PrEvENT - Prostate cancer: Evidence of Exercise and Nutrition Trial

Key Words: Randomised control trial; Cohort study; Mixed methods; Prostate cancer; Radical prostatectomy; Nutritional and physical activity intervention; Biomarkers; Feasibility trial; Accelerometers; Pedometers

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Abstract

This is the over-arching large cohort study with a nested feasibility randomised control trial, which will be conducted within the prostate cancer theme.

A cohort of men will be established, who will have newly diagnosed localised prostate cancer, and will be waiting to undergo radical prostatectomy at Southmead urological department, North Bristol NHS Trust.

These men will be recruited into the cohort study, additionally providing consent to participate in other research that is directly relating to the overarching trial.

Data will be collected when men enter the cohort study, and biological samples will be extracted during surgery (see additional project approval forms for further details).

Men will undergo surgery and following recovery, those who agree will be recruited to the nested RCT feasibility trial. Data will be collected at this stage about a number of outcomes including dietary and physical activity behaviour, urinary symptoms, psychological symptoms and causal beliefs.

Men will then be randomised into one of a number of intervention groups, consisting of a combination of a dietary and physical activity intervention, or the control.

Follow up data will be collected at either 1 or 3 months, and 6 months following randomisation. Key outcomes will be adherence to and tolerance of the intervention.