Participant Information Sheet

Study title: Colonoscopy check-up in people with Lynch syndrome.

Invitation

We would like to invite you to complete the 'Views, experiences, and challenges of colonoscopy check-up' questionnaire. As you may be aware, people living with Lynch syndrome are recommended to have regular check-up colonoscopies once they reach a certain age. A colonoscopy involves a small camera in a tube being passed into the bottom to look inside the large bowel for signs of cancer and for polyps (growths that sometimes can develop into cancer). We will refer to this as 'colonoscopy check-up'.

We would like to learn about your views, experiences, and challenges of living with Lynch syndrome and having colonoscopy check-up.

If you have a flexible sigmoidoscopy ('flexi sig') for your check-up, this questionnaire is relevant for you too. Where we refer to colonoscopies, please imagine that we are referring to flexible sigmoidoscopies instead.

Please take your time to read the following information carefully and discuss it with others if you wish. Please get in touch with us if you have any questions. Contact details are at the end of this information sheet. We suggest that you keep this information sheet for your records.

What is the purpose of the study?

In the UK, guidelines recommend that people living with Lynch syndrome have colonoscopy check-up every 2 years once they reach a certain age. However, people with Lynch syndrome face many challenges that can make it difficult to have the recommended colonoscopy check-up.

The Cancer Screening & Prevention Research Group (CSPRG) at Imperial College London (https://csprg.org.uk/) is performing a Lynch syndrome research registry pilot study (https://lynchregistry.org.uk/), which we will refer to as the 'registry pilot'. The registry pilot recruited people with Lynch syndrome who were living in England and participating in the Cancer Prevention Programme 3 (CaPP3) trial (http://www.capp3.org/). The recruitment process began in November 2022 and continued for one year.

We will use the 'Views, experiences, and challenges of colonoscopy check-up' questionnaire to collect information from people in the registry pilot. We will analyse this information, together with a few pieces of additional information previously collected as part of the registry pilot (see section 'How will my information be used?' below, page 3).

Our aim is to investigate the following research questions:

- what do people with Lynch syndrome think, go through, and find challenging about living with Lynch syndrome and having colonoscopy check-up?
- what percentage of people in the Lynch syndrome registry pilot are having colonoscopy check-up as recommended in the UK guidelines?
- what factors influence whether a person is more or less likely to have the recommended colonoscopy check-up (including patient factors and healthcare factors)?

You may have heard that starting in 2023, colonoscopy check-up for people living with Lynch syndrome is beginning to be carried out by the National Health Service (NHS) Bowel Cancer Screening Programme (BCSP). During this transition, it remains important to understand how people living with Lynch syndrome are being cared for, what needs to be improved, and which challenges need to be addressed. This research is part of a PhD project.

Why have I been chosen?
We are inviting you to take part because you are in the Lynch syndrome registry pilot, have provided consent to be contacted about future research, and are aged 25 years or older.

Do I have to take part?
It is completely up to you to decide whether or not to take part. If you decide to take part, you are free to withdraw from the research at any time, without giving a reason; you can do this by contacting the Investigator (Emma Robbins, e.robbins@imperial.ac.uk). A decision to withdraw, or a decision not to take part, will not affect your healthcare in any way.

What will happen to me if I take part?
Taking part will involve completing the 'Views, experiences, and challenges of colonoscopy check-up' questionnaire only. It will take around 15 minutes to complete.

What do I have to do?
To take part in the study, you have two options. You can choose between completing PAPER or ONLINE versions of the questionnaire and consent form. The only difference between the paper and online versions is the format.

For the PAPER option, please complete the paper questionnaire and consent form and return them in the freepost envelopes provided (no stamps are required). To keep your completed questionnaire separate from your personal details (name, signature) in your consent form, please return them **separately** using the **large envelope for your questionnaire** and **small envelope for your consent form.**

If you cannot find the paper questionnaire, consent form, or freepost envelopes in the pack you received in the post, please contact us to let us know.

For the ONLINE option, please use the provided web link or QR code. This will allow you to complete and submit the questionnaire and consent form online. The web link and QR code are written on the front page of the paper questionnaire.

Please complete and return/submit your questionnaire and consent form **within 3 weeks** of the day you received your pack in the post.

The paper questionnaire and the web link/QR code for the online questionnaire are meant for your use only. They are connected to you through a code number called a unique study ID. Please don't share a photocopy of the paper questionnaire or the weblink/QR code with anyone else.

How do I give my informed consent to take part?
To give your informed consent to take part, please either complete the paper consent form and return it in the small, freepost envelope provided, or complete the consent form online using the provided web link or QR code, as described above. You may withdraw your consent at any time, for any reason, by contacting the Investigator (Emma Robbins, e.robbins@imperial.ac.uk).

How will my information be used?
If you consent to take part, we will analyse the information collected by the questionnaire to answer our research questions. We will use a few additional pieces of information previously collected, with your informed consent, as part of the Lynch syndrome registry pilot. Only a small number of authorised members of the study team will have access to your information. We will link the information collected by this study questionnaire with the information previously collected about you, when you consented to be part of the registry pilot, using code numbers called unique study IDs. We aim to complete our analyses and share a summary of the results by the end of 2024 (see section 'What happens when the research study stops?' below, page 4).

How will my information be kept safe, secure, and confidential?
This research will comply with data protection laws described in the Data Protection Act 2018 and the General Data Protection Regulation 2016/679. It will comply with the CSPRG Information Governance Policy and NHS Data Security and Protection Toolkit; these describe the precautions that we have in place to ensure that patient information is kept safe and secure, including access restrictions (only allowing the information to be accessed by a small number of authorised members of the study team); firewalls (virtual shields for computer networks); encryption (changing the information to make it unreadable); and regular security checks.

Your confidentiality will be protected throughout the research. When working with your information, we will remove your name and swap it for a code number. Any other information that can identify you ('identifiable information') will be kept secret from everyone except for a few members of the study team, who will access it only when absolutely necessary for the research. Please find our full data confidentiality, privacy notice, and transparency statement below (page 5).

What are the possible disadvantages and risks of taking part?
There are no risks of physical harm associated with completing the questionnaire. A personal data breach is a possible risk; this is when personal information is accidentally or deliberately destroyed, lost, changed, revealed, or accessed by someone who is not supposed to have access to the information. It is our highest priority to protect your personal information and we will take all necessary measures to keep your information safe, secure, and confidential. The policies and precautions that we have in place to ensure this are summarised above (see section 'How will my information be kept safe, secure, and

confidential?', page 3). If a breach of confidentiality occurs, all participants will be notified as soon as possible using their given contact details.

We recognise that because the questionnaire is assessing challenges of living with Lynch syndrome and having colonoscopy check-up, it could possibly lead to negative feelings or emotions such as worry, anxiety, or upset. Please know that your participation in this study is completely voluntary and that if you start the questionnaire, you may skip any questions you prefer not to answer or stop the questionnaire at any time. If you experience negative feelings or emotions because of the questionnaire and feel that you need support, we recommend seeking support from a healthcare professional or through an NHS mental health helpline (https://www.nhs.uk/service-search/mental-health/find-an-urgent-mental-health-helpline). You may also contact us and we can provide details of relevant support services. Your well-being is greatly important to us. You may contact the Investigator (Emma Robbins, e.robbins@imperial.ac.uk) at any time, for any reason.

What are the possible benefits of taking part?
The questionnaire will help us understand what people with Lynch syndrome think, go through, and find challenging about living with the condition and having colonoscopy check-up. This will identify what changes need to be made to improve experiences of colonoscopy check-up for people with Lynch syndrome and help overcome the challenges that they face. We cannot promise that this research will help you directly, but the information we get might help improve the care of people living with Lynch syndrome. Participants might feel fulfilled knowing that their contributions could help improve services and experiences for present and future generations of families living with Lynch syndrome.

What happens when the research study stops?
Once the study is completed, we will share a summary of the results on the registry pilot website (https://lynchregistry.org.uk/) by the end of 2024. If you prefer to receive the results summary in the post, you can select this option on the first page of the questionnaire. We will only post the results summary to people who have completed and returned / submitted the questionnaire. We will also write up the results in an article which we will publish in a peer-reviewed journal. We will provide a link to the article on the registry pilot website. It will not be possible to identify any participant in any publication.

What if something goes wrong?
It is our priority to make sure that no harm is done by taking part in this research. If you are harmed by taking part, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this research, then you should immediately inform the Investigator (Emma Robbins, e.robbins@imperial.ac.uk). The normal NHS complaints mechanisms are also available to you. The Patient Advice and Liaison Service (PALS) offers advice and help in resolving concerns and complaints (https://www.nhs.uk/nhs-services/hospitals/what-is-pals-patient-advice-and-liaison-service/).

Who was involved in developing the research protocol?
The research protocol was developed by the CSPRG, with the help and expertise of:

- Dr Kevin Monahan
    - Honorary Clinical Senior Lecturer at Imperial College London (https://www.imperial.ac.uk/people/k.monahan)
    - Consultant Gastroenterologist and Endoscopist and Lead of the Lynch Syndrome Clinic and the Family Cancer Clinic at St Mark's Hospital, London (https://www.stmarkshospital.nhs.uk/consultants/monahan-kevin/)
- Dr Christian von Wagner
    - Reader in Behavioural Science and Health at University College London (https://www.ucl.ac.uk/epidemiology-health-care/people/von-wagner)
- A group of six patient representatives who have personal lived experience of Lynch syndrome

The patient representatives reviewed the protocol, confirming that it addresses questions important to people living with Lynch syndrome and that the methods for recruiting participants, obtaining informed consent, and collecting information from participants are appropriate and ethically acceptable.

DATA CONFIDENTIALITY, PRIVACY NOTICE, AND TRANSPARENCY STATEMENT
HOW WILL WE USE INFORMATION ABOUT YOU?
Research Study Title: Colonoscopy check-up in people with Lynch syndrome, IRAS 329468.

Imperial College London is the sponsor for this study and will act as the Data Controller for this study. This means that we are responsible for looking after your information and using it appropriately. Imperial College London will keep your personal data for:

- 10 years after the study has finished in relation to data subject consent forms.
- 10 years after the study has completed in relation to primary research data.

The study is expected to finish in December 2024. For more information / confirmation regarding the end date please contact the study team, see 'Where can you find out more about how your information is used' for contact information.

We will need to use information from you for this research project. This information will include your name, date of birth, and contact details. People within the College and study team (see section 'Sharing your information with others') will use this information to do the research or to check your records to make sure that the research is being done properly and the information held (such as contact details) is accurate.

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 keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

As a university, we use personally-identifiable information to conduct research to improve health, care, and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have

agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study.

Our legal basis for using your information under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows:

• Imperial College London - "performance of a task carried out in the public interest"); Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research (https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/).

Where special category personal information is involved (most commonly health data, biometric data and genetic data, racial and ethnic data etc.), Imperial College London relies on "scientific or historical research purposes or statistical purposes".

INTERNATIONAL TRANSFERS

There may be a requirement to transfer information to countries outside the United Kingdom (for example, to a research partner, either within the European Economic Area (EEA) or to other countries outside the EEA). Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a UK adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient research partner that incorporates UK approved standard contractual clauses or utilise another transfer mechanism that safeguards how your personal data is processed.

SHARING YOUR INFORMATION WITH OTHERS

We will only share your personal data with certain third parties for the purposes referred to in this participant information sheet and by relying on the legal basis for processing your data as set out above.

• Other Imperial College London employees (including staff involved directly with the research study or as part of certain secondary activities which may include support functions, internal audits, ensuring accuracy of contact details etc.), Imperial College London agents, contractors, and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.

POTENTIAL USE OF STUDY DATA FOR FUTURE RESEARCH

When you agree to take part in a research study, the information collected either as part of the study or in preparation for the study (such as contact details) may, if you consent, be provided to researchers running other research studies at Imperial College London and in other organisations which may be universities or organisations involved in research in this country or abroad. Your information will only be used to conduct research in accordance with legislation including the GDPR and the UK Policy Framework for Health and Social Care Research (https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/). This information

will not identify you and will not be combined with other information in a way that could identify you, used against you, or used to make decisions about you.

WHAT ARE YOUR CHOICES ABOUT HOW YOUR INFORMATION IS USED?
You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have because some research using your data may have already taken place and this cannot be undone. 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 this could affect the wider study or the accuracy of the data collected. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

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 sending an email to e.robbins@imperial.ac.uk, or
- by ringing us on 020 7594 3021

COMPLAINT
If you wish to raise a complaint about how we have handled your personal data, please contact the research team first by sending an email to e.robbins@imperial.ac.uk, or by ringing us on 020 7594 3021. Following our response, if you are not satisfied, please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502, and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ. If you remain unsatisfied with our response or believe we are processing your personal data in a way that is not lawful, you can complain to the Information Commissioner's Office (ICO)- via www.ico.org.uk. Please note the ICO does recommend that you seek to resolve matters with the data controller (us) first before involving them.

WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?
We will share a summary of the results on the registry pilot website (https://lynchregistry.org.uk/) by the end of 2024. If you prefer to receive the results summary in the post, you can select this option on the first page of the questionnaire. We will only post the results summary to people who have completed and returned/submitted the questionnaire. We will also write up the results in an article which we will publish in a peer-reviewed journal. We will provide a link to the article on the registry pilot website. It will not be possible to identify any participant in any publication.

WHO IS ORGANISING AND FUNDING THE RESEARCH?
The research is sponsored by Imperial College London and funded by Cancer Research UK.

WHO HAS REVIEWED THE STUDY?
The research protocol was reviewed by and received ethical approval from the London - Camden & Kings Cross Research Ethics Committee.

CONTACT FOR FURTHER INFORMATION

If you would like further information, please contact Emma Robbins on the following contact details:

Name: Emma Robbins

Telephone: 020 7594 3021

Email: e.robbins@imperial.ac.uk

It might not always be possible for us to fulfil requests but we will respond within one month. You can follow us on Twitter for updates on our research: @CSPRG_Imperial.

THANK YOU

Thank you very much for taking the time to read this information sheet.