AJCN. First published ahead of print November 20, 2013 as doi: 10.3945/ajcn.113.069393.

Health effect of the New Nordic Diet in adults with increased waist circumference: a 6-mo randomized controlled trial[1–4]

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ABSTRACT

Background: The regional Mediterranean Diet has been associated with lower risk of disease.

Objective: We tested the health effects of the New Nordic Diet (NND), which is a gastronomically driven regional, organic, and environmentally friendly diet, in a carefully controlled but free-living setting.

Design: A total of 181 centrally obese men and women, with a mean (range) age of 42 y (20–66 y), body mass index (in kg/m^2) of 30.2 (22.6–47.3), and waist circumference of 100 cm (80–138 cm) were randomly assigned to receive either the NND (high in fruit, vegetables, whole grains, and fish) or an average Danish diet (ADD) for 26 wk. Participants received cookbooks and all foods ad libitum and free of charge by using a shop model. The primary endpoint was the weight change analyzed by both completer and intention-to-treat analyses.

Results: A total of 147 subjects [81% (NND 81%; ADD 82%)] completed the intervention. A high dietary compliance was achieved, with significant differences in dietary intakes between groups. The mean (±SEM) weight change was −4.7 ± 0.5 kg for the NND compared with −1.5 ± 0.5 kg for the ADD (adjusted difference: −3.2 kg; 95% CI: −4.6, −1.8 kg; $P < 0.001$) for the completer analysis, and the difference was −3.0 kg (95% CI: −4.0, −2.1 kg) for the intention-to-treat analysis. The NND produced greater reductions in systolic blood pressure (adjusted difference: −5.1 mm Hg; 95% CI: −8.2, −2.1 mm Hg) and diastolic blood pressure (adjusted difference: −3.2 mm Hg; 95% CI: −5.7, −0.8 mm Hg) than did the ADD.

Conclusion: An ad libitum NND produces weight loss and blood pressure reduction in centrally obese individuals. This trial was registered at clinicaltrials.gov as NCT01195610. *Am J Clin Nutr* doi: 10.3945/ajcn.113.069393.

INTRODUCTION

Lifestyle interventions that focus on a healthy diet and physical activity are crucial in the prevention of hypertension (1) and the metabolic syndrome (2). Previous dietary research has primarily focused on health benefits of single nutrients or the macronutrient composition. Studies have shown that both low-fat, low-carbohydrate (3) and high-protein (4) diets may have a beneficial role in weight management and, thereby, in disease prevention. However, both low-fat and low-carbohydrate diets may be associated with low adherence, and long-term effects on health are disappointing (3). Diets are composed of foods rather than macronutrients, and thus, dietary recommendations on the basis of foods are more likely to be understood and adopted by the public. Recent, large epidemiologic and clinical studies of foods and whole diets indicated that fruit, vegetables, nuts, fish, and whole grain seem to prevent cardiovascular disease (5). Several meta-analyses of the regional Mediterranean diet, which is based on these foods, have shown that the diet has positive effects on weight loss (6), cardiovascular disease risk factors (7, 8), and the metabolic syndrome (9). Similarly, the food-based diet Dietary Approaches to Stop Hypertension (DASH)[5] (10) has positive effects on weight (11), metabolic syndrome, and particularly blood pressure (12). However, regional and cultural differences limit adherence to food-based diets transferred between populations. For example, in younger obese Danes, a Mediterranean-style diet resulted in a less regain of body weight and body fat and improved glucose homeostasis than did a control diet high in total fat (35% of energy) and saturated fatty acids (>15% of energy), but there was a significantly higher dropout rate in the Mediterranean-diet group (13). Participants also reported difficulties in integrating the Mediterranean diet into eating habits of their families (14). Dietary habits vary greatly in different parts of Europe (15), and to be successful, dietary guidelines must be sensitive to the local food culture.

The New Nordic Diet (NND) is a food-based dietary concept recently developed in the Nordic countries in collaboration with

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[2] The funder did not have any influence on the study design, data collection, data analysis, data interpretation, or content and submission of the manuscript.

[3] Supported by a grant from the Nordea Foundation Denmark. Local food companies provided foods for the shop.

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[5] Abbreviations used: ADD, average Danish diet; DASH, Dietary Approaches to Stop Hypertension; NND, New Nordic Diet.

Received June 25, 2013. Accepted for publication October 25, 2013.
doi: 10.3945/ajcn.113.069393.

the world-leading Copenhagen gourmet restaurant NOMA. The NND is based on regional foods in season, with a strong emphasis on palatability, healthiness, and sustainability, while staying in tune with regional food culture and dietary habits (16). In a 6-wk intervention study, a Nordic diet has been shown to improve blood lipids compared with in a control group (17). The Nordic diet has also been associated with lower mortality in a cohort of Danes (18). In the current study, the aim was to test the health effect of the NND if provided ad libitum in a highly controlled but free-living situation and, hence, if the NND could be a healthy and attractive alternative to the regional Mediterranean diet or DASH diet and easily adopted by Nordic populations. To test this aim, we compared the NND with the average Danish diet (ADD).

SUBJECTS AND METHODS

Study design and participants

A nonblinded, parallel, randomized, controlled dietary-intervention study was carried out between October 2010 and July 2011. A total of 277 men and women were recruited through the Danish recruitment website www.forsøgsperson.dk, by advertising on Facebook, through a piece published in University of Copenhagen and local food-company newsletters, and spots on national television from July to October 2010. After screening conducted by trained scientific personnel, 220 participants who were mainly living in the Copenhagen area were shown to be eligible for the study. Inclusion criteria were men and women between 18 and 65 y of age with waist circumferences ≥80 cm for women and ≥94 cm for men. Furthermore, we aimed to include participants with one or more of the following conditions: plasma triglyceride concentrations ≥1.7 mmol/L, HDL-cholesterol concentrations ≤1.03 mmol/L for men and ≤1.29 mmol/L for women, hypertension (systolic/diastolic blood pressure >130/85 mm Hg), and impaired fasting glucose (19). The medical treatment of hypertension and high cholesterol was allowed if the conditions were stable in the preceding 3 mo and could be expected to be stable throughout the study. People with diagnosed diabetes (types 1 and 2), familial hypercholesterolemia, a total cholesterol concentration ≥9 mmol/L, or hypertriglyceridemia (triglyceride concentration ≥3 mmol/L) were excluded as were individuals with weight loss ≥2 kg in the preceding 2 mo, with food allergies in conflict with the intervention, and pregnant or lactating women. All participants signed informed consent after receiving oral and written information. The study was approved by the ethical committee of the Capital Region of Denmark (reference H-3-2010-058). This trial was registered at clinicaltrials.gov as NCT01195610.

Random assignment and masking

Participants were randomly assigned to receive either the NND or ADD in a 3:2 ratio, with simple block randomization stratified according to BMI (in kg/m^2) (<33 or ≥33), age (<45 or ≥45 y), and enrolled as an individual or couple. Randomization blocks of 10 participants were used. The random assignment was concealed until the baseline examination. The randomization list was generated by the senior investigator who did not participate in the subsequent randomization procedure, which was carried out by a scientific assistant. On assignment to the diets at week 0, neither participants nor study personnel were blinded to the random assignment.

Procedures

The study consisted of a 26-wk dietary intervention with either the NND or ADD. Participants underwent examinations at weeks 0 (baseline), 12, and 26 (**Figure 1**). Before random assignment, participants underwent a 1 wk run-in period (weeks −1 to 0). Participants met individually with a dietitian on 9 occasions in the course of the intervention for general advice on healthy eating (eg, meal patterns, meal size, satiety, and eating behavior) and how to comply with the diet. Participants filled out a short questionnaire regarding their dietary compliance and satisfaction with the diet during these meetings (*see* online supplemental material under "Supplemental data" in the online issue for the dietary-compliance questionnaire). Participants were encouraged to maintain their regular physical activity habits throughout the intervention.

Examinations took place at the Department of Human Nutrition, University of Copenhagen, in the morning after an 8-h fast, where fasting body weight, waist circumference, hip circumference, sagittal diameter, body composition [by using dual-energy X-ray absorptiometry (Lunar Radiation Co)], and blood pressure were measured, and fasting blood samples were collected. At weeks 0 and 26, an oral-glucose-tolerance test was performed in addition to fasting blood samples. A 24-h urine collection was performed at weeks 0, 4, 12, 20, and 26. At each consultation visit with the dietitian (weeks 2, 4, 8, 16, 20, and 24), body weight was measured in a nonfasting state. The physical fitness level was measured with a submaximal test by using a bicycle ergometer (Ergomedic 839E; Monark Exercise AB) at weeks 0, 12, and 26 to control for changes in physical activity, and a self-administered modified version of Baecke's physical activity questionnaire (20) to measure physical activity habits was also completed at weeks 0, 12, and 26. *See* online supplemental material under "Supplemental data" in the online issue for details of measurement and biochemical analyses.

Diets

The NND was developed as part of the multidisciplinary 5-y research project "Optimal well-being, development and health for Danish children through a healthy New Nordic Diet," which has been described in detail elsewhere (16, 21). The basis of the diet is comprised of the following 15 food groups: fruit and vegetables (especially berries, cabbages, root vegetables, and

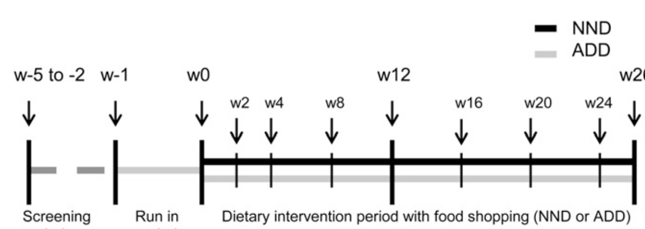

FIGURE 1. Schematic overview of the dietary intervention with the NND or ADD. Arrows represent physical examinations and meetings with the dietitian. w0 represents time of random assignment. ADD, average Danish diet; NND, New Nordic Diet; w, week.

legumes), potatoes, fresh herbs, plants and mushrooms gathered from the wild, nuts, whole grain, meats from livestock and game, fish and shellfish, and seaweed (*see* Supplemental Table 1 under "Supplemental data" in the online issue). Other food groups mentioned in the official Danish Food-based Dietary Guidelines are included in the NND but are not specified further [eg, dairy products (500 g milk/d; 25 g cheese/d), eggs (25 g/d), beverages, and sweets] (21). The majority of foods are organically grown and of Nordic origin. The macronutrient composition is based on the Nordic Nutrition Recommendations 2004 (22) but with a slightly higher protein content. A cookbook with 180 recipes (including starters, main course, and desserts) organized into menu plans according to the seasonal variation (3 menu plans for each season) was developed for the intervention to guide and inspire participants creating NND meals. The macronutrient composition and food groups of the ADD were designed to match the diet that is commonly eaten in the adult Danish population aged 15–75 y and as defined by the latest survey of dietary habits in Denmark performed in 2003–2008 (23). Characteristic food groups in the diet are refined grains including pasta and rice, meat, dairy and cheese, sugary products, convenience foods, and, to a lesser extent, low-fiber vegetables and imported fruit (eg, citrus, bananas, and melons). A cookbook with 99 recipes (including starters, main course, and desserts) of traditional Danish dishes was developed for ADD participants. The cookbook did not include menu plans because the seasonal variation was not important in the ADD. Both groups participated in cooking courses in their respective diets before the intervention. Courses were led by the same chefs and had a focus on creating great tasting meals according to guidelines for the diets.

Shop model

For both groups, foods and beverages (except coffee, tea, and alcoholic beverages) were provided from a study shop in the run-in and intervention periods as described previously (24, 25). Participants visited the shop at least once a week to collect food ad libitum and free of charge from a variety of foods. Because both groups were present in the shop simultaneously, shelves were color marked to illustrate the food reserved for each group. At check out, selected foods were weighed on a digital scale and registered in a web-based computer application designed for the study. Adjustments were made if the selected foods did not fulfill the dietary guidelines. *See* online supplemental material under "Supplemental data" in the online issue for an additional description of the shop model.

All participants consumed the ADD ad libitum in the run-in period, except for the last 3 d when participants were provided specific ADD foods in specific amounts to ensure that they were in energy balance. This standardization of the diet served to standardize participants to the same diet before the first clinical examination at week 0. Both groups were allowed to drink alcohol in the intervention period in amounts in accordance with the following current Danish national guidelines: ≤7 units/wk for women and ≤14 units/wk for men (1 unit = 12 g alcohol). Individual dietary intake was assessed by 3-d weighed dietary records. The records were performed on 2 weekdays and a Friday or Saturday before the examinations at weeks 0, 12, and 26. Nutrient intake was calculated with Dankost 3000 software (version 7.01, 2009; Dankost).

Statistical analyses

The change in body weight was considered a strong proxy for the improvement of health. Therefore, the primary outcome was the change in body weight from weeks 0 to 26 in completers as well as by using an intention-to-treat analysis. Secondary outcomes were changes in systolic and diastolic blood pressure, waist and hip circumferences, sagittal diameter, fat mass, diabetic risk factors [fasting plasma glucose, fasting serum insulin, and insulin resistance measured by HOMA-IR (26) and the Matsuda index (27)] and cardiovascular disease risk factors (plasma total cholesterol, HDL cholesterol, LDL cholesterol, VLDL cholesterol, and triglyceride concentrations), which were all performed as completer analyses. Completer analyses were chosen because the main aim was to show the potential effects of the 2 diet groups when studied in a very controlled setting, thereby assuming the highest possible dietary compliance, and because some secondary outcomes were only assessed at week 0. The sample size was calculated on the basis of previous findings that used the shop model (28), with the assumption of a 1.9-kg difference in weight change between groups at week 26. We assumed an SD of 3 kg in the NND group and 2 kg in the ADD group. Fifty-percent more participants were included in the NND group because this allowed sociologic substudies of the NND (data to be published separately). With an expected dropout rate of 20% in both groups, a total group size of 200 would result in a power of 99.8%. Any group differences >1.1 kg would result in a power >80%. The primary outcome was analyzed by a completer analysis including participants for whom we had data from weeks 0 (time of random assignment) and 26. A multiple linear regression analysis adjusted for sex, family status (single or couple), and baseline values was performed. A similar multiple linear regression analysis with the same adjustments was used for secondary outcomes. A mixed model, with the previously mentioned adjustments and the assumption that the weight change for dropouts followed the same course as for completers and weights were missing at random (29), was used for an intention-to-treat model. The model included all available observations at the 9 time points and a deterministic imputation on the basis of available cases for participants with only baseline data (n = 5).

Results are presented as mean (±SEM) changes within each group and mean (95% CI) differences, with corresponding P value between groups. Values with a skewed distribution were logarithmically transformed before additional analysis and are presented as raw estimates and P values for logarithmically transformed data. Statistical analyses were performed with STATA 11.2 software (StataCorp LP). *See* online supplemental material under "Supplemental data" in the online issue for additional details on statistical analyses.

RESULTS

Participants were well matched at the time of random assignment (week 0), with no differences between groups (**Table 1**; *see* Supplemental Table 2 under "Supplemental data" in the online issue). During the intervention, 34 of 181 randomly assigned participants dropped out (19%), in an amount that was evenly distributed between the 2 groups (**Figure 2**). The 147 completing participants were considered well matched at the

TABLE 1
Baseline characteristics at random assignment (week 0) of participants in a dietary intervention with the NND or ADD[1]

	NND (n = 113)	ADD (n = 68)	Difference between groups[2]	P[3]
Women [n (%)]	80 (71)	48 (71)	—	0.98[4]
Singles [n (%)]	77 (68)	52 (76)	—	0.23[4]
Age (y)	42.7 ± 13.1[5]	41.0 ± 13.0	1.68 (−2.29, 5.64)	0.41
Body weight (kg)	89.7 ± 16.4	90.3 ± 18.2	−0.64 (−5.82, 4.54)	0.81
BMI (kg/m^2)	30.1 ± 4.6	30.5 ± 5.3	−0.37 (−1.85, 1.11)	0.62
Fat mass (kg)	36.9 ± 10.9	37.3 ± 11.9	−0.44 (−3.87, 2.99)	0.80
Fat-free mass (kg)	53.0 ± 10.5	53.2 ± 10.4	−0.16 (−3.33, 3.00)	0.92
Fat percentage (%)	40.8 ± 7.4	40.9 ± 6.8	−0.04 (−2.22, 2.13)	0.97
Waist circumference (cm)	99.7 ± 11.9	100.8 ± 13.2	−1.06 (−4.82, 2.70)	0.58
Hip circumference (cm)[6]	110.7 ± 10.4	111.0 ± 11.8	−0.32 (−3.64, 3.00)	0.85
Sagittal diameter (cm)	23.0 ± 3.0	23.1 ± 3.6	−0.06 (−1.04, 0.92)	0.91
Physical fitness (mL · min^{-1} · kg^{-1})	26.7 ± 7.5	26.9 ± 6.8	−0.23 (−2.45, 1.98)	0.83
Systolic blood pressure (mm Hg)	122.5 ± 13.9	122.4 ± 13.2	0.05 (−4.07, 4.18)	0.98
Diastolic blood pressure (mm Hg)	81.0 ± 10.3	81.9 ± 9.3	−0.97 (−3.98, 2.04)	0.53
Triglycerides (mmol/L)	1.17 ± 0.66	1.14 ± 0.52	0.03 (−0.15, 0.22)	0.74
Total cholesterol (mmol/L)	4.63 ± 0.86	4.63 ± 0.87	−0.01 (−0.27, 0.25)	0.95
HDL cholesterol (mmol/L)	1.15 ± 0.28	1.16 ± 0.33	−0.01 (−0.10, 0.08)	0.84
LDL cholesterol (mmol/L)	2.95 ± 0.84	2.96 ± 0.81	−0.01 (−0.26, 0.24)	0.95
VLDL cholesterol(mmol/L)	0.53 ± 0.30	0.52 ± 0.24	0.01 (−0.08, 0.09)	0.84
Fasting plasma glucose (mmol/L)	5.31 ± 0.49	5.26 ± 0.42	0.05 (−0.09, 0.19)	0.52
Fasting serum insulin (pmol/L)	76.8 ± 50.5	73.0 ± 35.2	3.79 (−9.95, 17.5)	0.59
HOMA-IR	2.59 ± 1.8	2.41 ± 1.2	0.18 (−0.31, 0.68)	0.47
Matsuda index	5.84 ± 3.2	5.49 ± 2.7	0.35 (−0.56, 1.27)	0.45
CRP (mg/L)	4.97 ± 6.9	4.17 ± 5.58	0.79 (−1.17, 2.75)	0.43
Fructosamine (μmol/L)	206.7 ± 17.1	208.4 ± 14.2	−1.64 (−6.55, 3.26)	0.51
Potassium (mmol/L)	4.00 ± 0.2	4.01 ± 0.2	−0.01 (−0.07, 0.05)	0.80
Carbamide (mmol/L)	5.17 ± 1.1	5.13 ± 1.0	0.04 (−0.27, 0.36)	0.79
Fibrinogen (μmol/L)	10.2 ± 1.9	9.90 ± 1.8	0.31 (−0.27, 0.88)	0.29

[1] HOMA-IR was calculated as follows: fasting plasma glucose (mmol/L) × fasting plasma insulin (μU/mL) ÷ 22.5 (26). The Matsuda index was calculated as follows: 10,000 ÷ $\sqrt{}${[fasting glucose (mg/dL) × fasting insulin (μU/mL)] × [mean glucose (mg/dL) × mean insulin (μU/mL) concentrations during oral-glucose-tolerance test)]} (27). ADD, average Danish diet; CRP, C-reactive protein; NND, New Nordic Diet.
[2] All values are means; 95% CIs in parentheses.
[3] Between NND and ADD groups by using Student's t test, unless otherwise specified.
[4] With the use of the chi-square test.
[5] Mean ± SD (all such values).
[6] Only data on 111 participants in the NND group.

time of random assignment, and no statistical differences in baseline amounts were shown (all $P > 0.10$).

Dietary intake

Dietary intake, which was based on the 3 d individual weighed dietary records, is shown in **Table 2** (*see* Supplemental Table 3 under "Supplemental data" in the online issue). During the intervention, the NND group consumed less energy, and the energy density of their diet, including energy containing beverages, was lower than in the ADD group. In the NDD group, proportions of energy from total fat, SFAs, and added sugars was lower, and the dietary fiber content was higher, than in the ADD group. Except for a too low proportion of Nordic foods (80.2%) and too little seaweed (0.7 g/d), the NND group consumed a diet fully in accordance with NND principles (data not shown). The diet consumed in the NND group was significantly different from the ADD diet with $P < 0.001$ for all food groups except milk and milk products (P = 0.048) but not significantly different for beverages (eg, soft drinks and juices) (P = 0.28) (**Figure 3**). The number (±SEM) of days with food provided by the shop was equal in the 2 groups [NND: 173.2 ± 1.4 d in the NDD group and 170.6 ± 1.6 d in the ADD group (P = 0.21)]. The mean (±SEM) self-evaluated compliance to the NND on a 1 (very bad) to 5 (very good) scale was 4.3 ± 0.05, and the mean (±SEM) self-evaluated compliance to the ADD was 4.4 ± 0.04 (P = 0.07). The mean (±SEM) self-evaluated satisfaction with the NND was 4.8 ± 0.04, and the mean (±SEM) self-evaluated satisfaction with the ADD was 3.7 ± 0.13 ($P < 0.001$). The self-reported protein intake was reasonably well reflected in the 24-h urinary excretion of nitrogen (**Table 3**; *see* Supplemental Table 4 under "Supplemental data" in the online issue). The 24-h urinary excretion of sodium (Table 3; *see* Supplemental Table 4 under "Supplemental data" in the online issue) did not reflect the self-reported difference in sodium intake (*see* Supplemental Table 3 under "Supplemental data" in the online issue) between groups. The analysis of the fatty acid composition in whole blood (Table 3; *see* Supplemental Table 5 under "Supplemental data" in the online issue) showed good compliance to the diet (ie, increased blood status of total and long chain n−3 fatty acids as indicated by higher sums of EPA and DHA, a lower n−6:n−3 ratio, and a higher percentage of

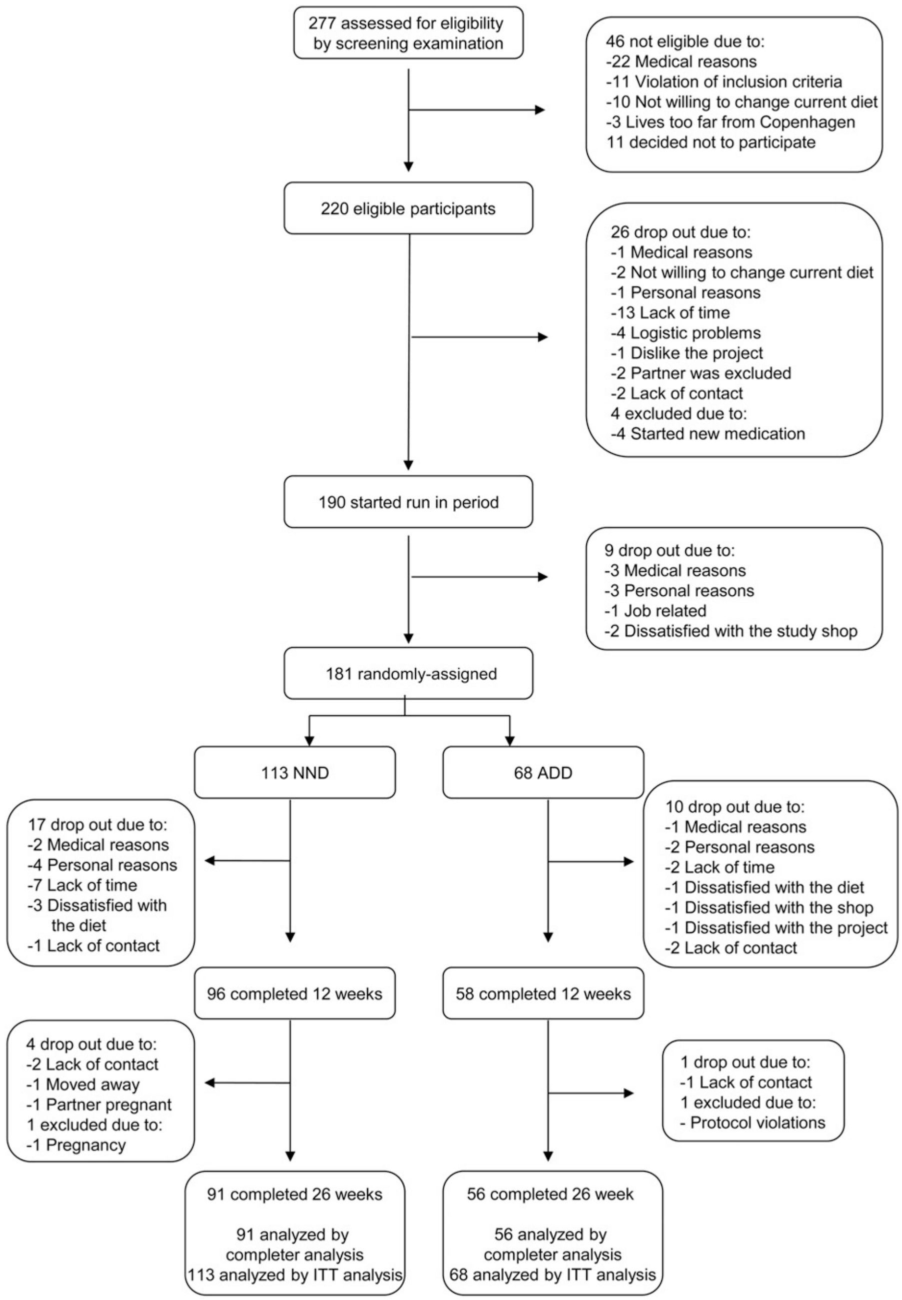

FIGURE 2. Participant flow diagram for participants in a dietary intervention with the NND or ADD. ADD, average Danish diet; ITT, intention-to-treat; NND, New Nordic Diet.

n−3 highly unsaturated fatty acids in total highly unsaturated fatty acids in the NND group.

Body weight and anthropometric measures

Weight loss occurred in both groups, but at week 26 the mean weight loss was −3.22 kg greater in the NND group (−4.74 ± 0.48 kg) than ADD group (−1.52 ± 0.45 kg) (**Table 4**). The greater weight loss in the NND group was accompanied by greater reductions in waist circumference, hip circumference, sagittal diameter, and body fat mass. There was no difference in changes in physical fitness between groups (Table 4). An intention-to-treat analysis that included the 181 participants who completed the week 0 examinations showed that the NND group lost 3.04 kg more than the ADD group did (95% CI: 2.13, 3.96 kg) (ie, essentially identical to the amount in the completer analysis. Trajectories of the 2 groups for both completer and intention-to-treat analyses are shown in **Figure 4**.

Cardiovascular disease and diabetes risk factors

Systolic and diastolic blood pressure, plasma triglyceride, total cholesterol, and VLDL cholesterol were reduced in the NND group compared with ADD group (**Table 5**). One participant in each group began antihypertensive medication during the study. Fasting glucose decreased in the NND group compared with

TABLE 2

Changes in energy intake, energy density, and macronutrient intake from weeks 0 to 26 on the basis of 3-d individual weighed dietary records for participants in a dietary intervention with the NND or ADD[1]

	NND (n = 73)	ADD (n = 47)	Difference between groups[2]	P[3]
Estimated energy requirement (MJ/d)[4]	10.9 ± 0.2[5]	11.1 ± 0.3	−0.2 (−0.8, 0.4)	0.54
Energy intake (kJ/d)	−1617 ± 322	149 ± 342	−1766 (−2730, −803)	<0.001
Energy density (kJ/100g)	−78.4 ± 12.6	9.1 ± 20.8	−87.5 (−132.9, −42.1)	<0.001
Protein (% of energy)	1.6 ± 0.4	−0.6 ± 0.3	2.1 (0.9, 3.3)	<0.001
Carbohydrate (% of energy)	0.9 ± 0.8	−2.3 ± 0.8	3.2 (0.9, 5.4)	0.006
Fiber (g/10 MJ)	7.3 ± 1.1	−12.0 ± 1.1	19.3 (16.1, 22.5)	<0.001
Added sugar (% of energy)	−1.3 ± 0.4	2.5 ± 0.6	−3.8 (−5.2, −2.4)	<0.001
Total fat (% of energy)	−3.6 ± 0.7	1.6 ± 0.8	−5.1 (−7.2, −3.1)	<0.001
SFA (% of energy)	−5.2 ± 0.3	−1.2 ± 0.4	−4.0 (−5.1, −3.0)	<0.001
MUFA (% of energy)	−1.7 ± 0.5	−0.8 ± 0.5	−0.9 (−2.3, 0.5)	0.19
PUFA (% of energy)	2.1 ± 0.3	0.5 ± 0.2	1.6 (0.9, 2.3)	<0.001
Alcohol (% of energy)	1.2 ± 0.3	1.3 ± 0.5	−0.1 (−1.2, 0.9)	0.78

[1] ADD, average Danish diet; NND, New Nordic Diet.
[2] All values are means; 95% CIs in parentheses.
[3] Between the NND and ADD group by using Student's t test.
[4] On the basis of weight and height as recommended by Schofield (30) and multiplied by a physical activity level of 1.5.
[5] Mean ± SEM (all such values).

ADD group. The difference in systolic blood pressure remained after adjustment for weight loss (adjusted difference: −3.29 mm Hg; 95% CI: −6.43, −0.13). In a subgroup of participants with prediabetes at baseline (n = 19; *see* Supplemental Table 6 under "Supplemental data" in the online issue), we observed a larger improvement in fasting insulin, HOMA-IR, and the Matsuda index in the NND group compared with ADD group (**Table 6**). A similar analysis that was based on women only (NND: n = 7;

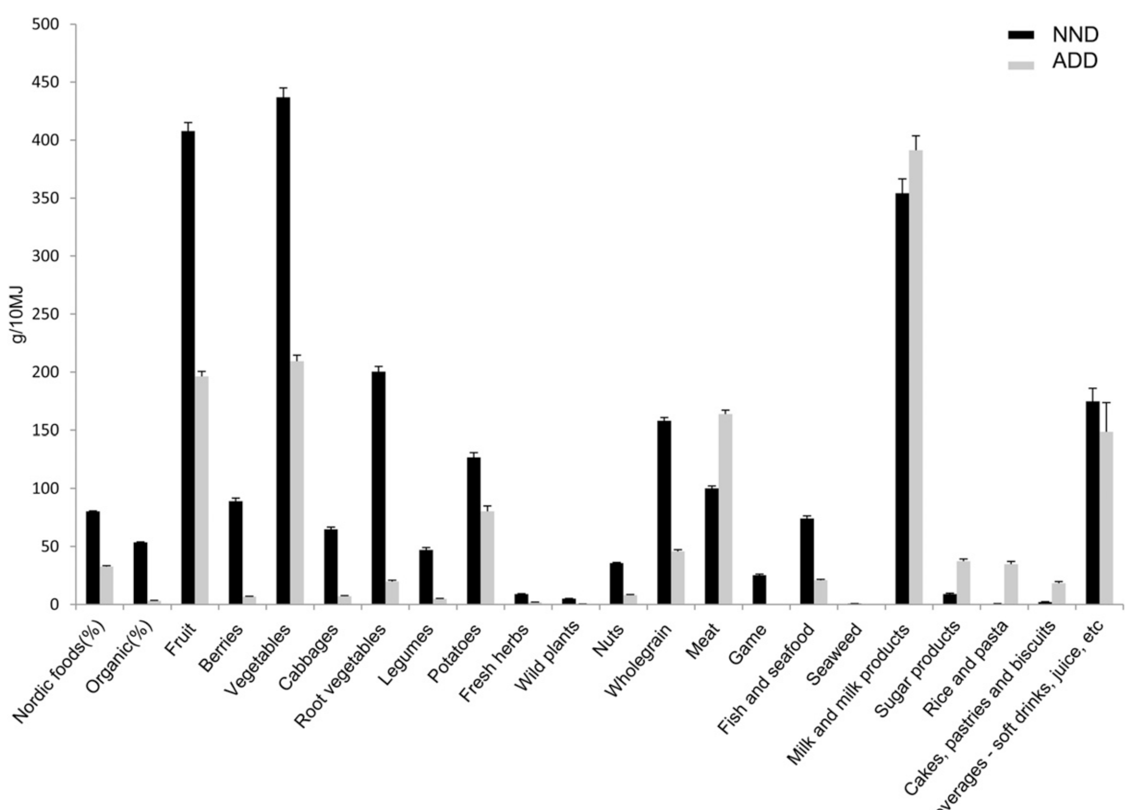

FIGURE 3. Mean (±SEM) intakes of food groups on the basis of data from the study shop for participants in a dietary intervention with the NND or ADD. The first 17 food groups (from Nordic foods to seaweed) represent food groups specified for the NND. All results were significantly different between the NND and ADD at $P < 0.001$, except for milk and milk products ($P = 0.05$) and beverages ($P = 0.28$) by using Student's t test. ADD, average Danish diet; NND, New Nordic Diet; %, percentage of the total amount.

TABLE 3
Biological compliance markers at weeks 0, 12, and 26 for completers in a dietary intervention with the NND or ADD[1]

	NND				ADD					
	n	Week 0	Week 12	Week 26	n	Week 0	Week 12	Week 26	Difference[2]	P[3]
Urine nitrogen (g/d)	90	14.9 ± 0.4[4]	14.0 ± 0.4	15.6 ± 0.6	53	15.5 ± 0.6	14.7 ± 0.6	15.0 ± 0.7	1.32 (−0.33, 2.97)	0.12
24-h sodium (g/d)	90	3.3 ± 0.1	3.3 ± 0.1	3.5 ± 0.2	53	3.5 ± 0.2	3.8 ± 0.2	3.4 ± 0.2	0.29 (−0.31, 0.89)	0.33
SFAs (%)	89	44.1 ± 0.3	43.5 ± 0.3	43.1 ± 0.2	56	44.3 ± 0.4	44.6 ± 0.3	44.1 ± 0.3	−0.81 (−1.89, 0.26)	0.14
MUFAs %	89	23.2 ± 0.2	24.3 ± 0.3	23.6 ± 0.2	56	23.5 ± 0.3	24.1 ± 0.3	23.7 ± 0.3	0.21 (−0.51, 0.93)	0.56
PUFAs (%)	89	30.8 ± 0.4	31.0 ± 0.3	32.3 ± 0.3	56	29.8 ± 0.5	30.0 ± 0.4	31.1 ± 0.4	0.20 (−1.28, 1.68)	0.79
n−6 FA (%)	89	25.1 ± 0.3	25.4 ± 0.3	25.8 ± 0.2	56	24.3 ± 0.4	25.0 ± 0.3	25.8 ± 0.3	−0.75 (−1.82, 0.32)	0.17
n−3 FA (%)	89	5.8 ± 0.2	5.4 ± 0.1	6.5 ± 0.2	56	5.5 ± 0.2	5.0 ± 0.1	5.2 ± 0.2	0.95 (0.42, 1.48)	<0.001
EPA + DHA (%)	89	4.2 ± 0.1	3.9 ± 0.1	4.8 ± 0.1	56	4.0 ± 0.1	3.6 ± 0.1	3.8 ± 0.1	0.83 (0.38, 1.28)	<0.001
n−3 HUFA in total HUFA (%)[5]	89	32.4 ± 0.6	32.0 ± 0.6	35.7 ± 0.6	56	32.3 ± 0.7	31.0 ± 0.6	30.6 ± 0.6	5.01 (3.81, 6.21)	<0.001

[1] ADD, average Danish diet; FA, fatty acid; HUFA, highly unsaturated fatty acid; NND, New Nordic Diet.
[2] All values are means; 95% CIs in parentheses.
[3] Between groups of the difference from week 0 to week 26 by using Student's t test.
[4] Mean ± SEM (all such values).
[5] (20:3n–3 + 20:5n–3 + 22:5n–3 + 22:6n–3)/(20:3n–3 + 20:5n–3 + 22:5n–3 + 22:6n–3 + 20:3n–6 + 20:4n–6 + 22:4n–6 + 22:5n–6 + 20:3n–9) × 100.

ADD: n = 5) gave essentially the same results (data not shown).

Adverse events

No serious adverse events were registered during the study. In total, 2.5 adverse events were registered for each participant during the study, with no difference between the groups (P = 0.49) (*see* Supplemental Table 7 under "Supplemental data" in the online issue). The type and pattern of adverse events reported do not suggest any causal effect of the diets.

DISCUSSION

The major findings of the study were the greater health improvements and weight loss produced by the NND. The weight loss was observed despite the fact that the diet was developed as highly palatable and offered ad libitum, and the study was not specifically designed as a weight-loss study. The study was presented to participants as a study of the broad health effects and culinary properties of the NND. Despite the focus on broader health effects, both groups achieved a weight loss, probably as a result of the dietetic counseling on appetite regulation. Body weight decreased (−3.22 kg compared with that of the ADD), and body composition, blood pressure, and fasting glucose improved more after 26 wk of intervention in the NND group than ADD group. A number of measures of compliance, such as the fatty acid composition in whole blood, urinary excretion of nitrogen, dietary registration in the shop, food records, and self-evaluated compliance and satisfaction, indicated good adherence to both diets. The diets were not reported as a major reason for dropout, and the NND group reported high satisfaction with the diet. The greater weight loss in the NND group could be caused by several factors. The NND group consumed significantly less energy (−1766 kJ/d) than the ADD did, despite the ad libitum design and the fact that the NND group's self-evaluated satisfaction with the NND was higher than the ADD group's self-evaluated satisfaction with the ADD. This result may have been because the NND causes higher early satiation or an enhanced sensation of satiety, possibly because of the lower energy

TABLE 4
Changes in body weight, body composition, anthropometric measures, and physical fitness from weeks 0 to 26 for completers in a dietary intervention with the NND or ADD[1]

	n	NND	n	ADD	Adjusted difference[2,3]	P[2]
Weeks of intervention	91	26.7 ± 0.2[4]	56	26.4 ± 0.2	0.29 (−0.21, 0.79)	0.25
Body weight (kg)	91	−4.74 ± 0.48	54	−1.52 ± 0.45	−3.22 (−4.62, −1.81)	<0.001
Fat mass (kg)	91	−4.54 ± 0.40	54	−1.88 ± 0.37	−2.70 (−3.87, −1.52)	<0.001
Fat-free mass (kg)	91	−0.02 ± 0.15	54	0.52 ± 0.18	−0.52 (−0.98, −0.05)	0.030
Fat percentage (%)	91	−3.24 ± 0.30	54	−1.45 ± 0.25	−1.87 (−2.73, −1.02)	<0.001
Waist circumference (cm)	90	−4.18 ± 0.52	53	−1.32 ± 0.58	−2.94 (−4.54, −1.34)	<0.001
Hip circumference (cm)	87	−2.95 ± 0.49	53	0.05 ± 0.64	−2.77 (−4.19, −1.35)	<0.001
Sagittal diameter (cm)	91	−1.88 ± 0.17	54	−1.00 ± 0.21	−0.83 (−1.36, −0.29)	0.003
Physical fitness (mL · min^{-1} · kg^{-1})	84	2.21 ± 0.67	48	1.98 ± 0.70	0.28 (−1.75, 2.32)	0.61[5]

[1] ADD, average Danish diet; NND, New Nordic Diet.
[2] Multiple linear regression analysis adjusted for sex, family status (couple or single), and baseline value.
[3] All values are means; 95% CIs in parentheses.
[4] Mean ± SEM (all such values).
[5] For logarithmically transformed data.

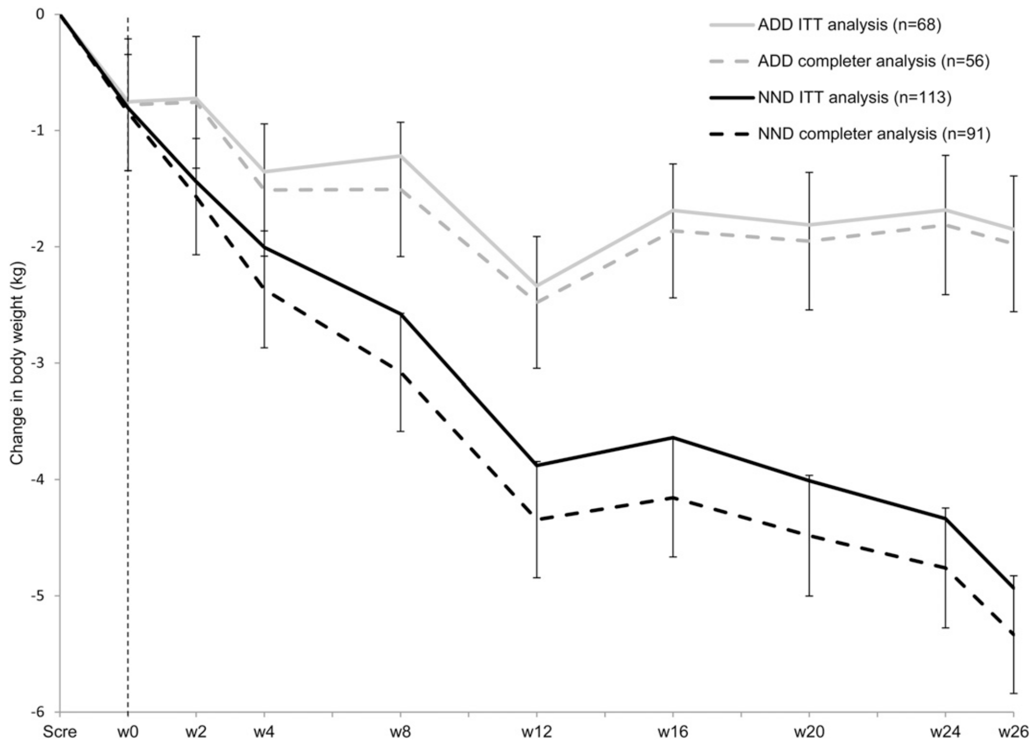

FIGURE 4. Changes (±SEMs) in body weight by completer analysis (n = 147) and intention-to-treat analysis (n = 181) of participants in a dietary intervention with the NND or ADD. The dashed line represents the time of random assignment. The completer analysis was conducted as a multiple linear regression adjusted for sex, family status (single or couple), and baseline body weight. The ITT was conducted as a mixed model adjusted for sex, family status (single or couple), and baseline body weight, with deterministic imputation on the basis of available cases for participants with only baseline data (n = 5). The model assumed that the weight change for dropouts followed the same course as for completers and weights were missing at random, with all available observations at the 9 time points included. ADD, average Danish diet; ITT, intention-to-treat; NND, New Nordic Diet; Scre, screening; w, week.

density of the NND (−88 kJ/100 g compared with that of the ADD), the higher dietary fiber content resulting from the higher content of whole grain, cabbages, and root vegetables (31). Note the observed discrepancy between the change in energy intake and lowering of body weight in the ADD group. We consider this result was likely caused by a slight underreporting of energy intake at baseline, but this underreporting may have been applicable to both groups because all participants were standardized to the same diet before baseline.

Compared with the ADD, the NND reduced systolic blood pressure by 5.1 mm Hg and diastolic blood pressure by 3.2 mm Hg. This effect was comparable with the effect of the Mediterranean diet and DASH. In elderly Spanish individuals at high risk of cardiovascular disease, the Mediterranean diet, with either olive oil or nuts, lowered systolic blood pressure by 5.9 and 7.1 mm Hg and diastolic blood pressure by 1.6 and 2.6 mm Hg compared with the low-fat control diet (32). In an 8-wk intervention study, the DASH diet lowered systolic blood pressure by 5.0 mm Hg and diastolic blood pressure by 3.0 mm Hg compared with a high-fat/low-fruit and -vegetable diet in a middle-aged population with slightly raised blood pressure (33). The reduced blood pressure shown in a previous study as well as in the current study could be of significant importance at the population level because even a small long-term reduction of blood pressure (1–4 mm Hg) has been predicted to reduce cardiovascular mortality by 5–20% (34).The NND reduced fasting glucose by 0.1 mmol/L more than the ADD did, and a tendency to a reduced fasting insulin concentration and HOMA-IR was seen. The effect on insulin, HOMA-IR, and the Matsuda index was significantly different in comparison with ADD (reduced by 67.2 pmol/L, reduced by 2.6, and increased by 2.3, respectively) in a subgroup of participants with prediabetes at baseline. These effects remained after adjustment for changes in body weight. In comparison, a meta-analysis of clinical trials showed that adherence to the Mediterranean diet is associated with significantly lower fasting glucose concentrations (−0.22 mmol/L) and significantly lower HOMA-IR (−0.45) (9). The effect of the DASH on diabetic risk markers seems to be less clear (35).

Most of the blood pressure–lowering effect of the NND is probably explained by the larger weight loss induced by the NND diet. However, some additional lowering effects seemed to remain after adjustment for weight loss, and this was probably a result of the combination of foods and not of single nutrients or foods because we did not see any difference in, eg, the urinary excretion of sodium, even though a difference in self-reported sodium intake was seen. Increased intakes of fruit, vegetables, fiber, and nuts (5) and a decreased intake of sodium (34) has previously been shown to reduce blood pressure, which could explain the improvements in blood pressure seen in the NND group. As for the improvements in diabetes risk factors, these may be a result of a combination of a reduced energy intake, lower intake of saturated fatty acids and added sugars, and increased intakes of fruit, vegetables, whole grain, and fibers, which are dietary factors related to lower risk of diabetes (36).

A major limitation of some of the previous food-based studies was an inadequate treatment provided to control groups compared

TABLE 5

Changes in diabetes and cardiovascular disease risk factors from weeks 0 to 26 for completers in a dietary intervention with the NND or ADD[1]

	n	NND	*n*	ADD	Adjusted difference[2,3]	*P*[2]	*P*[4]
Systolic blood pressure (mm Hg)	91	−4.48 ± 0.92[5]	54	0.72 ± 1.28	−5.13 (−8.16, −2.10)	0.001	0.041
Diastolic blood pressure (mm Hg)	91	−3.08 ± 0.78	54	0.11 ± 0.96	−3.24 (−5.66, −0.82)	0.009	0.33
Fasting plasma glucose (mmol/L)	90	−0.16 ± 0.04	56	−0.05 ± 0.04	−0.11 (−0.22, −0.01)	0.040	0.40
Fasting serum insulin (pmol/L)	90	−13.0 ± 3.30	56	−2.63 ± 3.20	−8.89 (−17.5, −0.27)	0.09[6]	0.38[6]
HOMA-IR	90	−0.52 ± 0.13	56	−0.08 ± 0.11	−0.36 (−0.68, −0.04)	0.07[6]	0.44[6]
Matsuda index	90	0.49 ± 0.27	51	−0.14 ± 0.20	0.70 (−0.06, 1.46)	0.08[6]	0.51[6]
Triglyceride (mmol/L)	90	−0.04 ± 0.04	56	0.16 ± 0.05	−0.17 (−0.29, −0.05)	0.004[6]	0.046[6]
Total cholesterol (mmol/L)	90	−0.17 ± 0.07	56	0.08 ± 0.06	−0.24 (−0.42, −0.06)	0.010	0.52
HDL (mmol/L)	90	0.01 ± 0.02	56	0.03 ± 0.02	−0.03 (−0.08, 0.02)	0.14[6]	0.46[6]
LDL (mmol/L)	90	−0.16 ± 0.06	56	−0.02 ± 0.05	−0.14 (−0.30, 0.02)	0.10	0.94
VLDL (mmol/L)	90	−0.02 ± 0.02	56	0.06 ± 0.02	−0.07 (−0.13, −0.01)	0.008[6]	0.05[6]
LDL:HDL ratio	90	−0.18 ± 0.07	56	−0.14 ± 0.05	−0.04 (−0.20, 0.12)	0.58	0.53
CRP (mg/L)	90	−1.5 ± 0.55	56	1.38 ± 0.53	−2.22 (−3.64, −0.81)	0.007[6]	0.043[6]
CRP (if CRP concentration <10 mg/L) (mg/L)	70	−0.58 ± 0.17	46	0.25 ± 0.19	−0.75 (−1.22, −0.28)	0.09[6]	0.28[6]
Fructosamine (μmol/L)	86	0.90 ± 0.91	55	0.16 ± 1.45	0.74 (−2.29, 3.77)	0.63	0.84
Potassium (mmol/L)	89	−0.03 ± 0.03	56	−0.03 ± 0.03	0.01 (−0.08, 0.07)	0.88[6]	0.47[6]
Carbamide (mmol/L)	90	−0.15 ± 0.08	56	−0.22 ± 0.12	0.06 (−0.20, 0.31)	0.39[6]	0.33[6]
Fibrinogen (μmol/L)	90	−0.58 ± 0.15	56	−0.05 ± 0.20	−0.39 (−0.84, 0.06)	0.13[6]	0.14[6]

[1] HOMA-IR was calculated as follows: fasting plasma glucose (mmol/L) × fasting plasma insulin (μU/mL) ÷ 22.5 (26). The Matsuda index was calculated as follows: 10,000 ÷ √{[fasting glucose (mg/dL) × fasting insulin (μU/mL)] × [mean glucose (mg/dL) × mean insulin (μU/mL) concentrations during oral-glucose-tolerance test)]} (27). ADD, average Danish diet; CRP, C-reactive protein; NND, New Nordic Diet.

[2] Multiple linear regression analysis adjusted for sex, family status (couple or single), and baseline value.

[3] All values are means; 95% CIs in parentheses.

[4] Multiple linear regression analysis adjusted for sex, family status (couple or single), baseline value, and weight change from weeks 0 to 26.

[5] Mean ± SEM (all such values).

[6] For logarithmically transformed data.

with test groups. We believe that, although the effects shown in the current study may seem slightly smaller than those shown by previous studies, this result was probably due, at least in part, to the careful matching of the type and frequency of the interventional guidance and control provided for each of the 2 dietary groups. Furthermore, participants in our study were generally at lower risk of comorbidities than were subjects in the other studies. Therefore, we considered the effect of NND to be comparable to the effects of the Mediterranean and DASH diets.

The current study showed beneficial effects of the NND in a healthier segment of the population, which suggested a preventive as well as treatment potential for the NND. The implication of the nonblinded study design is unknown, but participants' own beliefs in the diets may have influenced their efforts during the intervention. The use of completer analyses may have enlarged treatment effects in both groups, but because there were no differences in the dropout rate between groups, this method was unlikely to have affected the difference between the groups.

TABLE 6

Changes in diabetes risk factors for a subgroup of participants with prediabetes in a dietary intervention with the NND or ADD at week 0[1]

	n	NND	*n*	ADD	Adjusted difference[2,3]	*P*[2]	*P*[4]
Fasting plasma glucose (mmol/L)	14	−0.44 ± 0.11[5]	5	−0.26 ± 0.21	−0.35 (−0.81, 0.10)	0.12	0.15
Fasting serum insulin (pmol/L)	14	−37.4 ± 6.39	5	26.4 ± 13.1	−67.2 (−97.7, −36.7)	<0.001	<0.001
HOMA-IR	14	−1.59 ± 0.24	5	0.88 ± 0.52	−2.58 (−3.68, −1.48)	0.002[6]	0.008[6]
Matsuda index	14	1.28 ± 0.40	4	−0.74 ± 0.26	2.34 (0.18, 4.51)	0.006[6]	0.023[6]

[1] Prediabetes was defined as impaired fasting plasma glucose (fasting glucose concentration from 6.1 to 6.9 mmol/L and 2-h glucose concentration ≤7.8 mmol/L) or impaired glucose tolerance (fasting glucose concentration ≤7 mmol/L and 2-h glucose concentration from 7.8 to 11.0 mmol/L) (37). HOMA-IR was calculated as follows: fasting plasma glucose (mmol/L) × fasting plasma insulin (μU/mL) ÷ 22.5 (26). The Matsuda index was calculated as follows: 10,000 ÷ √{[fasting glucose (mg/dL) × fasting insulin (μU/mL)] × [mean glucose (mg/dL) × mean insulin (μU/mL) concentrations during oral-glucose-tolerance test)]} (27). ADD, average Danish diet; NND, New Nordic Diet.

[2] Multiple linear regression analysis adjusted for sex, family status (couple or single), and baseline value.

[3] All values are means; 95% CIs in parentheses.

[4] Multiple linear regression analysis adjusted for sex, family status (couple or single), baseline value, and weight change.

[5] Mean ± SEM (all such values).

[6] For logarithmically transformed data.

The particular strengths of the study were the free-living situation with a highly controlled dietary intake as a result of the use of the shop model and cookbooks and menu plans as well as the close verification of food intakes by biological markers, shop database food entry, and 3-d weighed dietary records. Furthermore, we showed a very high degree of satisfaction with and compliance to the NND.

The NND was designed by chefs from the internationally known, Michelin-acclaimed, Copenhagen restaurant NOMA, which was coincidentally pronounced the world's best restaurant in 2010, 2011, and 2012, with the specific aim to achieve the highest level of palatability possible. On the basis of participant responses, we believe this aim was achieved. However, because of the novelty of many of the recipes, use of some foods not readily available in everyday food shops, and participants voluntarily spent more time to prepare the meals, the large scale and longer-term use of the NND may be challenged. Sociological analyses will cover, eg, participant acceptance of the NND and provide insight into the real-life potential of the NND (data to be published separately). The cost of the diet is an additional issue for the long-term acceptance and use of the NND because some of the foods may be costly. Economic analyses of the NND will be published separately. The fact that the NND is based on specific foods, in contrast to macronutrients, and participants prepared and ate meals in accordance to the cookbook provided, the study findings could be easily translated into practice in the Danish society and other nearby regions and, thereby, serve as a tool to prevent lifestyle-related diseases. The concept of a healthy, regional, sustainable, seasonal, and highly palatable diet can, in principle, be applied everywhere in the world, not only in Nordic countries, such as the Mediterranean diet has spread to the rest of the world.

In conclusion, the health potential of the NND is considerable, and the NND seemed to be accepted by the participants, which supports its potential as an alternative to other regional diets, such as the Mediterranean diet. Overall, we believe that, taken together, the many strengths of the study design make the results transferrable for practical use in a Danish population. However, future and longer-term studies without the provision of foods and in a more diverse group of participants may be needed to document the usefulness, acceptance, and effect of the NND when applied in the general population.

We thank Claus Meyer, Meyers Madhus, Copenhagen, Denmark, and colleagues for providing NND recipes and the cookbook for participants and for guiding dieticians and other study personnel in the field of gastronomy. We also thank the whole study group including kitchen staff, dieticians, laboratory technicians, and students involved in the project, especially scientific assistant Rikke Larsen, who kept track of all participants. We thank Tina Cuthbertson for editing the final manuscript and all participants are for their participation in the study. We gratefully acknowledge all sponsors who provided foods to the shop. A full list of food sponsors is available at the study website (www.foodoflife.dk/shopus). We especially thank Rasmus Kromann-Larsen and Aspecto by Jesper Kromann-Larsen for the development of the data system used to register the composition of foods collected from the study shop. The study is part of the OPUS project "Optimal well-being, development and health for Danish children through a healthy New Nordic Diet."

The authors' responsibilities were as follows—SKP, TML, AD, AA, and BK: designed the research; SKP, TML, AD, and ABJ: conducted the research; KDS and SS: provided essential analyses; SKP, TML, CH, AA, and BK: analyzed and interpreted data; SKP and TML: wrote the manuscript and had primary responsibility for the final content of the manuscript; and all authors: contributed to the revision and final approval of the manuscript. Food sponsors did not have any influence on the study design, data collection, data analysis, data interpretation, or content and submission of the manuscript. None of the authors had a conflict of interest.

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