INFORMATION SHEET FOR PARTICIPANTS WITH ULCERATIVE COLITIS

Ethical Clearance Reference Number: HR/DP-23/24-33688

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of project

Building resilience to stress after a diagnosis of ulcerative colitis: a co-design study

Invitation Paragraph

I would like to invite you to participate in this research study. Before you decide whether you want to take part, it is important to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please contact me, if there is anything that is not clear or if you would like more information.

What is the purpose of the project?

The aim of this project is to co-design and develop an intervention to build resilience to stress amongst people newly diagnosed with ulcerative colitis.

Stress and the symptoms and psychological impact of ulcerative colitis all interact to affect the quality of life of those with the disease. It can affect all aspects of life, including work, leisure and relationships, as well as changing the way we perceive ourselves and our mental health. Developing resilience to stress at an early stage of living with ulcerative colitis may protect against poorer physical and mental health in the future. To date, no research study has developed an intervention to improve resilience to stress in people with newly diagnosed ulcerative colitis.

This study aims to develop a prototype resilience intervention in meaningful collaboration with people with ulcerative colitis and those who support them, using principles from Design Thinking and Experience-based co-design.

How will the research be done?

The study will involve a total of 30 participants, up to 15 people with ulcerative colitis and 15 healthcare professionals and other interested parties (such as people from UC charities, family members etc.). Participants will need to attend two online workshops, although each workshop will be run twice on different dates to accommodate the participants' availability. Each workshop will be 2.5 hours long.

A doctoral researcher (PhD student) with ulcerative colitis and/or her supervisors who have experience in conducting co-design workshops will facilitate the workshops to identify key stressors and co-design an intervention to support developing corresponding resilience factors.

Why have I been invited to take part?

You have been kind enough to express an interest in this study or we have identified you as someone who may be interested in taking part. All participants need to be able to participate in workshops in English. You can participate in this project if you have been diagnosed with ulcerative colitis for at least 6 months and are 16 years old or older.

What will happen if I take part?

If you decide to take part, you will be asked to attend two online workshops using Microsoft Teams which will be video- and audio-recorded. We will provide you with a Participant Consent Form, where you will consent to take part in the two online workshops. This will be provided via e-mail to be signed before the first workshop and you will be given a copy to keep.

In the first workshop, you will be asked to contribute individually and as part of group discussions to identify key stressors and prioritise areas for a resilience intervention to focus on. People with ulcerative colitis will get an opportunity to work together as a group as well as with healthcare professionals and others. You will be given information on current research on stress and UC, and how co-design can be used to develop interventions. We will discuss topics such as what are the early sources of stress, which of these are most important to address, and what can be done about these stressors. After the first workshop, the research team will put together the workshop outcomes, compare these with existing interventions and develop a prototype resilience intervention.

In the second workshop, participants will develop and test the prototype intervention, discussing the content, format and usability of the prototype as well as any improvements. It will also help propose success measures, methods, and resources for a future research study to see if the intervention is feasible.

Do I have to take part?

Participation is completely voluntary. You should only take part if you want to and choosing not to take part will not disadvantage you in any way. Participation or non-participation will not impact your own access to IBD support groups or NHS services. Once you have read the information sheet, please contact us if you have any questions that will help you decide about taking part.

What are the possible risks of taking part?

You will be asked to discuss your experiences of stress and ulcerative colitis, which may be uncomfortable or upsetting. You are under no obligation to disclose anything which would make you uncomfortable. We will be asking all participants to respect each other's contributions and to not disclose personal details outside of the workshops. The research team is very familiar with many of the sensitive issues involved in UC and will look to support all participants at all stages of the study.

What are the possible benefits of taking part?

The information gathered will be used to develop an intervention to improve resilience to stress for people with newly diagnosed UC. Although this may not benefit you personally, the information you give may help influence and shape support for people with UC in the future. Co-design studies also offer an opportunity to learn from the experiences of others and some participants in previous research have found that talking about these experiences has had a positive emotional impact on them.

What if I change my mind about taking part?

You are free to withdraw at any point of the project, despite having given consent to take part. You should let the research team know that you wish to withdraw and do not have to provide a reason for doing so. Withdrawing from the project will not affect you in any way. Unfortunately, you will not be able to withdraw your data from the project after you have participated in a workshop, as your contribution will be included in summarised data**.** No further details will be sought. If you have any questions or need more information about this study, please contact the lead researcher using the contact details below.

What will happen to the results of the project?

You will not be personally identifiable by name or any personal details in any report of this research. However, the information gathered will be used to guide the intervention development without using your name or details. The results of the project will be summarised in a PhD thesis and submitted for journal publication to disseminate to professional audiences. King's College London has an open access publication policy ensuring that all manuscripts are made freely available, enabling global access to clinicians, researchers, charities, patients and the public. We will also provide summaries to the charities involved in the research (Crohn's & Colitis UK and Bowel Research UK).

Data handling and confidentiality

Your data will be processed under the terms of UK data protection law (including the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018).

The study is being conducted by a PhD student in collaboration with King's College London (KCL), who are the sponsor for this study. The lead researcher is Jacqueline Black, and she will act as the data controller for your data collected as part of this study, which means she is responsible for looking after your information and using it properly.

If you decide to take part in this study, a secure database (containing your name and the details you supply) will be maintained by the lead researcher, stored electronically and accessed by a password. It will be saved on the server at King's College London and will

always remain confidential. These details will only be accessed by the study research team at KCL.

The video and audio recordings of the workshops will be stored on a secure server and accessed via a secure network and KCL OneDrive. Access is restricted to authorised personnel only and via secure password-controlled access. The audio recording will be destroyed on completion of the study.

At the end of the study, identifiable information from the consent forms, demographics and recordings will be deleted to ensure full anonymity. No participants will be identifiable in the final report. Data will be stored in a secure online storage repository provided by King's College London for up to 10 years, before being destroyed as confidential waste, in accordance with the sponsor's requirement.

Data Protection Statement

If you would like more information about how your data will be processed under the terms of UK data protection laws please visit the link below:
https://www.kcl.ac.uk/research/support/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research

Who should I contact for further information?

If you have any questions or require more information about this project, please contact me using the following contact details:

Jacqueline Black, PhD Student
E-mail: jacqueline.black@kcl.ac.uk

What if I have further questions, or if something goes wrong?
If this project has harmed you in any way or if you wish to make a complaint about the conduct of the project, you can contact King's College London using the details below for further advice and information:
The Chair, Health Faculties RESC (Purple), rec@kcl.ac.uk

Supervisor: Dr Wladzia Czuber-Dochan, Reader in Nursing and Applied Health Research, King's College London, Faculty of Nursing, Midwifery & Palliative Care, James Clerk Maxwell Building, Room 3.37, 57 Waterloo Road, London SE1 8WA
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Supervisor: Professor Christine Norton, Professor of Clinical Nursing Research, King's College London, Faculty of Nursing, Midwifery & Palliative Care, James Clerk Maxwell Building, Room 2.25, 57 Waterloo Road, London SE1 8WA
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Support service for people with ulcerative colitis
Crohn's & Colitis UK helpline
Tel: 03002225700
E-mail: helpline@crohnsandcolitis.org.uk

Thank you for reading this information sheet and considering taking part in this research.