

Adherence as a lifetime effort.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24529

Source

NTR

Brief title

RAP

Health condition

inflammatory bowel disease (IBD)

Sponsors and support

Primary sponsor: Amsterdam School of Communication Research ASCoR, University of Amsterdam

Merck Sharp & Dohme B.V., gevestigd te Waarderweg 39, 2031 BN te Haarlem

Source(s) of monetary or material Support: Amsterdam School of Communication Research ASCoR, TEVA Pharmachemie and Merck Sharp & Dohme BV

Intervention

Outcome measures

Primary outcome

1. Information recall;
2. Medication adherence.

Secondary outcome

1. Nurse-patient communication;
2. Current levels of generalized anxiety;
3. Psychological distress.

Study description

Background summary

The purpose of the study is to improve recall of information and medication adherence of IBD patients who receive a medication change to immunosuppressive drug classes used for long-term maintenance therapy. Specific aims are:

1. To examine the extent to which communication during the medical consultation is tailored to patients' needs;
2. To examine which communication techniques concerning promoting recall and adherence are used by IBD nurses and;
3. To examine patients' use of additional information sources;
4. To develop recommendations to tailor the communication process to the patients' needs and improve recall of information and adherence;
5. To implement an intervention, existing of a communication skills training combined with a web based application, based on these recommendations and;
6. To evaluate the effectiveness of this intervention.

Data collection will be in the Netherlands.

Study objective

Medication represents a keystone of modern treatment strategies for Inflammatory Bowel Disease (IBD). Appropriate use of the medication can help IBD patients to reduce the chance of relapse. Nevertheless, IBD patients represent a high-risk situation as it comes to non-adherence. Non-adherence rates have been described as varying from 20% - 40% and rises as high as 72% for long-term therapies. Appropriate use of the medication can help IBD patients to reduce the chance of relapse. Research shows that patients who are satisfied with their relation with their health care providers have better adherence. Clinical efforts to promote adherence depend on clinicians and nurses providing the message and patients

being able to recall it, i.e. to be able to understand and reproduce the message. However, 40-80% of the medical information presented by health care is immediately forgotten by patients. There is a growing body of empirical evidence that demonstrates that addressing patients' information needs (task oriented communication) and emotional needs (socio-emotional communication) will result in better recall and, consequently, might improve treatment adherence. Therefore, effective communication is crucial and patients' recall of advice is an intermediary step to action to maintain the medication-taking behaviour and promote treatment adherence.

Study design

1. Questionnaire 1 (before consultation nurse);
2. Consultation IBD-nurse (video-taped);
3. Questionnaire 2 (immediately after consultation nurse);
4. Questionnaire 3 (follow-up after 2 weeks by phone);
5. Questionnaire 4 (follow-up after 6 months by phone).

Intervention

A nurse-based and a patient-centered (eHealth) intervention.

Based on the first study, an intervention will be developed. This intervention will consist of a tailored communication device (eHealth) and a communication skills training. The first experimental group of nurses will receive a communication skills training, the second experimental group will receive the same communication skills training added with a supportive eHealth intervention for patients and the control group will continue in giving care as usual. Concerning the communication skills training, this will be one day with a follow-up after 6 weeks. The reminder system will prompt the patient on the moment they should take the medication. This could be daily, once a week, once in two weeks or once in eight weeks, it will depend on the treatment regimen.

Contacts

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Eligibility criteria

Inclusion criteria

1. The patient is diagnosed with Crohn's disease or Ulcerative Colitis;
2. The patient is starting with one of the following new medications Azathioprine (Imuran ®), 6-mercaptopurine (Purinethol ®), Infliximab (Remicade ®), Methotrexate (Ledertrexate ®), 6-tg (Lanvis), Adalimumab, (Humira) and other biologicals);
3. The patient is aged 18 years or older;
4. The patients can speak and read Dutch.

Exclusion criteria

The patient has any diagnosed cognitive limitation (according to the medical file).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL
Recruitment status: Recruiting
Start date (anticipated): 01-09-2009
Enrollment: 211
Type: Anticipated

Ethics review

Positive opinion
Date: 11-05-2011
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 NL2753

NTR-old NTR2892

Other METC VUmc / METC OLVG / METC UMC : 2008/281 / WO 10.034 / 10-347/C;

ISRCTN ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

Linn, A. J., Vervloet. M., Van Dijk L, Smit, E. G. & Van Weert, J. C. M (2011). Effects of eHealth interventions on medication adherence: a systematic review of the literature (in review).

Linn, A. J., Van Weert, J. C. M., Van Bodegraven, A. A. & Kanis, D. (2010). Promoting recall of information and treatment adherence in IBD patients (abstract). Journal of Crohn's & Colitis, 4(1), 121-122.