PARTICIPANT INFORMATION SHEET
(Family member/partner)

Ethical Clearance Reference Number:

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of project

Supporting psychosocial and emotional well-being and resilience in family members of people with IBD: RCT feasibility and acceptability study

Invitation paragraph

I would like to invite you to participate in this research project which forms part of my PhD study at King's College London (KCL). Before you decide whether you want to take part, it is important for you 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. Feel free to ask me if there is anything that is not clear, or if you would like more information.

About the study

We have developed an online internet-based resource (FamilyBridge for IBD website) for family members of people with Inflammatory Bowel disease (IBD), which includes Crohn's disease and ulcerative colitis. This platform offers peer support and information about IBD, strategies for coping and managing the condition, and guidance on self-care for caregivers.

What is the purpose of the feasibility and acceptability study?

We want to find out if our FamilyBridge for IBD website is practical and well-liked by family members of individuals with IBD. We are also testing how we plan to evaluate it. This will help us decide whether we should go ahead with a full evaluation of the programme. Your insights will be valuable in shaping the future of this website.

How will the research be done?

You will be asked to complete a short questionnaire (*Participant Eligibility Form*) to see if you meet our inclusion criteria. If you do, you will be asked to complete a consent form and some questionnaires (which will take about 1 hr). You will then be randomly allocated to one of 2 groups. One group will have access to the intervention (FamilyBridge for IBD website), while the other group will be on a 16-week waiting list before they can have access to the intervention. If you are in the intervention group, you will have continuous access to the FamilyBridge for IBD website 24/7 for 8 weeks.

To log into the website, you will be provided with a username and password specific to you. We encourage you to spend at least an hour per week engaging with the website and its content, and to use the content in a way that suits your individual needs. If you ever need help using the website, we are here for you (just reach out to use with any questions). You will find instructions within the programme itself, and our online coordinator is just an email away.

Our FamilyBridge for IBD website provides education, a peer forum for sharing experiences, and various interactive features. The website is divided into three main components, designed to provide informative content about IBD, aiming to enhance your understanding of the condition, improve your coping skills, and boost your resilience. The modules cover how to support someone with IBD, strengthen family relationships, and practice self-care. We provide links to additional resources and frequently asked questions to further assist you. On the website, you will find educational materials in various formats, including expert videos, video animations, toolkits, and downloadable fact sheets in both HTML and PDF formats. We also offer a "Peer Support Forum", where you can connect with others going through similar experiences. It is all about fostering a sense of community and support.

For those in the waitlist control group, no need to worry! You will gain access to the FamilyBridge for IBD website once the trial is completed (16 weeks after being allocated to the group). Access to the website will be available approximately 8 weeks after your registration.

Why have I been invited to take part?

You can participate in this project if:

- You are living with or have lived with an individual with IBD including parents, partner or spouse, child and siblings
- You are aged 16 years old or above
- You personally do not have IBD
- You are able to write and speak in English so that you can understand the study information and the website
- There is only one participant per family unit allowed

You cannot participate in the study if:

- You are a friend or colleague of the patient diagnosed with IBD
- You are aged below 16 years old
- You have never co-habited with the patient
- You are not fluent in written and spoken English (to understand the study information and procedures)

What will happen if I take part?

If you decide to take part, we will ask you to complete and return a signed consent form and the

baseline questionnaires via email (T0). First, you will be randomly assigned to either the intervention group (the FamilyBridge for IBD website) or the waitlist control group. In the intervention group you will be given access to the FamilyBridge for IBD website for 8 weeks. You will be encouraged to spend at least an hour per week engaging with the website as you feel necessary. For both the intervention group and the waitlist control group, you will be asked to complete a mental well-being questionnaire after 4 weeks (T1). This questionnaire, which includes questions such as 'Have you been feeling optimistic about the future?' will take no more than 15 minutes. At 8 weeks (T2), you will receive additional questionnaires to complete before exiting the study, including questions like 'Do you feel angry when you are around your relative?', which should take no more than 45 minutes to complete. At the point of exiting the intervention at 8 weeks, you will be offered information about participating in an exit interview. You can choose to exit the study with or without participating in the interview. If you express interested in online exit interview, we will reach out to you after the 8-week intervention period. Participants receiving the intervention and those on the waitlist will both be eligible to attend an exit interview. We will send you an email invitation with a separate information sheet and consent form. We will also follow-up with you at 16 weeks (T3), and you will be asked to complete the same questionnaires as at 8 weeks (T2).

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 upon your family member or your own access to IBD support groups or healthcare. Once you have read this information sheet, please contact us if you have any questions that will help you make a decision about taking part.

What are the possible risks of taking part?

In this study, we aim to provide valuable information and foster shared experiences among family members of individuals with IBD. We understand that the topics covered can sometimes be sensitive and emotionally challenging. While there is no direct risk to your safety, we acknowledge that discussing bowel disorders, family dynamics, and the psychological aspects of the disease can sometimes be distressing. We recognise that IBD is a private and potentially embarrassing condition, and these discussions may bring up emotional responses.

To minimise any potential distress, we have taken several precautions. Our research team has experience in comforting participants who may feel distressed during the study. We are here to help if you encounter any emotional difficulties. The resource also includes information on how to reach out to us or external support sources if needed. You can discuss any concerns with our research team, we will get back to you within 24 hours to arrange a time to discuss your concerns and give you support. The research supervisors are experienced in dealing with sensitive health issues.

You can always contact your GP or Trust IBD healthcare team for additional support. We have also included information about other sources of help, such as the Crohn's & Colitis UK helpline, at the end of this participant information sheet, should you require further assistance. Your well-being is important to us, and we are committed to making this experience as comfortable and supportive as possible. If you have any questions or concerns, please don't hesitate to reach out to us.

What are the possible benefits of taking part?

The information gathered will be used to develop an intervention to improve the quality of life of the family members of people diagnosed with IBD in future studies. Although this may not benefit you personally, the information you give may help influence and shape IBD services in the future. You may request a summary of the final report on the study once the study is finished at the end of 2024. We hope to make the FamilyBridge online resource freely accessible to family members of individuals with IBD like you in the future.

Data handling and confidentiality

Your privacy and data protection are important to us. We want to ensure that your information is handled securely and in compliance with UK data protection laws, including the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018.

This study is a collaborative effort involving a PhD student, her supervisors, and KCL, which serves as the sponsor. KCL, as an institution, is the Data Controller responsible for your data. It will act as the data controller, ensuring that your information is handled properly.

Only authorised participants can safely access the resource by using their unique username and password. We kindly ask all participants to follow the ground rules, which will be sent to everyone via email at the same time as the instructions for using the website, to maintain a safe and supportive online environment.

All data collection and analysis will take place within KCL premises. We will keep a secure database containing your name, work details, and contact information. This database is electronically stored and password-protected on the KCL server. It will always remain confidential and will only be accessible to the study research team at KCL.

We will anonymise information during data collection by using unique participant IDs (used on transcripts) and consent form ID numbers. A password-protected codebook matching these IDs will be created and stored separately from anonymised data. No personal names or identifying information will be used in any publications or documents resulting from this study. The date for when all data will no longer be stored in an identifiable form is 31/01/2025.

Your privacy and the security of your data are our top priorities. If you have any questions or concerns, please feel free to reach out to us. Thank you for being a part of our research community.

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

What if I change my mind about taking part?

You have the right to withdraw from the study at any time, even after giving consent to participate. Withdrawing from the project will not affect you in any way. Your right of refusal to participate will be respected throughout the project, and your reasons will be ascertained if possible. However, you do not have to provide a reason for withdrawing if you do not wish to. We will retain the data collected up to the point of your withdrawal, including baseline data and responses to assessments conducted during the study. This data will be kept for analysis purposes, and will be de-identified or anonymised to protect participant confidentiality. However, you are able to withdraw your data from the project until 31st August 2024. After this date, the point of data analysis will no longer be possible (due to the committed use of data from all participants in merged analysis). 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?

The information gathered will be used to guide the intervention refinement without using your name or details. The results of the project will be summarised in thesis for PhD programme. We will submit the results for publication in multidisciplinary academic journals (such as *Gut*, *Inflammatory Bowel Diseases*, or *Journal of Crohn's & Colitis*) to disseminate to professional audiences. KCL has an open access publication policy ensuring that all manuscripts will be made freely available, enabling global access to clinicians, researchers, charities, patients and the general public. We will also provide summaries to the charities Crohn's & Colitis UK and Bowel Research UK.

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:

Parichat Thapwong, PhD Student

KCL, Faculty of Nursing, Midwifery & Palliative Care
James Clerk Maxwell Building, 57 Waterloo Road, London SE1 8WA

E-mail: Parichat.thapwong@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:

Lead 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
E-mail: wladzia.czuber-dochan@kcl.ac.uk, Tel: 020 7848 3531

Support service for participants
Crohn's & Colitis UK helpline
Tel: 03002225700
E-mail: helpline@crohnsandcolitis.org.uk

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