

between SEF and SEE. Predictors of change over time including age, clinical and psychological factors, were examined using multiple regression and the population average GEE model.

**Results:** At baseline, 2087 women completed the SEF items, of whom 56% reported that they lacked interest in sex, and 40.6% women were sexually active. SEF and SEE were correlated over all time points ( $r = 0.5-0.66$ ) but SEE scores were generally low. Proportions of women reporting 'a little', 'quite a bit' or 'very much' SEE were 34%, 39% and 22% respectively. Older age, CT and HADS anxiety and depression were significantly associated with worse baseline SEF/SEE with no effect of type of surgery, time since surgery, endocrine therapy or body image (BI). SEF improved significantly from baseline to 6 months ( $p < 0.001$ ) but thereafter declined up to 60 months ( $P < 0.001$ ) towards baseline levels. Psychological variables affecting decreased SEF were poorer body image and increased HADS depression and anxiety. Age greatly impacted SEF with patients  $\geq 50$  years (proxy for post-menopausal status) reporting significantly worse SEF compared to those aged  $< 50$  ( $p < 0.001$ ). There was a steady decrease of SEE over time from 0-60 months with similar variables affecting this change, except for HADS anxiety, which was not significant.

**Conclusion:** Although CT has an initial adverse effect, sexual functioning and enjoyment appear to be mainly affected by age and psychological variables over time. The observed associations with depression and body image warrant further investigation and results will be reported. Women should be informed of likely treatment effects and offered appropriate advice and support.

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### Factors affecting body image concerns in early breast cancer

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**Introduction:** To explore the contribution of age, clinical and psychological factors on body image concerns, in women with early breast cancer treated in the START trial. This is a UK multicentre randomised trial of adjuvant radiotherapy in which quality of life will be an important secondary endpoint.

**Methods:** Women participating in the quality of life (QL) sub-study completed the 10-item Body Image Scale (BIS) and 14-item HADS, together with other standardised QOL measures, at baseline (after surgery and adjuvant chemotherapy but before radiotherapy) and at 6, 12, and 24 and 60 months follow-up. At baseline, the independent effects of age, clinical factors (time from surgery, type of surgery, chemotherapy, endocrine therapy), depression and anxiety were identified using multiple regression analysis. Change over time was tested using the Generalised Estimating Equations model.

**Results:** 2181 (99%) women completed baseline QL questionnaires, (mean age 56.9 years, range 26-87). 17.1% women had mastectomy, 82.9% underwent conservative surgery; median time from surgery was 8.0 weeks (IQR 5.6-19.6). One third of patients received adjuvant chemotherapy (CT). 75% women reported BIS concerns of any severity at baseline; the most prevalent body image items rated as 'quite a bit' or 'very much' were '... feeling less physically attractive', '... feeling less sexually attractive', '... feeling less feminine' and '... dissatisfied with your body'. Significantly worse BIS summary scores ( $p < 0.001$ ) at baseline were found for women of younger age, having mastectomy, and/or receiving chemotherapy. BIS scores improved significantly from baseline to 1 year ( $p < 0.001$ ) and were stable from 1-5 years ( $p = NS$ ). There was no apparent negative effect on BIS scores from radiotherapy or endocrine therapy. From 0-12 months, poorer body image was predicted by age, having mastectomy, receiving chemotherapy, and greater anxiety and depression; these factors also predicted the most prevalent body image concerns. CT had no further effect from 12-60 months but the other factors remained.

**Conclusions:** Overall body image concerns improve over time and whilst the impact of CT remits after one year, the negative effects of age, mastectomy, anxiety and depression persist. A subgroup of patients at risk of body image disturbance can thus be identified. Neither radiotherapy nor endocrine therapy appear to have an influence on body image scores.

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### Patients' views of distress and interference with daily activities due to side effects from chemotherapy for early breast cancer: the TACT (Taxotere as Adjuvant ChemoTherapy) trial experience

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**Introduction:** 4162 women with early breast cancer were randomised to receive adjuvant chemotherapy (CT) in the TACT trial (FECx4 followed by taxotere x4; (FEC-T)) vs FECx8 or epirubicin x4 + CMF x4 (E-CMF)) in which Quality of Life (QL) is an important secondary endpoint. This analysis describes the patient experience of chemotherapy side effects from treatment, in terms of distress and interference with activities, rather than just severity.

**Methods:** A protocol specific measure of 15 toxicities in the form of a daily diary card (not reported) and two additional questions, relating to *distress due to side effects* and extent of *interference in daily activities* from side effects was requested from all patients in the QL study. Questions were completed during CT (cycles 1, 5, and 8) and at 9, 12, 18 & 24 months. Patients rated *distress* and *interference* for each toxicity as 'not at all', 'a little', 'quite a bit', 'very much'. Toxicities rated as *distressing* or *interfering* with day to day activities (quite a bit/very much) by  $>10\%$  patients at each time point were collated.

**Results:** Toxicity questions were completed by 455, 468, 410, 667, 645, 604 & 576 patients at cycle 1, 5 & 8 and at 9, 12, 18 & 24 months respectively. In cycle 1, *distressing* effects were nausea, vomiting, tiredness and constipation, reported by 30.4%, 20.1%, 30% and 13% patients respectively. Nausea, vomiting and tiredness also *interfered* with daily activities in similar proportions of patients. During successive cycles, most (12/15) symptoms were reported as *distressing*, with the exception of vomiting, skin problems, and lack of appetite. Symptoms most likely to *interfere* with activities on CT were nausea, tiredness, sore mouth, breathlessness, pain in muscles/joints and painful/gritty eyes, affecting 13%-54% patients, with greatest increases for breathlessness and painful muscles/joints. Following CT, only tiredness and pain in muscles/joints were reported as *interfering* by  $>10\%$  patients but persisted up to 2 years from baseline. Over 10% of patients reported *distress* due to skin problems, tingling hands/feet, swollen hands/feet, nail changes, tiredness and painful muscles/joints at some point following treatment, with the latter two persisting for up to 2 years.

**Conclusion:** Most CT side effects cause more distress than interference with daily activities. Whilst most functional effects reduce over time, distress may persist for up to 2 years post CT and warrants more attention from treating teams.

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### The psychological impact of regular surveillance in women at increased risk for hereditary breast cancer

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**Aim** To identify women at risk for hereditary breast cancer adhering to regular surveillance who experience increased distress.

**Methods** 357 High-risk women (cumulative life time risk  $>15\%$ ) participating in the psychological sub-study of the national MRISC-study, regarding the evaluation of MRI-screening in high-risk women were studied. Questionnaires, administered before and after two surveillance-visits (C1, C2), assessed the psychological impact of adhering to the surveillance programme (annual MRI and mammography, biannual clinical breast examination). Outcome variables were BC specific distress (Impacts of Event Scale) and general distress (Hospital Anxiety and Depression Scale). With regression analyses and Structural Equation Modelling subgroups of women who were vulnerable for psychological distress and the courses of distress around surveillance were explored.

**Results** At baseline (i.e. two months before the surveillance visit) three factors were found to be associated with higher levels of BC specific distress: excessive breast self examination while being younger than 40 years of age; risk overestimation (cognitive and affective), and being

closely involved in the BC-process of a sister. The course of distress in general remained within normal limits and decreased significantly after a surveillance appointment, except for BC specific distress around C2 due to a lower pre-screening score than C1. The courses of excessive breast self-examiners and risk over-estimators differed significantly for BC specific distress around C1; they had higher scores; and the course for general distress was significantly different for women being closely involved in the BC-process of a sister (C2). Furthermore, coping styles were associated with psychological distress, whereby particularly passive coping had the strongest negative association with psychological distress.

**Conclusion** In general, adhering to regular surveillance does not induce clinically relevant psychological distress. However, we identified factors associated with psychological distress. These women may be in need for extra counselling and special attention of the physicians involved.

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# **The benefit of individualised programmes of complementary therapies for breast cancer patients at Breast Cancer Haven**

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**Aim:** To understand the concerns breast cancer patients express when seeking complementary therapies and to evaluate the effect that receiving individualised programmes of complementary therapies has on these concerns. The Breast Cancer Haven Programme offers support, education and complementary therapies to meet the needs of the patients before, during and after conventional medical treatment for breast cancer.

**Experimental procedure:** 410 patients over 2 sites completed the Measure Yourself Concerns and Wellbeing (MYCaW) questionnaire stating and scoring (out of 6) two primary concerns they had, before beginning a programme of complementary therapies. The concerns were rescored after 10 hours of complementary therapy treatment. On the second questionnaire patients were also asked to state 'what other major events were happening in their life' and 'what had been the most beneficial aspect of visiting this centre'.

**Results:** 30 categories have been identified ranging from physical to psychosocial concerns, such as, feeling anxious about impending chemotherapy treatment, the impact of low energy levels on normal life, to wanting to manage stress, learning how to relax or gaining clear information and advice. A mean improvement in the concern scores from 5 (SD+/-1.1) to 2.8 (SD+/-1.7), ( $p=0.001$ ) was demonstrated, (where 6 is as bad as it can be and 0 is as good as it can be). Any improvement in score over 1.5 units is considered a significant improvement in the concern. The data has identified the other aspects most beneficial to the Visitors, such as the support and understanding received, the environment and the experience and professionalism of the therapists. Further analysis is being carried out to identify whether particular combinations of therapies have successfully addressed specific concerns, or whether it is the individualised aspect to the package of complementary therapies that is most beneficial, irrespective of the combination of therapies received.

**Conclusion:** This study has demonstrated that individualised packages of complementary therapies, integrated alongside conventional medical treatment can be used to significantly improve a variety of physical and psychosocial concerns for women with breast cancer. This data can be used to elucidate effective ways of offering complementary therapies to breast cancer patients either within or outside of a conventional medical setting.

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# **Quality of Life is more influenced by personality than by type of surgical treatment in early stage breast cancer**

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**Introduction:** Quality of Life (QoL) plays an important role when deciding on surgical treatment in early stage breast cancer. In previous studies it is claimed that breast conserving therapy (BCT) will result in a better QoL compared to modified radical mastectomy (MRM).

QoL and QoL-related concepts are influenced by personality traits, especially trait anxiety and neuroticism. To assess the influence of personality combined with the type of surgical treatment, a longitudinal prospective cohort study was done.

**Methods:** Every woman who visited the hospital for the first time for having a palpable lump in the breast or an abnormality on a mammography and was referred by a general practitioner, was asked to participate. Before diagnosis, they completed a set of questionnaires and again at 1, 3, and 6

months after diagnosis and surgical treatment. Questionnaires used were the NEO-FFI to determine the level of neuroticism and extraversion, the STAI to establish the level of trait and state anxiety and the WHOQOL-100 to measure QoL.

**Results:** Between September 2002 and April 2005, 229 women were included in the study. Of these women, 101 (44.1%) were diagnosed with early stage breast cancer.

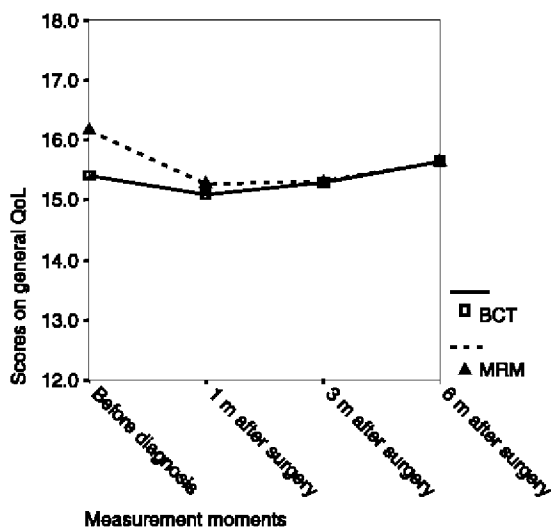


Figure 1.

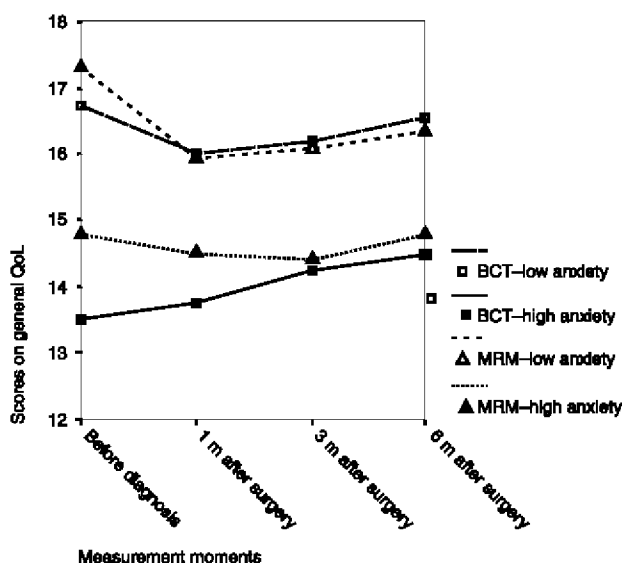


Figure 2.

Two women were not operated, 34 women underwent BCT (33.6%) and 65 women were treated with MRM (64.4%).

There was no difference between the scores on general QoL for both groups on all measurement moments (see Figure 1). In regression analyses, trait anxiety was responsible for up to 27.5% of the variance in QoL scores.

Half of the women in both the BCT and MRM group scored high on trait anxiety. Logistic regression showed that patients with a high score on trait anxiety experienced a low overall QoL at six months after diagnosis (OR 2.1; 95% CI=0.623-7.001;  $p=0.02$ ) irrespective of the surgical treatment (see figure). When the women were divided in four groups based on their surgical treatment (BCT vs MRM) and their scores on trait anxiety (low vs high), the scores on general QoL showed significant differences between the groups on all measurement moments ( $p=0.007$ ) (see Figure 2).

**Conclusion:** Trait anxiety has more impact on QoL in early stage breast cancer than type of surgical treatment.