

# COGNITIVE-EXISTENTIAL GROUP PSYCHOTHERAPY FOR WOMEN WITH PRIMARY BREAST CANCER: A RANDOMISED CONTROLLED TRIAL

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## SUMMARY

**Background.** We conducted a randomised, controlled trial of cognitive-existential group therapy (CEGT) for women with early stage breast cancer receiving adjuvant chemotherapy with the aim of improving mood and mental attitude to cancer.

**Methods.** Women were randomised to 20 sessions of weekly group therapy plus 3 relaxation classes or to a control arm receiving 3 relaxation classes. Assessments, independently done at baseline, 6 and 12 months, included a structured psychiatric interview and validated questionnaires covering mood, attitudes to cancer, family relationships, and satisfaction with therapy.

**Results.** Three hundred and three of 491 (62%) eligible patients participated over 3 years. Distress was high pre-intervention: 10% were diagnosed as suffering from major depression, 27% from minor depression and 9% from anxiety disorders. On an intention-to-treat analysis, there was a trend for those receiving group therapy ( $n=154$ ) to have reduced anxiety ( $p=0.05$ , 2-sided) compared to controls ( $n=149$ ). Women in group therapy also showed a trend towards improved family functioning compared to controls ( $p=0.07$ , 2-sided). The women in the groups reported greater satisfaction with their therapy ( $p<0.001$ , 2-sided), appreciating the support and citing better coping, self-growth and increased knowledge about cancer and its treatment. They valued the CEGT therapy. Overall effect size for the group intervention was small ( $d=0.25$ ), with cancer recurrence having a deleterious effect in three of the 19 therapy groups. Psychologists as a discipline achieved a moderate mean effect size ( $d=0.52$ ).

**Conclusion.** CEGT is a useful adjuvant psychological therapy for women with early stage breast cancer. Interaction effects between group members and therapists are relevant to outcome. Group-as-a-whole effects are powerful, but the training and experience of the therapist is especially critical to an efficacious outcome. Copyright © 2003 John Wiley & Sons, Ltd.

## INTRODUCTION

Substantial psychosocial morbidity occurs in women diagnosed with early stage breast cancer. For instance, Dean (1987) found that, using the

Present State Examination, one in 10 had a major depressive disorder and 18% minor depression 3 months post-surgery, while Harrison and Maguire (1995) found a prevalence rate of 17% for combined anxiety and depression using the DSM-III classification. Moreover, sustained distress affects up to 80% of women during their initial treatment programme (Hughes, 1982) and may persist for 2 years (Northouse, 1989; Irvine *et al.*, 1991; Maunsell *et al.*, 1992). Concerns revolve around threat of death, recurrence, an

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uncertain future, side effects of treatment, sexuality, infertility, body image and relationships.

Meta-analyses confirm the role of psychological therapies in reducing this morbidity (Meyer and Mark, 1995; Devine and Westlake, 1995; Sheard and Maguire, 1996). However, models to deal with the issues that specifically arise in the newly diagnosed patient and their effect on survival are in need of development and testing. To this end, we devised and piloted with 7 groups involving 48 patients an approach incorporating existential and cognitive dimensions (Kissane *et al.*, 1997). This emphasises education, cognitive reappraisal (Moorey and Greer, 1989) and promotion of enhanced coping (Fawzy *et al.*, 1990), each pertinent to those with early stage cancers, in conjunction with existentially oriented (Yalom, 1980) and supportive-expressive (Classen *et al.*, 1993) strategies, the latter two originally used in the advanced cancer setting. A group model was favoured given its potential to promote a supportive environment and its cost effectiveness.

We report here the findings of a randomised, controlled trial of CEGT with women with early stage breast cancer, receiving adjuvant chemotherapy. We hypothesised that CEGT would reduce distress and enhance coping. We also sought to examine whether this approach could be applied by suitably trained and supervised therapists drawn from such disciplines as psychiatry, clinical psychology, social work, occupational therapy and oncology nursing.

## METHODS

### Purpose

The trial was designed to test the efficacy of CEGT in reducing psychological distress and enhancing cognitive attitudes in women diagnosed with primary breast cancer; we also wish to explore its effect on disease-free and overall survival (not however the subject of this report).

### Design and sample

Patients were recruited between August 1994 and February 1997 from the oncology departments of nine metropolitan hospitals in Melbourne, Australia. Ethical approval was obtained

from each institution. All patients gave informed consent for both the trial and the subsequent study of survival. Eligibility criteria were age under 65 (lest the disease biology behaved differently in older age groups), histologically confirmed diagnosis of early stage breast cancer, operational English and geographic accessibility. Exclusion criteria were prior history of cancer (other than non-melanocytic skin cancers), psychotic illness, dementia and intellectual disability. We focused primarily on stage II disease, but accepted women with stage I who had high-grade histology or negative hormone receptor status and were receiving chemotherapy. Staging was confirmed by review of operative notes and reports of tumour size, histology, axillary lymph node involvement, hormone receptor status, haemoglobin, leucocytes and blood film, electrolytes and urea, calcium, liver function tests, chest X-ray and bone scan. All patients received the standard treatment that their oncology departments offered for their clinical circumstances.

A sample of 150 patients in each condition was based on consideration of the survival analysis using the method of Akazawa *et al.* (1991), permitting recognition of a 15% difference in survival over 5 years with a 0.05 level of significance, a 10% rate of censoring, a study duration of 5 years, and a hazard rate of 2:1 comparing control to treatment. For the RCT outcome study, to allow for interactional effects between the treatment arms and time, a sample of 240 with an alpha level of 0.01 and a medium effect size would generate a power of 0.82.

Trained research assistants conducted a baseline assessment. Randomisation was independently directed by our statistician (D. McK.), using a computer-generated allocation schedule, stratified on nodal status [ $> 3$  positive nodes/  $\leq 3$ ], hormone receptor status [ $+/-$ ] and tumour size [ $\geq / < 2$  cm]. Patients were assigned to either group therapy (CEGT plus 3 relaxation classes) or control (3 relaxation classes) (see trial flow diagram, Figure 1). Thus, a brief intervention—relaxation therapy—was a feature of both arms to obviate demoralisation possibly arising in women randomised to a condition with no treatment whatsoever. Once randomised, research assistants placed consecutive patients into groups with the next available pair of therapists. Research assistants independently carried out assessments 6 and 12 months after the baseline assessment. The blinding of research assistants to the randomisa-

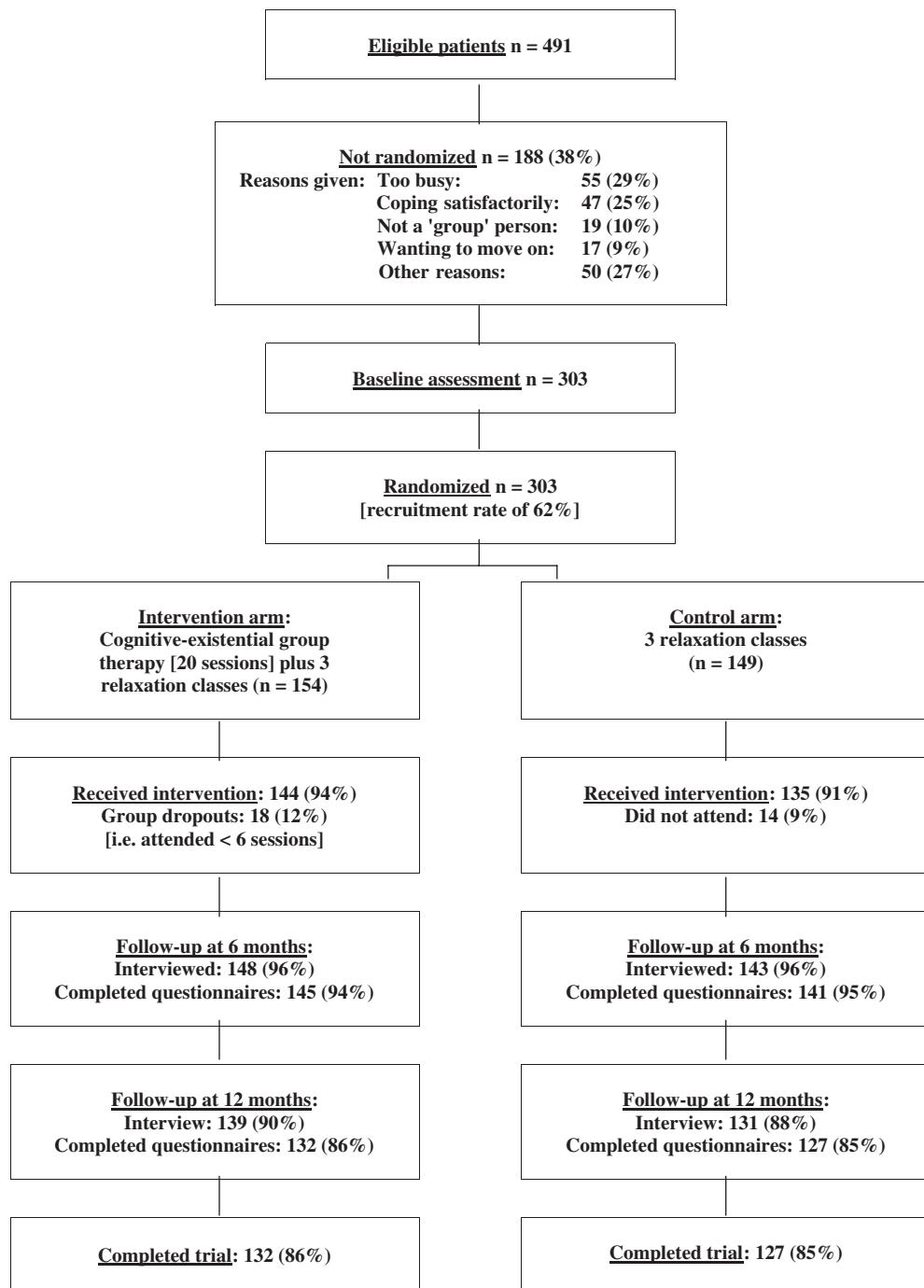


Figure 1. Trial profile outlining RCT design with numbers of patients at each stage.

tion allocation is not methodologically possible in research of this type.

### *Intervention*

This manualised group therapy had 6 goals: promoting a supportive environment; facilitating grief over losses; reframing negative thoughts; enhancing problem solving and coping; fostering hope; and examining priorities for the future. Groups, comprising 6–8 patients and 2 therapists (one always a woman) met for 20 weekly sessions, each lasting 90 min. Preparation of each patient individually in a standardised and manualised pretreatment session was an intrinsic feature to reduce dropouts. Groups typically began with a series of patients' narratives of their experience of illness, and early sessions focused on grief and existential concerns. Cognitive aspects were integrated during the middle phase. Typical themes covered have been described elsewhere (Kissane *et al.*, 1997) and included the threat of death; fear of recurrence; living with uncertainty; understanding treatment with chemotherapy, radiotherapy and hormones; the doctor–patient relationship; body- and self-image; sexuality; surgical reconstruction; relationship with partner, friends and family; and life style and future goals. For uniformity, we added relaxation classes to the end of sessions 10–12. The women were encouraged to exchange phone numbers and to meet informally (for example, over refreshments after each session) in order to reinforce the support gained in the therapy group.

In the 50-min relaxation classes, women were taught how to use progressive muscle relaxation with guided imagery, the technique being standardised through use of a therapist's manual. A relaxation tape was issued to all women for continued use at home. These classes were so scheduled as to minimise interaction so that a group environment was not readily replicated.

### *Therapists and fidelity of intervention*

Fifteen therapists, recruited from psychiatry, psychology, social work, occupational therapy and oncology nursing, were trained through a series of workshops utilising our 68-page 'manual' covering the components of the intervention, preparation of members, process of therapy, and mapping out of

typical potential themes. The senior therapist within any co-therapy couple had led a pilot group to attain familiarity with the model. Each pair of therapists attended weekly supervision with one of the chief investigators (DWK, SB, GCS, PM) in which they presented their process notes recorded about the previous session to optimise fidelity with the treatment guidelines. Supervisors maintained a checklist for each group to ensure that each theme was covered as described in the manual. Where an issue was considered inadequately explored, it was revisited during the next session until adequately elaborated. Handouts and homework on cognitive aspects were included to boost a uniform approach. Daily records of negative automatic thoughts were reviewed and supervisors noted which examples of thinking errors were selected to model their disputation for the group. Research assistants subsequently collated supervisors' checklists and confirmed coverage of designated themes by all groups.

We intentionally trained a number of professional staff and rotated co-therapy pairs so that we could minimise a therapist effect (Crits-Christoph and Mintz, 1991). In so doing, we sacrificed co-therapy experience in favour of exploration of the generalisability of the model. In fact, one therapist led 5 groups, 4 led 4, 2 led 3, 3 led 2 and 5 could only devote time to a single group.

### *Measures*

Research assistants were trained to administer the *Monash Interview for Liaison Psychiatry (MILP)* (Clarke *et al.*, 1998), a structured psychiatric interview validated against the Structured Clinical Interview for DSM-IIIR (SCID). This has been designed for use with the medically ill and has a greater coverage of somatisation and grief. A computer algorithm generates DSM-IV diagnoses (American Psychiatric Association, 1994). The MILP was administered at baseline, 6 and 12 months, together with the following self-report questionnaires:

*Affects Balance Scale (ABS)*—The ABS (Derogatis, 1992) is a 40-item adjective-rating scale designed to measure change in affective states. Its 4 positive subscales are joy, contentment, vigour and affection; and its 4 negative ones, anxiety, depression, guilt and hostility. Similar to the Profile of Mood States, it has the advantage of covering positive affect more substantially.

Positive and negative symptom total scores are derived from the sum of relevant subscales.

*Hospital Anxiety Depression Scale (HADS)*—This 14-item scale is used commonly in the medically ill to rate anxiety and depression (Zigmond and Snaith, 1983).

*Mental Adjustment to Cancer Scale (MAC)*—The MAC (Watson *et al.*, 1988) is a 40 item measure covering 5 attitudes to cancer: fighting spirit, denial, fatalism, helpless—hopelessness and anxious preoccupation. In an Australian re-validation, Osborne *et al.* (1999) divided fighting spirit (FS) into 2 subscales: FS minimising illness and FS positive orientation to illness; fatalism into fatalism-revised and loss of control; a new factor called angst emerged and helpless—hopeless remained unchanged. This factor structure based on the Australian culture had good concurrent validity with the Hospital Anxiety and Depression Scale (Zigmond and Snaith, 1983) and the Medical Coping Modes Questionnaire (Feifel *et al.*, 1987).

*Family Assessment Device (FAD)*—The generic subscale of the McMaster measure of family functioning is a useful, brief measure of relationships and perceived support (Epstein *et al.*, 1983).

*Satisfaction with therapy and other treatments*—A 10-point visual analogue scale assesses satisfaction with overall psychological care, together with an open-ended question, which invites the women to describe their perception of the experience. A checklist records their use of general practitioners and other counsellors, psychotropic medication, complementary therapies, community-based self-help groups and telephone support services.

#### Data analysis

Two hypotheses were specified prior to the data analysis: (i) patients receiving group therapy will have greater reduction in ABS Negative Symptom Total than controls; (ii) patients receiving group therapy will have greater increases in their MAC Fighting Spirit—Positive Orientation to Illness than controls.

Data analyses were conducted using SPSS (1999), StatXact (1999), EGRET for Windows 2.0.1 (1999) and the SPLUS-2000 (1999) statistical software packages. Given the number of comparisons, a *p*-value of 0.01 was used to define statistical significance and all tests were 2-sided.

The Fisher Exact test for dichotomous variables, the Pearson Chi-square test for contingency tables for non-ordinal categorical data, the Cochran-Armitage test for trend for ordinal data, and the t-test for continuous variables were used to compare the therapy and control arms at baseline.

The comparison of the randomisation arms was based on an intention-to-treat analysis. For continuous outcome variables, variance components models of analysis (Venables and Ripley, 1999; Laird and Ware, 1982; Everitt, 1998) were applied in which the randomisation arm and time of assessment were modelled as fixed factors and effects due to therapist pair, specific group membership and patient were modelled as random factors. The model also incorporated a covariate term, which transformed the baseline scores and accounted for intra-individual variation (Chambless and Roebuck, 1993). All baseline differences were thus controlled for. The restricted maximum likelihood method (Corbeil and Searle, 1976; Rao, 1997) was used to estimate the coefficients and variance components in the model. Two statistical contrasts using parameter estimates were applied: comparing average scores at 6 and 12 months with baseline, and scores at 6 with those at 12 months. A further analysis was performed to compare the arms at individual time points by subtracting the score at enrolment from the score at the given point. Change in score at each point was then analysed adopting a variance components model in which the randomisation arm was modelled as a fixed factor and effects due to therapist pair, specific group membership and patient modelled as random factors. Each hypothesis was tested by computing the Wald statistic.

Dichotomous variables (DSM-IV diagnoses) were analysed using logistic regression models with distinguishable binomial random effects (Collett, 1991). Randomisation and time of assessment were modelled as fixed factors and effects due to individual patients modelled as a random factor. A likelihood ratio test was performed to compare the randomisation arms.

Effect sizes were computed for each group and for disciplinary groupings (psychology, psychiatry and social work/occupational therapy/nursing) based on the discipline of the senior therapist in a co-therapy couple. This effect size is the difference in mean change between treatment and control arms as a ratio of the pooled standard deviation and it illustrates the clinical significance of the treatment (Borenstein, 1997).

## RESULTS

### *Demographic and clinical features of the entire sample*

Three hundred and three women were enrolled out of the 491 eligible (62%) (see Figure 1). Reasons for refusal included: busy, coping, wanting to move on and not being a 'group' person. Sociodemographic and clinical data are available in a previously published paper (Kissane *et al.*, 1998); most were middle aged (mean age 46.3 (SD 8.2)), married (76%), Australian-born (73%) and educated to senior high school or beyond (70%). Half were working (48%), and of these, 53% were in professional posts. Sociodemographic variables by randomisation arm are presented in Table 1. Clinical variables by randomisation arm are presented in Table 2.

Most women (83%) had stage II breast cancer; 87 (29%) had more than 3 axillary lymph nodes

involved, suggesting a higher risk of recurrence. Conservative breast surgery was undertaken in 164 women (54%); mastectomy in 139 (46%). One hundred and seventy four (57%) received radiotherapy; 287 (95%) chemotherapy. Cyclophosphamide/Methotrexate/Fluorouracil [CMF] was given to 202 (67%) and Adriamycin/Cyclophosphamide [AC] to 85 (28%). Hormone therapy was added later in 145 (48%) women. Baseline interviews occurred a median 92 days (mean 102, S.D. 56) after surgery. The therapy and control arms were similar sociodemographically, and with respect to clinical aspects of the cancer and its treatment.

### *Baseline affective and psychiatric features*

Rates of DSM-IV psychiatric disorders are seen in Table 3. A third of the entire sample suffered from a form of depressive disorder, but the therapy and control arms did not differ in this

Table 1. Sociodemographic variables by randomization arm

Factor	Category	Group (n = 154)	Control (n = 149)	P
Age	Mean	45.4	47.3	
	Median	45	47	
	S.D.	8.0	8.3	
	Range	26–64	26–65	
Marital status	Married	112 (73%)	117 (79%)	
	Separated	2 (1%)	5 (3%)	
	Divorced	15 (10%)	16 (11%)	
	Widowed	7 (5%)	3 (2%)	
	Single	18 (12%)	8 (5%)	0.15
Education (highest level)	Primary	0	2 (1%)	
	Yr 6–10	40 (26%)	51 (34%)	
	Yr 11–12	43 (28%)	47 (32%)	
	Tertiary	71 (46%)	49 (33%)	0.02
Occupation	Professional	90 (58%)	71 (48%)	
	Clerical	48 (31%)	57 (38%)	
	Semiskilled	15 (10%)	14 (9%)	
	Unskilled	1 (1%)	7 (5%)	0.07
Current employment	Working	74 (48%)	72 (48%)	
	Home duties	35 (23%)	33 (22%)	
	Unemployed	4 (3%)	5 (3%)	
	Retired	11 (7%)	19 (13%)	
	Disabled	30 (20%)	19 (13%)	
	Student	0	1 (1%)	
				0.34

Table 2. Clinical variables by randomisation arm

Factor	Category	Group (n=154)	Control (n=149)	P
Family history of breast cancer	Yes	62 (40%)	55 (37%)	
	No	92 (60%)	94 (63%)	0.64
Family history of other cancer types	Yes	109 (71%)	100 (68%)	
	No	45 (29%)	48 (32%)	0.62
Nulliparous	Yes	32 (21%)	21 (14%)	
	No	122 (79%)	128 (86%)	0.13
Stage of breast cancer	I	18 (12%)	31 (21%)	
	II	136 (88%)	118 (79%)	0.04
Tumour size in mm	Mean	22.2	21.6	
	median	20	20	
	S.D.	9.5	9.0	
	Range	5–50	5–45	
	≤ 10 mm	11 (7%)	11 (8%)	
	11–20 mm	72 (47%)	65 (44%)	
	21–30 mm	47 (31%)	53 (36%)	
	31–40 mm	19 (12%)	14 (10%)	
	41–50 mm	5 (3%)	4 (3%)	0.58
	Unknown		2	
Histological grade	I	7 (5%)	11 (8%)	
	II	59 (42%)	54 (39%)	
	III	75 (54%)	74 (53%)	0.63
	Unknown	13	10	
Oestrogen receptor status	Positive	94 (63%)	90 (64%)	
	Negative	56 (37%)	51 (36%)	0.90
	Unknown	4	8	
Progesterone receptor status	Positive	108 (73%)	104 (74%)	
	Negative	40 (27%)	37 (26%)	0.89
	Unknown	6	8	

Table 3. Frequency of DSM-IV psychiatric disorders at baseline

Diagnosis	Group arm n=154	Control arm n=149	P
Current psychiatric diagnoses	55 (36%)	58 (39%)	0.64
Major depression	17 (11%)	12 (8%)	0.32
Minor depression <sup>a</sup>	47 (30%)	35 (24%)	0.23
Anxiety disorders <sup>b</sup>	11 (7%)	16 (11%)	0.37

<sup>a</sup>Minor depression is the sum of adjustment disorder with depressed mood, dysthymia and depressive disorder not otherwise specified.

<sup>b</sup>Anxiety disorders is the sum of adjustment disorder with anxious mood, generalised anxiety disorder and panic disorder.

respect. However, on continuous measures, significant differences were found on contentment, vigour, affection and the ABS positive symptom total ( $p < 0.01$ ) with control patients scoring higher levels on positive affects (see Table 4).

#### Compliance and confounding variables

Compliance with treatments was high (see Figure 1), with 144 (94%) assigned to the group arm and 135 (91%) assigned to control attending

Table 4. Baseline comparison of primary outcome psychosocial subscales

Scale	Group Mean (S.D.)	Control Mean (S.D.)	Mean difference [95% CI] (Group–Control)	<i>p</i>
<b>Affects Balance Scale (ABS):</b>				
Pos symptom tot	45.8 (11.4)	49.9 (10.7)	−4.1 [−6.6–−1.6]	0.001**
Neg symptom tot	21.2 (12.0)	17.8 (11.1)	+3.4 [0.7–6.0]	0.01
<b>Hospital Anxiety &amp; Depression Scale (HAD):</b>				
Anxiety	6.1 (3.9)	5.3 (4.0)	+0.8 [−0.1–1.7]	0.07
Depression	3.7 (3.1)	3.1 (2.7)	+0.6 [−0.1–1.2]	0.08
<b>Mental Attitude to Cancer Scale (MAC):</b>				
Anx preoccup	10.9 (2.9)	10.7 (2.8)	+0.3 [−0.4–0.9]	0.38
Fatalism	8.0 (2.0)	8.2 (2.2)	−0.2 [−0.7–0.3]	0.38
FS minim illness	15.3 (2.2)	15.8 (2.1)	−0.5 [−0.9–0.0]	0.07
FS pos orien	30.6 (3.2)	30.3 (3.7)	+0.3 [−0.5–1.1]	0.45
Helpless-hopeless	8.5 (2.3)	8.7 (2.8)	−0.2 [−0.8–0.4]	0.43
Loss of control	7.8 (1.9)	7.8 (1.9)	−0.2 [−0.6–0.2]	0.37

Pos symptom tot = Positive symptom total; Neg symptom tot = Negative symptom total; Anx preoccup = Anxious preoccupation; FS minim illness = Fighting spirit—minimising the illness; FS pos orient = Fighting spirit—positive orientation.

\*\**p*<0.01.

at least one of their sessions. Overall dropout rate (<6 sessions) from group therapy was 12%.

There were no significant differences post-intervention between the randomisation arms in their use of general practitioners, other counsellors, treatment with antidepressants or other psychotropic medication, use of complementary therapies including art, music, meditation or yoga therapies, and attendance at 'look good, feel better' programmes, 'living with cancer' programmes, self-help groups in the community or use of cancer help-lines (telephone).

#### *Change in affect and family relationships*

When baseline differences were carefully controlled for, group therapy failed to significantly reduce ABS negative symptom total scores (see Figures 2 and 3). A trend for improvement was evident for HAD-anxiety (see Table 5). Noteworthy was the trend towards preserved family functioning over 6 months for women in the therapy condition compared to deterioration in the controls (see Figure 4); therapy possibly helped to sustain relationships. There were no outcome differences between arms on DSM-IV diagnoses.

The overall effect size for improvement in ABS total negative affect was  $d=0.254$ , and for HAD-anxiety was  $d=0.217$ . Effect sizes by discipline of therapist are shown in Figure 5. Psychologists achieved a moderate effect size of  $d=0.515$ .

A negative effect size for ABS Negative Symptom Total was evident in three out of 19 (15%) therapy groups, one an outlier at −0.98. These results help to explain the small effect size accomplished for the overall study. While new life events were infrequent within the cohort, they were noteworthy in these discrete groups with negative outcomes. One patient developed cerebral metastases quite early in the life of the group with the poorest outcome; recurrence of breast cancer again emerged in the next poorest group. Even allowing for these group-as-a-whole effects, psychologists as a discipline achieved the best outcome in their application of the model (see Figure 5).

#### *Change in attitude to cancer*

Our model places emphasis on helping patients live with uncertainty, cope actively with their concerns and avoid worry over minor aches and

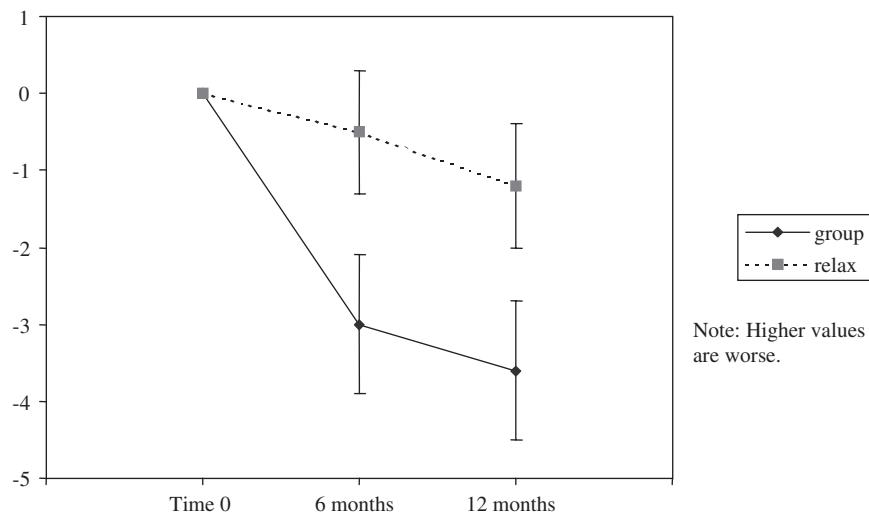


Figure 2. Change in Affects Balance Scale (ABS) Negative Symptom Total by time in months.

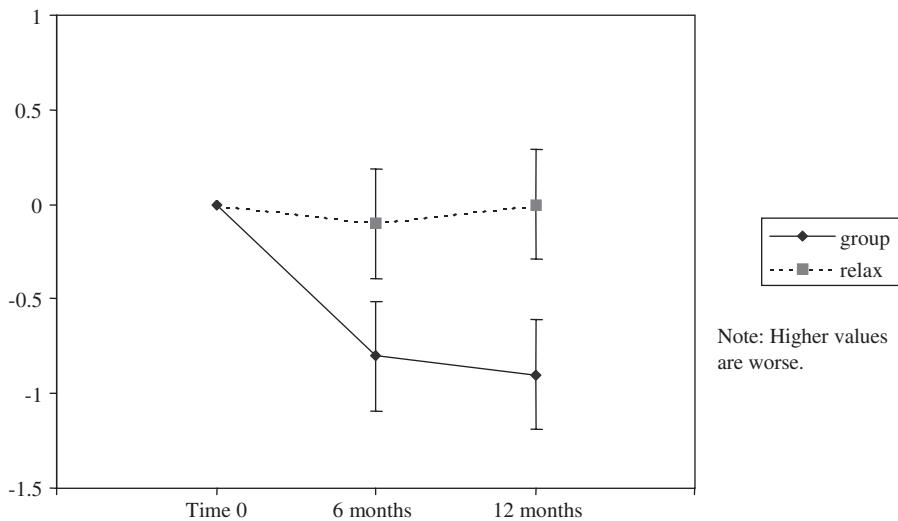


Figure 3. Change in Hospital Anxiety Depression Scale (HAD) Anxiety Subscale by time in months.

pains. However, apart from a trend towards reduced MAC anxious preoccupation in the group therapy arm (see Figure 6), there were no differences on fighting spirit and positive confrontation scales. Indeed, there was a trend in group therapy patients for these variables to diminish slightly.

The women rated their satisfaction with psychological care on a visual analogue scale (see Table 6). Group therapy patients felt significantly more satisfied ( $p < 0.001$ , 2-sided). Moreover, they offered substantially more positive qualitative feedback, emphasising the benefit of other women's support ( $p < 0.001$ ), improved coping

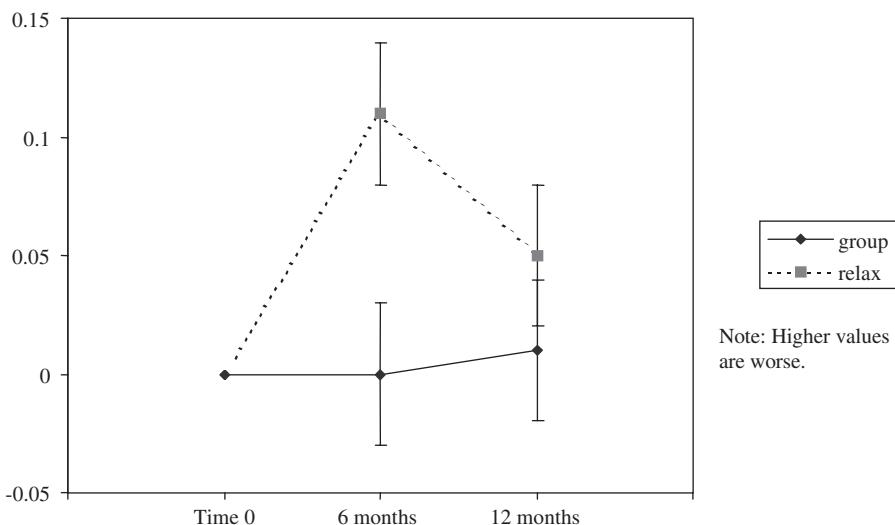


Figure 4. Change in Family Assessment Device (FAD) General Scale by time in months.

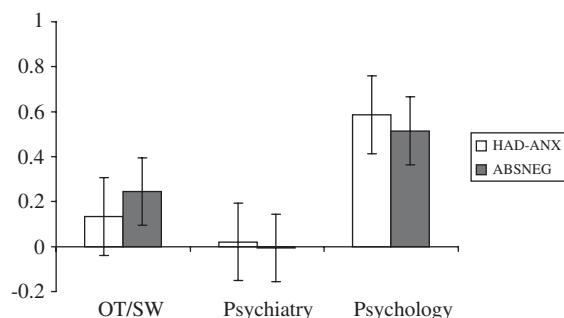


Figure 5. Effect sizes for ABS Negative Symptom Total and HAD-anxiety by clinical discipline of the therapist. OT/SW = Occupational Therapist or Social Worker.

( $p < 0.001$ ), greater knowledge ( $p < 0.001$ ), personal growth ( $p < 0.001$ ) and appreciating both therapists and programme ( $p < 0.001$ ).

## DISCUSSION

CEGT has been used in this trial in an attempt to improve adjustment in women with early stage breast cancer who receive adjuvant chemotherapy

and/or radiotherapy. It provides a supportive environment, a sense of better coping and greater knowledge about breast cancer and its treatment, personal growth and satisfaction with the therapeutic experience. The model seems to protect family functioning, highlighting social benefits that flow from treatment.

This therapy had been originally designed for women receiving adjuvant chemotherapy. The randomisation was therefore stratified by known prognostic factors in an endeavour to ensure that arms were carefully balanced. However we ended up with arms balanced for the described prognostic factors, but unbalanced in the distribution of the 49 women with stage I disease, more being assigned to the control arm ( $p = 0.04$ ). This resulted in a baseline difference reflected in the control arm particularly displaying more positive affects, presumably associated with their sense of a more optimistic prognosis. We needed therefore to control for this difference in our analysis.

As our statisticians incorporated methodology into the analysis to control for all of the baseline differences, what had appeared to be a significant improvement in negative affect (see preliminary report—Kissane *et al.*, 2000) lost significance at our prior specified level of  $p < 0.01$ . The effect size was small and invited further exploration of group and therapist effects. Three groups out of 19

Table 5. Comparison of change scores [mean (S.D.)] between randomisation arms [intention-to-treat analysis]

Scale	Group therapy arm		Control arm		<i>P</i>
	6 months	12 months	6 months	12 months	
Affects Balance Scale (ABS)					
Pos symptom tot	+ 3.8(9.5)	+ 2.8(10.9)	+ 2.9(9.0)	+ 2.6(10.4)	0.93
Neg symptom tot	-3.0(10.6)	-3.6(11.3)	-0.5(9.2)	-1.2(10.2)	0.19
Hospital Anxiety Depression Scale (HAD)					
Anxiety	-0.8(3.3)	-0.9(3.4)	-0.1(3.4)	0.0(4.1)	0.05
Depression	-0.8(3.0)	-0.9(3.5)	-0.5(2.5)	-0.6(2.7)	0.70
Family Assessment Device (FAD)					
General scale	+ 0.0(0.4)	+ 0.01(0.37)	+ 0.11(0.42)	+ 0.05(0.45)	0.07
Mental Adjustment to Cancer Scale (MAC)					
Anx preoccupation	-0.9(2.4)	-1.3(2.7)	-0.5(2.4)	-0.8(2.4)	0.11
Fatalism	0.1(1.9)	0.2(1.8)	0.3(1.8)	0.0(1.8)	0.77
FS minim illness	-0.1(1.9)	-0.2(1.8)	0.1(1.9)	-0.1(2.1)	0.24
FS pos orient	-0.2(3.1)	-1.1(3.2)	-0.2(3.1)	-0.3(3.0)	0.16
Helpless-hopeless	-0.1(2.4)	0.2(2.6)	0.0(2.3)	-0.1(2.4)	0.68
Loss of control	-0.1(1.8)	-0.1(1.9)	-0.2(1.7)	-0.1(1.6)	0.96

The reported *p*-values in this table are the average change scores between 6 and 12 months compared with baseline. Higher values are better for ABS positive affects; lower values for ABS negative affects, HAD, FAD & MAC. Pos symptom tot = Positive symptom total; Neg symptom tot = Negative symptom total; Anx preoccupation = Anxious preoccupation; FS minim illness = Fighting spirit—minimising the illness; FS pos orient = Fighting spirit—positive orientation.

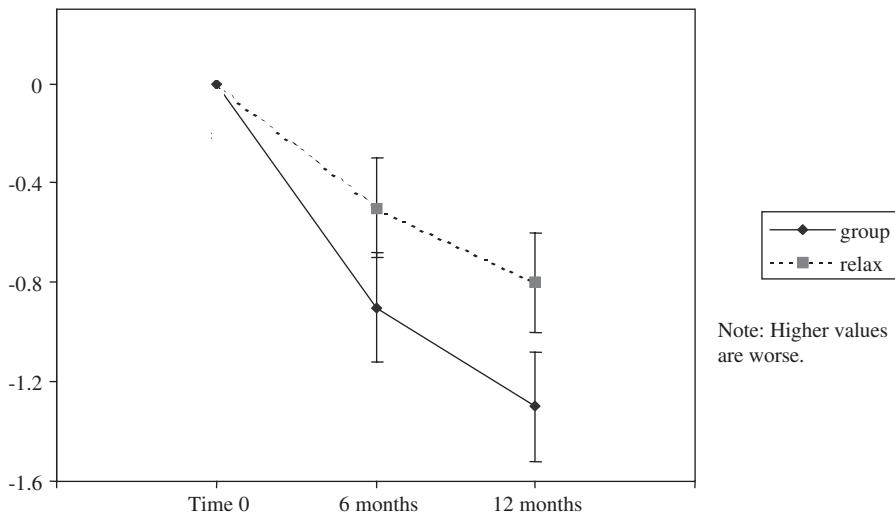


Figure 6. Change in Mental Attitude to Cancer Scale (MAC) anxious preoccupation subscale by time in months.

(15%) experienced a deterioration in ABS negative affects, which is in keeping with the long recognised observation that 10–15% of psy-

chotherapy interventions, like biological therapies, have adverse effects (Gurman and Kniskern, 1978). For two groups, this negative effect size

Table 6. Satisfaction with care and percentages of unsolicited, qualitative comments made by patients about the interventions

Category	Group therapy	Control arm	Anova or chi-square
Mean (S.D.) satisfaction with care on a 10 point VAS <sup>a</sup>	7.9 (1.8)	6.9 (2.4)	$F=15.18^{**}$
Positive experience	75%	60%	$\chi^2=6.88^*$
Gained support	70%	15%	$\chi^2=83.2^{**}$
Improved coping	45%	18%	$\chi^2=23.5^{**}$
Increased knowledge	28%	1%	$\chi^2=37.5^{**}$
Self-growth	27%	6%	$\chi^2=20.9^{**}$
Liked therapists	20%	4%	$\chi^2=16.9^{**}$
Liked program	17%	0%	$\chi^2=24.1^{**}$

<sup>a</sup>Visual Analogue scale.\* $p<0.01$ ; \*\* $p<0.001$ .

was small ( $d = -0.08, -0.19$ ), but in the third, this effect size was  $d = -0.98$ . New life events were the key precipitants, the development of metastatic cancer while still receiving adjuvant chemotherapy for their primary disease proving to be a most distressing experience.

Although therapists worked actively to contain any 'sense of contagion' from cancer recurrence, some group-as-a-whole loss of confidence may have ensued when these patients subsequently died during the first year of follow-up. We specified strategies for the therapists to use in the event of cancer recurrence, but concede that in the absence of continued clinical contact with the therapists beyond the formal end to group therapy, containment of such demoralisation over time is difficult for those who have grown close to an ill group member. Despite the increase in anxiety that occurred in these three groups with new life events, their members still rated their global satisfaction with psychological care very highly.

A second unexpected finding was a discipline effect with our psychologists outperforming their colleagues in demonstrating a moderate effect size for their groups. They brought greater prior experience with cognitive-behavioural therapy to the project. Their relative success raises questions about the broad generalisability of the model to other disciplines less well trained in the techniques of cognitive therapy. Such disciplinary effects were partly confounded by the presence of more seriously ill patients in the groups with adverse outcomes. The methodological challenges inherent in using a larger pool of therapists in the application of such research are also highlighted (Crits-Christoph and Mintz, 1991). Our results generate more questions than they answer and call for further research that teases out the specific

benefits of cognitively oriented therapy in patients with early stage and potentially curable cancers.

We had anticipated that an approach highlighting reappraisal of negative attitudes would have led to improved adjustment as measured by the MAC. If anything, a slight diminution in constructs like fighting spirit occurred. This contrasts with a study of individually applied cognitive-behavioural therapy to a clinical sample selected by screening in which fighting spirit was observed to rise (Greer *et al.*, 1992). One possible explanation is the impact of the existential aspects of our therapy, in which anxiety about death is explicitly faced and used to focus attention on the value of living in the present. This precludes a resort to denial or avoidance. Importantly, anxiety did not mount as a result; on the contrary, it was ameliorated. Furthermore, women who volunteered qualitatively a sense of enhanced coping also appreciated the treatment's cognitive dimensions. Other hypotheses offered by Edmonds *et al.* (2000) regarding no expected MAC changes include a lack of sensitivity of such measures with 'flooring effects' leaving little margin for improvement, or a regression to the mean, some patients benefiting considerably, others much less so. Indeed, we did as therapists note differential gains.

The purist would argue rightly that we should have tested therapists' fidelity to the model more rigorously. Recording sessions with audio and video was beyond our funding. Our awareness of this key issue is seen in our diligent efforts to supervise therapists closely, and to remind them incessantly about adhering to the guidelines laid out in our manual. Our supervisors' checklists on themes covered and cognitive homework provided evidence of adherence to the model. Nonetheless, our finding of an effect for therapist discipline

highlights the importance of fidelity to the model in any methodologically sound psychotherapy study. The trade-offs between the number of therapists used, generalisability of the findings and therapist efficacy is methodologically challenging. Clinical service realities are such that interventions are particularly valuable if psychologists, social workers, other allied health professionals and oncology nurses can apply them. The caveat is clearly that staff do need to be suitably trained and considerable experience in psycho-oncology is highly desirable.

Not all patients are comfortable in a group; some might be ambivalent about revealing their sensitivities and distress to others. A clinical service therefore has to offer a range of therapies, including individual, group and family, to meet the needs of all patients. Nonetheless, nearly two-thirds of women agreed to participate when this group experience was offered as an intrinsic part of the clinical programme, a very encouraging result. Moreover, the supportive network we saw develop in all 19 groups reassures us that group therapy has this distinct advantage.

In the past, literature reviews have offered consensus that group and individual interventions are equally efficacious (Trijsburg *et al.*, 1992; Andersen, 1992; Krupnick *et al.*, 1993), although the number of trials generating confidence about this remains few. Randomised trials of group therapy involving women with breast cancer have proven beneficial outcomes, but have been methodologically limited by small samples of heterogeneous cancers (Telch and Telch, 1986; Cunningham and Tocco, 1989). Brief coping skills interventions have been successfully delivered to other cancer types such as gynaecological (Cain *et al.*, 1986) and melanoma (Fawzy *et al.*, 1990); advanced breast cancer has been separately studied (Ferlic *et al.*, 1979; Spiegel *et al.*, 1981; Edelman *et al.*, 1999; Classen *et al.*, 2001; Goodwin *et al.*, 2001). Group intervention studies, especially full scale RCTs with newly diagnosed women with early stage breast cancer (Spiegel *et al.*, 1999; Fukui *et al.*, 2000) are very few in number, no doubt because of the time and costs involved. One recent US multicentre study is a noteworthy example of a comprehensive 12-week supportive-expressive intervention (Spiegel *et al.*, 1999), but this study also failed to deliver a statistically significant change in negative affect. Our Japanese colleagues have reported an even briefer 6-week model (Fukui *et al.*, 2000). Is there

an optimal duration for groups to meet this clinical need? In our pilot work (Kissane *et al.*, 1997), we planned a 12-session programme at weekly intervals, but soon realised this was insufficient to cover all the themes the members wished to deal with. After eliciting their feedback, we extended the programme to 20 sessions before commencing this controlled trial. In fact, members attended an average of 16 sessions. A degree of absenteeism is inevitable given the concurrent chemotherapy or radiotherapy. With our comparative experience of the pilot and definitive trial, we are inclined to the longer course since it offers a greater chance for a trusting, supportive 'culture' to crystallise, and the therapeutic mechanisms to operate satisfactorily. Yet we quickly acknowledge the cost benefit of briefer interventions if these can be demonstrated to work.

Overlap between the supportive-expressive and cognitive-existential models is considerable, yet the cognitive emphasis on coping is made more overt through the latter model, and is intuitively appealing for use with newly diagnosed primary patients. We favour the application of a cognitively oriented model in early stage cancer where preparation for survivorship is one goal. Issues such as living with uncertainty and fear of recurrence can be approached from each perspective, but an adaptive adjustment is achieved when both the emotional and cognitive dimensions are equally attended to in a balanced manner.

To conclude, we are of the view that our group approach can play a useful therapeutic role for a majority of women with newly diagnosed breast cancer. We hope colleagues in the field will replicate the study in the hope of demonstrating generalisability to other settings. While there is interest in the contribution that such interventions might make to increase survival, their benefit in enriching quality of life should lead them to be an essential component of comprehensive cancer care. We commend the notion of professionally led, adjuvant group support as an effective means of improving the 'total' clinical care of a vulnerable and deserving patient population.

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