THE IMPACT OF DIABETIC FOOT ULCER ON HEALTH RELATED QUALITY OF LIFE (HRQL) AND EMPLOYMENT AMONG RURAL DIABETIC POPULATION IN SOUTH KERALA

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Dissertation submitted in partial fulfillment of the requirement for the award of the degree of Master of Public Health

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Finally I would like to convey my heartfelt thanks to my caring husband for his support throughout the study period.

Certificate

I hereby certify that the work embodied in this dissertation entitled "Impact of diabetic foot ulcer on health related quality of life and employment among rural diabetic population" is a bonafide record of original research work undertaken by Ms. Sithara S Pillai, in partial fulfilment of the requirement for the award of the "Master of Public Health" degree under my guidance and supervision.

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Declaration

I declare that the work embodied in this dissertation entitled "Impact of diabetic foot ulcer on health related quality of life and employment among rural diabetic population" is the result of my original field research. It has not been submitted to any other university or institution for the award of a degree.

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Dedication

To my husband Vivek Venugopal for his encouragement and support throughout the study;

To my parents Sasidharan Pillai and Rethnamma S Pillai for the value of education they instilled in me.

Abstract

Background: With a diabetic prevalence of 8.6% India is ranked at the top with respect to the burden of diabetes. HRQL (Health related quality of life) information is necessary to measure the effectiveness of the treatment, patient management and policy decisions. Diabetic foot ulcer is an important complication of diabetes and increasingly affects the working population. Evidence on HRQL, employment related factors and expenditure related factors is extremely rare in Kerala- particularly among rural diabetic population. This study was conducted with an objective to measure the health related quality of life among diabetic patients with healed and unhealed foot ulcer in the rural population.

Method: A cross sectional survey among 118 diabetic foot ulcer patients (mean years of age was 57.66 ± 7.71; 66.9% were males) selected randomly from the patients attending the outpatient department of a major diabetic care centre. Information was collected on socio-demographic variables, disease and treatment related factors, family life, employment and expenditure using a pre-tested structured interview schedule. The twenty nine item DFS- SF was used to measure the health related quality of life, after validation of the scale among the same rural diabetic population. For the working population the economic loss was calculated by total value of man days lost.

Results: The mean ± SD of total HRQL score for healed and unhealed group is 74.86 ± 12.11 and 59.92 ± 15.41 respectively. After adjusting for ulcer duration and sex the difference between the mean scores was 16.75 (95% CI = [-22.66, -10.81]). Median value of total man days lost was 26000 Rs with a range of 450 to 720000 Rs.

Conclusion: The mean HRQL score is significantly different between healed and unhealed groups even after adjustment for other predictors. There is a considerable economic burden imposed on households by diabetic foot ulcer which warrants greater attention to this condition. A multidisciplinary approach is needed to reduce the social and economic consequences of diabetic foot ulcer.

GLOSSARY OF ABBREVATIONS

ANCOVA	**Analysis of covariance**
ANOVA	**Analysis of variance**
CI	**Confidence interval**
CWIF	**Cardiff wound impact scale**
DFS	**Diabetic foot ulcer scale**
DFS SF	**Diabetic foot ulcer scale short form**
DFU	**Diabetic foot ulcer**
DM	**Diabetes mellitus**
EVI	**Economic value of individual**
GDP	**Gross domestic product**
HRQL	**Health related quality of life**
PVD	**Peripheral vascular disease**
QOL	**Quality of life**
SD	**Standard deviation**
SEM	**Standard error of mean**
SF 36 v 2	**Short form 36 v 2**
TCC	**Total Contact Cast**
UAE	**United Arab Emirates**
UK	**United Kingdom**
USA	**United states of America**
USD	**Unites states dollar**
WHO	**World health organization**

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Chapter 1: Introduction and review of literatures

'Need for national campaign to encourage physicians to remove patient's shoes and socks and to examine the feet' - Paul Brand (1914–2003) who added science to the art of foot care

1.1. Introduction

Diabetes mellitus is one of the major chronic non communicable diseases that affect millions globally. Evidence shows that diabetes has become a major epidemic in newly industrialised and developing nations. With a diabetic prevalence of 8.6 percent, India is ranked at the top with respect to the burden of diabetes.[1] Diabetes is a serious health problem that needs special attention and public health interventions in the 21st century. Sandeep et al from the Madras Diabetes Research foundation summarize the situation of diabetes in India as follows: "Diabetes in India is no longer a disease of the affluent. Studies have shown that poor diabetics are more prone to complications as they have less access to quality health care. This presents an alarming picture as the poor would find it more difficult to cope with the diabetes epidemic".[2]

Diabetes has been classified as Type1 and Type 2. In Type 1, the person's body is unable to produce insulin and he/she requires a continuous supply of insulin as treatment, whereas in Type 2, the person's body cells fail to use the produced insulin or there may be some insufficiency of insulin.[3] Uncontrolled blood glucose level for a long duration can damage heart and blood vessels, eyes, kidneys and nerves. People with diabetes are also prone to infections. In most of the high income countries diabetes has became a primary cause for cardio vascular diseases, blindness, kidney failure and lower limb amputation.[1] The nerve and blood vessel damage due to the uncontrolled diabetes leads to a variety of foot problems. These conditions worsen in the presence of infection and lead to ulcer formation. This eventually increases the risk of a person for lower limb

amputation. The risk for amputation among people with diabetes is 25 times more than that among people without diabetes.[4] Effective control over blood glucose level, blood pressure and cholesterol can delay or even prevent the development of diabetes related complications.[1]

1.2. Background

Diabetes is a chronic disease that occurs when the pancreas does not produce enough insulin, or when the body cannot effectively use the insulin that it produces. Hyperglycaemia, or raised blood sugar, is a common effect of uncontrolled diabetes. Over a period of time, this leads to serious damage to many body systems, especially to nerves and blood vessels.[5] Globally, the number of diabetics in 2011 is 366.2 million and the projected value for 2030 is 551.8 million. The prevalence of Type 2 diabetes is increasing all over the world and nearly 80 percent of the people with diabetes live in low and middle income countries. Around 4.6 million deaths in 2011 is attributed to diabetes.[1] Population based studies across the world show that the incidence of Type 2 diabetes mellitus is increasing among young adults. This will lead to an increase in the prevalence of micro and macro vascular complications associated with diabetes.[6]

The large and growing population of India and the high prevalence of diabetes among its population have increased the burden of diabetes in India.[7] In a review in the year 2000, Andrew J.M. Boulton stated that "The hallmark of diabetic foot problems in India is gross infection: major contributing factors for its late presentation include the frequency of barefoot gait, attempts at home surgery, trust in faith healers, often undetected diabetes, rodents nibbling at insensitive feet while the patients sleep on the floor, maggots pouring out of open wounds and red ants swarming inside the dressing ".[8]

1.3. Prevalence Studies:

1.3.1. Global scenario

The global prevalence of foot ulcer ranges from 1.4 percent to 11.9 percent.[8] A population based study among Type 2 diabetics in three cities of UK by Kumar et al in 2009 showed that the prevalence of neuropathy was 41.6 percent and the prevalence of peripheral vascular disease was 11percent. Out of 811 patients studied 43 had current or past foot ulcers.[9] A cross sectional multi centre study of randomly selected diabetic patients from diabetic clinics of UK showed that the overall prevalence of neuropathy was 28.5 percent (Type 1 DM - 22.7 percent and Type 2 DM -32 percent). This study also showed that there is an increase in the prevalence of diabetic peripheral neuropathy with age - ranging from 5 percent in 20-29 year age group to 44.2 percent in 70- 79 year age group. They also found an association between prevalence of peripheral neuropathy and duration of diabetes – ranging from 20.8 percent in people with diabetes for less than 5 years to 36.8 percent in those for more than 10 years.[10] Studies from US show that among diabetics, 2 – 3 percent will develop foot ulcer each year and more than 15 percent will develop foot ulcer during their life time.[11]

1.3.2. Studies from India

Vaz et al, in a cross sectional study in the rural areas of Goa, shows that there is a high prevalence of diabetes - 10.3 percent - with a prevalence of 8.4 percent among males and 12 percent among females. They also found that the prevalence of complication of diabetes was high in rural area: neuropathy was 60 percent and peripheral vascular disease (PVD) was 11.5 percent. [12, 13] A prospective study by Jayaprakash et al in 2009 showed that the prevalence of neuropathy was 34.9 percent and PVD was 12.6 percent. Among the studied population, 9 percent reported foot ulcer at the time of the study and

2.3 percent reported previous history of foot ulcer.[14] In India, high prevalence of diabetes is found in the age group of 45- 64 years compared to that in the older age group (greater than 65) in the developed countries Such as US.[15]

1.3.3. Studies from south India

A study on diabetes in urban Kerala by Kutty et al in 1998 showed that the prevalence of Type 2 DM gradually increases with age. According to the study, the overall prevalence of Type 2 DM among urban population of Trivandrum was 16.3 percent.[16] A study in Neyyattinkara taluk of Trivandrum district showed that over all age adjusted prevalence of Type 2 DM among 30 – 64 years age group was 9.2 percent for men and 7.4 percent for women.[17] The study by Thankappan et al in 2010 showed that the total prevalence of diabetes was 14.8percent for weighted samples. They also found that the DM was more prevalent among rural population (20.6 percent) compared to urban population (14.8 percent).[18]

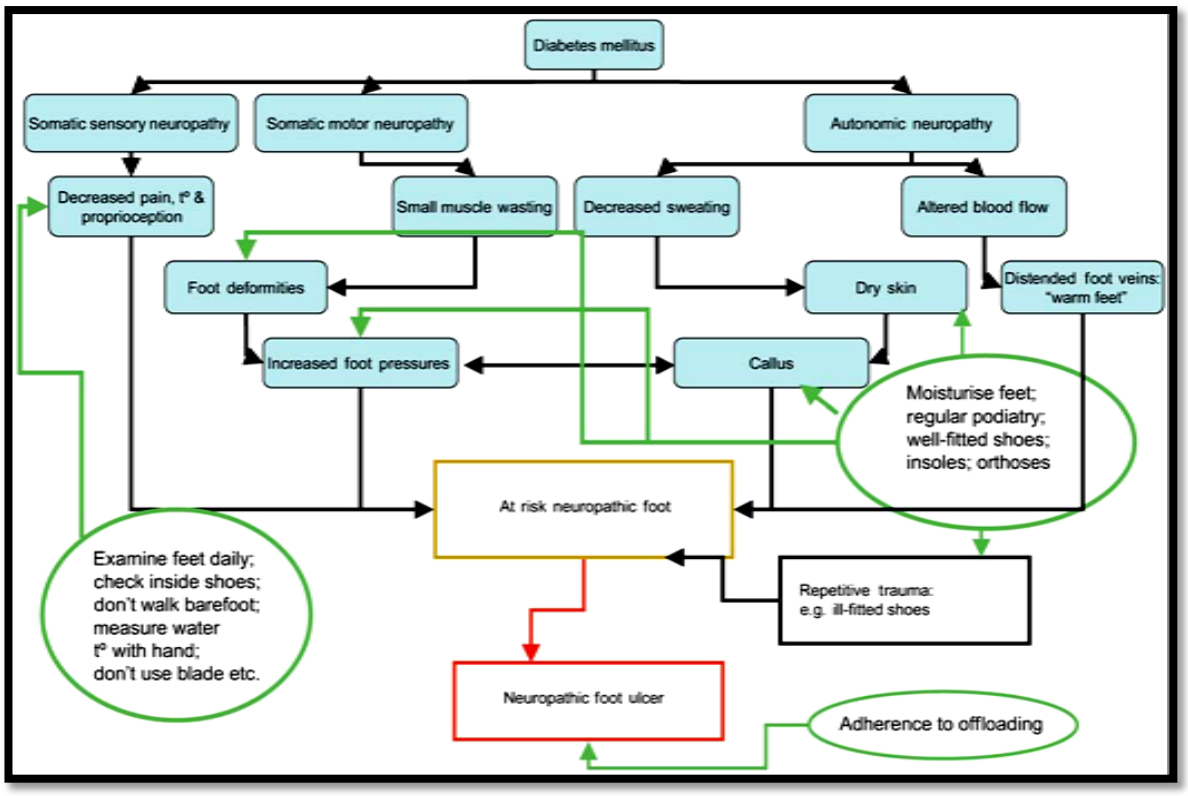
The prevalence of neuropathy was found to be 27.5 percent and 19.1 percent in two separate clinic based studies from Chennai.[2] A study in South India by Viswanathan et al showed that prevalence of foot infection was higher among rural patients (34 percent) than that among urban patients (26 percent). They also found that amputation rates have the same pattern - in rural it was 8 percent compared to 3 percent in the urban population. Recurrent rate and surgical interventions were also higher among rural than the urban patients.[19]

1.4. Pathways to foot ulceration

A qualitative study by Gale et al titled - Patients' perspectives on foot complications in type 2 diabetes – shows that ‘participant’s belief model’ on the pathway to lower limb

amputation is different from the 'medical model'. This difference in understanding in the foot care may lead to foot ulceration. Author narrates a patient's belief that poor blood circulation is the only reason for nerve and tissue damages in the foot. Such patients regularly walk barefoot to increase the blood circulation to their feet as preventive foot care. However, this behavior may lead to foot ulceration.[20]

The major contributory causes to foot ulceration are peripheral neuropathy and peripheral vascular disease.[21] Other contributory factors such as foot deformity, longer duration of diabetes, other micro vascular complications, bare foot walking, high plantar pressure, stepping on a sharp object, past history of foot ulcer or amputation comprise the intrinsic and extrinsic factors for foot ulceration.[21, 22, 23] Studies show that foot ulcers from a single pathology are very rare, majority of them occurs from an interaction of two or more contributory factors.[22] For example the high pressure sites in the foot are prone to get plantar ulcer.[24] High foot pressure along with the insensitivity in the foot completes one pathway to foot ulcer.[25] Recent evidence show that the factors such as psychological distress (depression and anxiety), stress, negative affect and lack of social support have impact on wound healing.[26, 27]



[**Fig. 1** Causal pathways to foot ulceration emphasising the key role of the patient in ulcer prevention (spheres and arrows) t°,temperature. Illustration courtesy of L. Vileikyte.[28]]

An Iranian study shows that major risk factors for the development of foot ulcer in the Iranian diabetic population are older age, low educational level, smoking habit, living alone, the frequency of poor diabetes control.[29]

A study among the Bahrain diabetic population showed that prevalence rate of neuropathic complication in diabetics was higher in that region compared to those reported among diabetics in USA and Europe. The study showed that the prevalence rate of diabetic neuropathy increased with the duration of diabetes, ranging from 5 percent at 1 year of diagnosis to 48 percent at more than 11 years. The study also found a positive correlation between neuropathy, peripheral vascular diseases and glycated hemoglobin level. The researchers attributed relatively high proportion of diabetic foot ulcer among diabetic population of Bahrain to elevated levels of glycated hemoglobin.[30]

A hospital based study in UAE shows that Asian middle-aged-diabetics are at high risk of getting diabetic foot ulcers compared to those from Middle East. This study also shows that post prandial blood glucose levels were less among diabetics with foot ulcer compared diabetics without foot ulcer.[31]

1.5. Treatment Modalities

The main interventions to reduce the foot pressure include extra depth shoes, custom-molded shoes with addition of Rocker sole based on the deformity of the foot.[32] Understanding the importance of dressings and bandages for foot ulcer healing, Brand promoted Total Contact Cast (TCC) for managing the plantar foot ulcer. The TCC will help to reduce the mobility of the foot and thereby reduces the time for wound healing.[33] Randomized control trials from different studies also reiterate the importance of 'pressure off loading' to improve the wound healing.[34, 35]

1.6. Health related quality of life (HRQL) Studies

In a review, Price says that only few data are available on life experiences of patients with infection and diabetic foot ulcer. She also conveys that HRQL in patients with foot ulcer may be poorer than those who had amputation, because many of the patients live with the fear of recurrence of foot ulceration and potential lifelong disability.[36]

In a review, Reiber states that "Increasingly, clinicians and policymakers use health related quality of life information for patient management, reimbursement, and policy decisions." HRQL is a multidimensional concept which includes the following : aspects of survival; the effect of disease or impairment on social, psychological, and physical function; patient health perception; social opportunity and satisfaction.[11]

Patients with diabetes have an increased risk for getting peripheral neuropathy, peripheral vascular diseases, impaired wound healing and decreased ability to fight infection. Lower extremity ulcer is a major concern- both for the patients and for the physicians who treat them - from a quality of life and economic stand point. Studies that evaluated the quality of life of diabetic foot ulcer patients have shown that there is a reduction in their physical, emotional and social functions.[11] Individuals with chronic non healing wounds experience a variety of adverse effects on their day to day life.[37] A ten year - follow up study of diabetic and non diabetic population indicated that mortality risk for diabetics with history of foot ulcer is 2.29 times more than that of the non diabetic population.[38]

Factors such as living alone, low educational level, presence of at least one complication, older age, presence of Type 2 DM, higher Wagner grade, longer duration of diabetic foot ulcer lead to lower HRQL among diabetics. The extended healing time for diabetic foot ulcers has huge impact on patient's HRQL, which resulted in a significant role limitation and social functioning in the diabetics with foot ulcer compared to diabetics without foot ulcer.[29]

Diabetic foot ulcers are positively correlated with reduction in the mobility and deficit in daily activities that adversely affect the HRQL. A comparative study between diabetic patients with foot ulcer and without foot ulcer shows that diabetic foot ulcer is an expensive complication among diabetics. It precedes 84 percent of lower limb amputations and it increases the risk of death by 2.4 percent.[39, 40]

In a comparative study among healed and unhealed foot ulcer patients, Goodridge et al, found that presence of foot ulcer has huge negative impact on diabetic patients. The evaluation of unhealed group with CWIS(Cardiff wound impact scale) showed that well being component score is significantly diminished in the presence of ulcer.[41] In another study by Lis Ribu et.al, patients were followed up for one year and it is found that their

quality of life increased gradually with the healing of ulcers. They also found a significant change in the social functioning between healed and unhealed group. They concluded that if HRQL is poor in the follow up, that means poor prognosis of ulcer.[42] Iversen et al in a ten year follow up study on diabetic foot ulcer patients found that the history of foot ulcer significantly affects the psychological well being of the person and leads to depressive symptoms among diabetics.[43]

1.7. Translation and validation of diabetic foot ulcer scale short form (DFS - SF)

Clinicians and policy makers increasingly use 'improvement in patient's functional status and quality of life' as a basis for choosing different therapeutic options among diabetic patients.[44] HRQL measure may explain why patients with similar conditions respond differently to the treatment.[11]

In 2000, Abetz et al developed and validated the diabetic foot ulcer scale (DFS) to measure the impact of diabetic foot ulcer and its treatment on quality of life of diabetics. This scale has 58 items grouped into 11 domains. The scale shows good test - retest validity and is sensitive to changes in the wound status.[45] In 2003 Bann et al developed a short form of DFS to reduce the burden on patients and the number of outcome measures. The DFS - SF has 29 items under 5 subscales, it shows good psychometric properties, reliability and is sensitive to wound healing.[46]

Even though the need to study QOL of foot ulcer patient is well known, an instrument to measure the QOL specific to India is yet to be developed. Hui et al translated and validated DFS – SF for Chinese population. They found that the internal consistency of all scales of the Chinese DFS-SF was consistently high (Cronbach's alpha ranged from 0.8 to 0.92) and the item convergent and discriminant validity were satisfactory (median corrected item-scale correlation ranged from 0.63 to 0.84). Moreover, the instrument

established good construct validity when correlated with the SF-36. It showed good sensitivity between patients with healed and unhealed DFU, with different types of foot ulcer, with different Wagner grade, and with differing episodes of DFU.[47] A comparative study of HRQL and clinical correlates of QOL among French patients with and without foot ulcer using SF 36 and DFS shows an independent inverse relationship between good HRQL domain of leisure and Wagner grade or number of ulcers. In this study age is found to be significantly associated with domains of daily activities, physical health and dependence.[48]

Disease specific questionnaires are important to address the co morbidities while assessing HRQL in diabetic patients with foot ulcers. A study by Jaksa et.al in Canadian population validated the domains of CWIS with SF 36 v2. These two quality of life scales showed a correlation among several domains of HRQL. Patients with open ulcers show a significantly low CWIS score compared to patients with healed ulcers.[49]

1.7.1. The procedure of validation

Validating a scale is a process by which we calculate the degree of confidence we are able to put on inferences we build about individuals from their scale scores.

Measurement scales: Measurement instruments that are collections of items intended to reveal levels of theoretical variables, not readily observable by direct means, are usually referred to as scales. Scale items are usually intended to understand the construct- the variable that can't be measured directly.[50]

The phenomenon or construct reflected from a scale is referred as the latent variable. The true score from a scale is defined as the actual magnitude estimated for a latent variable at a particular time and place for each individual.

Reliability is regarded as a prerequisite for the validity of a scale. Reliability concerns how much a variable influences a set of items, while validity concerns whether the variable is the underlying cause of item co variation.[50]

Scale reliability is the proportion of variance attributable to the true score of the latent variable.

Types of reliability

- Test retest reliability
- Internal consistency
- Split half reliability or odd even reliability

Types of validity

- Content validity
- Criterion related validity
- Construct validity

Construct validity of a scale consists of two parts, the convergent validity and the divergent validity. For a scale to have good construct validity, it should have a positive and high correlation (convergent validity) and a positive and low correlation (divergent validity) with a scale measuring similar but different construct. Short form (SF) – 36 v 2 is a well validated generic scale developed by WHO for measuring quality of life, it measures 8 domains of health with 36 items.[51]

1.8. Studies on impact on employment

Diabetic foot ulcers are associated with reduced mobility and disability related to activities of daily living. Qualitative studies on foot ulcer show that it has huge impact on psycho social activities such as reduced in social activities, increased family tensions for patients and their caregivers, limited employment, and financial hardship.[39] Holzer et al in a study concluded that lower extremity ulcers occur in a large number of working age diabetic population and foot ulcers contribute significantly to the morbidity associated with diabetes.[52] A survey by Minor 'on the effect of diabetes on female labour force decisions' found that any type of diabetes will reduce the productivity of an individual and thereby reduce their earning capacity. He also found that Type 2 DM has a major role in the overall negative effects of diabetes.[53]

In a focus group study, Brod found that in the employment domain, work was significantly affected due to lower extremity ulcers. Half of the patients had either retired early, lost their jobs or were out of work due to foot ulcer. For those who are employed, their productivity is found to have been reduced; their clinical appointments resulted in losing work hours and sometimes even missing a better career opportunity. Manual workers are more affected than office workers. In younger patients loss of employment opportunities resulted in diminished self esteem.[54] A study by Kapur et.al shows that direct medical expenditure is only a very small part of the expenditure involved in diabetes treatment. He added that indirect costs from lost man days, change in work, wage loss, and intangible costs from the suffering and the effect on family members are huge. The indirect cost on the non-earning members is calculated on the basis of economic value of individual (EVI) model.[55, 56]

1.9. Family consequences studies

In a qualitative study, Brod demonstrated that not only diabetic foot ulcer patients but also their care givers and partners are also affected directly or indirectly. The study of 14 patients and 11 care givers reported a significant reduction in social activities, increased family tensions, lost time from work and negative effects on general health among both the groups.[54] Data from1983-1990 show that the length of stay in hospital for diabetic patients with foot ulcer is 59 percent more than that of the patients without ulcer.[11]

1.10. Expenditure or economic impact studies

Poor are the most affected by the chronic diseases; the disease expenditure and the reduced productivity leads to a lower GDP.[44]

Health and economic consequences of diabetes are huge and they lead to high and growing cost to the country.[1] Individuals with diabetes utilize more health resources and the high expenditure is attributed to the late complications and the lost man days or lost economic opportunities.[56] Foot ulcers are an expensive problem both in the developed and developing countries. Providers and payers are under tremendous pressure to consider the economic aspect of foot ulcer care. Reiber in a review of burden of foot ulcers states that “most studies measure only direct costs (visits, hospitalizations, procedures, treatments, dressings, referrals), since indirect costs (pain, suffering, family inconvenience) are hard to quantify and price.”[11] Expenditure for diabetes care is directly proportional to the number of complications. There is a significant difference in medical expenditure incurred by urban and rural subjects.[57] Ramsey et al in a study found that the relative cost of care for foot ulcer patients in the year before diagnosis is 1.5 – 2.4 times

greater than that of their counter parts without foot ulcer. In the year of diagnosis it rose up to 5.4 times than that of the control group.[40]

Economic consequences of diabetic foot ulcers among rural diabetics are not well studied. The major cost for healing the infected foot ulcer is attributed to the topical treatments.[58]

Although many of the lower extremity ulcers will heal with standard treatment, some are more resistant and need costly ongoing medical care. Some of these conditions are deep infections, osteomylitis and amputation. Holzer et al found that total payments for the treatment of lower extremity ulcers in the population averaged USD 2687 per patient per year and USD 4595 for each ulcer episode. They also found that 80 percent of these costs account for inpatient care.[52] In a prospective study, Apelqvist and colleagues found that the average cost for primary healing was USD 6664 and that for healing with amputation was USD 44790. In above mentioned groups costs for in-patient care were 37 percent and 82 percent (of total average costs) respectively. The costs for topical treatment of the ulcers in out-patient care were 45 percent of the total average cost for primary healed and 13 percent for patients who healed with amputation. The cost of products used for ulcer dressings was 21 percent of total costs for topical treatment.[59]

An analysis by Ramachandran et.al in India showed that total median expenditure on diabetes care is Rs 10,000 (USD 227) in urban and is Rs 6,260 (USD 142) in rural subjects. This study also illustrated that lower income group spent a higher proportion of their income on diabetes care. Only 3.2 percent of the rural population compared to 14.2 percent of the urban population obtained medical reimbursement. A significant increase in medical reimbursement is observed from 1995 (2 percent) to 2005 (21.3 percent).[57]

In India diabetic foot infection is a major cause for hospitalization among diabetes patients.[7] Major components of cost of illness include direct costs(consultation,

investigations, treatment, drug), indirect costs (man days lost, disability payment, social security, tax rebate) and intangible costs (pain, anxiety, depression, loss of enjoyment).[55]

1.11. Diabetes education – Prevention and care of foot ulcer

The recent evidence shows that diabetes education, awareness and motivation for self care have a major role in care, reduction of complications and overall reduction of economic costs of diabetes.[55] Assal JP showed that primary interventions like patient education and awareness of foot problems can lead to a significant reduction in amputation rates.[60] Comprehensive patient education is a necessary requirement to equip the diabetic with self management skills to maintain the glycemic control.[61]

Chapter 2: Rationale and objectives of the study

2.1. Rationale for the study

- Kerala has the highest prevalence of diabetes in India.
- With the onset of epidemiologic transition, lots of people from the rural area are affected with diabetes. Majority of them depend on agricultural employment.
- Studies show that the chance of getting foot ulcer is high among rural people, as a considerable population works in the agricultural fields.
- Diabetic foot ulcer causes them to lose many man days and adversely affects their economic stability. Thus it seriously affects their health related quality of life.
- Diabetic foot ulcers can be easily prevented, if timely intervened with a proper guideline for care and treatment of diabetes.

2.2. Objectives of the study

2.2.1. Major objectives

- To measure the impact of foot ulcer on health related quality of life (HRQL) among healed as well as unhealed diabetic foot ulcer patients
- To validate the diabetic foot ulcer scale short form (DFS – SF) in rural population of Kerala setting
- To assess the impact of diabetic foot ulcer(DFU) on employment related characteristics

2.2.2. Minor objectives

- To understand the family adjustments such as role change, earning capacity etc.
- To measure the quantum and pattern of direct medical expenditure between healed and unhealed diabetic foot ulcer patients.

Chapter 3: Methodology

3.1. Operational definitions

Diabetic Foot – The foot of a diabetic patient that has potential risk of pathologic consequences including infection, ulceration and/ or destruction of deep tissues associated with neurologic abnormalities and various degrees of peripheral vascular disease and/ or metabolic complications of diabetes in the lower limb.[5]

Diabetic Foot Ulcer – Means any break in the cutaneous barrier extending through the full thickness of the dermis, and did not heal after one month.[63]

Quality of life (QOL) – I adopted the WHO definition of QOL as "Individuals' perception of life in the context of their culture and value system in which they live and in relation to their goals, expectations, standards and concerns".[62]

QOL – Means the state of contentment in a conscious individual due to his or her satisfaction in physiological, psychological, social and spiritual aspects of life.[63]

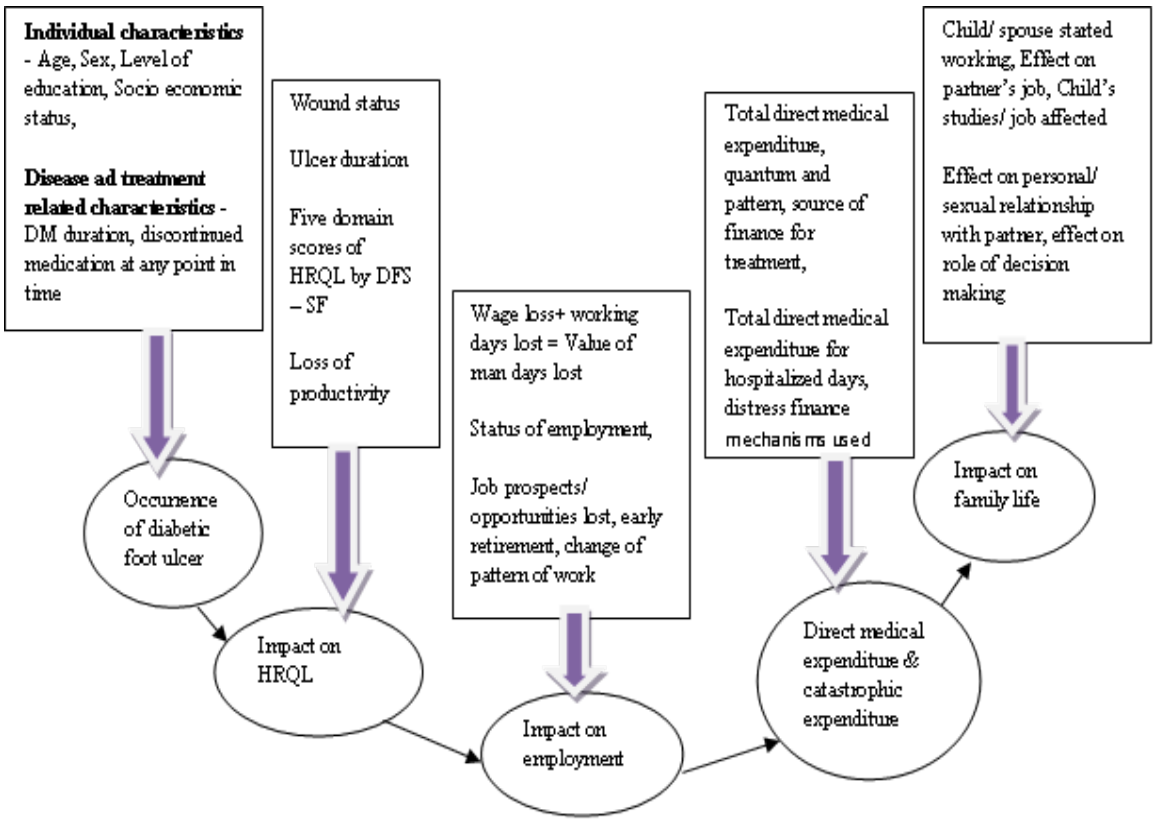
3.2. Formative research

After finalizing the objective, formative research was carried out in ten diabetic foot ulcer patients from three different diabetes clinics. In-depth interviews had been carried out to understand the knowledge of the patients about their disease condition, change in their employment status and impact on their work pattern, major problems they faced after the occurrence of foot ulcer, expenditure pattern, health seeking behaviour, and changes which occurred in their family life. A key informant interview with a practising diabetic foot ulcer physician was carried out to understand the treatment modalities used for foot ulcer care and deductive themes were generated after the interviews, using the guidelines for formative research (See Annexure 1) as template.

The findings from in depth interviews were used to finalize the questionnaire to conduct the research among similar diabetic population.

3.2.1. Conceptual framework – A framework was created after the analysis of themes from formative research. (See Fig. 3.2.1)

Fig.2 Conceptual framework



3.3. Study design

This was a cross sectional descriptive study of diabetic foot ulcer patients. Both 'Quantitative' and 'Qualitative' research methods were included. The study had three components as follows:

Component 1: Validation of diabetic foot ulcer scale short form among randomly selected patients from the diabetes clinic.

Component 2: Cross sectional survey of diabetic foot ulcer patients attending the outpatient department of Medical trust hospital, Panthalam.

Component 3: Case study research of two selected patients from the sample.

3.4. Translation and validation of the DFS –SF

3.4.1. Linguistic validation

The linguistic validation of the Malayalam version of DFS SF was done as an initial step to use the scale in Kerala setting. The steps involved were forward and back translation and cognitive interviews. Forward and back translations were carried out by experts. However there was some mismatch in the English version. Hence the process of back translation was repeated with the help of another English scholar. A final copy of the English version was prepared from the two available English versions. There was 90 percent match between the original version (See Annexure 2) and back translated version (See Annexure 3) of DFS SF. Five cognitive interviews have been carried out among the diabetic foot ulcer patients who attended the outpatient department of the diabetic hospital to measure the understanding of the scale and its sub items (See Annexure 4 for the results of cognitive debriefing). All participants were able to understand the questionnaire and scoring mechanism used in Malayalam DFS SF.

3.4.2. Measures of reliability and validity:

Methods of reliability and validity were used to validate the scale in Kerala setting.

Face validity was explored by showing the scales to experts and getting their approval. Internal consistency was measured by Cronbach's alpha (α). The formula to calculate α is given below:

$\alpha = k/k\text{-}1(1-\Sigma\sigma i2 / \sigma yi2)$,

where k is the number of items in the scale, σi2 is the variance of the i^{th} item, σyi2 is the total variance of the k item scale. Instead of correlations, this formula is based on covariance.[50] Construct validity of DFS SF was calculated by estimating convergent

validity with a similar scale – SF 36 v 2 (See Annexure 5), a scale to measure quality of life.

3.4.3. Study setting

The study setting used was Medical Trust hospital, Panthalam.

3.4.4. Sample size

We recruited 50 subjects for validation of the scale however one case was removed due to documentation error.

3.4.5. Sample selection procedures

Participants were selected serially as they approach the physician for consultation, after confirming the consent. No one refused consent. Both healed and unhealed foot ulcer patients were included. Data were collected between 15th June 2012 and 30th June 2012.

3.4.6. Data collection techniques

For measuring the construct validity I interviewed participants with two different scales (diabetic foot ulcer scale short form (DFS - SF), which was developed by MAPI Trust, France[46] and SF- 36 v 2, a standardised general quality of life questionnaire to measure the quality of life. To measure the reliability I interviewed nine out of 49 participants with DFS –SF again after a period of 15 days from their first interview.

3.4.7. Data analysis

Data were cleaned manually and entered into Epidata 3.1, then imported into software R 2.14 for statistical analysis. In DFS SF the raw items were reverse coded such that one represented the best quality of life, which was scored as 100 and five represented the worst quality of life, which was scored as zero.[45]

DFS-SF subscale scores were calculated as follows:

Score = [(sum−min) /range] × 100, where sum is the sum of the raw item scores, min is the minimum possible sum of item scores, and range is the possible range of the sum of

item scores. All of the DFS SF sub scales were scored from zero to 100, with higher scores indicating better quality of life.[45]

To measure reliability, test and retest values were entered directly into the software R 2.14 and the correlation coefficient computed.

3.5. Cross sectional survey

3.5.1. Study setting

This study was carried out among the DFU patients who attended the Medical Trust hospital (Diabetes Research Centre) Panthalam. This hospital was chosen because it caters to patients from all socio economic strata. Diabetics were selected based on the inclusion and exclusion criteria. The hospital also acts as a referral centre for many of the PHC's and major hospitals in nearby districts.

3.5.2. Sample size

Sample size was estimated - using R with a power of 90%, alpha error at 5%. I assumed a mean ± SD of 58±20 for unhealed ulcer group and of 70±20 for the healed ulcer group. Based on this, the sample size estimated was 118. The values used were based on a published study from UK.[45] After obtaining the consent, all of them were selected for the study.

3.5.3. Sample selection procedures

Participants were selected serially from the outpatient department of the hospital as they approached the physician for foot ulcer care. (See Annexure 6 for the consent form used by the physician to refer the patients for considering into the study). The first patient who satisfied the inclusion criteria was selected as the first subject followed by other patients who were willing to participate in the study. I interviewed an average number of four individuals per day. Data was collected between 1st July 2012 and 10th September 2012.

3.5.4. Sample Selection criteria

Inclusion criteria

- Diabetics who had at least one incidence of foot ulcer in their lifetime
- Persons with current/ previous history diabetic foot ulcer with a duration of more than 1 months and less than 2 years.
- Age between 30 - 70 years.

Exclusion criteria

- Individuals with cognitive or mental illness
- Pregnant women
- Bed Ridden patients

3.5.5. Data collection techniques

Participants were interviewed with a pre-tested structured interview schedule. The schedule included two parts - the questionnaire with 46 items (See Annexure 7) used to capture socio demographic details, disease and treatment related details, employment and family life characteristics and the validated DFS-SF used to assess the HRQL of foot ulcer patients.

3.5.6. Data storage and data cleaning

Special precaution was taken to maintain the confidentiality and privacy of the personal information collected from the study participants. The data were cleaned manually and then entered into Epidata 3.1.

3.5.7. Variables under the study – Definitions and characteristics (See Table 3.5.7.1 and Table 3.5.7.2)

Table 3.1 Predictor variables

Variables	Type	Definition
Age	Dichotomous	Age was collected as a continuous variable. It was divided into two groups (group = Less than or equal to 60 years and group 2 = More than 60 years).
Sex	Dichotomous	Females and males
Education	Categorical	Years of schooling was divided into four groups, up to seven years= Upper primary; Eight to ten years= High school; 11 to 12 years= Higher secondary; More than 13 years= Higher education.
Marital status	Categorical	Marital status at the time of interview.
Socio economic status	Categorical	Composite variable created from the house hold assets owned and average monthly household expenditure.
Living status	Categorical	Either live alone or with others.
Employment	Categorical	The employment status of the participant at the time of the study.
Duration diabetes	Continuous	Reported years of being diagnosed as diabetic.
Ulcer duration	Continuous	The duration reported by patients when they first noticed the presence of wound.
Wound status	Dichotomous	Healed wound group was defined as patients at the stage of healing or those who were classified as Wagner grade 0 at the time of interview. Healed patients include those who don't need any wound dressing and who can walk without any difficulty.
Stopped diabetic medication	Dichotomous	Any time stopped diabetic medication at any time after being diagnosed as diabetic.
Ulcer history	Categorical	Incidence of foot ulcers till now.
Less productive	Categorical	The extent to which the patient feels less productive due to the presence of foot ulcer.
Financial source	Categorical	The source of money for the direct medical expenditure during hospitalized days.
Number of work days lost	Continuous	Work days lost due to the presence of the current ulcer
Wage loss per day	Continuous	Wage loss that occurred due to absenteeism from work

Variables	Type	Definition
Loss of job opportunities	Dichotomous	Any loss of job prospects/ opportunities due to foot ulcer
Early retirement	Dichotomous	Had to quit job due to foot ulcer
Change in pattern of work	Dichotomous	Any change in pattern of work due to foot ulcer

Table 3.2 Outcome variables

Variables	Type	Definition
Five domain (sub scale) scores	Continuous	The average of the item scores in each domain.
HRQL score	Continuous with normal distribution	The average of the five domain scores
Value of man days lost	Continuous with a skewed distribution	The product of total work days lost due to foot ulcer and wage loss per day.
Direct medical expenditure	Continuous	Direct weekly medical expenditure for the foot ulcer care
Direct medical expenditure during hospitalization	Continuous	Direct weekly medical expenditure during hospitalized days = (The ratio of total direct medical expenditure due to hospitalization to total hospitalized days) * 7
Distress finance mechanism	Categorical	Different mechanisms used by the participants or their family to manage the catastrophic health spending.

3.5.8. Data analysis

Statistical analysis performed using R 2.14 and SPSS 16.

Table 3.3 Frame work used for analysis

Univariate analysis: Calculated descriptive statistics for the predictors and outcome variables.
Bivariate analysis: Two way factor ANOVA was performed to find out the major predictors of health related quality of life in each of the five domains separately, holding wound status as constant in one axis.
Multivariate analysis: Analysis of covariance **(**ANCOVA) was carried out to compute the adjusted mean difference in the two wound status groups, i.e. healed and unhealed after adjusting for influential variables such sex and duration of ulcer.

3.5.9. Analysis of HRQL score

Initially all the descriptive statistics were calculated for all the variables collected. The composite variable 'socio economic status' was created from the data collected on reported monthly household expenditure and the household assets owned by the study participants.

We grouped the total sample into two (healed and unhealed) based on the status of wound and then compared the major characteristics of the groups. Two way factor ANOVA was done on the different domains of the scores with wound healing as one factor and variables such as age, sex, socio economic status and other relevant characteristics separately as the other factor.

The average of the total subscale scores was coined as 'Total quality of life' to get an overall picture of the factors associated with HRQL among foot ulcer patients.

Our primary objective was to compare the HRQL in the two groups of patients, i.e. healed and unhealed. We hypothesised that the quality of life in diabetic foot ulcer patients differs depending on various factors. The most important of which is the status of

the wound. For this we used analysis of covariance (ANCOVA) using the 'lm' function in R. ANCOVA assumes that the regression slopes of continuous outcome variable will be different but parallel in the two groups after adjusting for other covariates. The covariates we adjusted were ulcer duration and sex, after testing and ruling out interaction effect between predictors.

See Annexure 8 for the equations (R commands) used for the analysis of the primary objective.

3.5.10. Analysis of employment characteristics

We created a composite variable 'total value of man days lost'- by multiplying the total work days lost with the wage loss per day- to measure the impact of foot ulcer on employment. We found that the total value of man days lost was not showing normal distribution. Hence non parametric test (Wilcoxon rank sum test) was used to analyze the outcome variable and predictors such as sex, age and wound status. The proportion of patients who had early retirement or loss of job prospects due to foot ulcer was also estimated from the collected data.

3.5.11. Family characteristics

The proportion of patient's partners' who were forced to go for work and proportion of patients' whose children had to discontinue their schooling/ lost work days were estimated by univariate analysis. The impact on patient's parteners' job and effect on their physical and sexual life were also estimated.

3.5.12. Direct medical expenditure

Weekly direct medical expenditure was calculated from patient reported data of treatment expenses under different heads. Average weekly direct medical expenditure was calculated by dividing the total medical expenditure reported by the patient by the total hospitalized days for the treatment of current foot ulcer. The validity of the direct

expenditure reported by the subjects was validated by matching with hospital bills in a random sample.[57]

3.6. Case study research

3.6.1. Study setting

Medical Trust hospital, Panthalam.

3.6.2. Sample size

Two individuals were selected for discussion to describe the impact of foot ulcer and the disease dynamics.

3.6.3. Sample selection procedure

Patients selected randomly from the main sample, who gave consent for in depth discussion about their disease dynamics and its impact on their life. A special consent with particular reference to the use of voice recording device was obtained. Two cases were selected based on the severity of wound status.

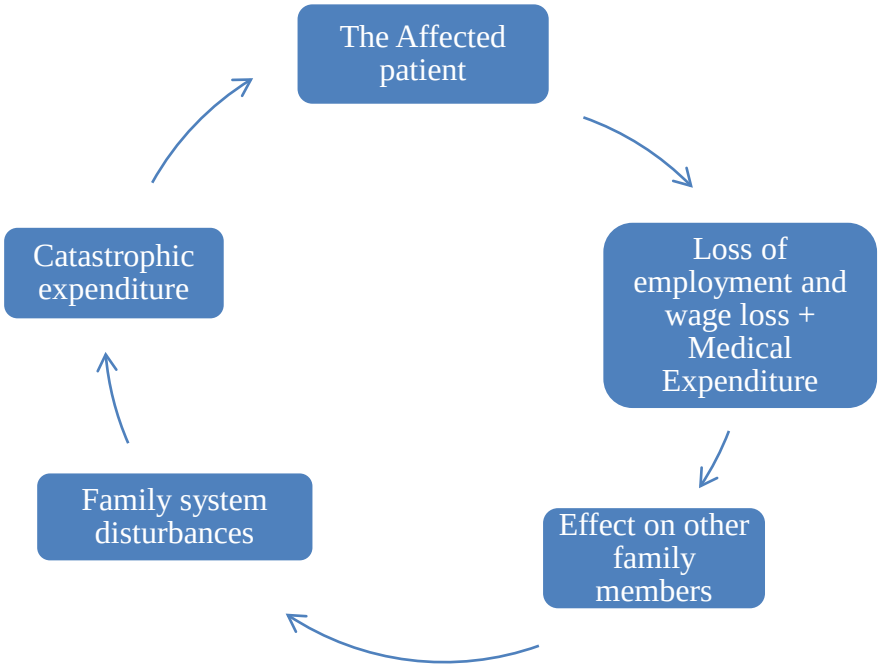
3.6.4. Data collection technique

Case study research guidelines (See Annexure 9) were used to capture qualitative data from the patients. In depth discussions were carried out in the hospital when patients came for follow up visit.

3.6.5. Data analysis

Two cases were analyzed based on the themes created after in depth discussion. See fig. 3.6.5.1 for deductive themes generated from formative research used for case study analysis.

Fig. 3 Deductive themes used for case study analysis



3.7. Ethical considerations

The research conducted was cleared by the Sree Chitra Tirunal Institute for Medical Sciences and Technology's ethics review board. Informed consent- oral and written consent- was taken from all participants before the interview. Participants were allowed to withdraw from the study at any point of time. Privacy and confidentiality of the information's collected from patients were maintained. There was very little risk for the participant as such. (See Annexure 10-13 for consent form, participant information sheet, health education pamphlet used).

Chapter 4: Results

4.1. Scale validation

4.1.1. Assessment of reliability

4.1.1.1. Temporal stability

Test retest correlation for the total HRQL score was 0.929.

4.1.1.2. Internal consistency

Internal consistency was assessed as a measure of reliability to measure inter item variability in each of the five domains of DFS SF and Cronbach's coefficient alpha estimated. (See Table 4.1)

Table 4.1 Internal consistency for different domains of the score (n=49)

Domain	**Number of Items in the scale**	**Internal Consistency**	
		Average Item Correlation	**Cronbach's Alpha (α)**
Leisure	5	0.50	0.84
Physical health	5	0.23	0.60
Daily Activities	5	0.43	0.79
Emotions	10	0.21	0.72
Treatment	4	0.30	0.63

4.1.2. Assessment of validity

4.1.2.1. Construct validity (See Table 4.2)

Table 4.2 Correlation matrix with SF 36 Vs DFS-SF (n=49)

DFS SF Scale	SF 36 V2 Scale							
	Pain Score	General Health	Social Functioning	Physical Functioning	Role Limitations due to physical health	Role Limitation due to emotional problems	Energy / Fatigue	Emotional Well being
Leisure	0.38	0.40	0.44	**0.59#**	0.24	0.28	0.22	0.37
Physical Health	**0.59#**	**0.62#**	0.29	0.35	**0.54#**	**0.58#**	**0.60#**	**0.58#**
Daily Activities	**0.52#**	0.45	0.37	**0.63#**	0.36	0.43	0.39	0.39
Emotions	0.48	0.47	0.35	**0.56#**	0.40	**0.57#**	0.43	**0.65#**
Treatment	**0.55#**	0.39	0.44	**0.57#**	0.30	0.39	0.30	**0.64#**

['#' denotes the domains which showed strong correlation between the above mentioned scales]

4.2. Cross sectional survey

4.2.1. Socio demographic and clinical characteristics of the study sample

The median age of the sample subjects was 58.5 years. Two third of the sample were male patients. See Table 4.3 for other socio demographic characteristics.

Table 4.3 Socio demographic characteristics of the study sample (n= 118)

Variables	Categories	Frequency (%)
Sex	Female	39 (33.1)
	Male	79 (66.9)
Age	≤60 yrs	74 (62.7)
	>60 yrs	44 (37.3)
Education	Upper primary	23 (19.5)
	High school	73 (61.9)
	Higher secondary	9 (7.6)
	Higher education	13 (11)
Socio economic status	Low	42 (35.6)
	Medium	37 (31.4)
	High	39 (33.1)
Marital status	Unmarried	3 (2.5)
	Married	106 (89.8)
	Widowed	9 (7.6)
Living status	Living alone	11 (9.3)
	With children	7 (5.9)
	With spouse	39 (33.1)
	With whole family	61 (51.7)

The mean duration of diabetes in the sample was 15 years with standard deviation of 7 years (range = 2 to 35 years). The mean ulcer duration for the sample was 7 months with a range of 1 to 24 months. Based on the status of the wound during the time of interview, the study sample was divided into two groups, healed and unhealed. Among the 118 patients interviewed, 87 (73.7 percent) were in the unhealed group and 31 (26.3 percent) were in the healed group. See Table 4.4 for the details.

Out the total sample of 118, 39 (33.1 percent) were reported that they stopped diabetic medication at some point in time after being diagnosed as diabetic. The main reasons for discontinuation of the diabetic medications were relief of symptoms (n=12), lack of knowledge (n=19), unaffordable (n=2), difficulty to go and buy medication (n= 5) and uncomfortable with the medicine (n=1). In the diabetic foot ulcer sample studied, only 49.2 percent reported single episode of foot ulcer, the remaining reported recurrent foot infection. The duration of hospitalization for healing of the current/ last foot ulcer ranges

from zero to 180 days, with a mean of 29 days and standard deviation of 27 days. The main sources of financial support for the treatment of foot ulcer were: own savings (50 percent), partner (11 percent), children (20.3), others (0.8), and more than one source (17.8 percent). Table 4.5 represents the socio demographic and clinical characteristics of the two groups studied.

Table 4.4 Disease characteristics of the study sample (n=118)

Variables	Categories	Frequency (%)
Status of wound	Healed	31 (26.3)
	Unhealed	87 (73.7)
Medication discontinued at any point in time	Yes	39 (33.1)
	No	79 (66.9)
History of foot ulcer	One time	58 (49.2)
	Two times	42 (35.6)
	Three times	7 (5.9)
	More than three times	11 (9.3)

Table 4.5 Socio demographic and clinical characteristics in the two groups

Indicators	Healed ulcer (n=31)	Unhealed ulcer (n=87)
Mean age in years (SD)	57.52 (8.4)	57.71 (7.5)
Sex (%)		
Female	38.70	31.00
Male	61.30	69.00
Education (%)		
Upper primary	35.50	13.80
High school	58.10	63.20
Higher secondary	3.20	9.20
Higher education	3.20	13.80
Socio economic status (%)		
Low	45.20	32.20
Medium	38.70	28.70
High	16.10	39.10
Mean DM duration in years (SD)	13.61(6.41)	15.76 (7.25)
Mean ulcer duration in months (SD)	9.48 (8.95)	6.44 (6.52)

4.2.2. HRQL measurements

There are five domains for the DFS SF. For each of these domains, subscale scores were calculated. See Fig.4 for the mean HRQL score with 95% CIs comparing healed and unhealed groups in five domains of DFS SF. A simple two way ANOVA was done for each of the sub scale scores separately. See Table 4.6 - 4.10 for the finding. Table 4.11 and Table 4.12 show the results of linear model and ANOCOVA.

Fig.4 Mean HRQL score with 95% CIs comparing healed and unhealed groups in five domains

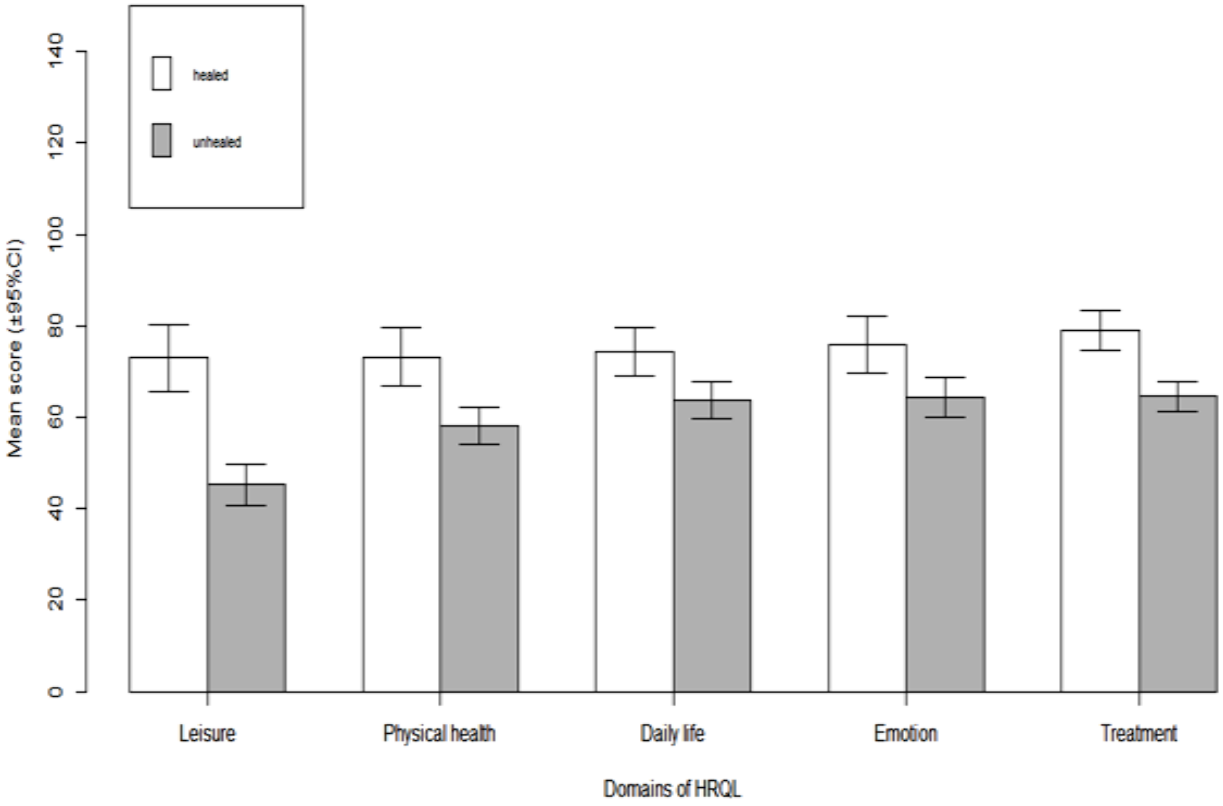


Table 4.6 Results of two factor ANOVA for Sub scale 1 – Leisure score, n (118)

Variables	**Mean±SD**	**Mean±SD**	**Adj p values for indicator variable**	**Adj p values for wound status**
Wound status	**Healed**	**Unhealed**		
	73.07±20.88(31)	45.23±22.03(87)		
Sex			0.57	0.00*****
Female	65.42±19.48(12)	46.30±24.83(27)		
Male	77.90±20.77(19)	44.75± 20.86(60)		
Age			0.42	0.00*****
≤60 yrs	74.38±25.29(16)	43.28±21.84(58)		
>60 yrs	71.67±15.66(15)	49.14±22.28(29)		
SES_groups			0.48	0.00*****
Low	75.36±21.26(14)	40.54±25.83(28)		
Medium	70.42±21.79(12)	49.00±23.23(25)		
High	73.00±21.39(5)	46.32±17.20(34)		
Education_groups			0.75	0.00*****
Upper Primary	73.18±21.36(11)	42.08±25.09(12)		
High School	71.11±21.46(18)	45.09±22.96(55)		
Higher Secondary	95.00±NA(1)	50.63±9.43(8)		
Higher education	85.00±NA(1)	45.42±22.10(12)		

['*' – Represnts the p value < 0.05]

Table 4.7 Results of two factor ANOVA for Sub scale 2 – Physical health score, n (118)

Variables	**Mean±SD**	**Mean±SD**	**Adj p values**	**Adj p values for wound status**
Wound status	**Healed**	**Unhealed**		
	73.23±18.28(31)	63.68±19.64(87)		
Sex			0.06	0.02*****
Female	72.5±14.22(12)	57.22±19.03(27)		
Male	73.68±20.81(19)	66.58±19.37(60)		
Age			0.23	0.02*****
≤60 yrs	78.44±15.57(16)	64.31±19.75(58)		
>60 yrs	67.67±19.81(15)	62.41±19.71(29)		
SES_groups			0.17	0.02*****
Low	70.00±22.27(14)	60.54±19.97(28)		
Medium	75.00±15.23(12)	64.00±22.31(25)		
High	78.00±13.51(5)	66.03±17.40(34)		
Education_groups			0.01*****	0.02*****
Upper Primary	60.46±21.03(11)	54.17±19.64(12)		
High School	79.17±12.28(18)	64.27±20.33(55)		
Higher Secondary	85.00±NA(1)	69.38±18.21(8)		
Higher education	95.00±NA(1)	66.67±16.00(12)		

[‘*’ – Represnts the p value < 0.05]

Table 4.8 Results of two factor ANOVA for Sub scale 3 – Daily activities score, n (118)

Variables	**Mean±SD**	**Mean±SD**	**Adj p values**	**Adj p values for wound status**
Wound status	**Healed**	**Unhealed**		
	75.81±14.84(31)	58.10±19.65(87)		
Sex			0.13	0.00*****
Female	68.75±9.08(12)	55.93±21.62(27)		
Male	80.26±16.20(19)	59.08±18.81(60)		
Age			0.62	0.00*****
≤60 yrs	75.31±12.31(16)	57.41±17.58(58)		
>60 yrs	76.33±17.57(15)	59.48±23.54(29)		
SES_groups			0.00	0.00*****
Low	71.07±14.96(14)	51.25±18.49(28)		
Medium	77.92±15.15(12)	58.80±20.27(25)		
High	84.00±10.84(5)	63.24±18.99(34)		
Education_groups			0.13	0.00*****
Upper Primary	70.00±17.89(11)	52.92±16.30(12)		
High School	77.78±12.27(18)	57.18±20.45(55)		
Higher Secondary	90.00±NA(1)	67.50±19.64(8)		
Higher education	90.00±NA(1)	61.25±18.60(12)		

['*' – Represnts the p value < 0.05]

Table 4.9 Results of two factor ANOVA for Sub scale 4 – Emotions score, n (118)

Variables	Mean±SD	Mean±SD	Adj p values	Adj p values for wound status
Wound status	**Healed**	**Unhealed**		
	74.44±17.82(31)	64.40±20.24(87)		
Sex			0.00*	0.01*
Female	66.88±16.38(12)	55.65±19.78(27)		
Male	79.21±17.40(19)	68.33±19.34(60)		
Age			0.16	0.02*
≤60 yrs	76.25±16.38(16)	61.42±20.40(58)		
>60 yrs	72.5±19.62(15)	70.35±18.87(29)		
Living status			0.01*	0.01*
Living alone	75.00±NA(1)	51.50±18.49(10)		
With children	NA	61.79±24.82(7)		
With spouse	83.13±12.25(12)	72.04±14.89(27)		
With whole family	68.61±19.33(18)	63.02±21.45(43)		
Employment			0.02*	0.01*
	77.29±19.38(12)	73.30±19.56(28)		
	74.69±11.91(8)	63.75±18.14(22)		
	81.25±8.84(2)	60.71±15.99(7)		
	91.25±5.30(2)	60.56±20.53(9)		
	62.50±20.57(7)	56.07±21.43(21)		
SES_groups			0.85	0.02*
Low	75.18±18.44(14)	62.32±17.95(28)		
Medium	75.63±14.58(12)	66.30±22.98(25)		
High	69.50±25.58(5)	64.71±20.34(34)		
Education_groups			0.46	0.02*
Upper Primary	78.18±18.41(11)	71.04±22.42(12)		
High School	71.53±18.23(18)	62.77±20.50(55)		
Higher Secondary	87.50±NA(1)	65.94±23.22(8)		
Higher education	72.50±NA(1)	64.17±15.24(12)		

['*' – Represnts the p value < 0.05]

Table 4.10 Results of two factor ANOVA for Sub scale 5 – Treatment score, n (118)

Variables	Mean±SD	Mean±SD	Adj p values	Adj p values for wound status
Wound status	**Healed**	**Unhealed**		
	79.03±12.35(31)	64.66±15.45(87)		
Sex			0.08	0.00*
Female	79.17±11.72(12)	59.72±16.11(27)		
Male	78.95±13.05(19)	66.88±14.75(60)		
Age			0.45	0.00*
≤60 yrs	81.64±12.39(16)	62.93±14.99(58)		
>60 yrs	76.25±12.09(15)	68.10±16.05(29)		
SES_groups			0.08	0.00*
Low	78.13±14.66(14)	61.38±15.78(28)		
Medium	79.69±9.66(12)	63.50±15.59(25)		
High	80.00±13.55(5)	68.20±14.79(34)		
Education_groups			0.01*	0.00*
Upper Primary	74.43±11.68(11)	59.38±18.56(12)		
High School	80.56±12.11(18)	63.86±15.76(55)		
Higher Secondary	100.00±NA(1)	78.91±7.42(8)		
Higher education	81.25±NA(1)	64.06±9.28(12)		

['*' – Represnts the p value < 0.05]

Table 4.11 Linear model of HRQL score on major predictors, n (118)

Predictors	Coefficients	Std Error	t value	P value
Ulcer duration	-0.39	0.18	-2.16	0.03
Sex	7.93	2.75	2.88	0.00
Wound status	-16. 75	2.99	-5.59	0.00

Table 4.12 ANCOVA showing adjusted difference in mean HRQL scores between healed and unhealed group, n (118)

	Mean value for the healed group	Mean value for the unhealed group	Difference between means	95 % CI for the difference between means
Unadjusted value	74.86	59.92	14.94	
Adjusted value	76.18	59.45	16.75	[-22.66, -10.81]

4.2.3. Employment related characteristics (See Table 4.13)

Table 4.13 Employment related characteristics of the study sample, n (118)

Variables	Frequency (%)
Employment status	
Yes	40 (33.9)
No, I am self employed	30 (25.4)
No, I am disabled	9 (7.6)
No, I am retired	11 (9.3)
No, I am housewife	28 (23.7)
Less productive due to ulcer	
None of the time	9 (7.6)
Some of the time	47 (39.8)
All of the time	62 (52.5)

Those who had opportunities of formal employment (n=86), 53 individuals (61.6 percent) reported that they lost some job prospects/ opportunities due to the presence of DFU and 38 people (44.2 percent) reported that they had to take early retirement from job. Out of the 110 patients, 41 cases (37.3 percent) reported that they had to change their usual pattern of work due to foot ulcer. See the Table 4.14 for the estimates of the employment related characteristics and the Table 4.15 which shows the results of Wilcoxon rank sum test to find out the predictors of total value of man days lost

Table 4.14 Estimates of the employment related characteristics, (n=70)

Variables	Mean ± SD	Median	Mini - Max
Work days lost	146 ± 199	60	3 – 730
Wage loss per day (Rs.)	626 ± 810	450	50 – 5000
Value of man days lost (Rs.)	74539 ± 123104	26000	450 - 720000

Table 4.15 Results of Wilcoxon rank sum test to find out the predictors of total value of man days lost, (n=70)

Predictor variables	Median	Minimum	Maximum	Frequency	P value
Sex					0.01*
Female	8776	450	45625	10	
Male	38250	490	720000	60	
Age					0.02*
≤ 60 yrs	36000	450	438000	47	
> 60 yrs	9000	490	720000	23	
Wound status					0.91
Healed	26000	2100	720000	20	
Unhealed	27250	450	438000	50	

['*' – denotes the p value <0.05]

4.2.4. Family life related characteristics

- 23.7 percent reported that the DFU condition affected their children's job/ studies.
- 11.9 percent reported that their spouse/child was force to go for work due to foot ulcer.
- 29.7 percent reported that the DFU affected their partner's jobs.
- 24.6 percent reported that they had to experience physical/ emotional abuse due to the presence of foot ulcer.

4.2.5. Quantum and pattern of direct medical expenditure

The major OPD expenses include expenditure for insulin/ oral hypoglycemic agents, antibiotics and other medications, dressing material, topical ointment, special footwear, podiatry service, lab investigations and travel. The extended hospital stay force the patients to seek different distress finance mechanisms such as debt, asset selling, loan, own savings. See the Table 4.16 for the direct medical expenditure related characteristics and Table 4.17 for different distress finance mechanisms used by the patient for the inpatient care of diabetic foot ulcer.

Table 4.16 Direct medical expenditure related characteristics, n (118)

Variables	Mean ± SD	Median	Mini - Max
Weekly direct medical expenditure and OPD visit expenses(Rs.)	1415 ± 646	1287	345 - 3757
Weekly direct medical expenditure for hospitalized days(Rs.)	8371 ± 3626	7717	0 - 23333

Table 4.17 Analysis of the distress finance mechanisms, n= 118

Distress finance mechanism	Frequency (%)
Debt	18 (15.30)
Asset selling	8 (6.80)
Loan	7 (5.90)
More than one method	11 (9.30)
Own savings	74 (62.70)

4.3. Case study research

Two cases were selected from the main sample based on their wound severity. One case was suffering from recurrent foot ulcer since on one year and another case had amputation due to foot ulcer.

Case study 1 - Amir

Amir was a 27 year old male, who worked in Gulf as a hotel staff, when he was first diagnosed as diabetic. He didn't have any symptoms of diabetes such as tiredness, polyphagia and thirst at first. When he accompanied his wife for her regular Gynec check up, doctor asked him to check his blood sugar and this revealed that he was a diabetic. He didn't have any family history of diabetes either, though all his 9 siblings were obese. He has been working in Gulf for more than 6 years. Since he was a hotel staff, his normal diet involved fast food, chicken biriyani and lots of carbonated drinks. He used to drink

carbonated drinks whenever he feels thirsty. He believes that this food habit is the reason for his disease.

The pathways to care seeking: He was diagnosed as diabetic in a private hospital in Kerala. At first he didn't take the diagnosis seriously and skipped medicines regularly. But later when he started experiencing joint pain, he suspected that it was because of his sugar levels. He believes that whenever his blood sugar level rises, he feels an increase in the joint pain. So he consulted a physician in a diabetic clinic and got medication. From then, he started taking medicines regularly. He used to make sure that he buy those medicines before he leaves to Gulf or ensure that somebody from India brings them for him when they come back to Gulf from India.

Incidence of foot ulcer: Amir noticed his first incidence of foot ulcer when he went for Hajj a year back. He didn't wear footwear and the heat on the floor caused burns on the plantar surface of his foot. However, he couldn't sense the burns because of neuropathy and he didn't consult the doctor for insensitivity on the foot; he mentioned that his blood sugar level was around 500 mg/dL, that time. Even though he noticed his burns after two weeks, he didn't consult the doctor for that. He tried some home remedies and tried soaking his feet in salt water mixed with turmeric powder for about three days. But it didn't heal the wound and the foot condition was really bad, pus and bad blood used to leak out from the wound as he walked. Then his sister-in -law came to his help and dressed his wound with betadine. This finally helped him and his wound got healed.

Once he was able to walk, Amir started going to work. His socks and shoes used to get wet and he didn't have option to change it during work. As a result of this, his feet got infected again. So he consulted a Malayali physician in Gulf and he advised Amir to cut off his toes and referred him to a Govt hospital in Saudi Arabia. Since the hospital wanted

a deposit of INR 1.5 lakhs, he decided to come back to India for the treatment. He consulted a diabetologist in a private hospital. At first his sugar level was between 300 and 350 and it gradually came down as he started taking insulin. Also, he reduced the dosage of insulin as he achieved glycemic control. The wound got healed in two months.

It went on like that for a while till he got injured during some construction work at his house. Cement and dust caused another infection on the same wound. This time the wound was worse and it created a deeper wound on the big toe of his right leg. He consulted a physician at the Medical Trust hospital, took two months rest and then went back to Saudi. But within a month, the toes on his left leg got ulcer as he was wearing a tight shoes at his work. Then he came to India and underwent treatment at this hospital. He has been taking insulin for the past three months, without changing its dose by himself. Also, he uses a special shoe with Rocher sole to offload his weight on the foot ulcer.

Impact on family: Amir's family life was also affected due to foot ulcer. His wife takes care of his foot ulcer care. She does the cleaning and dressing of the wound, though she doesn't have any knowledge of diabetic foot ulcer. His food habit has also changed. He stopped eating junk food and started following the diet advised by the doctor. His wife believed that he has to take more food to counter the medicines he takes. So she feeds him more than he is advised to eat. He wishes to go for work in Saudi again but is afraid that he will have to stand continuously as part of the job. So his family advised him to seek some job/ business in India. He has other family commitments also. He has to take care his 10 year old son and his wife's family as her parents died long back. His family is very supportive and scolds him for not taking sufficient rest.

Means of financing care: Diabetes treatment has cost him lots of money. He used to approach private hospitals as the foot ulcer care is absent in the nearest government hospital. He had been hospitalized for 35 days in Saudi and another month in India. Together he spent around 2.5 lakhs for the treatment. He need one bottle of insulin for a week and spent about INR 100 per day for the care of foot ulcer.

Case study 2 - Kumaran

Kumaran was a heavy built man in his mid forties. He was diagnosed as diabetic shortly after his marriage. He had a family history of diabetes. His parents also had diabetes. Before marriage, Kumaran had undergone a surgery for gastric ulcer in a private hospital. It seems they injected 2 bottles of glucose after the surgery and the doctor warned him about a possible chance of hernia or diabetes in the future. After 2-3 years of marriage, Kumaran noticed that he has some diabetic symptoms such as tiredness and hunger. So he consulted a doctor and later was diagnosed as diabetic. He has been taking medicines for the past 16 years and started taking insulin for the last 1 year. He was a construction worker and used to go for work till his feet got amputated two months back. In fact he was healthy enough to go for work even three days prior to amputation. He used to drink alcohol and used to claim that his job demanded that. But after the surgery he stopped taking alcohol. He was a non smoker throughout his life, but he reported use of tobacco in the form chewing.

Pathways of health seeking – Kumaran initially approached a nearby private hospital where the doctor gave him some ointments. Since there was no improvement in his condition even after couple of months, he was sent to Medical College for further treatment. In Medical College, he got admitted for couple of days. Within a few days he got fever due to the infection from wound. At the medical college, he consulted a

surgeon, since the ulcer got worsened in four days the doctor amputated his toes and later half of his foot. Also he was diagnosed as having nephropathy. After giving the basic treatment, medical college discharged him and advised him to continue the treatment in a nearby primary health center.

Incidence of foot ulcer – He has been suffering from foot ulcer for the past 2 and half yrs. Wound was visible during the interview. Due to swelling and peeling off skin, it was infected.

Patient reported that his kidney function was normal when he was admitted to the hospital and complained that it was after the medication that he was diagnosed as having nephropathy.

Kumaran's wife takes care of him. She takes care of his diet and wound dressing. They got to know about the Medical Trust Hospital from their cousin who took treatment there.

In the hospital, he was given the total contrast cast to off-load pressure. He wore that plaster for 45 days. I met him at the hospital when he came to remove the plaster. He seems to be very happy and mentioned the following - **"Today I will be free from the weight of this plaster, my whole leg lost its shape, but my caring wife will help me to get back the leg into good shape."**

Impact on family: Diabetic foot ulcer has seriously impacted the life of Kumaran and his family. He couldn't go for work after the amputation. He has to support his wife and two children. His eldest girl studies in class 10. Her father's disease affected her studies too. His wife took extra care of him. They even re arranged their house in order to cope with his new disability. He was devastated mentally after the amputation. He was very much depressed as the wound was not healing even after the amputation. At one point in

time, he even lost faith in all government hospitals. However, he has overcome that stage and now believes that all this happened because of his carelessness. He was very happy in the fact that his wife stood by him throughout his difficulty.

Means of financing care: His family members gave him the required financial support during the treatment phase. They also got some help from an NGO for the medicinal expenses.

[The cases has been renamed in order to protect the privacy and confidentiality]

Chapter 5: Discussion

5.1. Scale validation

The DFS SF demonstrates good scaling properties in general, and has good reliability and validity. It showed good construct validity with SF 36 v 2. This is similar to published studies from UK, USA and China.[45- 47]

5.2. Cross sectional survey

5.2.1. Sample characteristics

The mean ± SD of age in years for rural diabetic population studied was 57.66 ± 7.71. This is similar to reported research from South India.[19]

Based on the wound status, the patients were grouped into healed and unhealed. Two groups did not differ from each other with respect to other demographic characteristics.

Among the 118 patients studied, only 39 (33.1 percent) were females. Among patients with foot ulcer there is a preponderance of males. This is found not only in India, but also in countries like UK, where almost everyone with foot ulcer may be receiving foot care. A study from Manchester, UK by Reiber shows only 32.6 percent were females. [21]

This confirms our supposition that the male preponderance in our sample is not due to any bias. Therefore this can't be explained as a result of bias favouring the male in receiving foot care. The male preponderance could be attributed to higher tobacco use and consequent vascular problems along with more exposure to outdoor occupations. This reveals that young male diabetic working population is at high risk of getting diabetic foot ulcer at an early age. This is consistent with studies by Alberti[6] and Holzer[52].

The majority of the study population were manual labourers including agricultural workers, carpenters, and drivers. Their knowledge regarding foot care practices were

very minimal. Many of the patients reported that they were not instructed to take the medication regularly to maintain good glycemic control.

5.2.2. HRQL measured using DFS- SF

The DFS SF has five subscales to measure different domains of quality of life such as leisure, physical health, daily activities, emotions and treatment. Wound status was the main predictor of good QOL. The mean scores for each of the sub scales were significantly different in the two wound status group (healed and unhealed foot ulcer). Same finding has been found in other populations.[45- 48] Based on the hypothesis tested, it was concluded that HRQL was consistently higher in the healed group, even after it was adjusted for other predictors such as sex, ulcer duration.

5.2.3. Impact on employment related characteristics

Majority of the study sample reported that they had to take early retirement, had loss of job opportunities and had to change their pattern work due to the occurrence foot ulcer. This is similar to the reported research by Brod.[54] As we expected the impact of diabetic foot ulcer among young working population was higher than that in older working population. This shows the importance of early healing among young diabetics, which will directly contribute to increase in national income. This is consistent with the research by Patout.[64] Timely interventions and health education for diabetic foot ulcer focusing young diabetics will help to reduce the overall impact of diabetes on the economy, as the prevalence of diabetic population increases along with young working population.[6]

5.2.4. Impact on family life

The diabetic foot ulcer had a heavy impact on the family life of the rural population. Since most of them thrive on the daily wages, the occurrence of foot ulcer disturbed the social and financial equilibrium of the family. This confirms the finding by Brod.[54] The impact was more prominent on the young adults who were self employed. Physical and

sexual relationship between the partners also got impaired due to the presence of foot ulcer. In the case of house wives who were affected by the foot ulcer, their household activities got affected and their partner's had to compromise their job. When an earning member of the family was affected by the foot ulcer, another family member was forced to go for work. Some people reported that the condition of the foot ulcer affected their children's job and some others reported that their children had to drop out of school. It may affect the future prospects of the family. This effect is difficult to quantify.

5.2.5. Quantum and pattern of direct medical expenditure

Out of the 118 patients interviewed 44 (37.3 percent) were reported that they had to depend on some distress finance mechanism to manage the catastrophic health spending. Patients with longer duration of ulcer end up in catastrophic level of health spending. Similar findings have been found from India. Longer duration of ulcer increases the financial burden on the family. This again emphasises the early intervention and prevention.

5.3. Qualitative analysis

The two case study discussions show that the pathways to care seeking for foot ulcer are complicated. Since foot ulcer is not taken as a serious complication in the beginning people end up spending lot of money in foot care as well as missing employment opportunities. It may end up in loss of limb. It emphasizes all the more both the need for creating awareness about this condition as well as the need for early intervention.

5.5. Strengths and limitations of the study

5.5.1. Strengths

- The scale used to measure the parameters of quality of life is validated in the same population of DFU patients.

- As the cases were interviewed in the OPD, the validity of the reported medical expenses was easy to measure.
- As the data were collected by the PI, the Inter observer variability is absent.
- This is a quantitative study which is reinforced by finding from qualitative component.

5.5.2. Limitations

- This is not a population based study.
- Some of the questions related to their personal life could have created biases, however the bias is similar in all cases.

Chapter 6: Conclusion and recommendations

Diabetic foot ulcer is a neglected disease not only by the patient but also by the society and the health system. Early detection and good glycemic control will reduce the incidence of foot ulcer. The DFS SF is a good scale to measure the latent variable, HRQL. It has good construct validity against SF 36 v2. This scale can be used among the rural diabetic foot ulcer population for estimating the HRQL. The HRQL is related to the healing of the diabetic foot ulcer. The study reveals that wound status is a major predictor for good HRQL among diabetic foot ulcer patients. The diabetic foot ulcer has to be actively treated so that to prevent deterioration of quality of life.

The health system must focus on ensuring the early healing of wound by proper patient education and treatment modalities. Proper health education focusing on the healthy habits, diet control, physical activity, compliance to diabetic medication is necessary to reduce the burden of diabetic complication in rural diabetics. Diabetic foot ulcer adversely affects the employment status of the patient. A multidisciplinary approach is needed to reduce the social and economic consequences of diabetic foot ulcer. The health system should involve a diabetologist and a podiatry specialist for the management of foot ulcer. The system should also be able to provide attentive management with multiple modalities for early healing of foot ulcer.

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Annexure 1

Guidelines for formative research

Objective - To assess the impact of diabetic foot ulcer on rural population, to develop themes for interview schedule

In depth Interview guidelines

1. **When the incidence of ulcer occurred and how long you hospitalized during first incidence?**
   When did you notice the ulcer for the first time?
   Did you approach a health centre?
   Any delay occurred in going to the hospital?
   If Yes what was the reason for delay?
   Any one accompanied you to see the doctor and who?
   Any difficulties in transportation? The mode of transportation?
   Please explain the pathways of care seeking
   Medical expenditure and other opportunity costs due to ulcer?(wage loss for the patient and for the supporting person, medicines, dressing , food and travel)

2. **Who support you to take care of this ulcer?**

3. **what are the restricted activities due to DFU?**

   Is there any limitation due to ulcer?
   Diet pattern and drugs?
   Care given to foot , any restriction in bathing, how frequently they took bath?

4. **Impact on work related activities ?**
   restrictions in doing specific work,
   couldn't take up promotion,
   early retirement,
   punishments due to absence from work
5. **Absenteeism from job due to FU – wage loss incurred due to restricted movement, bed rest and hospitalization**

6. **The pattern and quantum of medical expenditure – Monthly expenditure on medication, dressing, travel cost, cost for accompanying, other than the usual diabetic drug expenditure**

7. **The recurrence of foot ulcer and hospitalization pattern – How frequent, precautions taken after first incidence, life adjustments to avoid ulcer**

8. **Any change in the infrastructure of the household to avoid injuries and to off load the pressure after getting ulcer?**

9. **Adjustments and Role reversal in the family –**
   The bread winner role changed due to ulcer,
   divorce, rejection from family, social rejection,
   effect on children's education,
   not able to get married due to ulcer?
10. **Health care provider advice ?**
    Did they receive any?
    Who gave counselling?
    How much they could follow?
    Peer support in medication, dressing and preventive aspects?
    Effect on Decision making role?
11. **House wife's role affected due to ulcer?**

ANNEXURE 2

Diabetic Foot Ulcer Scale-Short Form

INSTRUCTIONS:

These questions ask about the effect that foot ulcer problems may have on your daily life and well-being. Please read each question carefully and think about the effect of your foot ulcer problems.

Answer every question by circling one number on each line. If you are unsure about how to answer a question, please give the best answer you can.

Diabetic Foot Ulcer-Short Form

1. How much have your foot ulcer problems:					
	Not at all	A little bit	Moder-ately	Quite a bit	A great deal
a) stopped you from doing the hobbies and recreational activities that you enjoy	1	2	3	4	5
b) changed the kinds of hobbies and recreational activities that you enjoy doing	1	2	3	4	5
c) stopped you from getting away for a holiday or a weekend break	1	2	3	4	5
d) made you choose a different kind of holiday or short break than you would have preferred	1	2	3	4	5
e) meant that you had to spend more time planning and organising for leisure activities	1	2	3	4	5

2. Because of your foot ulcer problems, how often have you felt:					
	None of the time	A little of the time	Some of the time	Most of the time	All of the time
a) fatigued or tired	1	2	3	4	5
b) drained	1	2	3	4	5
c) that you had difficulty sleeping	1	2	3	4	5
d) pain while walking or standing	1	2	3	4	5
e) pain during the night	1	2	3	4	5

3.	**Because of your foot ulcer problems, how often have you:**					
		None of the time	A little of the time	Some of the time	Most of the time	All of the time
a)	had to depend on others to help you look after yourself (such as washing and dressing yourself)	1	2	3	4	5
b)	had to depend on others to do household chores such as cooking, cleaning or laundry	1	2	3	4	5
c)	had to depend on others to get out of the house	1	2	3	4	5
d)	had to spend more time planning or organising your daily life	1	2	3	4	5
e)	felt that doing anything took longer than you would have liked	1	2	3	4	5

4. Because of your foot ulcer problems, have you felt:						
		Not at all	Slight-ly	Moderately	Quite a bit	Extremely
a)	angry because you were not able to do what you wanted to do	1	2	3	4	5
b)	frustrated by others doing things for you when you would rather do things yourself	1	2	3	4	5
c)	frustrated because you were not able to do what you wanted to do	1	2	3	4	5
d)	worried that your ulcer(s) will never heal	1	2	3	4	5
e)	worried that you may have to have an amputation	1	2	3	4	5
f)	worried about injury to your feet	1	2	3	4	5
g)	depressed because you were not able to do what you wanted to do	1	2	3	4	5
h)	worried about getting ulcers in the future	1	2	3	4	5
i)	angry that this has happened to you	1	2	3	4	5
j)	frustrated because you have difficulty in getting about	1	2	3	4	5

5	**Because of your foot ulcer problems, how often were you bothered by:**					
		None of the time	A little of the time	Some of the time	Most of the time	All of the time
a)	having to keep the weight off your foot ulcer	1	2	3	4	5
b)	the amount of time involved in caring for your foot ulcer (including dressing changes, waiting for the district nurse and keeping the ulcer clean)	1	2	3	4	5
c)	the appearance, odour or leaking of your ulcer	1	2	3	4	5
d)	having to depend on others to help you care for your foot ulcer	1	2	3	4	5

THANK YOU FOR COMPLETING THE QUESTIONNAIRE

Annexure 3

.

Diabetic Foot Ulcer Scale – Short Model (Back translated version)

INSTRUCTIONS:

These questions are meant to understand how foot ulcers affect your day to day life and well being. Please read each questions carefully and think about how the issues related to foot ulcers affect you.

Answer each question by circling one number on each line. If you are unsure about the correct answer to a question, please give the most appropriate answer.

1. **How much have your foot ulcer problems:**					
	Nil	A little	Mode rately	Quite a bit	Very much
a) Prevented you from enjoying your recreational activities and hobbies	1	2	3	4	5
b) Altered the recreational activities and hobbies that you enjoy	1	2	3	4	5
c) Prevented you from taking a holiday or going out on a week end.	1	2	3	4	5
d) Forced you to choose a different kind of holiday or shot break than what you have preferred.	1	2	3	4	5
e) You had to spend more time in planning and organizing your leisure activities.	1	2	3	4	5

2. **Because of your foot ulcer problems, how often you felt**					
	None of the time	A few times	Some of the time	Most of the time	Always
a) Tired	1	2	3	4	5
b) Drained	1	2	3	4	5
c) That you had difficulty sleeping	1	2	3	4	5
d) Pain while walking or standing	1	2	3	4	5
e) Pain during night	1	2	3	4	5

3. Because of your foot ulcer problems, how much have you:					
	Never	A few times	Some times	Most of the times	Always
a) Had to depend on others to look after yourself (cleaning / dressing up)	1	2	3	4	5
b) Had to depend on others for house hold activities such as cooking, cleaning and washing.	1	2	3	4	5
c) Had to depend on others for going out from home.	1	2	3	4	5
d) Had to spend more time in planning and executing day to day activities.	1	2	3	4	5
e) Felt that you are taking more time for doing anything.	1	2	3	4	5

4.	**Because of your foot ulcer problems, you felt:**					
		Not at all	Slightly	Moderately	Quite a bit	Very much
a)	Angry for not being able to do what you wanted to do	1	2	3	4	5
b)	Frustrated by others for doing things for you that you would prefer doing yourself.	1	2	3	4	5
c)	Disappointed for not being able to do things that you wanted to do	1	2	3	4	5
d)	Worried that your ulcers would never heal.	1	2	3	4	5
e)	Worried that you may have to have an amputation of your feet or toes	1	2	3	4	5
f)	Worried that your feet will get injured.	1	2	3	4	5
g)	Depressed for not being able to do what you required to do.	1	2	3	4	5
h)	Worried about getting ulcers in future	1	2	3	4	5
i)	Angry that this has happened to you	1	2	3	4	5
j)	Disappointed for the difficulty in reaching various places.	1	2	3	4	5

5 How often have you bothered by your foot ulcer:					
	None of the time	A little of the time	Some of the time	Most of the time	All the time
a) Having to keep your weight off the feet that has ulcers.	1	2	3	4	5
b) The time required for caring the foot ulcer (for cleaning, dressing changes and waiting for the nurse)	1	2	3	4	5
c) The external appearance, odour or leaking of your ulcer	1	2	3	4	5
d) Being dependent on others for helping to care your ulcer.	1	2	3	4	5

Thank you for completing the questionnaire.

Annexure 4

Report on cognitive debriefing of the translated version of DFS - SF

Cognitive interviews were carried out among five diabetic foot ulcer patients with varying severity of ulcer. This includes two females and three males. The interview was conducted at the outpatient department of Medical trust hospital, Pantham – a well-known diabetic research center in Southern Kerala. The subjects are explained about the goal of the interview prior to the interview session. I have used the translated Malayalam version of DFS-SF questionnaire for interviewing the subjects. I also provided one copy of the questionnaire to the subjects for their understanding of the language used.

Case 1

A fifty three year old male patient came for dressing of his wound. He was a married man and father of three children. He got 10 years of formal education and is doing some business for a living. The business involves both walking and sitting for prolonged hours. He reported that he is diabetic for the past 15 years. The duration of his present foot ulcer was three months and the Wagner grade for his ulcer is 3. He had previous history of foot ulcers. He understood all the questions in right way and didn't have any problem in marking scale scores. Even though the language was clear he advised me to modify some sentences which are culturally not acceptable.

Case 2

A fifty seven year old male patient came to outpatient department. He had history of diabetes for 20 years. He had history of foot ulcer with one toe amputated. Now the wound is healed with an ulcer grade 0. He went to school for 10 years and works as a pastor in a worship centre. He had difficulty in understanding the first question in the fifth sub scale about weight bearing. He didn't have difficulty in answering the other questions. I have modified the question and retested in other patients.

Case 3

A fifty six year old female patient came for dressing her wound. She is diabetic for the last 16 years. She had history of foot ulcer for 18 months with severity of Wagner grade 1. She had only 8 years of education. She couldn't understand the questions 1 and 5 in the sub scale 1. She couldn't understand the fourth question in the third sub scale as it was too long. But she scored the quality of life correctly when I explained the meaning of the question. I modified that question and tested among other patients.

Case 4

Fourth case was a retired private employee. He was confused with the question on depression and marked the highest score for that. When I enquired, I understood that he was depressed for some other personal problem. He didn't have any problem in

understanding other questions. He even mentioned that the options are easily understandable. He preferred English to Malayalam to answer the questions.

Case 5

A thirty seven year old female patient came for dressing. She had history of diabetes for 10 years. She was suffering from foot ulcer for 6 months. She was a graduate in commerce but currently not working. She didn't have any issue in understanding the questions and marked all the scale scores correctly. But she complained the similarity between the questions in the third subscale and she gave same scores for both the questions.

Conclusion

The goal of the cognitive interviews is achieved. It is found that the scale is specific to measure the construct - health related quality of life - among diabetic foot ulcer patients. The translated version of DFS – SF is culturally acceptable and contextually relevant to the target population.

Annexure 5

SF-36v2™ Health Survey

This survey asks for your views about your health. This information will help you keep track of how you feel and how well you are able to do your usual activities.

Answer every question by selecting the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

---

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐	☐	☐	☐	☐

---

2. Compared to one year ago, how would you rate your health in general now?

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
☐	☐	☐	☐	☐

---

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
b Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐
c Lifting or carrying groceries	☐	☐	☐
d Climbing several flights of stairs	☐	☐	☐
e Climbing one flight of stairs	☐	☐	☐
f Bending, kneeling, or stooping	☐	☐	☐
g Walking more than a mile	☐	☐	☐
h Walking several hundred yards	☐	☐	☐
i Walking one hundred yards	☐	☐	☐
j Bathing or dressing yourself	☐	☐	☐

---

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

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Cut down on the amount of time you spent on work or other activities	☐	☐	☐	☐	☐
b Accomplished less than you would like	☐	☐	☐	☐	☐
c Were limited in the kind of work or other activities	☐	☐	☐	☐	☐
d Had difficulty performing the work or other activities (for example, it took extra effort)	☐	☐	☐	☐	☐

5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Cut down on the amount of time you spent on work or other activities	☐	☐	☐	☐	☐
b Accomplished less than you would like	☐	☐	☐	☐	☐
c Did work or activities less carefully than usual	☐	☐	☐	☐	☐

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

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

None	Very mild	Mild	Moderate	Severe	Very severe
☐	☐	☐	☐	☐	☐

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

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

How much of the time during the past 4 weeks...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Did you feel full of life?	☐	☐	☐	☐	☐
b Have you been very nervous?	☐	☐	☐	☐	☐
c Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐
d Have you felt calm and peaceful?	☐	☐	☐	☐	☐
e Did you have a lot of energy?	☐	☐	☐	☐	☐
f Have you felt downhearted and depressed?	☐	☐	☐	☐	☐
g Did you feel worn out?	☐	☐	☐	☐	☐
h Have you been happy?	☐	☐	☐	☐	☐
i Did you feel tired?	☐	☐	☐	☐	☐

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

11. How TRUE or FALSE is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
A I seem to get sick a little easier than other people	☐	☐	☐	☐	☐
B I am as healthy as anybody I know	☐	☐	☐	☐	☐
C I expect my health to get worse	☐	☐	☐	☐	☐
D My health is excellent	☐	☐	☐	☐	☐

Thank you for completing these questions!

Annexure 6

Consent form for referring patient for participating in the study

The impact of diabetic foot ulcer on health related quality of life and employment among rural diabetic population of southern Kerala.

Achutha Menon Centre for Health Science Studies,
Sree Chitra Tirunal Institute for Medical Sciences & Technology,
Thiruvananthapuram, Kerala, India. PIN-695011

Ms Sithara S Pillai, who is a student of public health at Achutha Menon Center, Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram is conducting a study among persons with diabetic foot ulcer to study the impact of foot ulcer on quality of life of diabetic patients. There will be no direct benefits to you for participating in this interview but she will provide you a health education pamphlet regarding care and prevention of diabetic foot ulcer. Everything you will say will remain private and confidential. If you agree to participate in the interview please indicate your agreement. However you are free to quit the interview at any point of time if you feel so. Ms Sithara S Pillai shall provide you with more information about the study. By signing this consent form, I indicate that I am willing to share my contact details including residential address and phone numbers.

❑ Yes, I am agreeing for the reference

Signature/Left thumb impression ……

Name and Address: ……

……

Signature of the treating doctor…….

Name and address ……..

…….

Date: …….

Annexure 7

Interview schedule

Impact of diabetic foot ulcer on health related quality of life and employment among the rural diabetic population of Southern Kerala

Hospital ID: -------

Contact details of the respondent- ----------

Date**:--/--/2012**

No:	Questions	Options	Answers & Indicate answer code
	Demographic details		
1.	How old are you? (to be verified with date of birth)		-----Years --/--/----
2.	Sex	1. Female 2. Male	☐ ☐
3.	Is it located in a panchayath or municipal area?	1.Rural 2.Urban	☐ ☐
4.	Level of education(Years of education completed)		---------- Years
5.	What all household assets are present in your house? (Need to be verified with NFHS household survey questions) – Tick as many as relevant.	1. Ownership of land 2. Own house 3. Electricity 4. Water supply 5. Fan 6. Television 7. Computer 8. Internet connection 9. Gas connection 10. Cattle 11. Landline telephone 12. Mobile phone	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

		13. 14. 15.	Bicycle Motor cycle Car/Jeep/Van	☐ ☐
6.	Average monthly household expenditure (Last month)			---------- Rs/-
7.	Marital status	1. 2. 3. 4.	Single Married Separated/ Divorced Widow/widower	☐ ☐ ☐ ☐
8.	With whom are you staying (Tick as many as relevant)	1. 2. 3. 4. 5.	Living alone With children With parents With spouse With whole family	☐ ☐ ☐ ☐ ☐
Disease characteristics				
9.	Duration of DM (from the date of diagnosis reported by the patient)			-------- Years
10.	What is the status of your wound? (Tick Not healed if at least one wound is not healed)	1. 2.	Healed Not healed	☐ ☐
11.	If healed, no: of days since healed?			------- days
12.	If not healed, present grade of ulcer (Verified and recorded from physician's clinical note)?	1. 2. 3. 4. 5.	Grade 1 Grade 2 Grade 3 Grade 4 Grade 5	☐ ☐ ☐ ☐ ☐
13.	Duration of present/ last foot ulcer			------- Months
14.	How many ulcers you had till now?	1. 2. 3. 4.	One Two Three More than three	☐ ☐ ☐ ☐
Treatment related characterestics				
15.	Are you continuing the same initial diabetic medications prescribed for you? (If yes jump to Q. 18)	1. 2.	Yes No	☐ ☐

16.	If No, Why? (If Ans. 2,3, 4,5 jump to Q.18)	1. I Stopped the medication 2. Doctor changed the medication 3. Doctor stopped the medication 4. I changed the medication 5. Others (please Specify)	☐ ☐ ☐ ☐ ☐
17.	Have you stopped diabetic medication any time, If Yes why was the medication discontinued by you?	1. Symptoms relieved 2. Lack of knowledge 3. Unaffordable 4. Not comfortable with the medicines 5. Difficulty to go and buy medicines 6. As advised by friends or relatives 7. Others (Specify)	☐ ☐ ☐ ☐ ☐ ☐ ☐
18.	Do you get the diabetic medications in your PHC? (If Ans. 1, 4 jump to Q. 20)	1. Always 2. Sometimes 3. Never 4. Don't know	☐ ☐ ☐
19.	If not what will you do?	1. Go to another govt hospital 2. Purchase from outside 3. I will stop medications 4. Others (Specify)	☐ ☐ ☐ ☐
20.	Have you received any podiatry services in your PHC?	1. Always 2. Sometimes 3. Never 4. Don't know	☐ ☐ ☐ ☐
21.	How many days of hospitalization you had for the treatment of present/last foot ulcer?		------ days
22.	Do you have any financial support/ health insurance coverage for the foot ulcer treatment?	1. Yes 2. No	☐ ☐
23.	Have you ever approached the panchayath for any financial support for	1. Yes 2. No	☐ ☐

<table>
<tr><td></td><td>the treatment of foot ulcer? (If No jump to Q. 24)</td><td></td><td></td></tr>
<tr><td>24.</td><td>If yes, what were the results/ response?</td><td>1. Rejected my application
2. No response
3. Received one time assistance
4. Receiving ongoing assistance
5. Financial support is not available at Panchayath</td><td>☐
☐
☐
☐</td></tr>
<tr><td>25.</td><td>Have you been enrolled in any financial scheme through the panchayath?</td><td>1. Yes
2. No</td><td>☐
☐</td></tr>
<tr><td>26.</td><td>Are you aware of any project/program related to diabetes under your panchayath?</td><td>1. Yes
2. No</td><td>☐
☐</td></tr>
<tr><td>27.</td><td>Sources of financial support for the treatment of foot ulcer? (Tick as many as relevant)</td><td>1. Own savings
2. Partner
3. Parents
4. Children
5. Public insurance
6. Private insurance
7. Employer reimbursement
8. Others (Specify)
9. More than one source</td><td>☐
☐
☐
☐
☐
☐
☐
☐
☐</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td>28.</td><td><u>Direct Medical expenditure</u></td><td>
<table>
<tr><th>Items</th><th>Tick as many as relevant</th><th>Expenditure(INR)</th></tr>
<tr><td>Oral hypoglycaemic agents(OHA)</td><td></td><td></td></tr>
<tr><td>Insulin</td><td></td><td></td></tr>
<tr><td>Travel to hospital</td><td></td><td></td></tr>
<tr><td>Consultation fee</td><td></td><td></td></tr>
<tr><td>Wound dressing</td><td></td><td></td></tr>
<tr><td>Antibiotics</td><td></td><td></td></tr>
<tr><td>Topical ointments</td><td></td><td></td></tr>
<tr><td>Footwear</td><td></td><td></td></tr>
</table>
</td><td>-------
--Rs/-</td></tr>
</table>

		Instrument to clean the slough/ wound			
		Other medical expenses (specify)			
29.	Average direct weekly medical expenditure for healed/ unhealed?				---------- Rs/-
30.	What is the distress finance mechanisms used in the absence of health insurance coverage?	1. Debt 2. Asset selling 3. Loan 4. Others(Specify) 5. More than one			☐ ☐ ☐ ☐ ☐
Employment related characteristics					
31.	Are you at present in paid employment?	1. Yes 2. No, I am self employed 3. No, I am unemployed 4. No, I am disabled 5. No, I am retired 6. No, describe			☐ ☐ ☐ ☐ ☐ ☐ ---------- ----------
32.	If employed/self employed/others like working at home, how many hours you work per week?				-------- hrs
33.	How many hours you stand during your working time?				---------- hrs
34.	Have you felt that been less productive at work due to foot ulcer?	1. None of the time 2. Some of the time 3. All of the time			☐ ☐ ☐
35.	How many working days/time lost due to the foot ulcer treatment?				---------- days
36.	What is the average per day wage loss due to absenteeism?				---------- Rs/-
37.	Have you felt any loss of job prospect/opportunities (promotion, grade	1. Yes 2. No			☐ ☐

	etc.) due to the foot ulcer?			
38.	Did you take any early retirement from employment/job due to the foot ulcer?	1. 2.	Yes No	☐ ☐
39.	Did you change the pattern of work you do due to foot ulcer?	1. 2.	Yes No	☐ ☐
Family life characteristics				
40.	How is the personal relationship between you and your partner after the occurrence of foot ulcer?	1. 2. 3. 4.	Same as before Improved Deteriorated Not applicable	☐ ☐ ☐ ☐
41.	How much have you felt that there has been a decline in your sexual relationship after the occurrence of ulcer?	1. 2. 3. 4. 5.	Not at all A little Some A great deal Not applicable	☐ ☐ ☐ ☐ ☐
42.	Were your children's education/ job affected due to your disease condition?	1. 2. 3.	Yes No Not applicable	☐ ☐ ☐
43.	How have you felt that your role to take decisions in your family becomes compromised?	1. 2. 3. 4.	None A little Some A great deal	☐ ☐ ☐ ☐
44.	Did your spouse/ child start working after you had foot ulcer?	1. 2. 3.	Yes No Not applicable	☐ ☐ ☐
45.	Did your disease condition affect the working time/job of your partner?	1. 2.	Yes No	☐ ☐
46.	Are you facing any abuse (physical/ mental) due to the presence of foot ulcer?	1. 2.	Yes No	☐ ☐

Annex 8

R functions used for sample size estimation and data analysis

1. Epi calc. command for sample estimation with mean and SD =

n.for.2means(58,70,20,20,alpha=0.05,power=0.9)

2. Variance test =
var.test(value_mandays_lost[woundstatus==0],value_mandays_lost[woundstatus==1])

3. Non parametric test used – Wilcoxon rank sum test =

wilcox.test(value_mandays_lost[woundstatus==0],value_mandays_lost[woundstatus==1]
, correct=FALSE)

4. Two way factor ANOVA =

```
modelanova1<-aov(total_hrql_score~woundsta+sex)
summary(modelanova1)
```

5. Adjusted mean difference

```
M1<-lm(Total_HRQL_Score~ULCERDUR+SEX+WOUNDSTA)
summary(M1)

bw1<-coef(M1)[2]
bw2<-coef(M1)[3]

HRQL_adj_Healed<-mean(Total_HRQL_Score[WOUNDSTA==0])-
((bw1)*(mean(ULCERDUR[WOUNDSTA==0])-
mean(ULCERDUR))+(bw2)*(mean(SEX[WOUNDSTA==0])-mean(SEX)))

HRQL_adj_Unhealed<-mean(Total_HRQL_Score[WOUNDSTA==1])-
((bw1)*(mean(ULCERDUR[WOUNDSTA==1])-
mean(ULCERDUR))+(bw2)*(mean(SEX[WOUNDSTA==1])-mean(SEX)))

c(HRQL_adj_Healed,HRQL_adj_Unhealed,HRQL_adj_Healed - HRQL_adj_Unhealed)

confint(M1)[4,]
```

6. Bar diagram with mean and SEM

```
#script for creating graph comparing HRQL in healed and unhealed
Healed<-c(73.06,73.22,74.43,75.81,79.03)
conf.healed<-1.96*c(3.75,3.28,2.67,3.20,2.22)
Unhealed<-c(45.23,58.10,63.68,64.40,64.66)
```

```
conf.unhealed<-1.96*c(2.36,2.11,2.11,2.17,1.66)
#create vectors for values and SEs.
mean<-rbind(Healed,Unhealed)
conf<-rbind(conf.healed,conf.unhealed)
bplot<-
barplot(mean,xpd=F,ylim=c(0,150),main="",col=c("white","gray"),xlab="Domains of
HRQL",ylab="Mean score (±95%CI)",beside=T)
legend(1,150,cex=0.7,c("healed","unhealed"),fill=c("white","gray"))
axis(side=1,at=c(2,5,8,11,14),labels=c("Leisure","Physicalhealth","Daily
life","Emotion","Treatment"))
arrows(bplot,mean+conf,bplot,mean-conf,angle=90,code=3)
```

Annexure 9

Guidelines for Case study research – Individual patient discussion

Themes for data collection and analysis

1. **History of diabetes**
   - ✓ Diagnosis of DM - family history of diabetes.
   - ✓ Duration of DM,
   - ✓ Diet and treatment pattern – adherence, if not reason, any support from family or friends to take care of the treatment.
   - ✓ Pathways of care seeking,
2. **Development of complications**
   Types of complications, symptoms experienced, treatment sought
3. **Occurrence of foot ulcer**
   - ✓ Signs and symptoms of the problem – how acute it was, who and when
   - ✓ Seek medical care - Any delay occurred in going to the hospital - The reasons for delay - Anyone accompanied to hospital - The mode of transportation - Any difficulties in transportation
   - ✓ Systems of medicine – chose for medical care,
   - ✓ The pathways of care seeking – symptoms not relieved, lack of faith in the doctor, referrals, discontinued by himself/ herself, uncomfortable
   - ✓ Length of hospital stay – no of days hospitalized for the treatment of a single foot ulcer.(including hospitalization in various sysems)
   - ✓ Health care provider advice (on foot ears, foot cleaning, medication etc– received or not, whether satisfied, who gave advice, whether the case could follow, if not the reason,
   - ✓ Peer support in medication, dressing and preventive aspects
4. **The effect of foot ulcer on over all life of the individual**

   Changes or adjustments happened in the life after the diagnosis of foot ulcer – day to day life, the difference in general quality of life after the occurrence of foot ulcer, House hold activities affected due to ulcer, support to take care of this ulcer, Precautions taken after first incidence, Life adjustments to avoid foot ulcer, The recurrence of foot ulcer and hospitalization pattern – frequency of foot ulcer
5. **The foot ulcer effect on the employment of the individual**
   - ✓ Impact on work related activities
   - ✓ Restrictions in doing specific work,
   - ✓ Couldn't take up promotion,
   - ✓ Early retirement,
   - ✓ Job prospects
   - ✓ Punishments due to absence from work

- ✓ Absenteeism from job due to foot ulcer – wage loss incurred due to restricted movement, bed rest and hospitalization

6. **Effect on family life**
   - ✓ Adjustments and role reversal in the family – the bread winner role changed due to ulcer,
   - ✓ Divorce, rejection from family, social rejection or discrimation experienced due to foot ulcer.
   - ✓ Effect on decision making role
7. **The restrictions – personal problems due to foot ulcer**

   Limitations in doing day to day activities, **a**ny restriction in bathing, toilet, Foot wear practices, managing the problem.

8. **Explain the effect of foot ulcer total household adjustments and change in expenditure pattern**

- ✓ Change in the infrastructure of the household to avoid injuries and to off load the pressure after getting ulcer
- ✓ Effect on children's education and job

9. **Cost of diabetic foot ulcer treatment-** any catastrophic health expenditure, source of finance for treatment.
   The pattern and quantum of medical expenditure – monthly expenditure on medication, dressing, travel cost, cost for accompanying, accommodation, food expenses, other than the usual diabetic drug expenditure etc.
   Opportunity costs due to ulcer - wage loss for the patient and for the supporting person, house wife's economic value, intangible costs – suffering due to foot ulcer,

Annexure 10

Participant information sheet

You are invited to participate in the study: Impact of diabetic foot ulcer on health related quality of life and employment among rural diabetic population. Before you involve in the interview it is important for you to understand why the research is being done and what is the importance for doing this study.

1. What is the purpose of the study?
   This study aims to find out the impact of diabetic foot ulcer health related quality of life, to make a valid disease specific questionnaire for QOL of diabetic foot ulcer patients. This also aims at the effects of employment such as man days lost, wage loss, absenteeism, early retirement etc.
2. Why this hospital was chosen for the study?
   The medical trust hospital caters patients from all socio economic status and the catchment area is widely spread to the nearby districts as well.
3. How you are being selected?
   The sample size set at 250 to do proper statistical procedures. Participants will be randomly selected from the patients attending outpatient department of the hospital. They include both healed and unhealed foot ulcer patients.
4. What will happen to you if you take part in the study?
   There is no risk for you to participate in the study. You are free to stop the participation in the study at any point of time and you are allowed to exclude any question which you don't feel to answer.
5. Will your participation in the study be kept confidential?
   All information collected during the course of this research will be kept strictly confidential. Your personal information will not be included while writing the report.
6. What will be the benefit if you participate in the study?
   If you participate in this study you have no direct benefits, but you will receive a health education pamphlet for diabetic foot care.
7. Who is funding for the research?
   I will be doing this research from my own expenses. Applied for student grant in some organizations.
8. What will happen to the results of the study?
   The results of the study will be used in my MPH thesis. The findings from the study will be evaluated my guide and will present that to institution as a working paper to consider for publishing in scholarly journals.

Contact for further information:

In case if you need any clarification regarding the study and your participation feel free to contact anyone mentioned below,

Sithara S Pillai,	Dr. Anoopkumar Thekkuveettil,
MPH Scholar,	Member Secretary,
AMC,SCTIMST	Institutional Ethics Committee
Trivandrum, Kerala	SCTIMST, Trivandrum
Mobile - 09400642250	Tele - 0471- 2520256/ 257

Annexure 11

Informed consent for interview

The impact of diabetic foot ulcer on health related quality of life (HRQL) and employment among rural diabetic population of Southern Kerala

MPH dissertation
June – September 2012

Good morning/afternoon/evening,
I am Sithara S Pillai, currently studying for Masters in public health at Sree Chitra Tirunal Institute for Medical Science and Technology (SCTIMST), Trivandrum. As part of my dissertation, I am conducting a study on "The impact of diabetic foot ulcer on health related quality of life and employment among rural diabetic population of Southern Kerala". The aim of the research is to study the effect of foot ulcer and its healing.

I chose the Medical trust hospital (MTH), Panthalam for conducting the study. I will be selecting the participants randomly from the patients attending the outpatient department of the diabetic clinic at MTH.

The information provided by you in the interview will be kept confidential and will be used only for research purpose. The information provided by you will not be disclosed to anyone under any circumstances. There will be no specific benefit to you for participating in this interview but you will be provided with a health education pamphlet for prevention and care of your foot ulcer. I will be ready to answer your queries regarding your treatment and foot ulcer problems. The approximate time I will take is about 30-40 minutes.

The participation in the study is purely voluntary. You are free to refuse to participate at any point in time during interview.

Are you willing to participate in this study?

Yes, I am willing to participate in the above mentioned study.

No, I am not willing to participate in the above mentioned study.

Signature/thumb impression of the participant and date:

Signature of the investigator and date:

Annexure 12

Informed consent for case study

The impact of diabetic foot ulcer on health related quality of life (HRQL) and employment among rural diabetic population of Southern Kerala

MPH dissertation
June – September 2012

Good morning/afternoon/evening,
I am Sithara S Pillai, currently studying for Masters in public health at Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Trivandrum. As part of my dissertation, I am conducting a study on "The impact of diabetic foot ulcer on health related quality of life and employment among rural diabetic population of Southern Kerala". The aim of the research is to study the effect of foot ulcer and its healing.

I chose the Medical trust hospital (MTH), Panthalam for conducting the study. I will be selecting the participants randomly from the patients attending the outpatient department of the diabetic clinic at MTH.

The information provided by you in the interview will be kept confidential and will be used only for research purpose. The information provided by you will not be disclosed to anyone under any circumstances. There will be no specific benefit to you for participating in this interview but you will be provided with a health education pamphlet for prevention and care of your foot ulcer. I will be ready to answer your queries regarding your treatment and foot ulcer problems. The approximate time I will take for the discussion is 1 hour.

The participation in the study is purely voluntary. You are free to refuse to participate at any point in time during interview.

Are you willing to participate in this study?

Yes, I am willing to participate in the above mentioned study.

No, I am not willing to participate in the above mentioned study.

Signature/thumb impression of the participant and date:

Signature of the investigator and date:

Annexure 13 Health education pamphlet

പാദ വ്രണത്തെക്കുറിച്ചും അതിന്റെ സംരക്ഷണത്തെക്കുറിച്ചും അറിഞ്ഞിരിക്കേണ്ട കാര്യങ്ങള്

പാദ വ്രണം എന്താണ്?

പ്രമേഹ രോഗികളുടെ പാദത്തില് ഉണ്ടാകുന്ന എല്ലാ മുറിവുകളും പാദ വ്രണമാകണമെന്നില്ല. ഒരു മാസമായിട്ടും ഭേദമാകാത്ത മുറിവാണ് പാദ വ്രണം. ഇതിന്റെ ചികിൽസയ്ക്കായി വിദഗ്ധ വൈദ്യ സഹായം ആവശ്യമാണ്.

പ്രമേഹ രോഗികളില് പാദ വ്രണം ഉണ്ടാകുന്നതിനുള്ള കാരണങ്ങള്

- രക്തത്തിലെ പഞ്ചസാരയുടെ അളവ് അമിതമാകുക
- ഇത് മൂലം കാലിലെ രക്തയോട്ടവും സ്പർശന ശേഷിയും കുറയുന്നു
- പുകവലി
- മദ്യപാനം
- നടക്കുമ്പോള് പാദ രക്ഷകള് ഉപയോഗിക്കാതിരിക്കുക.
- ചെറിയ മുറിവുകള് വേണ്ട വിധം പരിചരിക്കുന്നതിലെ അശ്രദ്ധ.

പാദവ്രണം വരാതെ നോക്കുവാനുള്ള മുൻകരുതലുകള്

- രക്തത്തിലെ പഞ്ചസാരയുടെ അളവ് നിയന്ത്രണം
- പ്രമേഹത്തിനുള്ള മരുന്ന് കൃത്യമായി കഴിക്കുക.
- ചിട്ടയോടെയുള്ള ഭക്ഷണ ശീലം
- ശാരീരിക വ്യായാമം
- പുകവലി ഒഴിവാക്കുക

പാദത്തിന്റെ പരിചരണം

- വിശദമായ പാദ പരിശോധന - കണ്ണാടി ഉപയോഗിച്ച് ദിവസേന പാദം പരിശോധിക്കുക. നിർദ്ദിഷ്ടമായ കാലയളവില് വൈദ്യ പരിശോധന നടത്തുക.

- പാദ രക്ഷയുടെ ഉപയോഗം - പാദത്തില് മുറിവുകള് വരാതിരിക്കാന് ഉചിതമായ പാദരക്ഷകള് (MCR ചെരുപ്പ്)ഉപയോഗിക്കുക. നടക്കുമ്പോള് നിർബന്ധമായും പാദ രക്ഷകള് ഉപയോഗിക്കുക

- പാദ പരിചരണ രീതികള് -- പാദം എപ്പോഴും ശുചിയാക്കി വയ്ക്കുക , കാൽപ്പാദങ്ങളുടെ ഉൾവശവും വിരലുകൽക്കിടയിലും ദിവസേന പരിശോധിക്കുക, പാദത്തിന്റെ മൃദുത്വം നിലനിർത്തുക, കുളികഴിഞ്ഞ ഉടന് നഖ പരിചരണം ചെയ്യുന്നതായിരിക്കും ഉത്തമം.
- പാദങ്ങളില് എന്തെങ്കിലും മാറ്റങ്ങള് വന്നിട്ടുണ്ടെങ്കില് അവ നിരീക്ഷിച്ചു രേഖപ്പെടുത്തുകയും ഡോക്ടറെ അറിയിക്കുകയും ചെയ്യുക.
- കൂടുതല് പ്രവർത്തന നിരതനാകുക: ദിവസവും കുറച്ചു സമയം വ്യായാമത്തിനായി മാറ്റി വയ്ക്കുക

പാദ വ്രണം വന്നതിനു ശേഷമുള്ള പാദ പരിചരണം

- പാദ വ്രണം ഉണ്ടായതിനു ശേഷം കൂടുതല് വഷളാകാതിരിക്കാനായി പാദ പരിചരണവും ചികിത്സയും തേടുക. രക്തത്തിലെ പഞ്ചസാരയുടെ അളവ് ശരിയായ അളവില് നില നിർത്തുക. ഉചിതമായ രീതിയില് വിശ്രമവും ചികിത്സയും നടത്തുക. പതിവായി കാല് പാദം വ്യത്തിയാക്കി മരുന്ന് വച്ച് കെട്ടുക.

പാദ വ്രണം എന്നെങ്കിലും ഉണ്ടായിട്ടുണ്ടെങ്കില് സ്വീകരിക്കേണ്ട മുൻകരുതലുകള് :

- ഡോക്ടറുടെ നിർദ്ദേശ പ്രകാരമല്ലാതെ മരുന്ന് മാറ്റുകയോ നിർത്തുകയോ ചെയ്യരുത്. നടക്കുമ്പോള് പാദ രക്ഷകള് കർശനമായും ഉപയോഗിക്കുക.

പ്രമേഹം മൂലമുള്ള പാദ വ്രണത്തിന്റെ ചികിത്സയിലെ പ്രധാന ഘടകങ്ങള്:

- വ്രണം പഴുക്കുന്നത് തടയുക
- പാദ വ്രണങ്ങളിന്മേലുള്ള ശരീര ഭാരം ഒഴിവാക്കുക, ഇത് ഓഫ് ലോഡിംഗ് എന്നറിയപ്പെടുന്നു.
- വ്രണങ്ങളോട് ചേർന്നുള്ള നിർജ്ജീവമായ ചർമ്മവും മാംസ ഭാഗങ്ങളും നീക്കം ചെയ്യുക , ഇതിനെ ഡിബ്രൈട്മെന്റ് എന്ന് വിളിക്കുന്നു.
- മരുന്ന് വച്ച് കെട്ടുക.
- രക്തത്തിലെ പഞ്ചസാരയുടെ അളവ് ശരിയായ തോതില് നിലനിർത്തുക.