Reviewer’s report

Title: The Individualized Diet and Exercise Adherence Pilot Trial (IDEA-P) in Prostate Cancer Patients Undergoing Androgen Deprivation Therapy: Study Protocol For A Randomized Controlled Trial

Version: 2 Date: 17 June 2014

Reviewer: Everardo Saad

Reviewer’s report:

The authors are conducting a single-blind (only study personnel), randomized controlled pilot trial to examine the feasibility and preliminary efficacy of implementing a group-mediated cognitive behavioral (GMCB) exercise and dietary lifestyle intervention among patients with prostate cancer undergoing androgen-deprivation therapy (ADT), under the hypothesis that the high attrition and poor adherence rates observed in previous studies on lifestyle interventions may have been due to failure to provide patients with the self-regulatory skills required to adopt and maintain behavioral changes. Patients are randomized to the GMCB lifestyle intervention or standard care. GMCB includes counseling delivered via small-group sessions, supervised and unsupervised exercise sessions, and phone calls, as well as nutritional counseling sessions. I believe the study design adequately test the hypothesis, and sufficient details are provided to allow replication of the work or comparison with related analyses. The planned statistical analysis appears appropriate, pending the issue on stratification outlined below. Of note, writing is very clear.

Major Compulsory Revisions
None.

Minor Essential Revision
Although authors clearly and convincingly explain why formal sample-size estimation was not entertained for this pilot trial, the relatively small sample size allows for important imbalances between both arms in terms of baseline factors that may eventually be associated with outcomes, thus affecting authors' ability to estimate the effect size for the future phase III trial. Therefore, authors should at least explain whether stratified randomization is being used, and, if not, the reason why.

Discretionary Revisions
None