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: 24 July 2009

Reviewer: Stephen P Messier

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Major Complusrory Revisions

This manuscript examines the question whether participant understanding of the informed consent affects the outcome measures in a 12-month clinical trial. As someone who has experienced the frustration of explaining a clinical trial to a participant in detail only to have them quit because it wasn't what they expected, the premise of this manuscript is timely, and unique.

Unfortunately, the methods are vague. The authors estimated whether the participants attained good, moderate, or poor results. It is unclear what constitutes good, moderate, and poor. Exactly what were the outcomes measured? Table 1 indicated that good is attaining over 70%. 70% of what outcomes? The results section is just too vague. I would think compliance to the intervention would be a key outcome measure, yet these data are nowhere to be found.

In summary, the basic idea of the study is excellent and this information is important for clinical trial investigators. However, much greater detail is needed if the results are to be of value.

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

Quality of written English: Not suitable for publication unless extensively edited

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

'I declare that I have no competing interests'