Reviewer's report

Title: 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

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Reviewer: Andrew Vickers

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1. The sample size calculations are all wrong. First off, the authors are looking for a change of 7.4 with a with an SD of 6.2. This gives a sample size of 15 per group, not 36. Second, the correct analysis is by Analysis of Covariance (ANCOVA) with baseline score as a covariate. As baseline fat mass and post-treatment fat mass are likely highly correlated, this is the most efficient analysis. Appropriate sample size calculations can be found in Frison and Pocock (1992) and in Stata software. Third, no SD is given for the fatigue or FACT scores so the calculations cannot be checked. But my guess is that 36 patients per group will in no way have enough power for a 1 point difference on the fatigue scale.

2. The randomization section is insufficiently precise. Exact procedures need to be described to stop investigators either guess treatment allocation beforehand or changing it afterwards. Just saying that sealed envelopes will be used is not enough. Personally, I have never understood the use of envelopes given the ubiquity of computers (see http://www.ncbi.nlm.nih.gov/pubmed/17022927)

3. Who does the body composition measurement? Are they blinded?

4. The statistical plan is quite out of keeping with contemporary practice. “Last observation carried forward” should not be used (it is worse than just dropping missing data); change scores are inefficient compared to ANCOVA (see http://www.ncbi.nlm.nih.gov/sites/entrez/16269081 and http://www.ncbi.nlm.nih.gov/pubmed/11701584) ; it is simply nonsense to add variables that are imbalanced to a regression analysis: this is a randomized trial.

5. The authors claim that theirs is the first trial to look at body composition changes in patients with prostate cancer undergoing ADT. What about http://www.ncbi.nlm.nih.gov/pubmed/19949016 ?