Reviewer's report

Title: Prevention of non-communicable disease in a population in nutrition transition: Tehran Lipid and Glucose Study Phase II, Rationale & Study Design

Version: 1 Date: 6 February 2008

Reviewer: Larry Friedman

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The major problem is that it is sort of a protocol, but not entirely. With some re-organization and some clarifications, it could be published as a protocol. To be published otherwise, it would need to have major revisions. For example, the design features that make this trial special (such as duration, family-oriented intervention) would need to be emphasized and many of the routine design features (which, unfortunately, make up a large portion of this manuscript) would need to be de-emphasized.

In connection with this last comment, even if it were published as a protocol, there are far too many details in the Biochemical Measurements section and the Biostatistical Considerations section. Other sections, have unnecessary sentences (eg, the first two sentences in the Physical Activity Levels section; the first two sentences in the Rose Angina Questionnaire section). There are also too many references.

There is insufficient information about the eligibility and exclusion criteria (eg, age range entered) and whether more than one participant per family is allowed. If yes, it would be important to describe how that affects the intervention and analysis. Similarly, it is implied that more than one participant per school or classroom is enrolled. How that affect the analysis should be discussed.

Follow-up is projected for 20 years. That is an extremely long time for a clinical trial. Retention is discussed, and a bit (though not enough) about keeping the intervention group and the control group separate. But the impact of temporal changes in society and family structure should be discussed. Also, how outcome assessment will be kept independent of the knowledge of the investigators should be mentioned. How will the investigator team and support for the study be maintained for 20 years?

There are some relatively minor issues. In the Definitions for Risk Factors section, first sentence, JNC VI is cited. There has been a JNC VII. In the Dietary Interventions, Clinics section, reference 28 does not refer to DASH. Reference 1 cites Wikipedia. Because there is no assurance of accuracy, Wikipedia should not be used as a reference for a scientific publication.

Finally, the language needs some editing. Understandably, since English is not the native language of the authors, some review and editing (singular/plural agreement; inserting "the" or "a") would be required. In a few places,
inappropriate words or words with the wrong suffix are used.

In summary, perhaps the easiest "fix" would be to have the authors follow the structure of a protocol. But even then, they would have to both streamline and add additional information as I've indicated above.