ISRCTN61071324 https://doi.org/10.1186/ISRCTN61071324

Can we use an online intervention supporting psychosocial and emotional well-being in family members of individuals with inflammatory bowel disease (IBD)?

Submission date
18/01/2024

Recruitment status
No longer recruiting

Registration date
19/01/2024

Overall study status
Completed

Last Edited
28/02/2024

Condition category
Digestive System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
An online internet-based resource, known as the FamilyBridge for IBD website, has been developed to assist family members of individuals with Inflammatory Bowel Disease (IBD), including Crohn's disease and ulcerative colitis. This platform provides resources for peer support and information on IBD, as well as strategies for coping with and managing the condition. Additionally, it offers guidance on self-care for both primary caregivers and other family members. The objective is to assess the practicality and acceptance of the FamilyBridge for IBD website among family members of those with IBD. Furthermore, an ongoing examination of the planned evaluation methods will inform the decision on whether to proceed with a comprehensive evaluation of the program.

Who can participate?
• Individuals living with or having lived with someone with IBD, including parents, partners, spouses, children, and siblings.
• Participants aged 16 years or above.
• Those who personally do not have IBD.
• Individuals who can write and speak in English to understand the study information and the website.
• Only one participant per family unit is allowed.

What does the study involve?
After signing the consent form and completing the baseline questionnaires, participants will be randomly allocated to one of two groups. One group will receive access to the intervention (FamilyBridge for IBD website), while the other group will be placed on a 16-week waiting list before gaining access to the intervention. Participants in the intervention group will have continuous access to the FamilyBridge for IBD website 24/7 for eight weeks.
To log into the website, participants will receive a unique username and password. Participants are encouraged to spend at least one hour per week engaging with the website's content,

adapting its use to their individual needs. Support is available if needed; participants can reach out to us with any questions. Instructions are provided within the program, and assistance is available via email through our online coordinator.
For participants in the waitlist control group, access to the FamilyBridge for IBD website will be granted once the trial is completed (16 weeks after group allocation). Website access will be available approximately eight weeks after registration.

What are the possible benefits and risks of participating?
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 participants personally, the information participants give may help influence and shape IBD services in the future. Participants may request a summary of the final report on the study once the study is finished at the end of 2024.

There is a potential risk of participants becoming distressed when reading the provided information or sharing their emotionally challenging experiences. This distress may arise from the sensitive and embarrassing nature of bowel disorders, the intricacies of family dynamics, and the emotional impact that discussions about the psychological aspects of the disease can have on family members of individuals with IBD. To minimise any potential distress that might occur during participation in this study, we have implemented several precautions. In case of distress, the research team, which has extensive experience in comforting distressed patients, will be available to assist. The resource also provides information on how participants can seek support from both the project team and external sources.

Where is the study run from?
King's College London (UK)

When is the study starting and how long is it expected to run for?
November 2023 to November 2024

Who is funding the study?
European Crohn's and Colitis Organisation (Austria)

Who is the main contact
Parichat Thapwong, k1815045@kcl.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Miss Parichat Thapwong

ORCID ID
https://orcid.org/0000-0001-5222-6739

Contact details
57 Waterloo Road
London
United Kingdom

SE1 8WA
+44 7710023181
K1815045@kcl.ac.uk

Additional identifiers

Protocol serial number
HR/DP-23/24-40544

Study information

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

Study objectives
This study aims:
1. To assess the feasibility of a future definitive RCT by monitoring recruitment and retention rates, outcome measure completion, and reasons for nonparticipation.
2. To evaluate the acceptability, feasibility, and utility of a web-based online intervention as a whole and of each of its individual components, with the goal of refining the intervention as needed.
3. To identify appropriate primary outcome measures for a definitive RCT and produce means and confidence intervals for calculating effect sizes to inform the design of a definitive trial.
4. To identify and assess the methods and outcome measures for a process evaluation of a future definitive RCT.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/01/2024, King’s College London Research Ethics Committee (Research Ethics Office, 3rd Floor, 5-11 Lavington Street, London, SE1 0NZ, United Kingdom; -; rec@kcl.ac.uk), ref: HR/DP-23/24-40544

Primary study design
Interventional

Study design
Two-arm feasibility randomized controlled trial with an embedded qualitative evaluation

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Supporting psychosocial and emotional well-being and resilience in family members of people with inflammatory bowel disease (IBD)

Interventions

The web-based online intervention delivers psychoeducation, a peer forum, and incorporates various interactive components.
Following the completion of baseline questionnaires, participants allocated to the intervention group will be granted continuous 24/7 access to the online intervention for a duration of 8 weeks. From the outset, participants will be encouraged to engage with the intervention for a minimum of one hour per week, with flexibility to select the content to their specific needs. Participants will receive support in utilising the intervention, including instructional information integrated within the programme, as well as access to assistance via the online coordinator's email. After the 16-week trial period, the waitlist control group will be granted access to the website.
Participants in the control group will have access for 8 weeks after their registration on the website.

Randomisation will be performed after participants have provided informed consent and completed and returned the baseline questionnaire. Participants will be randomly allocated to either the online resource (website) or waitlist control arm, using a 2:1 ratio generated in the Statistical Package for Social Sciences (SPSS). The randomisation sequence was generated electronically by an independent statistician with no prior patient contact. The trial coordinator, who will maintain blinding until this stage, will then access the randomisation database to allocate participants into two groups. However, it's important to note that, given the nature of the intervention, neither the participants, the statistician, the research team, nor the website moderator will be able to remain blinded to the treatment allocation after randomisation.

Intervention Type
Behavioural

Primary outcome(s)
In this feasibility study, we will gauge the outcome by measures as outlined below:
1. Recruitment: Recruitment will be quantitatively evaluated by tracking the following participant counts:
1.1. Those expressing interest in taking part and sent Participant Information Sheet (PIS)
1.2. Participants asking further questions
1.3. Participants who have provided their consent
1.4. Participants who have been randomised into the study

1.5. Additionally, we will provide a description, including sex, age, the relationship with the person with IBD, and the types of IBD, of the individuals who were excluded to assist in identifying possible future eligibility criteria. We will also actively seek reasons for non-participation to gain insights into this aspect of the study. However, participants do not have to provide a reason for withdrawing if they do not wish to.

2. Retention: We will assess retention by analysing the withdrawal rates during the intervention and by evaluating the rates of participants who furnish both baseline and follow-up data. Additionally, we will inquire about the reasons behind participants declining to continue with the intervention or with the research. However, participants do not have to provide a reason for withdrawing if they do not wish to.

3. The feasibility of using potential clinical outcomes: We will quantitatively evaluate this outcome by:
3.1. Examining the completion rates for data collection forms involves assessing both the return of outcomes and identifying missing individual items.

3.2. Assessing the appropriateness and diversity of the data to serve as outcome measures for clinical effectiveness.

4. Acceptance, adherence to and fidelity of the intervention will be assessed by:
4.1. Analysing feedback, reflections, and insights shared by participants through exit interviews.
4.2. Evaluate the competence in organising and moderating the website.
4.3. Analysing usage patterns (number and length of log-ins)

5. To inform the process evaluation for the future definitive trial, we will:
5.1. Assess the feasibility and challenges of scaling up the process evaluation to a larger study.
5.2. Evaluate the acceptability and appropriateness of the interview process and identify any potential barriers to participation.
5.3. Identify factors that may facilitate or hinder the successful implementation of the intervention in a larger study.
5.4. Test and refine measures for assessing the reach, dose, and fidelity of the intervention.

Progression criteria:
The outcome measure relating to recruitment, retention, and adherence/fidelity will be assessed using Red-Amber-Green (RAG) criteria, which are defined as follows:
1. Confirmation of adequate recruitment for a definitive trial.
Go: 48 or more family members recruited over 4 months;
Review and consider revising: 30-47 family members recruited over 4 months;
Stop: < 30 family members recruited over 4 months
2. Confirmation of adequate retention for definitive trial
Go: 80% or more participants retained
Review and consider revising: 65-79% participants retained
Stop: < 65% participants retained
3. Confirmation of adequate fidelity to the intervention
Go: 80% or more of participants in intervention group view information giving or engage blog sharing or peer group forum; 1 hour or more per week will be spent in the intervention.
Review and consider revising: 50-79 % of participants in intervention group read information giving or engage blog sharing or peer group forum; 30 mins-1 hr per week will be spent in the intervention.
Stop: < 50% of participants in intervention group read information giving or engage blog sharing or peer group forum; < 30 mins per week will be spent logged in to the intervention.

The criteria for assessing the progress based on the data related to the completion of outcome measures will be evaluated using the following progression criteria.
Go: < 10% missing data in each completed questionnaire booklet and/or < 10% of questionnaires not returned at all
Review: > 10% missing data in each completed questionnaire booklet and/or >10% not returned at all

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
30/11/2024

Eligibility

Key inclusion criteria
1. Living with or have lived with an individual with IBD including parents, partner or spouse, child and siblings
2. Aged 16 years old or above
3. No IBD themselves
4. Able to write and speak in English so that you can understand the study information and the website.
5. Only one participant per family unit

Participant type(s)
Carer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 Years

Sex
All

Key exclusion criteria
1. Friend or colleague of the patient diagnosed with IBD
2. Aged below 16 years old
3. Never co-habited
4. Insufficient ability with written and spoken English to understand the study information and procedures

Date of first enrolment
15/03/2024

Date of final enrolment
30/05/2024

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
King's College London
57 Waterloo Road
London
United Kingdom
SE1 8WA

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Research organisation

Funder Name
European Crohn's and Colitis Organisation

Alternative Name(s)
ECCO

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
Austria

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.0	20/12/2023	19/01/2024	No	Yes