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# The effectiveness of a psycho-educational group after early-stage breast cancer treatment: results of a randomized French study

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## Abstract

**Background:** Many women with breast cancer need psychological help to cope more effectively after treatment. Cognitive and behavioural techniques are not yet well established in France. A multi-site randomized study was conducted to evaluate the effects of a psycho-educational group intervention in this population.

**Methods:** Two hundred and three patients, recruited after primary treatment, were randomly assigned either to a treatment group (psycho-educational intervention) or to a waiting-list control group. The 8-week programme of 2 h sessions comprised of thematic discussions, information and training in stress management techniques. Evaluation at baseline, after 8 sessions, and 1 month after programme completion, included evaluations using the STAI, POMS, MAC, EORTC QLQ-C30 and EORTC QLQ-BR23 breast module scales.

**Results:** We observed a significant reduction in anxiety (STAI, POMS) among group participants, a reduction in anger, depression and fatigue (POMS), a significant improvement in vigor and interpersonal relationships (POMS), in emotional and role functioning, in health status and fatigue level (EORTC QLQ-C30). In contrast, coping strategies (MAC) were not significantly different between groups. No group-related negative effects were observed and the global satisfaction levels were very high.

**Conclusion:** This study demonstrates the feasibility and effectiveness of a psycho-educational intervention, which can accelerate the reduction of those negative affects which are present at the end of treatment. It represents an excellent complement or an alternative to individual psycho-oncologic therapeutic support, widely proposed in France, and should now be tested in groups with other types of cancer and at other disease phases.

**Keywords:** group therapy; psycho-education; randomized controlled trial; breast cancer; oncology

## Introduction

Women facing a diagnosis of breast cancer frequently develop psychopathological disturbances during medical treatment [1] or during follow-up [2], particularly anxiety, depression or both.

After treatment, women are concerned by the threat of death, the risk of recurrence, their uncertainty for the future, physical and treatment

related problems, fatigue, sexuality, body image, relationships and occupational difficulties [3–6]. In this remission phase also called re-entry transition [7], they are confronted with many individual challenges in reverting from ‘cancer patient’ back to ‘person’ and they have to cope with a new experience of the disease in a complex rehabilitation process [8,9].

All these concerns can create psychosocial adjustment disturbances, including anxiety, depression,

other affects or coping disabilities. Symptoms of anxiety can arise from follow-up medical examinations, as can post-traumatic symptom disorders when dealing with physical and mental changes, feelings of abandonment by professionals or isolation from the partner and family [7].

Because of the high prevalence of psychological or psychiatric problems in breast cancer patients, a wide range of psychosocial interventions have been developed, which are diverse in type, target population, format and outcome [10–13]. The meta-analysis by Sheard and Maguire [14] exploring anxiety and depression, reported a positive impact of psychotherapeutic interventions, with group interventions proving to be superior.

A number of studies have assessed the efficacy of cognitive behavioural techniques (CBT) or psycho-educational methods inspired from CBT in cancer patients, and a majority of these studies found significant positive outcomes for anxiety, depression, fatigue and general cancer distress [15,16]; among them, a recent meta-analysis [17] concerning breast cancer confirmed the efficacy of CBT both on distress and pain, and confirmed effect sizes found for distress in previously published meta-analyses [14,15,18].

To our knowledge, most studies assessing the effectiveness of psychosocial interventions in early-stage breast cancer have been performed for diagnosis or initial treatment rather than during the remission phase [3,12,19,20].

With some exceptions [21,22], most trials have been performed in English-speaking cultures, preventing extrapolation of results to the French context. Indeed, psycho-oncology in France has been developed mainly by the professionals trained in the use of psychodynamic techniques, involving individual patient follow-up using psychoanalytic methods, with a reluctance for consultation-liaison techniques. Very few psycho-oncologists are trained in CBT, brief therapy techniques and concepts of patient education. French patients are not familiar with group approaches, whether they concern psychology, psychiatry or oncology.

Given our cultural context, which is quite different from Anglo-American cultures and those of many other European countries, the challenge was to explore the feasibility of new psycho-oncology approaches in France [23], using both group formats and therapeutic tools from the psycho-educational field.

## Methods

### Purpose

This randomized trial aimed to assess the effectiveness of a psycho-educational group (PEG) intervention on anxiety, mood, mental adjustment

and quality of life in early-stage breast cancer. As our first objective, we hypothesized a significant reduction in anxiety—a possible result of post-treatment patients' feelings—in the PEG compared with the control group (CG). Our secondary objectives included an improvement of patients' adjustment strategies and quality of life profiles as a result of the group intervention.

### Design and sample

After receiving permission from the Institutional Review Board of Clinical Research and National Ethics Committee, this randomized pre–post intervention study was conducted in three French cancer centres. Eligible women (1) were 18 or older, (2) had completed primary breast cancer treatment (radiation alone or combined chemoradiotherapy 15 days to 1 year before testing), (3) had no recurrence or metastases, (4) had working knowledge of French, (5) had no psychiatric diagnosis such as severe cognitive disorders, mood disorders (ongoing or recent history of depression requiring hospitalization) or serious personality disorders.

Approximately 1000 letters were sent out, and an estimated 20% of those patients contacted answered positively. Randomization was performed to distribute the eligible patients after an interview to clarify their motivations. The final sample consisted of 203 early-stage breast cancer patients (Paris, 107; Toulouse, 51; Lyon, 45) randomized between the 'immediate' treated group (TG:  $n = 102$ ) and the 'deferred' control group (CG:  $n = 101$ ). Randomization by sealed letter was performed at each site, with a readjustment of the number of subjects in each group after every eighth subject. After randomization, patients who dropped out were not replaced. Patients who missed four group sessions were excluded from the analyses.

Assessments were performed three times on all participants: 1 week before starting the immediate intervention (E1), the second after completion of the intervention (E2) and the third, one week before the beginning of the deferred intervention (E3). Assessment at E1 was performed in the hospital and E2 and E3 were done at home (Figure 1).

### Intervention

On the basis of previous studies with group interventions for women with breast cancer [24–28], a psychoeducationally structured model based on CBT principles was developed. Patients were taught to routinely use thought records, to practise problem-solving and cognitive restructuring, to communicate better with caregivers and health professionals through role-play, and to practice relaxation. Unlike a comprehensive CBT

<p>Treated Group n = 102                  Psycho-educational intervention therapy                  (8 x 2 -hour-sessions)</p> <p>E1                  excluded from analyses : 10                  (data missing : 0; abandonment : 10)</p> <p>n = 92</p> <p>E2                  excluded from analyses : 7                  (data missing : 1; abandonment : 6)</p> <p>n = 85</p> <p>E3                  excluded from analyses : 4                  (data missing : 4; abandonment : 0)</p> <p>n = 81 (79 %)</p>	<p>Control Group n = 101                  (Waiting Group)</p> <p>excluded from analyses : 5                  (data missing : 1; abandonment : 4)</p> <p>n = 96</p> <p>excluded from analyses : 3                  (data missing : 0 ; abandonment : 3)</p> <p>n = 93</p> <p>excluded from analyses : 6                  (data missing : 0 ; abandonment : 6)</p> <p>n = 87 (86 %)</p>
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Figure 1. Trial profile outlining RCT design with numbers of patients at each stage

Table 1. Socio-demographic and clinical variables by randomization arm (significant data only)

Variables		Group (n 5 102)	Control (n 5 101)	P
Age	Mean (SD)	54.5 (9.3)	51.6 (9.6)	0.03
Marital status				0.34
Education				0.47
Occupation				0.41
Return to work				0.24
Psychological assistance before diagnosis of cancer				0.41
Psychological assistance since diagnosis of cancer	None	45	27	0.02
	Psychotherapy	9	11	
	Psychotropic	23	28	
	Psychotherapy and psychotropic	16	23	
Psychological assistance at randomization				0.64
Previous therapy group experience				0.25
Time between diagnosis and randomization (months)				0.62
Time between end of treatment and randomization (months)				0.86
Stage				0.89
Radiotherapy				0.68
Chemotherapy	No	56	39	0.02
	Yes	46	62	
Endocrine therapy				0.32

approach, all PEG exercises were initiations combined with general medical information and peer exchanges on defined themes (causes and significance of cancer, impact of treatments on body image, managing uncertainty, improving communication with loved ones, etc.). The programme included 8 weekly 2 h sessions. The groups were composed of 8–12 participants led by 2 therapists, either psychologists or psychiatrists, trained in group therapy and BCT [23].

The intervention was free of charge for patients, therapists being paid by hospital and research funding. The detailed content of this PEG has been

described elsewhere [29] and a manual (2001) can be obtained by written request from the first author. Monthly meetings were organised with leaders, co-leaders and investigators to ensure the coherence of intervention delivery.

### Measurements

Socio-demographic and medical data, disease stage, time since diagnosis and treatments received – either medical (surgery, chemotherapy, radiotherapy) or psychological (individual support, psychotropic drugs) – were recorded (Table 1).

Table 2. Variables influenced by age and chemotherapy

	Confounding Variables	Inter-subject effects <sup>a</sup> P<0.05	Intra-subject effects <sup>b</sup> P<0.05
Anx	Age		0.006
Ang	Age		0.006
Fat	Age	0.012	0.048
ScG	Age		0.005
RF	Age	0.039	
EF	Age	0.033	
FA: fatigue	Age	0.004	
NV: nausea	Age*cte	0.034	
PA: pain	Age	0.031	
	Cte	0.010	
AP: appetite	Cte	0.016	
CO: constipation	Cte		0.012
	Cte*age		0.036
FI: financial difficulties	Age*cte		0.050
BRBI: body image	Age		0.020
BRSEF: sexual function	Age	0.012	0.005
BRST: side effects	Age		0.039
BRBS: breast symptoms	Cte	0.001	0.003
	Age		0.026

<sup>a</sup> Inter-subject effect: group effect.

<sup>b</sup> Intra-subject effect: time effect.

Patients completed validated French versions of the following self-report questionnaires.

Anxiety was measured using the State-Trait Anxiety Inventory (STAI, whose scores range from 20 to 80 with a higher score reflecting a higher level of anxiety [30,31]). Psychological adjustment was assessed with the Profile of Mood States (POMS) [32–34], comprising different scales: anxiety (with scores ranging from 0 to 36), anger (0 to 48), confusion (0 to 28), depression (0 to 60), fatigue (0 to 28), vigor (0 to 32), interpersonal relationships (0 to 28). It includes a global score (from –32 to 200). A higher score indicates an increasing intensity of the mood state, whether it be negative affects (e.g.: anxiety, anger) or positive affects (e.g.: vigor, relationships). The Mental Adjustment to Cancer Scale (MAC) [35–37] provides 5 subscales measuring fighting spirit (13–52), helplessness–hopelessness (11–44), anxious preoccupation (12–48), avoidance (5–20) and denial (3–12). Higher scores indicate a higher level of the mental adjustment score.

Patients' quality of life profiles were evaluated by the EORTC core quality of life questionnaire (EORTC QLQ-C30) [38,39] and breast cancer module (EORTC QLQ-BR23). Items are scored from 1 to 4, except the global health status items, which range from 1 to 7. A high score for functional or global health status scales represents a healthy level of functioning; a high score for a symptom scale/item indicates a high level of symptoms or problems [40].

The EORTC core was administered only at E1 and E3 to reduce evaluation fatigue.

## Statistical analyses

For missing data, we applied the method of data allocation recommended by Jöreskog & Sörbom [41] using PRELIS software.

Statistical analyses were performed using SPSS and LISREL software. Statistical significance was set at  $p=0.05$ .

The main objective of the statistical analyses was to compare the course of the two groups between E1 and E3, including E2, on STAI state and trait anxiety scales, after confirming their comparability at E1 on all socio-demographic and medical variables as well as psychosocial evaluations.

Quantitative socio-demographic data were analysed using parametric tests (Student t-test) and qualitative variables or variables without a normal distribution were analysed using non-parametric tests (Pearson's chi-square test or the Mann–Whitney U-test). We used general linear models to test dependent variables. These models present the advantage of providing t-test values for each variable, and a general value (Wilks' lambda) that takes all the variables entered into the model and their correlations into account.

We compared the course of the two groups between E1 and E3 using the general linear models with repeated measurements, which take all three measures into account, to distinguish between intra-subject effects (time effect and time-by-group interaction) and inter-subject effects. Statistical analyses also controlled for confounding variables, partly responsible for the variance of the scores of the variables measured.

The effects of confounding variables were tested in a preliminary analysis. First, they were entered as fixed criteria, without the group variable, in a repeated measures model for each dependent variable. If a significant effect was observed, then the variables were considered as covariates and remained in the complete model when the group differences were tested. If no significant effects were observed, only the groups were considered as independent variables, without covariates.

## Results

### Sample characteristics

Of the 203 women recruited for the study, 33 (16.3%) dropped out: 14 from the TG and 19 from the CG. The main reasons were: disappointment with the group ( $n=7$ ), disappointment with the randomized allocation ( $n=6$ ), work problems ( $n=4$ ), transportation problems ( $n=3$ ), family problems ( $n=3$ ), other non-cancer health problems

PEG after breast cancer treatment

Table 3. Comparison of change scores between randomization arms (Group: n = 81; Control: n = 87)

		E1 Mean (SD)	E2 Mean (SD)	E3 Mean (SD)		p	Eta <sup>2</sup>
STAI Y-A	Group	46.27 (13.87)	40.60 (11.43)	39.75 (10.55)	Intra-subject	0.001	0.06
	Control	43.85 (12.16)	45.77 (12.68)	43.85 (10.94)	Inter-subject Time x group	0.140 0.001	0.01 0.06
STAI Y-B	Group	47.53 (10.42)	43.22 (10.02)	42.25 (10.04)	Intra-subject	0.000	0.17
	Control	47.48 (9.31)	47.94 (10.46)	45.46 (10.17)	Inter-subject Time x group	0.064 0.010	0.02 0.04
POMS Anxiety <sup>a</sup>	Group	15.12 (8.11)	10.58 (6.89)	9.90 (6.44)	Intra-subject	0.001	0.07
	Control	14.69 (7.63)	14.71 (8.35)	12.78 (7.45)	Inter-subject Time x group	0.059 0.000	0.02 0.08
POMS Anger <sup>a</sup>	Group	13.83 (8.71)	9.74 (7.43)	9.49 (6.81)	Intra-subject	0.000	0.07
	Control	13.29 (8.64)	14.28 (9.11)	11.44 (7.91)	Inter-subject Time x group	0.124 0.005	0.01 0.05
POMS Confusion	Group	8.78 (4.85)	7.12 (4.73)	6.91 (4.74)	Intra-subject	0.000	0.11
	Control	9.84 (5.70)	10.11 (6.24)	8.90 (5.83)	Inter-subject Time x group	0.008 0.149	0.04 0.01
POMS Depression	Group	12.38 (11.45)	8.90 (10.21)	7.86 (8.61)	Intra-subject	0.000	0.14
	Control	13.46 (11.95)	13.54 (12.56)	11.40 (10.78)	Inter-subject Time x group	0.047 0.034	0.02 0.02
POMS Fatigue <sup>a</sup>	Group	10.01 (7.38)	7.74 (6.89)	6.86 (5.58)	Intra-subject	0.069	0.02
	Control	8.78 (6.85)	10.23 (7.08)	8.87 (6.84)	Inter-subject Time x group	0.370 0.000	0.01 0.07
POMS Vigor	Group	15.02 (5.29)	16.22 (6.28)	16.31 (5.96)	Intra-subject	0.109	0.02
	Control	15.21 (6.28)	14.51 (6.48)	15.00 (5.52)	Inter-subject Time x group	0.253 0.027	0.01 0.03
POMS Interpersonal Relationships	Group	17.64 (4.17)	18.91 (3.42)	18.80 (3.49)	Intra-subject	0.166	0.01
	Control	17.79 (3.74)	17.52 (3.85)	17.41 (3.67)	Inter-subject Time x group	0.072 0.007	0.02 0.04
POMS Global score <sup>a</sup>	Group	45.10 (36.70)	27.86 (35.24)	24.73 (30.91)	Intra-subject	0.001	0.06
	Control	44.85 (37.83)	48.37 (41.77)	38.39 (35.57)	Inter-subject Time x group	0.040 0.000	0.03 0.08
MAC Hopelessness/ Helplessness	Group	19.67 (5.96)	18.65 (5.25)	17.80 (5.10)	Intra-subject	0.000	0.12
	Control	19.26 (6.12)	19.23 (5.97)	18.46 (5.90)	Inter-subject Time x group	0.737 0.063	0.00 0.02
MAC Anxious Preoccupation	Group	27.58 (8.00)	24.99 (6.54)	24.22 (6.67)	Intra-subject	0.000	0.29
	Control	27.70 (6.70)	26.57 (6.84)	25.29 (6.62)	Inter-subject Time x group	0.352 0.183	0.01 0.01
EORTC Physical Functioning	Group	1.63 (0.53)	—	1.56 (0.46)	Intra-subject	0.027	0.03
	Control	1.57 (0.54)	—	1.51 (0.48)	Inter-subject Time x group	0.43 0.74	0.00 0.00
EORTC Role Functioning <sup>a</sup>	Group	1.84 (0.83)	—	1.55 (0.66)	Intra-subject	0.141	0.01
	Control	1.63 (0.74)	—	1.59 (0.70)	Inter-subject Time x group	0.372 0.017	0.01 0.03

# PEG after breast cancer treatment

Table 3. (Continued)

		E1 Mean (SD)	E2 Mean (SD)	E3 Mean (SD)		p	Eta <sup>2</sup>
EORTC Emotional Functioning <sup>a</sup>	Group	2.19 (0.73)	—	1.77 (0.61)	Intra-subject	0.006	0.04
	Control	2.11 (0.70)	—	2.06 (0.67)	Inter-subject Time × group	0.398 0.000	0.00 0.09
EORTC Cognitive Functioning	Group	1.88 (0.69)	—	1.77 (0.70)	Intra-subject	0.045	0.02
	Control	2.03 (0.77)	—	1.93 (0.77)	Inter-subject Time × group	0.122 0.995	0.01 0.00
EORTC Social Functioning	Group	1.70 (0.84)	—	1.42 (0.58)	Intra-subject	0.001	0.06
	Control	1.56 (0.78)	—	1.49 (0.76)	Inter-subject Time × group	0.754 0.062	0.00 0.02
EORTC Health Status	Group	4.53 (0.94)	—	4.88 (1.11)	Intra-subject	0.086	0.02
	Control	4.90 (1.09)	—	4.81 (1.03)	Inter-subject Time × group	0.302 0.005	0.01 0.05
EORTC Fatigue <sup>a</sup>	Group	2.24 (0.81)	—	2.08 (0.73)	Intra-subject	0.834	0.00
	Control	2.09 (0.68)	—	2.14 (0.77)	Inter-subject Time × group	0.408 0.036	0.00 0.03
EORTC Nausea	Group	1.27 (0.53)	—	1.13 (0.37)	Intra-subject	0.046	0.00
	Control	1.17 (0.38)	—	1.15 (0.39)	Inter-subject Time × group	0.482 0.090	0.00 0.02
EORTC Pain <sup>a,b</sup>	Group	1.91 (0.72)	—	1.68 (0.66)	Intra-subject	0.473	0.00
	Control	1.78 (0.76)	—	1.76 (0.76)	Inter-subject Time × group	0.922 0.056	0.00 0.02
EORTC Dyspnoea	Group	1.80 (0.90)	—	1.65 (0.84)	Intra-subject	0.031	0.03
	Control	1.82 (0.92)	—	1.69 (0.83)	Inter-subject Time × group	0.816 0.806	0.00 0.00
EORTC Sleep	Group	2.48 (1.09)	—	2.17 (1.05)	Intra-subject	0.021	0.03
	Control	2.26 (1.00)	—	2.20 (1.00)	Inter-subject Time × group	0.500 0.143	0.00 0.01
EORTC Financial Difficulties	Group	1.38 (0.76)	—	1.24 (0.64)	Intra-subject	0.042	0.03
	Control	1.37 (0.78)	—	1.30 (0.75)	Inter-subject Time × group	0.027 0.511	0.00 0.00
EORTC Body image <sup>a</sup>	Group	1.93 (0.88)	—	1.78 (0.80)	Intra-subject	0.002	0.06
	Control	2.04 (0.87)	—	1.91 (0.88)	Inter-subject Time × group	0.349 0.596	0.01 0.00
EORTC Future Prospects	Group	2.56 (0.90)	—	2.33 (0.69)	Intra-subject	0.000	0.11
	Control	2.64 (0.88)	—	2.33 (0.80)	Inter-subject Time × group	0.697 0.513	0.00 0.00
EORTC Breast Symptoms <sup>a,b</sup>	Group	1.88 (0.62)	—	1.76 (0.53)	Intra-subject	0.015	0.04
	Control	1.89 (0.61)	—	1.73 (0.55)	Inter-subject Time × group	0.707 0.560	0.00 0.00

<sup>a</sup> Inter-subject effect: group effect.

<sup>b</sup> Intra-subject effect: time effect.

Time × group: time/group interaction effect. Test controlled with 'age' as covariates; <sup>(b)</sup>Test controlled with 'presence of chemotherapy' as covariates. The EORTC QLQ-C30 and BR23 were administered at E1 and E3 only. EORTC QLQ-BR23 hair loss and sexual satisfaction items were not included in the analyses because of missing responses (in both cases) or irrelevance (no more alopecia). Non-standardized rough scores are used to maintain a uniform significance of the mean values.

(n=4), cancer recurrence (n=1), other reasons (n=).

Most patients attended all sessions. Absences were rare and were always motivated by material or health problems and were equivalent in both the TG and CG.

Patients who dropped out were not significantly different from PEG-participating patients as concerns their STAI, POMS and MAC scores at E1, but their socio-demographic characteristics were different. They were more frequently from the working class or were unemployed, compared with full-length participants who were more frequently from middle and high-level executive categories. They had also needed more extensive surgery (mastectomy with lymph node dissection versus tumorectomy) than did the other participants.

The overall missing data rate in questionnaires ranged from 0.02 to 6.29% (the sum of missing data divided by the product of the number of subjects and questionnaire items) depending on the questionnaire and assessment time. For up to 10% of the missing data, the described procedures were used to impute values, questionnaires being excluded afterwards.

#### Comparisons of baseline characteristics between groups

The two groups were comparable for all variables except age ( $p=0.03$ ) and the presence of chemotherapy ( $p=0.02$ ). The CG was younger (mean age: 51.60 versus 54.47) and had more frequently received chemotherapy (57 versus 43%). No significant difference was found for scores on the STAI, POMS, MAC, EORTC QLQ-C30 and QLQ-BR23 scales, except the EORTC QLQ-C30 'global health state' scale ( $p=0.01$ ), where the CG reported better health status (data not shown).

Age (50 or under versus over 50) influenced the time-course of the POMS anxiety, anger, fatigue and global scores, the EORTC QLQ-C30 or QLQ-BR23 emotional and role functioning, fatigue, body image, sexuality, adverse effects and symptom scales. The presence of chemotherapy influenced the course of the EORTC QLQ-C30 pain, appetite, constipation and QLQ-BR23 breast symptom scores.

#### Comparisons of change in scores within and between treatment groups

Some patients were removed from the statistical multivariate analysis because they did not complete the three evaluations, a fact which explains the reduction in number from 102 to 81 in the TG and from 101 to 87 in the CG.

As described in Table 3, in both groups changes were observed over time in the STAI trait and state anxiety scores, the POMS anxiety, anger, confusion,

depression and global scores, the MAC helplessness-hopelessness and anxious preoccupations scores, in the EORTC QLQ-C30 scores for physical, emotional, cognitive and social functioning, dyspnoea, sleep and financial difficulties, and in the QLQ-BR23 body image, future prospects and breast symptom scores.

Controlling for a time effect, significant group/time interactions indicate a positive effect of the intervention on anxiety, our primary outcome measure. This was evidenced for the STAI state and trait anxiety scales, explaining 6% and 4% of the variance in the STAI-state and STAI-trait anxiety scores, respectively (Table 3).

We also found positive results on other variables identified as secondary outcome measures. A greater reduction of negative affects and improvement in positive affects and in quality of life functional or symptom scales were observed in the TG compared with the CG. This concerned the POMS anxiety and global scores (8% of the variance explained by the model including the time/group interaction term), scores for fatigue (7%), anger (5%), interpersonal relationships (4%), vigor (3%) and depression (2%) and the EORTC QLQ-C30 scores, emotional functioning (9%), role functioning (3%), global health status (3%) and fatigue (3%).

In contrast, no effect of the PEG was evidenced on the MAC scale or on the POMS confusion scores.

The study aimed to test the effect of PEG interventions on psychosocial adjustment in post-treatment early-stage breast cancer patients, in a multi-site French study. Controlling for age and past chemotherapy, a PEG intervention effect was clearly visible, as measured 1-month post-intervention, regardless of the passage of time, on patients' levels of anxiety and on mood states (except confusion), emotional and role functioning, fatigue and overall health status. However, no effect of the PEG was observed on mental adjustment, i.e. measures of emotional, cognitive or behavioural responses to the breast cancer experience in these patients in remission. Lower levels of helplessness-hopelessness or anxious preoccupation were evidenced in TG and CG alike, reflecting spontaneous psychological improvement over time.

Our positive results are in line with data from other studies in different cultural contexts on the efficacy of group psychological therapy on mood disturbance, anxiety or depression in early-stage breast cancer patients [5,21,28], as well as on quality of life aspects, probably as a result of positive variations in emotional states [6,42].

As noted in this study, Kissane et al. [5] did not find any effect of their intervention on mental adjustment scores. Conversely, using a similar intervention, Fukui et al. [21] found higher scores for fighting spirit among treated patients,



immediately or 6 months after an educational intervention, and Helgeson et al. [43] highlighted better adjustment in post-diagnosis breast cancer patients participating in educational intervention compared with peer discussion groups.

Several hypotheses could explain our results; that is, the PEG effect observed on emotional states but not on mental adjustment.

The MAC scale has demonstrated its clinical sensitivity [44]. The lack of PEG effect on mental adjustment may be related to the psychotherapy technique used. Although our PEG was intended to teach targeted coping skills through techniques inspired from BCT, it was mixed with supportive-expressive moments in each session, which may have emphasized the experiential facet of the therapy to the detriment of the educational part. The PEG respected the reluctance of some of the groups to directly confront subjects considered to be taboo—some authors [25,26] think that this could be more effective in the long term. Indeed, groups may alleviate general anxiety by enabling patients to feel less isolated, legitimise personal feelings and find reassurance through peer exchanges, while maintaining a general avoidance attitude.

BCT-inspired techniques might need more than eight sessions to demonstrate improvement in adjustment strategies. Increases in anxiety for some patients while facing their experience during therapy could be a sign of mental adjustment, which could be beneficial in the long run. Further research is needed to pinpoint the specific mechanisms by which this type of intervention produces relief from anxiety or negative mood [45].

Our study presents certain methodological limitations.

The early implementation of the 'deferred' group therapy (for ethical reasons) prevented comparative assessment of long-term effects of the intervention.

Our results are based solely on subjective measures of psychological status, so there is a possible psychosocial bias (e.g. Hawthorne effect [46]). Objective measures such as return to work might be an important psychosocial outcome in breast cancer survivors [47].

There is no comparison of participants to non-participants.

The lack of complete data for one-fifth of the patients, who did not complete the questionnaires at all three evaluation times, weakens our results.

The sample was too small to evaluate differences between participating therapists (despite many efforts to ensure the consistency of intervention delivery), or to assess the specific impact of the PEG on sub-groups of patients defined by psychological characteristics.

However, despite these weaknesses, the PEGs clearly had an effect on our patients' anxiety and some aspects of mood and QOL.

Adding tools from group dynamics analysis could be useful in our PEGs so as to better understand the therapeutic process, including mechanisms of change.

Choosing anxiety as a primary outcome measure can be debated. Owen et al. [48] suggested variables reflecting patients' well-being as the most appropriate outcome measures to assess the effectiveness of psychological therapy in cancer patients.

Our PEG intervention recruited patients without criteria of significant clinical distress but, as recently suggested by various authors [49–51], short-term interventions could offer notable benefit to clinically distressed patients.

The interest of such interventions should now be tested in specific populations, bringing other socio-demographic variables into account like income or cultural origin (given the diversity of the French population), to determine which patients could benefit most [52,53].

## Conclusion

This experience proves that structured PEGs for French patients with early-stage breast cancer in remission have a positive effect on emotional states, especially in reducing anxiety levels. Although improvement in these outcomes was observed over time in both TG and CG, the PEG appeared to act as an accelerator of these effects. Further work should seek to identify and integrate breast cancer patients who particularly need this psychological approach, and to develop and test these psychotherapeutic techniques in the French cancer treatment milieu. PEGs represent an excellent complement or an alternative to the individual psycho-oncological treatment techniques, which are widely offered in France, and should now be tested in other types of cancer patients and in other stages of the disease.

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