

# Psychological Treatment May Reduce the Need for Healthcare in Patients With Crohn's Disease\*

Hans-Christian Deter, MD,\* Wolfram Keller, MD,\* Jörn von Wietersheim, PhD,<sup>†</sup> Günther Jantschek, MD,<sup>†</sup> Rainer Duchmann, MD,<sup>‡</sup> Martin Zeitz, MD,<sup>‡</sup> and the German Study Group on Psychosocial Intervention in Crohn's Disease

**Background:** Few published studies examine the influence of psychological treatment on health care utilization in Crohn's disease.

**Methods:** The present substudy of a prospective, randomized, multicenter trial conducted in 69 of 488 consecutive Crohn's disease (CD) patients was designed to investigate the way in which healthcare utilization is influenced by psychotherapy and relaxation in addition to standardized glucocorticoid therapy. Before and after a 1-year period of standardized somatic treatment the psychotherapy and control groups were compared with regard to hospital and sick-leave days. Predictors of healthcare utilization were analyzed.

**Results:** The comparison between groups before and after psychological treatment showed a significantly higher decrease of mean hospital days ( $P < 0.03$ ) and sick-leave days in the treatment group compared with the controls. When a covariate analysis was applied

to compare the data at randomization, the difference in hospital days remained statistically a trend ( $P < 0.1$ ). Multivariate regression analysis detected a significant gender and depression effect for hospital days (cor  $r^2 = 0.114$ ) and a significant gender and age effect for sick-leave days (cor  $r^2 = 0.112$ ).

**Conclusion:** A significant drop in healthcare utilization after psychological treatment demonstrates a clear benefit of this additional therapy. This is important, since the study failed to demonstrate significant changes in the psychosocial status or somatic course of study patients. Clinical and psychological factors influencing these outcomes are discussed.

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**Key Words:** Crohn's disease, health care utilization, outcome study, psychological intervention

Due to its chronic course with frequent relapses, inflammatory bowel disease (IBD) involves higher medical care utilization (doctor visits and hospital days per year) than other gastrointestinal (GI) diseases.<sup>1,2</sup> Direct costs comprise more than 50% of all costs, including those for sick-leave and in-hospital days incurred as a result of IBD.<sup>3</sup> Physical conditions and psychosocial factors are thought to influence the health status perception of IBD patients and hence also their medical care utilization.<sup>4</sup> Thus, the severity of illness in IBD patients does not necessarily predict the hospital admission rate.<sup>5</sup>

Due to its chronicity, Crohn's disease (CD) not only leads to physical complaints but also causes many patients to develop psychological symptoms<sup>6–12</sup> that may influence their health-related quality of life<sup>13–16</sup> and care-seeking behavior. There is evidence that psychosocial factors accelerate the progression of CD.<sup>17,18</sup>

Controlled studies on psychotherapeutic interventions and educational programs have reported both good<sup>19–22</sup> and discouraging results.<sup>23,24</sup> But very few studies have used assessments that include patients' physical, psychological, and healthcare status. Only two controlled studies have been conducted on healthcare utilization in CD, but no study has collected healthcare cost data from insurance companies.<sup>25,26</sup>

In a previously reported randomized trial, we found that psychotherapy did not affect the somatic and psychological

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From the \*Department of Psychosomatics and Psychotherapy, Charité Campus Benjamin Franklin, Berlin, Germany; <sup>†</sup>Department of Psychosomatic Medicine and Psychotherapy, Medical University Lübeck, Germany; <sup>‡</sup>Medical Clinic I Gastroenterology, Charité Campus Benjamin Franklin, Berlin, Germany.

Reprints: Prof. Dr. med. Hans Christian Deter, Department of Psychosomatic Medicine and Psychotherapy, Charité Campus Benjamin Franklin, Hindenburgdamm 30, 12200 Berlin, Germany (e-mail: deter@charite.de)

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outcome.<sup>27,28</sup> This article focuses on results relating to patients' healthcare utilization. The study aim was to assess the effectiveness of psychological treatment provided in combination with standardized medical treatment over a 4-year observation period. We therefore analyzed the effect of a psychological intervention on medical healthcare utilization. We investigated the following hypotheses: 1) Psychological treatment reduces healthcare utilization and sick-leave days in CD patients, and 2) Sociodemographic and psychological factors predict healthcare utilization.

## MATERIALS AND METHODS

### Recruitment and Screening Procedure

During the 2-year recruitment period in this randomized and prospective study, all consecutive CD patients from the four participating centers were documented by recording their anamnestic and underlying somatic clinical data. The criteria for inclusion in the study were: confirmed diagnosis of CD, age between 18 and 55 years, at least one active disease episode (defined as requiring drug treatment) in the last 2 years, and informed consent to participate and to be randomized in a psychotherapy or nonpsychotherapy group. The exclusion criteria were: psychotherapy or resection for CD within the last 2 years and no further relapse thereafter; ongoing immunosuppressive therapy or need for resection in the near future; and colostomy or ileostomy.

### Study Design and Procedures

Patients were randomly assigned to study groups. The randomization procedure served to hierarchically balance the most important prognostic factors in the following order: acute episode with a CD activity index (CDAI > 150)<sup>29</sup> at the time of randomization (yes, no); involvement pattern (small bowel only, small and large bowel, large bowel only); previous intestinal resections (yes, no); and patient age (<30 years, >30 years). This balance was also valid for the healthcare subanalysis. After selecting a randomization ratio of 2:1 (see Appendix 1), 40 patients were assigned to the psychotherapy group and 24 to the control group. Patients were clinically examined at baseline and every 3 months during the 2-year study period. Psychological examinations took place at baseline and after 12, 18, and 24 months. The same standardized drug treatment was provided in both groups (see below). All patients in the intervention group had therapy within the context of a psychological treatment program (see below). Patients in the control group had only eight control examinations. The study was approved by the local ethics committee.

### Patients

Due to the restrictive inclusion and/or exclusion criteria, only 108 of 488 consecutive patients were randomized in

the Psychosocial Intervention in Crohn's Disease (PICD) study: 37 were randomized to the control group and 71 to the psychotherapy group. The largest group of nonparticipants comprised patients without any relapse in the 2 years prior to the basic documentation (see Appendix 2). Comparison of the included and excluded patients disclosed no significant differences in the sex distribution, involvement pattern, or disease duration. As the inclusion/exclusion criteria indicate, the participants were younger on average than the nonparticipants, and fewer of them had undergone previous resections.

### Dropouts Due to Nonfulfillment of the Healthcare Utilization Criteria.

Thirty-nine of the 108 patients (36.1%) who met the inclusion and exclusion criteria could not be evaluated for healthcare utilization. Most of them failed to obtain the data from the German insurance companies within the collecting period. Fourteen other patients did not complete their psychosocial questionnaires and/or failed to present for control examinations and were thus ineligible due to nonfulfillment of the main somatic or psychological outcome criteria of the study. The dropout rate was 39.4% ( $n = 28$ ) in the psychotherapy group and 29.7% ( $n = 11$ ) in the control group. The patients who dropped out were younger on average, and fewer of them had undergone previous resection. Comparison with the eligible patients revealed no differences in the distribution of the involvement pattern, sex, or disease activity at the time of randomization.

The most important somatic parameters were evenly balanced between the two treatment groups. This also holds true for the sociodemographic data: the groups did not differ with respect to family status, partnership, children, or education level.

### Assessment of Healthcare Utilization

Data on hospital days (HD,  $n = 69$ ) and sick-leave days (SLD,  $n = 56$ ) were collected for 4 years from the various German health insurance companies with the informed consent of patients (no SLD data available for housewives, students, or unemployed patients). We were thus able to include data from 2 years of health outcome before randomization, 1 year after randomization during psychological treatment, and 1 year of follow-up. Analyses of costs (drugs, visits to the doctor, etc.) were planned but not performed due to insufficient data. Patients were also asked about SLD and HD at control examinations every 3 months during the 2-year study period to validate the data of the health insurance companies.

### Gastroenterological Assessment

Once included in the study, patients were subjected to the following<sup>28</sup>: complete history, clinical and laboratory examinations, colonoscopy, esophagogastroduodenoscopy,

x-ray of the small intestine, and CDAI calculations.<sup>29</sup> The CDAI was also recorded during all follow-up examinations and was used to decide what drug treatment was necessary. Each patient's course was documented for 2 years. Somatic data were recorded every 3 months during remission and once a week during acute attacks. Since the course of CD varies in terms of the length and severity of acute attacks as well as the frequency of various complications, it cannot be described on the basis of a simple criterion (e.g., episode length, CDAI level). Thus, in accordance with the European Cooperative Crohn's Disease Study,<sup>30</sup> we developed a ranking system categorizing the course of the disease within the 2-year follow-up from best to worst. The main groups (main rankings) were: relapse-free course; course with acute relapses; effectiveness of standard drug treatment; failure of standard drug treatment, but effective immunosuppressive therapy; failure of any drug treatment, including immunosuppressants, with and without the need for surgery.

The number of relapses as well as the length and severity of the disease activity in an episode were determined by using the CDAI values for Groups 1–3. The mean CDAI of the quarterly control examinations was calculated for Group 4. These data permitted a subranking within the main groups. It was thus possible to rank each patient in relation to every other patient with regard to the course of the disease. This rating was provided at the end of the study by an evaluation committee including at least one gastroenterologist from each participating center. The raters were blinded with respect to the patient therapy group.

### Psychosocial Assessment

The patients' psychosocial status was determined<sup>28</sup> on the basis of self-ratings of depression (Beck's Depression Inventory: BDI<sup>31</sup>), trait anxiety (STAI-X2<sup>32</sup>), and the health-related quality of life (HRQL<sup>33</sup>).

### Treatment

#### Drug Treatment.

Based on the study protocol of the European Cooperative Crohn's Disease Study (ECCDS),<sup>30</sup> we used a fixed dosing scheme for administering corticosteroids during acute episodes: 60 mg of prednisolone daily as the initial dose followed by weekly reductions to 40 mg, 30 mg, 25 mg, 20 mg, and 15 mg. Patients were given 10 mg a day from week 7–19 and 10 mg every other day from week 20–28. Sulfasalazine was allowed in patients with colonic CD, 5-ASA in all cases. If remission or a significant reduction of the CDAI<sup>29</sup> was not achieved after 6 weeks of drug treatment, the same scheme was repeated, beginning with 60 mg of prednisolone. No drug treatment was given during remission of the disease.

Deviations from the drug protocol due to the protracted follow-up time and the variability of disease severity was referenced in detail previously.<sup>27</sup>

#### Psychological Treatment.

For the intervention group, all participating centers provided basic short-term psychodynamic psychotherapy (20 hours) and a relaxation treatment program (10 autogenic training sessions). The total length of psychotherapy was not to exceed 1 year (the mean duration of therapy across the four study centers was 47.0 weeks (SD 31.2); the mean duration of the total number of verbal therapy sessions was 26.2 weeks (SD 20.5); the mean duration of the number of relaxation therapy sessions was 17.6 weeks (SD 10.4)).

The aim of verbal psychotherapy was to provide health education and health-promoting behaviors, to give patients greater responsibility and control over their treatment, and to improve their coping skills and adjustment to the disease. Another aim was to alleviate possible disease-related psychological distress and maladaptive interpersonal patterns. Although no manual was used, the psychotherapy provided was based on the principles of psychodynamic psychotherapy and was standardized within the study centers.<sup>28</sup>

### Statistical Analysis

The study evaluated both the patient selection and the homogeneity of the two therapy groups with respect to important somatic and psychosocial parameters. All group comparisons were performed with the Mann–Whitney *U*-test for continuous or ordinal variables and Fisher's exact test for categorical variables.

For the main analysis of healthcare utilization, the two treatment groups were compared with regard to their overall HD and SLD scores assessed 2 years before randomization (divided by two) and at the 1-year follow-up after psychological treatment with the *t*-test. The alpha errors of the two tests were adjusted according to Bonferroni–Holm in order to ensure an overall significance level of  $\alpha = 0.05$ .

The analysis of healthcare utilization was based on the assessment of each eligible patient in the group to which he or she was randomized, regardless of whether or to what extent he or she participated in psychotherapeutic interventions, and/or whether or not he or she was treated with corticosteroids according to the protocol.

A second step comprised covariance analysis and multivariate regression analysis of the whole sample of 69 CD patients to detect factors influencing healthcare utilization. All calculations were performed using the Statistical Analysis System (SAS Institute, Cary, NC).

### Ethical Considerations

The study was approved by the Ethics Committee of the Medical University of Luebeck according the Declaration of Helsinki.

**TABLE 1.** Anamnestic Data of Crohn’s Disease Patients in the Healthcare Utilization Study

		Control Group (n = 26)		Psychotherapy Group (n = 43)		
		n	(%)	n	(%)	
Age	<30 years	17	(65.4)	20	(46.5)	n.s.
	>30 years	9	(34.6)	23	(53.5)	
Sex	Female	13	(50)	26	(60.5)	n.s.
	Male	13	(50)	17	(39.5)	
Prior resections	yes	9	(34.6)	11	(25.6)	n.s.
	no	17	(65.4)	32	(74.4)	
Active disease (CDAI > 150) at randomization	yes	14	(53.8)	14	(32.6)	n.s.
	no	12	(46.2)	29	(67.4)	

CDAI, Crohn’s disease activity index; n.s., not significant.

**RESULTS**

**Anamnestic Data**

Major influencing factors did not differ between the CD treatment groups in the healthcare substudy of the randomized controlled trial (Table 1).

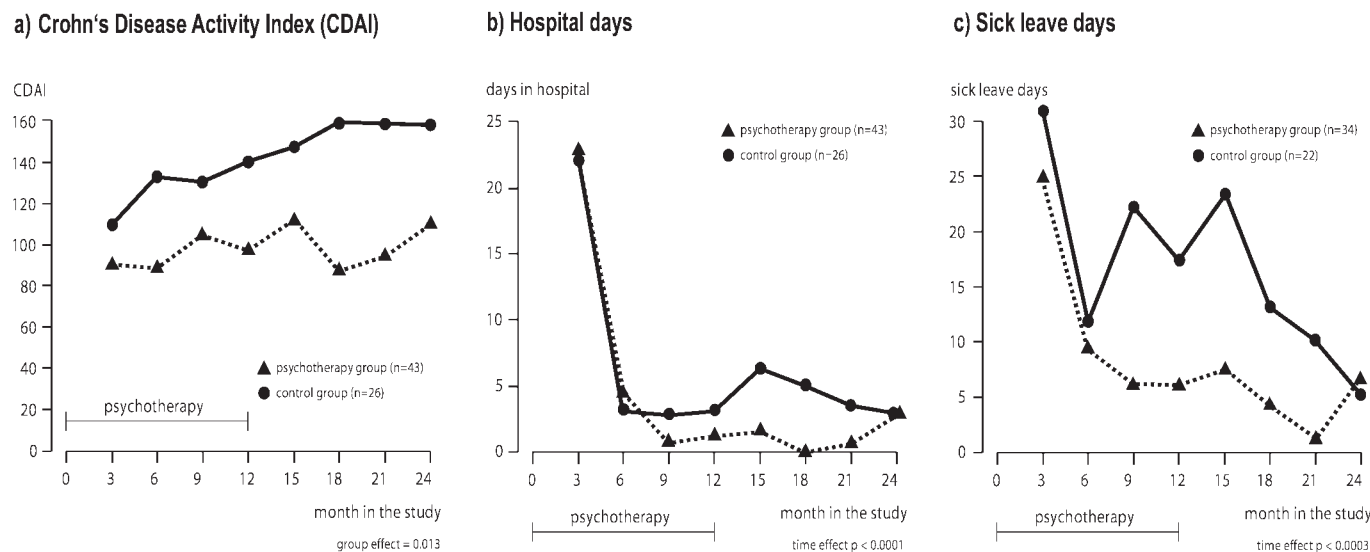
**Clinical Examinations**

In a first step, we collected the somatic and healthcare data from the quarterly control examinations and calculated the CDAI for each timepoint. Median CDAI values were higher in the control group compared with the psychotherapy group. The difference of CDAI between the control group and the psychotherapy group did not change significantly over time (Fig. 1a).

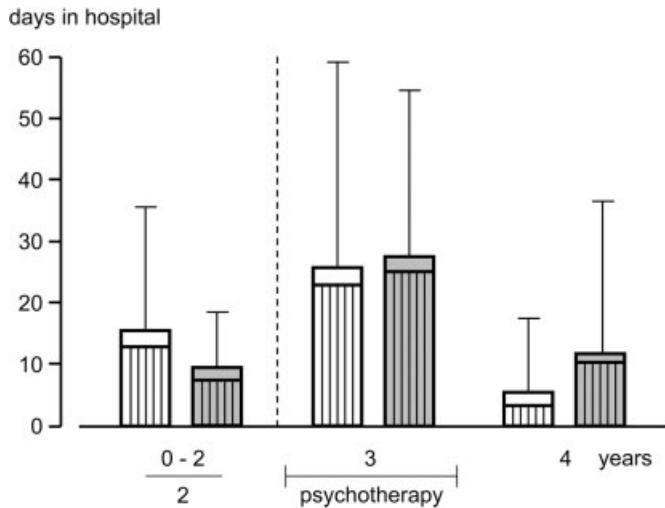
An intergroup comparison of healthcare utilization data (patients’ self report) obtained in the 2 years after randomization revealed a better course of HD and SLD in the psychological intervention group than in the control group (Fig. 1b,c). Patients were often randomized during in-patient treatment during active disease, which explains the high values of HD and SLD at randomization.

**Data From the German Health Insurance Companies**

The mean HD during the 2 years before randomization was 11.1 (SD 8.1) in the total patient population; it was higher in the psychotherapy group (12.3, SD 8.5) than in the



**FIGURE 1.** Crohn’s Disease Activity Index (CDAI, median), days in hospital and sick-leave days (self-report, median) in the course of time – treatment (n = 43) and control group (n = 26), data were selected every 3 months, 3rd–24th month after randomization).



**FIGURE 2.** Days in hospital in the course of disease were provided by insurance companies. Total days in hospital are given for the treatment group ( $n = 43$ ) (open bars) and the control group ( $n = 26$ ) (shaded bars). Days in hospital related to Crohn's disease only are indicated by hatched bars. *T*-test (4th year – 1st + 2nd year)  $P = 0.03$ .

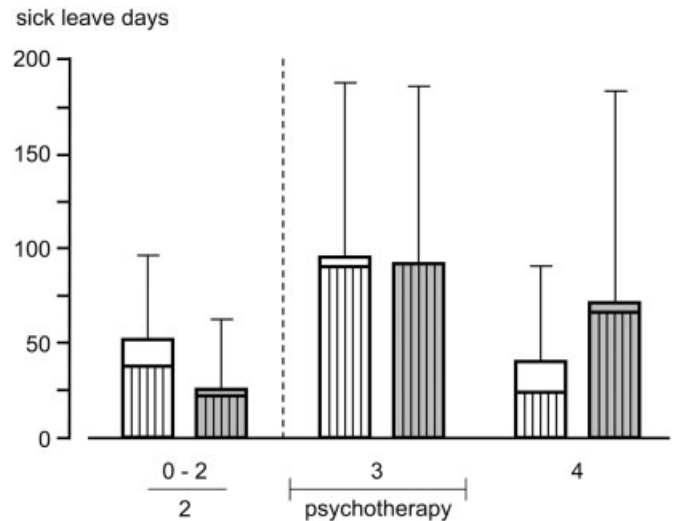
control group (8.7, SD 6.7,  $P = 0.07$ ). The mean SLD during the 2 years before randomization was 98.1 (SD 7.7). This initial value was lower in the control group than in the psychotherapy group but did not differ significantly between the two groups. The overall HD and SLD scores calculated for the total patient population within 2 years after randomization were 24.38 (SD 15.1) HD and 92.58 (SD 60.4) SLD.

The target criteria for intergroup comparison were the difference between healthcare utilization parameters HD and SLD 2 years before randomization divided by two and the year after psychological treatment (fourth year of study).

Under therapy, there was on average a reduction of annual hospital and sick leave days. Assessment of annual HD confirmed the favorable average somatic course of the psychotherapy group, and the finding was statistically significant ( $P = 0.03$ ). It revealed a significant tendency ( $P = 0.09$ ), even when including the different initial values of the two groups (covariance analysis). Compared with the time before randomization, HD increased in the first year and dropped in the second year thereafter. Interestingly, the decrease was significantly higher in the psychotherapy group than in the control group (Fig. 2).

Both groups showed an increase in the SLD in the first year after randomization and a drop in the year after the intervention. Comparing the year before randomization (2 years divided by two) and the year after the intervention disclosed a mean intergroup difference in favor of the psychological treatment (Fig. 3).

A simple monetary calculation of these results showed a 6.5 times higher benefit for psychological treatment when taking into consideration the HD, SLD, and costs of the



**FIGURE 3.** Sick-leave days in the course of disease were provided by insurance companies. Total sick-leave days are given for the treatment group ( $n = 34$ ) (open bars) and the control group ( $n = 22$ ) (shaded bars). Sick leave days related to Crohn's disease only are indicated by hatched bars. *T*-test (4th year – 1st + 2nd year) not significant.

psychological treatment (Table 2) and disregarding other possible costs and benefits.

### Predictor Analyses

The variables that predicted SLD in a univariate correlation analysis were gender, depression, anxiety, and severity of illness. In a multivariate analysis, only the first two vari-

**TABLE 2.** Effect of Psychotherapy on Hospital Days and Sick-leave Days During the Course of Disease: Estimated Financial Benefit<sup>a</sup>

	Difference 4 <sup>th</sup> year – 1+2 year		<i>t</i> -test	
	Mean	SD	F	<i>P</i>
Hospital days treatment ( $n = 40$ )	-10.5	21.4	2.0	0.03
control ( $n = 24$ )	+ 3.4	23.9		
Sick-leave days treatment ( $n = 31$ )	-13.0	58.6	—	n.s.
control ( $n = 16$ )	+ 46.1	110.9		

<sup>a</sup>Benefit for the treated patients in this study compared to the course of controls: Difference between the year after psychotherapy and the 2 years preceding the study (divided by two), data from German insurance companies: estimated financial benefit: 1 day in hospital = 250 Euro  $\times$  13.9  $\times$  40 = 139,000 Euro (1 sick leave day = 31 Euro  $\times$  59.1  $\times$  31 = 56,795 Euro) estimated costs of group psychotherapy (1 psychotherapy session = 100 Euro (20 sessions  $\times$  5 groups with 8 patients) = 10 000 Euro and individual psychotherapy (1 psychotherapy session = 50 Euro  $\times$  10 sessions with 40 patients) = 20,000 Euro; total 30,000 Euro.

**TABLE 3.** Factors Influencing Sick-leave Days and Days in Hospital

A) Univariate Correlation				
	Sick leave days	Significance	Hospital days	Significance
Gender	0.336	0.006	0.293	0.006
Age	—		0.203	0.059
Depression (BDI)	0.365	0.003	0.221	0.043
Anxiety (STAI)	0.314	0.038	—	
Quality of life	—		—	
Severity of disease	0.329	0.007	—	

B) Regression Analysis				
a) Sick leave days				
Factors in the model: gender, age, depression, anxiety and severity of illness, cor $r^2 = 0.189$ significant: gender ( $\beta = 43.01$ , $P = 0.032$ ), depression ( $\beta = 2.94$ , $P = 0.014$ ).				
b) Days in hospital				
Factors in the model: gender, age, depression, severity of illness, cor $r^2 = 0.114$ significant: gender ( $\beta = 19.86$ $P = 0.06$ ), age ( $\beta = 0.785$ , $P = 0.029$ )				

ables remained in the model. Gender, depression, and age predicted HD in the univariate analysis, but only gender and age remained significant in the multivariate model (Table 3).

## DISCUSSION

The present substudy of a prospective, randomized trial conducted in 69 of 488 consecutive CD patients was designed to investigate the way in which healthcare utilization is influenced by psychotherapy and relaxation in addition to standardized glucocorticoid therapy. We found a high rate of care-seeking behavior in our patient population. This enabled us to examine the effectiveness of psychological treatment in this high-utilizing sample.

Before and after a 1-year period of standardized somatic treatment, the psychotherapy and control groups were compared with regard to hospital and sick-leave days. The comparison between groups before and after psychological treatment showed a significantly higher decrease of mean HD ( $P < 0.03$ ) and SLD in the treatment group compared with the controls. When a covariate analysis was applied to compare the data at randomization, the difference in HD remained statistically a trend ( $P < 0.1$ ). Thus, the present study was able to demonstrate the effectiveness of a psychological treatment in reducing the health care utilization of CD patients.

With a view to presenting an appropriate description of the somatic course of the disease over a 2-year period, we developed a ranking scheme based on the ECCDS protocol,<sup>30</sup> ranging from the best to the worst clinical course. This

enabled very careful evaluation of the somatic outcome criterion and the CDAI in the patients. The results according to healthcare seem interesting in view of the fact that the study failed to support significant somatic improvement following the psychological intervention (the results on the somatic course of the disease in the care utilization substudy did not differ from those previously published in the main study<sup>27</sup>).

The influence of a psychological intervention on healthcare utilization contrasts with the fact that the control group had higher CDAI levels than the psychotherapy group in the course of the study. The argument that the psychotherapy group was more healthy and therefore could profit more from the therapy has to be contrasted with the fact that the psychotherapy group had more HD and SLD than the controls in the years before randomization. So both groups were comparable not only in clinical influencing factors at randomization (Table 1), but also according to healthcare utilization.

This seems also interesting in view of the fact that the study failed to support a significant psychological improvement following psychological intervention.

In the course of this substudy, there were also no significant changes in the psychological outcome criteria depression (BDI<sup>31</sup>), anxiety (STAI<sup>32</sup>) and health-related quality of life<sup>33</sup> between therapy and control group.<sup>28</sup> Psychological data indicated few psychological symptoms in our study patients. This is consistent with data indicating that patients with IBD perceive their level of psychosocial distress as low<sup>5</sup> and their health-related quality of life as quite good,<sup>11</sup> despite their symptoms.

Analgesic dependency occurred in very few cases in the treatment and control groups. Since only patients from GI clinics were included and patients who wanted psychological treatment were excluded from the randomized trial for ethical reasons, our patients represent a clearly nonpsychiatric sample and are therefore not comparable to the patients of Kaplan and Korelitz,<sup>34</sup> who found a higher percentage of analgesic dependency in their study.

It was interesting that healthcare utilization (HD, SLD) in this CD study group was higher than in other studies.<sup>2,5,25,26</sup> There is no doubt that the intervention group clearly benefits from the psychological intervention in terms of care utilization and probably also in a cost/benefit analysis.

Other factors could be responsible for this result. In psychological treatment studies it is impossible to completely control a placebo effect in a double-blind trial. But it is possible to control conditions of the spontaneous course of disease: Both groups got the same number of GI examinations ( $n = 7$ ) in the 2 years of study; moreover, we controlled the number of doctors visited over time, which was the same in the treatment and control groups. But through the additional hospital visits for the psychological therapy this treatment had a “specific” and an “unspecific” effect on healthcare utilization.

Moderating factors of the specific effect seem to be more effective disease self-management, better patient adherence, and more security in illness behavior during disease crises. A longer waiting time before (or avoidance of) bowel surgery may be another reason. To cope better with the illness or with stressful life events may lead to fewer psychic symptoms<sup>19–21</sup> and a better HRQL<sup>4,15,16</sup> and may influence the possibility of going to the hospital or going to work.<sup>5</sup> These aspects could only be partly detected by our psychological measurement,<sup>28</sup> but we assume they are meaningful for the change in healthcare utilization in the psychological treatment group.

Regarding the kind of applied psychological treatment in this study, it should be taken into consideration that 20 hours of psychological and interpersonal management and 10 hours of relaxation were a “high dose,” with a good effect on minimizing healthcare utilization. Inadequate treatment results can be minimized by spending some time communicating with CD patients<sup>35</sup> and by applying a sophisticated psychological treatment program (not only for information or education<sup>36,37</sup>) that focuses on changing patients’ coping capabilities and illness behavior.<sup>23,24</sup> Interestingly, these effects of a psychological intervention on high care utilization do not seem to be specific for CD but are also found in patients with other chronic diseases like asthma<sup>38</sup> or rheumatoid arthritis.<sup>39</sup>

The fact that women had much higher HD and SLD values than men suggests that factors other than the somatic course of illness could be important in this study on healthcare utilization.<sup>40</sup> Multivariate regression analysis detected a significant gender and depression effect for SLD (cor  $r^2 = 0.189$ ) and a significant gender and age effect for HD (cor  $r^2 = 0.114$ ). This is in agreement with other studies.<sup>5,7,25</sup>

For the interpretation of the results from the present study it should be appreciated that patients from specialized GI divisions of university medical centers with relapses in the last 2 years were selected in this randomized trial, but patients without relapses or those with surgery within the 2 years before randomization were excluded. Study subjects represent patients with disease distribution along the intestinal tract comparable with other studies<sup>41,42</sup>, but there were more female patients<sup>41</sup> and patients were older<sup>43,44</sup> than in other trials.

Looking at the number of HD and SLD examined in this study we must take into consideration the healthcare situation in Germany. Due to difficulties in collecting healthcare utilization data from German insurance companies led to a relatively high dropout rate of randomized patients. Thus, only 64% of PICD patients could be included in the healthcare substudy. The observation period for healthcare utilization was 4 years; we do not know if the effects of the psychological treatment will continue after the 1 year of follow-up.

Some characteristics limit the generalizability of the

current results. Since psychically disturbed patients who were interested in psychological treatment were excluded, very few patients with depression, anxiety, or a low HRQL were included in the study and thus the study did not include the full spectrum of CD patients. Study results therefore relate to a high-level healthcare population without severe psychiatric comorbidity.

Care-seeking behavior proved to be important for evaluating specific consequences of the disease. Due to its economic importance, this disease indicator can be modified to become a target criterion for therapy. As demonstrated in earlier therapy studies on CD patients, high utilizers are likely to benefit from psychological treatment. Healthcare utilization should be included in future therapy studies, especially those on high-utilizing CD patients with psychiatric comorbidity and after surgical interventions.<sup>45</sup>

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## REFERENCES

1. Katon W, Korff M v, Liu F, et al. A randomised trial of psychiatric consultation with distressed high utilizers. *Gen Hosp Psychiatry*. 1992; 14:86–98.
2. Verhoefs M, Sutherland L. Outpatient health care utilization of patients with inflammatory bowel disease. *Dig Dis*. 1995;11:1124–1128.
3. Hay AR, Hay JW. Inflammatory bowel disease: cost of illness. *J Clin Gastroenterol*. 1992;14:309–317.
4. Drossman DA, Patrick DL, Mitchell CM, Zagami EA, Appelbaum MI. Health-related quality of life in inflammatory bowel disease—functional status and patient worries and concerns. *Dig Dis Sci*. 1989;34:1379–1386.
5. Drossman D, Leserman J, Mitchel C, et al. Health status and health care use in persons with inflammatory bowel disease: a national sample. *Dig Dis Sci*. 1991;36:1746–1755.
6. Helzer JE, Chammas S, Norland CC, Stillings WA, Alpers DH. A study of the association between Crohn’s disease and psychiatric illness. *Gastroenterology*. 1984;86:324–330.
7. Andrews H, Barczak P, Allan RN. Psychiatric illness in patients with inflammatory bowel disease. *Gut*. 1987;28:1600–1604.
8. Gerbert B. Psychological aspects of Crohn’s disease. *J Behav Med*. 1980;8:649–656.
9. Deter HC, Rapf M, Gladisch R, Rohner R. Psychodiagnostische Verlaufuntersuchungen von Morbus-Crohn-Patienten während der internistischen Intensivbehandlung. *Z Gastroenterol*. 1993;31:703–710.
10. Fullwood A, Drossman DA. The relationship of psychiatric illness with gastrointestinal disease. *Annu Rev Med*. 1995;46:483–496.
11. Levenstein S, Li Z, Almer S, et al. Cross-cultural variation in disease-related concerns among patients with inflammatory bowel disease. *Am J Gastroenterol*. 2001;96:1822–1830.
12. Janke KH, Klump B, Gregor M, Meisner C, Haeuser W. Determinants of life satisfaction in inflammatory bowel disease. *Inflamm Bowel Dis*. 2005;11:272–286.
13. Bernklev T, Jahnsen J, Aadland E, et al. IBSEN Study Group: health-

- related quality of life in patients with inflammatory bowel disease five years after the initial diagnosis. *Scand J Gastroenterol*. 2004;39:365–373.
14. van der Eijk I, Vlachonikolis IG, Munkholm P, et al. EC-IBD Study Group: the role of quality of care in health-related quality of life in patients with IBD. *Inflamm Bowel Dis*. 2004;10:392–398.
  15. Mussell M, Bäcker U, Nagel N, Singer MV. Predictors of disease-related concerns and other aspects of health-related quality of life in outpatients with inflammatory bowel disease. *Eur J Gastroenterol Hepatol*. 2004;16:1273–1280.
  16. van der Zaag-Loonen H, Grootenhuys MA, Last BF, Derkx HH. Coping strategies and quality of life of adolescents with inflammatory bowel disease. *Qual Life Res*. 2004;13:1011–1019.
  17. Mittermaier C, Dejaco C, Waldhoer T, et al. Impact of depressive mood on relapse in patients with inflammatory bowel disease: a prospective 18-month follow-up study. *Psychosom Med*. 2004;66:79–84.
  18. von-Wietersheim J, Köhler T, Feiereis H. Relapse — precipitating life events and feelings in patients with inflammatory bowel disease. *Psychother Psychosom*. 1992;58:103–112.
  19. Milne B, Joachim G, Niedhardt J. A stress management programme for inflammatory bowel disease patients. *J Adv Nurs*. 1986;11:561–567.
  20. Schwarz SP, Blanchard EB. Evaluation of a psychological treatment for inflammatory bowel disease. *Behav Res Ther*. 1991;29:167–177.
  21. Smith GD, Watson R, Roger D, et al. Impact of a nurse-led counseling service on quality of life in patients with inflammatory bowel disease. *J Adv Nurs*. 2002;38:152–160.
  22. Elsenbruch S, Langhorst J, Popkirowa K, et al. Effects of mind-body therapy on quality of life and neuroendocrine and cellular immune functions in patients with ulcerative colitis. *Psychother Psychosom*. 2005;74:277–287.
  23. Maunder RG, Esplen MJ. Supportive-expressive group psychotherapy for persons with inflammatory bowel disease. *Can J Psychiatry*. 2001;46:622–626.
  24. Larsson K, Sundberg Hjelm M, Karlbohm U, Nordin K, Anderberg UM, Löf L. A group-based patient education programme for high-anxiety patients with Crohn disease or ulcerative colitis. *Scand J Gastroenterol*. 2003;38:763–769.
  25. Kennedy AP, Nelson E, Reeves D, et al. A randomized controlled trial to assess the effectiveness and cost of a patient orientated self management approach to chronic inflammatory bowel disease. *Gut*. 2004;53:1639–1645.
  26. Waters BM, Jensen L, Fedorak RN. Effects of formal education for patients with inflammatory bowel disease: a randomized controlled trial. *Can J Gastroenterol*. 2005;19:235–244.
  27. Jantschek G, Zeitz M, Pritsch M, et al and the German Study Group on Psychosocial Intervention in Crohn's disease. Effect of psychotherapy on the course of Crohn's disease. *Scand J Gastroenterol*. 1998;33:1289–1296.
  28. Keller W, Pritsch M, von Wietersheim J, et al. The German Study Group on Psychosocial Intervention in Crohn's Disease: effect of psychotherapy and relaxation on the psychosocial and somatic course of Crohn's disease: main results of the German Prospective Multicenter Psychotherapy Treatment Study on Crohn's Disease. *J Psychosom Res*. 2004;56:687–696.
  29. Best WR, Beckett JM, Singleton JW, Kern F. Development of a Crohn's disease activity index. *Gastroenterology*. 1976;70:439–444.
  30. Malchow H, Ewe K, Brandes JW, et al. European cooperative Crohn's disease study (ECCDS): results of drug treatment. *Gastroenterology*. 1984;86:249–266.
  31. Beck AT, Ward CH, Medelson M, Mock F, Erbaugh F. An inventory of measuring depression. *Arch Gen Psychiatry*. 1961;4:561–571.
  32. Spielberger CD, Gorsuch RL, Lushene RE. Manual for the State-trait Anxiety Inventory. Palo Alto, CA: Consulting Psychologist Press; 1970.
  33. Bullinger M. Forschungsinstrumente zur Erfassung der Lebensqualität bei Krebs — ein Überblick. In: Verres R, Hasenbring M editors. *Psychosoziale Onkologie. Jahrbuch der Medizinischen Psychologie* 3 (S.45–57). Berlin: Springer; 1989.
  34. Kaplan MA, Korelitz BJ. Narcotic dependence in inflammatory bowel disease. *J Clin Gastroenterol*. 1988;10:275–278.
  35. Husain A, Triadafilopoulos G. Communicating with patients with inflammatory bowel disease. *Inflamm Bowel Dis*. 2004;10:444–450; discussion, 451.
  36. Borgaonkar MR, Townson G, Donnelly M, Irvine JE. Providing disease-related information worsens health-related quality of life in inflammatory bowel disease. *Inflamm Bowel Dis*. 2002;8:264–269.
  37. Bregenzer N, Lange A, Fürst A, Gross V, Schölmerich J, Andus T. Patient education in inflammatory bowel disease does not influence patients' knowledge and long-term psychosocial well-being. *Z Gastroenterol*. 2005;43:367–371.
  38. Deter HC. Cost benefit analysis of psychosomatic therapy in asthma. *J Psychosom Res*. 1986;30:173–182.
  39. Brinkmann R, Deter HC, Brohl J, Eisele H. Ambulante Gruppentherapie bei Patienten mit chronischer Polyarthrit [Outpatient group therapy in patients with rheumatoid arthritis]. In: Deter HC, Schueffel W, editors. *Gruppen mit körperlich Kranken*. Berlin: Springer; 1988.
  40. Seibeni S, Cortinovis I, Beretta L, et al. Gruppo di Studio per le Malattie Infiammatorie Intestinali: gender and disease activity influence health-related quality of life in inflammatory bowel diseases. *Hepatogastroenterology*. 2005;52:509–515.
  41. Binder V. Epidemiology, course and socio-economic influence of inflammatory bowel disease. *Schweiz Med Wochenschr*. 1988;118:738–742.
  42. Mitchell CM, Guyatt G, Singer J, et al. Quality of life in patients with inflammatory bowel disease. *J Clin Gastroenterol*. 1988;10:306–310.
  43. Hellers G. Crohn's disease in Stockholm county 1955-1974. A study of epidemiology, results of surgical treatment and long-term prognosis. *Acta Chir Scand*. 1979;490(Suppl):1–84.
  44. Farmer RG, Whelan G, Fazio UW. Long-term follow-up of patients with Crohn's disease. *Gastroenterology*. 1985;88:1818–1825.
  45. Scarpa M, Angriman I, Ruffolo C et al. Health-related quality of life after restorative proctocolectomy for ulcerative colitis: long-term results. *World J Surg*. 2004;28:124–129.

## Appendix 1: Sample Size and Randomization

With a view to gathering more data for patients given psychotherapy, we decided to randomize patients to the control and psychotherapy groups at a ratio of 1:2 in each center. Taking this unequal allocation into account, the ultimately planned total sample size of 200 patients allowed us to detect a percentage difference of 20% between the two groups with a power of at least 77%.

## Appendix 2: Reasons for the Exclusion of Consecutive CD Patients From the Study (28)

Excluded patients, 380. One exclusion criterion, 279; age > 55 years, 8; refusal, 31; no acute attack within 2 years, 48; no acute attack after resection, 33; operation envisaged, 14; immunosuppressive therapy, 12; no specification, 12; ileostomy or colostomy, 6; other severe diseases, 6; wish for psychotherapy, 25; refusal of psychotherapy, 12; ongoing psychotherapy, 13; earlier psychotherapy, 14; other reasons, 45. Combination of two of these exclusion criteria, 85. Combination of three of these exclusion criteria, 16.