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Title The Feasibility of Conducting a Multicenter Randomized Controlled Trial of Treatment for Localized Prostate Cancer: The ProtecT (prostate testing for cancer and Treatment) Study

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Aim

To evaluate the feasibility of a full-scale multicenter, randomized controlled trial of treatments for localized prostate cancer, including: feasibility of 'case finding' in 3 UK cities, the reliability of PSA testing, and the psychosocial impact of case finding. To determine the most efficient/effective design for full-scale treatment trials, including specifying treatment arms and investigating comparative cost effectiveness of nurses and urologists in recruitment. To understand randomization and treatment decision-making. To pilot outcome measures and procedures for proposed main trial.

Conclusions and results

Case-finding: 8823 men (57% of invited) checked at prostate clinics. 879 (10%) had high PSA. Biopsy found 230 cases of prostate cancer (184 clinically localized). Detection rate was 2.1%. Positive predictive values confirmed that a PSA cut-point of 3ng/ml was suitable.
Randomized trial of recruitment: 90% of eligible cases consented to randomization to nurse or urologist. Effectiveness was similar in both arms, but the urologist arm was more expensive since higher salary costs outweighed their tendency for shorter appointments.
Randomized trial of treatment: The 3-arm trial was the most popular treatment trial option, with 84% opting for this rather than the 2-arm trial ($p<0.001$). Acceptance of treatment allocation was high (71% in 3-arm trial).
Qualitative research: PSA testing viewed as an opportunity to detect an unknown condition. Most men understood that the study involved investigation of treatments. Recruitment rose gradually during the feasibility study, from 30%–40% at outset to 70% by May 31, 2001.

Recommendations

A full-scale randomized trial of treatment for localized prostate cancer, preceded by case finding, is feasible in the UK. Case finding was acceptable and prostate cancer was detected in 2% of clinic attendees. No significant difference in urologist vs nurse ability to recruit men for the treatment trial, but nurses were more cost effective.

Methods

RCT of treatment preceded by community case finding, integrating qualitative research methods at each stage.
*Case-finding:*Men aged 50–69 years from specific primary care centers in 3 UK cities were invited to a 30-minute prostate check clinic where they were informed about the study and asked to consent to a PSA test. Men with elevated PSA were invited for biopsy.
Randomized trial of recruitment: Men with localized prostate cancer were asked to consent to randomization to a nurse or urologist to discuss recruitment, the need for a treatment trial, and the advantages/disadvantages of each treatment.
Randomized trial of treatment: All subjects were asked to consent to followup, and these formed the pilot for the trial procedures and outcomes.

Further research/reviews required

The NHS HTA Programme has funded a proposed full-scale, 3-arm randomized treatment trial to be undertaken in 9 clinical centers in the UK. It will involve over 100 000 men, and recruitment will take 5 years (commenced September 2001). An MRC Programme grant is being prepared to further investigate the role of qualitative research methods in RCTs.

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