**INFORMATION SHEET FOR PARTICIPANTS**

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

*Ethical Clearance Reference Number:* LRS-17/18-7313

**The feasibility of following the Crohn’s Diet**

We would like to invite you to participate in this original research project at King’s College London. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Choosing not to take part will not disadvantage you in any way. Ask me if there is anything that is not clear or if you would like more information.

**What is the purpose of the study?**

Our team of researchers from King’s College London are investigating how diet can be used as a treatment for Crohn’s disease. We have designed a new diet and eventually wish to test whether the diet can be used to manage Crohn’s disease and reduce gut inflammation. Before we do this, we need to find out how practical it is for people to follow the diet for 14 days by conducting this ‘feasibility’ study. A feasibility study is a small study that aims to highlight any issues before informing the design of a larger research trial.

The diet we have designed is called the Crohn’s Diet. The evidence for this diet is based on recent research which suggests that certain food ingredients may be involved in triggering gut inflammation.

Our primary aim is to assess the practicalities of following the Crohn’s Diet. We have developed a mobile phone application (App) and a booklet which will help you follow the diet. We will investigate the usefulness of these resources and how they could be improved based on your feedback. We will also assess your compliance to following the Crohn’s Diet and if following it changes the nutritional balance from your normal diet.

**Why have I been invited to take part?**

We are looking for adults with Crohn’s disease aged 18 or over. You may be eligible if you can answer ‘‘yes’’ to the following statements:

* I have stable Crohn’s disease (as defined as: no change in my Crohn’s disease medication in the last 3 months; no surgery for Crohn’s disease in the last 6 months; no change in my Crohn’s disease medications in the last 6 months)
* I am willing to partake in a study which involves making dietary changes for 14 days
* I am not underweight (Body Mass Index less than 18.5 kg/m2 is considered underweight)
* I have a smartphone with Android or IOS (Apple) software and am willing to download and use a free mobile phone application (App)

**What will happen if I take part?**

The study will take place over 4 weeks and you would attend King’s College London Waterloo Campus on 3 occasions (1 screening visit, 1 consultation visit and 1 follow-up visit). These visits can be scheduled based upon your convenience from Monday – Friday. The details of each visit are outlined below.

Pre-screening questionnaire (via telephone)

When you have read this information sheet and if you decide you may wish to take part, you would initially be screened on the telephone for eligibility according to our study criteria. This will include some questions about your medical history and medications. If you are eligible, we would invite you for a baseline visit at the research unit where we would measure your Body Mass Index to complete the screening process.

Screening visit (Study visit 1)

This visit would be booked at your convenience and lasts approximately 30 minutes. When you arrive we will:

* Explain the study to you in detail
* Give you the opportunity to ask any questions before you decide if you would like to participate
* Ask you to provide consent and sign two copies of the informed consent form if you would like to take part
* Measure your Body Mass Index (BMI) to complete the screening process. Volunteers with a BMI <18.5 kg/m2 will be excluded from participating
* If eligible, we will enrol you in the study
* Provide you with a 7-day food diary for you to record information on your food intake for the next 7 days

Consultation visit (Study visit 2)

The consultation visit would be scheduled at least 1 week following the screening visit. This visit should not last longer than 1 ½ hours. After returning your 7-day food diary, you will be asked to complete three questionnaires on your bowel habits and current quality of life. The consultation with a dietitian will involve:

* Learning how to follow the Crohn’s Diet for 14 days
* Discussing the Crohn’s Diet information booklet
* Showing you how to download and use the Crohn’s Diet Trial App. This App has a barcode scanner which helps you identify suitable and unsuitable foods whilst following the diet.
* Asking questions if you want further information on recipes, food shopping and eating out whilst you are on the diet
* We will provide you with another 7-day food diary to be completed during the last 7 days whilst you are on the Crohn’s Diet. These are to be returned on the follow-up visit.
* Provide you with the phone and email contact details of the study dietitian in case you have any questions whilst following the diet

*Telephone support*

We will ask if you would consent to being contacted by telephone during the intervention period for the purposes of identifying any issues/answering any queries you may have.

Follow-up visit (Study visit 3)

This visit would be scheduled after you had completed the Crohn’s Diet for 14 days. This follow-up visit should last no longer than 1 hour. At the visit the dietitian will:

* Collect the completed food diaries. These diaries will later be analysed to test if the nutritional balance of what you ate changed when you were on the Crohn’s Diet. The diaries will also help us assess how strictly you were able to follow the diet.
* Ask you to complete the same three questionnaires from the baseline visit which asks questions on your bowel habits and current quality of life.
* Ask you to complete questionnaires: about your experience on the diet; how closely you followed it; and how useful the dietitian advice, information booklet and Crohn’s Diet Trial App were in helping you follow the diet.

**Do I have to take part?**

Participation is completely voluntary. You should only take part if you want to and choosing not to take part will not disadvantage you in anyway. Once you have read the information sheet, please contact us if you have any questions that will help you decide about taking part. If you decide to take part we will ask you to sign a consent form before we take any of your measurements and you will be given a copy of this consent form to keep.

**Where will the study take place?**

Your study visits would take place in the Metabolic Research Unit at the Waterloo Campus of King’s College London. This is located on the 4th floor of the Franklin-Wilkins Building, 150 Stamford Street, SE1 9NH.

**Incentives**

You will receive £50 upon completion of the study to compensate for your time and to subsidise different groceries that may be required for the study.

**What are the possible risks of taking part?**

The risk associated with this study is negligible. The main burden for you is the need to modify your diet for 14 days. The Crohn’s Diet could be challenging to follow because certain pre-prepared and convenience foods are excluded. Supermarket food shopping might take a little longer as you will be using the App barcode scanner to find suitable foods. Online food shopping is not advised during the trial because barcodes are not available. There are still plenty of convenience foods, pre-prepared foods and ready-meals that are suitable, and these can still be eaten providing you check their suitability with the App barcode scanner.

The Crohn’s Diet can be nutritionally balanced and your dietitian will be able to help answer any questions you have whilst you are on the diet. If you are preparing food for other people, it is safe for them to eat the same meals as you.

**What are the possible benefits of taking part?**

The aim of this study is not to treat your Crohn’s disease. Taking part in this study will provide no direct benefit for you. This study is preliminary work to develop a diet which will eventually be tested as a treatment for Crohn’s disease. Your participation is likely to help improve the treatment of people with Crohn’s disease in the future.

**Data handling and confidentiality**

Your data will be processed in accordance with the General Data Protection Regulation 2016 (GDPR). All information collected in the study will be recorded and stored securely and anonymously using a study participant identification code on an encrypted, password-protected storage device at King’s College London. All anonymised records and data collected from the study will be retained for a period of 10 years following publication of the results to allow for additional analyses. Within this 10-year period, the research team might use this anonymised data for other research studies; for example, to help design a larger trial testing the Crohn’s Diet. After this time all data will be destroyed.

FoodMaestro (UK Registered Company No: 4093976) has worked with King’s College London to develop the Crohn’s Diet Trial mobile phone App. FoodMaestro will not require any personal information from you, such as your email address, to download and use the App. The company will not have any access to your research data. FoodMaestro uses cookies to access information on how users operate the functions of the App. The information FoodMaestro has access to includes: the food products searched for; users navigation through the App; and information on products users mark as ‘‘liked’’ or placed in their ‘‘shopping list’’. FoodMaestro uses this information to provide an individualised service to users, such as remembering your search preferences. FoodMaestro also uses this information to make improvements to their services, such as identifying how to reduce the number of clicks to get to popular features. FoodMaestro shares the data generated from the App with market research companies to inform the industry on key trends. By downloading and using the App, you are agreeing to FoodMaestro collecting and using your information as outlined above.

**Data Protection Statement**

The data controller for this project will be King’s College London (KCL). The University will process your personal data for the purpose of the research outlined above. The legal basis for processing your personal data for research purposes under GDPR is a ‘task in the public interest’ You can provide your consent for the use of your personal data in this study by completing the consent form that has been provided to you.

You have the right to access information held about you. Your right of access can be exercised in accordance with the General Data Protection Regulation. You also have other rights including rights of correction, erasure, objection, and data portability. Questions, comments and requests about your personal data can also be sent to the King’s College London Data Protection Officer Mr Albert Chan [info-compliance@kcl.ac.uk](file:///%5C%5Ckclad.ds.kcl.ac.uk%5Canywhere%5CUserData%5CPSStore02%5Ck1217397%5CMy%20Documents%5C2018%5Cinfo-compliance%40kcl.ac.uk). If you wish to lodge a complaint with the Information Commissioner’s Office, please visit [www.ico.org.uk](http://www.ico.org.uk).

**What if I change my mind about taking part?**

You are free withdraw at any point during the study, without having to give a reason. Withdrawing from the study will not affect you in any way. You are able to withdraw your data from the study up untilthe expected final day of recruitment on 01/02/2019, after which withdrawal of your data will no longer be possible as the data will have been anonymised and contain no personal-identifiable information.

**How is the project being funded?**

This study is being funded by the charity *forCrohns* (Registered Charity Number 1129871). This charity funds research and raises awareness of Crohn’s disease. Their website address is <http://forcrohns.org/site/>.

**What will happen to the results of the study?**

The results of the study will be summarised together for all of the participants, thus, there will be nothing that would identify an individual. You will not be identifiable in any part of the work. The results are intended to be published in a publicly-available scientific journal, presented at conference meetings, as well as written up for a PhD thesis. The results will help develop the design of a larger study testing the effects of the Crohn’s Diet.

**Who should I contact for further information?**

If you have any questions or require more information about this study, please contact the dietitian researcher using the following contact details:

Alicia Sandall

Doctoral Researcher and Registered Dietitian

Department of Nutritional Sciences, 4th floor, Franklin-Wilkins Building

150 Stamford Street, London SE1 9NH

alicia.sandall@kcl.ac.uk

0207 848 4552

If this study has harmed you in any way or if you wish to make a complaint about the conduct of the study you can contact King's College London using the details below for further advice and information:

Professor Kevin Whelan

Professor of Dietetics

Department of Nutritional Sciences, 4th floor, Franklin-Wilkins Building

150 Stamford Street, London SE1 9NH

kevin.whelan@kcl.ac.uk

0207 848 3858

**Thank you for reading this information sheet and for considering taking part in this research.**