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Introducing colon capsule endoscopy as a new diagnostic modality for patients with bowel symptoms in general practice: a feasibility study

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Abstract

Background Bowel symptoms are common in general practice and though most often benign they can also indicate colorectal cancer where a colonoscopy often is required to rule out malignant disease. Colon capsule endoscopy (CCE) is suggested as a more patient-friendly alternative to colonoscopy but its application in symptomatic patients in general practice needs further investigation.

Materials and methods We present a feasibility study of integrating initial triage for CCE into general practice. The technical success of CCE, patient acceptance, and the experiences of general practitioners (GPs) are assessed through qualitative interviews with participating GPs.

Results We were able to recruit some general practices from the area of interest, but inclusion of patients was low. The participating GPs welcomed the concept of CCE as a more patient-friendly procedure and most patients invited by the GP accepted inclusion. Difficulties remembering the project in the diverse everyday of general practice, GP shortage and general time restraints were reported as barriers for patient recruitment by the GPs.

Conclusion Before conducting large-scale implementation studies of CCE, our investigation highlighted critical barriers that need addressing: (1) Time Constraints and GP Shortages: The design of task divisions between sectors should carefully consider time limitations and the scarcity of GPs. (2) Low reinvestigation rates: Minimizing reinvestigation rates is crucial to reduce strain on both patients and healthcare systems.

Keywords Colon capsule endoscopy, Colonoscopy, Bowel symptoms, General practice, Feasibility

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Background

Colorectal cancer is the third most common cancer worldwide, and each year app. 5,000 Danes are diagnosed with incident colorectal cancer [1]. Despite implementation of a screening program for citizens aged 50–74 years only one in five colorectal cancers are detected through screening, and the majority of patients are still diagnosed following contact to the general practitioner (GP) with symptoms [2] Bowel symptoms, which span from abdominal discomfort to changes in bowel habits, are a common concern among patients in general practice. The diagnostic management can be challenging because the symptoms can be indicative of colorectal cancer but most often are benign, i.e. the predictive value is low [3]. To exclude malignant pathology, invasive procedures like colonoscopy are frequently required. However, these procedures can be burdensome for patients and resource-demanding for healthcare systems. The patient discomfort, invasiveness, costs and risk of adverse events related to colonoscopy may contribute to underutilization and delayed diagnosis, potentially impacting patient outcomes. As an appealing non-invasive alternative, colon capsule endoscopy (CCE) emerges. CCE provides a minimally invasive and patient-friendly approach for assessing colonic pathology without the need for sedation or gas insufflation [4].

CCE involves the ingestion of a pill-sized capsule containing two miniaturized cameras that traverses the gastrointestinal tract, capturing appr. 50,000 images of the colon. This technology holds potential advantages in terms of patient acceptance, accessibility, and safety, thereby addressing some of the limitations associated with conventional colonoscopy [5]. In a large meta-analysis CCE was found to have a sensitivity and specificity of 0.85 for polyps of any size when compared to colonoscopy [6]. When only looking at polyps larger than 9 mm the sensitivity increased to 0.87 and the specificity to 0.95.

Although CCE has shown promise in previous studies for assessing colonic pathologies in asymptomatic patients attending the colorectal cancer screening program [7], its application in evaluating colonic conditions in symptomatic patients in a general practice setting requires further investigation. The feasibility of implementing CCE as a routine diagnostic tool in such settings warrants comprehensive evaluation encompassing technical feasibility, patient acceptance, diagnostic yield, and cost-effectiveness.

This feasibility study aims to assess the practical aspects of integrating initial triage for CCE into general practice for evaluating patients with bowel symptoms. It seeks to evaluate the technical success of CCE, patient acceptance, and the experiences of general practitioners when introducing CCE as a novel diagnostic modality. The insights gained from this study have the potential to inform the design of large-scale clinical trials, allowing for accurate and detailed evaluation of patient acceptance, diagnostic precision, and the economic impact of CCE as a new and less invasive diagnostic approach for patients presenting with bowel symptoms.

Methods

CCE procedure

Patients eligible for this study were patients presenting with bowel symptoms to their GP where the GP normally would have chosen to refer the patient for colonoscopy after the GP's initial assessment. Table 1 describes inclusion and exclusion criteria.

The GP thoroughly briefed the patient about the study, including its procedures and the rationale behind offering CCE as an alternative to colonoscopy. Additionally, the GPs demonstrated the colon capsule to the patients. Written information about the study was also provided to the patients. Both verbal and written explanations were given, emphasizing that patients could withdraw from the study at any time without needing to provide a reason.

Table 1 Inclusion and exclusion criteria for patients eligible for the CCE feasibility study

Inclusion criteria

Patients > 40 years consulting their GP with at least one of the following symptoms:

1. Rectal bleeding but without ongoing bleeding/visual blood in stool at the time of consultation
2. Altered bowel habits > 1 month
3. Iron deficiency anemia
4. Other symptoms such as weight loss or abdominal pain where the GP normally would refer for colonoscopy

Exclusion criteria

1. Patients with visual blood in stool/ongoing rectal bleeding at the time of consultation
2. Patients at pre-known risk of not completing CCE due to gastrointestinal stenosis or fistula, difficulties swallowing or otherwise deemed unfit for CCE by the GP (cognitive impairment, frailty etc.)
3. Patients with pacemaker or other implanted electronic devices
4. Patients with allergies or contraindications to the bowel preparation drugs (including severe renal or cardiac failure)
5. Patients with stoma or previous colorectal cancer
6. Pregnant or breastfeeding patients
7. Patients unable to attend the outpatient research clinic
8. Patients with a waist circumference > 140 cm (to ensure that the recorder belt will fit properly).

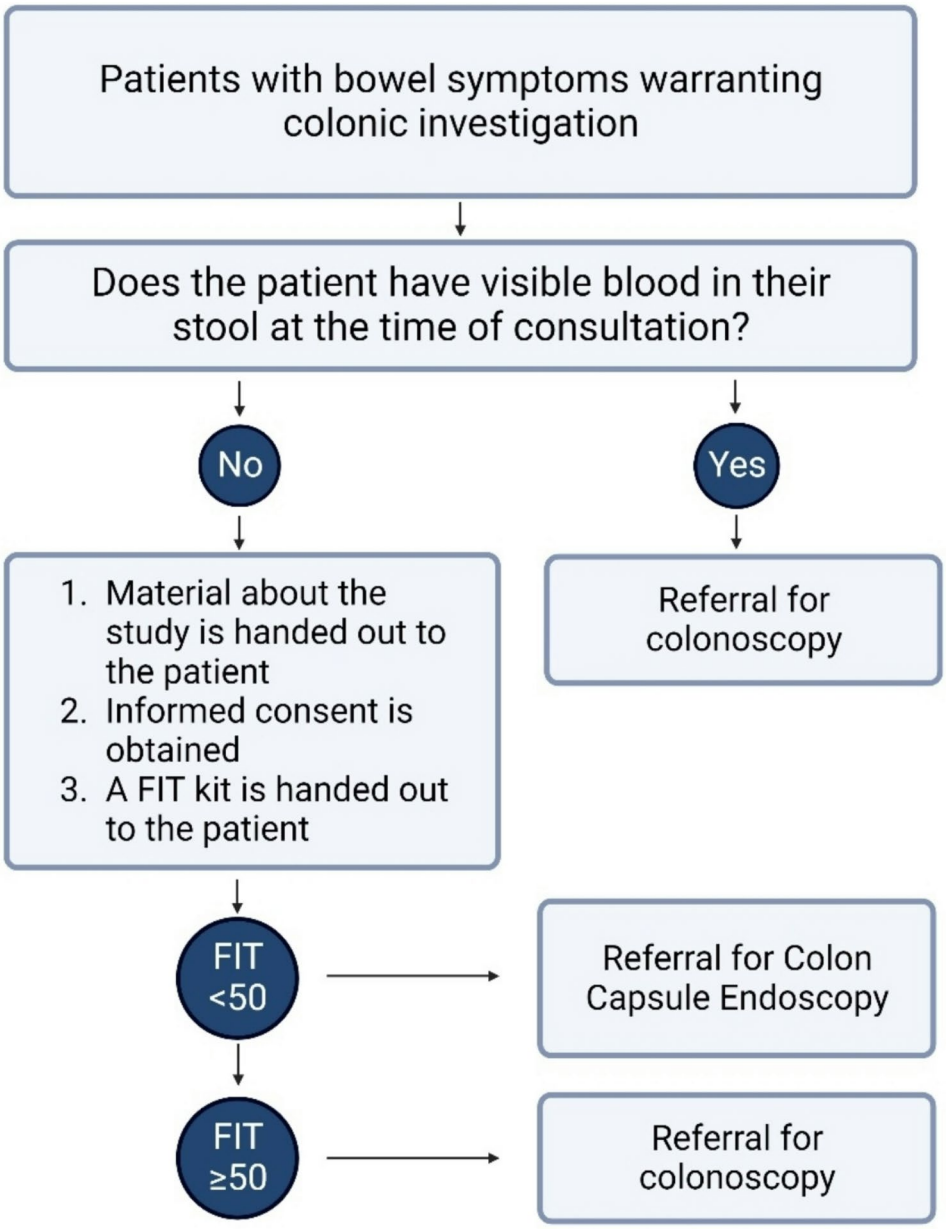

Fig. 1 Flow chart of the patient sampling procedure. Created with BioRender.com

If the patient consented to participate, the GP recorded the patient's age, sex, symptom presentation, duration of bowel symptoms, and handed out a sampling kit for fecal immunochemical testing (FIT) to detect hidden blood in the stool. The patient collected the stool sample at home and handed in the sample at the GP's office from which the sample was sent to a regional hospital laboratory for analysis. The laboratory informed the GP about the result within a few working days. Results were given as binary outcome of < 50 ng/mL buffer or ≥ 50 ng/mL buffer without further individual quantification. The GP then informed the patient about the FIT result and referred the patient to the Department of Surgery at Odense University Hospital indicating that the patient was participating in the CCE feasibility study and the result of the FIT, i.e. if the patient was eligible for CCE or a conventional colonoscopy should be performed. Patients fulfilling inclusion criteria and with a FIT result < 50ng/mL buffer were eligible for CCE whereas patients fulfilling exclusion criteria or with a FIT result ≥ 50 ng/mL buffer should have colonoscopy due to the higher risk of malignant pathology among individuals with increased FIT results [8] (Fig. 1).

Patients eligible for CCE were scheduled for a phone consultation with a dedicated CCE nurse from an external contractor (Corporate Health International, Hamburg, Germany). The nurse made a second screening for eligibility, repeated the information about the study and gave detailed information about the CCE investigation and instructed the patient in the bowel cleansing procedure. Patients were instructed to be on a clear liquid diet from the day before the CCE. We used polyethylene glycol (PEG) as a laxative (Movicol and MoviPrep, Norgine Denmark A/S, Herlev, Denmark). The bowel cleansing kit was sent to the patient's home and at the day of the scheduled CCE the patient came to an outpatient clinic where a CCE nurse assisted as the patient swallowed the capsule. Approximately 45 min prior to capsule ingestion, a 2 mg tablet of the prokinetic prucalopride (Resolor, Takeda Pharmaceuticals International, AG, Ireland) was administered. Afterwards the patient could return to their home awaiting capsule excretion. Throughout the investigation signals from the recorder indicated the timing of boosters prescribed to improve capsule transit. In this study we used a sulfate-based booster (Eziclen, Ipsen Pharma, Boulogne-Billancourt, France). Signal 1 was given by the recorder when the capsule reached the small bowel. Signal 2–4 were given two, four and six hours after signal 1 respectively. If the capsule had not been excreted before signal 4, the patient was instructed to insert a bisacodyl suppository (Dulcolax, Sanofi, Paris, France).

The CCE nurse was available for questions throughout the procedure. The patient returned the recorder after termination of the procedure. All investigations were carried out using PillCam Colon 2 (Medtronic, Minneapolis, Minnesota, USA). This second-generation system has an adaptable framerate of 4–35 images per second depending on the movement of the capsule [9]. The angle of view from each camera is 172 degrees. These are the most significant improvements compared to the first generations system having a fixed framerate of 4 images per second and an angle of view of only 156 degrees from a single camera. In this study we used the belt with a build-in recorder worn by the patient during the examination. The images were transmitted from the capsule to the recorder without the use of sensor arrays. Reporting on the CCE investigations was carried out using the cloud-based platform PillCam Web (Medtronic, Minneapolis, Minnesota, USA). Two doctors from the surgical research unit with experience in endoscopy were involved in the reading and reporting. No pre-reading was carried out in this trial. We used the Leighton-Rex scale for evaluation of the cleansing quality [10]. Based on the experience from previous studies conducted within the Surgical Research unit we considered the grade *poor* to be inadequate cleansing for a sufficient colonic evaluation while *fair*, *good* and *excellent* were considered adequate.

The GP and the patient were informed directly about the CCE result from the Department of Surgery. If indication of pathology requiring biopsy or polyp removal was found by CCE, if the patient could not complete CCE or if CCE was inconclusive due to inadequate bowel cleanliness the patient was invited to a conventional colonoscopy.

GP sampling

For this feasibility study we recruited GPs from Funen (app. 500,000 inhabitants and 319 GPs) where transportation of patients for CCE in the city of Odense was logistically realistic. GPs were invited through personal networks and regional newsletters aimed at GPs. Participation was voluntary and the GPs were reimbursed for their time spent participating in the feasibility study.

At inclusion the GPs were informed about the study and the practicalities in a start-up meeting. Further, the GPs were reminded about the study by e-mails during the study and were provided a laminated flowchart outlining the patient flow for their desk as a reminder. The GPs were given contact information to the research group and could contact the researchers if questions occurred. After the study the GPs were invited to an interview about their experiences and barriers.

Reimbursement for participation was DKK 1000 per GP for one hour start-up meetings, DKK 156,39 (amount equivalent to usual basic consultation fee) for extra time spent on informing each patient, additional DKK 156,39 for informing each patient about the FIT result and allocation to either CCE or colonoscopy and finally DKK 1000 per GP for one hour follow-up interviews after termination of the feasibility study.

GP interviews

To elucidate the GP's experiences with participating in the study, possible barriers for patient recruitment and aspects of the feasibility study to be improved before embarking on a large-scale study we invited the participating GPs for individual semi-structured interviews after termination of the feasibility study. The interviews were carried out by PFH. The interview guide was developed for this study and is available as supplementary material. The interviews were carried out for this manuscript and the results have not been published elsewhere. The GPs were offered to choose between online video interviews or face-to-face interviews. Five of the participating GPs agreed to be interviewed, three of them preferred face-to-face interview. The interviewed GPs comprised both men and women, GPs from different geographical areas and practice sizes/organizations and with a wide range of years of experience in general practice. Core topics of the interview guide are displayed in Table 1. After four interviews no additional information seemed to appear

and it was subsequently assessed that sufficient information power was reached with five interviews. The interview guide used was the same in each interview to ensure that predefined topics were covered without excluding the possibility to explore themes brought up by the GPs.

The subsequent data analysis was based on systematic text condensation, a method commonly used in qualitative studies in general practice and in projects seeking to understand professionals' experiences with a specific topic [11, 12].

Topics	Example of introduction
GP motivation	What was your motivation for participating in this study?
Overall experience with the study	What are your general thoughts about participating in this study?
Patient recruitment	What were your experiences with recruiting patients for the study?
Reimbursement	What do you think of the reimbursement for participation?
Patient attitudes/experiences	How did your patients react to the offer of participating in the study? Which kind of feedback did you receive from the patients after participating?
Barriers	Which barriers for patient recruitment did you experience? How could these barriers be overcome?
Improvement possibilities for future studies	What do you think should be changed to improve the project?

Ethics

The study was carried out in accordance with the Declaration of Helsinki. Prior to consenting to participate all GPs and patients were thoroughly informed about the study and that participation was completely voluntary and that they could withdraw from the study at any time without providing an explanation. The CCE procedure required a more extensive bowel cleansing procedure [13] than colonoscopy which both GPs and patients were informed about. Though triaging the patients with FIT, so that patients undergoing CCE had low risk of colorectal cancer, there still was a potential risk of delaying diagnosis of colorectal cancer as the time from referral to diagnosis in CCE is longer and a subsequent colonoscopy is needed for final diagnosis, if malignancy is suspected at CCE. However, the potential of a few days prolonged diagnostic interval is not considered to hamper patient prognosis [14].

The feasibility study was approved by the Regional Ethics Committee of Southern Denmark, project no. S-20,220,085. Further, the project was approved by the Research Counsil at Odense University Hospital, ID-no 305-2023-GB.

Results

We recruited 10 GPs from six general practices. Both partnership practices and singlehanded practices and male and female GPs were represented. Age of the GPs ranged from 38 to 60 years. Most practices were located in Odense. All practices participated in individual start-up meetings informing the GPs about the study and its procedures and tasks for general practice. The GPs were recruited from February to March 2023. Patient inclusion was initiated in April 2023. From April to December 2023 the GPs recruited 13 patients for the feasibility study. Three of the practices did not include any patients.

Five of the GPs agreed to participate in interviews after termination of the study. Interviews were carried out in December 2023 and took from 23 to 36 min.

Patients

A total of 54% (7/13) of the patients were women. Most had changes in bowel habits for more than four weeks as reason for colonic investigation. One of the 13 patients recruited for the study withdrew from inclusion after information because of transportation issues to the research clinic. A total of 10 patients had FIT result < 50 ng/mL and were referred for CCE. Two patients were excluded at the telephone consultation, as they were found not eligible for CCE (transportation issues and difficulties swallowing, respectively). Eight patients completed the CCE. In two cases there was indication for a subsequent colonoscopy, both due to incomplete visualization of the colon (one case of incomplete transit, one case of the cecum not being visualized). Although our very small sample of patients do not allow any statistical analyses the reinvestigation rate was comparable to other CCE studies [7, 15].

No significant pathology was found at CCE, 7/8 patients had diverticulosis located in the left colon and 4/8 patients had small polyps. The detected polyps were in the size range 4–7 mm and all registered as being sessile. As the colon is not insufflated in CCE the polyp appearance can be different from what is seen in colonoscopy. The Paris classification can therefore be difficult to use for morphological classifications in CCE. There were no contacts from patients to the research clinic nor the clinicians/researchers about complaints, questions, technical difficulties etc. No adverse events were registered. For the patients having a subsequent colonoscopy or a colonoscopy instead of CCE no significant pathology was detected.

GP experience

After termination of the feasibility study five GPs agreed to be interviewed about their experiences and barriers. From the analysis of the interviews we identified three themes: Time restraints, patient friendliness and task distribution.

Time restraints

One of the interviewed GPs had not included any patients and pointed out that lack of time was the main reason for non-recruitment:

> *GP no. 1: "I think the idea of the project is very good, but I simply did not have the time to inform the patients, hand out the FIT sampling kit and the information material and obtain consent (…) my 15 minutes consultation was already spent with talking to the patient about their symptoms and examining them."*

The diverse clinical aspects of general practice could make it difficult for the GPs to remember the project.

> *GP no 4: "I see around twenty patients with so many different complaints every day so several times I just forgot about the project and the thought that I should have recruited that patient actually first came to me after he had left my clinic."*

All GPs spent more time than in a usual consultation concerning bowel symptoms by informing the patient about the study and FIT sampling procedure but found that the extra time spent was well compensated by the extra remuneration offered in the study.

> *GP no. 3: "The extra time spent was well compensated."*
> *GP no. 2: "It took longer than normal with all the tasks related to the study, but I mean it is just swings and roundabouts – some consultations are longer than scheduled and some are shorter and in the end it all adds up."*

However, the GPs mentioned the time restraints in general practice as a general barrier to taking up new tasks.

> *GP no 5: "We are already overwhelmed with new tasks. The hospitals are continuously delegating new tasks to general practice, so it is very complicated to take in new tasks."*
> *GP no 2: "we simply do not have the time or capacity to new assignments."*

Patient friendliness

The four interviewed GPs who had recruited patients for the study were all generally positive about their participation in the feasibility study and all expressed that they wished CCE was a standard diagnostic possibility for their patients as it was much more patient-friendly. All had positive experiences with their patients accepting CCE.

> *GP no. 4: "More often I have to argue the necessity of colonoscopy compared to CCE."*

Several of the GPs stated that they experienced patients hesitating to contact them with bowel symptoms due to them knowing that they might be referred for a colonoscopy. The GPs thought having CCE as a diagnostic possibility could reduce the patient barriers for contacting the GP with bowel symptoms.

> *GP no 2: "Well, I think they might not be so hesitating to tell me about their bowel symptoms if they knew they could just swallow a pill to be examined. Nobody wants to be examined with the "garden hose"."*

Task division

All GPs suggested for improvement of the study that the GPs would hand out the FIT sampling kit and send in the stool sample but that the endoscopy unit should be responsible for informing the patient about the FIT result and allocate the patient to either CCE or colonoscopy.

> *GP no 1: "Well, it would be much simpler and easier if I just had to hand out the FIT test kit and refer the patient as usual and then the surgeons could decide whether the patient could be examined by CCE or colonoscopy."*
> *GP no 3: "I do not refer a patient to colonoscopy that often so each time I had to check the eligibility criteria and remember what to inform them about and what it was that I should do. I would prefer if someone else did that after I had examined and referred the patient."*

Discussion/perspectives

Main findings

In this feasibility study of introducing CCE as a new diagnostic modality for patients presenting with bowel symptoms to their GP, we were able to recruit some general practices, but inclusion of patients was low. Three of the practices did not include any patients. One of the singlehanded practices not including any patients was handed over to another GP during the study period,

possibly explaining the lack of patient recruitment from that practice.

The participating GPs welcomed the concept of CCE as a more patient-friendly procedure and most patients invited by the GP accepted inclusion. Difficulties remembering the project in the diverse everyday of general practice and general time restraints were reported as barriers for patient recruitment by the GPs.

Strengths and limitations

Although we could not recruit more than 10 GPs, it is a strength of our study that it was conducted among a variety of GPs regarding age, sex and clinical experience to reflect the diversity of GPs. Further, it is a strength that the feasibility and the GPs experiences were assessed through qualitative interviews allowing for a deeper understanding of their perspectives and identification of barriers. Had we used e.g. questionnaires to assess the GPs' experiences and views of aspects of the study to be improved we would have limited the informants' answers. Nevertheless, limitations may arise from the subjective nature of qualitative data as opinions can vary among GPs. It is plausible that the GPs we recruited for the feasibility study were more openminded to new tasks and new technology and that their positive attitude was not representative of all GPs. It could be relevant to further investigate the barriers of non-participating GPs.

Further, it is a limitation of our study that the patient recruitment was low. Had more GPs included more patients we would have been able to gain a broader insight into the feasibility aspects and perhaps more nuances to the GP and patient experiences. Additionally, the feasibility study does not capture financial aspects and regional logistic differences, requiring supplementary quantitative data for a comprehensive evaluation of implementing CCE in the diagnostic workup of patients with bowel symptoms in general practice.

It is important to keep in mind that our findings from this study carried out solely on Funen may not be universally applicable or actionable in all settings. In Denmark, patients with symptoms indicative of colorectal cancer are offered a colonoscopy. Other healthcare system might operate with different diagnostic modalities such as computed tomography colonoscopy, stool DNA tests etc. where barriers for testing may differ.

Implications

The integration of CCE into general practice could potentially streamline the diagnostic process, reduce procedural discomfort for patients, reduce patient barriers for healthcare seeking with bowel symptoms and facilitate earlier detection of colonic pathologies, thereby improving patient care and outcomes. Moreover, a successful implementation of CCE in general practice settings could alleviate the burden on specialized endoscopy units, optimizing the allocation of healthcare resources and enhancing overall healthcare efficiency.

Further, CCE seems a more sustainable diagnostic modality compared to colonoscopy. Patients can be examined with little transportation and even work during the CCE procedure. The need for specialized healthcare personnel is also diminished, even more so with implementation of artificial intelligence image analysis [16], which is important in times where staff shortages are evident in most healthcare systems.

However, before implementing CCE as a standard diagnostic opportunity accurate knowledge from large-scale studies of CCE in symptomatic patients from general practice is essential. For participating GPs it is important with continuous reminders to keep the project in mind in a diverse and hectic everyday. This may be achieved by integrating electronic reminders triggered by specific diagnosis in their patient filing systems. Future large-scale studies should focus on diagnostic yield, completion rates, re-investigation rates, and patient and GP satisfaction. Before conducting large-scale implementation studies of CCE, our feasibility investigation highlighted critical barriers that need addressing:

1. **Time Constraints and GP Shortages**: The design of task divisions between sectors should carefully consider time limitations and the scarcity of GPs.
2. **Low reinvestigation rates**: Minimizing reinvestigation rates is crucial to reduce strain on both patients and healthcare systems.

In conclusion, our feasibility study, exploring the introduction of CCE as a diagnostic modality for patients with bowel symptoms in general practice, represents a central step in enhancing the diagnostic tools available to healthcare providers. The insights gained from this study are important for designing future large-scale studies of CCE in general practice where diagnostic yield, completion rates, re-investigation rates, and patient and GP satisfaction are important to evaluate. A thorough investigation with an organizationally realistic design could serve as the foundation for testing CCE as a patient-friendly, accessible and sustainable diagnostic procedure, potentially reshaping the landscape of colonic diagnostics.

Abbreviations

GP	General practitioner
CCE	Colon capsule endoscopy
DKK	Danish kroner

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12875-025-02864-4.

Supplementary Material 1

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Author contributions
PH, JS, TBM, BSO and GB all contributed to the design of study. PH and BSO acquired the data for the study. PH drafted the manuscript and JA, BSO, TBM and GB revised it critically. PH, JS, TBM, BSO and GB approved the submitted version.

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Data availability
Data are given with permission from patients and GPs only to the researchers and the data are not publicly available.

Declarations

Ethics approval and consent to participate
The feasibility study was carried out in accordance with the Declaration of Helsinki. The study was approved by the Regional Ethics Committee of Southern Denmark, project no. S-20220085. Further, the project was approved by the Research Counsil at Odense University Hospital, ID-no 305-2023-GB. Prior to consenting to participate all GPs and patients were thoroughly informed about the study and that participation was completely voluntary and that they could withdraw from the study at any time without providing an explanation.

Consent for publication
All participants were informed that the project was a research project and that their data would be anonymized so no participant would be identifiable in subsequent publications. All participants (GPs and patients) gave informed consent to participate under these terms.

Competing interests
Benedicte Schelde-Olesen has received honoraria and participated in advisory board meetings for Jinshan Ltd. Jens Søndergaard has received fees from Abbott Rapid Diagnostics, Roche Diagnostics, Roche, Novo Nordisk A/S, and is member of the board of Steno Diabetes Center, Odense.

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