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A randomised controlled trial to evaluate the efficacy of a dietary and physical activity intervention on prostate cancer patients receiving androgen deprivation therapy

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The utilisation of Androgen Deprivation Therapy (ADT) in prostate cancer patients is associated with a number of adverse side effects. These include; changes in body composition; an increase in fat mass and a decrease in muscle mass, increased fatigue and a reduced Quality Of Life (QOL)⁽¹⁾. To date no study has evaluated the effect of a dietary and physical activity intervention on reducing these side effects. The aim of this study was to test the efficacy of a 6-month diet and physical activity intervention on reducing the side effects associated with ADT.

Patients were recruited from the cancer centre at Belfast City Hospital and randomly assigned to either an intervention arm receiving individualised dietary and physical activity advice ($n = 47$) or a standard care control arm ($n = 47$). In order to test the efficacy of the trial, a number of assessments were conducted at baseline, 3 months and 6 months. These included assessment of dietary intake using 7-day diet histories and measurements of weight, height, waist-hip ratio (WHR) and fat mass. In addition fatigue, quality of life and stress scores were assessed at each time point.

| Characteristics | Intervention | | | Control | | | MGD | 95 % CI | * <i>p</i> -value |
|--------------------------|--------------|------|-------|----------|------|------|-------|--------------|-------------------|
| | Endpoint | | | Endpoint | | | | | |
| | M | S.D | C | M | S.D | C | | | |
| Weight (kg) | 85.9 | 10.5 | -3.2 | 90.0 | 14.3 | +0.8 | -3.31 | -4.5, -2.1 | 0.001 |
| BMI (kg/m ²) | 29.0 | 4.5 | -0.95 | 30.0 | 4.5 | +0.3 | -1.08 | -1.5, -0.7 | 0.001 |
| W.C. (cm) | 103 | 10.7 | -3.7 | 107 | 12.1 | +0.4 | -3.26 | -4.6, -1.9 | 0.001 |
| WHR | .98 | 0.1 | -0.02 | 1.0 | 0.1 | 0 | -0.02 | -.03, -0.004 | 0.009 |
| Fat mass (%) | 30.8 | 5.8 | -1.8 | 32.8 | 5.8 | +0.4 | -2.1 | -2.8, -1 | 0.001 |
| Fat Mass (kg) | 26.9 | 7.8 | -1.9 | 30.1 | 9.6 | +0.6 | -2.4 | -3.5,-1 | 0.001 |
| Lean muscle mass (kg) | 59.8 | 6.6 | +0.5 | 59.1 | 5.2 | -0.7 | +0.4 | -1.3, 2.0 | 0.9 |
| Fatigue | 29.4 | 15.5 | -1.3 | 34.1 | 19.0 | +1.3 | -2.83 | -7.8, 2.1 | 0.26 |
| FACT-P | 118 | 21.1 | +2.2 | 117 | 22.6 | -0.6 | 2.8 | -1.3, 6.9 | 0.2 |
| Stress | 10.5 | 6.9 | -1.2 | 11.2 | 10.2 | +2.2 | -2.53 | -5.4, 0.3 | 0.08 |

MGD-Mean group difference; C-Change from Baseline; M-Mean; S.D-Standard deviation; BMI-Body Mass Index; W.C-Waist Circumference; WHR-Waist-Hip Ratio;

FACT-P – Functional Assessment of Cancer Treatment-Prostate.

* Between group comparisons adjusted for baseline measurements. (Calculated by use of ANCOVA).

Weight, BMI and % fat mass decreased significantly ($p < 0.001$) in the intervention arm compared to the control arm with a between group difference of -3.31 kg (95%CI $-4.5, -2.1$), -1.08 kg/m² (95%CI $-1.5, -0.7$) and -2.1% (95%CI $-2.8, -1$) for each respective measurement, after adjusting for baseline values. A significant reduction in waist circumference was also apparent in the intervention arm compared to the control arm with a between group difference of -3.26 cm (95%CI $-4.6, -1.9$) ($P = 0.009$). Fatigue and QOL scores improved in the intervention arm compared to the control arm, however these changes were not significant.

This intervention has proven beneficial at reducing the body composition changes associated with ADT. It would therefore be prudent to advise prostate cancer patients who begin ADT to modify their diet and lifestyle to help reduce these side effects.

1. Smith MR, Finkelstein JS, McGovern FJ *et al.* (2002) *J Clin Endo Metab* **87**, 599–603.