Author's response to reviews

Title: Live Well: A Practical and Effective Low-Intensity Dietary Counseling Intervention for Use in Primary Care Patients with Dyslipidemia - a Randomized Controlled Pilot Trial

Authors:

- Doina Kulick (dkulick@medicine.nevada.edu)
- Robert D Langer (rdlanger@ihcpm.com)
- Judith M Ashley (jashley@cabnr.unr.edu)
- Kim M Gans (Kim-Gans@Brown.edu)
- Karen Schlauch (schlauch@unr.edu)
- Chad Feller (feller@unr.edu)

Version: 3 Date: 8 March 2013

Author's response to reviews: see over
March 6, 2013

Dear Dr. Hanna Kaduszkiewicz:

We are like to thank the reviewers for their valuable feedback to our manuscript: MS 1868561623878402, “Live Well: A Practical and Effective Low-Intensity Dietary Counseling Intervention for Use in Primary Care Patients with Dyslipidemia - a Randomized Controlled Pilot Trial” for publication in BMC Family Practice.

Below we are outlining a point-by-point response to the concerns of the two reviewers.

Response to reviewer Bonnieca Islam:

We graciously appreciate your time and thank you for the valuable feedback. Here is a point-by-point response to your review:

MINOR ESSENTIAL REVISIONS

1) Spelling mistake: Abstract, Results paragraph: (counseling "started" at) instead of "stared at".
- Done.

2) Protocol, Dietary assessment paragraph: missing open bracket " [ " around citations 8-
- Done.

3) Results, Patients paragraph: Missing closed bracket " ) " in last sentence after 4.14 mmol/L in Group A
- Done.

4) Result, Lipids second paragraph, last sentence: forgot to put in Group "A" occurred and Group "B" occurred
- Done.

DISCRETIONARY REVISIONS

1) Participants paragraph- why were patients with a food score >250 excluded? Would they not be the ones to most likely benefit the most from the intervention?
- The subjects who scored more than 250 on the dietary assessment were excluded because their diet was already rather good. Thus an intervention to further improve their diet would not be warranted, or at least would be unlikely to result in clinically meaningful changes. (No changes in the manuscript)
2) Counseling materials: 98 page book as part of the educational materials, how much did it cost? How and why would another primary care clinic invest in this cost (primarily privately run, fee for service clinics)? This would be a barrier to implementing this intervention.

-Your comments are very valuable. We have not addressed the cost of the intervention in this manuscript. The cost to print the book is about $5.00/copy. In an exit survey, not presented in this paper, we asked participants how much they would be willing to pay for the book if they had to buy it. The majority were willing to pay between $5.00 and $10.00 (No changes in the manuscript)

3) For demographic characteristics, instead of years of education, it would be helpful to know how many individuals had post secondary education. It is also important to note is the socioeconomic status (SES) of your population as we know people of lower SES have additional barriers to living healthy. If this was conducted in a primarily "middle class" population, would the results of the intervention hold for a lower SES population?

-As we had a small sample size, we treated “level of education” as a continuous variable. We agree with the reviewer that, in a larger sample size, assessing the level of education as a categorical variable would be useful. (No changes in the manuscript)

The study sample comes from the patient population of a clinic that serves a population of heterogeneous SES: patients with private medical insurances as well patients on Medicaid (state insurance for the underserved). As this was developed as a pilot study with limited sample size we did not stratify patients on SES either for enrollment or in the analysis. Interestingly, because Medicaid patients do not have access to dietary counseling as part of their healthcare benefits, we noticed that they were very keen to enroll in the study. A study that will specifically address the effect of this intervention in the lower SES would be very useful indeed. (We addressed this in the limitations of the page 16).

4) Could you look at the data by age groups and see which age group the intervention was most beneficial?

-We tried to explore this, but we did not have enough power/sample size to make meaningful conclusions. This would be a very useful to explore in a larger sample. (We addressed this in the limitations of the page 16).

5) If group B had a statistically significant improvement in overall diet score between visit 1 and 2 (just from having contact with PCP), is the dietary intervention required? Could the improvement between V2 and V3 be attributed to individuals being motivated after reviewing lab results?

For future studies, maybe this could be an additional arm (review labs but no diet intervention at V2).

-Even though no blood results were reviewed by the physician with the patients in group B at visit 1, the patients in group B had free access to their own results (This information was added in Fig 1), as part of their usual care. We could include a review of the labs at visit 1 in a future design. Regardless of having a lab review at the first visit, all participants in both study groups knew that they qualified because their lipid panels were less than ideal and their dietary assessments indicated room for
improvement.

As the intervention was related to dietary counseling we did not disclose detailed information about the diet test results to patients in group B at visit 1, because we considered that to be part of the dietary intervention.

Other published dietary intervention studies, like ours, have found statistically significant improvements in the diet in the control group. This could be the result of motivated patients who were interested in participating in a lifestyles changes study, or could be due to a Hawthorn effect, both of which could underestimate the magnitude of the effect of the counseling intervention.

When comparing the diet score at visit 2 between the two groups there is a much larger improvement in diet in group A (which had the intervention) than group B (50.3 vs. 22.3 average change in diet scores). Also after group B received dietary counseling we noticed a much larger jump in diet scores (visit 3 vs. visit 2).

Nonetheless a future study with a larger sample size could include an arm that gets only the detailed diet test report and no other intervention.

Thank you for the attentive comments.

6) How do you explain the big jump in the percentage of those in Group B that ended up with "very good" diet quality at the end of 6 months (after 3 months of intervention) in comparison to Group A that had a longer period of time for the intervention? Was it because of worsening lipid markers from V1 to V2 being the motivator? As shown in Fig 5, at six months even though group B appears to have a larger percentage of patients with the very good diet, the difference was not statistically significant (p=0.55).

-Could a poorer lipid panel at visit 2 motivate the patients to adopt a better diet than the dietary intervention itself? It is possible, and the results at visit 3 should be interpreted with this in mind. Randomization is used to minimize potential confounding factors when comparing two groups: our 2 groups were truly randomized for the first 3 months only and these first 3 months are more suitable to be used to assess the effect of intervention between the two groups. Fig. 5 shows that at 3 months (visit 2), group A scored significantly better than group B, p=0.02.

Comparing the groups using repeated measures analysis, would not be statistically correct because of this mixed study design (3 months of randomized design, follow up by 3 months of intervention for all the subjects). Instead we chose to compare the two groups separately at visit 1, 2, 3 and interpret the results accordingly. Thank you for your attentive comments.

7) Table 2: Is there a way to report this data in a way that flows better? ie would it be better to have Time (V1 V2 V3, V2 vs V1 etc) along the top for both Group A and B?

-We are aware that Table 2 is rather large. We have tried different displays, including the one you suggested with the Time along the top. They were all actually more cumbersome to follow than the version chosen for this manuscript.
Response to reviewer Natalia Loskutova:
We graciously appreciate your time and thank you for the valuable feedback. Here is a point-by-point response to your review:

Major Compulsory Revisions:
1. In the discussion section (p15) of the manuscript, the authors claim that the modified diet scores correlated nearly perfectly with the original. I believe more details should be provided in the Methods/Results sections to support this claim.
   - In the RESULTS/Diet section we wrote: ”There was a very strong correlation between the “original” and “modified” diet scores, \( r = 0.967, p=0.0005 \). Preliminary analyses showed the relationship to be linear, with both variables normally distributed, as assessed by the Shapiro-Wilk test (\( P >0.05 \)), and there were no outliers.
   To further address the reviewer's concern and clarify our findings we have added the following sentence in the DISCUSSION section, page15: “It is important to note that our modified diet scores had nearly perfect correlation (Pearson correlation \( r = 0.967, p=0.0005 \)) with the original scores.

2. In the Results section (p13) the authors’ statement on the absence of significant changes in triglycerides in either groups contradicts the information provided in Table 2 where statistically significant changes are reported in Group B.
   - Thank you very much for pointing this error to us. The correction says (see page 13): “In contrast to the significant changes in total and LDL-cholesterol, there were no significant changes over time in HDL-cholesterol in either group, and the triglycerides showed only significant improvement in group B at visit 3.

3. Providing data on group comparison on diet, total and LDL-cholesterol changes over time would significantly strengthen the statement regarding significantly better magnitude of changes in Group A vs. Group B (p14), which currently is not supported by the results provided.
   - Thank you very much for pointing this out. We rewrote the entire paragraph (see page 14 last paragraph, continued on page15).

4. The Framingham Risk score is included in the analysis and appeared to change modestly but significantly in both groups – do authors believe that a 1-2 point reduction is clinically important? If so, the manuscript would benefit from a discussion on effects of the intervention on risk reduction.
   - We added some comments regarding this issue in the Results (page13, last paragraph) and Discussion sections (page15, second paragraph)
Thank you.

Sincerely,
Doina Kulick, MD, MS (corresponding author)