EFFECTS OF A POSITIVE EMOTION-BASED ADJUVANT PSYCHOLOGICAL THERAPY IN COLORECTAL CANCER PATIENTS: A PILOT STUDY

EFFECTS OF A POSITIVE EMOTION-BASED ADJUVANT PSYCHOLOGICAL THERAPY IN COLORECTAL CANCER PATIENTS: A PILOT STUDY

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Abstract

Objective: To examine the effectiveness of an "Enhancing Positive Emotions Procedure" (EPEP) based on positive psychology and cognitive behavioral therapy in relieving distress at the time of adjuvant chemotherapy treatment in colorectal cancer patients (CRC). It is expected that EPEP will increase quality of life and positive affect in CRC patients during chemotherapy treatment intervention and at 1 month follow-up.

Method: A group of 24 CRC patients received the EPEP procedure (intervention group), whereas another group of 20 CRC patients did not receive the EPEP (control group). Quality of life (EORTC-QLQC30), and mood (PANAS) were assessed in three moments: prior to enter the study (T1), at the end of the time required to apply the EPEP (T2, 6 weeks after T1), and, at follow-up (T3, one-month after T2). Patient's assessments of the EPEP (improving in mood states, and significance of the attention received) were assessed with Lickert scales.

Results: Insomnia was reduced in the intervention group. Treatment group had better scores on positive affect although there were no significantly differences between groups and over time. There was a trend to better scores at T2 and T3 for the intervention group on global health status, physical, role, and social functioning scales. Patients stated that positive mood was enhanced and that EPEP was an important resource.

Resumen

Objetivo: Examinar la eficacia de un programa basado en la Psicología Positiva y en la terapia cognitivo-conductual (EPEP) para incrementar emociones positivas y reducir malestar en pacientes de cáncer colorrectal (CRC) que reciben quimioterapia adyuvante. Se espera que el EPEP mejore calidad de vida y estados de ánimo durante la quimioterapia y en el seguimiento un mes después.

Método: Un grupo de 24 CRC recibió el EPEP (grupo de intervención: GI), y otro grupo de 20 CRC no recibió el EPEP (grupo control: GC). Se evaluaron la calidad de vida (EORTC-QLQC30) y los estados de ánimo (PANAS) en tres momentos: al entrar en el estudio (T1); 6 semanas después, tiempo de aplicación del EPEP (T2), y un mes después del T2 (seguimiento:T3). Las opiniones de los pacientes sobre el EPEP (mejoría del estado de ánimo e importancia de la atención recibida) fueron evaluadas con escalas Lickert.

Resultados: El GI mostró mejores puntuaciones en estado de ánimo positivo, aunque sin diferencias significativas con el GC. Las puntuaciones en T2 y T3 tendían a ser mejores en el GI en nivel global de salud, y en las escalas física, social y de rol, El GI redujo el nivel de insomnio. Los pacientes indicaron que el EPEP era importante y mejoraba el estado de ánimo.

Conclusiones: Los datos sugieren que el EPEP mejora el estado de ánimo positivo y la calidad de vida, y los pacientes lo consideraron

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André Cardoso Louro Universitat Autònoma de Barcelona. Factultat de Psicologia. Departament de Psicologia Bàsica, Evolutiva i de l'Educació E-mail: louro.andre@gmail.com Conclusions: CRC patients receiving EPEP during chemotherapy believed that this intervention was important. Furthermore, EPEP seems to improve positive affect and quality of life. EPEP has potential benefits, and its implementation to CRC patients should be considered.

Keywords: Colorectal Cancer, psychological Intervention, positive psychology, cognitivebehavioral therapy.

importante y útil. El EPEP es potencialmente beneficioso y debería considerarse la posibilidad de implementarlo en pacientes CRC.

Palabras Claves: Cáncer Colorrectal, intervención psicológica, psicología Positiva, terapia cognitivo-conductual.

INTRODUCTION

Colorectal cancer (CRC) is the third most common cancer in men and the second in women worldwide. Almost 60% of cases occur in developed regions. Deaths from colorectal cancer are estimated, worldwide, as 8% of all cancer deaths, making it the fourth most common cause of death from cancer⁽¹⁾. Colorectal cancer incidence rates as well as mortality rates have been diminishing for most of the past two decades. In spite of that, receiving a cancer diagnosis represents an enormous psychological challenge⁽²⁾. Cancer and its treatment including surgery/chemotherapy/radiotherapy can also impose a variety of physical and functional disabilities that compromise the patient's ability to work or to maintain independence⁽³⁾. Cancerrelated stressors faced by individuals with CRC include physical and psychological factors of the diagnosis, treatments, side effects, reactions of friends/family, followup procedures, and recurrence fears⁽⁴⁾. Deficits in emotional and social functioning and specific limitations like fatigue, dyspnea, insomnia, constipation, diarrhea, and financial difficulties are main factors hampering the quality of life (QOL) among colorectal cancer patients and seem to affect predominantly younger patients⁽⁵⁾.

To assess the impact of disease in individuals and families, it is important to evaluate the quality of life of the patients. The quality of life experienced by CRC patients is important for evaluating the full impact of the disease on individuals and their families. There is a need for an intervention based on psychological resources that will enable patients with cancer to live as positively as they can with the difficulties of a chronic, sometimes debilitating, disease and the aversive secondary effects of the medical treatment. A promising approach is one that focuses on the induction of positive emotions, especially for the benefits which these emotional experiences have in the short-term as well as in the medium and long-term⁽⁶⁾.

In oncology, some interventions that include positive psychology elements, have displayed encouraging preliminary results⁽⁷⁾. Although a global consensus of a positive therapies classification is needed to take one more step in structuring positive psychology⁽⁸⁾, some studies provided relevant evidence about the clear development of positive aspects from the cancer experience, but it is not still well known whether positive emotions would improve guality of life and disease evolution in CRC patients. A recent systematic revision⁽⁹⁾ suggests that positive affect (PA) was significantly associated with greater levels of general health, better social functioning, benefit finding, positive changes, low depression, less anxiety and greater psychological well-being. PA also increases when different activities are developed. However, the studies do not provide enough evidence about whether cancer stage or kind of treatment could influence in the PA and well-being relationship. Thus, further studies which analyse these features are needed. We consider that a fruitful line of research should be addressed to assess whether a psychological intervention, aimed to enhance positive affect, would increase quality of life and well-being in CRC patients. Furthermore, it would be interesting that this intervention can be easily provided to the patients, and applied while the patient is at the hospital receiving medical treatments. In this sense, sessions of chemotherapy could be an appropriate setting to give patients psychological assistance, since they must remain at hospital seated or lying down during several hours.

Thus, the purpose of this study is to examine the effectiveness to enhance positive affect and quality of life of a Psychological Intervention applied at the hospital at the same time that patient is receiving his/ her adjuvant chemotherapy schedule. This Psychological Intervention has been called "Enhancing Positive Emotions Procedure" (EPEP) and has been structured from a cognitive behavioral orientation.

METHOD

Participants

All participants were recruited between October of 2012 and February of 2014. Fifty-two subjects diagnosed with colorectal cancer were recruited at the Portuguese Institute of Oncology, Oporto, Portugal. These participants had a stage of II and III cancer and received the FOLFOX adjuvant chemotherapy treatment.

Initially, 107 patients which had those characteristics were approached. The flow of participants through the study is depicted in Figure 1. Reasons for excluding 57

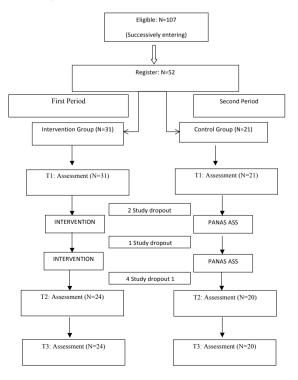


Figure 1. Design and Flow Diagram

cases were: analphabetic (n=1), having a prior cancer before actual colorectal cancer (n=5), receive other psychiatric or psychological support (n=22), or be receiving the 8th to 12th sessions of the FOLFOX procedure, since this situation precluded the application of the EPEP (see Procedure section). One additional man was not eligible since he was deaf.

Amongst the 52 participants which finally entered the study, 24 (psychological intervention group) completed their prescribed psychological intervention and follow-up assessment, whereas 20 patients (control group) followed the same procedure but without receiving the psychological intervention. There were 8 dropouts in the study (see figure 1). The reasons for dropouts were migration to other hospitals (n = 1), change of medical treatment (n = 5), refusal to continue the study (n = 1), and time constraints (n=1).

Table 1 shows the distribution of the number and percentage of participants and their demographic and clinical variables. There were no differences between the groups in any of demographic and clinical variables.

Table 1. Distribution of the nomber and percentage of participants	
the demographic and clinical variables	

Table 1 Distribution of the number and percentage of participants in function of

	Interventio	on Group	Control	Group	Tot	al
	Male	Female	Male	Female	Male	Female
Total	15(62.5%)	9(37.5%)	14(70%)	6(30%)	29(65.9%)	15(34.1%)
Age						
<50	4(26.7%)	2(22.2%)	3(21.4%)	0(0.0%)	7(24.1%)	2(13.3%)
50-59	4(26.7%)	3(33.3%)	3(21.4%)	4(66.7%)	7(24.1%)	7(46.7%)
=>60	7(46.7%)	4(44.4%)	8(57.1%)	2(33.3%)	15(51.7%)	6(40.0%)
Education						
Elementary School (1-4 grade)	7(46.7%)	4(44.4%)	6(42.2%)	2(33.3%)	13(44.8%)	6(40.0%)
(5-6 grade)	1(6.7%)	1(11.1%)	1(7.1%)	0(0.0%)	2(6.9%)	1(6.7%)
Middle School (7-9 grade)	3(20.0%)	4(44.4%)	5(35.7%)	3(50.0%)	8(27.6%)	7(46.7%)
Secondary School (11-12 grade)	3(20.0%)	0(0.0%)	0(0.0%)	1(16.7%)	3(10.3%)	1(6.7%)
Higher Education	1(6.7%)	0(0.0%)	2(14.3%)	0(0.0%)	3(10.3%)	0(0.0%)
Marital Status						
Married	13(86.7%)	3(33.3%)	12(85.7%)	5(83.3%)	25(86.2%)	8(53.3%)
Single	0(0.0%)	2(22.2%)	1(7.1%)	0(0.0%)	1(3.4%)	2(13.3%)
Divorce/Separated	2(13.3%)	2(22.2%)	1(7.1%)	0(0.0%)	3(10.3%)	2(13.3%)
Widowed	0(0.0%)	2(22.2%)	0(0.0%)	1(16,7%)	0(0.0%)	3(20.0%)
Type of cancer						
Colon	10(66.7%)	6(66.7%)	9(64.3%)	5(83.3%)	19(65.5%)	11(73.3%)
Rectal	5(33.3%)	3(33.3%)	5(35.7%)	1(15.7%)	10(34.5%)	4(26.7%)
Cancer stage						
Stage II	1(6.7%)	2(22.2%)	1(7.1%)	1(16.7%)	2(6.9%)	3(20.0%)
Stage III	14(93.3%)	7(77.8%)	13(92.2%)	5(83.3%)	27(93.1%)	12(80.0%)

Measures

PANAS: We used the Portuguese version of the Positive and Negative Affect Schedule (PANAS)⁽¹⁰⁾ which consists in a 20 emotions checklist with two sub scales, the positive affect and the negative affect. The psychometric data analyses resulted in a Portuguese version very similar to the original scale, sharing 13 items of the 20 from the American scale⁽¹¹⁾. All the original categories of emotion are represented in the Portuguese PANAS. Results indicate a good internal consistency (α =.86) for the positive affect scale and (α =.89) for the negative affect scale. Scores range from 10 - 50, with higher scores representing both higher levels for positive affect and negative affect. Watson, Clark & Tellegan⁽¹¹⁾ provided mean scores of their sample both for momentary and weekly affect. For positive affect were 29.7 (SD=7.9) and 33.3 (SD=7.2) respectively. For negative affect, were 14.8 (SD=5.4) and 17.4 (SD=6.2) respectively.

EORTC QLQ-C30: It was used the Cancer Quality of Life Questionnaire Core-30 (EORTC QLQ-C30, version 3). It is a 30item questionnaire, where twenty-four of the items form nine multi-item scales and six items are single-item symptom measures⁽¹²⁾. The scales are constructed by summation of the scores on the items. Multiitem subscales and single items intent to reflect the multidimensionality of the QoL construct⁽¹²⁾, namely: five functional subscales (physical, role, cognitive, emotional, and social); a global health/QoL subscale; three symptom subscales (fatigue, pain, and nausea/vomiting); and single items for the assessment of additional symptoms commonly reported by cancer patients (dyspnoea, appetite loss, sleep disturbance, constipation, and diarrhea); one more item relates to the perceived financial impact of cancer and cancer treatment, but will not be considered in this study. All the items scales are scored on 4-point Likert type scales ranging from 1 'not at all' to 4 'very much', except for the two items of the global health/QoL subscale, that uses a modified 7-point linear analogue scales. All of the scales and single item scales range in score from 0 to 100. A high score for functional scales and global health status/QoL represents high/healthy level of functioning and QoL. A high score for a symptom scale/item represents a high level of symptomatology or problems. The study of reliability through Cronbach alpha shows between 0.74 and 0.88, which is an appropriate internal consistency for multi item functional and symptom scales. The Portuguese version of the QLQC30⁽¹³⁾ has good metric properties, and measures the same constructs, being appropriate to be applied to people with cancer disease.

Psychological Treatment Evaluation: Participants at the Intervention Group were asked to answer a final questionnaire with the following items: 1. To what degree the EPEP has improved your positive emotions? 2. To what degree the EPEP has improved your quality of life? 3. To what degree the EPEP has been important to you? All these items were measured with a 0-10 numeric scale.

Procedure

The researcher approached all persons meeting eligibility criteria. All participants were given detailed information by the researcher about the present study. Written informed consent was obtained from each participant before participation in this study. Ethical approval of the study was given by the Portuguese Institute of Oncology.

Since the researcher had not enough time availability to assess and apply psychological intervention simultaneously to both treatment and control groups, it was decided to develop the study in two time periods. In the first one, patients were assigned to the intervention group until to achieve a sample size of 31 patients. Once the treatment group was completed, the next patients were assigned to the control group until a sample size of 21 patients was obtained. Table 2 resumes the procedure applied to the patients. Time 2 (T2) assessment was applied one month and half after the Time 1 (T1) assessment, and Time 3 (T3) assessment was applied one month after T2.

Table 2. Structure of sessions applied to treatment and control groups. For each session, it is indicated which measures were applied. Characteristics of the treatment sessions are specified at the procedure section

PROCEDURE	SESSION	TIME (Weeks)(*)	CYCLE OF CHEMOTHERAPY (•)	treatment group	CONTROL GROUP
ASSESSMENT (T1) Pre-Treatment PSYCHOLOGICAL INTERVENTION FOR THE TREATMENT GROUP (EPEP SESSION 1: Searching for alternative thoughts)	1	0	1-8	PANAS EORTC CLINICAL VARIABLES DEMOGRAPHIC VARIABLES	PANAS EORTC CLINICAL VARIABLES DEMOGRAPHIC VARIABLES
PSYCHOLOGICAL INTERVENTION FOR THE TREATMENT GROUP (EPEP SESSION 2: Planning a pleasure activity)	2	2	2-9	PANAS	PANAS
PSYCHOLOGICAL INTERVENTION FOR THE TREATMENT GROUP (EPEP SESSION 3: Creating positive meaning)	3	4	3-10	PANAS	PANAS
ASSESSMENT (T2) Post-treatment PSYCHOLOGICAL INTERVENTION (SESSION 4: Overview of the intervention)	4	6	4-11	PANAS EORTC NUMERIC SCALE FOR EVALUATION OF TREATMENT	PANAS EORTC
ASSESSMENT FOLLOW- UP (T3)	5	10	5-12	PANAS EORTC	PANAS EORTC

(*) Weeks varied between patients, since sometimes the chemotherapy session was delayed because of medical reasons.

(•) the range of Cycles of chemotherapy that patients had received when the session was applied. For example, patients who received session 1 at cycle 1 of chemotherapy, received session 2 at cycle 2 and finished their participation in the study at cycle 5; patients receiving session 1 at cycle 5, received session 2 at cycle 6 and finished their participation in the study in cycle 9; patients receiving session 1 at cycle 8, received session 2 at cycle 9 and finished their participation in the study in cycle 12.

On the first period (From September 2012 to March 2013) participants were invited to participate in study and then were successively entering and assigned to the EPEP. From September 2013 to December 2013, patients were invited to participate and then successively entering and assigned to the control condition. All the participants of control group were invited to participate in psychological intervention later. The numbers of cycles of chemotherapy treatment were 12 with an interval of 2 weeks each. This adjuvant treatment was given for about 6 months. Before starting each cycle, patients were assessed by using the National Cancer Institute common toxicity criteria, and the results allowed sometimes to delay the chemotherapy session. Thus, the time between sessions (weeks) was not always the same for all patients. Both the intervention and assessment were administrated when CRC patients were doing chemotherapy. Participants in both conditions met in individual sessions in a room equipped with armchairs where chemotherapy (FOL-FOX) was administered. Patients entered the study once the FOLFOX protocol was started. Thus, they were recruited between their first and eighth sessions of chemotherapy. Although it would be ideal to include all patients (both in treatment and control groups) just from their first FOLFOX protocol this was not possible because of the reasons of time availability for the researcher previously stated. Both the intervention and assessment were led by the researcher, who is a clinical psychologist with professional card.

The EPEP is designed to be implemented during chemotherapy treatment. Its features are teaching patients how to a) search for positive alternative thoughts; b) use activity scheduling and c) create positive meanings. It is expected that the EPEP should be a valuable tool to help them cope with the psychological distress associated with the diagnosis, stage of disease, treatment and its side effects and lack of social support. Building patient's coping skills during the treatment might prevent depressive and anxiety symptoms and maintain or improve quality of life. This study attempts to determine if patients at the Intervention Group, who will receive psychological intervention, improve positive affect and will preserve or improve quality of life greater than patients at the Control Group, who will not receive psychological intervention.

Design

The design of this study was of two groups with pre-post-test and follow-up comparisons. It was used a cluster sampling by time periods. Pre-tests (T1 assessment) were used to establish baseline information for the patients' levels of quality of life, and positive and negative moods. Post-tests (T2 and T3) were used to determine the effects of the interventions on quality of life and mood states.

Data analysis

For each EORTC and PANAS subscales it was performed a comparison of means with repeated measures applying a General Linear Model (GLM): the treatment was a between-subject factor and time of evaluation (pre, post and follow-up) was within-subject factor. To correct for violations of sphericity was used Greenhouse-Geisser correction to produce accurate significance (p) value.

RESULTS

Table 3 shows the mean and SD values of the subscales of EORTC QLQ-C30 version 3.0 obtained in intervention and control groups in the beginning of the intervention (pre), at the last session (post) and at the follow–up.

		Pre	(T1)			Pos	t (T2)			Follow-	Up (T3)	
	Interve (N=		Control	(N=20)		ention =24)	Control	(N=20)	Interve (N=		Control	(N=20)
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Global Health Status	73.95	17.25	66.25	20.31	77.77	14.88	65.83	16.64	81.59	12.28	66.66	19.68
Functional Scales								_				
Physical Functioning	89.44	12.26	78.66	14.28	90.00	9.63	80.66	14.96	87.77	12.53	73.00	20.79
Role Functioning	92.36	15.52	85.83	21.13	92.36	16.28	85.83	16.46	95.83	10.13	81.66	20.16
Emotional Functioning	82.98	13.34	77.50	16.24	85.06	13.45	79.16	19.21	84.72	13.82	71.25	24.25
Cognitive Functioning	90.97	12.98	85.00	17.01	92.36	9.80	86.66	17.60	93.75	9.59	88.33	16.31
Social Functioning	90.27	13.82	74.16	26.19	91.66	15.54	76.66	25.01	88.19	19.95	75.83	30.81
Symptom Scales												
Fatigue	10.64	13.30	22.22	16.51	13.42	15.70	26.66	21.14	15.74	16.68	31.66	26.06
Nausea and Vomiting	4.86	10.40	2.50	8.15	3.47	6.91	4.16	10.64	4.86	10.40	6.66	13.67
Pain	4.86	10.40	10.00	15.67	3.47	9.80	8.33	12.68	8.33	15.54	11.66	22.36
Dyspnea	1.38	6.80	0.00	0.00	1.38	6.80	3.33	10.25	0.00	0.00	1.66	7.45
Insomnia	22.22	27.21	33.33	35.86	18.05	27.76	36.66	30.39	13.88	19.45	33.33	30.58
Appetite Loss	2.77	9.41	6.66	17.43	5.55	16.05	11.66	19.57	6.94	19.60	11.66	19.57
Constipation	15.00 (N=20)	22.87	10.41 (N=16)	26.44	10.00	19.04	12.50	23.95	5.00	12.21	8.33	19.24
Diarrhea	10.00 (N=20)	15.67	6.25 (N=16)	18.13	8.33	18.33	14.58	20.97	6.66	13.67	10.41	20.06

Table 3. Mean and SD of the Scales of EORTC QLQ-C30 for each group (intervention and control) and each assessment time (pre, post and follow-up)

There were statistically significant differences between the intervention group and control group as a whole on the global health status (F= 6.273, p = 0.016), on the physical functioning (F= 7.931, p= 0.007), on the role functioning (F= 4.406, p= 0.042) and on the social functioning (F= 5.069, p=0.030). However, there were

lable 4. Mean and SD of scales of PANAS (positive affect and negative affect) for each group

no differences between the three times of evaluation and there were not any interaction between treatment and time of evaluation.

In the emotional functioning and cognitive functioning scales, there were not statistical differences between groups and times of evaluation. There were not any interaction between treatment and time of evaluation.

There were statistically significant differences between the intervention group and control group as a whole in the fatigue symptom (F= 7.077, p=0.011), and in the insomnia symptom (F= 5.719, p= 0.021). However, there were no differences between the three times of evaluation and there were not any interaction between treatment and time of evaluation. There were no differences in scores between groups for nausea, pain, dyspnea, appetite loss, constipation and diarrhea symptoms.

Table 4 shows the mean and SD values of the subscales of The Positive and Negative Affect Schedule (PANAS) obtained in intervention and control groups in the beginning of the intervention (pre: T1), intermedium (int1.), intermedium (int.2) at the last session (post: T2) and at the follow–up (T3).

In the positive affect there was a difference between the intervention group and the control group (F= 4.553, p =0.039), whit higher scores in the intervention group, while there were no differences between the five times of evaluation nor interaction between treatment and time of evaluation. There were not differences in scores for negative affect.

Figure 2 shows the number of patients who had scores between 0-4, 5-7 and 8-10 ranges in each of the numeric scales. When higher scores (8-10) are considered, almost all patients (23/24) gave importance to the EPEP, whereas more than 50% stated that there was an improvement in PA (15/24) and quality of life (13/24).

		(inter	(intervention		l conti	ol) ar	nd eac	ch as	sessme	ent tir	and control) and each assessment time (pre, intermedium, post and follow-up)	e, int	ermed	ium,	post a	nd fo	llow-r	(dr		
		Time1(Time1(Pre: T1)			Time2(int.1)	(int.1)			Time3(int.2)	(int.2)			Time4(Post: T2)	ost: T2)		Tim	e5 (Follo	Time5 (Follow-up: T3)	(1
	Interventic (N=24)	Intervention (N=24)	Control (N=20)	trol 20)	Intervention (N=24)	intion 24)	Control (N=20)	trol 20)	Intervention (N=24)	ention 24)	Control (N=20)	rol (0)	Intervention (N=24)	ntion 24)	Control (N=20)	0)	Intervention (N=24)	ntion :4)	Control (N=20)	rol (0)
	Mean	Mean SD Mean	Mean	SD	Mean	SD	SD Mean SD Mean	SD	Mean	SD	SD Mean SD Mean	SD	Mean	SD	SD Mean SD Mean	SD	SD Mean SD	SD	Mean SD	SD
Positive Affect	21.63	21.63 4.16 19.80	19.80	4.33	21.21	4.29	18.75	3.50	21.96	4.60	4.33 21.21 4.29 18.75 3.50 21.96 4.60 19.65 3.54 22.54 4.70 20.30 3.75 22.79 3.45 19.75 4.85	3.54	22.54	4.70	20.30	3.75	22.79	3.45	19.75	4.85
Negative Affect		17.17 3.22 15.80	15.80	3.51	16.33	3.66	16.05	3.06	17.46	3.85	3.51 16.33 3.66 16.05 3.06 17.46 3.85 16.45 3.80 16.67 3.63 15.95 2.54 16.83 3.57 16.45	3.80	16.67	3.63	15.95	2.54	16.83	3.57	16.45	3.50

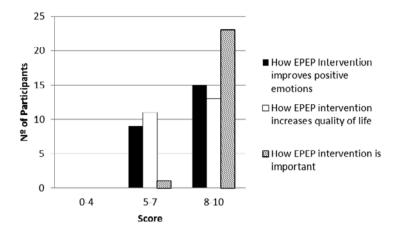


Figure 2. Number of Participants who scored into each range of scores for each EPEP feature

DISCUSSION

For quality of life, the intervention group had better scores on global health status, physical, role and social functioning scales than control group at all assessments. Although this condition does not preclude the analysis about whether the EPEP increased quality of life, it would be desirable that both intervention and control groups had similar scores at the pretest condition. We cannot explain why these differences appeared but some considerations could be made. A first explanation should consider that positive expectations appeared at the intervention group at the pretest level: since patients answered the EORTC-C30 questionnaire after knowing they belonged to a group which will receive psychological assistance, an optimistic bias in scoring items in some scales could be appeared. In this sense, it must be pointed out that differences in emotional and cognitive functioning scales did not reach statistical significance, although mean scores were also higher in the intervention group. Thus, this effect should be restricted to some areas where patients should be more inclined to experience expectations of improvement⁽¹⁴⁾. A second explanation could be due to the fact that the intervention group was recruited in a different period of time than control group and this could produce a biased sample. Furthermore, this bias could also be enhanced because of the small number of participants in both groups.

Whatever the case, and since statistical differences between treatment and control conditions in the scores evolution along the time were not observed, it cannot be stated that EPEP improved global health status in the treatment group. However, a trend to a better condition in the global, physical, role and emotional scales in the treatment group was observed. Specially, mean score in treatment group at follow-up (81.59) was near the upper level of the clinical normal range (83.3), and has increased from the mean scores at pretest condition (73.95) thus suggesting that an improvement in these patients has been achieved, since patients at the control condition did not change mean scores across the three measures (66.25, at pretest, and 66.66, at followup). It is possible that EPEP had produced slight improvements in patients, which would not be detected by general measures such as those provided by quality of life questionnaires. In fact, studies which applied interventions which were based on positive psychology procedures, such ours, to enhance patients' conditions (9) did not generally use quality of life measures, whereas the instruments chosen were mainly addressed to assess mood and emotional states. Thus, perhaps changes in quality of life measures as a result of a brief-intervention procedure such as the EPEP, would be difficult to produce, since such a result would require longer and larger interventions.

Concerning symptoms scores, the means observed in both patient groups at pretest and posttest were very low in nausea, pain, and dyspnea (lower than 20 points in a 0-100 points scale) and, because of that, they should not be discussed. The same consideration can be stated about diarrhea and constipation symptoms. Fatigue and appetite loss scores increased across measures and this is a normal evolution produced by chemotherapy procedures. It is difficult to expect that psychological procedures should produce better scores in our intervention group when a powerful biological agent such as chemotherapy side-effects is present. Thus, we think that insomnia is the only symptom which should perhaps be affected by the EPEP. In fact, we found that insomnia was reduced in the intervention group while the control group remained stable. However, as in the global health status case, this improvement did not reach statistical significance.

In summary, if we consider as a whole the Global Health Status and the Physical, Role, Social functioning, and Insomnia Scales, we can see the same evolution, suggesting that the intervention group had a slightly better condition than control patients, which could be produced by the EPEP. As it has been previously stated, perhaps these measures and scales are not suitable enough for observing the expected therapeutic effects.

Some studies with cancer patients found PA of PANAS scores higher than those in our sample⁽¹⁵⁻¹⁸⁾; but mean scores of NA were very similar. PA is not just the flip side of negative affective states. Rather, there is increasing support for the idea that positive mood and negative mood are related but distinct constructs⁽¹⁹⁾. In spite of that, the mean PA and NA total scores were low in comparison with the range provided in the original study⁽¹¹⁾. This can be explained because the original range provided by Watson et al.⁽¹¹⁾ was obtained in a sample of healthy persons. Furthermore, cultural differences could also produce different score levels. Thus, in the study of validation of PANAS Scale of the Korean version, Lim et al.⁽²⁰⁾ said that they had found lower total scores in contrast of others studies. These considerations need further research in Portuguese populations with healthy and non-healthy individuals to provide conclusions about whether CRC patients had normal or lower PA and NA than other persons.

On the other hand, it must be pointed out the fact that the treatment group had higher score on positive affect at the five times of evaluation in contrast with control group although there were no significantly differences between groups and over time. Although the previous considerations suggest that there was a slightly higher PA in the intervention group, which would be associated with better quality of life, it cannot be concluded, when PANAS scores are considered, that these effects were produced by the EPEP. It cannot be excluded that they could be related to the expectations effect mentioned above: patients at the intervention group could have increased their positive emotions because of knowing that they would be psychologically cared, but this fact should not affect negative emotions. It is possible that the EPEP was actually effective to produce several moments of PA in the intervention group across sessions which were not experienced by the control group, but that these moments were not reflected at the PANAS scores because of the retrospective assessment that patients had to make to answer the items. If these moments of PA were not very frequent and not very intense, they would not probably be remembered by the patients when answering the PANAS, but, at the same time, perhaps these PA moments, could have produced a "subliminal widespread effect" of benefits which allowed the slight effects of increasing quality of life in the intervention group. This hypothesis can be sustained by the patients' comments when describing how EPEP intervention improved positive emotions and increased guality of life. Thus, it can be stated, with caution, that EPEP should be useful to improve wellbeing in CRC patients receiving chemotherapy. Furthermore, participants of intervention group reported they enjoyed and benefited from their therapeutic experience when they were asked to evaluate the psychological intervention.

Some limitations of the study must be pointed out: The number of patients participating in this research does not allow the assumption of normality distribution of scores in the different features assessed. Thus, generalizations from this research study may not be appropriate and should be used with caution. Because we had not enough resources to develop a randomized study, we developed a non-randomized clinical trial study, with its constraints to achieve control over the confusing variables. Furthermore, although it was expected that both groups were similar at pretest measures, this condition was not always satisfied. Thus, it must be taken with caution that between groups differences could be produced by the EPEP.

Results offered by the present research are not conclusive, as it can be expected from a pilot study, but suggest that the EPEP can actually be useful and suitable for CRC patients since they can receive the EPEP at the same time they are following their medical schedules. It can be considered that EPEP did not allow higher effects because the procedure could not be applied in its optimal pattern to all patients at the intervention group (for example, time between EPEP sessions was too long in some cases because of the delays in applying chemotherapy when patients did not reach medical conditions required for receiving chemotherapy). On the other hand, maybe EPEP is too short, since other interventions in cancer patients use a higher number of therapeutic sessions than those provided by our EPEP (9). Further research is needed to confirm that a wider schedule of the EPEP would produce higher improvements in PA and NA in CRC patients.

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