Randomized Controlled Trial

Effect of a diet intervention on cardiometabolic outcomes: Does race matter? A randomized clinical trial

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Article info

Article history:
Received 1 October 2020
Accepted 15 December 2020

Keywords:
Cardiometabolic
Blacks
Plant-based diet
Race
Vegan
Whites

Summary

Background & aims: In the U.S., Blacks as a group have an earlier onset, greater severity, and earlier mortality from cardiovascular disease than their White peers. The aim of this study was to test whether Black and White individuals experience similar cardiovascular risk reduction in response to a dietary intervention.

Methods: In the course of a randomized trial assessing the effect of low-fat plant-based dietary intervention on cardiometabolic outcomes in overweight adults, this study compared the effects of a 16-week intervention in Black and White participants.

Results: We randomly assigned 244 participants to the intervention (n = 122, including 60 Blacks and 57 Whites) or control (n = 122, including 53 Blacks and 60 Whites) groups. The full study was completed by 222 (91.0%) participants. There were no significant differences between Blacks and Whites in changes in body mass index (Δ 2.3 kg/m² in both races; p-value for the difference between Blacks and Whites p = 0.99), insulin resistance (Blacks Δ 1.9, Whites Δ 0.85; p = 0.30), total cholesterol (Blacks Δ -0.73 mmol/L, Whites Δ -0.69 mmol/L p = 0.89), LDL-cholesterol (Blacks Δ -0.59 mmol/L, Whites Δ -0.68 mmol/L p = 0.76), or any other measure.

Conclusions: Our data suggest that a healthful plant-based diet improves measures of cardiometabolic health independent of race.

Trial registration: ClinicalTrials.gov number, NCT02939638.

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1. Introduction

In the U.S., Blacks as a group have an earlier onset, greater severity, and earlier mortality from cardiovascular disease than their White peers [1]. Some have suggested that such disparities reflect, in part, a physiologic vulnerability to cardiovascular disease related to race [2]. Such conjecture raises the question as to whether Black and White individuals experience similar cardiovascular risk reduction in response to a dietary intervention. If so, the notion of intrinsic vulnerability per se is less tenable. The DASH (Dietary Approaches to Stop Hypertension) diet significantly lowered blood pressure in all subgroups, and was particularly effective in Blacks and those with hypertension [3].

In the course of a randomized trial assessing the effect of low-fat plant-based dietary intervention on cardiometabolic outcomes in overweight adults, this secondary analysis compared the effects of the intervention in Black and White participants.

2. Materials and methods

The methods have been described previously [4]. Briefly, this randomized controlled study was conducted between February 2017 and February 2019 in Washington, D.C. The study protocol was approved by the Chesapeake Institutional Review Board. All participants gave written informed consent. Enrolled participants

Abbreviations: BMI, body mass index; HOMA-IR, Homeostasis Model Assessment Insulin Resistance; PREDIM, Predicted insulin sensitivity index.
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(n = 244) were aged 25–75 years, with a body-mass index between 28 and 40 kg/m². Exclusion criteria included history of diabetes, pregnancy or lactation, and recent or current smoking, alcohol or drug abuse.

2.1. Intervention

Participants were randomly assigned to an intervention group that was asked to follow a low-fat vegan diet (75% of energy from carbohydrates, 15% protein, and 10% fat) or a control group that was asked to make no diet changes. All participants were asked to maintain their customary exercise habits and medications, unless modified by their personal physicians.

2.2. Outcomes

All measurements were performed at baseline and 16 weeks. Dietary intake data over 3 consecutive days were collected and analyzed by staff members certified in Nutrition Data System for Research version 2016 (University of Minnesota, Minneapolis, MN). Body composition and visceral fat volume were assessed using dual energy X ray absorptiometry (iDXA; GE Healthcare, Chicago, IL, USA). Insulin resistance was calculated using the Homeostasis Model Assessment index (HOMA-IR).

2.3. Statistical analysis

For estimating sample size based on weight changes, we assume that the weight loss in the intervention group will have a distribution with a mean of 5.8 kg and a standard deviation of 3.2 kg, as observed in our previous randomized weight-loss trial [5]. In the control arm, we assume the average change in weight will be 1 kg, also with a 3.2 kg standard deviation. Under these assumptions and assuming a two-sided t-test with Type I error of 0.05 will be used for the primary efficacy comparison, a total of 22 participants, 11 per arm, are required for 90% power to detect a significant treatment effect between the two study arms.

Paired t-tests were calculated for the effect size in Black and White participants separately and for the difference between Blacks and Whites.

3. Results

Of 3115 people screened by telephone, 244 met participation criteria and were randomly assigned to the intervention (n = 122, including 60 Blacks and 57 Whites) or control (n = 122, including 53 Blacks and 60 Whites) groups. The full study was completed by 222 (91.0%) participants. There were no significant differences between Blacks and Whites in changes in body mass index (−2.3 kg/m² in both races; p-value for the difference between Blacks and Whites p = 0.30), total cholesterol (Blacks 171.7 ± 30.1, Whites 171.7 ± 4.6), LDL-cholesterol (Blacks 137.6 ± 20.7, Whites 137.6 ± 14.9), or any other measure (Table 1).

Table 1

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Black participants</th>
<th>White participants</th>
<th>Difference Blacks vs Whites</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dietary intake</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Energy intake (kcal/day)</td>
<td>−433 (−681 to −184)</td>
<td>−345 (−566 to −124)</td>
<td>−88 (−417 to +242) 0.60</td>
</tr>
<tr>
<td>Fiber intake (g/day)</td>
<td>+10.3 (+5.3 to +15.3)</td>
<td>+11.0 (+14.9 to −7.1)</td>
<td>−0.58 (−6.8 to +5.7) 0.86</td>
</tr>
<tr>
<td>Cholesterol intake (mg/day)</td>
<td>−234.6 (−297.5 to −171.7)</td>
<td>−207.6 (−277.7 to −137.6)</td>
<td>−27.0 (−123.4 to +69.4) 0.58</td>
</tr>
<tr>
<td>Saturated fatty acids (g/day)</td>
<td>−17.3 (−22.1 to −12.5)</td>
<td>−15.8 (−20.7 to −10.9)</td>
<td>−1.5 (−8.3 to +3.3) 0.66</td>
</tr>
<tr>
<td>Anthropometric variables and body composition</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>−2.3 (−5.0 to +0.30)</td>
<td>0.08</td>
<td>−2.3 (−2.8 to −1.9) 0.001</td>
</tr>
<tr>
<td>Fat mass (kg)</td>
<td>−3.6 (−4.5 to −2.8)</td>
<td>&lt;0.0001</td>
<td>−4.6 (−5.5 to −3.8) 0.001</td>
</tr>
<tr>
<td>Lean mass (kg)</td>
<td>−1.7 (−2.3 to −1.0)</td>
<td>&lt;0.0001</td>
<td>−1.5 (−2.0 to −0.95) 0.0001</td>
</tr>
<tr>
<td>VAT volume (cm³)</td>
<td>−189 (−301 to −76)</td>
<td>0.001</td>
<td>−267 (−428 to −105) 0.0014</td>
</tr>
<tr>
<td>Parameters of glycemic control and insulin resistance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fasting plasma insulin (µmol/L)</td>
<td>−79.9 (−158.9 to −0.87)</td>
<td>0.048</td>
<td>−23.9 (−39.4 to −8.5) 0.003</td>
</tr>
<tr>
<td>Fasting plasma glucose (mmol/l)</td>
<td>−0.38 (−0.87 to +0.12)</td>
<td>0.13</td>
<td>−0.78 (−1.3 to −0.21) 0.008</td>
</tr>
<tr>
<td>HOMA</td>
<td>−1.9 (−4.0 to +0.21)</td>
<td>0.08</td>
<td>−0.85 (−1.4 to −0.26) 0.005</td>
</tr>
<tr>
<td>Blood lipids</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total cholesterol (mmol/l)</td>
<td>−0.73 (−1.2 to −0.29)</td>
<td>0.001</td>
<td>−0.69 (−1.1 to −0.27) 0.002</td>
</tr>
<tr>
<td>Triglycerides (mmol/l)</td>
<td>+0.15 (+0.36 to −0.05)</td>
<td>0.14</td>
<td>+0.26 (+0.02 to +0.53) 0.06</td>
</tr>
<tr>
<td>HDL cholesterol (mmol/l)</td>
<td>−0.13 (−0.34 to +0.08)</td>
<td>0.23</td>
<td>+0.13 (+0.21 to +0.46) 0.45</td>
</tr>
<tr>
<td>LDL cholesterol (mmol/l)</td>
<td>−0.59 (−1.0 to −0.18)</td>
<td>0.005</td>
<td>−0.68 (−1.0 to −0.31) 0.0004</td>
</tr>
</tbody>
</table>

4. Discussion

A 16-week low-fat vegan dietary intervention improved cardiometabolic outcomes, with no difference between Blacks and Whites. In the U.S., Blacks tend to have higher risk of and mortality from cardiovascular disease than Whites [1]. Obesity prevalence was 38.4% in Blacks vs. 28.6% in Whites [6], paralleling higher diabetes prevalence (12% in Blacks and 7% in Whites). If such statistics suggest that Blacks are more prone than Whites to diet-related metabolic diseases, the current findings argue otherwise. A low-fat plant-based dietary intervention reduced body mass index, insulin resistance, fat mass, visceral fat, total and LDL-cholesterol, and fasting plasma glucose similarly in Blacks and Whites, suggesting that healthful diets improve health measures independent of race.

Statement of authorship

Drs Kahleova and Barnard had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Concept and design: Drs Kahleova and Barnard. Acquisition, analysis, or interpretation of data: All authors. Drafting of the manuscript: Drs Kahleova and Barnard. Critical revision of the manuscript for important intellectual content: All authors. Statistical analysis: Dr. Holubkov. Administrative,
technical, or material support: Kahleova, Rembert, and Nowak. Supervision: Drs Kahleova and Barnard.

Funding sources

This work was funded by the Physicians Committee for Responsible Medicine.

Declaration of competing interest

All authors except for Dr. Holubkov work for the Physicians Committee for Responsible Medicine in Washington, DC, a nonprofit organization providing educational, research, and medical services related to nutrition. Dr. Barnard is an Adjunct Professor of Medicine at the George Washington University School of Medicine. He serves without compensation as President of the Physicians Committee for Responsible Medicine and the Barnard Medical Center in Washington, DC. He writes books and articles and gives lectures related to nutrition and health, and has received royalties and honoraria from these sources.

References


