PARTICIPANT INFORMATION SHEET

Title of the study: Diet in Crohn's Disease

Investigators: Professor Simon Keely, Dr Kerith Duncanson, Dr Grace Burns, Dr Emily Hoedt

Sites: John Hunter Hospital, Newcastle Endoscopy Centre, Lingard Private Hospital

College of Health, Medicine and Wellbeing, University of Newcastle, Department of Gastroenterology John Hunter Hospital

Invitation

You are invited to take part in a study about the role of diet in Crohn's disease.

If you think that you might be interested in participating in this study, please take the time to read through this information sheet before making your decision. It may also be helpful for you to discuss potential participation in this study with a relative, health professional or counsellor before reaching a decision. If you are an Aboriginal or Torres Strait Islander person, we encourage you to have a relative, trusted health professional or counsellor with you during recruitment.

What is the purpose of this study?

People with Crohn's disease often report that diet is important in managing their health, but this has not yet been proven. In this study, we will investigate how different foods affect Crohn's disease symptoms and flares. This study is part of the PhD studies of Cheenie Nieva. Cheenie is supervised by the team listed above from the University of Newcastle.

Why am I being invited?

You are being invited to participate in this study because of one or more of the following reasons:

1. You are experiencing symptoms of Crohn's disease.
2. You have been diagnosed with Crohn's disease within the past five years.
3. You previously participated in a study conducted by the Digestive Health Biobank and agreed to be contacted to participate in future research.

What will I be asked to do?

This study is a dietary trial to find out if certain foods trigger Crohn's disease symptoms or relapse. Participants will be randomised (like tossing a coin) and asked to follow one of two

inflammatory bowel disease (IBD) diets for six months. A research dietitian will provide you with advice and support throughout the study. The dietitian will also ask about your symptoms and diet each month to check whether foods trigger your symptoms. You may be invited to continue in the dietary trial for a further six months. This would involve continuing with the same diet for a further six months or swapping over to the other IBD diet for another six-month period.

1. **To get started on the study you will be asked to attend an initial 1-hour appointment (in person if you live in the Newcastle area, or by telehealth). At this appointment the following will happen:**

    - A researcher will explain the study to you and give you an information sheet and consent form.
    - We will ask you permission to access your medical records, now and in the future. This will allow us to collect information relating to your diagnosis and test results such as your intestinal ultrasound (IUS).
    - We will discuss with you donating up to 8 extra small tissue samples during your scheduled endoscopic procedure. This may add a few minutes to your procedure time.
    - We will ask you to provide a small poo sample and information about your poo using a simple chart (Bristol Stool Chart).
      You will be asked to fill out a survey about Crohn's disease, your diet, medications, general health, and wellbeing.

If you live in the Newcastle area we may also discuss with you:

- Donating up to 8 extra small tissue samples during your scheduled endoscopic procedure. This may add a few minutes to your procedure time.
- Permission to collect a blood sample. If you agree, an experienced blood collector will take a sample of blood from your arm. The amount of blood taken (about 8 teaspoons or 42 mL) is like what is taken for your routine blood tests.

2. **To continue on the study, you will be asked to do the following:**

    - Participate in the dietary trial for six months.
    - Provide blood samples after three months and six months at the Hunter Medical Research Institute (if you live in the Newcastle area) at a time that suits you and complete a food frequency questionnaire (20 minutes) to assess your food intake.
    - Provide a small poo sample each month. We will give you six sample kits and instructions to take home for the collection. You can send these to the researchers via the reply-paid envelopes we provide. We will send you a reminder each month by email or text message when it is time to send your poo sample.
    - Attend a monthly face-to-face or telehealth dietitian appointment to check on your progress (30 minutes)
    - Complete a daily food checklist (5 minutes)
    - Complete a 24-hour food recall (15 minutes) one day per week, where you will record all the food and drinks you have consumed the previous day. The day of the week will change, but you will receive an email or text message to remind you to complete the recall.
    - Complete a monthly IBD questionnaire (5 minutes) to check on your symptoms.

3. **At the end of the study the following will happen:**

- We will access your medical records to collect information about your IUS results 6 months after starting the dietary trial. IUS is a special ultrasound scan that looks at the large and small intestine and will help determine whether you have responded to the diet.
- We will discuss with you donating an additional 8 biopsies at your next scheduled endoscopy if it is within 12 months of starting the dietary trial.
- We will ask you permission to donate a final set of blood and poo samples at the 12-month timepoint. An extra sample kit for poo collection will be provided.
- You will be offered a meeting with a research team at the end of the study to discuss the study results, including whether your symptoms were related to food.

A summary of the information above is shown in the table below:

What I will be asked to do?	**How long it should take me?**		**Month**						
		0	**1**	**2**	**3**	**4**	**5**	**6**	**12**
Initial appointment	1 hour	✓							
Food frequency questionnaire	20 minutes	✓			✓			✓	
Daily food checklist	5 minutes per day, totalling 2.5 hours per month		✓	✓	✓	✓	✓	✓	
Weekly 24-hour food recall	15 minutes per week, totalling 1 hour per month	✓	✓	✓	✓	✓	✓	✓	
Weekly IBD questionnaire	5 minutes per month	✓	✓	✓	✓	✓	✓	✓	
Monthly dietitian appointment	30 minutes		✓	✓	✓	✓	✓	✓	
Bristol Stool Chart	1 minute	✓	✓	✓	✓	✓	✓	✓	✓
Medical records: Researchers will access your medical records to learn any information relating to Crohn's disease that might be helpful during the study, such as your diagnosis and IUS results.									
What samples will I be asked to provide?	**How long will it take?**								
Blood	30 minutes	✓			✓			✓	✓
Poo	10 minutes	✓	✓	✓	✓	✓	✓	✓	✓
How much time will this take each month?		2.5 hours	4.25 hours	4.25 hours	5 hours	4.25 hours	4.25 hours	5 hours	<1 hour

Note: If you are booked for an endoscopy within 12 months after starting the dietary trial, we would ask you permission to donate up to 8 additional biopsy samples.

Do I have to participate in the study?

No. This study is completely voluntary. If you choose to take part, you can stop at any time, without giving a reason. If you decide not to participate, it will not affect your current or future

medical care and your future contact with John Hunter Hospital or Newcastle Endoscopy Centre in any way.

You can withdraw from the study without giving a reason. If you choose to withdraw, your samples and all the information we have collected about you or has been extracted from your medical records will be destroyed. It may not be possible to withdraw your data from the study results if these have already had your identifying details removed.

What will my samples be used for?

Your samples will be used for research to understand more about the causes of Crohn's disease. Any left-over samples (blood, biopsies, and poo) may be stored in the Digestive Health Biobank for future use in other research projects – with your consent. Related health data will also be available for the purpose of the Digestive Health Biobank.

Are there any risks?

Blood collection

This study involves three blood collections during the six-month study period. You may experience discomfort and minor bruising or swelling on your arm where the blood sample is collected. All blood samples are taken by experienced blood collectors.

Biopsy collection

This study also involves requesting your permission to take an extra eight tissue samples being collected during two routine endoscopies within a 12-month period. Patients undergoing routine colonoscopy or gastroscopy are at some risk of a puncture (hole) in the bowel or major bleeding from the bowel. This is rare but the extra biopsies collected for this study do increase these risks.

Can I have other treatments during this study?

Yes, you can continue all regular medications for the duration of the study.

Compensation for injuries or complications

If you suffer any injuries or complications as a result of this study, please contact your GP or the research assistants Gillian Harris or Rachel Whyte on (02) 404 20491 or (02) 404 20339 as soon as possible to arrange appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

What are the possible benefits of participating in this study?

This study could help to improve our understanding of Crohn's patients who respond to dietary change. You may benefit personally if your symptoms are responsive to diet, but this is not guaranteed.

Will I receive information about my results?
Yes, you will be told at the end of the study if your Crohn's disease is responsive to food. The results of the study will be shared in journals and conference presentations, but you will not be identified. You may also request a summary of the study by ticking a box on the consent form and including your mailing or email address.

Some genetic tests may be conducted on your samples. Occasionally, a researcher may come across a genetic variant which is inherited from a parent. This might be an indicator of Crohn's disease risk, or it could be in a gene related to another condition. If this information may help to better treat a condition or possibly stop it from developing in the first place, the information can be given to your doctor. You will be asked in the consent form whether you would want to be told about an inherited variant if one is detected in your sample.

You would be offered genetic counselling if an inherited genetic variant is found. The genetic counsellor would discuss the option of having clinical testing for this variant. She/he would discuss implications of this finding for your health checks or treatments and whether the information was relevant to other family members.

Will taking part in this study cost me anything?
No, participation in this study will not cost you anything. The dietitian will discuss food affordability as part of each consultation and tailor suggested foods to your requirements.

Where will my information and samples be stored?

Your test results (with your name stored separately from study data) will be stored in a secure research database at Hunter Medical Research Institute. Your blood and tissue samples will be sent to Hunter Medical Research Institute for testing. Any leftover samples will be stored at the Hunter Medical Research Institute for possible future research will the approval of the Human Research Ethics Committee. The Human Research Ethics Committee will decide whether your consent is needed at that time for another research project.

How confidential is the information I give?

All information collected is confidential. Any identifiable or potentially identifiable information about you in this study will remain confidential in accordance with Commonwealth Privacy Laws and the NSW Health Information and Records Privacy Act (2002) and will be disclosed only with your permission, except as required by law. Only the researchers and research coordinator named below will have access to your details and results that will be held securely in the John Hunter Hospital.

What if I have questions?
If you have any questions concerning this study, please contact the research team on (02) 404 20491 (02) 404 20339 or 0466 033 019 or email digestive.health@newcasle.edu.au

If you experience any symptoms or have any concerns relating to the study you can contact the research team using the above contact details.

Ethics:

This research has been approved by the Hunter New England Human Research Ethics Committee of Hunter New England Local Health District, Reference [2021/ETH01368].

Governance:
The conduct of this research has been authorised by the Hunter New England Local Health District to be conducted at the **John Hunter Hospital**, **Newcastle Endoscopy Centre and Lingard Private Hospital** sites.

Complaints about this research:
Should you have concerns about your rights as a participant in this research, or you have a complaint about the way the research is conducted, it may be given to the researcher, or, if an independent person is preferred, please contact the HNE Research Office, Hunter New England Local Health District, Level 3, POD, HMRI, Lot 1 Kookaburra Circuit, New Lambton Heights, NSW 2305. Telephone: (02) 4921 4140. Email: HNELHD-ResearchOffice@health.nsw.gov.au and quote reference number: 2021/ETH01368.

Thank you for taking the time to consider this study. If you wish to participate, please sign the attached consent form. This information sheet is for you to keep.

Yours Sincerely,

Cheenie Nieva (PhD Candidate, The University of Newcastle)