IBD-live: Teenagers at the wheel.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29580

Source
Nationaal Trial Register

Health condition

inflammatory bowel disease; relapse; Crohn’s disease; ulcerative colitis; eHealth; telemedicine; children; calprotectin; home monitoring

Sponsors and support

Primary sponsor: Prof. dr. F. Kuipers, Dean
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Source(s) of monetary or material Support: (1) ZonMw (the Netherlands Organisation for Health Research and Development)
(2) Innovatiefonds Zorgverzekeraars

Intervention

Outcome measures

Primary outcome

Primary outcome is relapse rate per group. Relapse is defined as moderate-severe disease

activity in combination with fCal >250 ug/g, necessitating induction therapy.

Secondary outcome

Secondary endpoints include the IMPACT-III score, which is a disease-specific quality of life score.

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

Background and Aims:

Conventional follow-up of teenagers with inflammatory bowel diseases [IBD] is done during scheduled outpatient visits regardless of how well the patient feels. We designed a telemonitoring strategy for early recognition of flares and compared its efficacy with conventional follow-up.

Methods:

We used a multicentre randomized trial in patients aged 10–19 years with IBD in clinical remission at baseline. Participants assigned to telemonitoring received automated alerts to complete a symptom score and send a stool sample for measurement of calprotectin. This resulted in an individual prediction for flare with associated treatment advice and test interval. In conventional follow-up the health check interval was left to the physician's discretion. The primary endpoint was cumulative incidence of disease flares. Secondary endpoints were percentage of participants with a positive change in quality-of-life and cost-effectiveness of the intervention.

Results:

We included 170 participants [84 telemonitoring; 86 conventional follow-up]. At 52 weeks the mean number of face-to-face visits was significantly lower in the telemonitoring group compared to conventional follow-up [3.6 vs 4.3, $p < 0.001$]. The incidence of flares [33 vs 34%, $p = 0.93$] and the proportion of participants reporting positive change in quality-of-life [54 vs 44%, $p = 0.27$] were similar. Mean annual cost-saving was €89 and increased to €360 in those compliant to the protocol.

Conclusions:

Telemonitoring is as safe as conventional follow-up, and reduces outpatient visits and

societal costs. The positive impact on quality-of-life was similar in the two groups. This strategy is attractive for teenagers and families, and health professionals may be interested in using it to keep teenagers who are well out of hospital and ease pressure on overstretched outpatient services.

Study objective

Use of IBD-live for 1 year:

1. Reduces the relapse rate from 40% to 25%;

2. Increases quality of life (assessed with the IMPACT-III questionnaire).

Study design

Primary outcome at 12 months.

Intervention

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.

Control:

Usual care consists of fixed, 3-monthly contacts with the IBD-team and includes a physicians' rating of disease activity and blood sampling.

Contacts

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Eligibility criteria

Inclusion criteria

Eligible patients are those: Aged 10 to 19 years, with quiescent IBD for more than 3 months before study enrolment, with IBD diagnosed (according to the Porto criteria) more than 6 months before enrolment, who have access to internet and weighing scale, with knowledge of the Dutch language, and with an adult caregiver who is willing to actively support participation.

Exclusion criteria

Potential participants will be excluded from the study if any of the following conditions occur:

1. Maintenance treatment with infliximab or adalimumab (for unavoidable frequent contact with health providers);

2. Presence of ileostomy or ileoanal pouch (as fCal cut-off is not validated for small bowel feces);

3. Presence of active perianal Crohn’s disease;

4. 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)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2013
Enrollment:	180
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	29-12-2012
Application type:	First submission

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
NTR-new	NL3601
NTR-old	NTR3759
Other	Innovatiefonds / ZonMw / Fonds NutsOhra : 2509 / 80-83700-98-131006 / 1301-002;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
https://doi.org/10.1186/s13063-015-0787-x
https://doi.org/10.1093/ecco-jcc/jjx169