Enhancing Patient Empowerment in Inflammatory Bowel Disease: A Randomized Controlled Study on On-Demand Telemonitoring

Published: 05-12-2024
Last updated: 18-01-2025

The primary objective is to assess the effect of on-demand telemonitoring for IBD patients on the cumulative incidence of persistent flares.

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON57142

Source
ToetsingOnline

Brief title
TOD-IBD: Empowering patients on-demand

Condition

- Gastrointestinal inflammatory conditions

Synonym
Inflammatory Bowel Disease (Crohn's disease and ulcerative colitis)

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: Door het Franciscus Gasthuis & Vlietland en

het Jeroen Bosch Ziekenhuis

Intervention

Keyword: Inflammatory Bowel Diseases, Patient Participation, Telemedicine

Outcome measures

Primary outcome

The primary outcome is the cumulative incidence of persistent flares at 12 months defined as a flare for a consecutive period of >= 12 weeks. A flare is defined as a FCP >= 250 µg/g on two consecutive measurements in a 12-week interval and a MIAH above cut-off at least once during the period of 12 weeks.

Secondary outcome

The secondary outcome measures include: Cumulative incidence of transient flares (lasting <12 weeks), proportion of patients in clinical and biochemical remission at 12 months, patient-reported disease activity (IBD-Control-8), quality of life (EQ-5D-5L, WIX, and SIBDQ), self-efficacy (IBD-SES), patient activation (PAM-13), total number of contacts with a healthcare provider, safety, and costs (healthcare costs, productivity costs, and patient costs). Baseline characteristics include patient, disease, and socio-demographic factors.

Study description

Background summary

Crohn's disease and Ulcerative Colitis (Inflammatory Bowel Disease (IBD)) are chronic intestinal inflammations with significant impact on quality of life.
Due to their chronic nature and complex treatment requiring regular outpatient appointments, IBD care puts a great burden on both the patient and the

healthcare system. Appropriate care, as described in the Integrated Care Agreement published by the Dutch ministry of Health, is becoming increasingly important. Telemonitoring is a promising alternative to regular outpatient visits, with evidence of improving the quality of care. We combined a clinical disease activity patient-reported outcome measure (the Monitor IBD At Home questionnaire) with a faecal calprotectin home test (SmarTest from Preventis) integrated in a new easy to use E-health application IBD Care Everywhere (IBD-CE) for IBD patients to determine disease activity at home.

In this study, we are investigating whether utilizing telemonitoring on-demand (telemonitoring at one's own discretion) is equally effective and safe compared to telemonitoring based on a fixed schedule. This concept offers the opportunity to align the treatment of the disease more closely with the principles of appropriate care, which can result in improved patient autonomy, increased satisfaction, and enhanced self-management, while simultaneously reducing the burden on the healthcare system.

Study objective

The primary objective is to assess the effect of on-demand telemonitoring for IBD patients on the cumulative incidence of persistent flares.

Study design

This is a pragmatic, multicenter, non-inferiority, parallel randomized controlled trial comparing on-demand telemonitoring with standard telemonitoring over a period of 12 months. Patients in the standard telemonitoring group follow a regular telemonitoring care pathway, which involves completing the Monitor IBD At Home (MIAH) questionnaire and performing a fecal calprotectin (FCP) home test according to a fixed schedule, in combination with the option to use it at their own discretion. The app provides follow-up advice based on the results of an algorithm. In the on-demand intervention group, patients can use the app at their own discretion when they experience symptoms but are not required to perform standard measurements when they are symptom-free. This allows them to have control over their monitoring activities.

Intervention

Subjects will be randomised into two groups:
- Control group (standard telemonitoring): Patients will be monitored according to a fixed telemonitoring schedule at their treating hospitals. This schedule is based on the patient's medication type and in adherence to national and international guidelines (35). Specific schedules corresponding to each medication type are described in detail in chapter to utilize the telemonitoring tool outside the fixed schedule at their own discretion in case

of symptoms.
- Intervention group (on-demand telemonitoring): Patients will have the flexibility to use the telemonitoring application at their own discretion in case of symptoms.

Study burden and risks

The risks of participation are negligible and the burden is minimised. No additional visits are scheduled and no invasive examinations are performed.

Contacts

Public
Jeroen Bosch Ziekenhuis

Henri Dunantstraat 1
's-Hertogenbosch 5223 GZ
NL
Scientific
Jeroen Bosch Ziekenhuis

Henri Dunantstraat 1
's-Hertogenbosch 5223 GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Aged >18 years.
- Confirmed IBD diagnosis according to current standards.
- Provided informed consent.
- Maintenance therapy with no medication changes in the last 3 months.
- Remission:
- Crohn*s disease
- Location = L1: Faecal calprotectin (FCP) < 150 µg/g and Harvey Bradshaw Index (HBI) < 5 or MIAH-CD < 0.3623618
- Location > L2: Faecal calprotectin (FCP) < 250 µg/g and Harvey Bradshaw Index (HBI) < 5 or MIAH-CD < 0.3623618
- Ulcerative Colitis: Faecal calprotectin (FCP) < 250 µg/g and Simple Clinical Colitis Activity Index scores (SCCAI) < 3 or MIAH-CU < 0.354215

Exclusion criteria

- Presence of a stoma.
- Presence of an ileo-anal pouch or ileorectal anastomosis.
- Participating in another prospective clinical trial that interferes with this trial.
- Have insufficient knowledge of the Dutch language to use the application.
- Do not have a smartphone or tablet with an internet connection.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2024
Enrollment:	422
Type:	Anticipated

Ethics review

Approved WMO Date:	05-12-2024
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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
ClinicalTrials.gov	NCT06179563
CCMO	NL86106.100.24