Online Data Supplement

Pilot randomized trial of a DASH intervention in adults with uncontrolled asthma

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Table E1. DASH trial eligibility criteria and screening process

	Pre-screening (Electronic health record data)	**PCP Clearance**	**Initial Screening** (Patient reports by phone or online)	**Group Orientation**	**Medical Screening** (In-person interview and physical exam and, if clinically indicated, study physician clearance[*]) **& Baseline Assessment**
Inclusion Criteria:					
Ethnicity: All ethnic groups			√		
Gender: Both men and women			√		
Age: 18-70 years	√		√		
Body mass index 18.5-39.9 kg/m^2	√			√	
Suboptimally controlled, persistent asthma: multi-stage screening[†]	√		√	√	
Kaiser member for ≥1 year	√		√		
PCP approval of study screening		√			
Able and willing to enrol and provide written, informed consent, i.e., to: 1) meet the time and data collection requirements of the study; 2) be randomized to one of the two intervention arms; 3) adhere to the recommendations of the study intervention as assigned; 4) participate in follow-up for 6 months; and 5) allow extraction of relevant information from their medical records.				√	√
Exclusion Criteria:					
Inability to speak, read or understand English		√	√	√	
DASH scores[‡] >5.5					
Intermittent asthma, defined as either seasonal asthma or (daytime asthma symptoms <2x/week and nocturnal symptoms <2x/month and no use of controller medications)			√	√	
Diagnosis of COPD (emphysema or chronic bronchitis) suggested by patient report of doctor diagnosis, spirometry, or smoking history[§]				√	
Current use of prescription or non-prescription weight-loss products or any dietary/herbal supplements and unwillingness to stop taking them for the duration of the study		√	√		
Current use of medications for treatment of psychosis or		√		√	

	Pre-screening (Electronic health record data)	**PCP Clearance**	**Initial Screening** (Patient reports by phone or online)	**Group Orientation**	**Medical Screening** (In-person interview and physical exam and, if clinically indicated, study physician clearance*) **& Baseline Assessment**
manic-depressive illness					
Regular use (>5 days/month) of oral corticosteroids		√		√	
Current use of insulin or oral hypoglycaemic agents					
Planning to undergo bariatric surgery during the study period			√		
Actively attempting to lose weight, or weight change >15 lbs during prior 3 months					
Consumption of >21 alcoholic drinks per week, or >=6 drinks on one occasion twice or more per week, or alcoholism as determined by the Alcohol Use Disorders Identification Test					
Inability to perform pulmonary function testing by spirometry				√	
Previous diabetes (other than during pregnancy) or diabetes diagnosed as a result of fasting blood glucose or haemoglobin A1c levels obtained through study screening		√	√	√	
Previous cardiovascular disease: e.g., coronary heart disease (myocardial infarction, angina pectoris, percutaneous coronary intervention, coronary artery bypass graft surgery), cerebrovascular disease (stroke, transient ischemic attack), peripheral vascular disease, heart failure, or aortic aneurysm					
Diagnosis of bipolar or psychotic disorder or hospitalization for psychological or emotional problems within the past 2 years		√	√		
Diagnosis of cancer (other than non-melanoma skin cancer) that is/was active or treated with radiation or chemotherapy within the past 2 years		√	√		
Inflammatory bowel disease, colostomy, malabsorption, or major gastrointestinal resection					
Diagnosis of a terminal illness and/or in hospice care		√	√		
Currently pregnant, lactating, or planning to become pregnant during the study period		√	√	√	

	Pre-screening (Electronic health record data)	**PCP Clearance**	**Initial Screening** (Patient reports by phone or online)	**Group Orientation**	**Medical Screening** (In-person interview and physical exam and, if clinically indicated, study physician clearance[*]) **& Baseline Assessment**
Already enrolled or planning to enrol in a research study that would limit full participation in the study or confound the interpretation of the study's findings				√	
Current or planned participation in a structured program that overtly focuses on diet and nutrition					
Family/household member of another participant or of a staff member			√		
No longer a Kaiser patient or planning to transfer care outside of Kaiser or move out of the area during the study period		√	√		
Investigator discretion for safety or protocol adherence reasons				√	√

[*]Clearance by the study physician who is an allergist and asthma specialist was required for patients with limited airway obstruction reversibility, very low lung function, possible angina, possible PVD, or possible major depression.

[ł]Multi-stage screening procedure to confirm suboptiomally controlled, persistent asthma:

- Pre-screening criteria: Documented history of high asthma-related emergency and/or inpatient encounters and/or high reliever medication usage. Using relevant data in electronic health records, an enriched pool of potentially eligible patients who likely had uncontrolled, persistent asthma were identified according to one or more of the following criteria:
    - at least 1 inpatient admission with a primary asthma diagnosis or a secondary asthma diagnosis accompanied by a primary asthma-related diagnosis during the past 12 months;
    - at least 1 emergency visit with an asthma diagnosis during the past 6 months;
    - at least 5 prescriptions for asthma medication filled during the past 6 months and at least 2 prescriptions for oral corticosteroids filled within the past 12 months;
    - at least 12 canisters of short-acting beta-agonists in the past 12 months;
    - at least 3 short-acting beta-agonist dispensing events during the past 12 months.
- Initial screening criteria: Patient reported physician diagnosis of asthma and Asthma Control Test (ACT) total score <20 or item score <3 for any of the first 4 questions regarding symptoms (3-6x/week or more), nighttime awakening (1x/week or more), interference with normal activity (at least some of the time), and rescue medication use for symptom relief (2-3x/week or more).
- Medical screening criteria: Physiological evidence of asthma with demonstrable reversibility of airway obstruction, or study physician's confirmation of asthma diagnosis based on chart review. As specified in a prior study by Wilson et al.,(E1) airway obstruction reversibility criteria vary by individual depending upon smoking history and controller medication use and are as follows:
    - For smokers and nonsmokers who do not use controller medications regularly (> 4 days a week), reversibility is determined by an increase in FEV1 of > 12% and > 200 mL from baseline after inhalation of 4 puffs of albuterol;

- For current or ex-smokers taking controller medications, reversibility is determined by an increase in FEV1 of > 8% and > 200 mL from baseline after inhalation of 4 puffs of albuterol;
- No reversibility criteria apply to never smokers who regularly use controller medications.

Patients who failed to reverse but who were cleared by study physician based on a comprehensive chart review (encounters, specialist diagnoses, pharmacy records, and past PFT reports) that confirmed asthma were eligible to participate.

[‡]DASH scores were calculated based on combining nine nutrient targets (i.e., total fat, saturated fat, protein, cholesterol, fibre, magnesium, calcium, sodium, and potassium). The intermediate target of each nutrient was half-way between the DASH target and population mean (based on the National Health and Nutrition Examination Surveys 2007-2008, latest data available at the inception of this study). For a nutrient, participants reaching the DASH target were assigned one point, those reaching the intermediate target were assigned a half-point, and those not meeting the intermediate target were given 0 point. The DASH score was the sum of points for all nine nutrients.(E2)

[§]Patients were excluded if they had a doctor's diagnosis of COPD, 25 or more pack-years of cigarette use, or the baseline post-bronchodilator FEV1/FVC <70%.

Table E2. Estimated mean changes from baseline to 3 months in DASH, asthma outcomes, weight, and blood pressure in the intention-to-treat population

		Change from baseline to 3 months		
	Baseline*	Intervention†	Control†	Difference (95% CI)‡
Intervention goal measure				
DASH score	2.3 ± 1.3	0.4 ± 0.3	-0.3 ± 0.3	0.7 (0.1, 1.4)
Fruits and vegetables (servings/day)§	4.4 ± 2.4	1.5 ± 0.5	0.2 ± 0.5	1.3 (0.3, 2.4)
Fat (g/day)	66.3 ± 40.7	-2.3 ± 4.7	-4.8 ± 4.6	2.5 (-8.3, 13.3)
Low fat/fat-free dairy (servings/day)§	1.0 ± 0.9	0.3 ± 0.2	-0.1 ± 0.2	0.4 (0.0, 0.8)
Sodium (mg/day)	2718 ± 1278	-186 ± 194	155 ± 190	-341 (-803, 122)
Asthma control				
ACQ	1.3 ± 0.8	-0.2 ± 0.1	-0.0 ± 0.1	-0.2 (-0.5, 0.2)
Asthma specific functional status				
MiniAQLQ, overall	5.2 ± 1.1	0.5 ± 0.2	0.3 ± 0.2	0.2 (-0.2, 0.6)
MiniAQLQ, symptoms	5.2 ± 1.3	0.4 ± 0.2	0.2 ± 0.2	0.2 (-0.2, 0.7)
MiniAQLQ, environment	4.6 ± 1.6	0.5 ± 0.2	0.6 ± 0.2	-0.1 (-0.7, 0.4)
MiniAQLQ, emotions	4.9 ± 1.5	0.5 ± 0.2	0.4 ± 0.2	0.1 (-0.5, 0.6)
MiniAQLQ, activities	6.0 ± 1.0	0.5 ± 0.2	0.1 ± 0.2	0.4 (0.1, 0.8)
Spirometry lung function test				
FEV1 (L)	2.6 ± 0.8	-0.0 ± 0.0	-0.0 ± 0.0	0.0 (-0.1, 0.1)
FVC (L)	3.8 ± 1.0	0.1 ± 0.1	0.0 ± 0.1	0.1 (-0.1, 0.2)
FEV1/FVC (%)	68.5 ± 11.3	-1.0 ± 1.0	-0.7 ± 1.0	-0.4 (-2.8, 2.1)
Weight and blood pressure				
Weight (kg)	76.5 ± 15.9	-1.4 ± 0.7	-0.2 ± 0.7	-1.2 (-2.8, 0.5)
Body mass index (kg/m^2)	27.9 ± 4.8	-0.6 ± 0.2	-0.1 ± 0.2	-0.5 (-1.1, 0.1)
Systolic blood pressure (mmHg)	117.4 ± 14.4	-3.0 ± 1.7	-3.1 ± 1.7	0.1 (-3.8, 4.1)
Diastolic blood pressure (mmHg)	74.9 ± 8.9	-0.6 ± 1.1	1.5 ± 1.1	-2.1 (-4.6, 0.4)

Abbreviations: ACQ, Asthma Control Questionnaire; CI, confidence interval; DASH, Dietary Approaches to Stop Hypertension; FEV1, forced expiratory volume in 1 second; FVC, forced vital capacity; MiniAQLQ, Mini Asthma Quality of Life Questionnaire.

Note: ACQ, range 0-6 with higher scores indicating worse asthma control; DASH, range 0-9 with higher scores indicating better DASH concordance.

*Values are means ± SD.

†Values are covariate-adjusted, mixed-model–based means ± SE.
‡Values are covariate-adjusted, mixed-model–based means (95% CIs).
§Servings were calculated using NDSR per the 2000 Dietary Guidelines for Americans. Fruit: 1 serving = 1 medium apple, banana, orange or pear, ½ cup of chopped, cooked, or canned fruit, ¼ of cup dried fruit, or 4 fluid ounces of fruit juice. Vegetables: 1 serving = 1 cup of raw leafy vegetables, ½ cup of other cooked or raw vegetables, or 4 fluid ounces of vegetable juice. Dairy: 1 serving = 1 cup of milk or yogurt, 1 ½ ounces of natural cheese, or 2 ounces of processed cheese.

Table E3. Estimated mean changes from baseline to 3 and 6 months in fasting glucose and lipids in the intention-to-treat population

		Change from baseline to 3 months			Change from baseline to 6 months		
	Baseline*	Intervention†	Control†	Difference (95% CI)‡	Intervention†	Control†	Difference (95% CI)‡
Fasting plasma glucose (mg/dL)	91.6 ± 8.7	-1.0 ± 2.8	0.1 ± 2.7	-1.1 (-7.4, 5.3)	-2.2 ± 2.8	1.1 ± 2.7	-3.3 (-9.7, 3.2)
Total cholesterol (mg/dL)	195.2 ± 35.0	-10.0 ± 6.0	2.5 ± 6.3	-12.5 (-26.7, 1.7)	-8.8 ± 6.0	-3.0 ± 6.0	-5.8 (-20.3, 8.8)
High-density lipoprotein cholesterol (mg/dL)	56.5 ± 12.7	-1.6 ± 1.7	-0.8 ± 1.8	-0.7 (-4.6, 3.1)	0.4 ± 1.7	-1.8 ± 1.7	2.1 (-1.9, 6.1)
Low-density lipoprotein cholesterol (mg/dL)	116.4 ± 30.3	-10.4 ± 5.6	-2.2 ± 5.7	-8.2 (-21.2, 4.8)	-5.8 ± 5.6	-5.8 ± 5.5	-0.1 (-13.3, 13.1)
Triglycerides (mg/dL)	114.7 ± 70.4	4.0 ± 9.5	14.0 ± 9.9	-10.0 (-32.2, 12.2)	2.8 ± 9.5	8.6 ± 9.5	-5.9 (-28.4, 16.6)
Triglycerides to high-density lipoprotein cholesterol ratio	2.2 ± 1.8	0.2 ± 0.3	0.3 ± 0.3	-0.1 (-0.7, 0.5)	0.02 ± 0.3	0.2 ± 0.3	-0.2 (-0.8, 0.4)

Abbreviations: CI, confidence interval.
*Values are means ± SD.
†Values are covariate-adjusted, mixed-model–based means ± SE.
‡Values are covariate-adjusted, mixed-model–based means (95% CIs).

REFERENCES

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