

Heartburn Health

Leading research into heartburn, indigestion and acid reflux

We invite you to take part in a research programme called Heartburn Health.

Thank you for your interest in supporting this research. Joining Heartburn Health would involve:



Allowing the Heartburn Health team to access information held about you by NHS England and other central UK NHS bodies.



Allowing the Heartburn Health team to contact you about research studies running as part of the programme.

Before you decide to take part, it is important to know why we are running this research and what it will involve. Please take time to read the following information carefully.

What is Heartburn Health?

Heartburn Health is a large, new programme run by the University of Cambridge and King's College London. It is enabling studies that explore and solve health problems related to heartburn, indigestion and acid reflux.

Millions of people in the UK suffer from these symptoms. Heartburn, indigestion and acid reflux can cause daily discomfort and mean some people need to take medication. In rare cases, these symptoms can also lead to more severe health problems including cancer.

The programme plans to collect health information from at least 120,000 people with reflux from across the UK. Researchers will then be able to apply to use the information to make new discoveries about reflux and its care.

Enabling lots of studies through the programme will lead to more discoveries, faster. Research done through Heartburn Health could revolutionise the

way we care for people with heartburn, indigestion and acid reflux.

We are inviting you to join Heartburn Health to help make these discoveries possible.

Why have I been invited to take part?

You have been invited because:

- You are female on your GP records and between the age of 65 and 79 years
- OR**
- You are male on your GP records and between the age of 55 and 79 years

The age is slightly different for men and women. This is because men tend to have health problems related to reflux at a younger age.

If you are transgender or gender diverse, you are welcome to join this programme.

Do I have to join the programme?

No. Joining is your choice. You may want to discuss the programme with friends or family. If you join and then change your mind, you can leave at any time. You can find more details in the 'How do I leave the programme' section below.

What would joining involve?

At this point, joining Heartburn Health simply involves reading and agreeing to the statements in the survey.

By joining Heartburn Health, you will agree to us:

1. Accessing and using records about your health.

We will access, store and use relevant information held about you in national health records to get a picture of your health. This may include records held by NHS England or other central UK NHS bodies (e.g. GP practices or NHS hospitals). To find and link these records, we will use some of your personal details, like name, date of birth and NHS number. When we store and use the records, we will use a code number instead of your personal details. We will refer to this coded data as your research data. People who do not need to know who you are will not be able to see your name or contact details. We will collect information about you from your records as long as the programme exists. You can ask us to stop at any time.

2. Contacting you about taking part in studies running as part of the programme.

Some studies in the programme will want to test something new or collect more information. We will ask for permission to contact you about taking part in these studies. Studies like this may include activities like completing surveys, giving samples (e.g. blood), having tests or trying new drugs. Full details will be shared when you are invited to take

part. Taking part in these studies will be completely voluntary. Agreeing to be contacted does not mean you need to take part.

Researchers will be able to apply to do two kinds of research:

1. **Research that only uses research data we already hold** within Heartburn Health
2. **Research that involves contacting people** in Heartburn Health to invite them to try something new or collect more information

Who will do the research and how will it work?

Some studies will be run by our team at the University of Cambridge and King's College London. Researchers from outside these universities can also apply to use the research data and run studies in Heartburn Health. These researchers could be from academic, non-profit and for-profit organisations from countries around the world.

All studies would need standard ethical approval. In addition, any researcher who applies to do a study with Heartburn Health will go through a strict application process. This includes a careful review by the Heartburn Health Access Board of the study and the researcher.

The Heartburn Health Access Board will only approve health-related studies that are for the public good and come from trusted researchers.

Researchers will only be able to access coded research data within our secure research environment.

We will never share your personal details with researchers or organisations unless you give us specific permission.

How long will I be involved for?

Heartburn Health will run for a very long time. We will collect information held about you in national records as long as the programme exists. This includes if you pass away or lose the ability to consent.

How do I leave the programme?

You can leave the programme at any time. This will not impact your care or legal rights and you will not need to give a reason for stopping.

What are the possible benefits of taking part?

This study could help improve the way we care for people with heartburn, indigestion and acid reflux in the future. By taking part, you are making that possible.

You will also receive regular newsletters which will include research updates and health and lifestyle advice. We hope this will help you manage and learn more about your symptoms.

What are the possible risks of taking part?

We are using every safety measure to make sure your information is secure. This includes meeting standards set by the National Cybersecurity Centre and the NHS. However, the risk of a security breach can never be zero. If a security breach happens, someone could see or use the information we have about you.

If we contact you about a research study running as part of the programme, we will tell you about any risks related to the study at that time.

How will my personal details be used?

A limited number of staff from Heartburn Health will have access to your personal details. This is so we can contact you and access health information

held about you in national records. Strict controls will be in place to protect your personal details.

How will my personal details and research data be kept confidential?

King's College London and the University of Cambridge have a responsibility to keep information collected about you safe and secure, and to ensure it is correct.

All your information will be protected in accordance with the Data Protection Act (2018) and UK General Data Protection Regulation (GDPR). The University of Cambridge will be the Data Controller for your information. This means that they will make decisions about how your data can be used. King's College London will be the data processor. This means they will manage your data as required by the University of Cambridge.

All the information we collect about you will be encrypted (described using a code) when it is in transit and at rest. It will be stored according to strict security standards.

Expert teams will continually assess and ensure that data is held in the most appropriate and secure way. This may include storage of personal details with a contracted GDPR compliant third-party storage provider within the UK, where they are the best data storage option.

If a third party storage provider is used, some employees will have access to your personal details and research data if needed for their role. They will be required to keep your information strictly confidential.

We will write any reports in a way that no one will be able to work out you took part. Your personal details may be accessed by members of the study team, auditors or regulatory authorities to check that the programme is run safely and accurately.

Researchers running studies as part of Heartburn Health will only be able to access your coded research data via our highly secure online data storage system. All activity in the system is closely watched. Researchers are unable to download or remove any information from the system.

We will never allow access to your information for anything other than health research for the public good. We will never sell or share your personal details for the purposes of advertising or, for example, to insurance companies.

What if something goes wrong?

Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge have specific arrangements in place if you suffer any harm because of this study. You can ask questions about the study at any time.

Who is organising and funding this study?

The University of Cambridge and Cambridge University Hospitals NHS Foundation Trust are joint sponsors of this programme. This means they oversee the study.

King's College London are responsible for running the programme.

The lead researcher responsible for the programme is Dr Thomas Round.

This work is programme by Cancer Research UK (SEBSTF-2021\100036, CRUK/22/005) and the NIHR HTA programme (NIHR135565).

Who has reviewed the programme?

The safety and ethics of this programme has been reviewed and approved by the UK Health Research Authority and the Research Ethics Committee.