diet. However, lack of available and free medications at the polyclinics was the most frequent factor mentioned by almost all respondents.

Some respondents mentioned that their relatives with diabetes were too careless at times about taking medication. Most of the respondents mentioned that they use alternative methods of diabetes treatment such as herbal remedies and homeopathy. They were worried that physicians, as a rule, did not explain what side effects could be due to medication. Among medical treatment the respondents mentioned diabeton and glucofaj as oral hypoglycemic drugs as well as insulin injection.

Several respondents stated that the combination of using herbal remedies with following the diet was more effective for controlling the blood sugar level than any prescribed medication. However, several respondents mentioned that their relatives with diabetes did not trust herbal remedies.

> "It is necessary to control blood sugar level."
>
> "He does not want to go to polyclinic and check the blood sugar level."
>
> "It is necessary to apply to the physician in case of having any complains to prevent further development of diabetes complications."
>
> "Unfortunately, my husband does not believe in medical treatment as well as in non-traditional treatment. He thinks that diabetes can not be cured."
>
> "The endocrinologist prescribed him several medications, which were too expensive."
>
> "I told to the physician that if you do not give me my medicine free of charge, there is no way I can afford the medicine."
>
> "Diabetes patients should receive medications from polyclinics free of charge; but we buy most prescribed medications."
>
> "If the diabetes patient does not have money to buy prescribed medications, it is a problem. He has to pray to God."

3.1.5 Knowledge about diabetes complications

Almost all respondents stated that diabetes had several complications that were more dangerous than diabetes itself, including vision impairment, cataract and blindness, as well as foot complications such as ulcerations, gangrene, and toe or leg amputations. Many respondents mentioned developing a coma as a complication of diabetes that could be the result of both increasing and decreasing of the sugar level in blood. Several respondents mentioned kidney diseases as a result of diabetes. Some respondents mentioned that diabetes could result in stroke due to high blood pressure.

Several respondents did not even know how to avoid diabetes complications. One of the respondents mentioned that prevention of diabetes complications was possible only in initial stages of the disease. A few of the respondents mentioned that controlling the blood

sugar level through taking prescribed medications carefully as well as following the diet regularly could prevent complications. Several respondents stated that each diabetes patient should be treated in the hospital at least twice a year and receive intravenous injection of appropriate medications: they clarified that their physician recommended this.

Several respondents mentioned that prevention of diabetes complications was possible only through using herbal remedies and following the diet. Most of the respondents mentioned about the importance of endocrinologists' patient counseling skills. Financial constraints were mentioned by most of the respondents as a barrier to prevention of diabetes complications.

"Diabetes is an awful disease with several terrible complications."

"Wounds developed on foot can be infected and hard to recover."

"I do not know anything regarding prevention of diabetes complications. I am sure that it is impossible to prevent diabetes complications; all organs and systems gradually suffer from diabetes."

"To my knowledge, we can prevent development of diabetes complication in the initial stages. Unfortunately, it is impossible to avoid diabetes complications in its late stages."

"Diabetes complications can be prevented by controlling the blood glucose level through following proper diet and taking medications."

3.2 Quantitative study

About 197 cases and 197 controls participated in this study. The contact rate was 93% and no one refused to participate. The response rate was 92% for cases and 91% for controls.

3.2.1 Descriptive statistics

Descriptive statistics (see Table 2) showed that controls were younger compared to cases (52 vs. 62) (see Fig.1). The rate of amputation of toe, foot or leg among cases was 27%. Controls had lower BMI compared to cases (27 vs. 30) (see Fig 2). The majority of the study population were males: 95% cases and 84% controls. The duration of diabetes was significantly longer in cases compared to controls (16 years vs. 8) (see Fig.3). Cases were mostly retired (79%) compared to controls (48%). The study population was mostly married (70% cases and 62% controls), had school (10 years) or professional technical education (13 years) (73% cases and 62% controls). The study population was mostly living in Yerevan and other cities of Armenia (91% controls and 72% cases).

The cases and controls were statistically significantly different with respect to age, gender, place of living, BMI, presence of hypertension, knowledge score, health status, duration of the disease, current smoking level, daily alcohol consumption, self-monitoring of blood glucose level, foot self-checking following the diagnosis of diabetes, foot checking by physician, physical activity level, adherence to treatment, following proper diet, and using non-traditional methods of diabetes treatment, and were similar with respect to family history and type of job.

3.2.2 Simple logistic regression analysis

Simple logistic regression results revealed statistically significant increase of the risk for diabetic angiopathy of lower extremities for several variables (see Table 3). The risk of diabetic angiopathy of lower extremities increased 1.13 times (OR=1.13; 95% CI: 1.07; 1.18) with one-unit increase in BMI. A statistically significant association was also estimated between current and former smoking and the risk of having diabetic angiopathy of lower extremities (OR=6.24, 95% CI: 2.85; 13.66 and OR=5.94, 95% CI: 2.51; 14.05, respectively).

The study detected a statistically significant association between moderate (10-20 cigarettes per day) and heavy (>20 cigarettes per day) smoking and the risk of having diabetic angiopathy of lower extremities (OR=7.94, 95% CI: 3.64; 19.42 and OR=9.42, 95% CI: 3.91; 17.01, respectively). Smoking one more cigarette per day increased the risk of developing diabetic angiopathy of lower extremities 1.12 times (dose-response relationship) (OR=1.12; 95% CI: 1.06-1.12).

Higher daily alcohol consumption (more than 3 drinks per day) increased the risk of developing angiopathy of lower extremities in diabetes patients 2.11 times (OR=2.11, 95% CI: 1.32, 3.37). The risk of having angiopathy of lower extremities in diabetes patients increased 1.61 times with one unit increase in MAS score (adherence to treatment) (OR=1.61; 95% CI: 1.37-1.87).

Poor self-monitoring of blood glucose level (less than once a day) increased the risk of having diabetic angiopathy of lower extremities 3.34 times (OR=3.34, 95%CI: 2.15, 5.17). The risk of having diabetic angiopathy of lower extremities was 6.16 times (95% CI: 3.36; 11.29) higher among those diabetes patients who did not check feet on a regular basis from the moment they were diagnosed with diabetes.

There was a statistically significant association between the duration of the disease and the risk of developing angiopathy of lower extremities in diabetes patients (OR=1.24, 95% CI: 1.18; 1.30). The risk of having diabetic angiopathy of lower extremities was 5.21 times (OR=5.21, 95% CI: 3.02; 8.91) higher in diabetes patients with hypertension compared to those who did not have hypertension. There was a statistically significant association between the presence of family history of having diabetes and the development of angiopathy of lower extremities in diabetes patients (OR=1.38, 95% CI: 1.03; 1.83). There was a statistically significant association between using of non-traditional methods of diabetes

treatment and the risk of developing angiopathy of lower extremities in diabetes patients (OR=2.33, 95% CI: 1.55, 3.51).

The results of a simple logistic regression also demonstrated a protective effect of physical activity (OR=0.53, 95% CI: 0.53, 0.79), following proper diet (OR=0.87, 95% CI: 0.81; 0.96) and knowledge regarding diabetes management (OR=0.72, 95% CI: 0.60; 0.86).

3.2.3 Checking for confounding

The results of a simple logistic regression analysis (see Table 3) showed that socio-economic status, spending for diabetes treatment, educational level, marital status, as well as having a working glucometer were not associated with the risk of developing angiopathy of lower extremities in diabetes patients. Age, gender as well as place of living and employment status were highly significantly associated with the risk of developing diabetic angiopathy of lower extremities.

Age was statistically significantly associated with such risk factors as physical activity level, presence of hypertension, and foot self-checking following the diagnosis. Gender was statistically significantly associated with self-monitoring of blood glucose level, alcohol consumption, following proper diet and physical activity level. There was no statistically significant association between place of living and employment status and the main risk factors.

The statistical approach to checking for confounding showed that age and gender were confounders of the relationship between development of diabetic angiopathy of lower extremities and such risk factors as self-monitoring of blood glucose level, physical activity level, presence of hypertension, daily alcohol consumption and foot self-examinations following the diagnosis.

3.2.4 Multiple logistic regression analysis

All the statistically significant variables were included in multiple logistic regression models (see Table 4). Models were tested by a Log Likelihood Ratio test to determine the best fitting model. Possible interactions between different statistically significant risk factors were examined. The results of the multiple logistic regression showed that there was evidence of interaction between physical activity level and physical health problems. The results of the multiple logistic regression also showed that there was interaction between adherence to treatment and using non-traditional methods of diabetes treatment.

In order to avoid colinearity, which occurs when two or more of the explanatory variables are highly correlated (76), the student-investigator calculated the Pearson correlation coefficients for poor self-monitoring of blood glucose level, current smoking level, daily alcohol consumption, presence of hypertension, self foot-checking following the diagnosis, BMI, duration of the disease, age and gender and did not observe significant correlation between them (see Appendix 7). These variables were also checked for colinearity using Variance Inflation Factor (VIF) method which revealed that none of the variables included in the final model were highly correlated.

Each full model has been tested against the nested model using the Log-likelihood Ratio Test (see Table 4); the best fitting (parsimonious) model included duration of the disease, self-monitoring of blood glucose level, presence of hypertension, current smoking level, BMI, foot self-checking following the diagnosis of diabetes, age and gender.

The model was tested with Hosmer-Lemeshow goodness-of-fit test which compared the observed and model predicted probabilities of development diabetic angiopathy of lower extremities across different risk factors. The Hosmer-Lemeshow Chi-square test statistics was 6.89 (prob > Chi^2 = 0.5485) which supported the assumption that the model was the best fitting model. The final model demonstrated also a good discrimination; the area under the

Receiver Operating Characteristics (ROC) curve was 0.8886 (see Appendix 8). The area under the ROC curve, which ranges from zero to one, provides a measure of the model's ability to discriminate between those subjects who experience the outcome of interest versus those who do not (57; 76).

The analysis showed that a one year increase in duration of the disease increased the odds of getting diabetic angiopathy of lower extremities 1.14 times (95% CI: 1.03; 1.25), after controlling for other variables. The odds of diabetic angiopathy of lower extremities was 2.78 times (95% CI: 1.51; 7.63) higher in case of poor self-monitoring of blood glucose level (less than once a day), after adjusting for other variables.

The odds of diabetic angiopathy of lower extremities was 6.10 times (95% CI: 1.26; 22.44) higher in diabetes patients with hypertension compared to those who did not have hypertension, after controlling for other variables.

One-unit increase in BMI (kg/m^2) increased the odds of getting diabetic angiopathy of lower extremities 1.20 times (95% CI: 1.08; 1.34), after controlling for other variables. The odds of diabetic angiopathy of lower extremities increased 1.11 times (95% CI: 1.07; 1.17) with smoking one more cigarette per day (dose-response relationship), given other variables were fixed.

The odds of diabetic angiopathy of lower extremities was 10.20 times (95% CI: 2.61; 30.51) higher among those diabetes patients who did not check feet on a regular basis from the moment they were diagnosed with diabetes, after controlling for other variables.

Because the majority of the study population were males (95% cases and 85% controls) the research team run the final model for the male population only. The odds ratios remained the same for all the variables in the model (see Table 5).

4. Discussion

4.1 Qualitative research

The most interesting findings of the in-depth interviews conducted with family members (primary care takers) of diabetes patients were the knowledge about diabetes and its complications, diet and nutrition, exercising, diabetes monitoring and impact of diabetes on family life.

Many respondents thought that there was no cure for diabetes. The majority expressed fear of severe complications of diabetes; and they felt that diabetes was a potential threat to life of their relatives. Not going to doctors was often mentioned as the barrier to early detection. Most of the primary care takers were ready to help their relatives to struggle with the disease. Several studies found that family behavior and attitude can support patients' psychosocial adaptation to illness like diabetes and subsequently patients' willingness to implement diabetes-management (self-care) strategies (17; 18).

Many respondents did not know enough about the diet of diabetes patients. This finding was consistent with the results of the quantitative research that demonstrated low levels of knowledge regarding proper diet for diabetes patents. The majority of the respondents did not know about the necessity and positive effects of physical activity for diabetes patients. These findings were also consistent with the results of the quantitative research that indicated that only 33.0% of cases and 48.0% of controls had moderate level of physical activities.

Most participants mentioned that their relatives with diabetes did not regularly test blood sugar level. Some of the inappropriate behavior and lack of knowledge was due to poor quality of medical care they received. Health care providers' lack of interest in the readings of diabetes patients' blood glucose tests was the reason some respondents gave for discontinuing blood glucose self-monitoring.

Many respondents found that the health care system providers little information to persons diagnosed with diabetes, making it difficult for those persons to understand how to manage diabetes. Participants reported that physicians of their relatives with diabetes knew little about the disease.

Some respondents mentioned that their relatives with diabetes were too careless at times about taking medication that were consistent with the findings of the quantitative research: mean of adherence to treatment (Morisky score) for cases was 2 ± 1 while for controls it was 1 ± 1.

Most of the respondents often quoted financial issues as the cause of poor patients' compliance to both medication and diet. It is known that the diabetes patients should get medications from the polyclinics free of charge (49). However, lack of available medications at the polyclinics was the most frequent factor cited by almost all of the respondents. Several studies found that in low/middle income countries, financial aspects continue to affect the care of patients with chronic diseases such as diabetes (72).

4.2 Quantitative research

This case-control study investigated the prevalence of risk factors for development of angiopathy of lower extremities in Type 2 diabetes patients in 397 diabetes patients aged 40 years and older and being treated in Hospital or Polyclinic of Police in Yerevan. The majority of the study population was males: 95% of cases and 84% of controls. Several studies found that males with diabetes were two times more likely to develop diabetes foot complication compared to females with diabetes due to behavioral and physiological peculiarities (10; 25).

The main findings demonstrated by this study were a statistically significant association between poor self-monitoring of blood glucose level (less than once a day),

duration of the disease, presence of hypertension, BMI, smoking level, and foot self-checking on a regular basis from the moment they were diagnosed with diabetes. These findings remained robust when the final model was run on the sub-sample of male study participants.

The findings of the current study regarding the association of duration of the disease and development of diabetic angiopathy of lower extremities were consistent with results from other studies, which reported mean duration of the disease for development of diabetic macro- and microangiopathy was 16 years with adjusted OR ranging from 1.22 to 1.43.

The results of the current study also indicated a higher risk of having diabetic angiopathy of lower extremities with poor self-monitoring of blood glucose level; existing literature reports adjusted OR ranging from 1.13 to 1.35 (23; 26; 60). The possible explanations of the association between poor blood glucose control and developing diabetic angiopathy of lower extremities are the following: long-standing elevated level of blood glucose level can damage small and large blood vessels, decreasing blood flow to the foot, as well as can damage the nerves of foot, and decreasing protective sensation (the ability to feel normal sensation in feet) (5; 26).

The findings of this study were consistent with the results from other studies that examined the relationship between smoking level and development of diabetic angiopathy of lower extremities (32; 33; 36; 37). Several studies indicated enhanced risk for micro- and macrovascular disease, as well as premature mortality from the combination of smoking and Type 2 diabetes (36).

Previous research also reported a statistically significant association between alcohol consumption and development of diabetic angiopathy of lower extremities (25; 33; 34). The results of the current study indicated a statistically significant association between heavy daily alcohol consumption and diabetic angiopathy of lower extremities.

Several studies have also found a protective effect of moderate alcohol consumption for development of macrovascular diabetes complication such as cardio-vascular disease (37). However, this study was unable to find this protective effect of moderate alcohol consumption due to limited data regarding diabetes complications other than diabetic angiopathy of lower extremities.

The results of the current study suggested that the presence of hypertension was a modifiable risk factor for development of diabetic angiopathy of lower extremities. and this result was consistent with findings from other studies, which presented the association of hypertension with both diabetic macro- and microangiopthy and reported adjusted OR ranging from 1.24 to 2.65 (95% CI: 1.13 - 2.41) (69; 70; 71).

The findings of the current study indicated higher risk of developing diabetic angiopathy of lower extremities among diabetes patients with higher BMI; this was consistent with results from previous studies that found that people with diabetes were commonly overweight, which nearly doubled the risk of developing diabetic angiopathy of lower extremities as well as other diabetes complications (31; 71).

The most important finding of this study was the importance of foot self-checking following the diagnosis of diabetes for preventing foot complications. The results of the current study indicated about 10 times higher risk of developing diabetic angiopathy of lower extremities among those diabetes patients who did not check their feet on a regular basis from the moment they were diagnosed with diabetes (adjusted OR= 10.20; 95% CI: 2.61, 30.51).

Although the effect of this factor is not well described in the literature, particularly in terms of OR, existing studies suggest that the risk of diabetes-related foot complications can be reduced by 49% to 85% by proper preventive measures, patient education, and appropriate foot self-care (23; 24; 78). One study suggested that the risk of developing foot ulceration in Type 2 diabetes patients was 10.3 times (OR=10.3; 95% CI: 6.33; 22.3) greater in patients

receiving standard therapy that included diabetic foot education and daily foot self-checking, than in patients receiving enhanced therapy, which also included use of an infrared skin thermometer to measure temperatures on six foot sites twice daily (79).

The results of the current study revealed that the majority of the study population (86.5% cases and 50.6% controls) did not check their feet from the moment they were diagnosed with diabetes. Previous research indicated that 33% of patients with Type 2 diabetes did not perform foot self-examination and more than 50% reported that their physician did not examine their feet (79).

4.3 Strengths of the study

- The cases and controls were identified from the medical charts based on the results of duplex- or dopler- angiography.
- The study considered all possible confounders and interactions suggested by literature.
- This study had quantitative and qualitative components, and the results were consistent.

4.4 Study limitations

- The diabetes complications other than angiopathy of lower extremities such as cardiovascular disease, renal diseases, retinopathy and neuropathy were not considered in this study.
- The study was conducted only in two health facilities chosen by convenience.
- The interviewer was aware of participants' case or control status; this could lead to a potential interviewer bias.

- Self-reported information regarding the presence of hypertension, adherence to medication and diet, physical activity was subject for reporting bias.

4.5 Recommendations

This mixed methods study identified numerous risk factors for development of diabetic angiopathy of lower extremities that warrant further investigations taking into account listed limitations.

Educational programs for diabetes patients and immediate family members are recommended regarding the diabetes self-management, especially routine self-monitoring of blood glucose level and daily foot self-checking (22; 23; 24) (see Appendix 5).

Educational programs for endocrinologists and for family physicians are recommended as well. Endocrinologists/family physicians should promote healthy lifestyle and effective ways of weight control among Type 2 diabetes patients.

Endocrinologists/family physicians should show diabetes patients how to care for their feet. Regular (at least annual) visual inspection of patients' feet, assessment of foot sensation and palpation of foot pulses by trained personnel is important for prevention of foot ulceration, gangrene or amputation (23; 81) (see Appendix 5).

5. Conclusion

This mixed methods study showed that multiple factors and mechanisms contribute to the development of diabetic angiopathy of lower extremities in Type 2 diabetes patients. Poor foot self-checking following the diagnosis of diabetes, poor self-monitoring of blood glucose level, current smoking level, presence of hypertension, BMI, and duration of the disease are predictive risk factors for angiopathy of lower extremities in Type 2 diabetes patients. The role of health care providers was essential, particularly as patients seemed to

need more information and guidance regarding the diabetes management, especially self-monitoring of blood glucose level and a daily routine of checking and caring for the feet.

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Table 1: Proposed research variables by name and type

Variable type/name	Type	Measure
Outcome (dependent) variable		
Diabetic angiopathy of lower extremities	Binary	1 (cases) or 0 (control group)
Independent variables		
Knowledge score	Numerical	Continuous variable: the number of correct responses regarding the knowledge items summed
BMI	Numerical	Continuous variable_____kg/m^2
BMI	Ordinal	1) underweight if BMI if BMI <18, 5 kg/m^2; 2) normal if BMI=18, 5-24.9 kg/m^2; 3) overweight if BMI =25-29.9 kg/m^2; 4) obesity if BMI>30kg/m^2 (52; 74)
Adherence to treatment	Binary	1 (yes) or 2 (no)
Self-monitoring of blood glucose level	Ordinal	1) 4 or more times a day; 2) 2 or 3 times a day; 3) once a day; 4) less than once a day; 5) never
Hypertension	Binary	1 (presence) or 2 (absence)
Family (diabetic) history	Nominal	1 (presence) or 2 (absence)
Duration of the disease	Numerical	Number of_____years
Smoking status	Nominal	1) never; 2) former; 3) current
Current smoking level	Numerical	Number of_____cigarettes per day
Current smoking level	Ordinal	1) mild smoker if smokes less than 10 cigarettes per day; 2) moderate smoker if smokes from 10 to 20 cigarettes per day; 3) heavy smoker if smokes more than 20 cigarettes per day (37)
Daily alcohol consumption	Ordinal	1) no alcohol use, 2) moderate alcohol consumption if consumes less than 3 drinks per day; 3) heavy alcohol consumption if consumes more than 3 drinks per day (33, 34).
Physical activity level	Binary	1) Moderate physical activity level; 2) Low physical activity level
Foot self-checking following the diagnosis of diabetes	Binary	1 (yes) or 2 (no)
Intervening Variables		
Age	Numerical	Number of _____ years
Gender	Binary	1 (male) or 2 (female)
Level of education	Ordinal	1) School (less than 10 years); 2) School (10 years); 3) Professional

		Technical education (10-13 years); 4) University/Institute (14-16 years); 5) Postgraduate
Marital status	Nominal	1) Never married; 2) Married; 3) Divorced; 4) Widow/widower
Employment status	Binary	1 (yes) or 2 (no)
Socio-economic status	Ordinal	1) less than 30,000 AMD; 2) 31,000 – 50,000 AMD; 3) 51,000 – 100,000 AMD; 4)100,000-250,000 AMD;5) more than 250,000 AMD; 88) Don't know/Not sure
Place of residence	Nominal	1) Yerevan: 2) Other cities of Armenia; 3) Marzes of Armenia

Table 2: Characteristics of study population

Variable name	Cases (n=197)	Controls (n=197)	p-value
Age (mean±SD	62±7	52±7	0.000
BMI (mean±SD)	30±4	27±5	0.000
Duration of the disease (mean±SD)	16±7	8±5	0.000
Gender			
Male	188 (95.4%)	166 (84.3%)	Fisher's exact
Female	9 (4.6%)	31 (15.7%)	0.000
Place of living			
Yerevan	111 (56.4%)	157 (79.7%)	
Other cities	32 (16.2%)	22 (11.2%)	0.000
Marzes of Armenia	54 (27.4%)	18 (9.1%)	
Job type			
Shift based	49 (24.9%)	49 (24.9%)	
Office based	49 (24.9%)	66 (33.5%)	0.128
Work without fixed hours	99 (50.2%)	82 (41.6%)	
Work/worked day shifts			
Yes	173 (87.8%)	171 (86.8%)	0.762
No	24 (22.2%)	26 (13.2%)	
Work/worked night shifts			
Yes	148 (75.1%)	131 (66.5%)	P=0.060
No	49 (24.9%)	66 (33.5%)	
Work/worked swing shifts			
Yes	99 (50.3%)	83 (42.1%)	P=0.106
No	98 (49.7%)	114 (57.9%)	
Marital status			
Never married	6 (3.1%)	3 (1.5%)	
Married	137 (69.5%)	162 (82.2%)	Fisher's exact
Divorced	2 (1.0%)	6 (3.4%)	0.002
Widow/Widower	52 (26.4%)	26 (13.2%)	
Educational level			
School (less than 10 years)	2 (1.0%)	4 (2.0%)	
School (10 years)	48 (24.4%)	33 (16.8%)	
Professional technical education (10-13 years)	96 (48.7%)	88 (44.7%)	Fisher's exact P =0.059
University/Institute (14-16 years)	51 (25.9%)	72 (36.5%)	
Postgraduate	………	………	
Socio-economic status:			
31,000-50,000 AMD	8 (4.1%)	14 (7.1%)	
51,000-100,000AMD	82 (42.6%)	64 (32.5%)	Fisher's exact
101,000-200,000 AMD	80 (40.6%)	90 (45.7%)	P=0.284
More than 200,000 AMD	21 (10.7%)	15 (7.6%)	
Spending for diabetes treatment			
Less than 30,000 AMD	29 (14.7%)	39 (19.8%)	
31,000 – 50,000 AMD	68 (34.5%)	53 (26.9%)	P=0.298
51,000 – 100,000 AMD	48 (24.8%)	61 (31.0%)	

101,000-250,000 AMD	18 (9.2%)	15 (7.6%)	
More than 250,000 AMD	33 (16.8%)	27 (13.7%)	
Employment status			
Yes	42 (21.3%)	102 (51.8%)	P=0.000
No (retired)	155 (78.7%)	95 (48.2%)	
Job Type			
Shift based	98 (24.9%)	49 (24.9%)	
Office based	115 (29.2%)	66 (33.5%)	P=0.128
Work without fixed hours	181 (45.9%)	82 (41.6%)	
Smoking status			
Current	154 (67.3%)	127 (73.4%)	Fisher's exact
Former	42 (18.3%)	38 (22.0%)	P=0.000
Never	33 (14.4%)	8 (4.6%)	
Current smoking level (# of cigarettes per day) (mean±SD)	24±7	15±9	P=0.000
Family history			
Absence	79 (40.1%)	96 (48.7%)	
Presence	83 (42.1%)	80 (40.6%)	P=0.074
Don't know	35 (17.8%)	21 (10.7%)	
Alcohol consumption			
Current	150 (76.2%)	142 (72.1%)	Fisher's exact
Former	41 (20.8%)	35 (17.7%)	P=0.015
Never	6 (3.0%)	20 (10.2%)	
Alcohol daily consumption			
Moderate	52 (34.7%)	75 (52.8%)	P=0.002
Heavy	98 (65.3%)	67 (47.2%)	
Hypertension			
Absence	124 (62.9%)	177 (89.9%)	P=0.000
Presence	73 (37.1%)	20 (10.1%)	
Self-monitoring of blood glucose level			
At least once a day	43 (21.8%)	95 (48.2%)	P=0.000
Less than once a day	154 (78.2%)	102 (51.8%)	
Physical activity level			
Low	132 (67.0%)	102 (51.8%)	P=0.002
Moderate	65 (33.0%)	95 (48.2%)	
Foot self-checking following the diagnosis of diabetes			
Yes	20 (13.5%)	52 (49.1%)	P=0.000
No	128 (86.5%)	54 (50.9%)	
Knowledge score (mean±SD)	3±1	2±1	P=0.002
Adherence to treatment (mean±SD)	3±2	2±1	P=0.000
Following proper diet (mean±SD)	4±2	5±1	P=0.006
BMI			
≤24.9	23 (11.7%)	97 (49.1%)	
25-29.9	49 (46.2%)	49 (25.0%)	P=0.000
≥30	83 (42.1%)	51 (25.9%)	
Foot checking by physician			
Every or most of the visits	122 (63.5%)	64 (32.5%)	P=0.000
At least one of the visits or never	72 (36.5%)	133 (67.5%)	

Foot checking by physician following the diagnosis	1.0	1.0	P=0.034
Yes	74 (53.6%)	47 (69.1%)	
No	64 (46.4%)	21 (30.9%)	
Patient satisfaction			
Satisfied	150 (76.1%)	151 (76.6%)	P=0.906
Dissatisfied	47 (27.9%)	46 (23.3%)	
Health care provider recommendations related to blood sugar level testing			
At least once a day	32 (16.2%)	47 (23.9%)	P=0.059
Less than once a day	165 (83.8%)	150 (76.1%)	
Health status			
Good	1 (0.5%)	12 (6.1%)	Fisher's exact
Poor	196 (95.5%)	185 (93.9%)	P=0.003
Having bodily pain			
Mild	29 (14.7%)	138 (70.0%)	P=0.000
Moderate	168 (85.3%)	59 (30.0%)	
Using non-traditional methods of diabetes treatment			
Yes	94 (47.7%)	134 (68.0%)	P=0.000
No	103 (52.3%)	63 (32.0%)	

Table 3: Simple logistic regression: testing for confounding

Variable name	Odds Ratio	95% CI	p value
BMI (continuous)	1.13	1.07-1.18	0.000
Duration of the disease (continuous)	1.24	1.18-1.30	0.000
Smoking status			
Never	1.0	1.0	1.0
Current	6.24	2.85-13.66	0.000
Former	5.94	2.51-14.05	0.000
Current smoking level (# of cigarettes per day)	1.12	1.06-1.12	0.000
Current smoking level			
Mild	1.0	1.0	1.0
Moderate	7.94	3.64-19.47	0.000
Heavy	13.87	5.85-32.90	0.000
Alcohol consumption			
Never	1.0	1.0	1.0
Current	3.52	1.38- 9.02	0.009
Former	3.90	1.41-10.80	0.009
Alcohol daily consumption			
Moderate (0-3 drinks)	1.0	1.0	1.0
Heavy (more than 3 drinks)	2.11	1.32-3.37	0.002
Self-monitoring of blood glucose level			
Once a day and more	1.0	1.0	1.0
Less than once a day	3.34	2.15-5.17	0.000
Foot self-checking following the diagnosis of diabetes			
Yes	1.0	1.0	1.0
No	6.16	3.36-11.29	0.000
Foot checking by the physician following the diagnosis			
Yes	1.0	1.0	1.0
No	1.95	1.05-3.58	0.035
Hypertension			
Absence	1.0	1.0	1.0
Presence	5.21	3.02-8.92	0.000
Physical activity level			
Low	1.0	1.0	1.0
Moderate	0.53	0.53-0.79	0.002
Family history			
Absence	1.0	1.0	1.0
Presence	1.38	1.03-1.83	0.027
Following proper diet (days per week)	0.87	0.81-0.96	0.006
Adherence to treatment (continuous)	1.61	1.37-1.87	0.000
Knowledge score (continuous)	0.72	0.60-0.86	0.006
BMI			
≤24.9	1.0	1.0	1.0
25-29.9	4.83	4.42-10.88	0.000

≥30	5.86	3.87-11.12	0.000
Using non-traditional methods of diabetes treatment			
No	1.0	1.0	1.0
Yes	2.33	1.55-3.51	0.000
Health status			
Good	1.0	1.0	1.0
Poor	12.71	1.63-48.83	0.015
Physical health problems			
No	1.0	1.0	1.0
Yes	3.68	2.84-4.9	0.000
Having bodily pain			
Mild	1.0	1.0	1.0
Moderate	13.54	8.24-23.04	0.000
Age (continuous)	1.19	1.15-1.25	0.000
Employment status			
Yes	1.0	1.0	1.0
No (retired)	3.96	3.55-6.16	0.000
Job Type			
Office based	1.0	1.0	1.0
Shift based	1.35	0.78-2.32	0.281
Work without fixed hours	1.63	1.02-2.61	0.043
Gender			
Female	1.0	1.0	1.0
Male	3.91	1.81-8.43	0.001
Place of living			
Yerevan	1.0	1.0	1.0
Other cities of Armenia	2.12	1.12-3.72	0.017
Marzes of Armenia	4.23	2.36-7.26	0.000
Educational level			
School (less than 10 years)	1.0	1.0	1.0
School (10 years)	2.91	0.52-13.08	0.233
Professional technical education (10-13 years)	2.18	0.89-12.21	0.375
University/Institute (14-16 years)	1.42	0.25- 8.03	0.694
Postgraduate	……	…..	……
Socio-economic status:			
31,000-50,000 AMD	1.0	1.0	1.0
51,000-100,000AMD	2.30	0.91-5.81	0.079
101,000-200,000 AMD	1.56	0.62-3.92	0.346
More than 200,000 AMD	2.45	0.82-7.31	0.108
Spending for diabetes treatment			
Less than 5,000 AMD	1.0	1.0	1.0
5,000 – 10,000 AMD	1.73	0.95-3.15	0.075
11,000 – 20,000 AMD	1.06	0.57-1.95	0.856
21,000 – 30,000 AMD	1.64	0.70-3.72	0.262
More than 30,000 AMD	1.61	0.82-3.32	0.164
Marital status			
Never married	1.0	1.0	1.0
Married	0.42	0.10-1.72	0.223

Divorced	1.16	0.02-1.38	0.097
Widow/Widower	…….	…...	……
Having working glucose meter			
Yes	1.0	1.0	1.0
No	1.49	0.96-2.31	0.076

Table 4: Multiple logistic regression models

	Variable name	Odds Ratio	Z	P value	95% CI	Log Likelihood Ratio test
Model 1	Duration of the disease	1.0 1.08 2.08	9.17	0.000	1.18-1.30	------
Model 2	Duration of the disease	1.14	4.72	0.000	1.08-1.20	Chi^2=20.58 P=0.0000 (compared with model 1)
	Self-monitoring of blood glucose level (less than once a day)	3.13	4.38	0.000	1.20-5.61	
	Age	1.12	5.35	0.000	1.08-1.19	
	Gender	4.12	2.75	0.006	1.12-8.86	
Model 3	Duration of the disease	1.11	3.06	0.002	1.04- 1.21	Chi^2=11.22 P=0.0008 (compared with model 2)
	Self-monitoring of blood glucose level (less than once a day)	2.72	2.85	0.004	1.59- 6.09	
	Foot checking following the diagnosis	6.29	6.62	0.000	2.72-13.70	
	Age	1.11	3.36	0.001	1.05- 1.18	
	Gender	3.22	1.86	0.063	0.93-11.65	
Model 4	Duration of the disease	1.12	2.92	0.002	1.04- 1.21	Chi^2=3.77 P=0.0521 (compared with model 3)
	Self-monitoring of blood glucose level (less than once a day)	2.78	3.32	0.004	1.61- 6.25	
	Foot checking following the diagnosis	5.98	4.33	0.000	2.58-13.11	
	Presence of hypertension	2.27	1.91	0.057	0.97- 5.36	
	Age	1.09	2.73	0.005	1.03- 1.16	
	Gender	3.22	1.85	0.064	0.93-11.15	
	The Hosmer-Lemeshow Chi-square test statistics was 7.28 (prob > Chi^2 = 0.5071)					
Model 5	Duration of the disease	1.11	2.86	0.004	1.04- 1.23	Chi^2=12.19 P=0.0005 (compared with model 4)
	Self-monitoring of blood glucose level (less than once a day)	2.76	2.75	0.006	1.51- 5.69	
	Foot checking following the diagnosis	7.74	4.67	0.000	3.16-17.88	
	Presence of hypertension	3.00	2.45	0.014	1.24- 7.22	
	BMI	1.16	3.41	0.001	1.07- 1.27	
	Age	1.10	2.82	0.003	1.03- 1.18	
	Gender	3.13	1.73	0.084	0.85-11.36	
	The Hosmer-Lemeshow Chi-square test statistics was 4.46 (prob > Chi^2 = 0.8138)					
Model 6	**Duration of the disease**	**1.14**	**2.49**	**0.013**	**1.03- 1.25**	**Chi^2=9.69 P=0.0009 (compared with model 5)**
	Self-monitoring of blood glucose level (less than once a day)	**2.78**	**2.22**	**0.038**	**1.51- 7.63**	
	Foot checking following the diagnosis	**10.20**	**4.18**	**0.000**	**2.61-30.51**	
	Presence of hypertension	**6.10**	**2.73**	**0.006**	**1.26-22.44**	
	BMI	**1.20**	**3.43**	**0.001**	**1.08- 1.34**	
	Current smoking level (# cigarette/day)	**1.11**	**4.16**	**0.000**	**1.07- 1.17**	
	Age	**1.10**	**2.24**	**0.008**	**1.01- 1.19**	
	Gender	**2.05**	**0.72**	**0.469**	**2.94-14.26**	
	The Hosmer-Lemeshow Chi-square test statistics was 6.89 (prob > Chi^2 = 0.5485)					

Model 7

Variable		z	p	CI	
Duration of the disease	1.17	2.64	0.008	1.03- 1.39	
Self-monitoring of blood glucose level	2.51	1.38	0.176	0.66- 9.34	
Foot checking following the diagnosis	11.38	3.79	0.000	3.23-40.11	Chi^2=4.23
Presence of hypertension	8.01	2.28	0.022	1.18-47.82	P=0.0397
BMI	1.14	2.04	0.042	1.01- 1.29	(compared
Current smoking level	1.09	2.94	0.003	1.03- 1.17	with model
Alcohol daily consumption (more than 3 drinks)	3.50	2.08	0.037	1.15-11.39	6)
Age	1.05	1.08	0.297	0.96- 1.15	
Gender	3.55	0.45	0.656	0.01-91.15	

The Hosmer-Lemeshow Chi-square test statistics was 5.52 (prob > Chi^2 = 0.7011)

Model 8

Variable		z	p	CI	
Duration of the disease	1.11	1.31	0.189	0.95- 1.38	
Self-monitoring of blood glucose level	2.15	0.99	0.360	0.46-11.67	
Foot checking following the diagnosis	32.44	3.23	0.001	3.22-67.52	
Presence of hypertension	3.68	1.15	0.249	0.40-33.78	Chi^2=28.74
BMI	1.33	2.85	0.004	1.11- 1.66	P=0.0000
Current smoking level	1.17	3.13	0.002	1.06- 1.29	(compared
Alcohol daily consumption (more than 3 drinks)	2.19	1.08	0.301	0.50- 9.64	with model 7)
Physical activity level	0.02	-3.67	0.000	0.06- 0.07	
Physical activity*physical health problems	4.07	3.20	0.001	1.70- 9.57	
Age	1.06	1.10	0.270	0.94- 1.16	
Gender	9.87	0.28	0.778	0.02-89.20	

The Hosmer-Lemeshow Chi-square test statistics was 3.97 (prob > Chi^2 = 0.8594)

Model 9

Variable		z	p	CI	
Duration of the disease	1.18	2.55	0.012	1.03- 1.33	
Self-monitoring of blood glucose level	3.28	1.59	0.111	0.78-14.08	
Foot checking following the diagnosis	29.00	3.95	0.000	5.75-91.13	
Presence of hypertension	5.66	1.57	0.117	0.61-49.84	Chi^2=0.35
BMI	1.15	2.10	0.035	1.02- 1.88	P=0.5583
Current smoking level	1.12	2.91	0.003	1.03- 1.20	(compared
Alcohol daily consumption (more than 3 drinks)	1.93	0.99	0.322	0.52- 7.78	with model 8)
Physical activity level	0.11	-2.60	0.010	0.02- 0.56	
Knowledge score	1.14	0.44	0.679	0.64- 2.07	
Adherence to treatment	0.95	-0.06	0.952	0.19- 4.51	
Age	1.03	0.67	0.506	0.92- 1.12	
Gender	4.73	0.34	0.738	0.28-99.56	

The Hosmer-Lemeshow Chi-square test statistics was 17.95 (prob > Chi^2 = 0.0216)

Table 5: Multiple logistic regression model for the subsample of men

Variable name	Odds Ratio	Z	P value	95% CI
Duration of the disease	1.13	2.44	0.015	1.03- 1.25
Self-monitoring of blood glucose level (less than once a day)	2.32	1.66	0.046	1.15- 6.25
Foot checking following the diagnosis of diabetes	10.17	4.15	0.001	3.40-30.38
Presence of hypertension	6.26	2.64	0.008	1.26-24.46
BMI	1.18	3.14	0.002	1.08- 1.31
Current smoking level (# cigarette/day)	1.11	3.92	0.000	1.05- 1.17
Age	1.10	2.46	0.014	1.01- 1.18

The Hosmer-Lemeshow Chi-square test statistics was 7.35 (prob > Chi^2 = 0.4994)

Figure 1: Age distribution of cases and controls

Graphs by having foot complications
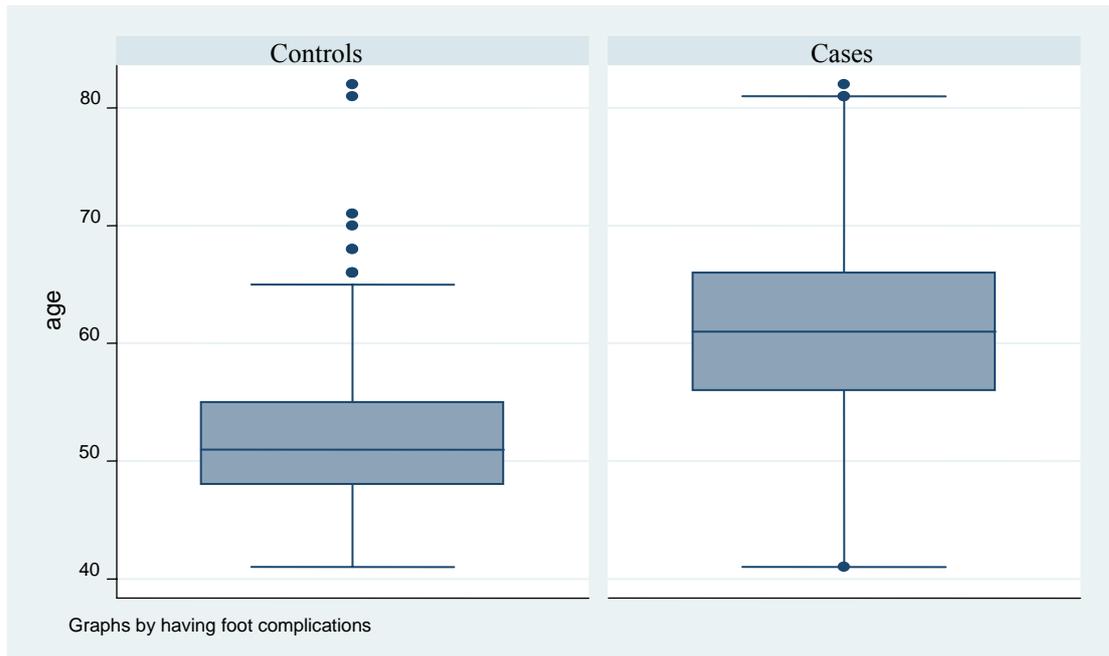
Figure 2: Distribution of cases and controls by BMI

Graphs by having foot complications
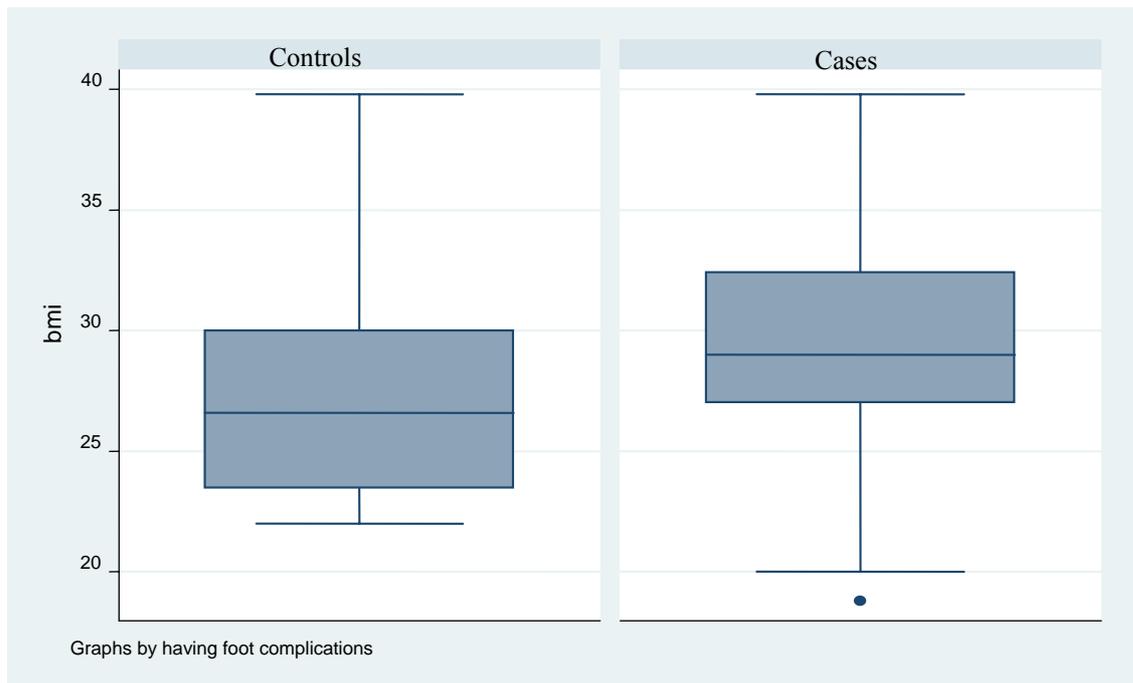
Figure 3: Distribution of cases and controls by duration of the disease

Graphs by having foot complications
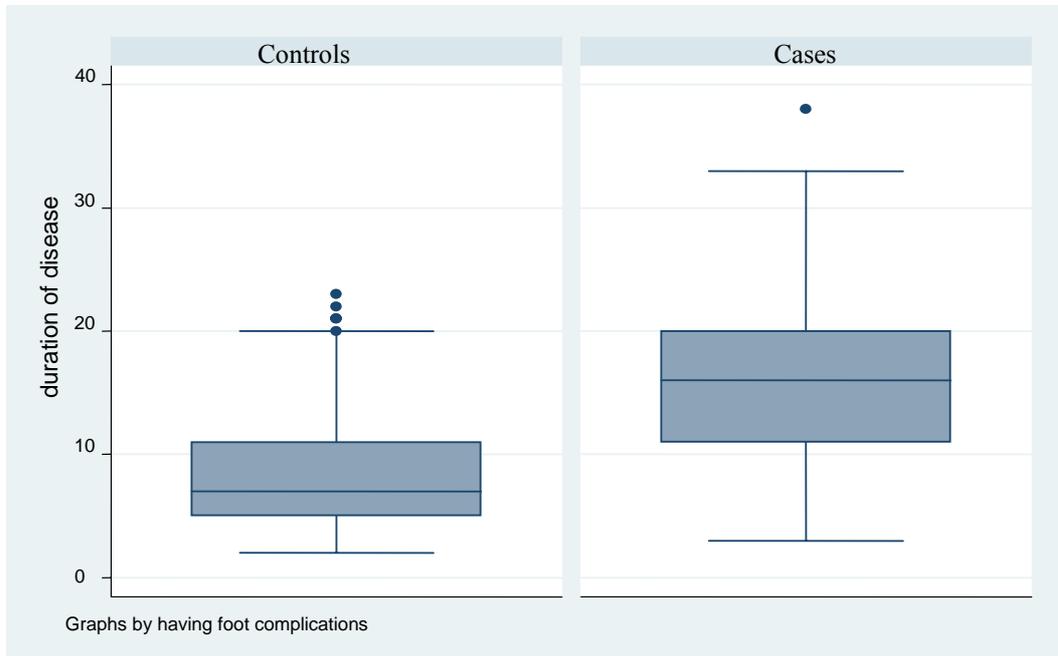
Appendixes

Appendix 1

Diabetes-related pathogenesis in the foot
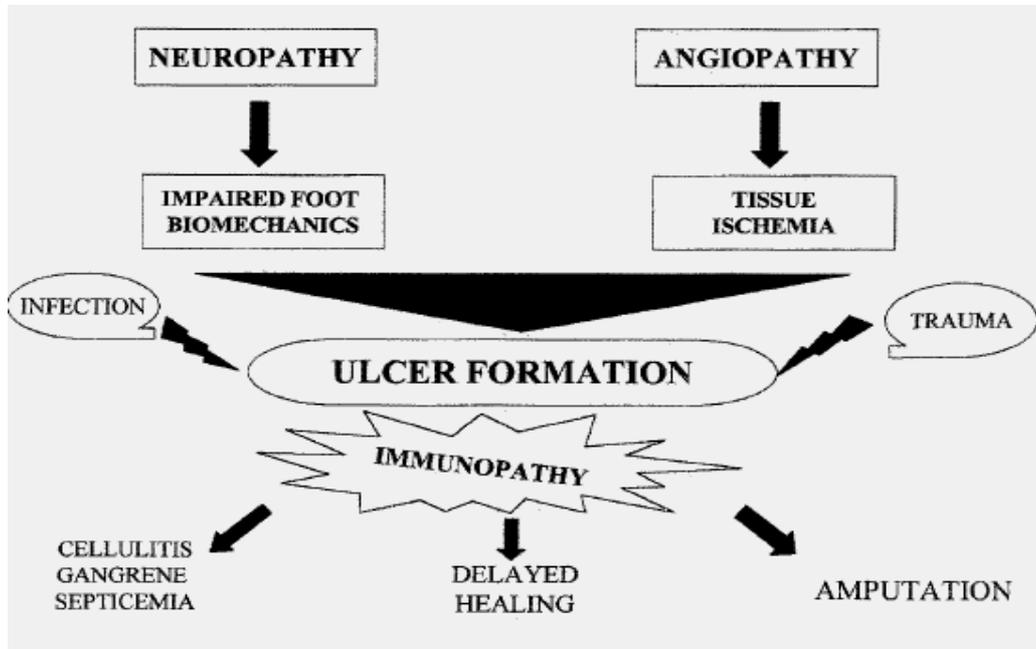
**Neuropathy—disturbance of the nervous system; Angiopathy—disturbance/abnormality of tone of the vessels; Immunopathy—pathology of immune system; Septicemia—blood purulent infection.

Source: Knokh L, Diabetic foot disease, *International Journal of Angiology,*2006, 9:1-6

Appendix 2

Mortality (Deaths) - C. Diabetes (mellitus) 2002
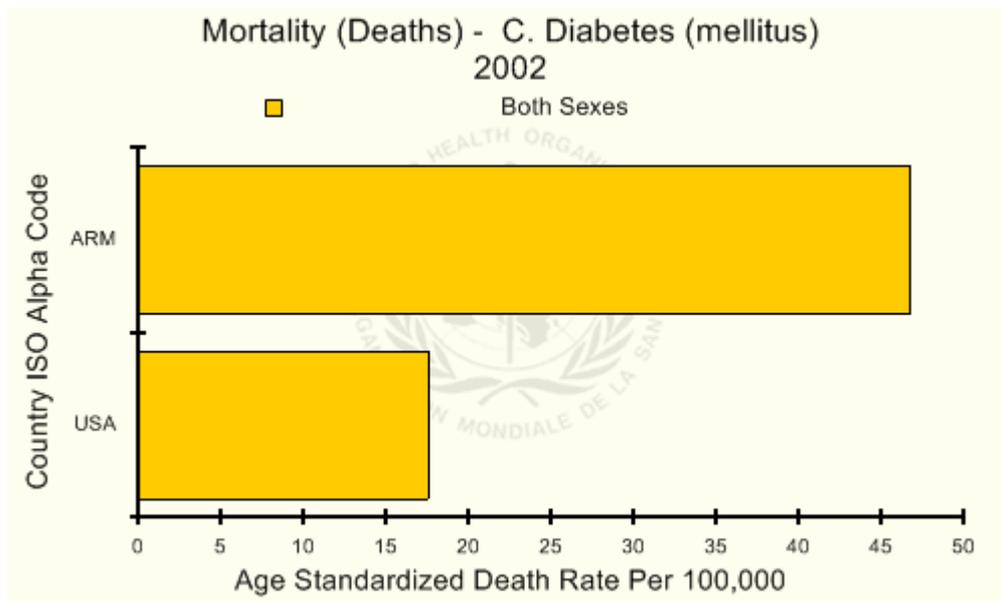
Source: Disease Risks Likely To Moderately Affect Regional Stability, Civil Society.
Institute for Intelligence studies.

Appendix 3

<u>Procedures for contact and recontact</u>

1. Someone answers to our call:

- Sorry for troubling you. Is it the _____ phone number?

- May I talk with _____?

2. It is necessary to make a maximum number of attempts to reach a number. If the number is not still reached prior to 10 days the data collection ends it will be considered as non- reached (non-contact).

3. We will let the phone ring at most seven times. If after seven times there is no answer, we will consider this call as no response. We will report it in the journal form and go ahead.

4. On busy numbers, it is necessary to call the number a maximum number of times until we reach it. If the number is not reached prior to 10 days the data collection ends it is considered as non- contact. .

5. For no response calls, we will come back to that number and after finishing the whole list until the end of the data collection.

6. If the call has been interrupted during the interview, it is necessary to call back and continue the interview.

7. If the desired person is mentioned to be not available, it is possible to make an appointment before the end of the data collection.

8. If the desired person has moved, it is possible to ask the person we will talk with if she/he has the phone number of the desired person.

9. If the desired person is willing to participate in the study but not at that particular time, we will make an appointment before the end of the data collection.

10. If the desired person is mentioned to be dead, we will apologize and present our condolence, and thank the person we are talking with. We will report this in the journal form.

11. The following journal form should be filled correctly. It is necessary for further identifying the contact rate, the refusal rate and the response rate.

Contact rate = # interviewed, #partially interviewed, #refused / All above and those not reached.

Refusal rate = # refused / Interviewed, partially interviewed, refused

Response rate = # interviewed / interviewed, part. Interviewed, refused, non-contact

For this purpose the final results will be identified by following categories:

- Partial or uncompleted interview: interviews: respondent terminated the interview part-way through it.

- Completed interview: we will complete an interview with selected respondent.

- Refused interview: selected respondent will refuse to participate in the study or will refuse to finish the entire interview.

- Non-contact: inability to contact the selected respondent.

Journal Form for quantitative study

ID	Age	Place of residence	Date of the First interview	Preliminary Results	Final Results
1					
2					
3					

Oral consent form for quantitative study

Title of Research Project: Prevalence of risk factors for development of microangiopathy of lower extremities in Type 2 diabetes patients.

Explanation of Research Project:

Dear _____,

My name is Yelena Petrosyan. I am a 2nd year student in the Master of Public Health Program at the American University of Armenia and I am working in the Hospital of Police as a physiotherapist. As a part of my Master Project, I am asking you to take part in a research study that aims to identify the most frequent conditions leading to foot complications in Type 2 diabetes patients served by the Hospital or Polyclinic of Police in Yerevan, to develop measures to help preventing these complications. You have been included in the project since you are one of the randomly selected diabetes patients, who are registered in the Hospital or Polyclinic of Police, Yerevan, and your name was obtained from the records maintained by these facilities. Your participation would be highly valuable for us. The interview will take approximately 20 minutes of your time.

Risk/Benefits

This study does not involve any kind of risks. Participation or refusal will not affect the medical care you receive. You will not receive any incentives, financial or other direct benefits. However, the obtained information will help us to explore the risk factors for diabetes foot complications and develop prevention programs.

Confidentiality

The information that you share will be confidential and anonymous. Please, be assured that your name and phone number will not be related to the information you provide. Only I have access to the table with names and phone numbers of the study participants and this information is kept locked; this table will be destroyed as soon as I finish the study. Any information that you provide will be coded and held anonymous. The collected information will be reported only as aggregate data to show the results of the survey.

Voluntariness

Your participation is absolutely voluntary. You can interrupt the conversation whenever you want and there will be no negative consequences for you. You can freely express any opinion. You can stop participating in the interview any time you want, or you can skip any questions you want. Participation or refusal will not affect the medical care you receive.

Whom to contact

If you need more information about the study, please do not hesitate to contact Varduhi Petrosyan, Associate Dean, College of Health Sciences: (010) 51 25 64, e-mail: *vpetrosi@aua.am* ; or the student-investigator Yelena Petrosyan, (093) 82 25 78, e-mail: *yelena_petrosyan@edu.aua.am*.

Thank you in advance.

<u>**Oral consent form for qualitative study**</u>

Title of Research Project: Prevalence of risk factors for development of microangiopathy of lower extremities in Type 2 diabetes patients.

Explanation of Research Project:

Dear _____,

My name is Yelena Petrosyan. I am a 2nd year MPH student at the American University of Armenia and I am working in the Hospital of Police as a physiotherapist. As a part of my Master Project, I am asking you to take part in a research study that aims to identify the most frequent conditions leading to foot complications in Type 2 diabetes patients served by the Hospital or Polyclinic of Police in Yerevan, to learn more about the experience of living with a diabetes patient, attitudes towards your own perception of diabetes management and to develop measures to help preventing these complications.

You are asked to participate in an interview, which will take about 25-30 minutes. If you do not mind, I will take notes during the interview in order not to lose any information.

Risk/Benefits

There is no risk for you as a participant in this study. You will not receive any direct benefits from participation. You will not incur any costs by participating in this study. Participation or refusal will not affect the medical care your relative with diabetes receives. However, your personal experience and participation could make a valuable input to this study and the obtained information will help us to explore the risk factors for diabetes foot complications and develop prevention programs. The only inconvenience will be your time spent on the interview.

Confidentiality

All the information will be kept confidential and anonymous. Only I have an access to the table with names and phone numbers of the study participants and this information is kept locked; this table will be destroyed as soon as I finish the study. Any information that you provide will be coded and held anonymous. The collected information will be reported only as aggregate data to show the results of the survey.

Voluntariness

Your participation in the study is voluntary. You have the right not to participate or drop out from the interview anytime.

Whom to contact

If you need more information about the study, please do not hesitate to contact Varduhi Petrosyan, Associate Dean, College of Health Sciences: (010) 51 25 64, e-mail: *vpetrosi@aua.am* ; or the student-investigator Yelena Petrosyan, (093) 82 25 78, e-mail: *yelena_petrosyan@edu.aua.am*

Thank you in advance!

Oral consent form for quantitative study (Armenian version)

<u>Հետազոտության անվանումը</u>՝ 2 տիպի շաքարային դիաբետով հիվանդների մոտ ստորին վերջույթների անգիոպատիայի առաջացման ռիսկային գործոնների տարածվածությունը:

<u>Հետազոտության բացատրությունը</u>

Իմ անունը Էլենա Պետրոսյան է: Ես Հայաստանի Ամերիկյան Համալսարանի Հանրային Առողջապահության ծրագրում ընդգրկված ավարտական կուրսի ուսանողուհի եմ և նաև աշխատում եմ Ոստիկանության Հոսպիտալում որպես ֆիզիոթերապևտ: Դիմում եմ Ձեզ այս հետազոտությանը մասնակցելու խնդրանքով (որը հանդիսանում է իմ դիպլոմային աշխատանքի մի մաս), որի նպատակներն են՝ հայտնաբերել Ոստիկանության Հոսպիտալում և Պոլիկլինիկայում բուժվող 2 տիպի շաքարային դիաբետով հիվանդների մոտ ստորին վերջույթների բարդությունների ն�ապաստող առավել հաճախ հանդիպող պատճառները և հայտնաբերել վերոհիշյալ բարդությունները կանխարգելելու միջոցներ: Լինելով պատահականության սկզբունքով ընտրված մասնակիցներից մեկը, որոնք գրանցված են Երևանի Ոստիկանության Հոսպիտալում և Պոլիկլինիկայում, Դուք ընդգրկված եք այս ծրագրում և Ձեր անունը վերցված է վերոհիշյալ հաստատությունների գրանցամատյանից: Ձեր մասնակցությունը շատ արժեքավոր է մեր համար: Հարցագրույցը կտնի մոտ 20 րոպե.

<u>Ռիսկ/Շահույթ</u>

Այս հետազոտությանը մասնակցելով՝ Դուք որևէ ռիսկի չեք դիմում: Մասնակցությունը կամ հրաժարվելը որևէ ձևով չի անդրադառնա Ձեր բուժման ընթացքի վրա: Դուք որևէ խրախուսանք, ֆինանսական կամ այլ ուղղակի շահույթներ չեք ստանա: Այնուամենայնիվ, հավաքագրված ինֆորմացիան կօգնի մեզ բացահայտել շաքարային դիաբետով հիվանդների մոտ ստորին վերջույթների բարդությունների ռիսկի գործոնները, որոնք կնպաստեն կանխարգելիչ ծրագրերի զարգացմանը:

<u>Գաղտնիություն</u>

Մեզ տրամադրված ինֆորմացիան կպահպանվի գաղտնի և անանուն: Խնդրում եմ, եղեք վստահ, որ Ձեր անունը և հեռախոսի համարը չի կցվի այն ինֆորմացիային, որը Դուք կտրամադրեք: Միայն ինձ հասանելի կլինի մասնակիցների անունների և հեռախոսահամարների ցանկը, որը կպահպանվի կողպված սենյակում, այն կոչնցացվի հետազոտության ավարտից անմիջապես հետո: Ձեր կողմից տրամադրված ինֆորմացիան կկոդավորվի և կպահպանվի անանուն: Հավաքագրված ինֆորմացիան կներկայացվի միայն որպես ընդհանրացված տվյալ՝ հետազոտության արդյունքները ցույց տալու նպատակով:

<u>Մասնակցության իրավունք</u>

Ձեր մասնակցությունը ամբողջությամբ կամավոր է: Դուք կարող եք զրույցը ընդհատել ցանկացած պահի և այն չի բերի որևէ բացասական հետևանքի: Դուք կարող եք ազատ արտահայտել Ձեր կարծիքը: Ցանկացած պահի Դուք կարող եք ընդհատել հարցազրույցը կամ կարող եք բաց թողնել ցանկացած հարց, որին չեք ուզում պատասխանել:

<u>Ում դիմել</u>

Եթե դուք ավելի շատ տեղեկատվության կարիք ունեք կապված հետազոտության հետ, կարող եք դիմել Վարդուհի Պետրոսյանին ՝Առողջապահական գիտությունների քոլեջի փոխդեկան, (010) 51 25 64, e-mail: *vpetrosi@aua.am* ; կամ Ելենա Պետրոսյանին՝ (093) 82 25 78, e-mail: *yelena_petrosyan@edu.aua.am*

Նախապես շնորհակալություն

<u>**Oral consent form for qualitative study (Armenian version)**</u>

<u>Հետազոտության անվանումը`</u> 2 տիպի շաքարային դիաբետով հիվանդների մոտ ստորին վերջույթների անգիոպատիայի առաջացման ռիսկային գործոնների տարածվածությունը:

<u>Հետազոտության բացատրությունը</u>

Իմ անունը Ելենա Պետրոսյան է: Ես Հայաստանի Ամերիկյան Համալսարանի Հանրային Առողջապահության ծրագրում ընդգրկված ավարտական կուրսի ուսանողուհի եմ և նաև աշխատում եմ Ոստիկանության Հոսպիտալում որպես ֆիզիոթերապևստ: Դիմում եմ Ձեզ այս հետազոտությանը մասնակցելու խնդրանքով (որը հանդիսանում է իմ դիպլոմային աշխատանքի մի մաս), որի նպատակներն են` հայտնաբերել Ոստիկանության Հոսպիտալում և Պոլիկլինիկայում բուժվող 2 տիպի շաքարային դիաբետով հիվանդների մոտ ստորին վերջույթների բարդություններին նպաստող, առավել հաճախ հանդիպող պատճառները, իմանալ ավելին շաքարային դիաբետով հիվանդի հետ ապրելու փորձի մասին , շաքարային դիաբետի բուժման վերաբերյալ սեփական ընկալման մասին և հայտնաբերել վերոհիշյալ բարդությունները կանխարգելու միջոցներ:

Դիմում եմ Ձեզ այս հետազոտությանը մասնակցելու խնդրանքով, որը կտևի մոտ 25-30 րոպե: Եթե Դուք դեմ չեք, ես նշումներ կկատարեմ հարցազրույցի ընթացքում ինֆորմացիա չկորցնելու նպատակով:

<u>Ռիսկ/Շահույթ</u>

Այս հետազոտությանը մասնակցելով Դուք որևէ ռիսկի չեք դիմում. Դուք որևէ շահույթ չեք ունենա կամ ֆինանսական տույժի չեք ենթարկվի մասնակցելով այս հետազոտությանը: Այնուամենայնիվ, Ձեր անձնական փորձը և մասնակցությունը արժեքավոր ներդրում կլինի այս հետազոտության համար և հավաքագրված ինֆորմացիան կօգնի մեզ բացահայտել շաքարային դիաբետով հիվանդների մոտ ոտքերի բարդությունների ռիսկ գործոնները, որոնք կնպաստեն կանխարգելիչ ծրագրերի զարգացմանը: Ձեզ պատճառված միակ անհարմարությունը կլինի այն ժամանակը, որը Դուք կտրամադրեք այս հարցազրույցին:

<u>Մասնակցության իրավունք</u>

Ձեր մասնակցությունը ամբողջությամբ կամավոր է: Դուք իրավունք ունեք չմասնակցել կամ ընդհատել հարցազրույցը ցանկացած պահի:

<u>Գաղտնիություն</u>

Մեզ տրամադրված ինֆորմացիան կպահպանվի գաղտնի և անանուն: Խնդրում եմ եղեք վստահ, որ Ձեր անունը և հեռախոսի համարը չի կցվի այն ինֆորմացիային, որը Դուք կտրամադրեք: Միայն ինձ հասանելի կլինի մասնակիցների անունների և հեռախոսահամարների ցանկը, որը կպահպանվի կողպված սենյակում, այն կոչնչացվի հետազոտության ավարտից անմիջապես հետո: Ձեր կողմից տրամադրված ինֆորմացիան կկողավորվի և կպահպանվի անանուն: Հավաքագրված ինֆորմացիան կներկայացվի միայն որպես համակարգված տվյալ՝ հետազոտության արդյունքները ցույց տալու նպատակով:

<u>Ում դիմել</u>

Եթե դուք ավելի շատ ինֆորմացիայի կարիք ունեք կապված հետազոտության հետ, կարող եք կապվել Վարդուհի Պետրոսյանին `Առողջապահական գիտությունների քոլեջի փոխդեկան, (010) 51 25 64, e-mail: *vpetrosi@aua.am* ; կամ Ելենա Պետրոսյան` (093) 82 25 78, e-mail: *yelena_petrosyan@edu.aua.am.*

Նախապես շնորհակալություն

Appendix 5

Clinical guidelines for prevention and management of foot problems in Type 2 diabetes patients (81; 82)

Guideline for diabetes patients' foot self-care

1. Washing and checking feet daily. It is necessary to check the entire surface of both feet for skin breaks, blisters, swelling, or redness, including between and undemeath the toes, where damage may be hidden.

2. Trimming nails carefully; trim toenails straight across and file the edges with an emery board or nail file.

3. Wearing shoes and socks at all times. Never walk barefoot. Wearing comfortable shoes that fit well and protect patient's feet and checking inside of shoes before wearing them.

4. Be more active, planning physical activity program.

5. Protect feet from hot and cold. Keep skin soft and smooth.

6. Screening for foot complications should be a routine part of most medical visits, but is sometimes overlooked. Do not hesitate to ask the healthcare provider for a foot check at least once a year, and more frequently if there are foot changes.

Clinical guideline for examination of diabetes patients' feet by physician

1. Care of people at low current risk of foot ulcers (normal sensation, palpable pulses) includes:

- Palpation of foot pulses

- Testing of foot sensation

- Inspection for any foot deformity and footwear

- Foot care education with each diabetes patient

2. Care of people at increased risk of foot ulcers (neuropathy or absent pulses or other risk factors) includes:

1. Arrange regular feet examinations (3-6 monthly)

At each examination:

- Inspect patient's feet
- Consider need for vascular assessment
- Evaluate footwear
- Enhance foot care education

3. Care of people at high risk of foot ulcers (neuropathy+absent pulses+ deformity or skin changes or previous ulcers) includes:

1. Arrange regular feet examinations (1-3 monthly)

At each examination:

- Inspect patient's feet
- Consider need for vascular assessment
- Evaluate and ensure the appropriate provision of intensified foot care education
- Skin and nail care

4. Care of people with foot care emergencies and foot ulcers new ulceration, swelling, discolouration) includes:

- Investigate and treat vascular insufficiency
- Initiate and supervise wound management
- Use dressings and debridement as indicated
- Use systematic antibiotic therapy for infection as indicated
- Insure an effective means of distributing foot pressures, including specialist footwear, orthotics and casts
- Try to achieve optimal blood glucose level

Appendix 2

<p style="text-align: center;">**Questionnaire**</p>

ID _____

Interview date ____/_____/_____ **(day/month/year)**

Interview start time _____ **(hours: minutes)**

Interview end time _____ **(hours: minutes)**

Answer to the questions should be marked by circling the numbers corresponding to the option participant chooses.

For example,

The capital of Armenia is
1. Yerevan
2. Gyumri

General Socio-Demographic Information

 1. What is your birth date? _____/_____/_____ (day/month/year)

2. Indicate your gender.

   1. Male

   2. Female

3. Your place of living

   1. Yerevan

   2. Other cities of Armenia

   3. Marzes of Armenia

 4. What is the highest level of education you have completed?

   1. School (less than 10 years)

   2. School (10 years)

   3. Professional technical education (10-13 years)

   4. University/Institute (14-16 years)

   5. Postgraduate

5. What is your current marital status?

   1. Never married

   2. Married

   3. Divorced

   4. Widow / Widower

6. Are you currently employed?

    1. Yes   **(Go to Q.8)**

    2. No (retired)

7. When did you retire? _____ ago

8. Please, specify the type of your job?

    1. Shift based

    2. Office work

    3. Both

    4. Other (specify) _____

9. In a typical week, do you work/worked day shifts?

    1. Yes

    2. No

    9.a. If yes, how many day shifts in a typical week?

circle one: 0 1 2 3 4 5 6 7

10. In a typical week, do you work/worked night shifts? (For example, midnight to 8:00 am)

    1. Yes

    2. No

    10.a. If yes, how many night shifts in a typical week?

circle one: 0   1 2 3 4 5 6 7

11. In a typical week, do you work/worked swing shifts?(For example, 4:00 pm to midnight)

    1. Yes

    2. No

    11.a. If yes, how many swing shifts in a typical week?

circle one: 0 1 2 3 4 5 6 7

12. About how old were you when you first learned that you had diabetes?

    _____years old

    88. Don't know/Not sure

13. Did/do anyone in your family have diabetes?

    1. Parents

    2. Grandparents

    3. Siblings

    4. None

88. Don't know/Not sure

14. Overall, how would you rate your health during the past 4 weeks?

  1. Excellent

  2. Very good

  3. Good

  4. Fair

  5. Poor

  6. Very poor

  88. Don't know/Not sure

15. During the past 4 weeks, how much did physical health problems limit your usual physical activities (such as walking or climbing stairs)?

  1. Not at all

  2. Very little

  3. Somewhat

  4. Quite a lot

  5. Could not do physical activities

  88. Don't know/Not sure

16. During the past 4 weeks, how much difficulty did you have doing your daily work, both at home and away from home, because of your physical health?

  1. None at all

  2. A little bit

  3. Some

  4. Quite a lot

  5. Could not do daily activities

  88. Don't know/Not sure

17. How much bodily pain have you had during the past 4 weeks?

  1. None

  2. Very mild

  3. Mild

  4. Moderate

  5. Severe

  6. Very severe

  88. Don't know/Not sure

18. Do you smoke cigarettes now?

1. Yes

2. No   **(Go to Q.21)**

19. **How many cigarettes do you smoke per day?**

_____ (number of cigarettes)

88. Don't Know/Not Sure

20. How old were you when you first started smoking cigarettes fairly regularly?

_____ years old.

21. Have you ever smoked?

1. Yes

2. No

22. Now, thinking about the moderate activities you do in a usual week (during last 7 days). Moderate physical activities make you breath somewhat harder than normal, such as brisk walking, bicycling, gardening, sweeping, washing windows, swimming in a regular pace, or anything else. How many days in a usual week do you do moderate physical activities for at least 10 minutes at a time?

_____Days per week

88. Don't know/Not sure

23. On days when you do moderate physical activities for at least 10 minutes at a time, how much total time per day do you spend doing these activities?

_____minutes per day

88. Don't know/Not sure

24. Now, think about the time you spent walking in the last 7 days. This includes at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, or leisure. During the last 7 days, on how many days did you walk for at least 10 minutes at a time?

_____ Days per week

88. Don't Know/Not Sure

25. How much time did you usually spend walking on one of those days?

_____minutes per day

88. Don't Know/Not Sure

**Next questions are about Diabetes Management**

26. Which of the following do you currently use to treat your diabetes? (Check all that apply)

1. Diet

2. Physical activity (Exercise).

3. Diabetes pills

4. Insulin injections

5. Not using any treatment

6. Other (specify) _____

88. Don't know/Not sure

27. Do you ever forget to take your medications?

1. Yes

2. No

28. Are you careless at times about taking your diabetes medications?

1. Yes

2. No

29. When you feel better, do you sometimes stop taking your diabetes medications?

1. Yes

2. No

30. Sometimes if you feel worse when you take your medications, do you stop taking them?

1. Yes

2. No

31. Is there a doctor you usually see for your diabetes?

1. Yes

2. No   **(Go to Q 34)**

31.a. If yes, please specify who is that doctor?

1. Polyclinic endocrinologist

2. Hospital endocrinologist

3. Other (specify) _____

32. How many times have you seen this doctor in the past 12 months?

1. Once a month

2. Twice a year

3. Once a year

4. Did not visit

33. Are you satisfied with the care you get from your doctor?

1. Very satisfied

2. Satisfied

3. Neither satisfied nor dissatisfied

4. Dissatisfied

5. Extremely dissatisfied

34. During the last 7 days, how often did you check your own blood sugar level at home?

       1. 4 or more times a day

       2. 2 or 3 times a day

       3. Once a day

       4. Less than once a day

       5. Never

       88. Don't know/Not sure

35. How do you use the results of blood sugar tests? (Check all that apply)

       1. To check or alter my diabetes tablets

       2. To check or alter the amount of insulin I take

       3. To help me decide how much physical activity I do

       4. To contact my diabetes doctor

       5. Other (specify)_____

36. How often did your doctor or health care provider recommend you test your own blood sugar level?

       1. Test 4 or more times a day

       2. Test 2 or 3 times a day

       3. Test once a day

       4. Test less than once a day

       5. Told me to test at home, but didn't say how often

       88. Don't know/Not sure

37. Do you have a working glucometer at home?

       1. Yes

       2. No

38. On average, over the past month, on how many days per week have you followed the diet?

       circle one: 0   1   2   3   4   5   6   7

       88. Don't know/Not sure

39. Have you ever had or were treated for high blood pressure?

       1. Yes

2. No

40. Please provide the last reading of your blood pressure_____ mm Hg

41. Did/do you (or someone in your family) regularly check your feet, including between your toes?

      1. Yes

      2. No   **(Go to Q. 45)**

      3. Not applicable (both feet amputated)

      88. Don't know/Not sure

42 If yes, during the last 12 months, how often did you check your feet?

      1. Once a year

      2. 2 or 3 times a year

      3. Once a month

      4. 2 or 3 times a month

      5. Once a week

      6. 2 or 3 times a week

      88. Don't know/Not sure

43. Are you (or someone in your family) checking you feet on a regular basis from the moment you were diagnosed with diabetes?

      1. Yes

      2. No

44. If no, please specify when you (or someone in your family) started regular checking your feet? _____

45. During the last 12 months, how often did your doctor or health care provider examine your feet?

      1. Every visit

      2. Most of the visits

      3. At least one of the visits

      4. None of the visits

      5. Not applicable (both feet amputated)

      88. Don't know/Not sure

46. Is your doctor or health care provider examining your feet on a regular basis from the moment you were diagnosed with diabetes?

      1. Yes   **(Go to Q. 48)**

2. No

47. If no, please specify when your doctor or health care provider started regular checking your feet? _____

48. Have you ever had a toe, foot or leg amputated?

1. Yes

2. No   **(Go to Q. 49 and 50)**

48.a. If yes, how old were you, when your toe, foot or leg was amputated?

_____ years old.   **(Go to Q 49.a and 50.a)**

49. What is your current weight? _____ kg.

49.a. Please state your weight before amputation _____ kg.

50. What is your height? _____ m.

50.a. Please state your height before amputation _____ m.

__Knowledge about diabetes__

51. I can avoid complications of diabetes

1. Strongly agree

2. Agree

3. Neither agree nor disagree

4. Disagree

5. Strongly disagree

88. Don't know/Not sure

52. Complications may occur if diabetes is poorly controlled

1. Yes

2. No

88. Don't know/Not sure

53. Good blood sugar control is a matter of luck

1. Strongly agree

2. Agree

3. Neither agree nor disagree

4. Disagree

5. Strongly disagree

88. Don't know/Not sure

54. What is a normal blood sugar level? _____ mm/l

55. Which of the following is highest in carbohydrates?

       1. Baked chicken

       2. Dutch cheese

       3. Baked potato

       4. Dairy butter

       88. Don't know/Not sure

56. Which of the following is highest in fat?

       1. Low fat milk

       2. Orange juice

       3. Bread

       4. Honey

       88. Don't know/Not sure

57. Which of the following foods provides low fat protein?

       1. Broiled fish

       2. Dutch cheese

       3. Carrots

       4. Chocolate

       88. Don't know/Not sure

58. Last month, the approximate amount of household income spent by all of your household members was:

       1. Less than 30,000 AMD

       2. 31,000 – 50,000 AMD

       3. 51,000 – 100,000 AMD

       4. 101,000-250,000 AMD

       4. More than 250,000 AMD

       88. Don't know/Not sure   .

59. How much money do you spend to treat and manage your diabetes per month on average?

       1. Less than 5,000 AMD

       2. 5,000 – 10,000 AMD

       3. 11,000 – 20,000 AMD

       4. 21,000 – 30,000 AMD

       5. More than 30,000 AMD

       88. Don't know/Not sure

60. How often do you have a drink containing alcohol?

       1. Never

       2. Used to drink, but don't drink any more

       3. Once a month or less

       4. Two to four times a month

       5. Two to three times a week

       6. Four or more times a week

       88. Don't know/Not sure

61. How many drinks containing alcohol do you have on a typical day when you are drinking?

       1. 1 or 2 drinks

       2. 3 or 4 drinks

       3. 5 or 6 drinks

       4. 7 or more drinks

       88. Don't know/Not sure

62. How often do you have five or more drinks on one occasion?

       1. Never

       2. Less than monthly

       3. Monthly

       4. Weekly

       5. Daily or almost daily

       88. Don't know/Not sure

Thank you so much for your time and effort!

Հարցաշար

Հարցագրույցի ամսաթիվը _____/_____/_____(օր/ամիս/տարի)

Հարցագրույցի սկսելու ժամը_____ (ժամ:րոպե)

Հարցագրույցի ավարտի ժամը_____(ժամ:րոպե)

Հարցերի պատասխանը պետք է նշվի շրջանակի մեջ վերցնելով այն թիվը, որը համապատասխանում է հարցագրույցի մասնակցի կողմից ընտրված տարբերակին: Օրինակ`

Հայաստանի մայրաքաղաքն է

① Երևանը

2. Գյումրին

Ընդհանուր Սոցիոդեմոգրաֆիկ տեղեկատվություն

1. Ո՞րն է Ձեր ծննդյան տարեթիվը. _____/_____/_____ օր/ամիս/տարի)

2. Նշեք Ձեր սեռը.

        1. Արական

        2. Իգական

3. Ձեր բնակավայրը.

        1. Երևան

        2. Հայաստանի այլ քաղաքներ

        3. Հայաստանի մարզեր

4. Նշեք ամենաբարձր կրթությունը, որ Դուք ստացել եք.

        1. Թերի միջնակարգ դպրոց (10 տարուց պակաս)

        2. Միջնակարգ (դպրոց, 10 տարի)

        3. Միջին մասնագիտական (ուսումնարան, 10-13 տարի)

        4. Բարձրագույն (ինստիտուտ կամ համալսարան)

        5.Հետդիպլոմային (մագիստրատուրա,ասպիրանտուրա, դոկտորանտուրա)

5. Ինչպիսի՞ն է Ձեր ընտանեկան կարգավիճակը.

        1. Չամուսնացած

        2. Ամուսնացած

        3. Ամուսնալուծված

4. Այրի/ ամուրի

6. Այժմ Դուք աշխատու՞մ եք.

        1. Այո   (Անցնել Հ.8)

        2. Ոչ (թոշակառու)

7. Ե՞րբ եք Դուք թոշակի գնացել. _____առաջ

8. Ի՞նչ բնույթ ունի/ուներ Ձեր աշխատանքը.

        1. Հերթափոխային

        2. Օֆիսային

        3. Երկուսն էլ

        4. Այլ (նշտել)_____

9. Շաբաթվա ընթացքում, Դուք ցերեկային հերթափոխո՞վ եք աշխատում /աշխատել եք. (Օրինակ՝ ից միՖև կեսգիշեր)

        1. Այո

        2. Ոչ

  9. ա. Եթե այո, ապա քանի՞ օր շաբաթվա ընթացքում.

    Նշեք մեկը. 0   1   2   3   4   5   6   7

10. Շաբաթվա ընթացքում, Դուք գիշերային հերթափոխո՞վ եք աշխատում /աշխատել եք. (Օրինակ՝ կեսգիշերից միՖև առավոտյան 8:00)

        1. Այո

        2. Ոչ

  10.ա. Եթե այո, ապա քանի՞ օր շաբաթվա ընթացքում. .

    Նշեք մեկը : 0   1   2   3   4   5   6   7

11. Շաբաթվա ընթացքում, Դուք երեկոյան հերթափոխո՞վ եք աշխատում /աշխատել եք. (Օրինակ՝ 16:00 միՖև կեսգիշեր)

        1. Այո

        2. Ոչ

  11. ա. Եթե այո, ապա քանի՞ օր շաբաթվա ընթացքում.

    Նշեք մեկը : 0   1   2   3   4   5   6   7

12. Մոտավորապես Դուք քանի՞ տարեկան եիք, երբ առաջին անգամ իմացաք որ Դուք շաքարախտ ունեք. _____ տարեկան

13. Ձեր ընտանիքի անդամներից որևէ մեկը ունի՞/ ուներ շաքարախտ.

        1. Ծնողները

        2. Պապիկները/ տատիկները

        3. Եղբայրները/ Քույրերը

4. Ոչ ոք

88. Չգիտեմ/ Դժվարանում եմ պատասխանել

14. Ընդհանուր առմամբ. ինչպե՞ս կգնահատեք Ձեր առողջական վիճակը անցած 4 շաբաթվա ընթացքում.

1. Գերազանց

2. Շատ լավ

3. Լավ

4. Բավարար

5. Վատ

6. Շատ վատ

88. Չգիտեմ/ Դժվարանում եմ պատասխանել

15. Անցած 4 շաբաթվա ընթացքում ինչքանո՞վ է Ձեր առողջական վիճակը սահմանափակել Ձեր առօրյա ֆիզիկական ակտիվությունը. (Օրինակ՝ քայլել կամ աստիճաններ բարձրանալ)

1. Ամենևին չի ազդել

2 Շատ քիչ

3. Մի քիչ

4. Բավականին

5. Չէի կարող ֆիզիկապես ակտիվ լինել

88. Չգիտեմ/ Դժվարանում եմ պատասխանել

16. Անցած 4 շաբաթվա ընթացքում Ձեր առողջական վիճակը ինչքանո՞վ է դժվարեցրել Ձեր առօրյա աշխատանքը տանը կամ դրսում.

1. Ամենևին չի ազդել

2 Շատ քիչ

3. Մի քիչ

4. Բավականին

5. Չէի կարող ֆիզիկապես ակտիվ լինել

88. Չգիտեմ/ Դժվարանում եմ պատասխանել

17. Անցած 4 շաբաթվա ընթացքում ի՞նչ աստիճանի ֆիզիկական/ մարմնական ցավ եք ունեցել,

1. Չեմ ունեցել

2. Աննշան

3. Թույլ

4. Բավականին

5. Սուր

6. Շատ սուր

88. Չգիտեմ/ Դժվարանում եմ պատասխանել

18. Այժմ Դուք ծխու՞մ եք.

1. Այո

2. Ոչ (Անցնել Հ. 21)

19. Քանի՞ գլանակ եք ծխում մեկ օրվա ընթացքում.

_____գլանակ

88. Չգիտեմ/ Դժվարանում եմ պատասխանել

20. Դուք քանի՞ տարեկան եիք երբ սկսեցիք կանոնավոր ծխել.

_____տարեկան

21. Դուք երբևիցե ծխե՞լ եք.

1. Այո

2. Ոչ

22. Այժմ մտածեք միջին ջանք պահանջող ֆիզիկական_գործողությունների մասին, որոնք սովորականից մի փոքր են արագացնում Ձեր շնչառությունը և կարող են ներառել արագ_q քայլը, հեծանիվ վարելը, պարտեզում աշխատելը, հատակը ավլելը, պատուհան լվալը, լոդանալը և այլն: Վերջին 7 օրվա ընթացքում քանի՞ օր եք կատարել միջին ջանք պահանջող ֆիզիկական գործողություն ամենաքիչը 10 րոպեի ընթացքում.

_____ օր շաբաթվա ընթացքում

88. Չգիտեմ/ Դժվարանում եմ պատասխանել

23. Որքա՞ն ժամանակ եք Դուք սովորաբար ծախսում միջին ջանք պահանջող ֆիզիկական գործողությունների վրա այդ օրերին.

_____ րոպե մեկ օրում

88. Չգիտեմ/ Դժվարանում եմ պատասխանել

24. Այժմ մտածեք այն ժամանակի մասին, որ Դուք ծախսել եք գրոնելու / ոտքով քայլելու վրա վերջին 7 օրվա ընթացքում: Այն ներառում է տանը, աշխատանքի վայրում կամ դրսում քայլելը, մի վայրից մյուսը ոտքով տեղափոխվելը, հանգստի, ժամանցի կամ մարզվելու նպատակով կատարվող գրոսանքը: Վերջին 7 օրվա ընթացքում քանի՞ օր եք Դուք գրոնել/ ոտքով քայլել ամենաքիչը 10 րոպեի ընթացքում.

_____ օր շաբաթվա ընթացքում

88. Չգիտեմ/ Դժվարանում եմ պատասխանել

25. Որքա՞ն ժամանակ եք Դուք ծախսել գրոսնելու/ ոտքով քայլելու վրա այդ օրերին.

_____ րոպե մեկ օրում

88. Չգիտեմ/ Դժվարանում եմ պատասխանել

<u>Հաջորդող հարցերը Շաքարային Դիաբետի բուժման և դեկավարման մասին են:</u>

26. Նշվածներից ո՞րն եք ներկայումս օգտագործում Ձեր շաքարախտի բուժման նպատակով. (*Նշեք բոլոր հնարավոր պատասխանները*)

     1. Դիետա (Սննդակարգ)

     2. Ֆիզիկական ակտիվություն (վարժություններ)

     3. Շաքարախտի դեմ հաբեր

     4. Ինսուլինի ներարկում

     5. Ոչ մի բուժում չեմ ընդունում

     6. Այլ (ճշտել)_____

     88. Չգիտեմ/ Դժվարանում եմ պատասխանել

27. Երբևիցե Դուք մոռանու՞մ եք ընդունել շաքարախտի դեմ Ձեր դեղորայքը.

      1. Այո

      2. Ոչ

28. Արդյո՞ք երբեմն Դուք անհետևողական եք շաքարախտի դեմ Ձեր դեղորայքը ժամանակին ընդունելու հարցում.

      1. Այո

      2. Ոչ

29. Երբ Դուք Ձեզ լավ եք զգում. Դուք որո՞շ ժամանակով դադարեցնու՞մ եք շաքարախտի դեմ դեղորայքի ընդունումը.

      1. Այո

      2. Ոչ

30. Երբեմն երբ դեղորայքն ընդունելիս Դուք ձեզ ավելի վատ եք զգում. Դուք դադարեցնու՞մ եք շաքարախտի դեմ դեղորայքի ընդունումը.

      1. Այո

      2. Ոչ

31. Կա՞ արդյոք որևէ բժիշկ, որին Դուք սովորաբար այցելում եք շաքարախտի պատճառով.

      1. Այո

      2. Ոչ   (Անցնել Հ. 34)

31.ա. Եթե այո, ապա ո՞վ է այդ բժիշկը.

        1. Ոստիկանության Պոլիկլինիկայի էնդոկրինոլոգ

        2. Ոստիկանության Հոսպիտալի էնդոկրինոլոգ

        3. Այլ (նշտել) _____

32. Քանի՞ անգամ եք այցելել այդ բժիկին անցած 12 ամսվա ընթացքում շաքարախտի կապակցությամբ.

        1. Ամիսը մեկ

        2. Տարին 2 անգամ

        3. Տարին մեկ

        4. Չեմ այցելել

33. Արդյոք Դուք բավարարվա՞ծ եք Ձեր բժշկի կողմից տրամադրված բուժօգնությունից.

        1. Շատ բավարարված

        2. Բավարարված

        3. Ոչ բավարարված ոչ էլ չբավարարված

        4. Չբավարարված

        5. Ծայրահեղ չբավարարված

34. Անցած 7 օրվա ընթացքում ի՞նչ հաճախականությամբ եք Դուք չափել Ձեր արյան մեջ շաքարի պարունակությունը.

        1. Օրը 4 անգամ

        2. Օրը 2 կամ 3 անգամ

        3. Օրը 1 անգամ

        4. Ավելի քիչ քան օրը 1 անգամ

        5. Երբեք

        88. Չգիտեմ/ Դժվարանում եմ պատասխանել

35. Ինչպե՞ս եք օգտագործում Ձեր արյան շաքարի պարունակության ստուգման արդյունքները.

        1. Ստուգել կամ փոխել շաքարի հաբերը

        2. Ստուգել կամ փոխել ներարկվող ինսուլինի քանակությունը

        3. Օգնում է վրրոշել ֆիզիկական ակտիվության տևողությունը

        4. Կապվել իմ բժշկի հետ

        5. Այլ (նշտել) _____

36. Ձեր բժիշկը ի՞նչ հաճախականությամբ է խորհուրդ տվել Ձեզ չափել արյան մեջ շաքարի պարունակությունը։

        1. Չափել օրը 4 անգամ

        2. Չափել օրը 2 կամ 3 անգամ

        3. Չափել օրը մեկ անգամ

        4. Չափել ավելի քիչ քան օրը 1 անգամ

        5. Խորհուրդ է տվել չափել տանը, բայց չի ասել թե քանի անգամ

        88. Չգիտեմ/ Դժվարանում եմ պատասխանել

37. Տանը ունե՞ք աշխատող գլյուկոմետր / արյան մեջ շաքարի պարունակությունը որոշող սարք.

        1. Այո

        2. Ոչ

38. Անցյալ ամսվա ընթացքում. միջինում մոտավորապես շաբաթվա քանի՞ օրն եք Դուք հետևել Ձեր սննդակարգին.

        Նշեք մեկը. 0 1 2 3 4 5 6 7

        88. Չգիտեմ/ Դժվարանում եմ պատասխանել

39. Դուք երբևիցե բուժվե՞լ եք արյան բարձր ճնշումից.

        1. Այո

        2. Ոչ

40. Խնդրում եմ Ձեզ ներկայացնել Ձեր արյան ճնշման վերջին ցուցանիշը.

        _____ մմ/սս

41. Արդյո՞ք Դուք (կամ տաք անդամներից որևէ մեկ) պանբերաբար զննում եք Ձեր ոտքերը՝ ներառյալ ոտքի մատերի ախանքները.

        1. Այո

        2. Ոչ   (Անցնել Հ.45)

        3. Անհնար է պատասխանել (ոտքերը ամպուտացված են)

        88. Չգիտեմ/ Դժվարանում եմ պատասխանել

42. Վերջին 12 ամսվա ընթացքում ի՞նչ հաճախականությամբ եք Դուք զննել Ձեր ոտքերը.

        1. Տարին մեկ

        2 Տարին 2 կամ 3 անգամ

        3. Ամիսը մեկ

        4. Ամիսը 2 կամ 3 անգամ

        5. Շաբաթը մեկ

6. Շաբաթը 2 կամ 3 անգամ

88. Չգիտեմ/ Դժվարանում եմ պատասխանել

43. Արդյո՞ք Դուք (կամ Ձեր ընտանիքի անդամներից որևէ մեկը) պարբերաբար զննում եք Ձեր ոտքերը Ձեզ մոտ շաքարախտը հայտնաբերելուց ի վեր.

1. Այո

2. Ոչ

44. Եթե ոչ, ապա նշեք խնդրում եմ թե Դուք (կամ Ձեր ընտանիքի անդամներից որևէ մեկը) ե՞րբ սկսեցիք պարբերաբար զննել Ձեր ոտքերը.

_____-

45. Վերջին 12 ամսվա ընթացքում ի՞նչ հաճախականությամբ է Ձեր բժիշկը զննել Ձեր ոտքերը.

1. Յուրաքանչյուր այցելության ժամանակ

2. Այցելությունների մեծամասնության ժամանակ

3. Այցելություններից մեկի ժամանակ

4. Այցելություններից ոչ մեկի ժամանակ

5. Անհնար է պատասխանել (ոտքերը ամպուտացված են)

88. Չգիտեմ/ Դժվարանում եմ պատասխանել

46. Արդյոք Ձեր բժիշկը պարբերաբար զննու՞մ է Ձեր ոտքերը Ձեզ մոտ շաքարախտը հայտնաբերելուց ի վեր.

1. Այո   (Անցնել Հ. 48)

2. Ոչ

47. Եթե ոչ, ապա նշեք խնդրում եմ թե Ձեր բժիշկը ե՞րբ սկսեց պարբերաբար զննել Ձեր ոտքերը.

_____

48. Երբևէ ենթարկվե՞լ եք ամպուտացիայի (մատը, թաքը, ոտքը).

1. Այո (Անցնել Հ. 49 և 50)

2. Ոչ

48.ա. Քանի՞ տարեկան էիք, երբ Ձեր ոտքը, թաքը կամ մատը ամպուտացվեց.

_____ տարեկան (Անցնել Հ. 49.ա. և 50.ա.)

49. Որն է Ձեր ներկա քաշը. _____կգ

49.ա. Խնդրում եմ նշեք Ձեր քաշը ամպուտացիայից առաջ. _____կգ

50. Որն է Ձեր հասակը. _____մ

 50.ա. Խնդրում եմ նշեք Ձեր հասակը ամպուտացիայից առաջ_____մ

*Շաքարային Դիաբետի մասին գիտելիքն*եր.
51. Ես կարող եմ խուսափել շաքարախտի բարդություններից.

>   1. Միանգամայն համաձայն եմ

>   2. Համաձայն եմ

>   3. Ոչ համայն եմ, ոչ էլ համաձայն չեմ

>   4. Համաձայն չեմ

>   5. Ամենևին համաձայն չեմ

>   88. Չգիտեմ/ Դժվարանում եմ պատասխանել

52. Շաքարախտի թերի վերահսկման դեպքում հնարավոր է բարդությունների առաջացում.

>   1. Այո

>   2. Ոչ

>   88. Չգիտեմ/ Դժվարանում եմ պատասխանել

 53. Արյան մեջ շաքարի լավ վերահսկումը բախտի բան է.

>   1. Միանգամայն համաձայն եմ

>   2. Համաձայն եմ

>   3. Ոչ համայն եմ, ոչ էլ համաձայն չեմ

>   4. Համաձայն չեմ

>   5. Ամենևին համաձայն չեմ

>   88. Չգիտեմ/ Դժվարանում եմ պատասխանել

54. Ո՞րն է նորմալ շաքարի պարունակությունը արյան մեջ. _____մմ/լ

55. Նշվածներից որի՞ մեջ է ամենաշատ ածխաջրերի պարունակությունը.

>   1. Տապակած հավ

>   2. Հոլանդական պանիր

>   3. Տապակած կարտոֆիլ

>   4. Կարագ

>   88. Չգիտեմ/ Դժվարանում եմ պատասխանել

56. Նշվածներից որի՞ մեջ է ամենաշատ ճարպի պարունակությունը.

    1. Ցածր յուղայնությամբ կաթ

    2. Նարնջի հյութ

    3. Հաց

    4. Մեղր

    88. Չգիտեմ/ Դժվարանում եմ պատասխանել

57. Նշվածներից ո՞րն է պարունակում ցածրկալորիականությամբ սպիտակուցներ.

    1. Խորոված ձուկ

    2. Հոլանդական պանիր

    3. Գազար

    4. Շոկոլադ

    88. Չգիտեմ/ Դժվարանում եմ պատասխանել

58. Մոտավորապես որքա՞ն գումար է ծախսել Ձեր ընտանիքը անցած ամսվա ընթացքում՝ հաշվի առնելով ընտանիքի բոլոր անդամների կողմից կատարված ծախսերը. *(Կարդացեք պատասխանները)*

    1. 30000 դրամից քիչ

    2. 31000-50000 դրամ

    3. 51000-100000 դրամ

    4. 101000-250000 դրամ

    5. 250000 դրամից ավել

    88. Չգիտեմ/ Դժվարանում եմ պատասխանել

59. Միջինում ո՞րքան գումար եք Դուք հատկացնում Ձեր շաքարախտի բուժմանը մեկ ամսվա ընթացքում.

    1. 5000 դրամից քիչ

    2. 5000-10000 դրամ

    3. 11000-20000 դրամ

    4. 21000-30000 դրամ

    5. 30000 դրամից շատ

    88. Չգիտեմ/ Դժվարանում եմ պատասխանել

60. Ի՞նչ հաճախականությամբ եք Դուք խմում ալկոհոլ պարունակող խմիչքներ.

    1. Երբեք

    2. Ունեի նման սովորություն, բայց այլևս չեմ օգտագործում

    3. Ամիսը մեկ կամ ավելի քիչ

4. Ամիսը 2-4 անգամ

5. Շաբաթական 2-3 անգամ

6. Շաբաթական 4 անգամ կամ ավել

88. Չգիտեմ/ Դժվարանում եմ պատասխանել

61. Ալկոհոլային խմիչք օգտագործելիս սովորաբար քանի՞ բաժակ եք խմում.

1. 1 կամ 2 բաժակ

2. 3 կամ 4 բաժակ

3. 5 կամ 6 բաժակ

4. 7 բաժակ կամ ավել

88. Չգիտեմ/ Դժվարանում եմ պատասխանել

62. Հաճա՞խ է պատահում արդյոք, որ առիթի դեպքում Դուք խմում եք 5 կամ ավելի բաժակ ալկոհոլ պարունակող խմիչքներ.

1. Երբեք

2. Ավելի քիչ քան ամեն ամիս

3. Ամեն ամիս

4. Ամեն շաբաթ

5. Ամեն օր կամ համարյա ամեն օր

88. Չգիտեմ/ Դժվարանում եմ պատասխանել

Շնորհակալություն Ձեր տրամադրած ժամանակի և ջանքերի համար

In-depth interview guide

Demographic information:

- **Gender**

                    1. Male   □   2. Female □

- **How old are you?**   _____ years old

- **What is the highest level of education you have completed?**

  1. School (less than 10 years)   □

  2. School (10 years)   □

  3. Professional technical education (10-13 years)   □

  4. University/Institute (14-16 years)   □

  5. Postgraduate   □

- **Are you currently employed?**

                              1. Yes.   □

                              2. No   □

- **Occupation**

                    1. Technical   □

                    2. Professional   □

                    3. Other (specify) _____

- **What is your relationship with a diabetes patient?**

                         1. Parent   □

                         2. Child   □

                         3. Spouse   □

                         4. Other (specify)_____

Interview questions:

1. Tell me what you know about diabetes.

- Probe: I am interested in anything you might have to say.

2. **Tell me please what was your emotional or psychological reaction when you learn that your relative has diabetes?**

- Probe: I am interested in any reactions you recall having at that time.

- Probe: Sometimes emotions can be very strong or difficult to describe so take your time.

3. **How does your family member's diabetes affect your family life?**
- Probe: I am interested in any effects you think are connected to having diabetes in the family.

4. **Tell me how you think diabetes is treated. Just list your ideas for me.**
- Probe: I am interested in conventional medical treatment as well as other treatments and remedies families might use.

5. **Tell me what you think about the diet and exercise recommended to your relative with diabetes.**

6. **Tell me what you think are the consequences of diabetes. Just list your ideas again**.
- Probe: I am interested in the complications, consequences, or changes that you think diabetes can lead to.

7. **Tell me how you think diabetes complications can be prevented.**
- Probe: just list your ideas for me.
8. **Is there anything that you would like to tell me that we have not discussed yet?**

Thank you very much for your time and participation!

<u>Խորացված հարցագրույցի ուղեցույց</u>

<u>*Դեմոգրաֆիկ տեղեկատվություն*</u>

- Ձեր սեռը.

  1. Արական   ☐

  2. Իգական   ☐

- Քանի՞ տարեկան եք. _____տարեկան

- Նշեք ամենաբարձր կրթությունը, որ Դուք ստացել եք.

  1. Թերի միջնակարգ (դպրոց, 10 տարուց ապակաս)   ☐

  2. Միջնակարգ (դպրոց, 10 տարի)   ☐

  3. Միջին մասնագիտական (ուսումնարան, 10-13 տարի)   ☐

  4. Բարձրագույն (ինստիտուտ կամ համալսարան)   ☐

  5. Հետդիպլոմային (մագիստրատուրա, ասպիրանտուրա, դոկտորանտուրա)

- Այժմ Դուք աշխատու՞մ եք.

  1. Այո   ☐

  2. Ոչ   ☐

- Ձեր մասնագիտությունը.

  1.Տեխնիկական   ☐

  2. Մտավոր   ☐

  3.Այլ (նշտել)_____

- Ո՞րն է Ձեր ազգակցական կապը շաքարային դիաբետով հիվանդի հետ.

  1. Ծնող   ☐

  2. Երեխա   ☐

  3. Ամուսին   ☐

  4. Այլ (նշտել)_____

<u>*Հարցագրույցի հարցեր*</u>

1. Ի՞նչ կարող եք ասել շաքարային դիաբետի (շաքարախտի) մասին:

- Նշտում` Ես հետաքրքրված եմ ցանկացած տեղեկությամբ, որին Դուք տիրապետում եք և կուզենայիք տրամադրել:

2. Ասացեք խնդրեմ, ինչպիսի՞ն էր Ձեր էմոցիոնալ կամ հոգեբանական ռեակցիան, երբ ձեր հարազատը ասեց, որ ինքը ունի շաքարային դիաբետ:

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- Նշտում՝ Ես հետաքրքրված եմ Ձեր մտաբերած ցանկացած ռեակցիայով, որը Դուք ունեիք այդ պահին:
- Նշտում՝ Երբեմն զգացմունքները կարող են լինել շատ ծանր և դժվար արտահայտվող, կարող եք չշտապել պատասխանելիս:

3. Ինչպե՞ս է Ձեր ընտանիքի անդամի շաքարային դիաբետը ազդում Ձեր ընտանեկան կյանքի վրա:
- Նշտում՝ Ես հատաքրքրված եմ ցանկացած ազդեցությամբ, որը կապված է ընտանիքում շաքարային դիաբետով տառապող հիվանդ ունենալու հետ:

4. Ասացեք խնդրեմ, ըստ Ձեզ ինչպե՞ս է շաքարային դիաբետը բուժվում: Կարող եք ուղղակի թվարկել Ձեր մտքերը:
- Նշտում՝ Ինձ հատաքրքրում է Ձեր կարծիքը կապված ավանդական դեղորայքային բուժման, ինչպես նաև այլ՝ ոչ ավանդական մեթոդների վերաբերյալ:

5. Ասացեք խնդրեմ ի՞նչ եք մտածում Ձեր շաքարային դիաբետով տառապող հարազատին նշանակված սննդակարգի և վարժությունների վերաբերյալ:

6. Ձեր կարծիքով որո՞նք են շաքարային դիաբետի հետևանքները: Պարզապես թվարկեք դրանք:
- Նշտում՝ Ինձ հատաքրքրում են բարդությունները, հետևանքները և այն փոփոխությունները, որոնք Ձեր կարծիքով առաջացնում է շաքարային դիաբետը:

7. Ասացեք խնդրեմ, ինչպե՞ս կարելի է կանխարգելել շաքարային դիաբետի բարդությունները:
- Նշտում՝ Պարզապես կարող եք թվարկել Ձեր մտքերը:

8. Կուզենայի՞ք որևէ բան ավելացնել, որ մենք չենք քննարկել:

Շնորհակալություն Ձեր տրամադրած ժամանակի համար

Appendix 7

Pearson correlation coefficients

```
. correlate age cursmoke sugartesting feetcheck drinks bmi duration hypertension gend
(obs=142)
```

	age	cursmoke	sugart~g	feetch~k	drinks	bmi	duration	hypert~n	gend
age	1.0000								
cursmoke	0.1689	1.0000							
sugartesting	0.1144	0.1278	1.0000						
feetcheck	0.2688	0.1293	0.2730	1.0000					
drinks	-0.0596	-0.0114	-0.1323	-0.0464	1.0000				
bmi	0.0283	0.0646	0.1194	0.0719	0.0992	1.0000			
duration	0.6614	0.1360	0.1600	0.2570	-0.1472	0.1006	1.0000		
hypertension	0.3462	0.1201	0.0954	0.1547	0.0255	-0.0585	0.1485	1.0000	
gend	-0.0197	0.0440	0.2193	0.0007	0.1742	-0.0041	0.0084	0.0888	1.0000

Variance Inflation Factor (VIF)

```
. vif
```

Variable	VIF	1/VIF
age	2.05	0.487410
duration	1.90	0.526714
sugartesting	1.21	0.828291
hypertension	1.18	0.844182
feetcheck	1.17	0.851239
gend	1.12	0.894512
drinks	1.11	0.900889
bmi	1.06	0.947548
cursmoke	1.05	0.949325
Mean VIF	1.32	

Appendix 8

Assessment of final model fit

1. Goodness-of-fit

Logistic model for angiopat, goodness-of-fit test

   (Table collapsed on quantiles of estimated probabilities)

        number of observations =   195
             number of groups =   10
    Hosmer-Lemeshow chi2(8) =   6.89
              Prob > chi2 =   0.5485

Model discrimination

. lroc

Logistic model for angiopat

number of observations =   195
area under ROC curve =   0.8886

Area under the ROC curve

Area under ROC curve = 0.8886