Reviewer’s report

Title: Is informed consent related to success in exercise and diet intervention as evaluated at 12 months? DR's EXTRA study

Version: 1 Date: 28 July 2009

Reviewer: Barton Palmer

Reviewer’s report:

I like the premise of this study. The idea being that effective consent not only fosters adherence to the bioethical principle of Respect for Persons, but that doing so may also foster the subject or participant’s engagement/commitment to the program to which he/she is consenting. This is important as it helps investigators and patients/subjects view the consent process as something more than just a regulatory compliance ritual to be “gotten through” and rather a dialogue that is in the mutual interest of both parties.

Minor essential revisions:

The two dependent variables (DVs) were (a) intervention implementation, and (b) intervention success in fostering changes in exercise or diet. Two questions related to these DVs were scored by intervention group personnel. More detail about the way these constructs were operationalized would be helpful here. What specific information/data was available to the persons answering these questions? What scoring guidelines and anchors were provided? Were inter-rater reliability and concurrent validity evaluated?

As naturalistic study, participant satisfaction with consent was not under experimental control. In the absence of either an experimental design or a clearer basis for discerning what factor influence intersubject variance in satisfaction, it is difficult to know whether satisfaction per se mediates the differences in the dependent variables, or if the association between satisfaction and the DVs reflects each being affected by some unmeasured or unidentified third factor.

Stepwise regression (with automated entry) is not an appropriate method for evaluating the causal role or importance of IVs on DVs. The intention/description of these analyses should clarified, i.e., whether used to test specific a priori models (if so, those should be stated and the order of entry specified) or (b) described as exploratory/hypothesis generation activities only.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.
Declaration of competing interests:

I declare that I have no competing interests