QUALITY OF LIFE OF PATIENTS LIVING WITH SYSTEMIC LUPUS ERYTHEMATOSUS, A CLINIC-BASED STUDY, KERALA, INDIA.

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DECLARATION

I hereby declare that this dissertation entitled **“Quality of life of patients living with Systemic Lupus Erythematosus, a clinic-based study, Kerala, India”** 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 Information derived from the published or unpublished work of others has been duly acknowledged in the text.

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CERTIFICATE

Certified that the dissertation titled **“Quality of life of patients living with Systemic Lupus Erythematosus, a clinic-based study, Kerala, India”** is a record of the research work undertaken by Dr Divya C S, in partial fulfilment of the requirements for the award of the degree of ‘Masters of Public Health’ under my guidance and supervision.

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CONTENTS

CHAPTERS **Page No.**

Chapter 1

INTRODUCTION AND LITERATURE REVIEW

Chapter 2

METHODOLOGY

Chapter 3

RESULTS

Chapter 4

DISCUSSION

ANNEXURES

LIST OF TABLES

LIST OF FIGURES

LIST OF ANNEXURES

GLOSSARY OF ABBREVIATIONS USED IN THE STUDY

SLE	Systemic Lupus Erythematosus
QOL	Quality of Life
HRQOL	Health Related Quality Of Life
SLAQ	Systemic Lupus Activity Questionnaire
ARD	Autoimmune Rheumatic Disorders
DM	Diabetes Mellitus
HTN	Hypertension
UK	United Kingdom
USA	United States of America
WHO	World health Organization
SLAM	Systemic Lupus Activity Measure
ANA	Antinuclear Antibody
ECLAM	European Consensus Lupus Activity Measurement
SLEDAI	Systemic Lupus Erythematosus Disease Activity Index
BILAG	British Isles Lupus Assessment Group
LAI	Lupus Activity Index
SLICC	Systemic Lupus Collaborating Clinics
ACR	American College of Rheumatology
NHP	Nottingham Profile
SIP	Sickness Profile

ABSTRACT

Background: Systemic lupus erythematosus (SLE) is a chronic autoimmune inflammatory disease that causes severe morbidity and negatively impacts on the quality of life of those affected. SLE being a rare disease in India, little is known of the Health Related Quality Of Life (HRQOL) of patients living with SLE. This study aims at finding the SLE related Quality of life of persons living with SLE and the factors related to it.

Method: This study is a clinic based cross-sectional survey. It was conducted among 125 participants who attended the outpatient clinic for SLE in a speciality clinic in central Kerala. Socio-demographic details and medical condition related information were collected using self-administered questionnaires. Health related quality of life of the patients were measured using a 34 item LUPUSQOL questionnaire and patient reported disease activity of SLE was measured using 24 item SLAQ. The data was analysed using SPSS (IBM SPSS version 21).

Results: Among the participants of the study, 88% were females. Among the eight domains of SLE related quality of life domains, the lowest scores were observed in the domains of body image (median -66.67) and being a burden to others (median 60) and the highest observed in the domains of Intimate relationship (Median -88) , Planning social arrangements (Median- 83.33) and Pain (83.33).HRQOL related to SLE was significantly lower among women, those aged ≥ 34 years, the married and those who incurred monthly expenditures ≥ Rs.4500 .It were also negatively correlated with disease activity as measured by SLAQ.

Conclusion: The health related quality of life among SLE patients in this study was relatively good. The HRQOL assessment indicates low quality of life especially in domains of body image and perception of being burden to others. . HRQOL was negatively correlated with disease activity in all domains. Therefore quality of life assessment during routine medical care of SLE patients may be beneficial for better medical and overall treatment outcomes.

CHAPTER 1

INTRODUCTION AND REVIEW OF LITERATURE

1.1 INTRODUCTION

Systemic Lupus Erythematosus (SLE) is a chronic autoimmune inflammatory disorder characterized by periods of active disease and remission. It is manifested as multisystem episodic inflammation leading to severe morbidity and mortality. There is considerable heterogeneity in the clinical presentation and course of the disease, because it affects multiple organs, causes varied tissue damages and leads to chronic debilitating ill health (Lisnevskaia et al., 2014). Due to the wide variety of symptoms, its nature of mimicking symptoms of many illnesses and involvement of multiple organs, time to an official diagnosis often takes several years (Ozbek et al., 2003). Despite the advances in serological and other diagnostic tests, the complexity and the variations in symptoms results in difficulty or delays in diagnosis.

SLE was considered as a universally fatal disease before the discovery of corticosteroids (D'Cruz, 2006). However diagnostic and therapeutic advances have vastly improved the prognosis and survival rate of people with SLE. Estimates from the developed countries indicate that the overall life expectancy of SLE patients is 10-30 years lower than that of the general population (Bernatsky et al., 2006; Hayter and Cook, 2012).

Despite the improvements in treatment facilities and care, those affected by SLE often suffer from long-term morbidities due to the complexity of the disease. It adversely affects their health related quality of life and their ability to work, resulting in substantial direct and indirect costs (Pons-Estel et al., 2010) .

Chronic health conditions with a protracted course are known to result in adverse physical health outcomes as well as negatively impact on the overall quality of life and wellbeing of those suffering from them. There has been considerable interest in research related to the health related quality of life among people suffering from chronic health conditions in the past decade in relation to achieving better treatment outcomes for them (Shofany, 2017). Research on SLE are mostly from the developed countries and they indicate that people affected with SLE have considerably lower health related quality of life than other chronic diseases (Yazdany, 2011).

1.2 REVIEW OF LITERATURE

Systemic Lupus Erythematosus (SLE) is a multisystem connective tissue disorder with exceedingly diverse clinical manifestations. It can be life threatening when major organs are affected otherwise it is a chronic debilitating illness (D'Cruz, 2006).

1.2.1 Prevalence and Incidence of SLE

Global estimates indicate that SLE is a relatively rare disease with prevalence rates ranging from 20 to 70 per 100,000 persons (Hayter and Cook, 2012, Pons-Estel et al., 2010). The prevalence of SLE is varied across countries.

The overall incidence of SLE in the United States has ranged from 1.8 to 23.2 cases per 100,000 person years (Ferucci et al., 2014). A review of the prevalence and incidence of SLE in Asian populations concluded that the prevalence rates varied among the countries and ranged from 30-70 per 100,000 population ; with higher prevalence in China (70) and lower in countries like India, Japan and Saudi Arabia (3.2 – 19.3) (Osio-Salido and Manapat-Reyes, 2010). The incidence rates from some of the

Asian countries like India, China, Japan and Saudi Arabia varied from 0.9 to 3.1 person years (Osio-Salido and Manapat-Reyes, 2010).

The overall incidence rate in Taiwan, of the major Autoimmune Rheumatic Disorders was estimated 29.8 per 100,000 person-years between 2005 and 2009 (See et al., 2013).

A temporal increase in burden of SLE has been reported mainly from the United States. In US, the incidence of SLE has increased from 1.0 to 7.6 from a period of 1955 to 1974 (Danchenko et al., 2006) which could be due to increased awareness, changes in diagnostic facilities and criteria, and environmental factors. Wide use of immunologic tests like the antinuclear antibody test may have also contributed to the detection of milder or subclinical forms of the disease.

The only population based study on SLE in India, surveyed 91,888 individuals in a semirural population near Delhi, reported a point–prevalence of 3.2 per 100,000 (95% CI 0–6.86) (Malaviya et al., 1993). It was hypothesized that SLE is predominantly a disease of modernization and therefore the prevalence was low in countries like India that is rural (Malaviya et al., 1993).

1.2.2 Differences across groups

There is a striking disparity when sex disaggregated data on SLE is examined. SLE affects women more than men and especially during the reproductive years. Studies report almost a 9:1 female to male ratio of disease incidence and a higher female predominance during peak reproductive years (D’Cruz, 2006). The incidence and prevalence of SLE in men is almost one tenth of that of women (Pons-Estel et al., 2010).

The age of onset among women is usually between late teen years and early 40s . The peak age of disease incidence for women is during reproductive age group (ages 20–

30 years), while in men it tends to have a peak in later middle age (ages 45–60 years) (Weckerle and Niewold, 2011). Paediatric SLE, is rare, with an incidence of 0.03- 0.09 children years and a prevalence of 3.3-8.8 per 100.000 children (Levy and Kamphuis, 2012).The mean age of disease onset appears to be lower in developing Countries (Tikly and V. Navarra, 2008).

Variations across ethnic groups in the burden of the disease have also been observed. The phenotypic expression of the disease also varies across the ethnic groups. In the United States, the prevalence of SLE is higher among the non-white populations. It is more frequent among the African- Americans, Hispanics and Asians than among Caucasians (Danchenko et al., 2006). The occurrence of SLE is three to four times higher among African-American women compared to Caucasian women (Danchenko et al., 2006). SLE has been described in the six major continents (Europe, North America, South America, Africa, Asia, and Australia). It is considerably less in Africa but high in the African descendants all over the world (Pons-Estel et al., 2010) which could be due to the low disease recognition, lack of diagnostic and specialised treatment facilities (Tiffin et al., 2014).

SLE was reported for the first time in India was in 1955 followed by another 2 cases and later, a series of eight cases until 1969 (Malaviya et al., 2016). SLE was extensively studied and reported since the establishment of a clinical immunology laboratory in a major teaching institution in New Delhi in 1986. From mid-1980 onwards other centres from different regions of India including Chennai, Mumbai, Calcutta and Hyderabad also started publishing their regional finding on SLE patients from these centres. Based on their report in 2016, the clinical and laboratory characteristics about 1366 SLE patients from the different regions of India, symptoms such as arthritis, rash, photosensitivity, seizures and psychosis were comparable to other racial groups. The immunological findings such as the presence of antinuclear antibody (ANA) and anti-DNA antibody positivity were also similar to those reported from among other racial groups across the world (Malaviya et al., 2016).

1.2.3 Prognosis of the illness: morbidity and mortality

According to a study conducted in multicentre international cohort in 2006, relatively high standardised mortality rate is observed in SLE patients compared to the general population (Bernatsky et al., 2006). In a study conducted in 2015, the different causes of mortality in SLE patients came out as infection (33.2%), renal involvement (18.7%), lupus encephalopathy (13.8%), and cardiovascular disease (11.5%) as the major causes (Wang et al., 2015). As per a study done in Pakistan in 2009, renal disease contributes not only to organ damage but also to the survival rate of the patient (Rabbani et al., 2009). It is observed that due to the difference in cultural practices and use of herbal medicines of unknown composition, Indian patients appears to have more flare up of disease condition than western countries (Kakati et al., 2015). The five year and 10 year survival rate of SLE patients in India was however found to be significantly lower when compared to those reported from the United States and Europe. These differences are thought to be due to the current status of the general public health care system in the country with less than optimal management facilities in hospitals, delay in diagnosis due to lack of awareness of the disease, referral bias and issues related to access where only serious patients reach major specialty hospitals. The others could be due to a difference in the severity of the disease among Indians, or a combination of genetic, environmental and/or sociocultural factors (Malaviya et al., 2016). In a literature review done in Morocco with a specific look at publications from Africa, Asia, and Latin America in last 20 years, the disease has mostly unfavourable outcomes including disease activity, work disability and mortality in these emerging countries. Lack of access to healthcare and poor socioeconomic status are thought to be the reasons for many health disparities (Tazi Mezalek and Bono, 2014). SLE treatment in these emerging countries is restricted by the availability and cost of immunosuppressive as well as considerable diagnostic delay. Poor adherence to treatment has also been aroused due to the low income as per a study done in North America, leading to bad clinical outcomes in SLE patients with a higher risk of flares, morbidity, hospitalization, and poor renal prognosis (Garcia Popa-Lisseanu et al., 2005). Research looking at the evaluating the high direct and indirect costs for patients affected with SLE have been from developed countries; particularly from Europe and North America (Tazi Mezalek and Bono, 2014).

The aim of good clinical treatment of SLE is to promptly detect improvement or worsening of symptoms and signs, diagnose acute and chronic disease activity and damages to organ systems. These are usually measured using clinical disease activity and organ damage measures such as ECLAM, SLAM R, SLAQ, LAI, BILAG and SLEDAI for disease activity and SLICC/ACR for assessing damage (Nuttall and Isenberg, 2013).

1.2.4 Disease activity measures

It is currently accepted that assessment of patients with SLE cannot be completed with a single index. Formal evaluation of the three aspects of the disease, disease activity, disease damage and patient related quality of life (QoL), is required for that. The three patterns of disease activity observed in SLE patients are disease flare, chronically active disease and quiescence. Other medical conditions and comorbidities add to this (Nuttall and Isenberg, 2013).

Systemic Lupus Activity Questionnaire for Population Studies (SLAQ) is a patient questionnaire that can be used to collect data from a large number of SLE patients outside the hospital setting. It is based on the SLAM (Systemic Lupus Activity Measure scoring tool which is administrated by clinicians in a hospital setting), but adapted for self-reporting. It involves putting a score of 0–3 (mild– severe, respectively) for 24 items in nine organ/systems. In addition, an overall disease activity score of 0–10 over the last 3 months is recorded. It is useful for large epidemiological studies where physician– Patient interaction may be impractical, because it is costly and time consuming. It is a validated initial screening tool for identifying patients who may have new or worsening disease activity (Yazdany et al., 2008).

Advances in medical diagnosis and treatment have improved the survival of SLE patients resulting in more and more people with SLE surviving for a longer period. This has shifted the focus to improving the quality of life of people with SLE as an outcome that is as important as merely improving the clinical symptoms and signs and disease activity. There has been a growing body of research on quality of life indicators in addition to clinical end points in the management of chronic diseases like SLE.

1.2.5 Quality of life and Health related quality of life

Quality of life, from the patient's subjective experience is now considered a major outcome measure of a disease. WHO has defined QOL as 'individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns' (*Social Science & Medicine*, 1995). Health-related quality of life is defined as those aspects of quality of life (QOL) that directly or indirectly related to health (Carr et al., 2001). The terms quality of life and health-related quality of life are often used interchangeably, even though they are two distinct concepts. Quality of life can be considered as a whole as overall satisfaction with life or can be broken down into different domains. On the other hand Health-related quality of life (HRQOL) includes physical, psychological and social domains which make it a much narrower concept. It can be considered as one's subjective assessment of the physical, psychological, and social domains of health (Hand, 2016). HRQOL is usually assessed in chronic diseases along with the factors affecting poor and good HRQOL (Megari, 2013).

1.2.6 Health Related Quality of Life (HRQOL) in SLE patients

In a study conducted using 3 large observational cohorts, individuals with SLE were more likely to rate their health as poor (47%) compared to individuals with Rheumatoid arthritis (RA) (37%) or Chronic Obstructive Pulmonary Disease (COPD) (40%) which reveals the fact that SLE patients are more likely to have poor HRQOL comparing to other similar chronic diseases (Yazdany and Yelin, 2010).

1.2.7 Assessment of HRQOL among people with SLE

For the assessment of Health Related Quality of life there are two approaches; one that is generic and the other which are disease specific. Generic questionnaires were developed for the general use and it can be used for a wide variety of diseases and populations. Generic questionnaires can be used to compare between patients who have different conditions (Panopalis and Clarke, 2006). Disease specific questionnaires are specific to the measure the outcome of one particular disease which is made of disease specific elements. The disease specific questionnaires are more responsive than generic questionnaires. In SLE disease specific questionnaires are developed recently and they are not widely used (Panopalis and Clarke, 2006).

1.2.7.1 Generic measures of quality of life among people with SLE

To date, generic health status questionnaires have been used to formally assess the health-related quality of life of patients with SLE. The Short Form 36 (SF-36) has been most widely used. It covers eight domains assessing physical function, social function, and role limitation due to physical or emotional factors, mental health, vitality, pain and general health perception. There are two summary scales: the physical component scale and the mental component scale. It is easily administered and is completed by the patient. Higher values indicate better health (range 0–100) (Griffiths et al., 2005). Other generic HRQOL questionnaires that have been used in SLE include the European QoL scale(EQ-5D) (*Health Policy*, 1990) the World Health Organization quality of life scale (WHOQOL-Bref) (*Psychological Medicine*, 1998), the Nottingham health profile (NHP) (Hunt et al., 1981)and the sickness impact profile (SIP) (Bergner et al., 1981). In case of SLE, the generic measures allows comparison between other diseases but a disadvantage is the questions may not be enough to capture the disease specific symptoms or issues.

1.2.7.2 Disease specific measures of quality of life among people with SLE

Three of the disease specific questionnaires used widely in SLE are Lupusqol, SLEQoL and L-QoL. Lupusqol is a validated SLE-specific HRQOL instrument with 34 items across 8 domains defined by patients as being important (McElhone et al., 2007). The instrument demonstrated good internal reliability (Cronbach's 0.88 to 0.95), good test-retest reliability (r 0.72 to 0.93), and good concurrent validity with the comparable domains of the SF-36 (r 0.71 to 0.79). It has good discriminant validity for different levels of disease activity, measured by the British Isles Lupus Assessment Group (BILAG) index, and organ damage measured by Systemic Lupus Collaborating Clinics (SLICC/ACR-DI) but not for all domains (McElhone et al., 2007). The University of Central Lancashire and East Lancashire Hospitals NHS Trust is the copyright holder for the Lupusqol. (www.lupusqol.com)

1.2.8 Factors affecting Quality Of Life of people with SLE

1.2.8.1 Factors affecting overall quality of life of people with SLE

A study on frequency, pattern and determinants of flare in systemic lupus erythematosus: A study from North East India, there has been a report of stress as an exacerbating factor in the activity and to have an impact on quality of life but not as a provoking factor for SLE (Kakati et al., 2015). In a study conducted on geoepidemiology of SLE, it is found that ethnicity and socioeconomic status are independently associated with disease activity and overall organ damage but when it comes to mortality, poverty and low socioeconomic status have a major role than ethnicity (Borchers et al., 2010). Certain studies have reported an association between lower oxygen consumption (direct measure of peak oxygen) and worse quality of life in patients with SLE mainly due to increased physical inactivity (Balsamo and SantosNeto, 2011).

In a study conducted by S. Khanna and H. Pal in north India on quality of life of SLE patients using WHOQOL-Bref as tool, it is evident that greater impairment of QOL is in physical and psychological domains. Patients scored higher in the social and environmental domains. This seems to be a reflection of the strong family support system prevalent in India and many other Asian countries. Also, the patients from north India doesn’t show expectation of accessing quality health care at time unlike that of developed Western societies. Difficulty in attaining healthcare is widely accepted in the less developed settings. The lack of negative correlation between QOL scores in the environmental domain and disease activity scores can probably be due to low expectation in the first place (Khanna et al., 2004).

There are studies on the effect of healthy lifestyle on SLE patients; three studies on tobacco observed an association with increased SLE activity and the onset of cutaneous damage. The studies on physical exercise, of heterogeneous quality, reported that aerobic activity is safe for SLE patients, leading to an increase of tolerance to exercise, physical and functional capacity for those with moderate or low activity. A reduction in fatigue, anxiety and depression, as well as improved quality of life, is also suggested though evidence for these outcomes is limited (Rodríguez Huerta et al., 2016).

Mortality in SLE patients were studied several times. From one study conducted in US, seventeen patients with SLE who were diagnosed according to the revised American College of Rheumatology criteria died between 1998 and 2007.

Fifteen of these patients were female and two were male. The median age was 25 years. The average duration of hospital stay was 10.29 days. Seven patients (41%) died of active SLE (three from pulmonary haemorrhage, two had renal failure, one had myocarditis and one had severe thrombocytopenia with upper gastrointestinal bleed), three patients (18%) died from infections (one contracted Staphylococcal septicaemia, another contracted tuberculous meningitis and the third patient had Pseudomonas septicaemia) and in seven patients (41%) the aetiology was multi-factorial (these showed both active SLE and evidence of infection) (Sharma et al., 2013). In total 10 patients had evidence of infection, two of these were community-acquired and the rest were hospital-acquired. This shows that comorbidities have a major role in the quality of life of SLE patients.

Infections occurring in patients with rheumatic diseases are of great importance in India. Studies from major centres in India have highlighted the common occurrence of infections in patients with SLE (26.5–42.3% of patients (Shyam and Malaviya, 1996). Tuberculosis was the most common infection and, notably, infections accounted for half the deaths in patients with lupus nephritis (Dhir et al., 2012).

Since women are more prone to SLE than men predominantly during their child bearing age, the reproductive health of women have an impact on the quality of life. Contraceptive methods and pregnancy can both adversely affect the health of women with SLE, thus careful planning and interventions are necessary to help women manage their reproductive health choices (Bellakhal et al., 2013). In a study conducted among pregnant women with SLE in USA, they concluded that flare rate of SLE during pregnancy was 31% (Bellakhal et al., 2013). In another study conducted in a tertiary care centre in North India, it was inferred that the disease activity can increase during pregnancy and can cause higher rates of obstetric complications (Aggarwal et al., 2011). Another study in western India concludes that the higher disease activity and cyclophosphamide therapy can cause irreversible amenorrhea in women with SLE (Kothari et al., 2016).

1.2.8.2 Factors affecting Health Related Quality of Life among people with SLE

Patient-reported outcomes studied thus far among people affected with SLE have included factors related to disease activity like flare, disease activity, damage, quality of life, health-related quality of life, pain, fatigue, sleep, depression, anxiety, stress, helplessness, social support, coping, disability, employment, sexual health, body image, access to care, satisfaction with care, compliance, marital health, adverse events, and financial burden in relation to their health related quality of life (Jolly, 2010).

In a study conducted in a multi-ethnic cohort study old age is found to predict poor HRQOL in SLE patients (Alarcón et al., 2004). According to another study from USA, Ethnicity, education, fibromyalgia and disease activity are important associates in some domains of HRQOL in SLE (Fonta et al., 2017). According to another study done in LUMINA cohort, HRQOL over the course of SLE is influenced by disease and non-disease related factors; age, poverty, fatigue, the degree of disease activity, damage, helplessness and abnormal illness-related behaviours (Sanchez et al., 2009). In a Swedish study it was found that patients who are working full time or part time scored better HRQOL than those who does not work (Almehed et al., 2010). In a patient reported outcomes in SLE study, it came out that depression is negatively correlated to HRQOL (Moldovan et al., 2011).

1.2.8.3 Disease activity measures in SLE

According to the literature, disease activity is one of the major factors affecting health related quality of life of SLE patients and it is to measure the disease (Chaigne et al., 2017).

When it comes to disease activity, a known disjunction exists between physician and patient perceptions of their SLE-related disease activity. Patients are known to focus more on their functional limitations resulting from SLE, whereas physicians tend to focus more on laboratory evaluations. Physician assessed disease activity and damage correlate poorly with the SLE patient’s self-reported health-related quality-of-life score (Jolly and Utset, 2004). In the light of this, Systemic Lupus Erythematosus Activity Questionnaire (SLAQ) (Karlson et al., 2003) is a scale developed in English. The validation study was conducted in a large observational cohort of persons with systemic lupus erythematosus (SLE). The SLAQ had excellent reliability, as reflected by Cronbach's alpha (0.87) and principal factor analysis (one factor accounted for 92% of the variance). SLAQ scores were strongly correlated with other health indices, including the Short Form 12 Physical Component Summary and the Short Form 36 Physical Functioning subscale. The study concluded that the SLAQ demonstrates adequate reliability, construct validity and responsiveness in the large, community based cohort and appears to represent a promising tool for studies of SLE outside the clinical setting. For SLE, only this instrument has been developed and validated to date which can be used outside the clinical setting. SLAQ is a self-administered questionnaire for the persons living with SLE, consists of 24 questions (Karlson et al., 2003).

1.3 RATIONALE

Research on non-communicable diseases in India is mostly restricted to major cardiovascular, respiratory and mental health condition resulting in very limited knowledge on chronic diseases such as SLE. Considering the complex and multisystem manifestation of symptoms, health professionals as well as healthcare facilities with the expertise and training to manage such conditions are limited in number. The difficulty in diagnosis and limited access to appropriate healthcare adversely affect the morbidity and mortality related to SLE. Despite the advancements in treatment and investigations and consequently the survival of SLE patients, due to the complexity and chronicity of the illness, the health related quality of life of the patients is highly compromised. Health related quality of life is increasingly considered important in assessing patient outcomes along with clinical outcomes of people affected by chronic diseases. Most studies from India are related to clinical outcomes of SLE and limited information is available regarding the impact of the disease on the quality of life. It is therefore important to assess the health-related quality of life from a patient perspective as it reflects a dimension of treatment response and disease process.

1.4 RESEARCH QUESTION

- What is the health related quality of life of patients diagnosed with systemic lupus erythematosus?

1.5 OBJECTIVES

- To assess the health related quality of life of patients diagnosed with systemic lupus erythematosus.
- To find the factors related to health related quality of life of patients diagnosed with SLE.

CHAPTER 2

METHODOLOGY

2.1Study type

Cross-sectional survey.

2.2 Study setting

The study was conducted in a specialised clinic for SLE at Ernakulam, Kerala. This was done because the prevalence of SLE is low and it would be difficult to recruit participants in a community based study. The specialty clinic was selected assuming that majority of patients with the condition seek healthcare from the SLE clinic at the centre.

2.3 Study population

Patients diagnosed with SLE and attending the outpatient department of specialised clinic for rheumatology at Ernakulam, Kerala

2.4 Sample size:

There is one SLE clinic in a week at the centre. On each lupus clinic day, about 20 to 25 patients came for outpatient consultation. A total of around 120-130 participants were expected to attend the clinic during the study period.

Inclusion criteria: patients of age 18 or above living with SLE.

2.5 Sample selection procedures:

All eligible consecutive patients who attended the clinic on subsequent clinic days during the study period were included in the study and a total sample size of 125 was achieved.

2.6 Data collection techniques

Data collection was done from June 1st 2018 to August 31st 2018. Information was collected from 125 participants using self-administered questionnaires. The participants were asked to fill the questionnaire during their waiting time for consultation. The missing information was filled over phone calls with the participant. The contents of the questionnaire are described below.

Section1:

In this section, the questions regarding the participants' sociodemographic details, Medical condition related to SLE, Comorbidities and the monthly medical expenditure on SLE treatment and management were included.

Section2:

Disease-specific health related quality of life (HRQOL) questionnaire was included in this section. Lupusqol is used to measure disease-specific HRQOL in adult SLE. It is a 34 item self-administered questionnaire for the patients. In the contents, eight domains are covered, including physical health, emotional health, body image, pain, planning, fatigue, intimate relationships, and burden to others. Among the 34, Individual subscales are given in the following table.

TABLE 2.1 HRQOL domains in Lupusqol questionnaire

Domains	**No. of questions**
Physical health	8
Pain	3
Planning	3
Intimate relationship	2
Burden to others	3
Emotional health	6
Body image	5
Fatigue	4

The questionnaire has a 5-point Likert response format (0=all the time, 1=most of the time, 2=a good bit of the time, 3=occasionally, and 4=never) with a recall period of four weeks. Each domain score could range from a lowest possible score of 0 (worst HRQOL) to a highest possible score of 100 (best HRQOL); where higher scores Indicate better quality of life.

The Lupusqol is a copyrighted instrument owned by University of Central Lancashire and East Lancashire Hospitals NHS trust, UK. Permission to use the English and Malayalam version (with a certificate of validation) was provided by the copyright owners. (Certificate of validation attached as Annexure VII)

The questions on physical health were based on the ability to do daily activities including heavy, moderate and light physical works done by the participants. Pain related questions were on how the pain due to lupus affected the activities, sleep and mobility of the patients. Planning domain questions were to assess how SLE affects the patient in organizing/ planning events in their life. Intimate relationship questions were based on how lupus affected the sexual relationship of the participants. The burden to others domain questions is to assess the concerns and worries of the patients if they perceive themselves as a burden for others. Emotional health domain questions are to assess participant's emotional variations resulting from lupus. Questions on body image domain of Lupusqol find how the participants perceive the changes in their body image due to SLE. Last 4 questions in Lupusqol are to assess the level of fatigue experienced by the participants as a result of SLE. The Lupusqol questionnaire is attached in appendix (Annexure II and IV).

Section3:

The Systemic Lupus Activity Questionnaire (SLAQ) is included in this section. SLAQ is used in situations where clinically based disease activity measures may be difficult to obtain. The SLAQ includes 26 items; in which 24 are related to the symptom activity. The other two include a question on the presence of flares and on global disease activity. The question on flare during past 3 months is assessed as no flare (0) Yes, Mild flare (1) Yes, moderate flare (2) and Yes, severe flare (3). The question on global disease activity is marked by the patient in a scale of one to ten, according to the disease activity during the past 3 months. It is rated as 0 for no activity and 10 for the most activity. The 24 questions related to disease activity are weight loss, fatigue, fevers, oral ulcers, malar rash, photosensitivity, vasculitis, other rashes, alopecia, lymphadenopathy, dyspnea, chest pain, Raynaud's phenomenon, abdominal pain, paresthesias, seizures, stroke, memory loss, depression, headaches, myalgias, muscle weakness, arthralgias, and joint swelling (Annexure II).

2.7 Ethical considerations

An informed consent was obtained from the participants. The information given by the participant is kept confidential and used for research purposes only. The participation in this study was voluntary and hence no direct benefit for the participant. There was no risk in participating in the study. If at any point the participant wanted to quit answering questions or chose not to answer some of the questions, they were allowed to do so and it did not affect the service provision from the centre in any way.

2.8 Data analysis

The data was entered and saved in Microsoft excel and exported to SPSS (IBM SPSS windows version 21) for data analysis.

Calculation of Lupusqol domain scores were done according to the instructions provided in the website www.Lupusqol.com. The mean raw domain score was calculated by adding up the item response scores for each domain and dividing this total by the number of items in that domain. Then the mean raw domain score was divided by four (the number of Likert responses [five] minus one) and then multiplied by 100. Hence the scores were transformed to values ranging from 0-100 for all the eight domains.

SLAQ scores ranges from 0 to 44. It was calculated according to the scoring pattern of each question in the scale. The total SLAQ score grades the severity of 24 symptoms, and is calculated using an algorithm developed by Karlson et al (Karlson et al., 2003) to be as analogous as possible to the score obtained using the SLAM (Systemic Lupus Activity Measure)(scale 0–47) (Castrejón et al., 2014) .The Symptom score is the sum of the non-graded presence (= 1) or absence (= 0) of symptoms, among the 24 investigated symptoms (scale 0–24). The severity of lupus flares is rated using the score ranging from o to 3.

Global disease activity is rated on the Patient Numeric Rating Scale (PNRS) ranging from 0 to 10.

Frequency tables and Mean (SD) and Median were used to describe data. Median scores in each domain of the HRQOL were compared between stratas of different sociodemographic factors, medical conditions and comorbidities. The statistical significance of the differences were tested using non parametric tests, Mann Whitney u test for comparing two categories and Kruskal Wallis test for more than two categories, . The relationship between disease-specific HRQOL and disease activity (SLAQ) was evaluated using Spearman's rho.

CHAPTER 3

RESULTS

This study was conducted among 125 patients who are living with Systemic Lupus Erythematosus (SLE). The characteristics and medical history of the participants, assessment of disease activity using the SLAQ (Systemic lupus activity Questionnaire), and the health related quality of life (HRQOL) and factors affecting quality of life are described in this section.

3.1. Characteristics of the participants

The sociodemographic details of the participants is given in Table 3.1.

TABLE 3.1 Characteristics of the participants

Variable	Category	No of participants (N)
Sex	Male	15 (12 %)
	Female	110 (88 %)
Age of participants	≤ 34 years	64 (51.2%)
	> 34 years	61 (48.8%)
	Mean ±SD (range)	35.8 ± 11(18 – 75).
Educational status	Up to 10th standard	26 (20.8 %)
	Higher secondary	36 (28.8 %)
	Diploma/Graduate and above	63 (50.4 %)
Marital status	Single	32 (25.6 %)
	Married	93 (74.4 %)
Occupation	Home maker	62 (49.6 %)
	Daily wage/ Self	15 (12 %)
	employment	30 (24 %)
	Salaried employment	18 (14.4 %)
	Student	
Monthly income of household	Below 10000	44 (35.2%)
	10001 – 20000	38 (30.4 %)
	20001 – 30000	20 (16 %)
	Above 30000	19 (15.2 %)

Among the participants, 88 percent were female. Mean age of the participants was 35.8±11 ranging from 18 to 75 years. Nearly 80 percent of them had an education level up to higher secondary or above. Most of them, i.e., 74.4 percent are married. Coming to the occupational status, 50 percent of them are home makers. Among the total participants, 35 percent of them have reported a household monthly income below Rs.10000.

3.2 Medical conditions of the participants

TABLE 3.2 Medical conditions of the participants

Variable	Category	No of participants (N)
Age of diagnosis of SLE	10 – 30	74 (59.2 %)
	31 – 50	43 (34.4 %)
	51 -70	8 (6.4 %)
Mean age of diagnosis		29.5 ± 11, Ranging from 13 to 66.
Flare up during pregnancy (N=88)	Yes	10 (8%)
	No	58 (46.4%)
	Not applicable	20 (16%)
History of fracture	Yes	13 (10.4 %)
	No	112 (89.6 %)
Difficulty in mobility	Yes	18 (14.4 %)
	No	107 (85.6 %)

Mean age of diagnosis of SLE was 29.5±11 ranging from 13 to 66 years. About 60 percent of them got diagnosed with SLE between the ages of 10 to 30 years. Among the female participants who were married, only 8 percent had flare up of disease during their pregnancy. Also 10.4 percent had a history of fracture. Around 14.4 percent of patients had difficulty in mobility (Table 3.2).

3.3 Comorbidities of the participants

Among the patients living with SLE, the most prominent comorbidity was found to be renal disease which was reported by almost one in four of the participants.

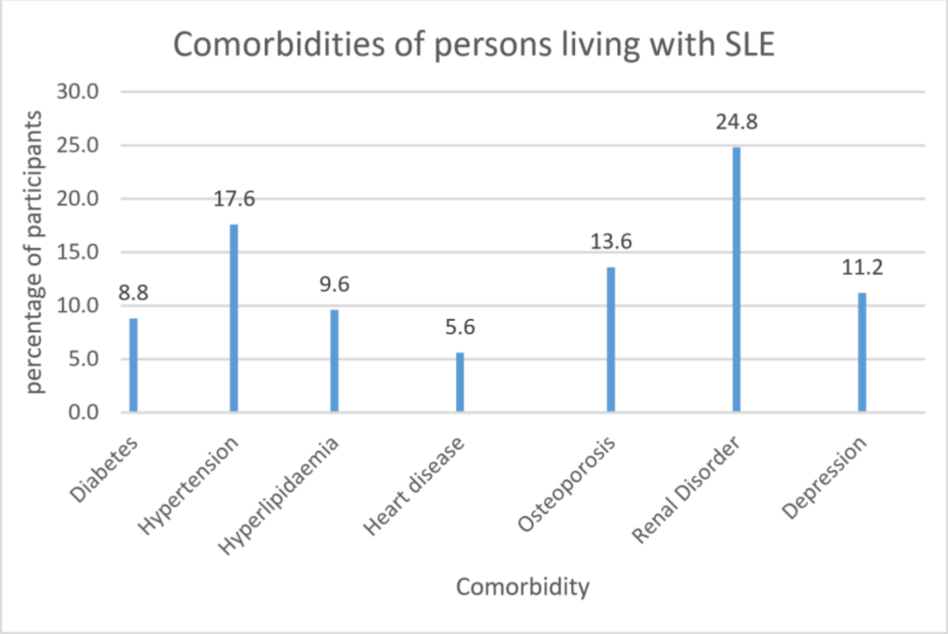

Figure 3.1 Comorbidities of persons living with SLE

3.4 Medical expenditure of the participants

The median amount of monthly expense of the participants for the medicines and investigative procedures were Rs.4500, ranging from Rs.1000 to Rs.40000. Among the total participants, only 26 (20.8 percent) of the participants had any kind of medical insurance.

The monthly expenditure of the participants is described using percentile values in Table.3.3.

TABLE 3.3 Monthly medical expenditure of the participants

PERCENTILE	MINIMUM	5	10	25	50	75	90	95	MAXIMUM
Amount	1000	1500	2000	2625	4500	7000	12300	20000	40000

The above table shows that 5 percent of the participants had a monthly medical expenditure below Rs.1500 and another 5 percent had above Rs.20000. Fifty percent of them are spending less than Rs.4500 on medical expenses of SLE including treatment and investigation.

3.5 Disease activity Of SLE in participants

Assessment of disease activity using the SLAQ (Systemic lupus activity Questionnaire) is reported as 4 sections. 36.1 percent of the participants reported flare up of disease in last 3 months. Among them only 3.2 percent had severe flare up. Using the 10 point scale the mean global disease activity was 2.78±1.8. SLAQ score of mean disease activity in the participants came out to be 8.30 ±8. Hence the disease activity was considerably low.

TABLE 3.4 SLAQ – Section 1

Variable	Category	No of participants
Patient global assessment of flare	Reported flare	44 (36.1%)
	No flare	78 (63.9%)
Patient assessment of flare severity (n=44)	Mild	32 (25.6%)
	Moderate	8 (6.4 %)
	Severe	4 (3.2%)

TABLE 3.5 SLAQ – Section 2

Variable	Category	Score
Patient global assessment of disease activity (0 – 10 scale)	Mean disease activity rating	2.78 ± 1.8
	Median	2.50
Disease activity (SLAQ) score (0 – 44 scale)	Mean disease activity (SLAQ) score	8.30 ± 8
	Median	6

3.6 Domain scores of health related quality of life

Health related quality of life (HRQOL) is reported in 8 domains, and all the domains have a median score of 60 or above, in which body image has the worst median score of 60. That means, 50 percent of the participants have body image domain score less than or equal to 60 (Table3.6).

TABLE 3.6 Percentiles of the domains of health related quality of life (Lupusqol)

		Physical health	Pain	Planning social arrangements	Burden to others	Body image	Fatigue	Emotional health	Intimate relationship (N=84)
Minimum		9	0	0	0	0	0	0	0
Maximum		100	100	100	100	100	100	100	100
Percentiles	25	57.8	58.3	50.0	41.7	40.0	43.7	50.0	50.0
	50	75.0	83.3	83.3	66.7	60.0	75.0	87.5	88.0
	75	90.6	100.0	100.0	100.0	80.0	93.7	100.0	100.0

The highest domain score was for the domain of emotional health with a median score of 87.5.For the domain Intimate relationship, response rate was low probably due to the fact that the questions were personal in nature. Among 125 participants, only 84 of them responded for these questions (a response rate of 67.2). It however had the highest domain score with the median score of 88.

3.7 Factors affecting SLE related quality of life

Factors affecting health related quality of life include the sociodemographic factors, medical conditions and disease activity. The median scores were compared using Mann Whitney U test (for two groups) and Kruskal Wallis test (for more than two groups).

3.7.1 Socioeconomic factors affecting SLE Related quality of life

In general, females have low HRQOL in all domains but statistically significant difference is observed at 5% level in the domains of physical health, pain, planning and fatigue. Physical health scores are significantly higher among younger (<=34years), not married and among students. Though it is not statistically significant, the median scores of physical health domain is increasing with higher level of education (Table 3.7)

TABLE 3.7 Socioeconomic factors affecting HRQOL domains

	Median values of the HRQOL domains							
Variables	Physical Health	Pain	Planning	Fatigue	Burden to others	Emotional health	Body image	Intimate Relationship
Sex								
male	90.63	91.67	100	93.75	83.33	91.67	70	100
female	70.31	75	83.33	68.75	66.67	72.92	55	88
P-values	0.002	0.009	0.041	0.002	0.105	0.128	0.326	0.198
Age group								
<=34 years	81.25	83.33	83.33	75	66.67	79.17	55	100
>34 years	68.75	75	83.33	75	66.67	75	60	81.5
P-values	0.028	0.107	0.813	0.721	0.633	0.446	0.683	0.721
Marital Status								
Single	89.06	91.67	83.33	75	66.67	79.17	52.5	
Married	71.88	75	83.33	75	66.67	75	60	
P-values	0.006	0.097	0.867	0.569	0.591	0.818	0.162	

Table continues…

	Median values of the HRQOL domains							
Variables	Physical Health	Pain	Planning	Fatigue	Burden to others	Emotional health	Body image	Intimate Relationship
Monthly income of household								
Below 10000 Rs	71.88	75	75	68.75	66.67	68.75	60	100
10001-20000	70.31	75	95.83	75	75	89.58	57.5	75
20001-30000	79.69	83.33	87.5	75	75	83.33	45	88
above 30000 Rs	75	83.33	83.33	75	66.67	79.17	60	94
P-values	0.964	0.998	0.41	0.943	0.418	0.113	0.929	0.487
Educational status								
Up to 10th standard	65.63	66.67	58.33	62.5	62.5	68.75	45	100
Higher secondary	71.88	75	87.5	75	75	77.08	65	88
Diploma/Graduate and above	81.25	83.33	83.33	75	66.67	79.17	60	88
P-values	0.113	0.205	0.089	0.531	0.28	0.188	0.26	0.926
Occupation								
Home maker	68.75	75	75	62.5	66.67	70.83	57.5	94
Daily wage/Self employment	78.13	91.67	83.33	81.25	66.67	87.5	60	100
Salaried employment	76.56	83.33	87.5	78.13	66.67	77.08	60	75
Student	90.63	91.67	100	78.13	79.17	79.17	52.5	100
P-values	0.007	0.093	0.756	0.418	0.608	0.691	0.636	0.278

3.7.2 Medical conditions affecting SLE related quality of life

Physical health domain scores are the lowest in those who are diagnosed at an age between 51 and 70. SLE related quality of life scores in domains of physical health, pain, planning, fatigue, burden to others and emotional health are low in those who had history of fracture and difficulty in mobility (Table.3.8).

TABLE 3.8 Medical conditions affecting HRQOL domains

	Median values of the HRQOL domains							
Variables	Physical Health	Pain	Planning	Fatigue	Burden to others	Emotional health	Body image	Intimate Relationship
Age of diagnosis of SLE								
10 – 30	81.25	83.33	83.33	68.75	66.67	75	55	100
31 – 50	68.75	75	100	81.25	75	83.33	65	81.5
51 -70	64.06	66.67	70.83	50	54.17	68.75	67.5	38
P value	0.054	0.256	0.624	0.472	0.441	0.78	0.411	0.187
History of fracture								
Yes	46.88	41.67	41.67	43.75	33.33	41.67	55	75.5
No	78.13	83.33	87.5	75	75	79.17	60	88
P value	0.001	0.004	<.000	0.005	0.002	0.007	0.406	0.362
Difficulty in mobility								
Yes	42.19	54.17	33.33	43.75	50	50	45	63
No	78.13	83.33	91.67	75	75	79.17	60	100
P value	<.000	0.001	<.000	<.000	0.008	0.003	0.341	0.093
Patient global assessment of flare								
No	81.25	91.67	100	78.13	75	85.42	60	100
Mild	60.94	58.33	66.67	53.13	50	62.5	50	63
Moderate	70.31	66.67	70.83	65.63	58.33	58.33	47.5	88
Severe	51.56	54.17	62.5	50	75	66.67	77.5	88
P value	0.307	0.225	0.707	0.74	0.976	0.97	0.41	0.481

3.7.3 Comorbidities affecting SLE related quality of life

Table 3.9 shows that in general the comorbidities affect the quality of life of SLE patients. In those who have diabetes, the domains scores of physical health, pain, planning, burden to others and intimate relationship is comparatively low. The difference between the groups is statistically significant at an alpha level 0.05. Physical health, fatigue and burden to others scores are low in those who are affected with hypertension. Physical health, pain, planning, fatigue and burden to others domain scores are low in osteoporosis patients with SLE. Scores of domains fatigue, burden to others and body image are low in those who have renal disorders. In persons those who reported as they felt depressed, all 8 domains of SLE related quality of life are low.

TABLE 3.9 Comorbidities affecting HRQOL domains

	Median values of the HRQOL domains							
Variables	Physical Health	Pain	Planning	Fatigue	Burden to others	Emotional health	Body image	Intimate Relationship
Diabetes								
Yes	65.63	58.33	41.67	58.75	50	70.83	40	38
No	75	83.33	83.33	75	70.83	75	60	100
P value	0.024	0.042	0.01	0.636	0.045	0.415	0.156	0.007
Hypertension								
Yes	64.06	66.67	66.67	50	50	56.25	45	88
No	78.13	83.33	83.33	75	75	79.17	60	88
P value	0.005	0.098	0.111	0.017	0.017	0.097	0.308	0.376
Hyperlipidaemia								
Yes	76.69	87.5	91.67	65.63	75	62.5	57.5	100
No	75	75	83.33	75	66.67	75	60	88
P value	0.491	0.352	0.65	0.652	0.611	0.572	0.724	0.464
Heart disease								
Yes	79	58.33	75	81.25	41.67	58.33	60	75
No	73.44	83.33	83.33	75	70.83	75	57.5	88
P value	0.602	0.293	0.623	0.705	0.075	0.5	0.927	0.455
Osteoporosis								
Yes	59.38	33.33	41.67	50	41.67	62.5	45	69
No	78.13	83.33	87.5	75	75	79.17	60	94
P value	0.001	<.000	0.001	0.029	0.024	0.074	0.092	0.192
Renal Disease								
Yes	68.75	75	75	62.5	50	66.67	45	63
No	76.56	83.33	91.67	78.13	75	79.17	60	100
P value	0.452	0.756	0.097	0.047	0.027	0.234	0.018	0.047
Depression								
Yes	53.13	54.17	33.33	46.88	41.67	47.92	45	50
No	78.13	83.33	91.67	75	75	79.17	60	100
P value	0.005	0.001	<.000	0.001	0.001	0.001	0.01	0.016

3.7.4 Medical expenditure affecting SLE related quality of life

Those who have a monthly medical expenditure of >Rs.4500 has low SLE related quality of life in domains of physical health, pain, planning, fatigue and emotional health (P<0.05).

TABLE 3.10 Medical expenditure affecting HRQOL domains

	Median values of the HRQOL domains							
Variables	Physical Health	Pain	Planning	Fatigue	Burden to others	Emotional health	Body image	Intimate Relationship
Insurance								
Yes	71.88	75	75	71.88	75	75	62.5	88
No	75	83.33	83.33	75	66.67	75	55	88
P value	0.384	0.841	0.46	0.871	0.383	0.869	0.658	0.671
Monthly medical expenditure								
≤4500	81.25	83.33	100	81.25	75	83.33	60	100
>4500	65.63	66.67	66.67	56.25	58.33	70.83	50	75
P value	0.002	0.009	0.001	0.023	0.11	0.029	0.117	0.075

3.7.5 Correlation between disease activity and HRQOL

TABLE 3.11 Correlation between HRQOL domains and disease activity (Spearman's rank correlation)

HRQOL Domains	**Correlation with disease activity**	**P value**
Physical health	-.541**	.000
Pain	-.519**	.000
Planning	-.475**	.000
Intimate relationship	-.329*	.002
Burden to others	-.498**	.000
Emotional health	-.504**	.000
Body image	-.229*	.010
Fatigue	-.615**	.000

**. Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

According to Spearman's rho, disease activity and HRQOL domains are negatively correlated and statistically significant. I.e., as the disease activity increases, all the domains of SLE related quality of life decreases. Physical health, pain, planning, burden to others, emotional health and fatigue has moderate negative correlation where intimate relationship and body image has a weak negative correlation.

CHAPTER 4

DISCUSSION

The interpretations of the study findings are presented in this chapter in the context of the existing literature. The implications of the research findings, the strengths and limitations of the study and finally the conclusions of the research are presented.

This study set out to examine the health related quality of life (HRQOL) and the factors associated with it, of patients diagnosed with Systemic Lupus Erythematosus (SLE). It was carried out among 125 people diagnosed with Systemic Lupus Erythematosus, attending the outpatient department of specialised clinic for SLE at Ernakulam, Kerala during the period from June 15 2018 to August 15 2018.

Almost 90 percent of the respondents who took part in the study were female, which may be due to the fact that SLE is a disease with high female preponderance, to the extent of up to a 9:1 female to male ratio as per studies (Justiz-Vaillant et al., 2015, Soto et al., 2004; Weckerle and Niewold, 2011). The mean age at diagnosis in the current study was 29.5± 11. When compared to another study in which mean age of clinical presentation is 35.5 (Metry et al., 2018) this is slightly better.

4.1 Findings of the study in the context of the current literature

Health related Quality of Life (HRQOL) was assessed using the Lupusqol scale which has 8 domains related to: Physical activity, Pain, Planning, Burden to others, Body image, Fatigue, Emotional health and Intimate relationship. Each domain score could range from a lowest possible score of 0 (worst HRQOL) to a highest possible score of 100 (best HRQOL); where higher scores indicate better quality of life.

Among the domains of the health related quality of life, body image had the lowest domain score with a median score of only 60 followed by burden to others with a median domain score of 66.7. Among the highest or the best median domain scores was the domain for emotional health which was 87.50. However the median scores in all the domains were equal or above 60 indicating relatively good HRQOL.

The domain of intimate relationship had the highest domain score of 88, but were answered by only 84 of the respondents. It could have been due to the fact that it may not have been applicable for them or may not have answered due to the very personal nature of the questions. It is in tune with the finding that though sexual problems affect the SLE related quality of life adversely, many people find it embarrassing to report them (Olesińska and Saletra, 2018).

Studies from various countries have found similar differences in terms of health related quality of life within different domains in their study populations. A study in Mexico found that the domains with the worst scores were in the domains of burden to others, fatigue, and emotional health, while the planning domain had the best score (Etchegaray-Morales et al., 2017) while others found fatigue as the most affected and intimate relationship as the least (Gordon et al., 2013). In the UK, among a cohort of outpatients with SLE, the worst scores were for fatigue and the best for body image (McELHONE et al., 2010).

It has been documented that the body image among people with SLE gets affected negatively when it tends to affect the skin and present as rashes on the face and other discomforting symptoms like discoloration or loss of hair that reduces the self- esteem of the patients about their appearance (Olesińska and Saletra, 2018). Similarly the feeling that they are a burden to others or the fear that they would become a burden to others is found to increase when their disability increases or when fatigue and depression affects their relationships (Olesińska and Saletra, 2018).

4.2 Factors associated with HRQOL:

The second objective of the study was to look at the factors associated with the health related quality of life among the people diagnosed with SLE.

In general, females had low health related quality of life in all the domains and was statistically significant in the domains of physical health, pain, and fatigue and planning. On the contrary, a study from UK concluded that there are no significant difference in Lupusqol scores according to sex or marital status (McELHONE et al., 2010).

Age was found to be associated with physical health domain scores; they were significantly higher among younger (<=34years), the not married and among students indicating better quality of life among them. The better quality of life in the physical domain for the unmarried and the students could be because they are more likely to belong to the younger age groups.

Similarly, quality of life in the physical health domain scores were the lowest among those who were diagnosed later (between 51 and 70 years) and the best among those who were diagnosed earlier (10- 30 years of age). Though it was not statistically significant, the median scores of physical health domain is increasing with higher level of education, the reasons for which may need further exploration but may be related to better awareness, better access to information regarding the condition etc . Similarly in a study conducted in Peru, the findings were older age at diagnosis was negatively correlated with HRQOL domains (Elera-Fitzcarrald et al., 2018). Though in the present study, age was not associated with the other domains of HRQOL, in another study, age appears to have a negative impact on HRQOL especially in physical health (Mcelhone et al., 2006).

In SLAQ (Systemic Lupus Activity Questionnaire), there are 26 questions in which first question is to assess the severity of flare in past three months. Next 24 questions are to assess disease activity in which the scores could range from 0 to 44. In the present study the mean disease activity is found as 8.30 ± 8 which indicates reasonably low score. The last question in SLAQ is the global assessment of disease activity in which the participant is asked to rate their disease activity of past 3 months in a scale of 1 to 10. In this study, the mean rating is 2.78 ± 1.8 which is very low could have contributed to the comparatively high HRQOL domain scores.

Disease activity was negatively correlated with all the domains of SLE related quality of life. Physical health, pain, planning, burden to others, emotional health and fatigue had moderately strong correlation whereas intimate relationship and body image had a weak correlation. Similar findings have emerged from many other studies (Etchegaray-Morales et al., 2017, Marder W et al, 2012, Elera-Fitzcarrald et al., 2018).

Presence of certain comorbidities was also associated with HRQOL among people with SLE. The most common reported comorbidity in the study was renal disorders which was reported by almost one fourth of the participants and the others were hypertension and osteoporosis. The pattern of comorbidities in people with SLE is similar to other such studies (Rees F et al., 2015, Molina et al., 2007). Around 11 percent of the respondents in the current study had reported as they felt depressed. There is considerable evidence that there is a high prevalence of those who reported as they felt depressed among those diagnosed with SLE (Zhang et al., 2017).

Those with diabetes had significantly low quality of life in the domains scores of physical health, pain, planning, burden to others and intimate relationship. Physical health, fatigue and burden to others domain scores are low in also those who are affected with hypertension. Similarly physical health, pain, planning, fatigue and burden to others domain scores were low among those with osteoporosis and the domains of fatigue, burden to others and body image were low in those with renal disorders.

In persons those who reported as they felt depressed, all the eight domains of SLE related quality of life were found to be low. Several studies have reported similar associations between depression and SLE related quality of life (Schmeding and Schneider, 2013, Etchegaray-Morales et al., 2017).

People with SLE who had history of medical conditions like a history of fracture and difficulty in mobility also reported low quality of life in the domains of physical health, pain, planning, fatigue, burden to others and emotional health.

The socioeconomic variables could not be explored in detail since it was a clinic based study; however those who had a monthly medical expenditure of more than 4500 rupees had low SLE related quality of life in domains of physical health, pain, planning, fatigue and emotional health. In this study, the medical expenses of the participants related to SLE for the past one month including expenses on consultation and investigation was asked and it ranged from Rs.1000 to Rs.40000. Since the disease course of SLE is unpredictable for each person and flare ups could happen and the costs of the drugs are across a wide range, the expenses may vary across the months. The health expenditure on the diseases and its negative impact on the health related quality of life has been reported by another study (Lau and Mak, 2009). Early diagnosis of SLE is a factor that could decrease the SLE related hospitalization and costs according to some studies (Oglesby et al., 2014).

4.3 Strengths and limitations of the study

- **Strengths**
    - Little is known about on health related quality of life of SLE patients in India.
    - Most studies have looked only at clinical outcomes
- **Limitations**
    - The main limitation of the study is that it was a specialized clinic based study and SLE patients who access regular care and therefore may not be applicable to the SLE patients in general.

4.4 Conclusion

The health related quality of life among SLE patients in this study was relatively good. The lowest scoring domains in the SLE related QOL among the participants were those related to their body image and the perception of being burden to others and the best score was in emotional health. HRQOL was negatively correlated with disease activity in all domains. Similarly presence of co- morbidities like diabetes hypertension and osteoporosis was associated low quality of life in almost domains except fatigue, emotional health and body image whereas those who felt depressed was associated with all the HRQOL domains. HRQOL related to SLE was significantly lower among women, those aged ≥ 34 years, the married and those who incurred monthly expenditures ≥ Rs.4500.

4.5 Recommendations

Routine patient reported quality of life assessment in the clinical care of SLE patients and public health support mechanisms may be required in the long term to improve their health related quality of life. Monitoring of clinical outcomes, disease activity and response to pharmacological treatment alone may not detect the patient's present condition. Quality of life assessment during routine medical care of SLE patients may be beneficial for their better medical and overall outcomes.

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ANNEXURE I

INFORMATION SHEET

Dear Sir/Madam,

I am Divya C S, a postgraduate student in Public Health studying at Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute for Medical Sciences and Technology in Trivandrum, Kerala. As a part of my course requirement I am conducting a study among persons living with SLE on their Health-Related Quality of Life and factors related. For the purpose of collecting information, I would like you to fill the questionnaire I give to you which will take 20 - 30 minutes time.

It is a routine procedure to obtain informed consent from the participant in a study. While there is no direct benefit for you individually, it is possible that the findings of the study will enhance scientific knowledge and enable us to develop better health polices to help people like you. I therefore, request you to participate in this survey.

The information given by you will not be disclosed to anyone under any circumstances anywhere in the public at any time. It will be kept confidential and used for research purposes only. Your participation in this study is purely of voluntary in nature. If at any point you want to quit answering questions or you chose not to answer some of the questions you may do so. You won’t be penalised for doing so.

If you have any queries or doubts please feel free to clarify those. I will try my level best to answer to any of your queries. My contact number is 9496882972. In case you need any clarifications about my credentials or the study, you can also contact Dr.Mala Ramanathan, Member Secretary of the Institutional Ethical Committee at Sree Chitra Tirunal Institute for Medical Science and Technology, Trivandrum on the number 04712524234.

Thank you.

CONSENT FORM

I ___________have read all the information in the study information sheet. I am over 18 years of age and hereby willingly give my consent to participate in the study.

I certify that:

1) I have fully understood the information provided about the study

2) My rights and responsibilities have been explained to me

3) I have been informed that there are no known risks associated with this study and explained the possible benefits

4) I am aware of the fact that I can opt out of the study at any time without having to give any reason

5) My identity will be kept confidential if the data is published

6) I have been provided information about individuals whom I can contact to seek clarifications during the study period.

I am willing to participate in this study (Circle the appropriate)

Yes No

If yes,

Signature or thumb impression of the participant.

Full name

Address

Phone Number

Date:

Place:

ANNEXURE II

Questionnaire

SECTION 1 PARTICIPANT ID. ☐

DATE

Please read the questions, fill the answers and tic (√) on the most appropriate.		
1	What was your age on your last birthday?	
2	Sex	☐ Male ☐ Female ☐ Transgender
3	What is the highest degree or level of school you have completed? *If currently enrolled, highest degree received.?*	☐ 1. No schooling ☐ 2. 1-7th standard ☐ 3. 8-10th standard ☐ 4. Higher secondary ☐ 5. Post higher secondary diploma /certificate ☐ 6. Graduate and Above ☐ 7. Others, Specify ☐
4	What is your marital status?	☐ 1.single, never married ☐ 2.Married ☐ 3.Widowed ☐ 4.Divorced ☐ 5. Separated
5	What is your occupation?	☐ 1. Home maker ☐ 2. Daily wage earners

		☐ 3. Salaried employment ☐ 4.Self-employment ☐ 5. Student ☐ 6.Others, specify ☐
6	What is the Monthly income of your household?	☐ 1.Below 10000 ☐ 2.10001-20000 ☐ 3.20001-30000 ☐ 4.Above 30000
7	What is your Monthly expenditure on Treatment including the medicines and investigation?	☐ 1. Below 1000 ☐ 2.1001-2000 ☐ 3. 2001-3000 ☐ 4.3001-4000 ☐ 5.Above 4000
8	Do you have any Insurance coverage? If YES, specify the type	☐ Yes ☐ No
9	At what age you got diagnosed with SLE?	
10	Have you been diagnosed of any of the given disease conditions other than SLE ?	☐ Diabetis ☐ Hypertension ☐ Hyperlipidemia ☐ Coronary Artery Disease ☐ Myasthenia Gravis ☐ Congested Heart failure ☐ Cerebro Vascular Accident

		☐ Malignancy ☐ Osteoporosis ☐ Renal failure ☐ Clinical depression
11	Do you have any history of fracture?	☐ No ☐ Yes If yes, please specify the body part,
12	Attempt only if woman; a. How many pregnancies did you have? b. Did you have flare up of SLE during any of your pregnancies?	☐ ☐
13	Do you exercise regularly?	☐ Yes ☐ No ☐ Difficult to exercise
	If yes, How regularly?	☐ dayily ☐ weekly ☐ monthly
14	Do you have any difficulty in mobility?	☐ Yes ☐ No

Section 2

LupusQoL Questionnaire

The following questionnaire is designed to find out how SLE affects your life. **Read** each statement and then circle the response, which is **closest to how you feel**. Please try to answer all the questions as honestly as you can.

Q.No	Questions	Response
1	**Because of my Lupus I need help to do heavy physical jobs such as digging the garden, painting and/or decorating, moving furniture**	☐ 1.All of the time ☐ 2.most of the time ☐ 3. good bit of the time ☐ 4.occasionally ☐ 5.never
2	**Because of my Lupus I need help to do moderate physical jobs such as vacuuming, ironing, shopping, cleaning the bathroom**	☐ 1.All of the time ☐ 2.most of the time ☐ 3. good bit of the time ☐ 4.occasionally ☐ 5.never
3	**Because of my Lupus I need help to do light physical jobs such as cooking/preparing meals, opening jars, dusting, combing my hair or attending to personal hygiene**	☐ 1.All of the time ☐ 2.most of the time ☐ 3. good bit of the time ☐ 4.occasionally ☐ 5.never
4	**Because of my Lupus I am unable to perform everyday tasks such as my job, childcare, housework as well as I would like to**	☐ 1.All of the time ☐ 2.most of the time ☐ 3. good bit of the time ☐ 4.occasionally ☐ 5.never
5	**Because of my Lupus I have difficulty climbing stairs**	☐ 1.All of the time ☐ 2.most of the time ☐ 3. good bit of the time ☐ 4.occasionally ☐ 5.never

6	**Because of my Lupus I have lost some independence and am reliant on others**	☐ 1.All of the time ☐ 2.most of the time ☐ 3. good bit of the time ☐ 4.occasionally ☐ 5.never
7	**I have to do things at a slower pace because of my Lupus**	☐ 1.All of the time ☐ 2.most of the time ☐ 3. good bit of the time ☐ 4.occasionally ☐ 5.never
8	**Because of my Lupus my sleep pattern is disturbed**	☐ 1.All of the time ☐ 2.most of the time ☐ 3. good bit of the time ☐ 4.occasionally ☐ 5.never
How often over the last 4 weeks		
9	**I am prevented from performing activities the way I would like to because of pain due to Lupus**	☐ 1.All of the time ☐ 2.most of the time ☐ 3. good bit of the time ☐ 4.occasionally ☐ 5.never
10	**Because of my Lupus, the pain I experience interferes with the quality of my sleep**	☐ 1.All of the time ☐ 2.most of the time ☐ 3. good bit of the time ☐ 4.occasionally ☐ 5.never
11	**The pain due to my Lupus is so severe that it limits my mobility**	☐ 1.All of the time ☐ 2.most of the time ☐ 3. good bit of the time ☐ 4.occasionally ☐ 5.never

12	**Because of my Lupus I avoid planning to attend events in the future**	☐1.All of the time ☐2.most of the time ☐3. good bit of the time ☐4.occasionally ☐5.never
13	**Because of the unpredictability of my Lupus I am unable to organise my life efficiently**	☐1.All of the time ☐2.most of the time ☐3. good bit of the time ☐4.occasionally ☐5.never
14	**My Lupus varies from day to day which makes it difficult for me to commit myself to social arrangements**	☐1.All of the time ☐2.most of the time ☐3. good bit of the time ☐4.occasionally ☐5.never
15	**Because of the pain I experience due to Lupus I am less interested in a sexual relationship**	☐1.All of the time ☐2.most of the time ☐3. good bit of the time ☐4.occasionally ☐5.never ☐6. not applicable
16	**Because of my Lupus I am not interested in sex**	☐1.All of the time ☐2.most of the time ☐3. good bit of the time ☐4.occasionally ☐5.never ☐6. not applicable
17	**I am concerned that my Lupus is stressful for those who are close to me**	☐1.All of the time ☐2.most of the time ☐3. good bit of the time ☐4.occasionally ☐5.never

18	**Because of my Lupus I am concerned that I cause worry to those who are close to me**	☐1.All of the time ☐2.most of the time ☐3. good bit of the time ☐4.occasionally ☐5.never
19	**Because of my Lupus I feel that I am a burden to my friends and/or family**	☐1.All of the time ☐2.most of the time ☐3. good bit of the time ☐4.occasionally ☐5.never
Over the past 4 weeks I have found my lupus makes me		
20	**Resentful**	☐1.All of the time ☐2.most of the time ☐3. good bit of the time ☐4.occasionally ☐5.never
	So fed up nothing can cheer me up	☐1.All of the time ☐2.most of the time ☐3. good bit of the time ☐4.occasionally ☐5.never
22	**Sad**	☐1.All of the time ☐2.most of the time ☐3. good bit of the time ☐4.occasionally ☐5.never
23	**Anxious**	☐1.All of the time ☐2.most of the time ☐3. good bit of the time ☐4.occasionally ☐5.never

24	**Worried**	☐1.All of the time ☐2.most of the time ☐3. good bit of the time ☐4.occasionally ☐5.never
25	**Lacking in self-confidence**	☐1.All of the time ☐2.most of the time ☐3. good bit of the time ☐4.occasionally ☐5.never
How often over the past 4 weeks		
26	**My physical appearance due to Lupus interferes with my enjoyment of life**	☐1.All of the time ☐2.most of the time ☐3. good bit of the time ☐4.occasionally ☐5.never
27	**Because of my Lupus, my appearance (e.g. rash, weight gain/loss) makes me avoid social situations**	☐1.All of the time ☐2.most of the time ☐3. good bit of the time ☐4.occasionally ☐5.never ☐6. not applicable
28	**Lupus related skin rashes make me feel less attractive**	☐1.All of the time ☐2.most of the time ☐3. good bit of the time ☐4.occasionally ☐5.never ☐6. not applicable
How often the past 4 weeks		
29	**The hair loss I have experienced because of my Lupus makes me feel less attractive**	☐1.All of the time ☐2.most of the time ☐3. good bit of the time ☐4.occasionally

		☐ 5.never ☐ 6. not applicable
30	**The weight gain I have experienced because of my Lupus treatment makes me feel less attractive**	☐ 1.All of the time ☐ 2.most of the time ☐ 3. good bit of the time ☐ 4.occasionally ☐ 5.never ☐ 6. not applicable
31	**Because of my Lupus I cannot concentrate for long periods of time**	☐ 1.All of the time ☐ 2.most of the time ☐ 3. good bit of the time ☐ 4.occasionally ☐ 5.never
32	**Because of my Lupus I feel worn out and sluggish**	☐ 1.All of the time ☐ 2.most of the time ☐ 3. good bit of the time ☐ 4.occasionally ☐ 5.never
33	**Because of my Lupus I need to have early nights**	☐ 1.All of the time ☐ 2.most of the time ☐ 3. good bit of the time ☐ 4.occasionally ☐ 5.never
34	**Because of my Lupus I am often exhausted in the morning**	☐ 1.All of the time ☐ 2.most of the time ☐ 3. good bit of the time ☐ 4.occasionally ☐ 5.never

SECTION 3

SLAQ

In the past 3 months, have you had a lupus flare? (A lupus flare is when your lupus gets worse) which of the following response best describes you?

☐ No, no flare

☐ Yes, Mild flare

☐ Yes, moderate flare

☐ Yes, severe flare

2. Please review the following list of lupus symptoms. IN THE PAST 3 MONTHS

how bad has each of the symptoms been?

		Mild	Moderate	Severe	No problem
A	Lost weight without trying				
B	Fatigue				
C	Fevers (>101◦F, 38◦C) taken by thermometer				
D	Sores in mouth or nose				
E	Rash on cheeks (shaped like a butterfly)				
F	Any Other Rash (Where? _____________)				
G	Dark blue or purple spots you could feel on your skin				
H	Rash or feeling sick after going out in the sun				

I	Bald patches on scalp, or clumps of hair on pillow				
J	Swollen glands(nodes) in the neck				
K	Shortness of breath				
L	Chest pain with a deep breath				
M	Fingers or toes turning dead white or very pale in the cold (Reynold’s)				
N	Stomach or belly pain				
O	Persistent numbness or tingling in your arms or legs				
P	Seizures				
Q	Stroke				
R	Forgetfulness				
S	Feeling depressed				
T	Unusual headaches				
U	Muscle pain				
V	Muscle weakness				
W	Pain or stiffness of joints				
X	Swelling in joints				

3. Please rate the disease activity of your lupus DURING THE PAST 3 MONTHS on the scale below, where 0 is no activity and 10 is the most activity. (Fill in the Rectangle for your most active day)

No activity

Most activity

ANNEXURE III

കാര്യവിവരണ പത്രിക

സർ/ മാഡം,

ദിവ്യ സി എസ് എന്ന ഞാൻ, ശ്രീ ചിത്ര തിരുനാള് ഇൻസ്റ്റിറ്റ്യൂട്ട് ഫോര് മെഡിക്കല് സയൻസസ്സ് ആന്റ് ടെക്നോളജി, തിരുവനന്തപുരം, കേരളയിലെ അച്ചുതമേനോൻ സെന്റര് ഫോര് ഹെല്ത്ത് സയൻസില്, മാസ്റ്റര് ഓഫ് പബ്ലിക് ഹെല്ത്ത് ബിരുദാനന്തരബിരുദ വിദ്യാര്ത്ഥിനിയാണ്. എന്റ പഠന പദ്ധതിയുടെ ഭാഗമായി SLE രോഗികളുടെ ആരോഗ്യ സംബന്ധമായ ജീവിത നിലവാരവും അതിനെ സ്വാധീനിക്കുന്ന ഘടകങ്ങളും എന്നതിൽ ഒരു പഠനം നടത്തുകയാണ്. പഠനത്തിന്റെ വിവരശേഖരണത്തിനു വേണ്ടി താങ്കളോട് ഒരു ചോദ്യാവലി പൂരിപ്പിക്കാൻ ആവശ്യപ്പെടുകയാണ്. ഇതിനായി താങ്കളുടെ 20 മുതല് 30 മിനിട്ടുവരെയുള്ള സമയം എടുക്കും. പങ്കെടുക്കുന്നവരുടെ കാര്യബോധത്തോടെയുള്ള സമ്മതം നേടുക എന്നത് പഠനത്തിനാവശ്യമാകയാല് ഇക്കാര്യത്തില് ഞാൻ താങ്കളുടെ സമ്മതം അഭ്യര്ത്ഥിക്കുന്നു. ഇതിൽ നിന്ന് താങ്കള്ക്ക് വ്യക്തിപരമായി നേരിട്ടൊരു നേട്ടവുമുണ്ടാകില്ല. എന്നാല് പഠനത്തിലെ കണ്ടെത്തലുകള് ശാസ്ത്രീയ അറിവ് വർദ്ധിപ്പിക്കുകയും താങ്കളെപ്പോലുള്ളവർക്ക് സഹായകമായ മെച്ചപ്പെട്ട ആരോഗ്യനയങ്ങള് വികസിപ്പിക്കാൻ ഞങ്ങളെ സഹായിക്കുകയും ചെയ്യും. ഈ പഠനത്തില് പങ്കെടുക്കാൻ ഞാൻ താങ്കളോടഭ്യര്ത്ഥിക്കുന്നു. താങ്കളുടെ വ്യക്തിവിവരങ്ങളും താങ്കള് നല്കിയ വിവരങ്ങളും സ്വകാര്യമായും രഹസ്യമായും സൂക്ഷിക്കുകയും ഗവേഷണവുമായി ബന്ധമില്ലാത്ത ആരോടും ഒരു കാലത്തും വെളിപ്പെടുത്താതിരിക്കുകയും ചെയ്യുന്നതാണ്. അത് രഹസ്യമായി സൂക്ഷിക്കുകയും ഗവേഷണാവശ്യങ്ങള്ക്കു മാത്രം ഉപയോഗിക്കുകയും ചെയ്യും. താങ്കളുടെ ഈ പഠനത്തിലുള്ള പങ്കാളിത്തം സ്വമേധയാ ആയിരിക്കും. എതെങ്കിലും സമയത്ത് താങ്കള്ക്ക് പഠനത്തില്നിന്നും പിൻവാങ്ങണമെങ്കില് അങ്ങനെ ചെയ്യാം. അതിനെത്തുടർന്ന് താങ്കൾക്ക് ഒരുതരത്തിലുള്ള പ്രശ്നങ്ങളും ഉണ്ടാകില്ല.

താങ്കൾക്ക് എന്തങ്കിലും ചോദ്യങ്ങളോ എന്റെ യോഗ്യതയെപ്പറ്റിയോ പഠനത്തെപ്പറ്റിയോ വിശദീകരണമോ ആവശ്യം ഉണ്ടെങ്കില് എന്നെയോ (കോൺടാക്ട് നമ്പർ- 9496882972) ഇൻസ്റ്റിറ്റ്യൂട്ടിലെ എത്തിക്സ് കമ്മിറ്റി മെമ്പർ സെക്രട്ടറി ഡോ മാല രാമനാഥനെയോ (കോൺടാക്ട് നമ്പർ- 0471 25 2434) ബന്ധപ്പെടാം.

നന്ദി

ഡോ. ദിവ്യ. സി. എസ്

സമ്മതപത്രം

പഠനത്തിന്റെ കാര്യവിവരണപത്രത്തില് നല്കിയിരിക്കുന്ന വിവരങ്ങള്

....   എന്ന ഞാൻ വായിക്കുകയും മനസ്സിലാക്കുകയും ചെയ്തു. 18 വയസ്സിനുമേല് പ്രായമുള്ള ഞാൻ ഈ പഠനത്തില് പങ്കെടുക്കാനുള്ള സമ്മതം സ്വമനസ്സാലെ ഇതിനാല് നല്കുന്നു.

എന്റെ അവകാശങ്ങളെക്കുറിച്ചും ഉത്തരവാദിത്തങ്ങളെക്കുറിച്ചും ഈ പഠനത്തില് പങ്കെടുക്കുന്നതില് അറിയപ്പെടുന്ന അപായങ്ങളൊന്നുമില്ലെന്നതും സാധ്യമായ നേട്ടങ്ങളും എന്നെ അറിയിച്ചു. പഠനത്തിനിടയില് വിശദീകരണമൊന്നും കൂടാതെ ഏതുസമയത്തും എനിക്ക് പഠനത്തില്നിന്നും പിൻമാറാമെന്ന വസ്തുതയും എന്റെ വ്യക്തിത്വവും വ്യക്തിപരമായ വിവരങ്ങളും സ്വകാര്യതയും രഹസ്യമായിരിക്കുമെന്നതും എനിക്ക് ബോധ്യമുണ്ട്.

പഠനകാലയളവില് കൂടുതലെന്തെങ്കിലും വിശദീകരണമാവശ്യമെങ്കില് ബന്ധപ്പെടാനുള്ള വ്യക്തികളുടെ വിവരങ്ങളും എനിക്ക് നല്കിയിട്ടുണ്ട് .

ഈ പഠനത്തില് പങ്കെടുക്കാൻ എനിക്ക് സമ്മതമാണ്.

അതെ   അല്ല

അതെയെങ്കില് പങ്കെടുക്കുന്നയാളുടെ

ഒപ്പ്/വിരലടയാളം

പൂര്ണ്ണമായ പേര്

വിലാസം

ഫോൺ നമ്പർ

തീയതി

സ്ഥലം

ANNEXURE IV

QUESTIONNAIRE

SECTION 1 പങ്കെടുക്കുന്നയാളുടെ ഐ ഡി ☐

താഴെ കൊടുത്തിരിക്കുന്ന ചോദ്യങ്ങൾക്ക് ഉത്തരം നൽകുക. / ഏറ്റവും അനുയോജ്യമായതിനു നേരെ (√) ചെയ്യുക.

1	കഴിഞ്ഞ ജന്മദിനത്തിൽ നിങ്ങളുടെ വയസ്സ് എത്രയായിരുന്നു?	
2	ലിംഗം	☐ സ്ത്രീ ☐ പുരുഷൻ ☐ ട്രാൻസ്ജെൻഡർ
3	നിങ്ങൾ പൂർത്തിയാക്കിയ ഉയർന്ന ബിരുദം അല്ലെങ്കിൽ വിദ്യാഭ്യാസ നിലവാരം ഏത്? നിലവിൽ പഠനത്തിലാണെങ്കിൽ ,ലഭിച്ചിട്ടുള്ള ഉയർന്ന ബിരുദം ഏത്?	☐ സ്കൂളിൽ പോയിട്ടില്ല ☐ 1-7 സ്റ്റാൻഡേർഡ് ☐ 8-10 സ്റ്റാൻഡേർഡ് ☐ ഹയർ സെക്കൻഡറി ☐ പോസ്റ്റ് ഹയർ സെക്കൻഡറി ഡിപ്ലോമ ☐ ഡിഗ്രിയോ അതിന് മുകളിലോ ☐ മറ്റുള്ളവ വ്യകതമാക്കുക
4	താങ്കളുടെ വൈവാഹിക നില എന്താണ്?	☐ അവിവാഹിതൻ/അവിവാഹിത ☐ വിവാഹിതൻ/ വിവാഹിത ☐ വിഭാര്യൻ / വിധവ ☐ വിവാഹമോചിതൻ/വിവാഹമോചിത ☐ വേർ പിരിഞ്ഞ് ജീവിക്കുന്നു
5	നിങ്ങളുടെ തൊഴിൽ എന്ത്?	☐ ഗൃഹഭരണം ☐ ദിവസ വേതന തൊഴിൽ ☐ ശമ്പള വ്യവസ്ഥയിലുള്ള തൊഴിൽ ☐ സ്വയം തൊഴിൽ ☐ വിദ്യാർത്ഥി / വിദ്യാർത്ഥിനി ☐ മറ്റുള്ളവ, വ്യക്തമാക്കുക

6	നിങ്ങളുടെ കുടുംബത്തിന്റെ മാസവരുമാനം എത്ര?	☐ 10000 ൽ താഴെ ☐ 10001-20000 ☐ 20001-30000 ☐ 30000 ന് മുകളിൽ
7	ചികിത്സായിനത്തിൽ മരുന്നുകളും പരിശോധനകളുമുൾപ്പെടെ നിങ്ങളുടെ പ്രതിമാസ ചെലവ് എത്ര?	☐ 1000 ൽ താഴെ ☐ 1001-2000 ☐ 2001-3000 ☐ 3001- 4000 ☐ 4000 ന് മുകളിൽ
8	നിങ്ങൾ ഇൻഷുറൻസ് ഉപഭോക്താവാണോ? ആണെങ്കിൽ വ്യക്തമാക്കുക.	☐ അതേ ☐ അല്ല
9	എത്രാമത്തെ വയസ്സിലാണ് നിങ്ങൾക്ക് SLE രോഗനിർണയം നടത്തിയത്?	
10	ഇവിടെ പരാമർശിച്ചിട്ടുള്ള രോഗങ്ങൾ നിങ്ങളിൽ കണ്ടെത്തിയിട്ടുണ്ടോ?	☐ പ്രമേഹം ☐ രക്തസമ്മർദ്ദം ☐ രക്തത്തിൽ കൊഴുപ്പ് കൂടിയ അവസ്ഥ ☐ ഹൃദ്രോഗം ☐ അർബുദം ☐ അസ്ഥികളുടെ തേയ്മാനം ☐ വൃക്ക സംബന്ധമായ അസുഖം ☐ വിഷാദം
11	താങ്കൾക്ക് അസ്ഥിയിൽ ഏതെങ്കിലും തരത്തിലുള്ള പൊട്ടലുകൾ ഉണ്ടായിട്ടുണ്ടോ? ഉണ്ടെങ്കിൽ ഏത് ശരീരഭാഗമെന്ന് വ്യക്തമാക്കുക	☐ ഉണ്ട് ☐ ഇല്ല

12	നിങ്ങൾ സ്ത്രീയാണെങ്കിൽ പ്രതികരിക്കുക നിങ്ങൾ എത്ര തവണ ഗർഭം ധരിച്ചു? ഏതെങ്കിലും ഗർഭ സമയത്ത് രോഗാവസ്ഥ കൂടിയതായി അനുഭവപ്പെട്ടോ?	
13	താങ്കൾ പതിവായി വ്യായാമം ചെയ്യാറുണ്ടോ?	☐ ഉണ്ട് ☐ ഇല്ല ☐ വ്യായാമം ചെയ്യാൻ ബുദ്ധിമുട്ടാണ്
	ഉണ്ടെങ്കിൽ പതിവായി എങ്ങനെ?	☐ ദിവസവും ☐ ആഴ്ചതോറും ☐ മാസംതോറും
14	താങ്കൾക്ക് ചലിക്കാൻ എന്തെങ്കിലും ബുദ്ധിമുട്ടുണ്ടോ?	☐ ഉണ്ട് ☐ ഇല്ല

SECTION 2

LUPUS QoL

ലൂപസ് ജീവിത ഗുണനിലവാര ചോദ്യാവലി

എസ്എല്ഇ (ലൂപസ്) നിങ്ങളുടെ ജീവിതത്തെ എങ്ങിനെ ബാധിക്കുന്നു എന്നു കണ്ടെത്താനായി രൂപകല്പന ചെയ്തിട്ടുള്ളതാണ് ചുവടെ കൊടുത്തിരിക്കുന്ന ചോദ്യാവലി. ഓരോ പ്രസ്താവനയും വായിച്ച ശേഷം നിങ്ങള്ക്ക് എങ്ങിനെ തോന്നുന്നോ അതിനോട് ഏറ്റവും അടുത്തു നില്ക്കുന്ന ഉത്തരം അടയാളപ്പെടുത്തുക. എല്ലാ ചോദ്യങ്ങള്ക്കും കഴിവതും സത്യസന്ധമായി ഉത്തരം നല്കാൻ ദയവായി ശ്രമിക്കുക.

കഴിഞ്ഞ 4 ആഴ്ചകളില് എത്ര മാത്രം.....		
1	എന്റെ ലൂപസ് രോഗം കാരണം പൂന്തോട്ടത്തിലെ മണ്ണുനീക്കുക, പെയിന്റിംഗ് അല്ലെങ്കില് അലങ്കാരപ്പണികള്, ഫര്ണിച്ചറുകള് നീക്കുക തുടങ്ങി കനത്ത ശാരീരിക അധ്വാനം	☐ 1 എല്ലായ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ ☐ 4 വല്ലപ്പോഴും ☐ 5 ഒരിക്കലുമില്ല

	ആവശ്യമുള്ള ജോലികള് ചെയ്യാൻ എനിക്ക് സഹായം വേണ്ടി വരുന്നു	
2	എന്റെ ലൂപസ് രോഗം കാരണം വാക്വം ക്ലീനര് ഉപയോഗിക്കുക, ഇസ്തിരിയിടുക, ഷോപ്പിംഗ്, ബാത്ത്റൂം വൃത്തിയാക്കുക തുടങ്ങി മിതമായ ശാരീരിക അധ്വാനം ആവശ്യമുള്ള ജോലികള് ചെയ്യാൻ എനിക്ക് സഹായം വേണ്ടി വരുന്നു	☐ 1 എല്ലായ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ ☐ 4 വല്ലപ്പോഴും ☐ 5 ഒരിക്കലുമില്ല
3	എന്റെ ലൂപസ് രോഗം കാരണം പാചകം/ഭക്ഷണം തയ്യാറാക്കുക, ജാറുകള് തുറക്കുക, പൊടി തുടയ്ക്കുക, എന്റെ മുടി ചീകുക അല്ലെങ്കില് വ്യക്തിഗത ശുചിത്വ കാര്യങ്ങള് ശ്രമിക്കുക തുടങ്ങി ലഘുവായ ശാരീരിക അധ്വാനം ആവശ്യമുള്ള ജോലികള് ചെയ്യാൻ എനിക്ക് സഹായം വേണ്ടി വരുന്നു	☐ 1 എല്ലായ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ ☐ 4 വല്ലപ്പോഴും ☐ 5 ഒരിക്കലുമില്ല
4	എന്റെ ലൂപസ് രോഗം കാരണം എന്റെ ജോലി, കുട്ടികളെ പരിപാലിക്കല്, വീട്ടുജോലി തുടങ്ങിയ ദൈനംദിന ചുമതലകള് ഞാനിഷ്ടെപ്പടുന്ന രീതിയില് ചെയ്യാൻ എനിക്ക് കഴിയുന്നില്ല	☐ 1 എല്ലായ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ ☐ 4 വല്ലപ്പോഴും ☐ 5 ഒരിക്കലുമില്ല
5	എന്റെ ലൂപസ് രോഗം കാരണം എനിക്ക് പടികള് കയറുവാൻ ബുദ്ധിമുട്ടുണ്ട്	☐ 1 എല്ലായ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ ☐ 4 വല്ലപ്പോഴും ☐ 5 ഒരിക്കലുമില്ല
6	എന്റെ ലൂപസ് രോഗം കാരണം എനിക്ക് കുറച്ച് സ്വാതന്ത്ര്യം നഷ്ടപ്പെടുകയും, മറ്റുള്ളവരെ ആശ്രയിക്കേണ്ടതായും വരുന്നു	☐ 1 എല്ലായ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ ☐ 4 വല്ലപ്പോഴും ☐ 5 ഒരിക്കലുമില്ല
7	എന്റെ ലൂപസ് രോഗം കാരണം എനിക്ക് കുറഞ്ഞ	☐ 1 എല്ലായ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ

	വേഗതയില് കാര്യങ്ങള് ചെയ്യേണ്ടി വരുന്നു	☐ 4 വല്ലപ്പോഴും ☐ 5 ഒരിക്കലുമില്ല
8	എന്റെ ലൂപസ് രോഗം കാരണം എന്റെ ഉറക്കത്തിന്റെ ക്രമം തടസ്സപ്പെട്ടു	☐ 1 എല്ലായ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ ☐ 4 വല്ലപ്പോഴും ☐ 5 ഒരിക്കലുമില്ല
9	എന്റെ ലൂപസ് രോഗം കാരണമുള്ള വേദന മൂലം കാര്യങ്ങള് എനിക്കിഷ്ടമുള്ള രീതിയില് നിര്വഹിക്കുന്നതിന് തടസ്സം നേരിട്ടു	☐ 1 എല്ലായ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ ☐ 4 വല്ലപ്പോഴും ☐ 5 ഒരിക്കലുമില്ല
കഴിഞ്ഞ 4 ആഴ്ചകളില് എത്ര മാത്രം…..		
10	ലൂപസ് രോഗം മൂലം ഞാൻ അനുഭവിക്കുന്ന വേദന എന്റെ ഉറക്കത്തിന്റെ ഗുണമേന്മയെ ബാധിക്കുന്നു	☐ 1 എല്ലായ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ ☐ 4 വല്ലപ്പോഴും ☐ 5 ഒരിക്കലുമില്ല
11	എന്റെ ചലനക്ഷമതയെ പരിമിതെപ്പടുത്തക്കവിധം കഠിനമാണ് ലൂപസ് രോഗം മൂലം ഞാൻ അനുഭവിക്കുന്ന വേദന	☐ 1 എല്ലായ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ ☐ 4 വല്ലപ്പോഴും ☐ 5 ഒരിക്കലുമില്ല
12	എന്റെ ലൂപസ് രോഗം കാരണം ഭാവിയിലെ ചടങ്ങുകളില് പങ്കെടുക്കാൻ പ്ലാൻ ചെയ്യുന്നത് ഞാൻ ഒഴിവാക്കുന്നു	☐ 1 എല്ലായ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ ☐ 4 വല്ലപ്പോഴും ☐ 5 ഒരിക്കലുമില്ല
13	എന്റെ ലൂപസ് രോഗ ത്തിന്റെ അനിശ്ചിതത്വം കാരണം എന്റെ ജീവിതം കാര്യക്ഷമമായി ക്രമീകരിക്കാൻ എനിക്ക് കഴിയുന്നില്ല	☐ 1 എല്ലായ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ ☐ 4 വല്ലപ്പോഴും

		☐ 5 ഒരിക്കലുമില്ല
14	മറ്റ് ആളുകളുമായി ഒത്തുചേരലുകള് മുൻകൂട്ടി തീരുമാനിക്കാൻ ബുദ്ധിമുട്ടാകുന്ന വിധത്തില് എന്റെ ലൂപസ് രോഗം ഓരോ ദിവസവും വ്യത്യസ്തമാകുന്നു	☐ 1 എല്ലായ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ ☐ 4 വല്ലപ്പോഴും ☐ 5 ഒരിക്കലുമില്ല
15	ലൂപസ് രോഗം കാരണം ഞാൻ അനുഭവിക്കുന്ന വേദന മൂലം എനിക്ക് ലൈംഗിക ബന്ധത്തില് താല്പര്യക്കുറവുണ്ട്	☐ 1 എല്ലായ്പ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ ☐ 4 വല്ലപ്പോഴും ☐ 5 ഒരിക്കലുമില്ല ☐ 793 ബാധകമല്ല
16	ലൂപസ് രോഗം കാരണം ഞാൻ അനുഭവിക്കുന്ന വേദന മൂലം എനിക്ക് സെക്സില് താല്പര്യമില്ല	☐ 1 എല്ലായ്പ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ ☐ 4 വല്ലപ്പോഴും ☐ 5 ഒരിക്കലുമില്ല ☐ 793 ബാധകമല്ല
17	എന്നോട് ഏറ്റവും അടുത്ത ആളുകള്ക്ക് എന്റെ ലൂപസ് രോഗം സമ്മര്ദമുണ്ടാക്കുന്നു എന്ന് ഞാൻ ആശങ്കപ്പെടുന്നു	☐ 1 എല്ലായ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ ☐ 4 വല്ലപ്പോഴും ☐ 5 ഒരിക്കലുമില്ല
18	എന്റെ ലൂപസ് രോഗം കാരണം എന്നോട് ഏറ്റവും അടു ത്ത ആളുകള്ക്ക് ഞാൻ ആധിയുണ്ടാക്കുന്നതായി ഞാൻ ആശങ്കെപ്പടുന്നു	☐ 1 എല്ലായ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ ☐ 4 വല്ലപ്പോഴും ☐ 5 ഒരിക്കലുമില്ല
കഴിഞ്ഞ 4 ആഴ്ചകളില് എത്ര മാത്രം.....		
19	എന്റെ ലൂപസ് രോഗം കാരണം എന്റെ സുഹൃ ത്തുക്കള്ക്കോ കുടുംബത്തിനോ ഞാനൊരു ഭാരമായതായി എനിക്ക് തോന്നുന്നു	☐ 1 എല്ലായ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ ☐ 4 വല്ലപ്പോഴും

		☐ 5 ഒരിക്കലുമില്ല
കഴിഞ്ഞ 4 ആഴ്ചകളിൽ എന്റെ ലൂപസ് രോഗം എന്നെ.....		
20	ദേഷ്യം പിടിപ്പിച്ചു	☐ 1 എല്ലായ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ ☐ 4 വല്ലപ്പോഴും ☐ 5 ഒരിക്കലുമില്ല
21	ഒന്നിനും സന്തോഷിപ്പിക്കാൻ കഴിയാത്ത വിധം എന്നെ മടുപ്പിച്ചു	☐ 1 എല്ലായ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ ☐ 4 വല്ലപ്പോഴും ☐ 5 ഒരിക്കലുമില്ല
22	ദു:ഖത്തിലാക്കി	☐ 1 എല്ലായ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ ☐ 4 വല്ലപ്പോഴും ☐ 5 ഒരിക്കലുമില്ല
23	ആശങ്കപ്പെടുത്തി	☐ 1 എല്ലായ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ ☐ 4 വല്ലപ്പോഴും ☐ 5 ഒരിക്കലുമില്ല
24	ആധിയിലാഴ്ത്തി	☐ 1 എല്ലായ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ ☐ 4 വല്ലപ്പോഴും ☐ 5 ഒരിക്കലുമില്ല
25	ആത്മവിശ്വാസക്കുറവുണ്ടാക്കി	☐ 1 എല്ലായ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ ☐ 4 വല്ലപ്പോഴും ☐ 5 ഒരിക്കലുമില്ല
കഴിഞ്ഞ 4 ആഴ്ചകളിൽ എത്ര മാത്രം.....		

26	ലൂപസ് രോഗം കാരണമുള്ള എന്റെ ശാരീരിക രൂപം എനിക്ക് ജീവിതം ആസ്വദിക്കുന്നതിന് തടസ്സമാകുന്നു	☐ 1 എല്ലായ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ ☐ 4 വല്ലപ്പോഴും ☐ 5 ഒരിക്കലുമില്ല
കഴിഞ്ഞ 4 ആഴ്ചകളില് എത്ര മാത്രം.....		
27	ലൂപസ് രോഗം കാരണമുള്ള എന്റെ ശാരീരിക രൂപം (ഉദാ: ചര്മ്മത്തില് ചുവന്നു തടിച്ച പാടുകള്, തൂക്കം വയ്ക്കല്/കുറയല്) സാമൂഹിക സാഹചര്യങ്ങള് ഒഴിവാക്കാൻ എന്നെ പ്രേരിപ്പിക്കുന്നു	☐ 1 എല്ലായ്പ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ ☐ 4 വല്ലപ്പോഴും ☐ 5 ഒരിക്കലുമില്ല ☐ 793 ബാധകമല്ല
28	ലൂപസ് രോഗം മൂലം ചര്മ്മത്തിലുള്ള ചുവന്നു തടിച്ച പാടുകള് എന്റെ ആകര്ഷകത്വം കുറയ്ക്കുന്നതായി എനിക്ക് തോന്നുന്നു	☐ 1 എല്ലായ്പ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ ☐ 4 വല്ലപ്പോഴും ☐ 5 ഒരിക്കലുമില്ല ☐ 793 ബാധകമല്ല
29	എന്റെ ലൂപസ് രോഗം കാരണം എനിക്ക് അനുഭവെപ്പട്ട മുടി കൊഴിച്ചില് എന്റെ ആകര്ഷകത്വം കുറച്ചു കളഞ്ഞതായി തോന്നുന്നു	☐ 1 എല്ലായ്പ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ ☐ 4 വല്ലപ്പോഴും ☐ 5 ഒരിക്കലുമില്ല ☐ 793 ബാധകമല്ല
30	എന്റെ ലൂപസ് രോഗ ചികിത്സ കാരണമുള്ള തൂക്കം വയ്ക്കല് എന്റെ ആകര്ഷകത്വം കുറച്ചു കളഞ്ഞതായി തോന്നുന്നു.	☐ 1 എല്ലായ്പ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ ☐ 4 വല്ലപ്പോഴും ☐ 5 ഒരിക്കലുമില്ല ☐ 793 ബാധകമല്ല
31	എന്റെ ലൂപസ് രോഗം കാരണം എനിക്ക് ദീര്ഘ സമയത്തേക്ക് ശ്രദ്ധ കേന്ദ്രീകരിക്കാൻ സാധിക്കുന്നില്ല	☐ 1 എല്ലായ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ ☐ 4 വല്ലപ്പോഴും

		☐ 5 ഒരിക്കലുമില്ല
32	എന്റെ ലൂപസ് രോഗം കാരണം എനിക്ക് അവശതയും അലസതയും തോന്നുന്നു	☐ 1 എല്ലായ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ ☐ 4 വല്ലപ്പോഴും ☐ 5 ഒരിക്കലുമില്ല
33	എന്റെ ലൂപസ് രോഗം കാരണം എനിക്ക് രാത്രി നേരത്തേ ഉറങ്ങേണ്ടി വരുന്നു	☐ 1 എല്ലായ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ ☐ 4 വല്ലപ്പോഴും ☐ 5 ഒരിക്കലുമില്ല
34	എന്റെ ലൂപസ് രോഗം കാരണം പ്രഭാതത്തില് ഞാൻ മിക്കവാറും ഊര്ജ്ജം വറ്റിയ നിലയിലാണ്	☐ 1 എല്ലായ്പോഴും ☐ 2 മിക്കവാറും ☐ 3 ചിലപ്പോഴൊക്കെ ☐ 4 വല്ലപ്പോഴും ☐ 5 ഒരിക്കലുമില്ല

നിങ്ങള് എല്ലാ ചോദ്യങ്ങള്ക്കും ഉത്തരം നല്കിയോ എന്ന് ദയവായി പരിശോധിക്കുക.

ഈ ചോദ്യാവലി പൂരിപ്പിച്ചതിന് നന്ദി.

Section 3

SLAQ

കഴിഞ്ഞ 3 മാസത്തിൽ താങ്കളുടെ ലൂപസ് രോഗാവാസ്ഥ പെട്ടെന്ന് കൂടിയതായി തോന്നിയോ? താഴെ കൊടുത്തിരിക്കുന്നതിൽ ഏത് അവസ്ഥയാണ് അതിനെ വിവരിക്കുക?

- ☐ ഒട്ടും കൂടിയില്ല
- ☐ ചെറുതായി കൂടി
- ☐ മിതമായി കൂടി
- ☐ വളരെയധികം കൂടി

ദയവായി താഴെ കൊടുത്തിരിക്കുന്ന ലൂപസ് ലക്ഷണങ്ങളുടെ ലിസ്റ്റ് വായിക്കുക. കഴിഞ്ഞ 3 മാസത്തിൽ ഈ ലക്ഷണങ്ങൾ എങ്ങനെയാണ് നിങ്ങൾക്ക് അനുഭവപ്പെട്ടത്?

		ചെറിയ തോതിൽ	മിതമായി	കഠിനമായി	കുഴപ്പമില്ല
A	അകാരണമായി ഭാരം കുറഞ്ഞു				
B	ക്ഷീണം				
C	പനി (> 101 °F, 38°C) തെർമോമീറ്ററിൽ അളന്നത്				
D	വായിലോ മൂക്കിലോ വ്രണങ്ങൾ				
E	കവിളുകളിൽ തിണർപ്പ് / ചൊറിഞ്ഞ് പൊട്ടൽ (ശലഭാകൃതിയിൽ)				
F	മറ്റെവിടെയെങ്കിലും തിണർപ്പ് (എവിടെ?__ _)				

G	കടും നീല അല്ലെങ്കിൽ പർപ്പിൾ നിറത്തിൽ പാടുകൾ തൊലിപ്പുറത്ത് അനുഭവപ്പെടുന്നു				
H	വെയിലത്ത് ഇറങ്ങിയതിനു ശേഷം സുഖമില്ലാതാവുകയോ തിണർപ്പുകൾ ഉണ്ടാവുകയോ ചെയ്യുന്നു				
I	തലയോട്ടിയിൽ രോമശൂന്യമായ ഭാഗങ്ങൾ അല്ലെങ്കിൽ തലയിണയിൽ ധാരാളമായി മുടിച്ചുരുളുകൾ				
J	കഴുത്തിൽ വീർത്ത ഗ്രന്ഥികൾ				
K	ശ്വാസം കിട്ടായ്മ				
L	ദീർഘശ്വാസത്തോടു കൂടിയുള്ള നെഞ്ചുവേദന				
M	തണുപ്പത്ത് കൈവിരലുകളോ കാൽവിരലുകളോ മരവിക്കുക /വിളറി വെളുക്കുക				
N	വയറുവേദന				
O	കൈകാലുകളിൽ നീണ്ടു നിൽക്കുന്ന മരവിപ്പ് അല്ലെങ്കിൽ തരിപ്പ്				

P	പെട്ടെന്നുണ്ടാകുന്ന വിറയലോട് കൂടിയ രോഗമൂർച്ഛ				
Q	പക്ഷാഘാതം				
R	മറവി				
S	വിഷാദം				
T	അസാധാരണമായ തലവേദന				
U	പേശി വേദന				
V	പേശികളുടെ ബലഹീനത				
W	സന്ധികളിൽ വേദന അല്ലെങ്കിൽ പിരിമുറുക്കം				
X	സന്ധികളിൽ നീര്				

3. ദയവായി നിങ്ങളുടെ കഴിഞ്ഞ 3 മാസത്തെ ലൂപസ് രോഗ പ്രവർത്തനത്തെ താഴെ കൊടുത്തിരിക്കുന്ന സ്കെയിലിൽ രേഖപ്പെടുത്തുക. (0 ഒട്ടും തന്നെ രോഗ പ്രവർത്തിയില്ല എന്നും 10 എറ്റവും കൂടുതൽ രോഗ പ്രവർത്തി എന്നും). നിങ്ങളുടെ നിർണയത്തിനനുസരിച്ച് കോളം കറുപ്പിക്കുക.

1	2	3	4	5	6	7	8	9	10

ANNEXURE V

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-16)

SCT/IEC/1205/MAY-2018 04.06.2018

Ms. Divya C S
MPH Student, AMCHSS
SCTIMST, Thiruvananthapuram

Dear Ms. Divya,

The Institutional Ethics Committee reviewed and discussed your application to conduct the study entitled "QUALITY OF LIFE OF PATIENTS LIVING WITH SYSTEMIC LUPUS ERYTHEMATOSUS, A CLINIC-BASED STUDY, KERALA, INDIA" (IEC/1205) on 18th May, 2018.

The following documents were reviewed:

Original submission

1. *Full proposal*
2. *Covering letter*
3. *IEC application form*
4. *TAC Approval letter*
5. *CV of Principal Investigator*
6. *Questionnaires English and Malayalam.*
7. *Patient Information Sheet in English and Malayalam*
8. *Informed Consent Form in English and Malayalam*
9. *Permission from outside institution for data collection.*

Revised submission

1. *Covering Letter addressed to the Chairperson, IEC, SCTIMST dated 31.05.2018 with checklist*
2. *Copy of IEC Recommendation Letter dated 21.05.2018*
3. *List of Amendments*
4. *Full proposal*
5. *IEC application form*
6. *TAC Approval letter*
7. *CV of Principal Investigator*
8. *Questionnaires English and Malayalam.*
9. *The Information Sheet and Consent Forms in English and Malayalam*
10. *Permission Letter from Centre for Arthritis and Rheumatism Excellence*

The following members of the Ethics Committee were present at the meeting held on 18th May, 2018 at G. Parthasarathi Board Room, AMCHSS, SCTIMST

SL. No.	Member Name	Highest Degree	Gender	Scientific /Non Scientific	Affiliation with Institution(s)
1.	Dr. R V G Menon	M Tech, PhD	Male	Lay Person (Chairman)	No
2.	Dr. Christina George	MD Psychiatry	Female	Clinician	No
3.	Dr. Harikrishnan S	MD, DM (Cardiology) DNB (Cardiology)	Male	Clinician	Yes
4.	Dr. Mala Ramanathan	PhD	Female	Social Scientist (Member Secretary)	Yes

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,

MRamanathan

Mala Ramanathan
Member Secretary, IEC

ANNEXURE VI

Dr. Shenoy's
CARE
Live Pain Free

Centre for Arthritis & Rheumatism Excellence
+91 484 3200020
+91 484 2702500
info@carecochin.com
Opp. Chevrolet Showroom,
NH 47, Nettoor, Ernakulam 682 040
www.carecochin.com

14 April 2018

To

The Director
Acutha Menon Centre for Health Science Studies
Sreechitra Thirunal Institute of Medical Science & Technology
Thiruvananthapuram

Sub: Permission to conduct research

Dear Sir,

We have been provisionally granted permission to Dr.Divya C S, to conduct research in this institution, for dissertation as part of the partial fulfillment of MPH course, under the subject "Quality of life of patients living SLE, a clinic based study". Kindly do the needful.

Thanking you

Yours faithfully

Authorised Signatory

Dr.Shenoy's CARE
Nettoor
Ph : 0484 3200020
Mob : 8606523355
Opp. Chevrolet Showroom

ANNEXURE VII

CORPORATE
TRANSLATIONS

Corporate Translations, Inc.
77 Hartland St. | East Hartford, CT 06108
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www.corptransinc.com

CERTIFICATION

This is to certify that Corporate Translations, Inc. has performed the following procedures on the ***Lupus QoL Questionnaire [CTi Job #: 58297]:***

- Two independent forward translations
- One harmonized forward translation
- One independent back-translation
- Reconciliation of back-translation and harmonized translation
- Review of back-translation by Survey Research Expert
- Review of harmonized translation by in-country representative
- Cognitive debriefing with five lupus patients in India
- Desktop publishing of validated translation
- Proofreading of validated translation

These documents were prepared by a team of translators and interviewers who are fully bilingual in both Malayalam for India and English. All procedures were performed in accordance with current industry standards and FDA guidance.

Authorized Signature:
Mary C. Gawlicki

Mary Gawlicki
President
Corporate Translations, Inc.

Date of Production: August 31, 2010

"Subscribed and sworn to before me

this 31 day of August, 2010"

CBergin
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Date Commission Expires: 9-30-11

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