Reviewer's report:

TLGS (Tehran Lipid and Glucose Study) is a large community based prospective study performed on a sample of 15005 individuals living in district-13 of Tehran, Iran. The first stage of the study, called phase I, started in 1998, is now finished. This article focuses on the rationale and study design of the second stage, i.e. phase II. The interventions being considered in phase II include life style and dietary interventions. Researchers are interested in the effects of interventions on NCD (Non Communicable Disease) risk factors and outcomes. Interventions were applied to 5630 individuals in the sample of 15005 residents and the rest of the sample forms the control group.

This is a large study that should be of interest to investigators worldwide. However, my general comment is that the paper reads like a manual of operations with little presentation of the baseline data. Only a few comparisons are provided comparing the two regions and these show a few significant (although small) differences in the regions.

1. Experimental design of phase II.

The adopted sampling method is multistage cluster random sampling (P. 4, line 8 from bottom). The trial is then said to be a "randomized community intervention" (P. 2, line 5 from bottom). The context implies district 13 was the selected cluster. Then within this district 15005 individuals were randomly chosen from residents covered by three medical centers. However, after this point it is not clear how randomization was involved in intervention assignment. 5630 participants in the sample, covered by one medical center that is far from the other two, were appointed to be the intervention group by the investigators without using any randomizing mechanism (P. 5, lines 3-5 and P. 10, line 7 from bottom). In other words, it is not clear that this is a randomized trial.

The authors said "residents of intervention area are similar to those resided in control region in baseline variables" (P. 10, lines 4-5 from bottom) and Table 2 was used to support their statement (P. 28). However, their Table 2 indicates, among the five listed variables, the two groups are significantly different in age and education, borderline different in body mass index, and as noted above, it would have been a much more interesting report if additional information has been provided in this table. No baseline adjustment plan was proposed.

2. Outcome variables.
The authors are very unclear in stating what the response variables are (P. 10, second paragraph). It is only mentioned occurrence of related events will be recorded and data from death certificate will be collected. Then what are the outcome variables? How are they defined quantitatively? Specifically, for each of the three research goals (P. 4, second paragraph) what outcome variables will be used?

Their “Biostatistical considerations” (P. 14) section should be organized according to the three research goals. Currently it is not clear how their research goals can be achieved using listed statistical methods. It will be nicer if steps and statistical analyses required by the three research questions can be stated separately.

4. Typos.
P. 3, line 9 from bottom: is Ä in
P. 10, line 7: patricipant Ä participant
P. 10, line 9: ocured Ä occurred
P. 10, line 11: cetificate Ä certificate
P. 14, line 19: Biostatical Ä Biostatistical
P. 15, line 8 from bottom: polychromous Ä polychotomous
P. 15, lines 6-7: need corrections

This article is in the scope of journal Trials. A major revision should make it acceptable for publication.