ISRCTN30800023 https://doi.org/10.1186/ISRCTN30800023

Persistence of gastrointestinal symptoms in irritable bowel syndrome and ulcerative colitis: from risk factors to modification

Submission date
12/07/2021

Recruitment status
No longer recruiting

Registration date
21/07/2021

Overall study status
Completed

Last Edited
17/12/2025

Condition category
Digestive System

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Current plain English summary as of 26/11/2021:
Background and study aims:
Ulcerative colitis (UC) and irritable bowel syndrome (IBS) are distressing chronic diseases associated with abdominal pain and altered bowel habits of unknown origin. Results from previous studies indicate that, across both diseases, increased levels of illness-related anxiety and dysfunctional symptom expectations contribute to symptom persistence. Thus, comparing both disorders with regard to common and disease-specific factors in the persistence and modification of gastrointestinal symptoms seems justified. Our primary hypothesis is that persistent gastrointestinal symptoms in UC and IBS can be improved by modifying dysfunctional symptom expectations and illness-related anxiety using expectation management strategies.

Who can participate?
Adults over the age of 17 with UC or IBS suffering from at least moderate gastrointestinal symptoms.

What does the study involve?
To assess the extent to which persistent somatic symptoms are modifiable in adult patients with UC and IBS, we will conduct an observer-blinded, 3-arm randomised controlled proof-of-concept trial. A total of 117 patients with UC and 117 patients with IBS will be randomly allocated into 3 groups of equal size: targeted expectation management aiming to reduce illness-related anxiety and dysfunctional symptom expectations in addition to standard care (intervention 1), non-specific supportive treatment in addition to standard care (intervention 2), or standard care only (control). Both active intervention groups will comprise 3 individual online consultation sessions and a booster session after 3 months. The primary outcome is baseline to post-interventional change in gastrointestinal symptom severity. For outcome assessment, study participants complete online self-report questionnaires at five measurement points over 1 year. Blood and stool samples are collected at the baseline assessment and after 3 months.

What are the possible benefits and risks of participating?
There is a potential that participants in the two intervention groups of the SOMAGUT-RCT study

will benefit from the interventions in terms of fewer gastrointestinal symptoms and reduced illness anxiety. The participants will also contribute to a better understanding of the effectiveness and mechanisms of action of a targeted expectation management intervention for persistent gastrointestinal symptoms and to the further advancement of evidence-based intervention strategies. To the best of our knowledge, for the participants, there is no risk for serious adverse events caused by the application of the study interventions.

Where is the study run from?
The SOMA.GUT-RCT is being conducted by the University Medical Centre Hamburg-Eppendorf, Hamburg, Germany. Since it is an online study, people with ulcerative colitis or irritable bowel syndrome from all over Germany can participate.

When is the study starting and how long is it expected to run for?
April 2020 to March 2025

Who is funding the study?
Deutsche Forschungsgemeinschaft, DFG (German Research Foundation)

Who is the main contact?
Prof. Dr. Bernd Löwe, b.loewe@uke.de

Previous plain English summary:
Background and study aims:
Ulcerative colitis (UC) and irritable bowel syndrome (IBS) are distressing chronic diseases associated with abdominal pain and altered bowel habits of unknown origin. Results from previous studies indicate that, across both diseases, increased levels of illness anxiety and dysfunctional symptom expectations contribute to symptom persistence. Thus, comparing both disorders with regard to common and disease-specific factors in the persistence and modification of gastrointestinal symptoms seems justified. Our primary hypothesis is that persistent gastrointestinal symptoms in UC and IBS can be improved by modifying dysfunctional symptom expectations and illness-related anxiety using expectation management strategies.

Who can participate?
Adults over the age of 17 with UC or IBS suffering from at least moderate gastrointestinal symptoms.

What does the study involve?
To assess the extent to which persistent somatic symptoms are modifiable in adult patients with UC and IBS, we will conduct an observer-blinded, 3-arm randomised controlled proof-of-concept trial. A total of 117 patients with UC and 117 patients with IBS will be randomly allocated into 3 groups of equal size: targeted expectation management aiming to reduce illness-related anxiety and dysfunctional symptom expectations in addition to standard care (intervention 1), non-specific supportive treatment in addition to standard care (intervention 2), or standard care only (control). Both active intervention groups will comprise 3 individual online consultation sessions and a booster session after 3 months. The primary outcome is baseline to post-interventional change in gastrointestinal symptom severity. For outcome assessment, study participants complete online self-report questionnaires at five measurement points over 1 year. Blood samples are collected at the baseline assessment and after 3 months; stool samples are collected at the baseline assessment.

What are the possible benefits and risks of participating?
There is a potential that participants in the two intervention groups of the SOMAGUT-RCT study

will benefit from the interventions in terms of fewer gastrointestinal symptoms and reduced illness anxiety. The participants will also contribute to a better understanding of the effectiveness and mechanisms of action of a targeted expectation management intervention for persistent gastrointestinal symptoms and to the further advancement of evidence-based intervention strategies. To the best of our knowledge, for the participants, there is no risk for serious adverse events caused by the application of the study interventions.

Where is the study run from?
The SOMAGUT-RCT is being conducted by the University Medical Centre Hamburg-Eppendorf, Hamburg, Germany. Since it is an online study, people with ulcerative colitis or irritable bowel syndrome from all over Germany can participate.

When is the study starting and how long is it expected to run for?
April 2020 to March 2025

Who is funding the study?
Deutsche Forschungsgemeinschaft, DFG (German Research Foundation)

Who is the main contact?
Prof. Dr. Bernd Löwe, b.loewe@uke.de

Contact information

Type(s)
Scientific

Contact name
Prof Bernd Löwe

ORCID ID
https://orcid.org/0000-0003-4220-3378

Contact details
University Medical Centre Hamburg-Eppendorf, Martinistraße 52
Hamburg
Germany
20246
+49 40 7410 59733
b.loewe@uke.de

Type(s)
Public

Contact name
Prof Bernd Löwe

ORCID ID
https://orcid.org/0000-0003-4220-3378

Contact details

University Medical Centre Hamburg-Eppendorf, Martinistraße 52
Hamburg
Germany
20246
+49 40 7410 59733
b.loewe@uke.de

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
DFG grant numbers LO 766/22-1 and LO 368/11-1

Study information

Scientific Title
Persistence of gastrointestinal symptoms in irritable bowel syndrome and ulcerative colitis: a 3-arm randomised controlled trial

Acronym
SOMA.GUT-RCT

Study objectives
Current study hypothesis as of 26/11/2021:
Hypothesis 1: Persistent gastrointestinal symptoms in ulcerative colitis (UC) and irritable bowel syndrome (IBS) can be improved by modifying dysfunctional symptom expectations and illness-related anxiety using expectation management strategies.
Hypothesis 2: In addition, further biological, psychological, and social factors contributing to the persistence of gastrointestinal symptoms in both UC and IBS can be identified.

Previous study hypothesis:
Hypothesis 1: Persistent gastrointestinal symptoms in ulcerative colitis (UC) and irritable bowel syndrome (IBS) can be improved by modifying dysfunctional symptom expectations and illness anxiety using expectation management strategies.
Hypothesis 2: In addition, further biological, psychological, and social factors contributing to the persistence of gastrointestinal symptoms in both UC and IBS can be identified.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/01/2021, Ethics Committee of the Hamburg Medical Association (Ethik-Kommission der Ärztekammer Hamburg, Weidestraße 122 b, 22083, Hamburg, Germany; +49 40 202299-240; ethik@aekhh.de), ref: 2020-10198-BO-ff

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Gastrointestinal symptoms in patients with irritable bowel syndrome or ulcerative colitis

Interventions
Current intervention as of 26/11/2021:
We will use the design of a three-arm randomised-controlled trial (RCT).
A fixed randomisation schedule, stratified by diagnostic group and sex, will be programmed and conducted electronically.

Experimental intervention 1 (GUT.EXPECT + SC):
This experimental intervention consists of an expectation management intervention (GUT. EXPECT) in addition to standard care (SC). The manualised intervention primarily aims at optimising expectations about symptoms, treatment outcome, and coping strategies and at reducing illness-related anxiety. The design of the intervention is based on the preferences expressed by patients in a pilot study, the demonstrated effectiveness of the expectation management intervention from the PSY-HEART and the PSY-BREAST trials, and other previous studies. The intervention consists of 3 individual online consultation sessions in intervals of 2 weeks each and a booster session after 3 months, with each session lasting 45 minutes. Homework will be given after each session to deepen the acquired skills. The intervention thus addresses the topics "dealing with anxiety", "improving expectations" as well as patients' need for information about their disease.

Experimental intervention 2 (GUT.SUPPORT + SC):
This experimental intervention consists of a non-specific supportive intervention (GUT. SUPPORT) in addition to SC. GUT.SUPPORT is identical to GUT.EXPECT in terms of common and non-specific treatment elements, i.e. time, personal attention and emotional support, but does not use specific interventions aimed at modifying expectations and illness-related anxiety.

Control intervention (standard care):
The control intervention consists of SC only. In all study groups, SC entails the patient's usual medical treatment without any interference by the study.

Previous intervention:
We will use the design of a three-arm randomised-controlled trial (RCT).
A fixed randomisation schedule, stratified by diagnostic group and sex, will be programmed and conducted electronically.

Experimental intervention 1 (GUT.EXPECT + SC):
This experimental intervention consists of an expectation management intervention (GUT. EXPECT) in addition to standard care (SC). The manualised intervention primarily aims at optimising expectations about symptoms, treatment outcome, and coping strategies and at reducing illness anxiety. The design of the intervention is based on the preferences expressed by

patients in a pilot study, the demonstrated effectiveness of the expectation management intervention from the PSY-HEART and the PSY-BREAST trials, and other previous studies. The intervention consists of 3 individual online consultation sessions in intervals of 2 weeks each and a booster session after 3 months, with each session lasting 45 minutes. Homework will be given after each session to deepen the acquired skills. The intervention thus addresses the topics "dealing with anxiety", "improving expectations" as well as patients' need for information about their disease.

Experimental intervention 2 (GUT.SUPPORT + SC):
This experimental intervention consists of a non-specific supportive intervention (GUT. SUPPORT) in addition to SC. GUT.SUPPORT is identical to GUT.EXPECT in terms of common and non-specific treatment elements, i.e. time, personal attention and emotional support, but does not use specific interventions aimed at modifying expectations and illness anxiety.

Control intervention (standard care):
The control intervention consists of SC only. In all study groups, SC entails the patient's usual medical treatment without any interference by the study.

Intervention Type
Behavioural

Primary outcome(s)
Gastrointestinal symptom severity assessed using the Irritable Bowel Syndrome - Severity Scoring System (IBS-SSS) at baseline, after 6 weeks, after 3 months (post-interventional follow-up), after 6 and 12 months

Key secondary outcome(s))
Current secondary outcome measures as of 26/11/2021:
1. Total somatic symptom severity measured using the Patient Health Questinnaire-15 (PHQ-15) at baseline, 6 weeks, 3 months, 6 months, and 12 months
2. Illness-related anxiety measured using the Somatic Symptom Disorder – B-Criteria Scale (SSD-12) at baseline, 6 weeks, 3 months, 6 months. and 12 months
3. Illness-related worries measured using the Whitley Index – 7 item scale (WI-7) at baseline, 6 weeks, 3 months, 6 months. and 12 months
4. Expectations of symptom severity measured using a Numeric Rating Scale (NRS) at baseline, 6 weeks, 3 months, 6 months, and 12 months
5. Expectations of coping with symptoms measured using a Numeric Rating Scale (NRS) at baseline, 6 weeks, 3 months, 6 months, and 12 months
6. Expectations of impairment due to somatic symptoms measured using a Numeric Rating Scale (NRS) at baseline, 6 weeks, 3 months, 6 months, and 12 months
7. Treatment expectations measured using the Treatment Expectation Questionnaire (TEX-Q) at baseline, 6 weeks, 3 months, 6 months, and 12 months
8. Disease activity measured using the Simple Clinical Colitis Activity Index (SCCAI) at baseline, 6 weeks, 3 months, 6 months, and 12 months
9. Time since last treatment measured using a single question at baseline, 6 weeks, 3 months, 6 months, and 12 months
10. Utilisation of medical treatment measured using gastrointestinal questions at baseline, 6 weeks, 3 months, 6 months, and 12 months
11. Adverse effects measured using a single question at baseline, 6 weeks, 3 months, 6 months, and 12 months
12. Evaluation of the interventions measured using Numeric Rating Scales (NRS) at 3 months

13. Systemic inflammation measured using C-reactive protein (CRP), interleukin 6 (IL-6), and tumour necrosis factor (TNF) at baseline and 3 months
14. Intestinal inflammation measured using faecal calprotectin at baseline and 3 months
15. Risk factors of somatic symptom persistence measured using the SOMACROSS research unit' s core instruments at baseline, 3 months, 6 months, and 12 months

Previous secondary outcome measures:
1. Total somatic symptom severity measured using the Patient Health Questinnaire-15 (PHQ-15) at baseline, 6 weeks, 3 months, 6 months, and 12 months.
2. Illness related anxiety measured using the Somatic Symptom Disorder – B-Criteria Scale (SSD-12) at baseline, 6 weeks, 3 months, 6 months. and 12 months.
3. Expectations of symptom severity measured using a Numeric Rating Scale (NRS) at baseline, 6 weeks, 3 months, 6 months, and 12 months.
4. Expectations of coping with symptoms measured using a Numeric Rating Scale (NRS) at baseline, 6 weeks, 3 months, 6 months, and 12 months.
5. Treatment expectations measured using the Treatment Expectation Questionnaire (TEX-Q) at baseline, 6 weeks, 3 months, 6 months, and 12 months.
6. Disease activity (ulcerative colitis only) measured using the Simple Clinical Colitis Activity Index (SCCAI) at baseline, 6 weeks, 3 months, 6 months, and 12 months.
7. Time to next treatment measured using a single question at baseline, 6 weeks, 3 months, 6 months, and 12 months.
8. Utilisation of medical treatment measured using a single question at baseline, 6 weeks, 3 months, 6 months, and 12 months.
9. Adverse effects measured using a single question at baseline, 6 weeks, 3 months, 6 months, and 12 months.
10. Satisfaction with interventions measured using a Numeric Rating Scale (NRS) at 3 months.
11. Systemic inflammation measured using C-reactive protein (CRP), interleukin 6 (IL-6), and tumour necrosis factor (TNF) at baseline and 3 months.
12. Intestinal inflammation measured using faecal calprotectin at baseline and 3 months.
13. Risk factors of somatic symptom persistence measured using the SOMACROSS research unit' s core instruments at baseline, 3 months, 6 months, and 12 months.

Completion date
01/03/2025

Eligibility

Key inclusion criteria
1. Diagnosis of ulcerative colitis (UC) or irritable bowel syndrome (IBS; Rome IV);
2. at least moderate gastrointestinal symptoms according to the Irritable Bowel Syndrome - Severity Scoring System (IBS-SSS ≥ 175);
3. UC/IBS treatment according to current German AWMF guidelines;
4. informed consent.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Necessity of acute emergency treatment
2. Acute suicidality
3. Psychotherapeutic treatment in the past 3 months
4. Insufficient German language skills

Date of first enrolment
04/04/2022

Date of final enrolment
24/02/2024

Locations

Countries of recruitment
Germany

Study participating centre
University Medical Centre Hamburg-Eppendorf, Department of Psychosomatic Medicine and Psychotherapy
Martinistraße 52
Hamburg
Germany
20246

Study participating centre
University Medical Centre Hamburg-Eppendorf, I. Department of Medicine
Martinistraße 52
20246
Germany
20246

Study participating centre
Israelitisches Krankenhaus
Orchideenstieg 14

Hamburg
Germany
22297

Study participating centre
Helmut-Schmidt-University / University of the Federal Armed Forces Hamburg, Hamburg, Germany
Holstenhofweg 85
Hamburg
Germany
22043

Study participating centre
University Medical Centre Hamburg-Eppendorf, Department of Medical Biometry and Epidemiology
Martinistraße 52
Hamburg
Germany
20246

Sponsor information

Organisation
University Medical Center Hamburg-Eppendorf

ROR
https://ror.org/01zgy1s35

Funder(s)

Funder type
Research organisation

Funder Name
Deutsche Forschungsgemeinschaft

Alternative Name(s)
German Research Association, German Research Foundation, Deutsche Forschungsgemeinschaft (DFG), DFG

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository (e.g., DRYAD Digital Repository; https://datadryad.org/stash). Study protocol and statistical analysis plan will be available at the ISRCTN registry. Individual participant data that underlie the reported results in a published article will be shared after de-identification beginning 3 months and ending 5 years following article publication. Data will be shared with researchers who provide a methodologically sound proposal to achieve aims in the approved proposal. Proposals should be directed to b.loewe@uke.de. To gain access, data requestors will need to sign a data access agreement. Informed consent from participants was obtained.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		28/11/2025	17/12/2025	Yes	No
Protocol article		14/06/2022	16/06/2022	Yes	No
Statistical Analysis Plan	version 10	19/09/2024	20/09/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes