Authors’ Reply: Comment on “An Online Intervention Comparing a Very Low-Carbohydrate Ketogenic Diet and Lifestyle Recommendations Versus a Plate Method Diet in Overweight Individuals With Type 2 Diabetes: A Randomized Controlled Trial”

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This letter is in response to the letter from Dr Andrew Reynolds [1] about our publication, “An Online Intervention Comparing a Very Low-Carbohydrate Ketogenic Diet and Lifestyle Recommendations Versus a Plate Method Diet in Overweight Individuals With Type 2 Diabetes: A Randomized Controlled Trial” [2].

As Dr Reynolds notes, our study had several differences between the two groups including different diets, psychological tools, sleep education, and number of lessons. Given the combination of intervention components, we did not attribute all of the differences in outcomes to the nutritional composition of the diet, but to the diet “and lifestyle recommendations.” It was our goal, if this preliminary trial showed promise, to follow up with factorial screening experiments to better assess each component of our multicomponent very low-carbohydrate diet intervention.

We are currently testing our very low-carbohydrate diet intervention in this way, and we hope to vary the dietary component in future research. We agree that a randomized trial that varies only diet is an ideal way to ascertain to what extent the nutritional composition of the diet, specifically, contributes to the outcomes.

However, important information can be learned about the overall effects of diet and lifestyle interventions without such screening experiments and intervention optimization. For example, the landmark Diabetes Prevention Program trial, with more than 3000 patients with prediabetes, compared a multicomponent low-fat, calorie-reduced diet and lifestyle intervention to metformin or medicine placebo groups [3]. The intact, multicomponent program is now used nationally, but to our knowledge, no research has carefully varied the dietary
component to examine if the low-fat dietary recommendations are optimal. Despite this, this multicomponent program is supported by the Centers for Disease Control and Prevention and will be soon reimbursed by Medicare. Even so, we believe that the field needs to do more screening experiments and intervention optimization.

We acknowledge the baseline differences on some of our outcome measures. This can happen even with classic randomized controlled trials. Nevertheless, our statistical evaluations emphasize interaction effects and, as such, they emphasize relative changes and fully incorporate baseline information. Therefore, we disagree that the interaction effects are due primarily to these baseline differences. With respect to a post-hoc power analysis, a power analysis reveals the likelihood of observing a significant effect. We disagree that once a study has been completed there is any value to a post-hoc power analysis. After study completion, we know for certain whether effects are significant (“power” = 100% for significant effects, and 0% for non-significant effects), and these results utilize observed variability rather than estimates of variability that would have informed a pre-study analysis.

Conflicts of Interest

Frederick Hecht is on the Scientific Advisory Board for Virta Health. No other author declares any conflict of interest.

References

1. Reynolds AN. Comment on “An Online Intervention Comparing a Very Low-Carbohydrate Ketogenic Diet and Lifestyle Recommendations Versus a Plate Method Diet in Overweight Individuals With Type 2 Diabetes: A Randomized Controlled Trial”. J Med Internet Res 2018;10(5):e180 [FREE Full text] [doi: 10.2196/jmir.7672]
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