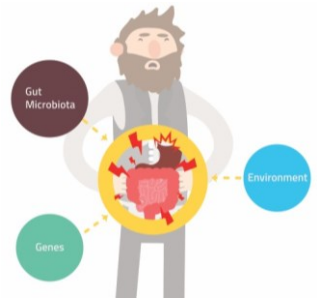
PREdiCCt
The PRognostic effect of Environmental factors in Crohn's and Colitis

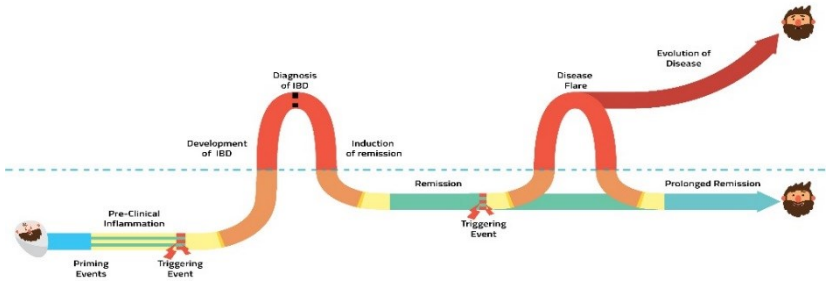
Understanding how environmental factors, diet and gut micro-organisms influence Crohn's Disease and Ulcerative Colitis flare

Introduction

Inflammatory bowel disease (IBD) is a chronic intestinal disorder which often confers a lifetime of unpleasant, intrusive and potentially dangerous burden of intestinal inflammation. It is hypothesised that the interplay between our genetic makeup, environment and gut microbiota influence disease onset as well as disease course. Currently it is very hard to predict which IBD patients in remission will flare and when.

The focus of the PREdiCCt study is towards understanding how diet, lifestyle and the gut microbiota influence flare and recovery in IBD.





Disease Flares in IBD

- How **often** do disease flares occur in IBD?
- What **causes** disease flare in IBD?
- Can we **predict** who will flare?
- What can people with IBD do to **prevent** flares? *"what should I eat doctors?"*
- Can we work out what factors are associated with prolonged (deep) **remission**?

Study Design

Prospective UK wide, multi-centre, observational cohort study involving **3100 patients with IBD in clinical remission** followed up for **24 months**.

Primary Objective: To determine which aspects of **a) baseline habitual diet, b) the environment, c) genetic variation** and **d) the gut microbiota**, predict disease flare in Crohn's disease and /or ulcerative colitis. The primary objectives are to test associations with:

- Total animal protein intake (red meat, dairy, poultry, fish)
- Dietary fibre
- N-6 PUFAs
- Dietary emulsifiers (lecithin)
- Total bacterial gene count in stool

Secondary Objectives: To build predictive models of IBD prognosis and natural history utilising multi-level clinical, environmental, microbial & genetic data.

Primary outcome:
1. Clinical flare

Secondary outcomes:
1. Hard clinical flare
2. Total number of clinical flares and hard flares in the 24 month follow-up

Study Procedures & Data Collection

An online **PREdiCCt** web-portal has been created to allow for timely accurate electronic data collection.

Phenotyping: Baseline **phenotyping** including date of diagnosis, disease location and behaviour, current and prior drug therapy, surgical interventions, family history, and smoking status. Plus standard clinical care blood tests.

Environmental, Lifestyle and Dietary Data Collection: Completed at home (within 14 days). Food Frequency Questionnaire & **4-day weighed food diary**. Validated questionnaires on **quality of life**, **emotions & mood**, stressful **life events**, global **physical activity**, **sleep**, **drug compliance** and foreign **travel**.

Sample Collection: **Salivary** and **stool** collection packs issued. Samples returned from patient's home by post. Host and genomic microbial DNA are extracted for whole-genome and metagenomic sequencing. Faecal Calprotectin and Short chain fatty acids measured on stool samples

Follow-up: **24 months follow-up of all patients**. Questionnaires through web-portal capture information on relevant investigations (imaging or endoscopy), hospitalisation or significant illness & document environmental exposures.

At **flare** patients return further stool samples for microbiome and faecal calprotectin analysis. Multiple flares captured during the study.

The **PREdiCCt** study is coordinated by the **University of Edinburgh** and **NHS Lothian** and has contributions from gastroenterologists & research scientists across the UK. It is funded by **Cure Crohn's & Colitis**, **Crohn's and Colitis in Childhood**, **NHS Lothian** and the **Chief Scientist Office**. If you would like to invest to help **PREdiCCt** expand please contact the Chief Investigator Charlie.lees@ed.ac.uk (**@Charlie_lees**).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