

# Multidisciplinary care for older patients with IBD: Geriatric IBD Outpatient Clinic - a pilot study

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Objective: To evaluate the impact of geriatric evaluation in older patients with IBD, reflected in the number and type of (diagnostic and/or interventional) recommendations made, based on a CGA.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Gastrointestinal inflammatory conditions
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON56349

### Source

ToetsingOnline

### Brief title

Geriatric IBD outpatient clinic: a pilot study

### Condition

- Gastrointestinal inflammatory conditions

### Synonym

Crohn's disease, ulcerative colitis

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Spaarne Gasthuis

**Source(s) of monetary or material Support:** door afdeling geriatrie uit Spaarne Gasthuis

## Intervention

**Keyword:** Comprehensive Geriatric Assessment (CGA), Inflammatory Bowel Disease (IBD), Older patients

## Outcome measures

### Primary outcome

Main study parameters/endpoints: The number and type of (diagnostic and/or interventional) recommendations, as outcomes of a CGA in older patients with IBD.

### Secondary outcome

To evaluate the number and type of detected geriatric deficits. To evaluate the impact of disease activity on the type of findings and recommendations, patient satisfaction and experiences regarding the additional geriatric care, and the clinical judgement of frailty status by the gastroenterologist and compare it with the outcomes of the geriatric assessment.

## Study description

### Background summary

Rationale: The number of older patients with Inflammatory Bowel Disease (IBD) is growing. Previous studies have shown that older patients with IBD have an increased risk on geriatric syndromes, including multimorbidity, polypharmacy and frailty. Literature and guidelines emphasize the importance of multidisciplinary treatment with a geriatrician in (selected) older patients with IBD. One previous cohort study used a Comprehensive Geriatric Assessment (CGA) to measure frailty in older patients with IBD and found a high prevalence of deficits in and frailty in this assessment. The next step is to gain insight in the diagnostic and/or interventional recommendations that can be made by a geriatrician based on the deficits that are found in a CGA.

### Study objective

Objective: To evaluate the impact of geriatric evaluation in older patients with IBD, reflected in the number and type of (diagnostic and/or interventional) recommendations made, based on a CGA.

## **Study design**

Study design: A prospective, single-centre pilot study.

## **Intervention**

The intervention which will be performed is a comprehensive geriatric assessment.

## **Study burden and risks**

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients will be contacted prior to their outpatient clinic visit by phone. They will be informed about the study, and an information letter will be sent by mail or post when they are interested to participate. During their regular visit to the outpatient clinic, they will be asked by their treating physician if they are willing to participate. When they provide informed consent, they will receive a consultation with a geriatrician following their regular visit to the outpatient IBD clinic. As the selected patients are labelled as frail, further evaluation by a geriatrician is recommended according to current Dutch guidelines and the Spaarne Gasthuis protocol. Therefore, this geriatric consultation is considered standard of care. This consultation will take approximately 60 minutes. This consultation will be considered as baseline. Patients are asked to fill out questionnaires. After three months questionnaires will be sent by post, as part of normal CGA procedure.

## **Contacts**

### **Public**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Diagnosis of Crohn\*s disease, Ulcerative Colitis or IBD-unclassified, confirmed by clinical, endoscopic and/or histologic findings
  - Scheduled for an outpatient visit to IBD clinic
  - Signed informed consent
  - Age  $\geq$  65 years
- or
- Age  $\geq$  60 years with polypharmacy ( $\geq$  5 non-IBD medications) and/or significant comorbidity (score  $\geq$  3 Charlson Comorbidity Index (CCI))

### Exclusion criteria

- Patients who had a consultation with a geriatrician in the last year
- Patients who are not willing to sign informed consent

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

## Recruitment

NL  
Recruitment status: Pending  
Start date (anticipated): 01-11-2023  
Enrollment: 40  
Type: Anticipated

## Medical products/devices used

Registration: No

## Ethics review

Approved WMO  
Date: 20-11-2023  
Application type: First submission  
Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register	ID
CCMO	NL85343.100.23