

**RISK FACTORS AND FOOTCARE PRACTICES IN RECURRENT DIABETIC
FOOT ULCERS: A HOSPITAL BASED CASE-CONTROL STUDY IN
PATHANAMTHITTA DISTRICT, KERALA.**

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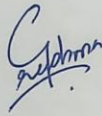
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DECLARATION

I hereby declare that this dissertation titled “Risk Factors and Footcare Practices in Recurrent Diabetic Foot Ulcers: A Hospital Based Case-Control Study in Pathanamthitta District, Kerala” is the bona fide record of my original research. It has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.



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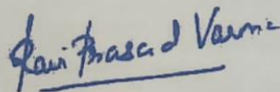
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CERTIFICATE

Certified that the dissertation titled "Risk Factors and Footcare Practices in Recurrent Diabetic Foot Ulcers: A Hospital Based Case-Control Study in Pathanamthitta District, Kerala" is a record of the research work undertaken by Dr. Greeshma Ramesh in partial fulfilment of the requirements for the award of the degree of "Master of Public Health" under my guidance and supervision.



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Glossary of Abbreviations

DM	Diabetics Mellitus
DFUs	Diabetic Foot Ulcers
PAD	Peripheral Arterial Disorders
PVD	Peripheral Vascular Diseases
BMI	Body Mass Index
HbA1C	Haemoglobin A1C
FBS	Fasting Blood Sugar
HDL	High Density Lipo-protein
LDL	Low Density Lipo-protein
TC	Total Cholesterol
NCDs	Non communicable Diseases
OPD	Outpatient Department
IPD	In Patient Department
PI	Principal Investigator
CI	Confidence Interval
SD	Standard Deviation
OR	Odds Ratio
OHA	Oral Hypoglycaemic Agent
BP	Blood Pressure
NP-NCD	National Program for Prevention and Control of Non - Communicable Diseases
RTA	Road Traffic Accidents

ABSTRACT

Background

Diabetic foot ulcers are serious complication of diabetic mellitus, recurrence of foot ulcers significantly affects the quality of life of the diabetic population and contributing to a major financial burden. Risk factors such as peripheral vascular disease (PVD), peripheral neuropathy and economic constraints increase the likelihood of recurrence. In Kerala's Pathanamthitta district, where elderly diabetic populations are rising, the recurrence of Diabetic Foot Ulcers (DFUs) poses significant clinical and public health challenges. This study aimed to identify the risk factors, foot care practices and financing mechanisms for health among patients with recurrent diabetic foot ulcers in a diabetic speciality hospital in rural Kerala.

Methodology

An unmatched case-control study was conducted in a diabetic specialty hospital in rural Kerala from November 2024 to April 2025. A total of 100 cases (patients with recurrent diabetic foot ulcer) and 200 controls (type 2 diabetes mellitus patients without recurrent diabetic foot ulcer having 10 years and more diabetic duration) were included. Data were collected using structured interviews and clinical records. Risk factors, foot care practices, and the extent of distress financing were assessed. Statistical analyses included bivariate and multivariate logistic regression, adjusting for potential confounders.

Results

The study found that male sex (Odds Ratio, OR=5.46, $p<0.001$), presence of Peripheral Vascular Diseases (PVD) (Adjusted Odds Ratio, AOR=2.02, $p=0.018$), priority ration card (indicative of lower socioeconomic status) (Adjusted Odds Ratio, AOR=2.30, $p=0.051$) were significant independent risk factors for recurrent Diabetic Foot Ulcers (DFUs). Poor

blood pressure control and peripheral neuropathy also showed higher odds for recurrence of foot ulcer. Although footcare practices were moderately followed in both groups, adherence was dissatisfactory. Distress financing was reported by 53% of cases, with gold pledging and borrowing from relatives being the most common strategies.

Conclusion

Recurrent Diabetic Foot Ulcers (DFUs) are influenced by a complex interplay of clinical, behavioural, and socio-economic factors. Male sex, Peripheral Vascular Diseases (PVD), neuropathy and lower socioeconomic status were key predictors. The study highlights the urgent need for comprehensive diabetic foot care, better socio-economic support, early detection of complications, and improved health insurance coverage to reduce the burden of recurrent Diabetic Foot Ulcers (DFUs) in Kerala.

CHAPTER 1

INTRODUCTION

1.1 Background

Diabetes Mellitus (DM) is a chronic metabolic disorder caused by defects in insulin secretion, leading to hyperglycaemia and improper action of insulin in the body. It is a significant global public health concern, resulting in high morbidity and mortality. One of the most severe complications of diabetes is the development of diabetic foot ulcers (DFUs), which are open sores or wounds on the foot. A recurrent diabetic foot ulcer is a new ulcer in a patient with a history of ulceration. Due to ongoing risk factors (like Peripheral vascular diseases (PVD), neuropathy) of recurrent diabetic foot ulcers play a significant role as the severity of complications affects the life of the diabetic population. Early detection of specific risk factors helps in better management and decreases the chance of recurrence. Footcare practices also play a significant role in the development and occurrence of recurrent foot ulcers.

The financial burden of Recurrent diabetic foot ulcers comprises of both direct medical cost (hospitalisation, treatment expenses, medications) and indirect cost (employment loss, productivity loss, reduced quality of life), which may lead to distress financing that in turn leads economic burden to the family.

1.2. Rationale of the study

DFU is a common complication in the diabetic population. The incidence, prevalence, and recurrence of DFUs seem to be high at an alarming rate and this affects the quality of life of the diabetic patients. The management and treatment of recurrent diabetic foot ulcers (DFUs) impose a significant economic burden on patients and caregivers. Direct medical costs, including hospitalisation, surgeries, wound dressing, wound care, and medication,

contribute heavily to this financial strain. Additionally, indirect costs, such as loss of productivity and caregiver burden, exceed the financial impact. Regardless of extensive researches on DFUs, gaps remain particularly in the context of recurrence in districts with an elderly population is more Pathanamthitta in Kerala. This study aims to address these gaps by focusing on specific risk factors and associated foot care practices, as well as the proportion of patients resorted to distress financing to meet the treatment and care of the patient. This hospital setting serves as a referral unit for many healthcare institutions and caters to patients of all socio-economic statuses.

CHAPTER 2

REVIEW OF LITERATURE

Worldwide over 463 million people are living with Diabetes Mellitus (DM). These patients are at a higher risk for developing multiple disease complications that are related with diabetes. Specifically, foot related problems cause serious morbidity and mortality among this diabetic population. Loss of sensations gangrene, infections and ulcerations are frequently affecting complications among diabetic patients. Global International Diabetes Federation estimates that 9.1–26.1 million diabetic individuals will develop diabetic foot ulcers (DFUs) every year.

Diabetic foot ulcers (DFUs) carry significant complications of DM, which may lead to infections, amputation, hospitalisation and even death. The recurrences of DFUs creates substantial burden to the patient as well as to the health system, demanding a comprehensive understanding of the risk factors associated with foot ulcers and effective footcare practices. The complications of non-healing ulcers, showing a significant rate of recurrent diabetic foot ulcers in South India.

2.1. Definition of Recurrent Diabetic Foot Ulcer

A recurrent diabetic foot ulcer is defined as a new ulcer in a patient with a history of ulceration, irrespective of location and time since the previous foot ulcer (Van Netten et al., 2020). Due to ongoing risk factors, recurrent diabetic foot ulcers play a significant role as a debilitating condition that affects human life.

2.2. Epidemiology of Diabetic Foot Ulcers

Globally, the prevalence of DFUs is approximately 6.3 percent of the diabetic population (Zhang et al., 2017). Population-based studies reports that the annual incidence of diabetic foot ulcers (DFUs) ranges from 1 percent to 4.1 percent, while the prevalence lies between 4.5 percent and 10 percent. The overall lifetime risk of developing a DFU can be as high as 25 percent. In India, about 25 percent of individuals with diabetes experience DFUs; among these, 50 percent develop infections necessitating hospitalisation, and 20 percent eventually require amputation (Patil et al., 2024). About one-fifth of the total diabetic population in India have DFUs, and among them, one-fourth have a history of diabetic foot ulcers and high-risk feet (Viswanathan et al., 2024). A study conducted in Kerala revealed that 41.51 percent of diabetic patients had non-healing ulcers, showing a significant rate of recurrent diabetic foot ulcers in South India. This underscores the urgent need for better foot care and diabetes management practices.

2.3. Recurrence Rate of DFUs

The recurrence rate of DFUs is 40 percent in the first year after healing, 50 percent at two years, and 65 percent at five year (Armstrong et al., 2017). Diabetic foot ulcers can take several weeks to heal, and the healing process is prolonged if blood sugar levels are not well-controlled or if there is constant pressure acting on the ulcer area. Approximately 24.2 percent of diabetic foot ulcers heal within 12 weeks (Ince et al., 2007).

2.4. Risk Factors for DFUs

Diabetic related comorbidities

Several risk factors contribute to the recurrence of diabetic foot ulcers, including socio-economic factors, addiction related factors, diabetic related co-morbidities, life style related factors, vitamin D status, foot related and ulcer factors. Proper foot care practices, including

regular inspections, hygiene, appropriate footwear, and patient education on foot care, are crucial in preventing the recurrence of DFUs. Early detection of specific risk factors helps in better management and decreases the chance of recurrence.

Peripheral Neuropathy

Peripheral Neuropathy is the most common and severe complications of diabetic foot ulcers. The nerve damage caused due to lack of sensation may leads to unnoticed wounds and ulcerations. Several researches shows that patients with peripheral neuropathy are at a higher risk of development of foot ulcers and its recurrences(Zhang et al., 2017).

Peripheral Vascular Diseases (PVD)

The chances of ulceration is more in patients with Peripheral Arterial Disorder(PAD), where there is lack of blood supply to the extremities, which affects the healing process(Armstrong et al., 2017). When Peripheral Arterial Disorders (PAD) combine with peripheral neuropathy leading to a condition known as neuro-ischemic foot, which is a risky condition for diabetic foot ulcers.

Other Diabetic related risk factors

The relationship between the severity of DFUs and Diabetic Retinopathy is particularly notable, as higher grades of diabetic foot ulcers correlate with more advanced stages of retinopathy(Sellman et al., 2019). Diabetic Nephropathy is significantly associated with recurrent diabetic foot ulcers. In the study, individuals with nephropathy seems to have a higher likelihood of repeated foot complications and mortality risks(Hsu et al., 2024).

Socio-demographic factors.

Individuals in the most deprived socioeconomic status are at a higher risk (1.44 times) of developing foot ulcers and its recurrence compared to those in the least deprived(Riley et al., 2021) .

Age

Various studies highlights, different factors that contribute the relationship between age and recurrent diabetic foot ulcers. Even though the recurrence rate does not show a significant variation across different age groups, older age is frequently associated with more severe complications of foot ulcers including recurrences. Age group greater than or equal to 65 years shows a high prevalence of ulcers with neural damage and ischemic ulcers which are associated with more severe complications of foot ulcers. However, older patients had a lower history of previous ulcers compared to younger adults, suggesting that age alone may not be a definitive predictor of recurrence(Rosinha et al., 2022).

Sex

There exists a significant difference in the severity, healing rates, and outcome of foot ulcers between men and women. Men generally present with more severe DFUs, while women exhibit better healing outcomes(Vanherwegen et al., 2023).

Place of Residence

Rural patients often present with more severe complications of recurrence of foot ulcers like major amputations compared to rural residences (Foss et al., 2023). The difference is due to socio-economic factors , disparities in healthcare access , quality of life and care(Riley et al., 2021).

Occupation

Studies indicate that lower educational level and unskilled occupations can aggravate the DFU outcomes and can lead to occurrence of recurrences. The occupation of individuals with recurrent foot ulcers scientifically affects the outcomes.

Addictions and lifestyle related factors

Smoking

Smoking and recurrent foot ulcers are significantly associated, which can increase the risk in diabetic patients as well as can affect the disease severity. Studies indicated that smoking causes impaired wound healing due to uncontrolled glycaemic level, oxidative stress on blood vessels all of which contribute to the development and recurrences of foot ulcers. Effect of smoking can increase the severity of peripheral neuropathy and vascular diseases which alters the vascular vessels and causing delayed healing of wound (Xia et al., 2019).

Tobacco use

Tobacco usage negatively affects the glycaemic control, which leads to higher blood glucose levels, which is very crucial for the development of foot ulcers and its recurrences (Guo et al., 2023). The risk will be elevated with the presence of other vascular complications like PVD and Neuropathy (Z Huang et al., 2019).

Alcohol consumption

In the risk factors of foot ulcers, use of alcohol is identified as a predictor for recurrent plantar ulcers (Aan De Stegge et al., 2021). This indicates that individuals who consume alcohol have a chance of developing Distal Symmetrical Polyneuropathy (DSP), which makes foot at a higher risk experiencing foot ulcers (Bell and Goncalves, 2021).

Physical Activity

Physical activity plays a crucial role in managing the risk of recurrent foot ulcers. Too little activity increases susceptibility to skin trauma while excess risk can cause recurrence. A balanced approach to activity level can reduce the risk of recurrences of foot ulcers up to 50 percent. Engaging in appropriate levels of physical activity can enhance overall health as well as can reduces the chances of foot ulcer recurrences. However, the individuals with foot ulcer history, can inconsistently increase the risk of trauma due to sudden activity.

Body Mass Index (BMI)

A meta-analysis reports that BMI does not show a significant differences in recurrence rate, but it remains as a crucial factor in the overall risk of developing DFUs(Z-H Huang et al., 2019).A study conducted in Sudan found that 56 percent of overweight patients had DFUs, compared to 46 percent of non-overweight patients, indicating a significant association $p=0.04$ (Eltilib, 2022). The relationship between Body Mass Index (BMI) and recurrent diabetic foot ulcers (DFUs) is significant, with various studies highlighting BMI as a critical risk factor.

Poor glycaemic control

The relationship between blood sugar levels and recurrent diabetic foot ulcers (DFUs) is significant, as poor glycaemic control is often associated with increased ulcer recurrence and complications. Elevated glycated haemoglobin HbA1c levels, particularly above eight percent , correlate with a higher chances of lower extremity amputation and impaired wound healing(Lane et al., 2020). Recurrent DFU patients often shows lower haemoglobin A1C levels compared to those with initial ulcers, indicating that even slight improvements in glycaemic control can influence recurrence rates say some literatures.

Vitamin D Level

The individuals with diabetic foot ulcers (DFUs) have significantly lower vitamin D levels and a higher prevalence of vitamin D deficiency compared to those without DFUs (Li et al., 2023). Vitamin D helps in reducing the depth and area of diabetic foot ulcer which helps in improved healing.

Other co-morbidities

Hypertension

Hypertension significantly contributes to the recurrence of diabetic foot ulcers (DFUs) through mechanisms such as peripheral artery disease and impaired wound healing. Patients with hypertension often experience peripheral vascular disease, which impairs blood flow and healing, leading to higher recurrence rates of DFUs (Hsu et al., 2024). Effective management of hypertension, alongside diabetes control, is crucial for preventing DFU recurrence. Certain medications like have shown promise in improving peripheral circulation and wound healing.

Dyslipidaemia

Cholesterol levels play a significant role in the development and healing of diabetic foot ulcers (DFUs). Research indicates that variations in lipid profiles, particularly low-density lipoprotein (LDL) and high-density lipoprotein (HDL) cholesterol, are associated with the risk and severity of DFUs in patients with diabetes. Higher levels of total cholesterol (TC) and low-density lipoprotein (LDL) are associated with an increased risk of developing diabetic foot ulcers DFUs (Ulloque-Badaracco et al., 2023). This lipid levels lipids contribute to atherosclerosis, which can restrict the blood flow to the lower limbs, increasing the risk of ulcer (Alsudairy et al., 2023).

Foot related factors

Foot deformity was identified as a significant factor that influences the recurrence of diabetic foot ulcers. Foot deformities like Charcot foot makes the complications worse in combination with other risk factors like neuropathy leading to Charcot Neuroarthropathy (Brekelmans et al., 2023). Charcot foot and post operative deformities are at a higher risk of re-ulcerations. While many ulcers reappear at same anatomical sites and contralateral foot ulcerations are present over 48 percent. While recurrences happening at the same location as initial site ulcer appeared reports as 17 percent (Peters et al., 2007). Other foot related factors like ulcers plantar ulcers, ulcer with osteomyelitis, non-healing ulcers are also at high risk of recurrence.

2.5. Footcare practices

Daily foot inspection involves checking for injuries, sores, blisters, swellings, or discoloration, using a mirror for unseen areas. Foot hygiene includes cleaning with soap or antiseptic solutions and proper moisturization. Nail care involves trimming ingrown nails and avoiding sharp objects for corns and calluses. Wearing comfortable shoes and using indoor slippers are essential and reduce the ulcer pressure with soft footwear is a preventive foot care behaviour. Regular check-ups with healthcare visits and addressing minor changes or symptoms are crucial in prevention. Maintaining blood glucose levels through timely monitoring helps prevent further complications. These practices collectively enhance foot care and prevent recurrent diabetic foot ulcers.

2.6. Healthcare Financing and financial distress

In India Non-communicable diseases (NCDs) contributes to distress financing in healthcare. The financial burden of NCDs such as cancer and cardio vascular disease often leads to resort to distress financing methods, including borrowing, relying on family and

friends for support. DM being a chronic long-standing morbidity that which creates huge financial burden to the patients and their families. A study conducted in South India bring out total annual out-of-pocket expenditure for the management of diabetic foot ulcers among the study participants was found to be ₹29 ,775(Seshadri et al., 2024) , with a catastrophic expenditure of 68.8 percent . Features of ulcer like high ulcer grade and area affected, long term ulcer duration, and previous history of ulcers increases the expenditure. Recurrent diabetic foot ulcers significantly increase healthcare costs, with treatment expenses up to 5.4 times higher in the following years after the first ulcer episode compared to patients without foot ulcers(Armstrong et al., 2017). The economic burden is more in rural and economically distressed areas also where access to care is limited which may leads to advanced disease stages and higher treatment costs(Tasman et al., 2024).

.2.7. Objectives of the study

2.7.a. Primary objective

- 1.To identify the risk factors associated with the recurrence of diabetic foot ulcers, in a diabetic specialty hospital in rural Kerala.
- 2.To assess the footcare practices followed by type 2DM patients with Recurrent DFUs and those without.

2.7.b. Secondary objective

1. To estimate the proportion of patients who resorted to distress financing mechanism for financing healthcare among patients with recurrent diabetic foot ulcers.

CHAPTER 3

METHODOLOGY

3.1. Study Type/ Design

This was an unmatched case control study to identify the risk factors associated with recurrent diabetic foot ulcer in patients with type 2 diabetic mellitus, and the footcare practices of the participants.

3.2. Study Setting

The study setting involved the Out-patient department (OPD) and In- patient Department (IPD) of Medical Trust Hospital and Diabetes Care Centre, Kulanada, Pathanamthitta. This hospital is a private institution run by a charitable trust, and functioning for almost 4 decades. The hospital almost exclusively cater to diabetes patients and has a dedicated a diabetic foot clinic. It is located in rural Pathanamthitta but caters to patients from neighbouring districts. The hospital has also been in the setting for several research studies in diabetes.(Vijayakumar et al., 2019).

3.3 Study Period

Study periods were from November 2024 to April 2025 data were collected from mid-January to mid-March.

3.4 Study Participants

3.4.1 Inclusion Criteria:

Cases: Patients with recurrent diabetic foot ulcers were taken from IPD.

Controls: Patients with type 2 diabetics mellitus having a duration more than 10 years were taken from OPD satisfying inclusion criteria is recruited for the study.

3.4.2 Exclusion Criteria:

Wounds due to road traffic accidents (RTA), wounds due to other traumas, severely ill individuals and patients who were not willing to participate in the study were excluded from the study.

3.5 Study Sampling

3.5.1 Sample size estimation

The sample size calculation, performed using OpenEpi version 3.01, assumed a two-sided confidence level of 95 percent and a power of 80 percent. With a case-to-control ratio of 1:2, the literature indicated a peripheral neuropathy exposure proportion of 50% among controls and at odds ratio of 2.15. (Huang et al.,2019). Thus, the sample size calculated for the sample size calculated is 88 for cases and 175 for controls. Considering a non-response rate of 10 percent, the final sample size was adjusted to 98 cases and 195 controls, which was rounded off to 100 cases and 200 controls making a total sample size of 300.

Peripheral neuropathy has a very high prevalence among diabetic patients, affecting up to 50 percent of this population (Bragg et al., 2024). Peripheral Neuropathy leads to a loss of protective sensation in the feet, making patients unaware of minor injuries that can develop into ulcers. This loss of sensation is a major contributing factor to the development and recurrence of diabetic foot ulcers (DFUs). The prevalence of peripheral neuropathy was chosen as the exposure level in the control population for sample size estimation.

3.5.2 Sample selection procedure

The sampling method involves selecting every 7th patient coming to the OPD for controls. For cases IPD of the hospital satisfying inclusion criteria is considered in the study. This ensures a systematic sample for analysis.

3.5.3 Sample selection procedure.

The sampling method aimed for was selecting every 7th patient coming to the OPD for controls and the IPD for cases eligible for recurrent DFUs in the study. A systematic sampling approach was envisioned, and this task of systematic selection was delegated to the OPD staff. However, the hospital has four functioning OPDs, and achieving accurate sampling of every seventh patient was challenging. Therefore, the PI verified the total OPD count of each day and aimed to select six-seven control participants in order to maintain some level of systematic sampling, ensuring a systematic sample for analysis. The inpatient unit has 95 beds distributed across two floors. The principal investigator (PI) visited each floor alternately for the selection of eligible cases.

3.6 Data collection techniques

A structured interview schedule was administered to the participants to gather information on socio-demographic details, medical history, family history, lifestyle behaviours, diabetes-related aspects, other comorbidities, and foot care practices. For the cases, the interview schedule included a section on healthcare financing mechanisms. Details of investigation reports and medication were also collected from the respective medical records (Annexure III). Data collection was done using a combination of pen-and-paper methods and the Open Data Kit platform for data entry. Data cleaning was performed in *xlsx.*, and analysis was conducted using SPSS 25.

.3.7 Data analysis

Numerical variables were summarized as means and standard deviations, or as medians and percentiles. Categorical variables were summarized as proportions. The baseline characteristics for cases and controls were compared using Chi-square tests. Odds ratios and 95 percent Confidence Intervals (CI) were computed for potential risk factors of recurrent diabetic foot ulcers. Variables significant at the bivariate level were included in the multivariate model to obtain independent associations of the risk factors with the outcome.

A descriptive analysis of the health financing mechanism and the proportion (95 percent CI) of patients reporting to the diabetic foot clinic was also computed.

The study was initiated after obtaining permission from the Medical Trust Hospital, Kulanada. The protocol and tools of the study were reviewed and cleared by the Institutional Ethics Committee (IEC) of SCTIMST (Letter No. SCT/IEC2340/DECEMBER/2023).

Written informed consent was obtained prior to data collection, and participants had the autonomy to withdraw at any stage. Privacy and confidentiality of all participants were ensured to the greatest extent possible. The final dataset does not contain any personal identifiers.

For details see appendix

CHAPTER 4

RESULTS

4.1 Profile of the participants

Cases

Among 100 cases the mean age was found to be 64.23 years with a Standard deviation (SD) of 10.465 and 82 percent were males while females constituted only 18 percent. Of the cases 62 percent were found to be rural inhabitants ;54 percent are unemployed and mean monthly income of the family is ₹13,012 with a Standard Deviation (SD) of ₹16,113 with a majority of cases being holders of non-priority ration cards.

Controls

In control participants the mean age was found to be 65.11 years with a standard deviation of 10.259. Female participants constitute majority of the control group. Rural inhabitants constituted a major proportion in the group with 65 percent, 62.5 percent of the controls were unemployed, having a family income of ₹14,143 with a Standard Deviation of ₹15,630 and have a high proportion of holders of non-priority cards.

Unlike cases, as most of the controls were females, all bivariate and multivariate analysis was done for adjustment for sex.

Table 4.1a Description of participants - Socio- demographic variables

Variable	Category		Cases N (%)	Controls N (%)
Age		Mean	64.23	65.11
		Standard deviation	10.465	10.259
Sex	Male		82 (82%)	87(43.5%)
	Female		18(18%)	113(56.5%)
Occupation	unemployed		54 (54%)	125(62.5%)
	employed		46(46%)	75(37.5%)
Monthly income of the family		Mean	13012.05	14143.27
		Standard deviation	16113.147	16530
Ration Card	Non priority		81 (81%)	180(90%)
	Priority		19 (19%)	20(10%)

For smoking status of the participants, the data showed that 20 percent of the cases have ever smoked compared to control which is 9 percent only. For smokeless tobacco use, 15 percent of the cases are current users verses 6 percent of controls, while 6 percent of cases and 7 percent of controls have ever used tobacco. Alcohol consumption reports that one percent in cases and 0.5 percent of the controls as current users, with 24 percent of cases and 12.5 percent of controls have ever used alcohol. When it comes to physical activity of

the participants 45 percent of the cases reports being physically active compared controls it is 65 percent.

Comorbidities and Blood Investigations

In cases of hypertension ,30 percent of the cases are hypertensive and it was 17.5 percent in controls , while a higher proportion of controls 82.5 percent had their blood pressure values under control versus 70 percent of the case group suggests the poor blood pressure were more prevalent in cases group .About 15 percent of the cases were affected with dyslipidaemia , while only 8 percent of the controls have the condition .Despite of this the use of statin medications was higher among controls 61 percent compared to cases it is 49 percent .

Table 4.1.b Participant characteristics -blood investigations

Variables	Category		Cases N (%)	Controls N(%)
FBS		Mean Standard Deviation	159.90 61.442	168.92 58.103
HbA1c		Mean Standard Deviation	8.69 2	8.541 2.136
Blood pressure control	Normal Hypertensive		70(70%) 30(30%)	165(82.5%) 35 (17.5%)
Total cholesterol		Mean Standard deviation	180.79 36.319	196.46 37

As in table 4.1. b. Total cholesterol values were slightly higher in controls than in cases, the mean in case group was found to be 180.79 with a standard deviation of 36.319 and a mean of 196.46 with a standard deviation of 37 were found controls. Regarding the blood investigation data, fasting blood sugar values (FBS) show that cases having a slightly lower mean 159.90 with a standard deviation of 61.44 compared to controls having a mean of 168.92 with a standard deviation of 58.103. HbA1c values also slightly differ with the cases group having a higher mean value of 8.69 with a standard deviation of 2 and in comparison, with controls the mean value is 8.54 with a standard deviation of 2. 136, indicating slightly poor blood sugar controls among the cases group. Cases show a higher rate of hypertension, and dyslipidaemia but a lower statin use and cholesterol levels with marginally poor glycaemia profile.

Diabetes Related Aspects

The duration of Diabetic Mellitus (DM) is nearly similar between case group and control group; the cases have a mean DM duration of 17.35 years with a standard deviation of 8.695 and in controls 17.49 years with a standard deviation of 6.92. The range of duration was found to be slightly different in both participant groups it is 4- 46 years in cases and 10- 45 years in controls. There observed an even distribution in family history of diabetes mellitus, it is 50 percent in cases and 51.5 percent in controls. Diabetic foot ulcer (DFU) family history data shows that 25 percent of cases and 20.5 percent of controls have had a history. Recurrent DFU family history is higher among case 24 percent than 19.5 percent in controls implying more severe disease complications among cases.

Regarding mode of medication, a higher proportion of cases are on insulin only group 35 percent, whereas on both – (insulin and oral hypoglycaemic agent) group 41 percent in cases. In control group 19.5 percent are on insulin only and 27.5 percent on both– (insulin

and oral hypoglycaemic agent) groups. Of 53 percent of the controls depends only on oral hypoglycaemic agent (OHA) and it is only 24 percent in cases. This reports that cases are more likely to require intensive treatment reflecting on more advanced or poorly controlled diabetes.

Table 4.1c Diabetic related comorbidities.

Variables	Category	Cases N (%)	Controls N (%)
Peripheral vascular diseases (PVD)	Present	63(63%)	103(51.5%)
	Absent	37(37%)	97(48.5%)
Retinopathy *	Present	32(32%)	57(28.5%)
	Absent	54(54%)	116(58%)
Nephropathy*	Present	17(17%)	35(17.5%)
	Absent	82(82%)	157(78.5%)
Neuropathy *	Mild	2(2%)	10(5%)
	Moderate	12(12%)	49(24.5%)
	Severe	85(85%)	130(65%)
	No	1(1%)	5(2.5%)

*27controls and 12 cases in retinopathy ,1case and 8 controls in nephropathy,6 controls in neuropathy data were found to be missing as they were not willing for concerned examinations.

As table 4.1.c shows peripheral vascular disease (PVD) is more prevalent among case group compared to control group. In comparison with the controls Diabetic Retinopathy is more common among cases. Severe neuropathy was observed in cases than compared to controls. The mean serum Creatinine values are slightly higher among control groups 1.1201 mg/dL with a standard deviation of 0.60 than in cases it is 1.0967 mg/dL with standard deviation of 0.363. The Prevalence of Diabetic Nephropathy is nearly similar among both cases group and control group. In case peripheral neuropathy only a very few participants reported no

peripheral neuropathy that is only 1 percent in cases and 2.5 percent in Controls, and severe condition is more prevalent among cases.

4.2 Assessments of footcare practices

Noticeable differences were observed with footcare practices in both cases and control. In cases 76 percent reported some kind of foot care practices where as it is 69 percent in controls. Self-examination for sores and blisters in foot were regular found to regular with 77 percent in cases and 75.5 percent in controls. In cases of foot examinations, no foot examinations were found in 15 percent of cases and 11 percent of controls. Of 62 percent of cases visits health care provider for the foot examination, and in controls it was found to be 71 percent. In case of foot hygiene daily foot washing was common among cases than control 71 percent and 64 percent respectively. The use of moisturizing cream on foot were found to be more common among cases 52 percent to that of controls 49 percent. A higher proportion of cases 31 percent were prescribed for modified or specialized footwears compared 17 percent in controls, reflecting on more severity of disease condition among cases. However, nail care practices varied slightly among cases and controls, 54 percent of cases trims their nails about once a month, compared to controls 50 percent. Only a smaller proportion of cases and controls performed nail trimming weekly (16 percent versus 20.5 percent). Regarding foot massage, a major proportion of cases and controls never performed it reports 68 percent in cases and 68.5 percent in controls. Although occasional practices were slightly more common among controls compared to cases. These finding suggests that some kind footcare awareness exists in both cases group and control group, to point out the differences is difficult. Cases demonstrated slightly better personal care foot care practices, likely due to the previous ulcer management experiences. Table 4.2.a shows the footcares practices among cases and controls.

Table 4.2a Footcare practices of cases and controls

Variables	Category	Cases (N%)	Controls(N%)
Do you perform any kind of footcare practices?	Yes	76 (76%)	138(69%)
	No	24(24%)	62(31%)
How often do you examine your foot for sores and blisters?	Daily once	77(77%)	151(75.5%)
	More than once a day	2(2%)	3(1.5%)
	Weekly once	6(6%)	24(12%)
	Never	15(15%)	22 (11%)
Do you visit healthcare provider for foot examination?	Yes	63(62%)	143(71.5%)
	No	37(37%)	57(28.5%)
How often do you wash your foot?	Once a day	71(71%)	128(64%)
	More than once a day	20(20%)	43(21.5%)
	Few days a week	0(0%)	3(1.5%)
	Most days of a week	5(5%)	10 (5%)
	Never	4 (4%)	16 (8%)
Do you use moisturizers for your foot?	Yes	52(52%)	98(49%)
	No	48(48%)	102(51%)
Have you been prescribed for any specific footwear?	Normal	63(63%)	160(80%)
	Specialised	31(31%)	34(17%)
	No footwear	6(6%)	6(3%)

How often do you trim your toenails?	About once a week	16(16%)	41(20.5%)
	About once a month	54(54%)	100(50%)
	Less than once a month	18(18%)	33(16.5%)
	Never	12(12%)	26(13%)
Do you massage your foot?	Sometimes	8(8%)	30(15%)
	Often	8(8%)	16(8%)
	Rarely	16(16%)	17(8.5%)
	Never	68(68%)	137(68.5%)

Regarding frequency of health care visit, 36 percent of cases reported visiting a health care provider every month, and was closely followed by 34 percent who visited every 3-6 months. In contrast, a higher proportion of controls 44 percent reported visiting every 3-6 months, with 36.5 percent visiting monthly. More number of cases (22 percent) visited a health care provider only when they have a problem and it was found to be 10 percent of controls, which may suggest that more reactive nature in cases rather than preventive behaviour. Of drying between toes after washing 23 percent of cases reported always doing compared to 22.5 percent of controls, but a larger proportion of cases 37 percent said that they rarely performed or never performed drying of their toe, while this was a higher population in controls 49 percent. This suggests that both groups showed poor adherences to important footcare behaviours. Majority of the cases and controls 83 percent and 84.5 percent respectively, were not used to wear pointed toed shoes reporting never doing so. Similar reporting was observed in sock usage for footcare suggesting low awareness and adherence to the preventive foot care behaviours.

Walking barefoot inside the house was more common among controls, where 30 percent reported walking barefoot at least sometimes, compared to 14 percent in case group. This reflects the greater caution among the case groups due to previous ulcer experiences. A

higher proportion of cases and controls reported never walking bare foot outside 86 percent and 90.5 percent respectively reflecting on differences in protective behaviours among cases and controls.

Self-management of corns and blisters were uncommon among both cases and control groups, 90 percent and 93 percent respectively never managed blisters. Similarly, 93 percent of cases and 95 percent of controls never dressed blisters by themselves. This result shows low level of risky selfcare behaviour among both groups.

Awareness of the risk factors of the DFUs were slightly higher among cases compared to controls (74 percent in cases and 70 percent in controls) suggests that the prior experiences of ulcers helped to be aware of the risk factors.

4.3Details of Foot Ulcers

In cases of details of the foot ulcers, among 100 cases left foot ulcers were common 44 percent and 41 percent of right foot ulcers. Bilateral ulcer conditions were observed in 15 percent of cases participants. A higher proportion of plantar ulcers 94 percent and 17 percent of dorsal ulcers were observed. Forefoot is the common ulcer site, which constituted 79 percent followed by hind foot ulcer 25 percent and mid foot ulcers 17 percent. Multiple ulcers on foot were reported by 28 percent of cases. Ulcer with osteomyelitis complication were found in 7 percent, Charcot foot and non-healing ulcers were observed 1 percent as complications of the ulcer wound.

4.4Distress Financing

This section pertains only for case group.

Financial distress is experienced by 53 percent of the cases. The primary financial challenge includes expenses of treatment 71 percent, medical expenses 61 percent, transportation expenses 27 percent, jobless or working hours loss in 26 percent. The major causes of distress financing are frequent hospital visits 83 percent, job loss 25 percent, medication cost 12 percent, with a minimal proportion being attributed from home care nursing services 8 percent and 1 percent for footcare 1 percent.

About 75 percent of the cases reported that cost of treatment and foot care practices affected income of last financial year. Gold pledging (67 percent) and borrowing from friends and family (67percent) were the most common financing method followed by asset selling 18 percent, use of own saving (13 percent), and smaller percent used personal loans (three percent), credit card (six percent), payday loans (five percent) and debt consolidations (four percent).

Among cases 46 percent had no insurance coverage while 41 percent were insured under Government health insurance schemes ,11 percent under private health insurance schemes. and 1 percent of senior citizen plans. Treatment burden was seen very high present that is 93 percent and footcare as a burden was reported by 60 percent.

4.5 Bivariate Analysis

Chi square analysis test and binary logistic regression was performed to examine the association between independent variables and outcome variable. The outcome variable, here is the diabetic patients with recurrent diabetic foot ulcer and patients with type 2 diabetes mellitus alone, binary logistic regression analysis repeated with sex to find out a sex adjusted odds ratios.

Male sex was significantly associated with the recurrence of diabetic foot ulcers. The crude odds ratio for male participants were found to be 5 times compared to female participants.

Priority Ration card holders had a higher prevalence of development of the recurrences of the foot ulcer compared to non-priority ration card holders. After adjusting with sex then adjusted odds ratio implies that participants from low socio-economic background had more than twice the risk of developing recurrence of foot ulcers as shown in table 4.5.a.

Table 4.5.a Crude odds ratios and Sex adjusted odds ratios of sociodemographic variables

Variables	Category	Control	Cases	Unadjusted odds ratio (OR)	P-value	Adjusted odds ratio OR (sex)	P value
Sex	Female**	113(56.5%)	18(18%)	5.917	<0.001	---	----
	Male	87(43.5%)	82(82%)	(3.307-10.586)			
Ration Card	Non-Priority**	180 (90%)	81 (81%)	2.111	0.031	2.419	0.021
	priority	20 (10%)	19 (19%)	(1.067-4.123)		(1.141-5.128)	

**Reference category

Table 4.5.b Bivariate Analysis -crude odds ratios and Sex adjusted ratios of BP under control and statin use.

Variables	Category	Control	Cases	Unadjusted odds ratio OR	P- value	Adjusted odds ratio OR (sex)	P-value
BP-under control	Normal**	165(82.5%)	70(70%)	2.020	0.014	1.934	0.033
	Hyper-tensive	35(17.5%)	30(30%)	(1.152-3.545)		(1.054-3.550)	

Statin use	No**	122(61%)	72(72%)	0.608 (0.361- 1.024)	0.061	0.623 (0.357- 1.080)	0.095
	Yes	78(39%)	28(28%)				

**Reference Category.

As in Table 4.5.b In blood pressure under control, the result indicated that individuals with uncontrolled hypertension had nearly twice odds of experiencing recurrence of DFU compared to those with blood pressure values under control. Even though the not statistically significant after adjustment with the use of statin medication may reduce the risk of recurrence of foot ulcers.

Table 4.5. c. Bivariate analysis of Diabetic related aspects and co morbidities.

Variables	Category	Control	Cases	Unadjusted- odds ratio (OR)	P- value	Adjusted- odds ratio (OR) (sex)	P- value
DM duration	Short duration **	112 (56%)	47 (46%)	1.435	0.142	1.498	0.127
	Long duration	88 (44%)	53 (53%)	(0.886- 2.324)		(0.891- 2.517)	
Recurrent foot ulcer family history	No**	161 (80.5%)	76 (76%)	1.304 (0.732- 2.321)	0.368	1.155 (0.622- 2.145)	0.649
	Yes	39 (19.5%)	24 (24%)				
PVD	No**	97 (48.5%)	37 (37%)	1.604	0.060	1.793	0.031

	Yes	103 (51.5%)	63 (63%)	(0.981- 2.622)		(1.055- 3.047)	
Neuropathy	No-moderate**	64 (33%)	15 (15%)	2.790 (1.493-	0.001	2.303 (1.189-	0.013
	Severe	130 (67%)	85 (85%)	5.213)		4.459)	
Insulin use	Not an insulin user**	106 (53%)	24 (24%)	3.571 (2.088-	<0.001	3.500 (1.979-	<0.001
	Insulin User	94 (47%)	76 (76%)	6.106)		6.979)	

**Reference category

In DM duration, the duration of disease condition cannot be a significant cause for recurrence of foot ulcers but when in association with other co morbidities the risk aggravates. A family history of recurrent foot ulcers did not show any statistically significant association with recurrence of foot ulcers. Peripheral vascular diseases is a major risk factor for the recurrences of foot ulcers. Severe neuropathy showed strong association with recurrence of the foot ulcers. Insulin use is associated with the foot ulcer recurrence, the adjusted odds value report three times higher odds in development of recurrent foot ulcers as table 4.5 c shows.

Table 4.5.d Bivariate analysis of foot care practices.

Variables	Category	Control	Cases	Unadjusted odds ratio (OR)	P-value	Adjusted odds ratio OR (sex)	P value
Footcare practices	No**	62(31%)	24(24%)	1.423	0.207	1.480	0.190
	Yes	138(69%)	76(76%)	(0.822-2.461)		(0.824-2.659)	

Foot wash	Poor hygiene **	29(14.5%)	9(9%)	1.715 (0.778-3.778)	0.181	1.807 (0.783-4.170)	0.165
	Good-hygiene	171(85.5%)	91(91%)				

**Reference category

Footcare practices were more common in cases, but there is no statical differences exist between cases and controls. The foot wash was found to be similar in both cases and controls but, with most washes at least once day. In controls poor foot hygiene is observed and the variable was not statistically significant as shown in table 4.5.d

The analysis was done for other various risk factors using both unadjusted and sex adjusted odds ratios. For age, lower odds in cases of individuals aged 60 years and above compared to age group under 60 years and this was not statistically significant either in unadjusted odds (OR:0.892(0.495-1.390),P=0.478) or in sex adjusted odds (OR;0.846(0.485-1.476),P=0.556) In case of addiction history a noticeable shift in significances observed , initially , individuals with addiction history showed a significantly higher odds (OR: 1.861(0.060-3.267) , but the association got disappeared after adjusting for sex (OR:0.990(0.537-1.824),p=0.974), suggesting that sex as a confounding variable during unadjusted analysis .With regards to control of diabetes both HbA1c and FBS values were considered .There existed no significant association on HbA1c levels . On other hand FBS had significantly lower odds compared to individuals with those of normal FBS (unadjusted OR: 0.346, (0.140-0.850) p=0.021: adjusting for sex (OR:0.285(0.105-0.776), p=0.014)) demonstrating a strong and significant inverse relationship. The odds direction slightly lowered in HbA1c case, unadjusted odds 1.286(0.592-2.794) to 1.138(0.494-2.622) on adjusting for sex leaving the p values insignificant. Similarly in case of Total cholesterol a

potentially protective relationship is observed, the association had significantly lowered odds in unadjusted OR: 0.547, $p=0.018$; on adjusting for sex OR :0.521, $p=0.017$.

Other variables such Statin use, callus formation, foot deformity corn management, foot massage, barefoot walking and use of foot moisturization did not show a statistically significant association in either unadjusted odds or sex adjusted odds. A non-significant association was observed in drying of foot with an increased odds (unadjusted OR: 1.598, $p=0.075$; on adjusting for sex OR:1.723, $p=0.054$) showing a potentially preventive behaviour that may benefit from further study.

In case of financial distress simple chi-square test was performed in case group participants who experienced financial distress. The test was analysed for ration card type, duration of DM, family income, sex, use of insulin, and only ration card showed a significant p value of $p=0.012$, and a chi square of 6.340(df -1) reporting lower socio-economic status is more affected with recurrence of diabetic foot ulcer.

4.6 Multivariate Analysis

To identify independently associated risk factors for the development of recurrence of diabetic foot ulcers, a binary logistic regression model was employed for multivariate analysis. This method was selected due to the interplay of multiple risk factors like socio demographic characters, comorbidities, treatment aspects, footcare behaviours; contribution for the development of the condition.

Variables with p value less than 0.1 in bivariate analysis were included in multivariable regression model to identify the important risk factors that potentials affect the condition were retained. Table4.6. a shows multivariate analysis the significant risk factors recurrence of foot ulcer.

In multivariate analysis p values of physical activity and statin use remained significant but odds showed protective effect again diabetic foot ulcer recurrence. These were not included in the model because of the logical challenge in explaining this associations. For example, it is problematic to conclude to say less physical activity is protective to foot ulcer.

Table 4.6a Multivariate analysis

Variables	Category	Crude odds ratio	P-value	Adjusted Odds ratios	P – value
Ration card	Non priority**	2.111 (1.069-4.169)	0.031	2.297 (0.997-5.293)	0.051
	Priority				
Sex	Female**	5.917 (3.307-10.586)	<0.001	5.464 (2.895-10.314)	<0.001
	male				
Neuropathy	Absent**	2.790 (1.493-5.213)	0.001	1.994 (0.976-4.075)	0.058
	present				
Peripheral vascular disease	Absent **	1.604 (0.981-2.622)	0.060	2.022 (1.128-3.624)	0.018
	Present				
BP under control	Normal**	2.020 (1.152-3.545)	0.014	1.816 (0.935-3.529)	0.078
	Hypertensive				
Insulin users	No**	3.571 (2.088-6.106)	<0.001	3.033 (1.659-5.547)	<0.001
	yes				

** Reference Category

Model characteristics

Omnibus tests of model coefficient were statically significant $\chi^2(8) = 86.426$, $p < 0.001$, The Hosmer–Lemeshow goodness-of-fit test was not significant ($\chi^2(8) = 12.157$, $p =$

0.144), indicating a good model fit. Nagelkerke pseudo-R square is 0.352 indicating 35.2 percent variations is explained in this model.

4.7 Risk Factors

The priority ration card being an indicative of lower socio-economic status, was having an association with two times increased odds of developing recurrent diabetic foot ulcers (odds ratio OR – 2.297,0.997-5.293), the results show significant p-value of 0.051 sex was strong predictor for foot ulcer recurrence, males have statically higher odds of recurrence of diabetic foot ulcers compared to females (OR= 5.464,2.895-10.314, $p < 0.001$). This five times increase odds indicates that male sex is a strong independent risk factor.

Neuropathy was associated with the complications of foot ulcers, with increased odds but this result reports statistically not significant (OR=1.994,0.976 -4.075), $p = 0.058$). Even though the direction of association suggests higher risk. In case of peripheral vascular diseases (PVD) showed a significant association with recurrence of foot ulcers (OR= 2.022, 1.128-3.624, $P=0.018$). This indicates the individuals with PVD are more than twice as likely to develop recurrence as compared individuals without the condition. Blood pressure control approaches significant p value ($p = 0.078$) with those having uncontrolled blood pressure values showed higher odds (OR=1.816,0.935-3.529). Even though not statistically significant, the direction of odds suggests that poor blood pressure control may contribute to the risk of development of recurrence of foot ulcers. Insulin users had nearly three times higher odds of developing recurrence complication compared to non-users of, which may reflect on severe insulin related complications.

On including addiction history to the model to find out the association with recurrence in male individuals found to be no significant association (OR=0.778,0.389-1.558, $p=0.479$),

implying addiction history was not having significant association with recurrence with recurrence of foot ulcers.

Other models and model characteristics

Then the model was repeated using backward conditional regression analysis where the test got all other results, odd ratios and p value similar to that of logistic regression enter model.

The test was again repeated with stringent p value of 0.05 for inclusion /removal and the result remains same that of the model. When the model was repeated after logically removing variables like physical activity and insulin user the omnibus test model coefficient was statistically significant, $\chi^2(8) = 67.703$, $p < 0.001$, indicating that the predictors effectively differentiate between the outcome groups. The Hosmer–Lemeshow test was not significant ($\chi^2(7) = 7.887$, $p = 0.455$), indicating that the model fits the data well. The pseudo-R square is 0.285, suggests that about 28.5 percent of the variance in the outcome is explained by the model. The risk factors are found to be ration card, sex, neuropathy, PVD, bp under control and statin use. The model was also repeated for sex division the omnibus test of model coefficient was statistically significant for both females ($\chi^2(7) = 18.361$, $p < 0.010$.) and males ($\chi^2(7) = 37.391$, $p < 0.001$), suggesting that the predictors effectively distinguish between the outcome categories in each sex group.

The Hosmer–Lemeshow test showed good fit for the female model ($\chi^2(7) = 4.457$, $p = .726$), while the male model indicated a poor fit ($\chi^2(8) = 14.821$, $p = 0.063$), suggesting that predicted values significantly differed from observed outcomes in males. The model explained approximately 24.1 percent of the variance in the outcome for females and 26.3 percent for males (Nagelkerke pseudo- $R^2 = 0.241$ and $.268$, respectively), indicating a moderate explanatory power in both groups. In females, neuropathy, statin use and bp under

control found to be significant risk factor. In males Ration card, PVD, insulin user, physical activity found to be a risk factors.



CHAPTER 5

DISCUSSION

This unmatched case control study explored various kind of risk factors, footcare practices and how the distress financing is associated with the occurrence of recurrent diabetic foot ulcers in rural Kerala. The findings from the study reports that certain modifiable risk factors play a crucial role in the development of recurrence of DFUs among the participants sociodemographic factors, diabetic comorbidities, medications, adherence to foot care practices. The study also explored financial aspects for care and treatment of the ulcer wounds.

The important risk factors identified are male sex, presence of peripheral vascular diseases, severe peripheral neuropathy, low socio-economic status indicated by a priority ration card, insulin the use of insulin is consequence rather than a concern. The combination of both clinical and socio demographic determinants underlines the multifactorial nature of development of recurrent foot ulcers. Male sex got significant association with recurrence of foot ulcers (Adjusted odds ratios=5.49, $p<0.001$), this study was consistent with (Vanherwegen et al., 2023). Men are more likely to experience the severe foot ulcers along with slow healing of the ulcer wound leading to severe complications. This might be a reflection of occupational exposures or delay in seeking care. Severe diabetic comorbidities like PVD and peripheral neuropathy increases the risk of development and recurrences of foot ulcers in diabetic patients. There exist a significant association of recurrence risk due to PVD (adjusted odds 2.02, $p=0.018$) and peripheral neuropathy (adjusted odds 1.99, $p=0.058$). Different studies shows that the presence of Peripheral neuropathy and peripheral vascular diseases can contribute neuro ischemic foot which is high risk condition in diabetic patients for the recurrence of foot ulcers. (Zhang et al.,

2017). This can lead to poor blood flow towards foot and lack of sensation which can lead to unnoticed wounds and poor wound healing.

Some socio-economic factors were also associated include presence of a priority ration card which is an indicative of low socio-economic status, doubled the odds of developing recurrence of foot ulcers (Adjusted odds ratio= 2.3, $p=0.051$) in socio-economically deprived populations, this financial constraints may lead to reduced health care seeking behaviours similarly, early interventions and use of protective footwears and adherence to footcare practices (Van Netten et al., 2020).

Patients with hypertension often experience peripheral arterial complications which can lead to impaired wound healing and higher recurrence of foot ulcers (Hu et al., 2024). Hypertensive individuals are 1.8 times at a higher risk of development of recurrent foot ulcers than those of normal blood pressure readings. The use of insulin is strongly associated with recurrence of foot ulcers. A higher rate of foot ulcer recurrence complications is observed in insulin users, adjusted odds 3.03, $p<0.001$. It has been reported that the use of insulin is likely to be an indication of poor glycaemic control (Lane et al., 2020b), poor control can lead to worse outcomes in diabetic foot ulcer patients. On the other hand, this could be a possible selection bias where insulin use is more common among inpatients where easy administration of insulin use will be common.

Regardless of expectations, variables such as glycaemic control and some foot care practices were not significantly associated in the adjusted models. This suggests that recurrence may be influenced more strongly by structural risk factors and long-term disease progression than by short-term behaviours.

5.1. Possible selection bias

Being an unmatched, hospital-based study, several biases relate with selection of patient may have had happen since cases and controls are drawn from IPD and OPD of the same study setting respectively. However, the community setting is unlikely different for both cases and controls.

Sex imbalance might be a reflection of selection bias where the female configuration is more in controls (56.5 percent) compared to the predominance to the male configuration in cases (82percent). This might have possibly led to overestimation of risk in male gender. However, male sex is consists of accords multiple studies, and the observed effects of sex is unlikely to be merely a bias. This may still affect some other variables in the study. For example , in control group the prevalence of dyslipidaemia is common since females constituted the majority of the control group and females are more prone to have high dyslipidaemia status (Phan and Toth, 2014) . Duration of DM is significantly associated with recurrence (Armstrong et al., 2017) In is study the unmatched study design attributed to the overlap of duration of cases and controls due duration difference in cases(range of duration 4- 46 years) and controls (range of duration 10 to 45 years).This might have made a group of cases that had duration less than 10 years to a subset that might have neutralized the effect of associations of duration through the outcome. Duration could be a potential effect modifier of the relationship under the study.

According to literature poor blood sugar level affect complications of foot ulcers (Lane et al., 2020) . However, in this an unexpected association is observed the in FBS variable probably due to due to reverse causation. Participants with DFU history might receive more rigorous monitoring and also, being in-patients continuous monitoring of FBS values and

timely treatment is possible, this may lead to better glycaemic control in cases at the time of data collection.

5.2. Possible measurement errors or misclassifications

According to the results the effect was low physical activity found to be protective (Adjusted odds = 0.47 $p=0.005$). High level of physical activity similarly low level of physical activity also affects recurrences, engaging in inappropriate levels of physical activity will increase the risk of recurrence. In the context of this study the prevailing disease condition in cases might have led to a low physical activity. The observed protective association between physical activity and recurrence might be an influence of the consequence rather than a risk factor for the development of ulcers. This could be due to the cross-sectional nature of assessment and level of activity in cases which was not considered before occurrence of the ulcer.

In the same way the health seeking behaviours, severity of complications and foot practices might have been influenced differences due to the severe complications in cases and milder complications in controls

5.3. Implications of other findings

Addictions like smoking(Xia et al., 2019) , alcoholism(Bell and Goncalves, 2021) , tobacco usage(Z-H Huang et al., 2019) significantly affects the outcome of recurrences and may lead to impaired wound healing .The crude analysis suggested a significant association between addiction history and recurrent diabetic foot ulcers. However, this association disappeared after adjusting for gender (OR=0.99, $p=0.974$) indicating that gender likely confounded the relationship. This outcome emphasizes a limitation of the unmatched case-control design, where confounders such as sex are not balanced by design and must be accounted for in the analysis. The findings suggest that addiction may not independently

contribute to DFU recurrence once gender differences are considered. Literature highlights that regular foot examination can reduce the rate of recurrences .(Van Netten et al., 2020).

In this study a higher proportion of cases reports footcare practices compared to controls (cases 76 percent and controls 70 percent). But only a fewer number of cases have reported regular health care visit. This probably shows reactive behaviour in cases due to prior experiences in foot ulcer management, rather than following consistent preventive measures. Distress financing was reported by 53 percent of the foot ulcer cases, and 43 percent of cases were not covered under any kind of health insurance. This implies that there exists as substantial financial constraints .As study conducted in South India reported catastrophic expenditures was 68.8 percent in diabetic foot ulcers(Seshadri et al., 2024) . This highlights the needs for financial protection and inclusion of health insurance coverage .

5.4. Strength and limitation

This case control study design helped to robust the result by identifying multiple risk factors of relatively rare outcomes like recurrent foot ulcers. The inclusion of clinical, socio economic as well as behavioural variables helped to understand recurrence from a non-medical perspective also. Conducting a study in a diabetic care centre with a dedicated podiatry unit reflected on a real-world setting. Exploring on distress financing and its coping up mechanism helped to include the influence of financial stress on recurrence of foot ulcers.

Since the study is not multi-centric and the participants were recruited from same diabetic centre, this may limit the generalizability of the study as the study left behind a wider diabetic population outside the study setting. Also, this diabetic care centre acts as a referral unit for many health care institutions, since the cases represent more severe conditions of

diabetes or more aware population than general population. Several variables like footcare behaviours, financial history were self-reported this and this might have been influenced with recall bias. There might be an effect of over estimation or under estimations of results due to reverse causality of some variables (Physical Activity, foot care practices). Even though a systematic sampling strategy was attempted the sampling method had inconsistencies due to the presence of four simultaneously functioning OPDs, which assured only some level of systematic sampling after analysis average OPD of a day. The study focused on the proportion of cases affected with distress rather than the extent of distress in detail.

Recommendations

- Strengthening foot care education encouraging daily inspection of foot, hygiene and use of protective footwears.
- Annual screening for diabetic related comorbidities like Peripheral vascular diseases and peripheral neuropathy.
- Establishment of community based diabetic foot clinic with podiatry units.
Enhancing financial protection by expanding insurance coverage or medical reimbursement for medications and footcare aids including specialised footwear.
- Integration of diabetic foot ulcers prevention and management in National Program for Prevention and Control of Non- Communicable Diseases. (NP-NCD) and Ayushman Bharath initiatives helps in reducing the burden in patients.

CHAPTER 6

CONCLUSION

This case control study helped to analyse multiple risk factors that are associated with recurrence of diabetic foot ulcers, in diabetic population in Kerala. The finding from the study underlined that interplay of various socio demographic factors, patient's behavioural patterns and clinical comorbidities together contribute to the recurrences of foot ulcers and severe complications of diabetes.

The key risk factors identified in multivariable analysis study constituted, sex (male), peripheral vascular disease, peripheral neuropathy, uncontrolled blood pressure, ration card status (priority ration card), and insulin use (may be a consequence rather than a cause). These risk factors alone or as a combination can worsen the conditions of a high-risk diabetic population.

Even though some kind of footcare practices were present in the study diabetic population the adherence to some attributes were found to be low among the cases. The prior ulcer experience might have led to the protective associations due to inadequacy in footcare current practice adherence.

Along with the analysis of clinical characteristics the study also drawn attention towards the economic constraints caused due to the recurrence of foot ulcers. The results showed that about half of the percentage of total cases experienced financial distress due to the disease, and the coping up mechanisms to the financial distress included gold pledging and borrowing from friends and family as distress financing options. the lack of health insurance security in while seeking care private institution extensively affected the cases. The possibility of selection bias was inevitable in study and this made challenges in

sampling methods, under or overestimations of some variables which might have affected in pointing out clinical and public health insights.

Beyond clinical management this study highlighted addressing on social determinants of health, financial security, and sustained patient's education along with adherence to behavioural patterns that helps in effective management and prevention of recurrence of foot ulcers and other diabetic related complications.

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ANNEXURE I

1. Description of participants - Age, Monthly Income, Physical Activity

Variables		Cases	Controls
Age	Median	64	65
	Range	42-90	38-93
Monthly income of the family	Median	6000	10000
	Range	1000-80000	1000-80000
Physical activity	Yes	45(45%)	130(65%)
	No	55(55%)	70(35%)

2. Description of participants -Blood Investigations, DM duration and Mode of Medication

Variables		Cases	Controls
FBS	Median	155.50	154.50
	Range	72-582	79-436
HbA1c	Median	8.2	8
	Range	5-14.50	5-14.5
Serum creatinine value	Median	1.05	0.98
	Range	0.41-2.35	0.08-6.38
DM duration	Median	16	15
	Range	4-46	10-45
Mode of medication	Both	41(41%)	55(27.5%)
	Insulin	35(35%)	39(19.5%)
	OHA	24(24%)	106(53 %)

3. Bivariate analysis of Age, Physical Activity, Addiction history and blood investigations

Variables		Controls	Cases	Unadjusted Odds ratio	P – value	Adjusted Odds ratio	P- value
Age	Age less than 60yrs *	58(29%)	33(33%)	0.829 (0.495-1.390)	0.478	0.846 (0.485-1.476)	0.556
	Age greater than or equal to 60yrs	142(71%)	67(67%)				
Total cholesterol	Normal *	103(51.5%)	66(66%)	0.547 (0.332-0.900)	0.018	0.521 (0.305-0.890)	0.017
	Elevated	97(48.5%)	34(34%)				
Addictions history	No history*	164(82%)	71(71%)	1.861 (1.060-3.267)	0.031	0.990 (0.537-1.824)	0.974
	History present	36(18%)	29(29%)				
Physical activity	No*	70(35 %)	55(55%)	0.441 (0.270-0.719)	0.001	0.469 (0.277-0.792)	0.005
	Yes	130(65%)	45(45%)				
HbA1c	Normal*	25(12.5%)	10(10%)	1.286 (0.592-2.794)	0.526	1.138 (0.494-2.622)	0.762
	Not under control	175(87.5%)	90(90%)				
FBS	Normal*	9(4.5%)	12(7%)	0.346 (0.140-0.850)	0.21	0.285 (0.105-0.776)	0.014
	Not under control	191(95.5%)	88(88%)				

*Reference category

ANNEXURE II

ACHUTHAMENON CENTRE FOR HEALTH SCIENCE STUDIES, SCTIMST,

THIRUVANANTHAPURAM-11

PARTICIPANT INFORMATION SHEET

Good morning/afternoon/evening

I am Dr. Greeshma Ramesh currently pursuing Master of Public Health (MPH) at SCTIMST (Sree Chitra Tirunal Institute of Medical Sciences and Technology). I am conducting a study, “Risk Factors and Footcare Practices in Recurrent Diabetic Foot Ulcers: A Hospital based Case-Control Study in Pathanamthitta District, Kerala”.as part of the requirement of the course.

Purpose of study

The aim of the research is to study the risk factors associated with the development of Recurrent Diabetic foot ulcer among patients with Diabetes Mellitus condition. For this study a secondary care setting in Pathanamthitta district (Medical Trust Hospital and Diabetes Care Centre, Kulanada) has been selected and the subjects will be interviewed as per your willingness for participation. Patients with Diabetes Mellitus having Diabetic Foot Ulcer coming to Medical Trust Hospital, Kulanada will be selected for the study. You have to spend a total of 20 minutes for an interview and answer a prepared set of questions as I will be recording the interview. If you participate in the study by answering the interview schedule, I will be grateful to you for providing the information.

Benefits from participation

There will not be any direct benefit for you if you participate in the study, but your participation will help in generating knowledge about Diabetes Mellitus and Diabetic Foot Ulcer and its recurrence.

Discomfort/harm from participation

Participation in the study will not impose any risk to health. Some questions related to your health, behaviour and personal history may cause a little bit discomfort. This will not affect your treatment in any ways.

Confidentiality

The information provided by you will be kept confidential and will be used for research purpose only. Your personal identity will not be revealed to anyone. All copies of the filled interview schedules and consent forms will be kept under custody of the principal investigator and will be destroyed when they are deemed no longer needed.

Voluntariness.

Your participation is voluntary and you are free to quit this interview at any point of time. If you have any doubt regarding the study please feel free to contact me.

Dr.Greeshma Ramesh

Principal investigator MPH 2023

AMCHSS, SCTIMST

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**ACHUTHAMENON CENTRE FOR HEALTH SCIENCE STUDIES, SCTIMST,
THIRUVANANTHAPURAM-11**

CONSENT FORM

I _____ aged _____

Declare that.

[1] I have read and understood the information in consent form

[2] The nature of the study and my involvement has been explained

[3] All my questions have been answered.

[4] By signing this consent form, I understand what will be expected from me

[5] I understand that the information will be used only for the study purpose

[6] I am aware that I can withdraw at any time.

☐ Yes, I am agreeing to the interview

Signature/Left thumb impression

If respondent only giving verbal consent and not willing to sign or thumb impression

Signature of the witness

Name and address & relation of the witness _____

☐ No, I am not participating in the interview.

ANNEXURES III

ACHUTHAMENON CENTRE FOR HEALTH SCIENCE STUDIES, SCTIMST, THIRUVANANTHAPURAM-11

INTERVIEW SCHEDULE -ENGLISH

a) Identification no -----

b) Case – recurrent diabetic foot ulcer ☐

Control -patient with type 2 DM ☐

c)Affected Foot: 1-RIGHT ☐

2-LEFT ☐

3-BILATERAL ☐

SECTION A

1. SOCIO-ECONOMIC FACTORS

VARIABLE	QUESTION	RESPONSE	
1.1.Age	Age in completed years?	----- yrs	
1.2.Sex		☐ 1.Male ☐ 2.Female ☐	
1.3.Residence	What is your Place of residence?	☐ 1.Urban ☐ 2.Rural ☐	
1.4.Occupation	What is your current occupation?	☐ 1.Agriculture ☐ 2.Employee ☐ 3.Business ☐ 4.Labourer ☐ 5.Household/homemaker ☐ 6.Retired ☐ 7.Others specify ☐	

1.5 Monthly income	Monthly income of the family?	-----	Approximately in rupees
1.6 Ration card colour	What is the colour of your ration card?	☐ 1.White ☐ 2.Pink ☐ 3.Yellow ☐ 4.Blue ☐ 5.No card ☐	

2. HEIGHT AND WEIGHT

2.1 Height	Height in cm	-----	Mention date
2.2 Weight	Weight in Kg	-----	Mention date

3. LIFE STYLE BEHAVIOUR

VARIABLE	QUESTIONS	RESPONSE	
3.1 Smoking status	1. Have you ever smoked? 2. Are you currently using any smoke tobacco products? 3. How long have you been smoking? 4. How often do you use smoke tobacco products?	☐ 1.Yes ☐ 2.No ☐ ☐ 1.Yes ☐ 2.No ☐ ----- Years/months ☐ 1.Daily ☐ 2.Weekly ☐ 3.Monthly ☐ 4.Rarely ☐	

3.2 Tobacco usage	1. Have you ever used smokeless tobacco? 2. Are you currently using any smokeless tobacco? 3. How long have you been using smokeless tobacco? 4. How often do you use smoke tobacco products?	☐ 1.Yes ☐ 2.No ☐ ☐ 1.Yes ☐ 2.No ☐ _____ Years/months ☐ 1.Daily ☐ 2.Weekly ☐ 3.Monthly ☐ 4.Rarely ☐	
3.3 Alcohol usage	1. Have you ever used alcohol? 2. Are you currently using alcohol?	☐ 1.Yes ☐ 2.No ☐ ☐ 1.Yes ☐ 2.No ☐	

	3. How long have you been using alcohol? 4. How often do you drink?	_____ Months/ years ☐ 1.Daily ☐ 2.Weekly ☐ 3.Monthly ☐ 4.Rarely ☐	
3.4 Physical activity (walking exercise , house hold activities etc)	Are you physically active as others of your age.	☐ 1.Yes ☐ 2.No ☐	

4.COMORBIDITIES

VARIABLES	QUESTIONS	RESPONSE	
4.1. Hypertension	1. Do you have hypertension? 2. How long are been hypertensive? 3. Are you under Medication? 4. How long are you under medication? 5. blood pressure value	☐ 1.Yes ☐ 2.No ☐ _____ Year /months ☐ 1.Yes ☐ 2.No ☐ _____ Year/months _____ mmHg	
4.2Dyslipidaemia	1. Do you have elevated cholesterol values? 2. How long are you elevated cholesterol values?	☐ 1.Yes ☐ 2.No ☐ _____ Year /months	

	3. Are you under Medication? 4. How long are you under medication? 5. Blood cholesterol value 6. Are you currently taking statin medications for cholesterol management? 7. No of medications prescribed daily.	☐ 1. Yes ☐ 2. No ☐ _____ Year/months _____ mg/dL 1. Yes 2. No ☐ -----	
--	--	--	--

5. BLOOD INVESTIGATION

5.1 FBS	Fasting blood sugar value	_____ mg/dL	Mention date
5.2 Glycaemic status	HbA1c	_____ %	
5.3 Vitamin D	Vitamin D level	_____ ng/mL	

6. DIABETIC RELATED DETAILS

VARIABLE	QUESTION	RESPONSE	
6.1 Duration of DM	How long have you been diabetic?	In years /months	

6.2 Family history of DM	1. Do you have any family history of DM. 2. Do you have any family h/o Diabetic foot ulcer? 3. Do you have family h/o Recurrent Diabetic foot Ulcer?	☐ 1.Yes ☐ 2.No ☐ ☐ 1.Yes ☐ 2.No ☐ ☐ 1.Yes ☐ 2.No ☐	
6.3. Medication of DM	1.Which mode of medication is using? 2. Number OHA medications prescribed daily? 3.What medications are used as OHA (Eg: Metformin)? 3.No of times of insulin intake? 4.Insulin details (Name)	☐ 1.OHA ☐ 2.Insulin ☐ 3.Both ☐ 4.None ☐ ----- 1. 2. 3. ----- -----	

7. DIABETIC RELATED COMORBIDITIES

VARIABLES		RESPONSE	
7.1 Peripheral Vascular Disease	Symptoms: -Peripheral pulsations =present or absent - Feet warm or cold - Ankle Brachial Index	Right _____ Left _____ ☐ Not done ☐ Data not available	Mention date
7.2 Diabetic Retinopathy	Examination of fundus	☐ 1. Background retinopathy ☐ 2. Pre-proliferative retinopathy ☐ Proliferative retinopathy ☐ 3. Advanced diabetic eye disease ☐ 4. Maculopathy ☐ 5. No Diabetic Retinopathy ☐ 6. Not done ☐ 6. Data not available ☐	Mention date
7.3 Diabetic Nephropathy	Serum creatinine : urine albumin	_____ ☐ Not Done ☐ Data not Available	
7.4 Peripheral Neuropathy	-Vibration Perception Threshold -Monofilament test -Symptoms – present or absent -Tuning fork test	☐ 1. Mild ☐ 2. Moderate ☐ 3. Severe ☐ 4. No Peripheral Neuropathy ☐ 5. Not done ☐ 6. Data not available ☐	

8. FOOT RELATED

VARIABLES		RESPONSE	
8.1 Callus	Examination of foot	☐ 1. Present ☐ 2. Absent ☐	

8.2 Foot deformity	Examination of Foot	☐ 1. Present ☐ 2. Absent ☐	
8.3 Site of ulcer	Site of ulcer	☐ RIGHT dorsal /plantar ☐ Fore foot ☐ Mid foot ☐ Hind foot _____ (specifications if any)	☐ LEFT dorsal /plantar ☐ Fore foot ☐ Mid foot ☐ Hind foot _____ (specifications if any)

SECTION B

FOOTCARE PRACTICES

SL NO	QUESTION	RESPONSE
1	Do you perform any kind of footcare practices?	☐ 1. Yes ☐ 2. No ☐
2	How often do you examine your foot for sores and blisters?	☐ 1. Daily once ☐ 2. More than once a day ☐ 3. Weekly once

		☐ 4.never ☐
3	Do you visit healthcare provider for foot examination?	☐ 1.Yes ☐ 2.No ☐
4	How often do you visit healthcare provider for foot examination?	☐ 1.Every month ☐ 2.Every 3-6 months ☐ 3.Once a year ☐ 4.Only when I have a problem ☐ 5.Never
5	How often do you wash your foot?	☐ 1.More than once a day ☐ 2.Once a day ☐ 3.Most days a week ☐ 4.few days a week ☐ ☐ 5.Never
6	Do you check your feet are properly dry after washing?	☐ 1.Often ☐ 2.Sometimes ☐ 3.Rarely ☐ 4.Never ☐
7	Do you dry your toes?	☐ 1.Always ☐ 2.Often ☐ 3.Sometimes ☐ 4.Rarely/Never ☐

8	Do you use moisturizers for you foot?	☐ 1.Often ☐ 2.Sometimes ☐ 3.Rarely ☐ 4.Never ☐
9	How often do you use moisturising cream on your foot?	☐ 1.Daily ☐ 2.Once a week ☐ 3.About once a month ☐ 4.Never ☐
10	How often do you put moisturising cream between your toes?	☐ 1.Daily ☐ 2.About once a week ☐ 3.About once a month ☐ 4.Never ☐
11	How often do you trim your toenails?	☐ 1.About once a week ☐ 2.About once a month ☐ 3.Less than once a month ☐ 4.Never ☐

12	Have you been prescribed for any specific footwear?	☐ 1.Normal Slippers, shoes ☐ 2.Specialized footwear prescribed by doctor ☐
13	Do you wear pointed-toed shoes?	☐ 1.Most of the time ☐ 2.Sometimes ☐ 3.Rarely ☐ 4.Never ☐
14	Do you wear socks for foot care?	☐ 1.Most of the time ☐ 2.Sometimes ☐ 3.Rarely ☐ 4.Never ☐
15	How often do you change your socks?	☐ 1.More than once a day ☐ 2.Daily ☐ 3.4-6 times a week ☐ 4.Less than 4 times a week ☐ 5.Not applicable ☐
16	Do you walk with bare foot inside the house?	☐ 1.Often ☐ 2.Sometimes ☐ 3.Rarely ☐ 4.Never ☐
17	Do you walk outside in bare foot?	☐ 1.Often ☐ 2.Sometimes ☐ 3.Rarely ☐ 4.Never ☐
18	Do you massage your foot?	☐ 1.Often ☐ 2.Sometimes ☐ 3.Rarely ☐ 4.Never ☐

19	Do you perform self -manage when you get a corn?	☐ 1.Often ☐ 2.Sometimes ☐ 3.Rarely ☐ 4.Never ☐
20	Do you self -manage dressing on a blister when you get one?	☐ 1.Often ☐ 2.Sometimes ☐ 3.Rarely ☐ 4.Never ☐
21	What techniques or practices you found more effective for improved blood circulation?	_____

22	Are you aware of any kind of the risk factors associated with diabetic foot ulcers?	☐ 1.Yes ☐ 2.No ☐
23	Do you know the signs of infection to look out for in your foot?	☐ 1.Yes ☐ 2.No ☐

SECTION C

Distress financing

1	Do you feel the treatment cost of diabetic foot ulcer is an extra burden to your family?	☐ 1.Yes ☐ 2.No ☐
2	Do you feel the cost of footcare is an extra burden to your family?	☐ 1.Yes ☐ 2.No ☐
3	What are the primary financial challenges you are currently facing due to diabetic foot care?	☐ 1.High medical expenses ☐ 2.Loss of income due to inability to work ☐ 3.Cost of medications and supplies ☐ 4.Transportation costs for medical visits ☐ 5.Other (please specify) (Can choose multiple options)
4	What are the main causes of your financial distress related to diabetic foot care?	☐ 1.Frequent hospital visits ☐ 2.Cost of specialized footwear ☐ 3.Cost of home care or nursing services ☐ 4.Loss of employment or reduced working hours ☐ 5.Other (please specify) (Can Choose multiple options)
5	Has taking care of your diabetic foot affected your finances in the past year?	☐ 1.Yes ☐ 2.No ☐
6	Which of the following financing	☐ 1.Personal loans ☐ 2.Credit cards ☐ 3.Payday loans

	options have you considered or used?	☐ 4. Debt consolidation ☐ 5. Borrowing from friends/family ☐ 6. Selling assets ☐ 7. Gold pledging ☐ 8. Other (please specify) (Can choose multiple options)
7	Do you have any insurance coverage?	☐ 1. Yes, I am covered under a government scheme (e.g., PM-JAY, KASP, MEDiSEP) ☐ 2. Yes, I am covered under a private health insurance plan ☐ 3. Yes, I am covered under a senior citizen health insurance plan ☐ 4. No, I do not have any health insurance coverage ☐

ANNEXURES IV

അച്യുതമേനോൻ സെന്റർ ഫോർ ഹെൽത്ത് സയൻസ് സ്റ്റഡീസ് (എഫ്എംസിഎച്ച്എസ്എസ്), ശ്രീ ചിത്ര തിരുനാൾ ഇൻസ്റ്റിറ്റ്യൂട്ട് ഫോർ മെഡിക്കൽ സയൻസസ് ആൻഡ് ടെക്നോളജി (എസ്സിടിഐഎഫ്എസ്സി) തിരുവനന്തപുരം - 1

പഠനവിവരണം

നമസ്കാരം,

ഞാൻ ഡോ. ഗ്രീഷ്മ രമേശ് എസ്സിടിഐഎഫ്എസ്സിയിൽ ശ്രീചിത്ര തിരുനാൾ ഇൻസ്റ്റിറ്റ്യൂട്ട് ഓഫ് മെഡിക്കൽ സയൻസസ് ആൻഡ് ടെക്നോളജി) മാസ്റ്റർ ഓഫ് പബ്ലിക് ഹെൽത്ത് (എംപിഎച്ച്) പഠിക്കുന്നു. “ആവർത്തിച്ച് ഉണ്ടാകുന്ന പ്രമേഹ പാദപ്രണത്തിലെ അപകട സാധ്യതാഘടകങ്ങളും പാദസംരക്ഷണ രീതികളും: പത്തനംതിട്ട ജില്ലയിലെ ഒരു ആശുപത്രി അധിഷ്ഠിത കേസ്-കൺട്രോൾ പഠനം”. എന്ന ഈ പഠനം കോഴ്സിന്റെ ആവശ്യകതയുടെ ഭാഗമായി അനിവാര്യമാണ്.

പഠനോദ്ദേശ്യം

ഈ പഠനത്തിന്റെ ഉദ്ദേശ്യം പ്രമേഹം മൂലം ആവർത്തിച്ച് ഉണ്ടാകുന്ന പാദവ്യുണങ്ങൾ വരാനുള്ള സാധ്യതാഘടകങ്ങളെക്കുറിച്ച് പഠിക്കുക എന്നതാണ്. ഈ പഠനത്തിനായി പത്തനം തിട്ട ജില്ലയിലെ മെഡിക്കൽ ട്രസ്റ്റ് ഹോസ്പിറ്റൽ ആന്റ് ഡയബറ്റിസ് കെയർ സെന്റർ, കൂളനട ആണ് ഞാൻ തിരഞ്ഞെടുത്തിരിക്കുന്നത്. ഇതുമായി ബന്ധപ്പെട്ട എല്ലാവരെയും അവരുടെ പൂർണ്ണസമ്മതത്തോടെയും അനുവാദത്തോടെയും, മാത്രം ഇതുമായി ബന്ധപ്പെട്ട ചോദ്യാവലി പൂരിപ്പിക്കുകയും ചെയ്യുന്നു.

. പ്രമേഹരോഗവും അതുമൂലമുണ്ടാകുന്ന പാദവ്യുണങ്ങളുമുള്ളവർ, പ്രസ്തുത ഹോസ്പിറ്റലിന്റെ ഒ പി-ഐപി വിഭാഗത്തിൽ വരുന്നതുമായ രോഗികളെയാണ് പഠനത്തിൽ ഉൾപ്പെടുത്തുന്നത്. നേരത്തെ ചിട്ടപ്പെടുത്തിയ ചോദ്യാവലി ഉപയോഗിച്ചുള്ള അഭിമുഖത്തിന് താങ്കളുടെ വിലപ്പെട്ട ഇരുപത് മിനിറ്റ് സമയം വിനിയോഗിക്കണമെന്ന് അഭ്യർത്ഥിക്കുന്നു. താങ്കൾ ഈ അഭിമുഖത്തിനായി തയ്യാറായി തരുന്ന മറുപടികൾ എന്റെ പഠനത്തിന് പൂർണ്ണ മായി ഉപയോഗിക്കാൻ സാധിക്കും എന്ന് ഞാൻ വിശ്വസിക്കുന്നു. അതുവഴി ഞാൻ താങ്കളോട് കൃതാർത്ഥയായിരിക്കും.

ആനുകൂല്യങ്ങൾ

താങ്കൾക്ക് ഈ പഠനം വഴി യാതൊരുവിധ സാമ്പത്തിക ആനുകൂല്യങ്ങളും ലഭിക്കുന്നതല്ല. ഈ പഠനത്തിൽ പങ്കെടുക്കുന്നതിലൂടെ പ്രമേഹത്തെപ്പറ്റിയും പ്രമേഹം മൂലമുണ്ടാകുന്ന പാദവണങ്ങളെപ്പറ്റിയും, പാദസംരക്ഷണ രീതികളെപ്പറ്റിയും താങ്കൾക്ക് കൂടുതൽ അറിവ് ലഭിക്കുന്നതാണ്.

ബുദ്ധിമുട്ടുകൾ, പ്രയാസങ്ങൾ

ഈ പഠനത്തിലേർപ്പെടുന്നതു വഴി താങ്കൾക്ക് യാതൊരുവിധ പ്രയാസങ്ങളും ഉണ്ടാകുന്നതല്ല. ആരോഗ്യാവസ്ഥയെക്കുറിച്ചുള്ള ചോദ്യങ്ങൾ ചെറിയ രീതിയിലുള്ള ബുദ്ധിമുട്ടുണ്ടാക്കാം. ഈ പഠനം താങ്കളുടെ ചികിത്സയെ ഒരു തരത്തിലും ബാധിക്കുന്നതല്ല.

വിശ്വസ്തത

താങ്കൾ തരുന്ന വിവരങ്ങൾ വളരെ സുരക്ഷിതമായി സൂക്ഷിക്കുകയും പഠനത്തിനായി മാത്രം ഉപയോഗിക്കുകയും ചെയ്യുന്നതാണ്. താങ്കളെ സംബന്ധിക്കുന്ന ഒരു വിവരങ്ങളും പുറത്താകുന്നതല്ല. അഭിമുഖ ചോദ്യാവലിയുടെ പകർപ്പുകൾ, സമ്മത പത്രം എന്നിവ മുഖ്യഗവേഷകന്റെ കൈവശം വയ്ക്കുന്നതും, പഠനാവശ്യങ്ങൾക്ക് ശേഷം നശിപ്പിക്കുന്നതുമാണ്.

സ്വേച്ഛയനുസരിച്ച് പെരുമാറാനുള്ള സ്വാതന്ത്ര്യം

താങ്കൾക്ക് സ്വന്തം താൽപര്യമനുസരിച്ച് ഈ പഠനത്തിൽ പങ്കുകൊള്ളാം. ഈ പഠനത്തിൽ നിന്ന് എപ്പോൾ വേണമെങ്കിലും പിന്മാറാം. പഠനസംബന്ധമായ എന്തു ചോദ്യങ്ങൾക്കും സംശയങ്ങൾക്കും താഴെ പറയുന്നവരുമായി ബന്ധപ്പെടാം

ഡോ. ഗ്രീഷ്മ രമേശ്

പ്രിൻസിപ്പൽ ഇൻവെസ്റ്റിഗേറ്റർ MPH 2023

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ഡോ.ശ്രീനിവാസ്.ജി.

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അച്യുതമേനോൻ സെന്റർ ഫോർ ഹെൽത്ത് സയൻസ് സ്റ്റഡീസ് (എഫ്എംസിഎച്ച്എസ്എസ്), ശ്രീ ചിത്ര തിരുനാൾ ഇൻസ്റ്റിറ്റ്യൂട്ട് ഫോർ മെഡിക്കൽ സയൻസസ് ആൻഡ് ടെക്നോളജി (എസ്റ്റിടിഐഎഫ്എസ്) തിരുവനന്തപുരം - 11

സമ്മതപത്രം

ഞാൻ----- വയസ്സ് ----- ഇതിനാൽ തെരുപ്പെടുത്തുന്നു.

1. സമ്മതപത്രത്തലെ എല്ലാം കാര്യങ്ങളും വായിക്കുകയും മനസ്സിലാക്കുകയും ചെയ്തു.
2. പഠനത്തെ സംബന്ധിക്കുന്ന വിവരങ്ങളും എന്റെ പങ്കിനെക്കുറിച്ചും വിവരിച്ചു തന്നു.
3. എന്റെ എല്ലാ ചോദ്യങ്ങൾക്കും മറുപടി നൽകി.
4. ഇതിൽ ഒപ്പിടുന്നതുവഴി, എന്നിൽ നിന്ന് പ്രതീക്ഷിക്കുന്നത് ഞാൻ മനസ്സിലാക്കി.
5. വിവരങ്ങൾ പഠനത്തിനായി മാത്രമേ വിനിയോഗിക്കുകയുള്ളൂ എന്ന് ഞാൻ മനസ്സിലാക്കുന്നു.
6. എനിക്ക് ഏതു സമയവും പഠനത്തിൽ നിന്നും പിൻമാറാമെന്ന് അറിയാം.
☐ അതെ ഞാൻ അഭിമുഖത്തിന് പൂർണ്ണമായും സമ്മതിച്ചിരിക്കുന്നു.

ഒപ്പ് / വിരലടയാളം_____

സമ്മതപത്രത്തിൽ ഒപ്പിടാൻ കഴിയാതെ സമ്മതം അറിയിക്കുന്നവർക്ക് വേണ്ടി

സാക്ഷി / ഒപ്പ്_____

പേര്, അഡ്രസ്സ്, ബന്ധം_____

☐ ഇല്ല, ഞാൻ ഈ പഠനത്തിനായി സഹകരിക്കുന്നില്ല

ANNEXURES V

അച്ചുതമേനോൻ സെന്റർ ഫോർ ഹെൽത്ത് സയൻസ് സ്റ്റഡീസ് (എഫ്എംസിഎച്ച്എസ്എസ്), ശ്രീ ചിത്ര തിരുനാൾ ഇൻസ്റ്റിറ്റ്യൂട്ട് ഫോർ മെഡിക്കൽ സയൻസസ് ആൻഡ് ടെക്നോളജി (എസ്റ്റിടിഐഎഫ്എസ്) തിരുവനന്തപുരം - 11

ഇന്റർവ്യൂ ഷെഡ്യൂൾ

എ) തിരിച്ചറിയൽ നമ്പർ -----

ബി) കേസ് - ആവർത്തിച്ച് ഉണ്ടാകുന്ന പ്രമേഹ പാദവ്രണം ☐

കൺട്രോൾ - ടൈപ്പ് 2 പ്രമേഹ രോഗി ☐

c) പാദവ്രണം ബാധിച്ച കാൽ: 1-വലത് ☐

2-ഇടത് ☐

3- ഉഭയകക്ഷി ☐

വിഭാഗം എ

2. സാമൂഹിക-സാമ്പത്തിക ഘടകങ്ങൾ

	ചോദ്യം	ഉത്തരം	
2.1.പ്രായം	നിങ്ങളുടെ പ്രായം?	----- വർഷം	
2.2.സെക്സ്	ലിംഗം	☐ 1. പുരുഷൻ ☐ 2. സ്ത്രീ ☐	
2.3.താമസസ്ഥലം	താങ്കളുടെ താമസസ്ഥലം ഏതാണ്?	☐ 1. നഗരം ☐ 2. ഗ്രാമം ☐	
1.5.തൊഴിൽ	താങ്കളുടെ ഇപ്പോഴത്തെ	☐ 1. കൃഷി	

	തൊഴിൽ എന്താണ്?	☐ 2. ജീവനക്കാരൻ ☐ 3. ബിസിനസ്സ് ☐ 4. തൊഴിലാളി ☐ 5. വീട്ടു ജോലികൾ ☐ 6. വിരമിച്ചവർ ☐ 7. മറ്റുള്ളവർ വ്യക്തമാക്കു നു ----- ☐	
1.5 പ്രതിമാസ വരുമാനം	കുടുംബത്തി ന്റെ പ്രതിമാസ വരുമാനം?	-----	ഏകദേശം രൂപയിൽ
1.7 റേഷൻ കാർഡി ന്റെ നിറം	താങ്കളുടെ റേഷൻ കാർഡി ന്റെ നിറമെന്താണ്?	☐ 1. വെളുത്ത നിറം ☐ 2. പിങ്ക് ☐ 3. മഞ്ഞ ☐ 4. നീല ☐ 5. കാർഡ് ഇല്ല ☐	

2. ഉയരവും ഭാരവും

2.1 ഉയരം	ഉയരം സെന്റിമീറ്ററിൽ	-----	തീയതി സൂചിപ്പിക്കുക
2.2 ഭാരം	ഭാരം കിലോഗ്രാമിൽ	-----	തീയതി സൂചിപ്പിക്കുക

3. ജീവിതശൈലി

	ചോദ്യങ്ങൾ	ഉത്തരം
3.1 പുകവലി	5. താങ്കൾ എപ്പോഴെങ്കിലും പുകവലിച്ചിട്ടു ണ്ടോ?	☐ 1. ഉണ്ട് ☐ 2. ഇല്ല ☐

	6. താങ്കൾ നിലവിൽ ഏതെങ്കിലും പുക പുകയില ഉൽപ്പന്നങ്ങൾ ഉപയോഗിക്കുന്നുണ്ടോ? 7. താങ്കൾ എത്ര കാലമായി പുകവലിക്കുന്നു? 8. പുകയില ഉൽപ്പന്നങ്ങൾ താങ്കൾ എത്ര ഇടവിട്ട് ഉപയോഗിക്കുന്നു?	☐ 1. ഉണ്ട് ☐ 2. ഇല്ല ☐ ----- വർഷം /മാസം ☐ 1.ദിവസേന ☐ 2. പ്രതിവാരം ☐ 3. പ്രതിമാസം ☐ 4. അപൂർവ്വമായി ☐
3.2 പുകയില ഉപയോഗം	4. നിങ്ങൾ എപ്പോഴെങ്കിലും പുകയില്ലാത്ത പുകയില ഉപയോഗിച്ചിട്ടുണ്ടോ? 5. നിങ്ങൾ നിലവിൽ പുകയില്ലാത്ത ഏതെങ്കിലും പുകയില ഉപയോഗിക്കുന്നുണ്ടോ?	☐ 1. ഉണ്ട് ☐ 2. ഇല്ല ☐ ☐ 1. ഉണ്ട് ☐ 2. ഇല്ല ☐

	6. പുകയില്ലാത്ത പുകയില നിങ്ങൾ എത്ര കാലമായി ഉപയോഗിക്കുന്നു? 5 പുകയില ഉൽപ്പന്നങ്ങൾ നിങ്ങൾ എത്ര ഇടവിട്ട് ഉപയോഗിക്കുന്നു?	_____ വർഷം /മാസം ☐ 1.ദിവസേന ☐ 2. പ്രതിവാരം ☐ 3. പ്രതിമാസം ☐ 4. അപൂർവ്വമായി ☐
3.3 മദ്യത്തിന്റെ ഉപയോഗം	5. നിങ്ങൾ എപ്പോഴെങ്കിലും മദ്യം ഉപയോഗിച്ചിട്ടുണ്ടോ? 6. നിങ്ങൾ നിലവിൽ മദ്യം ഉപയോഗിക്കുന്നുണ്ടോ?	☐ 1. ഉണ്ട് ☐ 2. ഇല്ല ☐ ☐ 1. ഉണ്ട് ☐ 2. ഇല്ല ☐

	7. നിങ്ങൾ എത്ര കാലമായി മദ്യം ഉപയോഗിക്കുന്നു? 8. നിങ്ങൾ എത്ര ഇടവിട്ട് മദ്യം ഉപയോഗിക്കുന്നു?	_____ മാസം / വർഷം ☐ 1. ദിവസേന ☐ 2. പ്രതിവാരം ☐ 3. പ്രതിമാസം ☐ 4. അപൂർവ്വമായി ☐
6.4 വ്യാധിമന്ദം(സ്ഥിരമായുള്ള നടത്തം, വീട്ടു ജോലികൾ)	താങ്കളുടെ പ്രായത്തിലുള്ള മറ്റുള്ളവരെപ്പോലെ നിങ്ങൾ ശാരീരികമായി സജീവമാണോ?	☐ 1. അതെ ☐ 2. അല്ല ☐

4. മറ്റു രോഗങ്ങൾ

	ചോദ്യങ്ങൾ	ഉത്തരം
4.1. ഹൈപ്പർടെൻഷൻ/ ബിപി/ രക്താതിമർദ്ദം	1. താങ്കൾക്ക് രക്താതിമർദ്ദം ഉണ്ടോ? 2. മരുന്ന് കഴിക്കുന്നുണ്ടോ? 3. രക്താതിമർദ്ദം എത്ര കാലമായി?	☐ 1. ഉണ്ട് ☐ 2. ഇല്ല ☐ ☐ 1. ഉണ്ട് ☐ 2. ഇല്ല ☐ _____ വർഷം / മാസം

	4. എത്രകാലമായി മരുന്ന് കഴിക്കുന്നു? a. രക്ത സമ്മർദ്ദത്തിന്റെ അളവ്	_____ വർഷം / മാസം _____ mmof Hg
4.2ഡിസ്റ്റിപിഡെമിയ / കൊളസ്ട്രോൾ	6. താങ്കൾക്ക് ഉയർന്ന കൊളസ്ട്രോൾ അളവ് ഉണ്ടോ? 7. താങ്കൾക്ക് കൊളസ്ട്രോൾ എത്രകാലം അളവ് ഉയർത്തുന്നു? 8. മരുന്ന് കഴിക്കുന്നുണ്ടോ? 9. താങ്കൾക്ക് എത്ര നാളായി താഴെയാണ് മരുന്ന്? 10. രക്തത്തിലെ കൊളസ്ട്രോൾ അളവ് 11. കൊളസ്ട്രോൾ നിയന്ത്രിക്കാനായി താങ്കൾ നിലവിൽ സ്റ്റാറ്റിൻ	☐ 1. അതെ ☐ 2. ഇല്ല ☐ _____ വർഷം / മാസം ☐ 1. അതെ ☐ 2. ഇല്ല ☐ _____ വർഷം / മാസം _____ mg/dL ☐ 1. ഉണ്ട് ☐ 2. അല്ല ☐

	മരുന്നുകൾ എടുക്കുന്നുണ്ടോ? 12. ദിവസവും നിർദ്ദേശിച്ചിരിക്കു ന്ന മരുന്നുകളുടെ എണ്ണം.	-----
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5. രക്തപരിശോധന

5.1 ഭക്ഷണത്തി ന് മുൻപ് രക്തത്തിലെ പഞ്ചസാര	ഭക്ഷണത്തിന് മുൻപ് രക്തത്തിലെ പഞ്ചസാരയു ടെ അളവ്	_____ mg/d L	തീയതി സൂചിപ്പിക്കു ക
5.2 ഗ്ലൈസെമിക് നില	HbA1c	_____ %	
5.3 വിറ്റാമിൻ ഡി	വിറ്റാമിൻ ഡി അളവ്	_____ ng/m L	

6. പ്രമേഹവുമായി ബന്ധപ്പെട്ട വിശദാംശങ്ങൾ

	ചോദ്യം	ഉത്തരം	
6.1 പ്രമേഹത്തിന്റെ കാലയളവ്	താങ്കൾ എത്ര കാലമായി പ്രമേഹരോഗിയാണ്?	വർഷങ്ങളിൽ / മാസങ്ങളിൽ	
6.2 രോഗത്തിന്റെ വിശദാംശങ്ങൾ	1. താങ്കളുടെ കുടുംബത്തിൽ പ്രമേഹ രോഗം ഉണ്ടായിട്ടുണ്ടോ? 2. താങ്കളുടെ കുടുംബത്തിൽ പ്രമേഹ പാദവ്യൂണങ്ങൾ ഉണ്ടോ? 3. താങ്കളുടെ കുടുംബത്തിൽ	☐ 1. ഉണ്ട് ☐ 2. ഇല്ല ☐ 1. ഉണ്ട് ☐ 2. ഇല്ല ☐ 1. ഉണ്ട് ☐ 2. ഇല്ല	

	ആവർത്തിച്ചുള്ള പാദവൃണങ്ങൾ ഉണ്ടോ?		
6.3. പ്രമേഹ രോഗത്തിന് ഉപയോഗിക്കുന്ന മരുന്നുകൾ	1. ഏത് തരം മരുന്നാണ് ഉപയോഗിക്കുന്നത്? 2. ദിവസേന നിർദ്ദേശിക്കുന്ന ഗുളിക യുടെ എണ്ണം? 3. ഉപയോഗിക്കുന്ന മരുന്നുകൾ ഏതൊക്കെയാണ് (ഉദാ: മെറ്റ്ഫോർമിൻ)? 4. ഒരു ദിവസം എത്ര തവണ ഇൻസുലിൻ എടുക്കാറുണ്ട്? 5. ഇൻസുലിൻ വിശദാംശങ്ങൾ (പേര്)	☐ 1. ഗുളിക ☐ 2. ഇൻസുലിൻ ☐ 3. രണ്ടും ☐ 4. ഒന്നുമില്ല ----- 1. 2. 3. ----- -----	

7. പ്രമേഹവുമായി ബന്ധപ്പെട്ട മറ്റു രോഗങ്ങൾ

	ചോദ്യം	RESPONSE	
7.1 പെരിഫറൽ	രോഗലക്ഷണങ്ങൾ:	വലത് _____ ഇടത് _____	തീയതി സൂചിപ്പിക്കുക

വാസ്തുലർ രോഗം	-പെരിഫറൽ സ്കന്ദനങ്ങൾ = നിലവിലുള്ള തോ ഇല്ലാത്തതോ - കാലുകൾ ചുടുള്ളതോ തണുത്തതോ - ആർക്കൽ ബ്രാക്യുയൽ സൂചിക(ABI)	☐ ചെഴിട്ടി ല്ല ☐ ഡാറ്റ ലഭ്യമല്ല	
7.2 ഡയബറ്റിക് റെറ്റിനോ പ്പതി	ഫണ്ടസിന്റെ പരിശോധന	☐ 1. ബാക്സ്ഗ്രൗണ്ട് റെറ്റിനോപ്പതി ☐ 2. പ്രീ- പ്രൊലിഫറേറ്റീവ് റെറ്റിനോപ്പതി പ്രൊലിഫറേറ്റീവ് റെറ്റിനോപ്പതി ☐ 3. അഡ്വാൻസ്ഡ് പ്രമേഹ നേത്രരോഗം ☐ 4. മാക്കുലോപ്പതി ☐ 5. ഡയബറ്റിക് റെറ്റിനോപ്പതി ഇല്ല	തീയതി സൂചിപ്പി ക്കുക
7.3 ഡയബറ്റിക് നെഫ്രോപ്പ തി	സെറം ക്രിയാറ്റിനൈൻ : യൂറിൻ ആൽബുമിൻ	☐ 6.പരിശോധി ച്ചിട്ടില്ല ☐ 7.ഡാറ്റ ലഭ്യമല്ല ☐	
7.4 പെരിഫെറ ൽ ന്യൂറോപ്പ തി	- വൈബ്രേഷൻ പെർസെപ്ഷൻ ത്രെഷോൾഡ് - മോണോഫില മെന്റ് ടെസ്റ്റ് - രോഗലക്ഷണ	☐ 1. മൈൽഡ് ☐ 2. മോഡറേറ്റ് ☐ 3. സിവിയർ ☐ 4.പെരിഫറൽ ന്യൂറോപ്പതി ☐ 5. പരിശോധിച്ചി ട്ടില്ല	

	ങ്ങൾ - ഉള്ളതോ ഇല്ലാത്തതോ - ട്യൂണിംഗ് ഫോർക്ക് ടെസ്റ്റ്	☐ 6. ഡാറ്റ ലഭ്യമല്ല ☐	
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8. പദവുമായി ബന്ധപ്പെട്ടത്

	ചോദ്യം	ഉത്തരം	
8.1 ക്യാ ലസ്	പാദ പരിശോധന	☐ 1. ഉണ്ട് ☐ 2. ഇല്ല ☐	
8.2 വൈകല്യം	പാദ പരിശോധന	☐ 1. ഉണ്ട് ☐ 2. ഇല്ല ☐	
8.3 പ്രണാമം ചെയ്ത സ്ഥലം	പ്രണാമം ചെയ്ത സ്ഥലം	വലത് പ്ലാന്റാർ/ഡോർസം ☐ മുൻ ഭാഗം ☐ മധ്യ ഭാഗം ☐ പിൻ ഭാഗം _____ (മറ്റു വിവരം ഉണ്ടെങ്കിൽ വ്യക്തമാക്കുക) (ഒന്നിലധികം തിരഞ്ഞെടുക്കുക)	ഇടത് പ്ലാന്റാർ/ഡോർസം ☐ മുൻ ഭാഗം ☐ മധ്യ ഭാഗം ☐ പിൻ ഭാഗം _____ (മറ്റു വിവരം ഉണ്ടെങ്കിൽ വ്യക്തമാക്കുക) (ഒന്നിലധികം തിരഞ്ഞെടുക്കുക)

വിഭാഗം ബി

പാദസംരക്ഷണ രീതികൾ

	ചോദ്യം	ഉത്തരം
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1	താങ്കൾ ഏതെങ്കിലും തരത്തിലുള്ള പാദസംരക്ഷണ രീതികൾ നടത്തുന്നുണ്ടോ?	☐ 1. ഉണ്ട് ☐ 2. ഇല്ല ☐
2	വ്രണങ്ങളും കുമിളകളും ഉണ്ടോ എന്ന് താങ്കൾ എത്ര ഇടവിട്ട് താങ്കൾ ജൂടെ പാദം പരിശോധിക്കുന്നു?	☐ 1. ദിവസവും ഒരു തവണ ☐ 2. ദിവസത്തിൽ ഒന്നിലധികം തവണ ☐ 3. ആഴ്ചയിൽ ഒരിക്കൽ ☐ 4. ഒരിക്കലും ☐
3	പാദം പരിശോധനയ്ക്കായി താങ്കൾ ഡോക്ടറെ സന്ദർശിക്കാറുണ്ടോ?	☐ 1. ഉണ്ട് ☐ 2. ഇല്ല ☐
4	പാദം പരിശോധനയ്ക്കായി താങ്കൾ എത്ര ഇടവിട്ട് ഡോക്ടറെ സന്ദർശിക്കുന്നു?	☐ 1. എല്ലാ മാസവും ☐ 2. ഓരോ 3-6 മാസവും ☐ 3. വർഷത്തിൽ ഒരിക്കൽ ☐ 4. എന്നിക്ക് ഒരു പ്രശ്നം ഉണ്ടാകുമ്പോൾ മാത്രം ☐ 5. ഒരിക്കലും ഇല്ല
5	താങ്കൾ എത്ര ഇടവിട്ട് പാദങ്ങൾ കഴുകുന്നു?	☐ 1. ദിവസത്തിൽ ഒന്നിലധികം തവണ ☐ 2. ദിവസത്തിൽ ഒരിക്കൽ ☐ 3. ആഴ്ചയിൽ മിക്ക ദിവസവും ☐ 4. ആഴ്ചയിൽ കുറച്ച് ദിവസം ☐ 5. ഒരിക്കലും ഇല്ല ☐

6	കഴുകിയ ശേഷം താങ്കളുടെ പാദങ്ങൾ ശരിയായി ജലാംശം മാറിയോ എന്ന് നിങ്ങൾ പരിശോധിക്കുന്നുണ്ടോ?	☐ 1. പലപ്പോഴും ☐ 2. ചിലപ്പോൾ ☐ 3. അപൂർവമായി ☐ 4. ഒരിക്കലും ഇല്ല ☐
7	കാൽവീരലുകൾക്ക് ഇടയിലെ ജലാംശം തുടച്ചു മറ്റുമോ?	☐ 1. എപ്പോഴും ☐ 2. പലപ്പോഴും ☐ 3. ചിലപ്പോൾ ☐ 4. അപൂർവമായി / ഒരിക്കലും ഇല്ല ☐

8	താങ്കളുടെ പാദത്തിന് മോയ്ച്ചറൈസർ ഉപയോഗിക്കാറുണ്ടോ?	☐ 1. പലപ്പോഴും ☐ 2. ചിലപ്പോൾ ☐ 3. അപൂർവമായി ☐ 4. ഒരിക്കലും ഇല്ല ☐
9	താങ്കളുടെ കാലിൽ എത്ര ഇടവിട്ട് മോയ്ച്ചറൈസിംഗ് ക്രീം ഉപയോഗിക്കുന്നു?	☐ 1. ദിവസേന ☐ 2. ആഴ്ചയിൽ ഒരിക്കൽ ☐ 3. മാസത്തിൽ ഒരിക്കൽ ☐ 4. ഒരിക്കലും ഇല്ല ☐
10	താങ്കളുടെ കാൽവീരലുകൾക്കിടയിൽ എത്ര ഇടവിട്ട് മോയ്ച്ചറൈസിംഗ് ക്രീം ഇടുന്നു?	☐ 1. ദിവസേന ☐ 2. ആഴ്ചയിൽ ഒരിക്കൽ ☐ 3. മാസത്തിൽ ഒരിക്കൽ ☐ 4. ഒരിക്കലും ഇല്ല ☐
11	താങ്കളുടെ കാൽനഖങ്ങൾ എത്ര ഇടവിട്ട് മുറിക്കാറുണ്ട്?	☐ 1. ആഴ്ചയിൽ ഒരിക്കൽ ☐ 2. മാസത്തിൽ ഒരിക്കൽ ☐ 3. മാസത്തിൽ ഒരു തവണയിൽ കുറവ് ☐ 4. ഒരിക്കലും ഇല്ല ☐

12	പ്രത്യേക പാദരക്ഷകൾ ഡോക്ടർ നിർദ്ദേശിച്ചിട്ടുണ്ടോ?	☐ 1.സാധാരണ ചെരുപ്പുകൾ, ഷൂസ് ☐ 2.പ്രത്യേകം തയ്യാറാക്കിയ ചെരുപ്പുകൾ ☐
13	താങ്കൾ പാദസംരക്ഷണത്തിനായി ഷൂസ് ധരിക്കാറുണ്ടോ?	☐ 1. മിക്കപ്പോഴും ☐ 2. ചിലപ്പോൾ ☐ 3. അപൂർവ്വമായി ☐ 4. ഒരിക്കലും ഇല്ല ☐
14	പാദസംരക്ഷണത്തിനായി താങ്കൾ സോക്ക് ധരിക്കാറുണ്ടോ?	☐ 1. മിക്കപ്പോഴും ☐ 2. ചിലപ്പോൾ ☐ 3. അപൂർവ്വമായി ☐ 4. ഒരിക്കലും ഇല്ല ☐
15	താങ്കളുടെ സോക്ക് എത്ര ഇടവിട്ട് മാറ്റുന്നു?	☐ 1. ദിവസത്തിൽ ഒന്നിലധികം തവണ ☐ 2. ദിവസേന ☐ 3. ആഴ്ചയിൽ 3.4-6 തവണ ☐ 4. ആഴ്ചയിൽ 4 തവണയിൽ കുറവ് ☐ 5. ബാധകമല്ല ☐
16	താങ്കൾ വീടിനകത്ത് ചെരിപ്പ് ധരിക്കാതെ നടക്കാറുണ്ടോ?	☐ 1. പലപ്പോഴും ☐ 2. ചിലപ്പോൾ ☐ 3. അപൂർവ്വമായി ☐ 4. ഒരിക്കലും ഇല്ല ☐
17	താങ്കൾ വീടിനുപുറത്ത് ചെരിപ്പ് ധരിക്കാതെ നടക്കാറുണ്ടോ?	☐ 1. പലപ്പോഴും ☐ 2. ചിലപ്പോൾ ☐ 3. അപൂർവ്വമായി ☐ 4. ഒരിക്കലും ഇല്ല ☐

18	താങ്കളുടെ കാൽ മസാജ് ചെയ്യാറുണ്ടോ?	☐ 1. പലപ്പോഴും ☐ 2. ചിലപ്പോൾ ☐ 3. അപൂർവമായി ☐ 4. ഒരിക്കലും ഇല്ല ☐
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19	ആണി രോഗം പോലെ ഉള്ള അസുഖങ്ങൾ തനിയെ ചികിത്സിക്കാറുണ്ടോ .?	☐ 1. പലപ്പോഴും ☐ 2. ചിലപ്പോൾ ☐ 3. അപൂർവമായി ☐ 4. ഒരിക്കലും ഇല്ല ☐
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20	പദത്തിൽ കുമിളകൾ വന്നാൽ സ്വയം ചികിത്സിക്കാറുണ്ടോ?	☐ 1. പലപ്പോഴും ☐ 2. ചിലപ്പോൾ ☐ 3. അപൂർവമായി ☐ 4. ഒരിക്കലും ഇല്ല ☐
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21	മെച്ചപ്പെട്ട രക്തചംക്രമണത്തിന് എന്തെങ്കിലും പ്രത്യേക കാര്യങ്ങൾ ചെയ്യാറുണ്ടോ?	_____
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22	പ്രമേഹ വ്രണം ബന്ധപ്പെട്ട ഏതെങ്കിലും തരത്തിലുള്ള അപകടസാധ്യത ഘടകങ്ങൾ താങ്കൾക്ക് അറിയാമോ?	☐ 1. അറിയാം ☐ 2. ഇല്ല ☐
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23	താങ്കളുടെ കാലിൽ ശ്രദ്ധിക്കേണ്ട അണുബാധയുടെ ലക്ഷണങ്ങൾ താങ്കൾക്ക് അറിയാമോ?	☐ 1. അറിയാം ☐ 2. ഇല്ല ☐
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വിഭാഗം സി

ഡിസ്ട്രസ്സ് ഫിനാൻസിങ് /ദുരിത ധനസഹായം

1.	പ്രമേഹ പാദവ്രണ ചികിത്സക്ക് വേണ്ടി വരുന്ന ചിലവ് തങ്ങളുടെ കുടുംബത്തിന് അധികഭാരമായി തോന്നുന്നുണ്ടോ?	☐ 1. ഉണ്ട് ☐ 2. ഇല്ല ☐
2.	പാദസംരക്ഷണത്തിന് വേണ്ടി വരുന്ന ചിലവ് തങ്ങളുടെ കുടുംബത്തിന്	☐ 1. ഉണ്ട് ☐ 2. ഇല്ല ☐

	അധികഭാരമാണെന്ന് നിങ്ങൾക്ക് തോന്നുന്നുണ്ടോ?	
3	പ്രമേഹ പാദ പരിചരണം കാരണം താങ്കൾ നിലവിൽ നേരിടുന്ന പ്രാഥമിക സാമ്പത്തിക വെല്ലുവിളികൾ ഞാനൊക്കെയാണ്?	☐ 1. ഉയർന്ന ചികിത്സാ ചെലവുകൾ ☐ 2. തൊഴിൽ എടുത്ത് വരുമാനം ഉണ്ടാക്കാൻ കഴിയാത്തതിനാൽ ഉണ്ടാകുന്ന സാമ്പത്തിക നഷ്ടം ☐ 3. മരുന്നുകളുടെയും അനുബന്ധ സാധനങ്ങളുടെയും ചെലവ് ☐ 4. മെഡിക്കൽ സന്ദർശനങ്ങൾക്കുള്ള യാത്രാ ചെലവുകൾ ☐ 5. മറ്റുള്ളവ (ദയവായി വ്യക്തമാക്കുക) (ഒന്നിലധികം ഓപ്ഷനുകൾ തിരഞ്ഞെടുക്കാം)
4	പ്രമേഹ പാദ പരിചരണവുമായി ബന്ധപ്പെട്ട താങ്കളുടെ സാമ്പത്തിക ക്ലേശത്തിന്റെ പ്രധാന കാരണങ്ങൾ എന്തൊക്കെയാണ്?	☐ 1. ഇടയ്ക്കിടെയുള്ള ആശുപത്രി സന്ദർശനങ്ങൾ ☐ 2. പ്രത്യേക പാദരക്ഷകളുടെ ചെലവ് ☐ 3. ഹോം കെയർ അല്ലെങ്കിൽ നഴ്സിംഗ് സേവനങ്ങളുടെ ചെലവ് ☐ 4. തൊഴിൽ നഷ്ടം അല്ലെങ്കിൽ ജോലി സമയം കുറയ്ക്കൽ ☐ 5. മറ്റുള്ളവ (ദയവായി വ്യക്തമാക്കുക)

		(ഒന്നിലധികം ഓപ്ഷനുകൾ തിരഞ്ഞെടുക്കാം)
5	നിങ്ങളുടെ പ്രമേഹ പാദം പരിപാലിക്കുന്നത് കഴിഞ്ഞ വർഷം നിങ്ങളുടെ സാമ്പത്തിക സ്ഥിതിയെ ബാധിച്ചിട്ടുണ്ടോ?	☐ 1. ഉണ്ട് ☐ ☐ 2. ഇല്ല ☐
6	ഇനിപ്പറയുന്ന ഫിനാൻസിംഗ് ഓപ്ഷനുകളിൽ ഏതാണ് താങ്കൾ പരിഗണിച്ചത് അല്ലെങ്കിൽ ഉപയോഗിച്ചത്?	☐ 1. പേഴ്സണൽ ലോണുകൾ ☐ 2. ക്രെഡിറ്റ് കാർഡുകൾ ☐ 3. പേഡേ ലോണുകൾ ☐ 4. കടം ഏകീകരണം ☐ 5. സുഹൃത്തുക്കളിൽ നിന്ന് / കുടുംബത്തിൽ നിന്ന് കടം വാങ്ങൽ ☐ 6. ആസ്തികൾ വിൽക്കൽ ☐ 7. സ്വർണ്ണ പണയം ☐ 8. മറ്റുള്ളവ (ദയവായി വ്യക്തമാക്കുക) ☐ _____ (ഒന്നിലധികം ഓപ്ഷനുകൾ തിരഞ്ഞെടുക്കാം)
7	താങ്കൾക്ക് എന്തെങ്കിലും ഇൻഷുറൻസ് പരിരക്ഷ ഉണ്ടോ?	☐ 1. അതെ, ഞാൻ ഒരു സർക്കാർ സ്കീമിന് കീഴിൽ ഉൾപ്പെടുന്നു (ഉദാഹരണത്തിന്, PM-JAY, KASP, MEDiSEP) ☐ 2. അതെ, ഒരു സ്വകാര്യ ആരോഗ്യ ഇൻഷുറൻസ് പ്ലാനിന് കീഴിൽ ഞാൻ പരിരക്ഷിക്കപ്പെടുന്നു ☐ 3. അതെ, ഒരു സീനിയർ സിറ്റിസൺ ഹെൽത്ത് ഇൻഷുറൻസ് പ്ലാനിന് കീഴിൽ ഞാൻ പരിരക്ഷിക്കപ്പെടുന്നു

		☐ 4. എനിക്ക് ആരോഗ്യ ഇൻഷുറൻസ് പരിരക്ഷയില്ല ☐
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ANNEXURE VI

MEDICAL TRUST HOSPITAL & DIABETES CARE CENTRE

Kulanada - 689 503, Pathanamthitta Dist., Tel : 04734 260431, E-mail: mthdcc@gmail.com



Date.....9/11/2024.....

NO OBJECTION CERTIFICATE

Whom so ever it may concern,

This is to certify that we have no objection in permitting the MPH student of SCTIMST, Trivandrum, Dr. Greeshma Ramesh, to conduct the study on "Risk Factors and Foot Care Practices in recurrent Diabetic Foot Ulcer" in this Institution.

Thanking You

Yours faithfully




Dr. G. VIJAYAKUMAR
MBBS, MD (Gen Med)
DTM & H, G Dip., DC
PHYSICIAN
Reg. No. 9733

ANNEXURE VII



श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
तिरुवनन्तपुरम - ६९५०११, केरल, इंडिया

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM
Thiruvananthapuram - 695 011, Kerala, India
(An Institute of National Importance under Govt. of India)

Grams : Chitramet, Phone : +91-471-2443152, Fax : +91-471-2550728 / 2446433, E-mail : sct@sctimst.ac.in, Website : www.sctimst.ac.in

Institutional Ethics Committee

CDSO Registration No: ECR/189/Inst/KL/2013/RR-24
DHR Registration No: EC/NEW/INST/2022/2775

SCT/IEC/2340/DECEMBER/2024

01.04.2025

Dr. Greeshma Ramesh
MPH Student, AMCHSS
SCTIMST, Thiruvananthapuram

Dear Dr. Greeshma Ramesh,

The Institutional Ethics Committee held on 30th December, 2024, reviewed and discussed your application to conduct the study titled **"RISK FACTORS AND FOOTCARE PRACTICES IN RECURRENT DIABETIC FOOT ULCERS: A HOSPITAL BASED CASE-CONTROL STUDY IN PATHANAMTHITTA DISTRICT, KERALA"** (IEC /2340) .

Principal Investigator	Dr. Greeshma Ramesh, MPH Student, AMCHSS, SCTIMST
Co-Principal Investigator(s)	Dr. Ravi Prasad Vanna, Professor, AMCHSS, SCTIMST
Duration of the study	6 months

The following members of the Ethics Committee were present at the meeting held on 30th December, 2024

SL. No.	Member Name	Highest Degree	Gender	Scientific /Non Scientific	Affiliation with Institution(s)
1.	Dr. Manoj Murhekar	MD (Preventive & Social Medicine)	Male	Social Scientist	No
2.	Dr. Annapurna.Y	MD	Female	Basic Medical Scientist	No
3.	Adv. Priya Kaimal	LLM, MBL	Female	Legal Expert	No
4.	Dr. Indu PV	MBBS, DPM, MPhil, PhD	Female	Clinician	No
5.	Dr. Rejnish Kumar	MBBS, MD, DNB	Male	Clinician	No
6.	Smt. Rekha Radhakrishnan	M.A (Eng.), B Ed	Female	Lay person	No
7.	Dr. Biju Soman	MBBS, MD, DPH, MSc, DLSHTM	Male	Basic Medical Scientist	Yes
8.	Dr. Syam K	MBBS, MD, DM	Male	Clinician	Yes
9.	Dr. Srinivas G	PhD	Male	Basic Medical Scientist (Member Secretary)	Yes

1

The following documents were reviewed:Original submission

1. IEC Application Form
2. Funding details and Budget
3. Covering letter addressed to the Chairperson, IEC, SCTIMST dated 09.12.2024 forwarded by HOD
4. Interview schedule in English and Malayalam
5. Informed Consent Form in English and Malayalam
6. Participant Information Sheet in English and Malayalam
7. Checklist Form
8. Proposal
9. Declaration Form
10. CV of PI and Co-PI

Revised submission

1. Covering letter addressed to the Chairperson, IEC, SCTIMST dated 13.01.2025
2. IEC Recommendation letter dated 09.01.2025
3. Proposal
4. Participant Information Sheet in English and Malayalam
5. Consent Form in English and Malayalam
6. Interview schedule in English and Malayalam

Revised submission on 26.03.2025

1. Covering letter addressed to the Member Secretary, IEC, SCTIMST dated 26.03.2025 regarding the change of the study title.
2. Proposal
3. Participant Information Sheet in English and Malayalam
4. Consent Form in English and Malayalam
5. Interview schedule in English and Malayalam

IEC Decision

The IEC approved the conduct of the study in the present form.

Remarks:

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

There was no member of the study team / Guide who participated in voting / decision making process. The ethics committee is organized and operated according to the requirements of Good Clinical Practice and the requirements of the Indian Council of Medical Research (ICMR).

Sincerely,



Dr. G. Srinivas
Member Secretary, IEC

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE (IEC)
SCTIMST, THIRUVANANTHAPURAM



ANNEXURE VIII

Risk Factors and Foot Care Practices in Recurrent Diabetic Foot Ulcers: A Hospital based Case-Control Study in Pathanamthitta District,Kerala

ORIGINALITY REPORT

3%

SIMILARITY INDEX

PRIMARY SOURCES

- 1 B. Sundaravadivazhagan, Sekar Mohan, Balakrishnaraja Rengaraju. "Recent Developments in Microbiology, Biotechnology and Pharmaceutical Sciences - International Conference on Recent Development in Microbiology, Biotechnology and Pharmaceutical Science", CRC Press, 2025
Publications 104 words — 1%
- 2 www.frontiersin.org
Internet 67 words — 1%
- 3 pmc.ncbi.nlm.nih.gov
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