OmniCarb: Carbohydrates and Lactate

Supplementary File

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Supplement Table S1: Achieved nutrient composition of the four diets used in the OmniCarb

Dietary pattern	**High carbohydrate/high glycemic index**	**High carbohydrate/low glycemic index**	**Low carbohydrate/high glycemic index**	**Low carbohydrate/low glycemic index**
Energy, kcal	2011	1998	2011	1993
Glycemic index	66	41	65	40
Carbohydrates, %kcal	58	57	41	40
Protein, %kcal	16	16	23	23
Fat, % kcal	27	27	37	37
Saturated, % kcal	6	6	7	7
Monounsaturated, % kcal	12	13	18	19
Polyunsaturated, % kcal	7	8	10	10
Animal protein, g	42	46	78	81
Vegetable protein, g	39	38	39	39
Fiber, g	32	37	29	33
Fructose, g	48	40	26	28
Cholesterol, mg	90	89	170	163
Calcium, mg	1032	1051	993	995
Potassium, mg	3963	4103	3949	4026
Sodium, mg	2245	2211	2305	2199
Magnesium, mg	462	429	468	440

Estimated from food analysis software (ESHA Food Processor SQL, V.10.2, ESHA Research). Note that macronutrient estimates may not sum to 100% due to rounding.

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Supplement Table S2. Inclusion and exclusion criteria for the OmniCarb trial

Inclusion Criteria

- Baseline SBP 120-159 mmHg and DBP <100 mmHg (mean over three screening visits) [note: stage 2 hypertension (SBP > 160 or DBP > 100 mmHg) based on the mean over three screening visits will be excluded, as well as a mean systolic BP > 170 or diastolic BP > 105 at any one visit]
- Age 30 or older
- Overweight or obese, as defined by a Body Mass Index (BMI) > 25 kg/m2
- Willing to eat at least one on-site meal/day, five days/week, and willing to eat study diets and nothing else during controlled feeding periods (run-in and intervention)
- Willingness to complete measurement procedures, including five OGTTs.

Medication Exclusions:

- Regular use of medications during the past 2 months that raise or lower BP
- Use of a lipid lowering agent (any in 3 weeks prior to first screening visit)
- Unstable dose of hormone replacement therapy, thyroid hormone replacement therapy and psychotropic medications known to cause weight gain or affect the outcome variables (unstable defined as a change in dose within two months of the SV1 visit)
- Use of insulin, oral hypoglycemic agent, lithium, coumadin (warfarin), oral corticosteroid, anti-psychotic drugs, weight loss medications, nitrate, or digitalis.

Medical History Exclusions:

- Active or prior CVD (stroke, MI, PTCA, CABG, congestive heart failure, symptomatic ischemic heart disease (angina), or ASCVD-related therapeutic procedure).
- Diabetes mellitus
- Cancer diagnosis or treatment in past two years (however, persons with non-melanoma skin cancer, localized breast cancer, or localized prostate cancer can enroll if they did not require systemic chemotherapy)
- Active inflammatory bowel disease, malabsorption, or major GI resection
- Renal insufficiency as determined by a serum creatinine > 1.2 mg/dL for women or > 1.4 mg/dL for men. These participants can enroll if their estimated GFR is > 40 ml/min by either the Cockcroft-Gault equation or the simplified MDRD equation.
- Emergency room visit or hospital stay for asthma or COPD in last six months
- Any serious illness not otherwise specified that would interfere with participation

Laboratory Exclusions:

- Fasting LDL cholesterol > 220mg/dL, triglycerides > 750 mg/dl
- Fasting blood glucose >125 mg/dl
- Serum transaminase > 2 times the upper range of normal, or a clinical diagnosis of hepatitis

Other Exclusions:

- Body weight over 420 pounds

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- Consumption of more than 14 alcoholic drinks per week, or consumption of 6 or more drinks on an occasion, one or more occasions per week
- Significant food allergies, preferences, intolerances, or dietary requirements that would interfere with diet adherence
- Weight loss or gain of >5% or more during prior 2 months
- Planning to leave the area prior to the anticipated end of participation
- Pregnant, breast feeding, or planning pregnancy prior to the end of participation
- Current participation in another clinical trial that manipulates diet or that will affect the outcome of this study (this criterion may be waived at the site PI's judgment).
- Investigator judgment (e.g. for concerns over safety, adherence, or follow-up or for inappropriate behavior)
- Vitamin, fish-oil, weight-loss, soy, mineral, or herbal supplements that cannot be stopped (supplement use is discouraged, but this criterion may be waived at site PI's judgment and if participant remains on a constant dosage throughout the study).
- Unable to measure baseline blood pressure (due to arm circumference > 50 cm or atrial fibrillation) or obtain baseline OGTT.
- Unable to maintain a stable weight during Feeding Period 1, which is defined as a loss or gain of > 3% of their initial weight at Week 4.

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Supplement Table S24: Subgroup Analysis of Between-Diet Comparisons of Change in Lactate

		Baseline No	**CG vs cg (β, 95% CI)**	**P***
Age, year				
	<60	119	-0.08 (-0.17, 0.02)	
	≥60	40	-0.10 (-0.25, 0.04)	0.78
Sex				
	Female	85	-0.04 (-0.14, 0.06)	
	Male	74	-0.13 (-0.25, -0.00)	0.29
Race				
	White	65	-0.10 (-0.20, 0.00)	
	Black	82	-0.07 (-0.19, 0.06)	0.70
BMI, kg/m^2				
	25-29.9	69	-0.07 (-0.19, 0.05)	
	≥30	90	-0.09 (-0.20, 0.02)	0.82
Hypertension status				
	No	117	-0.07 (-0.17, 0.02)	
	Yes	42	-0.11 (-0.24, 0.02)	0.69
Baseline fasting glucose				
	BG<100 mg/dL	102	-0.07 (-0.17, 0.03)	
	BG 100-125	57	-0.11 (-0.24, 0.03)	0.65
HOMA (median), units				
	≤1.48	80	-0.09 (-0.21, 0.03)	
	>1.48	79	-0.07 (-0.17, 0.03)	0.82

*The p values refer to significance of the interaction terms in each model. From top to bottom, the interaction terms are age x diet, sex x diet, race x diet, BMI x diet, hypertension status x diet, baseline fasting glucose x diet, and HOMA x diet, respectively.
CG: high carbohydrate, high glycemic index diet; cg: low carbohydrate, low glycemic index diet.
Abbreviations: HOMA: Homeostatic Model Assessment of Insulin Resistance