

Irish Section Meeting, 16–18 June 2010, Nutrition – Getting the Balance Right in 2010

## **A randomised controlled trial to evaluate the efficacy of a 6-month dietary and physical activity intervention for prostate cancer patients receiving androgen deprivation therapy: midpoint analysis**

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Treatment with androgen deprivation therapy (ADT) for prostate cancer is associated with changes in body composition, including increased fat and decreased lean mass, increased fatigue and decreased quality of life. No study till date has evaluated the effect of a dietary and physical activity intervention on these treatment-related side effects. The aim of our study was to evaluate the efficacy of a 6-month dietary and physical activity intervention in prostate cancer patients treated with ADT.

Prostate cancer patients prescribed ADT treatment for at least 6 months were recruited and randomly assigned to an intervention or control group. The intervention group met with a nutritionist to receive one-to-one counselling to help them modify their diet to meet healthy eating guidelines and achieve 30 min of brisk walking, 5 or more days per week. The control group received standard care. The primary outcomes were body composition, fatigue and quality of life at baseline, 3 and 6 months. Change in dietary intake, perceived stress, functional capacity and energy expenditure were investigated as secondary outcomes.

At time of analysis, 21 men had been recruited to each group. The men in the intervention group had a statistically significant reduction in mean body weight at 3 months (–2.7 kg, 95% CI –3.9 to –1.5), while weight in the control group increased (1.2 kg, 95% CI 0.2–2.3). Similarly BMI ( $P < 0.001$ ) and waist to hip ratio was significantly reduced in the intervention group compared to control group ( $P = 0.01$ ). The mean changes in the % of fat and total fat were –1.42% (95% CI –1.8 to –1.1) and –2.2 kg (95% CI –2.8 to –1.5) in the intervention group and 0.9% (95% CI 0.4–1.4) and 1.2 kg (95% CI 0.4–1.9) in the control group ( $P < 0.001$ ), respectively. There was a much greater reduction in mean fatigue scores in the intervention group (–4.5, 95% CI –9.1 to 0.04) compared to the controls (–0.9, 95% CI –4.3 to 2.6). Quality of life was higher for men in the intervention than control group ( $P = 0.05$ ). Functional capacity measured by a 6-min walk test increased significantly in the intervention group compared with the control group (26 m [95% CI 12.7–39.2] v. 1.1 m [95% CI –8.8 to 11.1],  $P = 0.003$ ).

The midpoint (3 month) results of this randomised controlled trial suggest that meeting healthy eating guidelines and including at least 30 min of brisk walking, 5 or more days per week can reduce the treatment-related side effects of ADT in prostate cancer patients. The impact of the intervention at 6 months will provide additional data which will inform future guidelines for prostate cancer patients treated with ADT.