UREC Reference Number: UREC/21.1.6.8

STUDY TITLE: PRESTO: Development of a new patient reported outcome measure (PROM) to assess psychosocial response to stoma in people with IBD

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 IBD since 2008. The research team includes IBD & rehabilitation researchers, a health psychologist and a biomedical ethicist. This study aims to develop a new PROM informed by the experiences of those living with IBD and a stoma, so that they can report outcomes relevant to the issues that matter to them.

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 is this study about? We are designing a new Patient-Reported Outcome Measure (PROM) to provide clinicians with a new quality of life psychosocial outcomes tool to assess outcomes in people who have been diagnosed with IBD and who have a stoma. We have done the first phase of the study and have collected data from people about their experiences of life with a stoma. We now need to deliver a DELPHI study to determine consensus on the most important items to include in the new PROM, from the clinicians' perspective.

Why do you need my help? You are being asked to participate as you are either a surgeon, gastroenterologist or specialist nurse working with people with IBD. Your expertise and contribution will ensure we produce a new PROM which meets patients' and clinicians' needs. We would like to ask for your help with our online Delphi study.

What will happen if I do decide to take part? We will check some demographic details with you (profession / specialism, job title, years working with people with IBD) to confirm your eligibility for the study. We will use this information when we publish the study to anonymously describe participants, thus verifying that we had the right people taking part. For the Delphi study, you will be asked to rank items for the draft PROM in order of importance. This may take four or five rounds, continuing until consensus is reached. Each round of ranking will take about 20 minutes of your time, and we expect four or five rounds. We are also inviting people with IBD and their significant others to participate in this DELPHI survey, so that we produce a PROM which contains items that are important to patients, their significant others, and clinicians.

Before you take part, we will remind you about the study and give you the chance to ask questions, so that you may give informed consent. You will be asked to sign a consent form confirming your involvement in the study, which we will countersign and send back to you as a PDF that cannot be altered.

How will the research be done? The DELPHI study will take place online. You will be sent an electronic link to access the online forms via a programme called Qualtrics, and given a unique Study ID number to use. You will not be able to be identified.

Who can take part? We are looking for male and female surgeons, gastroenterologists and specialist nurses from all four member countries of the UK, with a range of ages, who:

- have current registration with the professional regulatory body relevant to their specialism
- are currently practicing as a specialist gastroenterologist or colorectal surgeon OR
- specialist nurses caring for people with IBD and stomas AND
- have at least three years' experience in the specialist role

You will need to have access to a private computer with internet connection, to avoid any difficulties with NHS firewalls. 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.

Are there any risks to me in taking part? The study is very low risk for clinicians and no adverse consequences are anticipated.

What about confidentiality and anonymity? Your personal details (name, contact details) will remain confidential to Professor Lesley Dibley, Dr Ryan Essex & Dr Ann Hanrahan, (the research fellows on the study) 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. Other demographic data we collect from you will be reported anonymously. You will not be able to be identified.

If you agree to take part in the online Delphi survey, your identity will not be linked to your data – participation will be anonymous. In any reports or publications, anything which identifies you will be removed. We will use a study number or pseudonym to represent you instead.

What are the possible benefits? You may benefit from being able to contribute to the development of this new PROM, which will in turn help to influence clinical practice by producing a tool which will facilitate psychosocial assessment and support of your patients when they require stoma surgery for IBD. Better psychosocial support will likely improve the patient experience and personal outcomes in the longer term.. 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 with 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 paper 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. We also anticipate a follow-on study to use the new PROM in a future longitudinal cohort study.

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

Do I have to take part? It is up to you to decide whether to take part in this study or not. Even if you decide to take part, you are still free to withdraw from the study at any time up to 30th April 2023 without consequence. After then, the data you provide will have been analysed and combined with all other data. You do not have to give a reason for withdrawing.

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 us using the details below:

Professor Lesley Dibley Professor of Qualitative Nursing Research
University of Greenwich | Institute for Lifecourse Development | Centre for Chronic Illness and Ageing
Email: L.B.Dibley@Greenwich.ac.uk
I am currently working from home: please contact me by email

Dr Ryan Essex, Research Fellow
University of Greenwich | Institute for Lifecourse Development | Centre for Chronic Illness and Ageing
Email: R.W.Essex@Greenwich.ac.uk | Mobile: +447591 065535
I am currently working from home: please contact me by email, or via the study mobile number provided

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 above. 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.

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