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; $p = 0.001$).