

# The cost-effectiveness of fatigue management in patients with Crohn\*s disease (CD)

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Study of the cost-effectiveness of fatigue management in patients with Crohn\*s disease (CD)

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Gastrointestinal inflammatory conditions
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON33669

### Source

ToetsingOnline

### Brief title

The cost-effectiveness of fatigue management

### Condition

- Gastrointestinal inflammatory conditions

### Synonym

fatigue, tiredness

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Ely Broad Foundation

## Intervention

**Keyword:** cost-effectiveness, Crohn's disease, fatigue management

## Outcome measures

### Primary outcome

Aims of study:

1. The primary aim of the study is to assess the cost-effectiveness of a fatigue coping course in patients with CD.
2. Secondary aims are: improvement of fatigue and quality of life through the introduction of this specific coping strategy in IBD patients.

### Secondary outcome

see above

## Study description

### Background summary

Background: Inflammatory bowel diseases (IBD) are chronic inflammatory conditions that can affect the entire gastro-intestinal tract. IBD is still divided into 2 subcategories: Ulcerative Colitis (UC) and CD. Annually, 1400 patients with IBD are visiting the IBD out-patient clinic in the Erasmus MC. The average frequency of these visits is twice a year but this frequency rises to once per month in about 60% of patients. Reasons for increased frequency of visits are: relapse of the disease, side-effects of medication, and fatigue. It is known that about 41% patients with quiescent IBD (UC and CD) suffer from fatigue. They often score their symptoms similar to what is reported by cancer patients. The fatigue has a high impact on the quality of life, and leads to low employment and high disability rates. The costs related to IBD consist of direct costs (32%; inpatient care, outpatient care, self-care, medications and tests/procedures) and productivity costs (work absence, decreased incomes, premature death and decreased health related quality of life (HQoL). The direct costs vary between 6.000 euro- 40.000 euro per patient year, and are expected to be higher in IBD patients with fatigue than in those without, as shown previously in IBS patients. Fatigue may result in a defensive and ineffective use of medical attention and resources and therefore to more frequent visits,

more tests and often variable treatment. If an effective treatment would be offered to deal with the fatigue, this would redirect the medical attention seeking behaviour of the patient, and could result in a more cost effective way of treating these patients. No studies specifically aim to treat IBD patients with fatigue have been performed so far.

## **Study objective**

Study of the cost-effectiveness of fatigue management in patients with Crohn's disease (CD)

## **Study design**

Prospective, cross-over intervention study in CD patients

## **Intervention**

Subjects scoring high on the CIS compared to a healthy norm population (9th percentile) will be included for the intervention study. Patients randomized for a fatigue coping strategy will receive a course to learn to cope with fatigue. Control subjects will receive standard care. The training is based on the Problem Solving Therapy (PST) or Solution Focused therapy.

PST is a frequently used hands-on psychological intervention based on a general model of coping with stress. This model assumes that a chronic disease causes a number of stressful problems in daily living. These stressful problems increase the chances that the patients become anxious and depressed. The treatment goal of PST is to increase the capabilities of the patients to deal with the daily stressful problems caused by CD. In this way the anxiety and depression would be reduced. This method has been validated and shown to be successful in other patient groups with chronic diseases. For the purpose of this study the PST will be modified to focus on fatigue management (PSTF). The training is done in 10 group sessions during 3 months, and the patients have to do \*home work\* in between.

Another psychological intervention is Solution - Focused Cognitive Therapy (SFCT). SFCT is a brief hands-on psychological intervention based on the solution - focused model of solving problems.

Although problems, in this study caused by CD, can be overwhelming, there are always moments when the problem is not there or when the problem is less severe or slightly different than at other times. In other words, there are always exceptions to the problems. These exceptions interest the solution - focused therapist because they indicate that there are partial solutions that can be enlarged into total solutions. The solution - focused model offers a wide range of interventions that channel your attention towards constructing possible solutions. Instead of concentrating on the (why of the) problems in the past, the solution - focused model concentrates on the desired outcome.

The method has been empirically validated and shown to be successful in other

patient groups with chronic diseases. For the purposes of this study the SFCT will be modified to focus on fatigue management (SFCTF).

## Study burden and risks

Study Rationale and Relevance to IBD patients: IBD patients are suffering from a disabling chronic disorder which affects their daily lives negatively. A large group of this patients experience extreme fatigue which leads to a lower quality of life. Often no active disease is underlying this fatigue and no treatment options are available in improving this fatigue and subsequently their quality of life. This study is not aiming at finding the underlying pathogenesis of fatigue, however is designed to improve the coping of fatigue in IBD patients and aims to lower health care costs due to this intervention.

## Contacts

### Public

Selecteer

s Gravendijkwal 230  
3015 CE Rotterdam  
NL

### Scientific

Selecteer

s Gravendijkwal 230  
3015 CE Rotterdam  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

patients, older than 18 years, have to be in remission according to the investigator, based on accepted clinical parameters and medical records (CDAI < 150 and CRP < 10, or at endoscopy).

## Exclusion criteria

pregnancy or breastfeeding; subjects likely to require emergency surgery and subjects who have undergone bowel surgery within 3 months prior to this study. Subjects with a short bowel syndrome; with a neoplastic condition; with a history of clinically significant and/or persistent gastrointestinal disorder (other than CD, for example IBS), underlying psychiatric disorder (depression/anxiety disorder).

## Study design

### Design

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

**Primary purpose:** Health services research

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-09-2008
Enrollment:	80
Type:	Anticipated

## Ethics review

Approved WMO	
Date:	25-07-2008

Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-04-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-09-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

## 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	NL22792.078.08