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Egg Consumption and Dietary Pattern among Adults with Type 2 Diabetes: A Randomized Single Blind Cross-over Controlled Trial

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Abstract

Objective: In our previous report, we examined the dietary pattern with the inclusion of eggs in the diets among persons with Type 2 Diabetes Mellitus (T2DM), using Healthy Eating Index (HEI) 2010. In this report, we re-analyzed our data with the current version HEI-2015.

Methods: Randomized, controlled, single-blind, crossover trial of 34 adults (average age 64.5 years; 14 post-menopausal women, 20 men) with T2DM assigned to one of two possible sequence permutations of 2 different 12-week treatments (2 eggs/day inclusion or egg exclusion), with 6-week washout periods between treatment assignments. For the egg inclusion phase, participants received advice from a dietitian on how to preserve an isocaloric condition relative to the egg exclusion phase. Dietary pattern was assessed with HEI-2015 at baseline, 6 weeks and 12 weeks.

Results: Compared with the exclusion of eggs from the habitual diet, the inclusion of eggs marginally reduced the diet quality score for refined grain foods (-0.6±3.4 vs. 0.7±2.2; p=0.0543) at 12 weeks. The diet quality score for total protein foods improved significantly from baseline (0.3±0.6; p=0.0078) at 6 weeks with the inclusion of eggs. The quality of dairy foods score decreased from baseline at 12 weeks (-1.3±2.9; p=0.0089) with the exclusion of eggs.

Conclusions: Short-term daily inclusion of eggs in the habitual diet in adults with T2DM could lead to improved diet quality. Our findings with the current version of HEI-2015 are somewhat similar to those that we observed using the preceding version HEI-2010.

Keywords: Eggs; Diet Quality; Dietary Pattern; Type 2 Diabetes

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Introduction

Diabetes is a public health problem of epidemic proportions, affecting approximately 35 million individuals in the United States (US) [1]. Yet, only about 27 million of these individuals are diagnosed [1]. An estimated 35% adults aged 18 years and older have pre-diabetes; only 1 of 10 persons with pre-diabetes is aware [1]. Within 5 years of having pre-diabetes, 15-30% of persons with pre-diabetes are expected to develop Type 2 diabetes mellitus (T2DM) [1]. The complications of diabetes include stroke, cardiovascular disease (CVD), hypertension, blindness, nervous system damage, kidney disease, limb amputations, and biochemical imbalances that can cause acute life-threatening events [1]. Total medical costs, including lost work and wages, for persons diagnosed with diabetes are estimated to be $327 billion [2]. Compared to persons without diabetes, persons with diabetes have medical costs that are more than two times higher [2], a risk of death that is more than 50% higher [1], and rates of cardiovascular mortality that are 2 to 4 times higher [1].

Lifestyle intervention is the underpinning for prevention and management in T2DM [3]. In previous studies a reduction of as little as 5-7% in body weight led to significant improvement in cardio-metabolic risk factors among those at risk for and with T2DM [4-6]. Patients at risk for or with T2DM are typically advised to consume foods with a low glycemic index [7,8]. Diets with a low glycemic index have been shown to improve serum lipid profiles, reduce C-reactive protein levels, and aid in weight management, preventing T2DM and CVD [9,10]. Eggs are low in glycemic index, and are a nutrient-dense food with the highest quality protein [11]. Additionally, eggs are satiating, and therefore have the potential to regulate calorie intake and play an important role in body weight reduction [12]. The consumption of eggs has been associated with increased intake of some healthful foods and reduced intake of some less healthful foods [13,14]. Hence, eggs have the potential to improve diet quality.

In our previous report, we examined how the inclusion of eggs in the diets of persons with T2DM impacted their dietary pattern as assessed by the Healthy Eating Index (HEI) 2010 [15]. The HEI is designed to reflect the recommendations based on scientific evidence, from the Dietary Guidelines Advisory Committee [16]. The Dietary Guidelines are updated every 5 years. As a result, after the release of each Dietary Guidelines report, the HEI is amended through collaboration with the U.S. Department of Agriculture (USDA) and National Cancer Institute (NCI) to reflect the recommendations. Based on the 2015-2020 report [17], the Advisory Committee recommended that the daily consumption of added sugars should be < 10% of total caloric intake and emphasized the importance of adopting a plant-based dietary pattern to prevent the development of chronic diseases such as obesity, T2DM, and CVD. The HEI-2010 was updated to the current version HEI-2015 to align with these changes [18]. We recently re-analyzed data from our previous report [15], with the HEI-2015 to assess the extent to which the current HEI amendments impact the dietary pattern with the inclusion of eggs among persons with T2DM.

Methods

Study Design

This was a randomized, single-blind crossover trial designed with a 4-week run-in period and two treatment assignments to compare the effects of short-term daily inclusion or daily exclusion of eggs on dietary pattern, as assessed by HEI-2015, in adults with T2DM. Following a 4-week run-period of an ad libitum diet, participants were randomized to one of two possible sequence permutations, and then underwent repeated measurements with the inclusion of 10 to 14 eggs per week, or egg exclusion, for 12 weeks in their diet, with a 6-week washout between treatments. Participants were randomized to 1 of 2 sequence permutations of egg inclusion and egg exclusion from the habitual diet. Each permutation included a 12-week treatment phase, followed by a 6-week washout phase, followed by 12-week alternate treatment phase. This study was approved by the Griffin Hospital Institutional Review Board (IRB) and also registered at the clinicaltrials.gov website (NCT02052037) before recruitment and screening of potential participants into the study.

Recruitment and Screening

Potential participants were recruited from the Lower Naugatuck Valley in Connecticut through newspaper advertisements and flyers. Those who responded were pre-screened over the telephone by the study coordinator to assess their eligibility via a structured interview using predetermined inclusion criteria. Those who met preliminary eligibility criteria and agreed to participate were invited to undergo clinical eligibility screening, and were asked to sign a consent form approved by the IRB. All participants were informed of the option of discontinuing participation at any time during the study.

The clinical screening physical examination consisted of weight, height, and blood pressure measures obtained by experienced study personnel using calibrated equipment. Participants underwent a glycated hemoglobin A1c (HbA1c) assessment. The screening laboratory assays were performed at the Griffin Hospital clinical laboratory. Data from the clinical screening, together with the physical examination and clinical diagnosis of T2DM, were used to establish the participants' eligibility for enrollment into the study.

Participants

Thirty-four participants (20 men and 14 women) were enrolled in the study. Inclusion criteria included: males greater than 35 years of age; post-menopausal females not currently on hormone replacement therapy; non-smokers; clinical diagnosis of Type 2 diabetes mellitus for at least 1 year, but no more than 5 years; $6.5\% \leq$ HbA1c $\leq 8.0\%$; and 25 $kg/m^2 \leq$ BMI ≤ 40 kg/m^2. Exclusion criteria included: failure to meet inclusion criteria; anticipated inability to complete the study protocol for any reason; current eating disorder; use of anti-hyperglycemic, lipid-lowering, or antihypertensive medications, unless stable on medication for at least 3 months; use of glucocorticoids, antineoplastic agents, psychoactive agents, or nutraceuticals; regular use of fiber supplements; restricted diets (i.e., vegetarian, vegan, gluten free); and known allergy to eggs.

Randomization and Blinding

The study participants were randomized to 1 of 2 sequence permutations (egg-included and egg-excluded) by the study statistician using SAS software for Windows version 9.3 (SAS Institute, Cary, NC). Each sequence permutation consisted of a 12-week treatment period, followed by a 6-week washout period, followed by an alternative 12-week treatment period. The study coordinator enrolled the participants and assigned them to 1 of the 2 sequence permutations generated with SAS by the statistician. The PI and study personnel assessing the clinical outcome measures were blinded to the treatment assignments throughout the study. Participants were labelled as receiving either sequence A or B. Only the study coordinator knew the sequence allocations assigned to each participant. Treatment allocations of the study participants were revealed by the study coordinator upon conclusion of statistical analyses.

Procedure

Egg Inclusion Phase

A registered dietitian counseled the participants to include 2 eggs/day (10-14 eggs/week) as part of their otherwise habitual ad libitum diet, while preserving an isocaloric condition relative to the egg exclusion phase. Participants were given personalized guidance on how to make room calorically for 2 daily eggs in their diet, relative to their habitual intake during the egg exclusion phase, while giving them latitude in determining how to adjust for the approximately 150 to 300 extra daily calories from the eggs, to better approximate a real-world scenario. The participants were instructed to make approximate caloric adjustments for the eggs according to their preferred method of preparation, e.g., hard-boiled, poached, fried, scrambled, or as part of egg salad or an omelet) on a given day. Dietary patterns of the participants were evaluated at baseline, 6 weeks, and 12 weeks.

Egg Exclusion Phase: The dietitian counseled the participants by providing relevant meal planning guidance and instructions to follow their usual ad libitum diets during this phase, with the exception of avoiding eggs and specific egg-containing products. Dietary patterns of the participants were evaluated at baseline, 6 weeks and 12 weeks.

Outcome Measurement

Dietary Pattern

Dietary pattern over the course of the study was tracked by asking study participants to provide information on the foods and beverages consumed during a 3-day period (i.e., 2 weekdays and 1 weekend day). For each 3-day period, the study participants completed 3 successive 24-hour recalls using a web-based Automated Self-Administered 24-Hour Recall (ASA24) [19], which guided them through the course of completing the recall data. ASA24 utilized information regarding the reported foods and beverages to generate information about the amount of nutrients intake and food groups in its output files. The averages of the 3 dietary recalls were calculated and were used as estimations of dietary intake at each time point.

Food groups and nutrients generated from the ASA24 output files were used to populate the HEI algorithm to compute scores of the various components of HEI and overall diet quality [20]. HEI measures diet quality, independent of quantity, which is used to assess compliance with the U.S. Dietary Guidelines for Americans and to monitor changes in dietary patterns [21]. HEI is a scoring system that could be used to determine the quality of a given dietary pattern, set of foods, or menu. HEI gives emphasis to variety of food groups, nutrient density, and improvement of food and beverage choices within calorie needs. HEI is continually being updated based on the recommendations from the Dietary Guideline Advisory Committee.

In the recent update of HEI, most of the components in the previous version HEI-2010 were retained in the current version HEI-2015 [18]. However, the empty calories component was substituted with two separate components (added sugars and saturated fats) to better align with the added sugars recommendation (i.e., < 10% total caloric intake) while preserving the concept that these components included remaining calories in the diet. With the change in the empty calories component, alcohol is no longer specifically addressed within a single component as it was in the HEI-2010. The overall calories contributed from alcohol in the diet continue to be included in the total energy used as denominator to compute the HEI-2015 scores. Changes were also made to the method by which legumes are allocated to the components. In the HEI-2010, legumes were allocated to just 2 components: total vegetables and greens; and beans, while in the HEI-2015 version, legumes are allocated to 4 components (total protein foods; seafood and plant proteins; total vegetables and greens; and beans) to significantly improve the scores based on adoption of plant-based dietary patterns.

After the revision from HEI-2010 to HEI-2015, the HEI currently consists of 13 components. All of the key 2015-2020 Dietary Guidelines food choice recommendations that relate to diet quality are reflected in the HEI-2015's 13 components [22]. Nine of the components [i.e., total fruits (i.e., includes 100% fruit juice); whole fruits (i.e., includes all forms except juice); total vegetables (i.e., includes legumes (beans and peas)); greens and beans (i.e., includes legumes (beans and peas)); whole grains; dairy (i.e., includes all milk products, such as fluid milk, yogurt, and cheese, and fortified soy beverages); total proteins foods (i.e., includes legumes (beans and peas)); seafoods and plant proteins ((i.e., includes seafoods, nuts, seeds, soy products (other than beverages), and legumes (beans and peas)); and fatty acids (ratio of poly- and monounsaturated fatty acids (PUFAs and MUFAs) to saturated fatty acids (SFAs))] focus on adequacy (i.e., dietary components to increase); and 4 of the components (i.e., refined grains; sodium; added sugars; and saturated fats) focus on moderation (i.e., dietary components to decrease). The individual components are scored on a density basis out of 1,000 calories, with the exception of fatty acids, which is a ratio of unsaturated to saturated fatty acids. Reported intakes between minimum and maximum standards for each component of the HEI-2015 are scored proportionately. All 13 components are weighted equally, since all aspects are considered equally important [21]. Some aspects of the diets are represented by 2 components and are assigned a maximum score of 5 points each, while other components have a maximum of 10 points [21]. The total HEI scores range from 0 to 100 points [21]. Higher HEI scores indicate diets that align better with dietary recommendations [21]. The performance of the HEI-2015 has been evaluated through an assessment of its construct validity, reliability and criterion validity [23-25]. We analyzed the 13 components of the HEI-2015 to update a prior analysis that we conducted utilizing the preceding version HEI-2010 to assess the dietary pattern changes associated with the inclusion of eggs in the diets in persons with T2DM [15].

Statistical Analysis

The sample size estimations were based on our primary outcome measure, HbA1c. The sample size was estimated to provide at least 80% power to detect a minimal difference of -0.3% in HbA1c between egg inclusion and egg exclusion in the habitual diet, with maximum allowable type I error of 5%. Generalized linear models were used to compare the components of the HEI-2015 scores between the egg-included diets versus egg-excluded diets. Paired student t-tests were used to assess difference from baseline to endpoints for each treatment assignment. Regression models were used to control for covariates (i.e., age, gender, race, compliance, and treatment sequence). All analyses at endpoints were based on intention-to-treat principle. SAS software for Windows version 9.4 (SAS Institute, Cary, NC) was used to carry out all statistical analyses. P-values of <0.05 were considered statistically significant. Data are presented as mean ± standard deviation except otherwise stated.

Role of the Funding Source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Participants Recruited and Included in the Analysis

A total of 351 potential participants were pre-screened over the telephone. Of those who were screened by telephone, 179 did not meet the inclusion criteria, 58 did not complete the phone screening, 117 were eligible for clinical screening, 38 did not pass clinical screening, and 35 completed clinical screening. Thirty-four adults (20 men and 14 women) with T2DM enrolled in the study. Of these, 32 participants went on to complete the study. One participant withdrew for a health reason (i.e., a kidney stone) unrelated to the study intervention during the egg inclusion phase, and another dropped out due to a myocardial infarction while in the egg exclusion phase. The study flow diagram has been presented in our previous publication [13]. Most of the study participants were male (58.8%), mainly Caucasians (76.5%) with an average age of 64.5 years. Demographic characteristics and baseline information are presented in Table 1.

Efficacy Endpoints

Six Weeks: Compared with the exclusion of eggs from habitual diets, the inclusion of eggs did not improve significantly (p>0.05) any of the diet quality scores of the 13 components of HEI 2015. However, the inclusion of eggs improved the diet quality score for total protein foods (0.3±0.6; p=0.0078) and decreased the diet quality score for dairy foods (-1.4±2.9; p=0.0188) from baseline (Table 2).

Twelve Weeks: Compared with the exclusion of eggs from habitual diets, the inclusion of eggs marginally reduced the intake of refined grain foods (-0.6±3.4 vs. 0.7±2.2; p=0.0543). The diet quality scores for total vegetables; greens and beans; total fruit; whole fruit; total protein; seafood and plant proteins; healthful fatty acids; whole grains; sodium; added sugars; and saturated fats were unaffected (p>0.05) with the inclusion of eggs in habitual diets compared with their exclusion. However, while the diet quality score of whole fruit was unaffected

Table 1: Baseline characteristics.

Variable	Value
Gender	
Female	14 (41.2%)
Male	20 (58.8%)
Race	
Caucasian	26 (76.5%)
African American	3 (8.8%)
Hispanic	5 (14.7%)
Age (years)	64.5±7.6
Healthy Eating Index 2015 score	53.0±10.6
Adequacy Components	
Total Vegetables[1]	3.5±1.7
Greens and Beans[1]	2.0±1.7
Total Fruit[2]	2.6±1.9
Whole Fruit[3]	3.0±1.9
Whole Grains	3.3±2.8
Dairy[4]	5.7±2.7
Total Protein Foods[1]	4.6±0.7
Seafood and Plant Proteins[1,5]	2.1±1.5
Fatty Acids[6]	4.2±2.3
Moderation Components	
Sodium	3.3±2.4
Refined Grains	6.1±2.7
Added Sugars	8.6±1.9
Saturated Fats	4.6±2.4

[1]Includes legumes (beans and peas)
[2]Includes 100% fruit juice
[3]Includes all forms except juice
[4]Includes all milk products, such as fluid milk, yogurt, and cheese, and fortified soy beverages
[5]Includes seafood, nuts, seeds, soy products (other than beverages)
[6]Ratio of poly- and monounsaturated fatty acids (PUFAs and MUFAs) to saturated fatty acids (SFAs)

Table 2: Change in outcome measures from baseline at 6 weeks.

Variable	Eggs Excluded	Eggs Included	*p*-value
Healthy Eating Index 2015 score	1.2±10.8	-3.0±12.1	0.1582
Adequacy Components			
Total Vegetables	-0.2±2.3	-0.1±2.1	0.8696
Greens and Beans	-0.1±1.5	-0.6±1.9	0.2106
Total Fruit	0.01±1.4	-0.3±1.8	0.4190
Whole Fruit	0.03±1.5	-0.4±2.0	0.3611
Whole Grains	0.05±2.8	-0.4±3.2	0.5567
Dairy	-0.6±3.2	-1.4±2.9*	0.2669
Total Protein Foods	0.1±0.7	0.3±0.6*	0.3141
Seafood and Plant Proteins	0.3±1.7	-0.2±1.6	0.2234
Fatty Acids	0.3±3.8	0.2±3.1	0.9048
Moderation Components			
Sodium	0.5±3.4	-0.1±3.9	0.4998
Refined Grains	-0.5±3.2	-0.7±3.8	0.8357
Added Sugars	-1.1±3.7	-0.4±3.3	0.4347
Saturated Fats	-0.1±1.6	-0.4±2.0	0.4743

* indicate significant (p-value <0.05) change from baseline.

from baseline with the inclusion of eggs, the exclusion of eggs increased their score (0.4±1.1; p=0.0377). Diet quality of the dairy foods score was unaffected from baseline with the inclusion of eggs but decreased (-1.3±2.9; p=0.0089) with the exclusion of eggs (Table 3).

Discussion

Our data suggest that the inclusion of eggs in the habitual diets among persons with T2DM, improved the quality of total protein foods and decreased the intake of refined grain foods. The diet quality of dairy foods intake decreased with the exclusion of eggs from the habitual diets. The intake of total vegetables; greens and beans; total fruit; whole fruit; seafood and plant proteins; healthful fatty acids; whole grains; sodium; added sugars; and saturated fats were unaffected with the inclusion of eggs in the habitual diets. The findings of our

Table 3: Change in outcome measures from baseline at 12 weeks.

Variable	Eggs Excluded Diets	Eggs Included Diets	*p*-value
Healthy Eating Index 2015 score	-2.5±11.0	-0.4±10.9	0.4492
Adequacy Components			
Total Vegetables	-0.3±2.3	0.1±1.9	0.4642
Greens and Beans	-0.4±2.0	-0.2±1.9	0.6950
Total Fruit	0.2±1.0	0.3±1.5	0.8285
Whole Fruit	0.4±1.1*	0.1±1.6	0.4189
Whole Grains	0.4±3.5	-0.7±3.1	0.1727
Dairy	-1.3±2.9*	-0.4±3.0	0.2276
Total Protein Foods	-0.02±0.8	0.1±0.6	0.3738
Seafood and Plant Proteins	-0.2±2.0	0.1±1.7	0.5631
Fatty Acids	-0.3±3.6	0.1±3.2	0.6467
Moderation Components			
Sodium	0.7±2.7	0.1±2.9	0.3891
Refined Grains	0.7±2.2	-0.6±3.4	0.0543
Added Sugars	0.4±2.5	-0.4±1.7	0.1574
Saturated Fats	-0.4±3.4	-0.04±3.0	0.6654

* indicate significant (p-value <0.05) change from baseline.

analysis using HEI-2015 were somewhat similar to our findings when using the previous version of the HEI (i.e., HEI-2010) [15].

In this report using HEI-2015, just as with our previous report using HEI-2010, we observed an improvement in the quality of total protein foods score with the inclusion of eggs in habitual diet among those with T2DM. The association between protein intake and T2DM varies with dietary patterns [26]. In a prior study by Lombardo M, et al. (2020) [27], the consumption of plant-based proteins has been associated with lower risk of developing T2DM among those at risk for T2DM. In another study, diets enriched with plant-based proteins have been associated with lower risk of developing T2DM in patients with coronary heart disease [28]. Further, Virtanen HE, et al. (2017) [29], demonstrated in Finnish men from the prospective Kuopio ischemic heart disease risk factor study that the consumption of plant-based and egg proteins was associated with the prevention of T2DM. Conversely, the consumption of animal proteins has been associated with higher risk of T2DM [27].

Likewise, in our analysis with HEI-2015, we observed a reduction in the intake of refined grain foods, as we did in our previous report with HEI-2010 with the inclusion of eggs in habitual diets among those with T2DM. In an ecological evaluation by Gross LS, et al. (2004) [30], increased intake of refined grains with decreased intake of fiber was associated with an upward trend in the prevalence of T2DM observed in the U.S. In a meta-analysis by Aune D, et al. (2013) [31], of cohort studies, substituting refined grains with whole grains was associated with lower risk of T2DM. The consumption of whole grains has been associated with lower risk of T2DM [32-34]. Further, in a study by Villegas R, et al. (2007) [35], the consumption of food with high glycemic index and glycemic load was associated with increased risk of T2DM in Chinese women.

Additionally, in this updated analysis, just as with our previous analysis, we observed a reduction of the quality of dairy foods score with the exclusion of eggs at 12 weeks, while it was unaffected with the inclusion of eggs. In a prospective study by Choi HK, et al. (2005) [36], higher dairy intake, especially low-fat dairy, has been associated with lower risk of T2DM in men. Likewise, in a meta-analysis by Alvarez-Bueno C, et al. (2019) [37], higher intakes of total dairy products and low-fat dairy products were associated with lower risk of T2DM. In another meta-analysis by Gijsbers L, et al. (2016) [38], higher intake of dairy products, particularly yogurt, was associated with lower risk of T2DM.

The intake of total vegetables; greens and beans; total fruit; whole fruit; seafood and plant proteins; healthful fatty acids; whole grains; sodium; added sugars; and saturated fats were unaffected with the inclusion of eggs in habitual diets among those with T2DM. Increased intake of total vegetables; greens and beans; total fruit; whole fruit; seafood and plant proteins; healthful fatty acids; whole grains and reduced intake of sodium; added sugars; and saturated fats have been associated with lower risk of T2DM [32,39-43]. We did not see any meaningful improvement in total vegetables; greens and beans; total fruit; whole fruit; seafood and plant proteins; healthful fatty acids; whole grains; sodium; added sugars; and saturated fats intake, probably due to the small sample size.

This study has several limitations that should be considered as we interpret these data. First, the sample size was small, with just 34 participants enrolled, which may have precluded us from seeing significance differences. However, the study's crossover design reduced our data variation and therefore improved the study's statistical power. Second, our study participants were predominantly Caucasians, male, and the females were all post-menopausal; therefore, this limits our ability to generalize our findings to other racial and ethnic groups and to pre-menopausal women. Third, this study relied on self-report by participants regarding their intake of foods and beverages, which can introduce measurement and recall biases by under- or over-estimating. However, the validated tool (ASA24) used to capture dietary data provided guidance to the study participants through the course of completing their recall. In addition, dietary data were reviewed by the study dietitian before statistical analysis. Fourth, the study participants were not monitored on a daily basis and were not administered a supervised diet. Therefore, the reliability of the dietary intake data depends on the honesty of the participants. However, this can also be viewed as a strength of the study because it provides a more realistic scenario and potentially increases external validity. Fifth, due to the crossover study design, there was a possibility for potential carryover effects from preceding phase of the study. The randomization process by sequence permutation, together with the statistical analysis plan that controlled for treatment sequence, reduced or removed any potential carryover effects.

Conclusions

Despite the limitations stated above, our data suggest that the inclusion of eggs in habitual diets improved the quality of total protein foods and reduced the intake of refined grain foods among adults with T2DM. The quality dairy foods decreased with the exclusion of eggs in the habitual diets. The intake of total vegetables; greens and beans; total fruit; whole fruit; seafood and plant proteins; healthful fatty acids; whole grains; sodium; added sugars; and saturated fats were unaffected in the inclusion of eggs. Therefore, the inclusion of eggs led to the introduction of healthful foods and the reduction of less healthful foods among adults with T2DM. The results of this updated analysis based on the current HEI-2015 were somewhat similar to those of our previous analysis with the HEI-2010. A bigger multicenter study is warranted to elucidate these findings.

Author Contributions

Valentine Y Njike: Conceptualization; Funding acquisition; Investigation; Methodology; Data curation; Supervision; Formal data analysis; Writing - original draft; Writing - review & editing.

Genevieve Cecile M Kela: Data interpretation, Writing - review & editing.

Frank Masige Kussaga: Data interpretation, Writing - review & editing.

Nisar Khan: Data interpretation, Writing - review & editing.

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Victoria C Costales: Data interpretation, Writing - review & editing.

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Disclosure Statement

The authors have nothing to disclose.

Clinical Trial Registration Number

NCT02052037.

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