Heartburn Health

Leading research in heartburn, indigestion and acid reflux

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

Before you decide to take part, it is important you understand 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 a team based at the University of Cambridge, Cambridge University Hospitals NHS Foundation Trust (CUH) and Queen Mary University of London (QMUL). The aim is to build a community of volunteers willing to support research and enable studies that explore and solve health problems related to heartburn, indigestion and acid reflux.

Millions of people in the UK suffer from these symptoms which can cause daily discomfort and often require long term medication. In rare cases, these symptoms can also lead to more severe health problems including cancer.

The programme plans to collect heartburn related health information from at least 120,000 people with reflux from across the UK. This information will help researchers make new discoveries about reflux and improve the way we care for people with these symptoms.

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

Why have I been invited to take part?

You expressed an interest, or you were invited because your GP records show you are:

- Female between the age of 65 and 79 years

  OR
- Male 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. 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 online enrolment form.

By joining Heartburn Health, you agree to:

- The Heartburn Health team collecting heartburn related health information held about you in NHS records for many years
- The Heartburn Health team contacting you about future approved studies
- Your non-identifiable health information being used for approved studies for many years, including studies you have not been contacted about

Who will do the research and how will it work?

Collecting information held about you in NHS records

We will collect your health data now for use in future research studies. All studies will need ethical approval. We will access and store relevant heartburn related health information held about you in national health records. This will include records held by UK NHS bodies (e.g. GP practices or NHS hospitals).

Contacting you about future approved studies

Some studies may need to collect additional information if they are looking to test something new or need to know something not in your health records. For example, studies may invite you to complete surveys, give samples (e.g. blood), take tests or try new drugs.

The Heartburn Health Team may contact you about these studies. Full details will be shared when you are invited to take part. It will be entirely your choice whether to agree to these future invitations.

Approved studies may use your non-identifiable health data even if you are not contacted about the study. You may not be contacted because you are not suitable, there are resource limits, or you may be in the comparison group.

Comparison groups allow researchers to compare the data of people offered something new (like a drug or test) with people who are not, to see if it makes a difference. You may be in the comparison group based on information about you, such as your age, lifestyle habits or health conditions. You may also be selected at random.

Who will do the research

The Heartburn Health Team will run some of the future studies. They will be able to use your personal details to contact you and your non-identifiable health data to do the research.

Researchers from outside the Heartburn Health Team will also run future studies. These researchers could be from academic (university), non-profit and for-profit organisations from countries around the world. These will need both ethical approval and approval from the Heartburn Health Access Board.

The Heartburn Health Access Board will only approve health-related studies that are for the public good and come from trusted researchers. Researchers outside the Heartburn Health team will not have access to your personal details. If other researchers would like to contact you about an approved study, the Heartburn Health team will contact you on their behalf first.

Your data is strictly for health research. Researchers will only be able to access your information via a highly secure online system for approved studies. They will not be able to download or remove data.How long will I be involved for?

Heartburn Health will run for at least 12 years. 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 by visiting [Heartburn Health **website]. This will not impact your health care or legal rights.**

What are the possible benefits of taking part?

This programme 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 may be offered new tests or treatments in future studies which aim to improve your health.

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

What are the possible risks of taking part?

We are using every safety measure to make sure your information is secure. We follow strict 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.

How will we use information about you?

To send you a text message invitation to this programme, NHS England shared your name and mobile number with iPlato on behalf of the Heartburn Health team. You can find more details about this here [Heartburn Health website]. If you decide to join Heartburn Health, iPlato will share your personal details with the Heartburn Health team.

We will need to use information from you, your medical records, and your GP for this research programme.

This information will include your name, NHS number and date of birth. 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 data will have a code number instead. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep all information about you safe and secure.

What are your choices about how your information is used?

You can stop being part of the programme at any time, without giving a reason, but we will keep information about you that we already have.

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 hold about you.

If you agree to take part in this programme, your data may be used in future research studies approved by UK ethics and the Heartburn Health Access Board.

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/
- By asking one of the research team
- By visiting the [Heartburn Health website]
- By sending an email to the Data Protection Officer at CUH: Michelle Ellerbeck michelle.ellerbeck@nhs.net

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 with the programme?

CUH and the University of Cambridge have specific arrangements in place in the unlikely event you suffer harm because of Heartburn Health.

You can ask questions about the programme at any time. To complain or report a problem about the programme, you should contact Professor Rebecca Fitzgerald, Chief Investigator leading on this programme [insert email].

For independent advice on the programme, please contact [insert BEST4 Clinical Team email and phone number] who will put you in contact with the CUH Patient Advice and Liaison Service (PALS). PALS offers confidential advice, support and information on health-related matters.

Who is organising and funding this study?

The University of Cambridge and CUH are joint sponsors of this programme. This means they oversee the study. QMUL is responsible for running the programme.

The Chief Investigator (lead researcher) responsible for the programme is Professor Rebecca Fitzgerald. The Principal Investigator (clinical lead) responsible for the programme is Dr Thomas Round.

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

Who has reviewed the programme?

The safety and ethics of this programme have been reviewed and approved by the UK Health Research Authority and the West Midlands – South Birmingham Research Ethics Committee**.** The use of NHS data to invite people to this programme has been approved by the Health Research Authority based on advice from the Confidentiality Advisory Group. This Group is an independent body who provide expert advice on the use of confidential patient information.

Further information

For more information about Heartburn Health, visit our website at [website].