This design has created issues that are new for a coordinating center. Addressing confidentiality, specific staff members at the CC have patient contact only, all patient identifiers are kept in a locked office only accessible by those staff members, and patient contact is made on private direct phone and fax lines. Development of the consent and recruitment materials, counseling, teaching about randomization and keeping to a minimum the number of patients assigned to the centers and later found ineligible, all provide new challenges for a coordinating center.

The effectiveness of these plans will be periodically assessed and adjusted as needed to achieve recruitment efficiently.

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EVALUATION OF THE START (STANDARDISATION OF BREAST RADIOTHERAPY) TRIAL

Joanne Haviland, Judith Bliss, Mark Sydenham, Clare Cruickshank, John Yarnold on behalf of the Trial Management Group

Institute of Cancer Research

Sutton, Surrey, United Kingdom

Background: The aim of START is to test the effects of radiotherapy (RT) schedules using larger fraction sizes on rumour control, normal tissue responses and quality of life in women prescribed postoperative RT for early breast cancer. START is a highly successful trial involving over half of UK RT centres and completed accrual of 4,400 patients 18 months ahead of schedule. Little is known about the effects of trial participation.

Aim Of evaluation study: To evaluate how START had run, whether there was any impact on RT practice outside the trial, and any lessons for future trials.

Methods: In November 2002 a brief questionnaire was sent to all START centres.

Results: All 34 centres replied and the individual response rate was 132/350 (38%). All disciplines involved replied; mostly clinicians (42.6%) or radiographers (32.6%). Overall START was rated very highly, 64.3% of individuals said that START had had an impact on their practice outside the trial, or 88.2% of centres. Many were now using revised RT planning techniques and treatment as routine. Communication with patients and between departments has improved

Conclusions: START has had a beneficial impact on the centres, largely due to the integral RT Quality Assurance Programme, which assisted in standardising RT planning and treatment - effects that are long lasting outside the trial. There is now a committed network of centres for future UK RT trials. The survey has provided important and valuable information that can be fed back to the funding bodies and used when developing future trials. We suggest that such an evaluation is good practice for all trials.

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EXPERIENCES OF CONSUMER ORGANISATION INVOLVEMENT IN A UK MULTICENTRE RANDOMISED CONTROLLED TRIAL

A. Langston, M. McCallum, M. Cameron, M. K. Campbell and S. H. Ralston

University of Aberdeen

Scotland, United Kingdom

Background: Although, consumer involvement in individual studies is often limited, their involvement in health research is generally considered to be beneficial. This presentation aims to share our experiences of a more integrated relationship between a trial and a consumer organisation.

Setting: The PRISM trial is a UK multicentre, randomised controlled trial comparing treatment strategies for Paget's disease of the bone (PDB). The National Association for the Relief of Paget's Disease (NARPD) is the only UK support group for sufferers of PDB and has worked closely with PRISM from the outset. NARPD involvement is integral to the conduct of the trial and specific roles have included: peer-review; trial steering committee membership; provision of advice to participants, and promotion of the trial amongst PDB sufferers.