

The PEARL-AGE Study

Families and their microbiomes

Participant Information Sheet for PEARL-AGE

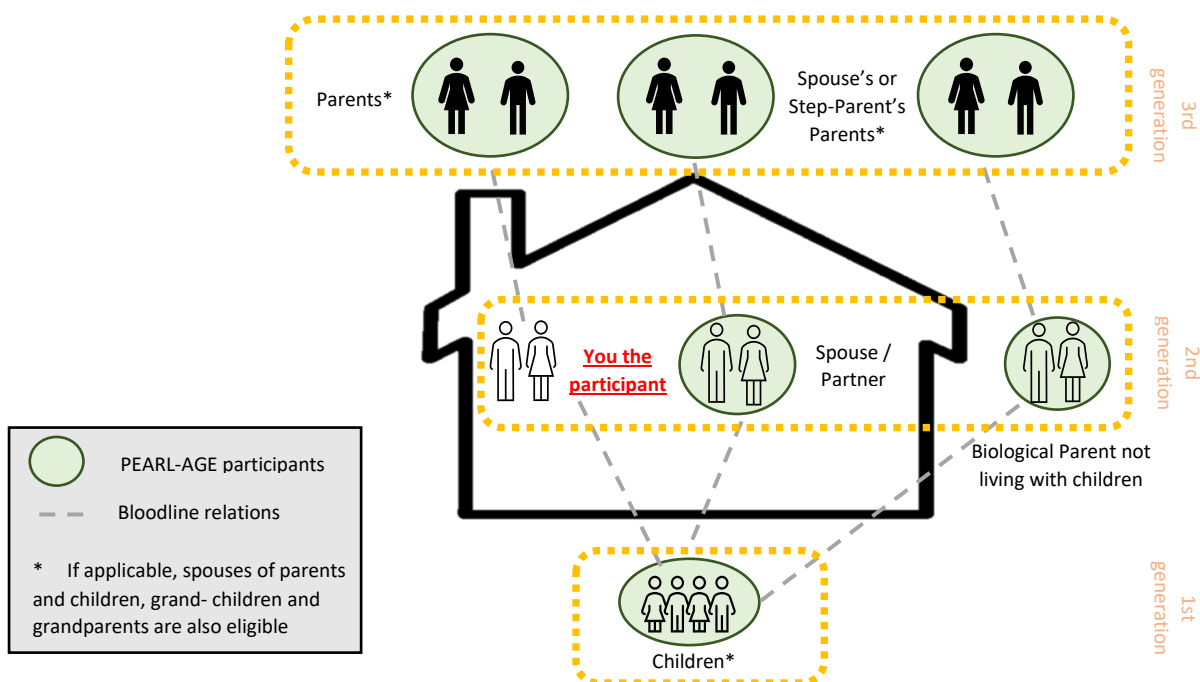
Project title:

PEARL-AGE STUDY

Invitation:

We are recruiting family members to a new study called PEARL-AGE. Below is a short summary of the new study. You decide whether or not to take part in this study.

The PEARL-AGE study will look at the transfer of microbes, such as bacteria and fungi, between family members. We are inviting you and your family. This includes husband/partner, parents of husband/partner, grandparents, grandparents of the husband/partner, children/step-children, their partners, grandchildren and great-grand-children. Please see a diagram below of all eligible family members, essentially we would like to recruit all family members of a family willing to participate:



Am I eligible?

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none">• Must have at least 3 generations of their family participate in PEARL-AGE.• Pregnant participants who wish to include their unborn child(ren) as one of the 3 generations of their family must be willing to consent on behalf of their unborn child(ren) • Adult participants must be able to consent for themselves and able to understand the questionnaire• Child participants must have a parent and/or guardian to provide assent on their behalf• Must be living in England• Must be willing to accommodate a small cool box to store and transport the biological samples until they are collected, if not having immediate access to the PEARL study freezer• Vulnerable participants such as participants with mild cognitive impairment may be included as long as they have full support from their family members.	<ul style="list-style-type: none">• Those currently in prison.• Those who are unable to provide written informed consent.• Living with or related to a member of the Research Study team.

What is the purpose of the study?

All of us have trillions of bacteria and other beneficial microbes in our guts. Collectively they are called the 'microbiome' and they play a critical role in protecting our health, right from the earliest moments of life when a baby is growing in the womb. They help us with digesting our food and even with programming our immune systems so that we can fight off infections. Anything that affects successful microbiome establishment can have knock-on effects on health in later life.

The data we collect in PEARL-AGE, will enable us to better understand how a healthy microbiome establishes in early life, and how it is maintained during ageing. For this, we want to recruit families to investigate how microbiomes differ amongst grandparents, parents/guardians, and children, including between any siblings. The results will provide the evidence needed to develop safe new strategies to enable modulation and maintenance a healthy microbiome during natural ageing. This would be a big step towards understanding how the whole family shares the best of their microbiome and what makes a healthy and happy gut.

We need your help to achieve this, and sincerely hope that you will consider taking part.

What do I have to do if I take part?

To take part in this study, we first need you to sign a consent form. You can do this by speaking to a member of the research team by video/telephone call (we are happy to use your preference of platform e.g. a call with video, without video, phone, Teams, Zoom, etc.); or we can make an appointment to meet you at the Quadram Institute Clinical Research Facility (QI CRF) at a time that is convenient to you. The QI CRF is an NHS facility of the Norfolk and Norwich University Hospital (NNUH).



Quadram Institute and Clinical Research Facility

The NNUH research nurses are part of the research team and will help during the consent appointment. The possibility to meet you face to face at the QI CRF facility will depend on local or national COVID-19 restrictions. On any of these occasions we will explain what taking part in the study entails, exactly how to collect the samples, and check you are eligible to take part; it also gives you the chance to ask any questions you might have and make an informed choice about whether to continue.

Once you are enrolled, we will ask you to collect two faecal samples 12 months apart, and one questionnaire each of the two times you collect samples. These questionnaires take approximately 20 minutes to complete and will ask about your general lifestyle, dietary preferences, and family closeness - the latter because we want to learn about microbial transfer in families. These questionnaires are completely confidential and will only be accessible to authorised researchers that are part of the study team.

Sample collection has been designed to be as easy as possible for you; there are two possible approaches:

- 1) You can collect the sample in the cool box we will provide; within 24hrs we, or a courier, will come to your home to collect the samples
- 2) If more convenient, you could bring the samples in the cool box provided to you yourself to the QIB here in Norwich within 24 hours of collecting the faecal sample.

You will be provided with a medical-grade cool box for you to transport your samples to the QIB and we would ask that this is returned to us after the sample is collected. Since we aim to collect samples from whole families, we encourage the collection of multiple samples from the same household in the same cool box, for everyone's ease and time (samples are packaged in several plastic bags, so they are cleanly separated).

CORONAVIRUS SAFETY MEASURES: While the UK government recommend social distancing measures to prevent the spread of coronavirus, we will be implementing a few changes in the way we run the study. During national or local lockdowns, we will not collect samples from participants homes until we are assured that it is safe to do so. We will send sample collection packs to

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participants in the post, and we ask that participants continue to collect their samples and freeze them with the provided ice packs until the research team are able to arrange a collection once social distancing measures are relaxed. We will continue to send reminders when your samples are due to be taken.

When collecting the samples from your home, we will maintain social distancing as per the government's guidelines. We (a member of the study research team or a courier) will knock on the door and maintain a safe distance while you place the cool box outside your door. Please then close your door and we will collect the sample and leave.

Please do not collect any samples and inform the study team if you or anyone in your household has:

- had symptoms of coronavirus (COVID-19) infection in the last 14 days (a high temperature, a new continuous cough, a loss or change to your sense of smell or taste) and are currently awaiting a test result.
- tested positive for coronavirus (COVID-19). We will arrange to collect the sample after you have received a negative test or 14 days after you no longer have any COVID-19 symptoms.
- had recent contact with someone who has coronavirus – ensuring you self-isolate if the NHS test and trace service advises you to do so.

What will happen with my sample?

When you provide a sample, they will be linked to you using a confidential unique identifier, this is called pseudonymised. Samples will be stored securely at QIB. At the end of the study, samples will be incinerated. If you give us explicit consent, they will be stored in the NRP Biorepository, a facility licensed by the Human Tissue Authority, in line with UK law. Here, your samples may be used for future ethically approved research, even after the PEAL-AGE study has finished. Sample storage for future research is entirely optional. If you would like more information about the NRP Biorepository, please contact the team at BioRepository@nnuh.nhs.uk.

Why are we asking for these particular samples?

These samples will help us to identify which microbes are passed between members of a family and what factors, e.g. antibiotics, diet, health, affect them most.

Microbes also produce compounds that we can detect in your samples; some are linked to important processes in you and your family's bodies, so it is important to identify whether they are present.

Additionally, your family relatedness influences the microbes that you have. We will evaluate this factor in your samples to better understand how the genes that you and your family have might influence the type of microbes that you have in your gut. We may use your probiotic strains in a commercial supplement to ensure that everyone has a balanced microbiome.

What is the purpose of the questionnaires?

The questionnaire that we ask you to complete will provide us with information about your general health, lifestyle, and dietary preferences. This allows us to determine whether these factors affect your gut microbiome. Not all of them are compulsory. It should take about 20 minutes to complete. We will send you this questionnaire via a digital link when they are due to be completed.

Can I find out about the results from this project?

We will not be providing individual results. However, QIB will provide you with a summary of the results of this research. We will share research findings with you through a summary report, and you will be asked to consent to us holding your contact details in order to share the results with you.

In addition, we will offer at regular intervals information evenings, where we will report on the progress of the project and share findings with participants.

Will you be looking at my own DNA from stool samples?

We will look at DNA from the microbes in your stool sample, this is different from your own DNA.

However, you can opt-in in the consent form to allow us to test for any relationships between your DNA (your genome) and the gut microbiome, and how this translates to sharing microbes between you and your family. No attempt will be made to establish family structures from the human genome analysis. This is entirely optional; we will not use your samples for this purpose unless you opt in for this in the consent form. If you give us your consent, DNA analysis will be done in collaboration with the Earlham Institute, a research institute part of the Norwich Research Park that works in partnership with QIB.

Would there be any benefit to me in giving stool samples?

Donating samples will have no direct health benefit to you. We aim at developing better health practices and medicines from this project that can benefit large parts of the population.

We want to make sure that you have no financial disadvantage from taking part in this study. Therefore, we will reimburse your time for collecting each faecal sample and completing the questionnaire with £20 each (voucher or bank transfer). In addition, if you choose to deliver your sample to the QIB yourself, we will reimburse your travel costs to the QIB (within reasonable distances) and invite you to the QIB café with a £5 voucher.

Are there any risks?

As long as you follow the instructions provided there should be no more health risk to you than when you normally empty your bowels.

How will we use information about you?

We will need to use information from you in this research project. This information will include your:

- Name/initials
- Contact details
- Date of birth
- General health, lifestyle and dietary information. This will be gathered from your answers to the two questionnaires we will ask you to complete 12 months apart.
- Data we will produce from the samples that you provide us

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your sample and resulting data will have a unique identifier number instead.

We will keep all information about you safe and secure.

We will keep all data about you confidential. Only the researchers at the QIB who are working on the study will have access to any confidential information you provide. Our security controls include physical and digital security controls to ensure confidentiality. Nobody outside of the core study group will be able to access information about you as all data derived from your samples will only be linked to your personal data using a unique code which we will allocate to you when you join the study. We will write our reports in a way that no-one can work out that you took part in the study – the data will be anonymized.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason. In that case, we will remove your personal information and not contact you any longer. Further, we will keep the research data we generated, because this might be already anonymized and at that point we cannot identify it as your data any longer.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we have collected already.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team: pearl-age@quadram.ac.uk

by sending an email to our data protection adviser: dpa@nbi.ac.uk or dpo@nbi.ac.uk

Will you contact me for future research?

With your consent, we would like to keep your contact details after the study has ended so that we have the potential to ask you to participate in future studies. This is entirely optional. Your contact details would be stored electronically on a secure computer system separately from the study data. You can ask us to have your contact details removed from our database at any time.

Who is funding and coordinating this research study?

The European Research Council is funding this research, and this research is being co-ordinated by Dr Falk Hildebrand with the Quadram Institute Bioscience and Earlham Institute.

What happens if something goes wrong, or I would like to make a complaint?

If you have a concern about any aspect of the study, you should ask to speak to a member of the research team by calling 01603 255106 or via email on pearl-age@quadram.ac.uk. If you remain unhappy and wish to complain formally, you can do this through Dr Antonietta Hayhoe, the chairperson of the Human Research Governance Committee (HRGC) at QIB: antonietta.hayhoe@quadram.ac.uk; 01603 255030.

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 email is pals@nnuh.nhs.uk and the office has an answerphone which is available 24 hours a day: 01603 289036 or 01603 289045.

Who has reviewed this study?

To protect your safety, rights, wellbeing and dignity the study has been reviewed and agreed by the QIB Human Research Governance Committee (HRGC) and an independent group called Yorkshire & The Humber - South Yorkshire Research Ethics Committee (REC) which is made up of expert and lay members.

RECs review research proposals and give an opinion about whether the research is ethical. They also look at issues such as 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.

What should I do now?

If you are interested in taking part in the study and would like to know more, you can speak to the PEARL-AGE recruitment team on 01603 255106, email pearl-age@quadram.ac.uk, or go to the study website <https://quadram.ac.uk/pearl-agestudy/> and complete the expression of interest form.

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

Thank you for taking the time to read this information