EFFECTS OF A MEDITERRANEAN DIET-BASED NUTRITIONAL INTERVENTION ON GUT MICROBIOTA, DISEASE ACTIVITY, AND NUTRITIONAL STATUS IN CHILDREN WITH SYSTEMIC LUPUS ERYTHEMATOSUS

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Purpose and Significance of the Study

The gut microbiota of individuals diagnosed with Systemic Lupus Erythematosus (SLE) differs from that of healthy individuals. Previous studies have demonstrated that the Mediterranean Diet has beneficial effects on gut microbiota and may improve disease-related parameters when applied to individuals with lupus. However, there is limited evidence on whether the positive effects of the Mediterranean Diet in SLE patients are mediated through improvements in gut microbiota, and data in pediatric lupus populations are particularly scarce.

In this context, the aim of this study is to investigate the effects of an individualized nutrition intervention based on the Mediterranean Diet on gut microbiota profile, disease activity, biomarkers, and nutritional status in children with SLE.

This study is important both scientifically and clinically. The findings are expected to provide insight into the effects of nutrition-based interventions on gut microbiota and inflammation in pediatric lupus patients and to support the use of personalized nutrition counseling as a complementary strategy in disease management. Furthermore, the study will help fill a gap in the literature and contribute to a better understanding of the role of diet in SLE management.

Methods

1.General Study Design

Approximately 30 children diagnosed with Systemic Lupus Erythematosus (SLE), who are followed at the Department of Pediatric Nephrology and Rheumatology at Erciyes University, will be included in the study. In addition, 30 healthy household members living in the same home as the patients will be recruited as the control group.

For participants meeting the inclusion criteria, the following assessments will be conducted at baseline and at the end of the study: gut microbiota analysis, anthropometric measurements, 3-day food records (including two weekdays and one weekend day), Mediterranean Diet Quality Index (KIDMED), International Physical Activity Questionnaire–Short Form (IPAQ), and Pittsburgh Sleep Quality Index (PSQI). In the patient group, Childhood Health Assessment Questionnaire (CHAQ), Systemic Lupus Erythematosus Disease Activity Index-2000 (SLEDAI-2K), and Systemic Lupus Erythematosus Damage Index (SLICC/SDI) scores will also be assessed. Biochemical parameters routinely measured at Erciyes University Faculty of Medicine Children’s Hospital will be obtained from patient records.

In the control group, stool samples, anthropometric measurements, and 3-day food records will be collected at baseline and at the end of the study, and KIDMED, IPAQ, and PSQI questionnaires will be administered.

Participants in the intervention group will receive individualized nutrition counseling based on the Mediterranean Diet. The intervention will aim to increase polyphenol intake, reduce the dietary inflammatory index, limit ultra-processed food consumption, and promote appropriate physical activity. At the end of the intervention, a focus group interview will be conducted with a subset of participants to explore their experiences and perceptions of the intervention.

The study will be conducted in accordance with registration on ClinicalTrials.gov. All participants will be informed about the study prior to enrollment, and written informed consent will be obtained from those who agree to participate.

2.Participants

This study is based on a previous study by Wang et al. (2022), which compared the gut microbiota of 19 SLE patients and 19 healthy household members and investigated the relationship between gut microbiota, diet, and clinical findings in SLE. Considering that approximately 35 SLE patients are followed at the Department of Pediatric Nephrology and Rheumatology at Erciyes University, it is aimed to recruit approximately 30 patients and 30 healthy household members as controls.

In this study, the intervention group will consist of children with SLE, while the control group will include healthy family members living in the same household. The main reason for selecting controls from the same household is to minimize environmental and dietary confounding factors that may affect gut microbiota composition. This approach is expected to provide a more reliable assessment of whether observed differences are related to SLE or the intervention.

A power analysis will be conducted after at least 50–60% of the data have been collected to evaluate the adequacy of the sample size. Based on the results, a decision will be made on whether to continue participant recruitment.

Eligibility Criteria

Inclusion Criteria

Intervention Group (SLE patients):

- Diagnosis of Systemic Lupus Erythematosus according to SLICC criteria
- Diagnosis of SLE at least 6 months prior to enrollment

Control Group (Healthy household members)

- Living in the same household as an SLE patient
- Body mass index (BMI) within the normal range

Exclusion Criteria

Intervention Group (SLE patients):

- Presence of active infection
- Renal failure or history of major trauma or surgery within the last 6 months
- Presence of additional chronic diseases accompanying SLE
- Use of antibiotics or probiotics within the last 4 weeks
- Following a special diet
- Illiteracy or cognitive impairment that may prevent understanding of the intervention

Control Group (Healthy household members):

- Presence of active infection
- Presence of chronic disease
- Use of antibiotics or probiotics within the last 4 weeks
- Following a special diet
- Illiteracy or cognitive impairment that may prevent understanding of the study procedures

3. Intervention: Individualized Nutrition Counseling

The intervention will be delivered through an individualized nutrition counseling approach to participants in the intervention group. Counseling will be conducted face-to-face by dietitian at the Pediatric Nephrology and Rheumatology outpatient clinic of Erciyes University Children's Hospital and will be tailored to each participant.

The primary aim of the intervention is to improve adherence to the Mediterranean Diet and promote healthier eating habits. At baseline, participants' dietary intake will be assessed using 3-day food records and KIDMED scores. Based on these assessments, individual dietary errors will be identified, and personalized nutrition recommendations will be developed accordingly.

Throughout the intervention period, weekly follow-up sessions will be conducted to support adherence and promote sustainable dietary behavior change.

The dietary intervention will be based on the principles of the Mediterranean Diet, with specific goals to increase polyphenol intake, reduce the dietary inflammatory index, and limit the consumption of ultra-processed foods. In addition, participants will receive guidance to increase their physical activity levels to support overall lifestyle improvement.

3.1 Intervention Schedule and Structure (12-Week Program)

A total of 12 sessions will be conducted with each participant, scheduled once per week over a 12-week period. The first session will last approximately 60 minutes, and sessions at weeks 1, 6, and 12 will be conducted face-to-face. The remaining sessions will be conducted via phone calls, video calls, or messaging and will last approximately 30 minutes.

Dietary recommendations provided during the sessions will be reinforced through weekly phone calls and text messages. Participants' adherence to the recommendations will be monitored and recorded throughout the intervention period. During weekly follow-ups, 3-day food records will be collected, and participants' progress toward the predefined dietary goals will be evaluated.

No food will be provided by the researchers; the intervention will focus solely on modifying participants' existing dietary habits.

3.2 Measurements and Interventions During Sessions

During the intervention, various measurements and samples will be collected from participants, and individual dietary counseling will be provided according to personalized goals. Stool samples will be collected, and anthropometric measurements including BMI will be assessed at the first and final sessions. Participants' 3-day food records will be obtained, and KIDMED scores will be calculated. Physical activity levels will be determined using the IPAQ, and sleep quality will be assessed using the PSQI. Additionally, CHAQ will be administered, and SLEDAI-2K and SLICC/SDI scores will be calculated. Routine blood test results will be reviewed.

During weekly follow-ups, participants will submit 3-day food records. Anthropometric measurements and body composition analyses will be repeated during sessions 1, 6, and 12.

4.Healthy household members Follow-up

Stool samples, anthropometric measurements, and 3-day food records will also be collected from control group participants at baseline and at the end of the study. Physical activity levels and sleep quality will be assessed using the IPAQ and PSQI, respectively. No dietary intervention will be applied to this group. This approach will allow changes observed in the intervention group to be evaluated by comparison with the control group data.

5.Gut Microbiota Analysis

5.1. Collection and Storage of Stool Samples

Stool samples will be collected from participants in both the SLE and control groups on the first day of hospital admission and at the final session by the researchers. Samples will be transferred to -80°C within 1 hour of collection and stored until analysis. All participants will be provided with clean, leak-proof plastic containers with a 50 mL capacity and a spoon. Instructions on how to use the containers will be given, and participants will be asked to fill the containers halfway with stool samples.

5.2. Analysis of Gut Microbiota

All stool samples collected from participants will be sent to the analysis center under cold chain conditions. DNA isolation and sequencing analyses will be performed by molecular biologists. The bioinformatic interpretation of the data obtained from the analyses will be conducted by a bioinformatics specialist.

5.3. DNA Extraction from Stool Samples

Stool samples were processed using the **DiaRex® Stool Genomic DNA Extraction Kit** (Number: SD-0323, Ankara). Briefly, 25–50 mg of stool sample was mixed with 250 µL of Stool Lysis (SLD) solution. Then, 15 mg of glass beads and 10 zircon beads were added, and the mixture was homogenized at 4000 rpm for 2 × 20 seconds using a homogenizer. After homogenization, 25 µL of Proteinase K (PKD) solution was added, and the samples were incubated at 56°C for 60 minutes.

Following incubation, the contents were centrifuged at 5000 × g for 5 minutes, and the supernatant was transferred to a new tube. To the supernatant, 200 µL of Lysis (LBD) solution was added, followed by incubation at 70°C for 10 minutes. After incubation, 250 µL of absolute ethanol was added to the lysate, and the mixture was transferred to a column. The column was centrifuged at 8000 × g for 1 minute, and the flow-through was discarded. Subsequent washing steps were performed according to the kit protocol. Finally, 100 µL of Elution (EBD) solution was added, incubated for 2 minutes, and centrifuged at 8000 × g for 1 minute to obtain genomic DNA.

6. Anthropometric Measurements

Height: Participants' height will be measured using an automatic stadiometer capable of measuring 90–200 cm with ±1 cm precision (**Densi GL-150, Istanbul**), with participants standing barefoot in light clothing. They will stand upright, looking straight ahead, with the upper part of the ear and the outer corner of the eye aligned with the horizontal plane (Frankfort Plane) (Pekcan, 2013).

Body Weight and Composition: Participants' body weight and composition will be assessed using a segmental bioelectrical impedance analysis device (**Tanita BC 418 MA**, https://tarti.com/tanita-bc-418-vucut-analiz-urun35.html, Accessed: 09.10.2025). Weight will be recorded in kilograms with 0.1 kg precision. The device will also measure and record body fat mass (kg) and percentage (%), and skeletal muscle mass (kg) and percentage (%). Measurements will be taken only after all required conditions are met for each participant.

Required Conditions for Measurement:

- Participants must stand on the device without socks and in light clothing.
- Participants should fast for at least 2–4 hours prior to measurement.
- Female participants must not be within 3 days before menstruation, during menstruation, or within 3 days after menstruation.
- Participants must not have any implanted devices, such as pacemakers.
- No metal should be present on the participant.

After measurement, participants will be monitored for three days to confirm whether menstruation begins, and data from participants who start menstruation during this period will be excluded (Pekcan, 2008; https://tarti.com/tanita-bc-418-vucut-analiz-urun35.html, Accessed: October 10, 2025).

Body Mass Index (BMI) will be calculated using the formula = weight (kg) / height $(m)^2$

7. Data Collection Tools

7.1. Dietary Intake Record

Three-day dietary intake records will be collected from participants at the beginning of the study and weekly, including two weekdays and one weekend day. The first day of the dietary record will be obtained during a face-to-face interview, and the remaining two days will be completed via phone interviews.

Portion sizes of consumed foods will be determined using the “Food and Meal Photo Catalogue: Measures and Portions” (Rakıcıoğlu et al., 2009). The dietary intake records will be collected and verified using the Multiple-Pass method, a multi-step approach that includes listing foods consumed the previous day, forgotten foods, meal times, details of consumed foods, and final review (Moshfegh et al., 2008).

Dietary intake amounts will be analyzed using Nutrition Support Computer Information System (BeBİS) 8.2, calculating daily servings for each food group as well as average energy, macronutrient, and micronutrient intake. The results will be evaluated according to the Turkey Nutrition Guide (TÜBER) for adolescent nutrition (TÜBER, 2022).

7.1.1. Assessment of Food Processing Levels Using the NOVA Classification

The NOVA classification will be used to calculate the proportion of processed foods in participants’ diets. Foods are categorized into four groups according to the recommendations of the Food and Agriculture Organization (FAO): unprocessed or minimally processed foods, processed culinary ingredients, processed foods, and ultra-processed foods (Monteiro, 2019). Consumption patterns of processed foods will be determined based on the NOVA classification.

7.1.2. Calculation of Dietary Inflammatory Index (DII)

The Dietary Inflammatory Index (DII) will be calculated based on the dietary intake records of adolescents. Using the dietary records, the average daily intake of energy, macronutrients, and micronutrients for 29 foods and food components included in the BeBIS program—developed for Turkey—will be determined. The consumption levels of these 29 foods and nutrients, based on the participants’ average daily intake, will be used to calculate the DII using the coefficients developed by Shivappa et al. (Shivappa et al., 2014). There is no established cutoff to classify the DII as low, moderate, or high. A higher DII score indicates a pro-inflammatory diet, whereas a lower DII score indicates an anti-inflammatory diet (Shivappa et al., 2014).

7.1.3. Determination of Dietary Polyphenol Content

The polyphenol composition of the diet will be calculated using three-day dietary records obtained from study participants, in combination with the Phenol-Explorer database. The Phenol-Explorer database includes data on flavonoids, phenolic acids, stilbenes, lignans, and other polyphenols and their subclasses, reported according to five different analytical methods (Rothwell, 2012; Rothwell, 2013; Neveu, 2010).

7.2. Mediterranean Diet Quality Index (KIDMED)

The Mediterranean Diet Quality Index (KIDMED) is a 16-item questionnaire developed by Serra-Majem et al. to assess dietary habits and diet quality, reflecting the characteristics of the Mediterranean diet. The Turkish validity and reliability of the index in adolescents were established by Apaydın Kaya and Temiz (2021).

The 16 items of the KIDMED questionnaire are scored as follows: items 1, 2, 3, 4, 5, 7, 8, 9, 10, 11, 13, and 15 receive a positive score (+1), while items 6, 12, 14, and 16 receive a

negative score (−1). The total KIDMED score is obtained by summing these item scores. Index scores are interpreted as follows: ≥8 points: optimal diet; 4–7 points: diet requires improvement; ≤3 points: very low diet quality (Serra-Majem et al., 2004).

7.3. Assessment of Physical Activity Levels

The International Physical Activity Questionnaire – Short Form (IPAQ-SF), developed by Craig et al. (2003), will be used to assess participants' physical activity levels. The IPAQ is a valid, reliable, and easily administered tool that can be quickly completed (Cherobin, 2016). The Turkish validity and reliability study of the questionnaire was conducted by Öztürk et al. (2005).

The questionnaire includes seven items assessing vigorous-intensity physical activities, moderate-intensity physical activities, walking, and sedentary time, all performed for at least 10 minutes in a single session during the past seven days. According to the scoring system, metabolic equivalents (METs) are assigned as follows: vigorous activities = 8.0 MET, moderate activities = 4.0 MET, walking = 3.3 MET, and sitting = 1.5 MET. For each activity type, minutes, days, and METs are multiplied to obtain a MET-minutes/week score, which is then used to classify physical activity levels.

Participants are classified as highly active if they engage in vigorous activity for at least 3 days per week achieving ≥1500 MET-min/week, or any combination of walking, moderate, or vigorous activity reaching ≥3000 MET-min/week. This level is considered sufficient to produce health benefits. Participants are classified as minimally active if they perform vigorous activity for at least 20 minutes on ≥3 days/week, moderate activity for ≥5 days/week, walking for ≥30 minutes on ≥5 days/week, or any combination of walking, moderate, or vigorous activity achieving ≥600 MET-min/week. Participants whose physical activity does not meet these criteria are classified as inactive (Öztürk et al., 2005).

7.4. Assessment of Sleep Quality

Participants' sleep quality will be assessed using the Pittsburgh Sleep Quality Index (PSQI). The PSQI was originally developed by Buysse et al. in 1989 in Pittsburgh, United States (Buysse, 1989), and its validity and reliability in Turkey were established by Ağargün et al. in 1996.

The PSQI is a self-report questionnaire that provides detailed information on sleep quality and disturbances over the past month. It consists of 18 items covering seven components: subjective sleep quality, sleep duration, sleep latency (time to fall asleep), sleep disturbances, habitual sleep efficiency, use of sleep medication, and daytime dysfunction. Each item is scored on a scale from 0 to 3. The scores of the seven components are summed to obtain a total score ranging from 0 to 21. A total score of less than 5 indicates good sleep quality, whereas a score of 5 or higher indicates poor sleep quality.

7.5. Childhood Health Assessment Questionnaire (CHAQ)

The Childhood Health Assessment Questionnaire (CHAQ) is a valid and reliable instrument frequently used to evaluate physical function in children with rheumatic diseases and is sensitive to clinical changes (Ramey, 1992). In children with active childhood systemic lupus

erythematosus (SLE), CHAQ has been reported to reflect functional limitations (Meiroin, 2008). The Turkish validity and reliability study was conducted by Özdoğan et al. in 2001.

The CHAQ consists of child (ages 8–19 years) and parent (ages 2–19 years) forms. These forms include a preface highlighting disease-related limitations and difficulties experienced during the week. CHAQ assesses physical function across eight domains—dressing and personal care, arising, eating, walking, hygiene, reach, grip, and activities—through a total of 30 items. Each item is scored from 0 to 3 based on the child's or parent's response: 0 = without difficulty, 1 = with some difficulty, 2 = with much difficulty, 3 = unable to do (Singh et al., 1994; El-soud & Youssef, 2015).

In this study, CHAQ will be administered and scored by rheumatologists during the first and last follow-up visits. Higher CHAQ scores indicate lower quality of life.

7.6. Systemic Lupus Erythematosus Disease Activity Index-2000 (SLEDAI-2K)

In patients with systemic lupus erythematosus (SLE), distinguishing disease activity from permanent damage is challenging. The SLE Disease Activity Index 2000 (SLEDAI-2K) is used to assess overall disease activity. The original SLEDAI scoring system was published in 1985, and symptoms appearing for the first time or relapsing in a patient were considered active. In 2002, SLEDAI-2K was developed to account for persistent active disease, incorporating ongoing manifestations such as alopecia, oral or nasal ulcers, rash, and proteinuria (Gladman, 2002).

The assessment includes 24 clinical features across nine organ systems, reflecting disease activity over the past 10 days. Scores range from 0 to 105, with values of 6 or higher indicating clinically significant disease activity.

7.7. Systemic Lupus Erythematosus Damage Index (SLICC/SDI)

The Systemic Lupus International Collaborating Clinics/American College of Rheumatology Damage Index (SLICC/SDI) was developed in 1996 to measure accumulated organ damage caused by the disease and its treatment. It provides an objective measure of morbidity and chronic damage during disease follow-up. The validity and reliability of this index have been established. The SLICC/SDI can detect accumulated organ damage even in inactive disease (Gladman, 1996; Eder, 2013).

The index consists of 41 items covering 12 organ systems. Total scores range from 0 to 49, with higher scores indicating greater damage. "Clinical damage" assessed by this index is defined as irreversible changes lasting at least 6 months, resulting from the disease itself or its treatment. Studies have shown that organ damage is more frequent in patients with persistent or recurrent disease activity (Urowitz, 1998; Stoll, 2004). Nevertheless, damage is assessed independently from disease activity using separate parameters. Early organ damage has been associated with poor prognosis and increased mortality (Stoll, 1996). The SLICC/SDI has also been applied in multiple studies involving childhood-onset SLE patients, demonstrating the relationship between disease activity, medication use, and damage accrual (Ravelli, 2003; Rood, 1999).

8. Biochemical Findings

Routine laboratory tests from patients followed at Erciyes University Faculty of Medicine Children's Hospital will be collected from patient records. These tests include:

- BUN (mg/dL)
- Creatinine (mg/dL)
- Erythrocyte Sedimentation Rate (mm/h)
- C-Reactive Protein (mg/L)
- Calcium (mg/dL)
- Phosphate (mg/dL)
- Alkaline Phosphatase (U/L)
- Parathyroid Hormone (PTH)
- 25-hydroxy Vitamin D3
- HbA1c (%)
- Total Cholesterol (mg/dL)
- LDL (mg/dL)
- HDL (mg/dL)
- Triglycerides (mg/dL)
- ALT (U/L)
- AST (U/L)
- Total Protein (g/dL)
- Albumin (g/dL)
- Complement C3 (mg/dL)
- Complement C4 (mg/dL)
- Anti-dsDNA
- Direct Coombs Test
- ACA IgG/M
- AB2GP IgG/A/M
- Lupus Anticoagulant (LA)
- Urinary Protein/Creatinine Ratio (mg/g)

The results will be evaluated according to age-appropriate laboratory reference ranges of Erciyes University Faculty of Medicine Children's Hospital.

9. Focus Group Interviews

At the end of the intervention, a focus group interview will be conducted with patients to collect qualitative experiences and perceptions regarding the intervention. The purpose of the focus group interviews is to gain a broader understanding of the intervention process and its effects.

A semi-structured guide with open-ended questions will be used to encourage participants' discussion. The questions will cover the following topics:

- Positive and negative aspects of the intervention
- Barriers encountered in changing dietary habits
- Perceived changes in health and well-being (physical and psychological aspects)
- Motivation to maintain behavioral changes

The focus group will include five voluntary participants from the intervention group. Each interview will last approximately 45 minutes. Audio recording will be made during the sessions, and participants will be informed about this procedure. Recordings will subsequently be analyzed using content analysis methods and then deleted.

Content analysis is a set of communication analysis techniques aimed at systematically examining the content of messages and extracting indicators related to the conditions under which these messages are produced or received. To facilitate analysis, MAXQDA software (Verbi, Berlin, Germany, 2015) or NVivo (QSR International, Australia, 1999) will be used.

10. Statistical Analysis

The data obtained will be analyzed using the IBM Statistical Package for Social Sciences (SPSS) version 27.0. Descriptive statistics will be presented as number (n) and percentage (%) for categorical variables, and mean ($\bar{X}$) and standard deviation (SD) for continuous variables.

Normality of continuous variables will be assessed using the Shapiro-Wilk test, histograms, and Q-Q plots. Comparisons between the intervention and control groups will be conducted using the Student's t-test for normally distributed data, or the Mann-Whitney U test for non-normally distributed data. For evaluating pre- and post-intervention measurements, repeated measures ANOVA will be applied.

For microbiota analyses, p-values between groups will be calculated using the Kruskal-Wallis test. In all statistical analyses, a 95% confidence interval will be used, and statistical significance will be set at $p < 0.05$.

Study Plan

This study aims to compare the gut microbiota of patients with Systemic Lupus Erythematosus (SLE) and healthy individuals living in the same household, and to evaluate the relationships among diet, microbiota, and clinical findings. The research will be conducted at the Pediatric Nephrology-Rheumatology Department of Erciyes University Faculty of Medicine, including approximately 30 SLE patients and 30 healthy family members living in the same household.

The study will include an intervention and a control group. Participants in the intervention group will receive individualized nutritional counseling based on the principles of the Mediterranean Diet, provided by a registered dietitian. The intervention will focus on increasing dietary polyphenol intake, reducing the dietary inflammatory index, and limiting ultra-processed food consumption. Counseling will last 12 weeks, with a total of 12 sessions planned. The first, sixth, and twelfth sessions will be conducted face-to-face, while the remaining sessions will be conducted via telephone or online. No dietary intervention will be provided to the control group.

At baseline and at the end of the study, stool samples will be collected from all participants, anthropometric measurements and body composition analysis will be performed, and three-day dietary records will be obtained. Diet quality, physical activity level, and sleep quality will be assessed using the KIDMED, IPAQ, and Pittsburgh Sleep Quality Index (PSQI) scales, respectively. Patients in the intervention group will also be monitored using the

CHAQ, SLEDAI-2K, and SLICC/SDI scales. Clinical laboratory data will be obtained from patient records.

Dietary records will be analyzed using the BeBIS program. The dietary inflammatory index (DII), polyphenol content (Phenol-Explorer database), and level of processed food consumption (NOVA classification) will be evaluated. At the end of the intervention, a focus group interview will be conducted with five voluntary participants from the intervention group to collect qualitative data on their intervention experiences, which will be analyzed using content analysis methods.

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