

Participant Information Sheet

Title of Project: Bacterial Diversity and Antimicrobial Resistance in the Gastrointestinal Tracts of River Swimmers in the United Kingdom (Poo-Sticks survey)

Researcher names: Elitsa Penkova, Dr Anne Leonard, Prof William Gaze, Prof Ruth Garside, Dr Andrew Singer, Dr Nicola Elviss

Invitation and brief summary:

Thank you for considering taking part in this project. Please, make sure that you understand all of the information provided in this information sheet before making your decision of whether or not to participate.

This research project focuses on studying antibiotic resistant bacteria that live in the gut of healthy adults. Specifically, we aim to examine individuals who frequently engage in recreational activities that involve getting your head wet (hereafter referred to as “swimming”) in inland freshwaters (hereafter referred to as “rivers”) across the UK and compare their gut bacteria to those of healthy adults who do not have contact with natural waters.

Purpose of the research:

The spread of antibiotic resistant bacteria poses a significant health challenge, as infections caused by these bacteria often do not respond to treatment. Identifying how these bacteria enter human populations is essential for controlling their spread, and the environment could be an important source. While recreational contact with faecally-polluted rivers is unlikely to result in life-threatening disease in healthy individuals, gut colonisation by antibiotic resistant bacteria could contribute to the spread of resistance in the community, including to people vulnerable to infection.

This project aims to explore the association between recreational swimming in rivers across the UK and gut colonisation by antibiotic resistant bacteria. Although the study may not establish a direct causal link, its findings could suggest the existence of such a link, paving the way for further investigation in future research. Moreover, the results may have implications for how we regulate water quality in rivers to safeguard public health.

Please, take time to consider all the information provided on this information sheet carefully. You are welcome to discuss this with your family and friends. If you are under the age of 18, we encourage you to discuss your participation in this research project with your parents or carers. You are welcome to ask the researchers any questions you have about the study. Contact details for the research team are provided at the end of this information sheet.

Why have I been approached?

If you regularly swim in rivers (three times or more in the past month), we would like to invite you to participate in this study. As frequent swimmers, you may have had exposure to antibiotic resistant bacteria that are sometimes present in river water. Your participation will help us understand the potential implications of such exposure on human health.

If you are not a regular swimmer (meaning you engage in recreational water activities less than once a month), we invite you to be part of our control group. Having a group of people who are not exposed to recreational water bodies will enable us to compare the effects of swimming in rivers on gut colonisation by antibiotic resistant bacteria relative to an unexposed population.

You will **NOT** be eligible to participate in this study if you answer 'yes' to any of the following questions:

- Are you under the age of 16?
- Have you been diagnosed with any underlying health condition that could make you more prone to infection and require frequent use of prescribed medication, such as antibiotics, laxatives, proton-pump inhibitors (PPIs), lipid-lowering statins, metformin, beta-blockers, angiotensin-converting enzyme (ACE) inhibitors, and selective serotonin reuptake inhibitor antidepressants (e.g. Irritable Bowel Syndrome (IBS), chronic heart or kidney disease, Crohn's disease, celiac disease, multiple sclerosis, diabetes, etc.)?
- Have you travelled outside Europe in the past six months?
- Have you had an overnight stay in a healthcare facility within the last six months?
- Have you or anyone you live with received a course of antibiotics treatment in the last six months?
- (Non-swimmers only) Do you live with someone who is a regular swimmer, i.e. someone who has swam three or more times in the past month?

What would taking part involve?

Study timeline

Enrolment is open from the start of May until the end of the bathing season (end of September). To enrol, you will be asked to complete a short survey to help us determine your eligibility and to provide contact details for the delivery of your faecal sample collection kit. Upon receipt of your kit, you have the flexibility to select a suitable time for collecting your faecal sample. However, once you have collected your faecal sample, please post it back to us (along with the completed questionnaire and consent form) on the same day, as soon as you can.

Receive your study kit

Once you have been enrolled in the study, you will receive a study kit sent to the address you provide. The study kit will include all the information and materials you need to participate.

You will be asked to complete a standard questionnaire (send as part of the kit) and provide information about yourself, your health and dietary habits, as well as your recent river visits within the UK.

Additionally, you will be provided with instructions on how to safely collect your faecal sample. Within this kit, you will find two faecal collection tubes: one will be used to screen your sample for live pathogens, while the second tube contains a preserving medium that will effectively deactivate all microbes within your sample – preserving microbial DNA. Please ensure to add your faecal sample to both tubes.

If you can, identify a non-swimmer

If you are a swimmer, we kindly ask you to identify and invite a person who is not a regular swimmer to take part in this study as part of our *control group*. This person should be approximately the same age and same sex as you, but must not be a person you live with. However, this is not a requirement and if you are unable to identify a non-swimmer who would like to take part, you are still welcome to participate in the study.

What are the possible benefits of taking part?

Taking part in this study will help us understand the impacts of recreational swimming in UK rivers on gut colonisation with antibiotic resistant bacteria. These results can inform further research into the spread of antibiotic resistance, and deliver wider benefits to society.

What are the possible disadvantages and risks of taking part?

The risks associated with participating in this study are low. Collecting a faecal sample is a non-invasive way to sample bacteria in your gut, and you may do this in the comfort and privacy of your own home at a time that is convenient to you. If you experience discomfort while defecating, we recommend that you contact your GP. If you decide to participate in the study, we will provide you with information on how to collect your faecal sample safely.

Can I change my mind and withdraw from this project?

Absolutely. Participation is entirely voluntary. If you wish to withdraw your participation you can do so at any point, without having to give a reason. If you decide to withdraw after submitting your sample, you can do so by contacting Elitsa Penkova by phone or via email (contact details are provided at the end of this information sheet), or another member of the research team at the University of Exeter (Dr. Anne Leonard, Prof. William Gaze, Prof. Ruth Garside).

Please note that once data analysis has commenced, we will no longer be able to remove the data you have submitted. The reason for this is because at this stage the data set will be anonymised and any personal information linking you to your data will have been deleted. Be assured that while we plan on publishing the findings from this study in a peer-reviewed journal, no personally identifiable information will be made publicly available, and you will not be identifiable from any data presented in our report.

What will happen to the samples I provide?

Faecal samples are being used to look for antibiotic resistant bacteria that live in the gut. Your sample will be tested for the presence of cefotaxime-resistant *Escherichia coli*, or more commonly known as *E. coli*. In addition, we will extract DNA from the bacteria in your faecal sample to understand what types of bacteria and antibiotic resistance genes may be present in your gut. Please note, that these data will not give us any other information about you or your personal health.

In addition to providing your faecal sample, you will be asked to complete a short questionnaire. The questionnaire will inquire about factors that may be associated with having antibiotic resistant bacteria in your gut. Additionally, we will collect some personal information, including age, socio-economic status, information about exposure risks within your household, travel history and some general health-related data.

We will ask you to provide a valid email address towards the end of the questionnaire. This information will be used for the following purposes:

- 1) To identify participants who wish to withdraw from the study after having submitted their faecal sample, questionnaire and consent form.
- 2) If you participated in our Nationwide Health Survey carried out by the same research team (www.ecehh.org/research/antimicrobial-resistance-in-rivers/), in the consent form you will have the option to allow us to use your email address to retrieve your survey answers from the Nationwide Health Survey and link these to your responses and gut data from this study. This might help us identify links between symptoms of illness, and the presence or absence of antibiotic resistant bacteria.

We plan on publishing our findings in a peer-reviewed journal, but be assured that no personally identifiable information will ever be made publicly available, and you will not be identifiable from any data presented in our reports.

How will my information be kept confidential?

The University of Exeter processes personal data for the purposes of carrying out research in the public interest. The University will endeavour to be transparent about its processing of your personal data and this information sheet should provide a clear explanation of this. If you do have any queries about the University's processing of your personal data that cannot be resolved by the research team, further information may be obtained from the University's Data Protection Officer by emailing informationgovernance@exeter.ac.uk or at www.exeter.ac.uk/ig/.

We will keep all information about you safe and secure and we will strictly adhere to Data Protection requirements to ensure full confidentiality of your information. Your contact details will be securely stored and permanently deleted as soon as your kit has been dispatched. Other personal information (e.g. email addresses) will be stored separately from the rest of the data you submit, and will be used for the reasons stated in the previous section. Please be assured that personal data will only be accessible to Elitsa Penkova and Anne Leonard and will not be used for any purposes other than those described above.

All information collected will be stored securely, with access limited to the University of Exeter researchers directly involved with this study. Personal information will be permanently deleted once data collection has ended. All other data will be securely stored for a period of 5 years after this project has been completed.

Will I receive any payment for taking part?

There is no payment for participating in this study.

What will happen to the results of this study?

The findings of this study will be reported in a peer-reviewed journal, however, any data you submitted will remain anonymous. We will produce a plain English language summary report, which will be made available on this project's webpage when it is ready (<https://www.ecehh.org/research/antimicrobial-resistance-in-rivers/>). In addition, we will aim to disseminate our findings further at conferences to the wider scientific community and the public. Again, any data you submitted will remain anonymous.

Can I find out the results of my faecal sample?

Individual participants will not be informed if antibiotic resistant bacteria are found in their samples. This decision is based on the understanding that gut colonisation by antibiotic resistant bacteria typically clears on its own after a short period and does not usually cause health problems in healthy individuals. Furthermore, there is currently no recommended treatment for eliminating antibiotic resistant bacteria that are not causing illness.

The results of the study, including the proportion of colonised individuals in both the swimmer group and the control group, will be presented in a report accessible on the European Centre for Environment and Human Health's website (www.ecehh.org). It's essential to note that individual results will not be identifiable in the report to maintain confidentiality.

If you have any concerns about your health, we recommend seeking advice from your GP. The focus of the study is to contribute to the understanding of the spread of antibiotic resistance among the population, and its potential association with recreational water activities such as swimming.

Who is organising and funding this study?

This project is part of a PhD in Medical Sciences, which is funded by the Natural Environment Research Council (NERC GW4+) and is supported by the UK Health Security Agency.

Brief summary of the research team and funders

Elitsa Penkova is an evolutionary biologist with five years of experience working on antibiotic resistance research within both academia and industry settings. In January 2023, she joined the University of Exeter's European Centre for Environment and Human Health to undertake a PhD in Medical Sciences.

Elitsa's PhD research is supervised by academics at the University of Exeter, including Dr Anne Leonard, Prof Ruth Garside and Prof Will Gaze. Research conducted by this group has made significant strides in the field of antimicrobial resistance, shedding new light on this critical issue and how it affects us globally. Their findings have had an impact on shaping the strategies adopted by governments and the World Health Organisation in tackling the global challenge of antimicrobial resistance.

Elitsa is the primary researcher for this study. She is based at the University of Exeter and her PhD is funded by the Natural Environment Research Council (NERC GW4+).

Additional supervisors on the PhD include Dr Andrew Singer at the UK Centre for Ecology and Hydrology, and Dr Nicola Elviss at the UK Health Security Agency.

Who has reviewed this study?

This project has been reviewed by the Research Ethics Committee at the University of Exeter (Reference ID: 4979205).

Contact for any questions or requests regarding your participation in this research

In the event of queries or requests you may contact me using the following contact information:

Elitsa Penkova, egp203@exeter.ac.uk

University of Exeter supervisory team:

Anne Leonard: Anne.Leonard@exeter.ac.uk

Ruth Garside: R.Garside@exeter.ac.uk

William Gaze: W.h.Gaze@exeter.ac.uk

To contact the University of Exeter Medical School & Health and Care Professions Research Ethics Committee, please email uemsethics@exeter.ac.uk

You can also contact the University Research Ethics and Governance Team if you wish to make a complaint or comment.

Please email cgr-reg@exeter.ac.uk,

Thank you for your interest in this project!