

Information Sheet



University of Reading PRECOG Study Information

Sheet

School of Psychology & Clinical Language Sciences

University of Reading PRECOG Study: Investigating the effects of prebiotics on cognition, mood, and gut microbiome

Researchers: Dr Piril Hepsomali, Dr Daniel Lamport, Miss Rebecca Colombage

We want to give you all the information you need about the University of Reading PRECOG study so you can decide if you'd like to take part. If you have any questions or would like to talk about the study, please feel free to contact the PDRA by email or phone (details are provided below).

What is the purpose and background of the PRECOG study?

We are studying how consuming prebiotic fibres can help improve your ability to carry out daily tasks. Prebiotic fibres are known to have health benefits.

Since these fibres can affect how the body works, we are also interested in measuring how many different types of microbes are present in your gut, and which specific types of microbes are there and how abundant each microbe is.

Who can take part in the study?

To take part in the PRECOG study, you need to be between 60-80 years old, have normal vision and hearing, a body mass index (BMI) under 30, and experience some memory or thinking difficulties. You should not have any diagnosed psychiatric or neurological conditions (including eating disorders), cardiometabolic conditions, gastrointestinal problems, or anaemia (please contact the researcher if you're unsure).

You will not be eligible if you currently smoke, drink more than the recommended amount of alcohol each week, are vegetarian or vegan, eat a lot of fibre, or have recently changed your diet. You also cannot take part if you have unmedicated high blood pressure, are taking blood thinners, antiplatelet medication, antidepressants, proton pump inhibitors, weight loss medication, or have food allergies.

If you have taken antibiotics for more than 3 days within the month before the study, you are also not eligible. If you regularly take vitamin or probiotic/prebiotic supplements, you may be asked to stop these during the study.

In the consent form, we will ask you to provide the contact details of your General Practitioner (GP) so we can reach out to them if we need more information about your health or medications.

What would taking part involve?

In this study, you will add a scoop of either prebiotic-fibre powder or a powder without prebiotic-fibres into your preferred drink (tea, coffee, water or juice) in the morning each day for 12 weeks. You won't know which type of powder you're adding to your drink. The study involves a maximum of two visits at the School of Psychology and Clinical Language Sciences Department at the University of Reading, separated by 12 weeks.

At the start, you will get a call from the researcher, where you'll answer some questions about your health, lifestyle, fibre intake, and any memory or thinking difficulties you may have. If you're eligible, you will then visit the university for test visits, each lasting no more than 2 hours.

For the test visits, you'll take cognitive and mood tests, share information about your diet and bowel movements, and have your weight, height, and blood pressure measured. We will also give you a stool collection kit and shown how to use it at home.

At home, you will collect your stool sample using the kit provided and send it using a pre-paid postage label.

Participation is completely voluntary. You can choose to withdraw from the study at any time, and you don't need to explain why. The lead researcher may also ask you to stop participating for reasons like health concerns, safety, or not following the study's rules.

What will happen to the samples and responses I give? Will my information be kept confidential?

In line with data protection laws, your personal information will be kept private. Your data will be identified only by a number, and the link between your name and this number will be stored securely in a separate place. After 1 year from the completion of the study, any information that links your data to your name will be destroyed, ensuring full anonymity.

Stool samples will be stored and processed by Myota Ltd. The tests will measure how many different types of microbes are present in your gut, and which specific types of microbes are there and how abundant each microbe is. The samples will be disposed of as clinical waste after testing.

The results of the study will be published in an academic journal, but your identity will remain anonymous in the publication. The data will also be preserved in anonymised form for future use by researchers. Only the overall results of the group will be shared, and no personal details will be included. If you'd like, you can request a copy of the results after the study is finished, and we can send them to you by mail or email.

Will I be paid to participate?

Yes, your time and help are greatly appreciated by the University, and you will be reimbursed for your participation in the study. You will receive £150 if you complete all three visits. If you decide to withdraw early, you will still be paid a portion of the £150 based on how much time you've spent in the study.

What are the possible advantages of taking part?

Your participation in our study is highly valuable, allowing us to examine the benefits of prebiotic fibres. The information we gather will contribute to raising awareness about how prebiotic fibres may affect cognitive, mental, and gut health.

What are the possible disadvantages/risks of taking part?

Taking part in the study will require a time commitment, but we hope the financial compensation will help make up for this. The overall risk of participation is very low. The study uses well-established methods, and all researchers involved are trained and experienced. The ingredients used in the study are commercially available and safe. If you have any concerns during the study, the research team is always available to assist you. Finally, participation is completely voluntary. You can choose to leave the study at any time, and you don't need to explain why.

What if something goes wrong?

If you have any concerns or complaints about the study, or if you experience any negative effects, we encourage you to let one of the research team members or the Head of School Professor Carmel Houston Price (hos-pcls@reading.ac.uk) know as soon as possible. We will do our best to resolve any issues quickly. The contact details for the researchers can be found on the last page of this document.

Who is organising and running the study?

The study is organised and run by research staff in the School of Psychology and Clinical Language Sciences at the University of Reading.

Who has reviewed this study?

The study has been reviewed by the University Research Ethics Committee (UREC) and has been given a favourable ethical opinion for conduct, which means that an independent group did not raise any objections to the study on ethical grounds and have permitted the study to proceed.

Data Protection information

The organisation responsible for protection of your personal information is the University of Reading (the Data Controller). Queries regarding data protection and your rights should be directed to the University Data Protection Officer at imps@reading.ac.uk, or in writing to: University of Reading, Information Management & Policy Services, Whiteknights House, Pepper Lane, Whiteknights, Reading, RG6 6UR, UK.

The University of Reading collects, analyses, uses, shares and retains personal data for the purposes of research in the public interest. Under data protection law we are required to inform you that this use of the personal data we may hold about you is on the lawful basis of being a public task in the public interest and where it is necessary for scientific or historical research purposes. If you withdraw from a research study, which processes your personal data, dependant on the stage of withdrawal, we may still rely on this lawful basis to continue using your data if your withdrawal would be of significant detriment to the research study aims. We will always have in place appropriate safeguards to protect your personal data.

If we have included any additional requests for use of your data, for example adding you to a registration list for the purposes of inviting you to take part in future studies, this will be done only with your consent where you have provided it to us and should you wish to be removed from the register at a later date, you should contact Dr Piril Hepsomali (P.Hepsomali@reading.ac.uk)

You have certain rights under data protection law which are:

- Withdraw your consent, for example if you opted in to be added to a participant register
- Access your personal data or ask for a copy
- Rectify inaccuracies in personal data that we hold about you
- Be forgotten, that is your details to be removed from systems that we use to process your personal data
- Restrict uses of your data
- Object to uses of your data, for example retention after you have withdrawn from a study

Some restrictions apply to the above rights where data is collected and used for research purposes.

You can find out more about your rights on the website of the Information Commissioners Office (ICO) at <https://ico.org.uk>

You also have a right to complain the ICO if you are unhappy with how your data has been handled. Please contact the University Data Protection Officer in the first instance.

Thank you for reading this information and for considering participation in our study.

The PREECOG Study Team

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Study location

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