Web-based home monitoring of disease activity and relapse risk

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To examine if use of a web-based program for continuous disease monitoring (IBD-live) improves disease course, quality of life and cost-efficiency of care, as compared to usual care.

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

Summary

ID

NL-OMON41416

Source
ToetsingOnline

Brief title
IBD-live: teenagers at the wheel

Condition

- Gastrointestinal inflammatory conditions

Synonym
Crohn's disease and ulcerative colitis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: ZonMw Doelmatigheidsonderzoek,Buhlmann Laboratories AG,Ferring,Innovatiefonds Zorgverzekeraars; Fonds NutsOhra

Intervention

Keyword: children, eHealth, inflammatory bowel disease, telemedicine

Outcome measures

Primary outcome

Primary outcome is the frequency of relapse at 12 months of follow-up. Relapse is defined as a clinical activity score >10 points necessitating steroid therapy, a 6 week course of exclusive enteral nutrition, aminosalicylate dose escalation, or introduction of anti-TNF antibodies.

Secondary outcome

- Disease specific quality of life measured with the IMPACT-III questionnaire

- Cost-effectiveness will be evaluated from a societal perspective, incorporating travel expenses and costs of parental absence from work, next to direct medical costs of IBD care.

Study description

Background summary

To prevent clinical relapse in teenagers with inflammatory bowel disease (IBD) there is a need to monitor disease activity continuously. Timely optimisation of medical treatment may nip a preclinical relapse in the bud and change the natural course of IBD. Traditionally, disease monitoring is done during scheduled visits, but this is when most patients report full control. IBD care could be more efficient if patients were seen at times of clinical need.

Study objective

To examine if use of a web-based program for continuous disease monitoring (IBD-live) improves disease course, quality of life and cost-efficiency of care, as compared to usual care.

Study design

Multicenter randomized trial comparing IBD-live with usual care.

Intervention

Teenagers assigned to IBD-live will use the flarometer -an automatic cumulation of disease activity and fecal calprotectin (fCal)- to estimate probability of relapse. In case of high risk treatment is intensified in accordance with national guidelines; low risk means that maintenance therapy is unchanged; and intermediate risk requires optimisation of drug adherence.

Study burden and risks

There is no additional risk in the control group. In the intervention group scheduled doctor-patient encounters and blood drawings will be reduced to once every 6 months. The 6-months interval between two phlebotomies may hinder early recognition of thiopurine-related toxicity, although we expect to find a low incidence of this adverse reaction among eligible participants. Patients from both groups are instructed to contact the local IBD-team if they experience relapse, or if at any time they want a consultation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

age 10 to 19 years,
quiescent IBD for more than 3 months before study enrolment,
IBD diagnosed (according to the Porto criteria) more than 6 months before enrolment,
access to internet and weighing scale
knowledge of the Dutch language
adult caregiver who is willing to actively support participation

Exclusion criteria

maintenance treatment with infliximab or adalimumab,
presence of ileostomy or ileoanal pouch,
any comorbidity at the time of enrolment that requires hospitalization or frequent blood sampling.

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-06-2013
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO Date:	19-03-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	09-08-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	26-02-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-06-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-02-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-07-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL43086.042.13