

PROTOCOLIZED GROUP PSYCHOLOGICAL TREATMENT OF INFLAMMATORY BOWEL DISEASE: ITS IMPACT ON QUALITY OF LIFE

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Inflammatory bowel disease (IBD) is a chronic illness that greatly affects patients' quality of life. The main objective of the present study was to demonstrate the effectiveness of a protocolized psychological treatment programme in group format for improving the quality of life of these patients. The sample was made up of 57 inflammatory bowel disease patients (33 treatment group and 24 waiting list control group). The dependent variables were: digestive symptoms, systemic symptoms, functional effects, emotional function and social effects (Inflammatory Bowel Disease Quality of Life Questionnaire [SIBDQ], López-Vivancos and cols., 1999). The results showed that the psychological treatment programme for IBD was effective in producing a significant improvement in all the quality of life variables, by comparison with the waiting list control group. Although the differences were maintained in 4 of the 5 variables assessed at the 3-month follow-up, after 12 months the differences were only maintained in one of them.

KeyWords: Inflammatory bowel disease; cognitive-behavioural treatment; protocolized treatment; multi-component psychological treatment; quality of life.

La enfermedad inflamatoria intestinal (EII) es una enfermedad crónica que afecta notablemente a la calidad de vida del paciente. El principal objetivo de este estudio fue demostrar la eficacia de un programa de tratamiento psicológico protocolizado para mejorar la calidad de vida de estos pacientes. La muestra estuvo constituida por 57 pacientes diagnosticados de EII (33 programa de tratamiento en grupo y 24 grupo control en lista de espera). Las variables dependientes fueron: síntomas digestivos, síntomas sistémicos, afectación funcional, función emocional y afectación social (Cuestionario de calidad de vida en la enfermedad inflamatoria intestinal [SIBDQ], López-Vivancos y cols., 1999). Los resultados revelan que el programa de tratamiento psicológico resultó eficaz para producir una mejoría significativa en todas las variables de calidad de vida a la finalización del mismo, al compararlo con el grupo control en lista de espera. Si bien las diferencias se mantienen en 4 de los 5 aspectos evaluados a los 3 meses de seguimiento, a los 12 sólo se mantienen las diferencias en uno de ellos.

Palabras Clave: enfermedad inflamatoria intestinal; tratamiento cognitivo conductual; tratamiento protocolizado; tratamiento multicomponente; calidad de vida.

The term inflammatory bowel disease (IBD) refers to a group of chronic and recurrent illnesses of the digestive system that are characterized by inflammation of the walls of the gastrointestinal tract. This inflammation generates blisters, which can burst and turn into ulcers.

The IBD category includes Crohn's disease and ulcerative colitis, whose most characteristic symptoms,

though not the only ones –since these are systemic diseases that can affect the entire organism– are: diarrhoea, abdominal pain, fever, general malaise, tiredness, loss of appetite, debility, anaemia and weight loss (Pecasse, 1998; Vilaseca, Casellas & Guarner, 1996; Medline Plus, 2007).

Chronic diseases can considerably affect patients' quality of life, and consequently their physical, psychological, family and social dimensions. In the case of IBD the effects on quality of life can be even greater, since medical intervention involves the use of prolonged treatments (which frequently have adverse side effects), intrusive diagnostic tests, the possibility of surgical interventions, regular check-ups and/or hospital admissions.

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The concept of health-related quality of life would include aspects related to objective health parameters, patient's degree of functioning and interaction with his/her context, and other more subjective aspects such as self-perceived health and general sense of satisfaction.

In general terms, a patient's quality of life is determined by the extent of the physical effects of the illness, though it is not always possible to observe a direct relationship between severity of symptoms and deterioration of health-related quality of life, so that it is necessary to analyze other dimensions of how the patient is affected, such as: emotional (anxiety or depression), behavioural (lifestyle changes) and cognitive aspects (knowledge about the illness or false beliefs) of the patient, changes in the family dynamic and social and employment implications (MacPhee, Hoffenberg & Feranchak, 1998; López-Vivancos, Casellas, Badia, Vilaseca & Malagelada, 1999; Rubin, Hungin, Chinn & Dwarakanath, 2004).

The quality of life perceived by patients affects not only their physical and psychosocial aspects, but will also have important repercussions for the use of health services and the distribution of medical resources. In this regard, it has been observed that poorer quality of life predicts more visits to the doctor by such patients (de Boer, Sprangers, Bartelsman, de Haes, 1998).

The relationship between illness and psychosocial aspects, the fact that many patients do not know what to do or how to cope with the problems generated by the disease, and the high comorbidity between IBD and psychopathological disorders, have led some authors to develop and implement psychological intervention programmes (Susen, 1978; Joachin, 1883; Wakeman & Mestayer, 1985; Milne, Joachin & Nierdhardt, 1986; Shaw & Ehrlich, 1987; Schwarz & Blanchard, 1990; García-Vega & Fernández, 1995, 2004; Díaz-Sibaja, 2006), whose main objective is to teach these patients effective coping strategies that permit them to deal with the associated psychological disorders, improve their quality of life and meet more effectively the demands of the illness.

The report by the Task Force for the promotion and dissemination of effective psychological procedures, by the clinical psychology division of the American Psychological Association (APA, 1995), states that the efficacy of a given psychological treatment rests on the presence of the following three factors: a) being backed up by at least two different research studies, with inter-group experimental designs with at least 30 participants

in each group; b) the development of a protocolized treatment manual that clearly describes the entire assessment and treatment process; and finally, c) for the programme to have demonstrated its efficacy on being used with a sample identified in accordance with the same diagnostic criteria.

Protocolized treatment manuals offer clear advantages not only in clinical practice but also in research and in the training of psychologists (Hickling & Blanchard (1997). In clinical practice they save time for the clinician, insofar as they allow them to carry out the functional analysis of the illness, select the target behaviours of the treatment and choose the most suitable intervention strategies, on the basis of proven efficacy. In the research context, they facilitate the replication of results and the design of other experimental studies that seek to determine the differential efficacy of the various strategies making up the multi-component programme. As regards the training of other clinicians, these manuals facilitate the training of those professionals who wish to intervene in the psychological processes of IBD and the dissemination of strategies that have demonstrated their efficacy with these types of patients.

Finally, it is worth analyzing the interest aroused by group interventions compared to individual treatment. Such interest could be explained in terms of a better cost-benefit relationship and, on the other hand, the advantages offered by the group intervention format, such as permitting patients to learn from one another, the provision of different perspectives on the same problem, the boosting of motivation and treatment compliance, or support and reinforcement from the group (Corey, 1995; Morrison, 2001).

The main objective of the present experimental work was to demonstrate the efficacy of a protocolized psychological treatment programme administered in group format for improving the quality of life of patients with IBD. To this end we compared the results in quality of life of a group of patients who followed this programme with those of another group of patients who were not treated.

METHOD

Sample

The initial assessment of this research was carried out with a sample of 57 patients diagnosed with IBD (34 with Crohn's disease and 23 with ulcerative colitis) belonging to Crohn's and ulcerative colitis associations in Spain.

Exclusion criteria of the sample were age under 18, being in the active phase of the disease at the start of the

psychological intervention, being in psychological treatment at the same time as the intervention was scheduled to take place, and showing indications of severe psychopathology in the questionnaires filled out at the start of the treatment.

The sample was randomly distributed in two experimental groups, 33 making up the treatment group and 24 the waiting list control group.

As it can be seen in Table 1, there were no dropouts during the treatment sessions, since all those who began the treatment (N=33) finished it. However, the number of participants strongly decreased in the control group (by 41%), and likewise decreased in the experimental group follow-ups, sample mortality in this group at 12 months being 45%. Nevertheless, this last-mentioned result cannot be considered as drop-out frequency, since it was due to factors external to the patients. The therapist who imparted the group psychological treatment programme in Cádiz left the research project, so that it was only possible to carry out the 3-month follow-up with these patients.

Measurement instruments

Spanish version of the Inflammatory Bowel Disease Quality of Life Questionnaire (SIBDQ) (López-Vivancos, Casellas, Badía, Vilaseca & Malagelada, 1999). This questionnaire assesses health-related quality of life in patients with IBD. Its Spanish version contains 36 items grouped in the following 5 dimensions:

- Digestive symptoms.** Digestive symptoms that the patient has had in the last two weeks, made up of 8 items. The symptoms measured by this scale include: number of defecations, diarrhoea, frequency of stomach cramps, bleeding, etc.
- Systemic symptoms.** Less specific symptomatology, such as feelings of fatigue or tiredness, malaise, weight loss, nausea or feeling sick. This scale is made up of 7 items.
- Functional effects.** Extent of the effects of IBD on the patient's everyday activities, referring to aspects such as inability to study or work, difficulties for doing leisure activities, sleep alterations, or inability to do certain sports.
- Emotional function.** Emotional symptoms that may be found as a result of IBD. Among the items measured are: frustration, impatience or worry about having the illness, worry about the possibility of having to have an operation, fear of having cancer, sadness or demoralization due to the illness, etc.
- Social effects.** Social problems deriving from having

the illness, such as avoidance of social activities, feelings of shame due to certain symptoms, problems with sexual relations, or feeling of dissatisfaction with personal life and relationships.

Response options and scores for each scale are based on 7-point scale, where a score of 1 indicates the poorest quality of life and a score of 7 the best.

Procedure

The experimental study involved 5 phases: sample selection, initial assessment (pre-treatment), treatment, assessment of the effects of the intervention (post-treatment) and follow-up at 3, 6 and 12 months.

To select the sample we called the members of the Crohn's and Ulcerative Colitis Associations from Madrid and Cádiz to an information session in which the treatment programme was explained and they were informed about the signed commitment they would have to make, which involved, among other aspects, filling out the questionnaires and symptom self-registers at all scheduled assessment points, attending the sessions, being actively involved in the programme (reading the section corresponding to the session each week and doing the homework tasks) and keeping their medication invariable from the start of the programme or informing the therapists of any possible variations.

Once the sample had been selected and the participants assigned to the different experimental groups, we assessed the dependent variables by means of the measurement instruments previously described.

The patients on the group treatment programme were called to a joint assessment session, where they were given the different assessment questionnaires.

Control group patients on the waiting list were sent a letter enclosing the questionnaires and a stamped, addressed envelope, to be returned as soon as possible.

Group treatment

The full treatment programme comprised a total of 10 weekly face-to-face group sessions, each lasting two hours.

Table 1 Number of participants in each group and phase of the research					
Experimental group	Initial assessment	Post-treatment assessment	3-month assessment	6-month assessment	12-month assessment
Treatment group	33	33	31	22	18
Control group	24	14	–	–	–

The structure of each session covered the following aspects: a) review of the previous week's tasks and self-registers; b) didactic explanation of the different factors influencing the disorder; c) learning and practice of each therapeutic strategy; and d) setting of homework and self-register tasks. At the end of each session, patients were given a dossier summarizing the most important aspects of the session and the tasks recommended for the week.

A protocolized treatment manual was drawn up for this research (Díaz-Sibaja, M.A., Comeche, M.I. y Mas Hesse, B. 2009). This 136-page document addressed the therapists and described in a detailed way all the registers, exercises, group dynamics, homework tasks and explanations to be given by the therapist in each of the 10 intervention sessions. Likewise, patients were given a specially-recorded relaxation CD to serve as a guide and to help them learn the different activation-reduction techniques.

Below we briefly summarize the content of each session.

First session: information most relevant to IBD: characteristics, causes, symptoms, diagnosis and treatment possibilities.

Second session: coping model (analysis of factors that influence the disease and explanation of the different coping strategies).

Third session: problem-solving strategy. Also, starting to practice the "calming breathing" technique.

Fourth session: training in "progressive muscular relaxation".

Fifth session: social skills module. The objectives were: introducing the concept of assertiveness, eliminating obstacles that could interfere in assertive communication, and improving communication between patient and doctor.

Sixth and seventh sessions: social skills techniques, aimed at improving relationships with others, with family and with friends. Likewise, participants were taught to use attention-distracting techniques, with a view to reducing subjective feelings of distress generated by the symptoms.

Eighth and ninth sessions: cognitive restructuring procedure. Patients were taught to record, analyze, discuss and change those negative thoughts that generate feelings of anxiety and depression.

Final session. The aim of this session was to get patients to accept that they were an active, responsible and highly important part of the treatment of their illness, and that the strategies they had learned in the sessions could be used not only for problems related to

the disease but also for any other problem of everyday life.

At each session, each participant was given a summary of the concepts that would be worked on in that session and the tasks they were advised to do between sessions.

Control group

In the meantime, the control group waited to fill out once more the questionnaires corresponding to the post-test phase and begin the group intervention programme.

RESULTS

Given that the goodness of fit and homogeneity of variances criteria were not met, it was decided to use the Friedman non-parametric test. This test permits the analysis of the differences occurring in each of the variables in the different experimental phases (pre-treatment, post-treatment and follow-up at 3, 6 and 12 months).

Table 2 Pre-post treatment comparisons in the quality of life dimensions between treatment group and control group. (Friedman: * = p 0.05; difference between pre-test and each subsequent follow-up is accepted); (Eta coefficient: * = p 0.05; difference between the groups is accepted)							
Quality of Life Variable	Dimensions	Group	Before		After		
			Mean	Eta	Mean	Friedman	Eta
SIBDQ	Digestive Symptoms	Treatment (n=33)	5.39	0.34	5.78	0.01*	0.71
		Control (n=14)	5.57		5.53	0.59	
	Systemic Symptoms	Treatment (n=33)	4.92	0.76	5.56	0.0001*	0.81
		Control (n=14)	5.24		5.47	0.17	
	Functional Effects	Treatment (n=33)	5.51	0.81	5.99	0.02*	0.75
		Control (n=14)	5.74		5.84	1	
	Emotional Function	Treatment (n=33)	5.26	0.19	6.04	0.0001*	0.76
		Control (n=14)	5.78		5.84	0.56	
	Social Effects	Treatment (n=33)	5.73	0.26	6.24	0.01*	0.24
		Control (n=14)	5.90		5.85	0.74	
	SIBDQ (total)	Treatment (n=33)	5.36	0.37	5.92	0.0001*	0.80
		Control	5.65		5.71	0.29	

The comparative analyses between the two groups were made using the Eta correlation coefficient, but only during the pre-test and post-test phases, given the ethical problems involved in keeping the control group waiting for the 3, 6 and 12 months that the follow-up phase lasted.

Table 2 shows the results of the “before-after” comparisons between the experimental group and control group in each of the quality of life dimensions measured by the SIBDQ. Table 3 shows the results of the different measures made on the treatment group. As can be seen in these tables, the results obtained with the treatment group reveal a statistically significant improvement in the dimensions of the quality of life variable after the intervention has finished. Although

this improvement is maintained in the variables: digestive symptoms, systemic symptoms, emotional function and social effects at the 3-month follow-up, by the 12-month point it is only maintained in the emotional function dimension.

As far as the control group is concerned, no statistically significant differences are found in any of the variables between the pre-treatment phase and the post-treatment phase. The comparisons between the experimental group and control group scores are not statistically significant in any of the variables or at any of the measurement points, and this might be attributable to the high experimental attrition in the control group and the lack of homogeneity of variances.

Tables 4 and 5 show the clinical significance of the differences observed in the quality of life dimensions after application of the treatment, which is reflected in the reduced percentage of patients in the score categories indicating pathology and an increase in the percentage lying within the bounds of normality.

DISCUSSION

The main contribution of the present research is its having demonstrated the efficacy of a psychological treatment programme for producing a statistically and clinically significant improvement in the quality of life of patients with IBD.

Quality of Life Dimensions	Categories	Before		After		3 months		6 months		12 months	
		N	%	N	%	N	%	N	%	N	%
Digestive Symptoms	Severe	33	0	33	0	31	0	22	0	18	0
	Moderate		9.1		6.1		12.9		9.1		16.7
	Mild		69.7		48.5		35.5		45.5		38.9
	Remission		21.2		45.5		51.6		45.5		44.4
Systemic Symptoms	Severe	33	0	33	0	31	0	22	0	18	0
	Moderate		21.2		9.1		9.7		18.2		22.2
	Mild		63.6		57.6		71		45.5		38.9
	Remission		15.2		33.3		19.4		36.4		38.9
Functional Effects	Severe	33	0	33	0	31	3.2	22	0	18	0
	Moderate		29		6.1		9.7		9.1		11.1
	Mild		54.8		69.7		61.3		68.2		72.2
	Normal		16.1		24.2		25.8		22.7		16.7
Emotional Function	Severe	33	0	33	0	31	0	22	0	18	0
	Moderate		7		3		1.7		0		2.3
	Mild		42.3		14.9		21.7		20		18.2
	Normal		50.7		82.1		76.7		80		79.5
Social Effects	Severe	33	0	33	0	31	0	22	0	18	0
	Moderate		27.3		12.1		12.9		18.2		16.7
	Mild		57.6		57.6		45.2		59.1		61.1
	Normal		15.2		30.3		41.9		22.7		22.2

Quality of Life	Categories	Before		After		3 months		6 months		12 months	
		N	%	N	%	N	%	N	%	N	%
SIBDQ	Severe	33	6.1	33	0	31	0	22	0	18	0
	Moderate		3		3		6.5		4.5		5.6
	Mild		75.8		60.6		41.9		54.5		50
	Normal										

Quality of Life Variable	Dimensions	Before	After		3 months		6 months		12 months	
		Mean (n=33)	Mean (n=33)	Friedman	Mean (n=31)	Friedman	Mean (n=22)	Friedman	Mean (n=18)	Friedman
SIBDQ	Digestive Symptoms	5.39	5.78	0.01*	5.78	0.01*	5.64	0.51	5.40	0.62
	Systemic Symptoms	4.92	5.56	0.0001*	5.38	0.01*	5.35	0.28	5.11	0.13
	Functional Effects	5.51	5.99	0.02*	5.95	0.19	5.85	0.37	5.62	1
	Emotional Function	5.26	6.04	0.0001*	6	0.0001*	5.97	0.01*	5.76	0.02*
	Social Effects	5.73	6.24	0.01*	6.13	0.0001*	6.08	0.04*	5.92	0.62
	SIBDQ (total)	5.36	5.92	0.0001*	5.85	0.0001*	5.78	0.20	5.56	0.06

This improvement might be explained on the basis of the actual definition of the quality of life concept.

According to Felce and Perry (1995), the concept of quality of life would not be restricted to the absence of illness, but would rather include other aspects, such as functional limitations, emotional alterations, social and family relations, and the employment difficulties that can arise as a result of illness.

Of special relevance in this conceptualization of quality of life, is the person's subjective perception and appraisal of the bio-psycho-social consequences of the disease, so that the quality of life concept becomes a subjective interpretation, which will depend on the patient's perception of health and his or her opinion about the repercussions of the illness on his or her life.

The efficacy demonstrated by the psychological treatment programme validated in this study could be attributed to the fact that the coping strategies adapted for this type of patient, and taught over the course of the sessions, would cover all the dimensions in which patients' quality of life is affected, and which correspond to those considered by Cruzado and de la Puente (1997).

As regards the physical effects, one of the factors that best predicts how far these patients' quality of life is affected is the presence of symptomatic activity of IBD. In this regard, the psychological treatment programme designed for the present study has demonstrated its efficacy for reducing the digestive symptoms and systemic symptoms of the disease, which explains part of the improvement in quality of life observed. These results are similar to those described in the literature by Schwarz and Blanchard (1990) and García-Vega and Fernández (2004), and coincide with them in suggesting that psychological treatment programmes are effective in producing a significant reduction in the activity rate of IBD. Given the possible autoimmune aetiology of this illness, the improvement in physical symptoms after application of the psychological treatment programme may be explained on the basis of the relationship between stress and IBD. Stress has a substantial effect on the response of the immune system (Ziemssen & Kern, 2007), and specifically on the immunological function of the intestinal mucous (Anton, 1999; Maunder, 2000; Ferrier & cols., 2003), so that a reduction in stress would generate an improvement in the illness.

As far as psychological effects are concerned, the quality of life of these patients depends not only on physical symptoms, but will also be affected by the presence of emotional alterations, such as anxiety or

depression (Casellas, López-Vivancos, Vergara & Malagelada, 1999). The psychological treatment validated in the present study has shown itself to be effective in reducing the emotional consequences of IBD and the anxious-depressive symptoms of these patients, which would also explain the improvement observed in quality of life.

With regard to functional effects, early research already indicated that IBD had a marked effect on patients' working life and leisure-time activities (Sorensen, Olsen & Binder, 1987; Shivananda & cols., 1993). The improvement observed in physical and psychological symptoms in the wake of the psychological treatment programme, and the learning of a series of effective coping strategies for improving adaptation to the illness, may provide the explanation for the fewer adverse functional consequences observed in the results of this study, and hence, the improved quality of life.

Finally, IBD can also sometimes affect patients' social relations. In this regard, many patients, after a diagnosis of this illness, cut themselves off socially, have employment and financial problems and considerably restrict their leisure-time activities. Perceived social support is another of the psychosocial factors that influences the quality of life of these patients (Casellas, López-Vivancos, Vergara & Malagelada, 1999). The psychological treatment programme produced a significant improvement in social variables, reflected in increased frequency of use of the social support strategy and a reduction in the social consequences of the condition. Once again, the improvement in social variables partly explains the improvement observed in quality of life.

In sum, it seems reasonable to conclude that the psychological treatment programme was effective in producing improved quality of life in these patients for the following reasons: a) because it succeeded in producing a slight reduction in the physical and systemic symptoms of the illness; b) because the therapeutic techniques used were of proven efficacy in the treatment of emotional disorders, having produced highly favourable changes at the physiological, emotional, cognitive and behavioural levels (Pérez-Álvarez & García-Montes, 2001; Capafons, 2001); and c) because patients were provided with a series of coping strategies, such as relaxation, cognitive restructuring or social skills training, which are effective in meeting the demands of the disease at lower emotional cost and improving quality of life.

In general, the coping strategies related to the best prognosis for IBD are those involving active coping, such as seeking solutions, self-control and self-help thoughts, seeking social support, acceptance of and adaptation to the illness, and doing gratifying activities (Schmitt, 1997; Buceta & Bueno, 2001).

The use of these types of strategy, considered positive for the patient's adaptation to the disease, has also been associated with lower scores in depression and better quality of life (Díaz-Sibaja, Comeche & Mas-Hesse, 2006).

Another aspect we should like to analyze in this discussion is the finding that, while it is true that the improvement achieved at the end of the treatment programme is maintained at three months in 4 of the 5 quality of life variables measured, there is nevertheless a general tendency toward a reduction of the improvement with the passage of time. The majority of authors coincide in stressing the importance of follow-up sessions for the purpose of consolidating what was learned during the treatment phase, but also to motivate patients to use the coping strategies every day, until they eventually become habits of their daily lives.

One of the aspects that might explain why the follow-ups scheduled in the present study were not effective for maintaining the improvement in the post-treatment phase is that the intention of these follow-ups was more evaluative than therapeutic. Thus, although in the follow-ups mention was made of the different coping strategies taught, and participants were asked about their use, this reminder was informal in nature, and could therefore be expected to have less therapeutic effect.

The above reflection gives rise to the suggestion of introducing follow-up sessions, of a formal and protocolized nature, in which the techniques taught are reviewed and consolidated, and which analyze (and respond to) the factors that hinder their application in patients' everyday lives. This would permit, moreover, reinforcement of the improvement found in many of the variables at the 3-month follow-up, and hence continued improvement.

We should like to conclude by pointing out that the present study has served to validate a protocolized treatment manual for psychological intervention in IBD patients, and that this will bring, in relation to other protocolized treatment manuals, and as highlighted by Hickling and Blanchard (1997), some advantages in clinical practice, in research and in the training of psychologists.

The efficacy of this treatment programme would be

backed up by two of the criteria set out by the Task Force (1995): a) a protocolized treatment manual was drawn up, with clear descriptions of the entire assessment and treatment process; and b) the programme has demonstrated its efficacy on being used with a sample of patients identified in accordance with the same diagnostic criteria.

Given the ease of application of the present programme and its optimal results, the use of psychological intervention could clearly lead to a reduction in public health costs. Nevertheless, it is recommended that future research sets out to determine the differential efficacy of the different strategies making up the multi-component treatment programme and includes a cost-benefit analysis in support of its assertions.

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