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THE EFFECT OF GROUP PSYCHOSOCIAL SUPPORT ON SURVIVAL IN METASTATIC BREAST CANCER

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ABSTRACT

Background Supportive–expressive group therapy has been reported to prolong survival among women with metastatic breast cancer. However, in recent studies, various psychosocial interventions have not prolonged survival.

Methods In a multicenter trial, we randomly assigned 235 women with metastatic breast cancer who were expected to survive at least three months in a 2:1 ratio to an intervention group that participated in weekly supportive–expressive group therapy (158 women) or to a control group that received no such intervention (77 women). All the women received educational materials and any medical or psychosocial care that was deemed necessary. The primary outcome was survival; psychosocial function was assessed by self-reported questionnaires.

Results Women assigned to supportive–expressive therapy had greater improvement in psychological symptoms and reported less pain ($P=0.04$) than women in the control group. A significant interaction of treatment-group assignment with base-line psychological score was found ($P\leq 0.003$ for the comparison of mood variables; $P=0.04$ for the comparison of pain); women who were more distressed benefited, whereas those who were less distressed did not. The psychological intervention did not prolong survival (median survival, 17.9 months in the intervention group and 17.6 months in the control group; hazard ratio for death according to the univariate analysis, 1.06 [95 percent confidence interval, 0.78 to 1.45]; hazard ratio according to the multivariate analysis, 1.23 [95 percent confidence interval, 0.88 to 1.72]).

Conclusions Supportive–expressive group therapy does not prolong survival in women with metastatic breast cancer. It improves mood and the perception of pain, particularly in women who are initially more distressed. (N Engl J Med 2001;345:1719-26.)

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IN 1989, Spiegel et al.¹ reported a randomized trial of supportive–expressive group therapy in women with metastatic breast cancer. Supportive–expressive group therapy is a standardized treatment for those with life-threatening illness that encourages participants to express feelings and concerns about their illness and its effect on their lives in the supportive environment of a therapist-led group. The women who participated in such therapy lived a mean of 18 months longer than the women in the control group.^{2,3} However, since the statistical analysis of survival had not been planned, these results called for further investigation. Two recent randomized trials of two different psychosocial interventions for women with metastatic breast cancer⁴⁻⁷ did not show that group therapy prolongs survival, although transient positive effects on mood and self-esteem

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were found.⁵ Results of other randomized studies of psychosocial interventions in cancer patients have been inconsistent.⁸⁻¹¹

In the Breast Expressive–Supportive Therapy Study, we attempted to replicate Spiegel’s results.¹ Our primary objective was to determine whether the addition of supportive–expressive group therapy to routine care influenced the survival of women with metastatic breast cancer. Secondary outcomes were psychological functioning (e.g., mood, social support, and adjustment to illness), experience of pain, and the quality of life. In this article we report the results of the intervention in terms of survival, mood, and pain — the three elements that Spiegel et al. reported were affected by the intervention.^{2,3} Effects on the quality of life and other psychosocial outcomes will be reported separately.

METHODS

Study Protocol

The trial was coordinated at the Samuel Lunenfeld Research Institute at Mount Sinai Hospital, University of Toronto, Toronto. Other participating centers, all in Canada, included the Hamilton Regional Cancer Center, Hamilton, Ontario; the Ottawa Regional Cancer Center, Ottawa, Ontario; CancerCare Manitoba, Winnipeg; the Tom Baker Cancer Center, Calgary, Alberta; the British Columbia Cancer Agency, Vancouver; and Cross Cancer Institute, Edmonton, Alberta. Approval was obtained from the ethics committees of all participating centers; all the women provided written informed consent.

Women were recruited between 1993 and 1998. They were eligible if they had histologic confirmation of breast cancer at the time of diagnosis, if they had metastases outside of the breast and ipsilateral axilla, and if the treating physician most responsible for a woman’s care gave consent. Women were excluded if they met any of the following criteria: central nervous system metastases; active psychosis, untreated major depression, or severe character disorder (assessed at a prerandomization interview); planned participation in a therapist-led support group for patients with metastatic breast cancer outside of the study center (no such groups existed at the study centers when the study began); residence more than one hour from the study center; life expectancy of less than three months as assessed by the treating oncologist; or an inability to speak and read English. Potentially eligible women completed base-line psychosocial questionnaires and met with group leaders for psychological assessment. A detailed report regarding recruitment has been published elsewhere.¹²

Women in the intervention group attended weekly meetings lasting 90 minutes. Each group consisted of 8 to 12 women and two leaders. The leaders were psychiatrists, psychologists, social workers, or nurse clinicians who were experienced in leading group therapy; at least one of the two leaders in each group was a woman. The therapy was intended to foster support among group members and to encourage the expression of emotions about cancer and its broad-ranging effects on their lives (physical, emotional, social, and spiritual).^{13,14} Women were encouraged to interact with each other and to support each other outside of the group sessions. Participants were given the opportunity and support to speak about the effects of the illness, its treatment, and changes in their self-image, roles, and relationships with family members, friends, co-workers, health care providers, and others. The women also discussed the life-altering nature of the illness and strategies for coping and communicating. They were asked to attend the group sessions for at least one year, or longer if the sessions continued to be of benefit. A monthly 90-minute session was provided for family and friends.

Leaders received standardized training consisting of a detailed review of a therapy manual by Spiegel and Spira,¹³ 2-day workshops (attended by David Spiegel or his associate Catherine Classen) every 9 to 12 months that included discussion of therapeutic principles and reviews of videotaped sessions, and monthly review of a videotape of randomly selected sessions, with written feedback to promote the consistent delivery of the intervention.

Women in the control group did not receive any psychological therapy as part of the study. Women in either group could participate in peer support groups, or therapist-led support groups for patients with various types of cancer that did not involve supportive–expressive therapy, and they could receive any necessary medical, surgical, or psychosocial care. Every four to six months, all the women received educational materials about breast cancer and its treatment, as well as about relaxation and nutrition.

The primary outcome was survival; a secondary outcome was psychosocial function. Detailed information regarding medical status (vital status and Eastern Cooperative Oncology Group [ECOG] performance status), treatment received (chemotherapy, hormone therapy, radiation therapy, surgery, palliation, or other), and sites of metastatic disease was collected at study entry and every four months thereafter. These data were reviewed and coded centrally.

At base line and at 4, 8, and 12 months, the women were asked to complete psychosocial questionnaires that included the Profile of Mood States¹⁵ and the pain and suffering scales used by Spiegel and Bloom.³ They also provided information on their demographic characteristics and social support.

The calculation of the sample size was based on an expected three-year survival of 15 percent in the control group and 30 percent in the intervention group, a type I error of 0.05 (two-tailed), a power of 80 percent, and a randomization ratio of 2:1 (intervention group:control group). These assumptions yielded a sample size of 256 women (with an expected 205 deaths). Because recruitment was slower than expected, the follow-up period was longer than anticipated, and recruitment ended when we had enrolled 237 women. Analysis was performed after 201 deaths had occurred. Power calculations based on the prolonged follow-up period confirmed that the study had 85 percent power to identify an effect of the size specified a priori.

Randomization

Randomization, performed centrally with the use of sealed envelopes containing allocations from a computer-generated table of random numbers, was stratified according to the center (seven sites) and the presence or absence of visceral metastases. A 2:1 ratio of randomization (intervention group:control group) was used. In order to form an initial support group at each center, 14 to 18 women underwent randomization simultaneously. Once the support groups had been established, newly enrolled women underwent randomization individually. A total of 237 women underwent randomization. Two of them were found to be ineligible — one woman assigned to the control group did not have metastases, and one woman assigned to the intervention group had a carcinoma tumor. These women were excluded from the analysis.

Masking

No blinding was used in randomization or data collection. Psychosocial questionnaires were scored by a research assistant who had no knowledge of the subjects’ treatment assignment.

Statistical Analysis

Descriptive statistics were generated for all variables. Continuous variables with skewed distributions were transformed as follows: for the years from diagnosis to the first metastasis, the years from the first diagnosis of breast cancer to randomization, and all the Profile of Mood States subscales except the vigor–activity subscale, the square root was used; for the years from the first metastasis to randomization and for base-line pain, the log value was used. These transformations were reversed for the presentation of results. Two-sample t-tests were used for the comparison of contin-

uous variables, and Pearson's chi-square tests were used for the comparison of categorical variables.

The psychosocial analyses included the 218 women who completed base-line questionnaires during the four months before randomization. Follow-up scores from the 15-month period after randomization were averaged, and any change during the course of 1 year was calculated by subtracting the base-line scores from these averages. Changes were compared with the use of two-sample t-tests. Two sets of analyses of covariance were performed, the first one excluding interaction terms and the second one including these terms to allow treatment effects to depend on base-line status.

Univariate and multivariate Cox proportional-hazards models, stratified according to the study center and the presence of visceral or nonvisceral metastases at randomization, were used to assess effects on survival. The multivariate Cox model included factors that differed between groups at base line (age at diagnosis, nodal stage, the presence or absence of estrogen receptors and progesterone receptors, and the use or nonuse of adjuvant chemotherapy) and the time from the first metastasis to randomization.

An intention-to-treat approach was used for all analyses. Interim analyses were neither planned nor performed.

RESULTS

Intervention and Follow-up

Of the 235 women who entered the study, 158 were assigned to the intervention group and 77 to

the control group. Attendance at group-therapy sessions averaged 66.7 percent (3475 of 5208 possible person-sessions) and did not differ significantly among centers. The most common reasons for nonattendance were ill health, a need for medical treatment, and the inability to travel. Thirty women (19.0 percent) dropped out of group therapy after a mean of 3.5 months, and eight women did not attend any sessions. Participation after randomization in support groups outside of the study was reported by 8.2 percent of the women in the intervention group (13 of 158 women) and 10.4 percent of those in the control group (8 of 77 women, P=0.59). The rate of completion of the psychosocial questionnaires did not differ significantly between the two groups (70.5 percent of the women in the intervention group and 65.3 percent of those in the control group completed at least one follow-up questionnaire, P=0.43). Data on survival were available for all women.

Characteristics of the Subjects

Features of the two groups are shown in Tables 1 and 2. The groups were balanced in terms of the

TABLE 1. CHARACTERISTICS OF THE STUDY POPULATION AT RANDOMIZATION.*

CHARACTERISTIC	INTERVENTION GROUP (N=158)	CONTROL GROUP (N=77)	P VALUE
Age — yr	49.5±8.4	51.5±10.3	0.13
Duration of disease — yr			
Time from diagnosis to first metastasis	3.75±3.27	3.30±3.62	0.18
Time from first metastasis to randomization	1.69±1.71	1.68±2.51	0.21
Time from diagnosis to randomization	5.44±4.06	4.98±4.50	0.26
Sites of metastases — no. (%)			0.77
Any visceral	73 (46.2)	34 (44.2)	
Nonvisceral only	85 (53.8)	43 (55.8)	
ECOG performance status — no. (%)			0.70
0	56 (35.4)	23 (29.9)	
1	77 (48.7)	41 (53.2)	
2	25 (15.8)	13 (16.9)	
Estimated survival — no. (%)			0.28
3–12 mo	49 (31.0)	17 (22.1)	
>12 mo	78 (49.4)	46 (59.7)	
>3 mo, but otherwise unspecified	31 (19.6)	14 (18.2)	
Therapy for metastases — no. (%)			
Chemotherapy			
Ever	103 (65.2)	51 (66.2)	0.87
Current	65 (41.1)	30 (39.0)	0.75
Hormone therapy			
Ever	111 (70.3)	56 (72.7)	0.70
Current	68 (43.0)	36 (46.8)	0.59
Radiation therapy			
Ever	77 (48.7)	38 (49.4)	0.93
Current	5 (3.2)	5 (6.5)	0.24
Marital status — no. (%)†			
Ever married	142 (92.8)	70 (93.3)	0.89
Currently married	113 (73.9)	52 (69.3)	0.47
Presence of a "special person" or confidant — no. (%)‡			0.15
Yes	142 (94.7)	74 (98.7)	
No	8 (5.3)	1 (1.3)	

*Plus-minus values are means ±SD. All P values are two-tailed. ECOG denotes Eastern Cooperative Oncology Group.

†Data were available for 153 women in the intervention group and 75 in the control group.

‡Data were available for 150 women in the intervention group and 75 in the control group.

TABLE 2. CHARACTERISTICS OF THE STUDY POPULATION AT THE TIME OF THE INITIAL DIAGNOSIS OF BREAST CANCER.*

CHARACTERISTIC	INTERVENTION GROUP (N=158)	CONTROL GROUP (N=77)	P VALUE
Age (yr)	44.0±7.9	46.6±9.2	0.04
	no. (%)		
Menopausal status			0.001
Premenopausal or perimenopausal	126 (79.7)	50 (64.9)	
Postmenopausal	23 (14.6)	26 (33.8)	
Unknown	9 (5.7)	1 (1.3)	
Tumor stage			0.98
T1	38 (24.1)	18 (23.4)	
T2	46 (29.1)	21 (27.3)	
T3	14 (8.9)	7 (9.1)	
T4	9 (5.7)	6 (7.8)	
TX	51 (32.3)	25 (32.5)	
Nodal stage†			0.002
N0	38 (24.1)	25 (32.5)	
N1-3	112 (70.9)	39 (50.6)	
NX	8 (5.1)	13 (16.9)	
Metastasis stage			0.12
M0	141 (89.2)	63 (81.8)	
M1	17 (10.8)	14 (18.2)	
Estrogen-receptor status			0.06
Positive or equivocal	109 (69.0)	42 (54.5)	
Negative	33 (20.9)	20 (26.0)	
Unknown	16 (10.1)	15 (19.5)	
Progesterone-receptor status			0.01
Positive or equivocal	101 (63.9)	33 (42.9)	
Negative	28 (17.7)	24 (31.2)	
Unknown	29 (18.4)	20 (26.0)	
Type of surgery			0.17
Mastectomy	94 (59.5)	36 (46.8)	
Lumpectomy	56 (35.4)	35 (45.5)	
Other	8 (5.1)	6 (7.8)	
Locoregional radiation			0.36
Yes	70 (44.3)	39 (50.6)	
No	88 (55.7)	38 (49.4)	
Adjuvant chemotherapy‡			0.01
Anthracyclines	47 (33.3)	15 (23.8)	
Nonanthracyclines	60 (42.6)	20 (31.7)	
None	34 (24.1)	28 (44.4)	
Adjuvant tamoxifen‡			0.80
≤2 yr	18 (12.8)	6 (9.5)	
>2 yr	18 (12.8)	8 (12.7)	
None	105 (74.5)	49 (77.8)	

*Plus-minus values are means ±SD. All P values are two-sided.

†There were a mean (±SD) of 3.34±4.23 nodes involved in the women in the intervention group, as compared with 2.60±3.77 in the women in the control group (P=0.23).

‡Data exclude the women with metastases at the time of diagnosis (17 in the intervention group and 14 in the control group).

characteristics of the tumors and the treatments being received at the time of randomization. Women in the intervention group were younger than those in the control group at the time of diagnosis (mean age, 44.0 vs. 46.6 years; P=0.04) and were less likely to be postmenopausal (14.6 percent vs. 33.8 percent, P=0.001). They were also more likely to have had involvement of axillary nodes (70.9 percent vs.

50.7 percent, P=0.002). The tumors of the women in the intervention group were more likely to have had estrogen receptors (69.0 vs. 54.5, P=0.06) and progesterone receptors (63.9 percent vs. 42.9 percent, P=0.01), and the use of adjuvant chemotherapy was more common in the intervention group (75.9 percent vs. 55.6 percent, P=0.01). Only progesterone-receptor status was associated with survival (P=0.02); the imbalance in the distribution of this characteristic favored longer survival in the intervention group (data not shown).

Profile of Mood States

The Profile of Mood States¹⁵ is a self-administered questionnaire containing 65 items scored on a 5-point scale from “not at all” (0) to “extremely” (4). Items are grouped into six subscales and combined into a total mood-disturbance scale. At baseline, the scores for depression-dejection, tension-anxiety, and anger-hostility were not significantly different in the two groups (Table 3). However, scores during the year after randomization for total mood disturbance (P=0.02), depression-dejection (P=0.002), tension-anxiety (P=0.002), anger-hostility (P=0.007), and confusion-bewilderment (P=0.02) were significantly lower in the intervention group than in the control group. Adjustment for base-line inequalities diminished these differences but revealed a significant interaction between base-line score and effect of treatment. Women who were initially more distressed benefited from the intervention, whereas women who were not as distressed did not benefit (Fig. 1). The magnitude of the benefit in the more distressed women was 13.5 percent of the possible range of the scale. Scores for depression-dejection, tension-anxiety, anger-hostility, and confusion-bewilderment followed a similar course, but there were no significant differences in fatigue-inertia or vigor-activity. There were no significant interactions between treatment and study center in terms of total mood disturbance or any subscale.

Experience of Pain and Suffering or Hurt

Women recorded their “experience of pain and of suffering or hurt at this moment” on two 10-cm visual-analogue scales; the scale for the assessment of pain ranged from “not noticeable” to “excruciating — worst ever,” and the scale for assessment of suffering or hurt ranged from “easily bearable” to “agonizing — unbearable.”³ Base-line scores were low (Table 4), and the women in the intervention group reported less worsening of pain over the course of one year than the controls did (P=0.04). There was a significant interaction between treatment and base-line score (P=0.04); women in the intervention group benefited only if their base-line scores were high (Fig. 1). The magnitude of the benefit in these women was 15 percent of the range of the scale (1.54 cm). There

TABLE 3. PROFILE OF MOOD STATES.*

SCALE	POSSIBLE RANGE	BASE-LINE SCORES				P VALUE‡	1-YR CHANGE†		P VALUE‡	INTERACTION BETWEEN STUDY GROUP AND BASE-LINE SCORE P VALUE§
		INTERVENTION GROUP (N=146)		CONTROL GROUP (N=72)			INTERVENTION GROUP (N=102)	CONTROL GROUP (N=45)		
		raw score	T score	raw score	T score		change in score			
Total mood disturbance	-32 to 200	35.8±39.6	—	27.6±28.2	—	0.08	-1.8±31.7	+9.7±24.6	0.02	<0.001
Depression-dejection	0 to 60	12.0±11.9	48	9.1±8.4	45	0.09	-1.7±9.2	+2.6±7.1	0.002	<0.001
Tension-anxiety	0 to 36	11.3±7.8	47	9.2±6.1	43	0.06	-1.5±6.9	+1.9±5.7	0.002	0.003
Anger-hostility	0 to 48	8.7±8.4	49	6.4±5.5	45	0.06	-1.3±8.0	+1.9±5.5	0.007	0.002
Confusion-bewilderment	0 to 28	7.3±5.0	43	6.3±4.2	41	0.13	-0.5±4.1	+1.3±4.3	0.02	0.002
Fatigue-inertia	0 to 28	10.7±7.4	50	10.5±6.1	50	0.95	+0.7±6.0	+1.4±6.1	0.52	0.35
Vigor-activity	0 to 32	14.6±6.6	49	13.5±5.9	48	0.23	-1.8±5.3	-0.6±5.4	0.21	0.08

*Plus-minus values are means ±SD. The score for total mood disturbance is the sum of the scores for depression-dejection, tension-anxiety, anger-hostility, confusion-bewilderment, and fatigue-inertia, minus the score for vigor-activity. Higher scores reflect greater distress on all scales except vigor-activity. Higher scores on the vigor-activity scale reflect greater vigor. T scores were taken from published norms for college students⁶; the mean (±SD) normal T score was 50±10.

†Changes shown occurred over the course of one year.

‡P values are for the comparison between the intervention group and the control group. All P values are two-tailed.

§P values are from analysis-of-covariance models that included terms for the interaction between base-line score and treatment-group assignment. All P values are two-tailed.

were no significant differences in the experience of suffering or hurt. No significant interactions between treatment and study center existed for either variable. The use of analgesics, palliative radiation, or other therapy was not considered in this evaluation of pain.

Survival

Kaplan-Meier survival analysis showed that the median survival was 17.9 months in the intervention group and 17.6 months in the control group (Fig. 2). According to the univariate Cox model, the hazard ratio for death in the intervention group as compared with the control group was 1.06 (95 percent confidence interval, 0.78 to 1.45; P=0.72).

A multivariate Cox model identified no significant effect of the intervention on survival (hazard ratio, 1.23; 95 percent confidence interval, 0.88 to 1.72; P=0.22). Other variables included in the multivariate model were the presence or absence of progesterone receptors (P=0.01), the presence or absence of estrogen receptors (P=0.71), the time from first metastasis to randomization (P=0.50), age at diagnosis (P=0.85), nodal stage at diagnosis (P=0.40), and the use or nonuse of adjuvant chemotherapy (P=0.11). No significant interactions with treatment were identified for study center, marital status, or base-line total mood-disturbance score (P=0.51, P=0.26, and P=0.83, respectively). The effects of the intervention remained nonsignificant after adjustment for each of these variables.

DISCUSSION

The addition of supportive-expressive group therapy to standard care for women with metastatic breast cancer did not influence survival in our study. Women in the intervention group were younger than the controls and were more likely to have had nodal involvement and to have received adjuvant chemotherapy at the time of diagnosis, but these factors were not associated with the primary outcome. The presence of progesterone receptors in the tumor was more frequent in the intervention group, which favored longer survival; however, the inclusion of progesterone-receptor status in the multivariate analysis actually increased the hazard ratio for death, making a beneficial effect of the intervention on survival less likely. Minor differences in base-line mood did not influence these results. For these reasons, we do not believe that the imbalances between study groups vitiated the statistical analysis.

It is unlikely that an important effect on survival was missed because of inadequate power; our study had 99 percent power to identify a 25 percent improvement in three-year survival — the size of the improvement reported by Spiegel et al.¹ — and 85 percent power to identify the 15 percent improvement in three-year survival we had specified a priori. Nor was such an effect likely to be missed because of poor group participation; 95 percent of the women in the intervention group attended at least one group-therapy session, and 81 percent remained in-

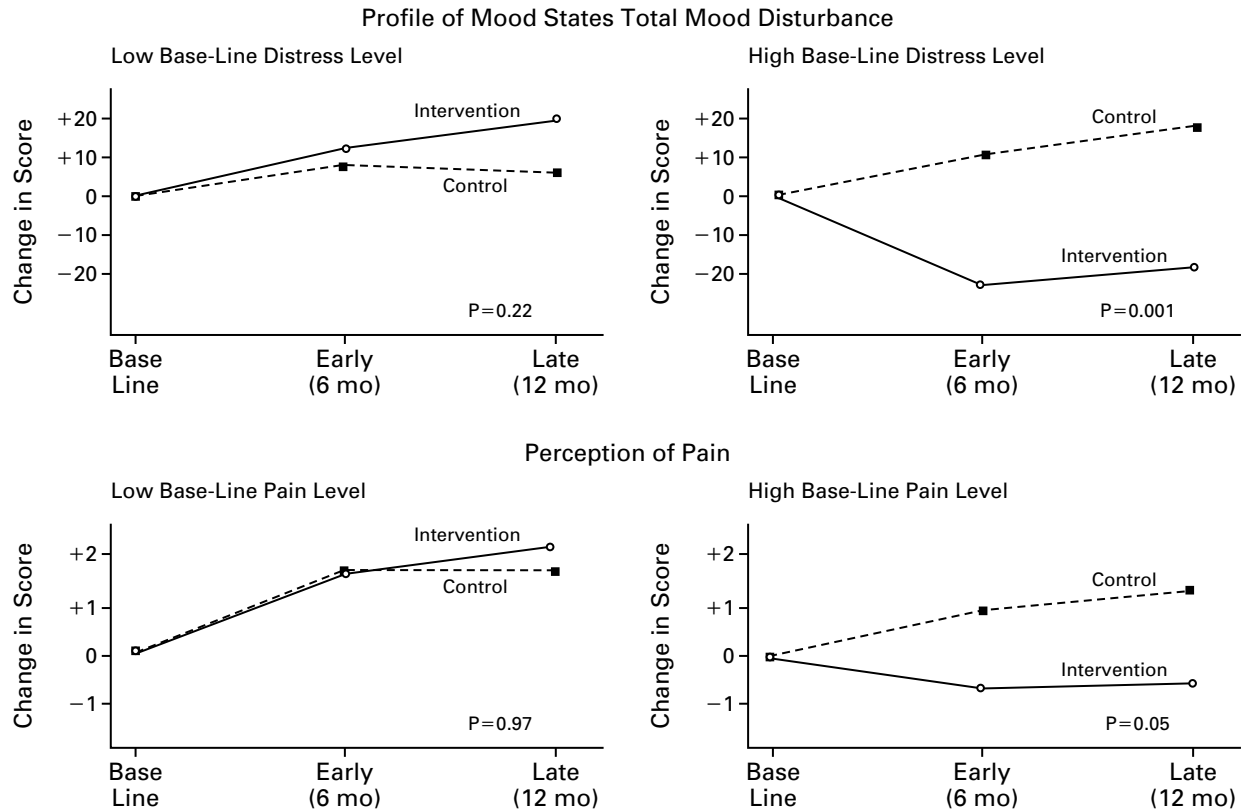


Figure 1. Interaction between Base-Line Score and the Effect of the Study Intervention in Terms of Total Mood Disturbance (Top Panels) and Perception of Pain (Bottom Panels).

For both variables, high scores reflect greater distress, and a change greater than 0 represents an increase in distress. A low base-line level of distress has been defined as a distress level below the median score, and a high base-line distress level as a distress level above the median. Women who reported a high degree of total mood disturbance or pain at base line benefited significantly from the intervention.

involved throughout the first year. Thus, our findings do not support the observation by Spiegel et al.¹ that supportive–expressive group therapy prolongs survival in women with metastatic breast cancer. Our results are, by contrast, consistent with those of Cunningham et al.⁴ and Edelman et al.⁷ indicating that psychosocial interventions do not prolong survival in women with metastatic breast cancer.

There were, however, psychosocial benefits of supportive–expressive therapy in women with metastatic breast cancer. The more distressed women benefited from the intervention, whereas those who were not so distressed did not, perhaps because of a “floor effect” (i.e., the response options on the questionnaires focused on distress and were not sufficiently broad to detect improvement when base-line distress was low); however, no woman had a base-line score of zero, and any worsening of scores (which would be likely when the medical status deteriorated) would have been readily detected.

The beneficial effect of the intervention on the experience of pain may have been attributable to the exercise in self-hypnosis and relaxation performed at the end of each group session, but other mechanisms are possible. During the sessions, the leaders did not intervene in the medical treatment of group members. However, when a woman expressed a concern about pain, the leaders responded by discussing the physical and emotional benefits of good pain control and fears of narcotic addiction. They encouraged members to discuss their pain management more fully with their physicians, who may have taken steps to improve pain control.

The beneficial psychosocial effects of our intervention are consistent with previous reports of the benefits of supportive–expressive therapy^{2,3,17} and other psychosocial interventions^{5,18} in metastatic breast cancer. These beneficial effects are evidence that supportive–expressive group therapy was delivered effectively in our study. On the basis of population-

TABLE 4. EXPERIENCE OF PAIN AND OF SUFFERING OR HURT.*

VARIABLE	POSSIBLE RANGE	BASE-LINE SCORE			1-Yr Change†			INTERACTION BETWEEN STUDY GROUP AND BASE-LINE SCORE
		INTERVENTION GROUP (N=141)	CONTROL GROUP (N=71)	P VALUE‡	INTERVENTION GROUP (N=99)	CONTROL GROUP (N=44)	P VALUE‡	P VALUE§
Experience of pain	0 to 10	1.9±2.4	1.7±1.9	0.80	+0.4±2.6	+1.3±2.3	0.04	0.04
Experience of suffering or hurt	0 to 10	2.0±2.7	1.9±2.3	0.76	-0.2±2.8	+0.4±2.4	0.18	0.24

*Plus-minus values are means ±SD. Higher scores indicate a greater degree of pain or of suffering or hurt.

†Changes shown occurred over the course of one year.

‡P values are for the comparison between the intervention group and the control group. All P values are two-tailed.

§P values are from analysis-of-covariance models that included terms for the interaction between base-line score and treatment-group assignment. All P values are two-tailed.

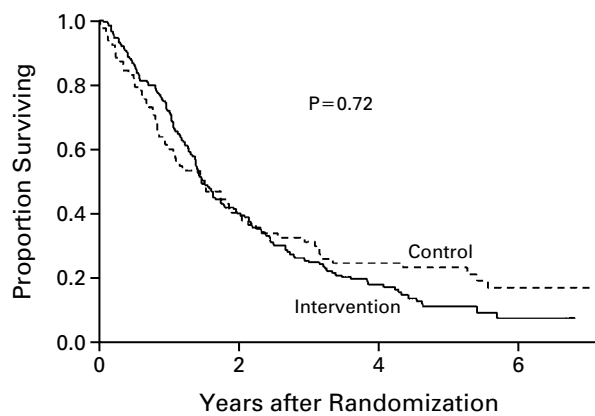


Figure 2. Kaplan-Meier Survival Curves for Women Assigned to the Intervention Group and the Control Group. There was no significant difference in survival between the two groups.

based data, we estimate that we randomly assigned 8.6 percent of potentially eligible women to treatment groups — a proportion that is in line with rates of 3 to 12 percent for chemotherapy and radiation-therapy trials.^{16,19,20} Nevertheless, we do not know whether our results are generalizable with respect to psychological factors. If our participants were more (or less) distressed than nonparticipants, the beneficial psychological effects we identified may not be representative. However, we cannot clarify this point because ethical considerations did not permit the collection of psychological information regarding non-participants.

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