Feasibility of a mobile application guiding patients with inflammatory bowel disease during biologic treatment

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In this study we aim to evaluate the feasibility of a mobile application guiding IBD patients during biologic treatment.

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

Summary

ID

NL-OMON48345

Source
ToetsingOnline

Brief title
Mobile application for IBD patients with biologics

Condition

- Gastrointestinal inflammatory conditions

Synonym
Crohn's disease and ulcerative colitis, Inflammatory bowel disease

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: Ziekenhuis Rijnstate

Intervention

Keyword: Biologic treatment, feasibility, Inflammatory bowel disease, Mobile application

Outcome measures

Primary outcome

Primarily, we will evaluate the satisfaction of patients with the mobile

application, actual use and adherence.

Secondary outcome

The satisfaction of care providers and change in number of outpatient visits

and telephone contacts will also be evaluated.

Study description

Background summary

Biologic treatment, including infliximab and vedoluzimab, can induce and maintain remission in patients with inflammatory bowel disease (IBD). However, biologics are associated with increased risk of infections. Therefore, it is important to regularly monitor patients for infections during the course of therapy. This process can be time consuming for patients as well as clinicians. Mobile applications, have the potential to guide patients and facilitate monitoring of biologic treatment.

Study objective

In this study we aim to evaluate the feasibility of a mobile application guiding IBD patients during biologic treatment.

Study design

This is a feasibility study with assessments at baseline and after implementation of the mobile application. The study period will cover 6-12 months.

Intervention

Patients will use a mobile application to guide them during biologic treatment. The mobile application consists of the following functionalities:
* A personal timeline consisting of information, reminders and a questionnaire with feedback from the gastroenterology nurse to prepare for next biologic treatment.
* Information about the patients* disease and treatment.
* General information modules, for example about vaccinations and medical terms.
* Information to provide patients with tools to decide when and how to consult their care-giver if they experience possible change in disease complaints.

Study burden and risks

We believe patients will benefit from using the mobile application. It has the potential to save time for patients as well as clinicians, previously spend on telephone contact between the gastroenterology nurse and patient to discuss a simple checklist to check for infections. Also, patients will be guided via reminders, for example when blood tests are needed. We believe risks are negligible. The results of blood tests and answers to questionnaire filled in via the application are checked manually for each patient by an experienced gastroenterology nurse. If there is any doubt about results obtained via the application, patients will be contacted by telephone as is standard care. Lastly, the requested time investment of patients is limited, with a short questionnaire (± 10 minutes) prior to implementing the application and after ± 6 six months.

Contacts

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Scientific
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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 inflammatory bowel disease (including Crohn*s disease, ulcerative colitis and IBD-unclassified) based on a combination of clinical, endoscopic, histologic and radiologic internationally accepted criteria.
- Treatment with biologics, for the purpose of this study only patients with biologics that are administered intravenously in the hospital every 4-10 weeks are included (infliximab or vedoluzimab).
- Aged 18 years or older.
- Having (access to) a tablet or smartphone.
- Having (access to) working internet connection.
- Ability to read and understand the Dutch language.

Exclusion criteria

- Patients recently started with biologic treatment (< 3 maanden)
- No access to a tablet or smartphone
- No internet access

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-03-2020
Enrollment:	55
Type:	Actual

Medical products/devices used

Generic name:	Patient Journey App
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	03-02-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-06-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL72353.091.19