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Effects of an educational intervention for managing fatigue in women with early stage breast cancer



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A B S T R A C T

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Purpose: This randomized controlled trial of outpatients with breast cancer (stage I or II) evaluated the effects of a 3-week educational intervention on patient levels of fatigue.

Methods: Norwegian outpatients were randomized into an intervention group ($n = 79$) and a control group ($n = 81$). Women with fatigue (>2.5 on a 0–10 numeric rating scale, NRS) completed the Fatigue Questionnaire (FQ) and the Lee Fatigue Scale (LFS) at baseline (after treatment) (T1), immediately after intervention (T2) and 3 months after intervention (T3).

Results: The mean fatigue score (NRS) at study entry was 6.1 (SD 1.7) and 36% ($n = 57$) had a score ≥ 7 . There were no statistically significant differences between the fatigue measures of women in the intervention and control group at T2 or T3 in the overall sample after the intervention. Using an NRS cut-off of 5, there was a borderline difference for women who scored <5 for chronic fatigue on FQ ($p = 0.062$) and a significant difference for energy on LFS ($p = 0.042$) where the women in the intervention group had less fatigue. Using an NRS cut-off score of 6, there was a borderline difference for women who scored <6 for fatigue on FQ ($p = 0.062$) and a significant difference for energy on LFS ($p = 0.021$) where women in the intervention group had more energy than those in the control group.

Conclusions: Further research is needed to identify psycho-educational interventions to reduce levels of fatigue and to tailor an intervention based on the level of fatigue. Fatigue measurements should be chosen more carefully.

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Introduction

Fatigue has been identified as the most problematic side effect in women with breast cancer (Hickok et al., 2005; Jacobsen et al., 1999; Longman et al., 1999). Fatigue is almost universal in cancer patients receiving cytotoxic chemotherapy, radiation therapy, bone marrow transplantation or treatment with biological response modifiers (Ahlberg et al., 2003; Dean et al., 1995; Hann et al., 1999; Wagner and Cella, 2004). Fatigue is characterized as persistent and not relieved by rest (Cella et al., 2002), and can persist for years after the end of treatment, thereby disrupting daily functioning and negatively affecting quality of life (Andrykowski et al., 1998;

Broeckel et al., 1998; Miaskowski and Lee, 1999; Smets et al., 1998). Breast cancer is the most common cancer diagnosis in women from developed countries (Jemal et al., 2008; Cancer Registry of Norway, 2012; Orem and Bedwell, 2010) so it is a major health problem. Fatigue is also the most frequently reported side effect of cancer treatments, with a prevalence ranging from 25% to 99% at different times during treatment regimens (Donnelly et al., 1995; Servaes et al., 2002), and several studies have shown that fatigue is also associated with other symptoms such as pain, dyspnoea (Stone et al., 1999; Utne et al., 2008), depressed mood (Mock et al., 1997), anxiety, depression (Stone et al., 2000) and hope (Schjolberg et al., 2011).

With the exception of exercise, there are relatively few evidence-based treatments to alleviate fatigue in cancer patients, other than treating the underlying cause if it is known and symptomatic treatment if it is necessary (Mock, 2004). Three broad approaches have been investigated to address cancer-related fatigue,

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which form the basis of most fatigue management programmes: exercise interventions, drug interventions and psychosocial interventions (Stone and Minton, 2008).

Physical exercise is known to be effective for reducing fatigue and improving tolerance of physical activity. A review of evidence for exercise as an intervention identified 20 experimental studies, which provided strong support for the positive effects of a range of activity- and exercise-based interventions for managing cancer-related fatigue (Stricker et al., 2004). The forms of exercise tested included home-based walking programmes (Mock et al., 1994, 1997, 2001; Schwartz et al., 2001) and supervised laboratory exercise bicycle formats (MacVicar et al., 1989). All of these studies reported lower levels of fatigue in subjects who exercised compared with the control groups. However, most of the studies in this area have methodological shortcomings because of their heterogeneous exercise characteristics and intervention doses (Mitchell et al., 2007). Furthermore, few studies required that the study participants had a clinically significant level of fatigue.

Minton et al. (2008) conducted a Cochrane review of randomized controlled trials (RCTs) of the pharmacological treatment of cancer fatigue and provided evidence for the use of three agents: methylphenidate, erythropoietin and darbepoetin. Erythropoietin and darbepoetin appeared to improve fatigue in anaemic patients and the evidence for the effectiveness of these agents was described as highly robust, which was supported by other systematic reviews (Bohlius et al., 2006; Jones et al., 2004). A more recent study also concluded that methylphenidate appeared to be effective for the management of cancer-related fatigue (Minton et al., 2011). However, cancer-related anaemia does not explain fatigue entirely because non-anaemic patients also experience fatigue and more research is needed in this area.

Psychosocial interventions vary in their content and approach, and a meta-analysis showed that these interventions may include cognitive behavioural therapy, supportive and expressive therapies and more psycho-educational approaches (Jacobsen et al., 2007). These interventions were performed on an individual basis or in group settings and there was considerable variation in the study size, design, methods and quality of previous studies (Jacobsen et al., 2007). Overall, the authors reported a small but significant positive effect of psychological interventions compared with the controls (Jacobsen et al., 2007). However, studies varied considerably in terms of their methodologies and most of the interventions were comprehensive so it was difficult to know the components of the interventions that addressed fatigue effectively.

Ream et al. (2006) demonstrated the beneficial effect of an educational intervention during chemotherapy, which reduced the distress, associated with fatigue and improved mood. However, they did not detect any significant change in fatigue severity. Arnes et al. (2007) undertook an RCT of a behaviour-based psychological intervention in patients undergoing chemotherapy. They found a significant improvement in fatigue severity and self-reported physical functioning at 1 month after the completion of chemotherapy. The effect on physical functioning persisted until 9 months after recruitment to the study whereas the effect on fatigue did not. They did not find a significant reduction in fatigue-related distress. Cognitive behavioural therapy has a documented effect in patients with chronic fatigue syndrome (Whiting et al., 2001), but no systematic studies in cancer patients could be found that tested the effectiveness of cognitive behavioural therapy on fatigue in breast cancer patients.

The provision of preparatory information to patients before undergoing treatments that induce fatigue can be beneficial (Golant et al., 2003; Johnson et al., 1988) and it has been suggested that it may be helpful to acknowledge that fatigue is a symptom worthy of intervention simply by asking the patients about it (Osse

et al., 2002; Passik et al., 2002). Barsevick et al. (2002) and Williams and Schreier (2004) found that fatigue was reduced after educating and counselling patients about fatigue. However, an Australian study of an educational intervention (Yates et al., 2005) found no significant differences in the pre- or post-test scores related to confidence in managing fatigue. However, a study of 396 breast cancer patients found that energy conservation strategies, such as priority setting, delegation and planning of activities, were effective for achieving a statistically significant improvement in the fatigue levels of patients who received the intervention compared with those patients who did not (Barsevick et al., 2004).

Given the importance of fatigue in breast cancer patients and the mixed results reported by previous studies of fatigue, the aim of the present study of a sample of outpatients diagnosed with breast cancer (stage I or II) was to implement an educational intervention to reduce patient levels of fatigue and to evaluate the effect of the intervention on patient levels of fatigue. All women recruited by the study were screened to determine their level of fatigue using a numeric rating scale (NRS) that ranged from 0 to 10 (0 = no fatigue and 10 = severe fatigue).

Methods

Sample and data collection methods

This study was an RCT where a psycho-educational intervention was provided to a group of patients to reduce their fatigue. The patients were recruited from outpatient clinics at a university-based cancer centre in Norway. Women diagnosed with breast cancer stages I or II were eligible to participate in this study if they were over 18 years of age, able to read, write and understand Norwegian, and gave their written consent. These women were selected because cancer prognosis is relatively good in these stages and the patient treatments are defined mainly as curative. All patients were receiving active treatment for cancer when they were recruited. After undergoing surgery, lumpectomy or total mastectomy, they were given chemotherapy and/or radiotherapy, and some were expected to receive hormone therapy for 5 years. The participants were required to have an NRS fatigue score ≥ 2.5 because this study evaluated an intervention to treat fatigue.

After they consented to participate, patients were given self-reporting questionnaires, which they completed at home and posted back to the investigator (first author). The randomization procedure was performed after the women had completed the baseline questionnaires. The participants in the intervention and control groups completed the questionnaires at baseline (the last week of radiotherapy) (T1), immediately after the intervention was ended (T2) and 3 months after finishing the intervention (T3). A single reminder was posted to women who had not returned their questionnaires within 2 weeks at all tests.

Intervention

The intervention aimed to improve the knowledge and skills of patients to help them to alleviate fatigue. The intervention identified various components, which included effective strategies to reduce fatigue, promote a balance between activity and exercise, conserve energy and promote restorative activities. The intervention was based on patient booklets developed by the Oncology Nursing Society (Culhane and Haberman, 1996) and the European Oncology Nursing Society (Richardson and Jodrell, 1997) through their respective programmes, Fatigue Initiative Research and Education and Action on Fatigue.

The intervention comprised an educational package that contained basic information about fatigue, i.e. a definition of fatigue,

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