

Comparing Very Low-Carbohydrate vs DASH Diets for Overweight or Obese Adults With Hypertension and Prediabetes or Type 2 Diabetes: A Randomized Trial

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ABSTRACT

PURPOSE Adults with a triple multimorbidity (hypertension, prediabetes or type 2 diabetes, and overweight or obesity), are at increased risk of serious health complications, but experts disagree on which dietary patterns and support strategies should be recommended.

METHODS We randomized 94 adults from southeast Michigan with this triple multimorbidity using a 2 × 2 diet-by-support factorial design, comparing a very low-carbohydrate (VLC) diet vs a Dietary Approaches to Stop Hypertension (DASH) diet, as well as comparing results with and without multicomponent extra support (mindful eating, positive emotion regulation, social support, and cooking).

RESULTS Using intention-to-treat analyses, compared with the DASH diet, the VLC diet led to greater improvement in estimated mean systolic blood pressure (−9.77 mm Hg vs −5.18 mm Hg; $P = .046$), greater improvement in glycated hemoglobin (−0.35% vs −0.14%; $P = .034$), and greater improvement in weight (−19.14 lb vs −10.34 lb; $P = .0003$). The addition of extra support did not have a statistically significant effect on outcomes.

CONCLUSIONS For adults with hypertension, prediabetes or type 2 diabetes, and overweight or obesity, the VLC diet resulted in greater improvements in systolic blood pressure, glycemic control, and weight over a 4-month period compared with the DASH diet. These findings suggest that larger trials with longer follow-up are warranted to determine whether the VLC diet might be more beneficial for disease management than the DASH diet for these high-risk adults.

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INTRODUCTION

Adults with hypertension, prediabetes or type 2 diabetes, and overweight or obesity are at increased risk of health complications, including stroke, end-stage renal disease, myocardial infarction, premature death, and death from COVID-19.¹⁻⁴ Separately, each of these conditions is prevalent; nearly one-half (47%) of adults in the United States have hypertension,⁵ approximately one-half have prediabetes or type 2 diabetes,⁶ and approximately 42% of US adults are obese.⁷

Evidence suggests the first-line treatment for these adults should be diet and lifestyle interventions, but experts disagree on which diet should be recommended.⁸⁻¹¹ The Dietary Approaches to Stop Hypertension (DASH) dietary pattern is rich in fruits, vegetables, whole grains, and low-fat dairy foods, restricts saturated and total fat, and is lower in sodium. A DASH diet is the standard-of-care dietary recommendation for blood pressure (BP) control by the American Heart Association.¹⁰ Another promising diet is a very low-carbohydrate (VLC) diet, also known as a ketogenic or “keto” dietary pattern, which is a very low-carbohydrate, moderate protein, higher-fat diet. A VLC diet has been found to decrease BP,^{12,13} and it is recommended as an option for glycemic control and weight loss by the American Diabetes Association.¹⁴ No studies to date have directly compared a DASH vs VLC diet for efficacy in improving measures of hypertension, diabetes, and weight loss in this population.

In addition, there is limited evidence for the efficacy of behavioral strategies to support dietary adherence and self-management for these 2 diets. Standard



Conflicts of interest: L.R.S.'s partner, H.B., is an inventor of software used in this study, which purchased a software services agreement for its use.

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behavioral treatment components include support for self-regulation including self-monitoring, goal setting, and providing personalized feedback.^{15,16} Other emerging approaches for self-management include skills training for the following: (1) mindful eating,¹⁷ (2) positive emotion regulation,¹⁸ (3) social support,^{19,20} and (4) cooking education.^{21,22}

In the Michigan's Hypertension, Diabetes, and Obesity Education Research Online (MHERO) trial, we randomized adults with this triple multimorbidity using a 2 × 2 diet-by-support factorial design, comparing a VLC diet vs a DASH diet, as well as comparing results with and without multicomponent extra support (mindful eating, positive emotion regulation, social support, and cooking), thus including the following 4 groups: VLC, VLC + support, DASH, DASH + support. We hypothesized that both dietary approaches and the extra supports would improve patient outcomes.

METHODS

We conducted the MHERO randomized trial in the United States (NCT03729479); this study was approved by the University of Michigan Institutional Review Board (HUM00146610). Recruitment began in January 2019, and data collection concluded in August 2020. All participants provided informed consent before participating.

Inclusion criteria included age 21 to 70 years, glycated hemoglobin (HbA_{1c}) ≥5.7% within the previous 12 months, a body mass index of 25 to 50 kg/m², ability to engage in light physical activity, and a systolic BP (SBP) of ≥130 mm Hg as measured in our laboratory using an average of 3 measurements with an Omron Professional IntelliSense Blood Pressure Monitor (HEM-907XL; Omron Healthcare Inc). We asked that all participants take their hypertension medication as normal before arriving at our laboratory.

Exclusion criteria included the following: current use of insulin, phenytoin, lithium, steroids, immunosuppressant drugs, or warfarin; severe renal or hepatic insufficiency; cardiovascular dysfunction (such as congestive heart failure, heart arrhythmias, and valvular heart disease); uncontrolled psychiatric disorder; current cancer treatment; pregnant or planning to be within 12 months; weight-loss surgery; vegan or vegetarian; currently enrolled in a formal weight-loss program (such as WeightWatchers); taking weight-loss drugs; untreated thyroid condition; and consumption of >30 alcoholic beverages per week.

We randomized participants to 1 of 4 groups using a 1:1:1:1 ratio. We stratified by body mass index (<30 kg/m² or ≥30 kg/m²) and sex (male or female). All outcome assessors were blinded to randomization.

All participants received access to a weekly, 4-month online program (with 16 weekly sessions), similar to our previous research,²³ with text messages, mailed cookbooks, e-mail-based coaching at least every 2 weeks, and encouragement for all participants to self-monitor their nutritional intake, weight,

and BP, and encouragement to self-monitor blood glucose if taking glucose-lowering drugs that might increase the risk of hypoglycemia. We included recommendations for physical activity and sleep hygiene beginning at week 6.

Participants in the VLC groups were encouraged to eat a VLC diet, decreasing their carbohydrate intake to 20 to 35 nonfiber g of carbohydrates a day, with the goal of achieving nutritional ketosis defined as a positive urine dipstick result (Ketostix; Bayer Diabetes Care). We encouraged participants to test ketones at least weekly.²⁴ Participants in the DASH groups were encouraged to follow the DASH diet, limiting sodium to <2,300 mg daily and fat intake to 20% to 30% of calories per day.²⁵ Participants were recommended to eat a variety of fruits and vegetables, lean meats and fish, whole grains, and low-fat dairy.

Participants in the extra support groups were provided information related to the following topics: (1) mindful eating skills including awareness of hunger and fullness sensations, awareness of triggers related to emotional eating, skills to help participants recognize but not act on food-related urges, and mindful responses to stress;¹⁷ (2) positive emotion regulation topics including noticing and savoring positive events, positive reappraisal, and gratitude. These skills are based on the positive pathways to health theoretical model¹⁸ and the hedonic theory of behavior²⁶ and might facilitate coping and adherence; (3) social support topics including strategies for sharing health information and effectively using one's social network. Previous research shows that seeking out and sharing health information is associated with lower SBP¹⁹; (4) food preparation topics including cooking skill basics and how to build flavor from sweet, salty, bitter, sour, and umami. Lack of cooking skills and confidence are barriers to achieving and maintaining dietary changes.^{21,22}

Measurements

We assessed physical and physiologic measures at baseline and within 1 month of completing the 16th week of the intervention (post). Participants received a \$100 Amazon gift card for completing postintervention measures. Fifteen participants (16%) were enrolled when the COVID-19 pandemic began, preventing the completion of some in-laboratory measures, and we had to stop recruitment with 51 potential participants in process, because the laboratory was temporarily closed.

Participants were asked to measure their BP at home at least once a week using a BP cuff (Omron 5 or 10; Omron Healthcare Inc). Given the white-coat effect, in which in-office BP can be quite elevated compared with home-measured BP,²⁷ we used the home-based measurement as our primary outcome. Baseline BP was an average of any measurements participants took for the first 2 weeks of the intervention, and outcome BP was an average of any measurements for the last 2 weeks.

Baseline and postintervention HbA_{1c} values were analyzed by the Michigan Diabetes Research Center Chemistry

Laboratory. For participants completing the study during the COVID-19 pandemic, we used a mail-in test (DTILaboratories, Inc) for their post HbA_{1c} value.

All participants received a body weight scale (BodyTrace, Inc). Baseline and postintervention body weight were measured in our laboratory, or for participants in the trial during the COVID-19 outbreak, via this home-based scale.^{28,29}

We assessed medications via self-report. We measured program satisfaction with the question, "How would you rate your overall satisfaction with the program?" rated from 1 = not at all satisfied to 7 = very satisfied.

To assess dietary adherence, staff conducted three 24-hour dietary recalls over a period of 1 week at postintervention, which we averaged. To assess adherence to the DASH diet, we created a DASH-adherence score based on the DASH recommendations for whole grains; vegetables; fruits; low-fat foods; nuts, seeds, and legumes; meat, poultry, and fish; sweets; fats and oils; and sodium. The score ranged from 0 to 90, with a higher score indicating greater adherence. In addition, we assessed total daily net (nonfiber) g of carbohydrates. We considered participants to be adherent to the DASH diet if postintervention, they had a DASH score of ≥ 40 based on prior research,³⁰ and to be adherent to the VLC diet if postintervention, they reported eating ≤ 90 g of daily g of net carbohydrates.

Analyses

We prespecified change in SBP as our primary outcome and change in HbA_{1c} and percent weight as our secondary outcomes. For our primary analyses, we conducted linear mixed regression models first using an intention-to-treat (ITT) analysis ($n = 94$). To examine the robustness of findings, we conducted linear regression models for participants with complete data ($n = 68$ for SBP, $n = 81$ for HbA_{1c}, and $n = 82$ for weight). The ITT analysis makes use of all available data at all time points, with the 3 outcomes as dependent variables, and time (pre, post), diet, and support allocation in a full-factorial design with all main effects and interaction terms. For each of the diet and support allocation factors, we report the pre-post change within each of the levels as well as a difference between these changes (interaction with time). A random subject intercept was used to account for within-subject clustering over time. The models were further adjusted for sex and age. For the complete-case analyses, involving participants with pre-post data, a change score was calculated by subtracting postintervention values from baseline values for each outcome. For weight, we also examined percent weight change. Each of these outcomes was used as the dependent variable in a linear regression model with diet, support, and their interaction as primary factors. The models were further adjusted for age and sex. Model diagnostics were carried out using residuals. For all other outcomes, data are shown as mean (SD) or n (%) unless otherwise stated. Analyses were conducted using IBM SPSS 28.0 (IBM Corp).

RESULTS

As shown in the Consolidated Standards of Reporting Trials enrollment flow diagram (Figure 1), 94 participants were randomized. Demographic characteristics of the randomized sample are presented in Table 1.

Table 2 presents results from the ITT analyses, with the β coefficients and SE values from the linear mixed models in Table 3. None of the outcomes of the ITT analyses showed a significant diet \times support \times time interaction or a significant support \times time interaction. We also conducted analyses for completers alone using change scores for each outcome, and none of the analyses showed a significant diet \times support interaction or a significant main effect of support. In Table 2, we report results for the main effect of diet within each group and the difference in these main effects across groups (diet \times time interaction). However, given that we were also interested in the effect of support, we further present those results in Table 4.

In the ITT analyses, SBP decreased more in the VLC group, a difference between the groups of -4.59 mm Hg ($P = .046$) (Table 2). Results were similar in the completers analysis; SBP decreased by 9.92 (SE, 1.76) mm Hg ($n = 33$) in the VLC group and by 4.49 (1.70) mm Hg ($n = 35$) in the DASH group, which was a statistically significant difference between the groups of -5.43 (2.41) mm Hg ($P = .028$).

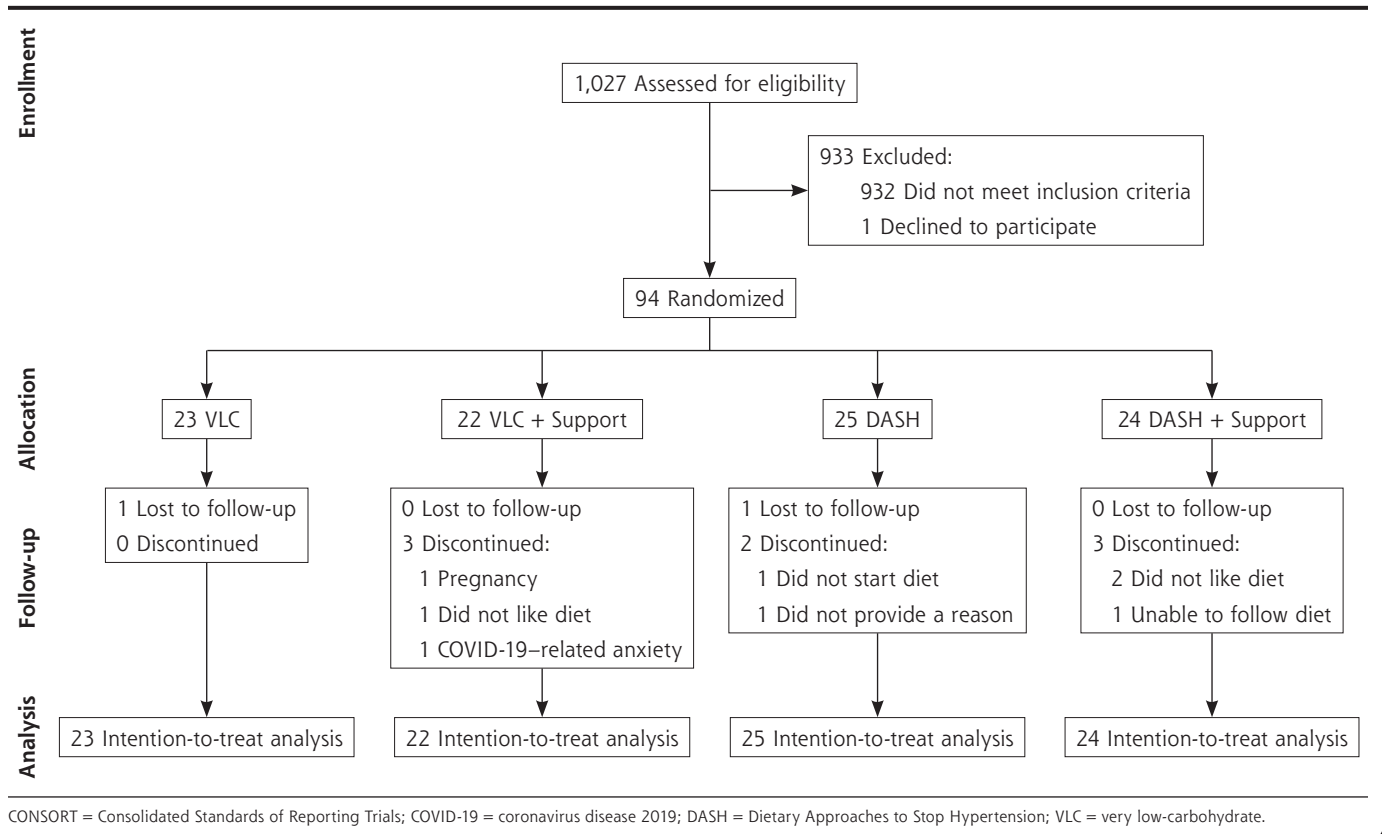
In the ITT analyses, HbA_{1c} decreased more in the VLC group, a statistically significant difference between the groups of -0.21% ($P = .034$) (Table 2). Results were similar in the completers analysis; HbA_{1c} decreased by 0.34 (SE, 0.08) % ($n = 39$) in the VLC group and by 0.14 (0.07) % ($n = 42$) in the DASH group, which was a difference between the groups of -0.20 (0.20) % ($P = .058$).

In the ITT analyses, weight decreased more in the VLC group, a statistically significant difference between the groups of -8.81 lb ($P = .0003$) (Table 2). Results were similar in the completers analysis; weight decreased by 19.90 (SE, 1.63) lb ($n = 41$) in the VLC group and by 11.80 (1.66) lb ($n = 41$) in the DASH group, which was a statistically significant difference between the groups of -8.09 (2.29) lb ($P = .001$). Percent weight decreased by 8.94 (SE, 0.67 ; $n = 41$) in the VLC group and by 4.94 (0.69 ; $n = 41$) in the DASH group, which was a statistically significant difference of percent weight between the groups of -4.00 (0.95 ; $P < .001$).

As described above and in Table 4, results were not significantly different by whether participants were assigned to the extra support group, although the nonsignificant results were lower (more improved) in the support groups. Results were similar in the completers analyses.

The interaction of diet \times support \times time was not statistically significant for the ITT analyses for SBP, but given that it was close to significant ($P = .06$), we explored it in more depth. Systolic BP decreased by 11.15 (SE, 2.17) mm Hg ($P = < .001$) in the VLC group without extra support, by 8.39 (2.50) mm Hg ($P < .001$) in the VLC group with extra

Figure 1. Participant CONSORT flow diagram.



support, by 2.20 (2.28) mm Hg ($P = .34$) in the DASH group without extra support, and by 8.17 (2.32) mm Hg ($P < .001$) in the DASH group with extra support. Therefore, it appears that extra support had some effect in conjunction with DASH diet on reduction of SBP.

Changes in drug regimens from baseline to postintervention are shown in Table 5. At baseline, 72 participants (76.6%) were taking ≥ 1 BP-lowering drug, and some discontinued or decreased these drugs; 31.3% in the VLC group, 43.8% in the VLC + Support group, 13.0% in the DASH group, and 5.3% in the DASH + Support group. At baseline, 24 participants (25.5%) were taking ≥ 1 glucose-lowering drug, including glipizide, sitagliptin, and metformin, and some discontinued or decreased these drugs; 40.0% in the VLC group, 75.0% in the VLC + Support group, and none in the DASH and DASH + Support groups. Dietary adherence at postintervention was 14/22 (63.6%) in the VLC group, 15/19 (78.9%) in the VLC + Support group, 18/23 (78.3%) in the DASH group, and 16/21 (76.2%) in the DASH + Support group.

Program satisfaction for all groups was high, with 94% of participants rating their satisfaction at or above the midpoint of the scale, and 73% rating themselves at the highest or second-to-highest level of satisfaction. Dropout was low, with 89% of participants completing post measures. There were no treatment-related serious adverse events.

DISCUSSION

In this study, we found that for adults with overweight or obesity, hypertension, and prediabetes or type 2 diabetes, a VLC diet showed greater improvements in SBP, glycemic control, and weight over a 4-month period compared with a DASH diet, although both dietary approaches improved outcomes. To our knowledge this is the first trial to compare these 2 dietary patterns in a population of adults with this high-risk set of metabolic conditions.

The addition of extra support did not have a statistically significant effect on outcomes, although the nonsignificant changes were lower (more improved) in the support groups. Thus, the extra support could have been helpful, but the trial might have been statistically underpowered to detect changes. It might also be that the support given in our standard program was sufficient. In addition, the VLC diet had stable, clinically significant effects on BP regardless of the additional psychosocial support; however, the effects of the DASH diet were dependent on the extra support, suggesting that the DASH diet might need to be integrated with psychologic support to induce clinically meaningful reductions in BP, similar to findings of other low-fat dietary interventions. It is also possible that the method of delivery for the support information was not sufficient to show an additive effect above the standard program. Of note, recent guidelines from the US Preventive Services Task Force recommend more intensive

interventions with interaction with a clinician, and our e-mail-based coaching might not have been sufficiently intensive.³¹

Our primary outcome in this study was exploratory, given that interventions using these combinations of

recommendations and supports had not been previously tested. Therefore, this trial was not intended to be powered to find statistically significant differences, and the number of participants recruited reflects the available sample size. That

said, with regard to the diet main effects, we found statistically significant outcomes, thus the study was not underpowered with regard to those. It is possible that the study was underpowered with regard to the extra support parameter and the interaction of that with diet. The effect size and variability estimates from this study could help inform larger studies that would be powered to detect differences in the extra support parameter.

The present results contribute to growing evidence regarding the effect of VLC and DASH dietary patterns on metabolic outcomes. For example, meta-analyses suggest that low-carbohydrate diets, especially a VLC diet, are more effective in decreasing hypertension than low-fat diets^{12,13} and that a VLC diet is also effective for glycemic control and weight loss.³² However, a systematic review and network analysis of 13 dietary approaches found that a DASH diet was the most effective for decreasing BP,³³ and an umbrella review of systematic reviews found that a DASH diet also decreases body weight and improves glycemic control.³⁴ In a meta-analysis, researchers found that across 30 randomized controlled trials of a DASH diet in adults with and without hypertension, the DASH diet decreased SBP

Table 1. Baseline Participant Characteristics

Characteristic	VLC	VLC + Support	DASH	DASH + Support
Sex, No. (%)				
Male	8 (34.78)	8 (36.36)	9 (36.00)	9 (37.50)
Female	15 (65.22)	14 (63.64)	16 (64.00)	15 (62.50)
Age, y	60.09 (6.03)	55.18 (10.48)	58.40 (8.11)	60.21 (6.19)
Race/ethnicity, No. (%), can be >1				
American Indian or Alaska Native	1 (4.35)	0 (0)	0 (0)	1 (4.17)
Asian/Pacific Islander	0 (0)	0 (0)	0 (0)	3 (12.50)
Black	4 (17.39)	4 (18.18)	6 (24.00)	5 (20.83)
Latine	0 (0)	2 (9.09)	1 (4.00)	1 (4.17)
White	19 (82.61)	18 (81.82)	19 (76.00)	15 (62.50)
College graduate, No. (%)	20 (86.96)	17 (77.27)	20 (80.00)	17 (70.83)
Married or long-term partner, No. (%)	21 (91.30)	17 (77.27)	20 (80.00)	18 (75.00)
Total household income, No. (%)				
≤\$35,000	0 (0)	1 (4.55)	3 (12.00)	3 (12.50)
\$35,001-\$75,000	6 (26.09)	8 (36.36)	4 (16.00)	8 (33.33)
≥\$75,001	10 (43.48)	12 (54.55)	18 (72.00)	11 (45.83)
Smoker, No. (%)	0 (0)	1 (4.55)	0 (0)	1 (4.17)
SBP, mm Hg	132.53 (11.13)	133.76 (13.71)	133.13 (8.58)	131.58 (10.85)
Diastolic BP, mm Hg	85.54 (9.54)	82.98 (9)	80.82 (8.2)	82.02 (8.24)
Weight, lb	222.22 (40.53)	213.14 (31.64)	236.25 (49.61)	227.08 (42.77)
BMI, kg/m ²	35.10 (5.71)	35.50 (4.69)	37.34 (6.20)	35.78 (5.42)
HbA _{1c} , %	6.09 (0.45)	6.13 (0.56)	6.26 (0.55)	5.99 (0.42)

BMI = body mass index; BP = blood pressure; DASH = Dietary Approaches to Stop Hypertension; HbA_{1c} = glycated hemoglobin; SBP = systolic blood pressure; VLC = very low-carbohydrate.

Note: Data are presented as mean (SD) unless otherwise noted.

Table 2. Estimated Mean (SE) of Outcomes Across Diet and Time From Linear Mixed Model

Outcome	VLC Diet				DASH Diet				Difference in Change (VLC Lower)	Between-Group P Value
	Baseline	Post	Change	Within-Group P Value	Baseline	Post	Change	Within-Group P Value		
SBP, mm Hg	133.72 (1.73)	123.95 (1.88)	-9.77 (1.66)	<.001	132.84 (1.69)	127.66 (1.80)	-5.18 (1.59)	.002	-4.59	.046
HbA _{1c} , %	6.09 (0.07)	5.74 (0.08)	-0.35 (0.07)	<.001	6.10 (0.07)	5.97 (0.07)	-0.14 (0.07)	.06	-0.21	.034
Weight, lb	219.24 (5.39)	200.10 (5.41)	-19.14 (1.73)	<.001	236.43 (5.1)	226.1 (5.2)	-10.34 (1.73)	<.001	-8.81	.0003

DASH = Dietary Approaches to Stop Hypertension; HbA_{1c} = glycated hemoglobin; SBP = systolic blood pressure; VLC = very low-carbohydrate.

Note: Outcomes were analyzed using a linear mixed model including all possible interactions between diet, support, and time and adjusted for age and sex. Results are presented collapsed over all other factors: support allocation, sex, and at the mean value of age. The between-group P value is calculated from a Z-test based on the estimated mean changes and the associated SE values reported in the table.

Table 3. Beta Coefficients and SE Values From Linear Mixed Model

Parameter	Systolic BP		HbA _{1c}		Weight	
	β Coefficient (SE)	P Value	β Coefficient (SE)	P Value	β Coefficient (SE)	P Value
Intercept	126.11 (9.23)	<.001	5.86 (0.37)	<.001	360.15 (29.96)	<.001
Baseline (vs follow-up)	8.17 (2.23)	<.001	0.16 (0.10)	.12	12.55 (2.53)	<.001
VLC (vs DASH) diet	1.99 (3.80)	.60	-0.10 (0.15)	.52	-31.91 (10.76)	<.001
No support (vs support)	7.43 (3.53)	.04	0.31 (0.14)	.03	10.19 (10.20)	.32
Time × diet	0.22 (3.35)	.95	0.23 (0.15)	.13	7.64 (3.58)	.04
Time × support	-5.97 (3.19)	.07	-0.05 (0.14)	.71	-4.43 (3.45)	.20
Diet × support	-11.40 (5.17)	.03	-0.26 (0.21)	.22	11.84 (14.99)	.43
Time × diet × support	8.73 (4.60)	.06	-0.04 (0.20)	.85	2.34 (4.89)	.63
Female (vs male)	-3.86 (2.26)	.09	0.15 (0.09)	.09	-28.50 (7.51)	<.001
Age, y	-0.004 (0.14)	.98	-0.002 (0.01)	.69	-2.12 (0.47)	<.001

BP = blood pressure; DASH = Dietary Approaches to Stop Hypertension; HbA_{1c} = glycated hemoglobin; VLC = very low-carbohydrate.

Table 4. Estimated Mean (SE) of Outcomes Across Support Groups and Time From Linear Mixed Model

Outcome	Extra Support				No Extra Support				Difference in Change (Extra Lower)	Between-Group P Value
	Baseline	Post	Change	Within-Group P Value	Baseline	Post	Change	Within-Group P Value		
SBP, mm Hg	133.22 (1.74)	124.94 (1.90)	-8.28 (1.68)	<.001	133.35 (1.67)	126.67 (1.78)	-6.68 (1.57)	<.001	-1.60	.49
HbA _{1c} , %	6.04 (0.07)	5.76 (0.08)	-0.28 (0.08)	<.001	6.15 (0.07)	5.94 (0.07)	-0.21 (0.07)	.004	-0.07	.51
Weight, lb	221.41 (5.31)	205.04 (5.36)	-16.37 (1.79)	<.001	234.26 (5.22)	221.15 (5.24)	-13.11 (1.66)	<.001	-3.26	.18

HbA_{1c} = glycated hemoglobin; SBP = systolic blood pressure.

Note: Outcomes were analyzed using a linear mixed model including all possible interactions between diet, support, and time and adjusted for age and sex. Results are presented collapsed over all other factors: diet, sex, and at the mean value of age. The between-group P value is calculated from a Z test based on the estimated mean changes and the associated SE values reported in the table.

by 3.2 mm Hg more than a variety of different comparison diets.³⁵ In our trial, the estimated mean difference in decrease between the VLC and DASH groups for SBP was 4.6 mm Hg in the ITT analysis, an even greater difference, and in the opposite direction; the VLC diet showed greater improvement than the DASH diet.

Our trial had several limitations. One is that we had to create our own definition of dietary adherence because there is no standard for this. Another was that we did not provide participants food; therefore dietary adherence likely varied more than if the trial were more prescriptive. Another limitation was that 36.2%

Table 5. Drug Regimen Changes for Participants Taking Drugs During Trial

Outcome	n/N (%)			
	VLC	VLC + Support	DASH	DASH + Support
BP drugs (n = 72)				
Discontinued or decreased	5/16 (31.3)	7/16 (43.8)	3/23 (13.0)	1/19 (5.3)
No change	8/16 (50.0)	6/16 (37.5)	15/23 (65.2)	12/19 (63.2)
Increased	2/16 (12.5)	1/16 (6.3)	2/23 (8.7)	NA
Missing	1/16 (6.3)	2/16 (12.5)	3/23 (13.0)	6/19 (31.6)
Blood glucose drugs (n = 24)				
Discontinued or decreased	2/5 (40.0)	3/4 (75.0)	NA	NA
No change	2/5 (40.0)	NA	8/10 (80.0)	3/6 (50.0)
Increased	NA	NA	2/10 (20.0)	NA
Missing	1/5 (20.0)	1/4 (25.0)	NA	3/6 (50.0)

BP = blood pressure; DASH = Dietary Approaches to Stop Hypertension; NA = not applicable; VLC = very low-carbohydrate.

Note: NA indicates no participants in the category.

of the sample were men, 24.5% were not White, 23.4% were not college graduates, and the sample was somewhat affluent, which restricts our ability to generalize the results. In addition, 15 of the participants were in the trial when the COVID-19 pandemic began in the United States in 2020, which might have affected their results and decreased our sample size.

We had recruitment challenges, in part, because participants had to have a measured, laboratory-based BP \geq 130 mm Hg despite any BP medications. Of the 138 people who were eligible based on initial screening, 95 (69%) were eligible after baseline BP measurement. This suggests that requiring an in-laboratory elevated baseline BP to confirm hypertension might have been too stringent.

In the MHERO trial of an online 4-month intervention, compared with a standard-of-care DASH dietary pattern, a VLC dietary pattern showed improvements in BP, glycemic control, and weight in adults with hypertension, prediabetes or type 2 diabetes, and overweight or obesity. These results provide initial evidence that a VLC dietary pattern might be more appropriate than the DASH dietary pattern for short-term disease management for these high-risk adults, and thus might have implications for clinical practice guidelines. Future research with larger samples, longer follow-up periods, and long-term outcomes is warranted.

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Key words: type 2 diabetes; hypertension; obesity; diet; very low-carbohydrate diet; DASH diet

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References

- Arauz-Pacheco C, Parrott MA, Raskin P; American Diabetes Association. Hypertension management in adults with diabetes. *Diabetes Care*. 2004; 27(Suppl 1):S65-S67. [10.2337/diacare.27.2007.S65](https://doi.org/10.2337/diacare.27.2007.S65)
- Alberti KG, Zimmet PZ. Definition, diagnosis and classification of diabetes mellitus and its complications. Part 1: diagnosis and classification of diabetes mellitus provisional report of a WHO consultation. *Diabet Med*. 1998;15(7): 539-553. [10.1002/\(SICI\)1096-9136\(199807\)15:7<539::AID-DIA668>3.0.CO;2-5](https://doi.org/10.1002/(SICI)1096-9136(199807)15:7<539::AID-DIA668>3.0.CO;2-5)
- Landsberg L, Aronne LJ, Beilin LJ, et al. Obesity-related hypertension: pathogenesis, cardiovascular risk, and treatment—a position paper of the The Obesity Society and The American Society of Hypertension. *Obesity (Silver Spring)*. 2013;21(1):8-24. [10.1002/oby.20181](https://doi.org/10.1002/oby.20181)
- Carrasco-Sánchez FJ, López-Carmona MD, Martínez-Marcos FJ, et al; SEMI-COVID-19 Network. Admission hyperglycaemia as a predictor of mortality in patients hospitalized with COVID-19 regardless of diabetes status: data from the Spanish SEMI-COVID-19 Registry. *Ann Med*. 2021;53(1):103-116. [10.1080/07853890.2020.1836566](https://doi.org/10.1080/07853890.2020.1836566)
- Million Hearts. Estimated hypertension prevalence, treatment, and control among U.S. adults. Updated Mar 22, 2021. Accessed Mar 2, 2023. <https://millionhearts.hhs.gov/data-reports/hypertension-prevalence.html>
- Centers for Disease Control and Prevention. *National Diabetes Statistics Report. Estimates of Diabetes and its Burden in the United States*. Updated Jun 29, 2022. Accessed Mar 2, 2023. <https://www.cdc.gov/diabetes/data/statistics-report/index.html>
- Stierman B, Afful J, Carroll MD, et al. National Health and Nutrition Examination Survey 2017–March 2020 prepandemic data files—development of files and prevalence estimates for selected health outcomes. *National Health Statistics Reports*. Published Jun 14, 2021. Accessed Mar 2, 2023. <https://stacks.cdc.gov/view/cdc/106273>
- Artinian NT, Fletcher GF, Mozaffarian D, et al; American Heart Association Prevention Committee of the Council on Cardiovascular Nursing. Interventions to promote physical activity and dietary lifestyle changes for cardiovascular risk factor reduction in adults: a scientific statement from the American Heart Association. *Circulation*. 2010;122(4):406-441. [10.1161/CIR.0b013e3181e8edf1](https://doi.org/10.1161/CIR.0b013e3181e8edf1)
- Cook NR, Cutler JA, Obarzanek E, et al. Long term effects of dietary sodium reduction on cardiovascular disease outcomes: observational follow-up of the trials of hypertension prevention (TOHP). *BMJ*. 2007;334(7599):885-888. [10.1136/bmj.39147.604896.55](https://doi.org/10.1136/bmj.39147.604896.55)
- Eckel RH, Jakicic JM, Ard JD, et al; American College of Cardiology/American Heart Association Task Force on Practice Guidelines. 2013 AHA/ACC guideline on lifestyle management to reduce cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines [published correction appears in *Circulation*. 2014;129(25 Suppl 2):S100-S101]. *Circulation*. 2014;129(25 Suppl 2):S76-S99. [10.1161/01.cir.0000437740.48606.d1](https://doi.org/10.1161/01.cir.0000437740.48606.d1)
- LeFevre ML; U.S. Preventive Services Task Force. Behavioral counseling to promote a healthful diet and physical activity for cardiovascular disease prevention in adults with cardiovascular risk factors: U.S. Preventive Services Task Force Recommendation Statement. *Ann Intern Med*. 2014;161(8):587-593. [10.7326/M14-1796](https://doi.org/10.7326/M14-1796)
- Santos FL, Esteves SS, da Costa Pereira A, Yancy WS Jr, Nunes JPL. Systematic review and meta-analysis of clinical trials of the effects of low carbohydrate diets on cardiovascular risk factors. *Obes Rev*. 2012;13(11):1048-1066. [10.1111/j.1467-789X.2012.01021.x](https://doi.org/10.1111/j.1467-789X.2012.01021.x)
- Bueno NB, de Melo ISV, de Oliveira SL, da Rocha Ataide T. Very-low-carbohydrate ketogenic diet v. low-fat diet for long-term weight loss: a meta-analysis of randomised controlled trials. *Br J Nutr*. 2013;110(7):1178-1187. [10.1017/S0007114513000548](https://doi.org/10.1017/S0007114513000548)
- Evert AB, Dennison M, Gardner CD, et al. Nutrition therapy for adults with diabetes or prediabetes: a consensus report. *Diabetes Care*. 2019;42(5):731-754. [10.2337/dci19-0014](https://doi.org/10.2337/dci19-0014)
- Wing RR, Tate DF, Espeland MA, et al; Study of Novel Approaches to Weight Gain Prevention (SNAP) Research Group. Innovative self-regulation strategies to reduce weight gain in young adults: the Study of Novel Approaches to Weight Gain Prevention (SNAP) randomized clinical trial. *JAMA Intern Med*. 2016;176(6):755-762. [10.1001/jamainternmed.2016.1236](https://doi.org/10.1001/jamainternmed.2016.1236)

16. Wing RR, Tate DF, Gorin AA, Raynor HA, Fava JL. A self-regulation program for maintenance of weight loss. *N Engl J Med*. 2006;355(15):1563-1571. [10.1056/NEJMoa061883](https://doi.org/10.1056/NEJMoa061883)
17. Kristeller JL, Wolever RQ. Mindfulness-based eating awareness training for treating binge eating disorder: the conceptual foundation. *Eat Disord*. 2011;19(1):49-61. [10.1080/10640266.2011.533605](https://doi.org/10.1080/10640266.2011.533605)
18. Moskowitz JT, Addington EL, Cheung EO. Positive psychology and health: well-being interventions in the context of illness. *Gen Hosp Psychiatry*. 2019;61:136-138. [10.1016/j.genhosppsych.2019.11.001](https://doi.org/10.1016/j.genhosppsych.2019.11.001)
19. Jones LM, Veinot TC, Pressler SJ. Cell phone information seeking explains blood pressure in African American women. *West J Nurs Res*. 2018;40(5):617-632. [10.1177/0193945916689069](https://doi.org/10.1177/0193945916689069)
20. Miller TA, Dimatteo MR. Importance of family/social support and impact on adherence to diabetic therapy. *Diabetes Metab Syndr Obes*. 2013;6:421-426. [10.2147/DMSO.S36368](https://doi.org/10.2147/DMSO.S36368)
21. Reicks M, Trofholz AC, Stang JS, Laska MN. Impact of cooking and home food preparation interventions among adults: outcomes and implications for future programs. *J Nutr Educ Behav*. 2014;46(4):259-276. [10.1016/j.jneb.2014.02.001](https://doi.org/10.1016/j.jneb.2014.02.001)
22. Wolfson JA, Bleich SN. Is cooking at home associated with better diet quality or weight-loss intention? *Public Health Nutr*. 2015;18(8):1397-1406. [10.1017/S13688980014001943](https://doi.org/10.1017/S13688980014001943)
23. Saslow LR, Moskowitz JT, Mason AE, et al. Intervention enhancement strategies among adults with type 2 diabetes in a very low-carbohydrate web-based program: evaluating the impact with a randomized trial. *JMIR Diabetes*. 2020;5(3):e15835. [10.2196/15835](https://doi.org/10.2196/15835)
24. Volek JS, Fernandez ML, Feinman RD, Phinney SD. Dietary carbohydrate restriction induces a unique metabolic state positively affecting atherogenic dyslipidemia, fatty acid partitioning, and metabolic syndrome. *Prog Lipid Res*. 2008;47(5):307-318. [10.1016/j.plipres.2008.02.003](https://doi.org/10.1016/j.plipres.2008.02.003)
25. Appel LJ, Moore TJ, Obarzanek E, et al; DASH Collaborative Research Group. A clinical trial of the effects of dietary patterns on blood pressure. *N Engl J Med*. 1997;336(16):1117-1124. [10.1056/NEJM199704173361601](https://doi.org/10.1056/NEJM199704173361601)
26. Williams DM. Exercise, affect, and adherence: an integrated model and a case for self-paced exercise. *J Sport Exerc Psychol*. 2008;30(5):471-496. [10.1123/jsep.30.5.471](https://doi.org/10.1123/jsep.30.5.471)
27. Pioli MR, Ritter AM, de Faria AP, Modolo R. White coat syndrome and its variations: differences and clinical impact. *Integr Blood Press Control*. 2018;11:73-79. [10.2147/IBPC.S152761](https://doi.org/10.2147/IBPC.S152761)
28. Pebley K, Klesges RC, Talcott GW, Kocak M, Krukowski RA. Measurement equivalence of e-scale and in-person clinic weights. *Obesity (Silver Spring)*. 2019;27(7):1107-1114. [10.1002/oby.22512](https://doi.org/10.1002/oby.22512)
29. Ross KM, Wing RR. Concordance of in-home "smart" scale measurement with body weight measured in-person. *Obes Sci Pract*. 2016;2(2):224-248. [10.1002/osp4.41](https://doi.org/10.1002/osp4.41)
30. Mellen PB, Gao SK, Vitolins MZ, Goff DC Jr. Deteriorating dietary habits among adults with hypertension: DASH dietary concordance, NHANES 1988-1994 and 1999-2004. *Arch Intern Med*. 2008;168(3):308-314. [10.1001/archinternmed.2007.119](https://doi.org/10.1001/archinternmed.2007.119)
31. Krist AH, Davidson KW, Mangione CM, et al; US Preventive Services Task Force. Behavioral counseling interventions to promote a healthy diet and physical activity for cardiovascular disease prevention in adults with cardiovascular risk factors: US Preventive Services Task Force recommendation statement. *JAMA*. 2020;324(20):2069-2075. [10.1001/jama.2020.21749](https://doi.org/10.1001/jama.2020.21749)
32. Yuan X, Wang J, Yang S, et al. Effect of the ketogenic diet on glycemic control, insulin resistance, and lipid metabolism in patients with T2DM: a systematic review and meta-analysis. *Nutr Diabetes*. 2020;10(1):38. [10.1038/s41387-020-00142-z](https://doi.org/10.1038/s41387-020-00142-z)
33. Schwingshackl L, Chaimani A, Schwedhelm C, et al. Comparative effects of different dietary approaches on blood pressure in hypertensive and pre-hypertensive patients: a systematic review and network meta-analysis. *Crit Rev Food Sci Nutr*. 2019;59(16):2674-2687. [10.1080/10408398.2018.1463967](https://doi.org/10.1080/10408398.2018.1463967)
34. Chiavaroli L, Vigiouliou E, Nishi SK, et al. DASH dietary pattern and cardio-metabolic outcomes: an umbrella review of systematic reviews and meta-analyses. *Nutrients*. 2019;11(2):338. [10.3390/nu11020338](https://doi.org/10.3390/nu11020338)
35. Filippou CD, Tsioufis CP, Thomopoulos CG, et al. Dietary Approaches to Stop Hypertension (DASH) diet and blood pressure reduction in adults with and without hypertension: a systematic review and meta-analysis of randomized controlled trials. *Adv Nutr*. 2020;11(5):1150-1160. [10.1093/advances/nmaa041](https://doi.org/10.1093/advances/nmaa041)