Enhancing the quality of life of patients with inflammatory bowel disease; a multicentre study investigating cognitive behavioral therapy

Published: 11-12-2008
Last updated: 11-05-2024

The primary objective is to investigate the short-term effectiveness of individual cognitive behavioral therapy in a Dutch sample of IBD patients on quality of life, cognitions, and attitudes.The secondary objective is to investigate the extent to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON32226

Source
ToetsingOnline

Brief title
CBT and IBD

Condition

- Other condition
- Gastrointestinal conditions NEC

Synonym
Inflammatory bowel disease

Health condition

geringe kwaliteit van leven, angst en depressie klachten

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Maag Lever Darm Stichting MLDS

Intervention

Keyword: Anxiety, Cognitive behavioral therapy, Depression, Inflammatory bowel disease, Quality of Life

Outcome measures

Primary outcome

Measures

Sociodemographic and clinical data

Sociodemographic data will include age, gender, educational level, employment

status, marital status, ethnicity, and treatment center.

Clinical data will be completed by the treating gastroenterologist, and will

include type of disease (Crohn's disease and ulcerative colitis), date of onset

of disease, having a colostomy, and comorbidity. Finally, disease activity of

each patient attending the outpatient department will be registered in an

electronic database, using the following illness specific questionnaires: the

Harvey Bardshaw index (HBI) for patients with Crohn*s disease and the Modified

Truelove and Witts Severity Index (MTWSI) for patients with ulcerative colitis.

Outcome measures

Primary outcome measure.

The Inflammatory Bowel Disease Questionnaire (IBD-Q) will be used to assess

primary outcome of the intervention. The IBD-Q measures health-related quality of life and consists of 32 items assessing four dimensions; bowel symptoms, systemic symptoms, emotional functioning, and social functioning. In addition to these four subscale scores, a total score can be calculated.

Secondary outcome

Secondary outcome measures.

The MOS SF-36 is a 36-item questionnaire assessing generic health-related quality of life or health status. The items can be aggregated into a Physical Component Summary score and a Mental Component Summary score, which will be used as outcome variables.

The Illness Perception Questionnaire-Revised (IPQ-R) assesses illness-related cognitions. The 48 items measure seven dimensions: timeline acute/chronic, timeline cyclical, consequences, personal control, treatment control, emotional representations, and illness coherence.

The 40-item Dysfunctional Attitude Scale (DAS) measures dysfunctional attitudes, including excessive and rigid beliefs.

All standard self-report questionnaires fulfill the following selection criteria. They: (a) are relatively brief, (b) have sufficient breadth of coverage, (c) are widely used, and (d) yield adequate to high levels of reliability and validity.

The Hospital Anxiety and Depression Scale (HADS; Zigmund et al., 1983; Spinhoven et al., 1997) assesses the possible presence of anxiety and depressive states. The HADS is considered to be unbiased by the presence of somatic illness and is found to be reliable and valid. It consists of two

sub-scales, anxiety and depression, both containing seven items. Each item is rated on a 4-point scale from 0 to 3.

Zigmond AS, Snaith RP. The hospital anxiety and depression scale. Acta Psychiatr.Scand. 1983;67:361-70.

Spinhoven P, Ormel J, Sloekers PP, Kempen GI, Speckens AE, Van Hemert AM. A validation study of the Hospital Anxiety and Depression Scale (HADS) in different groups of Dutch subjects. Psychol.Med. 1997;27:363-70.

The CES-D scale (The Centre for Epidemiologic Studies Depression Scale) is a short self-report scale designed to measure depressive symptomatology in the general population. Reliability, validity, and factor structure were similar across a wide variety of demographic characteristics in the general population samples tested. The scale should be a useful tool for epidemiologic studies of depression.

Radloff LS (1977) The CES D Scale: a self report depression scale for research in the general population. Appl. Psychol Measure 3: 385-401

Tertiary outcome measures

The SCID-I is a semi-structured interview for the classification of psychiatric disorders following the DSM-IV-criteria. SCID-I refers to AS-I disorders (for instance anxiety and depression disorders).

Groenestijn, M.A.C. van, Akkerhuis, G.W., Kupka, R.W., Schneider, N. & Nolen, W.A. (1998), SCID-I: Gestructureerd klinisch interview voor het vaststellen van DSM-IV stoornissen, Amsterdam, Harcourt Assessment.

The Utrechtse Coping Lijst (UCL) (Schreurs et al.,1984; 1988) is a valid and reliable self-report measure that assesses general coping behaviour in problem

situations. The subscales *depression reaction pattern* (7 items) and *avoidance* (8 items) will be used. A four-point response scale is employed, ranging from seldom or not to very often.

Schreurs PJG, Tellegen B, Willige van de G. Gezondheid, stress en coping: de ontwikkeling van de Utrechtse Coping Lijst. Gedrag: Tijdschr Psychol 1984; 12: 101-117.

Schreurs PJG, Willige G. Omgaan Met Problemen en Gebeurtenissen: De Utrechtse Copinglijst (UCL). Lisse: Swets & Zeitlinger, 1988.

All standard self-report questionnaires fulfill the following selection criteria. They: (a) are relatively brief, (b) have sufficient breadth of coverage, (c) are widely used, and (d) yield adequate to high levels of reliability and validity.

Study description

Background summary

Individuals with Inflammatory Bowel Disease (IBD; Crohn's disease and ulcerative colitis) have been found to report poorer quality of life and more psychological distress than comparison-controls from the general population. Poor quality of life in turn, may cause relapse and disease activity. Recent studies suggest that higher levels of distress in IBD patients are associated with illness-related cognitions and attitudes. One of the most promising interventions for enhancing quality of life and decreasing distress in people is cognitive behavioral therapy. Such therapy is aimed at amending unhelpful cognitions and attitudes and offers a well-developed intervention protocol that has been found to be effective in people with other chronic illnesses. In a recent exploratory, uncontrolled study cognitive behavioral therapy for IBD outpatients was found to be feasible and effective for the reduction of psychological distress. These exploratory results justify a further and more stringent investigation of this therapy*s effectiveness in IBD patients.

The primary objective is to investigate the short-term effectiveness of individual cognitive behavioral therapy in a Dutch sample of IBD patients on quality of life, cognitions and attitudes. IBD patients who have a poor level of mental quality of life will be randomly assigned to a treatment condition (n = 40) and a waiting-list control condition (n = 40). Patients will complete standardized self-report measures on quality of life, illness-related cognitions and attitudes prior to and one month following intervention or control period.
If found feasible and effective, a new cognitive behavioral therapy protocol can be offered to patients with IBD and, possibly, other gastroenterological diseases. By enhancing IBD patients' quality of life, we may also improve their physical health, and ultimately lower unnecessary health care consumption.

Study objective

The primary objective is to investigate the short-term effectiveness of individual cognitive behavioral therapy in a Dutch sample of IBD patients on quality of life, cognitions, and attitudes.
The secondary objective is to investigate the extent to which changes in quality of life are mediated by improvements in cognitions and attitudes.
The tertiary objective is to describe the population in terms of psychiatric diagnoses and to explore the coping styles used.

Our primary hypothesis states that cognitive behavioral therapy will improve quality of life and amend illness cognitions and attitudes in IBD patients.
Our secondary hypothesis states that improvements in quality of life are mediated by changes in illness cognitions and attitudes.

Study design

Experimental design
Conditions.
The present study is designed as a multi-center randomized clinical trial. All patients with ulcerative colitis or Crohn's disease attending the out-patient departments of the Academic Medical Center (AMC), the University Medical Center Nijmegen (UMC St Radboud) and the Leids University Medical Centre (LUMC), will complete the SF 36 as part of standard care.
Those patients who score on the mental health subscale at or below the cutoff score of 23 will be eligible for the study. The mental health subscale consists of 5 items that require a response on a 6-point scale (range 5-30). These patients are considered sufficiently burdened by the illness to expect a psychological intervention to be potentially effective. The cutoff score of 23 was chosen as scores of 23 and lower were found indicative (with a high level of sensitivity and specificity) of depression and anxiety in primary care patients.

Within each participating center, consenting patients will be randomly assigned to one of two conditions: cognitive behavioral therapy administered immediately or waiting list control condition. Randomization will be stratified by age and gender, and will be performed at the Department of Clinical Epidemiology and Biostatistics of the AMC. Participants assigned to the waiting-list control condition will wait eight weeks plus one month before they will be treated with cognitive behavioral therapy. This period corresponds to the duration of the intervention and follow-up assessment.

Assessments. Patients who consent to participate will be asked to complete the set of questionnaires (see below) via the web, and will be administered the SCID-I (see below) by telephone within two weeks following screening. After completion of the baseline assessment, patients will be randomly assigned to the treatment or waiting-list control condition. Treatment for those in the treatment condition will then start as soon as possible. The second assessment will take place four weeks following start of treatment and the third assessment one month following completion of treatment. Patients in the waiting list control condition will be asked to complete the questionnaires four times: in addition to the three assessments as described for the treatment condition, they will also complete the set of questionnaires after inclusion in the study, prior to randomization, i.e.3,5 months prior to the immediate pre-treatment assessment.

Intervention

Intervention

The intervention spans an 8-week period, consisting of eight weekly sessions, each lasting one hour. The cognitive behavioral therapy will be conducted by registered psychotherapists, specialized in conducting cognitive behavioral therapy. The first session will focus on the rationale of cognitive behavioral therapy, i.e. the influence of (irrational or dysfunctional) cognitions and attitudes on (maladaptive) feelings and behaviors. Additionally, goal setting will be initiated. These therapy goals will be unique for each patient. The subsequent sessions (2-6) will be targeted at identifying and amending irrational cognitions and attitudes related to IBD. Each session will address specific illness-related cognitions. Additionally, patients will be taught how dysfunctional cognitions and attitudes affect adversely feelings and behaviors. These dysfunctional cognitions and attitudes will be challenged and replaced by functional cognitions and attitudes. After each session, patients will be given home work. For example, patients will be asked to register negative experiences, and accompanying cognitions, feelings and behaviors. Clearly, some of the negative cognitions are realistic and reflect the limitations that the disease imposes. Such thoughts will be worked through, accepted or resolved. Finally, in the last two sessions, the newly learned cognitions and attitudes will be consolidated.

Study burden and risks

Burden.
In general there are few if any risks associated with the research in question. Since there is no indication and no evidence that the intervention might be harmful to patients, we do not anticipate premature termination of the study. Clearly, each individual patient has the right to withdraw from the study at any time he/she wishes.
One burden could be that participants will have to wait (8 weeks) for the cognitive behavioral therapy intervention in the waitinglist control condition. Secundary burden could be that participants are obliged to follow the treatment manual including 8 sessions and complementary home work assignments.

Benefits.
The most important benefit is that the cognitive behavioral therapy intervention will enhancing the quality of life of the IBD patients. And it may not only benefit the psychological well-being of patients with IBD, but also their physical health.
There is a compelling need to enhance the quality of life of patients with IBD. Poor quality of life is not only a consequence of the disease but may in itself be a causal factor. It may induce a higher level of symptom severity, more reporting of unexplained physical symptoms and poorer treatment adherence.

The structured program (detailed session by session manual) will lend itself well for quick transfer to and training of the professionals (psychotherapists). Thus, if found effective a new cognitive behavioral therapy protocol can be offered to patients with IBD and possibly other gastroenterological diseases in the Netherlands.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1100 DD Amsterdam
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1100 DD Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion criteria are: (1) a diagnosis of Crohn*s disease or ulcerative colitis; (2) age above 18; (3) a score on the mental health scale of the SF-36 of 23 or lower; (4) physically and mentally able to attend eight weekly sessions; (5) willing to give written informed consent; and (6) sufficient command of Dutch.

Exclusion criteria

Exclusion criteria are (1) known psychiatric disorders that may complicate treatment (e.g., psychosis); and (2) current treatment with psychotherapy.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-09-2009
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL22948.018.08