Reviewer's report

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

Version: 3 **Date:** 24 July 2007

Reviewer: Holle A Raynor

Reviewer's report:

General

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

As has been mentioned several times in previous reviews, the analyses used in this study give rise to great concern, given the study design. While it can be understood that the authors would choose to analyze their data at the individual level, as that increases the number of units to analyze, the design of the study does not allow this, for the following reasons:

1) Group randomized trials are studies in which 1) the unit of assignment are identifiable groups (defined broadly to any group that is not constituted at random, so there is some physical, geographical, social, or other connection among its members); and 2) the units of observation are members of the group. This appears to describe this trial.

2) Membership in the group (clinic) is not established at random, thus group members are not independent, and have some commonality, which can be reflected in a measure degree of intraclass correlation. This intraclass correlation reduces the variation among members of the same group so that the with-in group variance changes:

a. There usually is a variance inflation error that occurs in these designs.

b. When this is ignored Type I error rate increases – thus analyses that assume independence are not appropriate for group-randomized trials.

An excellent reference on this topic is:

Murray, D. M.. 1998. Design and Analysis of Group-Randomized Trials. Oxford University Press; New York.

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

Discretionary Revisions (which the author can choose to ignore)

What next?: Reject as not sufficiently sound

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.