

Randomised comparison of three weight control programmes during adjuvant treatment for early breast cancer

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Period of data collection: August 2008 - October 2011

Background: The idea for this study derived from a review of literature and constitutes a follow-up of previous work of weight gain in breast cancer patients and a survey of breast cancer patients' needs



Aims: To determine whether individualised weight control programmes are better than standard written advice for existing weight and preventing weight gain in first year after breast cancer treatment for women with early breast cancer. The project will involve a randomised controlled trial comparing:

1. A control group receiving standard written advice
2. A home based intensive mail and phone programme
3. A supervised group community based weight control programme

Data collection: The study will look at outcome over the first year of treatment amongst 480 early breast cancer patients.

Primary endpoint - Changes in body weight and composition (body fat, fat free mass, dual energy x-ray absorptiometry DXA, bioelectrical impedance) waist and hip circumference.

Secondary endpoints - Uptake and retention to the programmes and any adverse effects of the programmes.

Changes in:

1. Quality of life (functional assessment of cancer therapy; FACT-B, B_ES, -F).
2. Marker of breast cancer prognosis (insulin resistance, from fasting insulin, glucose HOMA).
3. Cardiovascular disease risk markers: total, LDL and HDL cholesterol, triglycerides, systolic/diastolic blood pressure.
4. Fitness: 12 minute walk test.
5. Arm mobility, function (quick DASH) and pain (pain rating scale, S-LANSS for neuropathic pain).
6. Dietary intake (7 day food diary) and activity (7 day activity diary) as measures of compliance.

7. Serum bone markers/bone specific alkaline phosphatase (BSAP) for bone formation and the cross linked C-telopeptides of type I collagen (CTX) for bone resorption.
8. Ipsilateral arm circumference (compared to contralateral arm) using perometer in women who have had ANC.
9. Isometric and isokinetic muscle strength of quadriceps amongst patients receiving aromatase inhibitors and age matched patients receiving tamoxifen.
10. Generic health status and quality of life (EuroQol EQ5D utility measure) and health resource usage to assess the relative cost effectiveness of the programmes.

It will also assess patients' experience of the interventions through indepth focus group discussions and individual interviews. Factors predicting adherence to interventions with scales of stage of behaviour change for weight control and exercise will also be explored.

Analysis: The primary analysis of the effect of the intervention will be an intention to treat based on comparisons between the groups defined at randomisation. The primary analysis will be tested using the regression modelling approach of generalised estimating equations (using the software package STATA) to allow all 3 time points to be analysed simultaneously, increasing power and allowing for better comparison across time points. Important confounding effects (such as age, baseline BMI, treatment, recruitment centre) will be included in the model. Secondary analysis will compare body fat at 12 months in the different treatment groups stratified by adjuvant treatment, and adherence to the programme to determine if there is an effect modification, using analyses of covariance.

To protect against bias the majority of outcome assessments and statistical analyses will be undertaken blinded to the group allocation.

Findings: This is an ongoing project.