

## **An exploratory analysis of women's free-text comments on their Quality of Life in the UK Standardisation of Breast Radiotherapy (START) Trials for early breast cancer**

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**Running title:** Quality of Life in context

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## **ABSTRACT**

**Objective** Exploratory analysis of patients' unsolicited written comments in the first 2 years of the START trial Quality of Life (QL) study highlighted a potential effect of non-treatment related problems on the ratings and interpretation of patient self-reported questionnaires. At 5 years' follow-up all eligible subjects were invited to write comments to further explore these findings.

**Methods** Using inductive qualitative methods informed by the exploratory analysis, comments were allocated to relevant themes. Key patient-reported outcome measures (PROMs), clinical and demographic factors were collated for patients who did and did not comment at 5 years and comparisons between the groups explored.

**Results** Of 2208 women completing baseline PROMs, 482 proffered comments from 0-24 months forming 9 distinct themes, including chronic conditions, life events and psychosocial concerns. At 5 years, 1041/1727 (60.3%) women contributed comments, of whom 500 randomly-selected participants formed the sample for analysis. Findings revealed comorbidity, impaired physical functioning and psychosocial problems as key themes, with prevalent adverse effects from local and systemic treatments. Eight new themes emerged at 5 years included ageing, concerns about future cancer and positive aspects of care. Women commenting were better educated, slightly older and more likely to have had chemotherapy compared with non-commenters. They had significantly worse

PROMs scores for global health and key QL domains relevant to the difficulties they revealed.

**Conclusions** Difficult personal circumstances and other health concerns affected many women's PROM ratings at 5 years' follow-up, in addition to on-going cancer treatment effects. Greater attention to multiple sources of distress and adversity could facilitate personalised care and aid interpretation of PROMs.

**Keywords**

Quality of life; patients' free-text comments; contextual factors; breast cancer; radiotherapy; clinical trials

## INTRODUCTION

The findings of the START Trials Quality of Life (QL) substudy [1] provided valuable information for patients and clinical teams about beneficial and unfavourable effects of the radiotherapy treatment (RT) groups under comparison, as an aid to future decision-making and clinical care provision. START tested a widely-used dose regimen (40 Gy in 15 fractions) and two test schedules of hypofractionated radiotherapy (fractions >2.0 Gy) against the international standard of 50 Gy in 25 fractions, in terms of local tumour control and late normal tissue effects. Findings from patients' ratings strengthened the evidence in support of the clinical findings in favour of hypofractionated regimens [2,3], which influenced clinical breast radiotherapy practice [4]. The QL findings were derived from standardised measures designed within a biomedical framework, which included questions relating to protocol-specific RT effects that helped distinguish between the regimens.

Such measures are very effective in supporting key endpoints in clinical trials and cover a range of largely biomedical domains to facilitate multidimensional comparisons between treatment arms and have contributed to clinical improvement. However they are not designed to encompass non-trial circumstances or individual experiences and so may not inform individual care. There has been extensive psychosocial research detailing the multiple and complex effects of breast cancer and its treatment [5-14], but to date there has been little opportunity for patients to express the meaning or relevance of non-

breast cancer symptoms, psycho-social problems or functional limitations in the context of a clinical trial [5,15]. However it is expected that randomisation will eliminate any bias due to individual circumstances for treatment comparisons in the trial setting.

Unexpectedly, during the first two years of Quality of Life (QL) data collection in the START trials, 22% of women wrote unsolicited comments at least once, or enclosed letters, when returning their QL booklets. These women frequently wanted to 'explain' that their responses to specific questionnaire items or subscales reflected the effects of other personal problems, life events or health issues rather than breast cancer or its treatment. Some women thought there should be space for such reporting: *"Completing the questionnaire I thought there should be a question about whether there are any factors/worries in your daily life that affect your answers"*. These patients also expressed concern that if contextual factors were sufficient to influence their questionnaire ratings they could be misattributed to effects of cancer treatments. The potential value of these comments in raising awareness of contextual problems in the clinical setting and of their possible influence on QL ratings warranted further exploration. We therefore conducted a qualitative study of the comments proffered up to 2 years and a summary of the sample composition, analysis and findings is presented in Appendix A. These were found to endorse the importance to quality of life of comorbidity and other contextual factors, not captured by the QL measures, and the potential for misattribution of ratings to breast cancer outcomes. If generalised, these contextual factors could lead to inferior QL outcomes for long-term survivors in whom the

interplay of contextual factors, life stress and ageing may impede adjustment and be detrimental to coping, decision-making and ongoing self-management. [16,-19].

Following on from this, and given the relatively small sample of women who proffered comments early on in the trial it was decided to invite comments from all women in the START trials completing PROMS at the 5-year assessment. The aims were: (a) to retrospectively explore reported health concerns and adverse contextual factors and see if they endorsed the proffered comments, and (b) to examine possible associations between QL scores derived from the quantitative questionnaire items and patients' reported health concerns and other adverse contextual factors.

## **MATERIAL AND METHODS**

Full details of the UK START trials and Quality of Life sub-study have been published separately [1-3]. The START trials were registered as an International Standard Randomised Controlled Trial, number ISRCTN59368779. Patients were recruited to the QL study from 31 of 35 radiotherapy centres in the UK between 1998 and 2002 and the main quality of life outcomes were published in 2010 [1]. Ethical approval was obtained from the South Thames Multi-Research Ethics Committee to request additional written comments from all patients completing the 5-year QL follow-up assessment; local ethics committees of all participating centres also gave approval. A blank page in the PROMS booklet was included and a patient information letter invited participants to report any health problems or events

that they thought might influence the answers they gave in their PROMS booklet (see Appendix B for full text).

The QL booklets comprised the EORTC QLQ-C30 core questionnaire [20], EORTC QLQ-BR-23 breast cancer-specific module [21], Hospital Anxiety and Depression Scale (HADS) [22], Body Image Scale (BIS) [23] and a health economics evaluation [24], for completion at home. The trials office (ICR-CTSU) at the Institute of Cancer Research (ICR) first checked the individual's current health status with their hospital team or family doctor before sending questionnaires. Prompts were sent for non-return of questionnaires by letter or telephone 3 weeks after mailing. At 5 years, all pages with comments in the QL booklets were logged on the Quality of Life study data-base.

The number of comments received on the 5-year questionnaires was too large to analyse using the entire written records and so comments from a random sample of 500 patients were used for the analysis, which followed a constant comparative methodology [25], as described for the proffered comments (Appendix A). Thus, for each patient commenting, each written comment was allocated to an appropriate theme: initially all 9 themes created from the proffered comments analyses were used (Appendix A).. Additional themes were formed and labelled, for comments that had not previously been submitted. All decisions ascribing comments to 'new' themes were made jointly by at least 3 coders. Where there was difficulty allocating a theme a consensus decision was made.

## **Statistical Methods**

Descriptive analyses compared demographic and clinical characteristics, and key quality of life scores between women who did and did not provide comments at 5 years. Quality of life subscale scores at 5 years were calculated as specified in the EORTC scoring manual [26].

A secondary analysis compared QL scores in 3 key domains (global health / QL, physical and emotional functioning) and 2 symptom items (BR23 'hot flushes' and 'worry about future health') for women commenting on an associated theme with women who commented on different themes, to investigate associations between themes and corresponding quality of life scores. EORTC subscales were selected that were considered most likely to reflect differences between patients commenting or not commenting on key areas of concern, based on exploration of data from the proffered comments. For graphical presentation, the EORTC subscales were arbitrarily grouped into the following categories 0-40, 41-60, 61-80, 81-100, as the distributions of scores were highly skewed.

Differences were tested using either the t-test or Mann-Whitney test for continuous variables, or the  $\chi^2$  test or  $\chi^2$  test for trend for categorical variables, as appropriate.

## **RESULTS**

At 5 years 91.2% (1728/1893) of eligible women completed QL questionnaire booklets and 60.2% (1041/1728) provided written comments; of these, 275/1041 (26.4%) had also proffered comments between 0-24 months. Four patients in the



random sample selected for this analysis were excluded as their comments indicated only administrative issues. There were no clear differences between the randomised schedules in the proportion of women providing comments at 5 years. A comparison of the characteristics of women commenting or not commenting at 5 years (Table 1) shows that 'commenters' were slightly older and better educated than 'non-commenters'; they were more likely to have received adjuvant chemotherapy and had significantly poorer quality of life across all EORTC functional subscales, and worse fatigue and pain symptom scores.

Seventeen themes emerged from the 5-year comments (see Table 2 and Appendix B), including nine derived from the unsolicited comments (see Table A.2 in Appendix A). The number of themes reported per person ranged from 1 to 9 (Figure 1).

The 'Chronic medical and physical functioning' themes were combined at 5 years due to frequent overlap of reported conditions; this was the most frequently used theme (34.3% women commented) compared with 26% reporting local breast related problems and 21.8% commenting on systemic treatment-related problems. In contrast to earlier proffered comments these local and systemic treatment-concerns were expectedly more prevalent at 5 years. The personal and individual impact of treatment related problems varied widely, highlighting their adverse impact on well-being, bodily changes, social activity, sex life, and satisfaction.

One in six women reported current or chronic mental health difficulties, usually unrelated to cancer, whilst job problems, life events and family problems were less prevalent at 5 years than earlier in the trial. New themes included concerns about a cancer family history (reported by only 2.8%), ageing effects (8.1%) or concerns about the future (11%), especially fears of recurrence. Both dissatisfaction and satisfaction with medical and hospital care were expressed. Overall, two thirds of all written comments were negative or expressed difficulties and concerns. However, at this final 5-year assessment point in the START trials 30% of written comments were brief remarks of gratitude for positive aspects of care and appreciation of trial participation; others reflected the value of personal support, positive life events and of making a good recovery (16.1%). (Appendix B shows examples from all the themes at 5 years).

Comparing quantitative QL ratings between groups of women commenting on specific areas of concern, Physical Functioning and Global Health/QL scores were significantly worse for women who commented in the 'Chronic Medical and Physical Functioning' theme compared with women who had commented in different themes (Figures 2a and 2b). Similar QL differences for Emotional Functioning and Global Health/QL were found for women commenting versus those not commenting in the 'Psychological problems' theme (Figures 2c and 2d). Further, significantly more women (34%) commenting on systemic treatment side effects rated their 'hot flushes' in the BR23 subscale as 'quite a bit' or 'very much' compared with 24.8% of 'non-commenters' on this item ( $p=0.018$ ). Scores on the BR23 'future perspective' item were significantly worse for those commenting on their personal fear of recurrence (45.3% responded 'quite a bit' or 'very much')

compared with women who did not comment in this theme (31.6% responded 'quite a bit' or very much', ( $p=0.016$ ).

## Discussion

Women's free-text comments in the START trials revealed many adverse personal circumstances at 5 years' follow-up as well as current and chronic health and psychosocial difficulties. For some women, breast cancer was not the only – or necessarily the main - determinant of their quality of life. For others, ongoing or late effects of multimodal breast cancer treatment significantly impaired their well-being. Overall, these comments endorsed and extended the proffered comments made by women earlier in the trial. They provide a broad, explanatory dimension to their quality of life ratings, and highlight negative effects of co-morbidity, life events and adverse psychosocial problems on many individual experiences of cancer and quality of life outcomes. These insights from a national radiotherapy trial setting are novel and informative but also resonate with many issues described by others, using examples from clinical research and practice and patients' testimonies [6,7]. From these, wide-ranging contextual factors were uncovered that were considered critical to understanding patients' resources and experience of cancer.

We confirmed a significant negative impact on quality of life ratings for 'commenters' compared with 'non-commenters' over all functional domains, as well as specificity of the effect of particular themes on related QL domains. Comments on psychological problems often referred to specific reasons for their QL ratings such as chronic mental health, family problems and general stress rather than

breast cancer, adding informative value to an earlier assessment of psychological problems in the START trials [27]. Adverse effects of local and systemic breast cancer treatment effects were expressed by women in their comments in addition to completing QL questions in these key areas, adding personal details of the impact of these treatment effects, such as on body image and sexuality. Comments about chronic or disabling conditions and co-morbidities were expectedly frequent in an ageing population and reflect evidence of both incident and chronic disease in survivors [13], These conditions are of concern as they can lead to an inferior prognosis and worse disease outcomes [13, 19, 28], as well as indicating supportive care needs.

Comments about fear of recurrence and existential concerns were the most prevalent in the new themes at 5 years and have been highlighted as a key problem in recent research [29,30]; other new issues reported may reflect women's increased awareness of genetic aspects, second cancers and the effects of ageing during survivorship. Expressions of positive outcomes and praise for health care and trial participation demonstrated good supportive care in the trials setting and far outweighed criticisms.

#### *What are the implications for future QL assessment?*

Many issues raised in the written comments were not covered by the PROMS and this calls into question the scope and interpretation of quality of life data in future RT trials. However the strength of these measures in the START trials was in determining selected biomedical outcomes from thousands of patients' ratings to

determine differences between the treatment regimens, enhancing the clinical findings; other studies have found an association of PROMS with improved supportive care and patient satisfaction [31]. However these questionnaires are not designed to differentiate between breast-cancer-related and more general health or contextual problems. Concerns have been raised about the selected agenda of QL measures [15], which limit the discovery of additional influences on wellbeing [7]. It has been suggested that the assessment in clinical trials needs to be broadened to include environmental, economic, medical and social factors [6,7,15 32]. Moreover with few exceptions [33], symptoms are reported in PROMS in terms of their occurrence and severity over time rather than the distress or disruption caused to daily life.

#### *What is the value of self-reported comments?*

Women's comments reveal the experience of cancer and the impact of adverse events and day to day difficulties, as well as the interrelatedness of health and personal or social circumstances. For example, losing a job after diagnosis can lead to developing depression. However, distinctions between the contribution of treatment and other causes (comorbidity, physiologic) to reported symptoms can still be difficult to determine. The value of this additional information extends beyond the randomised comparisons. However, can patients' free-text comments continue to make a valid contribution? Their utility has been endorsed in a large exploratory study of patients' views of cancer care [34] in which the potential value of free-text comments was described as 'illuminating' when highlighting potential causes for some inferior outcomes in a survey of mixed cancer patients [35]. Novel ways of analysis of these data have also been described [36]. However free-text

comments usually require a time-consuming methodology and analysis which is likely to preclude frequent use in large studies. Currently free-text comments are being invited in two further RT trials run by The Institute of Cancer Research in order to explore earlier stages of treatment and follow-up for which adequate data was not available in the START trials.

In support of our findings we found no significant difference between the different treatment schedules of the START trials in terms of frequencies of comments and can therefore be confident that there was no specific bias to the QL results on that basis. The QL sample gave good representation with respect to age and geographic area for breast cancer populations [37]. Using a constant comparative methodology enabled us to describe comments on the diverse social and medical context of women's breast cancer experience by creating distinct themes, but not to speculate on whether these women would be similar to age-matched population samples. We do not know if women commenting also reported and discussed their concerns with health professionals or received helpful interventions.

Considering potential confounders in our study, we recognise that women who chose not to comment may have felt non-cancer problems were irrelevant or inappropriate. Their apparent enhanced quality of life may reflect more adaptive coping, favourable resilience or adjustment to adversity. Beneficial effects of existing social care, psychological or medical intervention may also play a part. Women commenting were better educated and slightly older which may have

enhanced response rates whilst those receiving chemotherapy perhaps felt more impetus to report related problems.

In conclusion, this novel opportunity to synthesise quantitative and qualitative data in the START trials provides a broader understanding of the cancer experience and the influence of acute and chronic contextual problems. Awareness of our findings should help clinical teams to address the wider effects of contextual difficulties, comorbidity and late effects of treatment, and stimulate thought about the interpretation and future development of PROMs. Many women accept trial participation for altruistic reasons [38] and their feedback should help inform the provision of individualised supportive care for future patients.

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The funders had no role in the study design, collection, analysis and interpretation of data, writing of the report, nor in the decision to submit the article for publication.

## **Competing Interests**

The authors declare no competing interests.

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## Figure legends

**Figure 1:** Number of themes identified per person from the random sample of 500 women commenting at 5 years

**Figure 2:** Specificity of themes derived from comments provided at 5 years with corresponding 5 year EORTC QLQ-C30 subscale scores

Scores range from 0-100: higher scores indicate better functioning and global health Denominators vary due to missing data for some QL subscales

**Figure 2a:** Physical Functioning subscale scores for women commenting / not commenting about chronic medical problems

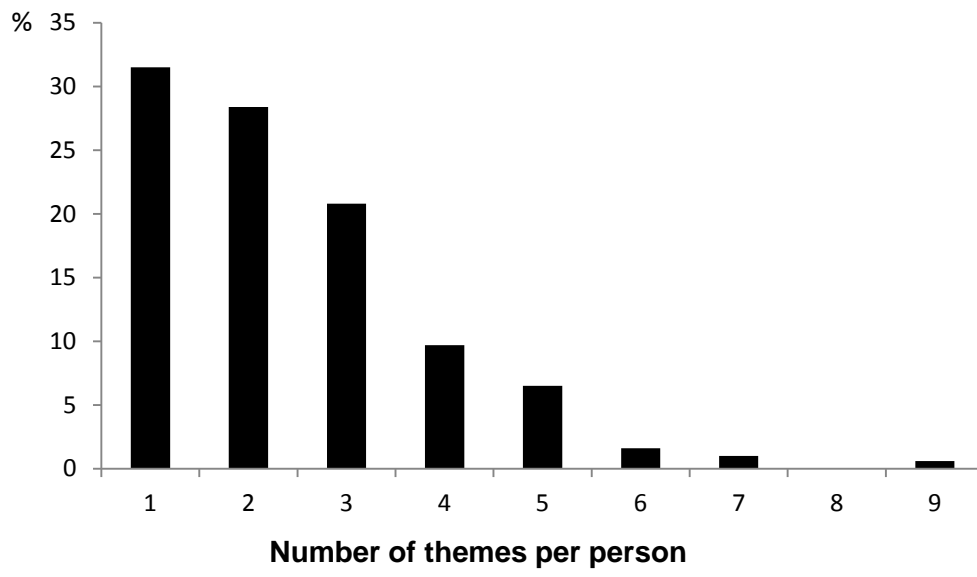
**Figure 2b:** Global Health / Quality of Life subscale scores for women commenting / not commenting about chronic medical problems

**Figure 2c:** Emotional Functioning subscale scores for women commenting / not commenting about psychological problems

**Figure 2d:** Global Health / Quality of Life subscale scores for women commenting / not commenting about psychological problems

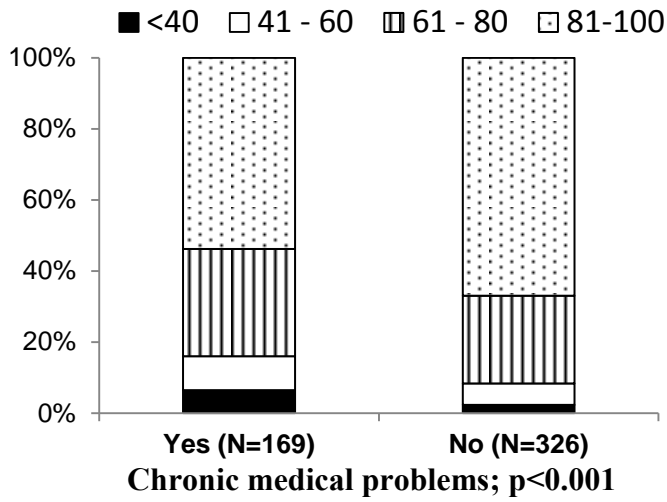


**Figure 1**

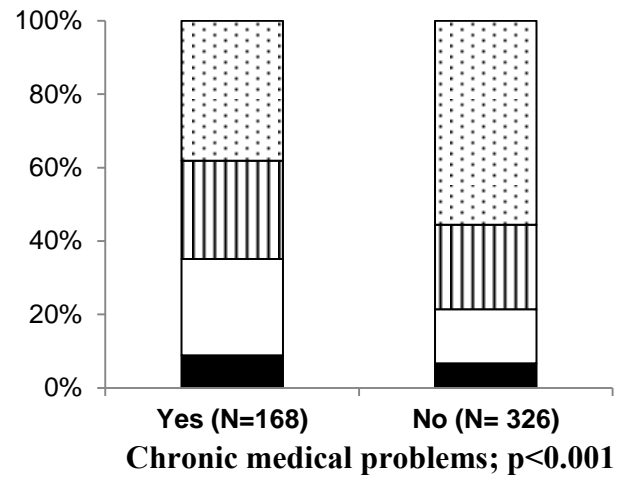


**Figure 2**

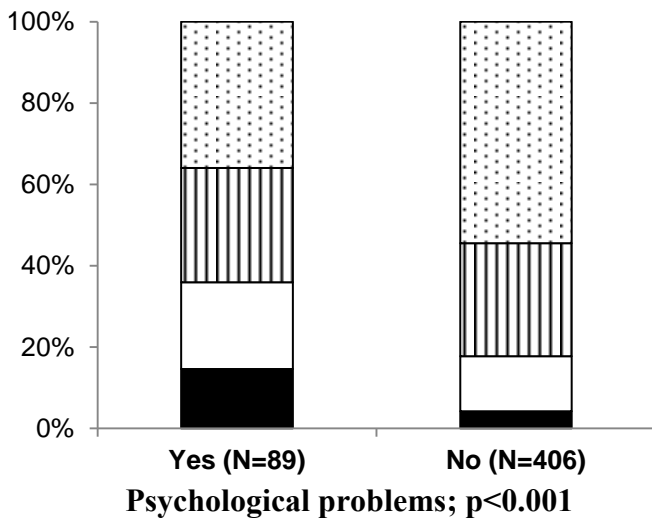
**Figure 2a: Physical functioning**



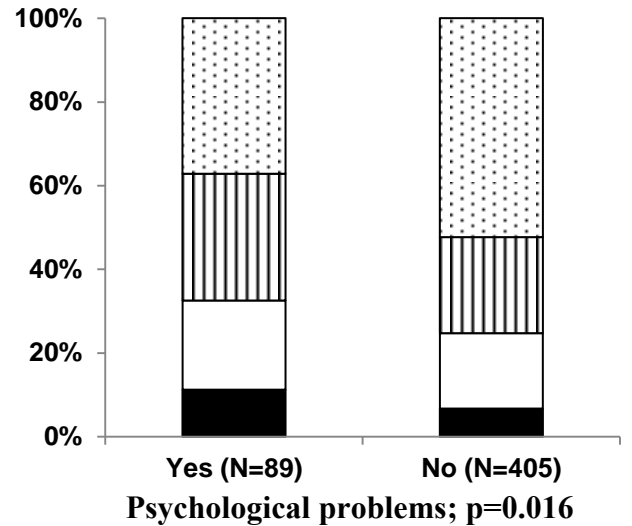
**Figure 2b: Global health / QL**



**Figure 2c: Emotional functioning**



**Figure 2d: Global health / QL**



**Table 1: Characteristics of women who wrote comments at 5 years and women who did not**

	<b>Women who commented at 5 years) N=1041 (%)</b>	<b>Women who returned 5-year form but who did not comment N=687 (%)</b>	<b>p-value</b>
<b>Age at baseline (years): mean (SD) [range]</b>	57.4 (10.0) [27-85]	56.2 (9.8) [28-82]	0.021 <sup>1</sup>
<b>Highest level of education achieved<sup>3</sup></b>			<0.001 <sup>2</sup>
None;	326/981 (33.2)	284/624 (45.5)	
School certificate / O-level / GCSE / NVQ or equivalent;	275/981 (28.0)	185/624 (29.6)	
A-level / HND or equivalent;	60/981 (6.1)	30/624 (4.8)	
Degree, post-graduate or professional qualification;	282/981 (28.7)	97/624 (15.5)	
Unknown – not completed on form	38/981 (3.9)	28/624 (4.5)	
<b>Type of surgery</b>			0.105 <sup>3</sup>
Breast-conserving surgery	906 (87.0)	578 (84.1)	
Mastectomy	135 (13.0)	109 (15.9)	
<b>Chemotherapy</b>			0.025 <sup>3</sup>
No	746 (71.7)	454 (66.1)	
Yes	295 (28.3)	229 (33.3)	
Unknown	0	4 (0.6)	
<b>Tamoxifen</b>			0.138 <sup>3</sup>
No	161 (15.5)	125 (18.2)	
Yes	880 (84.5)	558 (81.2)	
Unknown	0	4 (0.6)	
<b>EORTC QLQ-C30 subscale scores at 5 years<sup>4</sup>:</b>			
<b>Global health / QoL</b>			<0.001 <sup>2</sup>
0-40	76 (7.3)	34 (4.9)	
41-60	204 (19.6)	102 (14.8)	
61-80	267 (25.6)	167 (24.3)	
81-100	489 (47.0)	379 (55.2)	
Unknown	5 (0.5)	5 (0.7)	
<b>Physical functioning</b>			<0.001 <sup>2</sup>
0-40	41 (3.9)	19 (2.8)	
41-60	105 (10.1)	43 (6.3)	
61-80	228 (21.9)	115 (16.7)	
81-100	666 (64.0)	508 (73.9)	
Unknown	1 (0.1)	2 (0.3)	
<b>Emotional functioning</b>			0.011 <sup>2</sup>
0-40	46 (4.4)	32 (4.7)	
41-60	129 (12.4)	53 (7.7)	
61-80	284 (27.3)	172 (25.0)	
81-100	579 (55.6)	424 (61.7)	
Unknown	3 (0.3)	6 (0.9)	
<b>Role functioning</b>			<0.001 <sup>2</sup>
0-40	103 (9.9)	33 (4.8)	
41-60	46 (4.4)	18 (2.6)	
61-80	183 (17.6)	79 (11.5)	

81-100	705 (67.7)	552 (80.3)	
Unknown	4 (0.4)	5 (0.7)	
<b>Social functioning</b>			<0.001 <sup>2</sup>
0-40	59 (5.7)	22 (3.2)	
41-60	41 (3.9)	9 (1.3)	
61-80	136 (13.1)	63 (9.2)	
81-100	802 (77.0)	588 (85.6)	
Unknown	3 (0.3)	5 (0.7)	
<b>Cognitive functioning</b>			0.009 <sup>2</sup>
0-40	44 (4.2)	22 (3.2)	
41-60	67 (6.4)	28 (4.1)	
61-80	200 (19.2)	117 (17.0)	
81-100	727 (69.8)	515 (75.0)	
Unknown	3 (0.3)	5 (0.7)	
<b>Fatigue symptoms</b>			0.001 <sup>2</sup>
0-40	793 (76.2)	578 (84.1)	
41-60	167 (16.0)	67 (9.8)	
61-80	59 (5.7)	30 (4.4)	
81-100	21 (2.0)	10 (1.5)	
Unknown	1 (0.1)	2 (0.3)	
<b>Pain symptoms</b>			<0.001 <sup>2</sup>
0-40	859 (82.5)	618 (90.0)	
41-60	71 (6.8)	34 (4.9)	
61-80	70 (6.7)	17 (2.5)	
81-100	40 (3.8)	15 (2.2)	
Unknown	1 (0.1)	3 (0.4)	

SD= standard deviation. Unknown categories excluded from significance tests.

<sup>1</sup> t-test; <sup>2</sup>  $\chi^2$  test for trend; <sup>3</sup>  $\chi^2$  test; <sup>4</sup> Education data collected at 1 year after randomisation, so not available for all participants; <sup>4</sup> EORTC QLQ-C30 scores range from 0-100: *higher* scores indicate *better* functioning but *worse* symptoms

**Table 2: Themes derived from women’s invited comments at 5 years, showing most frequent component items, for the random sample of women who commented**

<b>NEGATIVE COMMENTS</b>	<b>Number (% of 496) of women reporting theme at 5 years</b>
<b>Chronic medical problems including physical functioning:</b> Asthma, breathlessness, diabetes, heart disease, hypertension, chronic conditions e.g. multiple sclerosis, migraine, Parkinson’s disease, rheumatoid and osteoarthritis, fractures or falls, back or joint pain, fibromyalgia, muscle pain or injury, mobility problems	170 (34.3)
<b>Breast and related problems:</b> Breast pain, arm lymphoedema, cancer recurrence in the breast, breast abnormalities, radiotherapy effects to the breast, body image	129 (26.0)
<b>Systemic treatment side effects:</b> Tamoxifen side effects, hot sweats, weight gain, sexual problems	108 (21.8)
<b>Surgery (excl. breast cancer related surgery) &amp; Hospital Admissions</b> Gynaecological, dental, or other surgery, orthopaedic, falls	28 (5.6)
<b>Acute or transient health problems:</b> Colds, viral infections, ‘stomach upset’	47 (9.5)
<b>Psychological problems:</b> Depression or taking antidepressant medication, history of mental illness (e.g. schizophrenia) anxiety disorders, panic attacks, stress	89 (17.9)
<b>Life events or family problems:</b> Bereavement, husband’s illness, house move, relationship problem	43 (8.7)
<b>Job problems:</b> Redundancy, early retirement, job loss and other job related issues	10 (2.0)
<b>Other cancers:</b> Any cancer other than second primary breast cancer / recurrence / metastasis	12 (2.4)
<b>Aspects of Care:</b> Problems with diagnosis, treatment or follow-up, GP or specialist	17 (3.4)
<b>Family history of cancer:</b> Family members with cancer, genetic risk	14 (2.8)
<b>Effects of aging:</b> Older age affecting recovery, uncertain symptom attribution, e.g. tiredness	40 (8.1)
<b>Future concerns:</b>	55 (11.1)

Cancer related worries, fear of cancer recurrence	
<b>POSITIVE COMMENTS</b>	
<b>Good aspects of care:</b> Gratitude to hospital staff and trials unit, felt well supported	149 (30.0)
<b>Good recovery from cancer:</b> Feeling back to normal, positive attitude	80 (16.1)
<b>Personal support:</b> Support from friends, family, GP, religion	27 (5.4)
<b>Positive life events:</b> e.g. grandchildren, family births, marriage	16 (3.2)

Percentages add up to >100% as some women have commented in more than one category

## **Supplementary Material**

### **Appendix A: A preliminary exploration of proffered comments received between 0 and 24 months in the Quality of Life substudy in the START trials**

#### **Methods**

Unsolicited letters or comments written in the QL booklets received between 0 and 24 months in the START trials quality of Life substudy were abstracted and typed verbatim for each patient (identified by their study ID) for each time point, in order to explore their content in more detail.

An inductive qualitative methodology described by Pope (2000) was used to create themes for collating comparable comments. The initial analysis of unsolicited comments was carried out by 2 coders (JM,PH), with overall guidance from an expert qualitative researcher (CM). Each comment was allocated to an appropriate theme created by the first author (JM) and reviewed by a second researcher (PH), A constant comparative method was used, where verbatim reports were compared both within and between participants' responses, to identify independent themes from their content. Where a theme was unclear, the classification was reviewed jointly until agreement was reached.

Many comments were written alongside a specific QL questionnaire item or subscale, which helped determine the appropriate theme. The patient's exact wording provided the over-riding factor in guiding categorisation, for example

*"Most of my concerns are caused by work rather than my illness and treatment"* would be categorised as a work-related comment.

Multiple comments from an individual patient were included in more than one category. For example: *"My life has changed drastically since I was diagnosed but it had nothing to do with my breast cancer.... Firstly I moved home, then my mother died, followed by my husband's death and finally with eye surgery and a diagnosis of arthritis....."* In this case the comments were allocated to three themes, 'life events', 'chronic medical/mobility' and 'surgery'.

Comments of a practical nature (such as apologies for late return of the questionnaire) were not coded. No assumptions were made about a concern or symptom having an enduring effect time (e.g. possible chronic disability or permanent functional difficulty) and no weighting was given to any of the proffered explanatory comments received.

## **Results**

Overall, 22% of women (482/2181) with evaluable data in the quality of life sub study proffered written comments in their booklets, or included letters, at least once between baseline and two years follow-up., increasing over time. The number of women making comments at baseline, 6, 12 and 24 months was 97/2181 (4.4%), 180/2046 (8.8%), 175/1985 (8.8%) and 236/1888 (12.5%) respectively. Characteristics of the overall trial cohort and the subgroup commenting over this time are shown in Table A.1 of this appendix. This shows broad comparability with



the overall trial cohort. Differences observed were generally small but statistical testing was not deemed reliable given the unselected nature of the women making comments.

Nine themes were created (Table A.2 in this appendix) and were relatively straightforward to identify; examples are shown in this appendix. Physical functioning and chronic medical problems were the most frequently used themes but psychological problems and life events / family problems were also often reported. These accounted for the majority of contextual life difficulties reported, many of which are not reflected in the self-report QL measures. Women frequently wrote alongside the relevant questionnaire item or PROM domain indicating that their rating reflected a non-cancer / non-treatment cause and wanted us to be aware of that.

Questions in the health economics section of the QL booklet concerning work status at one year follow-up showed that 77% women (834/1107) had returned to work at this point. Work status was unknown for 213 women and 580 were retired at baseline, but of those not returning to work 70 (50% of non-returnees) made explanatory comments, such as 'ill health', 'made redundant', 'retired early', or 'business closed'.

To investigate the women's concerns that their contextual problems may negatively affect associated QL ratings, we compared the EORTC functional domains and HADS Anxiety and Depression subscale scores for women commenting at the

same assessment point with those of women who did not comment on that occasion. These showed differences in the expected direction, that is, worse scores for women commenting on their concerns or contextual difficulties, for all variables (Data not shown). However, as the women commenting were a self-selected group, this was not deemed a reliable basis for inferring QL outcomes.

## **Implications**

Women's spontaneous comments, written in a naturalistic, unsolicited setting, highlighted concerns and situations in their lives that have been widely shown to affect the quality of life of breast cancer patients. They reflect the importance of the social context in the clinical trials setting and are relevant to the provision of support and holistic care. Such findings, if consistent in other trial patients, might encourage a more cautious interpretation of secondary endpoints in clinical trials such as START.

Therefore a decision was made to invite all patients to contribute comments at the final 5-year assessment, saying "*If you wish to write comments about any concerns, health problems or events which you think might affect the answers you give in the QL booklet, please do so*". This new analysis of invited comments is fully reported in the main paper.

## **References**

Pope C Ziebland S, Mays N. Qualitative research in healthcare: Analysing qualitative data. *BMJ* 2000; 320: 7227. 114

## **Themes derived from proffered comments (0-24 months follow-up), with examples**

### **Physical Functioning**

'I had difficulty completing the form as not sure which questions refer to breast cancer and which to general health. I have a crushed vertebra, which causes me considerable pain and discomfort. I suffer no pain from radiotherapy'

'I should stress that all slowness and extra time taken on simple tasks stems from a worsening hip condition. I am still waiting for a hip operation when I hope my mobility will be better next time you send me questions'

### **Chronic medical problems**

'I may be wrong but I feel any health symptoms I have are more to do with my heart problem, e.g. walking, breathing during strenuous activities, than my breast lumpectomy. I hope you will allow for this in my answers'

'Because I suffer from a mild form of MS my state of health depends on a level of fatigue. I don't think the cancer treatment has changed anything'

### **Breast related problems**

'After my operation, I came home and a nurse told me that my breast was infected, it really hurt and I had to return to have my breast drained, a very painful experience'

'I have been unable to answer some of the questions properly as a cancer was found in the other breast, a different type of cancer, it was removed and I now receive chemotherapy. I have no discomfort from the last cancer nor the radiotherapy'

### **Systemic treatment effects**

'I have come off tamoxifen as I put on loads of weight and my eyesight has been affected, also the hot flushes have been horrendous. I just wanted to make it clear why I'm dissatisfied with my appearance and why sometimes I'm a bit low'

'Please note that a lot of my replies are due to tiredness caused by difficulty sleeping. This is likely to be caused by the tamoxifen'

### **Surgery**

'A lot of my answers are affected by the fact that I had major heart surgery to have a mechanical heart valve replacement only 10 weeks before I had a mastectomy'

'Problems relate to hysterectomy operation. Still recovering'

### **Acute and transient health problems**

'The past week has definitely not been my 'best week'. I went down with a heavy cold and awful cough'

'Recovering from shingles which was very painful and my answers reflect this'

## **Psychological problems**

'I have been taking prozac since diagnosis and feel that this has affected my mood. I have experienced a change of mood since stopping HRT and commencing Tamoxifen with a return of menopausal symptoms'

'I have been feeling anxious and my GP has prescribed Seroxat tablets which I have been told will take a month or so to have an effect. So far I have been taking them for 2 weeks so hopefully when I complete the next booklet I will be feeling fine'.

## **Life events**

'My husband left me 2 weeks after surgery (not connected to surgery) and during my chemotherapy I got divorced....'

'My mother has also recently learnt that two of her cousins (on her mother's side of the family) have also had breast cancer...'

## **Job problems**

'I was extremely stressed by bullying in my work place before I was diagnosed. I have not yet returned to work but I am still emotionally affected by visits and phone calls from my employers Most of my concerns are caused by work rather than my illness and treatment'

'I returned to work for a period of two months only, before being signed off sick again... I eventually had to let the job go, as recommended by my doctor'

### **More than one theme**

'My life has changed drastically since I was diagnosed with breast cancer in 2000 but nothing to do with the breast cancer. Firstly I moved home, then my mother died, followed by my husband's death, and finally with eye surgery, and a diagnosis of arthritis for which I take strong painkillers'

'I feel tense or 'wound up' because I am looking after my 96 year old Aunt. I look forward with enjoyment to things rather less than I used to, because of my arthritis. Also my husband has prostate cancer'

**Table A.1: Characteristics of patients who proffered comments at 2 years and for the overall QL cohort enrolled in the START Trials Quality of Life study**

	<b>Overall Cohort N= 2208 (%)</b>	<b>Proffered comments subgroup (0-2 years) N= 482 (%)</b>
<b>Age at baseline (years): mean (SD) [range]</b>	56.9 (10.4) [26-86]	57.6 (10.6) [28-81]
<b>Highest level of education achieved<sup>1</sup></b>		
School certificate / O-level / GCSE / NVQ or equivalent	528/1899 (27.8)	114/438 (26.0)
A-Level / HND or equivalent	115/1899 (6.1)	31/438 (7.1)
Degree, post-graduate or professional qualification	439/1899 (23.1)	124/438 (28.3)
None of the above	725/1899 (38.2)	151/438 (34.5)
Unknown – not completed on form	92/1899 (4.8)	18/438 (4.1)
<b>Employment prior to diagnosis<sup>1</sup></b>		
Full-time	540/1899 (28.4)	130/438 (29.7)
Part-time	443/1899 (23.3)	87/438 (19.9)
Self-employed	132/1899 (7.0)	33/438 (7.5)
Retired or household work	1095/1899 (57.7)	263/438 (60.0)
Other (voluntary, job-seeking, student, sick leave)	281/1899 (14.8)	79/438 (18.0)
Unknown – not completed on form	41/1899 (2.2)	6/438 (1.4)
<b>Type of surgery</b>		
Breast-conserving surgery	1831 (82.9)	392 (81.3)
Mastectomy	377 (17.1)	90 (18.7)
<b>Adjuvant systemic therapy</b>		
None	128 (5.8)	32 (6.6)
Chemotherapy alone	224 (10.1)	50 (10.4)
Tamoxifen alone	1266 (57.3)	267 (55.4)
Chemotherapy & Tamoxifen	537 (24.3)	118 (24.5)
Other	42 (1.9)	14 (2.9)
Unknown	11 (0.5)	1 (0.2)
Global health/QoL during past week at baseline <sup>2</sup> : median (IQR)	66.7 (56.2-83.3)	66.7 (50.0-83.3)

SD= standard deviation, IQR=interquartile range

<sup>1</sup> Education and employment data collected at 1 year after randomisation, so not available for all participants (1899 and 438 1-year forms completed for overall cohort and 2-year proffered comments group respectively). Women could tick more than one employment category, hence percentages add up to >100%.

<sup>2</sup> Subscale from EORTC QLQ-C30; score ranges from 0-100, with *higher* scores indicating *better* global health / quality of life.

**Table A.2: Themes derived from women’s proffered comments showing most frequent component topics, received between baseline and 2 years’ follow-up in the START Trials**

<p><b>Physical functioning:</b></p> <p>Arthritis (rheumatoid and osteoarthritis) fractures or falls, back or joint pain, fibromyalgia, muscle pain or injury, mobility problems</p>
<p><b>Chronic medical problems:</b></p> <p>Asthma, breathlessness, diabetes, heart disease, hypertension, skin rashes, drug reactions (excluding Tamoxifen or other cancer therapies), chronic conditions e.g. MS. Migraine, Parkinson’s disease</p>
<p><b>Breast and related problems:</b></p> <p>Arm lymphoedema, cancer recurrence in the breast, radiotherapy effects on the breast</p>
<p><b>Systemic treatment side effects:</b></p> <p>Weight gain, hot sweats ‘tamoxifen side effects’</p>
<p><b>Surgery (excluding breast cancer related):</b></p> <p>Gynaecological, dental, or other surgery.</p>
<p><b>Acute or transient health problems:</b></p> <p>Colds, viral infection, ‘stomach bug’</p>
<p><b>Psychological problems:</b></p> <p>Depression or taking antidepressant medication, history of chronic mental illness (e.g. schizophrenia) anxiety disorders, panic attacks</p>
<p><b>Life events or family problems:</b></p> <p>Bereavement, husband’s illness, house move</p>
<p><b>Job problems:<sup>1</sup></b></p> <p>Redundancy, early retirement, job loss and other job related issues</p>

<sup>1</sup>Only collected in years 1 and 2



## **Appendix B: Themes & Examples of Comments made at 5 Years in the START Trials**

### ***Instructions given:***

*Written at the top of a blank page in the 5-year Quality of Life booklet: "Please feel free to add your own comments. We will be very pleased to have them"*

*A letter to every patient was enclosed with the 5-year QL Booklet, saying: 'If you wish to write comments about any concerns, health problems or events which you think might affect the answers you give in the QL booklet, please do so. You will find a blank sheet of paper at the end of the booklet. This is entirely voluntary, but please feel free to write as little or as much as you want. Your comments will, of course, remain anonymous and confidential but they may be used to help inform doctors and nurses about the results of the study in publications and we will ensure you cannot be identified by them.'*

### **Chronic Medical problems and physical functioning**

'Any negative replies I have given do not refer to my breast cancer treatment, but totally unconnected medical problems'

'Osteoporosis and IBS cause pain in my lower body. Not worried about breast cancer and doing OK'

'I suffer from diabetes, heart disease and IBS, this will have affected answers'

## **Breast and related problems**

'My main problems have been about the use of my right arm, post axillary clearance and this does limit my use of that arm for carrying bags and swimming, rowing etc'

'I have had further recurrences of cancer. I found lumps under my other arm, all were cancerous. Had a second mastectomy. Feel as if living with a time bomb'

'I feel self-conscious about my breast as red lines around armpit from RT and black ring around nipple'

'The skin problems with my affected breast are chiefly the noticeable outline of the radiotherapy area, which I understood would disappear in 6 to 12 months after cessations of treatment, but which now looks as if it will be a permanent feature'

## **Systemic treatment side effects**

'I was on Tamoxifen for 2years and Arimidex for 3 years.... these have made my life extremely uncomfortable and none of the remedies worked. This had a huge negative effect on sleeping, sex, weight-gain, morale and self-esteem as well as general life.....However the quality of life, even after cancer should be treated with equal importance and one should not be made to feel 'lucky to be alive!'

'The on-going problem of hot flushes has severely restricted my social life and also relationships with others'

'I feel cheated that the drugs took away all sexual desire.... Now at 57 my sex life will never return. But mentally I feel I should be enjoying sex'

### **Surgery (excluding breast cancer related surgery) and Hospital Admissions**

'I had a knee replacement in July. Had mild ulcerate colitis in Oct and admitted to hospital last week, this affects answers'

'Until this year felt very well, active and looking forward to a holiday of a lifetime. Then I was rushed to Hospital for keyhole surgery and they found an ovarian cyst. Been off work since'

'I have recently been in car accident and suffered a fractured sternum and whiplash. At present unable to carry out normal duties at home and work'

### **Acute or transient health problems**

'Suffering from double vision following eye tests. Awaiting results which is giving me anxiety..'

'My health and quality of life affected by cough and cold virus also sore throat which has kept me awake at night'

'These answers are not a true reflection of my breast cancer. I have had flu for the past week and am still recovering'

### **Psychological problems**

'Carer for husband for 10 yrs. Mood swings due to his illness'

'Felt quite low for some time, could be due to a lot of trouble at home with some of the family and nothing to do with my cancer...'

'My tension is nothing to do with my breast cancer. It is to do with my husband who wishes to spend retirement abroad. I don't wish to leave this country, friends & family. Causing tension and anxiety'

### **Life Events: General and Family problems**

'Just lost youngest daughter (39 years) to cancer'

'Since RT I have moved house, lost my husband, moved again, started part time business and met a new partner. Much of my anxiety or worry has been attributed to these life experiences'

'Widowed last year, which has affected my answers'

### **Life Events: Job problems:**

'After diagnosis I lost my job. I believe that there was a connection and that led to my depression and anxiety'

'I am tired a lot of time and feel unable to work and pursue leisure activities'

'I am uncertain about the future in relation to work. The saying "the misery of certainty is far worse than the certainty of misery'

### **Other cancers**

'I now have bowel cancer'

'I have been diagnosed with cancer of the ovary'

'I have acute myeloid leukaemia'

### **Aspects of Care (negative)**

'Delay in initial treatment, GP did not refer me for a year. Feelings of anger added to distress & anxiety'

'I've never seen my consultant and felt that everything was rushed and would have liked to speak to a breast care nurse about the alternative treatments....'

'Not enough support given when treatment is finished. More help should be given'

### **Family History of Cancer**

'I am v anxious and depressed because cancer is rife in my family'

'Work part-time, I am tired and anxious as family history of breast /ovarian cancer

'My sister died 10 yrs after diagnosis with ovarian cancer so it's at the back of my mind'

### **Effects of Ageing**

'I find it difficult to distinguish whether any minor problems are due to cancer treatment or to getting older e.g. occasional forgetfulness, weight gain'

'My aches & pains are due to age rather than treatment. Delighted with the team that took care of me. Health at my age is v good'

'My health problems are to do with age and arthritis'

### **Future concerns: Cancer related worries**

'In the last 6 months, 2 of my friends have died from breast cancer and another friend is in a hospice..... Mostly I consider myself to be well and cured of the illness, but from time to time I remember what I've been through and wonder what the future holds especially when I see my friends suffering'

'Even now 5 years on, I am very worried and sometimes I can't sleep properly, it is always on my mind'

'When I stopped Tamoxifen I felt very frightened, and worried that the cancer would re-occur. I felt as if a safety net had been pulled from under me'

### **Positive Comments:**

#### **Good Aspects of Care**

'Thanks for care and support during the 5 years'

'Been interesting doing the trial. Made me think about my health and well-being'

'Cancer turned out to be blessing'

'Pleased to have been part of the trial and hope it helps in some way'

#### **Good Recovery from Cancer**

'I remain positive, have an excellent social circle and enjoy my life. Cancer has given me a very positive outlook on life, I realise the value of friendship, grabbing opportunities and living each day to the full'

'I've changed my outlook to life – I take this as a wake-up call to appreciate life and to look after myself more carefully in terms of food and exercise. Through my treatment I was always worrying "what if" in case it came back. Now I've been discharged I feel a sense of relief to get on with life'

'I've tried to look into more spiritual and positive things in life and get on to life in a positive way'

### **Personal Support (friends, family, GP, religion)**

'Everyone has been so kind and happy to answer any questions and fears I had. I am a Christian and feel that my faith has played a vital part in my recovery'

'I have a positive attitude to most things and with the help of a loving family, great friends and neighbours with plenty of interests inside the home and outside'

'I have had a positive attitude the whole time and a lot of help from family, quite sure that helped. Plus most important of all I have real faith in God, in a very quiet way'

### **Positive Life Events**

'Recently completed a degree which has helped with my feelings of wellbeing & self-esteem. Each day feel stronger and more alive'

'Breast cancer has not held me back. 6 months walking in India'

'I have now qualified as a teacher, a new life and partner'

### **Mixed Comments (not mentioned in table)**

'Reconstruction (flap) has made a big difference, helped mentally. Felt depressed for other factors unrelated to health. Hot flushes improved and now stopped tam and hopefully lose some weight. Good thing about breast cancer has been the focus on important things in life'

'Have arthritis therefore trouble with a long walk. Have diabetes so feel nauseas at times. Treated for depression with Prozac for 9mnths. Now feel great look forward to future and consider myself very fortunate'

'Suffer slightly from depression 3 months after radiotherapy onwards and continuing. Receiving anti-depressants for anxiety stress and headaches. Information from the team was excellent. Completing the questionnaires has helped in appreciating how far I've progressed in 5 years'

### **Comments about commenting**

'I have a few symptoms unrelated to breast cancer. Facial nerve spasm affects my eyes. Q does not give an opportunity to say if any aspects of current health are felt to be linked with breast cancer. '

'Very concerned no questions asking other factors in my life. One problem was telling already stressed family members of my health problems - made my life even more difficult'