Participant Information Sheet

Reducing Cancer Risk in Social Networks of Bowel Cancer Survivors

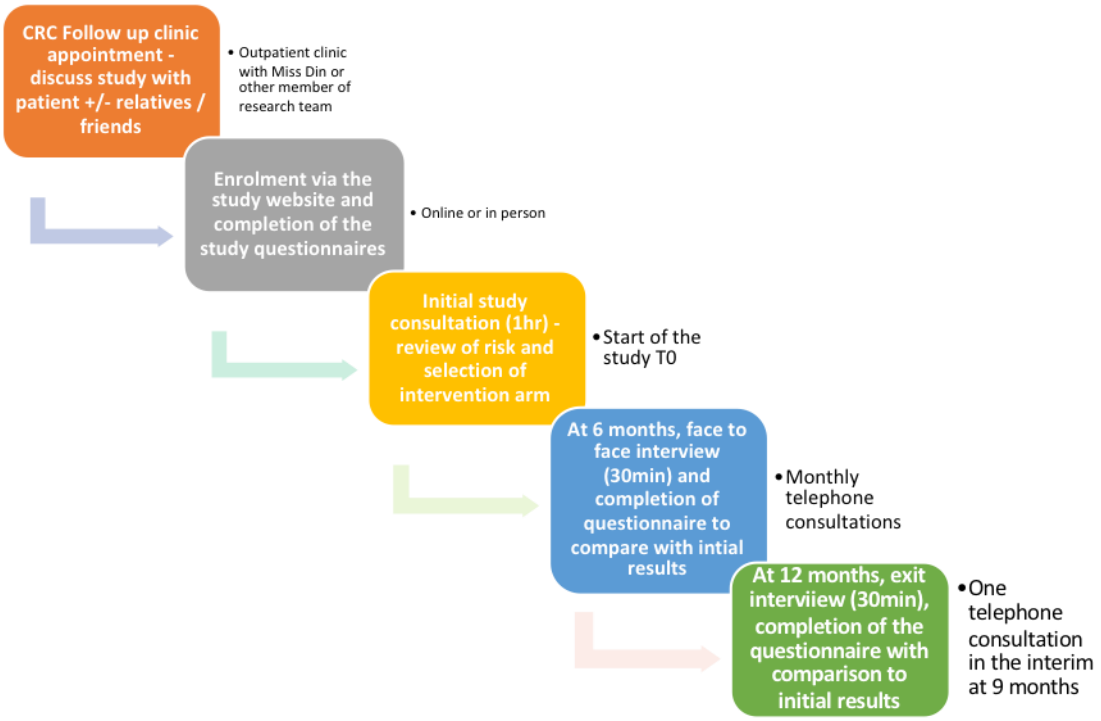
You are invited to take part in a research study. To help you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?
Bowel cancer is both common and potentially preventable in some cases. Some of the recognised risk factors include smoking, diet, obesity and lack of physical exercise. Tackling these risk factors may help reduce an individual's risk of developing bowel cancer. This study aims to help friends and relatives of bowel cancer survivors to consider lifestyle changes which can be implemented to reduce their risk of developing bowel cancer. We aim to recruit up to 20 participants.

Why have I been asked to take part?
You have been asked to take part in this study as you, a relative, a friend or someone you know has recently been diagnosed and treated for bowel cancer.

Do I have to take part?
No, it is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and will be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you or your relative / friend receive, or your legal rights. Before participating you should consider if this will affect any insurance you have and seek advice if necessary.

What will happen if I take part?
Once you agree to take part in the study, we will ask you to complete either an online or telephone questionnaire. Based on the answers you provide, we will estimate your personalised risk (either average, above average or below average risk) using a validated online colorectal (bowel) cancer risk calculator (www.ccrisktool.cancer.gov). Together with you, we will identify how one of these risk factors highlighted by the questionnaire may be modified by introducing lifestyle changes, that you feel you would like to focus on. The study will particularly focus on risks such as diet, physical activity, alcohol or smoking. Any risk factors that have been highlighted will be discussed with you and any recommended interventions will be agreed between you and the research team. Once identified and agreed upon, there will be a period of active intervention (**See below**) for 6 months during which the research team will monitor your progress monthly and provide support as required. At the end of the 6 month period, there will be a face-to-face or telephone exit interview to gain feedback on your experience and to discuss the results of the intervention. At 12 months from enrolment in the study, there will be a final interview to assess sustainability.



Physical activity intervention

We will aim to help promote increased physical activity through regular walks, running, or cycling. To track your level of physical activity (and inactivity), you will be given a Fitbit® for the 6 months of active intervention (this will be returned at the end of the 6 month period). The Fitbit® is a device which is worn around the wrist that monitors a number of parameters including steps taken, distance travelled, heart rate, sedentary periods, etc. In addition, we will discuss a personalised plan to increase your physical activity based on your ability and your current level of physical activity. If you choose this intervention, it can be started within a week of enrolling into the study. Our recommendation would be at least 30minutes of increased physical activity each day i.e. 210 mins per week. For those who have no set routine, 30 minutes of walking will be recommended, for those who currently walk routinely, a 30-minute run will be recommended, and for those who currently run routinely, a cycle for 30 minutes or other increased physical activity will be recommended following discussions with the research team. Throughout the 6-month period, we will track your progress through an online platform but will also be informal monthly follow-up from when you join the study.

Dietary intervention

If you elect to tackle dietary changes and associated weight loss, you will be assessed at an initial one-hour consultation (in person or over the telephone) with a research dietician. A food frequency questionnaire will be reviewed with you. In addition, you will be asked to keep a 48-hour food diary to guide eating patterns. Advice on red meat reduction and increased fibre in the diet will be tailored to the individual. A target weight reduction or reduction in the number of calories consumed per week will be discussed and agreed with the dietician. Alcohol consumption and target reduction will also be discussed where relevant. Following the initial meeting with the dietician, there will be a

monthly 15-minute telephone consultation over the 6-months of active intervention.

Smoking cessation
You will be referred to the existing Smoke-Free team and invited to attend an initial consultation at which time an individualised plan will be created. You will be assessed by 'stop smoking' advisors, products and support options discussed and then offered weekly behavioural support for 12 weeks by the smoking cessation service, following which this will be monitored on a monthly basis via telephone by the research team.

We anticipate no significant inconvenience if you take part, face-to-face visits will be made at your convenience and there will be opportunity to cover any travel costs to a **maximum of £10 per visit**.

What are the possible benefits of taking part?
You may get a direct benefit from taking part in this study. Implementing some of the lifestyle changes may help reduce your individual risk of developing bowel cancer and may improve your general health and fitness.

What are the possible disadvantages and risks of taking part?
There should be no direct risk of harm to you from taking part in the study. We anticipate a maximum of 3 1-hour visits for face-to-face interviews with regards to time commitment.

Will I benefit financially?
No. There will be no financial reward for taking part in the study. However, we recognise that you may need to travel a significant distance for face-to-face interviews and we will cover any travel expensed incurred in attending these meetings to a maximum of £10 per visit.

What if there is a problem?
If you have a concern about any aspect of this study please contact the study team (Gregory Ekatah or Angie Balfour – as detailed below) who will do their best to answer your questions.

In the unlikely event that something goes wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against NHS Lothian but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

What happens if I don't want to carry on with the study?
In the event that you withdraw consent, you will no longer be expected to take part in the study. If taking part in the physical activity arm of the study, the Fitbit will be returned to the study team. Data collected to the point of withdrawal may be included in analysis unless explicit instructions from you to the contrary. There will be no adverse effect on the care provided to any relatives of yours.

What happens when the study is finished?
At the end of the research (12 months from enrolling) we will have a feedback meeting and discuss your progress.

Will my taking part in the study be kept confidential?
All the information we collect during the study period will be kept confidential and there are strict laws which safeguard your privacy at every stage.

Study researchers will not access your medical records (nor those of your relatives) during this research and will only use information provided by you and data collected from you. Once you have signed the consent form, we will inform your GP that you are taking part in this study

To ensure that the study is being run correctly, we will ask your consent for responsible representatives from the Sponsor and NHS Institution to access your data collected during the study, where it is relevant to you taking part in this research. The Sponsor is responsible for overall management of the study and providing insurance and indemnity.

What will happen to the results of the study?
The data collected from the study will be analysed by the research team in Edinburgh. Your information will not be shared with research teams outside of Edinburgh. Once analysed, we will share our final results with our co-researchers based in England as well as Cancer Research UK (CRUK). The study will then be written up as a publication following analysis of the data. You will not be identifiable in any published results.

Who is organising the research?
This study has been co-sponsored by University of Edinburgh and NHS Lothian and funded by Cancer Research UK (CRUK).

Who has reviewed the study?
The study proposal has been reviewed by CRUK. All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC). A favourable ethical opinion has been obtained from the REC. NHS management approval has also been obtained.

If you have any further questions about the study please contact Gregory Ekatah (gregory.ekatah@nhs.net) or Angie Balfour (angie.balfour@nhslothian.scot.nhs.uk)

If you would like to discuss this study with someone independent of the study please contact: Mr Hugh Paterson, Consultant Colorectal Surgeon, Western General Hospital, Edinburgh**. Email:** hugh.paterson@nhslothian.scot.nhs.uk

If you wish to make a complaint about the study please contact NHS Lothian:

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