



Study Title: Investigating Microbiome Diversity in UK Populations

PARTICIPANT INFORMATION SHEET

Research Ethics Reference: SEM06220

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We would like to invite you to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. One of our team will go through the information sheet with you and answer any questions you have. Please take time to read this carefully and discuss it with others if you wish. Please ask us anything that is not clear.

What is the purpose of the research?

Inside the human intestine live a wide range of microorganisms and bacteria, collectively known as the gut microbiome. The gut microbiome has recently been identified as a key factor in health and disease, with the greater the number of microorganisms in the intestine being an indication of a healthy body. The gut microbiome is affected by many factors including genetics, lifestyle, diet, and exercise. Studies have shown that when comparing activity levels, active people have a more diversified gut microbiome than those who sit down a lot during the day. Different diets have also shown to help shape the gut microbiome in a positive way for health.

The aim of this study is to better understand the relationship that the gut microbiome has with exercise, genetics and diet. By asking our participants to complete a food diary, activity questionnaire and provide a stool sample, our study will look to identify differences in the gut microbiome in endurance vs power athletes (sprinters). Research has shown that changes to the microbiome can occur quickly. Not only will we look at differences between athletes but also look at the change in the microbiome of endurance athletes before and after an endurance event. Finally, we will look at a genetic influence on the microbiome in these athletes by comparing them to samples from a parent, sibling, or other volunteers from a similar ethnic group.

Why have I been invited to take part?

You are being invited to take part because our research team has identified that you are a power athlete, endurance runner, or are a genetically or ethnically related to one of these athletes already taking part in the study.

Please read this information sheet in detail before deciding whether you wish to take part or not. We aim to invite 60-150 volunteers to participate.

Do I have to take part?

No. It is up to you to decide if you want to take part in this research. We will describe the study and go through this information sheet with you to answer any questions you may have. If you agree to participate, we will ask you to sign a consent form and will give you a copy to keep. However, you would still be free to withdraw from the study at any time, without giving a reason and without any negative consequences, by advising the researchers of this decision. This

would not affect your legal rights. If you are a student at the University of Nottingham, there would be no disadvantages to your study or to you personally if you decide not to take part in this study, or if you decide to withdraw at any point. **If you wish to take part, then your family or household members are under no obligation to take part if they don't wish to - it will not affect your opportunity to participate in the study.**

What will happen to me if I take part?

Power (sprint) athletes, family or household members of athletes, or ethnic minority background participants

Upon completion of the participation consent form you will be asked to complete two (2) questionnaires and provide one (1) stool sample to the research team.

Food Frequency Questionnaire:

You will be required to complete a 3-day food diary to record your dietary intake before providing the stool sample.

Physical Activity, Lifestyle and Health Questionnaire:

You will be asked to complete a physical activity questionnaire and details of your personal and season best athletic performances if applicable, as well as details on your health, lifestyle and household structure.

Stool Sample:

You will be asked to donate a faecal (stool) sample in a collection kit which will be sent back to the research team in a postage prepaid box.

Endurance Athletes:

Upon completion of the participation consent form you will be asked to complete two (2) questionnaires and provide two (2) stool samples to the research team.

Food Frequency Questionnaire:

You will be required to complete a 3-day food diary to record your dietary intake before providing the stool sample.

Physical Activity, Lifestyle and Health Questionnaire:

You will be asked to complete a physical activity questionnaire and details of your personal and season best athletic performances if applicable, as well as details on your health, lifestyle and household structure.

Stool Sample:

You will be asked to donate a faecal (stool) sample on the day of any 18-26.2 mile athletic event in a collection kit **BEFORE** and **AFTER** the athletic event. The collection kit will either be collected by the research team at the athletic event or shipped to the research team in a postage prepaid box.

I am an athlete and don't have any family members who wish to take part

There is no obligation for your parents, siblings or household members to take part in the study, but we will still love you to continue.

My parents and siblings would like to take part, what do they need to do?

That's great they are willing to help.

Ask them to contact us at microbiomestudy@uniofnottm.onmicrosoft.com or message us on X (formerly Twitter) or Instagram @MicrobiomeStudy and we will send some study information out to them.

Are there any risks in taking part?

There are no foreseeable risks associated with taking part in this study.

Are there any benefits in taking part?

There will be no direct benefit to you from taking part in this research, but your contribution may help aid athletic performance in the future. Diet and exercise have the possibility of being used as a health treatment to encourage helpful bacteria to live in the gut. Our study also hopes to identify the health benefits of different types of exercise and diet on the gut microbiome, which could help a wider population, especially the elderly and frail.

Expenses and inconvenience allowance

Participants who provide the required samples and complete the questionnaires will be entered into a prize draw to win an Amazon gift voucher worth £25.

What will happen to any samples I give?

If you agree to give a faecal sample this will be used to identify gut microbes.

We would also like to seek your consent so that any remaining samples may be stored and used in possible future research – this is optional (please indicate you agree to this on the consent form). The samples will be stored with a code unique to you and securely at the University of Nottingham under the University's Human Tissue Research Licence (no 12265).

Some of these future studies may be carried out by researchers other than current team of Dr. Joanne Stocks, including researchers working outside the University. Any samples or data used will be anonymised, and you will not be identified in anyway. If you do not agree to this any remaining samples will be disposed of in accordance with the Human Tissue Authority's codes of practice.

What happens to the data provided?

Data will be used for research purposes only and in accordance with the General Data Protection Regulations. All data are kept on password-protected databases sitting on a restricted access computer system and any paper information (such as your consent form, contact details and any research questionnaires) would be stored safely in lockable cabinets in a swipe-card secured building and would only be accessed by the research team. Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at: <https://www.nottingham.ac.uk/utilities/privacy.aspx/>

Designated individuals of the University of Nottingham may be given access to data for monitoring and/or audit of the study to ensure we are complying with guidelines.

All such data are kept on password-protected databases sitting on a restricted access computer system and any paper information (such as your consent form, contact details and any research questionnaires) would be stored safely in lockable cabinets in a swipe-card secured building and would only be accessed by the research team.

Your personal data (address, telephone number) will be kept for five years after the end of the study, so that we can contact you about the findings of the study and possible follow-up studies (unless you advise us that you do not wish to be contacted). All other data (research data) will be anonymous and will be kept securely for 7 years. After this time your data will be disposed of securely.

We would like your permission to use anonymised data in future studies, and to share our research data (e.g. in online databases) with other researchers in other Universities and organisations both inside and outside the European Union. This would be used for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. All personal information that could identify you will be removed or changed before information is shared with other researchers or results are made public.

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

Even after you have signed the consent form, you are free to withdraw from the study at any time without giving any reason and without your legal rights being affected. Any personal data will be destroyed.

If you withdraw, we will no longer collect any information about you or from you but we will keep the anonymous research data that has already been collected and stored as we are not allowed to tamper with study records. This information may have already been used in some analyses and may still be used in the final study analyses. To safeguard your rights, we will use the minimum personally identifiable information possible.

What will happen to the results of the research?

The complete results will be published in peer-reviewed scientific publications or presented at conferences. All data will be anonymised, so no participants identified. We will also present the findings to interested members of the public via public engagement events and social media.

After the study has been concluded, participants may ask to receive a brief summary of the findings of the study, although individual results cannot be provided.

Who has reviewed this study?

All research involving people is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Faculty of Medicine and Health Sciences Research Ethics Committee (Reference number: SEM 06220).

Who is organising and funding the research?

This research is being organised by the University of Nottingham. It is being funded by the Nottingham Hospitals Charity with public engagement activities funded by Research England.

What if there is a problem?

If you have a concern about any aspect of this project, please speak to the Principal Investigator Dr. Joanne Stocks, who will do their best to answer your query. The researcher should acknowledge your concern and give you an indication of how she intends to deal with it. If you remain unhappy and wish to complain formally, you can do this by contacting the FMHS Research Ethics Committee Administrator, Faculty Hub, Medicine and Health Sciences, E41, E Floor, Medical School, Queen's Medical Centre Campus, Nottingham University Hospitals, Nottingham, NG7 2UH or via E-mail: FMHS-ResearchEthics@nottingham.ac.uk.

Contact Details

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact:

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