Author's response to reviews

Title: Adjunctive naturopathic care for type 2 diabetes: patient-reported and clinical outcomes after one year

Authors:

Ryan Bradley (rbradley@bastyr.edu)
Karen J Sherman (sherman.k@ghc.org)
Sharyl Catz (catz.s@ghc.org)
Carlo Calabrese (ccalabrese@npri.org)
Erica B Oberg (eoberg@bastyr.edu)
Luesa Jordan (jordan.l@ghc.org)
Lou Grothaus (grothaus.l@ghc.org)
Dan Cherkin (cherkin.d@ghc.org)

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Author's response to reviews: see over
Dear Editors:

We are pleased to submit our revised manuscript, which responds to the helpful comments from the reviewers, for consideration for publication in BMC Complementary and Alternative Medicine. Our title remains the same: "Adjunctive naturopathic care for type 2 diabetes: patient-reported and clinical outcomes after one year.” Below we offer a point-by-point response to each reviewer.

Re: comments from Dr. Evans: Thank you for providing the extra details to complete the citation; it is now corrected.

Re: comments from Dr. Najm:

1. **Clarify the background as context for the research question:** We now clarify that this study directly fills several research gaps, which were necessary to fill prior to conducting randomized trials of ND clinical approaches in diabetes. We note that this is the first prospective report of combined patient-reported and clinical outcomes, as well as the first report of outcomes of ND care provided to persons not previously pursuing ND care on their own initiative. This ND-naïve patient population makes our findings more generalizable to the broader U.S. population than those of previous studies. This content has been added to page 3, paragraph 3 (i.e., Background paragraph 3).

2. **Methodology:** We agree that a randomized trial would have provided more definitive results. We had wished to conduct a randomized trial but were unable to do so because the program announcement from the NIH National Center for Complementary and Alternative Medicine (NCCAM) specifically forbade the use of a randomized design. Nevertheless, we attempted to minimize the effects of confounding on our results by:
   a. Creating a comparison group of eligible but not invited patients for our clinical outcomes.
   b. Using rigorous statistical methods to model our results, adjusting for differences in probable confounders between groups.
   c. Reporting combined changes in patient-reported clinical and utilization outcomes in order to improve the interpretation of the results.

3. **Request for additional discussion points:**
   a. **Re: possible explanations for the observed drop in the number of ND visits after 6 months:** We now discuss our results in the context of other research on behavior-targeted interventions, and discuss the potential impact of the lack of a standardized visit schedule or treatment protocol on the outcomes. This content has been added to Discussion paragraph 1 on page 8.
   b. **Re: reason for smaller changes in outcomes after 6 months:** A brief discussion of this topic has been added to Discussion paragraphs 1 and 3 on page 8. The literature reported the most common barriers to sustaining changes in behavior include depression, low motivation for change, and reduced self-efficacy. Although we observed improvements in all three of these domains extending to 12 months, behavior change likely requires ongoing maintenance, support and patient empowerment which were not specifically embedded in our intervention. Additionally, because the confidence intervals for the effects at the two time points overlap, the apparent reduction in outcomes at 12 months may reflect random variation in participant response.
   c. **Re: the inclusion of diabetic counseling in usual care:** We captured total visits to primary care; emergency room care; specialty care including cardiology and endocrinology; and nutritionists but do not know how much counseling occurred during these visits. We saw no differences in use of emergency care, specialty care, or nutritionist care between the groups but did observe, and report, an increase of 1.5 visits/year to primary care in the ANC group. Regardless of the exact components of “usual care”, the changes in risk resulting from any beneficial services would have been captured in the results reported in the manuscript. This point is now included in Discussion paragraph 2 on page 7.
   d. **Re: consistency/standardization of NDs:** As we note on page 4, we deliberately recruited licensed NDs with at least 5 years in a general practice and we did not require that they practice in a standardized
manner. This lack of standardization reflects the pragmatic design of our study and strengthens our
design. We now explicitly state this point in Discussion paragraph 2 on page 8.

e. Re: how this study adds to the literature, and supports the need for an RCT; This report will contribute the
first prospectively collected observations to the literature of changes in outcomes during ND care for
diabetes. It also provides the only available data on outcomes in non-self-selecting patients. Because we
found clinically and statistically significant improvements in a small cohort of patients and limited
residual confounding by our choices in design and analyses, we believe the need for an RCT is
increasingly compelling. We have added these points to Discussion paragraphs 1 and 5 on page 7 and 8
respectively.

Thank you for your time in review and continued consideration of this manuscript for publication in BMC
Complementary and Alternative Medicine. Please contact me by email with any remaining questions or concerns:
dcherkin@ghc.org

Best regards,

Daniel C. Cherkin, PhD