Development and Feasibility Study of a Telemedicine Tool for All Patients with IBD: MyIBDcoach

Marin de Jong, MD,**[†] Andrea van der Meulen-de Jong, MD, PhD,[‡] Mariëlle Romberg-Camps, MD, PhD,[§] Juliette Degens, MD,**[†] Marco Becx, MD,^{||} Tineke Markus,[¶] Henny Tomlow, MSc,**** Mia Cilissen, MSc,* Nienke Ipenburg, MSc,[‡],** Marthe Verwey, MSc,[‡],** Laurence Colautti-Duijsens, MSc,[§] Wim Hameeteman, MD, PhD,* Ad Masclee, MD, PhD,**[†] Daisy Jonkers, MSc, PhD,**[†] and Marieke Pierik, MD, PhD*,[†]

Background: Tight control of disease activity, medication side effects, and adherence are crucial to prevent disease complications and improve quality of life in patients with inflammatory bowel disease (IBD). The chronic nature and increasing incidence of IBD demand health care innovations to guarantee future high-quality care. Previous research proved that integrated care by telemedicine can improve outcomes of chronic diseases. Currently available IBD telemedicine tools focus on specific patient subgroups. Therefore, we aimed to (1) develop a telemedicine system suitable for all patients with IBD in everyday practice and (2) to test this system's feasibility.

Methods: With a structured iterative process between patients, dietitians, IBD nurse-specialists, and gastroenterologists, myIBDcoach was developed. During 3 months, myIBDcoach's feasibility was tested by 30 consecutive outpatients with IBD of 3 hospitals. Thereafter, patients and health care providers completed a questionnaire covering satisfaction, accessibility, and experiences with myIBDcoach.

Results: MyIBDcoach enables continuous home-monitoring of patients with IBD and optimizes disease knowledge and communication between patients and health care providers. Besides disease activity, medication adherence, and side effects, myIBDcoach monitors malnutrition, smoking, quality of life, fatigue, life-events, work participation, stress, and anxiety and depression and provides e-learnings for patient empowerment. Patients graded the system with a mean of 7.8 of 10, and 93% would recommend myIBDcoach to other patients.

Conclusions: We developed myIBDcoach, which enables integrated care for all patients with IBD, regardless of disease severity or medication use. The feasibility study showed high satisfaction and compliance of patients and health care providers. To study myIBDcoach's efficacy, a multicenter randomized controlled trial has been initiated.

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Inflammatory bowel disease (IBD) is a chronic disorder of the gastrointestinal tract with a peak onset in early adulthood. Crohn's disease (CD) and ulcerative colitis (UC) are the 2 main subtypes, but

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Address correspondence to: Marieke Pierik, MD, PhD, Department of Gastroenterology and Hepatology, Maastricht University Medical Centre+, P. Debyelaan 25, 6202 AZ Maastricht, Netherlands (e-mail: M.pierik@mumc.nl).

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within these groups the clinical presentation is very heterogeneous with regard to disease location, disease behavior, occurrence of extraintestinal manifestations, and therapy response.² IBD has a significant impact on quality of life (QoL) and constitutes an economic burden because of direct and indirect health care costs.^{3–5}

Recent studies show that tight control of disease activity and early interventions in case of recurrence of intestinal inflammation are important to shorten flare duration and prevent complications.⁶ Furthermore, most available drugs are immunosuppressives which can have severe side effects.^{7,8} For these reasons, continuous and personalized monitoring of patients with IBD with regard to disease activity, medication use, and side effects is required. In addition, many aspects that may influence disease activity, such as stress, smoking, nutritional status, and treatment adherence are not followed systematically in most IBD clinics. Interventions on these aspects may significantly improve the long-term outcome of IBD.^{9,10} Furthermore, systematic registration of patient-reported outcome measures (PROMs) and work disability is increasingly requested by health care insurers to guarantee reimbursement of expensive drugs, whereas patients

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themselves also demand empowerment and more involvement with their therapy.

Continuous monitoring of this multifaceted, chronic, and invasive disease, given the increasing incidence of IBD, 11-13 will put significant pressure on gastrointestinal health care capacities. To guarantee personalized, high quality, efficient, and affordable health care for patients with IBD in the future, innovative solutions are warranted.

Health care at a distance, also known as telemedicine or eHealth, is a possible innovation that may contribute to the quality and efficiency of care for patients with IBD. 12,14,15 eHealth has already been implemented successfully for several other chronic diseases, such as congestive heart failure, 16,17 asthma, 18 hypertension, 19 chronic obstructive pulmonary disease, 20,21 and diabetes mellitus. 22,23 Mounting evidence shows that direct involvement of health care providers, promotion of patient empowerment and integrated care improve the outcome of chronic diseases. 24–27

Also for patients with IBD, several telemedicine systems have been developed. Cross et al developed a Home Telemanagement System for patients with UC, ^{28–32} composed of a netbook computer and an electronic weight scale that monitors symptoms, medication usage, and side effects. Elkjaer et al developed a web-based system (Constant Care) to monitor disease activity and QoL in patients with mild-to-moderate UC on 5-aminosalicylic acid (5-ASA) treatment.^{26,33} This program was also used for individualization of 5-ASA treatment and improvement of adherence in mild-to-moderate patients with UC¹⁰ and for individualization of infliximab (IFX) scheduling in patients with CD on IFX maintenance treatment.³⁴

Overall, these systems were shown to be feasible, safe, and well accepted by patients with IBD,^{35,36} but are developed for subgroups of patients with IBD with relatively mild disease. Therefore, we aimed (1) to develop a telemedicine system for all subtypes of patients with IBD in everyday clinical practice through close collaboration of patients, IBD nurse-specialists, and gastroenterologists using a structured approach and (2) to test the feasibility of this system in terms of compliance and satisfaction among patients and health care providers.

MATERIALS AND METHODS

Development of MyIBDcoach

Design and Content Development

Before the start of the development phase, the need for an integrated eHealth system for patients with CD in the Netherlands was evaluated among different stakeholders, i.e., patients with IBD from the Dutch IBD patients' organization,³⁷ dietitians, representatives from the pharmaceutical industry, gastroenterologists, and IBD nurse-specialists from academic as well as nonacademic hospitals (Fig. 1, phase I). Subsequently, they discussed the design of the telemedicine program further called as myIBDcoach, the relevant topics, and questionnaires to be included as well as safety

management of home-monitoring using a structured iterative process (Fig. 1, phases II–V). In addition, topics for e-learning modules were selected and subsequently developed by topic-specific experts and reviewed by an independent gastroenterologist (Fig. 1, phase VI).

To facilitate broad support and implementation of myIBD-coach and to improve cooperation between the various stakeholders, a foundation was instituted.³⁸ The director of the Dutch IBD patients' organization, 2 gastroenterologists, an accountant, and an assistant professor of health analytics systems constitute the board. Representatives of the aforementioned stakeholders as well as those of the IBD section of the Dutch Association for Gastroenterology (NVGE), the Dutch Association for Gastroenterologists (NVMDL), and the Association of IBD Nurse Specialists (N-NIC) form a separate committee which decides on the design and content of myIBDcoach.

Technological Development

The technological development of myIBDcoach was conducted by Sananet BV,³⁹ specialized in development and implementation of telemedicine and self-management tools. They integrated relevant information and questionnaires into both a web-based and an HTML application and created a secure link between patients and the hospital.

The system includes so-called monitoring modules, intensified monitoring modules, outpatient visit modules, e-learning modules, a plan, and an administrator page used by the health care provider (Fig. 2). The modules will be discussed in detail later. MyIBDcoach meets all legal requirements in line with the European laws regarding security and confidentiality of patient data.

Feasibility Study of MylBDcoach

After the technological and content development, a feasibility study was planned in 3 clinical centers to evaluate compliance, satisfaction, accessibility, and experiences with myIBDcoach from both health care providers and patients.

From November 2012 until March 2013, 30 patients were recruited from the tertiary referral centers Maastricht University Medical Center+ and Leiden University Medical Center, and from the nonacademic hospital Zuyderland Medical Center. Patients between 18 and 75 years of age, fulfilling the international diagnostic criteria for IBD, 40 were eligible for inclusion. Exclusion criteria consisted of inability to read or understand the informed consent form, lack of internet access by computer, tablet, or smartphone, or lack of a hospital admission because of IBD disease activity within 2 weeks before inclusion because of practical reasons.

Participating patients followed a short practical training on how to use myIBDcoach. After this, participants received a unique username and password and were asked to log on to http://www.mijnibdcoach.nl. During a 3-month study period, patients were requested to complete the myIBDcoach monitoring module monthly. At the end of the study period, patients and health care providers from the participating hospitals were asked to fill out an evaluation questionnaire regarding satisfaction, accessibility, and experiences with myIBDcoach.

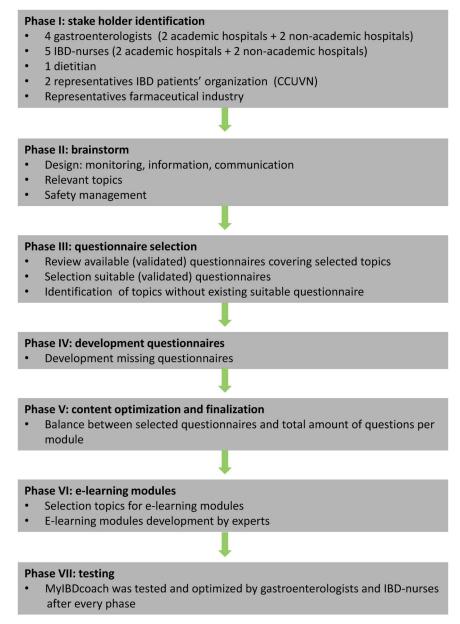


FIGURE 1. Different phases of design and content development of mylBDcoach.

Ethical Considerations

The study was approved by the Medical Research Ethics Committee of the Maastricht University Medical Center (METC azM/UM), which waived the requirement to obtain inform consent. The study protocol conformed to the provisions of the declaration of Helsinki.

Data Collection and Outcome Measures

Feasibility data in terms of satisfaction, accessibility, and experiences with myIBDcoach were collected from patients' and

health care providers' evaluation questionnaires. Compliance with myIBDcoach in this pilot study was predefined as $\geq 70\%$ adherence with the monthly monitoring modules. Demographic information was obtained from all patients at the time of recruitment.

Statistical Analyses

Descriptive analyses to evaluate demographic information and to assess feasibility with myIBDcoach were performed using IBM SPSS statistics 22.0.

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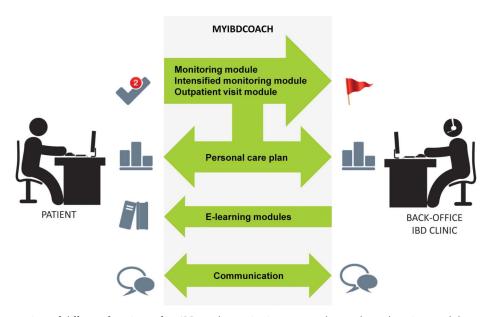


FIGURE 2. Schematic overview of different functions of mylBDcoach: monitoring, personal care plan, e-learning modules, and communication. An overview of content and frequency of modules is shown in Table 1. When values recorded from the questions of the monitoring modules exceed predefined thresholds, alerts (red flags) are created in the back-office.

RESULTS

Development of MyIBDcoach

Technological Development

A personal web-based telemedicine system for patients with IBD, myIBDcoach, was designed and developed as a secure webpage (http://www.mijnibdcoach.nl) and HTML application on a tablet or smartphone (Fig. 3). MyIBDcoach can be used as a stand-alone program; however, incorporation in different hospital electronic patient files is technically also possible. Sananet BV provides technical support for all participants (patients and health care providers).

Content Development

During the first brainstorm meeting with the identified stakeholders (Fig. 1, phase II), patients emphasized the importance of better communication with the hospital, tailored information about their disease and medication, as well as patient-centered care. Gastroenterologists noticed that a more holistic approach to the patient with IBD was needed, since many disease-related aspects, including nutrition, work productivity, smoking, and anxiety and depression were often not addressed in the current practice, but are of relevance for disease outcome and health-related QoL. Furthermore, the importance to monitor disease activity and side effects of (immunosuppressive) drugs was emphasized. Both gastroenterologists and the representatives from the pharmaceutical industry indicated better monitoring of therapy adherence to be of relevance to optimize treatment. Home-monitoring of disease activity and disease-related aspects at regular intervals requires validated PROMs, which are also demanded by governments for registration of efficacy endpoints for expensive drugs.



FIGURE 3. MyIBDcoach.

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Based on the literature review, validated PROMs on medication adherence, medication satisfaction, nutritional status, QoL, work productivity, anxiety and depression, social support, and fatigue were selected. When different validated questionnaires on the same topic were available in the literature, the shortest applicable questionnaire was chosen if there were no major advances of the other questionnaires, to constrain monitoring modules to a reasonable length.

Validated PROMs for disease activity and infectious events were not available in the literature (Fig. 1, phase III). Existing patient-reported disease activity questionnaires, such as the patient Harvey Bradshaw index and the patient simple clinical colitis activity index, are not validated against endoscopy and show poor correlation with endoscopic disease activity. 41-44 Therefore, myIBDcoach uses a newly developed Monitor IBD At Home questionnaire (MIAH)⁴⁵ (Fig. 1, phase IV). This is a symptom-based PROM that is validated against endoscopy and does not require laboratory tests or physical examination. The MIAH shows good diagnostic accuracy to screen for patients who need further assessment of disease activity with biochemical markers, imaging, or endoscopy, 45 and excellent accuracy when combined with a home calprotectin test.⁴⁶ A score of \leq 3.6 is defined as remission. In addition, a new questionnaire on medication side effects and infectious events was developed.

A schematic overview of the design of myIBDcoach is shown in Figure 2 and an overview of questionnaires as well as their frequency of monitoring is given in Table 1.

Monitoring Module

Patients are requested to complete the regular "monitoring module" monthly, which contains questions regarding disease activity (MIAH),45 extraintestinal manifestations, medication use, medication adherence (Morisky Medication Adherence Scale⁴⁷), satisfaction (Treatment Satisfaction Questionnaire for Medication⁴⁸) and side effects including infections. In addition, the monitoring module measures general disease aspects as QoL (euroQol instrument⁵¹ and Short Form Health Survey⁵²), work productivity (Work Productivity and Activity Impairment [WPAI⁵³]), nutritional status (Malnutrition Screening Tool⁴⁹ and Short Nutritional Assessment Questionnaire⁵⁰), fatigue, physical exercise, stress, life-events, anxiety and depression, social support, and self-management skills. When the disease is in remission, defined as 3 consecutive MIAH-scores ≤3.6, patients will be asked if they prefer to fill out the monitoring module once per 3 months. In case of a flare, defined as a MI-AH-score >3.6, patients are requested to log on weekly and complete the "intensified monitoring module" on disease activity and medication use until the symptoms subside.

TABLE 1. Design of mylBDcoach

Section	Function	Frequency
Monitoring module	 Monitors patient-reported disease activity (MIAH⁴⁵), extraintestinal manifestations, medication use, adherence (Morisky Medication Adherence Scale⁴⁷), satisfaction (Treatment Satisfaction Questionnaire for Medication⁴⁸) and side effects 	Monthly or every 3 months when sustained remission
	2. Monitors general disease aspects: nutritional status (Malnutrition Screening Tool ⁴⁹ and Short Nutritional Assessment Questionnaire ⁵⁰), QoL (euroQol instrument ⁵¹ , SF-12 ⁵²), work productivity (WPAI ⁵³), infections and single questions on fatigue, physical exercise, stress, life-events, anxiety and depression, social support, and self-management skills.	
Intensified monitoring module	Monitors patient-reported disease activity (MIAH ⁴⁵) and medication usage in case of a flare.	Weekly
Outpatient visit module	Registers patient-reported disease activity (MIAH ⁴⁵), extraintestinal manifestations, QoL (Short Inflammatory Bowel Disease Questionnaire ⁵⁴), smoking, work productivity (WPAI ⁵³), intimacy and sexuality, anxiety and depression (Hospital Anxiety and Depression Scale ⁵⁵), medication adherence, nutritional status (Malnutrition Screening Tool ⁴⁹ and SNAQ ⁵⁰), social support (social support list ⁵⁶) and fatigue (shortened fatigue questionnaire ⁵⁷), and a topic patients would like to discuss with their health care provider during the upcoming outpatient visit.	Yearly/when applicable
E-learning module	Offers patient-tailored information on 16 selected topics.	When applicable
Communication	Facilitates communication between patient and health care provider and provides systematic documentation of communication.	24/7 available
Personal care plan	Gives a clear overview of follow-up for both patient and health care provider.	24/7 available

MIAH, Monitor IBD At Home; MMAS-8, Morisky Medication Adherence Scale; TSQM, Treatment Satisfaction Questionnaire for Medication; MST, Malnutrition Screening Tool; SNAQ, Short Nutritional Assessment Questionnaire; EQ-5D, EuroQol instrument; SF-12, Short Form Health Survey; WPAI, Work Productivity and Activity Impairment; SIBDQ, Short Inflammatory Bowel Disease Questionnaire; HADS, Hospital Anxiety and Depression Scale; SSL, Social Support List; SFQ, Shortened Fatigue Questionnaire.

Back-Office

The administrator page, further called as back-office, is used by the patient's own health care provider, i.e., a gastroenterologist or an IBD nurse (specialist), and provides an overview of all participating patients per center. As myIBDcoach is a self-management system, patients are in the lead to contact the health care provider in case of symptoms or other questions. To ensure safety of homemonitoring, alerts (red flags) are created in the back-office when values recorded from the questions of the monitoring module exceed predefined thresholds. In case of an alert, the health care provider will contact the patient for further evaluation. Based on the extent and severity of the complaints, they decide whether the patient should be seen at the outpatient clinic. At any time, patients can communicate easily with their health care provider by sending a message through the secure connection to the back-office of the health care provider. Every new message creates an alert in the back-office.

Outpatient Visit Module

When a routine outpatient visit is scheduled, patients are asked to prepare this visit by completing the "outpatient visit module," which registers patient-reported disease activity (MIAH),45 extraintestinal manifestations,58 and parameters which may influence long-term disease outcomes such as QoL (Short Inflammatory Bowel Disease Questionnaire⁵⁴), smoking, work productivity (WPAI),53 intimacy and sexuality, anxiety and depression (Hospital Anxiety and Depression Scale⁵⁵), medication adherence, social support (Social Support List⁵⁶), and fatigue (shortened fatigue questionnaire⁵⁷). The values recorded from these questionnaires are presented in a clear overview to make the consultation with the gastroenterologist as efficient as possible and to make sure all relevant topics will be discussed and patients will be referred to other specialists when necessary. Furthermore, patients are given the opportunity to note what they would like to discuss with their health care provider during the visit.

E-Learning Modules

To improve patients' knowledge on IBD, we developed patient-tailored interactive e-learning modules about CD and UC in general, mesalamines, immunosuppressives or anti-tumor necrosis factor therapy, medication adherence, smoking cessation, (mal)nutrition, how to prevent or reduce symptoms (self-management), fatigue, work productivity, pregnancy, intimacy, anxiety and depression, influenza vaccination, and about how to receive adequate support from friends, family, and colleagues (Fig. 1, phase VI). Both patients and health care providers can start an e-learning module, i.e., patients can be advised to perform a certain e-learning module whenever their health care provider considers it desirable or when the patients themselves are interested in a specific topic.

Self-Management

All information derived from the monitoring and outpatient visit modules is presented in a personal care plan. The personal care plan summarizes all disease aspects in tables and graphs for

both the patient and the health care provider (Fig. 4). By providing insight in their personal care plan, we aim to improve patients' self-management and stimulate patient empowerment.

Results Feasibility Study of MyIBDcoach

MyIBDcoach was pilot-tested in 30 patients with IBD and 8 health care providers. Patient characteristics are shown in Table 2. Compliance with the monthly monitoring modules was 100%. Patients judged myIBDcoach with a mean score of 7.8 of 10, and health care providers gave a mean score of 8.0 of 10. Both patients and health care providers found the design and accessibility of the system of high quality. One patient thought that the system was time-consuming. Ninety-three percent of the patients would recommend myIBDcoach to other patients.

During the 3-month study period, 40% of the patients (n = 12) contacted their health care provider through myIBDcoach for urgent symptoms or general questions. Of these patients, 83% found that this contact had a positive contribution to the overall contact with their health care provider. Ninety percent of the patients completed at least 1 e-learning module. After completing the e-learning modules, most these patients felt that their general knowledge about their disease had improved.

DISCUSSION

This article describes the systematic development of the first telemedicine system that enables home-monitoring for all subtypes of patients with IBD. A pilot study proved that myIBDcoach is feasible for use in routine care and is well accepted by patients and health care providers. Patients were compliant with the program, indicated that myIBDcoach facilitated communication with their health care providers and that the e-learning modules improved their knowledge about IBD.

During this pilot study, adherence to the system was very high. In the literature, telemedicine tools faced attrition rates as high as 14% to 44% over time. 10,15,26,30,34 We aimed to increase compliance with myIBDcoach by involving patients in all stages of the development, by providing feedback to the patient in a personal care plan and by constraining questionnaires to a reasonable length with individualized frequency. To increase patient empowerment, myIBDcoach contains e-learning modules, promotes patients' self-management, and facilitates communication between patients and health care providers. The finding that 93% of patients would recommend myIBDcoach to other patients reflects a high patient satisfaction rate. Additionally, to enhance user friendliness, myIBDcoach can also be used on a smartphone or tablet.

Despite proven benefits of telemedicine for IBD and other chronic diseases, few systems are implemented in everyday care. One possible reason might be that previously published tools monitor, educate, or empower specific groups of patients ^{10,26,30,34} (Table 3). Contrary to this, we deliberately designed myIBDcoach for all subtypes of patients with IBD in different settings, regardless of phenotype, disease activity, or medication use. In addition, we wanted myIBDcoach to focus on all facets of this complex disease,

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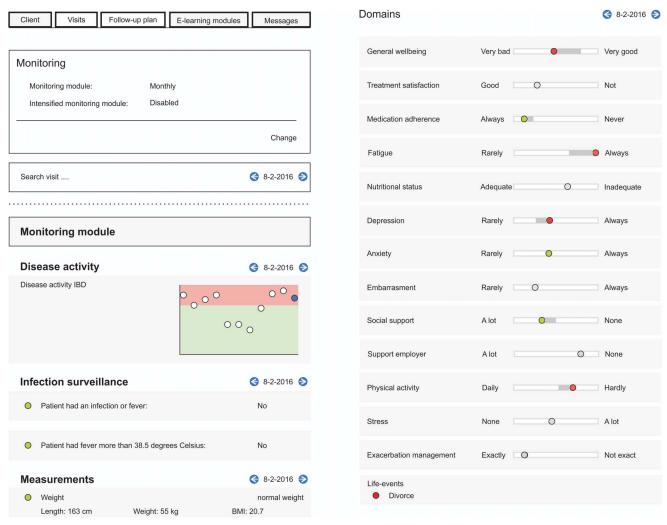


FIGURE 4. Personal care plan of mylBDcoach.

i.e., not only directly on IBD-related aspects, but also on stress, smoking, nutritional status, and treatment adherence, which may impact disease outcome and QoL. Prevention of treatment nonadherence for example, reported to be as high as 40% to 60% in

TABLE 2. Baseline Characteristics of the Participating Patients in the Feasibility Study

	Participating Patients (n = 30)
Age, mean (SD)	44.2 (11.7)
Gender, N (%)	
Male	12 (40.0)
Disease duration (yr), mean (SD)	14.7 (13.8)
Phenotype, N (%)	
CD	17 (56.7)
UC	13 (43.3)

patients with IBD, has a significant impact on the risk of disease relapse, hospitalization, health care costs, and work absenteeism. 9,10

Jackson et al¹⁵ recently reviewed the entire spectrum of eHealth interventions used for IBD management and provided recommendations for the design of future IBD eHealth technologies to facilitate implementation. They emphasized the importance of a framework for development, evaluation, and implementation of eHealth interventions and the relevance of patient and clinician involvement in all stages. MyIBDcoach was developed through close collaboration between patients, nurses, and gastroenterologists during all phases of the development. The rights for the content of the system are governed by a nonprofit foundation. The board and content committee of the myIBDcoach foundation consist of patients and clinicians from all important Dutch stakeholders involved in IBD care. The foundation carefully monitored all phases of the developmental and implementation process.

As the pilot study showed that IBD care with myIBDcoach is feasible and can be used for routine follow-up, we initiated

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TABLE 3. OVE	TABLE 3. Overview Previously Developed	oed and Tested Telemedicine Tools in IBD	edicine To	ols in IBD		
	Application	Study Population	Study Design	Assessments/Education	Frequency Measurements	Outcomes
Cross et al. (IBD 2012) ³⁰	UC-HAT: computer with electronic weight scale, decision-support server and web-based clinician portal	47 patients with UC	Randomized controlled trial	Symptoms, medication usage, adherence, and side effects, Disease specific education	Weekly	UC-HAT shows high acceptance and adherence to self-testing. No differences in disease activity, medication adherence and QoL between groups.
Pedersen et al. (AP&T 2012) ³⁴	Constant Care: web-based IFX treatment approach for patients with CD	27 patients with CD with IFX Controlled maintenance therapy trial	Controlled trial	Disease activity and fecal calprotectin	Weekly	Patients are able to self-manage with IFX using the web-guided maintenance therapy. No statistically significant differences in the mean interval between IFX infusions between groups were seen.
Elkjaer et al. $(Gut 2010)^{26}$	Constant Care: web-based telemonitoring	333 mild-moderate patients with UC with 5-ASA therapy	Randomized controlled trial	Randomized Disease activity, medication Remission: controlled usage, and QoL; E-monthly; trial learnings Relapse: Relapse: daily	Remission: monthly; Relapse: daily	Constant Care is feasible, safe, and cost-effective. Improvement of treatment adherence, IBD knowledge, QoL and shorter relapse duration in intervention group.
Pedersen et al. (IBD 2014) ¹⁰	Constant Care: web-based guided 95 mild-moderate patients with Prospective 5-ASA dose regulation UC with maintenance open-labb systemic and/or topical study 5-ASA therapy	95 mild-moderate patients with UC with maintenance systemic and/or topical 5-ASA therapy	Prospective open-label study	Disease activity and fecal calprotectin	Weekly	Feasible and safe. Web-guided 5-ASA therapy leads to improvement of therapy adherence.

a randomized controlled trial to investigate whether the integrated and holistic approach of myIBDcoach is safe and increases efficiency of IBD care compared with that of standard care. A total of 909 consecutive outpatients with IBD from academic and nonacademic hospitals, regardless of disease severity and activity, and treatment strategies ranging from no treatment to combined immunosuppressives, were included and randomized to care by means of myIBDcoach or standard care for 1 year. The primary endpoints are the number of outpatient visits and patient-reported quality of IBD health care. Secondary endpoints include disease outcomes (i.e., flares, corticosteroid use, hospitalizations, emergency visits, and IBD-related surgery), medication adherence, and QoL. We will also assess whether use of myIBDcoach leads to patient empowerment by an increase in knowledge about the disease and treatment and whether myIBDcoach is a suitable tool for structured collection of PROMs.

In conclusion, we developed myIBDcoach, which enables integrated and holistic care for all patients with IBD in both academic and nonacademic centers. The feasibility study showed high satisfaction of patients and health care providers with the system. After these positive results, a large multicenter randomized controlled trial has been initiated.

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5-ASA, 5-aminosalicylic acid; IFX, infliximab

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