Results:

	n	% 10 Year LR free
RT + TAM	98	100 ± 0
RT only	110	93 ± 3
TAM only	107	93 ± 3
Neither	96	82 ± 4

Entry was also allowed to *2-way randomisation* for units which had opted to give RT or TAM to all their cases. Analysis by randomisation then allowed RT versus no RT with both arms including some cases receiving TAM by elective choice of Unit (or) TAM versus no TAM, both including some cases receiving elective RT.

Results:

	n	% 10 Year LR free	% 15 Year LR free	W-G	*p*
RT	571	97 ± 1	93 ± 1	20.5	<0.000
No RT	568	88 ± 2	86 ± 2		
TAM	213	96 ± 2	92 ± 4	12.3	<0.000
No TAM	217	87 ± 3	83 ± 3		

Analysis by treatment received confirms that results from randomisation (intention to treat).

Survival overall (all cases) is 91 ± 1% at 10 years.

Conclusion:

1. Omission of any adjuvant therapy led to a recurrence rate of 1.8% per annum. This was reduced by the use of either TAM only or RT only.
2. Use of both TAM and RT produced no LR's.

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O-48 THE POST-OPERATIVE RADIOTHERAPY IN MINIMUM-RISK ELDERLY (PRIME) RANDOMISED TRIAL OF ADJUVANT RADIOTHERAPY AFTER BREAST CONSERVING SURGERY: IMPACT ON QUALITY OF LIFE AND COST-EFFECTIVENESS AT 5 YEARS

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Objectives: To assess whether in older women with 'low risk' axillary node negative breast cancer (T0–2, N0, M0) treated by breast conserving surgery and adjuvant endocrine therapy the omission of post-operative radiotherapy affects quality of life and is cost-effective.

Design: Randomised controlled multicentre trial.

Participants: Patients (255) with follow up to 5 years from the end of recruitment.

Interventions: Whole breast radiotherapy (40–50 Gy) or no breast radiotherapy.

Main outcome measures: Quality of life, anxiety and depression, cost effectiveness.

Results: No difference in overall quality of life or anxiety and depression was found. However, in the subscales of the EORTC QLQ C30 and BR23 questionnaires, there were significantly higher levels of insomnia within the non-irradiated group. By contrast, the irradiated patients reported higher levels of breast symptoms, and social function was slower to recover. The mean Quality Adjusted Life Years were similar in the two arms with marginally higher levels in the radiotherapy arm. The additional cost of providing radiotherapy was £2128 per patient. Local recurrence rates at 5 years were 6% (95% CI 0–12%) in the non-irradiated group and 0% in the irradiated group.

Conclusion: Breast radiotherapy is tolerated well by most older breast cancer patients without impairing their overall health related quality of life (HRQOL). Concerns about HRQOL should not be a primary consideration when deciding whether or not to recommend postoperative radiotherapy after breast conserving surgery and adjuvant endocrine therapy. The 'no radiotherapy option' is cost effective in the short term.

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O-49 THE INFLUENCE OF PATIENT-RELATED AND SURGICAL FACTORS ON OVERALL COSMESIS AND LATE TOXICITY AFTER ADJUVANT BREAST RADIOTHERAPY: RESULTS FROM THE CAMBRIDGE INTENSITY MODULATED RADIOTHERAPY (IMRT) TRIAL

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Background: The Cambridge Breast IMRT Trial demonstrated that improving dose distribution using IMRT leads to significant reduction in telangiectasia at comparatively early follow-up. The secondary aim was to elucidate the influence of patient-related and surgical factors on late toxicity and cosmesis.

Method: The influence of such factors on late toxicity assessed using photographic, clinical and patient-reported endpoints at 2 years following radiotherapy was analysed in 1014 patients.

Results: Patients with a moderate or poor baseline surgical cosmesis had an increased risk of moderate or poor overall cosmesis (odds ratio (OR) = 38.19; 95% CI 21.9–66.7; $p < 0.0005$), and of developing any clinically assessed breast shrinkage (OR = 4.96; 95% CI 3.67–6.71, $p < 0.0005$) and induration (OR = 2.78; 95% CI 1.92–4.01, $p < 0.0005$) at 2 years. Increased breast volume was significantly associated with the development of several late toxicity endpoints ($p < 0.0005$). Current smokers had an increased risk of developing pigmentation (OR = 2.09, 95% CI 1.23–3.54; $p = 0.006$). Post-operative infection requiring antibiotics was associated with increased risk of telangiectasia (OR = 3.39, 95% CI 1.94–5.91; $p < 0.0005$) and breast oversensitivity (OR = 1.78, 95% CI 1.27–2.49; $p = 0.001$).

Conclusions: Baseline post-surgery, pre-radiotherapy cosmesis is an important determinant of overall cosmesis at 2 years after radiotherapy. An important component of breast induration and shrinkage is actually due to surgery rather than radiotherapy. Larger breast volume, baseline surgical cosmesis, post-operative infection and smoking influence late radiotherapy toxicity. Modification of preventable risk factors such as post-operative infection and smoking may limit the development of late toxicity.

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O-50 TARGIT (TARGETED INTRA-OPERATIVE RADIOTHERAPY FOR EARLY STAGE BREAST CANCER): RESULTS FROM THE TARGIT A RANDOMIZED CONTROLLED TRIAL

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Background: After breast conserving surgery, 90% of recurrent cancer occurs within the index quadrant. Hence, restricting radiation therapy to the immediate area around the tumour bed after removal of the primary tumour may be adequate (Vaidya JS et al. Br J Cancer 1996;74:820–4).

Materials and methods: Using the technique of partial breast irradiation developed at UCL (Vaidya JS, Baum M, Tobias JS, et al. Ann Oncol 2001;12:1075–80) we launched the international TARGIT A randomized controlled trial in March 2000 comparing the policies of TARGIT versus standard whole breast external beam radiotherapy (EBRT) after breast conserving surgery with local recurrence as the main outcome measure (www.thelancet.com/protocol-reviews/99PRT-47). Accrual from 28 international centers reached 2232 in April 2010, with 80% power to detect a difference in relapse rate of 2.5% (the non-inferiority margin).

Results: Patient demographic and tumour characteristics are as follows: mean age 63 years (IQR 57–69), mean tumour size 12 mm (IQR 9–18 mm), N stage 17% +ve. We intend to present the unblinded data with an analysis of safety and efficacy.

Conclusions: If this analysis shows non-inferiority, then a clinically significant difference in early local recurrence between TARGIT and EBRT remains unlikely, making single session partial breast irradiation with TARGIT a plausible new standard of care in the near future.

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O-51 CLINICAL OUTCOME OF PATIENTS MANAGED IN A DEDICATED PRIMARY BREAST CANCER CLINIC FOR OLDER WOMEN (THE CLINIC)

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Background: The Clinic was established in 1973. Over the last decade, it has evolved into a combined surgical/oncology facility supported by dedicated breast care nurses. Also, surgery, with integral axillary staging, and adjuvant radiotherapy (RT) and systemic therapy have become standard for most patients though non-operative treatments (e.g. primary endocrine therapy (PET)) are used in others based on multi-disciplinary assessment in the Clinic. This study aimed to compare the clinical outcome across these periods.

Methods: Over 36 years (1973–2009), 1708 women $\geqslant$70 years with early operable primary breast cancer were managed in the Clinic according to a single set of clinical guidelines at any time point. Analysis was carried out based on retrospective review and continued update of patient records.

Results: As at 50-month median follow-up (maximum = 261):

	1973–1999	2000–2009	
N	917	791	
Treatment	*N* (%)	*N* (%)	
Surgery	392 (42.7)	446 (56.4)	
PET	510 (55.6)	324 (41.0)	
Primary RT	9 (1.0)	12 (1.5)	
No treatment	6 (0.7)	9 (1.1)	
Adjuvant endocrine therapy[a]	124 (31.7)	247 (55.5)	
Adjuvant RT[a]	15 (6.3)	155 (38.4)	
Outcome (% per annum)			*p*-value
Local recurrence[a]	2.2	0.5	<0.000
Regional recurrence[a]	1.8	0.4	<0.000
Contralateral cancer	0.7	0.4	0.091
Metastasis	2.9	1.9	<0.002
5-year breast cancer specific survival	80%	90%	<0.000
5-year overall survival	56%	68%	<0.000

[a] Surgery group only.

Conclusion: In this recent decade, while surgery became the predominant treatment, a significant proportion of patients (~40%) had non-operative therapies, selection of which was based on assessment in the Clinic. This management approach appears to produce excellent clinical outcome, which is significantly better than earlier period.

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O-52 EAST OF ENGLAND BREAST CANCER SURVIVAL CLOSE TO BEST IN EUROPE

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