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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.