

QUALITY OF LIFE

Changes in quality of life in patients with breast cancer

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Aim. To describe and compare changes in quality of life in two groups of patients with breast cancer and to identify factors predicting negative changes in quality of life within six months.

Background. Women with breast cancer suffer from various treatment side-effects, from psychological and social symptoms as well as decreased quality of life, creating a need for support that may persist throughout the breast cancer experience.

Design. This six-month longitudinal study involved a sample of 164 women, who were quasi-randomized between intervention ($n = 85$) and control groups ($n = 79$) after breast cancer surgery. Intervention group received support and education via telephone one week after the breast cancer surgery and face-to-face support six months after the surgery. Quality of life was estimated one week and six months after breast cancer surgery, using the Quality of Life Index - Cancer Version (QLI-CV) and the European Organisation for Research and Treatment of Cancer Breast Cancer - Specific Quality of Life questionnaire (EORTC QLQ-BR23).

Method. Data were analysed statistically using descriptive statistics and non-parametric tests. Factors predicting negative changes in quality of life within six months were investigated using logistic regression models with the enter method.

Results. Significant group difference in the magnitude of changes within six months was found in future outlook. Logistic regression analyses revealed six significant predictors of negative changes in quality of life within six months: education, employment status, having underaged children, chemotherapy, radiotherapy and hormonal therapy.

Conclusion. The results of this study underline the importance of identifying quality of life changes in patients with breast cancer and paying attention to those women with difficulties in adapting to being a cancer survivor.

Relevance to clinical practice. The findings of this study provide evidence which may help to create appropriate supportive interventions for both acute and long-term settings.

Key words: breast cancer, nurses, nursing, quality of life, women

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Introduction

Breast cancer has been the most common type of cancer for women in Finland since the 1960s. In 2008, an estimated

4200 new cases were diagnosed and the numbers are rising. Currently, one in nine Finnish women is expected to develop breast cancer during their lifetime. Although breast cancer is one of the leading cause of cancer deaths among Finnish

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women, mortality has increased only marginally since the early 1990s. Almost 90% of patients with breast cancer are still alive five years after receiving the diagnosis. The high survival rate is primarily attributable to improvements in prognosis and treatments (Finnish Cancer Registry 2007). The evidence also suggests that experiences and side-effects of breast cancer treatments (Rustoen & Begnum 2000) and the importance of quality of life (QOL) items (Rustoen *et al.* 1999) and QOL change over time (Engel *et al.* 2004, Maeda *et al.* 2008).

QOL assessments have become increasingly important in medicine, nursing science, sociology and psychology (O'Boyle & Waldron 1997). However, QOL is context dependent and therefore somewhat problematic, because it means different things to different people (Farquhar 1995). There is no single, universally accepted definition for the concept of quality of life (Joyce *et al.* 1999, Rustoen *et al.* 1999). The theoretical framework adopted in this study is based on Ferrans's definition, according to which QOL is 'a person's sense of well-being that stems from satisfaction or dissatisfaction with the areas of life that are important to her'. Ferrans's conceptual model is composed of four QOL domains: health and functioning, socio-economic, psychological and spiritual and family (Ferrans 1990).

The high prevalence of physical and psychological morbidity after breast cancer is well documented. In early breast cancer, the combined effects of breast surgery and its oncological treatments can cause dramatic changes in women's physical and psychosocial well-being and their QOL (Badger *et al.* 2004, 2007, Engel *et al.* 2004, Ganz *et al.* 2004, Avis *et al.* 2005, Burgess *et al.* 2005, Montazeri *et al.* 2008, Turgay *et al.* 2008, Salonen *et al.* 2009, Karakoyn-Celik *et al.* 2010). Patients with breast cancer often suffer from anxiety, depression (Badger *et al.* 2004, 2007, Burgess *et al.* 2005), stress, uncertainty (Sammarco 2001) and decreased physical and social functioning (Engel *et al.* 2004), which may all have an influence on how women cope with breast cancer and on their QOL several years after the diagnosis and treatments (Badger *et al.* 2004, 2007, Engel *et al.* 2004, Burgess *et al.* 2005).

Younger women are more likely to have emotional distress, breast cancer-specific concerns, symptoms of depression and disease-specific intrusive thoughts (Wentzel *et al.* 1999, King *et al.* 2000). In our earlier study, we found that women younger than 55 years had significantly poorer QOL in body image and in breast and arm symptoms compared to those aged 55 or over. Furthermore, age emerged as one of the strongest predictors of poor QOL in the global Quality of Life Index (QLI) score, health and functioning, socio-economic and family subscales (Salonen *et al.* 2009). Youn-

ger women often have to contend with very different issues and problems than older women, including concerns about having children when faced with a life-threatening illness, premature menopause leading to fertility loss, postmenopausal symptoms, greater concerns about sexuality and more career and work concerns (Andrykowski *et al.* 2000, Sammarco 2001, Avis *et al.* 2005). Most recently, Wyatt *et al.* (2008) found that older women fared better than younger women in physical and emotional well-being. Further, Rustoen *et al.* (2000) reported that the family's health was the least important to the youngest age group and job/unemployment the least important to the oldest group.

QOL is also affected by type of surgery. Several studies have reported less QOL disturbance with breast conserving therapy compared to total mastectomy, especially in relation to body image scores and sexual functioning (King *et al.* 2000, Engel *et al.* 2004). According to the study by Engel *et al.* (2003), the extent of axillary surgery significantly contributes to arm problems, and patients without arm problems had better QOL over five years than those with arm problems. Studies focusing on adjuvant treatments have reported negative effects on body image, psychosocial well-being (Kayl & Meyers 2006), physical function (Arora *et al.* 2001, Watters *et al.* 2003), role function, social function and global health status during adjuvant chemotherapy (Watters *et al.* 2003). In a recent study, Turgay *et al.* (2008) found that chemotherapy had a significantly negative effect on the QOL of patients with cancer. After chemotherapy, patients had lower general well-being, more physical symptoms, decreased activity, more sleep and sexual dysfunction and decreased social participation and work performance compared to before chemotherapy (Turgay *et al.* 2008).

Studies performed several months after diagnosis have shown that some patients treated for breast cancer have difficulty adapting to being a cancer survivor (Andrykowski *et al.* 2000, Rustoen *et al.* 2000, Engel *et al.* 2004, Burgess *et al.* 2005, Montazeri *et al.* 2008). Engel *et al.* (2004) found a significant improvement in the long-term (over four years) emotional and social functioning. Furthermore, fatigue, nausea, vomiting and future health worries and pain decreased and appetite and global QOL scores increased after three years. Most changes in QOL variables occurred between the first and second year after breast cancer surgery (Engel *et al.* 2004). Maeda *et al.* (2008) conducted controlled clinical trials with one pre-intervention session (three to four days after surgery) and two postintervention sessions (three and six months after discharge). The intervention consisted medical and psychological information and counselling. Maeda *et al.* (2008) found that 14 women in the intervention group showed significantly reduced anxiety at three months

and depression at six months. Andrykowski *et al.* (2000), on the other hand, found in their longitudinal study with 46 breast cancer survivors that post-traumatic stress symptoms did not diminish during one year. According to Engel *et al.* (2004), body image factors, sexual functioning and lifestyle factors did not improve over five years. In a nine-month longitudinal study with 131 newly diagnosed patients with cancer, Rustoen *et al.* (2000) found that family's health, family's happiness and relationship with spouse were rated as most important, but patients fluctuated in what was most important to them during nine-month study period. Further, Burgess *et al.* (2005) reported in their five-year observational cohort study that nearly 50% ($n = 222$) of women with early breast cancer had depression, anxiety or both one year after diagnosis, 25% after two, three or four years and 15% after five years. Long-term depression and anxiety were associated with previous psychological treatment, lack of an intimate confiding relationship, younger age and severely stressful non-cancer life experiences (Burgess *et al.* 2005). In the recent study by Karakoyun-Celik *et al.* (2010), sleeping difficulties, emotional status, fatigue and body appearance were related to both depression and anxiety.

Psychosocial factors, depressive symptoms (Lehto *et al.* 2005), psychological life stage (Sammarco 2001), received social support (Lehto *et al.* 2005, Arving *et al.* 2007) and coping strategies applied by women have emerged as the strongest predictors of coping and adjustment and QOL (Avis *et al.* 2005, Lehto *et al.* 2005, Manuel *et al.* 2007). In a study by Lehto *et al.* (2005), the escape-avoidance coping patterns appeared to be harmful in QOL, especially in additional symptoms and poorer well-being. Furthermore, Avis *et al.* (2005) found that use of wishful thinking, less using adaptive coping strategies and making changes were related to worse QOL. Positive cognitive restructuring was the most frequently used coping strategy, and women described this strategy as 'best' for coping with fear and uncertainty about the future (Manuel *et al.* 2007). According to Northouse *et al.* (2001), the strongest predictors of women's adjustment to breast cancer during the first year following the diagnosis were the severity of the illness and hopelessness.

The findings from earlier intervention studies strengthen the conclusion that individual and group support improve QOL in patients with breast cancer (Cox & Wilson 2003, Kärki 2005, Beurskens *et al.* 2007, Salonen *et al.* 2009). Based on the literature review of Cox and Wilson (2003), nurse led follow-up intervention was effective in managing symptoms and it also cut costs. Furthermore, in a recent randomised study by Beurskens *et al.* (2007), patients in the intervention group ($n = 15$) who received physiotherapy showed a significant improvement in shoulder mobility and

had significantly less pain than did the control group after three and six months of treatment. In our earlier study, women who took part in an individual telephone intervention ($n = 120$) one week after breast cancer surgery had better body image, less postoperative side-effects and a more positive future outlook than women in the control group ($n = 108$). Similar results have been reported by Kärki (2005), who found that individually tailored therapeutic exercise improved carrying and reaching.

Several studies have examined experiences and QOL of patients with breast cancer, but few studies have used a longitudinal design with an appropriate sample size to assess changes over time in QOL levels in intervention and control groups of patients with breast cancer. The main aim of this study was to monitor changes in QOL among patients with breast cancer in an intervention and control group.

The research questions of this study were as follows:

- 1 How did QOL change in the two groups of patients with breast cancer within six months?
- 2 Which factors predicted a worsening in QOL in the two groups?

Methods

Study design and sample

This longitudinal study was conducted as part of a quasi-randomised research project examining the effects of individual telephone support and education (one week after breast cancer surgery) and face-to-face support and education (six months after breast cancer surgery) on QOL of patients with breast cancer. The participants were recruited between August 2004–May 2007 by nurses in two Finnish hospitals. The inclusion criteria were age 18–75 years, newly diagnosed and operated breast cancer and ability to read and write Finnish. Patients with previous breast cancer surgery were excluded. The women were quasi-randomly assigned to intervention and control groups at baseline, one week after breast cancer surgery, as explained in Salonen *et al.* (2009).

The patients recruited were asked by the nurses, whether they were willing to take part in the study and to fill in consent forms. The nurses handed the questionnaires to the women, with instructions to complete the questionnaires at home and then mail them to the first author (PS) within two weeks. A letter was attached to each questionnaire, explaining the purpose of the study and assuring patients that participation was voluntary. Data were handled anonymously and confidentially.

At the end of the second intervention six months after the surgery, a physiotherapist (the first author) handed the

questionnaires to the women and asked them to complete and return the questionnaires within two weeks. The control group received their questionnaires by mail six months after breast cancer surgery. Only those patients with breast cancer in the intervention group who took part in both the telephone intervention and the face-to-face intervention and who answered both questionnaires were included in the study. From the control group, only those patients were included who answered the questionnaires both one week and six months after surgery. Both the intervention and control groups received usual care, which consisted of short postoperative advice in the hospital about how to exercise the shoulder and upper arm and how to avoid upper limb oedema. In this study, the first measurement point one week after surgery represented the baseline assessment and the second point six months after surgery represented the follow-up. The study protocol was approved by the ethics committee of Tampere University Hospital.

Interventions in this study

Based on the studies of Kärki (2005) and Sluijs (1991), the interventions in this study focused on providing support and information based on individual needs of patients with breast cancer. Two identical interventions designed on the basis of Sluijs (1991) themes of patient education in physical therapy were provided by a physiotherapist. The first intervention was delivered via telephone one week after surgery (physiotherapist at the hospital), before any adjuvant therapy, and the second intervention was delivered face-to-face six months after surgery (by the first author). The objective of these interventions was to offer support and guidance in physical functioning and provide opportunity for patients to ask questions about matters bothering them. However, the content of these two interventions were individually tailored based on the concerns that women wanted to discuss. The themes of the interventions were explained in closer detail in Salonen *et al.* (2009).

Instruments

QLI

The Ferrans and Powers QLI produces an overall QOL score and subscale scores for four specific domains, i.e. (1) health and functioning, (2) social and economic, (3) psychological and spiritual and (4) family. This two-part, 70-item instrument measures both satisfaction with various aspects of life and the relative importance of each aspect to the individual. Possible responses range in part one from 1 (very dissatisfied)–6 (very satisfied) and likewise in part two from 1 (very

unimportant)–6 (very important). The satisfaction responses are weighted by the related importance responses, giving an overall possible range of scores from 0–30. Higher scores indicate greater satisfaction with life. The reliability and validity of the QLI have been established earlier (Ferrans & Powers 1985, 1992, Ferrans 1990). The Ferrans and Powers English-language version was translated into Finnish using the back-translation technique with the authors' permission.

The European Organisation for Research and Treatment of Cancer Breast Cancer-Specific Quality of Life questionnaire (EORTC QLQ-BR23) consists of 23 items, which are rated on a four-point scale ranging from 1 (not at all)–4 (very much). Items assess therapy side-effects, arm symptoms, breast symptoms, body image and sexual functioning; in addition, there are single items to assess sexual enjoyment, anxiety caused by hair loss and future outlook. Scores range between 0–100. For scales evaluating function, a higher score represents a higher level of functioning. For scales evaluating symptoms, a higher score means more problems and a higher level of symptoms. The time frame for all questionnaire scales was the past week, except for items related to sexual activity where a four-week time frame was applied. This measurement tool is internationally well-known and has been validated with breast cancer patients (Aaronson *et al.* 1993, Sprangers *et al.* 1996). Permission to use the Finnish version of QLQ-BR23 was obtained from the EORTC Quality of Life Group.

Background variables

A structured instrument was used to assess demographic factors such as self-reported age, education, employment and having underage children. Data on breast cancer treatments were collected from patient files by the first author under the supervision of the second author.

Data analyses

The data were described using percentages, medians, lower and upper quartiles, means and standard deviations. The baseline characteristics of the intervention and control groups were compared using Pearson's chi-square test or Fisher's exact test. The QLQ-BR23 items were scored in accordance with the EORTC manual (Fayers *et al.* 2001). After scoring, all scale and single item scores were linearly transformed to a 0–100 scale. Group differences in QLQ-BR23 scores were interpreted for clinical relevance, according to Osoba *et al.* (1998) on a 100-point scale (small 5–10, moderate 11–19 and large ≥ 20 points). Higher scores represent more symptoms (systematic side-effects, breast symptoms, arm symptoms) and higher functioning (body image, sexual functioning, future perspective).

Continuous data were analysed with non-parametric tests because distributions were skewed. To see whether the QOL scores changed from baseline to follow-up, Wilcoxon Signed Ranks test was applied separately to the intervention and control group. Furthermore, to evaluate whether the change in QOL scores differed between the intervention and control group, change in score (calculated as follow-up score – baseline score – i.e. follow-up score minus baseline score) was calculated for each participant and the Mann–Whitney *U*-test was used to test group differences in the magnitude of change. Because of multiple testing in these analyses, *p*-values were corrected with Bonferroni correction by dividing the *p*-value 0.05 by the number of comparisons made (three). The limit for statistical significance in these analyses was thus set at $p < 0.017$.

To examine clinically significant changes in the Quality of Life Index Cancer Version (QLI-CV) and QLQ-BR23 subscales, we categorised the QOL changes over time. For QLI-CV subscales (Johnson *et al.* 1998), the following categorisation was used: worse ≤ -2 , no change or better ≥ -1.9999 . In QLQ-BR23, the cut-off points in body image, sexual functioning and future perspective were worse ≤ -10 , no change or better ≥ -9.9999 and subscales side-effects, breast symptoms and arm symptoms worse ≥ 10 and no change or better ≤ 9.9999 (Osoba *et al.* 1998).

Logistic regression models with the enter method were used to identify the factors associated with the worsening of QOL scores. The variables used in these models were group (control vs. intervention), age (under 55 years vs. at least 55 years), education (no professional vs. academic and vocational vs. academic), employment status (employed vs. retired), underaged children (no vs. yes), type of surgery (breast conserving vs. total mastectomy), axillary treatment (sentinel node biopsy vs. axilla dissection), chemotherapy (no vs. yes), radiotherapy (no vs. yes) and finally hormonal therapy (no vs. yes). Results were reported by odds ratios (OR) with 95% confidence intervals (95% CI). Statistical analysis was carried out using SPSS for Windows 15.0.1 (SPSS Inc., Chicago, IL, USA). The limit for significance in these analyses was set at $p \leq 0.05$.

Results

Description of participants at baseline

There were no statistical differences between the intervention and control group in their demographic characteristics or breast cancer treatments. Descriptive statistics showed that the mean age of women in the intervention group ($n = 85$) was 56.7 years, ranging from 31–73 years; in the control

group ($n = 79$), the mean age was 56.8 and range 37–75 years. Most of the women in both groups were 55 or over, had a vocational education, were employed and had no under-aged children. In both groups, about half of the women had undergone either total mastectomy or breast conserving therapy. Furthermore, most of the women in both groups had undergone axillary dissection. The majority of women received adjuvant treatment in the form of chemotherapy, radiotherapy and hormonal therapy alone or in combination (Table 1).

Changes in quality of life in groups within six months

Change in QOL between baseline and follow-up was evaluated separately for the intervention and control group. Measured by QLQ-BR23, changes over time in QOL followed the same general pattern in both groups. Six months

Table 1 Socio-demographic background and breast cancer treatments

	Intervention group ($n = 85$)		Control group ($n = 79$)		<i>p</i>
	<i>n</i>	%	<i>n</i>	%	
Age					
< 55 years old	36	42.4	28	35.4	0.365
≥ 55 years old	49	57.6	51	64.6	
Education					
No professional education	23	27.1	28	35.4	0.306
Vocational education	50	58.8	37	46.8	
Academic education	12	14.1	14	17.7	
Employment status					
Employed	60	70.6	51	64.6	0.558
Retired	23	27.1	27	34.2	
Other	2	2.4	1	1.3	
Underaged children					
No	66	77.6	67	85.9	0.175
Yes	19	22.4	11	14.1	
Type of surgery					
Breast conserving	41	48.2	38	48.1	0.986
Total mastectomy	44	51.8	41	51.9	
Axillary treatment					
Axillary dissection	48	56.5	46	58.2	0.820
Sentinel node biopsy	37	43.5	33	41.8	
Chemotherapy					
No	34	40.0	32	40.5	0.947
Yes	51	60.0	47	59.5	
Radiotherapy					
No	27	31.8	26	32.9	0.875
Yes	58	68.2	53	67.1	
Hormonal therapy					
No	28	32.9	27	34.2	0.867
Yes	57	67.1	52	65.8	

after surgery, body image decreased significantly in the intervention ($p = 0.001$) and control group ($p = 0.007$). Negative changes were also seen in systematic side-effects in the intervention group ($p \leq 0.001$) and in the control group ($p = 0.003$). Arm symptoms and breast symptoms decreased significantly in both groups within six months ($p \leq 0.001$). Future outlook improved significantly in the control group during the six-month follow-up ($p \leq 0.001$), but not in the intervention group. There were no significant changes in sexual functioning within six months. QLI-CV median scores for four subscales and for global QLI did not change significantly within six months (Table 3). According to the Mann–Whitney *U*-test, significant difference of magnitude of changes between groups was found in future outlook in that the change was greater in the control group ($p = 0.014$) (Tables 2 and 3).

Factors predicting negative changes in QOL within six months

Women receiving no chemotherapy and no hormonal therapy had a smaller risk of decreased body image scores than those who received chemotherapy or hormonal therapy as adjuvant treatments. Employed women had a greater risk of negative changes in body image than retired women. Sexual function-

ing, future outlook and side-effects were explained by chemotherapy in that women who did not get chemotherapy had a smaller risk of a poorer sexual functioning, poorer future outlook and increased side-effects compared to women who received chemotherapy. Furthermore, women with vocational education had a smaller risk to negative changes in arm symptoms than women with academic education (Table 4).

Employment status, having underaged children and radiotherapy, showed significant associations with negative changes in QOL when measured by QLI-CV (Table 5). Employed women had a smaller risk of more negative changes in their global QLI score and in health and functioning when compared to retired women. Women with no underaged children had a smaller risk to negative changes in family QOL than women with underaged children. Furthermore, women who did not receive any radiotherapy had a greater risk of decreased global QLI and socio-economic and family QOL than women who received radiotherapy as an adjuvant treatment.

Discussion

The main interest of this study was to examine QOL changes and to identify the best predictors of negative changes in

Table 2 The changes in QLQ-BR23 in intervention and control groups within 6 months

Subscale	Group	<i>n</i>	After 1 week (baseline)				After 6 months (follow-up)				<i>p</i> -value for the change between baseline and follow-up*	<i>p</i> -value for the difference of magnitude of changes between groups**
			M	SD	Md	IQ	M	SD	Md	IQ		
Body image [†]	Intervention	83	69.8	31.0	75.0	50–100	59.2	33.7	66.7	25–83	0.001 (M)	0.739
	Control	78	66.7	28.5	75.0	40–92	60.3	27.9	66.7	42–77	0.007 (S)	
Sexual functioning [†]	Intervention	79	30.6	27.0	33.3	0–50	30.4	28.1	33.3	0–50	0.822	0.608
	Control	75	24.4	22.6	16.7	0–33	24.2	23.3	33.3	0–33	0.844	
Future perspective [†]	Intervention	85	37.3	33.5	33.3	0–67	44.7	32.8	33.0	17–67	0.041 (S)	0.014
	Control	78	28.6	28.8	33.3	0–33	45.7	30.0	50.0	33–67	≤ 0.001 (M)	
Systematic side-effects [‡]	Intervention	84	21.6	14.7	19.0	10–33	31.2	19.8	27.8	17–44	≤ 0.001 (S)	0.864
	Control	79	26.5	15.2	23.8	14–38	35.1	22.6	33.3	17–52	0.003 (S)	
Breast symptoms [‡]	Intervention	83	30.6	16.0	25.0	17–42	18.0	15.7	16.7	8–25	≤ 0.001 (M)	0.211
	Control	75	30.3	16.9	33.3	17–42	22.0	19.0	16.7	8–33	≤ 0.001 (S)	
Arm symptoms [‡]	Intervention	85	32.4	22.8	33.3	11–44	21.2	19.6	11.1	11–33	≤ 0.001 (M)	0.775
	Control	75	33.8	22.0	33.3	22–44	24.3	20.0	22.2	11–33	≤ 0.001 (S)	

M, mean; SD, standard deviation; Md, median; IQ, interquartile.

*The changes within intervention and control groups were tested by Wilcoxon Signed Ranks test. *p*-values < 0.017 were considered statistically significant. Clinical difference according to mean scores: small (S) (5–10 points), moderate (M) (11–19 points), and large (L) (≥ 20 points).

**The difference in the magnitude of changes between intervention and control groups were tested by Mann–Whitney *U*-test. *p*-values < 0.017 were considered statistically significant (Bonferroni correction).

[†]Scores range from 0 to 100, with a higher score representing a higher level of functioning.

[‡]Scores range from 0 to 100, with higher score representing a greater degree of symptoms.

Table 3 The changes in QLI-CV in intervention and control groups within 6 months

Subscale	Group	n	After 1 week (baseline)			After 6 months (follow-up)					p-value for change between baseline and follow-up*	p-value for the difference of changes between groups**
			M	SD	Md	IQ	M	SD	Md	IQ		
Health/functioning [†]	Intervention	84	20.04	4.4	20.51	17–24	20.67	4.7	21.46	18–21	0.079	0.764
	Control	79	19.73	4.7	20.42	16–24	20.44	4.8	21.23	17–24	0.118	
Socio-economic [†]	Intervention	84	23.60	4.2	24.00	22–26	23.20	4.0	23.79	21–24	0.197	0.918
	Control	79	23.38	3.9	24.08	21–26	23.15	4.2	23.94	21–26	0.348	
Psychological/spiritual [†]	Intervention	85	20.82	5.0	21.36	18–24	21.04	5.2	22.07	18–25	0.728	0.563
	Control	78	21.00	4.9	21.40	18–25	20.69	4.8	21.43	18–24	0.651	
Family [†]	Intervention	82	25.10	4.1	26.40	23–29	24.93	4.9	25.35	23–29	0.268	0.790
	Control	75	25.17	4.4	26.10	24–29	24.92	3.8	25.20	23–28	0.195	
QLI-CV global score [†]	Intervention	85	21.75	3.9	22.70	19–25	21.91	4.2	22.98	20–25	0.392	0.811
	Control	79	21.54	4.0	21.67	19–25	21.65	4.1	22.38	19–24	0.773	

M, mean; SD, standard deviation; Md, median; IQ, interquartile; QLI-CV, Quality of Life Index Cancer Version.

p-values < 0.017 were considered statistically significant (Bonferroni correction).

*The changes within intervention and control groups were tested by Wilcoxon Signed Ranks test.

**The differences in the magnitude of changes between intervention and control groups were tested by Mann–Whitney U-test.

[†]Higher scores represent higher functioning.

QOL within six months. In both groups of patients, there was a clear tendency for breast and arm symptoms to decrease from one week to six months after surgery. These findings are in agreement with those of Montazeri *et al.* (2008), who concluded that breast symptoms, systematic therapy side-effects and patients' future outlook improved significantly over time. In this study, most of the women had by six months recovered from breast cancer surgery and had completed adjuvant treatments such as chemotherapy and radiotherapy. However, side-effects increased within six months due to chemotherapy, radiotherapy and ongoing hormonal therapy, which is consistent with results of earlier studies (Arora *et al.* 2001, Lehto *et al.* 2005). Several studies have reported that type of surgery (King *et al.* 2000, Engel *et al.* 2004) and adjuvant treatments (Arora *et al.* 2001, Watters *et al.* 2003, Kayl & Meyers 2006, Turgay *et al.* 2008) have negative effects on QOL, and it is obvious that women are relieved and look more positively to the future once adjuvant treatments are over. This result might also be explained by the patient's ability to adapt to the new situation, as has been reported in previous studies (Engel *et al.* 2004). Another possible explanation lies in the coping strategies women have applied (Avis *et al.* 2005, Lehto *et al.* 2005). However, some investigators have reported that women with breast cancer continue to have serious concerns about their illness several years after the diagnosis and surgery and that they suffer from long-term psychological stress reactions and depression, which may have had a major

effect on their QOL (Rustoen *et al.* 1999, Andrykowski *et al.* 2000, Burgess *et al.* 2005).

The present study demonstrated a significant improvement over time in patients' future outlook, but only in the control group. Furthermore, the magnitude of change was greater in the control group compared to the intervention group. One factor that might be contributed to this kind of finding is the guidance and education given to women in the intervention group. Women in the intervention group had more opportunities to discuss and get information about breast cancer, its treatments and future outcomes. Consequently, women were more conscious about their physical and psychosocial functioning and concentrated more on their disease. Second, and in keeping with the findings of Montazeri *et al.* (2008), body image scores decreased significantly over time in both groups. The evidence here is clear that the diagnosis of breast cancer and its treatments have a huge impact on women's body image, possibly for a long period. In particular, women who underwent mastectomy reported reduced sexual functioning and more difficulties with body image than patients who underwent breast conserving surgery (King *et al.* 2000, Engel *et al.* 2003, 2004).

The lack of intervention effects over time may be explained by the short duration of the support programme. A follow-up lasting longer than six months might have yielded more time-related group differences in QOL. This is supported by evidence from the longitudinal study of Engel *et al.* (2004), who reported that most changes in QOL occurred between

Table 4 Associations of demographic and breast cancer treatments to negative changes in QOL by QLQ-BR23. Logistic regression model were used, with results given as the odds ratios (OR) and 95% confidence intervals (CI)

	Body image OR (95% CI)	Sexual functioning OR (95% CI)	Future perspective OR (95% CI)	Side-effects OR (95% CI)	Breast symptoms OR (95% CI)	Arm symptoms OR (95% CI)
Group						
Intervention	1.00	1.00	1.00	1.00	1.00	1.00
Control	0.75 (0.37–1.52)	0.80 (0.38–1.67)	0.76 (0.29–1.95)	1.28 (0.63–2.61)	1.20 (0.43–3.32)	0.77 (0.33–1.78)
Age						
Under 55 years	0.40 (0.16–1.05)	0.45 (0.16–1.24)	1.77 (0.50–6.25)	1.96 (0.75–5.10)	0.82 (0.20–3.38)	0.82 (0.26–2.53)
At least 55 years	1.00	1.00	1.00	1.00	1.00	1.00
Education						
No professional	0.36 (0.12–1.09)	0.89 (0.29–2.70)	1.31 (0.23–7.53)	0.77 (0.25–2.34)	0.69 (0.16–3.06)	0.51 (0.16–1.59)
Vocational	0.52 (0.19–1.45)	0.72 (0.26–2.01)	2.22 (0.43–11.5)	0.60 (0.21–1.72)	1.00 (0.26–3.86)	0.31 (0.10–0.97)
Academic	1.00	1.00	1.00	1.00	1.00	1.00
Employment status						
Employed	2.53 (1.04–6.18)	1.95 (0.77–4.95)	0.36 (0.11–1.19)	1.67 (0.70–3.97)	0.45 (0.14–1.44)	0.77 (0.29–2.05)
Retired	1.00	1.00	1.00	1.00	1.00	1.00
Underaged children						
Yes	1.00	1.00	1.00	1.00	1.00	1.00
No	0.42 (0.14–1.20)	0.49 (0.16–1.51)	1.89 (0.41–8.59)	1.22 (0.41–3.64)	1.13 (0.22–5.84)	1.45 (0.32–6.58)
Type of surgery						
Breast conserving	1.00	1.00	1.00	1.00	1.00	1.00
Total mastectomy	0.64 (0.26–1.59)	0.84 (0.32–2.21)	0.54 (0.17–1.72)	0.60 (0.24–1.48)	2.44 (0.64–9.28)	0.38 (0.13–1.17)
Axilla treatment						
Axilla dissection	1.00	1.00	1.00	1.00	1.00	1.00
Sentinel node biopsy	1.90 (0.82–4.45)	1.03 (0.44–2.41)	1.77 (0.63–4.96)	1.02 (0.44–2.36)	1.67 (0.52–5.33)	1.65 (0.64–4.24)
Chemotherapy						
Yes	1.00	1.00	1.00	1.00	1.00	1.00
No	0.25 (0.11–0.58)	0.41 (0.17–0.97)	0.17 (0.05–0.61)	0.12 (0.05–0.29)	1.42 (0.47–4.27)	0.39 (0.15–1.05)
Radiotherapy						
Yes	1.00	1.00	1.00	1.00	1.00	1.00
No	1.00 (0.40–2.50)	1.37 (0.53–3.54)	1.22 (0.36–4.12)	2.44 (0.98–6.11)	0.80 (0.23–2.81)	1.38 (0.44–4.34)
Hormonal therapy						
Yes	1.00	1.00	1.00	1.00	1.00	1.00
No	0.30 (0.13–0.68)	0.99 (0.42–2.36)	0.90 (0.30–2.69)	1.28 (0.57–2.86)	0.62 (0.19–1.98)	1.00 (0.40–2.50)

one and two years after breast cancer surgery. In addition, more frequent intervention sessions might have had a positive effect on QOL over time, as reported in several recent studies (Kärki 2005, Badger *et al.* 2007, Beurskens *et al.* 2007). Furthermore, the data for this study were gathered within two weeks after the face-to-face intervention, which might have been too short a time to see significant changes in QOL.

Our intention here was to identify the strongest predictors of negative changes in women's QOL, because these are the women on whom we need to focus if we want to design effective interventions for patients with breast cancer. Our regression model suggests that the strongest predictors of negative changes in QOL within six months were education, employment, having underaged children, chemotherapy, radiotherapy and hormonal therapy.

The finding concerning the strong predictive power of chemotherapy and hormonal therapy for negative changes in

body image was not expected. Women who did not receive these adjuvant treatments had a smaller risk of a decreased body image. In our earlier study (Salonen *et al.* 2009), younger women reported significantly worse body image one week after the breast cancer surgery than older women. In this study, age did not predict negative changes in QOL when investigating the relationship between background variables and changes in QOL. This result suggest that younger women may have had poorer QOL already at baseline or they have adapted to their situation within six months and no longer concentrate on their disease but on recovering.

The results of the present study showed that, as expected, women who received no chemotherapy had a smaller risk of increased side-effects and a poorer future outlook. Furthermore, women who received no radiotherapy had a greater risk of decreased global QLI and socio-economic and family QOL. The explanation for this result might lie in the

Table 5 Associations of demographic and breast cancer treatments of participants to negative changes in QOL by QLI-CV. Logistic regression were used, with results given as the odds ratios (OR) and 95% confidence intervals (CI)

	QLI-CV global score OR (95% CI)	Health/functioning OR (95% CI)	Sosio-economic OR (95% CI)	Psychological/spiritual OR (95% CI)	Family OR (95% CI)
Group					
Intervention	1.00	1.00	1.00	1.00	1.00
Control	1.07 (0.48–2.41)	1.60 (0.73–3.54)	0.66 (0.30–1.42)	1.18 (0.55–2.52)	1.14 (0.53–2.43)
Age					
Under 55 years	2.50 (0.80–7.87)	2.22 (0.75–6.59)	2.43 (0.85–6.97)	1.66 (0.59–4.63)	0.65 (0.23–1.82)
At least 55 years	1.00	1.00	1.00	1.00	1.00
Education					
No professional	1.14 (0.33–3.88)	1.01 (0.31–3.30)	1.80 (0.54–5.98)	0.76 (0.25–2.26)	1.27 (0.41–3.98)
Vocational	0.82 (0.26–2.64)	0.87 (0.28–2.70)	0.95 (0.30–3.02)	0.55 (0.19–1.57)	0.92 (0.31–2.74)
Academic	1.00	1.00	1.00	1.00	1.00
Employment status					
Employed	0.32 (0.11–0.89)	0.32 (0.12–0.84)	0.38 (0.15–1.01)	0.56 (0.23–1.42)	1.42 (0.56–3.62)
Retired	1.00	1.00	1.00	1.00	1.00
Underaged children					
Yes	1.00	1.00	1.00	1.00	1.00
No	0.90 (0.27–2.94)	1.80 (0.48–6.71)	1.35 (0.43–4.28)	1.32 (0.40–4.37)	0.25 (0.08–0.79)
Type of surgery					
Breast conserving	1.00	1.00	1.00	1.00	1.00
Total mastectomy	0.51 (0.17–1.56)	0.64 (0.23–1.77)	0.84 (0.30–2.32)	0.73 (0.27–1.95)	0.41 (0.14–1.20)
Axillary treatment					
Axillary dissection	1.00	1.00	1.00	1.00	1.00
Sentinel node biopsy	1.26 (0.51–3.12)	0.83 (0.34–2.06)	1.98 (0.84–4.67)	0.96 (0.40–2.30)	1.42 (0.61–3.31)
Chemotherapy					
Yes	1.00	1.00	1.00	1.00	1.00
No	1.33 (0.55–3.20)	1.32 (0.55–3.14)	0.85 (0.37–1.98)	1.49 (0.65–3.43)	1.63 (0.71–3.74)
Radiotherapy					
Yes	1.00	1.00	1.00	1.00	1.00
No	3.17 (1.07–9.46)	0.98 (0.34–2.82)	3.70 (1.37–9.97)	1.22 (0.45–3.31)	4.16 (1.46–11.84)
Hormonal therapy					
Yes	1.00	1.00	1.00	1.00	1.00
No	0.79 (0.33–1.89)	1.13 (0.49–2.64)	0.42 (0.17–1.02)	0.52 (0.22–1.26)	0.75 (0.33–1.73)

increased social support associated with adjuvant treatments, as Lehto *et al.* (2005) concluded in their study. According to several studies, side-effects of chemotherapy and radiotherapy may significantly affect women's daily life and attitudes to the future (Schover *et al.* 1995, Kayl & Meyers 2006).

Furthermore, employed women had a smaller risk of negative changes in global QLI and in health and functioning than retired women. Results of our earlier study (Salonen *et al.* 2009) showed that employed women had poorer socio-economic QOL and more breast and arm symptoms than retired women one week after breast cancer surgery. It has been reported earlier that employed women have a better QOL than unemployed or retired women (Uzun *et al.* 2004). However, employed women in this study had a greater risk of decreased body image, which could be due to younger age. Furthermore, women with no underaged children experienced less negative changes in family functioning than those who did have underaged children. This is understandable in

that women who had small children had greater concerns about their future and family than women who did not have small children.

The most important strengths of the current study include its longitudinal design and the relatively large number of participants compared to recent longitudinal intervention studies (Badger *et al.* 2007, Maeda *et al.* 2008). The longitudinal data and appropriate sample size provide a stronger foundation for explaining the variability of the QOL process and for exploring the process of adjustment over time. For this purpose, we used a comprehensive battery of validated QOL measurement tools, and all assessments were made postoperatively and repeated six months later. The questionnaires were tested in a pilot study ($n = 35$) and found feasible. Furthermore, the intervention and control groups were comparable regarding demographic characteristics and breast cancer treatments. The sample is representative of patients with breast cancer, as their treatment is centralised in

Finland. The results of this study can therefore be generalised to all Finnish-speaking patients with breast cancer aged 18–75 in the Pirkanmaa hospital district in southern Finland. Furthermore, the results can be generalised with caution to all breast cancer survivors in Finland. In addition to these many strengths, the study also had some limitations that should be noted. First of all, we were not in the position to control whether patients had other diagnoses, even though these might have had a major influence on QOL results. Second, women's coping strategies may have been reflected in their QOL, but these were not taken into consideration in this study.

Conclusion

Both groups of patients made progress over the six-month follow-up with their recovery from breast cancer surgery and its treatments and showed improved QOL in some areas. Despite positive changes in QOL over time, there are also certain areas such as body image, side-effects and family functioning, which require special attention with a view to preventing future problems in family relationships and in physical health. Our findings on the role of age underscore the importance of supporting vulnerable young women whose concerns differ from those of older women. Although the results reported here did not show statistically significant time-related differences between the two groups, this is one of the first attempts to apply a quasi-experimental longitudinal design to explore the effects of short-term support and education given by a physiotherapist. The results of factors that predict negative changes in QOL provide important information for training purposes and for clinical practice when drawing up evidence-based guidelines for long-term support protocols with breast cancer patients. They also provide important clues for the further development of breast cancer support programmes.

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Relevance to clinical practice

This study provided valuable information about changes in newly diagnosed breast cancer survivors' QOL over time. Nurses and other health care professionals involved in the care of patients with breast cancer should pay more attention to the individual experiences and needs of survivors and target support accordingly, because QOL is very much an individual perception. Multiprofessional support and education is an essential part of the care of patients with breast cancer. Health care staff should make the best possible use of these results in developing support services for newly diagnosed breast cancer survivors.

Repeated measurements over long periods might be able to show statistically significant time effects in QOL. There is a continuing need for research to evaluate the effects of interventions and long-term changes in QOL of patients with breast cancer using longitudinal designs. This is an important area of study for understanding and supporting women with breast cancer.

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Contributions

Study design: PS, M-TT, P-LK-L, MK; data collection and analysis: PS, M-TT, P-LK-L, A-MK, MK and manuscript preparation: PS, P-LK-L, M-TT, A-MK, MK.

Conflict of interest

No conflict of interest.

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