

Yoga on QoL in SLE- Randomized Control Trial

**Dr Shobana Ramasamy¹, Dr Santhi Silambanan^{2*}, Dr Mahesh Kumar Kuppusamy³,
Dr Emmanuel Bhaskar⁴, Dr Chitra Murali⁵, Dr Krishnamurthy V⁶, Ms Poornima R⁷**

¹ Assistant Professor, Department of Physiology, ACS Medical College & Hospital, Chennai. email: shobana.rams@gmail.com.

² Professor, Department of Biochemistry, Sri Ramachandra Medical College & Hospital, SRIHER, Chennai. email: santhisilambanan@sriramachandra.edu.in

³ Assistant Medical Officer/Lecturer Grade II, Govt Yoga & Naturopathy Medical College, Chennai. email: doctor.mahesh1985@gmail.com

⁴ Professor, Department of Medicine, Sri Ramachandra Medical College & Hospital, SRIHER, Chennai. email: drebhaskar@sriramachandra.edu.in

⁵ Professor and Head, Department of Physiology, ACS Medical College and Hospital. email: drchitrayuvan@gmail.com

⁶ Senior Rheumatologist, Chennai Meenakshi Multispecialty Hospital. email: drvk56@gmail.com

⁷ Postgraduate student, Department of Yoga, Govt Yoga & Naturopathy Medical College, Chennai. email: poornimanandhu.r@gmail.com

*Corresponding author: Dr. Santhi Silambanan

KEYWORDS

auto-immune disease, meditation, quality of life, SLE, yoga.

ABSTRACT

Background: Systemic Lupus Erythematosus (SLE) is a multisystem, chronic autoimmune illness. Maintaining a high quality of life requires early diagnosis and treatment—ineffective routine management results in decreased social engagement and relaxation and lowered self-esteem. Numerous complementary therapies, including yoga and meditation, have demonstrated the potential in improving the health of these patients.

Objectives: This randomized controlled trial aimed to examine the effects of a yoga intervention on the Lupus Quality of Life Questionnaire (L-QoL), which gauges the quality of life in SLE patients.

Materials and Methods: Forty SLE patients were randomly assigned to the yoga intervention and control groups. The yoga intervention group participated in a 12-week program that included regular yoga sessions focusing on breathing techniques, gentle stretching, and relaxation. The control group received standard medical care and did not undergo yoga. Quality of life was assessed at the start and end of the intervention using L-QoL. A p-value of less than 0.05 was considered to be statistically significant.

Results: L-QoL questionnaire of the yoga intervention group showed a statistically significant improvement in scores ($p < 0.001$), indicating a higher quality of life. The intervention group reported increases in physical health, mental stability, pain management, and overall life satisfaction compared to the control group.

Conclusion: This study found that yoga therapy significantly enhanced the quality of life for people with SLE. Using yoga as a supplemental therapy could be a helpful way to improve the general health of SLE patients.

1. Introduction

The chronic, incurable autoimmune disease, systemic lupus erythematosus (SLE), is typified by the generation of antibodies against proteins found in the cytoplasm or nucleus. Its defining characteristics are widespread inflammation affecting several organ systems, a range of clinical symptoms, and a recurrent and remitting history. Women, primarily of reproductive age, make up around 90% of SLE patients.¹ This autoimmune illness is most likely caused by the altered hormonal pattern that occurs during pregnancy.² SLE is one of the chronic autoimmune diseases. Symptoms include widespread inflammation and the formation of antibodies against various macromolecules present in various human organs. Frequently occurring relapses and remittances exacerbate the condition.³ SLE affects connective tissues found in blood vessels and cartilage.⁴ As a result, the clinical manifestations differ from person to person and encompass many organs and systems, such as the skin, joints, kidneys, lungs, central nervous system, and hematopoietic system. All things considered, SLE progressively worsens with time, and harm the body's main organs which can be fatal.⁵

Uncertainty surrounds the precise pathophysiology underlying the autoimmune character of SLE. It is regarded as a condition with multiple contributing factors. Environmental circumstances cause the disease to begin and progress in a genetically predisposed person. Alterations in genes and sex hormones, sunshine, medications, and virus infections are some of the risk factors.⁶ According to research, the illness has an asymptomatic preclinical stage during which the autoantibodies are present in the blood. The preclinical phase lasts for around

five years, and as the illness progresses to a multisystem condition, it begins to exhibit SLE-like clinical signs.⁷ Most autoimmune processes may have harmed the body by this point. There are two types of genetic risk factors: monogenic and polygenic. This determines the disease's phenotypic, gender, and race variations and the age at which it manifests. A family history of SLE increases the likelihood of developing SLE and other autoimmune diseases. More than 100 susceptibility gene loci that predispose people to different autoimmune illnesses have been found by genome-wide association studies (GWAS).⁸ (Fig 1)⁹.

Reducing the symptoms and delaying the onset of organ involvement of various organs are common treatment goals for SLE patients. Research on the treat-to-target approach for SLE (T2T/SLE) prioritized remission or low disease activity (LDA) in 2014.¹⁰ Because SLE is so complex, treating a patient's clinical presentation requires a multidisciplinary approach. Complementary and alternative therapies have also been tried recently as a supplement to conventional medical treatments.¹¹ Few studies have specifically examined how yoga impacts SLE patients' quality of life. Given the intricacy of SLE and its profound impact on patients' lives, it is imperative to investigate the potential benefits of yoga for this population.

Type of Gene Function Disorder	SLE Susceptibility Genes With Common Variants	Gene Defects in Monogenic Forms of SLE
Defects in Apoptosis, Autophagy, DNA Repair, Lysosome Function	<i>ATG5, CDKN1B, DRAM1, CLEC16A, ATG16L2, ATG7, IRGM, LRRK2, MAP1LC3B, MTMR3, APOL1, NCF1/2, HIP1, SMG7, RAD51B, TERT, LYST, CTSB, GALC</i>	<i>PRKCD, NCF1, CYBB</i>
Clearance Defects	<i>ITGAM, FCGR2A</i>	<i>CIQ, CIR/CIS, C2/4, C3, PEPD</i>
TLR or IFN-I Signaling	<i>TLR7, IFIH1, IRF 5/7/8, MIR146A, JAK2, TYK2, RNASEH2C, SLC15A4, IRAK1</i>	<i>ADAR, IFIH1, DNASE1L3, TREX, RNASEH2C/2B/2A, DNASE1, SAMHD1, TMEM173, ACP5</i>
Proinflammation NFκB Signaling	<i>TNFAIP3, TNIP1, UBE2L3, PRKCB, NFKBIA</i>	
Immune Cell Signaling / Migration	<i>HLA Class II/III, PTPN22, BLK, BANK1, PXK, TNFSF4, ETS1, IKZF1/2/3, IL10, BAFF, STAT4, IL12A, TCF7, CD44, ZFP90, CD226, PRDM1, ARID5B, CHITA/SOCS1, PTPRC, AFF1, RASGRP3, BACH2, ELF1, SPRED2, LBH, LPP, CD80, LYN, CSK, CD40, CXCR5, TNFSF13B, CCL22, GRB2, DEF6, IL12B, SH2B3, PLAT, RASGRP1, ITPR3, DGKQ, IFNLR1</i>	<i>SHOC2, PTPN11, KRAS, FASLG, FAS, RAG 1/2</i>
Unknown Immune Function	<i>NMNAT2, TET3, TMEM39A, UHRF1BP1, ATXN1, JAZF1, WDFY4, EDEM3, ABHD6, MYNN, ANKS1A, CARMIL1, SLC17A4, XKR6, RPE1, PCNX3, OLIG3/LOC100130476, PKLA/ZC2HC1A, DHCR7/NADSYN1, PHLDB1, DDX6/TREH, GPR19/CREBL2, PLD2, NBDY, PRICKLE1, FAM98B, SIGLEC6, SYNGR1, CXorf21, PRPS2, FAM66B3P/PRAG1/CLDN23/MFHAS1</i>	

Fig. 1: Genes involved in SLE

1.1. Objective:

This randomised controlled study's objective was to evaluate the impact of a structured yoga intervention on the quality of life of SLE patients.

2. Methodology

2.1 Study Design

A randomized control trial design was used in this study to examine how a yoga intervention affected the quality of life for people with SLE. Each participating institution's Institutional Review Board accepted the study protocol (ACSMCH: Ref: No.335/2021/IEC/ACSMCH and SRIHER Ref: IEC-NI/21/FEB/77/39), and before enrolment, all subjects provided written informed consent. According to the article by the same authors, the same methodology was used.¹² The Declaration of Helsinki's tenets and the rules for good clinical practice were followed throughout the trial. According to the Indian Clinical Trial Registry of the Indian Council of Medical Research (ICMR), the study was registered (Ref: REF/2021/03/041865).

2.2 Participant Selection

2.2.1 Inclusion Criteria

Participants were eligible for inclusion if they met the updated American College of Rheumatology (ACR) categorization criteria for SLE, including positive antinuclear antibodies and certain clinical symptoms.¹³ SLE was officially diagnosed if at least four of the eleven criteria were satisfied. Participants in the study had to be at least eighteen years old and of both sexes.

2.2.2 Exclusion Criteria

Patients with human immunodeficiency virus (HIV) infection, acute infectious and metastatic diseases, other inflammatory or immunodeficiency disorders, SLE complications, associated comorbidities, or mental health issues, such as depression, were excluded.

2.3 Identification of study participants

Participants were eligible for inclusion if they met the updated ACR categorization criteria for SLE, including positive antinuclear antibodies and certain clinical symptoms by EB and KV.

2.4 Randomization

Using computer-generated randomization, participants (n=40) were randomized to either the control group (n=20) or the yoga intervention group (n=20). Allocation concealment was guaranteed to reduce selection bias. SS did randomization. The study participants were recruited by SR into the respective groups based on the number chosen by the participants. SR informed the guide about the number chosen by the participant. SS informed SR whether the participant would be recruited into the intervention or the control group. The process for randomization was as follows:

The study included 40 SLE participants. In each group, 20 underwent yoga intervention, while the other 20 were under conservative management. The Randomization was done by a Random Number Sequence Generator. The first 20 were considered the intervention (case) group, while the second 20 were considered the non-intervention (control) group.

2.5 Yoga Intervention

The yoga intervention group participated in twice-weekly supervised yoga sessions for 12 weeks. Each session, which lasted approximately 60 minutes and included a combination of physical postures, breathing exercises, and relaxation techniques, was specially created to fulfil the needs of SLE patients. The participants performed ten rounds of three cycles, each of which was Surya-Anuloma-Viloma Pranayama, Bhramari Pranayama, and Ujjayi Pranayama. They were also instructed to do five minutes of each Pranava Mantra and Savasana. Once a week, yogic counselling was conducted. Experienced yoga instructors- MKK and PR, who have expertise in adapting poses for people with chronic medical conditions, oversaw the sessions. (Table 1) (Fig. 2)

Table 1: Details of the Yoga interventions

S No	Yoga practice	Duration
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1	Surya-Anuloma- Viloma Pranayama (right nostril breathing)	Ten rounds of three cycles
2	Bhramari Pranayama (Humming Bee breathing)	Ten rounds of three cycles
3	Ujjayi pranayama	Ten rounds of three cycles
4	Pranava Mantra (Om chanting)	Five min
5	Savasana (corpse pose)	Five min
6	Deep Relaxation Technique (DRT)	20 min
7	Yogic counselling	Weekly once

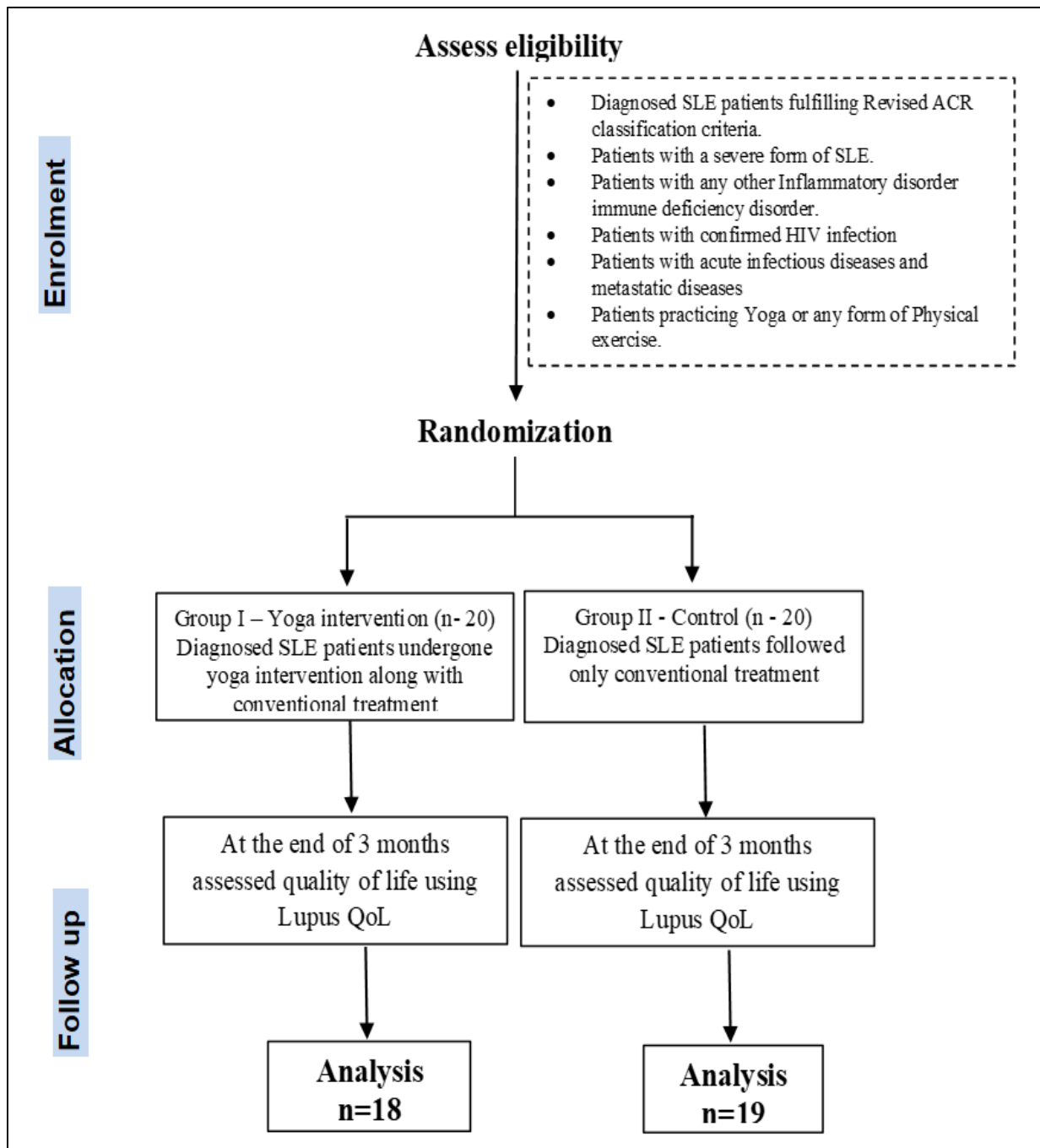


Fig. 2: CONSORT flow chart

2.6 Control Group

The control group received routine medical treatment for SLE without any extra help. Participants were

instructed to continue their routine life and abstain from organized yoga sessions and other complementary therapies during the study period.

2.7 Outcome Measures

Physical health (8 items), emotional health (6 items), body image (5 items), pain (3 items), planning (3 items), fatigue (4 items), intimate relationships (2 items), and burden to others (3 items) comprised the eight distinct domains of the 34 items in the validated Lupus Quality of Life (L-QoL) questionnaire. The evaluation of these areas was placed over four weeks.¹⁴ Each item was rated on a 5-point Likert scale, with total values ranging from 0 to 100. A better quality of life was associated with higher scores. The highest quality of life was represented by a score of 100 and the lowest by 0. None of the participants reported any negative side effects during the trial time. However, two patients from the yoga intervention group and one from the control group were lost to follow-up and did not complete the study.

2.8 Statistical Analysis

The continuous variables were displayed as mean and standard deviation, while categorical variables were shown as frequency. Student's t-test was used to compare the data of the L-QoL scores among the control and the yoga intervention groups. The Fisher's Exact test was used to compare the categorical variables. Statistical significance was defined as a p-value of less than 0.05. The analysis was conducted using R statistical program, version 4.2.1.

3. Results

In this study, 40 SLE patients—7 men and 33 women — with an average age of 44.32 ± 9.48 years were assessed. Table 2 displays descriptive statistics on the characteristics of the patients who participated in the current study. Age, BMI, and gender did not differ significantly. Marital status was considered because most of them were females, and there was no discernible difference. Demographical details are given in table 2.

Table 2: Demographical details of the study participants during recruitment into the study

Variables	Group I -Yoga intervention (n=20)	Group 2- Control Group (n=20)	p-value
Age (year) *	42.58 ± 12.56	45.21 ± 8.56	0.44
BMI (kg/m2) *	24.56 ± 4.56	22.47 ± 3.87	0.12
Sex (Male/ Female) #	4/16	3/17	0.99
Marital Status # (Yes/No)	17/3	15/5	0.69

*: data expressed in mean and standard deviation; student t test was used

#: data expressed as frequency (n); Fisher Exact test was used

When the baseline characteristics of the two groups were examined across the eight items, no statistically significant differences were found. After the intervention, the yoga group's total L-QoL score increased from 57.22 to 69.87 ($p=0.004$), significantly improving all parameters. Items including the degree of pain and doing daily tasks showed statistically significant improvement ($p=0.001$). There was also a statistically significant improvement in scores for other areas, including emotional instability, weariness, body shaming, and burdening others. There was a statistically significant performance improvement when the total scores following the yoga intervention were compared to the baseline.

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Table 3: Lupus QoL scale in SLE patients in both the groups with and without yoga intervention

S No	QoL Score in various items	Group I -Yoga intervention (n=18)		p-value #	Group II -Control (n=19)		p-value #
		Before	After		Before	After	
1	Physical disability	45.23 ± 12.56	67.56± 20.14	0.001**	49.56± 15.55	53.45± 19.89	0.33
2	Emotional instability	49.86± 9.87	57.53± 16.79	0.01*	52.45 ±16.56	50.45 ±11.82	0.53
3	Feeling of body shaming	51.78± 18.56	61.22± 20.14	0.03*	53.78 ± 19.78	59.89 ±16.57	0.13
4	Severity of pain	56.45± 14.50	69.78± 19.56	0.009**	53.28± 21.56	56.89± 23.45	0.47
5	Scheduling routine activities	66.56 ± 14.89	78.45± 10.25	0.001**	61.45± 18.89	69.85± 24.56	0.09
6	Fatigue	53.45± 14.87	63.12± 18.88	0.01*	56.79 ±18.87	53.89±15.55	0.45
7	Relationship with family members	54.20 ± 19.56	61.56± 11.28	0.04*	55.45± 21.23	59.88± 16.57	0.3
8	Feeling of burden to others	51.48 ± 13.56	60.15± 17.81	0.01*	50.45± 12.28	53.57 ±19.78	0.39
	Total Score	57.22± 21.33	69.87± 16.62	0.004**	59.89± 14.88	61.56 ±28.81	0.74

Data expressed as mean and standard deviation. # Paired 't' test was used.
p-value *: statistically significant; **: statistically highly significant

When the baseline characteristics of the two groups were examined across the eight items, no statistically significant differences were found. After the intervention, the yoga group's total L-QoL score increased from 57.22 to 69.87 ($p=0.004$), significantly improving all parameters. Items including the degree of pain and doing daily tasks showed statistically significant improvement ($p=0.001$). There was also a statistically significant improvement in scores for other areas, including emotional instability, weariness, body shaming, and burdening others. There was a statistically significant performance improvement when the total scores following the yoga intervention were compared to the baseline. The control group, consisting of SLE patients receiving normal therapy and yoga practice, showed no improvement in any of the items. The total score of the control group rose from 59.89 to 61.56 ($p=0.74$), with no appreciable changes observed across any of the areas. (Table 3)

4. Discussion

At an early age, SLE manifests as fever; however, it manifests as arthralgia in late adulthood. The musculoskeletal system (arthralgia, arthropathy, myalgia, frank arthritis, and avascular necrosis); pulmonary signs (pleurisy, pleural effusion, pneumonitis, pulmonary hypertension, and interstitial lung disease); gastrointestinal symptoms (nausea, dyspepsia, and abdominal pain); cardiac signs (pericarditis, and myocarditis); and haematologic system (leukopenia, lymphopenia, anemia, and thrombocytopenia) are among the clinical manifestations of SLE that differ depending on the organ systems involved.¹⁵

SLE is a complex disease with a confusingly varied clinical presentation. The advantages of the current therapeutic approaches are moderate. Treatment options for SLE include hydroxychloroquine, corticosteroids, immunosuppressive drugs, biologic drugs, therapies targeting interferons, cytokines and their receptors, intracellular signals, plasma cells, and T lymphocytes.¹⁶ Nonetheless, a significant amount of morbidity still exists, which tends to impact their quality of life (QoL) by affecting their mental and physical stability.¹⁷ A person's QoL is influenced by their expectations, standards of living, and perception of their living conditions, which are influenced by the dominant cultural and value systems.¹⁸ The disease's recurrence and remission impact a person's quality of life. Early disease diagnosis is quite challenging due to the variety of the illness process.

Yoga uses various techniques, including physical postures (asanas), breathing techniques (pranayama), and meditation, to encourage relaxation, stress reduction, and mind-body awareness. Previous studies have suggested that yoga can enhance mental well-being, physical fitness, and general quality of life, among other aspects of health. Yoga Prana Vidya (YPV) is an all-encompassing, integrated method that supports daily living and the healing process from sickness. Along with its positive effects on physical health, it fosters mental and

emotional well-being.¹⁹ One of the leading causes of chronic kidney disease (CKD) in Thailand is lupus nephritis (LN).

SLE is characterized by elevated sympathetic activity, which results in heart and kidney failure. It has been demonstrated that meditation improves quality of life and reduces sympathetic activity.²⁰ Yoga is a classic mind-body practice that has been shown to help with several clinical problems. Yoga is believed to lower the expression of markers that promote inflammation. Yoga may have additional beneficial effects by enhancing mucosal and cell-mediated immunity. However, yoga needs to be done for a long time to lessen inflammation.²¹ Yoga improves the sleep quality and helps the people with autoimmune disorders cope with anxiety and despair.²² The study's yoga intervention group's participants engaged in three cycles of 10 rounds of Ujjayi, Bhramari, and Surya Anuloma pranayama. In addition to weekly yoga instruction, participants practiced Pranava Japa for five minutes, Savasana for five minutes, and deep relaxation for twenty minutes. (Table 1) The yoga intervention group's participants were 42 years old, while the control group's participants were 45 years. The yoga intervention and control group participants did not have obesity, with body mass indices (BMIs) of 24 and 22 kg/m², respectively. Women constituted the majority of participants in both groups. Almost all of them were also married. (Table 2)

The prevalence of SLE in women has been covered in three Indian studies. With a female-to-male ratio of 19:1, Mathur et al. report that there are more female participants.²³ The female-to-male ratios were 14:1 and 8:1, respectively, according to Ghosh et al. and Malaviya et al.^{24,25} Since androgens depress the immune system and oestrogens boost it, sex hormones are known to affect SLE. The mean or median age of the participants in all three investigations was between 23 and 25.²³⁻²⁵ Southeast countries, including India, have been found to have lower SLE onset ages, and younger people are more likely to experience severe symptoms and unfavourable outcomes.²⁶

In the present study, the yoga intervention group's performance on the Lupus QoL questionnaire differed significantly from that of the control group, which received conventional therapy. The items with the highest response rates were physical impairment, degree of pain, and scheduling regular activities. The emotional and social components of the questionnaire received somewhat significant responses. There was no statistically significant difference between the baselines of the control and yoga intervention groups. A statistically significant difference was observed between the outcomes of the yoga intervention in group I and the control group following conventional treatment, indicating that yoga affects an individual's social, emotional, and physical well-being. The overall score displayed a similar pattern as well. (Table 3) The significant improvement in L-QoL scores among the participants in the yoga intervention group showed the beneficial effects of regular yoga practice on various well-being characteristics, including pain management, mental stability, physical health, and overall life satisfaction. Yoga may be a useful adjunctive therapy to improve the QoL for those with SLE.

Improving quality of life is the main objective of new SLE treatment guidelines. Yoga has been shown to enhance quality of life and reduce fatigue. Although there is relatively little information regarding SLE, research has indicated that yoga can help with the symptoms of osteoarthritis and rheumatoid arthritis. SLE yoga instructors and program participants noted the potential benefits of yoga treatment. Since patients reported feeling more balanced and aware of their bodies, yoga may be a helpful supplemental treatment for SLE symptoms. Yoga instructors also stressed the importance of adjusting yoga sessions to the variations in energy levels and physical capabilities that people with SLE frequently experience. The beneficial effects of yoga on the vagal nerve may account for the favourable sensations that patients have described. Vagal dominance occurs during yoga practice, and autonomic control is positively impacted. The classic inflammatory reflex is the phrase used to describe the relationship between inflammation, the immune system, and the brain. When the vagal nerve is activated, the spleen activates its acetylcholine receptor, inhibiting pro-inflammatory cytokines like interleukin (IL) and tumour necrosis factor (TNF)-alpha. One potential explanation for systemic inflammation in chronic autoimmune diseases is the impairment of this pathway.²⁷

According to Ji Yong-hui, studies are being conducted to determine how yoga Nidra impacts the depression and sleep issues experienced by female SLE patients. Both the Self-Rating Depression Scale and the overall Pittsburgh Sleep Quality Index ratings of the experimental group are significantly lower than those of the control group. Therefore, yoga Nidra can benefit female SLE patients with their depression and sleep problems. It helps to improve the physical and mental well-being of female SLE patients.²⁸ According to Middleton et al., SLE is associated with widespread tissue damage and inflammation. Asians, Blacks, and Hispanics are the main groups

affected, and it is more prevalent in women. Reducing organ damage and preventing flares are the main objectives of medical therapy.²⁷

Yoga and other mind-body therapies require simultaneous attentional and affective regulation, breathing, cognition, and bodily awareness. Patients who utilize yoga and other therapies reported feeling less melancholy and gaining the skills they need to take control of their lives and manage pain and emotional disturbances. Yoga techniques that encourage mental relaxation include gentle movement, meditation, guided visualization, and quiet breathing. Yoga claims that during flare-ups of SLE, the body needs help in transitioning from the sympathetic to the parasympathetic nerve systems. Without symptoms, a more thorough yoga practice that stresses proper alignment and exercises the joints through their full range of motion, such as a gentle vinyasa-style practice or an introduction alignment-based yoga class, may be beneficial. Yoga Nidra is also recommended as a restorative treatment for lupus patients at any stage. Since each lupus patient differs, yoga treatments can be customized to target specific symptoms.²⁷

Research indicates that in addition to the physiological symptoms caused by the involvement of several organ systems, SLE patients also experience stress, worry, sadness, and rage. There is evidence linking stress to both the onset and severity of SLE. The psychological symptoms may be reduced through spiritual practices like journaling, reading, meditation, mindfulness, and other complementary and behavioural treatments. A few years ago, a 56-year-old woman from New Delhi, India, received a diagnosis of SLE. The patient received regular pharmaceutical treatment in addition to a 10-week intervention consisting of 30 sessions centred on spiritual dispositions. According to the findings, stress levels and depression symptoms significantly decreased, and people's quality of life, coping mechanisms, and health resilience all improved.²⁹ In addition to the physical variables, the SLE patients in the current study who practiced yoga reported improvements in their mental well-being, ability to perform daily tasks, weariness, and family acceptance. (Table 3)

Along with self-reported pain, depression, and exhaustion, SLE patients also experience cognitive impairment across multiple domains and cognitive dysfunction is associated with disease activity. Not enough clinical attention has been given to these symptoms thus far. A recent comprehensive review of lifestyle therapy for SLE found that mental health and exercise therapies improve health-related quality of life (HRQoL) and symptoms of melancholy, anxiety, and exhaustion. More research has been done on the impacts of exercise, physical activity, and mental health than on social ties and sleep. Cognitive behavioural therapy seems to reduce depression symptoms, while aerobic exercise was found to be an effective lifestyle intervention for increasing aerobic capacity and reducing fatigue and depressive symptoms.³⁰

Renen Taub et al. found that mindfulness-based stress reduction (MBSR) improved symptoms, illness perceptions, and quality of life in 26 SLE patients in a randomized control study. Qualitative interviews revealed improved mindfulness components and decreased stress following MBSR. These findings show that MBSR has therapeutic potential for SLE patients, particularly in addressing psychological problems associated with the condition.³¹ The pathogenesis of SLE is thought to involve genetic, hormonal, immunologic, and environmental factors. Stress is known to trigger flare-ups of sickness and autoimmune disease. Because stress affects inflammation, the body undergoes numerous metabolic changes due to hormones, cytokines, and catecholamines. Mindfulness-based techniques improve quality of life and lower stress.³²

5. Limitations of the Study

A direct comparison of the current findings with previous research was impossible due to the small number of studies looking specifically at yoga therapies for SLE. To determine the best practices and customized interventions for each patient's needs and investigate the long-term impacts of yoga intervention in SLE therapy, initiatives to encourage accessibility and adherence to yoga programs among patients with SLE could also further enhance the potential therapeutic effects of this supplementary therapy.

6. Conclusion

The potential advantages of yoga as a supplemental therapy for raising the quality of life for people with SLE were highlighted in this study. The substantial gains in a number of Lupus QoL scale domains, such as pain management, mental stability, and physical health, indicated that consistent yoga practice can benefit the well-being of SLE patients. The therapeutic effects for people with SLE may be further enhanced by initiatives to improve accessibility and program adherence.

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NIL

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