

Report Supplementary Material 1

FIT for Follow-Up study documentation

FIT Reference: <Study_Number>
NHS Number: <NHS_Number>



Bowel Cancer Screening Programme

Southern Programme Hub
PO Box 1473
Guildford
GU1 9TU

Patient <Title> <Forename> <Surname>
Address1
Address2
Address3
Postcode

<Date>

Dear <Patient Title> <Surname>,

FIT for Follow-Up Study

I am writing to you to ask if you would consider participating in a research study called FIT for Follow-Up. This study compares the effectiveness of a simple new test called FIT (Faecal Immunochemical Test) with colonoscopy.

You are being invited to take part in this study because you had polyps removed as part of the NHS Bowel Cancer Screening Programme and it was recommended that you would need a follow-up colonoscopy after 3 years. If you agree to take part in the FIT for Follow-Up Study, you would have one or more FIT tests in addition to your colonoscopy.

The enclosed participant information sheet explains what this important study involves and how your participation can help.

If you have any questions or would like more information, do not hesitate to call our freephone helpline number **<freephone number>**, quoting reference 'FIT for Follow-Up'. Further information can also be found by visiting our website at www.fit4followup.org.uk.

We enclose a FIT kit with instructions for use. If you decide to take part, once you have completed the kit, please return it (along with the completed consent form and questionnaire) as soon as possible in the pre-paid envelope. If possible, post your kit so that it is likely to arrive with us on a weekday, i.e. avoid posting kits on a Friday, weekend or bank holiday.

Thank you for reading this letter. Please keep it for future reference.

Yours sincerely,

Prof Stephen Halloran MBE FRCPath
Director, Bowel Cancer Screening Southern Programme Hub

For office use only.....

<BAR_CODE>
DATE Sample Taken:
...../...../.....
dd mm yyyy
KIT

<Title> <Forename> <Surname>
Address1
Address2
Address3
Postcode
CONSENT
<BAR_CODE>

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 complete 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

Postgraduate Medical School
University of Surrey
Daphne Jackson Road
Guildford GU2 7WG



PARTICIPANT INFORMATION SHEET

Faecal Immunochemical Testing for Polyp Follow-Up

A study examining the effectiveness of a new stool test called FIT to detect polyps that may have grown since your last colonoscopy

Please keep this information leaflet
for future reference.

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:

*Professor Stephen Halloran,
Bowel Cancer Screening Programme,
Postgraduate Medical School,
University of Surrey,
Daphne Jackson Road,
Guildford GU2 7WG*

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*

Person details sticker



CONSENT FORM

Faecal Immunochemical Testing for Polyp Follow-Up

Researchers: Professor W Atkin and Professor S Halloran

Please, put your initials in **each** of the boxes below.

I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason. My medical care or legal rights will not be affected.

I confirm that I have read and understood the Participant Information Sheet (version 2.0, dated 28/11/2011) and have had the opportunity to ask questions.

I understand that, for the duration of the study, information held by the NHS, including records maintained by the NHS Information Centre, may be used to contact me or obtain information related to my bowel cancer screening.

I give permission to responsible individuals from the Research Group or those from appropriate regulatory authorities to have access to the relevant information from my records held by these organisations.

I agree to take part in the above study.

I agree to my GP being updated about my participation in this study.

Your name (Please PRINT)

Today's date (dd/mm/yyyy)

Signature

PLEASE, TURN OVER

PARTICIPANT QUESTIONNAIRE

Please answer the following questions to help us monitor your experience throughout the FIT for Follow-Up Study.

(Please tick your responses)

Was your overall experience of your most recent colonoscopy?			
Not at all acceptable	Not very acceptable	Fairly acceptable	Very acceptable
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Compared with other people of your sex and age, how would you rate your chances of getting bowel cancer?				
Much below average	Below average	Average	Above average	Much above average
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Over the last 2 weeks, how often have you worried about having bowel polyps?			
Not at all	Less than once a week	More than once a week	Every day
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Over the last 2 weeks, how often have you thought about your own chance of developing bowel cancer?			
Not at all	Less than once a week	More than once a week	Every day
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

HOW ARE YOU FEELING RIGHT NOW?

An important aim of this study is to monitor how people feel. Please read each statement below and tick the box that best indicates the way you feel right now.				
	Not at all	Somewhat	Moderately	Very much so
I feel calm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I am tense	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I feel upset	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I am relaxed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I feel content	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I am worried	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

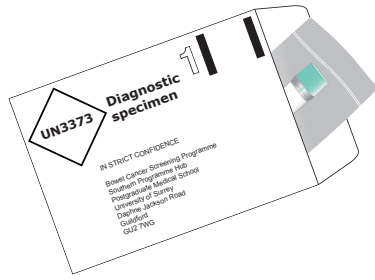
Today's Date <input type="text" value="dd"/> <input type="text" value="mm"/> <input type="text" value="yyyy"/>
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When completed, please return this form together with your FIT kit in the envelope provided.

Thank you for your time



7 Insert the tube into the zip-lock bag and close it firmly.



8 Put the zip-lock bag with tube into the return mailing envelope.

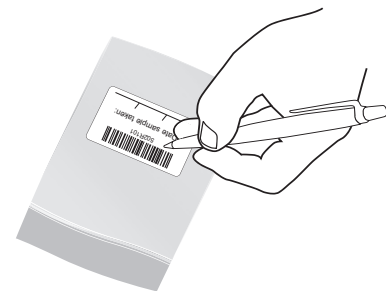
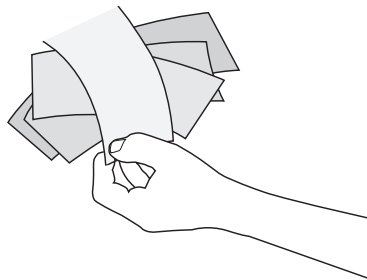
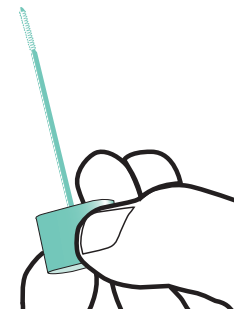
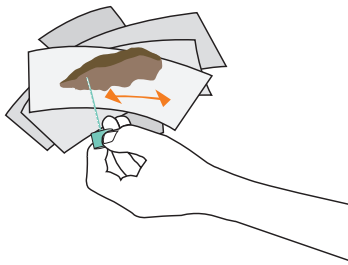
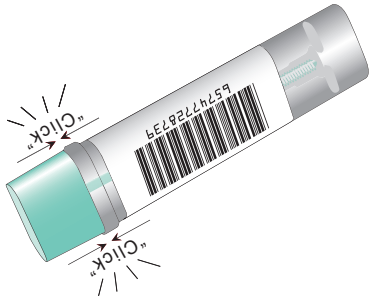


Please check!	
The date I took the sample is on the label on the zip-lock bag.	<input type="checkbox"/>
My test kit is in the zip-lock bag.	<input type="checkbox"/>
The zip-lock bag with the kit is in the return envelope.	<input type="checkbox"/>
Post immediately!	

9 Use this checklist to make sure you have done everything. Seal the envelope and post it right away.

FIT for Follow-Up freephone helpline 0800 783 0064

Please check!	
The date I took the sample is on the label on the zip-lock bag.	<input type="checkbox"/>
My test kit is in the zip-lock bag.	<input type="checkbox"/>
The zip-lock bag with the kit is in the return envelope.	<input type="checkbox"/>
Post immediately!	



 **FIT for Follow-Up**

FIT KIT



**Step-by-step instructions
Start here**



When you are ready to do the test.....



- ① Write the date on the label of the zip-lock bag.



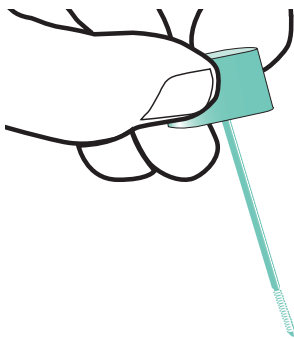
Prepare:
folded pieces of toilet paper
OR
a plastic bag to cover your hand
OR
a clean disposable container



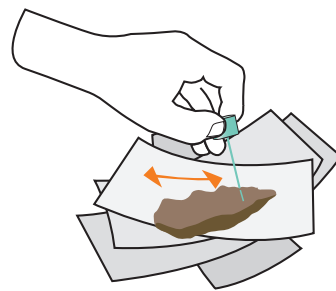
- ② Catch your bowel motion by one of the suggested methods above. The sample should be taken from a bowel motion that has not been in the toilet bowl since this could affect the test result.

- ③ Twist the green cap of the test tube and pull the stick out. Be careful not to spill the small amount of liquid in the tube.

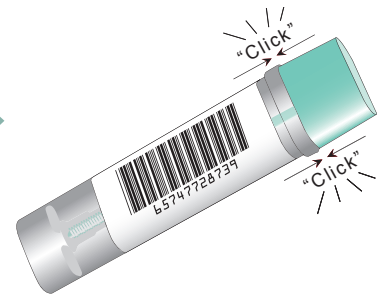
Collecting your sample.....



- ④ Use only the grooved end of the green stick to collect your sample.



- ⑤ Lightly scrape the surface of the bowel motion with the grooved end of the green stick. Only a small amount of stool is needed for the test.



- ⑥ Insert the green stick back into the test tube and push the cap back firmly until closed. DO NOT RE-OPEN.

Returning your sample.....