

Author's response to reviews

Title: Comparison of a Low Carbohydrate and Low Fat Diet for Weight Maintenance in Overweight or Obese Adults Enrolled in a Clinical Weight Management Program

Authors:

James D. LeCheminant (jlechem@siue.edu)
Cheryl A. Gibson (cgibson@kumc.edu)
Debra K. Sullivan (dsulliva@kumc.edu)
Sandra Hall (shall@kumc.edu)
Rik Washburn (rwashburn@ku.edu)
Mary C. Vernon (mvernonmd@yahoo.com)
Chelsea Curry (ccurry@ku.edu)
Elizabeth Stewart (estewart@transformed.com)
Eric C. Westman (westm001@mc.duke.edu)
Joseph E. Donnelly (jdonnelly@ku.edu)

Version: 3 **Date:** 17 July 2007

Author's response to reviews: see over

Reviewer's report:

General

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

While the authors have taken the term efficacy out of the manuscript and have referenced other studies with high attrition rates - most studies at this point in time with that high of attrition rate provide intent-to-treat and completers analyses. Ideally both of these analyses should be provided.

More detail has been provided about the dietary intake of participants, but a complete description is necessary. So a table of the energy intake and the macronutrient content of the diet at the main assessments points, along with indication of statistical outcomes, is necessary. As this study is testing two dietary prescriptions, a complete description of the dietary data is imperative.

It is still not clear why the authors are using participant as their unit of analyses. The authors state that assignment of diet was conducted at the clinic level, and while it is understandable why participants within a clinic were not randomized to the two diets, this reasoning does not allow the unit of analyses to be the participant. The analyses should take into account the clinic level as stated in the previous review.

1. We have analyzed the primary outcome of this study using intent to treat principles by including participants who had withdrawn from the study in a Proc Mixed analysis. We have included a statement of this in the statistics section. However, as there was no difference in the statistics using intent to treat or per protocol, we retained reporting of the data throughout the paper for the completers of the program only.
2. We have included a table of energy and macronutrient intake data that contains these outcomes by main assessment period.
3. Our use of the word clinic in the manuscript is synonymous with group. Although we used 3 cohorts for each dietary clinic/group, cohorts within each group did not differ by group leader and instruction. In addition, there was no statistical difference among cohorts within each group. Therefore, we pooled the data from each dietary condition making 2 clinics/groups (low fat and low carb) for analysis.

As this was the case, we had 2 options: analyze at the group level and use group means (n=2) or analyze using individual observations. As we had the individual data available, our biostatistician suggested analyzing using the individual means to increase power. In addition, we have used a mixed effects model for analysis. The model included the group component. According to our biostatistical support, assuming all variables in the model are categorical (which is the case for our analysis), adding the group variable into the model compares group means; thereby taking into account the group/cohort averages into the analysis. We are happy to do an analysis by group means (n=2) as was suggested; however, a t-test will likely not change the outcome as the group means are very similar.

Reviewer 2 report: There is a great deal of variability in what are described as compliant subjects. According to figures, body weight responses ranged from -23 kg to +17 kg in the low carb group. Similar responses should be reported for low fat. Certainly with this much variability statistical power is low. However, these varied responses are quite fascinating and clearly shows that some people do very well and some very poor on both diets. I really think that given the lack of other biological measures, this is the potential real value of the study and you have an opportunity to showcase the diverse responses to different diets and discuss the implications for managing body weight. As analyzed and written/discussed this is only done in a very superficial manner.

Author Response:

We appreciate your comment to increase discussion of variability and have added that finding that there was variability for weight change within each dietary group to the abstract, results section, and the conclusions. In addition, we have increased our discussion of this point in the Discussion section.