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 phase of the study and have collected lots of data about peoples' experiences of life with a stoma. We now need to turn this into the new PROM, and then 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 with either an interview or in completing the new questionnaire or both. 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? We will check that you are eligible for the study, and ask you to confirm your gender, age at diagnosis, age now, whether you have had surgery, highest level of education, current employment status, and county of residence within the UK. This information enables us to describe the people who took part, without identifying anyone. We need to do this when the study is published, so that we can show that we had the right people taking part. There are two parts of the study.

You can choose whether to take part in either one or both of the studies below:

A) **Cognitive interviews:** this will involve one one-to-one online interview in which we will ask you to complete the draft PROM. This will take place on Microsoft Teams with Professor Lesley Dibley or other members of the research team, at a time to suit you. The focus is on how easy it is to understand the questions, to check for any misinterpretation or language issues, or any other difficulties associated with filling the draft PROM in. This will take about 30 minutes of your time. We will then make design changes to the draft PROM, based on your comments.

B) **Validation**: you will be asked to complete the finalised new PROM twice, about two weeks apart. You will do this online using Qualtrics survey platform. The first time you complete it, you will also be asked to complete several other quality-of-life measures so that we can see how the new PROM compares to those. This will take around 40 minutes. The second time, you will only complete the PROM and this should take about 20 minutes.

We will start doing the cognitive interviews now and continue until approximately September 2025. The validation study will begin around September 2025 and continue until around December 2025. You can choose to take part in one or both parts of the study.

Before you take part, we will remind you about the study and give you the chance to ask questions. 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.

For the cognitive interview, we will take your consent just before the interview on Microsoft Teams. We will talk through the consent form and ask if you agree to each point. We will then sign it to confirm that you have consented. We will record this process using Microsoft Teams recording facility. For the validation study you will be asked to give consent using Qualtrics at both time points before starting the PROM.

You will need to have access to a computer with internet connection for the cognitive interview and validation. For the cognitive interview we will be using Microsoft Teams. You do not need to have Teams installed on your device, as you can join via the web.

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
    - or are awaiting stoma surgery

Even if you offer to take part, you may not be invited to do so if more people offer to take part in the study than are needed. We will let you know one way or the other. We are sorry, but people who had stoma surgery because of a condition other than IBD cannot take part.

How will you record the cognitive interviews? Cognitive interviews will be carried out on Microsoft Teams. We will use the automatic transcription facility which means that Microsoft Teams will produce a written word document of our conversation. We will not record any audio.

Are there any risks to me in taking part? There may be a small risk of you becoming a little distressed when you talk about your experiences. The team members who will do the interviews are all skilled researchers with extensive experience of caring for people with health conditions in clinical settings and during research projects. They will make sure that you feel emotionally safe before they leave you when your interview is over. If you do continue to feel distressed after the researcher has left, you can seek support via your GP or please call Crohn's and Colitis UK helpline on 0300 222 5700 or helpline@crohnsandcolitis.org.uk

What about confidentiality and anonymity? Your personal details (name, contact details) will remain confidential to members of the research team and will not be shared with anyone else. We will only use these details to contact you about this study. Personal data will be stored in line with the General Data Protection Regulations (GDPR) and deleted as soon as the study is completed.

Your identity will not be linked to your data meaning participation will be anonymous. We will use a study number to represent you instead. 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.

Your identity will be known by the team member who interviews you and the person who contacts you to arrange the interview. We will store the audio recording of the consent taking process separately from any of your other information. The digital transcripts will be kept securely on the University's central server for 10 years.

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 at any time without consequence. You do not have to give a reason for withdrawing. You can withdraw up to September 2025 for cognitive interviews and up to December 2025 for the validation study. After then, the data you provide will have been analysed and combined with all other data.

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 contact Dr Tiffeny James using the details below:

Dr Tiffeny James, Research Fellow
University of Greenwich | Institute for Lifecourse Development
Email: tiffeny.james@greenwich.ac.uk

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.

Professor Lesley Dibley Professor of Qualitative Nursing Research
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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