CAREGIVER BURDEN AND QUALITY OF LIFE AMONG PRIMARY CAREGIVERS OF HEMODIALYSIS PATIENTS AT TERTIARY CARE CENTERS IN THIRUVANANTHAPURAM CITY
A CROSS-SECTIONAL STUDY

Dr. AFINA AZEEZ

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ACHUTHA MENON CENTER FOR HEALTH SCIENCE STUDIES
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, THIRUVANANTHAPURAM
Thiruvananthapuram, Kerala. India – 695011
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DECLARATION

I hereby declare that this dissertation titled – “Caregiver burden and quality of life among the primary caregivers of hemodialysis patients at tertiary care centers in Thiruvananthapuram city- A cross-sectional study” is a bonafide record of my original research. It has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published and unpublished work of others has been duly acknowledged in the text.

Dr. Afina Azeez
Achutha Menon Center for Health Science Studies
Sree Chitra Tirunal Institute for Medical Science and Technology,
Thiruvananthapuram, Kerala, India – 695011

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CERTIFICATE

Certified that the dissertation titled - “Caregiver burden and quality of life among the primary caregivers of hemodialysis patients at tertiary care centers in Thiruvananthapuram city- A cross sectional study” is a record of the research work undertaken by Dr. Afina Azeez, in partial fulfilment of the requirements for the award of the degree of Master of Public Health under my guidance and supervision.

Guide: Dr. Srikant Ambatipudi

Assistant Professor

Achutha Menon Center for Health Science Studies

Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram

Thiruvananthapuram, Kerala. India -695011

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TABLE OF CONTENTS

Chapter 1. Introduction

Chapter 2. Methodology

Chapter 3. Results

Chapter 4. Discussion

References

Annexure

LIST OF TABLES

LIST OF FIGURES

GLOSSARY OF ABBREVIATIONS

ADL	Activities of daily activities
AOR	Adjusted odds ratio
CB	Caregiver burden
CKD	Chronic Kidney Disease
COR	Crude odds ratio
CI	Confidence Interval
DALY	Disease Adjusted Life Years
ESRD	End Stage Renal Disease
GBD	Global Burden of Disease
KRT	Kidney Renal Transplant
HD	Hemodialysis
PD	Peritoneal Dialysis
QoL	Quality of life
WHO	World Health Organization

ABSTRACT

Background: Chronic kidney disease is a leading chronic disease that impacts the physiological, psychological and functional ability of patients and their families. The primary caregiver is required to assist the patient in his or her everyday tasks. This may cause caregivers to feel burdened, resulting in a poor quality of life. The current study aims to examine the degree of caregiver burden and quality of life among the primary caregivers of hemodialysis patients.

Methods: Primary caregivers (N=200) of the patients undergoing hemodialysis at tertiary care centers were conveniently sampled. Data was collected through a structured interview schedule. Zarit Burden Interview and WHO Quality of Life BREF scale were used for assessing caregiver burden and quality of life of caregivers respectively. Univariate and multivariate analysis was used to identify the association between the variables.

Results: Majority (46%) of the caregivers reported mild to severe levels of caregiver burden. The caregivers without leisure time [AOR=3.1 (95% CI: 1.8-6.7)], monthly income of less than ₹20000 [AOR= 2.1 (95% CI: 1.1-4.5)], perceived financial stress [AOR= 2.3 (95% CI: 1.2-4.5)] and caregivers with more than three comorbidities [AOR= 4 .0 (95% CI: 1.6-9.9)] had an increased odds of caregiver burden. There was a significant association of caregiver burden with poor quality of life in each domain of WHO QoL BREF. The caregivers who had caregiver burden had an increased odds of poor physical [AOR-7.9(95% CI-3.8-16.2)], psychological [AOR-6.6(95% CI-3.0-14.3)], social [AOR-2.5(95% CI-1.3-4.7)] and environmental [AOR-4.3 (95% CI-2.1-8.8)] of quality of life.

Conclusion: The present study revealed the presence of mild to severe levels of caregiver burden and poor quality of life in each domain of WHO QoL BREF. This study opens new avenues of research and potential intervention to reduce caregiver burden and improve the quality of life of caregivers.

CHAPTER-1

INTRODUCTION

1.1 Background of the study

The term "caregiving" refers to the activity or profession of daily caring for a child, the aged, or the disabled. It may entail catering to an individual's mental or physical well-being. It may be long-term caregiving for someone with a chronic disease or physical impairment, or it can be periodic and occasional, as in the case of caring for someone with an acute sickness or an acute episode of a chronic condition (Greenlee and Scharlach, 2001**).** Caregivers are persons who provide care to people requiring assistance in taking care of themselves. A caregiver's typical tasks may include caring for someone who has a chronic illness or condition; managing medications or communicating with physicians and nurses on someone's behalf; assisting in bathing or dressing someone who is weak or disabled; or taking care of domestic chores, meals, or processes linked to health for someone who cannot do these things alone (van den Berg et al., 2004).

"Caregiver" can be formal and informal. The formal caregiver is the professional who has been academically educated/trained to fulfil the patient's unique requirements. They are commonly referred to as "providers," whereas the informal caregiver is a family member or friend who is asked or volunteers to perform the majority of the patient's day-to-day care in the family environment (Oliveira et al., 2007). Primary caregivers play an important role in health care since they are often the primary source of crucial patient information (Mitnick et al., 2010**).** The burden of caring for chronically unwell family members may cause stress for the caregiver. This caregiver stress has been linked to an increased risk issues with mental (Gallagher et al., 2018) and physical health (Gallagher and Hannigan, 2014), as well as poor immunity (Gallagher et al., 2009) and higher blood pressure (Gallagher and Whiteley, 2012).

Primary caregivers such as adult children or spouses are more vulnerable to stress (Jellema et al., 2019). Caregiving chores may need round-the-clock care and supervision, reducing time spent on other significant activities such as paid jobs and leisure activities (Kniepmann, 2014). Many primary caregivers reported their experience as extremely demanding and difficult in a study on the role of spouse caregivers for stroke survivors (Knecht-Sabres et al., 2016). Furthermore, partners and other family caregivers are more likely than the general population to have physical and mental health issues (Jellema et al., 2019). According to the British GP Patient Survey, primary caregivers had much worse health than their non-carer peers (Health, 2015).

Caregiving is a major public health issue that impacts the lives of millions of people. Caregivers help another individual with their social or health requirements. Caregiving tasks can grow and shift as the recipient's requirements alter, putting an additional burden on the carer. Caregiving may have a wide range of effects on the caregiver's life, including his or her capacity to work, engage in social interactions and relationships, and maintain physical and mental health (Caregiving for Family and Friends — A Public Health Issue, 2019).

With increased life expectancy and the development of more effective illness treatment resources, the job of the caregiver has grown crucial. Caring for a sick family member may be extremely demanding on the caregiver, resulting in hardship and changes in family relations (Delalibera et al., 2015).

With the onset of a chronic illness in the family, the sick family member requires care due to clinical complications of his state of health, and the caregiver's occupational life is adversely affected in the areas of occupational self-care, work, and leisure, because they have less time to take care of themselves, and to relate outside their family nucleus.

They experience challenges in their everyday life as a result of adverse implications such as overload, depressive symptoms, anxiety, and higher levels of stress (Pinto and Nations, 2012).

1.1.1 Caregiver Burden

Caregiver Burden can be defined as the extent to which caregivers perceive their emotional or physical health, social life and financial status in a decreasing manner because of the care they provide for a chronically ill, disabled, or elderly family member (Alshammari et al., 2021). The caregiver burden can have an objective dimension, which refers to the "visible" consequences of problems arising from caring functions, such as an excess of patient care, a change in the family routine, and life projects; and/or a subjective dimension, which is directly associated with subjective issues, such as the degree of distress experienced by the family member in the care given to the patient in daily routines (Soares Neto et al., 2011).The impacts of the caregiver burden may increase when all of the caring tasks are assigned to a single caregiver, who acting alone and without proper supervision, is more likely to deteriorate his or her quality of life and health, leading to exhaustion, and stress (Almeida et al., 2010).

1.1.2 Caregivers' Quality of Life

Caregivers' Quality of Life (QoL) is influenced by social, physical, and psychological factors like an obligation, everyday tasks, stress, discomfort, loss of sleep, and other significant health issues (Aljuaid et al., 2022). Since caregiver burden affects both the patient and the caregiver's well-being, it is critical to understand the characteristics linked to caregiver burden. Previous work done on caregiver’s quality of life suggest that caregiver burden is highly connected to caregiver’s quality of life and that lowering caregiver burden can enhance caregiver’s quality of life. Because caregivers spend so much time each day caring for patients, their daily activities are constrained, and they have little time to respond to their own needs. More than half of family caregivers have chronic health conditions such as heart disease and hypertension. Additionally, caregivers reported various degrees of physical weariness and deterioration in health during long-term care. Caregivers endure caregiver burden and a poor quality of life in general (Liu et al., 2020).

1.1.3 Chronic Kidney Disease

In India, Global Burden of Diseases 2015 ranks Chronic Kidney Disease(CKD) as the eighth leading cause of death (Wang et al., 2016). CKD now accounts for 3.0% of deaths, in South Asia (Misra et al., 2017). India has emerged as a 'hotspot', probably having the highest burden of CKD in South Asia (Abraham et al., 2016). Among the various Indian states, Kerala occupies a leading position in the incidence of CKD and associated ailments. In Kerala, majority of the patients are males, below 60 years. The mean duration of treatment was 5.26 years and mean age was 48.6 years and 62% of patients are in advanced stages of disease (Jacob et al., 2019).

Kidney failure treated with dialysis is called End Stage Renal Disease (ESRD) (Burrows et al., 2018). Diabetic nephropathy alone or in combination with hypertensive nephropathy is the most common causes of ESRD in developed and developing countries (Ghaderian et al., 2015). Regardless of several advantages of kidney transplantation, some patients choose hemodialysis (HD) for the treatment of ESRD (Gordon, 2001).

1.1.4 Importance of caregivers for ESRD patients

The ESRD or CKD, not only influences the patients but also the whole family by adversely impacting their socio-economic and psychological wellbeing. Especially, one of the family members, known as the primary caregiver who takes the accountability for the greatest care and needs of the patients (Peter, 2021). The CKD patients depend on their primary caregivers for daily activities and their medical requirements including administration of medicines, assisting them in transportation before and after dialysis, routine check-ups, maintaining personal hygiene, preparation of renal diet and other household activities (Mashayekhi et al., 2015). The primary caregivers split their time and attention between the existing demands of the patients and their own activities including professional, social and marital roles. They willingly take the responsibility of a diseased patient in its broader sense without any financial remuneration. This leads to immense physical, emotional and financial stress on them (Monárrez-Espino et al., 2021) and may result in greater reductions in caregiver's quality of life (Nataatmadja et al., 2021).

In the current scenario, COVID-19 has been declared as a global pandemic. COVID19 affects the HD patients badly, worsening their conditions which might result in death. So, utmost care should be given to HD patients to protect their life. It doubles the responsibility of the caregivers to make their loved ones from any complications or any other acute infections (Sharma et al., 2021). Caregivers who face caregiver burden without enough support or resources negatively influence the quality of care they provide (Liu et al., 2020). Therefore it is important to evaluate the caregiver burden as it affects both the patient's and caregiver's quality of life and the quality of care they provide (Joy et al., 2019).

1.2 Literature Review

The literature review was carried out using PubMed, Google scholar and SCTIMST Dspace. The keywords, including "Caregivers, Caregiver burden, Quality of life, Socio-demographic factors, Hemodialysis (HD), chronic kidney disease" and MeSH terms such as chronic kidney disease (CKD), End-Stage Renal Disease (ESRD), Renal failure, Hemodialysis (HD) were used for search. The Boolean operator 'AND' was used to combine search results.

1.2 .1 Chronic Kidney Disease (CKD)

Chronic kidney disease (CKD) can be defined as a condition in which kidneys are damaged and their ability to filter wastes from the blood is decreased. This can cause waste to build up in the body and can cause other health problems including high blood pressure, anaemia (low blood count), weak bones, poor nutritional health, and nerve damage. CKD also increases the risk of having heart and blood vessel disease. These problems may occur gradually over a long time. Early detection and treatment can often hold chronic kidney disease from getting worse. If kidney disease is not treated properly, it may eventually lead to kidney failure, which requires dialysis or a kidney transplant to survive ((Levey and Coresh, 2012), (Webster et al., 2017)). At this stage the patients require caregivers for providing help with their day to day activities (Mashayekhi et al., 2015).

1.2.2 Caregivers

Caregivers are individuals who are closely committed to providing care to the patients during the course of treatment. They play a major role in the management of the symptoms and needs of the patients to handle the disease (Joy et al., 2019).

1.2.3 Type of Caregivers

Formal caregivers are members of an organization who must adhere to certain standards of behaviour and practise. They might be professionals, support staff, or volunteers. Informal caregivers are not affiliated with any organization. They have no formal training and are not held to any norms of behaviour or practise. They might be relatives or neighbours. Informal or unpaid caregivers are the backbone of in-home long-term care (Caregiving for Family and Friends — A Public Health Issue, 2019).

1.2.4 Caregiver Burden and Quality of Life

A scientific review on the factors related to caregiver burden revealed that a variety of patient and caregiver related factors that have a positive and negative impacts on caregiver burden. These factors are classified into five groups such as socio demographic factors of both patient and caregiver, situational and relational factors, disease related factors, environmental and psychological factors. The inter connection of all these factors needs attention to recognize the overall impact of caregiver burden (Alshammari et al., 2021).

Caregiving duties in managing dialysis have proven to be stressful for the physical, social, and emotional health of informal caregivers. According to previous research, caregivers may experience depression, anxiety, fatigue, social isolation, relationship strains, financial difficulties, and stress as a result of the additional responsibility of managing their care recipient's treatment, dietary requirements, clinic appointments, and psychosocial issues. In contrast to developed countries, the caregiving procedure for HD patients is extremely difficult in low and middle-income countries where family caregivers provide more than 20 hours of care every week (Abebe et al., 2022).

The widespread availability of HD saves and extends the lives of ESRD patients but these patients, on the other hand, suffer from a variety of symptoms and complications, including profound fatigue, nausea, insomnia, hypotension, and muscle cramps (Garg et al., 2017). They are also required to adhere to extensive medication regimens, as well as dietary and fluid restrictions, all of which have an impact on their ability to travel, participate in social activities, and maintain employment (Reid et al., 2016).This often transmits into an intense care burden for their caregivers (Moskovitch et al., 2020). Primary caregivers face significant physical and psychological stress when caring for patients undergoing HD (Matthews et al., 2021).

According to research, the primary caregivers of CKD patients are male patients' partners, followed by daughters and other female relatives ((Gilbertson et al., 2019); (Mollaoğlu et al., 2013). It has been proposed that caregivers of CKD patients are influenced by two key elements. The first is the disruption to their social life caused by both HD and PD dialysis treatments, and the second is increased physical help after the patient loses functional independence (Low et al., 2008). When a caregiver feels burdened, the quality of care decreases. It may appear as a result of the care recipient's poor coping abilities and a lack of emotional support (Liu et al., 2020).

A comprehensive evaluation of 61 quantitative studies involving 5,000 caregivers of adult dialysis patients showed that caregiver burden and quality of life were poorer for dialysis users than for patients with other chronic health conditions. The caregiver had equivalent effects when the patient received either HD or PD; however, caregiver burden and quality of life were worse among caregivers of patients undergoing HD (Gilbertson et al., 2019). Low et al. discovered that caregivers who lived with a patient with ESKD suffered exhaustion, stress, isolation, life constraints, increased workload, financial implications, an altered relationship with the patient, and intimacy issues in marital relationships. Caregivers were generally reported to ignore their own health, however caregivers who took a vacation from the caregiving position had a favorable influence on their health (Low et al., 2008).

Caregivers of patients with HD and PD have a detrimental influence on work, leisure activities, and social activities (Cantekin et al., 2016). Patients with comorbid illnesses and greater physical dependence have been observed to lead to a greater caregiver burden (Walker et al., 2015).

1.2.5 Global Studies

Scientific investigations on the caregiver burden and factors linked with caregiver burden from Jordan revealed severe caregiver burden (CB) amongst the participants that were associated with increasing age of caregivers. The caregivers who had sufficient health literacy exhibited a lower level of burden (Abed et al., 2020). Studies conducted in Nigeria found mild to moderate CB amidst the caregivers in which female caregivers encountered a higher level of burden and less quality of life in comparison with the male caregivers. The researchers also pinpointed that anxiety, depression and burden were frequent among caregivers of CKD patients especially females compared to age and sex matched controls (Adejumo et al., 2019). A study conducted in USA reported moderate to extreme caregiving burden among different categories of caregivers. The caregivers with proper health and those who optimistically approach the caregiver role underwent a lesser degree of burden (Affinito and Louie, 2018).

Investigations conducted by public health researchers from Jordan showed a moderate degree of burden and it also manifests that staying along with the patient was the main variable which was positively correlated with the CB. Supplementary socio demographic elements of both patient and caregivers, hours of caregiving per week and years of care giving were not associated with CB (Alnazly, 2016).

A study conducted in Spain on the Health-Related Quality of Life (HRQOL) and caregiver’s burden showed moderate to severe burden. In addition, those caregivers who had insufficient social support and poor physical and mental health, experienced a higher caregiver burden. Further the number of caregiving hours, age of patients, morbid conditions of patients and caregivers and number of treatments were positively associated with CB (Alvarez-Ude et al., 2004). Research reports from Saudi Arabia revealed moderate to severe CB among the caregivers. The study showed a negative association of caregiver burden with the age of the caregivers. But the age of the patients was positively associated with the caregiver burden. While, the level of education of both patient and caregiver has a negative relationship with CB(Bayoumi, 2014).

Research conducted in Brazil regarding perceived burden and HRQOL of the caregivers of HD patients showed a moderate level of CB. The factors such as caregivers of the male patient with low literacy rates and those caregivers of patients with multiple comorbidities showed higher caregiver burden scores. Also, those caregivers who were females with an increased number of caring hours, showed higher burden levels (Belasco et al., 2006).

Scientific investigations conducted in Turkey to evaluate the burden of caregivers of HD and related variables showed a moderate level of CB. The caregivers who were female and being working, had three or more children, with lower income and those who offered care for more than five years were found to experience a higher level of CB. In accordance with this, they also reported that their role in family and working were negatively impacted with the caregiving. But other socio demographic factors including caregiver's age, education level, marital status, place of residence and dialysis sessions per week, were not related to CB (Cagan et al., 2018).

A study to determine the factors associated with CB of caregivers of HD patients in Indonesia showed no to low burden. Factors such as duration of caring hours, gender and education level were not significantly correlated to CB, but the lower income and older age of caregivers showed association with high CB (Faridah et al., 2020).

Likewise, a study conducted in USA displayed little to no burden (Affinito and Louie, 2018). Reports from Vietnam showed moderate to severe burden among caregivers. The spouses of patients ,the elderly, those who had comorbidities and provided a longer duration of caregiving to dependent patients showed higher caregiver burden (Hoang et al., 2019).

Jafari *et al.*, 2018 evaluated the level of burden and quality of life among caregivers of HD patients and their findings indicate a moderate to severe level of caregiver burden. The factors such as education level and self-care of the patients were negatively linked with CB. On the other hand, the age of caregivers was positively linked with caregiver burden. Other factors such as patient's age, gender of the patients and caregivers, occupation and income were not related to CB. Caregivers of patients having comorbidities showed a high CB scores. The quality of life of caregivers showed a negative association with the CB score (Jafari et al., 2018).

A survey organized among primary caregivers of HD patients from Turkey revealed mild to severe burden especially among female caregivers, also among young caregivers, single, well-educated, and those with comorbidities. The spouses of HD patients had low levels of CB in comparison with other relatives. Caregivers from the peripheral district or small town had a higher burden than those who are natives of centered districts. However, the researchers found no association between the occupation and income of caregivers and CB (Mollaoğlu et al., 2013).

Reports from investigations conducted among caregivers of Greece displayed a moderate burden. But there was no association between the age, gender, education, marital satisfaction, and employment status of caregivers with the patient status such as dialysis dependent or not with the CB (Paschou et al., 2018). Shah *et al.*, (2017) based on their observations from Pakistan reported mild, moderate CB and a positive association between the CB and factors such as duration of the patient on dialysis and hours of caregiving, low socioeconomic stat and highly dependent patients (Usman Shah et al., 2017).

A study from Nepal revealed a moderate to high burden and pointed out that increased CB was linked with low socio-economic status, lower education status, aged and lack proper social assistance. Widowed caregivers elicited higher CB levels in comparison with married women. However, the lowest levels of CB were observed in unmarried women. Spouses and parents of the ESRD patients had a higher CB as compared to other relatives. However, duration and frequency of dialysis and comorbidities of patients were not found to be significantly linked with CB. Caregiver burden is markedly associated with the quality of life (QoL) of caregivers (Shakya et al., 2017). Research reports from Japan reveals mild to moderate burden and factors such as spouses, those having chronic diseases and longer duration of care giving were linked with CB (Washio et al., 2012).

A study from China among primary caregivers of HD patients showed that 51% of the caregivers reported mild to moderate burden and 25.2% reported mild to severe burden. Age of the caregivers, low educational status, unemployment and increased duration of caring had resulted in higher levels of CB. Those who were physically and mentally healthy experienced low CB. Caregiver burden was considerably increased in caregivers with more than two comorbidities and patients with low income. Relationship with patient such as parents, spouses and adult children felt more burden than with other relatives (Zhang et al., 2020).

1.2.6 National Studies

A study conducted in Hyderabad by Nagarathnam *et al.*, (2019) among the caregivers of HD, PD, RT patients and their quality of life indicated moderate to severe burden among the caregivers of HD patients which also affected their quality of life. They revealed that the increased level of burden on caregivers of HD patients may be due to the elevated responsibilities such as supporting the patients in to and fro journey to the dialysis center, preparation of special diets and taking care of the complications of treatments. Also, social isolation and altered daily activities of the caregivers increased their burden (Nagarathnam et al., 2019). Recent report from Sikkim pointed out that more than half of the caregivers experienced mild to moderate burden. There was a marked link between the age and gender of caregivers and CB. Female caregiver had moderate to severe burden as compared to the male caregivers. Those caregivers who had poor educational status had higher CB. In addition, aged caregivers had higher CB. Occupational status of the caregiver also impacts the CB. Unemployed caregivers had high CB than others. The other factors such as age of the patient, number of comorbidities of patients and longer duration of dialysis were also associated with CB. Also there is a positive correlation between the CB and severity of depression in patients (Joseph et al., 2021). A study from Uttarakhand, India, on the burden of caregivers of patients undergoing HD indicated mild to moderate level of CB. The study also revealed that caring and being with the patient most of the time might affect the health and quality of life of the caregivers (Sharma et al., 2021).

A study from Lucknow, UP revealed that majority (43.3%) of the participants had mild to moderate caregiving burden. Besides, higher CB was experienced by elderly caregivers, specifically women, married, illiterate, those with three or more children, with an income generating and giving care for 1-2 years. Although no significant association was found with these variables (Peter, 2021).

1.2.7 Regional Studies

Limited studies have been done on the CB and quality of life in Kerala. A recent study conducted by (Joy et al., 2019) on the burden and resilience in caregivers of patients in maintenance HD showed moderate to severe burden among the caregivers. The factors comprising extent of care giving and time utilized for daily care were influenced by the CB. Female caregivers and those who struggled to perform the caregiver role experiences higher burden. However, the age of the caregiver had no association with burden. The study also showed that the caregivers experienced low resilience status due to the various elements such as physical and mental burden of the caregivers along with financial strains they experienced (Joy et al., 2019).

1.3 Gaps in Researches

A number of studies regarding CB and quality of life were conducted in developed countries. In India most of the studies were focused on the level of burden and associated factors. A study done in Kerala on Burden and resilience in caregivers of patients on maintenance HD (Joy et al., 2019) revealed that 80% of the caregivers had caregiver burden but it did not assess the quality of life of the caregivers.

1.4 Rationale of the study

Hemodialysis has become a highly safe medical procedure which can significantly extend the life of chronic kidney disease patients. It is nonetheless a stressful and lengthy process. However, a physical and psychological challenge associated with the long-term dialysis therapy causes negative impact on patients as well as caregivers. Recurrent hospitalization of the patient and factors related with ESRD can often lead to diminishing the quality of life of caregivers. There are very limited studies from Kerala focusing on the CB. The relation between CB and its association with quality of life of the primary caregivers remains underexplored. It is vital to realize the burden of primary caregivers of HD patients and provide timely intervention to enhance their quality of life. Hence, the present study was envisaged.

1.5 Objectives

- To analyse the level of caregiver’s burden and associated factors among the primary care givers of hemodialysis patients.
- To evaluate the quality of life of primary care givers of hemodialysis patients.

CHAPTER-2

MATERIALS AND METHODOLOGY

2.1 Study Design : A cross-sectional study was conducted to assess the level of caregiver burden and quality of life among the primary caregivers of HD patients.

2.2 Study Setting and Study Population: Primary caregivers of the hemodialysis patients at the designated hemodialysis centers aged 18 years or more in Thiruvananthapuram city, Kerala, India was invited to participate in the study.

2.3 Sample Size Estimation: Assuming that 80% caregivers experience moderate to severe levels of caregiver burden (Joy et al., 2019), with an absolute precision of 10% over the 95% confidence interval, the estimated sample size was 120. Assuming 20% non-response, the sample size was estimated to be 140.

2.4 Sample Selection Procedure:

Dialysis centers were contacted for their willingness to participate in the study. Primary caregivers of the patients undergoing HD at the participating centers were selected using a convenient sampling method. Sample selection process is explained in Figure 2.1.

2.5 Subject Selection:

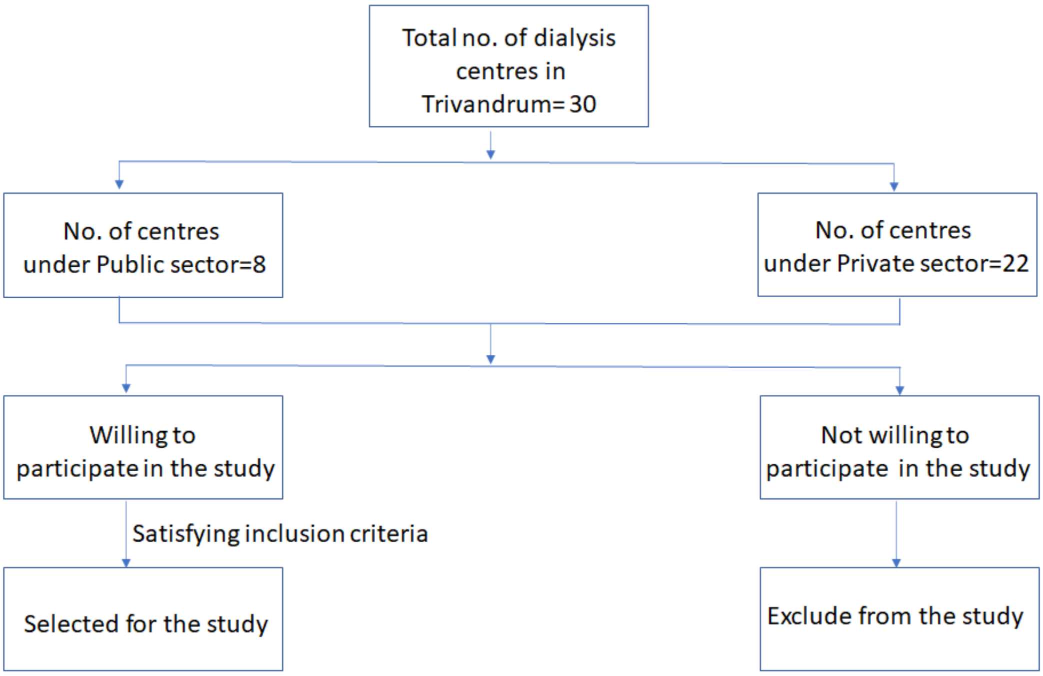
2.5.1 Inclusion Criteria:

1. Caregivers of age ≥ 18 years.
2. Persons who have provided care for ≥3 months.
3. Caregivers who were proficient in reading and writing the Malayalam language.

2.5.2 Exclusion Criteria:

1. Paid caregivers.
2. Caregivers of peritoneal dialysis patients.

Figure 2.1: Flowchart showing the sample selection procedure for the study



2.6 Data Collection Method:

A structured interview schedule in Malayalam was administered by the principal investigator. The Malayalam version of the study tool (here, structured interview schedule) was printed and retained with the principal investigator during the course of data collection. Responses received from the participants as answers to the queries in the interview schedule was noted in the print outs. The interview schedule was divided into 3 segments.

First section included the socio-demographic particulars of the participant (age, education, income, marital status, number of children, patient treatment linked details, socio economic particulars, transportation information, patient linked activities, etc.)(Annexure-3). The second section included the assessment of degree of caregiver burden assessed using Zarit Burden Interview Scale (Annexure 3). The third section covered the assessment of quality of life of the primary caregivers using WHO QoL BREF scale (Annexure-3). The participants had the choice to not answer questions and their involvement was absolutely voluntary.

2.7 Study Period:

The study was conducted during the time period of March 11th, 2022 to May 21st, 2022.

2.8 Data Collection Tools

Structured Interview Schedule based survey using the Zarit Burden Interview and WHO QoL –BREF scales.

2.8.1 Zarit Burden Interview:

Zarit Burden Interview (ZBI) was implemented for evaluating primary caregiver’s professed burden. It is one of the most frequently used tools for assessing burden and has been authenticated in many culturally or ethnically diverse populations. The revised version of ZBI comprises 22 items. Each item was scored using a 5-point scale. Response options vary from 0 (never) to 4 (nearly always). Higher the score, bigger was the perceived burden. The Malayalam version of the tool used in this study was kindly shared by Dr. Jomon Joy, Associate professor of Psychiatry, SUT academy of medical science (Joy et.al 2019). The final score was interpreted as: 0–21-little or no burden; 21–40 – mild-to-moderate burden; 41–60 – moderate-to-severe burden; and 61–88 – severe burden. The internal consistency of ZBI was evaluated using Cronbach’s alpha.

2.8.2 WHO QoL-BREF:

The WHO QoL–BREF, a shorter version of the WHOQoL-100 was used for assessing the quality of life among the primary caregivers of the individuals undergoing dialysis. It comprises of four domains namely physical, psychological, social, and environmental. Items on this measure were scored on a 5-point Likert scale. The scores span from 1 (low) to 5 (high) with escalating scores from 1 to 5 denoting higher QoL.

The raw domain scores acquired from the WHO QoL- BREF were transformed to a 4 - 20 score and then scaled in a positive direction (higher scores denote a higher quality of life). The mean score within each domain was calculated. The Malayalam version of this tool was used in this study after seeking permission from the author (Sreedevi et al., 2016). The internal consistency of the WHO QoL BREF scale was measured using Cronbach's alpha.

2.9 Ethical Consideration:

The present study received ethical clearance from the Institute Ethics Committee of Sree Chithra Tirunal Institute for Medical Science and Technology, Thiruvananthapuram, Kerala (SCT/IEC/1828/JANUARY/2022)(Annexure-7).Also, the permission from the Directorate of Health Service, Thiruvananthapuram, the Nephrology Department of Government Medical college ,Thiruvananthapuram and the concerned head of the private institutions were obtained before the start of the data collection (Annexure-8).The interview was performed warranting absolute privacy to the participant. The principal investigator and participant were the only persons present at the time of interview. All attempts were made to ensure confidentiality of the personal information gathered from the participant. The information gathered was not shared with anyone outside the study group and reporting was done in cumulative form only. Identity of the responder was not publicized at any point of time. All hard copies of filled interview schedules and consent forms were kept under the guardianship of principal investigator and will be appropriately discarded after a period of five years.

2.10 Data Analysis:

The data entry was done using Microsoft excel software and was then imported into SPSS version 25. All the statistical analysis was performed using SPSS version 25. Data cleaning was done before the analysis. Coding and recoding of the data were done prior to the analysis.

Frequencies and proportion were calculated for the categorical variables, and median, standard deviations were calculated for the continuous variables. Median age and age range were examined and independent test was applied to compare the mean and standard deviation in categorical variables. The level of burden was represented as frequencies and percentages in each category. The QoL was reported using Mean and Standard deviations for each domain.

For exploring the association between CB and quality of life with the independent variables, the dependent variables were dichotomized. Caregiver burden were classified into no burden and burden by keeping little/no burden as no burden and by pooling mild to severe level of burden-to-burden category. WHO QoL BREF scale was divided into two as good and poor based on the median score. Those scores below median were considered to have poor quality of life while those with scores greater than or equal to median were considered to have good quality of life.

2.11 Statistical Analysis

For analysis logistic regression was done with,

- Sociodemographic variables as the independent variable and caregiver burden as the dependent variable.

- Sociodemographic variables as the independent variable and each domain of the WHO QOL BREF as the dependent variable.
- Caregiver burden as the independent variable and each domain of the WHO QOL BREF as the dependent variable.

Bivariate analysis was executed using Chi-square test for categorical data. Binary logistic regression analysis was conducted to find out the correlates of caregiver burden and quality of life of the caregivers. Odds ratio was computed for all the associations assessed and the p-value obtained was used to determine whether the association were significant. A p value of ≤ 0.05 was used as cut off for statistical significance.

2.11.1 Multivariate Analysis

The factors which were found to have association with both Zarit Burden and WHO QoL BREF scales were selected for the multivariate analysis. For the analysis each domain of WHO QoL BREF scale was taken as the dependent variable and from the multiple models, the best model based on Hosmer and Lemeshow Test p-value was selected. The Hosmer-Lemeshow statistic indicates a good fit if the significance value is greater than 0.05.

2.12 Variables in the study:

Dependent variables:

The primary outcome of the study was the level of the caregiver burden and the secondary outcome variable was the quality of life of the primary caregivers of HD patients.

Independent variables:

Independent variables were the sociodemographic characteristics of the caregivers and the patients, transportation details, health related and caregiving aspects of the caregivers and treatment related factors of the patients and their dependency of their caregivers. Socio economic factors were assessed by income range.

2.13 Operational definitions of the variables in the study

Sociodemographic Variables of caregivers

- Age – Age in completed years as reported by the participant.
- Sex- Male/ Female as reported by the participant.
- Religion – religion followed as reported by the participants – Hinduism/ Christianity /Islam.
- Relationship of the caregiver to the patient -reported by the participants as spouses/mothers/daughters/son/siblings/others.
- Education – Highest level of education as reported by the participants.
- Income – Income of household categorised into two as below and above ₹20000/-
- Presence of comorbidities- Health related comorbidities of the caregivers were grouped as yes or no and number of comorbidities were grouped into 4 categories (0, 1, 2, ≥3).
- Leisure time- Availability of free time of the participants were categorised as yes and no.
- Source of treatment expenses-sources as reported by the participants
- Transportation details- the variables such as residency were categorised into rural and urban.
- Distance to the hospital- categorised as reported by the participants.
- Type of transportation-categorised into public and private transport as reported by the participants.

Variables related to the patients

- Age – age in completed years as reported by the caregivers.
- Sex of the patient-- Male/ Female as reported by the participant.
- Duration of the treatment- grouped into 3 categories as 3-6months/ 1-2years/more than 2 years.
- Number of weekly sessions-number of sessions per week were categorised into one session/two session and 3 sessions.
- Activities of the patients depend on caregivers- Activities of the patients depending on the caregivers were grouped into 2 categories dependent and independent.
- Caregiver burden- Caregiver Burden is a generally accepted term used to describe the emotional, physical and financial cost of the care by the primary caregivers.
- Primary /family caregivers**-** Individuals who care for members of their family of origin are referred to as "family caregivers," while those who care for their family of choice are also referred to as "family caregivers." (Mitnick et al., 2010)**.**

2.14 Expected outcome:

The expected outcome of the study was to assess the level of caregiver burden and the quality of life of the primary caregivers of HD patients.

CHAPTER 3

RESULTS

The findings of the study are presented in this chapter. The first section includes background characteristics of the caregivers, focusing on their socio demographic, socio economic, health related and care related factors. Patient characteristics and treatment related details were also described. In the second section findings of caregiver burden were explained and the results of quality of life of the caregivers were described in the third section. This is followed by the results of univariate and multivariate analysis focusing on the study objectives.

3.1 Socio-Demographic Characteristics of Caregivers

Socio-demographic characteristics of caregivers (N=200) are shown in Table 3. 1. The age of participants ranged from 22-85 years with a median age of 55 years. Majority of the caregivers were females (77.5%). About 69 percent of the caregivers belonged to Hindu religion and most of the participants were married (93.5%). About half of the participants had higher secondary or higher than secondary level of education. Majority of the caregivers in this study were the spouses (77.5%) of HD patients. More than half of the caregivers were homemakers (57%) and one fourth of them were unemployed and retired. The household income of about 70 percent of the caregivers were below ₹20,000.

Table 3.1 Socio-demographic characteristics of caregivers (N=200)

Variables	**N (%)**
Age in years (median and range)	55 (22-85)
Gender	
Male	45 (22.5)
Female	155 (77.5)
Religion	
Hindu	138 (69)
Muslim	27 (13.5)
Christian	35 (17.5)
Marital status	
Single	8 (4)
Married	187 (93.5)
Divorced	2 (1)
Widowed	3 (1.50)
Relation of the caregiver to the patient	
Spouse	155 (77.5)
Mother	12 (6)
Son	10 (5)
Daughter	15 (7.5)
Siblings	5 (2.5)
Others	3 (1.5)
Educational status	
No formal education	5 (2.5)
Primary School	26 (13)
High School	69 (34.5)
Higher secondary	36 (18)
Graduate	40 (20)
PG	19 (9.5)
Others	5 (2.5)
Employment status	
Home maker	114 (57)
Public Sector	12 (6)
Private Sector	10 (5)
Self employed	18 (9)
Daily wage earner	6 (3)
Unemployed	20 (10)
Retired	20
Income range (in ₹ per month)	
<20000	140 (70)
≥20000	60 (30)

3.2 Health Related and Care Giving Aspects of the Caregivers

The different factors related to the health related and care giving aspects of the caregivers are shown in Table 3. 2. Nearly, three fourth of the caregivers had presence of comorbidities (73.5%) and among them 75% of them had more than one comorbidity. More than half of the caregivers had perceived financial stress to meet the expenses for the patient treatment (51%) and nearly 63% of the caregivers depended on the relatives help, loans or the help of the charitable trusts. Most of them had no health insurance. Nearly 60% of the participants were from the rural areas and majority (83%) of them lived at a distance of more than five kilometers from the dialysis center. Most of them were (57.5%) depend on the public transport to reach the dialysis center.

Table 3.2: Factors related to the health related and care giving aspects of the caregivers

Variables	**N (%)**
Presence of comorbidity	
No	53 (26.5)
Yes	147 (73.5)
Number of comorbidities	
One comorbidity	50 (25)
Two comorbidities	42 (21)
Three comorbidities and more	55 (27)
Presence of leisure time	
No	102 (51)
Yes	98 (49)
Average caring hours	
<8 hours	188 (94)
>=8 hours	12 (6)
Perceived financial stress	
No	90 (45)
Yes	110 (55)
Source of treatment expenses	
Relatives Help	92 (46)
Own money	73 (36.5)
Trust Help	22 (11)
Loan debits	28 (14)
Insurance availability	
No	110 (55)
Yes	90 (45)

Locality	
Rural	118 (59)
Urban	82 (41)
Distance to the dialysis center	
<1 km	3 (1.5)
2-5 km	31 (15.5)
>5 km	166 (83)
Type of transportation	
Public transport	115 (57.5)
Private transport	85 (42.5)

3.3 Patient Characteristics

Table 3.3 represents the characteristics of hemodialysis patients (N=200) of the caregivers. Majority of the patients were in the age range of 20 – 86 years with median age of 61 years, prominently males (62%). The treatment duration for majority of the patients was greater than 2 years (50.5%) with two weekly sessions of dialysis (72%) and most of them were dependent on care givers for carrying out their day-to-day activities (53.5%).

Table 3.3: Patient characteristics (N=200)

Variables	**N (%)**
Age in years (median and range)	61 (20-86)
Gender	
Male	124 (62)
Female	76 (38)
Duration of treatment	
3 months - 6 months	39 (19.5)
6 months -12 months	24 (12)
1-2 years	36 (18)
>2 years	101 (50.5)
Number of weekly dialysis sessions	
One session	10 (5)
Two sessions	144 (72)
Three sessions	46 (23)
Activities of patients depending on caregivers	
Independent	93 (46.5)
Dependent	107 (53.5)

3.4 Assessing the Level of Caregiver Burden of Primary Caregivers

The level of caregiver burden is shown in Figure 3.1. Most of the caregivers in the study experienced mild-moderate caregiving burden. Among them, 42 percent reported mild to moderate level of burden and 11 percent reported moderate to severe burden. Only one percent caregivers reported severe level of burden.

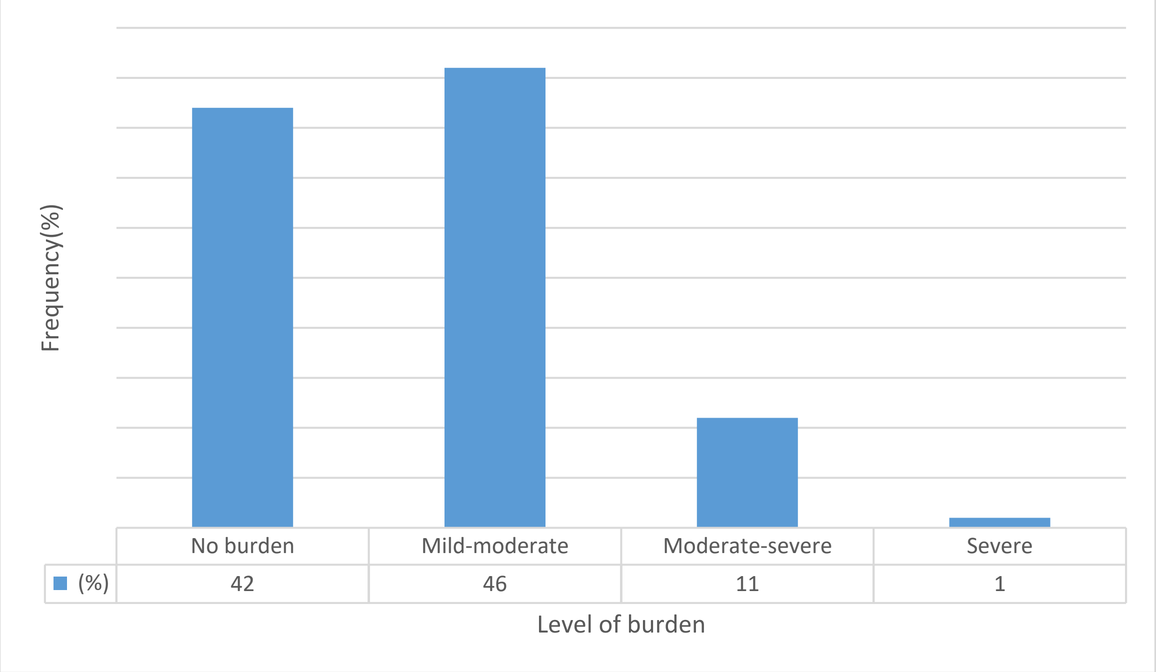


Figure 3.1. Level of burden among the caregivers based on the Zarit burden scale

3.5 Assessing the Quality of Life of Primary Caregivers

The mean and standard deviation of physical, psychological social and environmental domains of quality of life were 13.71(3.15), 12.92(3.46), 13.89(3.30), 12.67(2.89) respectively. The mean and standard deviation of overall quality of life was 2.94(1.01) and that of overall quality of health was 3.10(1.01). The mean score of each domain of quality of life is shown in Figure 3.2.

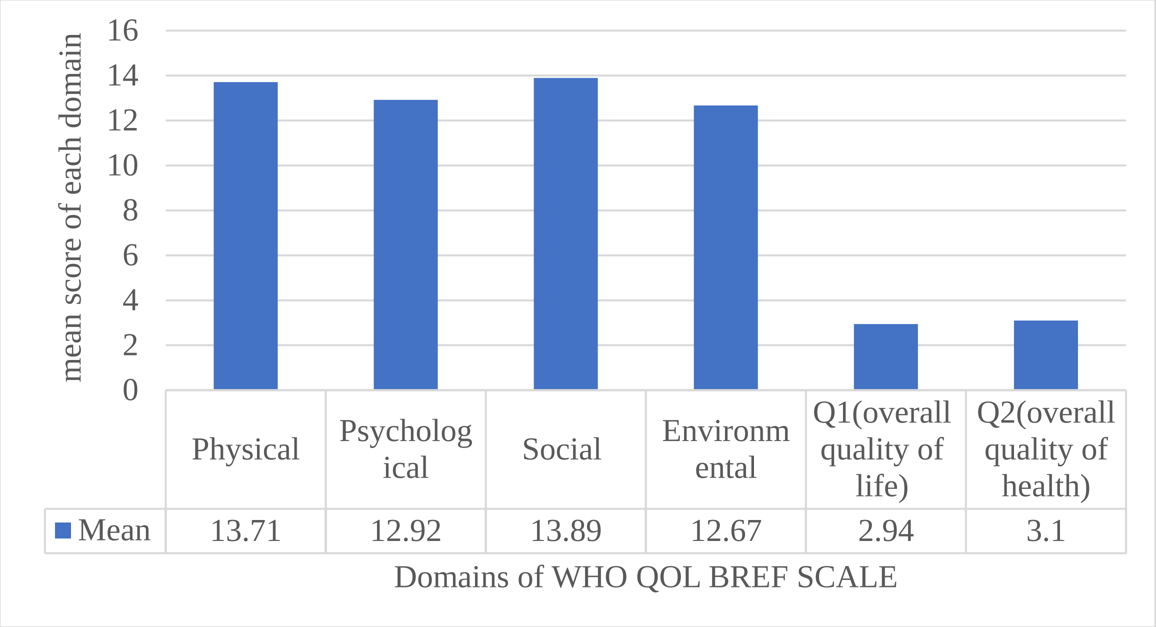


Figure 3.2: Mean score of each domain of WHO QoL BREF scale

3.6 Caregiver Burden and Socio-Demographic Characteristics

Among the male caregivers, 60 percent reported caregiver burden and 57.4 percent of the female caregivers experienced burden. Among the caregivers who reported burden, 75 percent were mothers of the HD patients followed by son (60%) and spouses (58.7%). Nearly two third of the participants (65%) who had less than ₹20000 of household income reported caregiver burden. About 66.7 percent of the caregivers who had presence of comorbidities and majority of the caregivers (71%) with more than three comorbidities reported burden of caregiving. Most of the caregivers with perceived financial stress (71.8%) and without leisure time (73.5%) experienced burden **(**Annexure -9).

The variables such as income range (p value=0.002), presence of comorbidities (p value=4.5E^-5), number of comorbidities (p vale=0.001), perceived financial stress (p value=1.5E^-5), leisure time (p value=8E^-6), average caring hours (p value=0.015) showed significant association with the level of caregiver burden and were selected for multi variate analysis by binary logistic regression (Table 3. 4).

Table 3.4: significant association of level of caregiver burden with various characteristics of caregivers

Variable	**Category**	**N**	**Zarit burden**		**P value (χ2)**
			No burden N (%)	Burden N (%)	
Income range	<20000	140	49 (35)	91 (65)	**0.002** (9.4)
	>=20000	60	35 (58.3)	25 (41.7)	
Presence of comorbidities	No	53	35 (66)	18 (34)	**4.5E^-5** (17.1)
	Yes	147	49 (33.3)	98 (66.7)	
No of comorbidities	1 comorbidity	50	20 (40)	30 (60)	**0.001** (17.1)
	2 comorbidities	42	13 (31)	29 (69)	
	>=3 comorbidities	55	16 (29)	39 (71)	
Perceived financial stress	No	90	53 (58.9)	37 (41.1)	**1.5E^-5** (19.2)
	Yes	110	31 (28.2)	79 (71.8)	
Leisure time	No	102	27 (26.5)	75 (73.5)	**8E^-6** (20.6)
	Yes	98	57 (58.2)	41 (41.8)	
Caring hours	<8 hours	188	83 (44.1)	105 (55.9)	**0.015** (5.9)
	>=8 hours	12	1 (8.3)	25 (41.7)	

3.7 Association of WHO QoL BREF Scale and Characteristics of Caregivers

3.7.1 WHO-QoL BREF Physical Domain

The association of physical domain with characteristics of caregivers was investigated and the results are represented in Table 3.5. The caregivers with presence of comorbidities (p value=6.7E^-9), increased number of comorbidities (p value=5.6E^-8) and without leisure time (p value=0.015) were found to have poor physical quality of life.

Table 3.5: Association of WHO-QoL BREF Physical domain with characteristics of caregivers

Variable	**Category**	**N**	**Physical domain of WHO QoL BREF**		**P value (χ2)**
			Good n (%)	**Poor n (%)**	
Presence of comorbidities	No	53	46 (86.8)	7 (13.2)	**6.6E^-9** (32.1)
	Yes	147	61 (41.5)	86 (58.5)	
No. of Comorbidities	1 comorbidity	50	24 (48)	26 (52)	**5.5E^-8** (34.9)
	2 comorbidities	42	15 (35.7)	27 (64.3)	
	>=3 comorbidities	55	21 (38.9)	33 (61.1)	
Leisure time	No	102	46 (45.1)	56 (54.9)	**0.015** (5.9)
	Yes	98	61 (62.2)	37 (37.8)	
Caring hours	<8 hours	188	105 (55.9)	83 (44.1)	**0.008** (6.9)
	≥8 hours	12	2 (16.7)	10 (83.3)	
Activities of the patient dependency on caregivers	Independent	93	59 (63.4)	34 (36.6)	**0.009** (6.9)
	Dependent	107	48 (44.9)	59 (55.1)	

3.7.2 WHO-QoL BREF Psychological Domain

The association of psychological domain with characteristics of caregivers was evaluated and the results are shown in Table 3.6. The psychological domain shows significant association with income range (p value=3.2E^-4), presence of comorbidities (p value =2E-4), number of comorbidities of the caregivers (p value=6E^-4), leisure time, average caring hours and perceived financial stress.

Table 3.6: Association of psychological domain with characteristics of caregivers

Variable	**Category**	**N**	**Psychological domain of WHO QoL BREF**		**P value ($\chi 2$)**
			Good n(%)	**Poor n (%)**	
Income range	<20000	140	65 (46.4)	75 (53.6)	**3.2E^-4** (13.8)
	>=20000	60	45 (75)	15 (25)	
Presence of comorbidities	No	53	44 (83)	9 (17)	**2E^-6** (22.8)
	Yes	147	66 (44.9)	81 (55.1)	
No. of Comorbidities	1 comorbidity	50	25 (50)	25 (50)	**6E^-6** (27.0)
	2 comorbidities	42	21 (50)	21 (50)	
	>=3 comorbidities	55	19 (35.2)	35 (64.8)	
Leisure time	No	102	43 (42.2)	59 (57.8)	**2E^-4** (13.8)
	Yes	98	67 (68.4)	31 (31.6)	
Perceived financial stress	No	90	61 (67.8)	29 (32.2)	**0.001** (10.7)
	Yes	110	49 (44.5)	61 (55.5)	
Caring hours	<8 hours	188	108 (57.4)	80 (42.6)	**0.006** (7.5)
	≥8 hours	12	2 (16.7)	10 (83.3)	

3.7.3 WHO-QoL BREF Social Domain

The caregiver’s characteristics which showed association with social domain of QoL is shown in Table 3.7. The factors such as relationship of the caregiver to the patient (p value=0.001), income range (p value=2.8E^-4), leisure time (p value=0.006), perceived financial stress (p value=0.001), average caring hours (p value= 0.002), distance to the hospital (p value=0.008) shows association with the poor social quality of life**.**

Table3. 7: Association of social domain with characteristics of caregivers

Variable	**Category**	**N**	**Social domain of WHO QoL BREF**		**P value (χ2)**
			Good n (%)	**Poor n (%)**	
Relation	Spouse	155	98 (63.2)	57 (36.8)	**0.001** **(**21.1)
	Mother	12	2 (16.7)	10 (83.3)	
	Son	10	8 (80)	2 (20)	
	Daughter	15	4 (26.4)	11 (73.3)	
	Siblings	5	2 (40)	3 (60)	
	Others	2	3 (100)	0.0	
Income range	<20000	140	70 (50)	70 (50)	**2.8E^-4** **(**13.8)
	≥20000	60	47 (78.3)	13 (21.7)	
Leisure time	No	102	50 (49)	52 (51)	**0.006** **(**7.7)
	Yes	98	67 (68.4)	31 (31.6)	
Perceived financial stress	No	90	65 (72.2)	25 (27.8)	**0.001** **(**12.6)
	Yes	110	52 (47.3)	58 (52.7)	
Caring hours	<8 hours	188	115 (61.2)	73 (38.8)	**0.002** **(**9.2)
	≥8 hours	12	2 (16.7)	10 (83.3)	
Distance to the hospital	<1 km	3	3 (100)	0	**0.008** **(**9.7)
	2-5 km	31	11 (35.5)	20 (64.5)	
	>5 km	166	103 (62)	63 (38)	

3.7.4 WHO-QoL BREF Environmental Domain

The caregiver's characteristics which are associated with the environmental domain is represented in Table 3. 8. The factors such as educational status(p value=0.012), relation of the caregiver to the patient(p value=0.006), income range(p value=2E^-6), presence of comorbidities(p value=3E^-6), number of comorbidities(p value=1.7E6-5), leisure time(p value=1.4E^-4), perceived financial stress(p value=2E^-6), average caring hours(p value =0.013), type of transportation(p value=0.019) and gender of the patients(p value=0.037) are significantly associated with the poor environmental quality of life.

Table 3.8: Association of WHO-QoL BREF Environmental domain with characteristics of caregivers

Variable	**Category**	**N**	**Environmental domain of WHO QoL BREF**		**P value (χ2)**
			Good n (%)	**Poor n(%)**	
Educational status	No formal education	5	2(40)	3(60)	**0.012** (16.3)
	primary	26	10(38.5)	16(61.5)	
	High school	69	29(42)	40(58)	
	Higher secondary	36	17(47.2)	19(52.8)	
	Graduate	40	28(70)	12(30)	
	Postgraduate	19	15(78.9)	4(21.1)	
	Others	5	2(40)	3(60)	
Relation	Spouse	155	82 (52.9)	73 (47.1)	**0.006** (16.2)
	Mother	12	1 (8.3)	11 (91.7)	
	Son	10	9 (90)	1 (10)	
	Daughter	15	6 (40)	9 (60)	
	Siblings	5	3 (60)	2 (40)	
	Others	2	2 (66.7)	1 (33.3)	
Income range	<20000	140	57 (40.7)	83 (59.3)	**2E^-6** (21.7)
	>=20000	60	46 (76.7)	14 (23.3)	

Presence of comorbidities	No	53	41 (77.4)	12 (22.6)	**3E^-6** (19.3)
	Yes	147	62 (42.2)	85 (57.8)	
Number of comorbidities	1 comorbidity	50	26 (52)	24 (48)	**1.7E^-5** (24.1)
	2 comorbidities	42	17 (40.5)	25 (59.5)	
	>=3 comorbidities	55	18 (33.3)	36 (66.7)	
Leisure time	No	102	39 (38.2)	63 (61.8)	**1.4E^-4** (14.6)
	Yes	98	64 (65.3)	34 (34.7)	
Perceived financial stress	No	90	63 (70)	27 (30)	**2E^-6** (22.4)
	Yes	110	40 (36.4)	70 (63.6)	
Caring hours	<8 hours	188	101 (53.7)	87 (46.3)	**0.013** (6.2)
	>=8 hours	12	2 (16.7)	10 (83.3)	
Type of transportation	Public	115	51 (44.3)	64 (55.7)	**0.019** (5.5)
	Private	85	52 (61.2)	33 (38.8)	
Gender of the patient	Male	124	71 (57.3)	53 (42.7)	**0.037** (4.3)
	Female	76	32 (42.1)	44 (57.9)	

3.8 Multi Variate Analysis of Caregiver Burden with Characteristics of Caregivers

All the independent variables which were found to have significant association with the outcome variables in univariate analysis (p value≤0.05) were included in the logistic regression analysis. Table 3.9 shows the results of association of the independent variables with level of caregiver burden. The caregivers without leisure time [AOR=3.1 (95% CI: 1.8-6.7)], monthly income of less than ₹20000 [AOR= 2.1 (95% CI: 1.1-4.5)] and perceived financial stress [AOR= 2.3 (95% CI: 1.2-4.5)] had an increased odds of having higher caregiver burden. We also found that the caregivers who had two comorbidities [AOR=3.6 (95% CI: 1.4-9.2)] had an increased odds of having higher caregiver burden. Importantly, caregivers with more than three comorbidities [AOR= 4 .0 (95% CI: 1.6-9.9)] had four times increased odds of caregiver burden compared to those without any comorbidities.

Table 3.9: Factors associated with level of caregiver burden

Variables	**Category**	**P value**	**Crude odds ratio (95% CI)**	**Adjusted odds ratio (95% CI)**	**P value**
Leisure time	Yes	Reference		Reference	
	No	**9E^-7**	3.9 (2.1-7.0)	3.4(1.8-6.7)	**2.3E^-4**
Income range	>=20001	Reference		Reference	
	<=20000	**0.003**	2.6 (1.4-4.8)	2.1 (1.1-4.5)	**0.046**
No. of comorbidities	No comorbidities	Reference		Reference	
	1 comorbidity	**0.012**	2.7 (1.25-6.1)	1.8 (0.74-4.4)	0.197
	2 comorbidities	**0.001**	4.1 (1.7-9.7)	3.6 (1.4-9.2)	**0.009**
	3 or more comorbidities	**3.4E^-5**	4.4 (1.9-9.8)	4 (1.6-9.9)	**0.002**
Perceived financial stress	No	Reference		Reference	
	Yes	**1.7E^-5**	3.6 (2.0-6.6)	2.3 (1.2-4.5)	**0.017**
Caring hours	<8 hours	Reference		Reference	
	>=8 hours	**0.040**	8.7 (1.1-68.7)	8 (0.75-8.5)	0.085

3.9 Association of Independent Variables with the Physical Domain of WHO QoL BREF

All the independent variables which were found to have significant association with each domain were included in the logistic regression analysis. Table 3.10 shows the results of association of the independent variables with physical domain of WHO QoL BREF. The caregivers who had caregiving duties of more than eight hours [AOR=6.4 (95% CI: 1.1-36.7)] and increased number of comorbidities [AOR=12.1(95% CI: 4.2-34.8)], [AOR=11.1 (95% CI: 4.0-30)] had an increased odds of having poor physical quality of life.

Table 3.10: Factors associated with the physical domain of WHO QoL BREF scale

Variables	**Category**	**P value**	**Crude odds ratio (95% CI)**	**Adjusted odds ratio (95% CI)**	**P value**
Leisure time	Yes	Reference		Reference	
	Not enough time	**0.016**	2 (1.1-3.5)	1.7 (0.9-3.2)	0.105
No of comorbidities	No comorbidities	Reference			
	One comorbidity	**5.9E^-7**	7.3 (2.8-19.2)	6.9 (2.5-19)	**1.7E^-4**
	Two comorbidities	**1E^-6**	21.1 (4.4-33.3)	12.1 (4.2-34.8)	**3E^-6**
	Three or more comorbidities	**2E^-6**	10.6 (4-27.7)	11.1 (4-30)	**2E^-6**
Caring hours	<8hours	Reference			
	>=8hours	**0.019**	6.3 (1.3-29.7)	6.4 (1.1-36.7)	**0.037**

3.10 Association of Independent Variables with the Psychological Domain of WHO QoL BREF

Table 3. 11 shows the results of association of the independent variables with psychological domain of WHO QoL BREF. The caregivers with no leisure time [AOR=2.8 (95% CI: 1.4-5.6)], monthly income of less than 20,000 [AOR=3.6 (95% CI: 1.6-8.3)]), increased number of comorbidities [AOR=3.7 (95% CI: 1.4-9.9)], [AOR=4.6(95% CI: 1.6-12.8)], [AOR=3.6(95% CI: 2.0-6.5)], and caregiving duties exceeding 8 hours [AOR=6.8(95% CI: 1.0-43.3)] had an increased odds of poor psychological quality of life.

Table 3.11: Factors associated with psychological domain of WHO QoL BREF

Variable	Category	P value	Crude odds ratio (95% CI)	Adjusted odds ratio (95% CI)	P value
Leisure time	Yes	Reference		Reference	
	No	**2.4E^-5**	3 (1.7-5.3)	2.8 (1.4-5.6)	**0.003**
Income range	>20000	Reference		Reference	
	<=20000	**3E^-4**	3.4 (1.7-6.7)	3.6 (1.6-8.3)	**0.002**
No of comorbidities	No comorbidity	Reference		Reference	
	One comorbidity	**9E^-5**	5 (2-12.4)	3.7 (1.4-9.9)	**0.009**
	Two comorbidities	**0.0001**	5 (2-12.8)	4.6 (1.6-12.8)	**0.004**
	Three or more comorbidities	**2E^-6**	9.2 (3.7-22.8)	3.6 (2.0-6.5)	**6E^-6**
Perceived financial stress	No	Reference			
	Yes	**0.001**	2.6 (1.5-4.7)	1.3 (0.62-2.3)	0.502
Caring hours	<8hours	Reference			
	>=8hours	**0.015**	6.7 (1.4-31.7)	6.8 (1.0-43.3)	**0.044**

3.11 Association of Independent Variables with the social Domain of WHO QoL BREF

Table 3.12 lists the results of association of the independent variables with social domain of WHO QoL BREF. The caregivers who were daughters had higher odds of poor social quality of life compared to the spouse [AOR-7.0 (95%CI-1.9-25.8)]. The caregivers with monthly income of less than ₹20,000 [AOR=2.8 (95% CI: 1.2-6.6)]), increased number of comorbidities [AOR=3.3(95%CI:1.3-8.6)] and caregiving duties exceeding 8 hours [AOR=6.7(95% CI: 1.3-35.4)] had an increased odds of poor social quality of life.

Table 3.12: Factors associated with social domain of WHO QoL BREF

Variable	**Category**	**P value**	**Crude odds ratio (95% CI)**	**Adjusted odds ratio (95% CI)**	**P value**
Relation of the caregiver to the patient	Spouse	Reference		Reference	
	Mother	**0.007**	8.6 (1.8-40.6)	4.4 (0.87-21.7)	0.073
	Son	0.30	0.43 (0.88-2.1)	1.6 (0.28-9.6)	0.582
	Daughter	**0.01**	4.7 (1.4-15.5)	7 (1.9-25.8)	**0.004**
	Siblings	0.307	0.25 (0.42-16)	4 (0.58-27.2)	0.159
Income range	>=20001	Reference		Reference	
	<=20000	**3.1E^-4**	3.6 (1.8-7.2)	2.8 (1.2-6.6)	**0.019**
Leisure time	Yes	Reference		Reference	
	No	**0.006**	2.2 (1.3-4)	1.8 (0.91-3.6)	0.086
No of comorbidities	No	Reference		Reference	
	One	0.130	1.8 (0.83-4.2)	1.4 (0.52-3.6)	0.515
	Two	0.384	1.5 (0.62-3.4)	1.4 (0.5-4)	0.529
	Three or more	**0.012**	2.8 (1.2-6)	3.3 (1.3-8.6)	**0.016**
Perceived financial stress	No	Reference		Reference	
	Yes	**4.4E^-4**	2.9 (1.6-5.3)	1.9 (0.91-3.8)	0.090
Caring hours	<8 hours	Reference		Reference	
	>=8 hours	**0.009**	7.9 (1.7-3.7)	6.7 (1.3-35.4)	**0.026**

3.12 Association of Independent Variables with the Environmental Domain of WHO QoL BREF

Table 3.13 represents the association of independent variables with environmental domain of WHO QoL BREF. The caregivers who had monthly income of less than ₹20,000 [AOR-3.9(95% CI (1.6-9.2)], no leisure time [AOR-3.0(95% CI-1.5-6.1)], used public transport for traveling to dialysis center [AOR-2(95% CI-0.98-4.2)], with perceived financial stress [AOR-2.0(95% CI-1.0-4.2)], increased caring hours of more than 8 hours [AOR-8.6(95% CI-(1.0-7.0) had higher odds of poor environmental quality of life.

Table 3.13: Factors associated with the environmental domain of WHO QOL BREF

Variable	**Category**	**P value**	**Crude odds ratio (95% CI)**	**Adjusted odds ratio (95% CI)**	**P value**
Income range	=<20001	Reference		Reference	
	<=20000	**8E^-6**	4.8 (2.4-9.5)	3.9 (1.6-9.2)	**0.002**
Leisure time	Yes	Reference		Reference	
	No	**1.6E^-4**	3.0 (1.7-5.4)	3.0(1.5-6.1)	**0.002**
No of comorbidities	No	Reference		Reference	
	0ne	**0.007**	3.2 (1.4-7.5)	2.0 (0.8-5.5)	0.147
	Two	**3.1E^-4**	5.1 (2.1-12.5)	5.6 (1.9-16.2)	**0.002**
	Three or more	**8E^-6**	7.0 (3.0-16.4)	8.0 (2.9-22.4)	**5.6E^-5**
Perceived financial stress	No	Reference		Reference	
	Yes	**6.4E^-5**	4 (2.3-7.4)	2 .0(1.0-4.2)	**0.051**
Caring hours	<8 hours	Reference		Reference	
	>=8 hours	**0.026**	5.8 (1.2-27.2)	8.6 (1.0-7.0)	**0.044**
Type of transportation	Public	Reference		Reference	
	Private	**0.019**	2.0 (1.1-3.5)	2.0 (0.98-4.2)	**0.050**
Gender of the patient	Male	Reference		Reference	
	Female	**0.038**	1.8 (1.0-3.2)	1.9 (0.90-4.0)	0.090

3.13 Association of Caregiver Burden with Quality of Life

The results of the association of level of caregiver burden with each domain of WHO QoL BREF scale is represented in Table 3.14. There was a significant association of caregiver burden with poor quality of life in each domain of WHO QoL BREF. The caregivers who had caregiver burden had an increased odds of poor physical [COR-9.4(95%CI-4.8-18.6)], psychological [COR-10.8 (95% CI-5.3-21.81)], social [COR-3.1(95% CI-1.7-5.7)] and environmental [COR-7.8 (95% CI-4.1-15.0)] of quality of life.

Table 3.14: Association of caregiver burden with each domain of WHO QoL BREF scale

Physical domain

Variable	**Category**	**N**	**Physical domain of WHO QoL BREF**		**P value ($\chi 2$)**	**COR (95%CI)**	**P value**
			Good (N)	Poor (N)			
Zarit burden	No burden	84	69 (82.1)	15 (17.9)	**4.8E^-12 (47.7)**		Reference
	Burden	116	38 (32.8)	78 (67.2)		**9.4 (4.8-18.6)**	**9.6E^-11**

Psychological domain

Variable	**Category**	**N**	**Physical domain of WHO QoL BREF**		**P value ($\chi 2$)**	**COR (95%CI)**	**P value**
			Good (N)	Poor (N)			
Zarit burden	No burden	84	71 (84.5)	13 (15.5)	**9.2E^-13 (51.0)**		Reference
	Burden	116	39 (33.6)	77 (66.4)		**10.8 (5.3-21.8)**	**4.0E^-11**

Social domain

Variable	Category	N	Physical domain of WHO QoL BREF		P value (χ2)	COR (95%CI)	P value
			Good (N)	Poor (N)			
Zarit burden	No burden	84	62 (73.8)	22 (26.2)	**1.9E^-4 (13.9)**		Reference
	Burden	116	55 (47.4)	61 (52.6)		**3.1 (1.7-5.7)**	**2.4E^-4**

Environmental domain

Variable	Category	N	Physical domain of WHO QoL BREF		P value (χ2)	COR (95%CI)	P value
			Good (N)	Poor (N)			
Zarit burden	No burden	84	66 (78.6)	18 (21.4)	**7.1E^-10 (42.4)**		Reference
	Burden	116	37 (31.9)	79 (68.1)		**7.8 (4.1-15.0)**	**5.9E^-10**

3.14 Physical Domain of WHO QoL BREF and Zarit Burden

Table 3.15 shows the result of multivariate analysis of caregiver burden and physical domain. The model with variables burden and increased number of comorbidities were selected as the best model (Hosmer and Lemeshow Test p-value =0.940). The caregivers with burden [AOR-7.9(95% CI-3.8-16.2)] and increased number of comorbidities [AOR-6.2(95% CI-2.2-17.8)], [AOR-9.5(95% CI-3.2-28.3)]. [AOR-7.7 (95% CI-2.7-21.9)] had increased odds of having poor physical quality of life.

Table 3.15: Results of multivariate analysis of Physical domain of WHO QoL BREF and Zarit burden

Variable	category	P value	Adjusted OR (95%CI)
Zarit burden	No burden	Reference	
	burden	**1.9E^-7**	7.9(3.8-16.2)
Number of comorbidities	No comorbidity	Reference	
	One comorbidity	**0.001**	6.2(2.2-17.8)
	Two comorbidities	**6.2E^-5**	9.5(3.2-28.3)
	Three or more comorbidity	**1.2E^-4**	7.7(2.7-21.9)

3.15 Psychological Domain of WHO QoL BREF and Zarit Burden

Table 3.16 shows the results of factors associated with burden and psychological domain. The final model was selected based on the Hosmer and Lemeshow Test p-value =0.843. The caregivers with burden [AOR-6.6(95% CI-3.0-14.3)], no leisure time [AOR-2.1 (95% CI-1.0-4.3)], with monthly income of less than ₹20,000[AOR-2.8 (95% CI-1.3-6.3)], and increased number of comorbidities [AOR-3.2(95% CI-1.2-9.0)], [AOR-3.1 (95% CI-1.1-8.9)], [AOR-6.8(95% CI-2.4-19.2)] had increased odds of having poor psychological quality of life.

Table 3.16: Results of multivariate analysis of psychological domain of WHO QoLBREF and Zarit burden

Variable	category	P value	Adjusted OR (95%CI)
Zarit burden	No burden	Reference	
	burden	**2.0E^-6**	6.6 (3.0-14.3)
Leisure time	Yes	Reference	
	No	**0.050**	2.1(1.0-4.3)
Number of comorbidities	No comorbidity	Reference	
	One comorbidity	**0.024**	3.2(1.2-9.0)
	Two comorbidities	**0.038**	3.1(1.1-8.9)
	Three or more comorbidity	**3.1E^-4**	6.8(2.4-19.2)
Income range	>=20001	Reference	
	<=20000	**0.012**	2.8(1.3-6.3)

3.16 Social Domain of WHO QoL BREF and Zarit Burden

In the final model of the social domain and Zarit burden, the factors such as burden of the care giver, low income range, number of comorbidities of the caregiver were associated with the poor social quality of life of the participants. The Hosmer and Lemeshow Test p-value of the final model =0.940. Table 3.17 shows the association of caregiver burden and social domain of WHO QOL BREF. The caregivers with burden [AOR-2.5(95% CI-1.3-4.7)] and monthly income of less than ₹20,000 [AOR-3.1(95% CI-1.5-6.3)], had increased odds of having poor social quality of life.

Table 3.17: Results of multivariate analysis of social domain of WHO QoL BREF and Zarit burden

Variable	**category**	**P value**	**Adjusted OR (95%CI)**
Zarit burden	No burden	Reference	
	burden	**0.007**	2.5(1.3-4.7)
Number of comorbidities	No comorbidity	Reference	
	One comorbidity	0.613	1.2(0.5-3.0)
	Two comorbidities	0.920	0.9(0.4-2.4)
	Three or more comorbidity	0.136	1.9(0.8-4.6)
Income range	>=20001	Reference	
	<=20000	**0.003**	3.1(1.5-6.3)

3.17 Environmental Domain of WHO QoL BREF and Zarit burden

The final model was selected based on the Hosmer and Lemeshow Test p-value =0.699. Table 3.18 shows the association of caregiver burden and environmental domain.

The caregivers with burden [AOR-4.3 (95% CI-2.1-8.8)], no leisure time [AOR-2.6 (95% CI-1.3-5.4)], with monthly income of less than ₹ 20,000[AOR-5.0(95% CI-2.2-11.3)], and increased number of comorbidities [AOR-3.7(95% CI-1.3-10.4)], [AOR-5.5(95% CI-2.0-12.5)] had increased odds of having poor environmental quality of life.

Table 3.18: Results of multivariate analysis of environmental domain of WHO QoL BREF and Zarit burden

Variable	**category**	**P value**	**Adjusted OR**
Zarit burden	No burden	Reference	
	burden	**9E^-5**	4.3(2.1-8.8)
Leisure time	Yes	Reference	
	No	**0.009**	2.6(1.3-5.4)
Number of comorbidities	No comorbidity	Reference	
	One comorbidity	0.214	1.8(0.7-4.9)
	Two comorbidities	**0.013**	3.7(1.3-10.4)
	Three or more comorbidity	**0.001**	5.5(2.0-12.5.)
Income range	>=20001	Reference	
	<=20000	**1.3E^-4**	5.0(2.2-11.3)

CHAPTER 4

DISCUSSION AND CONCLUSION

The present cross-sectional tertiary care hospital-based research was designed to assess the caregiver burden and quality of life among the primary caregivers of HD. In doing so, we were able to determine the level of caregiver burden, quality of life and the factors associated with it.

4.1 Sociodemographic and health related characteristics of the caregivers

In our study majority of the caregivers were females, married, having low educational status, which was comparable with many other studies which has been discussed below.

Age and Gender of the Caregivers

The median age of the caregivers in our study is 55 years with range of 22-85 years of age and that of patient with median age of 61 years with range of 22-87 years. This result is similar to a study done in Iran (Mashayekhi et al., 2015). In our study majority of the caregivers were females (77.5%). This finding is similar to many other studies conducted on the caregivers of HD patients irrespective of the region of the studies. The study conducted in Iran on the assessment of caregiver burden showed 68.6 percent of the caregivers were females (Mashayekhi et al., 2015) and in another study done in China (Zhang et al., 2020), majority (64%) were female caregivers. Also a study in Saudi Arabia, female caregivers were higher than male caregivers (70%) (Bayoumi, 2014).

This may be due to the gender norms existing in the society that females are more engaged with household and caring responsibilities of the family. It also may be due to the fact that majority of the patients in our study were males.

Marital and Relationship status

In the present study 93.5 percent of the caregivers were married and 77.5percent of them were spouses. Similar findings can also see in various studies. One of the studies in Nepal showed among the caregivers 75.6 percent were married and 70.9 percent were spouses of the patient(Shakya et al., 2017). The study in China revealed 90.7 percent of the caregivers were married and most of the caregivers were parents and spouses (Zhang et al., 2020). The study in Turkey showed 80.3 percent of female caregivers, 74.5 percent of the caregivers were married and 65 percent were spouses(Mollaoğlu et al., 2013).

In the Indian context, the study done in Lucknow showed majority of the caregivers were males (61.7%) and most of them were son /daughters (36.6%) (Peter, 2021). Similar was the findings of other studies in Uttarakhand and Sikkim in which majority of the caregivers were males 75 percent and 56.9 percent respectively Also most of the caregivers were son/ daughter (40%) in Uttarakhand study (Sharma et al., 2021), (Joseph et al., 2021)

Educational status and Income

In the current study, about 50 percent of the caregivers had higher secondary or more level of education and also 70 percent of the caregivers were with low monthly income of less than ₹20000. Similar findings were observed in a study in Sikkim. About 90 percent of the caregivers had higher secondary and above level of education and majority come under lower middle-income category (80.4%) (Joseph et al., 2021). In the study from Lucknow showed 61.7 percent come under monthly income of below 5000(Peter, 2021). The low monthly income may be the reason for the perceived financial stress among the caregivers and also the dependence on external financial resources in the present study.

The present study reported that majority (73.5%)of the caregivers had presence of comorbidities which is inconsistent with the findings of Mollaoğlu in which 70.5 percent of caregivers had no health issues (Mollaoğlu et al., 2013).

Patient Characteristics

In our study majority of the patients were males (62%). More than half of the patients undergoing the treatment for more than 2 years. Majority (72%) of the patients had weekly

2 sessions of dialysis. About 53.5 percent of the patients were depending on their caregivers for daily activities. These findings were similar to the findings of Shakya et al, in which majority of the patients(74.4%) had 2 sessions of weekly dialysis and undergoing dialysis for more than 2 years with mean duration of 14 months(Shakya et al., 2017). Also in the study of Alnazly, 65 percent of the patients were males and the mean duration of disease was 4.3 years (Alnazly, 2016).

4.2 Caregiver Burden

The level of caregiver burden was assessed by Zarit burden interview scale. Cronbach's alpha test was done to know the internal consistency of the tool, It is a standardized and pretested tool (Seng et al., 2010)**.**It has been used in India in assessing caregiver burden in various contexts (Rawat et al., 2017)**.** The present study showed mild to moderate level of caregiver burden among the caregivers. This finding is consistent with many other studies. Comparable findings were seen in the study conducted by Joy et al. (2019), in Kerala and studies conducted in Lucknow and Sikkim as well (Joseph et al., 2021), (Peter, 2021). In contrast with this result various studies revealed moderate to severe level of caregiver burden (Mashayekhi et al., 2015), (Jafari et al., 2018), (Abbasi et al., 2011)). These disparities in the result may be due to the socio-cultural differences in the study settings of the regions. In our study setting most of the caregivers felt a sense of responsibility to care for their loved ones rather than feeling burdened and did so willingly.

Many factors such as low socio-economic conditions, caregivers with comorbidities, no leisure time showed significant association with higher level of burden in our study. The caregivers who had low-income levels and thus were unable to meet the health care needs, were burdened with financial stress leading to higher caregiver burden. These findings were similar to the studies done by (Cagan et al., 2018)**,** (Alnazly, 2016) and (Abbasi et al., 2011) which showed caregivers with poor economic status were more vulnerable to have burden of caregiving. The caregivers with increased number of comorbidities are more prone to develop caregiver burden in this study. This may due to the fact that increased responsibility of caregiving , decreases the time available to cater to their health needs which is comparable with the findings of study conducted in Iran and China which revealed caregiver burden was considerably increased in caregivers with more than two comorbidities. (Zhang et al., 2020, Jafari et al., 2018).

The current study did not show any significant association with variables like gender of the caregivers, marital status, relation with the patient, educational status, occupational status and patient characteristics. However, the burden was more in female caregivers, those who were married, mothers followed by spouses and who had low educational status which is similar to the studies conducted in Lucknow (Peter, 2021)

In this study, caregiver burden score was more in caregivers who were working in public sectors and those who were skilled workers. This may be due to the work pressure along with the caregiver duties. This finding was inconsistent with the findings of (Joseph et al., 2021), (Peter, 2021), (Cagan et al., 2018) in which the level of burden was less with an income generating job.

Also higher education was associated with lesser caregiver burden in various studies (Jafari et al., 2018, (Zhang et al., 2020), (Joseph et al., 2021)), which is similar to the findings of the present study. Higher level of education may help to become aware of the disease and its complications, helps in increased access to information about health facilities thus helping to cope up with the burden of caregiving. In contrast to this,, the study by Mollaoğlu et al., 2013,showed higher education level was associated with increased burden. It may due to the stress of being aware of the complications of the disease.

In this study higher burden score was observed in mothers, spouses and children which was supported by the findings of other studies((Zhang et al., 2020), Jafari et al., 2018).It may be due to the existing cultural norms of our society such that the caring of a sick member is primarily by their family members. Also, the burden score was more in widowed and married caregivers which is similar to the study conducted by (Joseph et al., 2021).In contrast, the findings of Mollaoğlu et al., 2013,showed more burden in relatives of the patients other than family members and the caregivers who were unmarried. This difference in findings may be due to the difference in the study settings.

In the present study, the burden score is more with the increased duration of caregiving and time spent for caregiving per day but doesn't show significant association. But in other studies, showed significant association of burden score with the increased duration of caregiving and time spent for caregiving per day ((Zhang et al., 2020)and (Joy et al., 2019)). In the studies of (Cagan et al., 2018)and (Usman Shah et al., 2017) described a considerable association of level caregiver burden with the dependency of the patients on their daily activities, which is similar to the current study. This may be due to the increased work load experienced by the caregivers. Patient with increased capability of self-care resulted in lesser caregiver burden (Jafari et al., 2018). Long hours of caring per day along with poor health conditions of the caregivers of dependent patients resulted may increases the burden

4.3 Quality of life of the caregivers

In this study quality of life of the caregivers were assessed using WHO QoL BREF scale. It is a positively rated questionnaire assessing the quality of life in different domains of health. The translated Malayalam version of the tool was used in this study. It is a reliable tool and shows good internal consistency in this study (Sreedevi et al., 2016).

The quality of life of the caregivers were assessed through four domains of health such as physical, psychological, social and environmental. In our study we observed a significant reduction in the quality of life with an increase in care burden among the primary caregivers of hemodialysis patients in each domain of health. Along with higher burden score the factors such low economic status, increased hours of caring and increased number of comorbidities are associated with poor quality of life of the caregivers .These findings were supported by the findings of(Sharma et al., 2021).which revealed that caring and being with patient for most of the time resulted in poor health and quality of life. Abbasi in his study showed a negative association with the quality of life of the caregivers and the caregiver burden(Abbasi et al., 2011).The study conducted in Iran also revealed significant and inverse association of quality of life and caregiver burden (Jafari et al., 2018).

Belasco and Sesso reported that the quality of life of caregivers of hemodialysis (HD) patients was highly affected by the higher caregiver burden .The caregivers of most dependent patients ,increased hours of caring, long duration of treatment had higher caregiver burden. Caregiving may influence their physical and psychological wellbeing, resulted in feeling of exhaustion and stress which in turn affect their quality of life. The findings also revealed that increased care giver burden influences the quality of the care they provide as well as their quality of life both physically and psychologically. (Belasco et al., 2006, (Mollaoğlu et al., 2013).The findings of our study are also in accordance with this observation. According to the study of (Alvarez-Ude et al., 2004) the caregivers of HD showed considerable decrease in their energy level ,physical and mental health resulting in poor quality of life.

4.4 Strength and Limitations:

The study was conducted in 200 primary caregivers of hemodialysis patients attending tertiary care centers and tried to include adequate representation of the caregivers from both public and private sectors. The strength of our study is that it found out the level of caregiver burden and associated factors and its influence in the quality of life of the caregivers. To the best of our knowledge, there are no previous studies conducted in Kerala on the caregiver burden and quality of life among the primary caregivers of hemodialysis patients.

One of the limitations of our study is that it was a cross sectional study so that the causality cannot be established. In addition, the emotional status of the caregivers at the time of interview may have influenced the response, leading to information bias.

4.5 Conclusion

Our research observations suggested that caregiver burden is a reality among caregivers of hemodialysis patients. Caregivers have to sacrifice a lot during the care giving procedure. They undergo a tremendous amount of physical, psychological, social and economic stress, which is directly dependent on the severity of the disease. Women caregivers, especially spouses, are burdened of caregiver burden. In addition to this, they have to suffer from various comorbidities in addition to the care giving process. Bearing in mind that caregiver burden influences the quality of life of caregivers and quality of care they provide in a negative pattern, strict attention must be paid to the requirements of caregivers and they should be bestowed with adequate social, economic, physical and psychological support. Proper governmental and non-governmental assistance must be ensured at the required time for their well-being.

4.6 Public Health Relevance:

In Kerala there are no programmes to address the caregiver burden of primary caregivers of hemodialysis patients. There is an urgent need to develop healthcare interventions to improve the quality of life of the primary caregivers and reduce their level of burden. The issue of caregiver's burden seems to have escaped the attention of policy makers, primarily because of the lack of robust data on the caregiver burden in the State.

4.7 Recommendations:

Assessment of caregiver burden: With the involvement of the local self-government, the caregivers should be assessed once in 3 months about their conditions. Proper training and counselling should be provided by experts.

Provide respite care: Respite care means taking a break from caring, while the person you care for is looked after by someone else. It is useful for caregivers to get a few hours of their own and helps to reduce exhaustion and burnout. There are many options for respite care like providing manpower for assisting the patients for the procedure once in a week, arranging transportation facilities for the patients in a ward to the nearby tertiary care centers and also providing homecare facilities by trained staffs with the support of local self-governments.

Provide carer allowance: Implement health care plans to provide caregiver allowance to the caregivers of mostly dependent patients and those who have no other sources of income

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Annexure I
Participant information sheet (English)

Dear Sir/Madam,

Namaskaram, I am Afina Azeez, studying Masters of public health (MPH) at the Achutha Menon Center for Health Science Studies, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram. As a part of the course requirement, I am conducting a hospital-based study titled "Caregiver's burden and quality of life among the primary caregivers of hemodialysis patients at tertiary care centers in Thiruvananthapuram". I am contacting you to kindly participate in this research study. This information sheet and consent form may contain terms and information that you may not follow. Please feel free to ask me if any term/s or information is not clear.

Purpose of the study

Frequent hospitalizations of the patients and factors associated with the disease can lead to the reduction of caregiver's quality of life. Therefore, the evaluation of caregiver's burden and determination of their quality of life is very important.

Procedure

I would like to collect the data through an interview schedule that will take about 30 -60 minutes of your valuable time. You will be asked questions related to social, economic status and lifestyle. Questions inquiring about history of any chronic illness like diabetes, hypertension, depression etc. will also be asked. There will be questions about your response towards your caregiving duties and to assess your mental well-being.

Why have you been invited?

You are invited for this study since you fulfil the inclusion criteria defined for this study.

Voluntary participation

In this study, your participation is purely voluntary. You are free to take your own time to answer the question and if you are not willing, you can ask me to skip the question. You have the complete right to withdraw your participation from the study at any time during the interview.

Possible disadvantages and risks of taking part

Participation in the study imposes no risk to your health. One of the rare risks may be loss of confidentiality. We have taken measures to minimize the risks. You will be asked questions which you may find personal in nature such as questions about your behavior, disease/s you are suffering from and your feelings towards your caregiving duties.

Possible benefits of taking part

Though there might not be direct benefit for you from this study, the information you share will be useful for making possible interventions that would be supportive for caregivers of Hemodialysis patients in future. I assure you that all information that you will be sharing with me will be highly confidential and only used for research and publication purposes.

For any clarification regarding the study, you can contact me and for any queries on the authentication of this study, you can contact the Member Secretary, Institutional Ethics Committee (IEC) of SCTIMST.

Cost and financial benefit

There will be no costs to participate in this study and will not be paid for your participation in this study.

Confidentiality

All information related to you will be kept confidential and at no stage, your identity will be revealed. A respondent identification number will be assigned to each participant that will help to maintain the strict confidentiality of the data collected. Access to respondent identification number will be restricted to those analysing the data only. Participant confidentiality will be safe guarded during and after the study.

Results of the research study

Results will be published in Dspace SCTIMST. At no point, individual data will be published.

Contact information

If you have any research related questions you may contact me. If you would like to verify my credentials, member secretary of our institute's ethics committee may be contacted. Our addresses are as follows:

Dr. Afina Azeez
E-Code: 7818
MPH student, AMCHSS,
SCTIMST, Thiruvananthapuram
Ph: 9496238190
Email:afinazeez214@gmail.com

Dr. Srinivasa Gopala
Member secretary
Institutional Ethics Committee (IEC)
SCTIMST, Thiruvananthapuram
Ph:0471-2524689
Email: iec.mem.sec@sctimst.ac.in

Annexure II
Informed consent form (English)

INFORMED CONSENT FORM

I____have read/been read out the information in the information sheet. The nature of the study and my involvement has been explained and all my questions have been answered satisfactorily. By signing/ putting thumb impression, I confirm that I understand what will be expected of me and that I am willing to participate in this study. I understand that participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason. I understand that my identity will not be revealed in any information released to third parties or during publishing of data. I have been informed who should be contacted if the need arises. I have been given a copy of the information sheet and consent form for my record.

Place:

Date:

Signature of the participant:

Signature of the researcher:

Annexure III

Interview schedule (English)

Section A

Type of the hospital: Government/Private/others			
--			
Date of interview:			
Time of interview:			
Sl.No.	**ITEM**	**RESPONSE**	**REMARKS**
SOCIODEMOGRAPHIC DETAILS			
1	What was your age at your last birthday?	-----------------------	
2	You identify yourself with which gender?	1)Male 2) Female 3) Transgender	
3	What is your Religion?	1)Hindu 2) Muslim 3)Christian 4)Others : specify ---------------------------------	
4	What is the highest education you have received?	1)No formal education 2)Did not complete primary education 3)Primary school level (1 – 7th std) 4)High school level(8 -10 th std) 5)Higher secondary level(11- 12th std) 6)Graduate level 7)Post graduate level and above 8)Others Specify --------------------------------	
5	Are you currently married?	1)Never married 2) Married/cohabiting 3) Separated/Divorced 4) Widowed	
6	Are you currently employed?	1)Home maker 2) Working in govt sector 3) Working in private sector 4) Self-employed/Business 5) Coolie 6) Student 7) Unemployed (Able to work) 8) Unemployed (Unable to work) 9) Others: specify --	
7	What is the nature of the Job?	1)Part time 2)Full time	

8	How is the patient related to you?	1)Spouse 2) Father 3) Mother 4) son 5)Daughter 6)Siblings 7)Any other Relative :Specify ------------------------------------	
9	How many members are there in your family?	----------	
10	No of Children	----------	
11	Do you have enough leisure time?	1)Yes 2)No	
12	What sort of leisure activities do you have?		
13	Are you suffering from any of the mentioned disease/diseases?	1)Hypertension 2) Diabetes mellitus 3) Arthritis 4) Cardio Vascular Diseases 5) Mental health problems 6) Respiratory Problems 7)Don’t know/Not known. 8) Others: specify ---------------------------------	
SOCIOECONOMIC DETAILS			
14	What is the type of Ration card you have?	1)Yellow card 2) Pink card 3) Blue card 4) White card 5) No card	
15	What is the approximate monthly income of your family in the previous month (in Rupees)?	1)Below Rs. 5000 2) Rs. 5001 -10 000 3) Rs.10001-20000 4) Rs.20001-30000 5) Above Rs, 30 000	
16	Are you worried about raising money for treatment expenses?	1)No 2) Yes	
17	How do you meet the treatment expenses for Hemodialysis?		
18	Are you enrolled/utilizing any health insurance scheme?	1)No 2) Yes If yes, specify ---	

PATIENT TREATMENT RELATED DETAILS			
19	Age of the patient on his/her last birthday?	---------------------	
20	Sex of the patient?	1)Male 2) Female 3) Transgender	
21	How long are he/she is on Hemodialysis?	1)3 weeks – up to 6months 2)6months – upto12 months 3)1 – 2years 4)>2 years	
22	How many sessions of dialysis are there in a week?	-----------------------	
23	What was the duration of dialysis you have spent with the patient in the last session? (In hours)	-----------------------	
24	What is the average duration of time spent for caregiving (In hours)	-----------------------	
25	Do you have any wage loss by caregiving the patient?		
TRANSPORTATION DETAILS			
26	Place of residence	1)Rural 2) Urban Name of the place --	
27	What is the approximate distance of hospital from your house?	1)Less than 1 Km 2) Within 2 -5 Km 3) More than 5 Km	
28	How do you visit the hospital?	1)Using public transport 2) Using private transport 3) Vehicle from charitable trust 4) Others: Specify --	
PATIENT RELATED ACTIVITIES			
29	ACTIVITIES	RESPONSE	REMARKS
1	Eating and drinking	1) Dependent 2) Independent	
2	Bathing	1) Dependent 2) Independent	

3	Dressing	1) Dependent 2) Independent	
4	Urinating and defecating	1) Dependent 2) Independent	
5	Walking	1) Dependent 2) Independent	
6	Climbing stairs	1) Dependent 2) Independent	
7	Shopping	1) Dependent 2) Independent	
8	Cooking	1) Dependent 2) Independent	
9	Housekeeping	1) Dependent 2) Independent	

Section B

THE ZARIT BURDEN INTERVIEW

Zarit Burden Interview will be used for assessing caregiver's perceived burden. It is one of the most commonly used burden measures and has been validated in many culturally or ethnically different populations. The revised version contains 22 items. Each item is scored using a 5-point scale. Response options range from 0 (never) to 4 (nearly always). More the score, greater is the burden perceived. The Malayalam version of the tool will used in this study was shared by Dr. Jomon Joy, Associate professor of psychiatry, SUT academy of medical science (Joy et.al 2019).

THE ZARIT BURDEN INTERVIEW

Please circle the response the best describes how you feel.

	Never	Rarely	Sometimes	Quite Frequently	Nearly Always	Score
1. Do you feel that your relative asks for more help than he/she needs?	0	1	2	3	4	
2. Do you feel that because of the time you spend with your relative that you do not have enough time for yourself?	0	1	2	3	4	
3. Do you feel stressed between caring for your relative and trying to meet other responsibilities for your family or work?	0	1	2	3	4	
4. Do you feel embarrassed over your relative's behaviour?	0	1	2	3	4	
5. Do you feel angry when you are around your relative?	0	1	2	3	4	
6. Do you feel that your relative currently affects our relationships with other family members or friends in a negative way?	0	1	2	3	4	

7. Are you afraid what the future holds for your relative?	0	1	2	3	4	
8. Do you feel your relative is dependent on you?	0	1	2	3	4	
9. Do you feel strained when you are around your relative?	0	1	2	3	4	
10. Do you feel your health has suffered because of your involvement with your relative?	0	1	2	3	4	
11. Do you feel that you do not have as much privacy as you would like because of your relative? -	0	1	2	3	4	
12. Do you feel that your social life has suffered because you are caring for your relative?	0	1	2	3	4	
13. Do you feel uncomfortable about having friends over because of your relative?	0	1	2	3	4	
14. Do you feel that your relative seems to expect you to take care of him/her as if you were the only one, he/she could depend on?	0	1	2	3	4	
15. Do you feel that you do not have enough money to take care of your relative in addition to the rest of your expenses?	0	1	2	3	4	
16. Do you feel that you will be unable to take care of your relative much longer?	0	1	2	3	4	
17. Do you feel you have lost control of your life since your relative's illness?	0	1	2	3	4	

18. Do you wish you could leave the care of your relative to someone else?	0	1	2	3	4	
19. Do you feel uncertain about what to do about your relative?	0	1	2	3	4	
20. Do you feel you should be doing more for your relative?	0	1	2	3	4	
21. Do you feel you could do a better job in caring for your relative?	0	1	2	3	4	
22. Overall, how burdened do you feeling caring for your relative?	0	1	2	3	4	
Total Score (out of 88)						

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Interpretation of Score:
0 - 21 little or no burden
21 - 40 mild to moderate burden
41 - 60 moderate to severe burden
61 - 88 severe burden

Score values and interpretation are guidelines only, as discussed in:
Hebert R, Bravo G, and Preville M (2000). Canadian J Aging 19: 494-507.

Section C

Quality of life assessing scale (WHOQOL -BREF)

The WHOQOL –BREF, a shorter form of the WHOQOL-100 will be used for assessing the quality of life among the primary caregivers of the individuals undergoing dialysis. It consists of four domains of QOL, namely physical, psychological, social, and environment. Items on this measure are scored on a 5-point Likert scale. The scores range from 1(low) to 5(high) with increasing scores from 1 to5 denoting higher QOL.

The raw domain scores obtained from the WHOQOL- BREF were transformed to a 4-20 score and then scaled in a positive direction (higher scores denote higher quality of life). The mean score within each domain is used to calculate the domain and these are linearly transformed to 1-100 scale. The Malayalam version of this tool is used in this study after seeking permission from the translated author (Sreedevi et al., 2016).

QUALITY OF LIFE ASSESSING SCALE (WHO QOL –BREF)

Please read each question, assess your feelings, and circle the number on the scale for each question that gives the best answer for you

		Very poor	poor	Neither poor nor good	Good	Very good
1(G1)	How would you rate your quality of life?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
2 (G4)	How satisfied are you with your health?	1	2	3	4	5

The following questions ask about how much you have experienced certain things in the last two week

		Not at all	A little	A moderate amount	Very much	An extreme amount
3 (F1.4)	To what extent do you feel that physical pain prevents you from doing what you need to do?	1	2	3	4	5
4 (F11.3)	How much do you need any medical treatment to function in your daily life?	1	2	3	4	5
5 (F4.1)	How much do you enjoy life?	1	2	3	4	5

6 (F24.2)	To what extent do you feel your life to be meaningful?	1	2	3	4	5

		Not at all	A little	A moderate amount	Very much	Extremley
7 (F5.3)	How well are you able to concentrate?	1	2	3	4	5
8 (F16.1)	How safe do you feel in your daily life?	1	2	3	4	5
9 (F22.1)	How healthy is your physical environment?	1	2	3	4	5

The following questions ask about how completely you experience or were able to do certain things in the last two weeks.

		Not at all	A little	Moderately	Mostly	Completely
10 (F2.1)	Do you have enough energy for everyday life?	1	2	3	4	5
11 (F7.1)	Are you able to accept your bodily appearance?	1	2	3	4	5
12 (F18.1)	Have you enough money to meet your needs?	1	2	3	4	5
13 (F20.1)	How available to you is the information that you need in your day-to-day life?	1	2	3	4	5
14 (F21.1)	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5

		Very poor	Poor	Neither poor nor good	Good	Very good
15 (F9.1)	How well are you able to get around?	1	2	3	4	5

The following questions ask you to say how good or satisfied you have felt about various aspects of your life over the last two weeks.

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied

16 (F3.3)	How satisfied are you with your sleep?	1	2	3	4	5
17 (F10.3)	How satisfied are you with your ability to perform your daily living activities?	1	2	3	4	5
18(F12.4)	How satisfied are you with your capacity for work?	1	2	3	4	5
19 (F6.3)	How satisfied are you with yourself?	1	2	3	4	5
20(F13.3)	How satisfied are you with your personal relationships?	1	2	3	4	5
21(F15.3)	How satisfied are you with your sex life?	1	2	3	4	5
22(F14.4)	How satisfied are you with the support you get from your friends?	1	2	3	4	5
23(F17.3)	How satisfied are you with the conditions of your living place?	1	2	3	4	5
24(F19.3)	How satisfied are you with your access to health services?	1	2	3	4	5
25(F23.3)	How satisfied are you with your transport?	1	2	3	4	5

The following question refers to how often you have felt or experienced certain things in the last two weeks

		Never	Seldom	Quite often	Very often	Always
26 (F8.1)	How often do you have negative feelings such as blue mood, despair, anxiety, depression?	1	2	3	4	5

Did someone help you to fill out this form?
....

How long did it take to fill this form out?
....

Do you have any comments about the assessment………………………………………………………………………………….

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES & TECHNOLOGY • TRIVANDRUM

Annexure IV
Patient information sheet (Malayalam)

പങ്കെടുക്കുന്ന ആളിന്റെ അറിവിനുള്ള വിവരണ പത്രിക

നമസ്കാരം, ഞാൻ അഫീന അസീസ്, ശ്രീ ചിത്ര തിരുനാൾ ഇൻസ്റ്റിറ്റ്യൂട്ട് ഫോർ മെഡിക്കൽ സയൻസ് ആൻഡ് ടെക്നോളജി, അച്യുത മേനോൻ സെന്റർ ഫോർ ഹെൽത്ത് സയൻസ് സ്റ്റഡീസിൽ പൊതുജന ആരോഗ്യം എന്ന വിഷയത്തിൽ ബിരുദാനന്തര ബിരുദത്തിനു പഠിക്കുന്നു. അതിന്റെ ഭാഗമായി ഞാൻ “തിരുവനന്തപുരത്തെ തൃതീയ പരിചരണ കേന്ദ്രങ്ങളിൽ ഹീമോഡയാലിസിസ് രോഗികൾക്ക് പ്രാഥമിക പരിചരണം നൽകുന്നവരുടെ ബുന്ധിമുട്ടുകളും ജീവിത നിലവാരവും "എന്ന വിഷയത്തിൽ ഒരു പഠനം നടത്തുന്നു. ഈ ഗവേഷണ പഠനത്തിൽ പങ്കെടുക്കാൻ ഞാൻ താങ്കളെ ബന്ധപ്പെടുന്നു. ഈ വിവര ഷീറ്റിലും സമ്മത ഫോമിലും താങ്കൾ പാലിക്കാത്ത നിബന്ധനകളും വിവരങ്ങളും അടങ്ങിയിരിക്കാം. ഏതെങ്കിലും നിബന്ധനകൾ അല്ലെങ്കിൽ വിവരങ്ങൾ വ്യക്തമല്ലെങ്കിൽ എന്നോട് ചോദിക്കാൻ മടിക്കേണ്ടതില്ല

പഠനത്തിന്റെ ഉദ്ദേശം

രോഗികളെ പതിവായി ആശുപത്രിയിൽ പ്രവേശിപ്പിക്കുന്നതും രോഗവുമായി ബന്ധപ്പെട്ട ഘടകങ്ങളും പരിചരിക്കുന്നയാളുടെ ജീവിതനിലവാരം കുറയ്ക്കുന്നതിന് ഇടയാക്കും. അതിനാൽ, പരിചരിക്കുന്നയാളുടെ നിലയുടെ വിലയിരുത്തലും അവരുടെ ജീവിത നിലവാരം നിർണ്ണയിക്കലും അവരുടെ ആവശ്യങ്ങൾ നിർണ്ണയിക്കലും വളരെ പ്രധാനമാണ്.

നടപടിക്രമം

നിങ്ങളുടെ വിലപ്പെട്ട സമയത്തിന്റെ ഏകദേശം 30-60 മിനിറ്റ് എടുക്കുന്ന ഒരു അഭിമുഖത്തിലൂടെ വിവരങ്ങൾ ശേഖരിക്കാൻ ഞാൻ ആഗ്രഹിക്കുന്നു. സാമൂഹിക, സാമ്പത്തിക സ്ഥിതി, ജീവിതശൈലി എന്നിവയുമായി ബന്ധപ്പെട്ട ചോദ്യങ്ങൾ നിങ്ങളോട് ചോദിക്കും. പ്രമേഹം, രക്തസമ്മർദ്ദം, വിഷാദം തുടങ്ങിയ ഏതെങ്കിലും വിട്ടുമാറാത്ത രോഗങ്ങളുടെ ചരിത്രം അന്വേഷിക്കുന്ന ചോദ്യങ്ങളും ചോദിക്കും. നിങ്ങളുടെ പരിചരണ ചുമതലകളോടുള്ള നിങ്ങളുടെ പ്രതികരണത്തെക്കുറിച്ചും നിങ്ങളുടെ മാനസിക ക്ഷേമത്തെ വിലയിരുത്തുന്നതിനെ ക്കുറിച്ചും ചോദ്യങ്ങൾ ഉണ്ടാകും.

നിങ്ങളെ ക്ഷണിക്കുവാനുള്ള കാരണം

ഈ പഠനത്തിനായി നിർവചിച്ചിട്ടുള്ള മാനദണ്ഡങ്ങ ളിൽ താങ്കൾ ഉൾപ്പെടുന്നതിനാൽ ഈ പഠനത്തിനായി ക്ഷണിക്കുന്നു

സന്നദ്ധ പങ്കാളിത്തം

ഈ പഠനത്തിനായി നിങ്ങളുടെ പങ്കാളിത്തം പൂർണ്ണമായും സ്വമേധയാ ഉള്ളതാണ്. ചോദ്യങ്ങൾക്ക് ഉത്തരം പറയുവാൻ താങ്കൾക്ക് മതിയായ സമയം എടുക്കുവാനും ഏതെങ്കിലും ചോദ്യത്തിന് മറുപടി നൽകുവാൻ താല്പര്യം ഇല്ലെങ്കിൽ ചോദ്യം മാറ്റുവാനും പറയാവുന്നതാണ്. ഈ പഠനത്തിന്റെ ഏതൊരു ഘട്ടത്തിലും യാതൊരു വിശദീകരണവും നൽകാതെ തന്നെ താങ്കൾക്ക് പിന്മാറാവുന്നതാണ്.

പങ്കെടുക്കുന്നതിന്റെ ഭാഗമായുള്ള ദോഷങ്ങളും അപകടസാധ്യതകളും

പഠനത്തിൽ പങ്കെടുക്കുന്നത് നിങ്ങളുടെ ആരോഗ്യത്തിന് ഒരു അപകടവും ഉണ്ടാക്കുന്നില്ല. അപൂർവമായി ഉണ്ടാകുന്ന പ്രശ്നം രഹസ്യ സ്വഭാവം നഷ്ടപ്പെടൽ ആണ്. പക്ഷെ അത് സംഭവിക്കാതിരിക്കാനുള്ള നടപടികൾ ഞങ്ങൾ സ്വീകരിച്ചിട്ടുണ്ട്. എന്നിരുന്നാലും, താങ്കളോട് നിങ്ങളുടെ സ്വഭാവം, നിങ്ങൾ അനുഭവിക്കുന്ന രോഗം/രോഗങ്ങൾ, താങ്കളുടെ പരിചരണ ചുമതലകളോടുള്ള വികാരങ്ങൾ എന്നിവയെക്കുറിച്ചുള്ള ചോദ്യങ്ങൾ, ചോദിക്കും,

പങ്കെടുക്കുന്നതിന്റെ ഭാഗമായുള്ള നേട്ടങ്ങൾ

ഈ പഠനം മൂലം താങ്കൾക്ക് നേരിട്ട് പ്രയോജനമൊന്നുമില്ലെങ്കിലും നിങ്ങൾ പങ്കിടുന്ന വിവരങ്ങൾ ആരോഗ്യമേഖലയിൽ ഡയാലിസിസ് രോഗികളുടെ പരിചാരകരുടെ ബുന്ധിമുട്ടുകൾ അവരുടെ ജീവിതത്തെ എത്രമാത്രം പ്രതികൂലമായി ബാധിക്കുന്നത് കുറക്കുന്നതിന് ആവശ്യമായ നയ ശുപാർശകൾ ചെയ്യുന്നതിന് ഉപയോഗപ്രദമാകും. താങ്കൾ നൽകുന്ന വിവരങ്ങൾ ഗവേഷണാവശ്യത്തിനും പിന്നീടുള്ള ഫല പ്രസിദ്ധീകരണത്തിനും വേണ്ടി മാത്രമേ ഉപയോഗിക്കുകയുള്ളു എന്ന് ഞാൻ ഉറപ്പ് നൽകുന്നു. വ്യക്തിഗത വിവരങ്ങൾ രഹസ്യമായി തന്നെ സൂക്ഷിക്കുമെന്നും ഏതൊരു സാഹചര്യത്തിലും ആരുമായി പങ്കുവെക്കില്ലെന്നും ഉറപ്പുനൽകുന്നു.

പഠനത്തിന്റെ ചെലവും സാമ്പത്തിക നേട്ടവും

ഈ പഠനത്തിൽ പങ്കെടുക്കുന്നതിന് ചെലവുകളൊന്നും ഉണ്ടാകില്ല, ഈ പഠനത്തിൽ നിങ്ങളുടെ പങ്കാളിത്തത്തിന് പണം നൽകില്ല.

രഹസ്യസ്വഭാവം

നിങ്ങളുമായി ബന്ധപ്പെട്ട എല്ലാ വിവരങ്ങളും രഹസ്യമായി സൂക്ഷിക്കും, ഒരു ഘട്ടത്തിലും നിങ്ങളുടെ വ്യക്തിപരമായ വിവരങ്ങൾ വെളിപ്പെടുത്തില്ല. ശേഖരിക്കുന്ന വിവരങ്ങളുടെ കർശനമായ രഹസ്യാത്മകത നിലനിർത്താൻ സഹായിക്കുന്ന ഓരോ പങ്കാളിക്കും ഒരു തിരിച്ചറിയൽ നമ്പർ നൽകും. പ്രതികരിക്കുന്നവരുടെ തിരിച്ചറിയൽ നമ്പറിലേക്കുള്ള പ്രവേശനം വിവരങ്ങളുടെ വിശകലനം ചെയ്യുന്നവർക്ക് മാത്രമായി പരിമിതപ്പെടുത്തും. പഠന സമയത്തും ശേഷവും പങ്കെടുക്കുന്നവരുടെ രഹസ്യസ്വഭാവം സുരക്ഷിതമായിരിക്കും.

പഠനത്തിന്റെ ഫലങ്ങൾ

പഠനത്തിന്റെ ഫലങ്ങൾ Dspace SCTIMST-ൽ പ്രസിദ്ധീകരിക്കും. ഒരു ഘട്ടത്തിലും, വ്യക്തിഗത വിവരങ്ങൾ പ്രസിദ്ധീകരിക്കില്ല.

ബന്ധപ്പെടാനുള്ള വിവരങ്ങൾ

താങ്കൾക്ക് ഗവേഷണവുമായി ബന്ധപ്പെട്ട എന്തെങ്കിലും ചോദ്യങ്ങളുണ്ടെങ്കിൽ അല്ലെങ്കിൽ എന്റെ വിശ്വാസ്യത പരിശോധിക്കാൻ നിങ്ങൾ ആഗ്രഹിക്കുന്നുവെങ്കിൽ, ഇനിപ്പറയുന്ന വിലാസത്തിൽ നിങ്ങൾക്ക് എന്നെയോ ഞങ്ങളുടെ സ്ഥാപനത്തിലെ നീതി നിർവാഹക സമിതി (ഐ, ഇ, സി) സെക്രട്ടറിയുമായോ ബന്ധപ്പെടാം:

.

അഫീന അസീസ്
എം പി എച് വിദ്യാർത്ഥിനി
എ എം സി എച് സ് സ്
സ് സി ടി ഐ എം സ് ടി
തിരുവനന്തപുരം

ഫോൺ നമ്പർ: 9496238190
afinazeez214@gmail.com

ഡോ. ശ്രീനിവാസ ഗോപാല
മെമ്പർ സെക്രട്ടറി
നീതി നിർവാഹക സമിതി
സ് സി ടി ഐ എം സ് ടി
തിരുവനന്തപുരം

ഫോൺ നമ്പർ: 0471 2524689
iec.mem.sec@sctimst.ac.in.

Annexure V
Consent form (Malayalam)

സമ്മതപത്രം

ഞാൻ ....ഈ പഠനത്തിൽ പറഞ്ഞിരിക്കുന്ന കാര്യങ്ങൾ വായിച്ചു /കേട്ട് മനസിലാക്കി ഈ പഠനത്തിലുള്ള എന്റെ സ്വമേധയായ പങ്കാളിത്തം ഞാൻ ഒപ്പു പതിപ്പിച്ച് ഉറപ്പാക്കുന്നു. എനിക്ക് ഈ പഠനത്തിന്റെ ഏതൊരു ഘട്ടത്തിലും യാതൊരു വിശദീകരണവും നൽകാതെ തന്നെ പിന്മാറാമെന്നും ഞാൻ നൽകുന്ന വിവരങ്ങൾ രഹസ്യമായിത്തന്നെ സൂക്ഷിക്കുമെന്നും മനസിലായി. ഈ പഠനത്തിന്റെ സംശയങ്ങൾക്ക് ആരുമായി ബന്ധപെടാമെന്നും എന്നെ അറിയിച്ചിട്ടുണ്ട്. ഈ പഠനത്തിൽ പങ്കെടുക്കുവാൻ എനിക്ക് സമ്മതമാണ്.

സ്ഥലം:
തിയ്യതി:
പങ്കെടുക്കുന്ന ആളുടെ ഒപ്പ്..............................

ഗവേഷകയുടെ ഒപ്പ്..

Annexure VI
Interview Schedule (Malayalam)

ആശുപത്രിയുടെ തരം: സർക്കാർ/സ്വകാര്യം/മറ്റുള്ളവ --			
അഭിമുഖ തീയതി:			
അഭിമുഖ സമയം:			
ക്രമ നമ്പർ	**ഇനം**	**മറുപടി**	**കുറിപ്പുകൾ**
സാമൂഹിക ചുറ്റുപാട്			
1	കഴിഞ്ഞ ജന്മദിനത്തിൽ നിങ്ങളുടെ പ്രായം എത്രയായിരുന്നു	----------	
2	ലിംഗഭേദം	1)ആൺ 2)സ്ത്രീ 3) ട്രാൻസ്ജെൻഡർ	
3	മതം	1) ഹിന്ദു 2) മുസ്ലീം 3) ക്രിസ്ത്യൻ 4) മറ്റുള്ളവ: വ്യക്തമാക്കുക ------------------	
4	താങ്കൾ ഏതു തലം വരെ പഠിച്ചിട്ടുണ്ട്?	1)ഔപചാരിക വിദ്യാഭ്യാസമില്ല 2) പ്രാഥമിക വിദ്യാഭ്യാസം പൂർത്തിയാക്കിയില്ല 3)പ്രൈമറി സ്കൂൾ തലം (1 – 7th std) 4) ഹൈസ്കൂൾ തലം (8-10-ാം ക്ലാസ്) 5)ഹയർ സെക്കണ്ടറി ലെവൽ (11- 12 ക്ലാസ്) 6) ബിരുദതലം 7) ബിരുദാനന്തര തലവും അതിനുമുകളിലും 8) മറ്റുള്ളവ വ്യക്തമാക്കുക --	

5	നിങ്ങൾ ഇപ്പോൾ വിവാഹിതനാണോ?	1)വിവാഹം കഴിച്ചിട്ടില്ല 2)വിവാഹിതർ / സഹവാസം 3)വേർപിരിഞ്ഞു/വിവാഹമോചിതർ 4)വിധവ	
6	താങ്കളുടെ ഇപ്പോഴത്തെ തൊഴിൽ പരമായ നില എന്താണ്?	1)ഗൃഹജോലി 2) സർക്കാർ മേഖലയിൽ ജോലി ചെയ്യുന്നു 3) സ്വകാര്യ മേഖലയിൽ ജോലി ചെയ്യുന്നു 4) സ്വയം തൊഴിൽ/ബിസിനസ്സ് 5) കൂലി 6) വിദ്യാർത്ഥി 7)തൊഴിൽ രഹിതൻ (ജോലി ചെയ്യാൻ കഴിവുള്ളവൻ) 8)തൊഴിൽ രഹിതൻ (ജോലി ചെയ്യാനാകുന്നില്ല) 9) മറ്റുള്ളവ: വ്യക്തമാക്കുക --------------------------	
7	ജോലിയുടെ സ്വഭാവം എന്താണ്?	1)പാർട്ട് ടൈം 2) ഫുൾ ടൈം	
8	രോഗിയുമായുള്ള നിങ്ങളുടെ ബന്ധം എന്താണ്?	1) പങ്കാളി 2) അച്ഛൻ 3) അമ്മ 4) മകൻ 5) മകൾ 6) സഹോദരങ്ങൾ 7) മറ്റേതെങ്കിലും ബന്ധു: വ്യക്തമാക്കുക -------------------------------	
9	നിങ്ങളുടെ കുടുംബത്തിൽ എത്ര അംഗങ്ങളുണ്ട്?	----------	
10	കുട്ടികളുടെ എണ്ണം	------------------------	
11	നിങ്ങൾക്ക് മതിയായ ഒഴിവു സമയം ഉണ്ടോ?	1) ഇല്ല 2) അതെ	
12	നിങ്ങൾക്ക് ഏതുതരം ഒഴിവുസമയ		

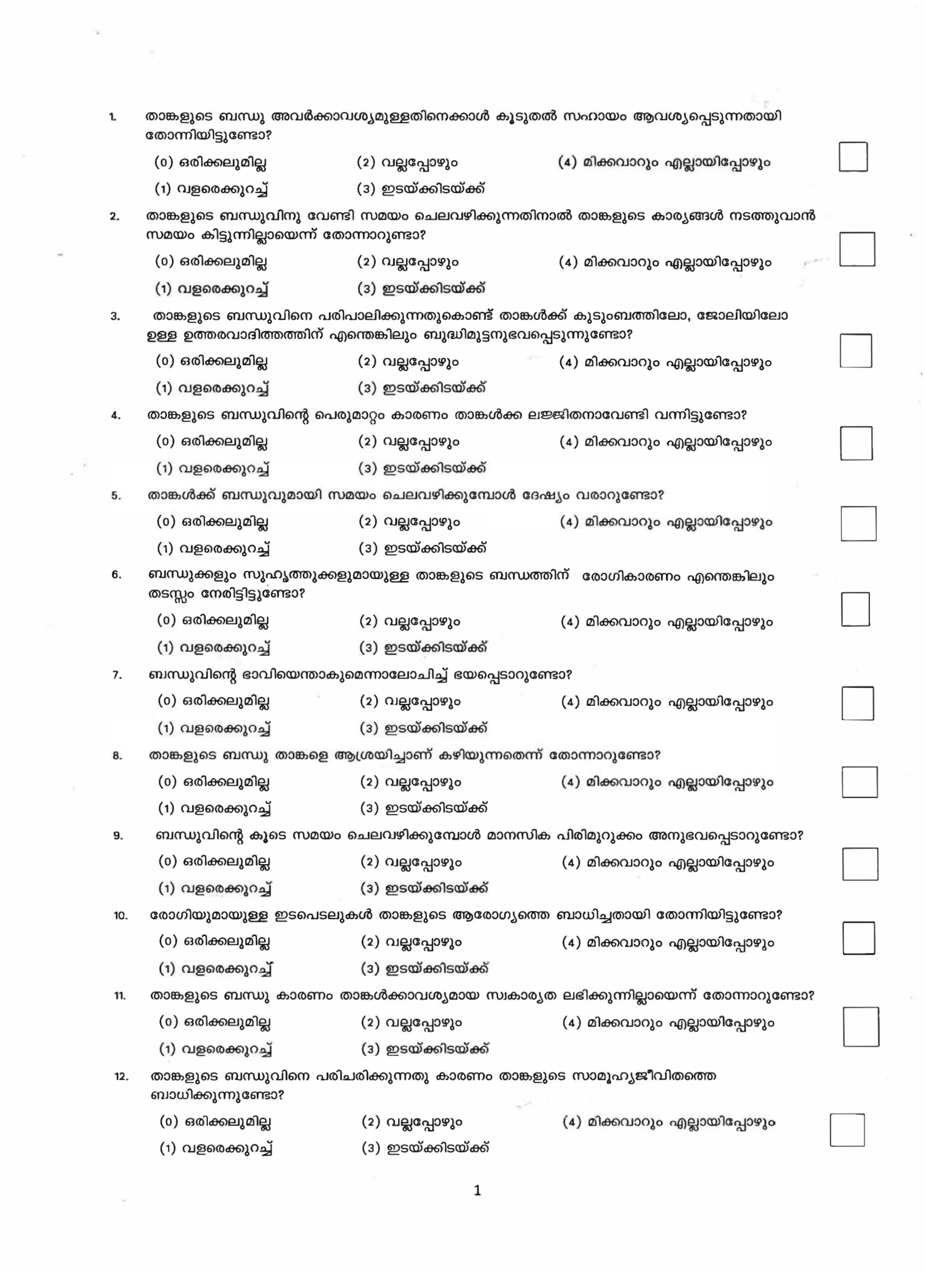
	പ്രവർത്തനങ്ങളാണ് ഉള്ളത്?		
13	ഇവിടെ പറഞ്ഞിരിക്കുന്ന ഏതെങ്കിലും അസുഖം താങ്കൾക്കുണ്ടോ?	1)രക്താതിസമ്മർദ്ദം 2)പ്രമേഹം 3) സന്ധിവാതം 4) ഹൃദയ സംബന്ധമായ രോഗങ്ങൾ 5) മാനസികാരോഗ്യ പ്രശ്നങ്ങൾ 6) ശ്വസന പ്രശ്നങ്ങൾ 7) മറ്റുള്ളവ : വ്യക്തമാക്കുക --------------------------------------	
സാമ്പത്തിക ചുറ്റുപാട്			
14	താങ്കളുടെ പക്കലുള്ള റേഷൻ കാർഡ് ഏതാണ്?	1) മഞ്ഞ കാർഡ് 2) പിങ്ക് കാർഡ് 3) നീല കാർഡ് 4) വെള്ള കാർഡ് 5) കാർഡ് ഇല്ല	
15	താങ്കളുടെ കുടുംബത്തിന്റെ കഴിഞ്ഞ മാസത്തെ വരുമാനം ഏകദേശം എത്രയാണ്?	1) 5000 രൂപയ്ക്ക് താഴെ 2) 5001 -10 000 രൂപ 3) 10001-20000 രൂപ 4) 20001-30000 രൂപ 5) 30000 രൂപയ്ക്ക് മുകളിൽ	
16	ചികിൽസാ ചെലവുകൾക്കായി പണം സ്വരൂപിക്കുന്നതിനെക്കുറിച്ച് നിങ്ങൾക്ക് ആശങ്കയുണ്ടോ?	1) ഇല്ല 2) അതെ	
17	ഹീമോഡയാലിസിസിനുള്ള ചികിത്സാ ചിലവുകൾ നിങ്ങൾ എങ്ങനെ നിറവേറ്റും?		

18	താങ്കൾ ഏതെങ്കിലും ആരോഗ്യ ഇൻഷുറൻസ് പദ്ധതിയിൽ അംഗമാണോ/ ഉപയോഗിക്കുന്നുണ്ടോ?	1) ഇല്ല 2) അതെ അതെ എങ്കിൽ, ഏതാണ് --	
ചികിത്സ സംബന്ധമായ വിവരങ്ങൾ			
19	കഴിഞ്ഞ ജന്മദിനത്തിൽ രോഗിയുടെ പ്രായം?	----------	
20	രോഗിയുടെ ലിംഗഭേദം?	1)ആൺ 2)സ്ത്രീ 3) ട്രാൻസ്ജെൻഡർ	
21	എത്ര നാളായി ഡയാലിസിസ് ചെയ്യുന്നു?	1) 3 ആഴ്ച - 6 മാസം വരെ 2) 6 മാസം - 12 മാസം വരെ 3) 1 - 2 വർഷം 4)>2 വർഷം	
22	ആഴ്ചയിൽ എത്ര ഡയാലിസിസ് സെഷനുകൾ ഉണ്ട്?	------------------------	
23	കഴിഞ്ഞ ഡയാലിസിസിൻറെ ദൈർഘ്യം എത്രയായിരുന്നു? (മണിക്കൂറുകളിൽ)	------------------------	
24	പരിചരണത്തിനായി ചെലവഴിക്കുന്ന സമയത്തിന്റെ ശരാശരി ദൈർഘ്യം എത്രയാണ്	------------------------	
25	രോഗിയെ പരിചരിക്കുന്നതിലൂടെ നിങ്ങൾക്ക് എന്തെങ്കിലും വേതന നഷ്ടമുണ്ടോ?		
യാത്ര സംബന്ധമായ വിവരങ്ങൾ			

26	താങ്കളുടെ താമസിക്കുന്ന സ്ഥലം	1) ഗ്രാമം 2) നഗരം സ്ഥലത്തിന്റെ പേര്: ---	
27	താങ്കളുടെ വീട്ടിൽ നിന്നും ആശുപത്രിയിലേക്ക് ഏകദേശംഎത്ര ദൂരം ഉണ്ട് ?	1) 1 കിലോമീറ്ററിൽ കുറവ് 2) 2 -5 കിലോമീറ്ററിനുള്ളിൽ 3) 5 കിലോമീറ്ററിൽ കൂടുതൽ	
28	താങ്കൾ എങ്ങനെയാണ് ആശുപത്രിയിൽ വരുന്നത്?	1) പൊതു ഗതാഗതം ഉപയോഗിക്കുന്നു 2) സ്വകാര്യ ഗതാഗതം ഉപയോഗിക്കുന്നു 3) ചാരിറ്റബിൾ ട്രസ്റ്റിൽ നിന്നുള്ള വാഹനം 4) മറ്റുള്ളവ: വ്യക്തമാക്കുക --	
രോഗിയുടെ ദൈനംദിന ആവശ്യങ്ങൾ			
29	**ദൈനംദിന ആവശ്യങ്ങൾ**	**മറുപടി**	**കുറിപ്പുകൾ**
1	കഴിക്കുക, കുടിക്കുക	1) ആശ്രയിക്കുന്നുണ്ട് 2) ആശ്രയിക്കുന്നുന്നില്ല	
2	കുളിക്കുക	1) ആശ്രയിക്കുന്നുണ്ട് 2) ആശ്രയിക്കുന്നുന്നില്ല	
3	വസ്ത്രം ധരിക്കുക	1) ആശ്രയിക്കുന്നുണ്ട് 2) ആശ്രയിക്കുന്നുന്നില്ല	
4	മലമൂത്ര വിസർജ്ജനം	1) ആശ്രയിക്കുന്നുണ്ട് 2) ആശ്രയിക്കുന്നുന്നില്ല	
5	നടക്കുക	1) ആശ്രയിക്കുന്നുണ്ട് 2) ആശ്രയിക്കുന്നുന്നില്ല	
6	കോവണിപടികൾ കയറുക	1) ആശ്രയിക്കുന്നുണ്ട് 2) ആശ്രയിക്കുന്നുന്നില്ല	
7	സാധനങ്ങൾ വാങ്ങുക	1) ആശ്രയിക്കുന്നുണ്ട് 2) ആശ്രയിക്കുന്നുന്നില്ല	
8	പാചകം ചെയ്യുക	1) ആശ്രയിക്കുന്നുണ്ട് 2) ആശ്രയിക്കുന്നുന്നില്ല	
9	വീട്ടുജോലികൾ ചെയ്യുക	1) ആശ്രയിക്കുന്നുണ്ട് 2) ആശ്രയിക്കുന്നുന്നില്ല	

Section B

THE ZARIT BURDEN INTERVIEW



1. താങ്കളുടെ ബന്ധു അവർക്കാവശ്യമുള്ളതിനെക്കാൾ കൂടുതൽ സഹായം ആവശ്യപ്പെടുന്നതായി തോന്നിയിട്ടുണ്ടോ?
(0) ഒരിക്കലുമില്ല (2) വല്ലപ്പോഴും (4) മിക്കവാറും എല്ലായിപ്പോഴും ☐
(1) വളരെക്കുറച്ച് (3) ഇടയ്ക്കിടയ്ക്ക്

2. താങ്കളുടെ ബന്ധുവിനു വേണ്ടി സമയം ചെലവഴിക്കുന്നതിനാൽ താങ്കളുടെ കാര്യങ്ങൾ നടത്തുവാൻ സമയം കിട്ടുന്നില്ലായെന്ന് തോന്നാറുണ്ടോ?
(0) ഒരിക്കലുമില്ല (2) വല്ലപ്പോഴും (4) മിക്കവാറും എല്ലായിപ്പോഴും ☐
(1) വളരെക്കുറച്ച് (3) ഇടയ്ക്കിടയ്ക്ക്

3. താങ്കളുടെ ബന്ധുവിനെ പരിപാലിക്കുന്നതുകൊണ്ട് താങ്കൾക്ക് കുടുംബത്തിലോ, ജോലിയിലോ ഉള്ള ഉത്തരവാദിത്തത്തിന് എന്തെങ്കിലും ബുദ്ധിമുട്ടനുഭവപ്പെടുന്നുണ്ടോ?
(0) ഒരിക്കലുമില്ല (2) വല്ലപ്പോഴും (4) മിക്കവാറും എല്ലായിപ്പോഴും ☐
(1) വളരെക്കുറച്ച് (3) ഇടയ്ക്കിടയ്ക്ക്

4. താങ്കളുടെ ബന്ധുവിന്റെ പെരുമാറ്റം കാരണം താങ്കൾക്ക ലജ്ജിതനാവേണ്ടി വന്നിട്ടുണ്ടോ?
(0) ഒരിക്കലുമില്ല (2) വല്ലപ്പോഴും (4) മിക്കവാറും എല്ലായിപ്പോഴും ☐
(1) വളരെക്കുറച്ച് (3) ഇടയ്ക്കിടയ്ക്ക്

5. താങ്കൾക്ക് ബന്ധുവുമായി സമയം ചെലവഴിക്കുമ്പോൾ ദേഷ്യം വരാറുണ്ടോ?
(0) ഒരിക്കലുമില്ല (2) വല്ലപ്പോഴും (4) മിക്കവാറും എല്ലായിപ്പോഴും ☐
(1) വളരെക്കുറച്ച് (3) ഇടയ്ക്കിടയ്ക്ക്

6. ബന്ധുക്കളും സുഹൃത്തുക്കളുമായുള്ള താങ്കളുടെ ബന്ധത്തിന് രോഗികാരണം എന്തെങ്കിലും തടസ്സം നേരിട്ടിട്ടുണ്ടോ?
(0) ഒരിക്കലുമില്ല (2) വല്ലപ്പോഴും (4) മിക്കവാറും എല്ലായിപ്പോഴും ☐
(1) വളരെക്കുറച്ച് (3) ഇടയ്ക്കിടയ്ക്ക്

7. ബന്ധുവിന്റെ ഭാവിയെന്താകുമെന്നാലോചിച്ച് ഭയപ്പെടാറുണ്ടോ?
(0) ഒരിക്കലുമില്ല (2) വല്ലപ്പോഴും (4) മിക്കവാറും എല്ലായിപ്പോഴും ☐
(1) വളരെക്കുറച്ച് (3) ഇടയ്ക്കിടയ്ക്ക്

8. താങ്കളുടെ ബന്ധു താങ്കളെ ആശ്രയിച്ചാണ് കഴിയുന്നതെന്ന് തോന്നാറുണ്ടോ?
(0) ഒരിക്കലുമില്ല (2) വല്ലപ്പോഴും (4) മിക്കവാറും എല്ലായിപ്പോഴും ☐
(1) വളരെക്കുറച്ച് (3) ഇടയ്ക്കിടയ്ക്ക്

9. ബന്ധുവിന്റെ കൂടെ സമയം ചെലവഴിക്കുമ്പോൾ മാനസിക പിരിമുറുക്കം അനുഭവപ്പെടാറുണ്ടോ?
(0) ഒരിക്കലുമില്ല (2) വല്ലപ്പോഴും (4) മിക്കവാറും എല്ലായിപ്പോഴും ☐
(1) വളരെക്കുറച്ച് (3) ഇടയ്ക്കിടയ്ക്ക്

10. രോഗിയുമായുള്ള ഇടപെടലുകൾ താങ്കളുടെ ആരോഗ്യത്തെ ബാധിച്ചതായി തോന്നിയിട്ടുണ്ടോ?
(0) ഒരിക്കലുമില്ല (2) വല്ലപ്പോഴും (4) മിക്കവാറും എല്ലായിപ്പോഴും ☐
(1) വളരെക്കുറച്ച് (3) ഇടയ്ക്കിടയ്ക്ക്

11. താങ്കളുടെ ബന്ധു കാരണം താങ്കൾക്കാവശ്യമായ സ്വകാര്യത ലഭിക്കുന്നില്ലായെന്ന് തോന്നാറുണ്ടോ?
(0) ഒരിക്കലുമില്ല (2) വല്ലപ്പോഴും (4) മിക്കവാറും എല്ലായിപ്പോഴും ☐
(1) വളരെക്കുറച്ച് (3) ഇടയ്ക്കിടയ്ക്ക്

12. താങ്കളുടെ ബന്ധുവിനെ പരിചരിക്കുന്നതു കാരണം താങ്കളുടെ സാമൂഹ്യജീവിതത്തെ ബാധിക്കുന്നുണ്ടോ?
(0) ഒരിക്കലുമില്ല (2) വല്ലപ്പോഴും (4) മിക്കവാറും എല്ലായിപ്പോഴും ☐
(1) വളരെക്കുറച്ച് (3) ഇടയ്ക്കിടയ്ക്ക്

13. രോഗി വീട്ടിലുള്ളതുകൊണ്ട് കൂട്ടുകാരെ വീട്ടിലേയ്ക്ക് ക്ഷണിക്കാൻ ബുദ്ധിമുട്ടുണ്ടോ? ☐

(0) ഒരിക്കലുമില്ല (2) വല്ലപ്പോഴും (4) മിക്കവാറും എല്ലായിപ്പോഴും
(1) വളരെക്കുറച്ച് (3) ഇടയ്ക്കിടയ്ക്ക്

14. നിങ്ങളുടെ ബന്ധുവിന് വേറെആരെയും ആശ്രയിക്കാൻ ഇല്ലാത്തതിനാൽ നിങ്ങൾ തന്നെ അവരെ പരിപാലിക്കണമെന്നൊരു തോന്നലുണ്ടോ? ☐

(0) ഒരിക്കലുമില്ല (2) വല്ലപ്പോഴും (4) മിക്കവാറും എല്ലായിപ്പോഴും
(1) വളരെക്കുറച്ച് (3) ഇടയ്ക്കിടയ്ക്ക്

15. താങ്കളുടെ മറ്റു ചിലവുകളോടൊപ്പം ബന്ധുവിന്റെ ചികിത്സയ്ക്ക് പണം തികയുന്നില്ലായെന്ന് തോന്നാറുണ്ടോ? ☐

(0) ഒരിക്കലുമില്ല (2) വല്ലപ്പോഴും (4) മിക്കവാറും എല്ലായിപ്പോഴും
(1) വളരെക്കുറച്ച് (3) ഇടയ്ക്കിടയ്ക്ക്

16. താങ്കളുടെ ബന്ധുവിനെ ഇനിയധികം കാലം താങ്കൾക്ക് ശുശ്രൂഷിക്കാൻ കഴിയില്ലായെന്ന് തോന്നിയിട്ടുണ്ടോ? ☐

(0) ഒരിക്കലുമില്ല (2) വല്ലപ്പോഴും (4) മിക്കവാറും എല്ലായിപ്പോഴും
(1) വളരെക്കുറച്ച് (3) ഇടയ്ക്കിടയ്ക്ക്

17. താങ്കളുടെ ബന്ധുവിന്റെ രോഗം താങ്കളുടെ ജീവിതത്തെ താറുമാറാക്കിയതായി തോന്നിയിട്ടുണ്ടോ? ☐

(0) ഒരിക്കലുമില്ല (2) വല്ലപ്പോഴും (4) മിക്കവാറും എല്ലായിപ്പോഴും
(1) വളരെക്കുറച്ച് (3) ഇടയ്ക്കിടയ്ക്ക്

18. താങ്കളുടെ ബന്ധുവിനെ പരിപാലിക്കാൻ മറ്റാരെയെങ്കിലും ഏൽപ്പിക്കണമെന്ന് ആഗ്രഹിച്ചിട്ടുണ്ടോ? ☐

(0) ഒരിക്കലുമില്ല (2) വല്ലപ്പോഴും (4) മിക്കവാറും എല്ലായിപ്പോഴും
(1) വളരെക്കുറച്ച് (3) ഇടയ്ക്കിടയ്ക്ക്

19. ബന്ധുവിന്റെ കാര്യത്തിൽ ഇനിയെന്തു ചെയ്യണമെന്ന് നിശ്ചയമില്ലാത്ത ഒരവസ്ഥ നിങ്ങൾക്ക് ഉണ്ടായിട്ടുണ്ടോ? ☐

(0) ഒരിക്കലുമില്ല (2) വല്ലപ്പോഴും (4) മിക്കവാറും എല്ലായിപ്പോഴും
(1) വളരെക്കുറച്ച് (3) ഇടയ്ക്കിടയ്ക്ക്

20. നിങ്ങളുടെ ബന്ധുവിന് വേണ്ടി കൂടുതലായി എന്തെങ്കിലും ചെയ്യേണ്ടതായി തോന്നുന്നുണ്ടോ? ☐

(0) ഒരിക്കലുമില്ല (2) വല്ലപ്പോഴും (4) മിക്കവാറും എല്ലായിപ്പോഴും
(1) വളരെക്കുറച്ച് (3) ഇടയ്ക്കിടയ്ക്ക്

21. താങ്കൾക്ക് കുറച്ചുകൂടെ നന്നായി ബന്ധുവിനെ പരിപാലിക്കാൻ കഴിയുമെന്ന് തോന്നാറുണ്ടോ? ☐

(0) ഒരിക്കലുമില്ല (2) വല്ലപ്പോഴും (4) മിക്കവാറും എല്ലായിപ്പോഴും
(1) വളരെക്കുറച്ച് (3) ഇടയ്ക്കിടയ്ക്ക്

22. മൊത്തത്തിൽ, നിങ്ങളുടെ ബന്ധുവിനെ പരിചരിക്കുന്നത് എത്രത്തോളം ഭാരമായി തോന്നിയിട്ടുണ്ട്? ☐

(0) ഒരിക്കലുമില്ല (2) ഇടയ്ക്കിടയ്ക്ക് (4) വളരെയധികം
(1) വളരെക്കുറച്ച് (3) മിക്കവാറും

ഇടപാടുകാരന്റെ സേവനത്തെക്കുറിച്ചുള്ള വിവരപട്ടിക

താങ്കളുടെ ബന്ധുവിനോടൊപ്പം വീട്ടിൽ കൂടെയുള്ളത് ആരാണ്?

താങ്കളുടെ ബന്ധുവിന് വീട്ടിനകത്ത് ഏതു രീതിയിലുള്ള സഹായമാണ് വേണ്ടത്?

Quality of life assessing scale (WHOQOL -BREF)

താഴെപറയുന്ന ചോദ്യങ്ങൾ താങ്കളുടെ ജീവിതത്തിന്റെ ഗുണനിലവാരം, ആരോഗ്യം, ജീവിതവുമായി ബന്ധപ്പെട്ട മറ്റ് മേഖലകൾ എന്നിവയെപ്പറ്റി നിങ്ങൾക്ക് എന്ത് തോന്നുന്നു. എന്നതിനെകുറിച്ചാണ്. ഓരോ ചോദ്യവും, അതിന് സാധ്യമായ ഉത്തരങ്ങളും ഞാൻ വായിച്ചുകേൾപ്പിക്കുന്നതായിരിക്കും. ദയവായി ഏറ്റവും അനുയോജ്യമായ ഉത്തരം തിരഞ്ഞെടുക്കുക. ഏതെങ്കിലും ഒരു ചോദ്യത്തിന്റെ ഉത്തരത്തെക്കുറിച്ച് ഉറപ്പില്ലെങ്കിൽ നിങ്ങളുടെ മനസ്സിലേക്ക് വരുന്ന ആദ്യത്തെ ഉത്തരമായിരിക്കും ഏറ്റവും ഉചിതം. കഴിഞ്ഞ 4 ആഴ്ചകാലത്തെ താങ്കളുടെ ജീവിതത്തെക്കുറിച്ചുള്ള മാനദണ്ഡങ്ങളും, പ്രതീക്ഷകളും, സന്തോഷങ്ങളും , ആശങ്കകളും മനസ്സിൽ വച്ചുകൊ ് ചോദ്യങ്ങൾക്ക് മറുപടി നൽകേ താണ്.

<table>
<tr><td>1</td><td>താങ്കളുടെ ജീവിതത്തിന്റെ ഗുണനിലവാരത്തെ താങ്കൾ എങ്ങിനെ കണക്കാക്കുന്നു?</td><td>വളരെ മോശം</td><td>മോശം</td><td>മോശവുമല്ല, നല്ലതുമല്ല</td><td>നല്ലത്</td><td>വളരെ നല്ലത്</td></tr>
<tr><td>2</td><td>താങ്കളുടെ ആരോഗ്യത്തെക്കുറിച്ച് താങ്കൾ എത്ര ക ് തൃപ്തൻ / തൃപ്തയാണ്?</td><td>വളരെ അതൃപ്തികരം</td><td>തൃപ്തികരം</td><td>തൃപ്തികരവുമല്ല, അതൃപ്തികരവുമല്ല</td><td>തൃപ്തികരം</td><td>വളരെ തൃപ്തികരം</td></tr>
<tr><td colspan="7">കഴിഞ്ഞ 4 ആഴ്ച്ചകാലമായി ചില കാര്യങ്ങൾ താങ്കൾക്ക് എങ്ങിനെ അനുഭവപ്പെട്ടു എന്നതിനെകുറിച്ചാണ് താഴെപറയുന്ന ചോദ്യങ്ങൾ</td></tr>
<tr><td>3</td><td>താങ്കൾ ചെയ്യേ കാര്യങ്ങളിൽനിന്ന് ശാരീരകവേദന എത്രത്തോളം താങ്കളെ തടഞ്ഞിട്ടു ്?</td><td>ഒട്ടുമില്ല</td><td>വളരെ ക്കുറച്ച്</td><td>മിതമായി</td><td>കൂടുതൽ</td><td>വളരെ കൂടുതൽ</td></tr>
<tr><td>4</td><td>ദൈനദിന ജീവിതത്തിന്റെ പ്രവർത്തനത്തിനായി എത്രത്തോളം വൈദ്യസഹായം താങ്കൾക്ക് ആവശ്യമാണ് ?</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>5</td><td>താങ്കൾ ജീവിതം എത്രമാത്രം ആസ്വദിക്കുന്നു?</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>6</td><td>അർത്ഥപൂർണ്ണമായ ജീവിതമാണ് താങ്കൾ നയിക്കുന്നതെന്ന് താങ്കൾ കരുതുന്നുേ ാ?</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>7</td><td>താങ്കൾക്ക് എത്രത്തോളം കാര്യങ്ങളിൽ ശ്രദ്ധ ചെലുത്താൻ സാധിക്കും?</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>8</td><td>താങ്കളുടെ ദൈനംദിനജീവിതത്തിൽ എത്രത്തോളം സുരക്ഷ താങ്കൾ അനുഭവിക്കുന്നു?</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>9</td><td>താങ്കളുടെ ചുറ്റുപാടുകൾ എത്രത്തോളം ആരോഗ്യകരമാണ്?</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="7">കഴിഞ്ഞ 4 ആഴ്ച്ചകളിൽ ചിലകാര്യങ്ങൾ എത്ര പൂർണ്ണമായി അനുഭവിക്കാനോ അല്ലെങ്കിൽ ചെയ്യുവാനോ സാധിച്ചു എന്നതിനെക്കുറിച്ചാണ് താഴെയുള്ള ചോദ്യങ്ങൾ.</td></tr>
<tr><td>10</td><td>താങ്കളുടെ ദൈനംദിനജീവിതത്തിനാവശ്യമായ ഉന്മേഷം അനുഭവപ്പെടുന്നുേ ാ ?</td><td>ഒട്ടുമില്ല</td><td>വളരെ ക്കുറച്ച്</td><td>ആവശ്യത്തിന്</td><td>മിക്കവാറും</td><td>പൂർണ്ണമായും</td></tr>
<tr><td>11</td><td>താങ്കളുടെ ശാരീരിക രൂപം താങ്കൾക്ക് സ്വീകാര്യമാണോ ?</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>12</td><td>താങ്കളുടെ ആവശ്യങ്ങൾ നിറവേറ്റാനാവശ്യമായ പണം താങ്കൾക്കുേ ാ ?</td><td></td><td></td><td></td><td></td><td></td></tr>
</table>

13	താങ്കളുടെ ദൈനംദിന ജീവിതത്തിനാവശ്യമായ വിവരങ്ങൾ താങ്കൾക്ക് എത്രത്തോളം ലഭ്യമാണ്?					
14	വിശ്രമവേളകളിലെ പ്രവർത്തനങ്ങൾക്കായി താങ്കൾക്ക് എത്രത്തോളം അവസരം ലഭ്യമാണ്?					
15	താങ്കളുടെ ചുറ്റുപാടുകളിലേക്ക് ശാരീരികമായി എത്രത്തോളം എത്തിപ്പെടാൻ കഴിയും ?	വളരെ മോശം	മോശം	മോശവുമല്ല, നല്ലതുമല്ല	നല്ലത്	വളരെ നല്ലത്
16	താങ്കളുടെ ഉറക്കം എത്രത്തോളം തൃപ്തികരമാണ്?	ഒട്ടും തൃപ്തികരമല്ല	തൃപ്തികരമല്ല	തൃപ്തികരവുമല്ല അതൃപ്തികരവുമല്ല	തൃപ്തികരം	വളരെ തൃപ്തികരം
17	ദൈനംദിന പ്രവർത്തികൾ ചെയ്യാനുള്ള കഴിവിൽ താങ്കൾ എത്ര തൃപ്തനാണ് / തൃപ്തയാണ്?					
18	ജോലി ചെയ്യാനുള്ള കഴിവിൽ താങ്കൾ എത്ര തൃപ്തനാണ്?					
19	താങ്കൾ താങ്കളിൽത്തന്നെ എത്ര തൃപ്തനാണ്?					
20	വ്യക്തി ബന്ധങ്ങളിൽ താങ്കൾ എത്ര തൃപ്തനാണ് / തൃപ്തയാണ്?					
21	ലൈംഗിക ജീവിതത്തിൽ താങ്കൾ എത്ര തൃപ്തനാണ് / തൃപ്തയാണ്?					
22	സുഹൃത്തുക്കളുടെ സഹായത്തിൽ താങ്കൾ എത്ര കണ്ട് തൃപ്തനാണ് / തൃപ്തയാണ്?					
23	ജീവിക്കുന്ന ചുറ്റുപാടുകളെക്കുറിച്ച് താങ്കൾ എത്ര കണ്ട് തൃപ്തനാണ് / തൃപ്തയാണ്?					
24	ആരോഗ്യസേവന ലഭ്യതയെക്കുറിച്ച് താങ്കൾ എത്ര കണ്ട് തൃപ്തനാണ് / തൃപ്തയാണ്?					
25	ഗതാഗതസൗകര്യത്തെക്കുറിച്ച് താങ്കൾ എത്ര കണ്ട് തൃപ്തനാണ് / തൃപ്തയാണ്?					
കഴിഞ്ഞ 4 ആഴ്ച്ചകളിൽ ചിലകാര്യങ്ങൾ താങ്കൾക്ക് എപ്പോഴൊക്കെ അനുഭവപ്പെട്ടിട്ടുണ്ട് / തോന്നിയിട്ടുണ്ട് എന്നതിനെക്കുറിച്ചാണ് താഴെയുള്ള ചോദ്യം						
26	സങ്കടം, നിരാശ, ഉത്കണ്ഠ, വിഷാദം എന്നീ നിഷേധാത്മകമായ തോന്നലുകൾ താങ്കൾക്ക് എപ്പോഴൊക്കെ ഉണ്ടായിട്ടുണ്ട്	ഒരിക്കലുമില്ല	വല്ലപ്പോഴും	കൂടെക്കൂടെ	മിക്കപ്പോഴും	എപ്പോഴും

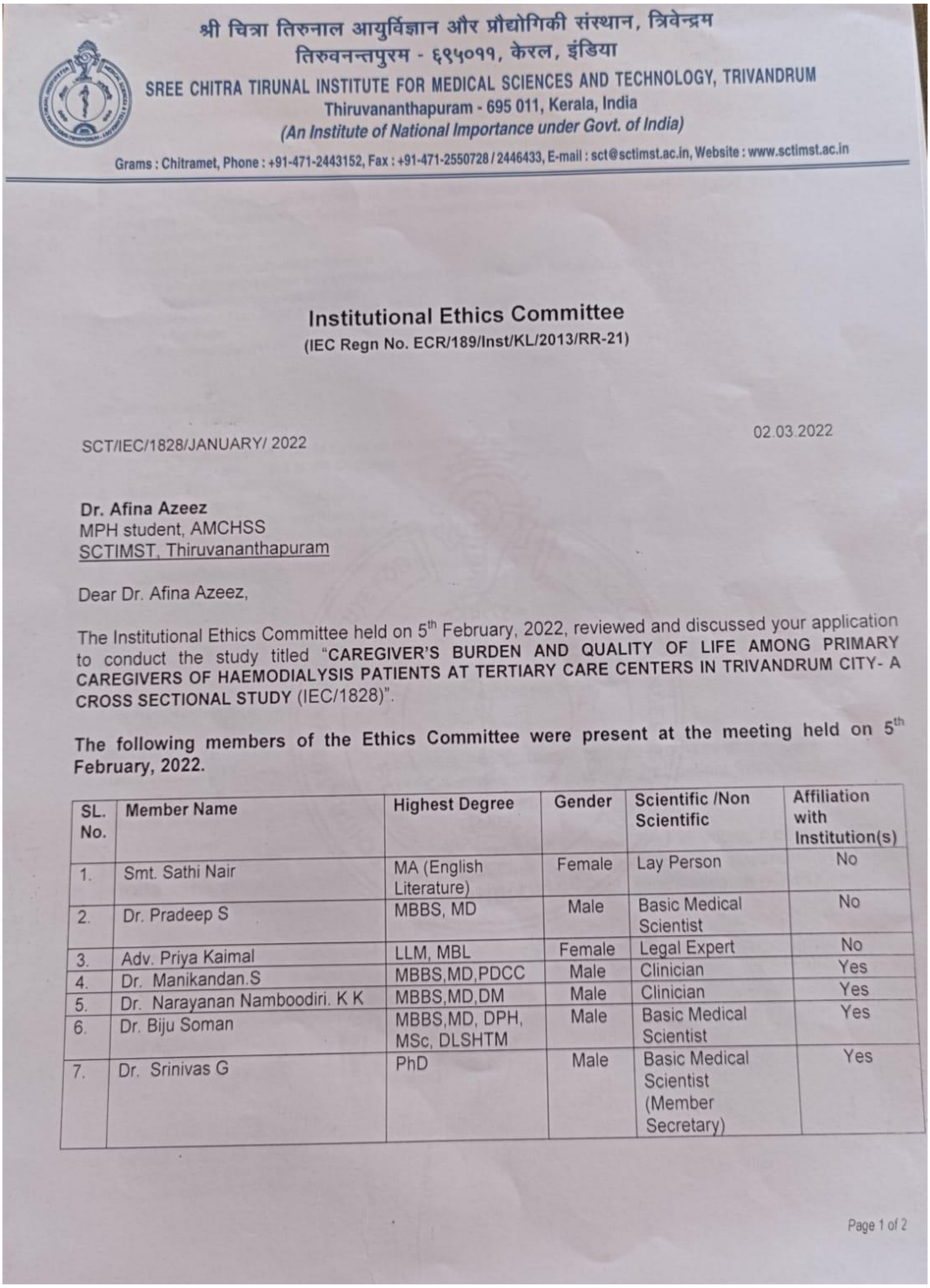
ഈ വിലയിരുത്തലിനെപ്പറ്റി നിങ്ങൾക്ക് എന്തെങ്കിലും കൂടുതലായി പറയാനുണ്ടോ ?

……………………………………..

Translated by Aswathy.S, Sandhya C, Bindu Menon, Rejani.G, AlMS, Kochi

Annexure - 7

Annexure VII
IEC approval letter



श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
तिरुवनन्तपुरम - ६९५०११, केरल, इंडिया
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM
Thiruvananthapuram - 695 011, Kerala, India
(An Institute of National Importance under Govt. of India)
Grams : Chitramet, Phone : +91-471-2443152, Fax : +91-471-2550728 / 2446433, E-mail : sct@sctimst.ac.in, Website : www.sctimst.ac.in

Institutional Ethics Committee
(IEC Regn No. ECR/189/Inst/KL/2013/RR-21)

SCT/IEC/1828/JANUARY/ 2022 02.03.2022

Dr. Afina Azeez
MPH student, AMCHSS
SCTIMST, Thiruvananthapuram

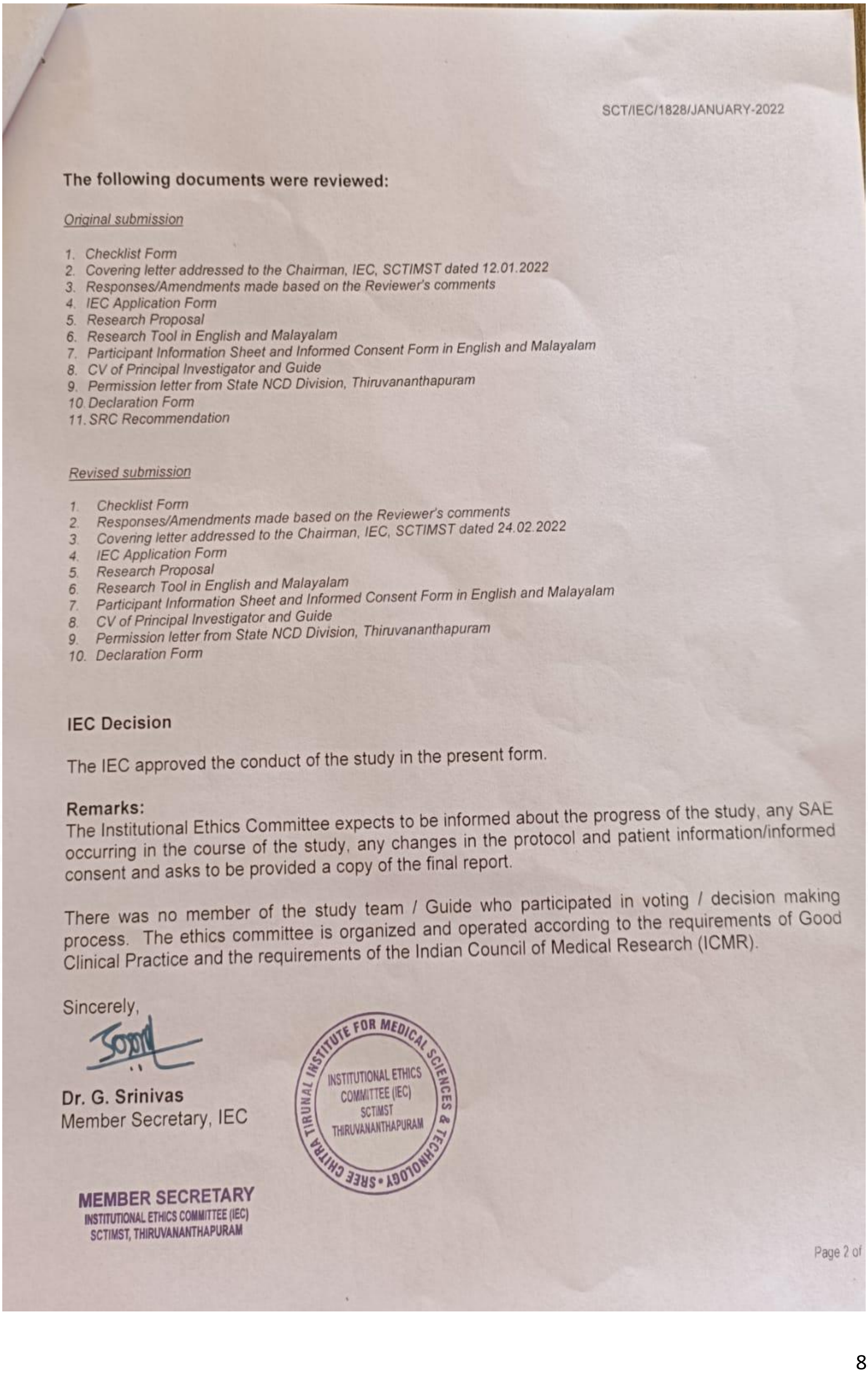
Dear Dr. Afina Azeez,

The Institutional Ethics Committee held on 5th February, 2022, reviewed and discussed your application to conduct the study titled "**CAREGIVER'S BURDEN AND QUALITY OF LIFE AMONG PRIMARY CAREGIVERS OF HAEMODIALYSIS PATIENTS AT TERTIARY CARE CENTERS IN TRIVANDRUM CITY- A CROSS SECTIONAL STUDY** (IEC/1828)".

The following members of the Ethics Committee were present at the meeting held on 5th February, 2022.

SL. No.	Member Name	Highest Degree	Gender	Scientific /Non Scientific	Affiliation with Institution(s)
1.	Smt. Sathi Nair	MA (English Literature)	Female	Lay Person	No
2.	Dr. Pradeep S	MBBS, MD	Male	Basic Medical Scientist	No
3.	Adv. Priya Kaimal	LLM, MBL	Female	Legal Expert	No
4.	Dr. Manikandan.S	MBBS,MD,PDCC	Male	Clinician	Yes
5.	Dr. Narayanan Namboodiri. K K	MBBS,MD,DM	Male	Clinician	Yes
6.	Dr. Biju Soman	MBBS,MD, DPH, MSc, DLSHTM	Male	Basic Medical Scientist	Yes
7.	Dr. Srinivas G	PhD	Male	Basic Medical Scientist (Member Secretary)	Yes

Page 1 of 2



The following documents were reviewed:

Original submission

1. *Checklist Form*
2. *Covering letter addressed to the Chairman, IEC, SCTIMST dated 12.01.2022*
3. *Responses/Amendments made based on the Reviewer's comments*
4. *IEC Application Form*
5. *Research Proposal*
6. *Research Tool in English and Malayalam*
7. *Participant Information Sheet and Informed Consent Form in English and Malayalam*
8. *CV of Principal Investigator and Guide*
9. *Permission letter from State NCD Division, Thiruvananthapuram*
10. *Declaration Form*
11. *SRC Recommendation*

Revised submission

1. *Checklist Form*
2. *Responses/Amendments made based on the Reviewer's comments*
3. *Covering letter addressed to the Chairman, IEC, SCTIMST dated 24.02.2022*
4. *IEC Application Form*
5. *Research Proposal*
6. *Research Tool in English and Malayalam*
7. *Participant Information Sheet and Informed Consent Form in English and Malayalam*
8. *CV of Principal Investigator and Guide*
9. *Permission letter from State NCD Division, Thiruvananthapuram*
10. *Declaration Form*

IEC Decision

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

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

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

Sincerely,

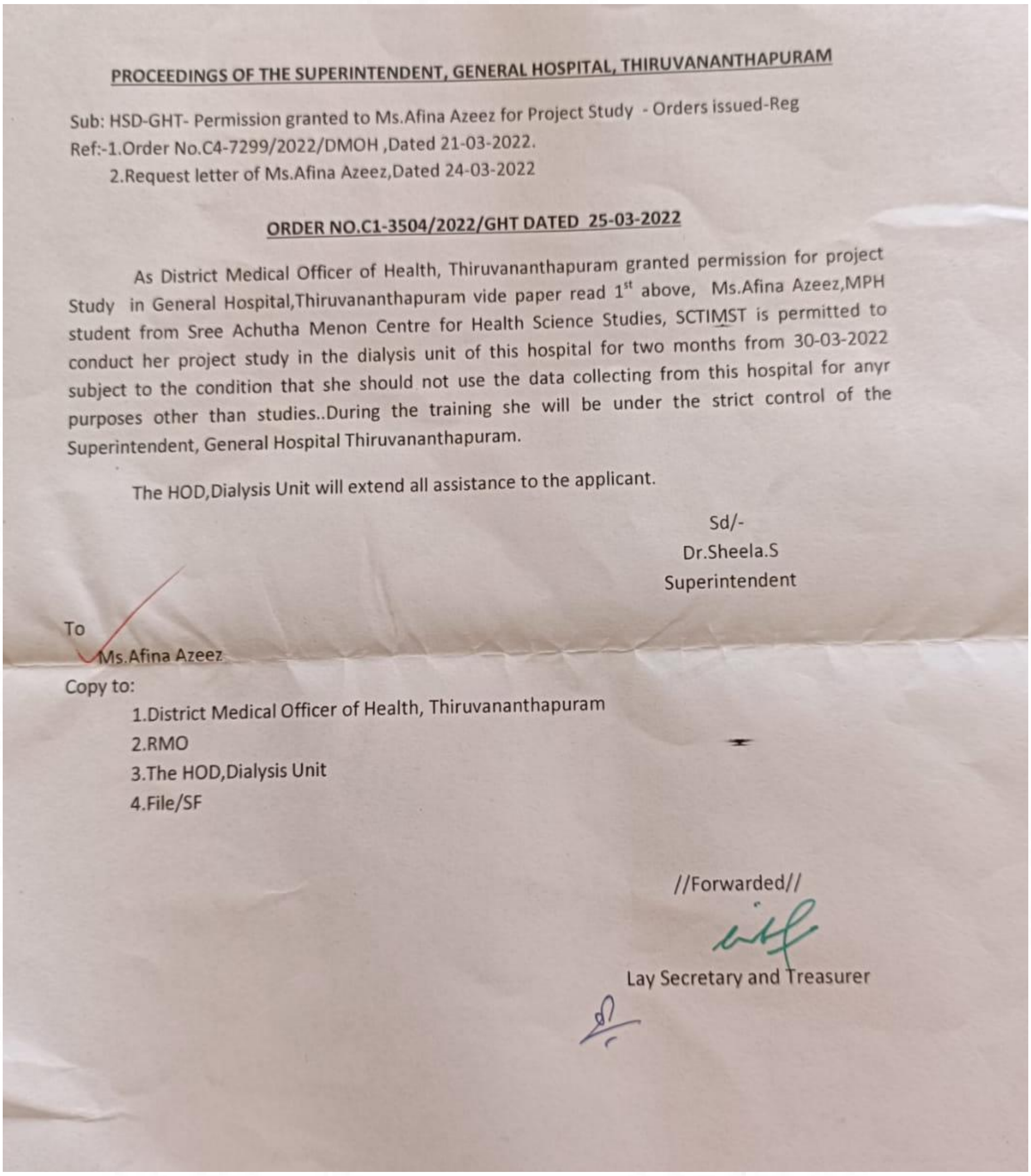
Dr. G. Srinivas
Member Secretary, IEC

INSTITUTIONAL ETHICS
COMMITTEE (IEC)
SCTIMST
THIRUVANANTHAPURAM

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE (IEC)
SCTIMST, THIRUVANANTHAPURAM

Annexure VIII

Permission letters from Hospitals



PROCEEDINGS OF THE SUPERINTENDENT, GENERAL HOSPITAL, THIRUVANANTHAPURAM

Sub: HSD-GHT- Permission granted to Ms.Afina Azeez for Project Study - Orders issued-Reg

Ref:-1.Order No.C4-7299/2022/DMOH ,Dated 21-03-2022.

2.Request letter of Ms.Afina Azeez,Dated 24-03-2022

ORDER NO.C1-3504/2022/GHT DATED 25-03-2022

As District Medical Officer of Health, Thiruvananthapuram granted permission for project Study in General Hospital,Thiruvananthapuram vide paper read 1st above, Ms.Afina Azeez,MPH student from Sree Achutha Menon Centre for Health Science Studies, SCTIMST is permitted to conduct her project study in the dialysis unit of this hospital for two months from 30-03-2022 subject to the condition that she should not use the data collecting from this hospital for anyr purposes other than studies..During the training she will be under the strict control of the Superintendent, General Hospital Thiruvananthapuram.

The HOD,Dialysis Unit will extend all assistance to the applicant.

Sd/-
Dr.Sheela.S
Superintendent

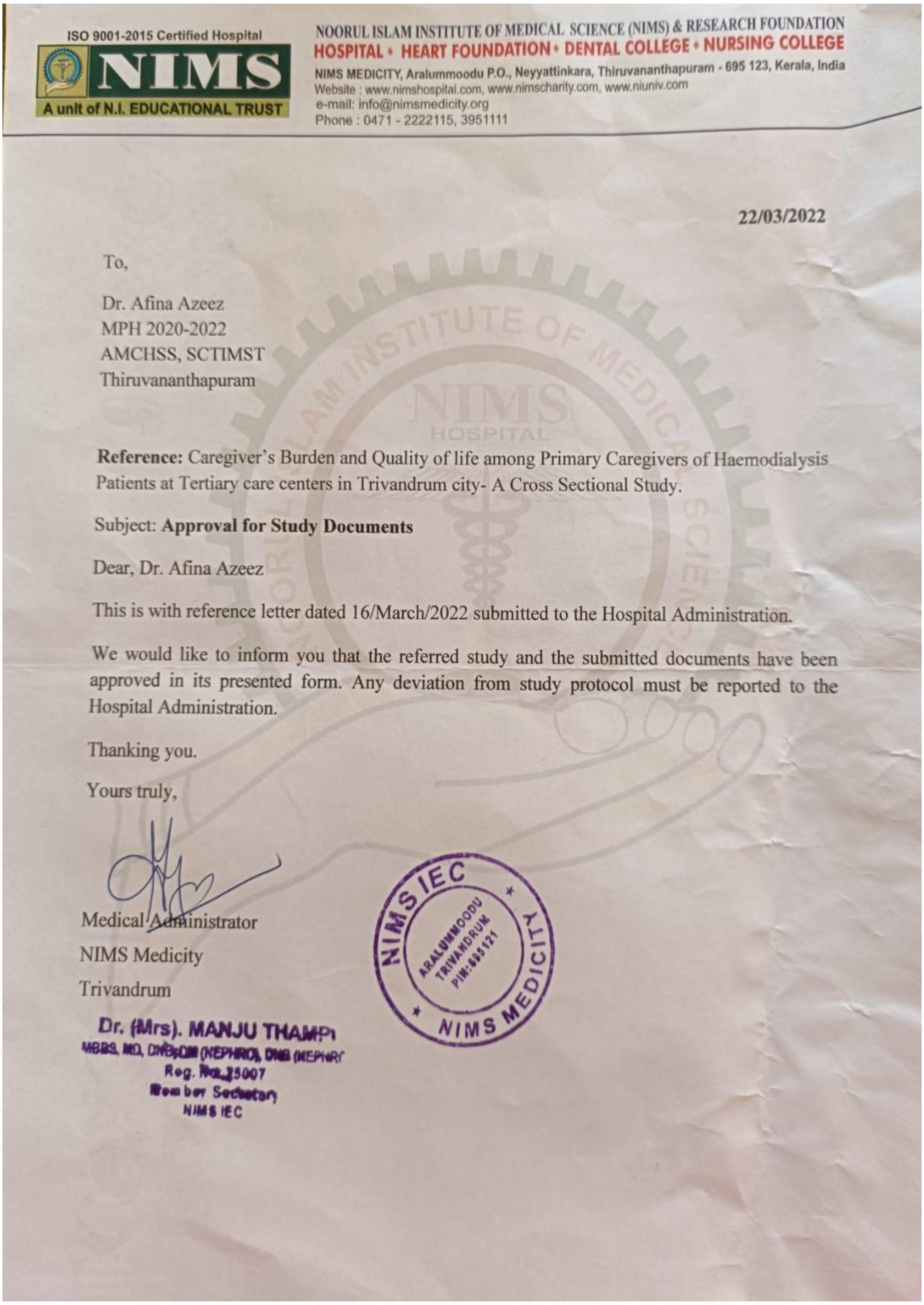
To
Ms.Afina Azeez

Copy to:

1.District Medical Officer of Health, Thiruvananthapuram
2.RMO
3.The HOD,Dialysis Unit
4.File/SF

//Forwarded//

Lay Secretary and Treasurer



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NOORUL ISLAM INSTITUTE OF MEDICAL SCIENCE (NIMS) & RESEARCH FOUNDATION
HOSPITAL • HEART FOUNDATION • DENTAL COLLEGE • NURSING COLLEGE
NIMS MEDICITY, Aralummoodu P.O., Neyyattinkara, Thiruvananthapuram - 695 123, Kerala, India
Website : www.nimshospital.com, www.nimscharity.com, www.niuniv.com
e-mail: info@nimsmedicity.org
Phone : 0471 - 2222115, 3951111

22/03/2022

To,

Dr. Afina Azeez
MPH 2020-2022
AMCHSS, SCTIMST
Thiruvananthapuram

Reference: Caregiver's Burden and Quality of life among Primary Caregivers of Haemodialysis Patients at Tertiary care centers in Trivandrum city- A Cross Sectional Study.

Subject: **Approval for Study Documents**

Dear, Dr. Afina Azeez

This is with reference letter dated 16/March/2022 submitted to the Hospital Administration.

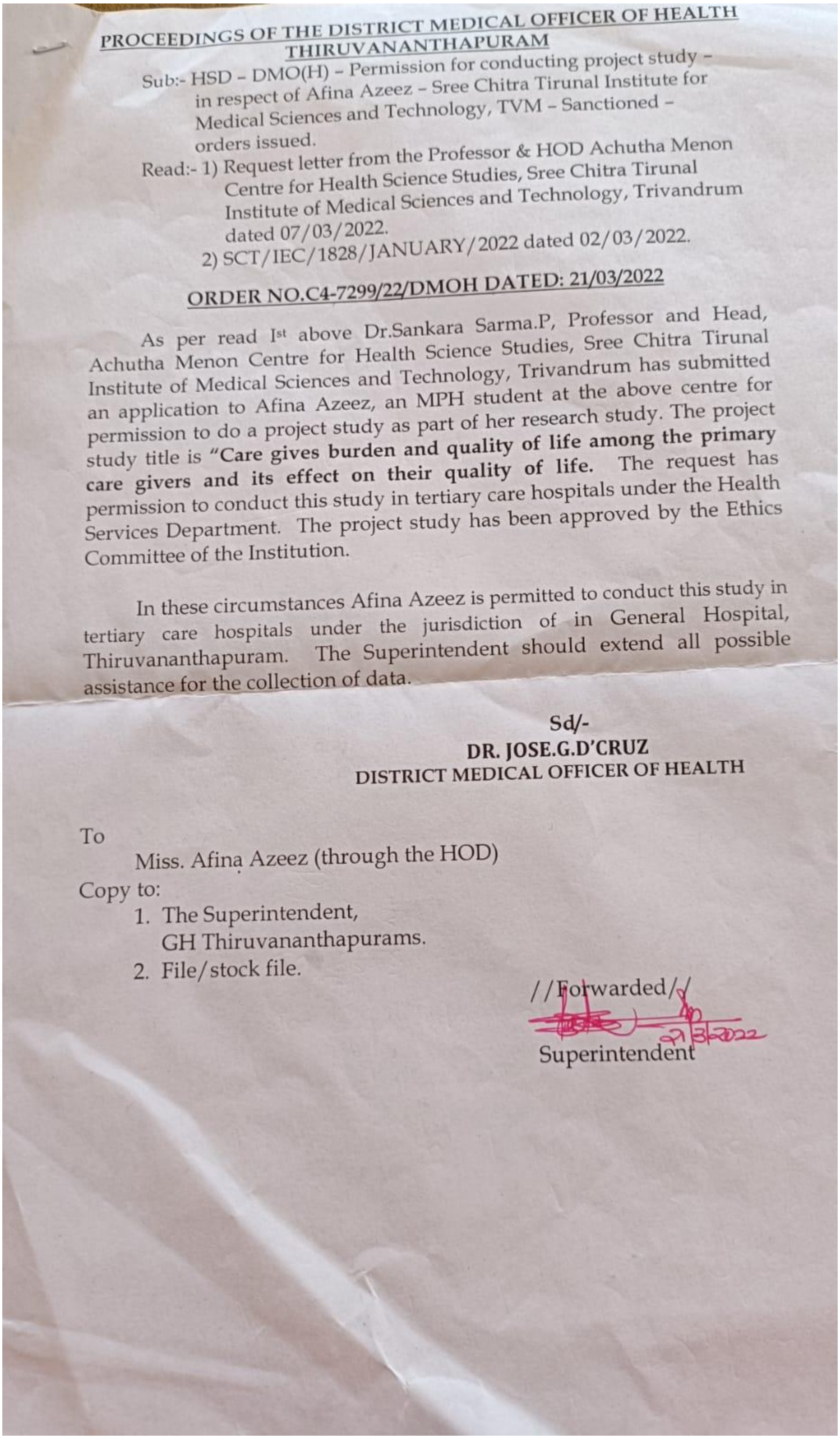
We would like to inform you that the referred study and the submitted documents have been approved in its presented form. Any deviation from study protocol must be reported to the Hospital Administration.

Thanking you.

Yours truly,

Medical Administrator
NIMS Medicity
Trivandrum

Dr. (Mrs). MANJU THAMPI
MBBS, MD, DNB, DM (NEPHRO), DNB (NEPHR
Reg. No. 25007
Member Secretary
NIMS IEC



PROCEEDINGS OF THE DISTRICT MEDICAL OFFICER OF HEALTH THIRUVANANTHAPURAM

Sub:- HSD – DMO(H) – Permission for conducting project study – in respect of Afina Azeez – Sree Chitra Tirunal Institute for Medical Sciences and Technology, TVM – Sanctioned – orders issued.

Read:- 1) Request letter from the Professor & HOD Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute of Medical Sciences and Technology, Trivandrum dated 07/03/2022.

2) SCT/IEC/1828/JANUARY/2022 dated 02/03/2022.

ORDER NO.C4-7299/22/DMOH DATED: 21/03/2022

As per read Ist above Dr.Sankara Sarma.P, Professor and Head, Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute of Medical Sciences and Technology, Trivandrum has submitted an application to Afina Azeez, an MPH student at the above centre for permission to do a project study as part of her research study. The project study title is **"Care gives burden and quality of life among the primary care givers and its effect on their quality of life.** The request has permission to conduct this study in tertiary care hospitals under the Health Services Department. The project study has been approved by the Ethics Committee of the Institution.

In these circumstances Afina Azeez is permitted to conduct this study in tertiary care hospitals under the jurisdiction of in General Hospital, Thiruvananthapuram. The Superintendent should extend all possible assistance for the collection of data.

Sd/-
DR. JOSE.G.D'CRUZ
DISTRICT MEDICAL OFFICER OF HEALTH

To

Miss. Afina Azeez (through the HOD)

Copy to:

1. The Superintendent,
   GH Thiruvananthapurams.
2. File/stock file.

//Forwarded//
21/3/2022
Superintendent

Annexure IX

Cross tabulation factors associated with caregiver burden and sociodemographic characteristics of caregivers and patients

Variable	Category	N	Zarit burden		P value (Chi square test)
			No burden N (%)	Burden N(%)	
Age group (in years)	Mean and SD		53.25 (13.6)	54.36(11.7)	0.059
Gender	Male	45	18(40)	27(60)	0.757
	Female	155	66(42.6)	89(57.4)	
Religion	Hindu	138	63(45.7)	75(54.3)	0.248
	Muslim	27	8(29.6)	19(70.4)	
	Christian	35	13(37.1)	22(62.9)	
Marital Status	Never married	8	5(62.5)	3(37.5)	0.307
	Married	187	78(41.7)	109(58.3)	
	Divorced	2	1(50)	1(50)	
	Widowed	3	0	3(100)	
Education	No formal education	5	2(40)	3(60)	0.735
	primary	26	8(30.8)	18(69.2)	
	High school	69	26(37.7)	43(62.3)	
	Higher secondary	36	17(47.2)	19(52.8)	
	Graduate	40	20(50)	20(50)	
	Pg	19	9(47.6)	10(52.6)	

	Others	5	2(40)	3(60)	
Employment	Home maker	114	45(39.5)	69(60.5)	0.899
	Public	12	4(33.3)	8(66.7)	
	Private	10	5(50)	5(50)	
	Self employed	18	8(44.4)	10(55.6)	
	Daily Wage Earner	6	2(33.3)	4(66.7)	
	Unemployed	20	10(50)	10(50)	
	Retired	20	10(50)	10(50)	
Relation of the caregiver to the patient	Spouse	155	64(41.3)	91(58.7)	0.378
	Mother	12	3(25)	9(75)	
	Son	10	4(40)	6(60)	
	Daughter	15	7(46.7)	8(53.3)	
	Siblings	5	4(80)	1(20)	
	Others	3	2(66.7)	1(33.3)	
No. of family members	2members	48	26(54.2)	22(45.8)	0.391
	3members	44	17(38.6)	27(61.4)	
	4members	52	21(40.4)	31(59.6)	
	5members	26	9(34.6)	17(65.4)	
	>=6members	30	11(36.6)	19(63.4)	
Income range	<20000	140	49(35)	91(65)	**0.002**
	>=20000	60	35(58.3)	25(41.7)	
Locality	Rural	118	49(41.8)	69(58.5)	0.870
	Urban	82	35(42.7)	47(57.3)	
Distance to the hospital	<1km	3	1(33.3)	2(66.7)	0.683
	2-5km	31	11(35.5)	20(64.5)	
	>5km	166	72(43.4)	94(56.6)	

Type of transportation	Public transport	115	49(42.6)	66(57.4)	0.839
	Private transport	85	35(41.2)	50(58.8)	
Age in years	Mean and SD		60.86 (12.34)	59.32(11.42)	0.516
Gender	Male	124	53(42.7)	71(57.3)	0.786
	Female	76	31(40.8)	45(59.2)	
Duration of treatment	3-6months	39	18(46.2)	21(53.8)	0.483
	6-12months	24	11(45.8)	13(54.2)	
	1-2years	36	11(30.6)	25(69.4)	
	>2years	101	44(43.6)	57(56.4)	
No of weekly sessions	1	10	4(40)	6(60)	0.091
	2	144	67(46.57)	77(53.5)	
	3	46	13(28.3)	33(71.7)	
Activities of the patient depend on caregiver	Independent	93	44(47.3)	49(52.7)	0.156
	Dependent	107	40(37.4)	67(62.7)	