Study Title: Decision-making in Inflammatory Bowel Disease Dysplasia

Patient Information Sheet
(Interviews and Questionnaires)

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<td>Chief Investigator, Study Co-ordinator &amp; Principle Investigator</td>
<td>Dr Misha Kabir</td>
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We would like to invite you to take part in a research study. Your participation is strictly voluntary, meaning that you may or may not choose to take part. To decide whether or not you want to be part of this research, the risks and possible benefits of the study will be described in this form so that you can make an informed decision. Before you decide whether 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.

Please ask us if there is anything that is unclear to you or if you would like more information. Take time to decide whether or not you wish to take part.

Before you start reading this, have a look at the descriptions of some of the medical terms we will use in the study:

**Colon**: Large bowel

**Surveillance colonoscopy**: This is performed in patients with Inflammatory Bowel Disease that affects most of the colon (either Ulcerative colitis or Crohn’s colitis) and who have had the disease for more than 8 years. These patients are at a slightly increased risk of getting colon cancer compared to the general population. Most patients, however, will not get colon cancer. A surveillance colonoscopy is like a normal colonoscopy and is normally performed every 1, 3 or 5 years. It is called a surveillance colonoscopy because the specialist will be looking for early changes in the colon which can be treated before cancer develops.

**Dysplasia**: This is a word to describe the early changes in the colon that can be found on surveillance colonoscopy. Dysplasia means there are changes in the cells in the lining of the bowel wall. These changes are considered pre-cancerous as they can change into cancer over time. In most patients who have a surveillance colonoscopy, we do not find dysplasia. If the specialist does find dysplasia in the colon, most of the time they are able to remove it completely during the colonoscopy. However, sometimes this cannot be removed. In these cases, the specialist may recommend surgery to have the colon removed to stop cancer developing in the future. Patients who do not want to have surgery can continue to be monitored with more frequent surveillance colonoscopies but the risk of cancer still remains.

**Colectomy**: Surgery to remove the large bowel.

1. **What is the purpose of the study?**

We want to know more about your thoughts on dysplasia (see description above) and the treatments for it. You may have been diagnosed with these early changes before and decided to have surgery or continue having surveillance colonoscopies. We would like to know more about how you made your decision and if there was anything we could have done to make the information you received clearer to you. If you have never been diagnosed with these early changes (dysplasia) before, we would still like to hear about what you know about this condition. We would like to know what would make you choose to have surgery or continue surveillance if you were hypothetically diagnosed with dysplasia and it could not be removed during the colonoscopy.
Using your valuable opinions, we aim to develop a support tool that future Inflammatory Bowel Disease (IBD) patients, diagnosed with dysplasia, can use to help them choose the right treatment for them.

2. Why have I been chosen?

We are inviting you to participate as you have Ulcerative Colitis or Crohn’s disease affecting the colon and have had it for at least 8 years.

3. Do I have to take part?

No. It is totally up to you to decide whether you take part or not. If you do not wish to take part in the study you do not have to give a reason. You will not be disadvantaged in any way, and it will not affect the standard of care you receive.

If you initially decide to take part and then change your mind at a later date you are free to withdraw without providing a reason. Once again you will not be disadvantaged in any way and your care will not be affected.

4. What will happen to me if I take part?

If you would like to complete the questionnaire online then please use this URL link provided: https://goo.gl/forms/aup3AH946t6GoS523. Alternatively, please email misha.kabir1@nhs.net if you would like to have it emailed or posted to you. You can choose to complete the questionnaire anonymously by completing the questionnaire but not providing your contact details at the end. However, you do need to complete your contact details if you would like to be considered for a prize draw for retail vouchers of your choice to a value of £100. Also, please note that by returning the form anonymously we will not know that it is you who has completed the form and therefore we will not be able to let you know the results of the study once it is completed.

In addition, you can also participate in a focus group interview or a one-to-one interview. However, you can choose to complete the questionnaire only and not participate in the interviews. The purpose of these interviews is to enable you to share your experiences as an IBD patient and your opinions on how your care should be delivered and communicated to you. We want to interview a diverse group of people in order to accurately reflect the opinions of all IBD patients. Therefore, we can also arrange an interpreter for you if you are more comfortable speaking in a different language to English. Please let us know that you will need the assistance of an interpreter by emailing misha.kabir1@nhs.net.

We will learn a lot from hearing about your thoughts during the interviews. In order to make sure that we accurately interpret your thoughts in the interview, we will need to audio record the interview on a digital recorder which will then be typed up. This record will be kept anonymised and confidential. The audio recording will be deleted once the anonymised typed up record has been checked for accuracy. To thank you for any participation in our interviews, we will give you a cash compensation for your time and travel (£30 for one-to-one interview; £40 for focus group interview). All the interviews will be led by Dr Misha Kabir, who is a

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research doctor based at St Mark’s Hospital. She is a gastroenterology registrar doctor with a research interest in improving how doctors communicate with their IBD patients.

If you would like to take part in an interview then please email misha.kabir1@nhs.net for more information or leave your contact details at the end of the questionnaire. If you would like to participate in a one-to-one interview and would prefer to speak in another language, then we can happily provide an interpreter for you. Just let us know.

5. **What will I need to do in a focus group interview?**

The focus group interview will take place in a private meeting room at St Mark’s Hospital, Harrow, London, on a specified date arranged with you and will last 60 to 90 minutes. There will also be 5-7 other IBD patients with you in the room. The interviewer will ask your group a few questions on your opinions about dysplasia, the risk of colon cancer, surgery and colonoscopy surveillance. We will also ask about your thoughts on how doctors should communicate to patients about these topics. You will all then be given turns to voice your thoughts. We hope to generate an interesting discussion between all members of the group. The setting will be informal and relaxed. It is usual for some participants in a group to be more vocal than others, but the interviewer will act as a moderator to ensure that everyone has their say! We also will ask all the participants to respect the confidentiality of everyone else in the room and not reveal your identity to any outsiders who have not participated in the research.

6. **What will I need to do in a one-to-one interview?**

You will be interviewed by the research fellow, Dr Misha Kabir, on a one-to-one basis. The interview will last 30 to 45 minutes and she will ask you questions on your opinions about dysplasia, the risk of colon cancer, surgery, colonoscopy surveillance and how doctors should communicate to you about all these topics. We will aim the interview setting to be private but informal so that you feel relaxed enough to voice your thoughts. Depending on your availability and preference, the interview can take place in a private meeting room at St Mark’s Hospital, in a quiet room at your place of work, or on the phone or Skype. Please note that the environment would need to be quiet so that the quality of the audio recording is high. If the interview does not take place at St Mark’s Hospital, you will still receive a cash compensation to thank you for your time but this will not include travel costs.

7. **What are the possible disadvantages and risks of taking part?**

We do not anticipate any major risks with you participating in this research but we are sensitive to the fact that talking about or even thinking hypothetically about getting cancer or a pre-cancerous condition such as dysplasia could be upsetting. If you have any questions or concerns about the study, then please contact Dr Misha Kabir for more information, before you agree to participate. If you think that the issues discussed in this study might be too upsetting or make you anxious, then we would suggest that you do not take part and thank you for having taken the time to read this information.

If you do take part in an interview, you may start to talk about something that upsets you or you may hear someone else’s story that upsets you. The interviewer will then pause the audio recording to allow you time to consider whether you want to withdraw from participating in the
study. Your welfare is our utmost priority and your decision to withdraw will not affect the standard of care you subsequently receive.

8. **What are the possible benefits of taking part?**

Taking part in this study will not affect the standard of your usual clinical care. However, the information we get from this study may help us to communicate with and treat patients with IBD better in the future.

9. **What will happen if I don’t want to carry on with the study?**

You are free to withdraw from the study at any time and do not have to give a reason. Your future treatment will not be affected.

10. **What happens when the research study stops?**

We will only contact you after the research study stops if you have requested to be kept informed of the study findings.

11. **What if something goes wrong?**

London North West University Hospitals NHS Trust holds insurance policies which apply to this study. If you experience serious and enduring harm or injury as a result of taking part in this study, you may be eligible to claim compensation without having to prove that London North West University Hospitals NHS Trust are at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone’s negligence, then you may have grounds for 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 the Chief Investigator Dr. Misha Kabir (contact details found at the end of the form). The normal National Health Service complaints mechanisms are also available. If you want to speak to or make a complaint to somebody independent from the research team then please contact the Patient Advice and Liaison Service (PALS) at London North West University Healthcare NHS Trust on LNWH-tr.PALS@nhs.net or 020 8869 5118.

12. **Will my taking part in this study be kept confidential?**

Yes. All information which is collected about you during the course of the research will be kept strictly confidential.

London North West Healthcare University NHS Trust is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake 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 properly. If you have taken part in an interview then London North West Healthcare University NHS Trust will keep identifiable information about you for 2 years after the study has finished. If you have completed a questionnaire only, then we will not keep your identifiable information about you for as long as that. Once your answers from the questionnaire have been transferred to our database, we will delete any identifiable data from them. All data will be stored on password protected software and in locked and dedicated
rooms at St Mark’s Hospital and the hospital where you are treated which will only be accessible by authorised personnel. All data will be stored in this manner until the study has closed, and then personal identifiable data will be kept in secure storage in the St Mark’s and Northwick Park Research & Development Department two years after the study has closed. 

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how patient information is used in health and care research from the Health Research Authority at www.hra.nhs.uk/information-about-patients. If you would like to speak directly to someone regarding how your data will be used then please email misha.kabir1@nhs.net.

13. What will happen to the results of the research study?

The results of the study will be published in journals and the researchers will present the results at conferences and seminars. Please note that you will not be identified in any report/publication. If you are interviewed, the researcher will ask you whether you would like to see the copy of the typed-up report of your interview and the final results as presented in a published journal. If you would be interested, then the report/publication will be sent to you by post or by email as per your preference.

14. Who is organising and funding the research?

This research is being sponsored by London North West University Healthcare NHS Trust. The study is being funded by an award given to the lead researcher, Dr Misha Kabir, by the registered charity Guts UK and the pharmaceutical company Dr Falk. The doctor conducting this research project is not being paid for including you in this study.

15. Who has reviewed the study?

This study has been reviewed by the South Central - Berkshire Research Ethics Committee and the Health Research Authority who have both given their approval for the study to proceed (IRAS ID no: 249003; REC ref no 18/SC/0466).

Contact for Further Information

Dr. Misha Kabir (Clinical Research Fellow)
Wolfson Endoscopy Unit (level 2), St Mark’s Academic Institute
Watford Road,
Harrow, Middlesex HA1 3UJ
Email: misha.kabir1@nhs.net

You will be given a copy of the patient information sheet and a signed consent form to keep if you agree to participate in an interview.

Thank you for reading this patient information sheet. We are thankful for any time you can spare to participate in this study.