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# Psychosocial group intervention for patients with primary breast cancer: A randomised trial

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ABSTRACT

*Purpose:* To test the effectiveness of a psycho-educational group intervention to improve psychological distress measured by POMS TMD, Quality of Life measured by European Organisation for Research and Treatment of Cancer (EORTC), the core and breast cancer module, Mental Adjustment measured by MAC and marital relationship measured by BLRI in women with primary breast cancer conducted 10 weeks after surgery. A secondary outcome was 4-year survival.

*Patients and methods:* We randomly assigned 210 patients with primary breast cancer to a control or an intervention group. Patients in the intervention group were offered two weekly 6-h sessions of psycho-education and eight weekly 2-h sessions of group psychotherapy. All participants were followed up for Quality of Life, coping ability and social relations 1, 6 and 12 months after the intervention and on survival 4 years after surgical treatment.

*Results:* No statistically significant effects of the intervention were found on any of the psychosocial questionnaire outcomes. There were not enough cases of death to analyse overall survival. The only statistically significant result was for patients who used anti depressive medication, for whom almost all measures improved over time, in both the control and intervention groups.

*Conclusion:* Psycho-education and group psychotherapy did not decrease psychological distress or increase Quality of Life, Mental Adjustment or improve marital relationship among patients with primary breast cancer.



## 1. Introduction

In a nationwide study of depressive symptoms 3–4 months post-surgery among Danish women treated for early stage breast cancer, the results indicated an increased prevalence of depressive symptoms and major depression of 13.7% compared to population based samples.[1] In another nationwide, population-based cohort of cancer patients, we found that women with breast cancer were at a significant, almost twofold increased risk for hospitalisation with an affective

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disorder during the first year after diagnosis, with increased risks for the most severe conditions in a spectrum covering mood disturbance to severe suicidal depression.[2] In Denmark, with a population of 5.5 million, female breast cancer accounted for more than 4000 cases in 2009 and was thus the most incident and prevalent cancer in women.[3] As in most other affluent, industrialised regions of the world, survival has improved, and survivorship-related issues are, therefore, important aspects of overall cancer treatment[4,5] and the high prevalence of depressive symptoms among Danish breast cancer patients implies sufficient unmet psychosocial needs in this patient group to warrant the development and implementation of an intervention such as the one tested in the present trial.

Several intervention strategies have been used over the past 20 years to improve the emotional adjustment of breast cancer patients and prevent the negative psychosocial effects of a cancer diagnosis and treatment.[6–9] The basis of these strategies is research on psychosocial factors in cancer derived from the Lazarus and Folkman theory of stress, appraisal and coping,[10] focusing especially on coping as 'ongoing cognitive and behavioural efforts to manage specific external and/or internal demands that are appraised as taxing or exceeding the resources of the person'.[11] Having cancer is seen as stressful and often exceeds the resources of patients, resulting in symptoms of depression and anxiety and feelings of helplessness and hopelessness.[11] Patients with a poor problem-solving ability also report more symptoms of depression and anxiety.[12,13] Research on control and adjustment to serious illness suggests that a belief in personal control allows adaption and reduces anxiety and depression.[14]

The interventions most often used to address these psychosocial problems are psychodynamic existential psychotherapy,[6,7,9,15] cognitive–behavioural therapy[16] or a combination of methods,[17] in an individual or a group setting. There is, however, conflicting evidence of the effectiveness of interventions for breast cancer patients. Interventions for women with metastatic breast cancer had no effect on major psychological problems or survival,[6–8] and interventions for women with primary, non-metastatic breast cancer had only a limited or no effect on psychological variables[9,17–19] and no effect on survival.[20] In regard to survival as a primary end-point, a rather extensive review from 2007 noted that no randomised clinical psychosocial intervention trial among cancer patients has yielded any effect on survival.[21]

It seems as if the interventions using cognitive–behavioural therapy are slightly more efficient than other intervention modalities.[19] This could be explained by the nature of the patients' problems; the problems arise because of a crisis in life (life threatening disease) where the patients feel loss of control rather than an early repressed trauma that would be the target for more psychodynamic and existential inspired modalities. However, every intervention with cancer patients does probably include the existential aspect of life as the patients situation is possibly life threatening and the conflicting results may also be a result of different measurement methods.[22] Another explanation could be that individual difference variables moderate the effects of an intervention whatever the intervention modality is.[23]

We report the results of a randomised trial on the effects of a combined psycho-educational and cognitive–supportive intervention on the primary outcomes of psychological distress, Quality of Life, Mental Adjustment and the marital relationship or for single patients, the relationship to a significant other person among Danish women with primary, operated breast cancer. A secondary outcome is the effect of the intervention on survival, with upto 4 years of follow-up after the date of primary surgery.

## 2. Methods

### 2.1. Patients

Eligible patients were 18–70 years of age with stages I–IIIA primary breast cancer[24] diagnosed and treated at the University Hospital of Copenhagen, Herlev, Denmark. The women were informed by their surgeon about the project and contacted by a project nurse 1–2 weeks after surgery, at the time of the final biopsy result. The patients gave oral and written consent, completed a baseline questionnaire, and were then immediately randomised to the intervention or the control group in the following way: via the internet, the nurse logged onto the database of the project which was housed in the Danish Cancer Society, typing the number of the baseline questionnaire. This number became the number of the patient and the randomisation status would appear. The number of the questionnaire was not known to the nurse before a sealed envelope with the questionnaire was broken by the patient. The randomisation programme generated a balanced number of random assignments to the two groups in blocks of randomly varying sizes of 6, 8 or 10 patients. This ensured equal distribution of patients in the two groups and reduced possible confounding from season or calendar time.

No formal power calculation was conducted, however, the intended number of patients in the protocol was set to 250, which should have been sufficient to detect significant changes in the primary outcome but only 205 patients were randomised and 176 analysed. Post hoc power calculation was done and with a mean difference of 5 and a standard deviation of 2, a study with 205 participants will have the power of 95% to detect a difference between intervention group and control group. Between 1st October 2003 and 1st December 2005, the physicians reported 369 eligible patients for the project (Fig. 1). Of these 6 (1.6%) were excluded before randomisation on the basis of information obtained at the recruitment interview. Of the 363 patients who met the inclusion criteria, 210 (57%) agreed to participate, and 153 (43%) refused due to the distance involved for follow-up visits, lack of time or feeling no need for support. Of the 210 patients originally assigned to the project, five were excluded from the analyses: two because of age (>70) and three because they changed their minds about participating after they had filled out the baseline questionnaire. Another 8 patients (4%) dropped out of the intervention group: 6 before the group was initiated and 2 after the first session. All of the 8 patients in the intervention group who dropped out agreed to fill out follow-up questionnaires and 7 of the patients did so.

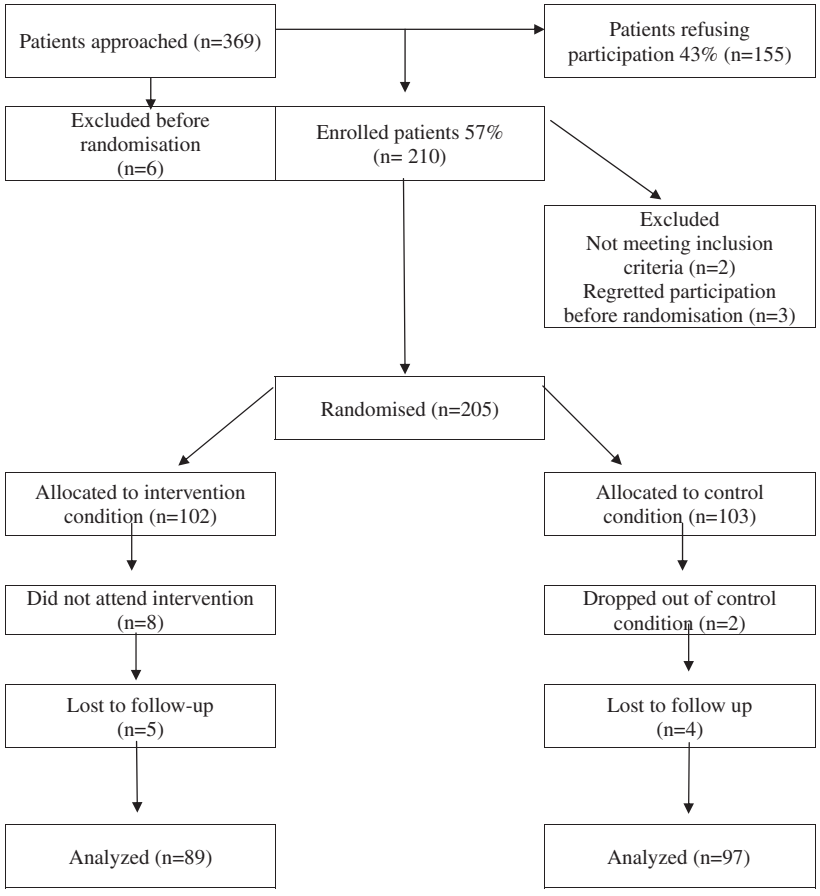


**Fig. 1 – CONSORT diagram for inclusion in the randomised cognitive–supportive intervention among Danish women with primary, early-stage breast cancer, 2003–2006, Copenhagen.**

Of the 103 patients originally assigned to the control group, two dropped out shortly after randomisation because of the result of the randomisation.

### 2.2. *Baseline clinical measures*

Clinical information was obtained from the Danish Breast Cancer Cooperative Group[25] clinical database and consisted of prognostic factors and treatment. The information on the breast cancer included date of primary surgery, tumour size, number of tumour-positive lymph nodes, oestrogen and progesterone receptor status and whether the patient had received chemotherapy and/or hormone therapy and radiotherapy.

### 2.3. *Questionnaire outcome measures*

The design incorporated baseline assessment before randomisation and three follow-up assessments, at 1, 6 and 12 months after the intervention. The questionnaire covered sociodemographic factors and included questions on the amount and kind of social or psychological support received from mental health professionals and use of antidepressants. The major outcome of the study was psychological distress, Mental Adjustment, Quality of Life and marital relationship. Distress was measured by The Profile of Mood States short form scale. This instrument contains 37 items to measure six mood or affective states: tension–anxiety, depression–dejection, anger–hostility, vigour–activity, fatigue–inertia and confusion–bewilderment.[26] The results are summed to obtain a total mood disturbance score for affective state. The scale has been used in numerous studies, which have shown it to be valid and reliable.[27–31] The short form of the scale maintains the factor-based six-subscale structure of the original version.[26] Mental Adjustment was elicited by the Mental Adjustment to Cancer scale,[32] which has been used in several studies[6,16,33] and consists of five subscales: helplessness–hopelessness, anxious preoccupation, fighting spirit, cognitive avoidance and fatalism. Quality of life was assessed from the QLQ-C30 core questionnaire of the European Organisation for Research and Treatment of Cancer (EORTC)[34] and the complementary breast cancer module EORTC QLQ-BR23.[35] These are well-established tools for assessing the Quality of Life of patients with cancer and both have been proven to be reliable and valid.[36,37]

Marital relationship (the degree of empathy and congruence provided by the spouse or the adult to whom the respondent felt most attached to, i.e. 'significant other') was measured by the Rarret-Lennard Relationship Inventory.[38] Originating from a Rogerian framework, the Barret-Lennard relationship inventory was designed to measure marital or interpersonal relationships in general and higher levels of

empathy and congruence are thought to indicate healthier and more adaptive relationships[39] which has shown its importance in adapting to the cancer situation.[40] In a prior intervention study of patients with malignant melanoma, the interpersonal relationship to a significant other improved after the intervention even though the partner was not participating in the intervention.[41]

The overall survival of all patients was determined from the unique personal identification number assigned by the Central Population Register to all Danish residents who were alive on 1 April 1968 or born thereafter. The Central Population Register holds information on survival and is updated daily.[42]

### 2.4. *Group intervention*

The group intervention was based on existential–cognitive group therapy, as outlined by Kissane et al.[43], but was shorter and differently organised. The six goals outlined by Kissane to meet the overall aim of improving patientś Quality of Life are: promoting a supportive environment, facilitating grief over multiple losses, altering maladaptive cognitive patterns, enhancing problem-solving and coping skills, fostering a sense of mastery and providing an opportunity to sort out priorities for the future.[43] The intervention had two parts. The first was 12 h of education at the outpatient clinic, conducted as two weekly sessions. Two medical breast cancer specialists and two nurses specialised in breast cancer gave lectures about the treatment modalities, the rationale behind the chosen treatment and why treatment may be different for each patient. The nurses also provided information about possible side-effects of the treatments, stressed that the side-effects were 'normal'. A social worker talked about the social rights of women undergoing long treatment and rehabilitation. A dietician gave a lecture on healthy diets, went through each woman's daily nutrition from a diet diary collected before the intervention, and gave advice about changing the diet if necessary and how to lose or gain weight. A psychologist talked about stress management, problem-solving, coping and cognitive reframing to examine and deal with negative thoughts, from cognitive–behavioural theory. Sexual problems were discussed by a specially trained nurse, and a physiotherapist taught the women how to avoid lymphedema and how to train the shoulder and arm if their mobility had been limited by the breast operation. She also gave advice on how to keep the body in shape. The aim of this part of the intervention was to give the patients a general view of their situation and what they were going through, to engender a sense of mastery and control.

In the second part of the intervention, groups of eight women met eight times over 8 weeks for 2.5-h sessions in a cancer counselling clinic. An experienced clinical psychologist (EHB) led the group, in cooperation with two nurses from the Clinical Research Unit at the Department of Oncology, Herlev Hospital, Copenhagen. The nurses had more than 15 years' experience in oncology nursing. They participated for two reasons: to learn how to lead counselling groups if the intervention became a standard part of treatment for primary cancer at the department; and to be able to respond to questions about treatment and its side-effects that were often asked by the women in the group, to clear up any misunderstandings or worries and keep the focus of the group on psychological matters.

The main purpose of the group was to share 'cancer stories' and, in doing so, to reveal negative thinking and to integrate the elements of cognitive therapy[43] smoothly into the group work. Homework was added where appropriate and the results were shared in the group. Themes pertinent to breast cancer were woven in, including: anxiety about death; dealing with fear of recurrence and living with uncertainty; body- and self-image; sexuality; relationships with partner, children, family, friends and colleagues; returning to work; guilt and shame and goals. The group members met informally after every session for ½ h over light refreshments and were encouraged to stay in contact after termination of the intervention.

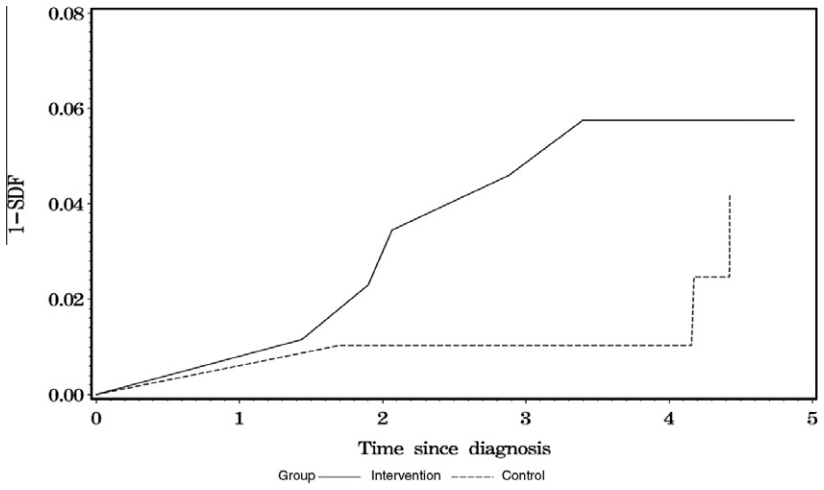


**Fig. 2 – Kaplan-Meier estimates of 5-year survival in the randomised cognitive–supportive intervention among Danish women with primary, early-stage breast cancer, 2003–2006, Copenhagen.**

### 2.5. *Statistical analyses*

Differences in the baseline characteristics of the two groups were compared by the two-sample *t* test. The main effects of the intervention were based on analyses of covariance. The three follow-up times were analysed separately, and the analyses were adjusted for the baseline values of the given scale. All models were furthermore adjusted for age,

**Table 1 – Socio-demographic and biological, characteristics of 205 patients with primary breast cancer included in a randomised intervention study of education and group therapy, Copenhagen, Denmark, 2003–2006.**

| | | Intervention group (IG) No = 89 | | Control group (CG) No = 97 | | IG versus CG | Dropout IG (No = 8) | Dropout CG (No = 2) | Participants versus dropouts |
|---|---|---|---|---|---|---|---|---|---|
| | | No. | % | No. | % | P† | No. | No. | P† |
| Age at inclusion (years) | | | | | | 0.40 | | | 0.70 |
| | 30–39 | 5 | 6 | 8 | 8 | | – | 1 | |
| | 40–49 | 29 | 33 | 25 | 26 | | 5 | – | |
| | 50–59 | 36 | 40 | 37 | 38 | | 2 | 1 | |
| | 60–70 | 19 | 21 | 27 | 28 | | 1 | – | |
| Marital status | Married/co-habiting | 65 | 73 | 73 | 75 | 0.84 | 5 | 1 | 0.78 |
| | Single patients# | 22 | 25 | 23 | 24 | | 3 | 1 | |
| | Missing | 2 | 2 | 1 | 1 | | – | – | |
| Level of education | No education | 8 | 9 | 11 | 11 | 0.20 | 1 | 1 | 0.59 |
| | <3 years of Special training | 28 | 31 | 44 | 45 | | 2 | – | |
| | ⩽4 years of College | 27 | 30 | 25 | 26 | | 3 | – | |
| | >4 years of University | 11 | 12 | 7 | 7 | | 1 | – | |
| | Other | 12 | 13 | 7 | 7 | | 1 | – | |
| | Unknown | 3 | 3 | 3 | 3 | | – | 1 | |
| Surgery | Mastectomy | 28 | 31 | 38 | 39 | 0.08 | 4 | – | 0.24 |
| | Lumpectomies | 52 | 58 | 58 | 60 | | 4 | 2 | |
| | Other | 7 | 8 | 1 | 1 | | – | – | |
| | Missing | 2 | 2 | 0 | 0 | | – | – | |
| Size of tumour | 1–10 mm | 21 | 24 | 13 | 13 | 0.01 | 2 | – | 0.80 |
| | 10.1–20 mm | 38 | 43 | 41 | 42 | | 3 | 1 | |
| | 20.1–40 mm | 18 | 20 | 37 | 38 | | 3 | 1 | |
| | >40 mm | 8 | 9 | 6 | 6 | | – | – | |
| | Missing | 4 | 4 | 0 | 0 | | – | – | |
| Lymph node status | Positive | 48 | 54 | 53 | 55 | 0.11 | 4 | – | 0.24 |
| | Negative | 37 | 41 | 44 | 43 | | 4 | 2 | |
| | Missing | 4 | 4 | 0 | 0 | | – | – | |
| Degree of malignancy | I | 24 | 27 | 21 | 22 | 0.13 | 3 | – | 0.37 |
| | II | 40 | 45 | 46 | 47 | | 3 | 2 | |
| | III | 14 | 16 | 25 | 26 | | 2 | – | |
| | Missing | 11 | 12 | 5 | 5 | | – | – | |
| Receptor status | Oestrogen positive | 66 | 74 | 76 | 78 | 0.11 | 8 | 2 | - |
| | Oestrogen negative | 19 | 21 | 21 | 22 | | – | – | |
| | Missing | 4 | 4 | 0 | 0 | | – | – | |
| Treatment | Chemotherapy | 2 | 2 | 1 | 1 | 0.54 | – | – | 0.60 |
| | Radiation | 11 | 12 | 10 | 10 | | – | – | |
| | Antihormones | 2 | 2 | 4 | 4 | | 1 | – | |
| | Chemo + antihormes | 3 | 3 | 1 | 1 | | – | – | |
| | Chemo + radiation | 17 | 19 | 18 | 18 | | – | – | |
| | Radiation + antihormones | 18 | 20 | 26 | 27 | | 1 | – | |
| | Chemo + radiation + anti | 24 | 27 | 31 | 32 | | 3 | – | |
| | None | 12 | 13 | 6 | 6 | | 3 | 2 | |
| Professional support | Yes | 11 | 12 | 9 | 9 | 0.50 | 1 | – | 0.65 |
| | No | 78 | 88 | 88 | 91 | | 7 | 2 | |
| Use of antidepressants | Yes | 22 | 25 | 22 | 23 | 0.75 | 1 | – | 0.65 |
| | No | 67 | 75 | 75 | 77 | | 7 | 2 | |

† Student-T Test.
# Including widowed and divorced.

education, marital status, treatment for breast cancer and use of antidepressants. Models including follow-up times were also adjusted for use of antidepressants at the given follow-up time.

All women were followed from the date of operation for breast cancer until the date of death or end of follow-up (31st May 2009). Because of the small number of deaths (six in the intervention group and three in the control group), only Kaplan-Meier estimates were performed. The software used was the SAS statistical package v.9.0 for the Unix platform.

This study is registered at ClinicalTrial.gov, Protocol Registration System, National Institute of Health, USA, Identifier: NCT01108224.

## 3. Results

The randomised groups did not differ with regard to demographic variables (Table 1). Women in the intervention group had statistically significant larger tumours than those in the control group ($P = 0.01$). The only statistically significant positive result was found for the group of patients who used antidepressive medication. For almost all measures, users of antidepressive medication in both the control and the intervention groups improved over time (Table 2). No statistically significant effects of the intervention were found on the Profile of Mood Scale, on either total mood disturbance or the subscales (Table 3). No statistically significant effect of the intervention was found for the EORTC scale; however, the Quality of Life of control patients was higher at baseline and decreased to a lower level than among the intervention patients at 1 year (Table 3) but the result was still not statistically significant.

The intervention had no effect on the relationship inventory scale (Table 3).

No statistically significant effects of the intervention were found on overall survival (Fig. 2). Six patients in the intervention group and three in the control group had died at the time of follow-up. None of the baseline mood or coping scores predicted time to death. Likewise, analyses of changes in the scores of total mood disturbance and Mental Adjustment to Cancer in relation to survival 6 month after the intervention did not change this overall result (data not shown).

## 4. Discussion

In this large, controlled, randomised study of women treated for primary breast cancer, we found no major effect of a psychosocial intervention on either psychosocial outcome

**Table 2 – Baseline means in Profile of Mood State, Mental Adjustment to Cancer, European Organisation for Research and Treatment of Cancer (EORTC) and RI with 95% confidence interval (CI) in the randomised cognitive–supportive intervention among Danish women with primary, early-stage breast cancer, 2003–2006, Copenhagen.**

| | Mean | | Estimate | CI | P-value |
|---|---|---|---|---|---|
| | IG | CG | | | |
| *Profile of Mood State* | | | | | |
| Total mood disturbance | 14.7 | 13.3 | 1.6 | –4.6–7.8 | 0.61 |
| Confusion | 3.8 | 3.1 | 0.5 | –0.4–1.5 | 0.28 |
| Anger | 2.4 | 2.8 | –0.4 | –1.4–0.6 | 0.45 |
| Depression | 5.9 | 5.9 | –0.1 | –1.7–1.5 | 0.91 |
| Fatigue | 5.5 | 5.1 | 0.3 | –1.1–1.6 | 0.69 |
| Anxiety | 6.9 | 7.1 | –0.3 | –1.7–1.1 | 0.72 |
| Vigour | –9.9 | –10.8 | 1.5 | –0.1–3.1 | 0.06 |
| *Mental Adjustment to Cancer* | | | | | |
| Fighting spirit | 12.2 | 12.6 | –0.5 | –1.0–0.1 | 0.12 |
| Helplessness–hopelessness | 11.4 | 11.6 | 0.1 | –0.9–1.1 | 0.83 |
| Anxious preoccupation | 20.0 | 20.4 | –0.1 | –1.4–1.2 | 0.87 |
| Cognitive avoidance | 9.1 | 9.5 | –0.1 | –0.8–0.6 | 0.81 |
| Fatalism | 13.3 | 13.8 | –0.4 | –0.9–0.2 | 0.21 |
| *EORTC* | | | | | |
| Physical Function | 87.2 | 86.1 | 0.8 | –3.3–5.0 | 0.69 |
| Emotional Function | 69.7 | 67.2 | 2.2 | –4.2–8.7 | 0.50 |
| Sexual Function | 75.6 | 79.7 | –2.8 | –9.0–3.3 | 0.36 |
| Role Function | 46.2 | 50.3 | –6.5 | –16.4–3.3 | 0.19 |
| Cognitive Function | 68.2 | 67.9 | –0.3 | –7.4–6.9 | 0.94 |
| Pain | 40.3 | 41.8 | –0.9 | –7.3–5.5 | 0.77 |
| Fatigue | 23.8 | 23.8 | 0.9 | –4.8–6.6 | 0.76 |
| Nausea | 13.1 | 10.8 | 2.0 | –4.1–8.0 | 0.53 |
| QoL | 60.9 | 63.2 | –3.5 | –9.5–2.5 | 0.25 |
| *Relationship Inventory* | | | | | |
| Congruence | 0.1 | –0.9 | 1.5 | –0.6–3.6 | 0.15 |
| Empathy | 3.8 | 4.4 | 0.2 | –2.1–2.6 | 0.87 |

**Table 3 – Estimates of changes from baseline in POMS, MAC, EORTC and Relationship Inventory at 1 month (T1), 6 months (T2) and 12 months (T3) follow-up with 95% CI in the randomised cognitive–supportive intervention among Danish women with primary, early-stage breast cancer, 2003–2006, Copenhagen.**

| | T1 | | | | | T2 | | | | | T3 | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Mean | | Estimate | CI | *P*-value | Mean | | Estimate | CI | *P*-value | Mean | | Estimate | CI | *P*-value |
| | IG | CG | | | | IG | CG | | | | IG | CG | | | |
| *Profile of Mood State* | | | | | | | | | | | | | | | |
| Total mood disturbance | –2.8 | –2.9 | 2.7 | –1.8–7.2 | 0.24 | –6.5 | –7.1 | 3.5 | –2.0–8.9 | 0.21 | –8.5 | –7.0 | 2.6 | –3.4–8.7 | 0.39 |
| Confusion | –0.6 | –0.6 | 0.8 | 0.2–1.4 | 0.01 | –0.8 | –0.6 | 0.7 | –0.1–1.4 | 0.08 | –0.8 | –0.3 | 0.2 | –0.7–1.2 | 0.62 |
| Anger | –0.5 | –0.1 | –0.4 | –1.3–0.4 | 0.35 | –0.2 | –0.5 | 0.3 | –0.7–1.3 | 0.52 | –0.3 | –0.4 | 0.1 | –1.0–1.2 | 0.84 |
| Depression | –1.2 | –1.2 | 0.3 | –1.0–1.5 | 0.68 | –1.9 | –1.7 | 0.2 | –1.2–1.6 | 0.80 | –2.4 | –1.9 | 0.1 | –1.4–1.5 | 0.93 |
| Fatigue | 1.2 | 1.0 | 0.7 | –0.6–2.0 | 0.28 | 0.1 | –0.4 | 1.0 | –0.2–2.3 | 0.10 | –0.6 | –0.6 | 0.5 | –0.8–1.8 | 0.46 |
| Anxiety | –1.7 | –2.1 | 0.4 | –0.7–1.5 | 0.46 | –2.2 | –2.5 | 0.4 | –0.7–1.5 | 0.48 | –2.6 | –2.6 | 0.4 | –0.8–1.6 | 0.51 |
| Vigour | 0 | 0 | 0.8 | –0.6–2.2 | 0.25 | –1.6 | –1.3 | 0.6 | –0.9–2.1 | 0.44 | –1.8 | –1.2 | 1.0 | –0.6–2.6 | 0.24 |
| *Mental Adjustment to Cancer* | | | | | | | | | | | | | | | |
| Fighting spirit | 0.1 | –0.3 | 0.2 | –0.3–0.7 | 0.42 | –0.4 | –0.7 | 0.1 | –0.5–0.7 | 0.83 | –0.2 | –0.7 | 0.3 | –0.3–0.9 | 0.26 |
| Helplessness–hopelessness | –0.2 | 0.4 | –0.6 | –1.5–0.2 | 0.15 | –0.4 | –0.2 | –0.1 | –1.1–0.9 | 0.82 | –0.3 | 0.4 | –0.5 | –1.6–0.6 | 0.39 |
| Anxious preoccupation | –1.2 | –0.2 | –1.0 | –1.9–0.0 | 0.04 | –1.6 | –1.3 | –0.3 | –1.5–0.8 | 0.58 | –1.9 | –1.2 | –0.6 | –1.9–0.6 | 0.29 |
| Cognitive avoidance | 0.7 | 0.6 | 0.2 | –0.3–0.7 | 0.41 | 0.8 | 0.3 | 0.6 | –0.0–1.2 | 0.06 | 0.8 | 0.8 | –0.1 | –0.7–0.5 | 0.76 |
| Fatalism | 0.1 | –0.5 | 0.5 | –0.0–1.1 | 0.07 | –0.4 | –0.7 | 0.4 | –0.2–1.0 | 0.19 | –0.6 | –0.9 | 0.2 | –0.4–0.8 | 0.48 |
| *EORTC* | | | | | | | | | | | | | | | |
| Physical Function | –1.9 | –0.6 | –2.4 | –6.5–1.7 | 0.25 | 0.1 | 0.3 | –0.2 | –3.4–3.0 | 0.92 | 1.0 | 0 | 1.4 | –2.6–5.3 | 0.49 |
| Emotional Function | 4.8 | 7.6 | –2.1 | –7.6–3.3 | 0.44 | 8.6 | 12.7 | –3.2 | –9.0–2.6 | 0.28 | 10.4 | 12.2 | –2.0 | –7.3–3.4 | 0.47 |
| Sexual Function | –3.6 | –1.6 | –5.3 | –11.3–0.6 | 0.08 | 2.9 | 1.7 | –2.1 | –7.9–3.7 | 0.48 | 3.0 | –2.3 | 1.5 | –5.5–8.4 | 0.68 |
| Role Function | 21.3 | 18.1 | –0.2 | –9.9–9.4 | 0.96 | 34.3 | 32.6 | –0.8 | –8.3–6.7 | 0.82 | 39.2 | 32.0 | 6.1 | –1.6–13.8 | 0.12 |
| Cognitive Function | 12.6 | 12.4 | 0.3 | –5.2–5.7 | 0.92 | 15.9 | 13.3 | 2.5 | –2.9–7.9 | 0.36 | 16.5 | 14.6 | –0.5 | –6.0–4.9 | 0.84 |
| Pain | –3.8 | –7.0 | 2.8 | –3.8–9.4 | 0.40 | –6.1 | –9.7 | 3.6 | –3.1–10.3 | 0.29 | –10.0 | –10.0 | –0.1 | –6.9–6.7 | 0.98 |
| Fatigue | 5.7 | 5.3 | 2.3 | –3.0–7.7 | 0.39 | –2.7 | –2.4 | 1.4 | –3.4–6.3 | 0.56 | –3.8 | –5.6 | 4.0 | –0.8–8.8 | 0.10 |
| Nausea | 7.8 | 7.7 | 2.8 | –4.4–10.0 | 0.44 | –4.9 | –1.5 | 0.5 | –4.5–5.5 | 0.84 | –6.4 | –0.6 | –1.8 | –6.7–3.2 | 0.49 |
| QoL | –2.4 | 0.6 | –4.6 | –11.4–2.3 | 0.19 | 6.4 | 5.0 | –0.6 | –7.0–5.8 | 0.85 | 8.7 | 3.7 | 2.1 | –4.5–8.7 | 0.54 |
| *Relationship Inventory* | | | | | | | | | | | | | | | |
| Congruence | –0.3 | 1.0 | –0.6 | –2.6–1.4 | 0.54 | –1.0 | 1.1 | –0.7 | –2.6–1.1 | 0.43 | –0.8 | 0.3 | –0.3 | –1.8–1.3 | 0.75 |
| Empathy | –0.6 | –0.7 | –0.3 | –2.2–1.6 | 0.75 | –2.1 | –1.1 | –1.6 | –3.6–0.4 | 0.12 | –1.6 | –2.0 | 0.6 | –0.9–2.1 | 0.45 |

or survival. Women prescribed antidepressive medication fared better on all psychological outcomes. The overall result of this study is in line with the paucity of positive results in other, similar studies.[6–9] There may be several explanations.

Firstly, the intervention might not reflect the approaches that women find most important for addressing their psychosocial problems. This was not, however, the clinical impression of the intervention groups, who reported a high level of cohesiveness; the drop-out rate was low, and several groups continued to meet regularly years after termination of the intervention, inviting the intervention psychologist to join them once or twice a year.

Second, the lack of evidence of an effect in our and other studies[6,44–46] might be due to the choice of outcome measures and the responsiveness of the instruments to changes in individuals. The complexity of the emotional issues faced by women with breast cancer makes it difficult to obtain valid measures of aspects of adjustment more subtle than distress after a cancer diagnosis. Other aspects of adjustment might be changed after the intervention, e.g. in this study we observed that women in the intervention group compared to the control group fared better on all Quality of Life measures except social role function, however, not reaching significance.

Third, the lack of evidence might be due to a ceiling effect: the women in the project may not have been distressed enough to show an effect of the intervention. Those in real need of a psychosocial intervention, the most distressed women, may be those who refuse to participate in randomised studies. We know little about why some women refused to participate; however, we conducted a small survey ($n = 64$) during the study,[47] which showed that the most frequent reasons were associated with practical circumstances, time and dislike of group therapy. These findings support the conclusion that the intervention model attracts a selected group of women, who have time at their disposal and resources to overcome the practical circumstances of participation.

The lack of a positive effect on psychosocial outcome variables makes it unlikely that the intervention would enhance survival. This result is not surprising, as replication studies of psychosocial interventions for patients with recurrent breast cancer[7–9] did not corroborate the survival benefit found by Spiegel and collegues.[15] More recent studies also failed to find an initial benefit on psychosocial outcomes[9] or survival[17] among patients with primary breast cancer. But as we have only a total of 9 deaths out of 210 randomised, survival in our study is not a measurable outcome.

The finding that almost 25% of the patients in both groups used antidepressants is in line with reports of the prevalence of clinical depression among patients with breast cancer.[48] Antidepressants appeared to improve the Quality of Life of women regardless of randomisation group. Randomised studies of treatment of depressive symptoms in early-stage breast cancer confirm these results, and it has been recommended that patients be screened for depressive symptoms and treated adequately.[49,50] Our results support this recommendation.

Our study contributes to the series of findings of a lack of association between psychosocial intervention and reduction of distress, and enhancement of Quality of Life and Mental Adjustment to the Cancer situation.[17] This is in line with meta-analyses and reviews of psychosocial interventions that provided no convincing evidence for reductions in a wide range of distress outcomes.[51] Promising research in interventions that engage women in physical activity show improved Quality of Life and reduced mortality[52–54] and in view of the results of this study and the current state of the art in psychosocial oncological intervention research, we suggest that these aspects of cancer survivor-ship should be integrated into overall cancer care and only for patients who need these services. Thus in order to find an effect, various types of screening may be included in clinical follow-up.[55,56]

## Conflict of interest statement

None declared.

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