Heartburn Health

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 new research programme run by a team based across 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 to improve care for people with heartburn, indigestion and acid reflux. Heartburn Health is collecting health information from at least 120,000 people with reflux from across the UK and invite these volunteers to relevant research studies. This information will help researchers make new discoveries about reflux and related health conditions.

We are inviting you to join Heartburn Health for the chance to take part in ground-breaking research and 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.

Barrett’s oESophagus Trial 4 (BEST4): A Randomised Control Trial Comparing capsule sponge Test Screening to Usual Care 1

IRAS 332589 Heartburn Health Participant Information Sheet V6.0 27Mar2025

Previously: IRAS 332589 BEST4 Screening Heartburn Health PIS V5.0 16Oct2024

English and Polish version available online https://www.heartburnhealth.org/ | Wersja angielska I polska dostępna online https://www.heartburnhealth.org/

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:

- Heartburn Health collecting health information from your NHS records for many years
- Heartburn Health 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 aiming to improve the health of people with reflux. All studies will have ethical approval.

Health information we collect may include clinical visits, test results, treatments and procedures for acid reflux or related health conditions (e.g. ulcers, stricture or cancer in the food pipe).

We may collect and combine information about you from NHS England or other central UK health service bodies (e.g. registries, GP practices or NHS hospitals) if needed for the research. Identifiable data may also be shared with NHS England or other UK health service bodies to access relevant health information from your NHS records for research purposes. You can find further details about the type of information we will collect, and where we will collect this from, on our website.

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.

Full details will be shared when you are invited by the Heartburn Health team 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 do not meet the criteria for the study, 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 selected for the comparison group 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 contact details (e.g. name, mobile number, email, postal address) to contact you and your non-identifiable health data to do the research.

Researchers from outside the Heartburn Health team may also run future studies. These researchers could be from academic (university), non-profit and for-profit (commercial) organisations from countries around the world. These organisations could benefit financially from Heartburn Health.

You can find information about the organisations involved in running Heartburn Health and studies using the programme on our website.

Studies run by researchers outside the Heartburn Health team will need 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. These researchers will not have access to your identifiable personal details (e.g. name, mobile number, NHS number). If these 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.

Importantly, Heartburn Health will keep all your information safe and secure.

How long will I be involved for?

Heartburn Health will run for at least 12 years. We will collect information held about you in NHS records as long as the programme exists unless you ask us to stop. 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 phoning us on 08082 814772 or completing a form on https://www.heartburnhealth.org/about-the-programme/leaving-the-programme/. You will have the option to:

(1) Stop future contact but allow us to continue collecting health information from your NHS records

(2) Stop future contact and stop us collecting health information

Leaving the programme will not impact your health care or legal rights. To make sure the research is reliable, we will keep the information that we already have.

What are the possible benefits of taking part?

You may not benefit directly by taking part in Heartburn Health. However, 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. We will update the website with findings from studies using Heartburn Health where possible.

You will receive regular newsletters with 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. In the unlikely event of a breach, we will alert you.

How will we use information about you?

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 obtain and link to data held about you in your NHS records to do the research.

This may include employees from third-party organisations providing technical support required to run the programme. This will only occur where necessary, under secure arrangements, with appropriate contracts in place. Some of these organisations may be based outside the UK, however, all third parties must meet UK GDPR standards. You can find information about the organisations involved at https://www.heartburnhealth.org/.

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.

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.

Where can you find out more about how your information is used?

- At https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/
- By asking one of the research team
- By visiting https://www.heartburnhealth.org/
- By sending an email to the Data Protection Officer at CUH: Michelle Ellerbeck michelle.ellerbeck@nhs.net

Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge are the sponsors and joint data controllers. You can find more information on our website https://www.heartburnhealth.org/.

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 I have questions or complaints about the programme?

If you have any questions about the programme, please visit our website https://www.heartburnhealth.org/. If you have a complaint or wish to report a problem about

Heartburn Health, please contact Professor Rebecca Fitzgerald, the Chief Investigator, at cuh.heartburnhealth@nhs.net.

If you would prefer to speak to someone not involved in running the trial, you can contact the CUH Patient Advice and Liaison Service (PALS) at 01223 216756, available Monday to Friday from 9 am to 4 pm.

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 https://www.heartburnhealth.org/.

Share Feedback

Please visit https://www.heartburnhealth.org/useful-information/contact-us/ to share any thoughts or suggestions about the Heartburn Health programme. All feedback is completely anonymous.