Full Participant Information Sheet

We invite you to take part in a research study called:

The MOTION Study
Microbiome of the ageing gut and its effect on human gut health and cognition.

Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. We appreciate there is a lot of information here, so please take your time to read it carefully and discuss it with relatives and friends if you wish. You are free to decide whether to take part in this study. If you choose not to take part, this will not affect the care you receive from your own doctors.

Why are we doing this study?

The mission of the Quadram Institute Bioscience (QIB) is to understand how food and the gut microbiota (the microbes that live in our intestine) are linked to the promotion of health and the prevention of disease, with an emphasis on diet- and age-associated diseases. We will use this knowledge to develop evidence-based strategies to maximise positive impacts of food on health, from early life to the extension of a healthy lifespan in old age and reduce the economic and societal costs of chronic diseases. The photograph above is the new purpose-built QIB which is located on the Norwich Research Park and can be seen from the Norfolk & Norwich University Hospital (NNUH). The study visits over 4 years will be every 6 months and take place here in the Quadram Institute Clinical Research Facility (QI CRF). We would like to recruit 360 participants to help us better understand how the microbes that live in our intestine change as we age. We all carry millions of

Norfolk and Norwich University Hospitals NHS Foundation Trust, James Paget University Hospitals NHS Foundation Trust and Norfolk and Suffolk NHS Foundation Trust – working in partnership.
beneficial microbes in our gut and they do not usually cause us harm. In fact, many bacteria do many helpful things for us such as aiding digestion of the food we eat and protecting us against infections. New strategies are required to address an increasingly ageing UK population by preventing or delaying age-related diseases and maintaining good health for as long as possible. We will also explore whether gut microbes contribute to age-related conditions in our brain which might cause us to develop problems with memory, reasoning or thinking. We call this mild cognitive impairment or MCI.

In order to answer our research questions, we would like to collect some data and samples from you over a period of just over 4 years (49 months).

**Why am I being asked to take part in this study?**

Your participation will help us to understand in more detail about this link between our gut and our health including cognition.

There are one of 4 ways you will have received this invitation to take part in our study.

1. Your GP has sent you this information by post and feels that you may be interested to find out more.
2. You have already taken part in the NHS Bowel Cancer Screening Programme (BCSP) and you have already undergone a colonoscopy either one year or three years ago and you are due for another colonoscopy soon as part of the routine screening programme. A member of the BCSP team will have contacted you about your planned colonoscopy and sent you a routine Pre-colonoscopy Health Questionnaire to complete. With this Questionnaire, you will have received a study Introduction Letter informing you that the letter of invitation to take part in the study and full study information would be sent to you a few days later separately.
3. You have previously developed some mild memory problems and the Clinical Team who performed a memory assessment feel that you may fit the criteria to take part in our study.
4. You have voluntarily registered to be on the QIB participant database to receive study information that may be of interest to you.

Though every effort will be made to try and avoid it, there may be an occasion when you might receive the invitation twice to take part, for example through 1 and 2 above. We apologise in advance if this does happen.
This Information Sheet will explain in detail what would be required if you agreed to take part, but we would need to check that you are eligible first by meeting both the Inclusion and Exclusion Criteria.

**Inclusion Criteria:**

You **must** be able to say yes to all of the following:-

- Male or female aged at least 60 years.
- Must be able to understand the study and provide signed and dated informed consent.
- Must be able to provide a stool (poo) sample within 24 hours of study visits (or within 24 hours afterwards).
- Must be willing to undergo blood tests at each visit.
- Must be able to complete the cognitive tests/associated questionnaires, Health Questionnaires and be familiar with using an ipad/tablet. The Study Researcher will provide support with using the ipad/tablet and assist you as necessary during each study visit.
- If you have MCI, you will be eligible to participate providing you satisfy all other criteria.

**Exclusion criteria:**

You will not be able to enter the study if **ANY** of the following apply prior to consenting to take part in the study:

- Currently taking part in an interventional study.
- Living with or related to any member of the research team.
- Have a diagnosis of Dementia, Parkinson’s Disease, Alzheimer’s Disease, Creutzfeldt-Jakob Disease (CJD) or Picks Disease.
- Schizophrenia.
- Bipolar disorder.
- Obsessive Compulsive Disorder.
- Untreated current clinical depression.
- Have irreversible brain injury.
- Have had a stroke.
- Have epilepsy.

If, during the course of the study, you meet any of the **above** exclusion criteria, unfortunately we will need to withdraw you from the study.

If, during the course of the study, you develop any of the conditions listed **below**, you may need to be withdrawn from the study.

- Take more than a daily dose of probiotics.
Current or history of cancer in the last 5 years, except for squamous or basal cell carcinomas of the skin that have been medically managed by local excision.

Have a long-standing gastrointestinal or liver function abnormality requiring ongoing medical management or medication.

If you have made any major changes to your diet in the last month (for example changed to vegan, vegetarian or stopped eating red meat).

If you have a history of any liver problems, for example Hepatitis B or Hepatitis C.

History of alcohol, drug or substance abuse.

Major surgery of the gastrointestinal tract, apart from gall bladder or appendix removal in the past five years.

Any major bowel surgery at any time.

History of an inflamed bowel, for example Ulcerative Colitis, Crohn's disease or Diverticulitis.

Persistent, infectious gastroenteritis, colitis or gastritis, persistent or long-term diarrhoea of unknown cause, Clostridium difficile infection (recurrent) or Helicobacter pylori infection (untreated).

Constipation.

Regular use of laxatives.

If you develop any of the conditions listed in the above exclusion criteria or your general health changes during the course of the study, please inform the Study Researcher as soon as possible.

What will happen to me if I decide to take part and where will I need to go?

Your involvement in the study will be approximately 49 months so just over 4 years in total.

To help us understand how gut microbes affects our body and brain as we age, we need to collect certain data and samples from you at approximately 6-monthly time points over 4 years. We will need to collect stool and blood samples, data from health & lifestyle questionnaires and perform different types of cognitive tests and associated questionnaires at different time points during the study. Cognitive tests are used to look at your memory, reasoning and thinking over time. Most of the cognitive tests we are asking you to do as part of this research study are also used in hospital setting which help doctors diagnose various levels of cognitive function. Any results from you will not be indicative of any clinical diagnosis and will be used only for the purposes of this research study. Copies of your cognitive tests and all other tests will be sent to
your GP routinely as part of the study. If you are concerned about anything, you will be able to follow this up with your GP. If you feel upset while you are doing any of these tests, we will stop straight away.

We will also need to collect some measurements of your height and body composition. For this we will ask you to stand on a special set of scales with your shoes and socks off. These scales will also tell us what your weight and Body Mass Index (BMI) is. Afterwards, once you are sitting down, we will also record your blood pressure (BP) and your hand grip strength using a special instrument that you hold in your hand and squeeze. Taking these measurements should not cause you any discomfort, but sometimes the BP cuff can become a little tight for a few moments.

Over a period of 4 years, we ask that you will be willing and able to do the following once you have been enrolled in to the study: -

1. Attend the QI CRF every 6 months for a combination of the following:
   - Drop off stool samples.
   - Provide blood samples – 255 mls in total. This is the same as 51 teaspoons in total over 4 years.
   - Complete health and lifestyle questionnaires at time points.
   - Measure your height, Tanita scales measurements (body composition), BP and hand grip strength measurements.
   - Undergo cognitive tests and associated questionnaires.
   - Take home your stool collection pack ahead of your next visit.

2. We would also like to collect some data and photographs of your retina which is at the back of your eye. The retina is one of the parts of our body that shows early signs of ageing and is very easily seen by an Ophthalmologist (eye specialist). For this, you would need to attend Beccles Hospital (pictured right) for an OCT (Optical Coherence Tomography) scan and **bring any glasses that you wear with you and a list of your current prescribed medication.** This will be around your Baseline visit, and around Study Visits 4 & 8 (usually a Wednesday). This is a non-invasive and painless procedure which is very similar to when you have your eyes tested routinely.

   This more sophisticated machine takes pictures and measurements of the thickness of your retina and its blood supply. For this, you will be given eye drops which help relax the eye muscles and dilate your pupil. You will only receive the eye drops in your right eye, but both of your eyes will be looked at. If you cannot have the drops in your right eye, then the left eye will be used for
the drops. The reason for this is to help the Ophthalmologists decide if the eye drops are necessary.

If there is a reason you cannot have drops in either eye, the Ophthalmologist will just make a note of this and continue. You will need to allow about 2-3 hours for this appointment in total, but it takes about 3 hours for the effects of blurred vision to wear off so someone will need to accompany you to take you home. If it is a sunny or bright day, you are advised to wear sunglasses afterwards. If you experience prolonged symptoms of dry mouth, blurred vision, stinging eyes or sensitivity to light, you should consult a doctor promptly. Appointments will be made in advance and you will be notified of the date on your personalised visit schedule. This will be given to you at your Baseline Visit. Free car parking is available and travel expenses will be reimbursed. If you are recruited on to the study and you are waiting to have a colonoscopy as part of the NHS Bowel Cancer Screening Programme, when you come to have your OCT scan at around the Baseline Visit and Study Visit 8, the researchers would like to do some extra measurements to do with the blood supply of your retina. This is called an OCT (A) scan - Optical Coherence Tomography (Angiography) scan. Again, this is painless and will not take any additional time and you will still have the eye drops as explained above.

**There are 2 subgroups in this study.**

Not everyone will be involved in these groups. You may be involved in one subgroup, both or neither. The Study Researcher will explain this when you attend for your Pre-Study Visit.

**Subgroup 1 – colon biopsies (optional).**

If you participate in this study and you are on the BCSP waiting to undergo a colonoscopy as part of routine clinical care, your doctor performing this procedure may decide to take some biopsies as part of this routine care. This will be discussed with you by your doctor or specialist nurse as part of preparing you before the procedure.

As part of this research study, we would like to collect additional research tissue biopsies of your colon so that we can look at the types of cells that attach themselves to the lining of your bowel. We would like to ask your
permission with your written consent to request 6-8 very small research tissue biopsies in total, each measuring 3mm by 3mm by 3mm from your large bowel for research purposes. If you would like to take part in the study, but not be in the tissue biopsy subgroup (subgroup 1), it will not affect your participation in the study or any clinical care you receive. You would still have your colonoscopy as part of routine clinical care and continue with the study as usual.

If you decide to be part of subgroup 1 and need to undergo a further routine care colonoscopy after 1 or 3 years (providing you are still on this study), we would like to again ask your permission to collect the same number of samples at a later date.

You may not be on the BCSP when you receive this Information Sheet, but if you decide to take part in this study and need to undergo a colonoscopy as part of the BCSP routine care within the next 4 years, we would ask for you to inform us.

Following the colonoscopy, the researcher will contact you to arrange your next scheduled appointment if one has not already been arranged.

**Subgroup 2 – brain MRI scans (optional).**

For the second subgroup, 30 participants will be offered a brain MRI scan at around the Baseline Visit and around Study Visit 8. We would like to reassure you that the result of your Pre-Study Visit tests (see page 9) and a combination of being offered the brain MRI scan is not indicative of any diagnosis and is purely for the purposes of this research study. *This scan is optional, and the researcher will discuss this with you*. If you would like to take part in the study, but not be in the brain MRI subgroup, it will not affect your participation in the study or any clinical care you receive.

**Brain Magnetic Resonance Imaging (MRI)** – The scanning procedure will involve you having your head scanned within the MRI machine. You will be provided with earplugs and additional ear protection from the noise of the scanner, as well as pillows, foam padding, and blankets to ensure comfort during the scan. You will be provided with a button to alert MRI staff of any complications or discomfort during the scan, and the scan will be stopped immediately at any time if you wish. The scan will last
approximately 1 hour and you will need to keep your head very still until you are told it is ok to move. There are no known adverse side effects with having a single or multiple MRI scans of any length, even repeated scans after short intervals provided that you do not have any metal within or on the body. The MRI scans do not involve injection of radioactive compounds or exposure to potentially harmful radiation.

If you would prefer not to have an MRI, this is fine. Some participants cannot have MRIs because they have an implanted medical device such as artificial joints, stents, ear implants, a pacemaker or any other internal object that is metal or electrical. Some participants find the scanner is too confining for them. The Study Researcher will go through a checklist with you and make sure you are happy with everything. MRI staff will ask a set of safety questions on the day of your scan to make sure that you don’t have anything in your body that might be affected by the scans.

Appointments will be made in advance and you will be notified of the date on your personalised Study Appointment Schedule. This will be given to you at the Baseline Visit.

We have split the 49 months in to two phases – Phase 1 and Phase 2 which are described below. The Phases explain what we will be asking you to do and when.

**Phase 1- Screening and Recruitment Phase**

- **Telephone Contact** – approximately 20 minutes.

Once the Study Researcher receives your completed reply sheet or online expression of interest (www.quadram.ac.uk/motionstudy), you will be contacted via your preferred method to arrange a telephone call. This will take about 20 minutes and the researcher will go through the Information Sheet and take time to go through the Inclusion and Exclusion Criteria with you. You will also have the opportunity to ask any questions.

If you are unsure about your medical history, we would ask you to check this with your GP and get back to us as we want to make sure you are eligible to take part.
The Study Researcher will then explain what will happen at the Pre-Study Visit and how long it will take. The study researcher will also explain to you the process of consenting to take part in the study.

**Pre-Study Visit – approximately 2.5 hours.**

If you have had some mild memory problems in the past and were seen by a Specialist Clinical Team from the Norfolk & Suffolk Foundation Trust (NSFT), you will be seen for your Pre-Study Visit by the NSFT Research team. All other recruiting streams will be seen by the study research team. The exact same process will be followed by both streams.

The study visit will last for about 2.5 hours. We appreciate that this is quite a long time for this visit, but you will be offered comfort breaks with refreshment as you need them. The researcher will go through the whole study in detail and then using a checklist, will make sure that all the following study information has been provided:

- You will be shown the stool collection device and cool box along with instructions for use.
- We will discuss the options of when to bring your stool sample to the QI CRF.
- You will be shown a copy of the Health Questionnaires and the cognitive tests etc.
- We will then go through the Informed Consent Form. The Study Researcher will go through each point and ensure you are happy and understand everything. By signing this form, you are not obliged to take part and can withdraw from the study at any time.
- You will be given a copy of your consent form to keep. A copy will also be sent to your GP and another copy will be inserted in to your NNUH hospital records.
- The Study Researcher will also ask you to read the Biorepository (tissue bank) Information Sheet and consent form. Consent to this allows us to store your samples in the Norwich Biorepository Bank during and at the end of the study. This will enable other researchers to access your samples for their ethically approved research. We will not need to take any additional samples or biopsies for this and your samples will remain anonymised at all times. If you would prefer to have more time to consider the Biorepository Information Sheet, this is fine. If you are happy to consent at the Pre-Study Visit, you will be given a copy for your records.
- If you are still happy to proceed, we will perform a cognitive test and a questionnaire (see Cognitive Tests on page 15). This will form the final...
eligibility check and in order for you to be included in to the study, your score will need to be within a certain range. Both will take about 5 minutes each to complete. It is anticipated that the results of the cognitive tests will take up to 5-10 working days and the Study Researcher will contact you by your preferred method as soon as they are available.

- On the same day as your Pre-Study Visit, you will be provided with your Baseline Visit stool collection pack before you leave and reimbursed for any travel and car parking expenses. You will also be given a freepost Study Withdrawal Postcard for you to complete if you wish to withdraw at any point during the study.

If you are found to be eligible to continue in the study, the Study Researcher will contact you and arrange your Baseline Study Visit. If, unfortunately, you do not meet the final eligibility check, you will be thanked for your time and interest in the study. The Study Researcher will inform you that you need to be withdrawn from the study. Please be reassured that the result is not indicative of any clinical diagnosis and is purely for the purposes of this research study. We will send your GP copies of all the tests we do as part of this study. You can discuss your results with your GP if you have any concerns. If you are withdrawn from the study, we will make arrangements to collect your stool collection pack from you.
A summary of Phase 1 is provided below.

**PHASE 2 - SAMPLE AND DATA COLLECTION PHASE. BASELINE VISIT TO STUDY VISIT 8.**

You will receive a reminder telephone call or text in advance of all appointments. You will also be reminded to let the Study Researcher know if you have taken or are taking antibiotics within two weeks of your scheduled appointment as this will need to be rescheduled. This is because a two-week washout is required from when you took your last dose. Please also let us know if you have any travel or flu vaccinations within 28 days of your scheduled appointment. We would like you to make a note of any antibiotics or vaccines on your Study Appointment Schedule that we will give you.

Travel and parking costs will be reimbursed at the end of each visit and you will be offered light refreshments and comfort breaks. Study visits will take place at QI CRF. To allow for any holidays or work shift patterns, you can be seen for your study visit up to one month before or one month after your scheduled appointment at QI CRF.

**Baseline Visit – approximately 2 hours.**

- **Blood sample** – 40 mls (8 teaspoons).
- **Complete the Full Health Questionnaire.**
Physical measurement collection (height, Tanita scales measurement, BP and hand grip strength measurements).

Complete a series of 9 cognitive tests and associated questionnaires.

You will be provided with your Study Appointment Schedule and your Study Identification carry card (the Study Researcher will go through these with you). You will also receive a freezer magnet with the study logo which will help remind you to freeze your ice-packs ahead of your stool sample collection.

We will arrange your OCT/OCT (A) scan appointment within one month after your Baseline Visit appointment. If you are in the sub-group for a brain MRI, we will arrange this within 6 weeks after your Baseline visit. You will receive appointment letters for both scans.

**Study Visits 1, 3, 5 & 7 – each visit will take approximately 2 hours.**

Study Visit 1 will be 6 months from the Baseline Visit.
Study Visit 3 will be 18 months from the Baseline Visit.
Study Visit 5 will be 30 months from the Baseline Visit.
Study Visit 7 will be 42 months from the Baseline Visit.

The following will happen at each visit:-

- Drop off the cool box containing your stool sample.
- Pick up any replacement stool collection items ahead of next study visit.
- Blood sample – 15 ml (3 teaspoons).
- Complete the Partial Health Questionnaire.
- Complete a series of 9 cognitive tests and associated questionnaires.

The Study Researcher will explain the following to you at the end of each of the following study visits:-

- **Study Visit 3** - remind you that you will receive an appointment letter from Beccles Hospital for your OCT scan, which will be scheduled to take place within one month before or one month after Study Visit 4.
- **Study Visit 7** - remind you that you will receive an appointment letter from Beccles Hospital for your OCT (A) scan. This appointment will be scheduled for around 4 weeks before Study visit 8 and will take place at Beccles Hospital. If applicable, the Study Researcher will go through the MRI checklist and remind you that you will receive an appointment letter for a brain MRI scan at NNUH around 6 weeks before Study Visit 8. Both scans will be scheduled prior to Study Visit 8 where possible so that you can be reimbursed for any travel and parking costs at Study Visit 8 (final visit).
Study Visits 2, 4, 6 & 8 – each visit will take approximately 45 mins.
Study Visit 2 will be 12 months from the Baseline Visit.
Study Visit 4 will be 24 months from the Baseline Visit.
Study Visit 6 will be 36 months from the Baseline Visit.
Study Visit 8 will be 48 months from the Baseline Visit.

The following will happen at each visit: -

- Drop off the cool box containing your stool sample.
- Pick up any replacement stool collection items ahead of your next study visit (apart from Study Visit 8).
- Blood sample – 40 ml (8 teaspoons).
- Physical measurement collection (height, Tanita Scales Measurement, BP and hand grip strength measurements).
- Complete the Partial Health Questionnaire.

The Study Researcher will provide the following to you at the end of each of the following study visits:

- Study Visit 4 - as a thank you for your participation so far and for any inconvenience, you will receive a Love2shop voucher to the value of £10.
- Study Visit 8 – you will receive a further Love2shop voucher to the value of £15. We will collect your cool box and any other remaining items from the stool collection pack. We will also write to your GP at the end of the study to request some routine data your GP will have collected from you over time. This is called the eFI (electronic Frailty Index) and we would like to use this data (which will be anonymised) to see if there are any links between these scores and the samples and data we have collected from you over the course of the study.

We would like to send you a one-page newsletter either via an online link or provided as a hard copy at the appropriate study visit to provide recruitment updates, study reminders and sign post you to study related information of interest.
A summary of phase 2 is provided in the table below.

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<tr>
<th>Participation</th>
<th>PHASE 2</th>
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<td>Pick up stool collection pack for next visit</td>
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<td>Colonoscopy Tissue Biopsy</td>
<td>IF INVITED FOR A COLONOSCOPY AS PART OF THE NHS BOWEL CANCER SCREENING PROGRAMME</td>
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Summary of Phase 2
Set out below is an explanation of each test/sample/procedure and why we are asking for it.

**Stool sample collection** - This is done to compare the numbers and types of microbes over time. You will be provided with a stool collection device, cool box, 3 ice-packs and instructions on how to collect and store your sample. Samples will be collected at home and need to be stored as cool as possible within the cool box. The sample will need to be delivered to the QIB within 24 hours of producing the sample and will coincide with a scheduled Study Visit. If it is not possible to produce your sample before your scheduled appointment, please still attend for your study visit as you will have up to 24 hours after your appointment to produce a sample. This can be brought in by yourself (mileage will be reimbursed), or the study researcher can come and collect your sample from your home (providing someone can be available to hand over the specimen). If this is the case, we will make arrangements with you when you attend for your study visit.

**Cognitive Assessment Tests** – These are designed to capture memory, reasoning and thinking. There is a combination of 9 tests/questionnaires in total that will be used in this study. One of these cognitive assessments is used by doctors as part of a diagnosis for dementia. However, the cognitive assessments that you complete as a part of this study will not be used for this purpose, but to record the levels of cognition over time for research purposes only. Two will be used at the Pre-study Visit and will take about 5 minutes each to complete. We will ask you to complete the remaining 7 at the Baseline Visit and Study Visits 1, 3, 5 & 7. Each test lasts from between 5 to about 15 minutes and are a combination of either completing the test/questionnaire yourself on paper or using an ipad/tablet device (we will supply this), or the Study Researcher will ask you questions and write your answers down. These will take place at the QI CRF as part of your visits and be done by a trained member of the research team who will guide you through each test/questionnaire and provide any support you need.

**Brain Magnetic Resonance Imaging (MRI) Scans (Optional)** – We will look at all the data and samples we collect from you and see if they are related to any changes in the structure and organisation of the brain over time.

**Colonoscopy Biopsies** – Not everyone on the study will have a routine care colonoscopy, but if you do as part of the NHS Bowel Cancer Screening Programme and are happy to provide research biopsies, we would like to use your tissue biopsies to find more information on the interaction between microbes and intestinal cells. Your biopsies will be stored in our laboratory.
facilities of QIB and at the Norwich Biorepository (see separate Information Sheet for more details) where it will be available for other doctors or researchers. You can find more information about the storage of the samples at the Norwich Biorepository in a specific Information sheet that will be provided you with a consent form. We will also work with fresh biopsies that will be processed and used immediately after collection. Some of the donated samples will be used to better understand how your genes influence the numbers and different types of bacteria that you have in your gut. Previous studies have identified a variety of genes that may influence what types of microbes are found in the gut. It is important to stress that all types of analyses done using the donated samples, including genetic analyses, have no clinical relevance to you, your relatives or the treatment you receive. Please be aware that you can change your mind at any time and decide not to give a sample. Giving consent does not oblige you to give a sample. If you do not want to donate the biopsies we will respect your decision, and this will not in any way affect the treatment that you will receive or your usual care at the NNUH.

Baseline (Full) Health Questionnaire – This will tell us which groups of foods you tend to eat and how much and often (diet), also, whether you smoke or drink alcohol (lifestyle). We would also like to know of any medications you take that are either prescribed by a doctor or a Nurse Practitioner, or any medications/supplements you purchase over the counter. We are also very interested if you are prescribed a course of antibiotics if you develop an infection. This is done to compare any changes in microbe populations over time.

Follow-up (Partial) Health Questionnaire – This is a shortened version of the Baseline Health Questionnaire. For each visit, as above, we would like you to bring in a list of all your current medication that is either prescribed or anything that you have bought over the counter. We are also very interested in any antibiotics you have taken, or vaccinations received over the whole period of the study.

Blood samples – This will be done at the QI CRF by a trained member of the research team. 40mls which is the same as 8 teaspoons will be taken from a vein in your forearm at the Baseline Visit and Study Visits 2, 4, 6 & 8. The samples we are taking at these time points are to see if there are any links between the microbes in your gut and how these can affect for example
proteins involved in the immune system and signalling pathways for healthy organ function.

At Study Visits 1, 3, 5 & 7, we will take 15mls of blood which is the same as 3 teaspoons. One sample will be used to tell us about the health of several key organs such as the heart, bones, liver and kidneys. Each of these organs secrete different factors (proteins) into the bloodstream. These levels of proteins go up and down according to our age and health status. Therefore, by measuring the levels of these proteins at these time points, we can obtain an indication of the health status of the different organs over time.

You will not directly receive any results from these research tests. However, the second sample we will be taking at Study Visits 1, 3, 5 & 7 is a Full Blood Count (FBC), Biochemistry and Troponin I. These are common tests to evaluate someone’s overall health as it measures lots of different types of cells, for example red cells to detect things like anaemia and white cells to detect infection. The results of these tests will be used only for the levels of different types of cells and not to diagnose any conditions. We will send copies of all blood results to your GP and you will be able to discuss these with your GP.

You will not need to fast for any blood samples and refreshments will be available.

**Are there any benefits to taking part?**

The information we obtain from this study may help in the understanding of how our gut microbiome can influence our health and cognition as we age.

**Will my GP be informed?**

Yes, it is routine practice for us to inform your GP that you are participating in a study at QIB. This is one of the things that you are agreeing to when you sign the consent form to take part in the study.

**What happens if something is found during the OCT scan, blood sample, brain MRI scan, or colonoscopy (as appropriate)?**

You may still be able to continue in the study if you wish. If it is not possible for you to continue because you need to be referred for Specialist Consultant Care, we will unfortunately need to withdraw you from the study. We will send you a withdrawal letter and a copy will be sent to your GP. We will keep any data and samples we have already collected from you.

**Are there any risks or side effects from participating in this study?**

There can be a small amount of discomfort associated with taking blood. This generally only occurs on insertion of the needle. You should not experience pain during the procedure or afterwards. You may develop a small bruise at
the site where the blood sample was taken but this will fade like any bruise. If you are taking any medication to thin your blood, please tell the person taking blood in advance. The risks associated with having a colonoscopy and any biopsies will be discussed with you by the doctor or nurse prior to consenting you for the procedure.

**Do I get paid for doing this study?**
Participating in this study is entirely voluntary. However, we do recognise that being involved in the study may cause you some inconvenience.
As a thank you for your time and participation in the study and to acknowledge any inconvenience, you will be given a Love2shop voucher to the value of £10 at the end of Study Visit 4. A further £15 voucher will be given to you at the end of the study (Study Visit 8). Mileage to QI CRF, NNUH and Beccles Hospital along with any car parking charges will be reimbursed. Taxi and bus fares will be reimbursed upon production of a valid receipt.

**PRIVACY NOTICE**

**Will my taking part in this study be kept confidential?**
QIB is the sponsor for this study based in the United Kingdom. We will be using information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. QIB will keep identifiable information about you for at least 15 years after the end of the study in a secure archive at the QIB or designated secure off-site location. Your rights to access, change or move your information are not affected, 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 study, 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. You can find out more about how we use your information by contacting Shelina Rajan at motion@quadram.ac.uk
The NNUH will use your name, NHS number and contact details to make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. All information collected about you during this study will be kept strictly confidential. We follow Ethics and Research Governance and Good Clinical Practice (GCP) requirements.
The study will comply with EU General Data Protection Regulation (GDPR) and the UK Data Protection Act 2018. The legal bases used under the regulation that we employ to process your personal information is for tasks carried out in the public interest, which this study and associated research is.
Your personal information will be stored in locked filing cabinets at the QIB. Suitable security measures and precautions are also taken for any confidential or personal data processed or stored electronically.

Once enrolled on to the study, you will be issued with a unique study identification number. These numbers will be used to protect your personal information and samples so that no one will be able to work out they are yours. These codes are also kept in a locked filing cabinet at QIB separate from your personal information.

Any communication, relating to the study, to you or from you that is sent or received on the study mobile phone will be handled in accordance with the terms set out by the QIB Data Protection Officer. Access to your personal records is restricted to the study team, study nurses, NHS medical staff and your GP. All research is subject to inspection and audit and, although your records may be accessed for this purpose, any personal information is held anonymously and remains confidential.

Please note that QIB Clinical Research Facility (CRF) has CCTV cameras in use for security purposes. Cameras on the outside cannot identify who specific individuals are who enter and leave the building. However, cameras within the public areas of the building would be able to identify individuals. This is the same security system that operates in most organisations and is designed to protect the public and staff.

To discuss any data protection policy or compliance related queries, please contact the QIB Data protection officer on dpo@nbi.ac.uk or call 01603 450067.

During participation in the study, you may receive a letter from the Study Researcher inviting you to attend the CRF to provide an audio/video recording of your experience of taking part in the study. This material will be used to promote public awareness of the study and we will always respect your rights to privacy and anonymity where expressed. We may also ask you to provide anonymised quotes for use in research reports and publications. This is completely optional and we will ask your written consent for these activities. You may decline this invitation and it will not affect your participation in the study.

What happens when the research study ends?
Findings of this study will be reported in the scientific literature. No individual’s data will be identified.

What will happen to my samples?
All data and samples will be anonymised. The people who analyse the information will not be able to identify you and will not be able to find out your
name, NHS number or contact details. Samples we collect from you will be stored securely at the QIB. If you have agreed to your samples being stored in the Norwich Biorepository, then we will also store them, anonymised, here and will be used for back-up purposes and for future ethically approved research.

What if relevant new information becomes available or changes to the study are made?
If this happens, we will tell you. If changes to the study have to be made, you may be asked to sign another consent form.

Will I be told the results of the study?
The results of the study will be published in scientific journals and presented at national and international scientific meetings. We are unable to tell you any of your individual results since it is only possible to draw conclusions from the group as a whole. At the end of the study, we will provide feedback of what we have found as a result of your help and what it may mean for future research. We will update our websites to fill you in on all the exciting research that we have performed on your precious samples.

What if there is a problem?
If you have a concern about any aspect of the study, you should ask to speak to the Clinical Studies Officer Shelina Rajan on 01603 255149 or 07876182564 who will try to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the chairperson of the Human Research Governance Committee (HRGC) at the QIB – Dr Antonietta Melchini antonietta.melchini@quadram.ac.uk

What if something happens to me while I am on the study?
If you are harmed by taking part in this research project there are no special compensation arrangements. If you are harmed due to someone’s negligence, you may have grounds for legal action, but you may have to pay for it. Regardless of this, if you wish to complain or have any concerns about the way you have been treated whilst taking part in this study at the NNUH clinics, there will be a local hospital complaints procedure that you can follow. The PALS (Patient Advice and Liaison Service) is a confidential service designed to support patients, relatives and carers. Their website is pals@nnuh.nhs.uk and the office has an answerphone which is available 24 hours a day: 01603 289036 or 01603 289045.
QIB accepts responsibility for carrying out trials and as such will give consideration to claims from participants for any harm suffered by them as a result of participating in the trial, with the exception of those claims arising out of negligence by the participant. QIB has liability insurance in respect of research work involving human participants. Please note that the Institute will not fund any legal costs arising from any action unless awarded by a court.

**Who has reviewed this study?**

To protect your safety, rights, wellbeing and dignity the study has been reviewed by the QIB Human Research Governance Committee (HRGC) and an independent group called the Research Ethics Committee (REC) which is a Committee of 15 members, a third of whom are 'lay' - their main professional interest is not in a research area, nor are they a registered healthcare professional. RECs review research proposals and give an opinion about whether the research is ethical. They also look at issues such as the participant involvement in the research. The committees are entirely independent of research sponsors (the organisations responsible for the management and conduct of the research), funders and the researchers themselves. This enables them to put participants at the centre of their review. This study has been reviewed and approved by the East Midlands – Nottingham 1 REC on 30th March, 2019.

**What should I do now?**

If you are interested in taking part in the study and would like to know more, then please complete the reply sheet attached and return it in the Freepost envelope provided. Alternatively, you can complete this form online at [www.quadram.ac.uk/motionstudy](http://www.quadram.ac.uk/motionstudy)

If you would like to speak to someone in the first instance, please contact the Clinical Studies Officer Shelina Rajan on **01603 255149** or **07876182564** or email [motion@quadram.ac.uk](mailto:motion@quadram.ac.uk)

If you are not interested in taking part in the study or you are not eligible, you do not need to do anything. No one will contact you about the study.

*Thank you for taking the time to read this information.*