PRESTO: Development of a new patient reported outcome measure to assess psychosocial response to stoma in people with inflammatory bowel disease

We would like to invite you to take part in this original study being carried out by a team of researchers led by Professor Lesley Dibley, Centre for Chronic Illness and Ageing, Institute for Lifecourse Development at The University of Greenwich, London. Lesley is a chronic illness researcher and has researched patient experiences of inflammatory bowel disease (IBD) since 2008. The research team includes IBD & rehabilitation researchers, a health psychologist and a biomedical ethicist. This study aims to develop a new questionnaire informed by the experiences of those living with IBD, so that they can report outcomes relevant to the issues that matter to them.

What is this study about? We aim to produce a new questionnaire, designed with input from people with IBD who have had stoma surgery. This kind of questionnaire is called a patient-reported outcome measure (PROM). We have done the first phases of the study which involved collecting lots of data about peoples' experiences of life with a stoma and turning the information into the new PROM. We now need to check that it works as we intend.

Why do you need my help? You are being asked to participate as you might be able to help in completing the new PROM. We are looking for people who have been diagnosed with IBD, are at least 18 years old and either have or are waiting for a stoma.

Do I have to take part? It is up to you to decide whether to take part in this study or not. You should only take part if you want to. Choosing not to take part will not disadvantage you in any way. Before you decide if you want to take part, it is important that you understand why the research is being carried out and what you would be asked to do. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear, or if you would like more information. You can contact us using the details on the final page.

What will happen if I do decide to take part? If you decide to take part, you will be asked to complete the new PROM twice, about two weeks apart. You will do this online using the secure Qualtrics survey platform. The first time you complete it, you will also be asked to complete several other quality-of-life questionnaires so that we can see how the new PROM compares to those. You will need to complete all of these in one session which will take around 40 minutes The second time, you will only complete the PROM and one of the quality-of-life questionnaires which will take around 15 minutes.

Before you take part, we will remind you about the study and give you the chance to ask questions by emailing us using the contact details at the bottom of this information. We want to be certain you are fully informed and that you wish to take part. You will be asked to give your consent for your involvement in the study at both points before completing the questionnaires on Qualtrics.

You will need to have access to a computer or smart phone with internet connection to access Qualtrics and complete the questionnaires. There is a link at the bottom of this information sheet which will take you to the Qualtrics page. Once there, you can read this information again and if you decide to take part, give your consent and then complete the new PROM and the other questionnaires. If you do this, you will then receive an email two weeks later asking you to complete the new PROM again and one of the quality-of-life-questionnaires.

Who can take part? We are looking for people who:

- Are at least 18 years old
- have a confirmed diagnosis of IBD that can be confirmed
- and have ***EITHER***:
    - had stoma surgery within the last 10 years
    - or are awaiting stoma surgery

We are sorry, but people who had stoma surgery because of a condition other than IBD cannot take part.

Are there any risks to me in taking part? There may be a small risk of you becoming a little distressed when you answer questions about your well-being. If you feel distressed, you can seek support via your GP or use the Crohn's and Colitis UK helpline by phone (0300 222 5700) or email (helpline@crohnsandcolitis.org.uk).

What if I change my mind about being involved? Even if you decide to take part, you are still free to withdraw from the study without consequence. You do not have to give a reason for withdrawing. You can withdraw up to December 2026. After then, the data you provide will have been analysed and combined with all other data. If you complete the first set of questionnaires but then do not complete the second set two weeks later, we will keep the information you provided the first time unless you contact us to withdraw from the study.

How will we use information about you? We will need to use information from you for this research project. This information will include your gender, type of diagnosis, age at diagnosis, age now, whether you have had surgery and if not, when this is planned for, your highest level of education, current employment status, and county of residence within the UK. We will use this information to check that you are eligible for the research; to do the research; to describe the people who took part without identifying anyone; and to check your records to make sure that the research is being done properly.

We will also ask for your email address so that we can:

1) send you an email two weeks after you complete the first set of questionnaires to ask you to complete the second set and

2) link your first and second set of responses.

Your email address will be stored with your data within the secure Qualtrics server and available only to the researchers listed in this information sheet. Once we have finished collecting data, we will download it into an excel spreadsheet and permanently delete it from Qualtrics. We will remove your email address from the data and give you a unique identification (ID) number. We will create a second password protected spreadsheet linking your email addresses to your ID number. That way, if you want to withdraw your data, you can email us, and we will be able to identify which data is yours and delete it, but other researchers who help with analysing the data will not know your identity. All data will be stored on secure University of Greenwich SharePoint folder.

In any reports or publications, anything which identifies you will be removed, such as names, the hospital you attended, or the name of your surgeon. Other data we collect from you such as treatment type, and employment status will be reported anonymously.

University of Greenwich is the sponsor of this research. University of Greenwich is responsible for looking after your information. We will keep all information about you safe and secure by using password protected files accessible only to the research team.

How will we use information about you after the study ends? 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. We will keep your study data for a maximum of 10 of years on the University of Greenwich's central server. The study data will then be fully anonymised and securely archived or destroyed.

What are my choices about how my information is used? You have the right to ask us to access, remove, change, or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

If you agree to take part in this study, you will have the option to take part in similar ethically approved research taking place at University of Greenwich using your anonymised data, meaning there will be nothing to identify you in future research.

Where can you find out more about how your information is used? You can find out more about how we use your information:

- by asking one of the research team using our contact details below
- by sending an email to the University of Greenwich Data Protection Officer and University Secretary, Peter Garrod at compliance@gre.ac.uk

What are the possible benefits? You may benefit from being able to talk freely about your concerns and experiences. What you tell us will enable us to evidence the long-term impacts of IBD and stoma surgery and help us develop the new PROM. It will help us continue our research to provide information which informs government policy (such as that related to definitions of disability), employment rights (including enabling practices to facilitate employment in people facing challenges) and health care (including understanding that the consequences of IBD do not end when clinical treatment is concluded). We will send you a summary of the findings of this part of the study, unless you tell us you do not want to receive this.

What will you do with the results of the study? The new PROM will enable people who are diagnosed with IBD and have a stoma to accurately report the impact of their diagnosis and treatment on all areas of their life. We will also publish at least two academic papers arising from the whole study and present our findings at a range of medical and nursing conferences. All data used in academic papers, conference presentations and reports will be anonymous. You will not be able to be identified.

Who is funding the study? This study is not receiving external funding but is being hosted by the University of Greenwich.

What happens now? You should spend at least 24 hours deciding if you want to take part or not. If you ***do not*** wish to take part, you do not have to do anything else.

If you ***do*** want to take part, please follow the link below which will take you to the Qualtrics page. Here you can read this information sheet again and if you decide to take part, you can give your informed consent and then complete the questionnaires:

You can access the survey in Qualtrics by:

- Clicking here
- Or typing the following address into your browser: http://bit.ly/4r7cXZc
- Or scanning the QR code:

What if I need to know more, before I can decide? For information and independent guidance about taking part in medical research, please visit: http://www.nihr.ac.uk/get-involved/take-part-in-research.htm

What if there is a problem? If you have a concern about any aspect of this study, or need more information, please contact Professor Lesley Dibley using the details below. Lesley will do her best to answer your questions. If you have a complaint, you should talk to a member of the research team who will try to answer your questions.

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This study is sponsored by the University of Greenwich. The sponsor will, at all times, maintain adequate insurance in relation to the study, in respect of any claims brought by or on behalf of a study participant.

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