

The cost-effectiveness of fatigue management in patients with Inflammatory Bowel Disease (IBD)

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

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

Summary

ID

NL-OMON34314

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: Erasmus MC, Universitair Medisch Centrum Rotterdam

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

Intervention

Keyword: cost-effectiveness, cytokines, fatigue management, inflammatory bowel disease

Outcome measures

Primary outcome

Aims of the study:

1. The primary aim of the study is improvement of fatigue and quality of life through the introduction of this specific coping strategy in IBD patients by performing a randomized controlled trial of Solution Focused Therapy.

Secondary outcome

1. Secondary aim is: to assess the cost-effectiveness of a fatigue coping course in patients with CD.
2. To investigate the mechanisms behind fatigue and the effects of psychological intervention on several cytokines known to be involved in IBD.

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.

Furthermore we aim to explore the mechanisms which lead to fatigue in IBD patients because of the lack of knowledge on the pathogenesis of fatigue. We hypothesize that the ongoing inflammation in the gut plays an important role in the pathogenesis in fatigue even in IBD patients in remission and on medical therapy, which can be determined by different cytokine levels. Increased levels of the anti-inflammatory cytokine TGF-beta have been detected in sera from patients suffering from Chronic Fatigue Syndrome (CFS). Interestingly this cytokine is also increased in sera of IBD patients in clinical remission. Another study showed that endotoxin-stimulated ex vivo production of tumor necrosis factor-alpha and IL-beta was significantly lower in CFS compared to healthy controls. The question remains whether this effect was the result of a shift in leukocyte subpopulations or defective function of the TNF/IL-1b producing cells. Other studies demonstrated increased leucocyte apoptosis of which one study pointed this phenomenon down to the neutrophil population. The latter also showed that neutrophils from CFS expressed more TNFRI death receptor molecules. Together these data show that there is evidence for involvement of the immune system in patients suffering from chronic fatigue. Therefore we will measure a wide variety of cytokines known to be involved in IBD before, during and after the psychological intervention. We will measure these cytokines in fatigue patients, in fatigue controls waiting for the intervention and in non-fatigue controls with IBD.

Study objective

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

Study design

Prospective, cross-over intervention study in CD and UC patients

Intervention

The training is Solution - Focused Cognitive Therapy (SFT). SFT is a brief 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. Even amidst the worst possible mess there are always things to be found that still work or can be made to work.

Solutions belong to the future while problems belong to the past. 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 SFT will be modified to focus on fatigue management (SFT).

The training is done in 7 group sessions during 3 months, and the patients have to do *home work* in between. The Solution - Focused Principles:

1. If it's not broken, don't fix it.
2. If something is working, do more of it.
3. If it is not working, do something different.
4. Small steps can lead to large changes.
5. The solution is not necessarily directly related to the problem.
6. The language requirements for solution development are different from those needed to describe a problem.
7. No problem happens all the time. There are always exceptions that can be utilized.
8. The future is both created and negotiable.

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

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Inclusion criteria for the fatigue group were: age > 18 years, remission of the disease (CDAI < 150) and a high score on the Checklist Individual Strength (CIS subscale fatigue >= 35).; Inclusion criteria for the non-fatigue group: age > 18 years, remission of the disease (CDAI < 150) and a high score on the Checklist Individual Strength (CIS subscale fatigue < 35).

Exclusion criteria

Exclusion criteria were: pregnancy; surgery within 3 months prior to this study, neoplastic condition; other gastrointestinal diseases; psychiatric disorder (Hospital Anxiety and Depression Scale (HADS) score > 10).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	14-08-2010
Enrollment:	126
Type:	Actual

Ethics review

Approved WMO	
Date:	14-07-2010
Application type:	First submission
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

CCMO

ID

NL32020.078.10