Supplement 1: Causes of Secondary Sclerosing Cholangitis and Alternate Liver Diseases

Secondary causes of sclerosing cholangitis include, but are not limited to:

- IgG4-related cholangitis
- Cholangiopathy due to acquired immunodeficiency syndrome
- Drug-induced sclerosing cholangitis
- Trauma
- Ischaemic cholangiopathy
- Choledocholithiasis
- Sclerosing cholangiopathy as a sequela of hepatopancreatobiliary resection

Alternate causes of liver disease include, but are not limited to:

- IgG4-related cholangitis
- Viral hepatitis
- Alcohol-related liver disease
- Clinically significant metabolic associated fatty liver disease
- Drug-induced liver disease
- Hereditary haemochormatosis
- Alpha-1-antitrypsin disease
- Primary biliary cholangitis
- Wilsons disease
- Budd-Chiari Syndrome
- Primary or secondary hepatopancreatobiliary cancer

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Supplement 2: Hepatic Decompensation

Hepatic decompensation is evidenced by one or more of the following:

- Variceal haemorrhage
- Ascites
- Hepatic hydrothorax
- Hepatic encephalopathy

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Supplement 3: Indicators of Advanced Hepatic Dysfunction

Laboratory evidence of advanced hepatic dysfunction, as evidenced by one or more of the following:

- Serum bilirubin value > 55umol/L (or conjugated hyperbilirubinaemia >45 umol/L)
- Serum albumin <32 g/L
- Platelet level < $140x10^9$/L
- Child-Turcotte-Pugh score >B7
- MELD score > 15

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University Hospitals Birmingham
NHS Foundation Trust

FARGO: A randomised, phase IIa, multi-centre, placebo-controlled trial of FAecal microbiota transplantation in primaRy sclerosinG chOlangitis

PARTICIPANT INFORMATION SHEET

WE INVITE YOU TO TAKE PART IN A RESEARCH TRIAL

- Before you decide we would like you to understand why this research is being done and what it would involve for you.
- Please take your time to read the following information carefully. You may want to talk to others about the trial before taking part.
- Joining the trial is entirely your decision. If you choose not to take part, this will not affect the care you get from your own doctors.
- You can stop taking part in the trial at any time.
- One of our team will go through this information sheet with you. Please do not hesitate to ask us if there is anything unclear or if you would like more information.

IMPORTANT THINGS THAT YOU NEED TO KNOW

- We want to see if patients with Primary Sclerosing Cholangitis (PSC) and Inflammatory Bowel Disease (IBD) can be safely treated with Faecal Microbiota Transplant (FMT).
- FMT involves taking faeces (stool) from the gut of a healthy donor, treating it in a laboratory and transferring it to the bowel of someone else.
- You have been invited to take part because you have PSC and IBD.
- You will attend a hospital appointment to check you are eligible to take part in the trial.
- If you are eligible and wish to take part, you will need to attend **eight** hospital appointments over 8 weeks for treatment. Half of participants will receive FMT and the other half will receive FMT Placebo.
- After you have finished all treatment visits, you will have a further **four** follow-up visits, once every 12 weeks (see Figure 1 below).
- In this trial we will collect information from you. This information will be handled in accordance with the General Data Protection Regulation.

CONTENTS

1. Why are we doing this trial?
2. What do I need to know about the treatment used in this trial?
3. Why am I being asked to take part?
4. Why take part?
5. What will happen to me if I take part?
6. What will happen to the blood and tissue samples I give?
7. Patient Questionnaires: Symptoms and Quality of Life information
8. Possible side effects to you
9. Pregnancy and effects on an unborn child / newborn
10. More information about taking part
11. Your confidentiality
12. How to contact us

HOW TO CONTACT US

If you have any questions about this trial, please talk to the doctors who organise it:

Dr. Palak Trivedi – 01213714672

Dr. Rachel Cooney – 01213714987

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1. WHY ARE WE DOING THIS TRIAL?

- We want to see if Faecal Microbiota Transplant (FMT) can be used to safely treat people with Primary Sclerosing Cholangitis (PSC) and Inflammatory Bowel Disease (IBD). This will include looking at the effects, compared to placebo, on your symptoms of PSC and IBD, in addition to your quality of life.

2. WHAT DO I NEED TO KNOW ABOUT THE TREATMENT USED IN THIS TRIAL?

- FMT has been shown to improve symptoms and reduce the amount of inflammation in IBD.
- FMT has also been shown to be safe when given to people who have PSC and IBD. A research summary is available at www.pscsupport.org.uk/FARGO
- There is an imbalance of the 'normal' microbiome (e.g. bacteria, viruses, and fungi) in the gut of people with PSC and IBD. This imbalance is believed to lead to the development (and possibly worsening) of liver disease in PSC.
- It is believed that FMT treatment can restore the imbalance in the gut microbiome and that this can lead to the reduction in symptoms of PSC and IBD and improve liver blood tests and quality of life.
- FMT involves the transplantation of faeces (stool) from a healthy individual to a person with PSC and IBD.
- FMT is prepared from stool collected from unrelated, anonymous, healthy donors. The stool is treated in a laboratory at the University of Birmingham. The donors are carefully screened and the donated stool carefully tested to ensure that it is as clean and safe as possible before it is made into doses of FMT suitable for treatment purposes.
- There may be times when there is a limited supply of donors and this may lead to a limited supply of stool to prepare the FMT. Therefore, there may be times when you will not be able to take part in the trial. This will not affect you if you have been registered on to the trial.
- Half of participants will receive FMT and the other half will receive FMT Placebo.
- FMT or FMT Placebo will be administered via colonoscopy or enema.
- If you are selected to receive FMT, you will receive 360g of FMT in total over the 8-week treatment period. This is approximately equivalent to the volume of one can of soft drink.

3. WHY AM I BEING ASKED TO TAKE PART?

- You have been diagnosed with PSC and IBD and we believe you may be eligible to take part in the trial. You will only be invited to participate if you are aged ≥18 years and your doctor considers you to be fit enough to undertake a colonoscopy and its associated bowel preparations.
- The trial will involve approximately 58 people with PSC and IBD. Individuals will be recruited from specially selected hospitals in the UK.
- Taking part in research is always voluntary. If you are interested in taking part, you will be given this information sheet to keep. If you agree to take part, we will ask you to sign a consent form before starting the trial. You are completely free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive for your PSC and IBD.

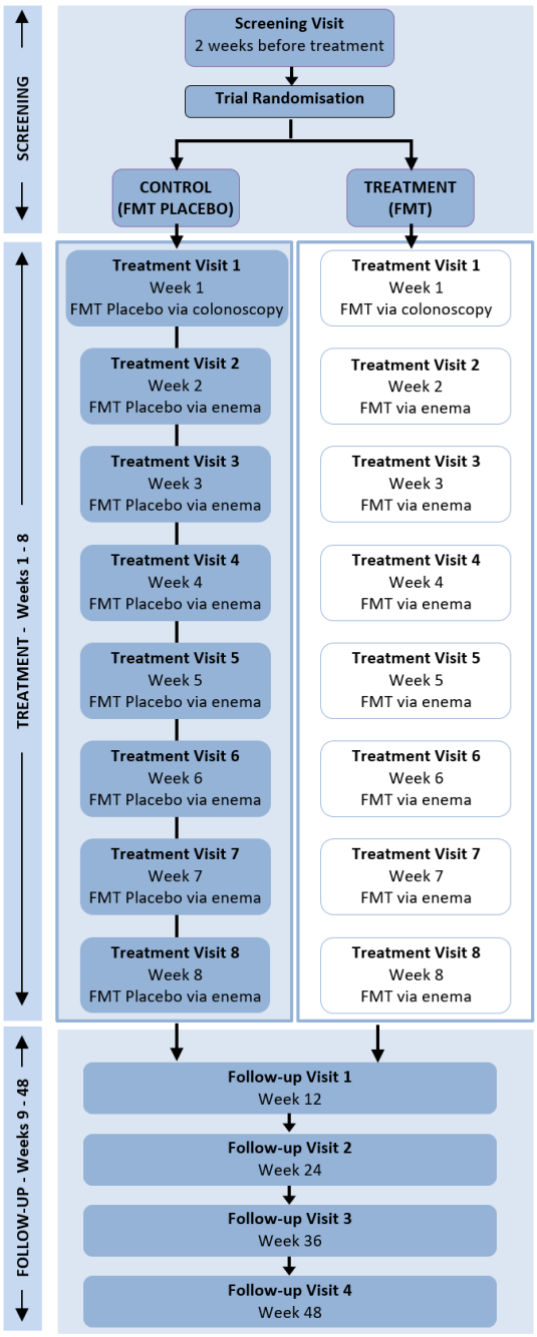
4. WHY TAKE PART?

- We hope the FMT will benefit patients by restoring the balance of microbiome in the gut, resulting in the improvement of patients' symptoms of PSC and IBD, and improve liver blood tests and scans. However, there is no guarantee that the treatment will work for patients. At present we do not know whether FMT is of any benefit to people with PSC and IBD, therefore we need to do this trial to find out. The main benefit

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will be that information gained from the trial will help doctors in the treatment of patients with PSC and IBD in the future.

Figure 1: Trial Timeline



5. WHAT WILL HAPPEN TO ME IF I TAKE PART?

- If you decide to take part you will be asked to sign a consent form and will be given a copy of this to keep.
- You will need to attend **eight** scheduled hospital appointments over 8 weeks for treatment.
- After you have finished all treatment visits, you will have a further **four** follow-up visits. These will be once every 12 weeks for 48 weeks. These follow-up visits will align with your routine clinic visits where possible. You will not receive any additional treatments as part of the trial during the follow-up visits.
- What you will be asked to do at each trial visit is explained below (see Figure 2 below).
- It is important you follow the instructions given by your trial doctor or research nurse throughout the trial.

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SCREENING VISIT

- At first, you will be invited to attend a hospital appointment to assess your suitability to take part in this trial. This may involve more than one appointment within a 2-week period.
- Some of the tests and procedures at this hospital appointment will be in addition to those you undergo for your usual PSC and IBD care.
- If after screening you are found to be suitable for the trial, you will be officially entered into the trial, and be randomised to a treatment group.

RANDOMISATION AND BLINDING

- This is a 'randomised controlled trial'. This means that a computer will randomly put each participant into one of two groups:
    - Faecal Microbiota Transplant (FMT)
    - FMT Placebo
- A placebo is a dummy treatment which will have no effect on your PSC or IBD.
- Neither you nor your doctor can choose which group you will be allocated. Half of the participants will be randomised to receive FMT and the other half will be randomised to receive FMT Placebo. This means there is equal chance of receiving FMT or FMT Placebo. This is essential to ensure a fair comparison is made between the two groups.
- This trial is a 'single-blind trial'. This means that you will not know which treatment you will receive. Your doctor and medical team will know which treatment you receive, but some of the medical team involved in collecting research data will also be blinded to your treatment allocation.
- You will be given a Patient Identification Card. It will contain your Trial Number but it will not show if you are in the FMT or FMT Placebo group. It will detail emergency contact numbers that you can use if you feel unwell at any time. You must carry the card with you at all times and show it to your GP or any other doctor you may see for the duration of the trial. This is important in case the doctor treating you needs to know the treatment you are receiving for medical reasons.

TREATMENT VISITS (WEEKS 1-8)

- This is when you will be given the FMT or FMT Placebo.
- These hospital visits are in addition to those you undergo for your usual PSC and IBD care.
- The first treatment dose (Week 1) will be given via colonoscopy. This involves taking a bowel cleaning preparation drink on the day before the colonoscopy. This will be a macrogol based bowel preparation (e.g. Moviprep® or Plenvu®). The colonoscopy usually takes between 30-45 minutes. Following this treatment, you may have to stay in hospital for up to 6 hours for monitoring.
- In the treatment visit weeks 2-8, you will be given your treatment via enema. You will not need to take a bowel cleaning preparation for these treatment visits. Following these treatments, you may have to stay in hospital for between 1-2 hours for monitoring and to complete trial assessments.
- You will be given a single dose of loperamide before each treatment. This will reduce the chances of a bowel movement immediately ejecting the contents of the FMT or FMT Placebo following treatment.

FOLLOW-UP VISITS (WEEKS 12-48)

- Three of these hospital visits are in addition to those for your usual PSC and IBD care. The last follow-up visit will be in line with your routine clinic visit, where possible.
- These visits are designed to check your general health and to understand what effect the treatment has had on you, your bowel disease and liver disease. These will be similar to your usual outpatient visits. No additional treatments specific to the trial will be given during this time.

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FIGURE 2: VISIT SCHEDULE

	Screening	Treatment								Follow-up			
Week	Week -2	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 12	Week 24	Week 36	Week 48
Visit Window (days)	± 7	± 3	± 3	± 3	± 3	± 3	± 3	± 3	± 3	± 7	± 7	± 7	± 7
Proposed Date	DD/MMM/YY	DD/MMM/YY	DD/MMM/YY	DD/MMM/YY	DD/MMM/YY	DD/MMM/YY	DD/MMM/YY	DD/MMM/YY	DD/MMM/YY	DD/MMM/YY	DD/MMM/YY	DD/MMM/YY	DD/MMM/YY
Informed Consent	x												
Medical History	x												
Eligibility Assessment	x												
Randomisation	x												
Blood Tests	x	x		x		x			x	x	x	x	x
Stool Tests	x	x	x	x	x	x	x	x	x	x	x	x	x
Urine Tests	x	x				x			x	x			x
Medication Review	x	x	x	x	x	x	x	x	x	x	x	x	x
Adverse Events	x	x	x	x	x	x	x	x	x	x	x	x	x
Pregnancy Test	x	x				x			x	x			
Fibroscan®	x												x
PSC Measures	x	x		x		x			x	x	x	x	x
IBD Measures	x	x	x	x	x	x	x	x	x	x	x	x	x
Colonoscopy / Sigmoidoscopy		x								x			x
Patient Questionnaires	x								x	x	x	x	x
Patient Diary	x	x	x	x	x	x	x	x	x	x	x	x	x
Trial Treatment via colonoscopy		x											
Trial Treatment via enema			x	x	x	x	x	x	x				
Research Colon Biopsy Samples		x								x			x

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Visit Window

It is important that you are able to come to your appointments on the days planned by the research team. The 'Visit Window' shows how flexible we can be when arranging the dates with you.

Medical History

We will ask about your previous health, including date/year you were diagnosed with PSC and IBD.

Blood Tests

These tests will monitor your health and wellbeing. They will help us understand the effect of FMT on blood markers of PSC and IBD. About 20mls of blood (4 teaspoons) is taken in the same way as other normal blood tests. At some of your trial visits, a research blood sample of about 65mls (13 teaspoons) will be taken to measure your response to treatment. We aim to collect research samples at the same time as routine bloods to minimise the need for more needles.

Stool Tests

At the screening visit, a sample of your stool will be tested for any bacterial or parasite infections. Samples of your stool will also be tested for levels of faecal calprotectin, which is a marker of inflammation in the gut.

At some of your treatment visits, a research stool sample of about 10g will be collected to look at how well the treatment has worked at changing your gut microbiome, both in terms of its contents but also the way the gut microbes work. We will provide you with a kit for collecting stool at home. You will need to collect this sample before taking bowel preparation. We ask that keep your stool sample in a refrigerator prior to bringing it with you to your hospital visit.

Urine Tests

At the screening visit, a sample of your urine will be tested for alcohol and drugs.

At some of your treatment visits, a research urine sample of approximately 5mLs (1 teaspoon) will be taken to look at the composition of bile acids in your urine.

Medication Review

We will ask about any medicines you are taking (including over-the-counter medicine, supplements, vitamins or herbal treatments), whether prescribed or bought from a pharmacy. If you are unsure about taking a particular medication, please check with your trial doctor or nurse before taking it. It is recommended that you keep a list of medications and bring it with you to each visit.

Adverse Events

Safety is of utmost importance. We will closely monitor you throughout the duration of the trial. You should also let your trial doctor or nurse know immediately if there are any major changes in your general health during treatment and between visits and if you have any concerns regarding the trial. If you see another doctor/nurse/healthcare person you must tell them you are taking part in this trial and that they can contact your trial doctor or nurse for information. If you are admitted to a hospital between your trial visits you must inform your trial doctor and/or nurse as soon as possible. We will give you with a card with the necessary contact details.

Pregnancy Test

If you are a woman and able to have children, a urine test will be done to see if you are pregnant.

COVID Test

It is not necessary to have a COVID-19 test done prior to entry into the trial. However, if you have had a confirmed COVID infection, the trial doctor and/or nurse may decide to delay your treatments or trial visits.

Vibration-controlled transient elastography (Fibroscan®)

This is an ultrasound machine used to scan your liver. This provides a measure of liver stiffness which will help us understand the condition of your liver.

PSC and IBD Measures

The results of your blood tests, scans and examinations will be used to calculate levels of PSC and IBD activity.

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Colonoscopy / Sigmoidoscopy

This procedure is used to assess inflammation of the colon. A colonoscopy is a procedure in which a trained medical professional uses a flexible, narrow tube with a light and tiny camera, called a colonoscope. This will be placed into your bottom and used to look inside the length of your large intestine.

We will give you a bowel cleaning preparation to take the day before returning for your hospital visit. This is a special drink that will clear your bowel.

It is standard care to offer sedation with a colonoscopy, so you may feel groggy after the procedure. You will not be able to drive for at least 24 hours after the procedure.

Every participant will have a colonoscopy at Week 1 and Week 48. You will receive your first treatment dose during the colonoscopy at Week 1.

A sigmoidoscopy is a similar procedure to the colonoscopy. It is less invasive as it only looks at the lower part (last third) of your large intestine. A flexible sigmoidoscopy is required at Week 12. You will not need a full bowel cleaning preparation; rather we will give you a bowel cleaning enema just prior to the sigmoidoscopy.

Enema

Seven of your treatment doses at weeks 2-8 will be given by an enema. This means the liquid dose will be inserted into your bottom.

Patient Questionnaires and Patient Diary

You will be asked to fill in questionnaires about your quality of life and symptoms related to PSC and IBD. You will also be asked to complete a daily diary of your IBD symptoms, including the number of stools, the number of stools with blood and whether or not you had pain and/or cramps in your tummy.

Research Biopsy Samples

During a routine colonoscopy and sigmoidoscopy, biopsy samples are taken from your colon as per standard of care. The exact amount of biopsies taken varies from person to person, but normally a minimum of twelve are taken: 2 from each section of your colon. In a standard sigmoidoscopy, between 4-6 biopsies are usually taken. As part of the FARGO trial, we will collect up to 12 extra biopsy samples for research (1-2 from each different section of your colon). These samples will be sent to a lab for evaluation. We will look at how the treatment has affected your gut.

6. WHAT WILL HAPPEN TO THE BLOOD AND TISSUE SAMPLES I GIVE?

Routine blood and stool samples will be taken at most treatment visits to monitor your safety. These routine samples will be disposed of after the test as per local practice. Additional research blood, stool, urine and biopsy samples will be taken during the trial to monitor what effect the treatment is having on your body. Our research also includes extracting DNA of microbes from your gut (e.g. bacteria, viruses, and fungi) and other chemicals from the samples. These samples will be transferred to, stored, and analysed at different locations:

Sample	Location for Analysis	Country
Blood	University of Birmingham	UK
Blood	Imperial College London	UK
Blood	Royal Free London Hospital	UK
Blood	Nordic Biosciences	Norway
Colonic Biopsy	University of Birmingham	UK
Colonic Biopsy	Earlham Institute, Norwich	UK
Stool	University of Birmingham	UK
Stool	Imperial College London	UK
Stool	Earlham Institute, Norwich	UK

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Urine	Imperial College London	UK

It is possible that there will be some research samples remaining after our tests and we will ask your permission as to whether these can be stored in a tissue bank for future medical research that receives approval from a Research Ethics Committee. This is optional on the FARGO Informed Consent Form and whether or not you agree to further use of your samples will not affect your entry into the trial. The research samples will be looked after by the University of Birmingham.

These samples will be labelled using your trial number, initials and date and time of the sample collection prior to storage. Only the trial team will be able to link that code with your personal details. This data is required to correctly match the sample to the clinical data. No data that can identify you will be given out to people not connected with this trial.

7. PATIENT QUESTIONNAIRES: SYMPTOMS AND QUALITY OF LIFE INFORMATION

WHY ARE WE ASSESSING POSSIBLE SIDE-EFFECTS, SYMPTOMS AND HOW YOU FEEL?

It is important for us to understand how FMT affects the way you feel. Some treatments can make people feel better but others can cause symptoms or possible side-effects that make people feel worse. We will ask you about any new symptoms at every visit. We would also like you to let us know about how you feel during the trial by completing questionnaires.

WHAT DO THE QUESTIONNAIRES ASSESS?

We ask that four questionnaires are completed at some of your trial visits. These questionnaires will take you about 10 minutes to complete.

- The Primary Sclerosing Cholangitis-Patient Reported Outcome (PSC-PRO) Questionnaire has 29 questions used to assess your PSC symptoms
- The Short Form 36 (SF-36)) has 36 questions that measure quality of life
- The 5D-itch Questionnaire has 5 questions used to measure symptoms of itching
- The Short Inflammatory Bowel Disease Questionnaire (SIBDQ) has 10 questions to assesses quality of life related to your IBD

You will be also be asked to fill in a diary on your IBD symptoms for 7 days prior to each trial visit. You will be asked to fill in this diary in a paper booklet. The diary will take you around 5 minutes to fill in.

CAN SOMEONE FILL IN THE QUESTIONNAIRES FOR ME?

No. We really want to understand your point of view, so we ask that you fill in the questionnaires.

HOW OFTEN WILL I HAVE TO FILL IN QUESTIONNAIRES?

We ask that you fill in the questionnaires at your screening visit and then at weeks 8, 12, 24, 36 and 48 of the trial. This will allow us to compare the results of your questionnaires and assess if and how the treatment has affected how you feel.

8. WHAT ARE POSSIBLE SIDE EFFECTS?

FMT has been used in previous trials and found to be well tolerated with little-to-no side effects. However, you may experience some of the following:

Common side effects:

- Gastrointestinal adverse events including bloating, changes to bowel habit, flatulence, diarrhoea, cramp, or abdominal pain

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Rare side effects:

- Gastrointestinal adverse events including constipation, belching, nausea and vomiting and colitis
- Urinary tract infection
- Fever
- Low blood pressure
- Increased heart rate

You will be monitored closely during treatment and should report any side effects to your trial doctor or nurse during the trial (number given below). You will be given appropriate medication to prevent and treat any side effects that might occur. If you notice any symptoms or possible side-effects once you have left the hospital then please contact your trial doctor (contact details are provided below). Your safety is our primary concern.

If you are in the FMT Placebo group, there are no anticipated side effects, however, your symptoms of PSC and IBD may not improve or may worsen.

Side effects from tests or procedures done as part of this trial:

- **Blood test:** Taking blood may cause bruising at the place where the needle goes into the skin. Fainting and, in rare cases, infection may occur.
- **Fibroscan®:** There are no risks associated with this procedure. It is not an invasive test and is painless.
- **Endoscopy (colonoscopy or sigmoidoscopy):**
    - *Discomfort*: When undergoing endoscopy, you may feel some discomfort or bloating. This is usually short lasting (typically no more than a few hours), and rarely severe.
    - *Bleeding*: The risk of bleeding is low (about 1-6 per 1000 procedures). Mostly this does not require any treatment, but if severe might require a blood transfusion.
    - *Perforation (tear)*: The risk of causing a tear in the bowel lining is very low (around 1 in 5000 chance for sigmoidoscopy, and 1 in 3000 for colonoscopy). If this happens, you may require a scan to confirm the diagnosis. If a tear is small, it may be treated with antibiotics and closely monitored in hospital. But if this fails or the tear is large you may require emergency surgery.
    - *Sedation*: Sedation will be offered at the colonoscopy procedure. If sedation is offered, there is a risk of oversedation, which can cause a drop in blood oxygen or blood pressure. If oversedation occurs, you will be monitored closely during and after your procedure for these issues. If there are any signs of these developing then they should be treated immediately. You should not drive or operate heavy machinery for at least 24 hours while the effects of sedation are affecting your body.
    - *Side effects related to bowel preparation for colonoscopy and sigmoidoscopy*: Side effects of bowel preparations include hunger, nausea, abdominal pain, bloating, vomiting, thirst, dizziness and dehydration. Side effects of restrictions on eating and drinking before the procedure, and/or of medications to clear stool out of the large bowel, can occasionally lead to dehydration or salt imbalances in the blood, which may need treatment with fluid given through an intravenous drip.
- **Enema:** The rectal enema is generally well tolerated and is very similar to other enema preparations that are prescribed to treat colitis. Side effects may include:
    - *Discomfort:* You may feel some discomfort as the nozzle and enema is inserted into the rectum.
    - *Bleeding:* The risk of significant bleeding is exceptionally rare.
    - *Urgency to use the toilet*
- **Colonic Mucosal Biopsy:** Taking a biopsy from the colon is painless. Biopsies are approximately 2mm^3 (about the size of a pin head). As the biopsies are taken only from the surface lining of the colon, the risk of any damage is extremely low. Obtaining extra biopsies during your procedure will not expose you to any

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additional discomfort or significant added risk compared to a routine standard of care colonoscopy or flexible sigmoidoscopy.

- **Other procedures** like physical examinations, blood pressure measurements, and weight and height measurements are generally of no risk to you

9. PREGNANCY AND POTENTIAL EFFECT TO AN UNBORN OR NEWBORN CHILD

At the present time, there is very limited data on the use of FMT in pregnancy and therefore the risk of harm to an unborn or newborn child is unknown. For this reason, you should not take part in this trial if you are pregnant, breastfeeding or you may become pregnant during the trial period.

It is essential that women taking part in this trial should use a highly effective method of contraception whilst taking part in the trial.

Your trial team will discuss this with you at your first visit.

Forms of **acceptable** contraceptive that may be used include:

- Combined (oestrogen and progestogen containing) hormonal contraception such as - oral (pill), intravaginal (vaginal ring), transdermal (patch)
- Progestogen-only hormonal contraception associated with inhibition of ovulation – pill, injected or implantable
- Intra-uterine device (IUD), intrauterine hormone-releasing system (IUS), bilateral tubal occlusion, vasectomised partner or sexual abstinence.

Forms of contraceptive which are **NOT acceptable** include:

- Progestogen-only oral hormonal contraception, where inhibition of ovulation is not the primary mode of action
- Male or female condom with or without spermicide
- Cap, diaphragm or sponge with spermicide
- Periodic abstinence (calendar, symptothermal, post-ovulation methods), withdrawal method (coitus interruptus), spermicides only, and lactational amenorrhoea method (LAM) are not acceptable methods of contraception.

Though no adverse reports in pregnancy or breast-feeding have been reported, we are taking precautions to avoid any harm to potential children. If you are breast-feeding, you cannot take part in the trial.

If you are female and of childbearing potential you will have a pregnancy test before treatment starts, at certain time points through treatment and after the treatment period has finished. If you become pregnant, the pregnancy will need to be monitored. We will ask you for consent to receive information about the outcome of the pregnancy from your and baby's medical notes. This information will be documented on a separate release of medical Information form.

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10. MORE INFORMATION ABOUT TAKING PART



Will I get paid for taking part?

- You will not be paid for taking part in this trial. However, reasonable travel expenses incurred by you and/or your companion/carers can be reimbursed, up to a maximum of £30 per treatment visit on production of receipts. Travel by car will be reimbursed at the standard National Health Service (NHS) patient reimbursement rate of your local NHS trust (typically 23 pence per mile)
- If you feel that it is likely that your expenses are going to be higher than the £30 per treatment visit, due to the distance that you have to travel to the hospital, car parking charges or any other reason, then please discuss this with the local hospital team. Depending on individual circumstances, it may be possible to find additional ways to help with extra travel or accommodation costs. Please discuss this with your research nurse
- Depending on local hospital arrangements, food and drinks may be provided by the hospital during visits. Please ask your local research team for details





Are there any medications I cannot take whilst I am on this trial?

You should discuss any changes to your medication with your trial medical team to make sure they do not cause problems with your trial treatment.

Whilst taking part in this trial, you will not be allowed to:

- Receive any vaccination including boosters less than four weeks before or after administration of any of the trial treatment
- Start any new experimental therapies other than the therapy detailed in this trial
- If you are currently receiving corticosteroids, systemic immunosuppression, fibric acid derivatives, farnesoid-X-receptor agonists, anti-gastrointestinal motility agents, bile acid sequestrants (e.g. colestyramine) or ursodeoxycholic acid (UDCA), the dose must stay the same for at least 12 weeks before you enter the trial
- Receive any antibiotics, probiotics and prebiotic preparations

If you have to change your dose or start any of these medications during your trial treatment, you may have to pause or stop the trial treatment



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What will happen if I don't want to carry on with the trial?

- Taking part in this trial is voluntary. You are free to withdraw from this trial at any time. Your decision not to take part will not affect your future medical care or any benefits to which you are entitled
- If you decide you do not wish to carry on with the trial, you will have the option to:
  - Withdraw from the trial completely
  - Withdraw from treatment but carry-on attending follow-up visits
  - If you withdraw from treatment, trial treatment will stop
  - If you choose to take part, but withdraw later, we would still like to collect information about your treatment as this will be invaluable to our research. If you would prefer that we do not collect any further information, please let your trial team know when you withdraw from the trial
  - Information already collected before your withdrawal from the trial may still be used for research purposes





What if relevant new information becomes available?

- Sometimes we get new information about the treatment being studied
- If this happens, your trial doctor will inform you and discuss with you whether you should continue in the trial
- If you decide not to carry on, your trial doctor will make arrangements for your normal care to continue
- If you decide to continue in the trial, he/she may ask you to sign an updated consent form
- It is possible that your trial doctor might suggest you withdraw from the trial. He/she will explain the reasons and arrange for your care to continue. If the trial is stopped for any other reason, we will tell you and arrange your continuing care



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What happens if something goes wrong?

- If you have a concern about any aspect of this trial, you should ask to speak to the trial doctor who will do their best to answer your questions. You can use the contact details at the end of this information sheet
- If you remain unhappy and wish to complain formally, you can do this through your hospital's Patient Advice and Liason Services (PALS):

  Telephone: 01213713280

  Email: PALS@uhb.nhs.uk
- In the event that something does go wrong, and you are harmed due to someone's negligence, then you may have grounds for a legal action for compensation against the University of Birmingham (as Sponsor of the trial) or the NHS Trust who treated you but you may have to pay your legal costs
- The University of Birmingham has in place Clinical Trials indemnity coverage for this trial which provides cover for the University's legal liability for harm caused to participants which comes about through the University's, or its staff's, negligence in relation to the design or management of the trial and may alternatively, and at the University's discretion, provide cover for non-negligent harm to participants. The University of Birmingham is independent of any pharmaceutical company, and as such it is not covered by the Association of the British Pharmaceutical Industry (ABPI) guidelines for participant compensation.
- NHS Trust and Non-Trust Hospitals have a duty of care to patients treated, whether or not the patient is taking part in a clinical trial, and the normal National Health Service complaints system will still be available to you (if appropriate)
- If you have private medical insurance, you should tell your insurer that you are





What will happen to the results of the trial?

- At the end of the trial, the information collected will be analysed and published in recognised medical journals. The identity of the patients who took part in the trial will remain confidential
- Should you wish to discuss the results of the trial, you should contact your trial Doctor; you will have the opportunity, if you wish, to be informed of your treatment group and the results of the trial once fully analysed
- Additionally a plain English summary will be published on the Research Summaries section of the Health Research Authority (HRA) website at the end of the study https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/



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Who has reviewed this trial?

- All research in the NHS is looked at by independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This trial has been reviewed and given favourable opinion by a Research Ethics Committee. It has also been reviewed by the Medicines and Healthcare products Regulatory Agency and by the NHS Health Research Authority
- While the trial is ongoing the results will be reviewed by an independent Data Monitoring Committee (DMC) to ensure that it is appropriate to continue with the trial





How have patients been involved in this trial?

- The Trial Management Group for this trial has a patient representative. They have provided advice on the trial design and reviewed this information sheet and helped us to develop it so that it is clear and correct. They will also be involved in the ongoing management of this trial.





Who is organising and funding the research?

- This trial is being sponsored by The University of Birmingham. The trial is being run by the FARGO Trial Office at The University of Birmingham
- Funding is being provided by LifeArc and PSC Support



11. YOUR CONFIDENTIALITY

All information collected about you for this trial will be subject to the General Data Protection Regulation and Data Protection Act 2018 and will be kept strictly confidential.

University of Birmingham is the Sponsor for this trial based in the UK. The use of the word 'we' in this information sheet refers to the Sponsor (i.e. the University of Birmingham). With your consent, we will be using information from your medical records, collected by your trial team, in order to undertake this trial and will act as the data controller for this trial. This means that the University of Birmingham are responsible for looking after your information and using it properly. University of Birmingham and the NHS will keep identifiable information about you for at least 15 years after the trial has finished, to allow the results of the trial to be verified if needed.

All information collected by the Sponsor will be securely stored at the FARGO Trial Office at the University of Birmingham on paper and electronically and will only be accessible by authorised personnel. The only people in the University of Birmingham who will have access to information that identifies you will be people who manage the trial or audit the data collection process.

With your permission, your trial doctor will provide your initials and month and year of your birth when you enter the trial and they will notify your GP that you intend to participate in the trial. They will also send a copy of your signed Informed Consent Form in the post to the FARGO Trial Office. This is to ensure the correct consenting procedures have been followed.

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The NHS will use your name and contact details to contact you about the research trial, and make sure that relevant information about the trial is recorded for your care, and to oversee the quality of the trial. Your trial doctor or research nurse may also need to send a copy of your Informed Consent Form to other healthcare professionals (e.g. your GP) to prove that you have given consent to take part in the trial before they will provide information.

In the FARGO Trial Office you will be identified by a unique trial number. In routine communication between your hospital and the FARGO Trial Office, you will only be identified by your trial number and initials. On occasion you will also be identified by your month and year of birth. Data may be provided to the FARGO Trial Office on paper or electronically.

By taking part in the trial you will be agreeing to allow research staff from the FARGO Trial Office at the University of Birmingham to look at the trial records, including your medical records. It may be necessary to allow authorised personnel from government regulatory agencies (e.g. the Medicines and Healthcare products Regulatory Authority (MHRA), Sponsor and/or NHS bodies to have access to your medical and research records. This is to ensure that the trial is being conducted to the highest possible standards.

Individuals from the Microbiome Treatment Centre at the University of Birmingham, will have access to some of your personal medical data (your initials and month and year of your birth) for safety monitoring purposes.

In addition, if you have provided research samples for the trial, your trial number and initials will be passed onto personnel at external (to your local hospital) laboratories to help them identify the samples.

All individuals who have access to your information have a duty of confidentiality to you. Under no circumstances will you be identified in any way in any report, presentation or publication arising from this trial.

Anonymised information collected about you may also be shared with other researchers and used to support other research.

If you choose to withdraw from the trial treatment, we would still like to collect relevant information about your health, as this will be invaluable to our research. If you have any objection to this, please let your trial doctor know.

You can withdraw your consent to our processing of your data at any time. Your rights to access change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the trial, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. Under the provisions of the General Data Protection Regulation and Data Protection Act 2018, you have the right to know what information the Trial Office have recorded about you. If you wish to view this information, or find more about how we use this information, please contact Legal Services at the address below or email dataprotection@contacts.bham.ac.uk. Please note that a small fee may be payable to retrieve this information.

Legal Services, University of Birmingham, Edgbaston, B15 2TT

You can find out more about how we use your information in our Privacy Policy on our website https://www.birmingham.ac.uk/research/crctu/data-protection.aspx

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12. HOW TO CONTACT US

If you have any questions or concerns about your disease or this clinical trial, please discuss them with your doctor. You can get in touch with the doctors and nurses at any time to discuss any doubts or worries you may have about the trial, and we will give you a card with contact details. Contact details are also shown below:

Trial Doctor	Dr. Palak Trivedi	Tel: 01213714672 (Secretary)
	Dr. Rachel Cooney	Tel: 01213714987 (Secretary)
Research Nurse(s)	Michelle Panton	Tel: 01213718182 / 07920148119
	Penelope Rogers	Tel: 01213718182
	Khush Bhandal	
	Gifty Essel	
Hospital Details	Queen Elizabeth	
	Hospital Birmingham	
	Mindelsohn Way	
	Edgbaston, Birmingham	
	B15 2GW	
	Tel: 0121 371 2000	

You may also find it helpful to contact your local Patient Advice and Liaison Service (PALs) (if available locally) who provide advice and support to patients, their families and their carers. You can find information about PALS on the NHS website: www.nhs.uk/nhs-services/hospitals/what-is-pals-patient-advice-and-liaison-service. You can find your local nearest PALS office at the above website. The contact number of your local Patient Advice and Liaison Service or local advisory service details (where available) is shown below:

PALS Contact: Patient Advice and Liaison Service (PALS) Tel: 0121 3713280

You may also wish to contact PSC Support, a UK patient organisation for patients with PSC.

- Website: www.pscsupport.org.uk
- Email: hello@pscsupport.or.uk
- Postal Address: PSC Support, Unit 23056, PO Box 4336, Manchester, M61 0BW

Thank you for reading this Participant Information Sheet

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Supplementary Table 5. Schedule of Events

	Screening	Treatment Phase								Follow-up Phase			
	Week -2	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 12	Week 24	Week 36	Week 48
Visit Window (days)	± 7	± 3	± 3	± 3	± 3	± 3	± 3	± 3	± 3	± 7	± 7	± 7	± 7
Trial Treatment		x	x	x	x	x	x	x	x				
Informed Consent	x												
Eligibility Assessment	x												
Randomisation	x												
Medical History	x												
Concomitant Medications	x	x	x	x	x	x	x	x	x	x	x	x	x
Pregnancy Test	x	x				x			x	x			
Stool Microbiology	x												
Urine Drug Screen	x												
Standard Blood Tests[1]	x	x		x		x			x	x	x	x	x
MRCP	x												
Child-Turcotte-Pugh Score	x	x		x		x			x	x	x	x	x
MELD Score	x	x		x		x			x	x	x	x	x
Adverse Events	x	x	x	x	x	x	x	x	x	x	x	x	x
PSC Prognostic Scoring and Surrogate Biomarkers of Liver Fibrosis													
VCTE	x									x			x
Enhanced Liver Fibrosis Score		x				x				x			x
UK-PSC Score	x	x		x		x			x	x	x	x	x
Amsterdam-Oxford PSC Score	x	x		x		x			x	x	x	x	x
IBD Activity Stratification													
Faecal calprotectin	x	x				x				x			x
Partial Mayo Score	x	x	x	x	x	x	x	x	x	x	x	x	x
Mayo Colitis Score		x								x			x
SES-CD Score		x								x			x
Patient-Reported Outcome Measures													
PSC-PRO questionnaire	x								x	x	x	x	x
SF-36 questionnaire	x								x	x	x	x	x
5D-itch questionnaire	x								x	x	x	x	x
SIBDQ questionnaire	x								x	x	x	x	x
Research Samples													
Colonic biopsies - Colonoscopy		x											x
Colonic biopsies - Sigmoidoscopy										x			
Blood samples		x				x			x	x			x
Urine samples	x	x				x			x	x			x
Stool samples	x	x	x	x	x	x	x	x	x	x	x	x	x

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University Hospitals Birmingham
NHS Foundation Trust

Queen Elizabeth Hospital Birmingham
Mindelsohn Way
Edgbaston
Birmingham B15 2GW

Tel: 0121 627 2000

FARGO: A randomised, phase IIa, multi-centre, placebo-controlled trial of **FA**ecal microbiota transplantation in prima**R**y sclerosin**G** ch**O**langitis

INFORMED CONSENT FORM

Site: Queen Elizabeth Hospital Birmingham **Patient Trial Number:** ☐☐

Principal Investigator: Dr Palak Trivedi

Please initial each box

1. I confirm that I have read and understand the Patient Information Sheet (version ..... dated.....) for the above trial. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I give permission for my personal details, including my initials and month and year of birth to be given to the FARGO Trial Office when I am randomised to the trial as well as a copy of this consent form. ☐
4. I understand that relevant sections of my medical notes and data collected during the trial may be looked at by individuals from the University of Birmingham, regulatory authorities, Sponsors and/or NHS bodies, where it is relevant to my taking part in this research. I understand this information will be held in a confidential manner. I give permission for these individuals to have access to my records. ☐

CRCTU-ICF-QCD-001, version 2.0b

Original to be kept in the Investigator Site File, 1 copy in hospital notes, 1 copy to the patient, 1 copy to the FARGO Trial Office

CONFIDENTIAL ON COMPLETION

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Chair: Dame Yve Buckland Chief Executive: Jonathan Brotherton

5. I understand that limited patient identifiable information from the trial may be provided to other 3rd parties (e.g. pharmaceutical companies or other academic institutions) for research, safety monitoring or licensing purposes. This additional information ensures that samples can be correctly identified prior to processing in either internal or external laboratories. ☐

6. I understand that my data, and information from my samples will only be used by researchers in a form that protects my anonymity. Anonymised data and information derived from research samples may be shared with other research organisations as part of this trial, or in future research. This may include academic institutions, clinical research groups or commercial (for-profit) companies. I understand that this data may be transmitted outside the European Economic area to countries which may have a different level of data protection to that in the UK. ☐

7. I agree to the collection, transfer and storage and analysis of blood, stool, urine, and biopsy samples for use in translational research associated with the FARGO trial. ☐

8. I understand that some of the blood, stool, urine, and biopsy samples collected as part of the FARGO trial may be sent to another laboratory in the United Kingdom, and also to countries outside the United Kingdom, for analysis as part of this trial. My identity will remain confidential. ☐

9. I understand that if I withdraw from the trial, any samples and data that have been collected up to the date of my withdrawal will be analysed and used as part of the research. ☐

10. I agree to my GP being informed of my participation in this trial. ☐

11. I give consent that my GP and specialist doctors involved in my healthcare may be contacted and access given to my medical notes held by my GP. ☐

12. I agree to take part in the FARGO Trial. ☐

OPTIONAL CONSENT

The following are optional and will not affect entry into the trial. **Please initial one box only**:

	No	**Yes**
13. I give consent for any remaining blood, stool, urine or biopsy tissue samples left over at the end of the trial being stored and used for future ethically approved research studies.	☐	☐

_____	_____	_____
Name of patient	**Date**	**Signature**
_____	_____	_____
Name of person taking consent *You must have signed the Site Signature & Delegation Log*	**Date**	**Signature**

Original to be kept in the Investigator Site File, 1 copy in hospital notes, 1 copy to the patient, 1 copy to the FARGO Trial Office

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<To be printed on local hospital headed paper>



FARGO: A randomised, phase IIa, multi-centre, placebo-controlled trial of **FA**ecal microbiota transplantation in prima**R**y sclerosin**G** ch**O**langitis

Participant Instructions for Stool Collection

1. Check your FARGO stool sample collection kit

This kit is to be used for collecting your stool (poo) sample for the FARGO Trial.

Check that your kit contains the following items:

- **OM-AC1 Toilet Accessory.** This folds out and goes on your toilet seat to collect the stool sample
- **Tube 1 (DNA/RNA Shield™ Faecal Collection Tube).** This tube contains some liquid
- **Tube 2 (30ml Universal Tube).** This is an empty tube

If you are missing any items, please contact your research team (see contact details below)

2. When to collect your stool sample

- Collect your stool sample on the day of your trial visit appointment (ideally within 6 hours of your appointment).
- If you are taking bowel preparation ahead of a colonoscopy, collect the stool sample BEFORE you start your bowel preparation.

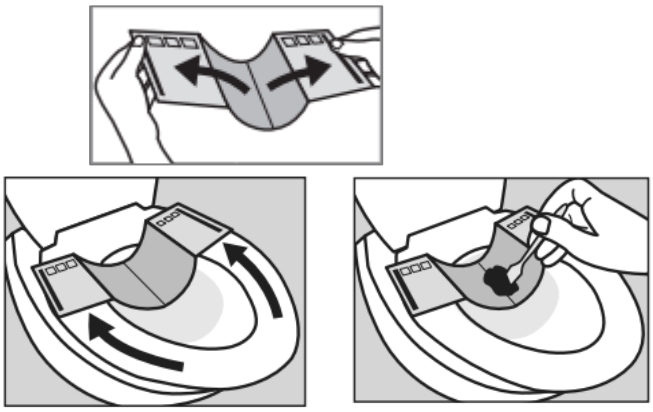
3. How to collect your stool sample

- Ensure that your Trial Number is correct on the 2 tubes.
- Write the date the stool sample was collected on the 2 tubes.
- Make a note of the time the stool sample was collected. The FARGO Research Team will need this information.

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- Collect stool using the **OM-AC1 Toilet Accessory:**
  - Do NOT let toilet water, urine, toilet cleaning products or fragrance touch the stool sample, toilet accessory or the collection tubes. **If some urine touches them, please make a note on the label.**
  - Carefully peel open edge with ▲; repeat for edge with ■.
  - Attach the sticky surface of the accessory to BACK of the toilet seat with sticky surface close to the outer edge of the seat and press firmly.
  - Go to the toilet to pass your stool. The accessory should catch the stool (poo) as it falls



4. Put the stool sample into the tubes

Tube 1: DNA/RNA Shield™ Faecal Collection Tube (the one with some liquid in it)



- Unscrew the cap of Tube 1 carefully without spilling any of the liquid. The cap has a spoon fixed to it.
- Use the spoon to scoop **one spoonful** of stool and carefully place it into Tube 1.
- Tighten the cap and mix it throughly into the liquid by turning the tube upside down and back again 10 times.

Tube 2: 30ml universal tube (the empty tube)



- Unscrew the cap of Tube 2. This has a spoon fixed to it.
- Use the spoon to scoop **three large spoonfuls** of stool and place them into Tube 2.
- Tighten the cap.

- Flush any unused stool sample away and wash your hands thoroughly
- Drop the used accessory into the toilet. Wait for one minute for paper to become soft, then flush. Alternatively, dispose in the rubbish bin.
- Keep your stool samples at room temperature
- Bring your stool samples to your trial visit appointment and give them to the FARGO Research Team

If you have any questions, please contact your research team.

Research Team Contact Details:

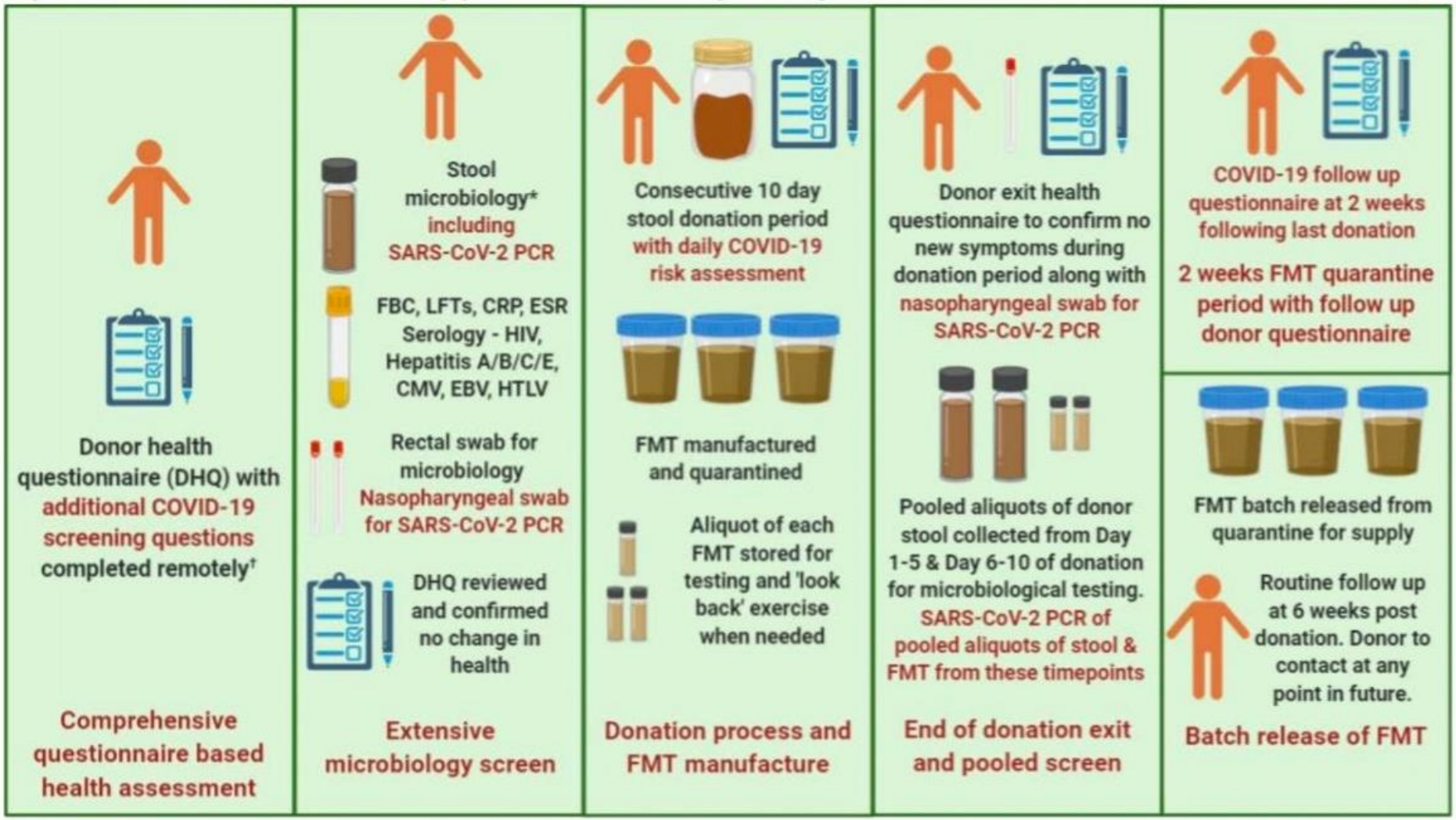
CONTACT: <INSERT LOCAL CONTACT DETAILS>

ADDRESS: <INSERT LOCAL CONTACT DETAILS>

TELEPHONE: <INSERT LOCAL CONTACT DETAILS>

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Reference: Quraishi MN, Shabir S, Manzoor SE, et al. The journey towards safely restarting faecal microbiota transplantation services in the UK during the COVID-19 era. Lancet Microbe 2021; published online Feb 19. https://doi.org/10.1016/S2666-5247(21)00036-7.

UNIVERSITY OF BIRMINGHAM | MICROBIOME TREATMENT CENTRE

FMT Donor Health Questionnaire

Please complete this form and answer all the questions. If you are unsure of the answer, please discuss this with the doctor when you hand in the questionnaire. Not all medication or medical conditions will stop you from making the donation, so please mention every medical condition or medicine.

Donor Information

Donor First name			
Donor Surname			
Telephone number			
Donor date of birth			
Occupation			
Date			
Weight (kg)		BMI*	
Height (m)		WC† (cm)	

*Body mass index

You can calculate your BMI using the NHS website:

https://www.nhs.uk/live-well/healthy-weight/bmi-calculator/

†Waist circumference

Please answer the following questions by marking an X in the appropriate box.

Gastrointestinal conditions	YES	NO
Do you have an early morning regular bowel habit?	☐	☐
Do you have normal bowel habits? E.g. Passing ≥1 and no more than 2 formed stools daily	☐	☐
Do you have a history of chronic diarrhoea or per rectal bleeding?	☐	☐
Do you have a history of inflammatory bowel disease?	☐	☐
Do you have a history of irritable bowel syndrome, idiopathic chronic constipation or chronic diarrhoea?	☐	☐
Do you have a history of gastrointestinal malignancy or known polyposis?	☐	☐
Do you have a history of celiac disease?	☐	☐
Do you have a history of congenital or chronic liver disease?	☐	☐
Do you have a history of major gastrointestinal surgery (e.g. gastric bypass)?	☐	☐

Autoimmune conditions	YES	NO
Do you have a history of connective tissue disease?	☐	☐
Do you have a history of thyroid disease?	☐	☐
Do you have a history of inflammatory arthritis?	☐	☐
Do you have a history of psoriasis?	☐	☐
Do you have a history of alopecia?	☐	☐

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UNIVERSITY OF BIRMINGHAM | MICROBIOME TREATMENT CENTRE

FMT Donor Health Questionnaire

Atopic conditions	YES	NO
Do you have a history of asthma?	☐	☐
Do you suffer from eczema?	☐	☐
Do you have a history of eosinophilic disorders of the gastrointestinal tract?	☐	☐

Chronic Pain	YES	NO
Do you have a history of chronic fatigue syndrome?	☐	☐
Do you have a history of fibromyalgia?	☐	☐

Cardiovascular / Metabolic conditions	YES	NO
Do you have a history of diabetes (Type 1 or Type 2)?	☐	☐
Do you have a history of high blood pressure?	☐	☐
Do you have a history of high cholesterol?	☐	☐
Do you have a history of high fasting glucose?	☐	☐
Do you have a history of heart disease (e.g. atherosclerosis, myocardial infarction, congestive heart failure)?	☐	☐

Neurological conditions	YES	NO
Do you have a history of multiple sclerosis?	☐	☐
Do you have a history of Parkinson's disease?	☐	☐
Do you have a history of Alzheimer's disease or dementia disorders?	☐	☐

Immunosuppression	YES	NO
Do you take calcineurin inhibitors (tacrolimus or cyclosporine)?	☐	☐
Do you take glucocorticoids (steroids)?	☐	☐
Do you take any biological agents?	☐	☐
Do you take any anti-TNF drugs?	☐	☐
Have you ever received chemotherapy?	☐	☐
Have you ever had any form of transplantation (e.g. solid organ, bone marrow, cornea etc)	☐	☐
Do you think you are immunosuppressed?	☐	☐
Have you received blood/blood products in the past 4 months?	☐	☐

Mental health and well being	YES	NO
Have you ever been diagnosed by a clinician with any of the following?		
Anxiety	☐	☐
Depression	☐	☐

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Bipolar disorder	☐	☐
Schizophrenia or delusional disorder	☐	☐
Eating disorder (e.g. anorexia and or bulimia)	☐	☐

Infectious diseases	**YES**	**NO**
Have you had a known infection in the last 2 weeks? E.g. cold	☐	☐
Have you had a needle stick injury within the last 4 months?	☐	☐
Are you known to have HIV, hepatitis B or hepatitis C?	☐	☐
Have you been exposed to HIV, hepatitis B or hepatitis C in the last 12 months?	☐	☐
Have you ever been treated for Tuberculosis (TB)?	☐	☐
Have you ever been treated for Lymes disease?	☐	☐
Have you ever been treated for Brucellosis?	☐	☐
Have you ever been treated for infective endocarditis?	☐	☐
Have you ever been treated for a liver abscess?	☐	☐
Have you been treated for a sexually transmitted infection (STI) in the last 3 months?	☐	☐
Have you ever been notified that you are at increased risk of Creutzfeldt-Jakob disease (CJD) for public health purposes?	☐	☐
Do you originate from, or share sexual partners or have a parent who originates from, areas with high-incidence of Human T cell Lymphotropic Virus? E.g. Caribbean, Japan, South America, and Africa.	☐	☐
Have you had any known exposure yourself or to anyone confirmed or suspected to be infected with the monkeypox virus in the last 21 days?	☐	☐
Do you currently have any cold sores?	☐	☐
Do you currently have any anal ulcers or suffer from persistent anal itching?	☐	☐
Have you been treated for a pinworm infection in the last 3 months?	☐	☐

Social	**YES**	**NO**
Have you had sexual contact with an individual known or suspected of having HIV, AIDS or hepatitis?	☐	☐
Have you had sex with a new partner or multiple partners in the last three months?	☐	☐
Have you had sex for drugs or money (both receiving and/or paying)?	☐	☐
Do you use illicit drugs including IV, oral, or inhaled?	☐	☐
Have you had a tattoo or body piercing in the last 6 months?	☐	☐
Have you received acupuncture outside of a licensed/ UK approved facility in the last 4 months?	☐	☐
In your work or volunteering activities do you come into contact with animal or human tissues?	☐	☐
Do you drink alcohol?	☐	☐

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UNIVERSITY OF BIRMINGHAM | MICROBIOME TREATMENT CENTRE

FMT Donor Health Questionnaire

- Number of units consumed on average per week: _____

Do you currently smoke (cigarettes, e-cigarettes, cigars, shisha)?	☐	☐
• If No, have you ever smoked?	☐	☐

- If you have been a previous smoker, how long since you quit? _____

Medications and vaccinations	YES	NO
Do you take proton pump inhibitors?	☐	☐
Have you taken antibiotics in the last 3 months?	☐	☐
Have you ever received growth hormone, insulin from cows, or clotting factor concentrates?	☐	☐
Have you ever taken an experimental medicine or experimental vaccine?	☐	☐
Have you received a vaccination in the last one month?	☐	☐

Dietary and travel	YES	NO
Do you follow a strict vegan diet?	☐	☐
Have you travelled outside Europe, North America or Australasia in the last 3 months?	☐	☐
Have you suffered from a febrile illness while abroad in any country in the last 3 months?	☐	☐
Have you been hospitalised overnight abroad in the last year?	☐	☐

Other medical and family history	YES	NO
Do you have any history of cancer?	☐	☐
Have any of your first degree relatives been diagnosed with colon cancer under the age of 55?	☐	☐
Have any of your first degree relatives been diagnosed with a hereditary cancer?	☐	☐
Do any of your first degree relatives have inflammatory bowel disease?	☐	☐
Do you take any medications?	☐	☐
Do you have any other medical conditions not listed above?	☐	☐

COVID-19 specific questions	YES	NO
Have you been vaccinated against COVID-19?	☐	☐
If Yes, have you received your: 1st dose ☐ 2nd dose ☐ Booster ☐		
Have you tested positive for COVID in the last 3 months:	☐	☐

- If Yes, when did you test positive (DD/MMM/YYYY) _____

Type of test: LFT ☐ PCR ☐ Blood antigen (finger-prick) ☐ Blood antibody ☐

- If No, when was your last negative COVID-19 screen?: (DD/MMM/YYYY)_____

Type of test: LFT ☐ PCR ☐ Blood antigen (finger-prick) ☐ Blood antibody ☐

For peer review only

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UNIVERSITY OF BIRMINGHAM | MICROBIOME TREATMENT CENTRE

FMT Donor Health Questionnaire

Have you experienced any of the following new unexplained symptoms in the past 30 days:

• Fever	☐	☐
• Shortness of breath	☐	☐
• Sore throat	☐	☐
• Chills	☐	☐
• Muscle aches/pain	☐	☐
• Loss of smell	☐	☐
• Loss of taste	☐	☐
• New and persistent cough	☐	☐

If you answered yes to any question(s) **throughout the questionnaire** please give details in the space provided below:

……
……
……
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……

If the UoBMTC clinicians decide that you are eligible to be included/continue as a FMT donor, you will be contacted around 2 weeks before the donation period and asked to attend a Donor Screening Review, where you will be asked to provide your written consent to becoming a UoBMTC stool donor. You will also be asked to provide various screening samples (stool, rectal & nasopharyngeal swabs, blood).These screening samples will be screened for various infections and microorganisms.

The infections and microorganisms which will be tested for include:

Human Immunodeficiency Virus	Hepatitis A Virus	Hepatitis B Virus
Hepatitis B Virus	Hepatitis C Virus	Hepatitis E Virus
EBV (EBNA)	Syphilis	CMV
Norovirus	Rotavirus	SARS-CoV-2
C.difficile	*Strongyloides*	*Helicobacter pylori*
Shigella	*Salmonella*	*Campylobacter*
Escherichia coli O157	*Cryptosporidium*	*Giardia*
ESBL	VRE	CPE
MRSA	Microsporidia	*Entamoeba coli*
HTLV 1-2 (if indicated)	*Entamoeba hystolytica*	Ova, cysts and parasites

If you have any questions about these tests done, please discuss these with the UoBMTC clinician prior to having your samples taken. All blood, stool and swab samples taken for microbiology testing will be made anonymous using a confidential donor code. A UoBMTC clinician will review your microbiology testing results and you will be informed of your suitability to commence as a donor thereafter.

Signature of Donor:……Date:……..

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FMT Donor Health Questionnaire

Internal Use Only:

To be completed on initial review of the DHQ:

Name	Signature	Date reviewed	Proceed to next stage?
1.			
2.			

Clinician/Others Comment:.....
.....
.....
.....
.....
.....
.....

New Donor: Y ☐ N ☐ **Assigned Donor ID: FMTDON_____**

Date of DHQ Review consent (DD/MMM/YYYY) .....

Please tick the appropriate statement below:

I confirm there has been **no changes** to my health since completing this questionnaire. ☐

Since completing this questionnaire, there **has been changes** to my health as discussed. ☐

	Name	Signature
Donor		
Clinician		

Clinician/Others Comment:
.....
.....
.....
.....
.....
.....
.....

Does the donor require any additional microbiology screening?

	Y	N	Status: (if previously tested & date of screen)
HTLV 1-2	☐	☐	
Strongyloides	☐	☐	
Microsporidia	☐	☐	
CMV	☐	☐	
EBV (EBNA)	☐	☐	

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