

Supportive-expressive group therapy for women with metastatic breast cancer: survival and psychosocial outcome from a randomized controlled trial

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Abstract

Background: Mixed reports exist about the impact of supportive-expressive group therapy (SEGT) on survival.

Methods: From 485 women with advanced breast cancer recruited between 1996–2002, 227 (47%) consented and were randomized within an average 10 months of cancer recurrence in a 2:1 ratio to intervention with 1 year or more of weekly SEGT plus three classes of relaxation therapy (147 women) or to control receiving three classes of relaxation therapy (80 women). The primary outcome was survival; psychosocial well-being was appraised secondarily. Analysis was by intention-to-treat.

Results: SEGT did not prolong survival (median survival 24.0 months in SEGT and 18.3 in controls; univariate hazard ratio for death 0.92 [95% CI, 0.69–1.26]; multivariate hazard ratio, 1.06 [95% CI, 0.74–1.51]). Significant predictors of survival were treatment with chemotherapy and hormone therapy ($p < 0.001$), visceral metastases ($p < 0.001$) and advanced disease at first diagnosis ($p < 0.05$). SEGT ameliorated and prevented new DSM-IV depressive disorders ($p = 0.002$), reduced hopeless–helplessness ($p = 0.004$), trauma symptoms ($p = 0.04$) and improved social functioning ($p = 0.03$).

Conclusions: SEGT did not prolong survival. It improved quality of life, including treatment of and protection against depression.

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Introduction

Since the initial supportive-expressive group therapy (SEGT) invention reported a mean survival advantage of 18 months [1], two randomized controlled trials of cognitive [2,3] and one of SEGT [4] could not demonstrate improved survival for women with advanced breast cancer, although the cognitive trials failed to deliver sustained psychological benefit. Psychosocial and psycho-educational interventions for mixed types of cancer (melanoma, gastrointestinal, lung and leukemia) have found beneficial [5–7] and non-beneficial [8,9] effects on survival, leaving some uncertainty about the potential for such therapies to impact survival [10].

Putative mechanisms include greater adherence to anti-cancer treatments, improved self-care,

altered disease biology or enhanced host resistance. Depression has been associated with shortened survival [11], possibly through reduced self-care and compliance with anti-cancer treatments. Treatment-induced improvements in adherence [12] were relevant to survival in Richardson's sequential cohort study [5], but not Spiegel's SEGT trial [13]. We found attention to treatment adherence compatible with SEGT even though it was not an intrinsic feature of the original model [14].

In a multi-site RCT of SEGT based in Melbourne, Australia, we examined survival as the primary outcome. We included structured psychiatric interviews to generate DSM-IV diagnoses of psychiatric disorders and delivered relaxation therapy to both arms of the study to prevent demoralization from being randomized

to a no-treatment control condition. We report here on the impact of SEGT on survival, psychosocial outcomes and treatment adherence.

Methods

Study protocol

Participants were recruited between May 1996 and March 2002 from seven public hospitals in Melbourne, Australia. Ethics approval was obtained from each institution. The women were eligible if they had histologically confirmed diagnosis of Stage IV breast cancer (defined by ICD-TNM) [15], geographic accessibility, and their treating physician indicated a prognosis of 1 year or more. They were ineligible if over 70 years, had a history of other cancers (except basal cell carcinoma), inadequate English, intellectual disability or dementia. During the trial, the women continued to receive standard oncological treatment at their respective centres.

Group therapy consisted of weekly 90-min sessions of SEGT [16]. The model aims to improve relationships with family, friends and physicians, create a new network of support and foster coping skills. A safe forum to express feelings allows participants to confront existential issues. Each group, which was open and ongoing in nature, was facilitated by an experienced group of co-therapists drawn from psychiatry, psychology or social work. A standardized preparation of the women by the therapists was incorporated to ensure a smooth integration of new members into the group. Women were encouraged to participate for 1 year or more. Outside interaction between members was encouraged. Leaders received standardized training through detailed review of the therapy manual, observation of Spiegel's training videotapes, and attendance at a workshop conducted by Spiegel. To ensure both adherence to the treatment manual and optimize competent delivery of the therapy, each co-therapy pair met with a senior group analyst every 2 weeks for supervision in which process notes were shared and discussed; all therapists and supervisors met quarterly across the 6 years to receive feedback about fidelity and promote uniform application. To ensure effective sessions, each group had up to 12 members at any one time; illness or holidays usually precluded full attendance. Five SEGT groups occurred across 7 years, being led by nine therapists who formed co-therapy pairs in differing combinations. One key difference was that we elected not to conclude each group with a segment of hypnosis.

Women assigned as controls attended three relaxation classes (each lasting 1 h) over a 3-week period. They were taught progressive muscular relaxation and guided imagery with a structured

and manualized method, these classes avoiding any semblance of a psychotherapeutic group. Women were given a tape and encouraged to practice relaxation daily. Three relaxation classes were also provided to the women receiving group therapy to ensure that the only difference between the two conditions was SEGT. These classes followed group sessions for 1 h over three consecutive weeks annually. An occupational therapist taught all relaxation.

The design incorporated baseline assessment prior to randomization and four follow-up points at 6 monthly intervals. Each assessment involved a structured psychiatric interview, the *Monash Interview for Liaison Psychiatry* (MILP) [17]. The reliability and validity of the MILP compare well with the Structured Clinical Interview for DSM-IV (SCID) [17]. Additional psychosocial questionnaires were the *EORTC Quality of Life C-30 Questionnaire* [18], *Impact of Event Scale* [19], *Mini-Mental Adjustment to Cancer Scale* [20], and the recording of details of self-help or other psychosocial treatments. Women were asked to rate their experience of SEGT and the relaxation classes on a visual analogue scale of 1–10 (10 = most positive; 1 = least). Responses to open questions ('Can you tell me what it was like participating in this program?') were transcribed and coded into appropriate response categories. Demographic and clinical data were collected from the women and their medical records at baseline. Date of death was confirmed from the Victorian State Cancer Registry, which receives mandated reporting from pathology services and the State's death registry. Subsequent treatment data (chemotherapy, hormone therapy, bisphosphonates, radiation therapy and surgery) were abstracted from medical records following death or at the analysis censoring point, if the women remained alive at that time.

Given that survival was the primary outcome, a power analysis using Akazawa *et al.*'s Monte-Carlo simulation method [21] was conducted to determine that a total sample size of 220 participants with a 2:1 randomization ratio was sufficient to detect a 15% improvement in survival with 90% statistical power (assuming exponential distribution with survival in the control group = 10%, survival in the SEGT group = 25%; significance level 0.05, two-tailed; censoring rate 15%; drop out rate 25%). Further power analysis was conducted to ensure that a sample of 220 was sufficient to detect pre- and post-therapy differences in psychosocial outcomes. Using the Design-Power [22] statistical package and pilot psychosocial data from 38 patients, a sample of 220 participants with a 2:1 randomization ratio had an 89% statistical power to detect an effect size of 0.20 in anxiety and depression (two-tailed alpha = 0.05, assuming that the SEGT standard deviation is 0.47 and the Control group standard deviation is 0.42).

Randomization and blinding

Eligible consenting patients were independently allocated in a ratio of 2:1 to treatment and control arms respectively, by a stratified randomization process (utilizing an 'adaptive biased coin design') at the Statistical Centre of the Peter MacCallum Cancer Institute. Stratification ensured arms were balanced on three prognostic factors: (i) visceral or non-visceral metastases; (ii) less than three, or three or more visceral sites; and (iii) positive or negative oestrogen receptor status. For practical reasons, neither researchers nor participants were blinded to the randomization outcome. Participants were assigned to the next available therapy group or relaxation class.

Statistical analysis

Using an intention-to-treat approach, overall survival analysis was measured from the date of randomization to the date of death or date of analysis. The primary survival analysis was based on an overall Kaplan–Meier estimator comparing the survival curves. Secondary analyses included Cox proportional-hazards models, stratified by randomization and site of SEGT delivery. Additional co-variables included visceral metastases, use of adjuvant chemotherapy and hormone therapy since randomization, disease-free time interval from primary to secondary diagnosis, and baseline depression status. Generally, we report only results that are statistically significant without exceeding the maximum number of co-variables [23,24]. Psychosocial outcomes were analyzed by slopes analysis [25], which created a regression line and equation of the line for each set of outcome variables where participants had completed at least two time points. The slopes were used in analysis of variance comparisons between treatment and control arms and applied to the subsample for whom there was a baseline DSM-IV diagnosis of depression.

Cancer treatments since randomization were compared between group therapy and control arms for chemotherapy by number of cycles; hormone therapy and bisphosphonates by months of treatment; radiation treatments and surgical interventions by events. Analysis of covariance was used to examine the relative contributions of time and group membership to cumulative treatment with chemotherapy and hormone therapy.

Results

Recruitment and participation

Of the 485 women referred as eligible, 227 (47%) consented to participate, were assessed and then 147 participants were randomized to group and 80

to control (see Figure 1). Many study refusers gave more than one reason. Sixty one (27%) refusers were 'too busy', 46 (20%) cited treatment reasons, 41 (18%) were 'coping satisfactorily', 35 (16%) gave practical reasons—child care or transport, 22 (10%) wanted to 'move on' and 20 (9%) were not a 'group person'. Most attrition during follow-up was due to death. Of the 14 who withdrew, a third were 'too busy' ($n = 4$), another third felt 'upset' ($n = 5$) and the remainder ($n = 5$) gave no reason. Treatment data were missing for 13 of the 227 (5.7%): five received treatment interstate and eight had medical records missing.

Characteristics of the subjects

Analysis at baseline showed no statistically significant differences between the two arms of the study in any demographic (Table 1) or clinical (Table 2) characteristics. For the 112 (76%) women receiving group intervention, their overall attendance rate was 72% (4165 sessions out of a possible 5772 offered). Mean group session attendance was 37 (SD 43), range 1–226. Nineteen (17%) attended SEGT for five or fewer sessions; five of these had died. For the control arm, 51 (64%) participated in relaxation classes, with an attendance rate of 75% (115 classes out of a possible 153). The mean number of classes attended was 2.3 (SD 0.8), range 1–3. Relaxation classes were also conducted annually and attended by 60 (54%) group patients in their first year; 47 (42%) joined group after relaxation classes were offered that year and missed subsequent classes.

Participation in community self-help groups was not significantly different between arms, and ranged between 6–22 (5–15%) people in the group arm and 3–10 (4–13%) controls across the four follow-up time points.

Psychiatric diagnoses

Most of DSM-IV psychiatric disorders at baseline related to mood, with one-third of the sample having a form of depression [major depression (7%), dysthymia (1.3%), adjustment disorder with depressed or with mixed anxious and depressed mood (24.2%)]. Rates in the group intervention [47/147 (32.0%)] and control arms [27/80 (33.8%)] did not differ significantly ($p = 0.76$) at baseline; use of antidepressants was not significantly different.

However, 6 months later (see Figure 2), statistically significant differences emerged (chi-square = 9.264, $p = 0.002$, effect size = 0.23). At T2, 21/34 (62%) women in the treatment arm improved compared with 8/20 (40%) controls. Of those depression free at baseline, 74/83 (89%) receiving SEGT remained depression free compared with 28/40 (70%) controls (chi-square = 6.996, $p = 0.008$, effect size = 0.24). Comparison at later follow-up

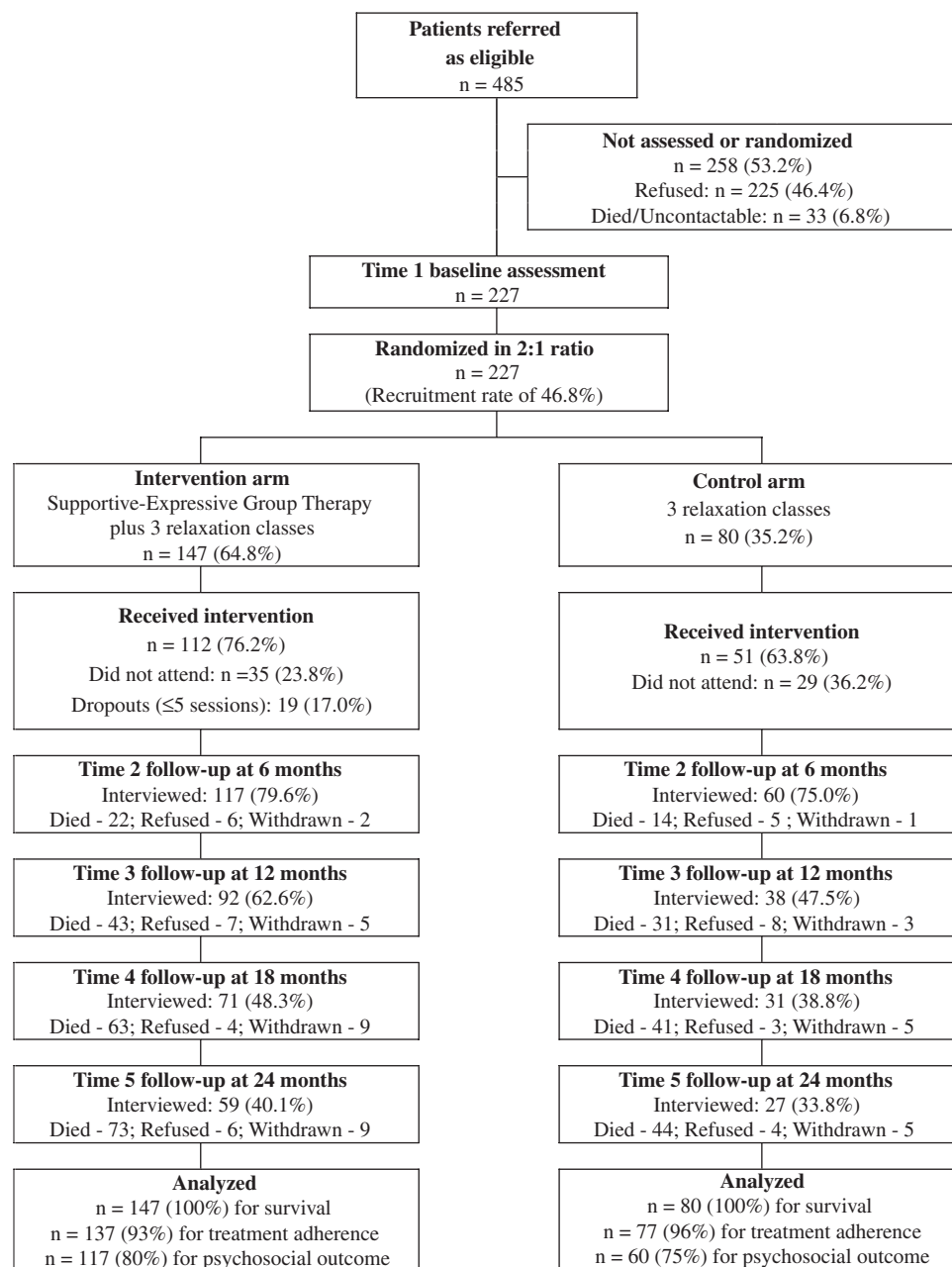


Figure 1. Flowchart of randomized controlled trial of supportive-expressive group therapy for 227 women with metastatic breast cancer. Deaths and study withdrawals are recorded cumulatively down the chart; refusers are specific to a time point and may complete later follow-up if health permits

points revealed no further significant differences, but the trend throughout was for those receiving SEG T to have less depression than controls. At their final assessment (closest to death), irrespective of time point, women who were depression free at baseline fared better in SEG T in that they were more likely to remain so than controls (chi-square = 5.125, $p = 0.024$, effect size = 0.20).

Quality of life and psychosocial outcomes

The treatment and control arms were statistically similar on all quality of life and psychosocial measures at baseline. Using slopes analysis, significant improvement from SEG T occurred in the

EORTC QoL C-30 Social Functioning Scale ($F = 4.56$, $p = 0.03$) and for those with a baseline diagnosis of depression, significant improvement from SEG T in intrusive thoughts as measured by Impact of Event Scale ($F = 4.61$, $p = 0.04$) (see Table 4). Better attitudinal coping was evident through reduction in scores on the helplessness–hopelessness subscale of the Mini-MAC for SEG T ($F = 4.89$, $p = 0.03$).

Appraising perceptions of group and relaxation experiences

By 6 months, 80% (90/112) of the group participants cited helpful aspects of their experience:

Table 1. Demographic characteristics of study sample at baseline (no statistically significant differences between intervention and control groups)

Demographic characteristics	Intervention group (n = 147)	Control group (n = 80)
Referral source No. (%)		
Public hospitals	93 (63.3%)	48 (60.0%)
Private practitioners	54 (36.7%)	33 (40.0%)
Age at study entry		
Mean (SD, Range) yr	51.9 (9.0, 25–69)	51.3 (9.2, 28–68)
Age at primary diagnosis		
Mean (SD, range) yr, (excludes Stage IV women)	46.9 (8.9, 23–66)	46.0 (8.7, 30–66)
Age at metastatic diagnosis		
Mean (SD, Range) yr	51.6 (9.0, 25–69)	50.7 (9.2, 28–68)
Marital status No. (%)		
Married/living together	108 (73.5%)	53 (66.3%)
Separated/divorced	21 (14.3%)	15 (18.8%)
Widowed	5 (3.4%)	5 (6.3%)
Never married	13 (8.8%)	7 (8.8%)
Country of birth No. (%)		
Australia	99 (67.3%)	59 (73.8%)
English speaking country	27 (18.4%)	10 (12.5%)
Non-English speaking country	21 (14.3%)	11 (13.8%)
Highest level of education No. (%)		
Primary	3 (2.0%)	4 (5.0%)
Secondary: Year 7–10	51 (34.7%)	26 (32.5%)
Secondary: Year 11–12	32 (21.8%)	24 (30.0%)
Tertiary	61 (41.5%)	26 (32.5%)
Current employment No. (%)		
Paid employment	52 (35.4%)	24 (30.0%)
Home duties	25 (17.0%)	11 (13.8%)
Unemployed	3 (2.0%)	1 (1.3%)
Retired	37 (25.2%)	18 (22.5%)
Disabled or ill	30 (20.4%)	26 (32.5%)

caring and sharing were mentioned by 48%, support by 46% and exchange of information by 33%. For those in the control arm, 51% reported they had learned to relax, 14% worried less and another 14% described improved breathing. On the Visual Analogue Scale, the mean rating of the experience was 7.2 (SD 2.3, median 8.0) for group and 7.6 (SD 1.6, median 8.0) for controls, suggesting that randomization to the control condition did not induce a demoralizing effect. No adverse events were reported at any stage.

Survival

The primary outcome, the Kaplan–Meier survival analysis, showed that the median survival was 24.0 months in the intervention arm and 18.3 months among controls (Figure 3). According to the univariate Cox model, the hazard ratio for death in the SEGT arm as compared with controls was 0.92 (95% CI, 0.69–1.24; $p = 0.60$), which entailed a width of confidence interval similar to that

observed in Goodwin *et al.* with a sample of 235 women (hazard ratio of 1.06 with 95% CI: 0.78–1.45).

In a secondary analysis, additional co-variables were entered in a multivariate Cox model (Table 3) to examine the effect of SEGT on survival after controlling for patient baseline characteristics. The multivariate Cox model identified no main effect of SEGT on survival (hazard ratio, 1.06; 95% CI, 0.74–1.51; $p = 0.76$) in contrast with a significant main effect of the cumulative number of cycles of chemotherapy and months on hormone therapy (hazard ratio, 0.92; 95% CI, 0.91–0.94, $p = 0.000$). Other variables in the multivariate model included visceral metastases at randomization ($p = 0.000$), stage 3 or 4 disease at initial diagnosis ($p = 0.019$), disease-free interval from primary to metastatic disease ($p = 0.66$) and the presence of baseline DSM-IV depressive disorders ($p = 0.11$). The rules in minimizing model overfit indicated no more than nine predictors [23,24]. No significant interaction effect was found between SEGT and cumulative dose of treatment with chemotherapy and hormone therapy ($p = 0.80$) (Tables 3 and 4).

Adherence to cancer treatment

Cumulative median number of cycles of chemotherapy for the SEGT arm was 10 (range 0–137) and for the control arm 6 (range 0–87), while the cumulative number of months receiving hormone therapy was 9 (range 0–83) for SEGT and 5 (range 0–85) for control. Summing cumulative treatment scores for chemotherapy and hormone therapy gave a median 24 (range 0–160) for SEGT and 16 (range 0–119) for control; the Mann–Whitney test yielded a significance level of $p = 0.05$. Cumulative counts of radiation treatment episodes per patient were median 1.0 (range 0–8) for the SEGT arm and 1.0 (range 0–12) for the control arm; for surgical events, median 0 (range 0–16) for SEGT and 0 (range 0–13) for control; and for months receiving bisphosphonates, median 7 (range 0–62) for SEGT and 4 (range 0–81) for control.

Using analysis of covariance, SEGT membership accounted for only 1.5% of the variability in cumulative cycles of chemotherapy and hormone therapy, whereas time between randomization and death or censoring lifted this percentage of variance to 68.5%—time was the main contributor to the amount of anti-cancer treatment received. As a *post hoc* analysis, the contribution of depression to treatment adherence was examined. Depressed patients received significantly less anti-cancer treatment on average (months = 26.9) than non-depressed patients (months = 38.0), $F(1, 66) = 4.68$, $p = 0.03$.

Table 2. Clinical characteristics of study sample at baseline (no statistically significant differences between intervention and control groups)

Clinical characteristics	Intervention group (n = 147)	Control group (n = 80)
Breast cancer stage at initial diagnosis No. (%)		
Stage I	21 (14.3%)	12 (15.0%)
Stage II	81 (55.1%)	44 (55.0%)
Stage III	11 (7.5%)	4 (5.0%)
Stage IV	27 (18.4%)	10 (12.5%)
Unknown	7 (4.8%)	10 (12.5%)
Breast surgery No. (%)		
Lumpectomy	41 (27.9%)	22 (27.5%)
Mastectomy	91 (61.9%)	56 (70.0%)
None	15 (10.2%)	2 (2.5%)
Oestrogen receptor status No. (%)		
Positive	97 (66.0%)	51 (63.8%)
Negative	43 (29.3%)	27 (33.8%)
Unknown	7 (4.8%)	2 (2.5%)
Progesterone receptor status No. (%)		
Positive	89 (60.5%)	52 (65.0%)
Negative	43 (29.3%)	24 (30.0%)
Unknown	15 (10.2%)	4 (5.0%)
Primary chemotherapy No. (%) (excludes Stage IV women)		
Yes	82 (68.3%)	40 (57.1%)
No	38 (31.7%)	30 (42.9%)
Primary hormone therapy No. (%) (excludes Stage IV women)		
Yes	47 (39.2%)	29 (41.4%)
No	73 (60.8%)	41 (58.6%)
Visceral metastases (e.g. liver, lung, brain) No. (%)		
Yes	82 (55.8%)	42 (52.5%)
No	65 (44.2%)	38 (47.5%)
Metastatic sites (some had more than one site) No. (%)		
Bone	99 (67.3%)	57 (71.3%)
Lung	43 (29.3%)	30 (37.5%)
Liver	49 (33.3%)	22 (27.5%)
Supraclavicular node	24 (16.3%)	16 (20.0%)
Brain	5 (3.4%)	3 (3.8%)
Skin	2 (1.4%)	2 (2.5%)
Other	16 (10.9%)	7 (8.8%)
Number of metastatic sites No. (%)		
< 3 different sites	119 (81.0%)	67 (83.8%)
≥ 3 different sites	28 (19.0%)	13 (16.3%)
Chemotherapy - secondary No. (%)		
Yes	86 (58.5%)	54 (67.5%)
No	61 (41.5%)	26 (32.5%)
Hormone therapy - secondary No. (%)		
Yes	94 (63.9%)	55 (68.8%)
No	53 (36.1%)	25 (31.3%)
Time from primary to secondary diagnosis Mean (SD, Range) months (excludes Stage IV women)	55.5 (51.5, 4–251)	51.4 (28.9, 9–125)
Time from primary diagnosis to randomization Mean (SD, Range) months (excludes Stage IV women)	65.3 (52.8, 7–258)	64.0 (34.5, 13–183)
Time from secondary diagnosis to randomization Mean (SD, Range) months	9.4 (10.5, 1–61)	11.9 (14.3, 1–91)

Discussion

The addition of SEGT to standard oncological care did not influence survival in this RCT of group therapy for women with metastatic breast cancer. Our overall findings are in keeping with those of

Cunningham *et al.* [2], Edelman *et al.* [3] and Goodwin *et al.* [4]. Importantly, psychosocial well-being was improved by SEGT. In this RCT, clinical depression was both assuaged and new cases of onset were prevented by SEGT. This finding assists the debate about whether these

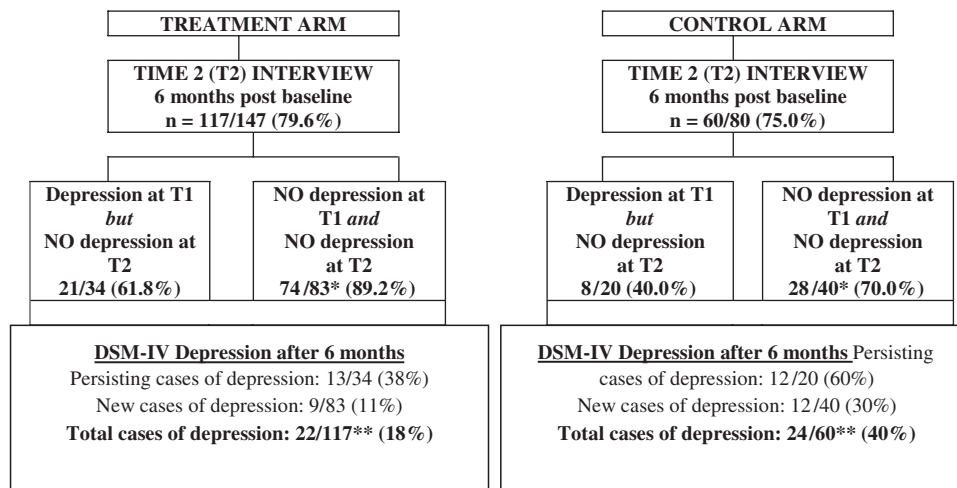


Figure 2. Prevalence of DSM-IV diagnoses of depression at 6 months post-randomization (*p = 0.008; **p = 0.002)

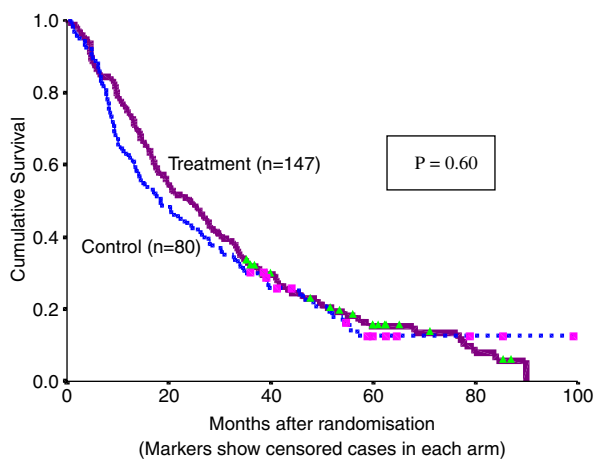


Figure 3. Kaplan-Meier survival curves for women assigned to the group therapy treatment and the control arms. There was no significant difference in survival between the two arms

treatments should only be applied to highly distressed patients. In preventing the development of helplessness-hopelessness, we have highlighted the manner in which women in groups sustain humor, creativity, and sense of purpose in their lives despite progressive illness and frailty as they approach their death [14]. Role modeling, enhancement of problem-solving and group support have all been proposed as therapeutic factors [26]. Analysis of our cohort at the final assessment, the one conducted closest to their death, upheld our finding of a significant prevention of new onset depression as striking evidence of the prophylactic benefits of SEGT.

Turning to the group intervention itself, refusers and dropouts were not systematically different from other women in this study. How acceptable is group therapy to women with advanced breast cancer? Our recruitment and dropout rates highlight that this intervention appeals to less than half the eligible women. The burden of anti-cancer

treatment is very high, with complications of chemotherapy causing hospitalization and morbidity for several and delaying their commencement of psychosocial treatments. As patients waited to join a group or relaxation class, ambivalence about further treatments emerged, with 23.8% not accepting group placement, 36% not accepting relaxation classes. Geographic distance to an assigned group disappointed some; others had hoped for a preferred treatment and were unhappy with the outcome of randomization. Cross-institutional involvement was also necessary with patients being drawn from two to three general hospital oncology units to sustain a flow of patients to any treatment center—this movement proved a deterrent to some. Finally, with respect to dropouts, five women died unexpectedly after their randomization, while 14 withdrew from group, citing fear and distress from listening to others' stories. These are challenges for program development. Therapists need to prepare patients carefully, helping them to differentiate initial from later perceptions of the experience, and using the group-as-a-whole to reassure beginners about the quality of the overall experience, thus preventing dropouts [14].

Allowing for the burden that any clinical trial brings, however, strong evidence emerges of sufficient optimization of psychosocial well-being to warrant clinicians informing patients of the availability and potential benefits of such a program. Meta-analyses have clarified that both the experience of therapists and the length of intervention are important in generating benefit in advanced cancer [27]. Members of one of our groups wrote a book about their experience [28], endorsing professionally led group therapy. Their testament to the creativity of the women, their meaningful and shared existence which, in turn, led to courageous acceptance of their dying speaks qualitatively in ways that quantitative data can fail to do. In demonstrating that SEGT not only treats

Table 3. Final multivariate Cox regression analysis for predictors of death

Variable	Beta coefficient	Hazard ratio	95% CI for hazard ratio	p-value
Visceral metastases at randomization	0.653	1.922	1.358–2.721	0.000***
Stage 3 or 4 at diagnosis	0.501	1.650	1.087–2.504	0.019*
Presence of baseline DSM-IV depressive disorders	0.299	1.348	0.937–1.940	0.108
Supportive-expressive group therapy (SEGT)	0.055	1.056	0.740–1.508	0.762
Time elapsed from primary to secondary diagnosis	0.001	1.001	0.997–1.005	0.664
Chemotherapy plus hormone therapy treatments	−0.079	0.924	0.911–0.936	0.000***

* $p < 0.05$; *** $p < 0.001$.**Table 4.** General linear and slopes analysis of quality of life and psychosocial outcomes measures (T = Treatment; C = Control)

Measure	Slopes analysis (at least two time points) $n = 115(T); n = 56(C)$	Slopes analysis plus DSM-IV depression at baseline $n = 33(T); n = 19(C)$	General linear model for patients completing data at all five time points $n = 55(T); n = 20(C)$
EORTC QoL C-30 (emotional functioning)	$F = 2.00, p = 0.16$	$F = 2.64, p = 0.11$	$F = 0.46, p = 0.76$
EORTC QoL C-30 (physical functioning)	$F = 0.18, p = 0.68$	$F = 2.53, p = 0.12$	$F = 1.17, p = 0.33$
EORTC QoL C-30 (social functioning)	$F = 4.56, p = 0.03^*$	$F = 1.94, p = 0.17$	$F = 1.00, p = 0.41$
Impact of Event Scale (total score)	$F = 3.33, p = 0.07$	$F = 4.61, p = 0.04^*$	$F = 1.22, p = 0.31$
Beck Depression Inventory (short cognitive form)	$F = 1.22, p = 0.27$	$F = 1.24, p = 0.27$	$F = 2.05, p = 0.10$
Affect Balance Scale (negative symptoms)	$F = 0.48, p = 0.49$	$F = 0.24, p = 0.63$	$F = 1.74, p = 0.15$
Mini-MAC (helpless/hopelessness)	$F = 0.45, p = 0.50$	$F = 4.89, p = 0.03^*$	$F = 4.20, p = 0.004^{***}$

* $p < 0.05$; *** $p < 0.001$.

but also prevents depression, we have added another reason for group therapy to be seriously considered as an appropriate model of support for patients with advanced cancer.

The conduct of an RCT involving patients with advanced cancer introduces several constraints. The recruitment period is extensive, with many patients buffeted by relapsing symptoms, which precludes their follow-up. A bias could ensue in that those who drop out may be more severely affected by their illness. Our findings then might under-represent the prevalence of psychiatric illness, with resultant impact on functional and psychosocial outcomes. Further methodological limitations include missing data: we elected to not impute quality of life data where only a single observation had been made. Our analysis using a general linear model for patients completing all data points did not differ significantly from our slopes analysis that imputed missing data.

We sought to examine whether SEGT promoted adherence to anti-cancer treatment as we had noted clinically that women increased their understanding of these. Length of life was the major reason for patients receiving more anti-cancer treatment, with group membership only making a tiny contribution

for these Caucasian women. There could be merit in delivering SEGT to minority populations, in which the contribution of health beliefs about cancer and its treatment are explored. In the last two decades, while the mortality rate from breast cancer has decreased by approximately 7% in younger white women [29], African American women have failed to realize such reductions, and older African American women have experienced an increase in mortality, despite a lower incidence of disease than their white counterparts [30,31]. While some of this disparity is attributed to lower rates of screening and late diagnosis, treatment has been identified as suboptimal [32–34]. Groups homogeneous for a minority population offer a method of empowerment, attention to health beliefs and resultant awareness of the benefits of treatment [35].

The debate about group therapy influencing survival has focused on psycho-neuroendocrinological (e.g. lowered serum cortisol levels) [36] and psychoneuroimmunological (e.g. reduced NK-cell activity) [37] mechanisms and been discussed over the past decade. Recent studies have failed to demonstrate survival differences; the key benefit is improved psychological well-being.

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Ethical Considerations: This study conformed to all local and national ethical guidelines and received ethical committee approval from all institutions involved in this study.

Editors Note

Letters to the Editors are invited on this paper to be received in the Editorial Office no later than 2 months from the online publication date.

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