

Effect of Inflammatory Bowel Disease on sexual function in men and women: A controlled study

Published: 11-07-2011

Last updated: 27-04-2024

The present study aims to extent the sparse knowledge on sexual function in IBD by 1) examining the prevalence of sexual problems in men and women with IBD (including Crohn*s disease and ulcerative colitis), 2) comparing this with the prevalence of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational non invasive

Summary

ID

NL-OMON38172

Source

ToetsingOnline

Brief title

Effect of Inflammatory Bowel Disease on sexual function

Condition

- Gastrointestinal inflammatory conditions
- Sexual dysfunctions, disturbances and gender identity disorders

Synonym

sexual complaints, sexual problems

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: inderdiend geld van de polikliniek

Intervention

Keyword: Crohn's disease, Female sexual function, Inflammatory Bowel Disease, Male sexual function, Sexuality

Outcome measures

Primary outcome

Sexual functioning as measured with validated questionnaires. The International Index of Erectile Function (IIEF) will be used in the male participants, and the Female Sexual Function Index (FSFI) in the female participants

Secondary outcome

Depression as measured with a validated questionnaire (the Hospital Anxiety and Depression Scale, HADS).

Disease-specific quality of life (measured with the S-IBDQ,),

Disease activity (as measured with the The Harvey Bradshaw Index (for Crohn*s disease) and the Simple Clinical Colitis Activity Index SSCAI (for ulcerative colitis),

Body image (as measured with the EORTC-QLQ-CR 38).

From the medical records of the IBD patients the following data will be retrieved: classification of Crohn*s disease or ulcerative colitis (Montreal Classification) duration of the disease, use of medication (corticosteroids), co-morbidities, and operations.

Study description

Background summary

Inflammatory bowel disease (IBD) includes Crohn's disease (CD) and ulcerative colitis (UC). These diseases typically manifest in adolescence or early adulthood and are characterized by a chronically relapsing course. Abdominal pain, fatigue, and diarrhea are typical symptoms in active disease. These symptoms may be aggravated by the embarrassing features of incontinence and bad odour. Complications may include perianal disease and malnutrition. Surgery, possibly including the installation of ostomy, and medical therapy with corticosteroids may be associated with changes in bodily appearance. In consequence, IBD is likely to have a substantial impact on issues of body image, intimacy and sexuality. Furthermore, mood disorders, particularly depression, are reported to be common in IBD (1), and since sexual dysfunction is known to be related to depression (2), depression may be an important determinant of sexual functioning in patients affected with IBD.

Despite the relevance of possible sexual problems, knowledge about the extent of sexual dysfunction in persons affected with IBD is scarce. Timmer et al (3) studied a male sample from the German national patient organization, and found that sexual function measured with the International Index of Erectile Function (IIEF) was not impaired as compared to healthy controls. However, sub-analyses showed impaired function on all domains of the IIEF in the subgroup of men with active disease in this sample. In a study in a clinical group of 98 male patients attending the department of internal medicine of a university hospital, 44% percent of the patients reported to feel severely comprised sexually due to their IBD (4). In this group, all IIEF scores were within one standard deviation of the means of a normal population, except for sexual desire, which was significantly lower in patients. Disease activity and depressive mood had a significant influence on sexual function. In addition, feelings of sexual attractiveness, and masculinity were strongly influenced by disease activity.

In women, Moody and Mayberry (5) described decreased sexual activity in women with Crohn's disease, based on structured interviews with 50 women with friend controls. Twenty-four percent of the cases abstained from sexual activity altogether because of their disease (4% in controls), and dyspareunia was also more common in patients. More recently, Timmer et al (6) reported a study in a female sample from the national patient organization, and a clinical sample of female patients attending the department of internal medicine of a university hospital. Sexual function, assessed by the Brief Index of Sexual Function in Women (BISF-W), was not significantly impaired in women with IBD as compared to healthy controls. Depressive mood was strongly associated with sexual function. In addition, disease activity was related to sexual desire, and use of steroids was associated with low pleasure and orgasm scores. In the clinical sample, 80 % of the women reported low interest in sexual activity, with 17 % reporting no sexual activity at all. Feelings of attractiveness, femininity, as well as satisfaction with bodily appearance were strongly influenced by disease activity.

Taken together, the very few studies on IBD and sexual function show mixed results. In general, male and female persons affected with IBD did not report more sexual problems than healthy controls. However, during active disease,

sexual function and feelings of attractiveness are diminished. In addition, as can be expected, depression seems to affect sexuality in IBD patients.

Study objective

The present study aims to extend the sparse knowledge on sexual function in IBD by 1) examining the prevalence of sexual problems in men and women with IBD (including Crohn's disease and ulcerative colitis), 2) comparing this with the prevalence of sexual problems in age-matched control groups, 3) studying the influence of IBD related clinical factors on sexuality, and 4) studying the mediating effect of depression on sexual function.

Study design

Matched controlled survey study, comparing sexual dysfunction scores of male and female patients with IBD with gender and age-matched controls.

Study burden and risks

Participants will be asked, by written information sent to their home-address, whether they are willing to complete a web-based questionnaire about Inflammatory Bowel Disease and sexuality. The questionnaire will consist of:

- 7 questions about socio demographic variables, for women extended with 5 questions about contraceptives, pregnancy, menopause etc.,
- the 15-item International Index of Erectile Function (IIEF(7) or the 19-item Female Sexual Function Index (FSFI)(8),
- 3 questions about distress about sexual problems,
- the 14-item Hospital Anxiety and Depression Scale (HADS(9),
- For IBD patients: the 10-item Short version of the Inflammatory Bowel Disease Quality-of-Life Questionnaire (IBDQ, (10), 3 body image related and 7 stoma related items from the EORTC module for colorectal cancer patients (11), 11 questions about disease activity(12;13), and 1 question about willingness to be informed about future research on IBD and sexuality.

There will be no risk for the participants. The burden may be to complete a questionnaire about an intimate subject, which will take about 30 minutes. There will be no direct benefit for the participants, although completing the questionnaire may break down possible barriers to ask for help for sexual problems.

Contacts

Public

Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2300 RC
NL

Scientific

Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2300 RC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients will be eligible for inclusion if they 1) are ≥ 18 and < 80 years old, 2) have Crohn's disease or ulcerative colitis, and 3) have a stable heterosexual relationship for at least 3 months.

Exclusion criteria

1) have no diseases other than diseases secondary to IBD

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2012
Enrollment:	1500
Type:	Actual

Ethics review

Approved WMO	
Date:	11-07-2011
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO	
Date:	18-07-2012
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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

NL35443.058.11