

**Factors associated with diabetes related distress among adult Type 2 diabetic patients in
Yerevan, Armenia**

Master of public health integrating experience project

Research Grant Proposal Framework

by

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LIST OF ABBREVIATIONS:

DM	Diabetes Mellitus
ADA	American Diabetes Association
IDF	International Diabetes Federation
WHO	World Health Organization
CDC	Center of Disease Control
AADE	American Association of Diabetes Educators
DD	Diabetes Distress
BMI	Body Mass Index
MOH	Ministry of Health
NIAC	National Information and Analytics Center
DDS	Diabetes Distress Scale
SDSCA	Summary of Diabetes Self-Care Activities

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EXECUTIVE SUMMARY

Diabetes Mellitus is one of the major and challenging public health issues worldwide. Diabetes Mellitus is ranked to be 4th leading cause of death among non-communicable diseases.

According to the International Diabetes Federation, by 2035 the number of people with diabetes will rise to 592 million, with more than 58 million people in the European region, which is expected to reach about 67 million by 2045. Studies show that two times more people with type 2 diabetes (DM) suffer from depression compared to those without diabetes. The negative effect of depression on DM can be described by diabetes distress (DD). Taking into account comorbidity of depression and DM, a new descriptive term has been suggested - diabetes distress (DD). DD has been defined as an emotional state causing significant emotional distress, which does not meet the criteria for Major Depressive Disorder. DD is highly prevalent in the population and is a serious mood disorder that affects the feelings, thinking and daily activity of those who suffer from it. The symptoms of DD are: anxious mood, feeling of hopelessness and guilt, decreased energy, difficulty in concentration, insomnia, loss of appetite and weight loss. Presence of diabetes related distress affects the quality of life of people with type 2 diabetes and can lead to complications and difficulties in diabetes self-management. Studies show that approximately 45% of people with type 2 diabetes suffer from diabetes related distress.

The prevalence of diabetes in Armenia is 12.3%. According to the World Health Organization report, the proportional mortality ratio of diabetes is highest in the region. This can be a consequence of not adequate diabetes self-management caused by diabetes related distress (DD).

Currently there are no studies to investigate the prevalence of DD, the influence of diabetes related distress on glycemic control among Armenian Type 2 diabetic population which shows the need for exploration of diabetes related distress. The aim of the study is to explore if

diabetes related distress is related to glycemic control among Armenian Type 2 diabetic population above 18 years of age in Yerevan, Armenia. Study will utilize a cross-sectional survey design which will be done by using self-administered questionnaires. The questionnaire will include sections about socio-demographic characteristics of participants, glycemic control, about diabetes self-management, and diabetes related distress. The estimated duration of the study is three months.

The study findings can lead to development of interventions that will concentrate on early identification of diabetes distress among type 2 diabetic patients of Yerevan, which can lead to more effective glycemic control and a higher quality of life for those who suffer from diabetes.

Background

Diabetes Mellitus

According to the World Health Organization (1999) “the term diabetes mellitus (DM) describes a metabolic disorder of multiple etiologies characterized by chronic hyperglycemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action, or both”.^{1,pg-2} Insulin is a hormone which regulates the level of glucose in the blood.² Diabetes mellitus is characterized by hyperglycemia (elevated level of glucose in the blood) either because of absolute or relative deficiency of insulin hormone.¹ The etiological classification of DM include type 1 diabetes (insulin-dependent diabetes or juvenile onset diabetes) which is mainly characterized by absolute deficiency of insulin; type 2 diabetes (non-insulin-dependent or adult onset diabetes) which is characterized by relative deficiency of insulin; gestational DM (diabetes diagnosed during the second or third trimester of pregnancy which usually disappears after giving birth) and specific types of DM due to other causes, which includes rare conditions such as different types of monogenic DM (latent autoimmune diabetes of adults (LADA) or maturity onset diabetes of the young (MODY)), diabetes caused by rare syndromes (e.g., Wolfram syndrome), diabetes caused by exocrine diseases of pancreas (e.g., pancreatitis) and drug-induced or chemical-induced diabetes (e.g., treatment with glucocorticoids, treatment of HIV/AIDS).³ Diabetes affects all the systems of the body, because it causes metabolic disturbance.³ The paper will focus on Type 2 DM as according to the National Diabetes Statistics report (2017) “Type 2 DM accounts for 90 to 95 percent of all diabetes cases.”⁴ The complications of diabetes are diabetic retinopathy, diabetic nephropathy, diabetic neuropathy, cardiovascular diseases and macro and micro-angiopathy.⁵

Global Burden

Diabetes mellitus is a major public health issue worldwide; it is one of the most challenging health problems of the century. The World Health Organization (WHO) estimates that 422 million people worldwide had diabetes and 1.5 million deaths were caused by diabetes in 2016.⁶ DM was the 4th leading cause of death among non-communicable diseases in 2016.⁷ According to the International Diabetes Federation (IDF), by 2035 the number of people who suffer from diabetes will rise to 592 million, with more than 58 million people in the European region, which is expected to reach about 67 million by 2045.⁸ More than 80% of those who suffer from DM live in low- and middle-income countries.⁶ In the countries of former Soviet Union the prevalence of non-communicable diseases presented a growing challenge because of the rapid economic and demographic changes.⁹ Despite the presence of health system reforms in many former Soviet Union countries, which mainly focus on primary health care, healthcare remains fragmented and patient-centered care is not well established.¹⁰ Programs mainly focusing on treatment of particular disease in isolation make it difficult to treat diseases such as diabetes which affect whole body system.¹⁰ By integration of these programs the spending on diabetes care increases and makes difficulties for patient-friendly models of healthcare.¹⁰ The low accessibility of diabetes care in many regions of former Soviet Union countries and out-of-pocket payments to GPs and nurses was identified as one of the reasons for poor primary healthcare services in many former Soviet Union countries.¹⁰ In many former Soviet Union countries doctors reported that the time spent on bureaucracy is higher than for individualized patient care.¹⁰

The WHO estimates that in the Russian Federation the prevalence of DM among adult population is 9% with less than 1% proportional mortality ratio.¹¹ WHO 2016's data indicate

that the prevalence of diabetes in the Republic of Georgia was 15% and proportional mortality ratio due to DM was 1%.¹² The WHO estimates that the prevalence of DM in the Islamic Republic of Iran was 10.3% with and the proportional mortality ratio 2% in 2016.¹³ According to the WHO 2016's data, 13% of Turkey's population suffers from diabetes.¹⁴

Diabetes Distress

According to WHO "Depression is a common mental disorder that presents with depressed mood, loss of interest or pleasure, decreased energy, feelings of guilt or low self-worth, disturbed sleep or appetite, and poor concentration".¹⁵ Depression and distress are comorbid conditions.¹⁶ A meta-analysis was done to find out the prevalence of depression among diabetic patients.¹⁷ The results showed that the odds of depression are doubled among both Type 1 and Type 2 diabetic patients compared with non-diabetic patients.¹⁸ Taking into account comorbidity of depression and DM, a new descriptive term has been suggested- diabetes related distress (DD).¹⁹ DD was defined as an emotional condition causing significant emotional distress which does not meet the qualifications for Major Depressive Disorder (DSM-V criteria).¹⁹ Studies found little or no evidence of a statistically significant relationship between Major Depressive Disorder and poor glycemic control or between major depressive disorder symptoms and poor glycemic control, but found that emotional distress caused by diabetes and its self-management has statistically significant relationship with A1C level in the blood (glycemic control).¹⁹

The negative effect of depression on DM can be described by DD.^{18,20} Many patients above 18 years of age who suffer from DM and depressive symptoms go through emotional distress coming from patients concerns about DM.²¹

The literature has described diabetes distress (DD) or diabetes related distress as an emotional state during which people experience feelings such as anxiety, guilt, or feeling of hopelessness that arise from living with DM and the difficulties of self-management of DM.^{22,23} It is hard to give a specific definition to diabetes related distress, as it is a condition distinct from depression but is highly associated with it.^{18,20} DD involves emotional symptoms that are similar with depression. Though there are similarities between DD and major depressive disorders, depression and DD are different conditions and require distinct coping strategies.^{18,20} Unlike depression, DD does not suppose psychopathology, diabetes distress is a presumed reaction to DM whereas major depressive disorder refers to how individuals accept their life generally.^{23,24} Diabetes related distress is not fully understood and addressed by physicians.^{22,25} DD is highly prevalent in the population and is a serious mood disorder that affects the feelings, thinking and daily activity of those who suffer from it.¹⁵ The symptoms of DD are: anxious mood, feeling of hopelessness and guilt, decreased energy, difficulty in concentration, insomnia, loss of appetite and loss of weight.²²

Distress among diabetic patients is strongly associated with adherence to diabetes treatment, glycemic control and diabetes self-management and health outcomes, such as , obesity, atherosclerosis and dyslipidemia.^{26,27}

The reasons of DD are multifactorial.²⁸ Diabetes specific stressors can be fear of experiencing hypoglycemia, living with fluctuating blood glucose levels, the continuous need to measure blood glucose level and to balance insulin doses with the increasing or decreasing level of blood glucose level and carbohydrate intake, need for physical activity and dietary control.²⁸ For type 2 diabetes the stressors are mainly related to food restriction, obesity and social impact, such as lack of support from family members and friends.²³

The presence of distress can affect quality of life of patients with diabetes which can lead to complications and difficulties in self-management.²⁹ In a longitudinal study, over 18 months the prevalence of diabetes distress was reported to be from 18% to 45% with an incidence of 38% to 48%.²⁵ In the Diabetes Attitudes, Wishes and Needs second study (DAWN 2) diabetes related distress was reported to be 44.6% and about 40.0% participants stated that their diabetes medication negatively affected participants ability to live a normal life.³⁰

Many studies show that the factors related to diabetes distress are age, gender, weight (BMI), low self-efficacy, the level of health care providers support, and poor dietary control.^{7,31,32} Some studies show that low education level and presence of diabetes complications like diabetic retinopathy, hypertension or diabetic nephropathy are the most frequent reasons or predictors of diabetes distress.³³

Young age was positively associated with diabetes distress; this can be associated with diabetes related stressors, like continuous monitoring of glycemic level, and day to day stressors like work, financial issues and other responsibilities.⁷ Some studies show that women are more likely to develop diabetes distress.³⁴ In other studies men were less likely to develop diabetes distress when having a support from a spouse.³⁵ Weight stigma can lead to numerous psychological, physical and social consequences and those who are overweight are more likely to develop distress.³⁶ As a result, by lowering weight, diabetic patients may overcome distress. Polonsky et al. stated that the more days diabetic patients follow healthy dietary plan, the less stressed they become.³⁷ To optimize health related quality of life of diabetes patients, the American Diabetes Association suggests to integrate psychological care tools in all primary care departments, so all the providers can assess the level of DD and monitor the performance of self-care activities by patients to minimize the possible psychological problems.³⁸ DAWN 2 study indicated that

although healthcare professionals were aware of mental health factors affecting diabetes self-management, only 52% of healthcare providers asked diabetic patients about the effect of diabetes on their quality of life.^{39,30}

Many studies suggest that DD is positively associated with adherence to diabetes treatment, poor glycemic control and self-management of DM which leads to hyperglycemia and diabetes complications among patients with both Type 1 and Type 2 DM.^{40,41,42} By the increase of the level of distress, the adherence to diabetes treatment and self-management behaviors decreases.⁴³ Studies found that distressed patients showed less days of glucose self-monitoring compliance, lower compliance with healthy diet, exercise and foot care, a strong association was found between HbA1c level (measure that shows glycemic control) and distress.⁴⁴

Diabetes self-management is an important element in diabetes care as the main part of diabetes day-to-day care is made either by a patient or by a family member of a diabetic patient.

American Association of Diabetes Educators (AADE) suggests seven types of behaviors that diabetic patients can apply for effective diabetes self-management: healthy eating, physical activity, blood glucose level monitoring, compliance with medications, risk reduction behavior (such as visiting health care specialists to prevent the complications of diabetes and stop smoking), problem solving (accepting life with diabetes, analyzing the differences of life with diabetes and learning to manage life with diabetes) and coping with diabetes.^{45,46} According to literature these behaviors were positively correlated with correct glycemic control, reduction of probability of diabetic complications and improved quality of life.^{47,48,49}

Situation in Armenia

According to the WHO 2016 report, the prevalence of diabetes in Armenia was 12.3% (men 11.1% , women 13.5%).⁵⁰ The proportional mortality ratio of diabetes in Armenia is the highest in the region – 3%; in Georgia the proportional mortality ratio in 2016 was 1%, in the Islamic Republic of Iran and in Turkey it was 2%.^{13,14,50} The International Diabetes Federation, in collaboration with the Armenian Diabetes Federation, reported that there were 168,400 cases of diabetes in 2017 in Armenia.⁵¹ According to the National Institute of Health National Information and Analytic Center’s (NHIAC) health statistics report, the incidence of DM in Armenia increased almost twice from 1990 to 2015 among 15 years old and older population, in 1990 the incidence of DM was 1.4%, in 2005 was 1.6%, in 2010 it increased to 2.1% and in 2015 it was 3.2%.^{52,53} There are approximately 80 000 new diabetes cases diagnosed in Armenia each year.⁵⁴ Although there are major improvements of diabetes screening programs, continuous care in primary care facilities is often hard to attain for diabetes patients.⁵⁴ Absence of national diabetes registry makes it hard to track individual cases.⁵⁴

As stated above diabetes distress is closely associated with poor diabetes self-management. According to the “Rapid appraisal of diabetes care in Armenia” study, there were many barriers to good diabetes self-management, including socio-economic factors, difficulties in managing appropriate insulin treatment and blood glucose control, lack of education and knowledge about diabetes and diabetes self-care.⁵³ According to the study diabetes day-to-day care was hard for some participants because of the fatigue caused by diabetes.⁵³

A qualitative study was done to assess diabetes perception among Armenian Type 2 DM patients.⁵⁵ The study findings showed that many participants had fear of serious complications of DM and felt that DM is a probable threat to life of their family members because of the

probability of developing DM.⁵⁵ Almost all participants mentioned stress as the main cause of diabetes.⁵⁵ Participants mentioned presence of anxious mood among diabetes patients, which affects the whole family.⁵⁵

The study on the “prevalence of and major risk factors associated with diabetic retinopathy in Gegharkunik province of Armenia: cross-sectional study”, which included variables such as the use of diabetes medication, blood glucose level, physical activity and smoking status, found that 96% of study population were taking diabetes medication weekly, about half of participants were physically active and 8% of participants were current smokers.⁵⁶ The majority of participants described their health status as “satisfactory” or “bad”.⁵⁶

Lack of knowledge about diabetes self-management and lack of availability of diabetes treatment medication can be reasons for poor diabetes self-management in Armenia.⁵⁷ In a study conducted in Yerevan, Armenia, about 34% of participants stated that they faced difficulties when receiving insulin from polyclinics, majority of participants were using both polyclinic and pharmacy insulin and only 35.7% of participants were receiving their monthly insulin dose from only polyclinics.⁵⁷ Study showed that only about half of participants were regularly performing blood glucose level self-monitoring at home and about one third were performing blood glucose level self-monitoring only in case of distressing health conditions.⁵⁷

Currently, there are no studies investigating the prevalence of diabetes related distress and the influence of DD on poor glycemic control among Armenian Type 2 diabetic population, which shows the need for exploration of diabetes related distress among Armenian population.

The proposed study findings could lead to development of interventions concentrating on early identification of diabetes distress among diabetes patients which can lead to more effective

glycemic control. For example, patients experiencing diabetes distress can be referred to a mental healthcare specialist who will follow up those patients. Moreover, training programs could be organized for health providers dealing with diabetes patients to raise their awareness about DD and how to recognize it. Early identification of this problem can allow healthcare professionals to tailor diabetes management and treatment individually for each patient considering also if the patient has a supportive family environment or not. Diabetes self-management education would also be needed in combination with diabetes distress management tools in order to reach more effective glycemic control.

Aim of the study:

The aim of the study is to explore if diabetes related distress is related to glycemic control among Armenian Type 2 diabetic population above 18 years of age in Yerevan, Armenia.

Research Questions:

- What is the estimated prevalence of diabetes related distress among adult Type 2 diabetic population in Yerevan?
- What is the level of diabetes self-management among adult Type 2 diabetic population in Armenia?
- Is diabetes related distress a factor related to developing poor glycemic control among Type 2 diabetic patients in Yerevan, Armenia, after adjusting for confounders, including DM self-management?

Methods

Study Design

To answer the research question, a cross-sectional survey with self-administered questionnaires will be conducted. The cross-sectional study is chosen because it is a snap-shot view, less time consuming and comparatively inexpensive.⁵⁸

Study Population

The target population for the study will include Type 2 diabetic patients above 18 years of age living in Yerevan, Armenia. The inclusion criteria for the study participants will be: being adult Type 2 diabetic patients who are registered in the register journal of endocrinologists of polyclinics of Yerevan, Armenia and who speak and read Armenian.

Patients with other types of diabetes (Type 1 DM, gestational DM, MODY diabetes, LADA diabetes and diabetes associated with particular syndromes), cancer and with psychiatric illnesses will be excluded.

Sample Size

Sample size was calculated using standard formula for difference in proportions in comparison of two equal size groups for cross-sectional and cohort studies.⁵⁹ The first group will consist of Type 2 diabetic patients with Diabetes Distress and second group will consist of Type 2 diabetic patients who did not develop Diabetes Distress.

Fleiss (1981) formula:⁵⁹

$$\hat{n} = (z_{1-\alpha/2} \sqrt{2PQ} + z_{1-\beta} \sqrt{P_1Q_1 + P_2Q_2})^2 / (P_1 - P_2)^2$$

For confidence level= 95% when α is 0.05 ($Z_{1-\alpha/2}= 1.96$) and the power $(1-\beta)$ is 0.8 Z is $\beta=0.842$.

As there are no studies which will show the prevalence of Diabetes Distress among Armenian population, study investigator will use data from similar studies.^{60,61} Proportion of Type 2 diabetic patients with poor glycemic control among those with diabetes distress was 65.75% and the proportion of Type 2 diabetic patients with poor glycemic control among those without diabetes distress was 38.53%.^{60,61}

$$P_1=0.6575$$

$$P_2=0.3853$$

$$Q_1= 1-P_1=0.34$$

$$Q_2=1-P_2=0.61$$

$$P= P_1+P_2/2= 0.14$$

$$Q=1-P= 0.86$$

$$n= (1.96\sqrt{2* 0.14*0.86+ 0.842\sqrt{0.6575*(1-0.6575) + 0.3853(1-0.3853)}})^2 / (0.6575-0.3853)^2$$

$$n=123$$

$$N=2n=246$$

Sampling Strategy

There are twelve districts in Yerevan (Achapnyak, Avan, Arabkir, Davtashen, Erebuni, Kentron, Malatia-Sebastia, Nor Nork, Nork-Marash, Nubarashen, Shengavit, and Kanaker-Zeytun). There is only one ambulatory-polyclinic for each of the following administrative districts: Achapnyak,

Avan, Davtashen, Nor Nork, Nork-Marash and Nubarashen. There are two or more ambulatory-polyclinics for administrative districts of Arabkir, Erebuni, Kentron, Malatia-Sebastia, Shengavit, and Kanaker-Zeytun). “RANDBETWEEN” function of Excel will be used to select one polyclinic per administrative district of Yerevan by simple random sampling technique. Twelve polyclinics will be randomly chosen.⁶² The study investigator will randomly select participants from the journal of registration of the selected polyclinic endocrinologist (narrow-specialist). The journal of registration by polyclinic narrow-specialists is a form approved by the Minister of Health of the Republic of Armenia (order number 35-N) and which contains information about the patients and their diagnosis (Type 2 DM in this case).

“RANDBETWEEN” function of Excel will be used to select participants by simple random sampling technique. Twenty one participants will be chosen from registration journals of each endocrinologist. Telephone numbers will be collected from the medical records. Eligible participants will be called out and asked whether they want to participate in the study and if the potential participant will be interested in the study, the researcher can arrange appropriate time for a meeting in a polyclinic, so participant will be able to fill in the questionnaires and return in back to the study investigator. In some cases if the student investigator will not be able to reach participants or if they refuse to participate in the study, the study investigator will randomly chose another participant from the list to reach the desired sample size. Later the student investigator will calculate the response rate.

Study Variables and Instruments

The main outcome variable of interest is the level of glycemic control. The main independent variable of the study is diabetes distress status (continuous variable) which consists of “emotional burden, physician-related distress, regimen related distress and diabetes related

interpersonal distress domains.” Diabetes self-management level (diet, exercise, foot care and medication adherence), socio-demographic variables such as age, gender, marital status, education, socio-economic status and employment status, diabetes treatment nature (oral medication, insulin or diet only), years of diagnosed diabetes will be the potential confounding variables of interest.

Diabetes status domain contains information about years of diagnosed diabetes (how many years passed after diabetes was diagnosed) and blood glucose level during the last measurement which will be a tool for measuring the level of glycemic control. The level of fasting plasma glucose, during last measurement, of less than 3.9 mmol/l or more than 7.0 mmol/l will be considered as not adequate glycemic control and the level of fasting plasma glucose equal or between these measures will be considered as adequate glycemic control.

The Socio demographic domain contains questions about gender, age, marital status, educational status, employment status, and household monthly expenditures.

Diabetes Distress Scale (DDS) will be used to assess the diabetes related distress.³⁷ The DDS is a reliable and validated scale.³⁷ It is a 17 item scale focusing on four domains, which are emotional burden scale, physician related distress, regimen related distress and diabetes related interpersonal distress.^{63,64} The total score is calculated by summing patients’ responses and dividing to 17 (items), the mean score of three and higher is considered as distressed (mean score<3 is considered low distress, mean score=3 is considered mild distress, mean score>3 is considered as severe distress).

The Summary of Diabetes Self-Care Activities (SDSCA) is a scale developed by Toobert and Glasgow, it is a 24 item instrument will be used to assess diabetes self-management.^{65,66} SDSCA

is a multidimensional measure which helps to assess five elements of the scale which are: “diet, exercise, blood-glucose testing, foot-care and smoking status.”^{65,66,67} For smoking status the scale is the number of cigarettes smoked per day. SDSCA was chosen because it is a reliable and valid scale and has a multidimensional measure of diabetes self-care behaviours.⁶⁶

The questionnaire was developed in English then translated into Armenian. The questionnaire will be pretested before the data collection starts. Appendix 1 present the study instrument.

Data Analysis

Investigator will enter the collected data into an electronic database. The SPSS 21.0 statistical package for Windows will be used. The investigator will check the data by randomly comparing 10% of questionnaires with entered data in order to find mistakes and do data cleaning. After that data will be transformed from SPSS to STATA 10 package.

Descriptive statistical analysis including mean, standard deviation, and frequency distribution will be obtained for the study variables. The study will utilize simple and multivariable logistic regression analyses to calculate unadjusted and adjusted odds ratios (OR) and 95% confidence intervals (CI) for measures of strength of association between independent variables and glycemic control.

Before the main analysis, some of the continuous variables of the study will be dichotomized. The main dependent variable of interest will be dichotomized in the following way: fasting plasma glucose of less than 3.9 or more than 7.0 mmol/l will be considered as poor glycemic control and the level of fasting plasma glucose between 3.9 and 7.0 mmol/l will be considered as good glycemic control. The cut-off point for diabetes distress status, the main independent

variable of interest, will be three, so a DDS continuous variable will be dichotomized into scores less than three as not distressed and equal or above three as distressed.

The diabetes self-management variable consists of the mean score of four scales (summing all scores under four domains and divided by the number of items in the scale) including the diet control, exercise, foot care activities and blood glucose testing.⁶⁶ The mean score of less than three will be considered as not appropriate self-care and the mean score of equal or more than three will be considered as appropriate self-care.

To identify potential confounding between the main dependent and independent variables, diabetes self-management variable and each of the socio-demographic characteristics and other potential confounding variables will be tested with the dependent and the main independent variables separately using simple logistic regression analysis. Results with the p-value less than 0.05 will be considered as statistically significant. Those variables that will have statistically significant association with both the dependent and the main independent variables will be considered as confounders and will be fitted into the final multivariable logistic regression model to control for confounding. The VIF (variance inflation factor) statistics test will be used to check for multicollinearity between DDS and SDSCA scores, and other variables included in the final regression model.

Ethical Considerations

The Institutional Review Board (IRB) of the American University of Armenia gave a preliminary approval to the proposed study. Before starting the survey the participants will receive an oral consent form and after obtaining participants' approval the survey will be conducted. The participants will be informed about the study purpose, expected risks and

benefits of participation in the study and the confidentiality of the study. They will be informed that the participation in the study is voluntary and there will be no penalty if the participant chooses not to participate in the study. The only inconvenience for the participant is going to be the time spent during the survey. Participants will be informed about the confidentiality of the study and no personal identifiers will be collected during the data collection. All the data collected during the survey will be protected by password and only the study investigator can access to the collected data. All the questionnaires will be archived at the end of the study. The Telephone Script Form and Oral Consent Form are presented in Appendices 2 and 3, respectively.

Resources

Study personnel will consist of a project coordinator, data collectors and data analyst (biostatistician). Study coordinator (study investigator) will be responsible for managing all activities for appropriate investigation of the study and for the preparation of the final report. Two data collectors will participate in the survey and data collection process. The biostatistician will conduct the data analysis in consultation with the study investigator.

Data collection will be done in polyclinics throughout Yerevan, so to manage data collection process travel expenses are required. Office supplies (papers, pens, folders) will be needed for the survey process. Data collectors will need mobile phones to contact potential participants and make appointments for the survey. Appendix 4 presents the estimated schedule of activities.

Budget

In total budget is estimated to be 1,369,440 AMD to conduct the study. The budget is calculated based on personnel expenses such as research team salaries, travel expenses and other project related expenses. Staff members will receive their salaries on a monthly basis. The estimated expenditure list for the project is provided in Appendix 5.

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Appendices

Appendix 1: Questionnaire

Questionnaire

ID # _____

Date of Survey _____ (Day/Month/Year)

Instructions for Completing the Questionnaire

Dear participant first read carefully each question and the possible response options. Choose the option that best represents your response and circle the number of the option. Some questions should be answered by words or by a number. There are blank lines next to these questions for you to write your response. Please follow the instructions in *Italics*. These instructions will help you to complete the questionnaire and indicate which questions to skip for your particular case. Some questions may look like others, but each one is different. Please, try to answer ALL THE questions.

Part 1: Socio-demographic characteristics

1. Gender	(0) <input type="checkbox"/> Female (1) <input type="checkbox"/> Male
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2. Your birth year	
3. What is your marital status?	(0) <input type="checkbox"/> Married (1) <input type="checkbox"/> Single (2) <input type="checkbox"/> Widowed (3) <input type="checkbox"/> Divorced (999) <input type="checkbox"/> Other
4. What is the highest grade you finished?	(0) <input type="checkbox"/> No education (1) <input type="checkbox"/> School (12 years or less) (2) <input type="checkbox"/> Professional technical education/College (3) <input type="checkbox"/> University (4) <input type="checkbox"/> Postgraduate (999) <input type="checkbox"/> Other (Specify) _____
5. Do you currently work? (including self-employment, farming, and seasonal/migrant work) <i>(If NO, go to next question. If YES, go to the question 7)</i>	(0) <input type="checkbox"/> Yes (1) <input type="checkbox"/> No
6. Which of the following best describes your situation?	(0) <input type="checkbox"/> Unemployed, looking for a job (1) <input type="checkbox"/> Unemployed, but not looking for a job (2) <input type="checkbox"/> On maternity leave (3) <input type="checkbox"/> Can not work due to permanent disabilities (999) <input type="checkbox"/> Other _____
7. Approximately how much are the average expenses of your household members per month?	(0) <input type="checkbox"/> Less than 50,000 drams (1) <input type="checkbox"/> From 51,000 to 100,000 drams (2) <input type="checkbox"/> From 101,000 to 300,000 drams

	(3) <input type="checkbox"/> Above 300,000 drams (777) <input type="checkbox"/> Do not know/ Not sure (888) <input type="checkbox"/> Refused to answer
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Part 2: Diabetes status:

1. When were you first diagnosed with diabetes?	Year _____
2. What was the level of glucose in the blood when you measured it last time?	
3. What is the nature of your diabetes treatment?	(0) <input type="checkbox"/> Nothing (1) <input type="checkbox"/> Diet (2) <input type="checkbox"/> Oral medication (3) <input type="checkbox"/> Insulin injection (999) <input type="checkbox"/> Other(Specify) _____ (777) <input type="checkbox"/> Do not know

Part 3: Diabetes self-care behavior

A:Diet	Number of Days							
1. On average, over the past month, how many days per week have you followed your eating plan?	0	1	2	3	4	5	6	7
2. On how many of the last seven days did you eat daily five or more servings of either fruits or vegetables?	0	1	2	3	4	5	6	7
3. On how many of the last seven days did you eat high fat foods such as red meat or full-fat dairy products?	0	1	2	3	4	5	6	7
4. On how many of the last seven days did you space carbohydrates evenly through the day?	0	1	2	3	4	5	6	7

5. On how many of the last seven days have you followed a healthful eating plan?	0	1	2	3	4	5	6	7
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B: Exercise	Number of Days							
6. On how many of the last seven days did you participate in at least 30 minutes of physical activity?	0	1	2	3	4	5	6	7
7. On how many of the last seven days did you participate in a specific exercise session (such as such swimming, walking, biking)?	0	1	2	3	4	5	6	7

C: Blood Sugar Testing	Number of Days							
8. On how many of the last seven days did you test your blood sugar?	0	1	2	3	4	5	6	7
9. On how many of the last seven days did you test your blood sugar level as many times as your doctor recommended per day?	0	1	2	3	4	5	6	7

D: Smoking	
10. Have you ever smoked at least 100 cigarettes in your lifetime? <i>(If no, go to the question 15)</i>	(0) <input type="checkbox"/> Yes (1) <input type="checkbox"/> No
11. Have you smoked a cigarette—even one puff—during the past seven days? <i>(If no, go to the question 12)</i>	(0) <input type="checkbox"/> Yes (1) <input type="checkbox"/> No
11a. If yes, how many cigarettes did you smoke on an average day? <i>(Number of cigarettes)</i>	
12. At your last doctor's visit, did anyone ask about your smoking status?	(0) <input type="checkbox"/> Yes (1) <input type="checkbox"/> No
13. If you smoke, at your last doctor's visit, did anyone counsel you about stopping smoking or offer to refer you to a stop smoking program?	(0) <input type="checkbox"/> Yes (1) <input type="checkbox"/> No

14. When did you last smoke a cigarette?	<input type="checkbox"/> (0) More than two years ago <input type="checkbox"/> (1) One to two years ago <input type="checkbox"/> (2) Four to twelve months ago <input type="checkbox"/> (3) One to three months ago <input type="checkbox"/> (4) Within the last month <input type="checkbox"/> (5) Today <input type="checkbox"/> (777) Do not know
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E: Foot Care	Number of Days							
15. On how many of the last 7 days did you check your feet?	0	1	2	3	4	5	6	7
16. On how many of the last 7 days did you inspect the inside of your shoes?	0	1	2	3	4	5	6	7
17. On how many of the last 7 days did you wash your feet?	0	1	2	3	4	5	6	7
18. On how many of the last 7 days did you soak your feet?	0	1	2	3	4	5	6	7
19. On how many of the last 7 days did you dry between your toes after washing?	0	1	2	3	4	5	6	7

F: Medications	Number of Days							
20. On how many of the last seven days, did you take your recommended diabetes medication?	0	1	2	3	4	5	6	7

21. Do you take Insulin? <i>(If No, go to the question 22)</i>	(0) <input type="checkbox"/> Yes (1) <input type="checkbox"/> No							
21a. If Yes, On how many of the last seven days did you take your recommended insulin injections?	0	1	2	3	4	5	6	7
22. Do you take pills to lower your blood sugar? <i>(If No, go to the question 23)</i>	(0) <input type="checkbox"/> Yes (1) <input type="checkbox"/> No							
22a. If Yes, On how many of the last seven days did you take your recommended number of diabetes pills?	0	1	2	3	4	5	6	7

G:Self-Care Recommendations	
23. Have your doctor ever recommended you to follow a healthy diet? (low-fat, lots of fruits and vegetables, less sweet, reduce calories you eat)	(0) <input type="checkbox"/> Yes (1) <input type="checkbox"/> No
24. Have your doctor ever recommended you to follow an exercise plan?	(0) <input type="checkbox"/> Yes (1) <input type="checkbox"/> No
25. Have your doctor ever recommended you to test your blood sugar every day using a machine to read the results.	(0) <input type="checkbox"/> Yes (1) <input type="checkbox"/> No
26. Which of the following medications for your diabetes has your doctor prescribed? Please check all that apply.	(0) <input type="checkbox"/> An insulin shot 1 or 2 times a day. (1) <input type="checkbox"/> An insulin shot 3 or more times a day. (2) <input type="checkbox"/> Diabetes pills to control my blood sugar level. (3) <input type="checkbox"/> Diet pills in combination with insulin shots.

(4) I have not been prescribed either insulin or pills for my diabetes

(999) Other (specify): _____

Part 4: Diabetes Distress (exhaustion of adaptable processes of organism because of the long term stress) Scale (DDS)

DIRECTIONS: Consider the degree to which each of the following items may have distressed or bothered you DURING THE PAST MONTH and circle the appropriate number. If you feel that a particular item is not a bother or a problem for you, you would circle "1". If it is very bothersome to you, you might circle "6".

	Totally Disagree	Disagree	More Disagree, Then Agree	More Agree, Then Disagree	Agree	Totally Agree
1. Feeling that diabetes is taking up too much of my mental and physical energy every day.	1	2	3	4	5	6
2. Feeling that my doctor doesn't know enough about diabetes and diabetes care.	1	2	3	4	5	6
3. Feeling angry, scared and/or depressed when I think about living with diabetes.	1	2	3	4	5	6
4. Feeling that my doctor doesn't give me clear enough directions on how to manage my diabetes.	1	2	3	4	5	6
5. Feeling that I am not testing my blood sugars frequently enough.	1	2	3	4	5	6
6. Feeling that I am often failing with my diabetes routine.	1	2	3	4	5	6

7. Feeling that friends or family are not supportive enough of self-care efforts (e.g. planning activities that conflict with my schedule, encouraging me to eat the "wrong" foods).	1	2	3	4	5	6
8. Feeling that diabetes controls my life.	1	2	3	4	5	6
9. Feeling that my doctor doesn't take my concerns seriously enough.	1	2	3	4	5	6
10. Not feeling confident in my day-to-day ability to manage diabetes.	1	2	3	4	5	6
11. Feeling that I will end up with serious long-term complications, no matter what I do.	1	2	3	4	5	6
12. Feeling that I am not sticking closely enough to a good meal plan.	1	2	3	4	5	6
13. Feeling that friends or family does not appreciate how difficult living with diabetes can be.	1	2	3	4	5	6
14. Feeling overwhelmed by the demands of living with diabetes.	1	2	3	4	5	6
15. Feeling that I don't have a doctor who I can see regularly enough about my diabetes.	1	2	3	4	5	6
16. Not feeling motivated to keep up my diabetes self-management.	1	2	3	4	5	6
17. Feeling that friends or family does not give me the emotional support that I would like.	1	2	3	4	5	6

Thank You!

Հարցաթերթիկ

Համապատասխանության համար _____

Հարցազրույցի օրը _____ (Օր/Ամիս/Տարի)

Հարցաթերթիկի լրացման ցուցումներ

Հարգելի՛ մասնակից, ուշադիր կարդացեք յուրաքանչյուր հարց և պատասխանների ներկայացված տարբերակները: Ընտրեք այն տարբերակը, որն ավելի մոտ է Ձեր կարծիքին և նշում կատարեք՝ շրջանակի մեջ վերցնելով Ձեր նախընտրած տարբերակի առջև գրված թիվը: Որոշ հարցերի պետք է պատասխանել բառերով կամ թվերով: Այդ հարցերին հաջորդում են դատարկ տողեր, որպեսզի Դուք գրեք Ձեր պատասխանը: Խնդրում ենք հետևել շեղագիր գրված ցուցումներին: Այդ ցուցումները կօգնեն Ձեզ լրացնել հարցաշարը և ցույց կտան, թե որ հարցերը Դուք պետք է բաց թողնեք: Որոշ հարցեր կարող են նման լինել մյուսներին, սակայն դրանցից յուրաքանչյուրը տարբեր է: Խնդրում եմ, փորձեք պատասխանել ԲՈՒՈՐ ՀԱՐՑԵՐԻՆ:

Մաս 1: Սոցիալ-ժողովրդագրական տվյալներ

1. Մեռը	(0) <input type="checkbox"/> Բգական (1) <input type="checkbox"/> Արական
2. Ծննդյան տարեթիվը (Օր/Ամիս/Տարի)	
3. Ամուսնական կարգավիճակ	(0) <input type="checkbox"/> Ամուսնացած (1) <input type="checkbox"/> Չամուսնացած (2) <input type="checkbox"/> Այրի (3) <input type="checkbox"/> Ամուսնալուծված (999) <input type="checkbox"/> Այլ
4. Կրթություն	(0) <input type="checkbox"/> Կրթություն չունեմ (1) <input type="checkbox"/> Միջնակարգ դպրոց (12 տարի կամ քիչ) (2) <input type="checkbox"/> Միջին մասնագիտական կրթություն/քոլեջ (3) <input type="checkbox"/> Ինստիտուտ/Համալսարան (4) <input type="checkbox"/> Հետդիպլոմային/Ասպիրանտուրա (999) <input type="checkbox"/> Այլ (Մանրամասնել) _____
5. Տվյալ պահին աշխատո՞ւ մ եք? (ներառյալ ինքնազբաղվածությունը, գյուղատնտեսությունը և	(0) <input type="checkbox"/> Այո (1) <input type="checkbox"/> Ոչ

<p>սեզոնային/միգրացիոն աշխատանքները)</p> <p><i>(Եթե Այո, ապա անցեք 7-րդ հարցին, եթե Ոչ՝ շարունակեք)</i></p>	
<p>6. Ներքոհիշյալներից ո՞րն է լավագույնս ներկայացնում ձեր իրավիճակը</p>	<p>(0) <input type="checkbox"/> Գործազուրկ եմ, փնտրում եմ աշխատանք</p> <p>(1) <input type="checkbox"/> Գործազուրկ եմ, բայց չեմ փնտրում աշխատանք</p> <p>(2) <input type="checkbox"/> Գտնվում եմ երեխայի խնամքի արձակուրդում</p> <p>(3) <input type="checkbox"/> Չեմ կարող աշխատել մշտական անաշխատունակության պատճառով</p> <p>(999) <input type="checkbox"/> Այլ (Մանրամասնել)</p>
<p>7. Միջինում, ամսական որքա՞ն գումար են ծախսում Ձեր ընտանիքի անդամները</p>	<p>(0) <input type="checkbox"/> 50,000 դրամից քիչ</p> <p>(1) <input type="checkbox"/> 51,000-ից մինչև 100,000 դրամ</p> <p>(2) <input type="checkbox"/> 101,000-ից մինչև 300,000 դրամ</p> <p>(3) <input type="checkbox"/> 300,000 դրամից ավել</p> <p>(777) <input type="checkbox"/> Չգիտեմ/Վստահ չեմ</p> <p>(888) <input type="checkbox"/> Հրաժարվում եմ պատասխանել</p>

Մաս 2: Ծախարախտի կարգավիճակ:

1. Ե՞րբ են Ձեզ մոտ առաջին անգամ ախտորոշել ՇԴ	Տարի _____
2. Ինչքա՞ն էր գլուկոզայի թիվն արյան մեջ վերջին ախտորոշման ժամանակ	
3. ՇԴ-ի հետ կապված ինչպիսի՞ բուժում եք ստացել	(0) <input type="checkbox"/> Ոչ մի բուժում (1) <input type="checkbox"/> Դիետա (2) <input type="checkbox"/> Դեղորայքաբուժում (3) <input type="checkbox"/> Ինսուլինոթերապիա (999) <input type="checkbox"/> Այլ (Մանրամասներ) _____ (777) <input type="checkbox"/> Չգիտեմ

Մաս 3: Շաբարախտի ինքնախնամքի վարքագիծ

A: Դիետա	Օրերի քանակ							
1. Միջինում, անցած ամսվա ընթացքում, շաբաթական քանի՞ օր եք հետևել դիետայի ծրագրին	0	1	2	3	4	5	6	7
2. Վերջին 7 օրվա ընթացքում, քանի՞ օր է եղել, որ կերել եք մրգերի կամ բանջարեղենի 5 և ավելի բաժին	0	1	2	3	4	5	6	7

3. Վերջին 7 օրվա ընթացքում, քանի՞ օր եք կերել ճարպոտ սնունդ (Օր.՝ կարմիր միս կամ յուղոտ կաթնամթերք)	0	1	2	3	4	5	6	7
4. Վերջին 7 օրվա ընթացքում, քանի՞ օր եք օրվա ընթացքում հավասարաչափ բաշխված ճարպաթթուներ կերել	0	1	2	3	4	5	6	7
5. Վերջին 7 օրվա ընթացքում, քանի՞ օր եք հետևել առողջ սնվելու ծրագրին	0	1	2	3	4	5	6	7

B:Մարզում	Օրերի քանակ							
6. Վերջին 7 օրվա ընթացքում, քանի՞ օր եք առնվազն 30 րոպե ֆիզիկական աշխատանք կատարել	0	1	2	3	4	5	6	7
7. Վերջին 7 օրվա ընթացքում, քանի՞ օր եք մասնակցել հատուկ պարապմունքների (Օր.՝ լող, քայլք, հեծանվավազք)	0	1	2	3	4	5	6	7

C: Արյան մեջ գլյուկոզայի որոշում	Օրերի քանակ							
8. Վերջին 7 օրվա ընթացքում, քանի՞ օր եք որոշել արյան մեջ գլյուկոզայի մակարդակը	0	1	2	3	4	5	6	7
9. Վերջին 7 օրվա ընթացքում, քանի՞ օր եք որոշել արյան մեջ գլյուկոզայի	0	1	2	3	4	5	6	7

մակարդակը , որը խորհուրդ էր տվել Ձեր բուժող բժիշկը								
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D: Ծիւելու կարգավիճակ	
10. Ձեր ամբողջ կյանքի ընթացքում դուք ծխե՞լ եք 100 և ավելի սիգարետ <i>(Եթե ոչ,անցնել 15-րդ հարցին)</i>	(0) <input type="checkbox"/> Այո (1) <input type="checkbox"/> Ոչ
11. Վերջին 7 օրվա ընթացքում, ծխե՞լ եք, նույնիսկ մեկ գլանակ <i>(Եթե ոչ,անցնել 12-րդ հարցին)</i>	(0) <input type="checkbox"/> Այո (1) <input type="checkbox"/> Ոչ
11a. Եթե այո, օրական մոտ քանի՞ գլանակ եք ծխում <i>(Գլանակների քանակը)</i>	
12. Բժշկի մոտ վերջին այցելության ժամանակ, Ձեզ հարցրել են Ձեր ծիւելու մասին	(0) <input type="checkbox"/> Այո (1) <input type="checkbox"/> Ոչ
13. Եթե ծխում եք, բժշկի մոտ վերջին այցելության ժամանակ, ինչ-որ մեկը ձեզ խորհու՞րդ տվել է դադարեցնել ծխելը կամ առաջարկել է ծխելը դադարեցնելու ծրագիր .	(0) <input type="checkbox"/> Այո (1) <input type="checkbox"/> Ոչ
14. Վերջին անգամ ե՞րբ եք ծխել	(0) <input type="checkbox"/> Ավելի քան 2 տարի առաջ (1) <input type="checkbox"/> 1-2 տարի առաջ (2) <input type="checkbox"/> 4-12 ամիս առաջ

	(3) <input type="checkbox"/> 1-3 ամիս առաջ (4) <input type="checkbox"/> Անցած ամսվա ընթացքում (5) <input type="checkbox"/> Այսօր (777) <input type="checkbox"/> Չգիտեմ
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E: Ոտքերի խնամք	Օրերի քանակ							
15. Վերջին 7 օրվա ընթացքում, քանի՞ օր էք ստուգել Ձեր ոտքերը	0	1	2	3	4	5	6	7
16. Վերջին 7 օրվա ընթացքում, քանի՞ օր էք ստուգել Ձեր կոշիկի ներսային մակերեսը	0	1	2	3	4	5	6	7
17. Վերջին 7 օրվա ընթացքում, քանի՞ օր էք լվացել Ձեր ոտքերը	0	1	2	3	4	5	6	7
18. Վերջին 7 օրվա ընթացքում, քանի՞ օր էք թրջել Ձեր ոտքերը	0	1	2	3	4	5	6	7
19. Վերջին 7 օրվա ընթացքում, քանի՞ օր էք լվանալուց հետո չորացրել ոտքերի մատների միջմատային մասերը	0	1	2	3	4	5	6	7

F: Դեղորայք	Օրերի քանակ							
20. Վերջին 7 օրվա ընթացքում, քանի՞ օր եք ընդունել նշանակված բուժումը	0	1	2	3	4	5	6	7
21. Ինսուլին ներարկում եք Ձեզ <i>(Եթե ոչ,անցնել 22-րդ հարցին)</i>	(0) <input type="checkbox"/> Այո (1) <input type="checkbox"/> Ոչ							
21a. Եթե այո, վերջին 7 օրվա ընթացքում, քանի՞ օր եք ներարկվել ինսուլին	0	1	2	3	4	5	6	7
22. Հակաշաքարախտային դեղորայք ստանում եք <i>(Եթե ոչ,անցնել 23-րդ հարցին)</i>	(0) <input type="checkbox"/> Այո (1) <input type="checkbox"/> Ոչ							
22a. Եթե այո, վերջին 7 օրվա ընթացքում, քանի՞ օր եք ընդունել նշանակված հակաշաքարախտային դեղորայքը	0	1	2	3	4	5	6	7

G: Ինքնահսկողության խորհուրդներ	
23. Ձեր բժիշկը երբևէ խորհուրդ տվե՞լ է Ձեզ հետևել առողջ սննդակարգի (ցածր ճարպայնությամբ դիետա, մեծ քանակությամբ մրգերի և բանջարեղենի օգտագործում, քաղցրի սահմանափակում, նվազեցնել սննդի կալորիականությունը)	(0) <input type="checkbox"/> Այո (1) <input type="checkbox"/> Ոչ

24. Ձեր բժիշկը երբևէ խորհուրդ տվե՞լ է Ձեզ հետևել ֆիզիկական ակտիվության պլանի:	(0) <input type="checkbox"/> Այո (1) <input type="checkbox"/> Ոչ
25. Ձեր բժիշկը երբևէ խորհուրդ տվե՞լ է Ձեզ ամեն օր ստուգել արյան մեջ գլյուկոզայի պարունակությունը գլիկոմետրի օգնությամբ:	(0) <input type="checkbox"/> Այո (1) <input type="checkbox"/> Ոչ
26. Հետևյալներից որ՞ դեղորայքն է ձեզ նշանակել Ձեր բժիշկը շաքարային դիաբետի համար. Նշել համապատասխանող տարբերակները	<p>(0) <input type="checkbox"/> Ինսուլինի ներարկում օրական 1 կամ 2 անգամ.</p> <p>(1) <input type="checkbox"/> Ինսուլինի ներարկում օրական 3 կամ ավել անգամ.</p> <p>(2) <input type="checkbox"/> Հաբեր, որոնք կարգավորում են գլյուկոզայի մակարդակն արյան մեջ.</p> <p>(3) <input type="checkbox"/> Հաբեր, համակցված ինսուլինոթերապիայի հետ.</p> <p>(4) <input type="checkbox"/> Ինձ չեն նշանակել ոչ՝ դեղորայք, ոչ՝ ինսուլին.</p> <p>(999) <input type="checkbox"/> Այլ (Մանրամասներ)</p>

Մաս 4: Դիաբետիկ Դիսթրես : երկարատև սթրեսի հետևանքով օրգանիզմի

հարմարողական պրոցեսների հյուծում

Ոռդեցույց: Նկատի ունեցեք այն աստիճանը, ըստ որի ստորև նշված տարբերակները կարող էին անհանգստացնել ձեզ Անցած Ամսվա ընթացքում և շրջանակի մեջ

վերցրեք պատասխանը: Եթե կարծում եք, որ տվյալ խնդիրը Ձեզ անհանգստություն չի պատճառել, ապա շրջանակի մեջ առեք «1», եթե խիստ անհանգստացրել է՝ «6»:

	Լիովին համաձայն չեմ	Համաձայն չեմ	Ավելի շատ համաձայն չեմ , քան համաձայն եմ	Ավելի շատ համաձայն եմ, քան համաձայն չեմ	Համաձայն եմ	Լիովին համաձայն եմ
1. Կարծում եմ, որ ՇԴ-ն ամեն օր ինձանից խլում է չափից շատ մտավոր եւ ֆիզիկական էներգիա	1	2	3	4	5	6
2. Կարծում եմ, որ իմ բժիշկը բավական գիտելիքներ չունի ՇԴ-ի եւ ՇԴ-ի բուժման վերաբերյալ	1	2	3	4	5	6
3. Ինձ զգում եմ ջղային, վախեցած եւ/կամ ճնշված,	1	2	3	4	5	6

երբ մտածում եմ ՇՆ-ով ապրելու մասին						
4. Կարծում եմ, որ իմ բժիշկը ինձ հստակ ցուցումներ չի տալիս ՇՆ-ի վերահսկողության համար	1	2	3	4	5	6
5. Կարծում եմ, որ ես բավականին հաճախ չեմ ստուգում գլյուկոզան արյան մեջ	1	2	3	4	5	6
6. Երբեմն զգում եմ, որ խախտում եմ ՇՆ-ի բուժման ռեժիմը:	1	2	3	4	5	6
7. Թվում է թե ընտանիքս ու ընկերներս ինձ չեն աջակցում շաքարախտի	1	2	3	4	5	6

<p>ինքնավերահսկող դրոյան ջանքերում (օրինակ՝ կազմակերպում են միջոցառումներ, որ չեն համընկնում իմ բուժման գրաֆիկի հետ, խրախուսում են ինձ ուսել «Ոչ ճիշտ» սնունդ):</p>						
<p>8. Կարծում եմ, որ ՇԴ-ն կառավարում է իմ կյանքը</p>	1	2	3	4	5	6
<p>9. Կարծում եմ, որ իմ բժիշկը լուրջ չի վերաբերվում իմ խնդրին</p>	1	2	3	4	5	6
<p>10. Կարծում եմ, որ ճիշտ չեմ</p>	1	2	3	4	5	6

կազմակերպում շաքարախտիս խնամքը						
11. Թվում է թե, անկախ նրանից ինչ էլ անեմ՝ ունենալու եմ լուրջ բարդություններ	1	2	3	4	5	6
12. Կարծում եմ, որ այնքան էլ չեմ պահպանում առողջ սովելու ծրագիրը	1	2	3	4	5	6
13. Կարծում եմ, որ ընկերներս ու ընտանիքս չեն պատկերացնում թե ինչքան դժվար է ապրել ունենալով շաքարախտ	1	2	3	4	5	6

14. Ճնշված եմ զգում որ ստիպված եմ ապրել շաքարախտով	1	2	3	4	5	6
15. Թվում է թե չկա այնպիսի բժիշկ ում կարող եմ անընդհատ դիմել ՇԴ-ի հետ կապված հարցերով	1	2	3	4	5	6
16. Բավականին մոտիվացված չեմ զգում, որպեսզի պահպանեմ ՇԴ- իս բուժման և խնամքի ռեժիմը	1	2	3	4	5	6
17. Կարծում եմ, որ ընտանիքս ու ընկերներս ինձ չեն տրամադրում այն էմոցիոնալ աջակցությունը որն ինձ անհրաժեշտ է	1	2	3	4	5	6

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ՇՆՈՐՀԱԿԱԼՈՒԹՅՈՒՆ

Appendix 2: Telephone Script Form

Telephone Script Form

If someone answers the phone:

Hello, my name is Lilit and I am an endocrinologist and graduate student of Gerald and Patricia Turpanjian School of Public Health at the American University of Armenia (AUA). As a part of my thesis project and with the AUA faculty members support I am conducting a study to investigate factors associated with diabetes distress among Type 2 diabetic patients in Armenia. The investigation may contribute to improved health among diabetic patients in Armenia. You have been contacted because you have been registered as a Type 2 diabetic patient in the regional polyclinic. Your contact information was assessed by the permission of the polyclinic director. We will include 246 participants in the study. Participation in the study will involve filling questionnaire that will be provided to you. It will take approximately 10-15 minutes to complete. Your involvement in this study will be limited to this single meeting. Does this sound like something you may be interested in?

- **If subject says YES proceed below**
- **If subject says NO end call and tell them thank you for the time they spent and that their contact information will be destroyed after phone call.**

You agreed to participate in the study and now I would like to schedule for an appointment. Do you agree to visit polyclinic that you are registered in and participate in the study?

- **If subject agreed on the meeting, proceed below**
- **If subject do not agree, tell them thank you for the time they spent and that their contact information will be destroyed.**

What date and time would be appropriate for you?

- **Review calendar to ensure there are NO other appointments for the suggested time. Visits should be scheduled in 30 minute blocks.**

Thank you for your interest and we'll see you soon.

Հեռախոսագանգ իրականացնելու ուղեցույց

Եթե որևէ մեկը պատասխանում է հեռախոսագանգին.

Ողջույն, իմ անունը Լիլիթ է, ես էնդոկրինոլոգ եմ և Հայաստանի ամերիկյան համալսարանի (ՀԱՀ) Թրփանճեան Հանրային առողջության մագիստրատուրայի ավարտական կուրսի ուսանողուհի: Իմ գիտական աշխատանքի շրջանակներում, ՀԱՀ-ի հետազոտական խմբի անդամների աջակցությամբ իրականացնում եմ ուսումնասիրություն, Տիպ 2 շաքարային դիաբետի հետևանքով առաջացած դիսթրեսի գործոնները պարզելու համար. Ձեզ հետ կապվել ենք, քանի որ ըստ պոլիկլինիկայի գրանցման մատյանի Ձեր մոտ ախտորոշվել է Տիպ 2 Շաքարային Դիաբետ: Ձեր հեռախոսահամարը վերցրել ենք պոլիկլինիկայի ղեկավարի թույլատվությամբ: Ուսումնասիրության շրջանակներում հարցումն անցկացնելու ենք 246 մասնակիցների հետ: Մասնակցությունը հետազոտությանը սահմանափակվելու է պատասխանելով հարցերին հարցաթերթիկ լրացնելու միջոցով, որը կտրամադրվի Ձեզ անհատական հանդիպման ժամանակ: Հարցաթերթիկը լրացնելը կտևի մոտավորապես 10-15 րոպե: Ձեր մասնակցությունն այս ուսումնասիրությանը կսահմանափակվի միայն տվյալ հարցումով: Կարծում եք, որ սա կհետաքրքրի՞ Ձեզ:

- **Եթե հարցվողը պատասխանում է այո, ապա շարունակեք**

- Եթե հարցվողը պատասխանում է ոչ, ավարտեք հեռախոսագանգը, շնորհակալություն հայտնեք տրամադրած ժամանակի համար և ոչնչացրեք նրա տվյալները:

Դուք համաձայնվեցիք մասնակցել հետազոտությանը և այժմ ես կցանկանայի պայմանավորվել ` Ձեր տեղամասային պոլիկլինիկայում հարցումն իրականացնելու համար: Համաձայն եք այցելել ձեր տեղամասային պոլիկլինիկա և մասնակցել հարցմանը:

- Եթե հարցվողը համաձայնում է, ապա շարունակեք:
- Եթե հարցվողը չի համաձայնում մասնակցել, ապա ավարտեք հեռախոսագանգը, շնորհակալություն հայտնեք և ոչնչացրեք նրա տվյալները:

Ո՞ր օրը և ժամն են առավել հարմար Ձեզ` հարցումն իրականացնելու համար

- Վերանայեք օրացույցը, որպեսզի համոզվեք, որ առաջարկվող ժամի համար չկա որևէ այլ հանդիպում: Հանդիպման համար պլանավորեք 30 րոպե ժամանակահատված:

Շնորհակալություն հետաքրքրության համար և մինչ հանդիպում:

Appendix 3: Oral Consent Form

American University of Armenia

Institutional Review Board #1

Oral Consent Form

Title: Factors associated with diabetes related distress (exhaustion of adaptable processes of organism because of the long term stress) among adult diabetic patients in Yerevan, Armenia.

Hello, my name is Lilit and I am an endocrinologist and graduate student of Gerald and Patricia Turpanjian School of Public Health at the American University of Armenia (AUA). As a part of my thesis project and with the AUA faculty members support I am conducting a study to investigate factors associated with diabetes distress among Type 2 diabetic patients in Armenia. The investigation may contribute to improved health among diabetic patients in Armenia. You have been contacted because you have been registered as a Type 2 diabetic patient in the regional polyclinic. Your contact information was assessed by the permission of the polyclinic director. We will include 246 participants in the study. Participation in the study will involve filling questionnaire that I will provide to you now. If you are willing to participate in the survey, I will ask you to fill in this questionnaire.

It will take approximately 10-15 minutes from you to complete this questionnaire. Your involvement in this study will be limited to this single survey. Your participation is voluntary and there is no risk linked to participation. You may refuse to answer or skip questions that you do not want to answer and stop whenever you feel discomfort. If you refuse to participate in the

study, it will not affect your further medical care at your polyclinic in any way. There is no direct benefit from the study, but it will help to get a better understanding about the factor associated with not effective self-management of diabetes.

The information you provide will be confidential. Your name will not be recorded in the questionnaire. Only aggregate results will be reported.

If you have more questions about this study, you can contact the Dean of the Turpanjian School of Public Health of American University of Armenia and study director, Varduhi Petrosyan, at (060) 612592. If you feel you have not treated fairly or have been hurt by joining this study, please contact Varduhi Hayrumyan Human Participants Protections Administrator (+37460) 612561.

Do you agree to participate in the study? (YES or NO). Thank you.

If yes, please kindly, fill the questionnaire.

Հայաստանի ամերիկյան համալսարան

Գիտահետազոտական էթիկայի թիվ 1 հանձնաժողով

Բանավոր իրազեկ համաձայնության ձև

Շաքարային դիաբետ ունեցող մարդկանց մոտ Շաքարային Դիաբետի (երկարատև սթրեսի հետևանքով օրգանիզմի հարմարողական պրոցեսների հյուծում) հետ կապված գործոնները հետազոտություն, Երևան, Հայաստան

Ողջույն, իմ անունը Լիլիթ է, ես էնդոկրինոլոգ եմ և Հայաստանի ամերիկյան համալսարանի (ՀԱՀ) Թրփանճեան Հանրային առողջության մագիստրատուրայի ավարտական կուրսի ուսանողուհի: Իմ գիտական աշխատանքի շրջանակներում, ՀԱՀ-ի հետազոտական խմբի անդամների աջակցությամբ իրականացնում եմ ուսումնասիրություն, Տիպ 2 շաքարային դիաբետի հետևանքով առաջացած դիաբետի գործոնները պարզելու համար. Ձեզ հետ կապվել ենք, քանի որ ըստ պոլիկլինիկայի գրանցման մատյանի Ձեր մոտ ախտորոշվել է Տիպ 2 Շաքարային Դիաբետ: Ձեր հեռախոսահամարը վերցրել ենք պոլիկլինիկայի ղեկավարի թույլատվությամբ: Ուսումնասիրության շրջանակներում հարցումն անցկացնելու ենք 246 մասնակիցների հետ: Ուսումնասիրությանը մասնակցելու համար պետք է լրացնել մի հարցաթերթ, որը ես Ձեզ քիչ հետո կտրամադրեմ: Եթե Դուք ցանկանում եք մասնակցել ուսումնասիրությանը, կխնդրեմ լրացնել այս հարցաթերթիկը:

Հարցաթերթիկ լրացնելը ձեզանից կիսի մոտավորապես 10-15 րոպե: Ձեր մասնակցությունն այս ուսումնասիրությանը կսահմանափակվի միայն տվյալ հարցումով: Ձեր մասնակցությունը կամավոր է և մասնակցության հետ կապված ռիսկեր չկան: Դուք կարող եք հրաժարվել պատասխանել կամ բաց թողնել այն հարցերը, որոնց չեք ցանկանա պատասխանել և դադարեցնել հարցազրույցը եթե անհարմարություն զգաք: Հարցմանը մասնակցելը չի ազդի պոլիկլինիկայում Ձեր հետագա այցելությունների վրա և չի ունենա բացասական հետևանքներ:

Ուսումնասիրությանը մասնակցելուց ուղղակի օգուտ չեք ստանա, բայց Ձեր կողմից ստացված տեղեկությունը կօգնի ավելի լավ պատկերացում կազմել շաքարային դիաբետի ոչ էֆեկտիվ ինքնահսկողության հետ կապված գործոնները պարզելու համար:

Ձեր կողմից տրված տեղեկությունները լինելու են գաղտնի: Ձեր անունը չի գրանցվի հարցաթերթիկի վրա: Կիրառարակվեն միայն հարցման ընդհանրացված արդյունքները:

Հետազոտության հետ կապված հարցերի դեպքում կարող եք զանգահարել Հանրային առողջապահության ֆակուլտետի դեկան և այս հետազոտության ղեկավար Վարդուհի Պետրոսյանին հետևյալ հեռախոսահամարով (060) 612592: Եթե դուք կարծում եք, որ այս հետազոտությանը մասնակցելու ընթացքում Ձեզ լավ չեն վերաբերվել կամ մասնակցությունը Ձեզ վնաս է պատճառել, կարող եք զանգահարել

ՀԱՀ Էթիկայի հանձնաժողովի համակարգող՝ Վարդուհի Հայրումյանին հետևյալ
հեռախոսահամարով (+37460) 612561:

Համաձայն էք մասնակցել հետազոտությանը: (Այո կամ Ոչ): Շնորհակալություն:

Եթե համաձայն էք, խնդրում եմ սկսեք լրացնել հարցաթերթիկը:

Appendix 4: Schedule of Activities

	Month 1				Month 2				Month 3			
	1 we ek	2 wee k	3 wee k	4 we ek	1 we ek	2 wee k	3 wee k	4 wee k	1 wee k	2 wee k	3 wee k	4 wee k
IRB Approval												
Provision of study instrument/questionnaire printing												
Meeting with administration of polyclinics												
Sampling												
Data collection												
Data entry/Cleaning												
Data analysis												
Final report preparation												

Budget Category	Unit Cost in AMD	Number of Units	Total Cost in AMD
Research Team Salaries			
Project Coordinator	250,000	3 months	750,000
Data Collector	1000 (per survey)	246	246,000
Data Analyst/ Biostatistician	250,000	1 month	250,000
Travel Expenses			
Car (Taxi)	2,000 (per visit)	12 polyclinics	24,000
Office Supplies			
Papers/ Stationary	10,000		10,000
Printing	10 (AMD per page)	3,444 (pages)	34,440
Mobile Phone Calls	5,000 (package)	3 months	15,000
Other expenses			40,000
Total Budget			1,369,440

Appendix 5: Budget