ProDiet: The Feasibility of a Randomised Controlled Trial of Dietary Interventions for Men at Elevated Risk of Prostate Cancer

Introduction and Objective: Prostate specific antigen (PSA) testing identifies many men with elevated levels just below biopsy thresholds and others with negative biopsies. However, these men are at increased risk of subsequent prostate cancer diagnosis. The ProDiet study aimed to establish the feasibility of utilising dietary interventions in these men within a randomised trial.
Materials and Methods: A total of 469 men aged 50-69 years with PSA levels between 2.0-2.95 ng/ml or a negative biopsy result were identified through community-based PSA testing in the ProtecT (Prostate cancer testing and Treatment) randomised trial of localised prostate cancer treatments (ISRCTN 20141297). Men were randomised to daily lycopene (44 to active lycopene, 44 to placebo capsules, 45 to lycopene-rich diet) and green tea (45 to active supplement, 45 placebo capsules, 43 drink) in a 3x3 factorial design for 6 months. Men completed dietary records (FFQ) and questionnaires at enrolment and 6 months after randomisation. Trial outcomes included recruitment, retention and adherence rates, PSA and serum levels of green tea and lycopene compounds at baseline and at 6 months. 20 participants were interviewed in a nested qualitative analysis. ProDiet trial ISRCTN 95931417.
Results: A total of 133 men were randomised (28%) and 124 completed follow-up (93%). Compliance with interventions was high, 93/112 (83%) stated that they took all the capsules and 75/112 (67%) adhered to the dietary options. Interviews revealed that men regarded the interventions as ‘simple’ and ‘straightforward‘ with routines established around mealtimes to increase adherence. The interventions were palatable with few side effects, which were usually transient. There was little change in PSA levels over the six month study period. For example, with the green tea drink the mean PSA level at baseline was 3.84 ng/ml and 3.85 ng/ml at follow-up; with the lycopene rich diet, 3.37 ng/ml at baseline and 3.42 ng/ml at follow-up. Some men continued the interventions and most would consider participating in a longer trial.
Conclusions: High adherence to multiple dietary interventions suggested that a definitive dietary prevention trial for men with an elevated risk of prostate cancer is both feasible and acceptable.