

PARTICIPANT INFORMATION SHEET

Faecal Immunochemical Testing for Polyp Follow-Up

We are inviting you to take part in a research study. Before you decide whether to take part, it is important to understand why the research is being done and what is involved. Please read this leaflet and, if you wish, discuss it with friends, relatives or your GP.

What is the purpose of the study?

We are looking at whether a new and improved home-based stool kit called FIT (faecal immunochemical test) is as good as colonoscopy at detecting polyps in the large bowel. The FIT test detects human blood in stool which would suggest that polyps may be present. The FIT test is different from the one you received last year from the NHS Bowel Cancer Screening Programme. It involves a different detection method and only uses one stool sample. Your colonoscopic surveillance will continue under the NHS Bowel Cancer Screening Programme as normal, regardless of whether or not you participate in this study.

Why have I been chosen?

We are inviting people who participated in the NHS Bowel Cancer Screening Programme, who had polyps removed and were recommended for three yearly follow-up colonoscopy. Our study needs over 8000 participants so we are contacting many people like you all over the country.

Do I have to take part?

It is up to you to decide whether to take part. If you decide to take part you are free to withdraw at any point without giving us your reasons. The quality of medical care you receive in the future will not be affected by your decision.

What is involved if I decide to take part?

We ask you to sign the consent form and complete the enclosed FIT test and post them back as soon as possible. If the test finds traces of blood, you may have new polyps and we will arrange for you to have an early colonoscopy at your usual Screening Centre. Most people will not have any traces of blood detected and will have their follow-up colonoscopy as planned by the NHS Bowel Cancer Screening Programme. Two more FIT tests will be sent to you over the next two years. On each occasion, we will send the results to you within 3 weeks, and inform your GP. Each time you do the test, we will ask you to fill in a short questionnaire telling us how you feel about using the test.

Will my data be kept confidential?

Yes. We have made provisions for all the data to be kept protected and confidential. We will inform your GP of your participation and test results. The study may require access to the information held by the NHS and records collated and maintained by the NHS Information Centre to provide information about your health status. Only the information related to bowel cancer screening and your bowel health will be needed to complete the study. This is to make sure that the information collected for the study is accurate. Your name will not be disclosed in any publication or report.

What if something goes wrong?

It is very unlikely that anything will go wrong. As required by law, Imperial College London holds insurance policies, which apply to research studies. If you experience serious and enduring harm or injury because of taking part in this study, you may be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation. If you are harmed due to someone's negligence, 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 study, then you should immediately inform one of the Chief Investigators:

Sally Benton,
Bowel Cancer Screening Programme,
Southern Programme Hub,
PO Box 1473,
Guildford GU1 9TU

OR
Professor Wendy Atkin,
Cancer Screening and Prevention Research Group,
Imperial College London,
Room 505 Wright Fleming Building,
Norfolk Place,
London W2 1PG

The usual NHS complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the:

Joint Research Office,
Imperial College London and Imperial College Healthcare NHS Trust,
G02, Sir Alexander Fleming Building,
South Kensington,
London SW7 2AZ

PARTICIPANT INFORMATION SHEET (continued)

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What are the possible benefits of taking part?

If the FIT test proves to be as good as colonoscopy in detecting polyps, then it may be used as a method of follow-up in the future, either in combination with colonoscopy or on its own. You may benefit personally from taking part in the study by having polyps detected by the test and removed by colonoscopy earlier than usual.

What are the possible disadvantages of taking part?

Some people may find that using FIT every year makes them more worried about bowel cancer. If your test is positive it may suggest that you have a polyp in your bowel and require a colonoscopy. In some people, there will be no polyps present despite the positive FIT. This is commonly referred to as a 'false positive' test result.

What happens when the study is finished?

We will analyse the data collected during the study and will publish the results in the UK and in international medical journals. All participants will receive a letter informing them of the study results and where they were published.

Who is organising and funding the study?

The Health Technology Assessment Programme, part of the NHS National Institute for Health Research, is funding the study. Imperial College London, University College London and the South of England Hub of the NHS Bowel Cancer Screening Programme are organising and running it.

Who has reviewed the study?

The London - City & East Research Ethics Committee has approved the study.

How do I take part?

If you have decided to take part, please do the following:

- 1 Sign and date the consent form.
- 2 Complete a short questionnaire on the back of the consent form.
- 3 Complete the enclosed FIT kit according to the instructions.
- 4 Put the completed FIT kit and the consent form together in the return envelope provided.

When you have completed the FIT kit, it is important that you return it to us as soon as possible.

Freephone helpline 0800 783 0064

Website: www.fit4followup.org.uk

Thank you very much for reading this document and for taking part in our research. Your contribution is invaluable and may help improve the way people with bowel polyps are followed up.

NHS Bowel Cancer Screening Programme
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