SUPPLEMENTARY DATA

The set of data, tables and figure has been provided by the authors to give readers additional information about their work. For this reason, we would like this file of supplemental material to be included with our paper, in case of acceptance, as online-only supplemental material.

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2. Trial enrollment criteria

Inclusion criteria:

Eligible participants were community-dwelling adults (aged 55-75 y in men; 60-75 y in women) with overweight/obesity [body mass index ≥27 and <40 kg/m^2], who met at least three components of the MetS according to the updated harmonized criteria of the joint statement from International Diabetes Federation/National Heart, Lung and Blood Institute/American Heart Association (IDF/NHLBI/AHA-2009) (1): hypertriglyceridemia [≥150 mg/dL (≥1.7 mmol/L)] or drug treatment for elevated triglycerides; low concentrations of HDL cholesterol [<50 mg/dL (<1.3 mmol/L) and <40 mg/dL (<1.03 mmol/L) in women and men, respectively] or drug treatment for low HDL cholesterol; elevated blood pressure (systolic ≥130 mmHg and/or diastolic ≥85 mmHg) or being treated for hypertension; high fasting plasma glucose [≥100 mg/dL (≥5.5 mmol/L)] or drug treatment for hyperglycemia; and elevated waist circumference for European individuals (≥88 cm in women and ≥102 cm in men).

Exclusion criteria:

- Illiteracy or inability/unwillingness to provide with the written informed consent or communicate with study staff.
- Documented history of previous CVD, including: angina, myocardial infarction, coronary revascularization procedures, stroke (ischemic or hemorrhagic, including transient ischemic attacks), symptomatic peripheral artery disease that required surgery or was diagnosed with vascular imaging techniques, ventricular arrhythmia, uncontrolled atrial fibrillation, congestive heart failure (New York Heart Association Class III or IV), hypertrophic cardiomyopathy, and history of aortic aneurysm ≥ 5.5 cm in diameter or aortic aneurism surgery.
- Institutionalization (the participant is a permanent or long-stay resident in a nursing home).
- Active malignant cancer or history of malignancy within the last 5 years (except non-melanoma skin cancer).
- Inability to follow the recommended diet (due to religious reasons, swallowing disorders, etc) or to perform physical activity.
-A low predicted likelihood to change dietary habits according to the Prochaska and DiClemente Stages of Change Model (Nigg et al., 1999).
- Inclusion in another weight loss program (> 5 kg) in the 6 months before the selection visit.
-History of surgical procedures for weight loss or intention to undergo bariatric surgery in the next 12 months.
-History of small or large bowel resection or inflammatory bowel disease.
-Obesity of unknown endocrine origin (except for treated hypothyroidism).
-Food allergy to any component of the Mediterranean diet.
-Immunodeficiency or HIV-positive status.
-Cirrhosis or liver failure.
-Serious psychiatric disorders, including schizophrenia, bipolar disorder, eating disorders, and depression with hospitalization within the last 6 months.
-Any severe co-morbidity condition with less than 24 months' life expectancy.
-Alcohol abuse or addition (or total daily alcohol intake >50g) or drug abuse within the past 6-m.
- History of major organ transplantation.
- Concurrent therapy with immunosuppressive drugs or cytotoxic agents.
- Current treatment with systemic corticosteroids.
- Current use of weight loss medication.
- Concurrent participation in another randomized clinical trial.
- Patients with an acute infection or inflammation (e.g., pneumonia) were allowed to participate in the study 3 months after resolution of such condition.
- Any other condition that might interfere with adherence to the study protocol.

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3. 17-item questionnaire to assess adherence to the energy-restricted Mediterranean diet used in the intervention arm of the PREDIMED-PLUS trial.

Questions	Criteria for 1 point*
1. Do you use olive oil as main culinary fat?	Yes
2. How many fruit units (including natural fruit juices) do you consume per day?	≥3
3. How many vegetable servings do you consume per day? (1 serving = 200g [consider side dish as half serving])	≥2 (≥1 portion raw or as salad)
4. How many servings of white bread do you consume per day? (1 serving = 75g)	≤1
5. How many servings of cereals and whole grains (bread, rice, pasta) do you consume per week?	≥5
6. How many servings of red meat, hamburger or meat products (ham, sausage, etc) do you consume per week? (1 serving = 100–150g)	≤1
7. How many servings of butter, margarine, or cream do you consume per week? (1 serving = 12g)	<1
8. How many sweetened beverages (soft drinks, cola, bitter, juices without added sugars) do you drink per week?	<1
9. How many servings of legumes do you consume per week? (1 serving = 150g)	≥3
10. How many servings of fish or shellfish do you consume per week? (1 serving = 100-150g of fish or 4-5 units or 200g of shellfish)	≥3
11. How many times per week do you consume pastries, such as cookies, custard, sweets or cakes?	<3
12. How many servings of nuts (including peanuts) do you consume per week? (1 serving = 30g)	≥3
13. Do you preferentially consume chicken, turkey, or rabbit meat instead of veal, pork, hamburger, or sausage?	Yes
14. How many times per week do you consume vegetables, pasta, rice, or other dishes seasoned with *sofrito* (sauce made with tomato and onion, leek, or garlic and simmered with olive oil)?	≥2
15. Do you preferentially add non-caloric artificial sweeteners to beverages (such as coffee or tea) instead of sugar?	Yes
16. How many servings of white bread, rice and/or pasta do you consume per week?	<3
17. How many glasses of wine do you drink per day?	2- for men 1-2 for women

* '0' points if these criteria are not met.

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4. 14-item questionnaire to assess adherence to the non-energy restricted Mediterranean diet (in the control group) of the PREDIMED-PLUS study.

Questions	Criteria for 1 point*
1. Do you use olive oil as main culinary fat?	Yes
2. How much olive oil do you consume in a given day (including oil used for frying, salads, out-of-house meals, etc)?	≥4 tbsp
3. How many vegetable servings do you consume per day? (1 serving = 200g [consider side dish as half serving])	≥2 (≥1 portion raw or as salad)
4. How many fruit units (including natural fruit juices) do you consume per day?	≥3
5. How many servings of red meat, hamburger or meat products (ham, sausage, etc) do you consume per day? (1 serving = 100–150g)	<1
6. How many servings of butter, margarine, or cream do you consume per day? (1 serving = 12 g)	<1
7. How many sweetened or carbonated beverages do you drink per day?	<1
8. How much wine do you drink per week?	≥7 glasses
9. How many servings of legumes do you consume per week? (1 serving = 150g)	≥3
10. How many servings of fish or shellfish do you consume per week? (1 serving = 100-150g of fish or 4-5 units or 200g of shellfish)	≥3
11. How many times per week do you consume commercial sweets or pastries (not homemade), such as cakes, cookies, biscuits, or custard?	<3
12. How many servings of nuts (including peanuts) do you consume per week? (1 serving = 30g)	≥3
13. Do you preferentially consume chicken, turkey, or rabbit meat instead of veal, pork, hamburger, or sausage?	Yes
14. How many times per week do you consume vegetables, pasta, rice, or other dishes seasoned with *sofrito* (sauce made with tomato and onion, leek, or garlic and simmered with olive oil)?	≥2

* '0' points if these criteria are not met.

SUPPLEMENTARY DATA

5. Objectives in terms of weight loss, energy-restricted Mediterranean dietary intervention and intensive physical activity and behavioral program in the intervention group.

Participants allocated to the intervention group were prescribed an energy-restricted MedDiet, accompanied by physical activity promotion and behavioral support, with the purpose of accomplishing specific weight-loss objectives. These objectives were achieving an average reduction of ≥8% of the initial body weight and an average reduction of ≥5% of initial waist circumference in the first 6-months, and maintaining these reductions throughout the duration of the study. The PREDIMED-Plus final aim targets a between-group average absolute difference in weight-loss and waist circumference reduction of ≥5%. To this end, they attended to monthly individual sessions during the first year, with the purpose of reinforcing individualized dietary and physical activity counseling using problem-solving interviews for successful weight loss.

The energy-restricted MedDiet aimed at an energy reduction of 600 kcal/day (about 30% of estimated energy requirements) according to each participants' basal metabolic rate and physical activity level, using the Institute of Medicine equations (http://www.nap.edu/books/0309085373/html/), and with a macronutrient distribution of 40-45% carbohydrate, 35-40% fat and 20% protein. Qualitatively, the diet promoted the inclusion of food items and their corresponding frequency of consumption according to the 17-point questionnaire. Dietary advice encouraged the consumption of typical and seasonal MedDiet foods and recommends refraining from foods characteristic of the Western dietary pattern. Briefly, it involved the frequent consumption of extra-virgin olive oil, raw nuts, fruits and vegetables, whole grains, legumes, lean meat and fish, and low-fat dairy products. Reduced consumption of animal fats, sugar-sweetened beverages, commercial sweets, pastry and snacks, processed foods and refined grains was encouraged, while wine intake was restricted to one or two glasses/day for women and two or three glasses/day for men. Along with the explanation of the intervention diet, participants in the IG received supporting dietary materials, including general recommendations, a dietary plan, open menus and seasonal recipes, all according to the aimed energy restriction calculated for each participant (energy restricted diets from 1200 to 3000 kcal/day were available). Based on the projected and achieved monthly weight-loss objectives and the accomplishment of the scores achieved in the 17-item questionnaire, the dietitians delivered personalized and updated dietary counseling throughout the entire intervention.

Participants were encouraged to gradually increase their level of physical activity to at least 45 minutes per day after 6 months of intervention, and their progress was monitored. The physical activity program included aerobic activities, such as brisk walking or any equivalent activity of moderate intensity (e.g. aquagym, biking, swimming, etc.). The dietitians adapted the recommendations to the participants' preferences and advised them to switch between activities with the same metabolic equivalence of tasks. To progressively increase the time spent in brisk walking, a pedometer (Yamax SW200 Digi-Walker) was provided to each participant to self-monitor steps and enhance motivation. In addition, dietitians encouraged participants to engage in resistance, balance, and flexibility training twice or more a week, for which a leaflet with practical information and types of activities was delivered. In addition, physical activities and resistance, balance, and flexibility training are showed by videos in the group sessions scheduled for this aim. The degree of adherence to these activities was monitored quarterly and problem-solving interviews were carried out to overcome any difficulty. For research purposes only, GENEActive accelerometers were randomly provided to a subsample of participants (at least, to 50% of intervention group participants and 20% of control group participants) to objectively quantify time and intensity of motions during 24-hour periods of one week.

Behavioral support included problem-solving strategies and practical tools to facilitate participants' self-control on emotional eating or stress-driven behaviors, such as over intake, consumption of highly palatable foods or engaging in sedentary behaviors. Moreover, it included self-management approaches to improve participants' autonomy and empowerment in order to increase their long-term adherence to the dietary and physical activity recommendations.

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6. Intervention in the PREDIMED-Plus control group.

Participants in the control group received educational sessions with the same content to that used in the PREDIMED study (1). Accordingly, dietitians recommended an energy-unrestricted traditional MedDiet and individual visits and group sessions were programmed every 6 months during the first year. The energy-unrestricted traditional MedDiet used in PREDIMED has demonstrated to reduce cardiovascular events (2) when compared to advice on a low-fat diet, while maintaining a steady body weight or a slightly reduced weight in the long term (3). Dietitians explained the traditional MedDiet with emphasis on improving dietary quality (i.e., focusing on food groups and their frequency of consumption). Dietary material and instructions about the traditional MedDiet but unrelated to calorie control were delivered together with material including general lifestyle recommendations for the management of metabolic syndrome. No specific advice for increasing physical activity or losing weight was provided to participants in the control group.

7. Anthropometric, body composition and blood pressure measurements.

Weight and height were measured with light clothing and no shoes with calibrated scales and a wall-mounted stadiometer, respectively. BMI was calculated as weight (kg) divided by the square of height (m). Waist circumference was measured halfway between the last rib and the iliac crest by using an anthropometric tape. Total body fat and total lean mass were evaluated in a random subset of PREDIMED-Plus participants (n=135) from 6 centers by dual-energy x-ray absorptiometry (DXA) scanner (Lunar iDXA and DXA Lunar Prodigy Primo, GEHealthcare) at baseline and 12 months. Blood pressure was measured using a validated semiautomatic oscillometer (Omron HEM-705CP, Netherlands) after 5 minutes of rest in-between measurements. All anthropometric variables were determined in duplicate, except for blood pressure (in triplicate), at baseline, 6 and 12 months visits by trained staff.

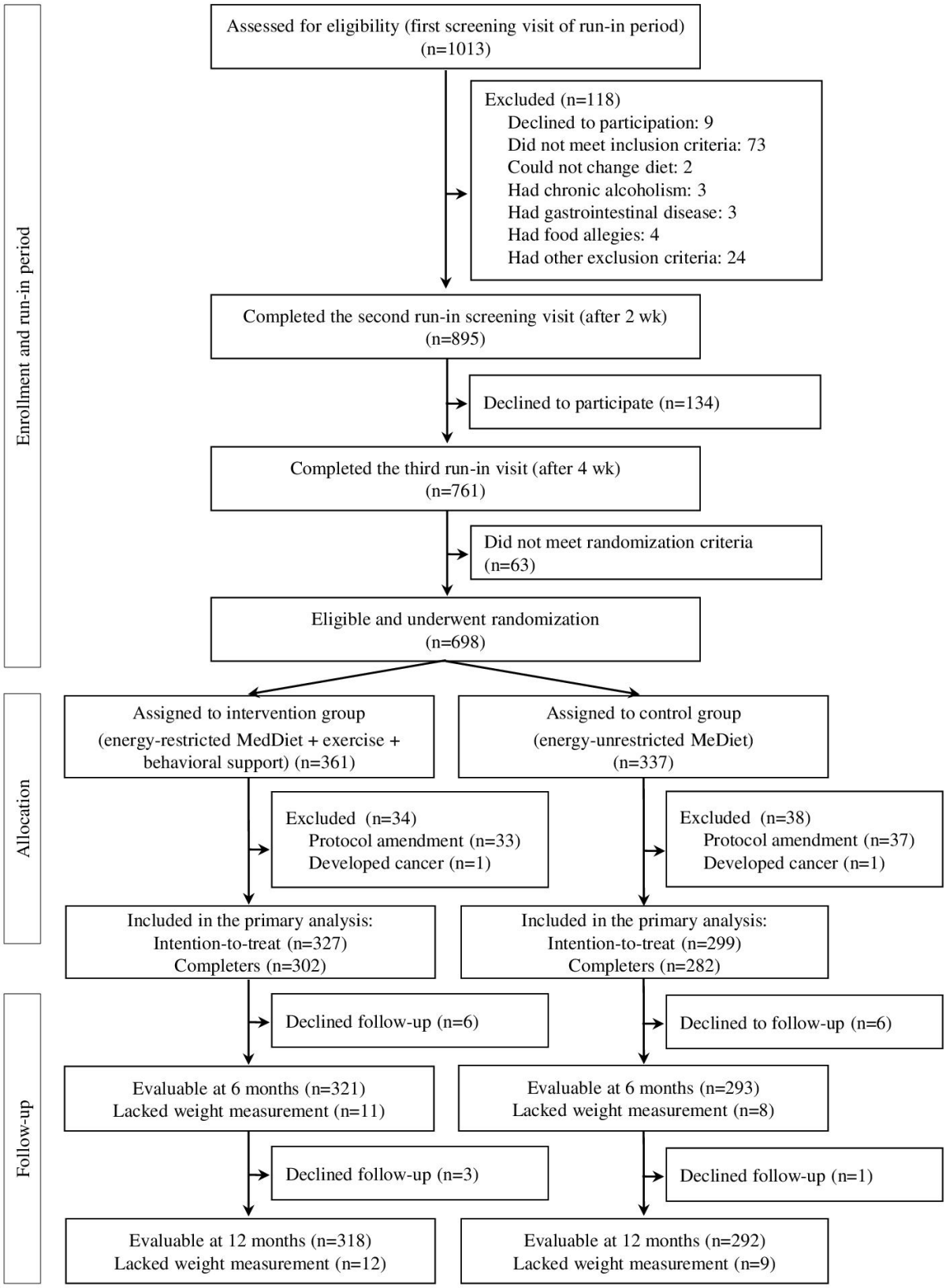
8. Biochemical measurements.

Fasting serum insulin was measured using a chemiluminescent immunoassay method (Advia Centaur, Siemens Healthcare, USA). The lower limit of detection was 0.3µIU/ml. Insulin sensitivity was assessed by the HOMA-IR index, calculated as fasting insulin (µIU/ml) multiplied by fasting glucose (mmol/L) divided by 22.5.

Other outcomes included 12-months changes in the circulating levels of leptin, C-peptide and several inflammatory markers [hs-CRP, cytokines (IL-6, IL-8, IL-18, TNF-α) and chemokines (monocyte chemotactic protein-1 (MCP-1) and Regulated on Activation, Normal T cell Expressed and Secreted (RANTES) cytokine]. Because of lack of blood samples at either baseline or 12 months visits, the analyses for all markers (except for hs-CRP; n=494) were limited to 497 participants. The simultaneous determination of leptin, C-peptide, IL-6, IL-8, IL-18, TNF-α, MCP-1, and RANTES was performed in serum with bead-based multiplexing technology using a XMAG-Luminex assay (Biorad, Hercules, California, USA). Briefly, standards, blanks, controls, and the participants' samples were incubated with the suspension of beads covered with antibodies specific for the tested molecules. After the incubation and washing steps, the cocktail of biotinylated detection antibodies was applied, followed by incubation with streptavidin-phycoerythrin solution. The fluorescence signal was read on a BioPlex 200 equipment (Biorad). The lower limits of detection were 0.88, 0.09, 0.34, 0.36, 0.29, 0.47, 0.4 and 0.19 pg/ml, respectively. Serum hs-CRP levels were also centrally measured using a wide-range latex-enhanced immunoturbidimetric assay on an ADVIA 2400 analyzer (Siemens Healthcare Diagnostics Inc., Tarrytown, NY, US). The detection limit was 0.4 mg/dl. Participants with levels of IL-6 (n=69) and TNF-α (n=127) below the detectable limits at baseline or 12-months measurement, and those with levels of C-peptide (n=1), IL-6 (n=31) and TNF-α (n=75) below the detectable limits in both baseline and 12-months, were set to be one-half the lower limit of detection. Outliers (box plot) were set as the population mean value (hs-CRP, n=2; IL-6, n=2; TNF-α, n=6).

SUPPLEMENTARY DATA

9. Supplementary Figure S1. Study flow diagram



SUPPLEMENTARY DATA

10. Supplementary Table S1. Proportion of participants (%) achieving the goal at baseline and changes in the percentage of participants achieving the goal for each of the 17-item of the Mediterranean diet score at 6- and 12-months of intervention by treatment group (completers-only).

17-item of the Mediterranean diet score	Intervention group (n=292)	Control group (n=273)	Intervention *vs* control	
			Between-group difference	*P* value
1. Use of olive oil as main culinary fat				
Baseline	76.7 (71.8 to 81.5)	71.1 (65.6 to 76.5)		
6-month change	14.0 (8.7 to 19.3)	18.3 (12.6 to 24.0)	-4.3 (-12.0 to 3.4)	0.28
12-month change	20.2 (15.3 to 25.1)	20.1 (14.6 to 25.6)	0.1 (-7.2 to 7.4)	0.98
2. Vegetables ≥ 2 servings/d				
Baseline	41.7 (36.1 to 47.5)	46.1 (40.2 to 52.1)		
6-month change	26.7 (20.1 to 33.3)	5.8 (-9.5 to 12.7)	20.8 (11.4 to 30.3)	<0.001
12-month change	28.4 (21.8 to 35.0)	8.4 81.5 to 15.3)	20.0 (10.5 to 29.5)	<0.001
3. Fruits ≥ 3 servings/d				
Baseline	47.3 (41.5 to 53.0)	47.9 (42.0 to 53.9)		
6-month change	23.6 (16.9 to 30.3)	2.9 (-4.1 to 10.0)	20.7 (11.8 to 30.4)	<0.001
12-month change	24.6 (18.2 to 31.1)	13.5 (6.7 to 20.4)	11.1 (1.7 to 20.5)	0.02
4. Red or processed meats ≤ 1 servings/wk				
Baseline	56.5 (50.7 to 62.2)	59.7 (53.8 to 65.5)		
6-month change	15.1 (7.8 to 22.2)	3.2 (-3.4 to 10.0)	11.7 (1.9 to 21.6)	0.02
12-month change	18.8 (11.8 to 25.8)	1.1 (-5.9 to 8.1)	17.7 (7.8 to 27.6)	<0.001
5. Butter, cream, margarine < 1 servings/wk				
Baseline	78.8 (74.0 to 83.5)	78.0 (73.1 to 82.9)		
6-month change	14.0 (8.7 to 19.3)	7.7 (2.4 to 12.9)	6.3 (-1.1 to 13.8)	0.09
12-month change	14.3 (9.3 to 19.4)	9.2 (3.5 to 14.8)	5.2 8-2.3 to 12.7)	0.17
6. Soda drinks < 1 servings/wk				
Baseline	78.8 (74.0 to 83.5)	71.0 (65.3 to 76.1)		
6-month change	9.2 (4.2 to 14.2)	8.4 (2.6 to 14.2)	0.8 (-6.7 to 8.4)	0.83
12-month change	8.9 (3.8 to 13.9)	2.9 (-3.6 to 9.5)	5.9 (-2.2 to 14.1)	0.15

7. Legumes ≥ 3 servings/wk				
Baseline	13.3 (9.4 to 17.2)	19.4 (14.7 to 24.1)		
6-month change	22.3 (16.1 to 28.4)	12.1 (6.4 to 17.8)	10.2 (1.7 to 18.5)	0.02
12-month change	32.2 (25.7 to 38.5)	1.31 (7.0 to 19.3)	19.0 (10.1 to 27.9)	<0.001
8. Fish or seafood ≥ 3 servings/wk				
Baseline	52.7 (46.9 to 58.5)	49.1 (43.1 to 55.1)		
6-month change	17.8 (11.3 to 24.2)	6.6 (0.9 to 13.1)	11.2 (2.1 to 20.3)	0.02
12-month change	19.2 (12.6 to 25.6)	12.4 (5.9 to 18.9)	6.7 (-2.4 to 15.9)	0.15
9. Commercial bakery < 3 servings/wk				
Baseline	66.7 (61.3 to 72.2)	63.4 (57.6 to 69.1)		
6-month change	14.7 (8.3 to 21.1)	9.1 (2.8 to 15.5)	5.6 (-3.4 to 14.6)	0.22
12-month change	17.8 (11.3 to 24.2)	9.8 (3.4 to 16.3)	7.9 (-1.2 to 17.0)	0.09
10. Nuts ≥ 3 servings/wk				
Baseline	49.3 (43.5 to 55.0)	37.0 (31.2 to 42.7)		
6-month change	36.3 (29.7 to 42.8)	29.7 (22.8 to 36.5)	6.6 (-2.7 to 16.0)	0.16
12-month change	36.6 (30.1 to 43.2)	36.3 (28.9 to 43.5)	0.3 (-9.3 to 10.1)	0.93
11. Poultry more than red meats				
Baseline	77.1 (72.2 to 81.9)	80.1 (75.8 to 85.3)		
6-month change	16.1 (10.9 to 21.2)	4.7 (-0.4 to 9.9)	11.3 (4.0 to 18.6)	0.002
12-month change	16.1 (10.8 to 21.3)	2.9 (-2.9 to 8.7)	13.1 (5.3 to 20.9)	0.001
12. Use of sofrito sauce ≥ 2 servings/wk				
Baseline	49.6 (43.8 to 55.4	52.7 (46.7 to 58.7)		
6-month change	12.0 (4.9 to 19.0)	4.3 (-3.2 to 12.0)	7.5 (-2.7 to 17.9)	0.15
12-month change	19.2 (11.6 to 26.7)	6.9 (-0.4 to 14.4)	12.2 (1.6 to 22.9)	0.02
13. No added sugar				
Baseline	67.1 (61.7 to 72.5)	63.7 (57.9 to 69.4)		
6-month change	12.0 (6.2 to 17.7)	-0.3 (-6.1 to 5.4)	12.3 (4.2 to 20.4)	0.003
12-month change	11.9 (6.1 to 17.9)	2.2 (-3.2 to 7.5)	9.7 (1.7 to 17.8)	0.02
14. Refined bread ≤ 1 servings/d				

Baseline	51.0 (45.2 to 56.7)	49.4 (43.5 to 55.4)		
6-month change	30.5 (23.5 to 37.4)	11.7 (4.8 to 18.5)	18.7 (8.9 to 28.5)	<0.001
12-month change	31.8 (24.9 to 38.7)	10.9 (3.9 to 18.1)	20.8 (11.1 to 30.7)	<0.001
15.Whole grain bread/pasta ≥ 5 servings/wk				
Baseline	28.4 (23.2 to 33.6)	20.8 (16.0 to 25.7)		
6-month change	35.6 (28.7 to 42.4)	16.1 (10.3 to 21.9)	19.5 (10.4 to 28.5)	<0.001
12-month change	34.2 (27.2 to 41.3)	14.6 (8.3 to 20.9)	19.5 (10.0 to 29.1)	<0.001
16. Refined pasta/rice <3 servings/wk				
Baseline	36.6 (31.1 to 42.2)	38.1 (32.2 to 43.9)		
6-month change	24.3 (17.1 to 31.5)	4.0 (-2.7 to 10.8)	20.2 (10.3 to 30.2)	<0.001
12-month change	30.8 (23.6 to 37.9)	2.9 (-4.3 to 10.1)	27.9 (17.8 to 38.0)	<0.001
17. Wine 2-3 (men), 1-2 (women) glasses /d				
Baseline	17.1 (12.8 to 21.5)	24.9 (19.7 to 30.0)		
6-month change	10.0 (5.1 to 14.7)	-0.7 (-4.9 to 3.4)	10.7 (4.3 to 17.1)	0.001
12-month change	9.2 (4.7 to 13.7)	-1.1 (-5.4 to 3.3)	10.3 (4.1 to 16.6)	0.001

Values expressed as percentage (95% CI). *P* values for differences between groups by Chi-square tests.

SUPPLEMENTARY DATA

11. Supplementary Table S2. Baseline and 6- and 12-month changes in 17-point Mediterranean diet score, energy expenditure in leisure-time physical activity, 30-s chair-stand test and sedentary behaviors by treatment group.

Variable	Intervention Group		Control Group		Intervention *vs* Control			
					Between-group difference			
	Intention-to-treat (MI)	Completers-only	Intention-to-treat (MI)	Completers-only	Intention-to-treat (MI)	*P* value	Completers-only	*P* value
17-point Mediterranean diet score	n=327	n=292	n=299	n=273				
Baseline	8.9 (8.7 to 9.2)	8.9 (8.6 to 9.2)	8.8 (8.5 to 9.1)	8.8 (8.5 to 9.1)				
6-month change	3.3 (3.0 to 3.7)	3.3 (2.9 to 3.7)	1.3 (1.1 to 1.6)	1.3 (1.1 to 1.6)	2.0 (1.5 to 2.4)	<0.001	2.0 (1.5 to 2.4)	<0.001
12-month change	3.7 (3.4 to 4.1)	3.7 (3.4 to 4.1)	1.6 (1.3 to 1.9)	1.6 (1.3 to 1.9)	2.1 (1.7 to 2.6)	<0.001	2.2 (1.7 to 2.6)	<0.001
Sedentary time (hours/d)*	n=327	n=292	n=299	n=273				
Baseline	4.6 (4.3 to 4.8)	4.6 (4.3 to 4.9)	4.6 (4.2 to 4.8)	4.5 (4.2 to 4.8)				
6-month change	-0.17 (-0.43 to 0.10)	-0.18 (-0.45 to 0.10)	0.02 (-0.24 to 0.28)	0.04 (-0.21 to 0.31)	-0.19 (-0.56 to 0.19)	0.33	-0.22 (-0.61 to 0.15)	0.24
12-month change	-0.41 (-0.67 to -0.14)	-0.41 (-0.67 to -0.14)	-0.11 (-0.39 to 0.17)	-0.03 (-0.30 to 0.23)	-0.30 (-0.68 to 0.09)	0.13	-0.37 (-0.75 to 0.01)	0.05
TV-viewing time (hours/d)	n=327	n=294	n=299	n=275				
Baseline	3.0 (2.8 to 3.2)	3.0 (2.8 to 3.2)	3.1 (2.9 to 3.2)	3.1 (2.9 to 3.3)				
6-month change	-0.01 (-0.19 to 0.17)	-0.1 (-0.20 to 0.17)	0.16 (-0.04 to 0.35)	0.19 (-0.01 to 0.38)	-0.17 (-0.43 to 0.10)	0.22	-0.21 (-0.48 to 0.07)	0.15
12-month change	-0.19 (-0.38 to -0.01)	-0.19 (-0.37 to -0.01)	0.14 (-0.07 to 0.35)	0.17 (-0.03 to 0.38)	-0.34 (-0.63 to -0.05)	0.02	-0.36 (-0.64 to -0.08)	0.01
Total leisure-time physical activity (METs.min/d)	n=327	n=294	n=299	n=276				
Baseline	361.5 (325.1 to 397.9)	379.1 (339.7 to 418.4)	416.4 (371.5 to 461.3)	424.5 (376.6 to 472.3)				
6-month change	99.1 (48.0 to 150.1)	106.3 (56.0 to 156.5)	-4.6 (-50.1 to 41.4)	-8.1 (-52.9 to 36.7)	103.6 (35.4 to 171.9)	0.003	114.3 (44.5 to 184.2)	0.001
12- month change	108.0 (64.2 to 151.8)	112.5 (70.7 to 150.3)	4.01 (-44.3 to 52.4)	2.8 (-43.9 to 49.7)	104.0 (37.8 to 170.1)	0.002	109.7 (44.4 to 174.9)	0.001
30-s chair-stand test (counts)†	n=327	n=278	n=299	n=258				

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Baseline	12.5 (11.9 to 13.0)	12.6 (12.0 to 13.1)	12.1 (11.6 to 12.7)	12.2 (11.6 to 12.7)				
6-month change	1.6 (1.1 to 2.0)	1.6 (1.1 to 2.1)	1.4 (0.9 to 1.9)	1.4 (0.9 to 1.9)	0.1 (-0.6 to 0.8)	0.71	0.2 (-0.5 to 0.9)	0.59
12-month change	2.3 (1.9 to 2.8)	2.4 (1.9 to 2.9)	1.9 (1.3 to 2.4)	1.9 (1.3 to 2.5)	0.4 (-0.3 to 1.2)	0.27	0.5 (-0.3 to 1.2)	0.23

Values expressed as mean (95% CI). Abbreviations: MI, multiple imputation. *Sedentary time include the sum of hours/d spent in TV-viewing, sitting while using computer, sitting on journeys (for work purposes or leisure time, as driver or passenger car, subway, bus, etc) and total sitting. †30-s chair-stand test based on the number of counts participants stand-and-sit within 30s. *P* values for between-groups differences were calculated using linear regression models with robust standard errors to account for intra-cluster correlations.

SUPPLEMENTARY DATA

12. Supplementary Table S3. Baseline and 6- and 12-month changes in the consumption of key food items by treatment group (completers-only).

Key food	Intervention group (n=285)	Control group (n=252)	Intervention *vs* control	
			Between-group difference	*P* value
Virgin olive oil (g/day)				
Baseline	35.1 (33.1 to 37.1)	37.6 (35.6 to 96.7)		
6-month change	3.7 (1.4 to 5.9)	3.8 (1.8 to 5.7)	-0.1 (-3.1 to 2.9)	0.96
12-month change	5.1 (2.7 to 7.4)	3.8 (1.6 to 5.9)	1.3 (-1.9 to 4.5)	0.43
Nuts (g/day)				
Baseline	16.3 (13.9 to 18.5)	13.8 (11.7 to 15.9)		
6-month change	14.1 (11.2 to 16.9)	8.7 (5.9 to 11.4)	5.4 (1.4 to 9.3)	0.007
12-month change	15.5 (12.2 to 18.7)	11.4 (8.6 to 14.1)	4.1 (-0.1 to 8.4)	0.05
Vegetables (g/day)*				
Baseline	354.4 (336.6 to 372.6)	354.6 (335.6 to 373.7)		
6-month change	-1.8 (-20.2 to 16.4)	-22.1 (-40.56 to -3.7)	20.3 (-5.8 to 46.3)	0.12
12-month change	33.7 (10.9 to 56.5)	13.3 (-7.2 to 33.8)	20.4 (-10.6 to 51.4)	0.19
Fruits (g/day)†				
Baseline	396.6 (350.5 to 408.6)	377.5 (341.8 to 413.1)		
6-month change	-7.6 (-37.5 to 22.3)	-26.4 (-63.2 to -10.4)	18.8 (-128 to 65.8)	0.43
12-month change	-4.6 (-33.5 to 24.3)	-41.1 (-79.4 to -3.0)	36.6 (-10.7 to 83.8)	0.12
Legumes (g/day)				
Baseline	21.8 (20.2 to 23.5)	21.2 (19.7 to 22.6)		
6-month change	1.5 (-0.2 to 3.3)	2.6 (0.6 to 4.5)	-1.1 (-3.7 to 1.5)	0.43
12-month change	3.2 (1.5 to 4.9)	3.0 (0.6 to 4.5)	0.2 (-2.3 to 2.8)	0.86

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Total cereals (g/day)				
Baseline	147.0 (137.9 to 156.0)	141.4 (132.1 to 150.7)		
6-month change	-17.5 (-28.3 to -6.7)	-9.6 (-19.2 to -0.02)	-7.9 (-22.5 to 6.6)	0.28
12-month change	-34.6 (-44.0 to -25.2)	-6.4 (-16.5 to 3.8)	-28.3 (-42.1 to -14.4)	<0.001
Refined cereals(g/day)‡				
Baseline	108.6 (99.1 to 118.3)	107.9 (97.6 to 118.3)		
6-month change	-58.9 (-69.6 to -48.1)	-27.1 (-36.8 to -17.5)	-31.7 (-46.3 to -17.1)	<0.001
12-month change	-64.1 (-74.3 to -53.8)	-19.7 (-3.1 to -9.2)	-44.4 (-59.1 to -29.7)	<0.001
Whole-grain cereals (g/day)§				
Baseline	39.3 (31.5 to 47.2)	36.9 (29.3 to 44.6)		
6-month change	39.5 (28.3 to 50.6)	15.5 (8.1 to 22.8)	23.9 (10.3 to 37.7)	<0.001
12-month change	28.3 (18.8 to 37.9)	12.2 (3.7 to 20.7)	16.1 (3.1 to 29.0)	0.01
Fish and seafood (g/day)				
Baseline	108.2 (102.6 to 113.8)	102.5 (96.4 to 108.6)		
6-month change	3.8 (-1.5 to 9.1)	1.3 (-4.2 to 7.2)	2.5 (-5.2 to 10.2)	0.52
12-month change	9.8 (2.4 to 17.2)	1.5 (-4.1 to 7.3)	8.2 (-1.3 to 17.8)	0.08
Meat and meat products (g/day)				
Baseline	150.1 (142.1 to 158.1)	158.9 (150.6 to 167.3)		
6-month change	-16.4 (-23.2 to -9.6)	-19.4 (-26.7 to -11.9)	3.0 (-7.1 to 13.0)	0.56
12-month change	-20.0 (-27.8 to -12.3)	-23.6 (-31.6 to -15.6)	3.6 (-7.6 to 14.8)	0.52
Lean meat (g/day)#				
Baseline	85.0 (80.0 to 90.0)	90.2 (84.2 to 96.1)		
6-month change	7.6 (2.1 to 13.0)	-3.8 (-9.5 to 1.9)	11.3 (3.4 to 19.2)	0.005
12-month change	5.7 (0.1 to 11.3)	-4.7 (-10.4 to 0.8)	10.5 (2.5 to 18.5)	0.01
Red meat (g/day)**				

Baseline	62.8 (57.5 to 67.7)	66.8 (61.5 to 72.1)		
6-month change	-22.4 (-26.9 to -17.8)	-15.1 (19.9 to -10.3)	-7.2 (-13.9 to -0.6)	0.03
12-month change	-24.7 (-29.6 to -19.7)	-18.1 (-23.5 to -12.8)	-6.5 (-13.8 to 0.8)	0.07
Pastries, cakes and sweets (g/day)				
Baseline	30.3 (25.5 to 35.1)	28.9 (24.1 to 33.7)		
6-month change	-18.0 (-22.6 to -13.4)	-6.2 (-11.0 to -1.4)	-11.8 (-18.4 to -5.2)	<0.001
12-month change	-18.7 (-23.9 to -13.4)	-12.1 (-16.9 to -7.4)	-6.5 (-13.6 to 0.6)	0.07
Dairy products (g/day)				
Baseline	359.8 (335.6 to 384.1)	393.8 (366.1 to 422.4)		
6-month change	-12.8 (-36.7 to 11.1)	-21.3 (-43.7 to 1.0)	8.5 (-24.5 to 41.5)	0.61
12-month change	-5.3 (-30.6 to 20.0)	-30.6 (-55.3 to -5.8)	25.3 (-10.3 to 60.8)	0.16
Alcohol (g/day)				
Baseline	9.1 (7.6 to 12.5)	10.7 (8.8 to 12.5)		
6-month change	-1.1 (-2.3 to 0.1)	-1.6 (-2.8 to -0.5)	0.5 (-1.1 to 2.2)	0.49
12-month change	-0.8 (-2.1 to 0.4)	-1.3 (-2.6 to -0.1)	0.5 (-1.2 to 2.4)	0.55

Values expressed as mean (95% CI). *Vegetables excluding potatoes. †Fruits include fresh fruits but not olives, dry fruit and fruit in syrup. ‡Refined cereals include plain pasta, bread, rice, pizza and breakfast cereals. §Whole-grain cereals include whole-wheat pasta, whole grain breads and brown rice. #Lean meat includes poultry (chicken and turkey), rabbit, ham and Spanish ham. **Red meat includes beef, pork, lamb and processed meat (hamburgers, cold meat except ham and Spanish ham, and bacon). *P* values for between-groups differences were calculated using independent samples t-tests.

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13. Supplementary Table S4. Baseline and 6-and 12-month changes in energy and nutrient intake by treatment group (completers-only).

			Intervention *vs* control	
	Intervention group (n=285)	**Control group (n=252)**	**Between-group difference**	***P* value**
Energy intake (kcal/day)				
Baseline	2320 (2252 to 2387)	2354 (2277 to 2430)		
6-month change	-212 (-279 to -145)	-124 (-188 to -60)	-88 (-181 to 5)	0.06
12-month change	-221 (-291 to -150)	-120 (-192 to -48)	-100 (-201 to 0.4)	0.05
Carbohydrate				
Baseline (% of energy)	41.8 (40.9 to 42.6)	41.2 (40.3 to 42.1)		
6-month change (% of energy)	-3.3 (-4.1 to -2.4)	-1.5 (-2.2 to -0.6)	-1.8 (-3.0 to -0.6)	0.002
12-month change (% of energy)	-4.6 (-5.3 to -3.7)	-1.9 (-2.7 to -1.1)	-2.6 (-3.8 to -1.4)	<0.001
6-month change (g/day)	-39.4 (-48.4 to -30.3)	-20.8 (-29.9 to -11.8)	-18.5 (-31.3 to -5.7)	0.005
12-month change (g/day)	-46.3 (-55.7 to -36.9)	-21.6 (-31.0 to -12.2)	-24.7 (-38.0 to -11.3)	<0.001
Protein				
Baseline (% of energy)	17.4 (17.1 to 17.8)	17.3 (17.0 to 17.7)		
6-month change (% of energy)	0.8 (0.4 to 1.2)	-0.1 (-0.4 to 0.2)	0.9 (0.4 to 1.4)	<0.001
12-month change (% of energy)	0.9 (0.5 to -1.3)	-0.01 (-0.4 to 0.3)	0.9 (0.4 to 1.5)	<0.001
6-month change (g/day)	-3.9 (-6.7 to -1.2)	-4.9 (-7.6 to -2.2)	1.0 (-2.9 to 4.8)	0.62
12-month change (g/day)	-4.0 (-6.8 to -1.2)	-4.8 (-7.7 to -1.9)	0.8 (-3.2 to 4.9)	0.68
Total fat				
Baseline (% of energy)	38.2 (37.4 to 39.0)	38.5 (37.7 to 39.4)		
6-month change (% of energy)	2.6 (1.7 to 3.4)	1.9 (1.0 to 2.7)	0.7 (-0.5 to 1.9)	0.25

12-month change (% of energy)	3.6 (2.8 to 4.5)	2.1 (1.2 to 2.9)	1.5 (0.3 to 2.8)	0.01
6-month change (g/day)	-3.5 (-7.2 to 0.2)	-1.1 (-4.5 to 2.3)	-2.4 (-7.5 to 2.6)	0.35
12-month change (g/day)	-1.6 (-5.4 to 2.36)	-0.5 (-4.6 to 3.4)	-1.0 (-6.5 to 4.6)	0.72
Saturated fatty acids				
Baseline (% of energy)	9.8 (9.5 to 10.1)	9.9 (9.6 to 10.1)		
6-month change (% of energy)	-0.9 (-1.2 to -0.6)	-0.5 (-0.7 to -0.2)	-0.5 (-0.8 to -0.1)	0.02
12-month change (% of energy)	-0.8 (-1.0 to -0.5)	-0.6 (-0.9 to -0.3)	-0.2 (-0.5 to 0.2)	0.42
6-month change (g/day)	-4.6 (-5.6 to -3.6)	-2.7 (-3.6 to -1.7)	-1.9 (-3.3 to -0.5)	0.007
12-month change (g/day)	-4.3 (-5.3 to -3.3)	-3.0 (-4.2 to -1.8)	-1.3 (-2.8 to 0.2)	0.10
Monounsaturated fatty acids				
Baseline (% of energy)	19.5 (18.9 to 20.0)	19.8 (19.3 to 20.3)		
6-month change (% of energy)	2.6 (1.9 to 3.3)	1.6 (1.0 to 2.3)	1.0 (0.1 to 1.9)	0.04
12-month change (% of energy)	4.5 (3.8 to 5.2)	2.6 (2.0 to 3.3)	1.9 (0.9 to 2.8)	<0.001
6-month change (g/day)	1.4 (-1.0 to 3.8)	1.4 (-0.7 to 3.5)	0.002 (-3.2 to 3.2)	0.99
12-month change (g/day)	5.1 (2.6 to 7.6)	3.6 (1.3 to 5.9)	1.5 (-1.9 to 4.9)	0.39
Polyunsaturated fatty acids				
Baseline (% of energy)	6.2 (6.0 to 6.5)	6.0 (5.8 to 6.3)		
6-month change (% of energy)	1.6 (1.3 to 1.9)	1.0 (0.7 to 1.3)	0.6 (0.2 to 1.0)	0.006
12-month change (% of energy)	1.3 (1.0 to 1.6)	1.0 (0.8 to 1.3)	0.3 (-0.1 to 0.7)	0.12
6-month change (g/day)	2.2 (1.4 to 3.1)	1.6 (0.7 to 2.5)	0.6 (-0.6 to 1.8)	0.34
12-month change (g/day)	1.4 (0.6 to 2.3)	1.5 (0.6 to 2.4)	-0.1 (-1.3 to 1.2)	0.92
Dietary cholesterol				
Baseline (g/day)	392.0 (370.9 to 413.1)	390.6 (374.9 to 406.4)		
6-month change (g/day)	-49.8 (-69.7 to -30.0)	-37.0 (-50.5 to -23.6)	-12.8 (-37.4 to 11.8)	0.31
12-month change (g/day)	-44.7 (-67.6 to -21.8)	-40.4 (-54.4 to -26.3)	4.4 (-32.1 to 23.4)	0.75

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Dietary fiber				
Baseline (g/day)	27.4 (26.2 to 28.6)	26.6 (25.4 to 27.8)		
6-month change (g/day)	3.3 (1.9 to 4.6)	1.5 (0.2 to 2.7)	1.8 (-0.1 to 3.6)	0.06
12-month change (g/day)	2.8 (1.6 to 4.0)	1.6 (0.3 to 2.9)	1.2 (-0.6 to 2.9)	0.19

Values expressed as mean (95% CI). *P* values for between-groups differences were calculated using independent samples t-tests.

SUPPLEMENTARY DATA

14. Supplementary Table S5. Mean body weight loss (kg) at 6- and 12-months in specific subgroups by treatment group (completers-only).

	Change in body weight (kg)[1]		Intervention *vs* Control	
	Intervention group	**Control group**	**Between-group difference**	***P* value**
Subgroups	**(n=302)**	**(n=282)**		
Sex				
Men	(n=138)	(n=133)		
6-month change	-2.9 (-3.5 to -2.2)	-0.2 (-0.8 to 0.3)	-2.6 (-3.4 to -1.7)	<0.001
12-month change	-3.9 (-4.8 to -3.1)	-0.8 (-1.5 to -0.2)	-3.1 (-4.2 to -2.0)	<0.001
Women	(n=164)	(n=149)		
6-month change	- 2.0 (-2.4 to -1.6)	-0.6 (-1.1 to -0.2)	-1.4 (-2.0 to -0.8)	<0.001
12-month change	-2.7 (-3.3 to -2.2)	-0.6 (-1.1 to -0.1)	-2.1 (-2.9 to -1.4)	<0.001
Age, years				
< 65	(n=128)	(n=120)		
6-month change	-2.6 (-3.3 to -1.9)	-0.6 (-1.1 to 0.1)	-2.0 (-2.9 to -1.1)	<0.001
12-month change	-3.5 (-4.3 to -2.7)	-1.0 (-1.7 to -0.3)	-2.5 (-3.6 to -1.4)	<0.001
≥ 65	(n=174)	(n=162)		
6-month change	-2.2 (-2.6 to -1.8)	-0.3 (-0.8 to 0.1)	-1.9 (-2.5 to -1. 3)	<0.001
12-month change	-3.1 (-3.7 to -2.5)	-0.5 (-1.0 to -0.3)	-2.6 (-3.4 to -1.8)	<0.001
BMI (kg/m^2)				
< 30	(n=80)	(n=77)		

6-month change	-1.6 (-2.2 to -1.0)	-0.3 (-0.8 to 0.3)	-1.3 (-2.1 to -0.5)	0.001
12-month change	-2.5 (-3.0 to -1.9)	-0.4 (-0.9 to 0.2)	-2.1 (-2.9 to -1.3)	<0.001
≥ 30	(n=222)	(n=205)		
6-month change	-2.7 (-3.2 to -2.2)	-0.5 (-0.9 to 0.1)	-2.2 (-2.8 to -1.5)	<0.001
12-month change	-3.6 (-4.2 to -3.0)	-0.9 (-1.4 to -0.3)	-2.7 (-3.5 to -1.9)	<0.001
Type 2 diabetes				
No	(n=169)	(n=152)		
6-month change	-2.3 (-2.9 to -1.8)	-0.6 (-0.9 to 0.2)	-1.8 (-2.5 to -1.1)	<0.001
12-month change	-3.4 (-4.1 to -2.7)	-0.8 (-1.2 to 0.2)	-2.7 (-3.6 to -1.8)	<0.001
Yes	(n=133)	(n=130)		
6-month change	-2.5 (-3.0 to -2.0)	-0.3 (-0.9 to 0.3)	-2.2 (-2.9 to -1.4)	<0.001
12-month change	-3.1 (-3.7 to -2.5)	-0.8 (-1.5 to -0.1)	-2.3 (-3.3 to -1.4)	<0.001
Insulin treatment				
No	(n=285)	(n=259)		
6-month change	-2.5 (-2.8 to -2.0)	-0.4 (-0.8 to -0.1)	-2.0 (-2.5 to -1.5)	<0.001
12-month change	-3.4 (-3.9 to -2.9)	-0.7 (-1.1 to -0.3)	-2.7 (-3.3 to -2.0)	<0.001
Yes	(n=18)	(n=23)		
6-month change	-1.5 (-2.7 to -0.3)	-0.6 (-3.0 to 1.8)	-0.9 (-3.7 to 1.9)	0.51
12-month change	-2.0 (-3.8 to -0.3)	-1.1 (-3.6 to 1.3)	-0.9 (-3.7 to 1.9)	0.57
Statin treatment				
No	(n=163)	(n=142)		
6-month change	-2.4 (-2.9 to -1.9)	-0.4 (-0.8 to 0.03)	-2.0 (-2.7 to -1.3)	<0.001

12-month change	-3.6 (-4.2 to -3.0)	-0.9 (-1.5 to -0.3)	-2.7 (-3.6 to -1.8)	<0.001
Yes	(n=139)	(n=140)		
6-month change	-2.4 (-3.0 to -1.8)	-0.5 (-1.0 to 0.1)	-1.9 (-2.7 to -1.2)	<0.001
12-month change	-2.9 (-3.6 to -2.2)	-0.5 (-1.2 to 0.1)	-2.4 (-3.3 to -1.4)	<0.001
Education level				
Primary education	(n=152)	(n=150)		
6-month change	-2.5 (-2.9 to -2.0)	-0.6 (-1.1 to -0.1)	-1.9 (-2.6 to -1.2)	<0.001
12-month change	-3.1 (-3.8 to -2.5)	-0.9 (-1.4 to -0.3)	-2.2 (-3.1 to -1.4)	<0.001
Secondary education/ academic/graduate	(n=150)	(n=132)		
6-month change	-2.3 (-2.9 to -1.7)	-0.3 (-0.8 to 0.2)	-2.1 (-2.8 to -1.3)	<0.001
12-month change	-3.4 (-4.2 to -2.7)	-0.5 (-1.2 to 0.1)	-2.9 (-3.8 to -1.9)	<0.001

Values are mean (95% CI). Abbreviations: BMI, body mass index. *P* values for between-groups differences were calculated using independent samples t-tests. Results were also qualitatively similar after adjusting by baseline values.

SUPPLEMENTARY DATA

15. Supplementary Table S6. Baseline and 12-month changes in lean and fat mass by treatment group in a subset of participants with body composition data (completers-only).

Body composition	Intervention Group	Control Group	Intervention *vs* Control	
			Between-group difference	***P* value**
Total fat mass (kg)	n=73	n=66		
Baseline	34.68 (33.13 to 36.23)	33.74 (31.95 to 35.54)		
12-month change	-1.9 (-2.68 to -1.19)	-0.16 (-0.95 to 0.62)	-1.77 (-2.85 to -0.70)	0.001
Total lean mass (kg)	n=73	n=66		
Baseline	49.01 (46.66 to 51.37)	50.39 (47.95 to 52.83)		
12-month change	-0.44 (-0.78 to -0.09)	-0.05 (-0.46 to 0.36)	-0.39 (-0.92 to 0.14)	0.14
Lean mass/fat mass ratio	n=73	n=66		
Baseline	1.46 (1.37 to 1.56)	1.57 (1.45 to 1.69)		
12-month change	0.09 (0.05 to 0.13)	0.01 (-0.07 to 0.08)	0.09 (0.01 to 0.17)	0.04

Values expressed as mean (95% CI). *P* values for between-groups differences were calculated using independent samples t-tests. Results were also qualitatively similar after adjusting by baseline values.

SUPPLEMENTARY DATA

16.Supplementary Table S7. Baseline and 6- and 12-month changes in glucose metabolism-related parameters and lipid profile by treatment group for participants with normoglycemia: intention-to-treat (multiple imputation, MI) and completers-only.

Variable	Intervention Group		Control Group		Intervention *vs* Control			
					Between-group difference			
	Intention-to-treat (MI)	Completers-only	Intention-to-treat (MI)	Completers-only	Intention-to-treat (MI)	*P* value	Completers-only	*P* value
Glucose (mmol/L)	n=54	n=48	n=43	n=39				
Baseline	4.98 (4.90 to 5.07)	4.99 (4.90 to 5.09)	4.95 (4.81 to 5.08)	4.94 (4.79 to 5.08)				
6-month change	0.14 (-0.03 to 0.30)	0.12 (-0.04 to 0.29)	0.27 (0.06 to 0.47)	0.25 (0.04 to 0.46)	-0.13 (-0.39 to 0.13)	0.32	-0.13 (-0.39 to 0.14)	0.34
12-month change	0.23 (0.07 to 0.40)	0.21 (0.05 to 0.39)	0.34 (0.12 to 0.56)	0.30 (0.09 to 0.52)	-0.10 (-0.38 to 0.16)	0.43	-0.09 (-0.35 to 0.18)	0.51
HbA1c (%)*	n=54	n=22	n=43	n=21				
Baseline	5.4 (5.2 to 5.5)	5.4 (5.3 to 5.6)	5.4 (5.3 to 5.6)	5.4 (5.4 to 5.6)				
6-month change	0.11 (-0.09 to 0.32)	0.10 (-0.10 to 0.20)	0.09 (-0.11 to 0.25)	0.10 (-0.10 to 0.10)	0.02 (-0.18 to 0.22)	0.84	0.0 (-0.17 to 0.17)	0.99
12-month change	0.06 (-0.13 to 0.28)	0.0 (-0.10 to 0.20)	0.09 (-0.02 to 0.26)	0.10 (0.0 to 0.10)	-0.04 (-0.21 to 0.14)	0.68	-0.10 (-0.27 to 0.07)	0.24
HbA1c (mmol/mol)*	n=54	n=22	n=43	n=21				
Baseline	35.18 (33.61 to 37.06)	36.07 (34.42 to 37.70)	35.81 (34.47 to 37.40)	35.52 (35.52 to 37.70)				
6-month change	1.19 (-0.96 to 3.52)	1.09 (-1.09 to 2.18)	0.97 (-1.17 to 2.73)	1.09 (-1.09 to 1.09)	0.22 (-1.99 to 2.44)	0.84	0.0 (-1.83 to 1.83)	0.99
12-month change	0.69 (-1.38 to 3.09)	0.0 (-1.10 to 2.18)	1.09 (-0.26 to 2.90)	1.09 (0.0 to 1.09)	-0.40 (-2.35 to 1.55)	0.68	-1.09 (-1.92 to 0.74)	0.24
Insulin (pmol/L)	n=54	n=46	n=43	n=35				
Baseline	119.4 (100.7 to 138.2)	122.2 (104.6 to 139.7)	135.9 (114.4 to 157.5)	133.5 (111.9 to 155.1)				
6-month change	-	-	-	-	-	-	-	-
12-month change	-30.3 (-46.3 to -14.3)	-29.7 (-44.8 to -14.5)	-16.6 (-34.2 to 1.0)	-13.8 (-31.6 to 3.9)	-13.7 (-37.5 to 10.1)	0.25	-15.8 (-39.2 to 7.5)	0.18†
HOMA-IR index	n=54	n=46	n=43	n=35				
Baseline	3.70 (3.17 to 4.23)	3.74 (3.23 to 4.25)	4.19 (3.49 to 4.90)	4.13 (3.41 to 4.83)				
6-month change	-	- -	-	-	-	-	-	-

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12-month change	-0.72 (-1.25 to -0.20)	-0.72 (-1.26 to -0.21)	-0.23 (-0.83 to 0.36)	-0.16 (-0.76 to 0.73)	-0.49 (-1.30 to 0.31)	0.23	-0.56 (-1.35 to 0.23)	0.16†
Total cholesterol (mmol/L)	n=54	n=47	n=43	n=38				
Baseline	5.42 (5.15 to 5.68)	5.31 (5.04 to 5.58)	5.48 (5.21 to 5.74)	5.48 (5.21 to 5.77)				
6-month change	0.17 (-0.07 to 0.41)	0.16 (-0.10 to 0.42)	0.07 (-0.15 to 0.29)	0.07 (-0.14 to -0.27)	0.10 (-0.23 to 0.42)	0.56	0.09 (-0.23 to 0.42)	0.58
12-month change	-0.11 (-0.39 to 0.16)	-0.14 (-0.38 to 0.11)	-0.08 (-0.38 to 0.22)	-0.06 (-0.39 to 0.26)	-0.03 (-0.44 to 0.36)	0.86	-0.08 (-0.48 to 0.33)	0.71
HDL cholesterol (mmol/L)	n=54	n=47	n=43	n=39				
Baseline	1.30 (1.22 to 1.39)	1.29 (1.19 to 1.39)	1.32 (1.24 to 1.41)	1.30 (1.22 to 1.39)				
6-month change	0.12 (0.07 to 0.18)	0.13 (0.08 to 0.19)	0.08 (0.02 to 0.13)	0.08 (0.02 to 0.13)	0.04 (-0.04 to 0.13)	0.29	0.06 (-0.03 to 0.14)	0.17
12-month change	0.03 (-0.02 to 0.08)	0.04 (-0.01 to 0.08)	0.04 (-0.02 to 0.11)	0.05 (-0.02 to 0.11)	-0.01 (-0.09 to 0.08)	0.83	-0.01 (-0.08 to 0.07)	0.90
LDL cholesterol (mmol/L)	n=54	n=47	n=43	n=38				
Baseline	3.34 (3.10 to 3.56)	3.25 (3.02 to 3.48)	3.37 (3.13 to 3.61)	3.37 (3.11 to 3.61)				
6-month change	0.09 (-0.12 to 0.31)	0.09 (-0.14 to 0.33)	0.03 (-0.17 to 0.23)	0.03 (-0.15 to 0.22)	0.06 (-0.24 to 0.36)	0.68	0.06 (-0.24 to 0.36)	0.70
12-month change	-0.15 (-0.25 to 0.22)	-0.04 (-0.24 to 0.17)	-0 .09 (-0.36 to 0.18)	-0.08 (-0.37 to 0.20)	0.07 (-0.27 to 0.43)	0.67	0.04 (-0.31 to 0.39)	0.80
Total cholesterol/HDL cholesterol ratio	n=54	n=47	n=43	n=38				
Baseline	4.32 (4.04 to 4.61)	4.32 (4.01 to 4.63)	4.26 (3.98 to 4.54)	4.27 (3.97 to 4.56)				
6-month change	-0.27 (-0.51 to -0.03)	-0.32 (-0.58 to -0.06)	-0.20 (-0.41 to 0.01)	-0.17 (-0.36 to 0.02)	-0.06 (-0.38 to 0.26)	0.69	-0.15 (-0.47 to 0.17)	0.36
12-month change	-0.25 (-0.50 to 0.01)	-0.29 (-0.53 to -0.04)	-0.23 (-0.48 to 0.03)	-0.19 (-0.43 to 0.06)	-0.02 (-0.38 to 0.34)	0.91	-0.10 (-0.44 to 0.25)	0.57
Triglycerides (mmol/L)	n=54	n=47	n=43	n=39				
Baseline	1.69 (1.50 to 1.89)	1.69 (1.47 to 1.90)	1.69 (1.49 to 1.90)	1.72 (1.50 to 1.94)				
6-month change	-0.11 (-0.28 to 0.07)	-0.16 (-0.36 to 0.03)	-0.08 (-0.27 to 0.10)	-0.06 (-0.24 to 0.11)	-0.02 (-0.29 to 0.24)	0.86	-0.10 (-0.36 to 0.16)	0.46
12-month change	-0.29 (-0.48 to -0.09)	-0.31 (-0.50 to -0.12)	-0.07 (-0.23 to 0.09)	-0.05 (-0.21 to 0.10)	-0.22 (-0.48 to 0.04)	0.10	-0.25 (-0.50 to -0.01)	0.04

SUPPLEMENTARY DATA

Triglyceride/HDL cholesterol ratio	n=54	n=47	n=43	n=39				
Baseline	1.42 (1.19 to 1.65)	1.45 (1.19 to 1.71)	1.37 (1.15 to 1.59)	1.40 (1.18 to 1.62)				
6-month change	-0.20 (-0.37 to -0.02)	-0.26 (-0.45 to -0.07)	-0.16 (-0.33 to 0.01)	-0.13 (-0.29 to 0.02)	-0.03 (-0.28 to 0.21)	0.78	-0.12 (-0.37 to 0.12)	0.32
12-month change	-0.29 (-0.48 to -0.09)	-0.32 (-0.50 to -0.13)	-0.10 (-0.26 to 0.06)	-0.08 (-0.23 to 0.07)	-0.19 (-0.45 to 0.07)	0.15	-0.23 (-0.47 to 0.01)	0.05†

Values expressed as mean (95% CI) unless otherwise indicated. Abbreviations: MI, multiple imputation.*For Hb1Ac, data are median (interquartile range). *P* values for between-groups differences were calculated using linear regression with robust standard errors to account for intra-cluster correlations or median regression analyses if data were skewed. Normoglycemia in participants without diabetes, was defined as fasting plasma glucose < 99 mg/dL (5.5 mmol/L) or HbA1c of 5.6% (38 mmol/mol). Results were also qualitatively similar after adjusting by baseline values unless otherwise indicated. †*P*<0.05 after adjusting by baseline values.

SUPPLEMENTARY DATA

17. Supplementary Table S8. Baseline and 6- and 12-month changes in glucose metabolism-related parameters and lipid profile by treatment group for participants with prediabetes: intention-to-treat (multiple imputation, MI) and completers-only.

Variable	Intervention Group		Control Group		Intervention *vs* Control			
					Between-group difference			
	Intention-to-treat (MI)	Completers-only	Intention-to-treat (MI)	Completers-only	Intention-to-treat (MI)	*P* value	Completers-only	*P* value
Glucose (mmol/L)	n=129	n=118	n=119	n=106				
Baseline	5.80 (5.70 to 5.90)	5.84 (5.74 to 5.94)	5.86 (5.73 to 5.97)	5.85 (5.72 to 5.97)				
6-month change	0.01 (-0.08 to 0.10)	0.01 (-0.08 to 0.11)	-0.11 (-0.21 to 0.01)	-0.10 (-0.19 to 0.01)	0.12 (-0.02 to 0.26)	0.08	0.11 (-0.02 to 0.24)	0.11
12-month change	0.0 (-0.12 to 0.12)	-0.01 (-0.13 to 0.12)	0.05 (-0.11 to 0.22)	-0.02 (-0.14 to 0.09)	0.05 (-0.11 to 0.22)	0.54	0.02 (-0.15 to 0.19)	0.85
HbA1c (%)*	n=129	n=80	n=119	n=68				
Baseline	5.8 (5.6 to 6.0)	5.8 (5.7 to 6.0)	5.8 (5.6 to 6.0)	5.8 (5.7 to 6.0)				
6-month change	-0.08 (-0.26 to 0.10)	-0.10 (-0.20 to 0.10)	-0.01 (-0.19 to 0.19)	-0.10 (-0.20 to 0.10)	-0.07 (-0.21 to 0.05)	0.23	0.0 (-0.11 to 0.11)	0.99
12- month change	-0.10 (-0.30 to 0.08)	-0.10 (-0.30 to 0.0)	0.0 (-0.19 to 0.12)	0.0 (-0.20 to 0.10)	-0.10 (-0.19 to -0.02)	0.02	-0.10 (-0.19 to -0.01)	0.03
HbA1c (mmol/mol)*	n=129	n=80	n=119	n=68				
Baseline	39.89 (38.16 to 42.09)	40.43 (38.79 to 42.07)	39.89 (38.06 to 42.07)	39.89 (37.70 to 42.07)				
6-month change	-0.95 (-2.88 to 1.09)	-1.10 (-2.18 to 1.09)	-0.07 (-2.14 to 2.12)	-1.10 (-2.18 to 1.09)	-0.87 (-2.32 to 0.58)	0.23	0.0 (-1.23 to 1.23)	0.99
12-month change	-1.13 (-3.31 to 0.89)	-1.10 (-3.28 to 0.0)	-0.01 (-2.12 to 1.29)	0.0 (-2.18 to 1.09)	-1.13 (-2.07 to -0.19)	0.02	-1.09 (-2.13 to -0.01)	0.03
Insulin (pmol/L)†	n=125	n=101	n=117	n=91				
Baseline	134.1 (121.0 to 147.1)	134.8 (121.6 to 147.9)	141.4 (125.3 to 157.4)	140.5 (124.8 to 156.2)				
6-month change	-	-	-	-	-	-	-	-
12-month change	-27.7 (-40.1 to -15.4)	-30.2 (-42.2 to -18.3)	-9.5 (-21.7 to 2.81)	-9.3 (-21.2 to 2.6)	-18.3 (-0.36 to -0.03)	0.05	-20.9 (-37.3 to -4.1)	0.01

SUPPLEMENTARY DATA

HOMA-IR index‡	n=125	n=101	n=117	n=91				
Baseline	4.89 (4.41 to 5.37)	4.88 (4.38 to 5.37)	5.09 (4.52 to 5.63)	5.12 (4.55 to 5.69)				
6-month change	-	-	-	-	-	-	-	-
12-month change	-1.05 (-1.52 to -0.58)	-1.05 (-1.53 to -0.57)	-0.32 (-0.81 to 0.16)	-0.33 (-0.81 to 0.14)	-0.72 (-1.37 to -0.08)	0.03	-0.72 (-1.39 to -0.04)	0.03
Total cholesterol (mmol/L)	n=129	n=116	n=119	n=104				
Baseline	5.45 (5.29 to 5.60)	5.42 (5.25 to 5.58)	5.41 (5.24 to 5.58)	5.44 (5.27 to 5.62)				
6-month change	-0.04 (-0.17 to 0.09)	-0.03 (-0.16 to 0.11)	-0.08 (-0.21 to 0.05)	-0.09 (-0.23 to 0.04)	0.04 (-0.14 to 0.22)	0.66	0.06 (-0.12 to 0.26)	0.49
12-month change	-0.14 (-0.29 to 0.01)	-0.12 (-0.27 to 0.04)	-0.17 (-0.33 to -0.02)	-0.20 (-0.35 to -0.04)	0.03 (-0.19 to 0.26)	0.77	0.08 (-0.14 to 0.30)	0.46
HDL cholesterol (mmol/L)	n=129	n=115	n=119	n=102				
Baseline	1.30 (1.25 to 1.36)	1.31 (1.26 to 1.37)	1.29 (1.24 to 1.34)	1.28 (1.23 to 1.34)				
6-month change	0.07 (0.04 to 0.10)	0.06 (0.03 to 0.10)	0.05 (0.02 to 0.08)	0.05 (0.02 to 0.07)	0.02 (-0.02 to 0.06)	0.34	0.02 (-0.02 to 0.06)	0.42
12-month change	0.08 (0.05 to 0.11)	0.08 (0.04 to 0.11)	-0.01 (-0.04 to 0.03)	0.0 (-0.03 to 0.03)	0.09 (0.04 to 0.13)	<0.001	0.08 (0.03 to 0.12)	0.002
LDL cholesterol (mmol/L)	n=129	n=115	n=119	n=102				
Baseline	3.42 (3.27 to 3.56)	3.39 (3.23 to 3.54)	3.36 (3.21 to 3.51)	3.39 (3.22 to 3.56)				
6-month change	-0.06 (-0.18 to 0.05)	-0.07 (-0.18 to 0.05)	-0.08 (-0.21 to 0.04)	-0.10 (-0.23 to 0.03)	0.02 (-0.15 to 0.19)	0.81	0.03 (-0.14 to 0.21)	0.71
12-month change	-0.15 (-0.29 to -0.01)	-0.14 (-0.27 to 0.003)	-0 .16 (-0.31 to -0.02)	-0.16 (-0.30 to -0.02)	0.01 (-0.19 to 0.22)	0.89	0.02 (-0.17 to 0.22)	0.80
Total cholesterol/HDL cholesterol ratio	n=129	n=115	n=119	n=102				
Baseline	4.39 (4.19 to 4.61)	4.30 (4.10 to 4.52)	4.35 (3.17 to 4.53)	4.40 (3.20 to 4.60)				
6-month change	-0.26 (-0.39 to -0.14)	-0.24 (-0.36 to -0.11)	-0.24 (-0.36 to -0.13)	-0.25 (-0.37 to -0.13)	-0.02 (-0.18 to 0.15)	0.82	0.01 (-0.16 to 0.18)	0.90
12-month change	-0.39 (-0.53 to -0.24)	-0.34 (-0.49 to -0.20)	-0.14 (-0.29 to 0.002)	-0.16 (-0.30 to -0.02)	-0.24 (-0.45 to -0.04)	0.02	-0.19 (-0.39 to 0.02)	0.07§

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Triglycerides (mmol/L)	n=129	n=116	n=119	n=104				
Baseline	1.57 (1.47 to 1.67)	1.54 (1.45 to 1.64)	1.66 (1.53 to 1.78)	1.67 (1.53 to 1.81)				
6-month change	-0.11 (-0.19 to -0.02)	-0.09 (-0.17 to -0.01)	-0.11 (-0.23 to 0.01)	-0.10 (-0.23 to 0.02)	0.0 (-0.15 to 0.15)	0.99	0.01 (-0.13 to 0.16)	0.85
12-month change	-0.16 (-0.25 to -0.07)	-0.13 (-0.21 to -0.05)	-0.01 (-0.14 to 0.12)	-0.01 (-0.16 to 0.12)	-0.15 (-0.31 to 0.01)	0.06§	-0.11 (-0.27 to 0.05)	0.16§
Triglyceride/HDL cholesterol ratio	n=129	n=115	n=119	n=102				
Baseline	1.32 (1.20 to 1.44)	1.28 (1.16 to 1.40)	1.41 (1.26 to 1.58)	1.43 (1.25 to 1.62)				
6-month change	-0.15 (-0.25 to -0.06)	-0.13 (-0.22 to -0.04)	-0.16 (-0.29 to -0.03)	-0.15 (-0.29 to -0.02)	0.01 (-0.16 to 0.17)	0.92	0.02 (-0.14 to 0.19)	0.76
12-month change	-0.21 (-0.30 to -0.11)	-0.18 (-0.27 to -0.09)	-0.02 (-0.17 to 0.12)	-0.04 (-0.20 to 0.11)	-0.19 (-0.36 to -0.01)	0.03	-0.14 (-0.32 to 0.04)	0.13§

Values expressed as mean (95% CI) unless otherwise indicated. Abbreviations: MI, multiple imputation.*For Hb1Ac, data are median (interquartile range). † and ‡, determined only in participants without insulin treatment. *P* values for between-groups differences were calculated using linear regression with robust standard errors to account for intra-cluster correlations or median regression analyses if data were skewed. Prediabetes was defined as fasting plasma glucose of 100 to 125 mg/dL (5.6 to 6.9 mmol/L) or HbA1c of 5.7 to 6.4% (39 to 47 mmol/mol). Results were also qualitatively similar after adjusting by baseline values unless otherwise indicated. §$P<0.05$ after adjusting by baseline values.

SUPPLEMENTARY DATA

18. Supplementary Table S9. Baseline and 6- and 12-month changes in glucose metabolism-related parameters and lipid profile by treatment group for participants with diabetes: intention-to-treat (multiple imputation, MI) and completers-only.

Variable	Intervention Group		Control Group		Intervention *vs* Control			
					Between-group difference			
	Intention-to-treat (MI)	Completers-only	Intention-to-treat (MI)	Completers-only	Intention-to-treat (MI)	*P* value	Completers-only	*P* value
Glucose (mmol/L)	n=144	n=128	n=137	n=116				
Baseline	7.77 (7.45 to 8.07)	7.72 (7.40 to 8.05)	7.54 (7.21 to 7.88)	7.51 (7.17 to 7.85)				
6-month change	-0.38 (-0.62 to -0.14)	-0.35 (-0.59 to -0.11)	0.17 (-0.08 to 0.43)	0.18 (-0.09 to 0.44)	-0.55 (-0.90 to -0.20)	0.002	-0.53 (-0.89 to -0.17)	0.004
12-month change	-0.59 (-0.86 to -0.32)	-0.58 (-0.84 to -0.31)	0.22 (-0.13 to 0.57)	0.27 (-0.09 to 0.64)	-0.81 (-1.25 to -0.36)	<0.001	-0.86 (-1.31 to -0.40)	<0.001
HbA1c (%)*	n=144	n=91	n=137	n=85				
Baseline	6.7 (6.1 to 7.3)	6.6 (6.1 to 7.1)	6.6 (6.2 to 7.4)	6.6 (6.2 to 7.2)				
6-month change	-0.19 (-0.47 to 0.07)	-0.10 (-0.40 to 0.10)	0.0 (-0.28 to 0.35)	0.0 (-0.30 to 0.30)	-0.19 (-0.35 to -0.04)	0.01	-0.10 (-0.25 to 0.05)	0.19
12-month change	-0.25 (-0.72 to 0.16)	-0.20 (-0.70 to 0.20)	0.0 (-0.38 to 0.36)	0.0 (-0.30 to 0.30)	-0.25 (-0.47 to -0.03)	0.03	-0.20 (-0.39 to -0.01)	0.04
HbA1c (mmol/mol)*	n=144	n=91	n=137	n=85				
Baseline	49.20 (43.17 to 56.30)	48.63 (43.16 to 54.09)	48.91 (43.97 to 57.26)	48.63 (44.26 to 55.19)				
6-month change	-2.12 (-5.13 to 0.81)	-1.10 (-4.37 to 1.09)	0.0 (-3.10 to 3.86)	0.0 (-3.28 to 3.28)	-2.12 (-3.78 to -0.46)	0.01	-1.09 (-2.27 to 0.54)	0.19
12-month change	-2.68 (-7.85 to 1.77)	-2.18 (-7.65 to 2.18)	0.02 (-4.15 to 3.94)	0.0 (-3.28 to 3.28)	-2.71 (-5.11 to -0.32)	0.03	-2.18 (-4.28 to -0.08)	0.04
Insulin (pmol/L)†	n=115	n=91	n=109	n=86				
Baseline	133.7 (120.3 to 147.2)	133.4 (120.4 to 146.4)	124.7 (108.1 to 139.9)	123.4 (108.7 to 138.1)				
6-month change	-	-	-	-	-	-	-	-
12-month change	-22.1 (-36.7 to -7.4)	-21.9 (-35.6 to -8.3)	0.3 (-17.0 to 17.6)	-1.42 (-16.0 to 13.0)	-22.4 (-44.5 to -0.20)	0.04	-20.5 (-40.4 to -0.62)	0.04
HOMA-IR index‡	n=115	n=91	n=109	n=86				
Baseline	6.23 (5.53 to 6.94)	6.27 (5.56 to 6.97)	5.48 (4.75 to 6.21)	5.46 (4.82 to 6.11)				
6-month change	-	- -	-	-	-	-	-	-

12-month change	-1.34 (-2.06 to -0.62)	-1.40 (-2.06 to -0.73)	0.17 (-0.62 to 0.95)	0.15 (-0.56 to 0.87)	-1.51 (-2.51 to -0.50)	0.004	-1.55 (-2.52 to -0.58)	0.002
Total cholesterol (mmol/L)	n=144	n=129	n=137	n=115				
Baseline	4.77 (4.63 to 4.92)	4.72 (4.57 to 4.87)	4.77 (4.61 to 4.92)	4.86 (4.69 to 5.03)				
6-month change	-0.14 (-0.27 to -0.02)	-0.10 (-0.23 to 0.02)	-0.09 (-0.22 to 0.03)	-0.10 (-0.22 to 0.02)	-0.05 (-0.23 to 0.12)	0.56	0.0 (-0.17 to 0.17)	0.97
12-month change	-0.13 (-0.24 to -0.003)	-0.11 (-0.23 to 0.01)	-0.15 (-0.27 to -0.04)	-0.16 (-0.28 to -0.05)	0.03 (-0.14 to 0.19)	0.73	0.05 (-0.11 to 0.22)	0.50
HDL cholesterol (mmol/L)	n=144	n=128	n=137	n=113				
Baseline	1.20 (1.15 to 1.25)	1.21 (1.15 to 1.26)	1.25 (1.19 to 1.30)	1.23 (1.18 to 1.29)				
6-month change	0.05 (0.02 to 0.08)	0.05 (0.02 to 0.09)	0.01 (-0.02 to 0.04)	0.01 (-0.02 to 0.04)	0.04 (-0.001 to 0.09)	0.05	0.04 (-0.003 to 0.01)	0.07
12-month change	0.06 (0.02 to 0.09)	0.06 (0.02 to 0.10)	0.0 (-0.03 to 0.03)	0.0 (-0.03 to 0.03)	0.05 (0.01 to 0.10)	0.02	0.06 (0.01 to 0.11)	0.01
LDL cholesterol (mmol/L)	n=144	n=127	n=137	n=113				
Baseline	2.80 (2.67 to 2.93)	2.73 (2.60 to 2.87)	2.76 (2.63 to 2.88)	2.84 (2.70 to 2.98)				
6-month change	-0.12 (-0.23 to -0.01)	-0.07 (-0.18 to 0.04)	-0.10 (-0.20 to 0.01)	-0.10 (-0.21 to 0.001)	-0.02 (-0.17 to 0.13)	0.78	0.03 (-0.11 to 0.18)	0.67
12-month change	-0.13 (-0.23 to -0.02)	-0.10 (-0.21 to 0.002)	-0 .17 (-0.28 to -0.06)	-0.17 (-0.28 to -0.06)	0.05 (-0.10 to 0.20)	0.54	0.07 (-0.08 to 0.22)	0.37
Total cholesterol/HDL cholesterol ratio	n=144	n=127	n=137	n=113				
Baseline	4.14 (3.98 to 4.31)	4.07 (3.90 to 4.24)	3.98 (3.81 to 4.14)	4.07 (3.90 to 4.24)				
6-month change	-0.26 (-0.34 to -0.18)	-0.22 (-0.34 to -0.11)	-0.12 (-0.23 to -0.01)	-0.13 (-0.24 to -0.02)	-0.14 (-0.29 to 0.02)	0.08	-0.09 (-0.25 to 0.07)	0.25
12-month change	-0.24 (-0.35 to -0.13)	-0.24 (-0.35 to -0.13)	-0.13 (-0.25 to -0.01)	-0.13 (-0.25 to -0.01)	-0.11 (-0.27 to 0.05)	0.16	-0.11 (-0.27 to 0.05)	0.18
Triglycerides (mmol/L)	n=144	n=128	n=137	n=116				
Baseline	1.68 (1.56 to 1.81)	1.66 (1.54 to 1.77)	1.66 (1.55 to 1.78)	1.69 (1.57 to 1.82)				
6-month change	-0.16 (-0.26 to -0.07)	-0.17 (-0.26 to -0.08)	-0.01 (-0.10 to 0.01)	-0.01(-0.10 to 0.09)	-0.16 (-0.29 to -0.03)	0.02	-0.16 (-0.30 to -0.02)	0.02
12-month change	-0.12 (-0.23 to -0.01)	-0.13 (-0.23 to -0.02)	0.04 (-0.09 to 0.17)	0.04 (-0.09 to 0.18)	-0.16 (-0.33 to 0.02)	0.08	-0.17 (-0.34 to 0.002)	0.05§

SUPPLEMENTARY DATA

Triglyceride/HDL cholesterol ratio	n=144	n=127	n=137	n=113				
Baseline	1.54 (1.38 to 1.71)	1.51 (1.36 to 1.66)	1.46 (1.32 to 1.60)	1.48 (1.34 to 1.63)				
6-month change	-0.17 (-0.27 to -0.06)	-0.17 (-0.28 to -0.05)	-0.03 (-0.13 to 0.08)	-0.03 (-0.14 to 0.08)	-0.14 (-0.29 to 0.01)	0.06	-0.14 (-0.29 to 0.02)	0.08
12-month change	-0.14 (-0.27 to -0.02)	-0.15 (-0.28 to -0.03)	0.04 (-0.10 to 0.17)	0.02 (-0.12 to 0.16)	-0.18 (-0.37 to 0.01)	0.06	-0.17 (-0.36 to 0.01)	0.07

Values expressed as mean (95% CI) unless otherwise indicated. Abbreviations: MI, multiple imputation.*For Hb1Ac, data are median (interquartile range). † and ‡, determined only in participants without insulin treatment. *P* values for between-groups differences were calculated using linear regression with robust standard errors to account for intra-cluster correlations or median regression analyses if data were skewed. Diabetes was defined as previous diagnosis of diabetes or HbA1c ≥6.5% (48 mmol/mol), use of antidiabetic medication or having fasting glucose >126 mg/dl (7.0 mmol/L) in the screening visit plus fasting glucose >126 mg/dl (7.0 mmol/L) at baseline visit. Results were also qualitatively similar after adjusting by baseline values unless otherwise indicated. §$P<0.05$ after adjusting by baseline values.

SUPPLEMENTARY DATA

19. Supplementary Table S10. Proportion of participants (%) using drugs at baseline and changes during the intervention by treatment group (completers-only).

Drugs	Intervention group (n=318)	Control group (n=292)	Intervention *vs* control	
			Between-group difference	*P* value
Oral hypoglycemic agents				
Baseline	35.8 (30.5 to 41.1)	36.7 (31.1 to 42.2)		
6-month change	0.9 (-1.1to 2.9)	1.0 (-1.4 to 3.4)	0.1 (-3.2 to 3.1)	0.96
12-month change	0.0 (-2.9 to 2.9)	-2.0 (-5.2 to 1.1)	2.0 (-2.2 to 6.3)	0.34
Insulin				
Baseline	6.6 (3.8 to 9.3)	7.8 (4.7 to 10.9)		
6-month change	0.6 (-0.2 to 1.5)	-0.3 (-1.8 to 1.2)	-0.9 (-0.7 to 2.6)	0.26
12-month change	1.6 (0.1 to 2.9)	0.0 (-1.3 to 1.3)	-1.6 (-0.3 to 3.5)	0.11
Lipid-lowering drugs				
Baseline	52.2 (46.9 to 58.0)	56.8 (51.1 to 62.6)		
6-month change	2.2 (1.1 to 5.5)	0.3 (-3.5 to 4.2)	1.8 (-3.2 to 6.9)	0.47
12-month change	0.3 (-3.8 to 4.4)	0.3 (-3.9 to 4.6)	0.03 (-5.9 to 5.9)	0.99
Statin use				
Baseline	46.0 (40.4 to 51.4)	49.6 (43.8 to 55.4)		
6-month change	1.9 (-1.7 to 5.4)	2.1 (-1.2 to 5.3)	-0.2 (-5.1 to 4.7)	0.95
12-month change	1.9 (-2.0 to 5.8)	4.1 (0.5 to 7.6)	-2.2 (-7.5 to 3.1)	0.41
Antihypertensive agents				
Baseline	76.4 (71.7 to 81.1)	79.7 (75.1 to 84.4)		
6-month change	1.2 (-1.8 to 4.4)	0.3 (-3.0 to 3.7)	0.9 (-3.6 to 5.5)	0.70
12-month change	3.1 (0.2 to 6.0)	2.0 (-1.1 to 5.2)	1.0 (-3.2 to 5.3)	0.61

SUPPLEMENTARY DATA

Thiazide drugs*				
Baseline	26.1 (21.2 to 30.9)	26.4 (21.3 to 31.4)		
6-month change	2.5 (-1.2 to 6.3)	2.4 (-1.7 to 6.5)	0.1 (-5.4 to 5.7)	0.97
12-month change	4.1 (-0.2 to 8.4)	4.1 (-0.02 to 8.2)	0.02 (-6.0 to 5.9)	0.99
ACEi/ARB use				
Baseline	59.4 (54.0 to 64.8)	62.6 (57.0 to 68.2)		
6-month change	3.1 (-0.1 to 6.3)	2.0 (-1.7 to 5.8)	1.1 (-3.9 to 6.0)	0.67
12-month change	5.3 (-1.6 to 9.1)	3.7 (-0.02 to 7.7)	1.6 (-3.8 to 7.0)	0.57

Values expressed as percentage (95% CI). Abbreviations: ACEi, angiotensin-converting enzyme inhibitors; ARB, angiotensin type 2 receptor blocker. *Thiazide drugs include thiazides and thiazide-like diuretics. *P* values for differences between groups by Chi-square tests.

SUPPLEMENTARY DATA

20. Supplementary Table S11. Baseline and 12-month changes in cardiovascular risk biomarkers by treatment group (completers-only).

Markers	Intervention group	Control group	Intervention *vs* control	
			Between-group difference	*P* value
Leptin (ng/ml)	n=261	n=236		
Baseline	19.0 (17.0 to 20.9)	20.6 (18.4 to 22.8)		
12-month change	-2.5 (-3.6 to -1.4)	-0.2 (-1.4 to 0.9)	-2.2 (-3.8 to -0.6)	0.006
C-peptide (ng/ml)	n=261	n=236		
Baseline	1.51 (1.44 to 1.56)	1.60 (1.52 to 1.68)		
12-month change	-0.07 (-0.11 to -0.02)	-0.05 (-0.10 to 0.001)	-0.02 (-0.08 to 0.05)	0.62
hs-CRP (mg/L)*	n=258	n=236		
Baseline	2.31 (1.07 to 4.70)	2.41 (1.42 to 5.61)		
12-month change	-0.07 (-1.03 to 0.67)	-0.12 (-1.13 to 1.01)	0.05 (-0.19 to 0.29)	0.68
IL-6 (pg/ml)*	n=261	n=236		
Baseline	1.33 (0.55 to 2.02)	1.31 (0.56 to 2.34)		
12-month change	0 (-0.57 to 0.62)	0.01 (-0.69 to 0.65)	-0.01 (-0.17 to 0.15)	0.90
IL-8 (pg/ml)	n=261	n=236		
Baseline	9.11 88.40 to 9.82)	9.46 /8.68 to 10.24)		
12-month change	0.25 (-0.72 to 1.23)	1.19 (-0.44 to 2.84)	-0.94 (-2.81 to 0.92)	0.32
IL-18 (pg/ml)	n=261	n=236		
Baseline	90.6 (84.2 to 97.0)	89.1 (82.9 to 95.3)		
12-month change	-5.0 (-7.9 to -2.0)	-0.3 (-3.8 to 3.1)	-4.7 (-9.2 to 0.1)	0.04
TNF-α (pg/ml)*	n=261	n=236		
Baseline	1.78 (0.23 to 3.88)	1.74 (0.23 to 3.88)		
12-month change	-0.01×10^{-1} (-1.55 to 1.13)	-0.05×10^{-2} (-1.49 to 1.0)	0.0 (-0.03×10^{-2} to 0.03 $\times 10^{-2}$)	0.99
MCP-1 (pg/ml)	n=261	n=236		
Baseline	69.5 (65.3 to 73.6)	73.6 (68.8 to 78.5)		
12-month change	-1.9 (-4.9 to 1.1)	4.2 (-0.5 to 9.0)	-6.1 (-11.7 to -0.6)	0.03
RANTES (ng/ml)	n=261	n=236		
Baseline	10.2 (10.0 to 10.4)	10.1 (9.8 to 10.3)		
12-month change	0.1 (-0.1 to 0.2)	0.1 (-0.1 to 0.3)	0.1 (-0.3 to 0.2)	0.65

SUPPLEMENTARY DATA

Values expressed as mean (95% CI) unless otherwise indicated. *Values expressed as median (P25, P75) and the between-group differences are medians (95% CI). Abbreviations: hs-CRP, high sensitive C-reactive protein, IL, interleukin; TNF-α, tumor necrosis factor alfa; MCP-1, monocyte chemoattractant protein-1; RANTES, regulated on activation, normal T-expressed and secreted. *P* values for between-groups differences were calculated using independent t-tests or median regression analyses if data were skewed.

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