RESEARCH PLAN

Modified vs Standard CDED: Evaluation of a Nordic Adaptation of Nutritional Therapy in Paediatric Crohn’s Disease

NCT number:

Date: 2025-09-29

Nordic Adaptation of the Crohn's Disease Exclusion Diet

Information for children aged 6–11 years

We would like to ask if you want to take part in a research project. Here you can read about what the project is about and what it means to participate.

What is the study about?

We are investigating whether a special diet can help children with Crohn's disease feel better.

How does the study work?

We are contacting you because your doctor believes you may feel better by following a special diet called the Crohn's Disease Exclusion Diet (CDED). We want to find out whether a Nordic version of the diet (Nordic CDED) works just as well. The original version of CDED is already used by other children. It means that you will drink nutrition drinks and eat certain foods from a food list. You will follow the diet for 20 weeks to help reduce your intestine problems.

During the study, we collect information about your health, just like during your usual visits to the hospital. If you choose to take part, your doctor, nurse, or dietitian will fill in different forms when you come to the hospital. They include information about your age, intestinal symptoms, medications, test results, weight, and height. We will also ask you and your parents about how you are feeling and what you are eating. All information is stored safely and kept anonymous.

How do you say yes to participating in the study?

Both you and your guardians will be asked if you want to take part in the study. Your guardians have received more information and a form about the study. If you want to participate, your guardians will sign a consent form. You will not receive any payment for taking part in the study.

If you do not tolerate the nutrition drinks well (nausea, diarrhea, or vomiting) or if the diet becomes too difficult for you to follow, the study will be stopped, and you will continue with your usual follow-up and medical treatment.

Taking part is completely voluntary. You can say no without explaining why, and you can stop participating at any time without giving a reason. This will not affect your future treatment.

Study contact

Name: Nalleli Vivanco Karlsson, Registered Pediatric Dietitian, PhD

Address: Pediatric Medicine, Skaraborg Hospital Skövde, 549 49 Skövde

Email: nalleli.vivanco.karlsson@vgregion.se

Nordic Adaptation of the Crohn's Disease Exclusion Diet

Information for children/adolescents aged 12–14 years

We would like to ask if you would like to take part in a research project. This document gives you information about the project and what it means to participate.

What is the study about?

We are conducting a study on a dietary treatment for children and young people with Crohn's disease.

How does the study work?

We are contacting you because your doctor believes you may benefit from a specific dietary treatment. It is called the Crohn's Disease Exclusion Diet (CDED), and it means you will follow a liquid diet and a specific food list for 20 weeks. This treatment may help you feel better and reduce inflammation in your intestines.

We want to find out whether a new Nordic version of the diet (Nordic CDED) works as well as the original version. CDED is already used by other children, and through this study we collect information about your health in the same way as during your regular check-ups.

If you decide to take part in the study, your doctor, dietitian, or nurse will fill in a few digital forms at your appointments. These include information about your age, type of disease, medications, test results, weight, and height. We will also ask you about how you are feeling and what you are eating.

All information is stored securely in a protected system and cannot be linked back to you personally.

How do you say yes to participating in the study?

Both you and your guardians will be asked if you want to take part in the study. Your guardians have received more information and a form about the study. If you want to participate, your guardians will sign a consent form.

Taking part is completely voluntary. You can say no without explaining why, and you may withdraw at any time without giving a reason. This will not affect your future treatment.

Study contact

Name: Nalleli Vivanco Karlsson, Registered Pediatric Dietitian, PhD

Address: Pediatric Medicine, Skaraborg Hospital Skövde, 549 49 Skövde

Email: nalleli.vivanco.karlsson@vgregion.se

Nordic Adaptation of the Crohn's Disease Exclusion Diet

Information for adolescents aged 15–17 years

We would like to ask if you would like to participate in a research project. This document provides information about the project and what it means to take part.

What is the project about, and why are we asking you to participate?

We are conducting a study on dietary treatment for children with Crohn's disease. The treatment, called the Crohn's Disease Exclusion Diet (CDED), consists of a liquid diet and a specific food list to follow for 20 weeks. The goal of the treatment is to help you achieve remission, meaning to reduce inflammation in your intestines.

In this study, we want to investigate whether a new, Nordic-adapted version of the diet (Nordic CDED) is as effective as the original version. CDED is already used by children in pediatric care, and we now want to adapt it to Nordic eating habits.

We have contacted you because your doctor believes you may benefit from this dietary treatment. Through the study, we gather information about your health, just as during your regular clinic visits

The research sponsor for this project is the Västra Götaland Region. The research sponsor is the organization responsible for the project. The study has been approved by the Swedish Ethical Review Authority; the reference number for the approval is **2025-05123-01**.

How does the project work?

The study mainly documents information that is already collected during your regular visits to the pediatric clinic. The purpose is to investigate whether a Nordic version of the diet (Nordic CDED) works as well as the original CDED treatment. The original CDED is already used in pediatric care.

If you choose to participate, a doctor, dietitian, or nurse will complete digital forms at your usual check-ups. These include information about your age, type of disease, current treatment, test results, weight, and height. We will also ask questions about your eating habits and quality of life.

The treatment is divided into four stages:

- Two weeks with only liquid nutrition.
- Gradual reintroduction of regular foods and reduction of liquid nutrition over three six-week periods.

We will follow you for a total of 24 weeks, and you will meet with a dietitian at least four times during the study

If you choose to participate, you will not need to undergo any extra examinations or tests beyond your regular care. All information is stored securely in an IT system designed for research.

Possible consequences and risks of taking part

The study does not require any extra visits, examinations, or tests, as all information is obtained from your medical records.

If you experience side effects from the liquid nutrition—such as nausea, diarrhea, or vomiting—or if the diet becomes too difficult to follow, the study will be stopped. You will continue with your standard medical treatment and follow-up as before.

Information is collected by authorized healthcare staff and stored securely in a protected IT system (eCRF). Results are presented at a group level, meaning that no individual participant can be identified. Therefore, the risk that someone could access your personal information is very low.

The study may contribute to improved care for children and adolescents with Crohn's disease in the future.

What happens to my data?

The project will collect and register information about you. After you submit the forms, the information will be processed using a specialized data system. During this process, all data will be pseudonymized. When results from the study are published, it will not be possible to identify you as an individual because results are presented at a group level.

Storage and security

All data is stored according to the regulations of the Västra Götaland Region. Personal data is stored securely on a computer at Skaraborg Hospital and is handled only by authorized staff. The information will not be shared outside the hospital. The code key and consent documents are stored separately and handled according to GDPR.

Your rights

You have the right to:

• Know what information we have about you

• Request corrections to inaccurate information

• Request deletion of information (unless it is needed for the research)

• Restrict how your information is used

What is stored and for how long?

The study collects information on:

• Your diagnosis, treatment, and test results

• The effect of the dietary treatment on health and quality of life

• Growth and other relevant health information

All data is stored in a protected IT system (eCRF) and used only for research. Personal information is replaced with a code so that no unauthorized person can see your identity. Data is stored for up to 25 years after the study ends and is handled according to the EU General Data Protection Regulation (GDPR).

The results are analyzed by the researchers at Skaraborg Hospital Skövde.

What happens with my samples?

All information collected in the study is coded. This means no one can see that the information comes from you. Only the principal investigator has access to the code key and can link the code to your name. The code key and signed consent forms are stored securely in locked cabinets at the Research, Education and Development Unit (FoUUI) at Skaraborg Hospital and handled according to GDPR.

If you wish to withdraw your consent, you can do so at any time by contacting the principal investigator, Nalleli Vivanco Karlsson (contact information below). If new research is planned that is not part of this study, the Ethical Review Authority will decide whether new consent is needed.

How do you get information about the study results?

The results will be published in scientific articles, where no individual participants can be identified. Your test and examination results that are part of your regular care will be communicated to you as usual by your clinic. If you would like to access the published study, you can contact the principal investigator, Nalleli Vivanco Karlsson.

Insurance and compensation

You are covered by patient insurance. No financial compensation is provided for participation in the study.

Participation is voluntary

Taking part in the study is completely voluntary. You can withdraw at any time without giving a reason. This will not affect your future care or treatment. If you wish to end your participation, contact the project leader (see contact details below).

For more information, you may contact:

Principal Investigator

Nalleli Vivanco Karlsson, Registered Pediatric Dietitian, PhD

Address: Pediatric Medicine, Skaraborg Hospital Skövde, 549 49 Skövde

Email: nalleli.vivanco.karlsson@vgregion.se

SkaS Data Protection Officer

DSO team, Legal Unit, Västra Götaland Region

Contact: Martin Stawe

Address: Regionens Hus, 405 44 Gothenburg

Email: skas.dso@vgregion.se

If you believe your personal data has been handled incorrectly, you may file a complaint with the Swedish Authority for Privacy Protection (IMY).

Nordic Adaptation of Crohn's Disease Exclusion Diet

Information for Custodians of Research Participants

We are contacting you to ask for your consent for your child to participate in a research project. The purpose of this document is to provide clear information about the study, so that you can decide whether you want your child to take part.

What is this project, and why do we want your child to participate?

We are conducting a study on dietary treatment for children with Crohn's disease. The treatment, called the Crohn's Disease Exclusion Diet (CDED), consists partly of liquid nutrition, provided through oral nutritional supplements, combined with specific foods according to a structured meal plan. The diet should be followed for 20 weeks. The purpose of the treatment is to help your child achieve remission, meaning a reduction of intestinal inflammation. In this study, we want to investigate whether a new, Nordic-adapted version of the diet (Nordic CDED) is as effective as the original version. CDED is already used for children in pediatric care, and now we want to adapt it to Nordic dietary habits.

We are contacting you because we have received information from your child's treating physician that your child may benefit from this dietary treatment.

The research principal for the project is the Västra Götaland Region. The research principal is the organization legally responsible for the project. The research has been approved by the Swedish Ethical Review Authority, reference number **2025-05123-01**.

How does the project work?

The study will primarily document information already collected as part of your child's standard medical care. The aim is to evaluate whether a Nordic-adapted version of the dietary treatment (Nordic CDED) is as effective as the original CDED. The original CDED is already used in pediatric care in several parts of the world and is included as a possible dietary treatment for Crohn's disease in international pediatric guidelines.

If you agree to let your child participate, a member of the medical team (physician, dietitian, or nurse) will complete forms (paper/digital) during routine follow-up visits. These forms will include information such as age, disease type, current medical treatment, test results, weight, and height. We will also ask you and your child questions about quality of life and eating habits before, during, and after treatment (food frequency questionnaire, 3-day and 24-hour dietary records).

The Nordic CDED consists of four phases:

- **Phase 0 (Week 0–2):** Exclusive enteral nutrition, during which your child will receive liquid nutrition in the form of oral nutritional supplements.
- **Phase 1 (Week 3–8):** Nutritional supplements combined with a limited selection of allowed foods. Processed foods, animal fats, gluten, and dairy products are avoided.
- **Phase 2 (Week 9–14):** Gradual introduction of more foods, while continuing supplements and avoiding certain foods considered harmful for the gut.

- **Phase 3 (Week 15–20):** A more liberal diet, although some foods are still avoided to help maintain remission and support long-term health.

We will follow your child for a total of 24 weeks, and a dietitian will meet with you at least four times during the treatment.

Participation in the study does **not** involve any additional clinical examinations, blood or stool tests, or visits beyond those included in standard care. For study purposes, you and/or your child will record food intake at several time points by completing a food frequency questionnaire (via link, approx. 15 minutes) and a 24-hour and a 3-day food diary (paper form, approx. 30 minutes). You will also complete a quality-of-life questionnaire about your child on two occasions (approx. 15 minutes). All collected information is stored in a secure IT system (electronic Case Report Form, eCRF) designed for research.

Possible consequences and risks of participating

The study involves no additional visits, tests, treatments, or procedures, as all such information is obtained from the patient record. The only additional information collected relates to your child's dietary habits and perceived quality of life.

If your child experiences difficulties tolerating the liquid nutrition — for example, nausea, diarrhea, or vomiting — or if the diet becomes too difficult to follow, participation in the study will end. Your child will then continue with standard medical treatment and follow-up as usual.

There is a risk that the dietary treatment may be experienced as demanding for the family, as the child must follow a specific diet. The treatment may also involve increased food costs. Some children may not like all foods included in the diet, which could make adherence more challenging and impact mealtimes at home. To help, a dietitian will always be available for guidance and support. The dietitian will help adapt the meal plan to your child's needs and preferences and provide advice to make the treatment easier for both the child and the family.

All collected information will be handled by the responsible researcher and research team and stored in a secure IT system (eCRF) designed for research. Results will only be reported at group level, meaning no individual child can be identified. The risk of intrusion into personal privacy is therefore considered low.

The knowledge gained from this study may contribute to improved care and treatment options for children and adolescents with Crohn's disease.

How are your child's personal data protected?

To protect your child's privacy, a method called pseudonymization is used. This means personal identifiers are replaced with a code. A special key is required to link data to your child, and only the responsible researcher has access to this key. When results are published, no individuals can be identified.

How are the data stored?

All information is handled according to the Västra Götaland Region's security regulations. Your child's personal identity number is replaced with a code and stored on a secure computer at Skaraborg Hospital. Only the research team has access, and the data are stored separately from the code key. Personal data are handled within the hospital and are not shared externally.

How will the data be used?

The collected data will be stored according to the Västra Götaland Region's retention rules. During registration, your child's identity number is replaced with a code, which makes it impossible to identify individuals.

The data are stored on a secure computer at Skaraborg Hospital, connected to a server within the Västra Götaland Region. Information is processed only within the hospital and not shared externally. Only the responsible researcher has access to the code key and raw data, which are stored separately for increased security.

The code key and consent forms are handled according to GDPR and stored in a locked, restricted-access area. The legal basis for processing personal data is your consent, and all data are archived in a way that prevents unauthorized access.

Under the EU's General Data Protection Regulation (GDPR), you have the right to access the data collected about your child, free of charge, and to request corrections of any inaccuracies. You may also request deletion or restriction of data processing. However, the rights to deletion and restriction do not apply if the data are necessary for the research.

If you wish to access the data, you may contact the principal researcher, **Nalleli Vivanco Karlsson**, using the contact information below. You may also contact the regional Data Protection Officer (DSO-team):

Contact person: Martin Stawe

Email: skas.dso@vgregion.se

Address: Regionens Hus, 405 44 Göteborg

If you are dissatisfied with how personal data are handled, you may file a complaint with the Swedish Authority for Privacy Protection (Integritetsskyddsmyndigheten).

How is study information collected and handled?

The study will collect and register data on the dietary treatment, quality of life, and information related to your child's Crohn's disease, including diagnosis, treatment, tests, examination results, and growth from the patient record. You can always obtain information about all tests and examinations performed within the study through your child's treating physician.

All data are stored in a secure IT system (eCRF) and used only for scientific purposes. Before storage, your child's name and identity number are replaced with a unique study code. The data are handled in a manner that ensures no unauthorized person can access them.

Data will be stored for up to **25 years** after the study concludes and processed in accordance with GDPR. The analysis will be performed by the principal researchers at Skaraborg Hospital in Skövde.

What happens to your child's samples?

All study data will be coded (pseudonymized), meaning they cannot be directly linked to your child. Only the research team has access to these data. Only the principal researcher has access to the code key. The code key and signed consent forms are stored according to GDPR in locked, secure areas at the Research and Development Unit (FoUUI) at Skaraborg Hospital.

If you wish to withdraw your consent, you can contact **Nalleli Vivanco Karlsson** using the details below. If new future research is planned, the Ethical Review Authority will determine whether new consent is required.

How will you receive information about the study results?

Results from your child's standard clinical tests and examinations will be provided as usual through your child's care provider.

The study results will be published in one or more scientific articles. No participants can be identified. If you wish to access the published article(s), you may contact the principal researcher.

Insurance and compensation

Participants are covered by patient insurance. There is no financial compensation for participation.

Voluntary participation

Participation is voluntary. You may withdraw your child from the study at any time. You do not need to give a reason, and withdrawal will not affect your child's future care or treatment.

To withdraw participation, contact the project leader (see below).

Project contacts

Principal Researcher:
Nalleli Vivanco Karlsson, Licensed Pediatric Dietitian, PhD

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