Reviewer's report

Title: Bone Mineral Density (BMD) Changes in a Bone Health Plan Using Two Versions of a Bone Health Supplement: A Comparative Effectiveness Research (CER) Study

Version: 2 Date: 8 June 2010

Reviewer: Meghan G Donaldson

Reviewer's report:

Major Compulsory Revisions

1. The principal concern I have is the reporting of this open label non-randomized trial. I would strongly suggest that the authors review and adhere to the reporting guidelines as documented by the CONSORT statement (http://www.consort-statement.org/home/). I recognize that the investigators chose to conduct a non-randomized study but I believe the CONSORT statement still applies. This will help to better organize the manuscript and will also provide a framework to address the concerns I have with the study. Please see J.P. Mohrn et al "A comparison of Warfarin and Asprin for the prevention of Recurrent Ischemic Stroke" NEJM vol 345:14444-1451 Nov 15 2001 as an example of reporting a CER study.

   a) Could the authors please justify the study design (a non randomized study)

   b) The authors did not specify a primary outcome (or a combined primary outcome). The authors state:

   “The purpose of this study was to conduct a CER comparing the changes in BMD, blood chemistries and self-reported quality of life between and within two groups of subjects following the identical bone-health plan but with two versions of the AlgaeCal bone-health supplement.”

   This statement is not revisited in the Methods section of the manuscript. From this statement one is left to guess that there are 3 primary outcomes for this study. Clearly defining the primary outcome (or a combined primary endpoint) will then inform the type of analysis. It is also unclear which comparison is of primary interest (change between groups or change within groups).

   c) It is also unclear how these 3 endpoints are being measured. The authors’ state that “DXA” will be used but they do not specify what instrument they are using (Lunar, Hologic???) and what site they are measuring (femoral neck, proximal femur, lumbar spine?). What instrument is used to measure quality of life? What is the 43 item blood panel measuring?

   d) The authors do not provide a sample size calculation.

   e) The authors need to provide justification for a 6-month intervention. If changes
in BMD are of interest this typically requires at least 2 bone remodeling cycles (roughly 8-10 months) (see Khan, McKay “Physical Activity and Bone Health” 2001).

2. The authors need to report a baseline table describing the participants in this study (age, sex, physical activity, quality of life, BMD, height, weight etc etc).

3. Please provide details regarding how participants were enrolled in this study. Were they recruited from campus, posters, TV advertisement, physician offices?

4. Materials and Methods (Bone Health Plan section). Please provide a reference for the study “a recent in vitro study demonstrated that AC…”

5. Materials and Methods (Health Literacy section). The authors need to provide additional details about the pamphlet that was provided to participants. For example, is it a government or?

6. Materials and Methods (Physical Activity section). This section regarding the physical activity intervention requires more detail. Were the participants asked to target a certain number of steps each day or was some type of goal implemented. I believe this was one of the messages from the JAMA review article re: pedometer interventions.

7. Materials and Methods. How was safety evaluated?

8. Results. Please edit your Figure of “flow of participants’ to reflect the CONSORT guidelines.

9. Results. Please provide tables with baseline and 6-month data for all relevant outcomes (BMD, step-counts from the pedometer, quality of life, blood panels etc)

10. Results. Please provide safety results.

Minor Revisions (typos etc)

1. Please limit the use of abbreviation in the text. For example the use of SG for Surgeon General.