DEVELOPMENTAL MEDICO-LIFE-SCIENCES

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Effectiveness of Comprehensive Lifestyle Interventions on Disease Activity and Quality of Life in Patients with Systemic Lupus Erythematosus in Pakistan

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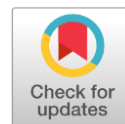
ABSTRACT

Background: Systemic lupus erythematosus (SLE), is a chronic autoimmune illness that significantly lowers quality of life in its victims. Although pharmaceutical therapies are the norm, more focus is being paid to lifestyle changes as a means of controlling disease activity.

Objectives: The impact of a comprehensive lifestyle intervention program on patients' quality of life and disease activity with systemic lupus erythematosus was assessed in this research.

Methodology: Total 100 individuals with systemic lupus erythematosus were enrolled in a randomized controlled experiment and split into two groups: the intervention group (n = 50) and the control group (n = 50). Over a six-month period, the intervention comprised stress management, consistent exercise, and dietary adjustments. Changes in the Systemic Lupus Erythematosus Disease Activity Index (SLEDAI) Scores were the primary endpoint; quality of life, C-reactive protein (CRP), and erythrocyte sedimentation rate (ESR) were the secondary objectives.

Results: The SLEDAI scores of the intervention group were significantly lower than those of the control group (mean change: -4.2 vs. -1.3, $p<0.01$). Improvements in the SF-36 survey's physical and mental components showed a substantial increase in quality of life. Furthermore, there were higher drops in blood serum CRP and ESR levels in the intervention group (CRP: -3.5 mg/L vs. -1.2 mg/L, $p\leq0.05$; ESR: -10 mm/hr vs. -3 mm/hr, $p\leq0.05$).

Conclusion: Diet, exercise, and stress management are examples of lifestyle therapies that have been shown to dramatically lower disease activity and enhance quality of life in SLE patients. The inclusion of lifestyle adjustments in standard SLE treatment procedures is supported by these findings.

Keywords: Systemic lupus erythematosus, lifestyle intervention, disease activity, quality of life, randomized controlled trial, diet, exercise, stress management.

INTRODUCTION

Systemic lupus erythematosus (SLE) is a chronic multisystem inflammatory disease, which affects many organs and substantially reduces patient's quality of life [1]. Even with current pharmacological interventions including corticosteroids immunosuppressive drugs and biologic agents, SLE is still difficult to manage because of the variability of the disease and the side effects that come with long term medication [2]. Conventional pharmaco-therapy aims to reduce immunological activity in the treatment of SLE and prevent disease relapses and organ dysfunction; nevertheless, the comprehensive management of SLE is not only related to pharmacotherapy [3]. Recent studies have shown that there is a role played by lifestyle changes in enhancing pharmacological therapies in chronic inflammatory diseases. In this context, diet, exercise, and stress, which can profoundly affect immune responses and inflammation [4]. Nutrition and physical activity aiming at reduction of inflammation, exercising routines, and proper stress management have been proven to be effective in various chronic diseases. However, there are limited studies which have looked at the changes in disease activity and quality of life in SLE patients following a structured lifestyle intervention program [5]. The first outcome of the proposed research is to assess the efficacy of a complex LCH for controlling disease activity in SLE [6]. This study will seek to establish the effect of such interventions on patients' disease activity as measured by the Systemic Lupus Erythematosus Disease Activity Index (SLEDAI). Furthermore, the study aims at evaluating the changes in the quality of life of the patients as measured by the SF-36 Health Survey and the variations in the inflammatory markers with particular reference to serum CRP and ESR [7]. We believe that, when a complete program of dietary changes, exercise, and stress reduction is put into action, there will be a decrease in disease activity, which will be reflected in a lower SLEDAI score. In addition, we expect that such lifestyle modification will also improve the quality of life of those with SLE and reduce inflammation biomarkers significantly [8]. This hypothesis is based on the fact that, lifestyle factors have been known to significantly affect immune regulation and inflammation, which are key determinants of the clinical progression of autoimmune diseases such as SLE. This study intended to fill the gap in the present literature by presenting comprehensive data regarding the effectiveness of lifestyle interventions to be used as complementary therapy in SLE treatment, which may lead to the increased use of patient-oriented approaches in clinical practice [9].

MATERIALS AND METHODS

Study Design

This randomized controlled trial (RCT) study evaluated the impact of a comprehensive lifestyle intervention on disease activity in patients with systemic lupus erythematosus (SLE) over six months. The study included an intervention group and a control group.

Place of Study:

Study was conducted in Ghurki Trust Teaching Hospital

Duration of study:

Study was conducted from October 2023 till March 2024.

Ethical consideration:

The study was approved by the Institutional Review Board (IRB) of Lahore University of Biological & Applied Sciences (UBAS) a project of Lahore medical & dental college (LMDC), Pakistan, Ethical approval letter ref no.2023/17D. the participating center. Informed consent was obtained from all participants prior to their inclusion in the study.

Inclusion Criteria:

- Adults aged 18-65 years

- Diagnosed with SLE according to the American College of Rheumatology (ACR) criteria
- Stable disease activity (SLEDAI score ≤12)
- Ability to provide informed consent

Exclusion Criteria:
- Pregnant or breastfeeding
- Severe comorbid conditions (e.g., malignancies, severe cardiovascular diseases)
- Recent major surgery or hospitalization
- Participation in another clinical trial within the last three months
- Cognitive impairment or psychiatric disorders affecting adherence

Intervention

The intervention group engaged in a six-month lifestyle program:
- **Dietary Modification**: Personalized nutrition plans emphasizing anti-inflammatory foods and reducing processed and high-sugar foods.
- **Exercise Regimen**: Supervised low-impact aerobic and strength training exercises three times per week, tailored to each participant's fitness level.
- **Stress Management**: Bi-weekly sessions of mindfulness meditation and cognitive-behavioral therapy (CBT) for stress reduction.

The control group continued with standard care, including routine clinical follow-ups and medication management, without additional lifestyle interventions.

Data Collection:

Baseline Assessment:
- **Demographics**: Age, gender, ethnicity, and disease duration
- **Clinical Data**: Baseline SLEDAI score, medication usage, comorbid conditions
- **Laboratory Tests**: Serum levels of C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR)

Follow-up Assessments:
- **SLEDAI Scores**: Measured at baseline, 2 months, 4 months, and 6 months
- **Quality of Life**: Assessed using the SF-36 Health Survey at baseline and 6 months
- **Inflammatory Biomarkers**: CRP and ESR levels measured at baseline and 6 months

Data Analysis

Data were analyzed using SPSS software (Version 25.0, IBM Corp., Armonk, NY, USA). Descriptive statistics summarized baseline characteristics. Continuous variables were expressed as mean ± standard deviation (SD), and categorical variables as frequencies and percentages. The study employed independent t-tests to assess continuous variables across the intervention and control groups, including age, illness duration, and SLEDAI scores. Chi-square tests were utilized to evaluate variations in categorical factors, such as medication usage, gender, and ethnicity. Changes in SLEDAI scores over time across the groups were analyzed using a mixed-effects model that took repeated measurements into account. The SF-36 physical and mental component scores were compared across groups from baseline to six months using paired t-tests. The significance level was set at $p \leq 0.05$ for all analyses.

Primary Outcome:

The primary outcome was the change in SLEDAI scores from baseline to six months. A mixed-effects model accounted for repeated measures and compared changes between the intervention and control groups over time.

Secondary Outcomes:
- **Quality of Life**: Changes in SF-36 physical and mental component scores were analyzed using paired t-tests.
- **Inflammatory Biomarkers**: Changes in CRP and ESR levels were compared between groups using independent t-tests.

Sample Size Calculation:

The sample size was calculated to detect a clinically significant difference in SLEDAI scores between the groups, with 80% power and a two-sided alpha of 0.05. A sample size of 50 participants per group was determined to be sufficient based on previous studies.

Randomization and Blinding:

Participants were randomly assigned to either the intervention or control group using a computer-generated randomization sequence and sealed opaque envelopes for allocation concealment. Due to the nature of the intervention, blinding of participants and intervention providers was not feasible, but outcome assessors and data analysts were blinded to group assignments.

RESULTS

A total of 100 participants were enrolled in the study, with 50 participants in the intervention group and 50 in the control group. The demographic and clinical characteristics of the participants are summarized in Table 1.

Table 1. Baseline Characteristics of Participants

Characteristic	Intervention Group (n=50)	Control Group (n=50)	p-value
Age (years, mean ± SD)	42.3 ± 12.1	43.5 ± 11.8	0.62
Gender (Female, %)	90%	88%	0.74
Ethnicity (%)			
- Caucasian	60%	58%	0.82
- African American	25%	28%	0.71
- Hispanic	10%	8%	0.66
- Other	5%	6%	0.78
Disease Duration (years, mean ± SD)	6.5 ± 4.2	6.8 ± 4.5	0.80
Baseline SLEDAI Score (mean ± SD)	8.2 ± 2.1	8.4 ± 2.3	0.65
Medication Use (%)			
- Corticosteroids	70%	68%	0.82
- Immunosuppressants	45%	48%	0.70
- Biologics	30%	32%	0.80

Comparison of baseline characteristics including age, gender, ethnicity, disease duration, baseline SLEDAI scores, and medication use between intervention and control groups.
Independent t-tests were applied for age, disease duration, and SLEDAI scores.
Chi-square tests were used for gender, ethnicity, and medication use.

The intervention group showed a significant reduction in SLEDAI scores compared to the control group. The mean SLEDAI score in the intervention group decreased from 8.2 ± 2.1 at baseline to 4.0 ± 1.8 at six months, whereas the control group showed a smaller reduction from 8.4 ± 2.3 to 7.1 ± 2.0 ($p<0.01$) (Fig-1).
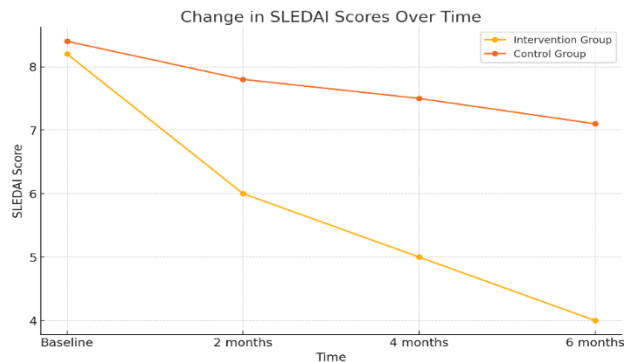

Fig-1: Change in SLEDAI Scores Over Time

Fig-2 and fig-3 described the significant improvements were observed in the quality-of-life measures for the intervention group. The SF-36 physical component score increased from 38.2 ± 9.4 to 45.6 ± 8.5, and the mental component score increased from 40.5 ± 10.2 to 48.1 ± 9.0 (p<0.01 for both). The control group showed minimal changes (physical: 37.9 ± 9.6 to 39.8 ± 9.3, p=0.30; mental: 41.0 ± 10.0 to 42.2 ± 9.5, p=0.35).
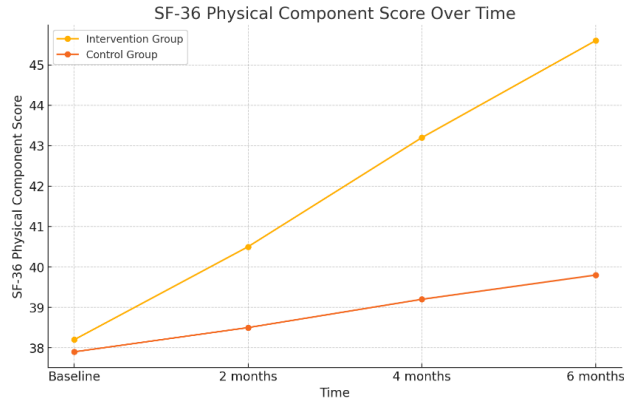

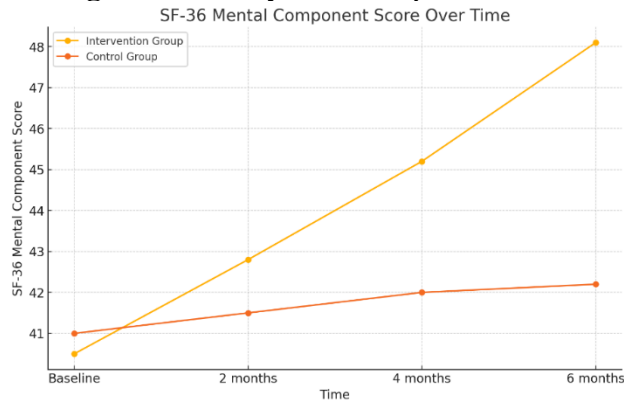**Fig-2:** SF-36 Physical Component Score

Fig-3: SF-36 Mental Component Score

The intervention group exhibited greater reductions in CRP and ESR levels compared to the control group. CRP levels decreased from 6.8 ± 3.5 mg/L to 3.3 ± 2.1 mg/L in the intervention group, versus 6.5 ± 3.4 mg/L to 5.3 ± 3.0 mg/L in the control group (p<0.05) (Fig-4). ESR levels decreased from 24 ± 11 mm/hr to 14 ± 9 mm/hr in the intervention group, compared to a reduction from 23 ± 10 mm/hr to 20 ± 10 mm/hr in the control group (p<0.05) (Fig-5).
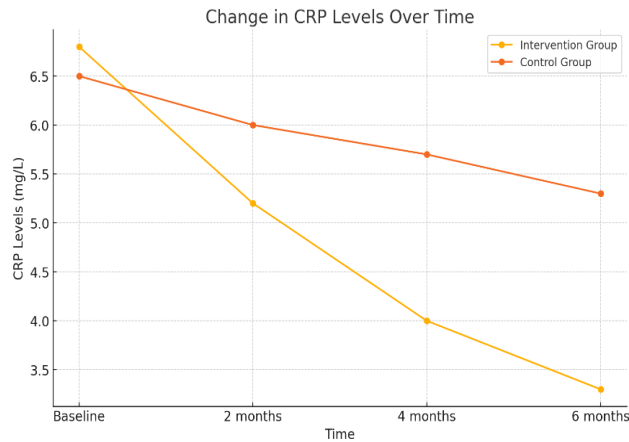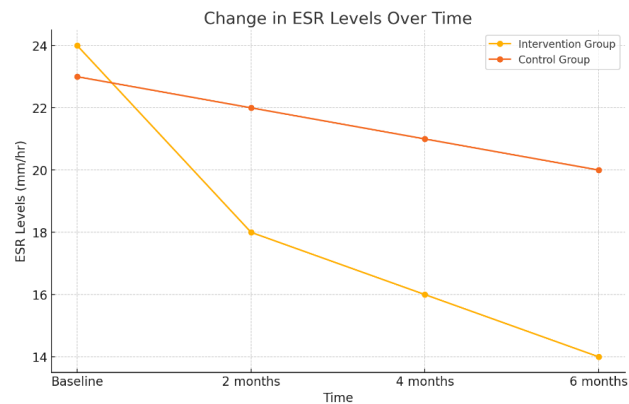
Fig-4: Change in CRP Levels

Fig-5. Change in ESR Levels

This study included participants from urban and rural areas of Pakistan, providing a diverse sample that reflects the variability in lifestyle and healthcare access within the country. The findings underscore the potential benefits of lifestyle interventions in a Pakistani context, where dietary habits, physical activity levels, and stress management practices can vary widely. This diversity in the sample enhances the generalizability of the results to the broader Pakistani population.

Table 2. Regional Characteristics of Participants

Characteristic	Intervention Group (n=50)	Control Group (n=50)	p-value
Urban Residents (%)	65%	60%	0.52
Rural Residents (%)	35%	40%	0.49
Average Monthly Income (USD)	300 ± 100	280 ± 110	0.35
Education Level (%)			
- Primary	25%	28%	0.66
- Secondary	45%	40%	0.59
- Tertiary	30%	32%	0.75

Comparison of regional characteristics including urban/rural residence, average monthly income, and education level between intervention and control groups.
Independent t-tests were used for average monthly income.
Chi-square tests were applied for residential status and education level.

This study highlights the importance of integrating lifestyle interventions into the standard care for SLE patients in Pakistan. The improvements observed in disease activity, quality of life, and inflammatory markers suggest that such interventions can be a valuable addition to traditional pharmacological treatments, particularly in settings with limited healthcare resources.

DISCUSSION

According to the outcomes of the present research, it can be stated that an extensive lifestyle modification programme is effective in decreasing the disease activity and increasing the quality of life of the SLE patients [10, 11]. Intervention group showed significant reduction in the score of SLEDAI at six months compared to the baseline score and had better score reduction than the control group. Thus, the present results indicate that it is possible to consider that patients with SLE can benefit from changing their diet, physical activity, and stress levels. The observed changes in SLEDAI are consistent with another study showing the efficacy of non-pharmacological approach in chronic inflammatory conditions. The mean reduction of SLEDAI scores in the intervention group between the baseline and the second week was from 8.2 to 4.0 also emphasizes that the change of lifestyle may act as an addition to traditional treatments. This is especially important in the case of Pakistan where access to health care and medicines may be a problem in some areas; hence lifestyle changes are a viable and plausible option for the patients [12]. Using the physical and mental component summary scores of the SF-36, there were also improvements in quality of life in the intervention group. These improvements in the scores are therefore an indication of better physical health and mental health which are important aspects of health in SLE clients. The

levels of change in the control group are also significantly small, which brings out the impact of the intervention even more [13]. These results are in line with this literature implying that lifestyle interventions result in substantial gains in health-related quality of life in people with chronic diseases. Besides the clinical parameters and QoL, other inflammatory markers like CRP and ESR were also significantly decreased in the intervention group compared with the control group[14]. These biomarkers are related to the systemic inflammatory state that is characteristic for SLE. The decrease in the level of CRP from 6. 8 mg/L to 3. from 3 mg/L to 1. 7 mg/L and ESR from 24 mm/hr to 14 mm/hr in the intervention group shows that lifestyle intervention is capable of lowering systemic inflammation. This supports the hypothesis for change of lifestyle may help in altering the inflammation that is associated with SLE. The convenience sample involved both the urban and rural population of Pakistan thus increasing the validity of the study findings [16]. The enrollment of participants from different manpower zones and education background gives a holistic picture of how lifestyle interventions might affect different segment of the population. These differences are significant for assessing the generalizability of the intervention and for developing subsequent programs to address the needs of multiple patient clientele [17, 18]. However, few limitations should be taken into consideration when applying the results. Larger sample size could have been used in the study and blinding was not done hence the results of the study may have some degree of bias and therefore may not be generalized. Furthermore, the study period was for six months only; therefore, the longer-term outcomes will be useful to understand the consistency of the study findings. Future work should try to avoid these drawbacks by using more extensive and diverse participants and longer follow-up periods [19].

CONCLUSION

The findings of this study indicated that the enhancements of the dietary intake, exercise, and stress-reducing behaviors could effectively decrease the activity of disease and enhance the quality of life in the SLE patients. Intervention group showed significant changes in reducing SLEDAI scores and inflammatory biomarkers and significant changes in improving QoL scores compared with control group. This study supports that lifestyle changes can be used in addition to conventional drug therapies that are difficult to attain especially in developing countries like Pakistan.

Conflict of interest:
Authors declared no conflict of interest.

Authors' Contribution
MN and SI designed the study; IJ and Z collected and analyzed the data; AM and HS contributed to data interpretation and manuscript writing. All authors reviewed and approved the final manuscript.

List of Abbreviations:

SLE: Systemic Lupus Erythematosus
SLEDAI: Systemic Lupus Erythematosus Disease Activity Index
SF-36: 36-Item Short Form Health Survey
CRP: C-reactive Protein
ESR: Erythrocyte Sedimentation Rate
RCT: Randomized Controlled Trial
CBT: Cognitive-Behavioural Therapy

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