

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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Study Protocol and Statistical Analysis Plan

Approved by the Human Subjects Protection Review
Board (Ethics Committee)

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INFORMED CONSENT FORM

(Intervention Group – Child)

Dear,

My name is Dietitian Sabriye Ballı.

We are conducting a study with our patients who have Systemic Lupus Erythematosus (SLE). The aim of this research is to evaluate the effects of nutrition counseling intervention on the gut microbiota, clinical outcomes, and nutritional status of these patients. Through this study, we hope to gain new knowledge that may also help your recovery. We invite you to participate in this study entitled “*Effects of a Mediterranean Diet-Based Nutrition Intervention on Gut Microbiota, Disease Activity, and Nutritional Status in Children with Systemic Lupus Erythematosus.*”

The study will be conducted by myself, Assoc. Prof. Dr. Zeynep Caferoğlu Akın, and Assoc. Prof. Dr. Ayşenur Paç Kısarslan. If you choose to participate, we will ask you to come to the hospital in a fasting state for your routine check-up. You will have your weight, body fat and muscle composition measured, and your height will be taken. You will complete a short questionnaire (approximately 10 minutes) and record everything you eat and drink for three days. Over 12 weeks, we will have weekly meetings with you, both in-person and remotely. During these meetings, you will record your food intake for three days.

At the first and last sessions, we will collect stool samples for analysis and use scales such as the *Mediterranean Diet Quality Index (KIDMED)* to evaluate your diet quality, the *International Physical Activity Questionnaire (IPAQ)* for physical activity, and the *Pittsburgh Sleep Quality Index (PSQI)* for sleep quality. Additionally, we will use the *Childhood Health Assessment Questionnaire (CHAQ)* to assess your quality of life and the *Systemic Lupus Erythematosus Disease Activity Index-2000 (SLEDAI-2K)* and *Systemic Lupus Erythematosus Damage Index (SLICC/SDI)* to evaluate the effects of the disease on you.

The results of this study will provide valuable information for children with SLE. Your identity will not be disclosed to anyone else, including other doctors.

Before deciding to participate, you should discuss this with your parents. We will also explain the study to your parents and obtain their consent. Even if your parents agree, your participation is voluntary. You can choose not to participate, and no one will be upset with you. Even if you initially agree, you may withdraw at any time, without giving a reason. If you decide not to participate, your medical care will remain unchanged, and the doctors will continue to treat you with the same attention and care.

If you experience any problems during the study, you can contact Assoc. Prof. Dr. Ayşenur Paç Kısarslan at +90 534 884 0893 or at the Pediatric Nephrology-Rheumatology Clinic, Erciyes University Children’s Hospital, at any time (24 hours).

If you agree to participate, please write your name and surname and sign below. After signing, a copy of this form will be given to you and your family.

VOLUNTARY CONSENT

I, the undersigned, declare that I have been fully informed about the study entitled “*Effects of a Mediterranean Diet-Based Nutrition Intervention on Gut Microbiota, Disease Activity, and Nutritional Status in Children with Systemic Lupus Erythematosus.*” I have read all explanations in the Informed Consent Form. The purpose and procedures of the study have been explained to me in writing and verbally by the person named below. I understand that my participation is voluntary and that I can withdraw at any time, with or without explanation, and that the investigators may remove me from the study if deemed necessary.

I consent to participate voluntarily in this study without any pressure or coercion.

Person Providing Information

Child

Parent/Guardian

Name, Surname:

Signature:

Phone No: +90 534 884 0893

Date:

Date:

INFORMED CONSENT FORM

(Intervention Group – Parent)

Dear Parent/Guardian,

The aim of this study is to evaluate the effects of nutrition counseling on gut microbiota, clinical outcomes, and nutritional status in patients with Systemic Lupus Erythematosus (SLE). This research, entitled “*Effects of a Mediterranean Diet-Based Nutrition Intervention on Gut Microbiota, Disease Activity, and Nutritional Status in Children with Systemic Lupus Erythematosus*,” aims to include 60 participants.

If you agree to allow your child to participate in the intervention group, your child’s height and weight will be measured, a body composition analysis will be performed, and your child will complete a short questionnaire (approximately 10 minutes) administered by Dietitian Sabriye Ballı. This questionnaire will record your child’s food intake for three days.

Your child will receive individualized nutrition counseling over 12 weeks, targeting healthy eating habits and dietary goals. Weekly meetings will be conducted in person and remotely, and 3-day food records will be collected. At the first and last sessions, stool samples will be collected, and scales such as the *Mediterranean Diet Quality Index (KIDMED)*, the *International Physical Activity Questionnaire (IPAQ)*, the *Pittsburgh Sleep Quality Index (PSQI)*, and the *Childhood Health Assessment Questionnaire (CHAQ)* will be used. Disease activity and damage will be evaluated using the *Systemic Lupus Erythematosus Disease Activity Index-2000 (SLEDAI-2K)* and the *Systemic Lupus Erythematosus Damage Index (SLICC/SDI)*.

Your child will be fully informed about the study in a way they can understand, and their consent will also be obtained. No changes will be made to your child’s medical care or treatment, and no invasive procedures will be performed during the study.

If you have any questions, you can contact Assoc. Prof. Dr. Ayşenur Paç Kısaarslan at +90 534 884 0893 or at the Pediatric Nephrology-Rheumatology Clinic, Erciyes University Children’s Hospital. Participation is free of charge, and no compensation will be provided.

You are free to consent initially and withdraw later at any time without giving any reason, without affecting your child’s medical care. Your child’s personal information will remain confidential.

VOLUNTARY CONSENT

I, the undersigned, declare that I have been fully informed about the study entitled “*Effects of a Mediterranean Diet-Based Nutrition Intervention on Gut Microbiota, Disease Activity, and Nutritional Status in Children with Systemic Lupus Erythematosus*.” I have read all explanations in the Informed Consent Form. The purpose and procedures of the study have been explained to me in writing and verbally by the person named below. I understand that my child’s participation is voluntary and that they can withdraw at any time, with or without explanation, and that the investigators may remove them from the study if deemed necessary.

I consent to my child’s voluntary participation in this study without any pressure or coercion.

Person Providing Information

Child

Parent/Guardian

Name, Surname:

Signature:

Phone No: +90 534 884 0893

Date:

Date:

INFORMED CONSENT FORM

(Healthy Group – Child)

Dear,

My name is Dietitian Sabriye Ballı. We are conducting a study with children to learn more about nutrition and gut microbiota in children of your age. The study, entitled “*Effects of a Mediterranean Diet-Based Nutrition Intervention on Gut Microbiota, Disease Activity, and Nutritional Status in Children with Systemic Lupus Erythematosus*,” aims to gain knowledge that may also help children with SLE.

If you choose to participate, we will ask you to come to the hospital in a fasting state. Your weight, body fat, and muscle composition will be measured, and your height will be taken. You will complete a short questionnaire (about 10 minutes) and record everything you eat and drink for three days. At the end of 12 weeks, these measurements will be repeated.

At the first and last sessions, stool samples will be collected, and your diet quality will be evaluated using the *Mediterranean Diet Quality Index (KIDMED)* and physical activity with the *International Physical Activity Questionnaire (IPAQ)*.

The results of this study will provide valuable information for children like you. Your identity will remain confidential.

Before deciding, you should discuss this with your parents. Your participation is voluntary, and you can choose not to participate, or withdraw at any time without giving a reason. Even if you decide not to participate, the doctors will continue to treat you as always.

If you have any problems during the study, you can contact Assoc. Prof. Dr. Ayşenur Paç Kısaarslan at +90 534 884 0893 or at the Pediatric Nephrology-Rheumatology Clinic, Erciyes University Children’s Hospital.

VOLUNTARY CONSENT

I, the undersigned, declare that I have been fully informed about the study entitled “*Effects of a Mediterranean Diet-Based Nutrition Intervention on Gut Microbiota, Disease Activity, and Nutritional Status in Children with Systemic Lupus Erythematosus*.” I understand that my participation is voluntary and that I can withdraw at any time. I consent to participate voluntarily.

Person Providing Information

Child

Parent/Guardian

Name, Surname:

Signature:

Phone No: +90 534 884 0893

Date:

Date:

INFORMED CONSENT FORM

(Healthy Group – Parent)

Dear Parent/Guardian,

The aim of this study is to evaluate gut microbiota and dietary factors in children, including healthy children like yours, in comparison with children with Systemic Lupus Erythematosus (SLE). The study, entitled “*Effects of a Mediterranean Diet-Based Nutrition Intervention on Gut Microbiota, Disease Activity, and Nutritional Status in Children with Systemic Lupus Erythematosus*,” aims to include 60 participants.

If you agree to allow your child to participate, their height, weight, and body composition will be measured. They will complete a short questionnaire (approximately 10 minutes), which includes personal, health, and nutrition-related information. This questionnaire will also record their food intake for three days. Stool samples will be collected at the first and last sessions, and diet and physical activity will be evaluated using the *Mediterranean Diet Quality Index (KIDMED)* and the *International Physical Activity Questionnaire (IPAQ)*.

Your child will be fully informed in an age-appropriate manner, and their consent will also be obtained. No changes will be made to your child’s medical care or treatment, and no invasive procedures will be performed.

If you have any questions, you can contact Assoc. Prof. Dr. Ayşenur Paç Kısaarslan at +90 534 884 0893 or at the Pediatric Nephrology-Rheumatology Clinic, Erciyes University Children’s Hospital. Participation is free, and no compensation will be provided.

You are free to consent initially and withdraw later at any time without giving any reason, without affecting your child’s medical care. Your child’s personal information will remain confidential.

VOLUNTARY CONSENT

I, the undersigned, declare that I have been fully informed about the study entitled “*Effects of a Mediterranean Diet-Based Nutrition Intervention on Gut Microbiota, Disease Activity, and Nutritional Status in Children with Systemic Lupus Erythematosus*.” I understand that my child’s participation is voluntary and that they can withdraw at any time. I consent to my child’s voluntary participation.

Person Providing Information

Child

Parent/Guardian

Name, Surname:

Signature:

Phone No: +90 534 884 0893

Date:

Date: