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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Iratxe Puebla

Executive Editor, BMC Complementary and Alternative Medicine

Dear Iratxe,

As you requested, I have incorporated a new paragraph into our manuscript providing additional details about the methodology we employed and how the study differs from the criteria for a clinical trial, in order to avoid any confusion on the part of the reviewers and readers, if the manuscript is accepted.

The new information has been incorporated into the first paragraph of the Methods which now reads:

Overview of Study Design

We invited a cohort of people with type 2 diabetes to receive up to 1-year of adjunctive naturopathic care (ANC). Unlike an experimental clinical trial with an established protocol, typically including specific treatment instructions and a schedule of visits, we took a very pragmatic, health services orientation with this research in order evaluate outcomes during and following exposure to naturopathy as a whole discipline. Although participants did have a maximum number of allowable ANC visits within the year, i.e., eight total visits for diabetes, neither the number of visits used, content of visits, or frequency of visits was dictated. Rather, all treatment recommendations and visit follow-up were left to the discretion of the individual ANC providers. Patient-reported outcomes (PROs) were collected via telephone interview at 6- and 12-months and responses were
compared to baseline values. Changes in hemoglobin A1c (HbA1c), lipids and blood pressure were compared between baseline and both 6- and 12-months within the ANC cohort, and to a usual care cohort created using data available in patients’ electronic medical records (EMR). With the exception of reminding participants about their required laboratory visits and conducting the telephone interviews, our study team did not contact the participants during the study to remind them to return to ANC or encourage them to follow any treatment advice. Rather we simply observed and recorded the ANC and usual care utilization patterns of participants, abstracted ANC visit contents from the visit chart notes, and measured and reported the changes in relevant PROs and in clinical laboratory risk measures standard in the clinical care of people with type 2 diabetes for one year following baseline interviews. All elements of the study were reviewed and approved by the Group Health Institutional Review Board.

Sincerely,

Dan Cherkin