Adherence as a lifetime effort.

Gepubliceerd: 11-05-2011 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24529

Bron
NTR

Verkorte titel
RAP

Aandoening

inflammatory bowel disease (IBD)

Ondersteuning

Primaire sponsor: Amsterdam School of Communication Research ASCoR, University of Amsterdam
Merck Sharp & Dohme B.V., gevestigd te Waarderweg 39, 2031 BN te Haarlem
Overige ondersteuning: Amsterdam School of Communication Research ASCoR, TEVA Pharmachemie and Merck Sharp & Dohme BV

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Information recall;

2. Medication adherence.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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 change 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.

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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 ®), Methotrexaat (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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2009
Aantal proefpersonen:	211
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-05-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2753
NTR-old	NTR2892
Ander register	METC VUmc / METC OLVG / METC UMC : 2008/281 / WO 10.034 / 10-347/C;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

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.