Effects of delayed psychosocial interventions versus early psychosocial interventions for women with early stage breast cancer

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Abstract

Objective: The importance of psychosocial counselling after a diagnosis of cancer has been acknowledged and many intervention studies have been carried out, with the aim to find out which types of intervention are most effective in enhancing quality of life in cancer patients. A factor which could be part of effective counselling could be the time of offering psychosocial counselling. The aim of this study was to research the effect of time of enrolment in a psychosocial group intervention on psychosocial adjustment.

Methods: In the present study, 67 women with early stage breast cancer were randomised in a psychosocial group intervention program starting within 4 months after surgery or in the same intervention program starting at least 3 months later.

Results: The main conclusion of this study is that women who started with their intervention early were less distressed at 6 months follow-up than women who were in the delayed condition. Medical and demographic variables were predictive for some psychosocial adjustment indicators, but were not associated with time of enrolment. Regardless of time of enrolment, women improved in distress, body image and recreational activities, but showed a decrease in social interaction.

Conclusion: Though results are limited, based on these results we suggest that psychosocial counselling should be offered as soon after diagnosis or surgery for breast cancer.

Practice implications: Women diagnosed with primary breast cancer should be able to start with psychological counselling soon after being diagnosed, to prevent them from becoming distressed at long term.

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1. Introduction

Medical treatment of breast cancer has improved significantly in the past decades. Consequently, patients live longer and the character of the disease has changed [1–3]. Yet, being diagnosed with breast cancer is still experienced as life threatening, often accompanied with psychosocial problems [4–7]. Acknowledging these problems, many psychosocial intervention programs have been developed and tested [8–11]. Its effectiveness in reducing emotional distress and improving coping abilities has been demonstrated in many studies [8–11].

The literature on interventions especially designed for women with breast cancer is extensive, with mixed results. Positive results were reported by Spiegel et al. [12]. Not only did the women who participated in the psychosocial support group live longer, they also reported a decline in psychological distress compared to women in the control group. Other intervention studies among women with breast cancer report only significant improvement of psychosocial adjustment just after the intervention is completed [13–15],...
which sometimes was not enhanced at follow-up a few months later [14]. In other long-term studies, the improvement was only slightly at the end of the intervention, but significant at follow-up [16–18]. These studies do not only report changes over time, but also in comparison with a control group [12,15,18]. However, not all intervention studies show positive results. An intervention study by Edmonds et al. [19] yielded a slight positive change in distress, but this change was noted in both participants and non-participants. In a study of Winick and Robbins [20], there were changes in distress, but these changes were mainly due to type of surgery and age, rather than to the interventions in which women participated. In another part of the recent study, we found that women who participated in an intervention program did not differ just after completion of the intervention from women who were on a 3 months waiting list and who were about to start with the intervention program [21].

A possible reason for these inconsistencies could be the differences in time in which the interventions have been offered. Some studies are limited to patients who are newly diagnosed [8,11,22,23] or to patients who recently had surgery [15], while in other studies time since diagnoses was not an inclusion or exclusion criterion [7,12,22,24]. It should also be noted, that time since diagnosis is not always mentioned [13]. Bloom and Kessler [25] suggested that early intervention could be important, because women are at risk for significant depression and mood disturbances in the first months after surgery. However, they also reported that women who did not receive any kind of counselling, were better adjusted 12–15 months after surgery than they were within 3 months after surgery. In a study by Edgar et al. [26] amongst patients with cancer of various sites, time of starting the intervention did not appear to be significant. Both participants of the early and of the late starting interventions reported significant improvement in psychosocial adjustment. There were no differences in therapy outcome for the early and delayed intervention.

The present study investigates the effects of a psychosocial group intervention for women with early stage breast cancer starting within 4 months after surgery or at least 3 months later. When the intervention starts within 4 months after surgery, we called it an early intervention. Most women in our study group who were assigned to this condition, were still under medical treatment or had just finished it. The intervention consists of an experiential existential group psychotherapy or participation in a social support group condition. These two forms were combined, because we could not demonstrate differences in intervention outcome as reported earlier [27]. The present part of the study focuses only on the effect of time of enrolment in a psychosocial group intervention on psychosocial adjustment. In addition, we describe whether demographic and medical variables are associated with psychosocial adjustment both at short term and at long term.

2. Methods

2.1. Subjects and procedures

Patients were recruited from several hospitals in the region of Rotterdam, The Netherlands. Eligible women were between 18 and 70 years of age, had surgery for primary breast cancer no longer than 4 months ago at the time of the first contact, had no distant metastases, sufficient knowledge of the Dutch language, and no psychiatric illness. They were informed about the study by an oncology nurse, who also judged the absence of psychiatric illness. Women were told that they would be randomly allocated to one of four conditions after the first interview: early start or starting after a waiting period of several months, and experiential existential group psychotherapy or social support group. If a woman was not motivated to participate, she could indicate this by returning an answering-form. If not returned within 3 weeks, the investigator attempted to contact the women by telephone. If they consented, an appointment was made for the first interview. During this interview, women were asked to sign a written informed consent and a set of questionnaires was handed over. Women were asked to complete these questionnaires at their earliest convenience.

After receiving the questionnaire, a patient was randomised into one of two conditions: early start or late start of the intervention. The intervention programs lasted 3 months. There were three measurements for all participants: the first was before randomisation (T0), the second just after completion of the intervention (T1) and the final measurement 6 months after completion of the intervention (T2).

2.2. Variables and instruments

Medical and demographic data were obtained from a questionnaire containing anamnestic questions (size of tumor, date of diagnosis and surgery, type of surgery (i.e. mastectomy or breast conserving therapy), number of affected lymph nodes, adjuvant therapy) and demographic questions (age, education, marital status, work status). The oncology nurse, who referred patients to the researcher, checked the information in medical records.

Psychosocial adjustment was measured with the Dutch version of the, Profile of Moods States (POMS), containing the subscales Depression, Anger, Fatigue, Tension, and Vigour [28], with the subscale Body Image and Sexual Functioning of the breast cancer specific module (QLQ-BR32) [29] of the EORTC QLQ-30 [30], and the subscales Recreation and Social Interactions of the Sickness Impact Profile (SIP) [31].

More information about the used questionnaires is described elsewhere [21,32].

All data, with the exception of the subscale Recreation of the SIP were collected at all measurements. The subscale Recreation of the SIP was only included at T0 and T1.
2.3. Interventions

In both types of interventions, women met for 12 weeks for 2.5 h. After the regular weekly sessions, two follow-up sessions were scheduled, 1 and 2 months later. Both groups were closed groups in which 6–10 women could participate. The groups were led by two trained group leaders, of which at least one had to be a woman.

The psychotherapy group was based on Experiential-Existential premises [33], enriched with cognitive Behavioral components [34], which was adapted for women with breast cancer. A specific manual was developed for this group [35]. Therapists who lead this group were familiar with this kind of therapy and were trained in how to lead a group in a study design.

The social support group had no specific manual. It was designed to let breast cancer patients share their mutual experiences with respect to the diagnosis and treatment for breast cancer. Group leaders were especially trained by the Comprehensive Cancer Center to lead this kind of group. They could ask for intervention and feedback from the trainer during the study period.

The topics discussed in each of the intervention were not fixed beforehand per session, but were chosen by the group members themselves. They had to choose the topic from a list of topics (see Box 1). Both interventions were already used in standard care. They are described in more detail elsewhere [27].

2.4. Statistical analyses

Missing data on item level were imputed if no more than 25% of item scores for a particular subscale and a particular participant were missing and if a subscale consisted of at least four items. The mean score of the remaining item scores of the pertinent person on the subscale at issue was multiplied by the mean of the scores of the other participants on that particular item. This score was then divided by the overall mean of that subscale.

Because of the high ratio between dependent variables and the number of participants, we limited the number of variables in the analyses. Intercorrelation coefficients were determined for subscales of the POMS. In case of sufficiently high intercorrelations, Principal Component Analyses were performed on the subscales of the POMS. This procedure has been described in more detail elsewhere [32].

Difference between the groups (early start versus late start) with regard to demographic and medical variables and with regard to the baseline values of psychosocial adjustment were tested with univariate analyses of variance (ANOVA) for the continuous data and Chi-square analyses for ordinal data.

The intervention effect was analyzed with univariate analyses of covariance (ANCOVA). These analyses were performed on all outcome variables at T2, using the baseline values (T0 values) of the corresponding variable as covariates and time of enrolling in the intervention (early start or late start) as the independent variables.

In addition, we used a more subtle method, namely, Random Regression Modelling (RRM) to simultaneously estimate the effect of passage of time, time of enrolling in the intervention (i.e. early or delayed start of the intervention), type of intervention (experiential existential group psychotherapy or social support group), age, type of surgery and stage of the disease on all outcome variables. RRM has many advantages above repeated measures ANCOVA and ‘classical’ regression analysis: it allows for missing data or an unequal number of data for each subject, and for the inclusion of fixed and time varying covariates. Furthermore, a realistic covariance structure (as opposed to compound symmetry or independence between repeated measures) can be implemented [36].

We run two series of analyses with each six different, corresponding tests. The first series focuses only on therapy effect and included time, time of enrolment and type of intervention as predictors. Of the six tests, time was incorporated as a fixed term (the slope of all individuals are equal) in three analyses and as a random term (slopes of individuals are specific per individual) in the other three. One analysis considered time as a linear variable, the second type included the time-square variable as a predictor and the third analysis added two interaction terms: time of enrolment and type of intervention, as one expects different changes over time in adjustment levels for the treatment modalities time of enrolment and type of intervention.

The second series of model testing were the same as the first (thus, six models were tested for each outcome variable).

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**Box 1. Topics to be discussed in intervention**

Topics which should be discussed in the psychosocial group interventions

| First session | • Introduction  
| • Rules of the group  
| • Feeling safe in the group |
| All other sessions | • Personal meaning of having (had) cancer  
| • Fear of recurrence  
| • Coping with feelings of uncertainty and control  
| • Coping with emotions  
| • Self image  
| • Body image  
| • Sexuality  
| • Intimacy  
| • Asking for social support  
| • Giving social support  
| • Coping with the partner  
| • Coping with other relatives  
| • Coping with the past  
| • Saying goodbye/farewell  
| • Holding on to changes  
| • Going on without going to ‘the group’ |
with the incorporation of the variables ‘age’, ‘stage of the disease’ and ‘type of surgery’.

The maximum likelihood method was used to test which model fitted best. A model was decided to have a better fit, if the maximum likelihood was at least significant better than the previous model [36]. All significant testing was fixed at 0.05 (two-tailed).

3. Results

3.1. Sample characteristics

Two hundred and fifty-one eligible women were contacted by the investigators by telephone. Initially, 104 women (41.4%) agreed to participate. These women were interviewed. Finally 87 (34.7%) women enrolled into the study. The reasons for not participating of 164 women were: (1) not interested (N = 26), (2) having enough support (N = 26), (3) being too emotionally distressed (N = 14), (4) could not be reached by telephone (N = 19), (5) other reasons such as distance and time (N = 27), and (6) unknown (N = 52). It is not known whether non-participants differ from participants, since no data were available from women who refused to participate.

Of the 87 women who started the study, 67 women (77.0%) completed the study. Of the 20 women who dropped out, 1 woman died, for 2 women attending a group became too emotional, 3 women were too ill to attend group meetings, for 1 woman the group meetings were not what she had expected, and 13 women did not feel like participating anymore without giving further reasons. Women who stopped participating, were significantly older (53.2 years; S.D. = 7.21 years) than women who continued participation (49.0 years; S.D. = 7.92 years). They did not differ on other demographic, medical and baseline outcome variable.

Of the 67 participants who completed the study, 20 women had affected lymph nodes. Most participating women had a mastectomy (65.7%). Three of them had had a breast reconstruction at T0. The mean age was 49.0 years (range = 29–68 years; S.D. = 7.92 years). Most women had finished secondary school as their highest education (67.1%). Fifty women had a partner, six of whom were not living with their partner. Of the 16 women who were single, 3 were never married, 10 were divorced and 2 women were widowed. Medical and demographic data are summarized in Table 1.

Of the 67 women participating, 33 were assigned to the early start of the intervention program, while the other 34

<table>
<thead>
<tr>
<th>Table 1 Medical and demographic characteristics</th>
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<tr>
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<tr>
<td>Early start (N = 33)</td>
</tr>
<tr>
<td>Time between surgery and T0 (weeks)</td>
</tr>
<tr>
<td>Mean</td>
</tr>
<tr>
<td>Stage</td>
</tr>
<tr>
<td>0</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>Missing</td>
</tr>
<tr>
<td>Number of affected lymph nodes</td>
</tr>
<tr>
<td>0</td>
</tr>
<tr>
<td>1–4</td>
</tr>
<tr>
<td>&gt;4</td>
</tr>
<tr>
<td>Missing</td>
</tr>
<tr>
<td>Type of surgery</td>
</tr>
<tr>
<td>Breast conserving therapy</td>
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<tr>
<td>Mastectomy</td>
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<tr>
<td>Age (years)</td>
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<tr>
<td>Mean</td>
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<td>Highest education</td>
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<tr>
<td>Primary school</td>
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<tr>
<td>Secondary school</td>
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<tr>
<td>Higher education</td>
</tr>
<tr>
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</tr>
<tr>
<td>Missing</td>
</tr>
</tbody>
</table>

215
were assigned to the delayed start condition. Of the 33 women who were assigned to the early starting intervention condition, 19 participated in the group psychotherapy condition and 14 in the social support group condition. Of the women who were assigned to the delayed interventions, 16 participated in the psychotherapy group intervention and 18 in the social support group. The mean time since surgery for women who started in the early intervention was 19.6 weeks (S.D. = 9.03 weeks) and for the women of the delayed intervention it was 31.9 weeks (S.D. = 7.41 weeks).

Women who started their intervention early did not differ on any demographic, medical or baseline variable from their counterparts who participated in the delayed intervention condition.

3.2. Data reduction

Intercorrelation coefficients were determined for the subscales of the POMS. Intercorrelations of the POMS subscales (r ≥ 0.35) were all statistically significant. Therefore, a Principal Component Analysis with Varimax Rotation was performed on the subscales of the POMS, which resulted in a two-dimensional solution. The first dimension represents Level of Distress and comprised the subscales Depression, Anger and Tension. The second dimension is composed of the subscales (reverse of) Fatigue and Vigour and represents Vitality. For both components, the means were calculated and used in the following analyses.

3.3. Impact of time of enrolment

The ANCOVAs showed that time of enrolment in the intervention is significant associated with distress at T2. Those who enrolled later in the intervention, appeared to be more distressed at follow-up than women who start with the intervention earlier (p = 0.03), controlling for baseline differences (see Fig. 1). After completion of the intervention (T1), this difference was not significant.

3.4. Changes over time

As indicated, we have tested two series of models: one with therapy predictors and another series that incorporated also medical and demographic variables. The fit of the more comprehensive models was always significant better (p ≤ 0.05) than for models without medical and demographic variables. Models in which time was assumed to be fixed were best fitting for some outcome variables (Body Image, Sexual Functioning and Recreation), whereas for other variables incorporating time as a random factor yielded the best fitting model. Models that included interaction terms were not significantly better than models without these terms.

As can be learned from Table 2, there were significant changes in Body Image and Recreation: changes over time in Distress, Body Image, Social Interactions and Recreation; Body Image improved and the number of recreational activities increased. There were also some non-significant changes in Distress and Social Interactions: distress and the number of social interactions decreased over time. None of the therapy modalities (time of enrolment and type of intervention) had any effect on outcome variables. Of the three additional predictors, age and type of surgery, had an effect on psychosocial adjustment. Older women and women with breast conserving therapy reported a more positive body image than younger women and women who had a mastectomy. In the same line, breast conserving therapy was also associated with better sexual functioning. Women with a more positive stage of disease reported better sexual functioning compared to women with a more unfavorable stage, although this effect was not significant.

Table 2
Estimation of adjustment variables by explanatory variables

<table>
<thead>
<tr>
<th>Explanatory variables</th>
<th>Adjustment variables</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Distress (t)</td>
</tr>
<tr>
<td>Time</td>
<td>−1.59</td>
</tr>
<tr>
<td>Time of enrolling in the</td>
<td>0.95</td>
</tr>
<tr>
<td>intervention</td>
<td></td>
</tr>
<tr>
<td>Type of intervention</td>
<td>−0.61</td>
</tr>
<tr>
<td>Age</td>
<td>−1.12</td>
</tr>
<tr>
<td>Type of surgery</td>
<td>1.20</td>
</tr>
<tr>
<td>Stage of disease</td>
<td>0.22</td>
</tr>
</tbody>
</table>

Significant at p ≤ 0.05.
4. Discussion and conclusion

4.1. Discussion

We tested whether women who were diagnosed with a primary breast cancer, benefited more from a psychosocial group intervention program when it was offered within 4 months after surgery compared to participation at least 3 months later.

We found that women offered the intervention at a later point in time were significantly more distressed 6 months after completion of the intervention compared to women who started within 4 months after surgery. This result suggests that women with early stage breast cancer should be able to get psychosocial counselling early after surgery, rather than waiting until a later moment.

Age, stage of the disease and type of surgery were associated with some of the psychosocial adjustment variables, but not with the time of offering the intervention. Our results are in line with results reported by Dunn et al. [37], who noted that women who were visited by a volunteer who had had breast cancer benefited more from this supportive visit when they were still in hospital then when the visit took place at a later point in time. Our result seems to contradict the findings of Bloom and Kessler [25] who found that after 12–15 months after surgery women were better adjusted than just after surgery. In the present study, follow-up was only 6 months and no changes could be reported. It could be that at 12 months follow-up, women are changed in a positive way. Bloom and Kessler advised to offer psychosocial intervention at a more distant time from surgery (i.e. after 9 months). However, based on the presented results, we cannot confirm the results of Bloom and Kessler. Finally, Edgar et al. [26] found no differences between different times of starting psychological interventions. They reported that, regardless of intervention timing, all women with breast cancer experienced lower levels of distress at 12 months follow-up. In line with the present study, they found no relationship between distress level and the patients’ stage of illness.

Knowing that time of enrolment in the intervention was of no significance for the outcome at 6 months follow-up for most psychological adjustment variables, we also studied whether patients’ psychological adjustment had changed over time. In our study sample, a weak relationship between Distress and Time and Social Interactions and Time exist: at follow-up women are less distressed and report less social interactions. The change over time in Body Image and Recreation was significant: both psychosocial adjustment indicators improved at follow-up. Results of other studies on therapy effect are sometimes similar [18,19,38], whereas in a study of Anotoni et al. [16] participants reported less depressive symptoms, but not an improvement in distress. A decline in depressive symptoms was also found by Youssef [13], but in his study sample participants fell within the range of depressed out-patients, while our study sample consisted of women who were well adjusted psychosocially at the start of the study. Other studies also report significant positive changes, though these changes were sometimes found in both the intervention and the control group [15,39] or were only short term [14,40]. In the study of Heinrich and Coscarelli Schag [39], the observed changes were only for psychological adjustment and not for level of activity, while our results suggests an improvement in recreational activities.

A second aim of the present study was to find out whether demographic and medical variables were associated with psychosocial adjustment at follow-up. Age appeared to be associated with Body Image: older women reported a more positive body image than younger women do. As expected, women who underwent a mastectomy reported a low body image at follow-up and had more problems with sexual functioning. This was also found in other studies among women with breast cancer [6,41].

A limitation of the present study could be that finally 26.7% of all eligible women completed the study. Although this is not a very high participation percentage, it confirms what is reported in other randomised intervention studies, which fully describe the number of eligible patients and the number of patients who completed the study [19,26,42]. Randomised studies with higher participation rates usually do not describe how many eligible patients were invited to participate or how many eligible patients were reached by other means [12,15,18,43]. These studies give, in our opinion an underscore of the real number of eligible patients. We stress that the women of our study are representative for women who are diagnosed with breast cancer and are willing to participate in a psychological intervention program.

Another limitation of the present study could be the short time between the start of the two interventions (3 months). Bloom and Kessler [25] suggested at the end of their study that it would be preferable that cancer patients would start in an intervention program at least 9 months after surgery and not as soon as possible. However, results of other studies [44,45] suggest that patients who do not participate in a psychosocial intervention, show a decline in psychological adjustment [44,45]; Telch and Telch [44] did even attributing the found therapy effect mainly to this decline. To study whether Bloom and Kessler [25] were right with their conclusion, or whether patients should be offered psychosocial counselling as soon after surgery as possible, the ideal situation would be one in which one group of women would start with their intervention within 3 months after surgery and one group starting the intervention about 9–12 months after surgery, because many patients have the strength themselves to adjust psychosocially rather well. However, the delay in the present study was set to a maximum of 7 months because of ethical reasons. During the time in which the women could not participate in the intervention groups, they were not offered any kind of counselling, apart from the standard support they would receive from their hospital. Neither did they receive any kind of information or education about breast cancer from the
researchers in the mean time. It was viewed unethical to withdraw women too long from psychosocial counselling.

4.2. Conclusion

We may conclude from this study, that the time of offering a psychosocial intervention program, no matter whether it is a group psychotherapy intervention or a social support group, to women suffering from breast cancer, is not related with changes in psychosocial adjustment. Passage of time was only related with Recreation and Body Image, and seems only to be weakly related with Distress and Social Interactions. However, those women who started in the delayed psychosocial intervention program, were more distressed at follow-up than women who started within 4 months after surgery.

4.3. Practice implications

Based on these results, we could suggest that women should be able to start with a psychosocial intervention program as soon as possible after surgery, to prevent them from becoming distressed. However, since in this study the delay in starting in an intervention was short (only 3 months), and our study sample was not that large, we recommend to test this suggestion in a larger study sample and with a longer delaying period.

References


