



Solution focused therapy: A promising new tool in the management of fatigue in Crohn's disease patients

Psychological interventions for the management of fatigue in Crohn's disease

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Abstract

Background: Crohn's disease patients have a decreased Quality of Life (QoL) which is in part due to extreme fatigue. In a pilot study we prospectively assessed the feasibility and effect of psychological interventions in the management of fatigue.

Methods: Patients with quiescent Crohn's disease and a high fatigue score according to the Checklist Individual Strength were randomized to Problem Solving Therapy (PST), Solution Focused Therapy (SFT) or to a control group (treatment as usual, TAU). Patients completed the Inflammatory Bowel Disease Questionnaire, the EuroQoL-5D, and the Trimbos questionnaire for Costs.

Results: Twenty-nine patients were included (12 TAU, 9 PST, 8 SFT), of these 72% were female, mean age was 31 years (range 20–50). The SFT group improved on the fatigue scale in 85.7% of the patients, in the PST group 60% showed improved fatigue scores and in the TAU group 45.5%. Although not significant, in both intervention groups the QoL increased. Medical costs lowered in 57.1% of the patients in the SFT group, in the TAU 45.5% and the in PST group 20%. The drop out rate was highest in the PST group (44%; SFT 12.5%; TAU 8.3%).

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Conclusions: PST and SFT both positively affect the fatigue and QoL scores in patients with Crohn's disease. SFT seems most feasible with fewer dropouts and is therefore a promising new tool in the management of fatigue in Crohn's disease patients.

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1. Introduction

Inflammatory Bowel Disease (IBD) patients suffer from a chronic relapsing disease with significant impairment of Quality of Life (QoL) which may lead to the development of psychological symptoms such as depression. This impacts the care-seeking behaviour of these patients.^{1–8}

Fatigue contributes to the impairment of QoL in IBD patients.^{9,10} One of the factors negatively influencing fatigue is disease activity and therefore induction of disease remission is a first requirement in the management of fatigue.^{11,12} However a large proportion of IBD patients in remission still suffer from disabling fatigue (41%).^{9,13}

Besides the impact on QoL, fatigue may also lead to low employment and high disability rates.¹⁴ Additionally, it can be hypothesised that fatigue has a negative influence on the medical consumption^{15,16} and therefore higher costs. The overall costs that are directly related to IBD consist of direct costs (15–44% e.g. inpatient care, outpatient care, self-care, medications and tests/procedures) and indirect costs (e.g. work absenteeism, decreased incomes).^{17–19} The direct costs vary between 1871 euro and 18,000 dollar per patient annually^{19–22}, the indirect costs are estimated between 842 euro and 7260 dollar.^{21,23} Although fatigue is one of the most important complaints of IBD patients management strategies are lacking.²⁴ Psychological interventions are used in IBD care for multiple goals (e.g. improving QoL, decreasing depression, decreasing flares). The conclusions from several studies show inconsistent results for these interventions.^{25–29}

In order to find out whether psychological interventions can improve fatigue, we performed a pilot study. We assessed the feasibility and a first impression of the effect of 2 different psychological interventions (Problem Solving Therapy (PST) and Solution Focused Therapy (SFT)), designed to manage fatigue. In PST, patients learn to solve problems in a structured way, using five steps (i.e. problem definition and goal setting, brain storm about solutions, weighting pro's and con's for each solution, choosing a solution and trying the solution and evaluation of the effectiveness).^{30–34} SFT has as a starting point that no problem exists always. The solution to a problem is thus finding the exception when the problem is not present. Once the exception is found, patients learn to do more what they do at that moment, so the problem disappears.^{35,36} Furthermore, SFT is shorter than PST (5 versus 10 sessions).

2. Methods

2.1. Patients

This study was approved by the ethical review board of the Erasmus MC Rotterdam, The Netherlands. Adult non-pregnant patients with proven Crohn's disease (CD) visiting the outpa-

tient clinic of the Department of Gastroenterology and Hepatology at the Erasmus MC were asked to participate and to fill in the Checklist Individual Strength (CIS).³⁷ This questionnaire is the validated Dutch Checklist Individual Strength (CIS-20) consisting of 20-items that are answered on a 7 point Likert scale. The CIS-20 is designed to measure five dimensions of fatigue: (1) subjective experience of fatigue (8 items): 8–56; (2) concentration (5 items): 5–35; (3) motivation (4 items): 4–28; (4) physical activity level (3 items): 3–21; (5) total score (20 items): 20–140. A higher score indicates more fatigue. Furthermore clinical disease activity was measured by the Harvey Bradshaw index (HBI).³⁸ Consecutive patients with a high score on the fatigue scale (≥ 35 on the CIS dimension 1) and in clinical remission ($HBI < 5$) were asked to participate in the study.

After written informed consent participants filled out different questionnaires. The QoL was estimated with the Inflammatory Bowel Disease Questionnaire (IBDQ) and the EuroQol-5D (EQ-5D).^{39,40} Furthermore patients filled in the Hospital Anxiety and Depression Scale (HADS).⁴¹ Patients with a HADS score of more than 10 on one or both of the two subscales were excluded. Other exclusion criteria included: breastfeeding; surgery 3 months prior or intended during the study period; short bowel syndrome, cancer, and underlying psychiatric disorders. Sociodemographic variables and clinical status were collected during history taking and from the medical record. These included gender, age, employment status and concomitant drugs. Phenotype was classified according to the Montreal classification.^{42,43} Blood samples were taken for regular blood screening of CRP (reference value: 0–9 mg/l), hemoglobin (reference value: females 7.5–10 mmol/l; males 8.5–11 mmol/l) and ferritin (reference value: females 10–150 $\mu\text{g/l}$; males 20–300 $\mu\text{g/l}$).

2.2. Randomization process

Eligible patients were randomized either to serve as a treatment as usual (TAU) group ($n=20$) or to participate in one of the psychological interventions ($n=20$). After baseline assessment, patients were randomized to treatment or not in blocks of 20 subjects using randomization lists drawn from a computer-generated series of random numbers. We randomised 20 patients for the intervention groups and 20 TAU patients.

2.3. Patient inclusion

Overall, 60 patients were assessed for eligibility. Twenty patients were excluded, because they did not meet the inclusion criteria (Fig. 1).

In total 40 patients intended to participate: 10 in the PST group, 10 in the SFT and 20 in the TAU group. During the screening period 5 patients dropped out because of pregnancy

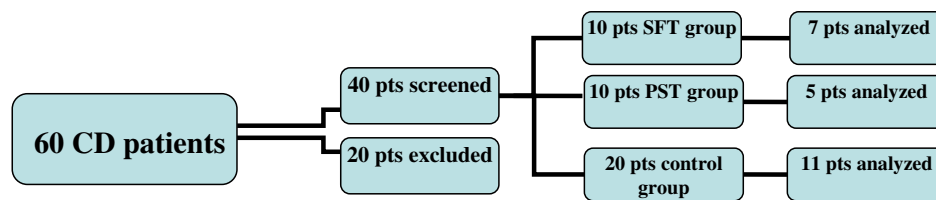


Figure 1 Patient inclusion.

(2) or relapse of disease (3). Six patients refused further continuation for unknown reasons.

The PST group started with 9 patients, the SFT group with 8 patients, and 12 patients were included in the TAU group. During follow up 6 patients refused to fill in the questionnaires for various reasons (i.e. lack of time, lack of concentration to fill in questionnaires).

2.4. Psychological interventions

The interventions were given by an experienced psychotherapist specifically trained to give PST and SFT courses.

2.5. Problem Solving Therapy group

The treatment goal of PST is to increase the capabilities of the patients to deal with the daily stressful problems caused by CD.⁴⁴ This is a 10 session's course during 3 months and based on a general model of problem solving, adjusted for the purpose of this patient population.

2.6. Solution Focused Therapy group

This is a 5 session's course during 3 months. It includes a brief psychological intervention based on the solution focused model of solving problems.^{35,45,46}

The solution-focused model offers a wide range of interventions that channel the attention of patients towards constructing possible solutions. The method has been empirically validated and shown to be successful in other patient groups with chronic diseases. For the purpose of this study the SFT was modified to focus on fatigue management in IBD patients.

2.7. Treatment as usual

The TAU received standard medical care and no additional psychological interventions. This group was chosen in this setting to rule out any intervention effect.

2.8. Cost-effectiveness

The cost-effectiveness of fatigue management was evaluated by the Trimbos institute for Medical Technology Assessment (iMTA) questionnaire for Costs associated with Psychiatric Illness (TiC-P) at baseline and at month 6. The TiC-P is a questionnaire for collecting data on health care utilisation and productivity losses.^{47,48} The TiC-P questionnaire collects data about medical consumption and productivity losses for the previous 3 months. Medical consumption includes the costs of outpatient clinic visits

of specialists, psychological care, visits of the general practitioner, the company doctor, paramedical care (e.g. physiotherapist), hospital admissions and costs of medication. Data for the TAU patients were collected at similar time-points.

2.9. Questionnaires during follow-up

Participants filled in the CIS, IBDQ, EQ-5D, HADS, HBI and Tic-P questionnaires at inclusion (at week 0, pre – study) and at month 6 (3 months after the last session of the intervention).

2.10. Statistical analysis

Because of the pilot design of this study a power calculation was not possible. Studies in this field and with similar design often start with 10 patients in both the intervention and control group. Therefore we decided to include 10 patients in each intervention group and 20 patients in the control group.

Statistical analyses were performed using descriptive statistics (means, sd). Statistical analyses of questionnaire results were carried out using the Chi-square test. The laboratory results were analyzed using non-parametric tests (i.e. Kruskal Wallis and Wilcoxon test), the HBI was analyzed using the Kruskal Wallis test.

The cost data is presented as the percentage of the patients, of which their costs have risen or fallen, based on medication costs, the costs of outpatient clinic visits and admissions of the last 3 months. Statistical analyses were performed with SPSS for Windows software (version 17.0). A two-sided p value of <0.05 was considered significant.

The data analyses were performed on the most recent samples at the end of the study (see Fig. 1).

3. Results

3.1. Patient characteristics

Patient characteristics are presented in Table 1. No significant differences were found between the groups with respect to mean age or medication use, disease activity (HBI) and Montreal classification (Table 1). CRP, hemoglobin and ferritin levels remained stable during follow-up and were similar between the different groups (Table 2).

3.2. Influence on fatigue

In the SFT group, the CIS subscale fatigue and CIS total score showed a decrease in 85.7% of patients from baseline to 3 months follow up (Table 3). The PST group showed a decreased CIS subscale fatigue and CIS total score in 60% of

Table 1 Patient characteristics of the SFT, PST, TAU group.

Patient characteristics	TAU	SFT	PST	Dropouts
Age in years, mean (sd)	32 (8.9)	29.9 (6.9)	30.9 (8.1)	28 (9.3)
Female gender (%)	65%	75%	78%	100%
Immunosuppressives (%)	17%	50%	56%	66.7%
Corticosteroids (%)	0%	0%	22%	0%
Biologicals (anti-TNF) (%)	42%	50%	22%	33.3%
Antidepressant (%)	0%	14%	20%	0%
Mean HBI, (sd)	2.9 (2.1)	4.4 (2.7)	2.0 (2.5)	2.7 (1.5)
Working/student (%)	100%	100%	80%	100%
Unemployment (%)	0%	0%	20%	0%
Ileostomy (%)	27%	0%	20%	17%
Ileocaecal resection (%)	0%	43%	40%	17%
Subtotal colectomy (%)	36%	0%	0%	17%
Short bowel syndrome (%)	0%	0%	0%	0%
Montreal classification (%)	(%)	(%)	(%)	(%)
Age of diagnosis				
A1	25.0	0	0	0
A2	75.0	100	100	100
A3	0	0	0	0
Location				
L1	25.0	12.5	44.4	33.3
L2	33.3	12.5	22.2	16.7
L3	41.7	75.0	22.2	50.0
L4	0	0	11.1	0
Behaviour				
B1	66.7	75.0	66.7	66.7
B2	0	0	0	0
B3	33.3	25.0	33.3	33.3
p	16.7	25.0	33.3	16.7

HBI: Harvey Bradshaw Index.

sd: standard deviation.

Montreal classification: A1=diagnosis at ≤16 yr, A2=diagnosis at 17–40 yr, A3=diagnosis at ≥40 yr of age); disease location (L1=terminal ileum, L2=colon, L3=ileocolon, L4=upper GI); disease behavior, (B1=inflammatory, B2=stricturing, B3=internal penetrating disease, p=perianal penetrating disease.

TAU: treatment as usual.

SFT: solution focused therapy.

PST: problem solving therapy.

patients. The control group showed in 45.5% of patients a decreased score on both CIS scales. No significant differences were observed between the groups.

3.3. Costs

The SFT treated group showed a decrease in total direct costs 3 months after finishing therapy in 57.1% of patients, which was 20% of the PST patients and 45.5% of the control patients (not significant). Contributing factors for the higher score in SFT were fewer visits to the outpatient clinic, lower medication costs and less hospital admissions during follow-up. Compared to the other groups this decrease was not significant. In the intervention groups there were no differences in the costs of medication, costs of outpatient clinic visits and admissions compared with the control group (Table 4).

3.4. Quality of life

The IBDQ total score of the intervention groups showed more patients with improved scores than the control patients from

baseline to follow up (SFT: 71.4%; PST: 60%; TAU: 50% of the patients). When comparing the intervention groups with the control group; no significant differences were observed.

The EQ-5D VAS scores ranged from 72 to 67 at baseline. The SFT group showed an increased mean VAS score in 71.4% of patients whereas the mean VAS scores of the PST increased in 25% of patients and in 54.5% of control patients. The EQ-5D Index showed similar results. No significant differences of the EQ-5D scores were seen between the intervention groups and the control group.

3.5. Anxiety and depression

All patients remained under the score of 10 points, meaning that no clinical significant depression or anxiety occurred during the 6-months study period.

3.6. Dropouts

The dropout rate during the intervention period was highest in the PST group (44%, 4pts), 1 patient in the SFT group (12.5%)

Table 2 Means of laboratory parameters.

	CRP (mg/l)		Hemoglobin (mmol/l)		Ferritin (µg/l)		Ferritin (µg/l)	
					Female	Male		
TAU								
Baseline (sd)	4.8	(4.7)	8.5	(0.9)	43.5	(44.0)	70.2	(59.3)
Follow up (sd)	4.0	(3.5)	8.5	(1.1)	65.0	(103.8)	79.3	(57.1)
SFT								
Baseline (sd)	1.4	(0.9)	8.5	(0.8)	31.2	(5.2)	117.5	(64.3)
Follow up (sd)	2.3	(0.7)	8.9	(0.7)	43.3	(23.3)	132.0	(38.2)
PST								
Baseline (sd)	3.0	(2.9)	8.7	(1.0)	28.0	(11.8)	110.0	(32.5)
Follow up (sd)	2.8	(2.4)	8.3	(1.2)	33.0	(16.6)	76.0	(0)

sd: standard deviation.
 CRP: C-reactive protein.
 mg/l: milligrams per liter.
 mmol/l: millimoles per liter.
 µg/l: microgram per liter.
 TAU: treatment as usual.
 SFT: solution focused therapy.
 PST: problem solving therapy.

and 1 patient in the control group (8.3%). Reasons for stopping: 3 patients had other responsibilities (work or study) and 3 patients stopped because the scope of the intervention did not meet their expectations. There were no significant different baseline characteristics between the dropouts and patients who finished the study period (see Table 1).

Table 3 Checklist Individual Strength scores between baseline and follow up (in %).

	TAU (%)	SFT (%)	PST (%)
CIS fatigue			
Increase	54.5	14.3	40.0
Decrease	45.5	85.7	60.0
CIS concentration			
Increase	40.0	50.0	60.0
Decrease	60.0	50.0	40.0
CIS motivation			
Increase	50.0	33.3	50.0
Decrease	50.0	66.7	50.0
CIS physical activity			
Increase	54.5	14.3	60.0
Decrease	45.5	85.7	40.0
CIS total			
Increase	54.5	14.3	40.0
Decrease	45.5	85.7	60.0

Increase: a higher score from baseline to follow up=impairment of this domain.
 Decrease: a lower score from baseline to follow up=improvement of this domain.
 TAU: treatment as usual.
 SFT: solution focused therapy.
 PST: problem solving therapy.

4. Discussion

We present the first study in which two different psychological interventions focusing on fatigue management in CD patients were compared with a TAU group. Although this was a small sized pilot study, we were able to demonstrate that these interventions have a positive effect on fatigue and health care costs. Comparing a longer term intervention (PST) and a short term intervention (SFT), the SFT showed more patients with less fatigue and better quality of life. In the TAU group the fatigue worsened in a high percentage during follow up. SFT intervention seems most feasible due to lesser dropout rate.

Similar to our results, in conditions like cancer-related fatigue, cognitive therapy already showed to improve fatigue.⁴⁹⁻⁵¹

Additional to lowering fatigue, SFT seems also to lower health care costs more often when compared with the costs for patients in the TAU and PST group. Costs of medication are the main factor contributing to the health care costs and was not related to the activity of disease, but less outpatient clinic visits were noted in the SFT group.

Table 4 Percentages (%) of increased and decreased total direct costs.

	TAU (%)	PST (%)	SFT (%)
Decreased costs	45.5	20.0	57.1
Increased costs	45.5	60.0	28.6
Equal costs	9.0	20.0	14.3

Decreased and increased total direct costs in euro: difference from baseline to follow up.
 TAU: treatment as usual.
 SFT: solution focused therapy.
 PST: problem solving therapy.

During the intervention period an unexpected high dropout rate occurred, especially in the PST group.

One of the factors contributing to the dropout rate could be that patients at the start of the intervention did not fully comprehend the impact of psychotherapy and were reluctant to further participation after the first session.

Furthermore, other factors such as age and accompanying lifestyle could influence the group process and potentially lead to dropout. Additionally, PST is a time-consuming intervention which could be a factor accountable for the higher dropout rate in this group. Hypothetically, the relatively large number of extra visits to the hospital for the PST intervention could interfere with work rhythms and thus result in a lower adherence.

This study is hampered by its small sample size. Therefore no firm conclusions can be drawn, but it gives rise to further research to confirm the results of this pilot study.

In conclusion, we believe that SFT is a promising new tool to manage fatigue in quiescent CD patients. A larger randomized controlled trial is needed to further investigate this fatigue management strategy.

Contribution of authors

LV: study design, acquisition of data, analysis and interpretation of data and drafting of the manuscript.

AS: participated in the design of the study and performed the statistical analysis.

TV: technical and material support, participated in the study design.

JB: participated in the design of the study and performed the statistical analysis.

EK: critical revision of the manuscript for important intellectual content MV: critical revision of the manuscript and analysis of data.

CW: critical revision of the manuscript for important intellectual content, study concept and design, study supervision.

All authors read and approved the final manuscript.

Disclosures

The authors report no conflicts of interest.

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