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Health effects of dietary patterns: critically important but vastly understudied

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The Dietary Guidelines for Americans recommend following a healthy dietary pattern (1, 2). This holistic approach reflects fundamental facts: individual nutrients and food components are consumed together and do not act in isolation (3, 4). Nonetheless, few clinical trials have tested the health effects of dietary patterns, especially trials that have explicitly tested a diet recommended by the Dietary Guidelines for Americans.

In this issue of the Journal, Krishnan et al. (5) address this gap by conducting a randomized, controlled, double-blind feeding study evaluating the 2010 Dietary Guidelines for Americans dietary pattern, which emphasizes fruits, vegetables, and whole grains; includes low-fat dairy products; and is reduced in sodium, solid fats, and added sugar. In this trial, 52 overweight or obese women with glucose intolerance and/or dyslipidemia were randomly assigned to the Dietary Guidelines for Americans dietary pattern or a typical American diet for 8 wk. Despite achieving a contrast in diet quality scores, there was no effect of the Dietary Guidelines for Americans–based diet on their primary outcomes, including change in fasting insulin, glucose, triglycerides, and oral glucose tolerance. They detected a significant ∼9-mm Hg reduction in systolic blood pressure (SBP) in the Dietary Guidelines for Americans group, but there was no significant between-group difference in SBP in the main intention-to-treat analyses.

Studying changes in glycemic parameters through improved diet quality without a reduction in body weight, as the investigators intended, is informative and has public health relevance, given the well-recognized challenges of achieving and sustaining weight loss. Critical issues in this trial are whether the study had sufficient power and whether the results are generalizable. Our opinion is that the power calculations were overly optimistic and that the trial was underpowered to detect a smaller yet more plausible effect of the Dietary Guidelines for Americans diet on fasting insulin. In their power calculations, the minimum detectable difference in fasting insulin was 5.32 mIU/mL, which corresponds to a net reduction of about one-third from the baseline level of ∼15 mIU/mL, whereas the observed difference was 2 mIU/mL. A second issue that may have affected study power was their eligibility criteria. For most outcomes, it is easier to detect a net difference when the baseline level of the outcome variable is high (6). In this trial, participants were eligible on the basis of abnormal baseline levels of either glucose or lipids, not fasting insulin. In this regard, the reality of designing and conducting a trial stands in contrast to the public health relevance; it is likely that following a healthy dietary pattern over a long period of time and early in life may be more beneficial, albeit harder to test, than adopting a healthy dietary pattern after individuals develop cardiometabolic abnormalities (the point at which dietary intervention trials are usually conducted).

Modifying diet through a healthy dietary pattern such as the Dietary Approaches to Stop Hypertension (DASH) diet and/or sodium reduction is a well-established strategy to lower blood pressure (7, 8). Given this prior evidence, one would expect that the Dietary Guidelines for Americans diet should lower blood pressure. There are several caveats to consider when interpreting the SBP findings reported by Krishnan et al. (5). First, the authors emphasize within-group reductions rather than between-group differences, which were not statistically significant. The investigators could have improved precision and power to detect a net difference by increasing the number of SBP measurements (9). Second, baseline SBP was higher by 5.4 mm Hg in the Dietary Guidelines for Americans group than in the typical American diet group; hence, the SBP reduction in the Dietary Guidelines for Americans diet group could, in part, be because of regression to the mean (10). Third, another potential reason for SBP reduction was an unexpected and differential change in weight [Krishnan et al., Supplemental Table 5 (5)]. Specifically, there was a greater reduction in weight in the Dietary Guidelines for Americans diet group than in the typical American diet (mean change of −4.1 compared with −1.4 kg), which may, in part, be because of the relatively low sodium intake in the Dietary Guidelines for Americans diet group. Fourth, SBP was not a primary outcome, and elevated SBP was not an inclusion criterion. The study population had a normal average SBP level at baseline, which makes it difficult to detect a change in SBP.

CMR is supported by a Mentored Research Scientist Development Award from the National Institute of Diabetes and Digestive and Kidney Diseases (K01 DK107782).

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First published online July 7, 2018; doi: https://doi.org/10.1093/ajcn/nqy173.

The overarching objective of this trial was to strengthen the evidence upon which to base policy that could have a broad, population-wide impact. There remains a need to conduct rigorous, adequately powered trials of dietary patterns. For future research, it would be worthwhile to consider the feasibility of a trial which tests the effects of dietary patterns in a large, diverse population with a sufficient duration in order to ascertain hard clinical outcomes. Second, the majority of dietary pattern studies have focused on achieving an ideal healthy diet; such trials typically appeal to those who are already consuming a good or moderate-quality diet. Trials designed to test more modest improvements in diet quality in high-risk populations who are consuming an unhealthy diet will likely have a greater public health impact. Third, studying other healthy dietary patterns endorsed in the dietary guidelines is warranted, such as the Mediterranean diet, and plant-based or vegetarian diets (2). Also, trials that test the effects of healthy, non-Western dietary patterns should also be conducted. It should be noted that trials of dietary patterns are challenging and expensive. Sufficient resources will be needed.

In summary, the trial reported by Krishnan et al. (5) addresses a gap in nutrition science—in a controlled feeding study, they assessed the cardiometabolic effects of a dietary pattern reflective of the Dietary Guidelines for Americans, i.e., a diet that is recommended for virtually all Americans. Nonetheless, there persists a need for rigorous, adequately powered trials that test the health effects of dietary patterns.

The authors' contributions were as follows—CMR: drafted the manuscript; and both authors: edited and provided final approval of the manuscript. Neither author reported a conflict of interest related to the study.

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