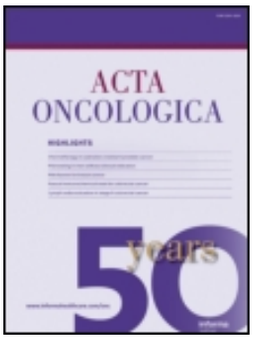

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ORIGINAL ARTICLE

Group versus individual stress management intervention in breast cancer patients for fatigue and emotional reactivity: A randomised intervention study

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ABSTRACT

Background. Fatigue and emotional reactivity are common among women suffering from breast cancer and might detrimentally affect these women's quality of life. This study evaluates if the stress management delivered either in a group or individual setting would improve fatigue and emotional reactivity among women with a newly diagnosed breast cancer.

Material and methods. Participants (n = 304) who reported elevated levels of distress at three-month post-inclusion were randomised between stress management in a group (GSM) (n = 77) or individual (ISM) (n = 78) setting. Participation was declined by 149 women. Participants completed the Multidimensional Fatigue Inventory (MFI-20) and the Everyday Life Stress Scale (ELSS) at the time of inclusion, 3- and 12-month post-inclusion. Analyses were made according to intention to treat and per-protocol principles. Mann-Whitney tests were used to examine differences between the two intervention groups.

Results. No significant differences were detected between the GSM and ISM groups on fatigue or emotional reactivity. In addition, there were no changes over time for these outcomes.

Conclusions. There were no differences between the two intervention arms with reference to fatigue or emotional reactivity; however, a clinically interesting finding was the low number of women who were interested in participating in a psychosocial intervention. This finding may have clinical implications when psychosocial support is offered to women with a newly diagnosed breast cancer and also in the planning of future studies.

Breast cancer is the most frequently diagnosed cancer within the female population. It is well known that early-stage breast cancer patients may suffer from fatigue which is one of the most common adverse events in the cancer trajectory [1] and up to 90% of all cancer patients experience some degree of fatigue [2,3]. Fatigue can be defined as a debilitating loss of energy and is a multidimensional symptom, which relates to both psychological and physiological aspects [3–5]. This loss of energy is not relieved by rest or sleep and it may be intensified by adjuvant cancer treatments, such as chemotherapy and radiation therapy [2]. Fatigue interferes with daily routines and participation in social activities [3,6] and has been reported to affect patients' daily lives more than, e.g. pain and nausea [3].

Moreover, about 50% of women also report feelings of irritability and frustration during their experience with fatigue [3], two aspects that may be included in the term 'emotional reactivity'. Emotional reactivity often takes the form of impatience, anger, hostility and aggravation [7] and may be triggered by small unexpected stressors, such as hassles related to work or caring for others. Costanzo [8] found that cancer survivors experienced the same day-to-day stressors as a cancer-free comparison group; however, survivors experienced the stressors as more severe and disrupting. These day-to-day

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stressors are often small, and may not even be remembered at the end of the day, and they are seemingly non-significant but they trigger emotional reactivity. When these stressors occur they mobilise a reaction to search for someone or something to blame. It may trigger the perception of the situation as unfair, which in turn evokes emotional reactivity manifested as hostility and impatience.

Whereas fatigue causes alterations in the daily routines of the patients and affects their interpersonal relationships, it has been suggested that the unexpected stressors are associated with more distress [9] and can increase negative affect. Fatigue and emotional reactivity are linked to an increased burden on the individual's psychosocial wellbeing and consequently, result in poor quality of life [3,8]. With an increasing number of long-term survivors, it is important to provide both physical and psychological care for those affected by breast cancer. Several types of interventions have been used to manage psychosocial distress in women with breast cancer but there is no consensus on which type of intervention is the most effective. Nonetheless, it is well established that cognitive behavioural therapy (CBT) is effective for the management of distress, both The Swedish Council on Technology Assessment in Health Care (SBU) [10] and The Norwegian Knowledge Centre for the health Services (NOKC) [11] concluded in their systematic reviews that there is evidence that CBT in proximity to a breast cancer diagnosis is beneficial in preventing future distress disorders. These two reviews included systematic searches for controlled trials in the Cochrane Library, The centre for Reviews and Dissemination database, Medline, EmBase, Chinal, PsychINFO, AMED, PEDro, PsycLit and the Excerpta Mediline [10,11]. Few intervention studies have investigated the effectiveness of CBT-based stress management interventions in a group versus individual setting for patients with cancer. The majority of reported studies using CBT-based interventions utilise a group format and have been compared to a no-therapy control group [12,13]. Accordingly, there has been a call for studies which compare CBT-based stress management interventions in a group versus individual format [10]. There are advantages and disadvantages for interventions in both group and individual settings. Interventions delivered in a group format offer several benefits for both the participants of the group and for the team delivering the intervention (time and cost effectiveness). Benefits for the participants include increased empowerment, improved self-esteem, sense of control, facilitating positive relationships, improved information about cancer and valuing the group context and social support from others in the same situation, which could facilitates the therapeutic progression [14–16]. However, not all individuals like to discuss their problems and feelings in a group and therefore might withdraw from such interventions [17]. Moreover, a review by Osborn and colleagues [13] concluded that individually based interventions were more effective than those delivered in a group setting. There is no consensus on the most effective way of addressing psychosocial problems in a breast cancer population. Therefore, we wanted to evaluate if a CBT-based stress management intervention delivered either in a group setting (group stress management, GSM) or an individual setting (individual stress management, ISM) would improve fatigue and emotional reactivity among women with breast cancer. Data presented here originates from Breast cancer And Stress project (BAS) [18].

Material and methods

Participants

Between May 2009 and August 2011, 901 patients were referred for adjuvant breast cancer treatment, after initial surgery, to the Department of Oncology at Falun, Gävle or Uppsala Hospital (Sweden). Eligible for the study were patients over the age of 18, that had undergone surgery for breast cancer stage I–III and were about to receive adjuvant chemo-, radiation- or hormonal therapy. Exclusion criteria were lack of fluency in Swedish and patients who had serious ongoing psychiatric diagnoses (e.g. psychosis and suicidal tendencies).

Procedure

All eligible women were approached by a study nurse before the oncological treatment and informed about the BAS-study. A week after receiving the initial information, patients were contacted by telephone and asked to participate in the study. Thereafter, a written statement of consent and a questionnaire was sent, with a prepaid return envelope, to the participants. Data were collected at time of inclusion (baseline), three months after inclusion, after the intervention ended and approximately 12 months after the initial assessment (see Figure 1 for details). The assessment at three months served as a screening tool for the intervention. If participants reported levels over the cut-off of ≥ 9 on the Impact of Events Scale (IES) and/or ≥ 11 on the Hospital Anxiety and Depression Scale (HADS) [19,20] three-month post-inclusion, they were contacted a second time by telephone and asked to participate in the intervention. The cut-off levels have previously been validated and are suitable as screening tools for clinical use

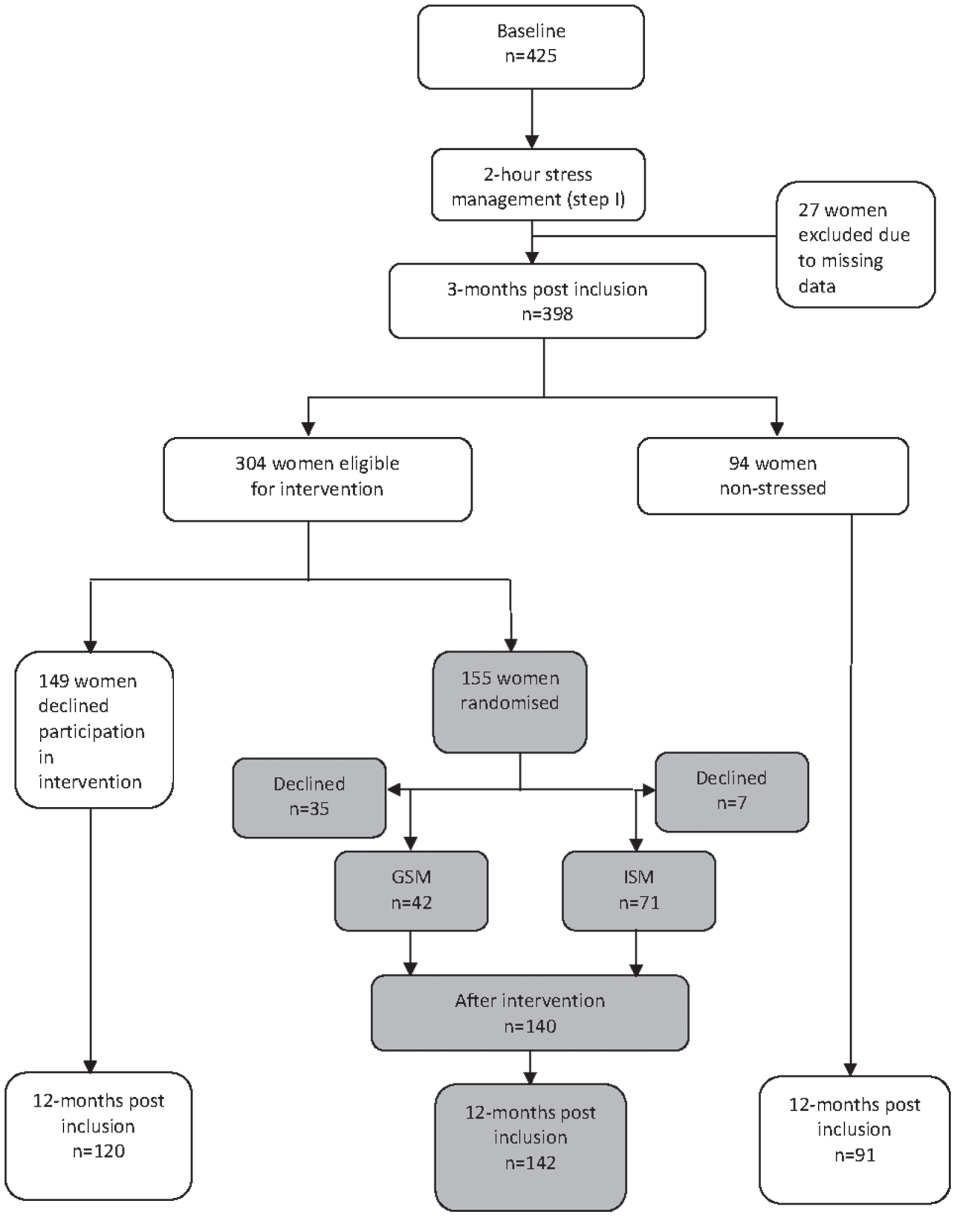

Figure 1. Flowchart of the patients throughout the study. Focus of this paper indicated in grey.

[21]. Randomisation was done in blocks of two to the stress management intervention in either GSM or ISM format. A senior researcher, not involved in the inclusion of participants, performed the randomisation procedure. Participants were not restricted from partaking in community support groups or using the standard help line available to all cancer patients for health-related questions.

Intervention. The intervention was derived and utilised techniques from CBT. Although the two intervention arms, GSM and ISM, differed in their frequency and set up, both the GSM and the ISM were designed to contain the same core components, the same relaxation techniques and homework assignments. The intervention was manual-based and delivered by nurses who were specifically trained in the six components as well as the techniques of the intervention. The training of the nurses was provided over several days and by two instructors who had extensive experience in both training staff as well as in the techniques used. All nurses involved in the intervention were also supervised monthly during the entire study period, in order to offer support on how to handle specific situations which might have arisen during the sessions and also for more general advice. Moreover, the interventions were monitored by audio recording and analysis of intervention sessions to achieve high fidelity of the intervention delivered. In the GSM, sessions 1 and 4 of the second

group were monitored after each nurse had finished their first group in the intervention. In the individual setting, the monitoring was performed during the second session and each nurse was monitored with two different participants. The aim of the monitoring was to ensure that the sessions contained the same core components in both intervention arms. The monitoring was performed by a psychologist trained in CBT with an extensive experience in CBT interventions for cancer patients.

The *GSM* consisted of 10 two-hour sessions over the course of three months. The group sessions were spaced approximately one week apart. Each group consisted of 3–8 participants who were enrolled 4.5–12.8-month post-diagnosis (M = 7.5 months). Each session covered a specific component (see Table I for details) and between the sessions, participants worked on homework assignments addressing the components. These assignments were discussed at the beginning of each session and time was allowed for feedback, both from the group participants and the group leaders. Social support within the group was intended to be an important component of the intervention in order to facilitate therapeutic progression.

The *ISM* consisted of 4–8 one-hour sessions over the course of 4.5 months and the first four sessions contained the six components. Participants were offered additional sessions, if they had unresolved problems which they wanted to address. This decision was made together with the participant to either end the treatment or continue with up to four additional sessions. Participants entered the intervention 4–8.5-month post-diagnosis. Each session covered

Table I. A description of the subjects of the intervention and when they were introduced and discussed in the GSM and ISM, respectively.

GSM sessions	ISM sessions	Subjects	Description	Techniques/Home assignments
1–2	1	*Introduction to stress and stress responses*	Both physiological and psychological responses to stress and the differences between short- and long-term stress were introduced. Common stress responses due to cancer diagnosis were also highlighted.	Relaxation exercise 'the stop button' and a stress diary
3–4	2–4	*Negative thoughts and stress behaviour*	Typical characteristics for stress behaviour and automatic negative thoughts were discussed. Participants used a diary to become aware of and to identify their negative thoughts.	Worksheet to monitor one's actions for thought and behaviour change
4–5	2–7	*Irritability and anger including typical stress behaviours*	The focal point was time urgency and irritability with other people's behaviour. Participants were to identify what are anger, situations and reactions connected to one's own anger reactions, and alternatives to these reactions.	Worksheets to aid identification of situations causing anger and actions for changing these reactions
6–7	2–7	*Quality of life and expectations of life*	Focus was on quality of life and expectations of life post-diagnosis. What was important to each participant, what did they want for their future, and how could they accomplish their goals.	Expressing their thoughts in writing
7–8	3–7	*Reactions to a cancer diagnosis*	This subject dealt with common psychological reactions to a breast cancer diagnosis. The participants discussed how and with whom to share one's thoughts and feelings about the cancer and from whom they want/expect support.	Worksheet for identifying from whom they want/ expect support and actions needed to highlight the need for support
9	3–7	*Sexuality*	Physiological and psychological aspects of breast cancer surgery and treatments in relation to one's identity and sexuality were discussed.	
10	8	*Recapturing*	Finally, key points from previous sessions were recaptured and participants were asked to reflect on aspects of the intervention, which were important and useful to them.	

1–3 components (see Table I) similar to the ones in the group intervention, which were introduced at the beginning of the session. Between sessions, participants were asked to actively work on assignments, which addressed issues dealt with during the past sessions.

Measures

Assessments included both standardised questionnaires and a brief questionnaire to assess patient demographics, e.g. age, income, work situation and children < 18 years of age. Medical data and primary treatments were collected from the Regional Breast Cancer Register of the Uppsala and Örebro Region in central Sweden.

The Multidimensional Fatigue Inventory (MFI-20) [22] was used to assess fatigue. The MFI-20 includes five scales, which correspond to general fatigue, physical fatigue, mental fatigue, reduced activity and reduced motivation. Somatic symptoms of fatigue are not included in the scale in order to exclude symptoms of somatic illnesses, independent of fatigue [23]. This instrument contains 20 statements for which the participant has to indicate the extent to which the statement applies to her on a five-point scale. A total score is calculated for each subscale by adding up the scores for the five individual items. The score for each subscale can range from 4 to 20 and higher scores indicate a higher degree of fatigue. The Swedish version of MFI-20 has been validated and has demonstrated good psychometric properties [24–26].

In addition, the Everyday Life Stress Scale (ELSS) [27] was used to assess emotional reactivity. This instrument was used to assess subjective responses to stressors, principally other people's behaviour. It consists of two major themes, i.e. time urgency/impatience and being easily aroused or irritable/hostile. These characteristics were measured on a four-point scale (0–3) by answering 20 short statements regarding self-rated stress behaviours in everyday life situations, e.g. 'I feel that time is urgent', 'I get irritated when others are fumbling or negligent' and 'People tell me to relax and calm down'. Scores can range from 0 to 60, whereby a higher score indicates more stressful reactions. A five-point increase or decrease is of major significance when used in repeated assessments [7]. The ELSS has been validated in a breast cancer population (in manuscript).

Strategies for analyses

To detect significant differences between GSM and ISM, a total of 64 participants were required for each intervention arm, i.e. a total of 128 participants, according to the power calculation. Intention to treat analysis included all participants in the groups to which they were randomised. Per-protocol analysis included participants who completed the intervention program. Mann-Whitney tests were used to calculate differences between the two intervention groups. Alpha was set at < 0.05 and all probability values were two-tailed. Missing responses in single items were replaced with the mean response for the participant, as long as half of the items were answered on the subscale.

Results

A consecutive series of patients ($n = 821$) were approached and asked to participate. Of those, a total of 395 patients (48%) rejected participation. Of those who stated why they did not want to participate in the intervention ($n = 108$), the most common reason for not participating was that they did not feel distressed (31%), were not able to participate due to other commitments, e.g. a sick spouse (19%) or that they had too far to travel (18%). Some women also stated that they were too busy (16%) or too tired (10%) to participate. Furthermore, 4% said that they did not want to be reminded of the breast cancer and 2% already had the support they needed. One woman was deceased prior to receiving the baseline questionnaire. A total of 425 patients (52%) answered the baseline questionnaire. A flowchart of the study design and patients participating in the study is presented in Figure 1. This study was approved by the Ethics Review Board in Uppsala, Sweden.

At three-month post-inclusion, 304 (72%) women reported elevated levels of distress and 155 (51%) of them were randomised between the two intervention arms, whereas 149 declined randomisation. Of the 77 participants randomised to GSM, 42 (54%) attended the group intervention, completing on average nine of the 10 group sessions. Of 78 participants in the ISM-group, 71 (91%) completed the intervention, on average attending five of eight sessions (mean 5.1 sessions) over the course of 4.5 months.

To determine whether the participants of the intervention and participants who declined the intervention differed significantly, χ^2-analyses and one-way between subjects ANOVA were computed. Three statistically significant differences were found between those who declined participation in intervention and those who participated. The ISM group had a higher number of other health complaints than the participants who declined the intervention χ^2 $(2, N = 302) = 6.260$, $p = 0.044$. More participants in the GSM group received chemotherapy than the other study participants χ^2 $(2, N = 301) = 7.050$, $p = 0.029$ (see Table II for details). Finally, the

Table II. Demographic and medical background data at inclusion for the total study participants and different subgroups in the intervention.

		Intervention		
	Total study participants n = 425 (%)	GSM n = 77 (%)	ISM n = 78 (%)	Declined intervention (not randomised) n = 149 (%)
Age, years				
Mean	59	57	58	59
Minimum-Maximum	29–82	29–78	37–79	32–81
Residential area				
Dalarna	126 (30)	25 (32)	25 (32)	44 (30)
Gävleborg	158 (37)	30 (39)	29 (37)	54 (36)
Uppsala	141 (33)	22 (29)	24 (31)	51 (34)
Social Status				
Annual household income (EUR), mean[a]	55 727	57 742	55 409	53 769
Annual household income (EUR), range[a]	3110 – 167 464	3110– 131 578	13 705 – 131 579	11 483 – 167 464
NHG[b]				
1	80 (19)	11 (14)	12 (15)	33 (22)
2	208 (49)	33 (43)	38 (49)	74 (50)
3	116 (27)	28 (36)	25 (32)	36 (24)
Type of surgery				
Sector resection + ax. surgery	287 (68)	54 (70)	45 (58)	35 (24)
Mastectomy	124 (29)	21 (27)	32 (41)	108 (72)
Adjuvant treatment				
Chemotherapy	211 (50)	49 (64)*	40 (51)	69 (47)
Radiation therapy	313 (74)	59 (77)	55 (71)	111 (75)
Hormonal therapy	233 (55)	39 (51)	45 (58)	83 (56)
Other health complaints	87 (20)	13 (17)	24 (31)*	26 (18)

[a]1 EUR = 8.36 SEK (Exchange rate 4 October 2013); [b] NHG, Nottingham Histologic Grade, range 1–3 (1 = better prognosis, 3 = worst prognosis).
*Statistical significant difference $p < 0.05$.

one-way between subjects ANOVA revealed a significant difference on the levels of reduced activity reported at three-month post-inclusion [$F(2301) = 5466$, $p = 0.05$]. Tukey's post-hoc test, showed that those who declined participation in the intervention reported significantly less reduced activity than participants in both of the intervention arms (see Table III for details).

The intention to treat analysis revealed no significant changes over time (3-month post-diagnosis to 12-month post-diagnosis) for the two intervention groups (data not shown). Moreover, there were no significant differences between the GSM and ISM interventions on fatigue and emotional reactivity (data not shown). The per-protocol analysis showed similar findings with no significant changes over time (3-month post-diagnosis to 12-month post-diagnosis) or differences between the two intervention groups on any of the outcome variables. Median values for MFI-20 and ELSS subscales at the different assessments points are presented in Table III.

Discussion

In the current study, we examined if there were differences in fatigue and emotional reactivity among women with breast cancer after attending a stress management delivered either in a group or individual setting. No significant differences were detected between the two intervention groups.

One aspect, which surprised us in the study, was the rather low interest in a psychosocial intervention among women with a newly diagnosed breast cancer. Only about half of the women who reported elevated levels of distress at three-month post-diagnosis accepted participation in the intervention. Women who rejected participation did not differ significantly from the women who accepted participation in the intervention on any of the outcome variables except for that they reported more elevated levels of reduced activity. However, the absolute difference of means was small (0.8).

A majority of the women who rejected participation stated that they did not feel the need for a stress management intervention as they were not distressed (contrary to the elevated levels of distress reported when screened) which is a clinically important finding. Furthermore, 18% stated a long distance from home to the hospital and therefore did not want to travel, especially during the winter months, which is not surprising considering the geographical catchment areas of the hospitals in the study. It is

Table III. Mean (SD) and median (range) for subgroups of study participants on the MFI and ELSS subscales at inclusion, 3-month post-inclusion and 12-month post-inclusion.

	Group intervention (randomised)	Individual intervention (randomised)	Declined intervention (not randomised)
Inclusion	M(SD)/Median(Range) n = 77	M(SD)/Median(Range) n = 78	M(SD)/Median(Range) n = 149
MFI–20[a]			
General fatigue	11.4 (2.2) / 11.0 (5–20)	11.6 (1.9) / 12.0 (6–16)	11.0 (2.3) / 11.0 (4–19)
Physical fatigue	12.6 (2.2) / 13.0 (4–19)	12.5 (1.8) / 12.0 (8–18)	12.1 (2.2) / 12.0 (4–20)
Mental fatigue	11.2 (1.9) / 11.0 (6–15)	11.0 (1.9) / 12.0 (6–15)	11.3 (1.8) / 12.0 (4–16)
Reduced activity	12.9 (1.8) / 13.0 (9–20)	12.4 (1.8) / 12.0 (7–18)	12.9 (1.8) / 13.0 (8–18)
Reduced motivation	13.1 (2.2) / 13.0 (7–19)	12.6 (2.2) / 12.5 (7–18)	13.2 (2.3) / 13.0 (7–19)
ELSS[b]	18.4 (10.4) / 18.0 (0–47)	19.1 (11.7) / 19.0 (1–48)	16.4 (11.6) / 13.0 (0–50)
3-month post-inclusion	n = 77	n = 78	n = 149
MFI–20[a]			
General fatigue	11.3 (2.2) / 11.0 (6–20)	11.1 (1.9) / 12.0 (4–17)	11.0 (1.9) / 11(5–19)
Physical fatigue	12.5 (1.7) / 12.0 (8–17)	12.5 (1.7) / 12.0 (4–18)	12.3 (1.9) / 12.0 (5–17)
Mental fatigue	11.0 (1.8) / 11.0 (6–15)	11.2 (1.9) / 12.0 (5–15)	11.2 (2.1) / 12.0 (4–17)
Reduced activity	13.4 (1.9) / 13.0 (9–18)	13.1 (1.8) / 13.0 (8–16)	12.6 (1.8) / 12.0 (8–19)*
Reduced motivation	13.1 (2.2) / 13.0 (7–18)	12.9 (2.4) / 13.0 (6–19)	12.8 (2.2) / 13.0 (5–18)
ELSS[b]	19.0 (10.2) / 16.0 (0–44)	19.6 (12.6) / 19.0 (0–53)	16.6 (12.2) / 15.0 (0–50)
12-month post-inclusion	n = 70	n = 72	n = 120
MFI–20[a]			
General fatigue	10.9 (2.0) / 11.0 (4–16)	11.2 (2.1) / 11.0 (4–16)	11.1 (1.8) / 11.0 (5–15)
Physical fatigue	12.2 (1.5) / 12.0 (9–16)	12.5 (1.9) / 13.0 (4–17)	12.1 (1.8) / 12.0 (7–17)
Mental fatigue	11.0 (1.9) / 11.0 (5–15)	11.3 (2.1) / 12.0 (4–16)	11.0 (1.9) / 11.0 (5–20)
Reduced activity	13.0 (1.8) / 13.0 (9–17)	12.9 (2.1) / 13.0 (4–18)	12.8 (1.6) / 13.0 (7–17)
Reduced motivation	12.6 (2.0) / 13.0 (8–17)	12.6 (2.5) / 13.0 (4–18)	12.6 (2.1) / 13.0 (5–17)
ELSS[b]	21.0 (12.2) / 21.0 (0–50)	19.1 (12.2) / 18.5 (0–53)	16.6 (12.2) / 14.5 (0–50)

[a]Scores 4–20; [b]Scores 0–60. *Statistical significant difference $p < 0.05$.

noteworthy that only 2% stated that they already had the support they needed and were therefore not interested in the intervention. Moreover, we found it especially difficult to recruit participants to the group intervention. Only 54% of the women who were randomised to the group intervention attended, and almost all of the non-attendees declined participation after the randomisation and prior to the first group session. Few women declined participation after the first group session, thus, once the women had attended the group session they tended to continue. Non-attendees of the group stated that they were hesitant to attend because they did not know the other group participants or did not want to discuss private matters in the group or for practical reasons, i.e. too far to travel. These kinds of problems have previously been reported in other studies. For example, Ussher et al. [17] investigated reasons for leaving or not attending support groups and found that practical issues, such as lack of time and work schedules, were often reported as reasons for not attending the group. The second most common reason for not attending a support group in Ussher et al.'s study [17] was having moved on emotionally. Groups may also be perceived as something that is for 'other people' with more need for support. Furthermore, participants who prematurely left a support group reported that the reason for leaving was that they did not like the atmosphere of the group and wanted 'people like me' in the group [17].

The findings from the present study indicate that both in future studies and in interventions which are to be implemented at clinics, it is important to consider the possible recruitment problems and other issues related to participation. For example, participation in interventions should be facilitated by the aid of accessibility and closeness to the participant. One suggestion could be to investigate the possibility of an internet-based intervention. There is strong evidence that internet-based CBT-interventions are as effective as traditional face-to-face interventions using the same techniques [28]. Furthermore, the recruitment problems in the group intervention in the present study lengthened the inclusion process and indicate that preference can be a key factor in determining the composition of the study and in particular the effectiveness of the intervention. Although randomised controlled trials are considered the gold standard in research future research should focus on evaluating interventions where the intervention mode is based on the preference of the participant. Preference trials allow at

least a subgroup of participants to select the treatment they would like to receive. Individuals who do not want to risk being randomised to an intervention arm which they consider undesired, may decline study participation therefore preference-based trials may improve the inclusion rate and participation compliance in an intervention. Research indicates that participants who have a choice are more likely to attend interventions than those participants who are randomised [29]. An aspect especially important to consider when offering interventions based on CBT, as these interventions require an active role of the participant. Moreover, for the clinical setting preference can be a key factor which should be considered as patients in general are more active in healthcare decisions than previously and preference trials are not well studied in the health education field.

Although there were no significant differences between the two intervention groups or changes over time, this study has several strengths. Firstly, all nurses were well trained in all of the components and the techniques used in the intervention prior to the start of the study. The intervention was manual-based and both the intervention arms contained the same core components. To ensure high fidelity, the interventions were monitored, with the monitoring taking place during the same session for all nurses to ensure that the intervention followed the manual. Furthermore, another strength of the study is that it is a multi-centre study. Participants were consecutively recruited from three hospitals to which all breast cancer patients from the catchment area are referred. The consecutive inclusion from these three hospitals is believed to have minimised the selection bias concerning the inclusion of the participants.

Study limitations

A limitation of the study was the lack of a control group. A control study was not included since methods from CBT have already been shown not only to reduce risk for PTSD [10] but also have a positive effect on quality of life and psychological wellbeing [28]. Moreover, the study did not aim at evaluating the intervention per se, rather we set out to evaluate the mode of delivery (group vs. individual). Thus, it is not possible to draw any conclusions from the results except that there are no differences between the two intervention arms or changes over time. Moreover, it cannot be excluded that the lengthy inclusion process and the low attendance rate, especially for GSM, might have introduced a selection bias of the participants that might have affected the outcome of this study.

Furthermore, it is important to consider the intervention per se. Although the intervention was well planned and monitored, it is possible that the intervention was too manual oriented and too focused on the components. An inexperienced group leader might have focused only on the components and subjects of the intervention and may not have been able to utilise the process of the therapy.

Conclusions

The results of the present study showed no significant differences between the two intervention groups or changes over time in either group; however, a clinically interesting finding was the low number of women who were interested in participating in a psychosocial intervention. This finding may have clinical implications when psychosocial support is offered to women with a newly diagnosed breast cancer and also in the planning of future studies.

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