

Integrated care for inflammatory bowel disease patients in the Netherlands with the novel telemedicine tool myIBDcoach: a randomized controlled trial

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The aim of this study is to compare standard care for IBD patients in 4 hospitals with care via the telemedicine tool myIBDcoach.

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

Summary

ID

NL-OMON41419

Source

ToetsingOnline

Brief title

The myIBDcoach trial

Condition

- Gastrointestinal inflammatory conditions

Synonym

Crohn's disease, ulcerative colitis

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: inflammatory bowel disease, integrated care, patient empowerment, Telemedicine

Outcome measures

Primary outcome

Primary endpoints:

Difference between study arms REGARDING:

- * Visits to the outpatient clinic
- * Patient satisfaction with IBD health care

Secondary outcome

Secondary endpoints:

Difference between study arms REGARDING:

- * Complications (hospital admissions, duration of hospital admission, need for steroid use)
- * Compliance
- * Patient reported quality of care
- * Medication adherence
- * Self-efficacy
- * Quality of life
- * Knowledge about the disease and treatment
- * Disease activity: amount of flares, mean relapse duration
- * Consumption of healthcare
- * Smoking

Study description

Background summary

Inflammatory bowel diseases (IBD) is an invalidating disease mainly diagnosed in young people. The disease is characterized by a heterogenic phenotype and the disease course by flares and remissions. As in most chronic diseases the economic burden of IBD is important due to direct health care costs and disability[1]. Health care reorganization for IBD patients in the Netherlands is necessary for several reasons. First chronic (sub)clinical mucosal inflammation results in irreversible bowel damage and complications and non-of the presently available drug is effective for all patients and many drugs have possible severe side effects. To prevent complications of the disease and side effect IBD should be monitored carefully. In the Netherlands however there is a shortage of gastroenterologist where the incidence of IBD is rising. Secondly evidence exists that direct involvement of health care workers, patient empowerment and integrated care can improve the outcome of chronic diseases [2]. Thirdly many clinically relevant aspects (e.g. malnutrition) of this complex disease are not systematically followed in routine care. Finally the government demands registration of efficacy endpoints for expensive drugs in the near future. Therefore we developed a web-based Telemedicine tool for IBD patients in collaboration with the Dutch IBD patient's organization (CCUVN). "myIBcoach" contains E-learning modules, monitors disease activity, disability, quality of life, adherence, infections, smoking status, side effects, stress and malnutrition on fixed time points with validated questionnaires, allows the patient to communicate with health care workers and gives feedback to the back office and the patient. A feasibility study in 30 IBD patients in 3 centres showed a high satisfaction and compliance of IBD-patients and health care workers with this telemedicine tool (J. Degens. et al JCC 2014).

Study objective

The aim of this study is to compare standard care for IBD patients in 4 hospitals with care via the telemedicine tool myIBDcoach.

Study design

A two-arm, randomized controlled trial among 1000 patients visiting the outpatient clinic of the MUMC, LUMC, Gelderse Vallei Ede, St. Antonius hospital Nieuwegein or Orbis MC.

Intervention

Patients will be randomized between 2 arms

1. Standard-care:

2. IBD-coach arm: patients are followed with the telemedicine tool myIBDcoach and one standard appointment after one year.

Patients in both study-arms are asked to fill-out a questionnaire at inclusion and after one year.

Study burden and risks

Both groups will be asked to fill out a questionnaire twice. Patients in the myIBDcoach arm can make an extra appointment to the outpatient clinic if they feel this is warranted. They are also advised to visit the outpatient clinic incase the healthcare worker notices an alarm signal in the IBD-coach. Therefore there is no risk involved.

Contacts

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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 confirmed Crohn's disease or ulcerative colitis
- age between 18 and 75
- Patient has/can use a computer or tablet or smart phone with a connection to the internet

Exclusion criteria

- Patients who do not speak Dutch
- Patient discharged from the hospital within 2 week prior to baseline

Study design

Design

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

Primary purpose: Health services research

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	11-08-2014
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO	
Date:	25-07-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO	
Date:	10-04-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL47697.068.14
Other	volgt

Study results

Date completed:	17-07-2016
Actual enrolment:	909