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Dietary Patterns and Weight Loss in New-onset Type 2 Diabetes Mellitus: A Sub-analysis of the St Carlos Study: A 3-year, Randomized, Clinic-based, Interventional Study

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Authors' contributions

This work was carried out in collaboration between all authors. Authors ALCP, MAR, NGT and IB designed the study. Author MF performed the statistical analysis. Authors NGT and AD wrote the protocol, and wrote the first draft of the manuscript. Authors IR, FS, RA, MG and LV researched data, and contributed to the study concept and design, acquisition of data and analysis and interpretation of data. All the authors contributed to the interpretation of data, discussion of results and critical review, and gave final approval of the last version to be published.

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ABSTRACT

Objective: To assess lifestyle patterns associated with weight loss in newly-diagnosed type 2 diabetic patients (T2DM) in the St Carlos Study.
Design: A 3-year, randomized, interventional study with three parallel groups.
Setting: A single-center, outpatient clinic-based study.
Participants: 195 newly-diagnosed T2DM were randomized to either the intervention group (self monitoring of blood glucose with-or-without an exercise program), or to the HbA1c control group. The same lifestyle-intervention protocol was applied in all patients.

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A questionnaire was applied to evaluate adherence to recommended lifestyle changes.
Main outcome measures: Patients were grouped by quartiles of body-weight loss at the end of follow-up.

Analysis: Multivariate linear-regression analyses were conducted to identify the independent effect of lifestyle patterns on three-year weight loss.

Results: Following a 3-year follow-up, median body weight loss was 2kg (IQR: -6/2.3). A higher level and an increase on physical activity, both leisure-time activity and sport exercise, and an increase in the nutrition score, mainly due to a higher consumption of nuts in substitution of cured sausages as snacks, and to a higher consumption of vegetables, legumes, whole grain cereals and fruits instead of juices, potatoes and white cereals, were associated to a greater weight loss ($p<0.05$). There was no association between low-fat diet and reduced body weight.

Conclusions and Implications: The application of simple recommendations (enhanced vegetable consumption, nuts for snacks, fruit instead of juices, wholegrain instead of processed cereals, legumes instead of potatoes, increased daily walking and stair-climbing) can achieve long-term, sustained weight loss in T2DM.

Keywords: Type 2 diabetes mellitus; lifestyle; dietary patterns; weight loss.

1. INTRODUCTION

Several lifestyle models have been shown to be effective in preventing the development of Type 2 Diabetes Mellitus (T2DM) [1-7]. Based on lifestyle patterns, different trials have demonstrated that it is possible to reduce the rate of progression to T2DM in high-risk individuals. Lifestyle interventions usually aim to achieve weight loss by reducing all fat intake and undertaking a program of moderate physical activity [8,9]. However, a Mediterranean diet that includes foods high in unsaturated fats has recently been shown to decrease the incidence of diabetes by over 50% in individuals at high cardiovascular risk [10].

Motivation to adhere to a healthy lifestyle is probably highest at the moment the initial diagnosis of T2DM is made in overweight or obese patients. Recommendations usually consist of the reduction of dietary energy and fat intake, together with the regular practice of exercise, with a goal of a 5-7% long-term lowering of body weight [11]. Although structured lifestyle programs have been effective in well-funded clinical trials [12], in routine practice, lifestyle changes are often inadequate: patients do not lose weight or they regain weight they have lost. Thus, the translation of results from clinical trials into routine clinical practice is often difficult [13]. Accordingly, various scientific societies have developed recommendations for the nutritional management of diabetes, in most cases with a goal of reducing body weight [11,14-15]. In this context, the use of antihyperglycemic drugs with a beneficial effect on weight is recommended, and bariatric surgery may be considered for some individuals with T2DM and a BMI ≥35kg/m2 [11]. Yet the role of eating patterns and specific foods in the management of diabetes and reduction of body weight have yet to be established [16]. Thus, scientific Diabetes societies are unable to recommend one specific mix of macronutrients for obese/overweight patients with diabetes.

A Mediterranean diet that includes extra-virgin olive oil or nuts is emerging as a dietary model with beneficial effects. Glycemic control improves [10], and the need for antihyperglycemic drug therapy in overweight patients with newly diagnosed T2DM is delayed [17]. Furthermore, cardiovascular events are reduced [18]. A Mediterranean diet is currently recommended by the American Diabetes Association (ADA) for weight loss, in all overweight or obese individuals who have or are at risk for diabetes [19].

The St Carlos study is an interventional trial in newly-diagnosed T2DM, aiming to achieve a high level of adherence to nutritional and physical activity recommendations, through the use of self-monitoring of blood glucose (SMBG) and a supervised exercise program, both easily applied in routine clinical practice. This study [20], offers an opportunity to assess the dietary patterns associated with weight loss.

The objective of the present study is to analyse the dietary and exercise models associated with a reduction in body weight in patients with newly-diagnosed T2DM.

2. MATERIALS AND METHODS

2.1 Design and Ethical Approval

The study was a randomised outpatient clinic-based interventional study with parallel groups. The study was approved by the St Carlos Hospital Ethics Committee, and all participants provided written informed consent. We recruited patients between January 2006 and December 2007, inviting all type 2 diabetic patients who attended the Endocrinology outpatient clinic and met the inclusion criteria to participate. The study design has been published previously [20]. Newly-diagnosed type 2 diabetic patients who were eligible for inclusion in the study were randomly assigned in a 2:1 ratio to one of two groups: (i) an intervention group that used the SMBG as an educational tool to evaluate lifestyle changes, as well as a therapeutic tool to apply step-by-step pharmacological treatment; or (ii) a control group receiving standard therapy based on HbA1c values.

2.2 Subjects

Initially, 250 eligible newly diagnosed type 2 diabetic patients were recruited for the study. Thirty-four patients were excluded and 21 patients declined to participate. The remaining 195 patients were randomized to the SMBG Intervention group (group I) (n=130) and to the HbA1c Control group (group C) (n=65). In addition, a supervised exercise program was offered to half the patients in the SMBG group (Ia: only SMBG and Ib: SMBG+supervised exercise). One hundred and eighty five patients completed a 3-year follow-up.

2.3 Intervention

SMBG six-point glycemic profiles were initially recommended to all patients every 3 days, as well as following any change in pharmacological therapy. After stabilization, defined as five complete SMBG profiles on target in two consecutive visits, patients were recommended to perform at least one profile every 2 weeks if they were on metformin or metformin plus pioglitazone or at least one profile per week if they were receiving any treatment other than metformin and/or pioglitazone. In the control group, SMBG was prescribed in all patients when the diabetes team considered it appropriate.

The training program in the SMBG-with-supervised-exercise group (Ib) consisted of 50 minutes of progressive mixed (aerobic and resistance) training in two supervised weekly sessions in the hospital, plus another two weekly sessions at home, for 20 weeks. Aerobic training was performed using cycle ergometer and treadmill. The aim was to reach 75% of the maximum heart rate (220-age). Resistance training consisted of 3 sets of exercises involving 8 to 10 repetitions for all main muscle groups. Each session included a warm-up and cool-down period, 20 minutes of aerobic exercise, and 20 minutes of resistance training. The first session was conducted by a physiotherapist who designed the exercise program for each patient individually. After the program, patients were asked to continue indefinitely with regular unsupervised training at home. The patients were asked to complete a logbook to estimate physical activity for the sessions at home, both during and after the 20-week supervised program. The parameters defined in the log-book were date, type and duration of exercise, and heart rate before and after the exercise. These data were evaluated in the following supervised session and/or used to modify the training plan in each patient.

2.4 Lifestyle Data Collection

All patients were received to a previously- published [20] lifestyle-intervention protocol, consisting of a personal 2-hour session, reinforced at each follow-up visit. A questionnaire was developed to evaluate adherence to recommended lifestyle changes as described previously [21]. This questionnaire is based on the American Diabetes Association (ADA) evidence-based nutrition recommendations [11] adapted to the Spanish population, following the Diabetes Nutrition and Complications Trial (DNCT), as previously reported [22-24]. The questionnaire included 3 questions regarding the level of physical activity. Two questions were related to daily leisure activity (walking and climbing stairs), and one to the frequency of sports exercise (at least 30 minutes of moderate-intensity exercise). The questionnaire also included 15 questions on the weekly frequency of consumption of vegetables, pieces of fruit, nuts, olive oil, oily fish, ibérico ham, cereal fiber, legumes, low-fat milk and dairy products, red meat, sauces, cookies and bakery products, juices and sugar-sweetened beverages, coffee, alcohol units and water as the sole beverage. This questionnaire was administered at the first visit and repeated at each follow-up visit.

To assess how differences in lifestyle factors were associated with diabetes onset, each lifestyle risk factor was scored as follows: when consumption frequency of certain foods or the amount of physical activity were considered to be beneficial to lower diabetes risk, a value of +1 was assigned, and if the consumption or physical activity frequency was considered to be detrimental, with an increase in diabetes risk, a value of -1 was assigned. Intermediate frequencies had a value of 0 [7]. We denominated the total sum from questions on the weekly frequency of consumption of foods the “nutrition score.” An increase in a score was defined as the difference between the three years and baseline scores.

2.5 Dietary and Physical Activity Patterns

To address the combined impact of several lifestyle factors, several composite variables were obtained:

- A low total-fat pattern (LTF) including: lean fish and seafood instead of oily fish, <20 cc of olive oil daily, <1 serving of nuts per week, >6 servings of skimmed milk and reduced fat dairy products per week, <2 servings of red meat per week, <2 servings of sauces including mayonnaise per week, and <2 servings of bakery products and pastries per week. This pattern represents the classic recommendations for weight loss.

- A low saturated fat pattern (LSF) including: >6 servings of skimmed-milk dairy products per week, <2 servings of red meat per week, <2 servings of sauces, excluding mayonnaise, per week, and <2 servings of bakery products and pastries per week.
- Nuts pattern: A non-calorie-restricted Mediterranean diet enriched with high-fat foods of vegetable origin, including a high nut intake instead of a processed-meat snack >3 times per week.
- Low density pattern: >12 servings of whole-grain cereals and legumes instead of white cereals and potatoes per week, >12 servings of vegetables per week and >12 servings of fresh fruit instead of juices per week.
- Daily life physical activity pattern: Walking at least 1 hour >5 days per week and climbing at least 4 floors of stairs, 4 times a day >5 days per week, as a representation of a leisure-time physically active lifestyle versus a sedentary lifestyle.

2.6 Laboratory Analysis and Data Collection

In addition, we measured changes in weight and waist circumference, glycemic control (including HbA1c, serum insulin, a homeostasis model assessment of insulin sensitivity, and antihyperglycemic drugs), and coronary risk factors (including lipid levels, blood pressure and hypolipemic and antihypertensive treatments). A venous blood sample was collected with a Vacutainer system (Becton Dickinson, Franklin Lakes, New Jersey) after overnight fasting (>10 h.). After 30 minutes, samples were centrifuged for 10 minutes in a refrigerated centrifuge, and serum was frozen at –80ºC until analysis. Total cholesterol (mg/dl), and low density lipoprotein (LDL, mg/dL), and triglycerides (mg/dL) (enzymatic autoanalyzer), and high-density lipoprotein (HDL, mg/dL) (enzymatic method modified with PEG—cholesterol oxidase, cholesterol esterase and peroxidase) were assessed. Hemoglobin A1c was measured in whole blood collected in an EDTA-3K tube. Hemoglobin A1c (standard¬ized International Federation of Clinical Chemistry) was determined by high-performance liquid chromatography of ionic exchange in gradient with a Tosoh G8 analyzer (Tosoh Co, Tokyo, Japan). The interassay coefficients of variation were 0.7% and 1.2% for hemoglobin A1c values of 38.8mmol/mol (5.7%) and 87.98mmol/mol (10.2%), respectively. Insulin was determined by a sandwich-type chemiluminescence immunoassay in solid phase in an Immulite 2000 Xpi (Siemens Healthcare Diagnostics, Munich, Germany). The method uses an insu¬lin murine monoclonal antibody fixed in the solid phase and an insulin polyclonal antibody from sheep conjugated with alkaline phosphatase. Homeostasis model assessment of insulin resistance (HOMA-IR) was assessed according to equation HOMAIR=(Fasting serum insulin (mcUI/mL) x Fasting serum (glucose mmol/L))/22.5.

2.7 Statistical Analysis

Qualitative variables were summarized by their frequency distribution. The continuous variables were summarized by the median and interquartile range (IQR:P25-P75). Comparisons between group differences for quantitative variables were evaluated through the Student's t test. Multivariate linear regression analyses were conducted to identify the independent effect of the patterns in the three years weight loss. We performed seven linear regression models, one for each of the increasing patterns, adjusted by baseline pattern score, BMI and HbA1c baseline values. Finally, a multivariate linear regression model was adjusted introducing the patterns that were significant in the previous model. Significance was set at p≤0.05. The data were processed with the STATA V.9.0 (STATA Corp. LP, Texas, USA) statistical package.

3. RESULTS

Initial characteristics of the study participants: 96 were female and 86 male, with a median age of 60 years (IQR:50-67), with a body mass index of 30 (27-33), and a HbA1c level of 6.6% (6.4-6.9) at baseline. After 3 years of follow-up there was a median reduction in body weight of -2kg (IQR: -6;2.3).

Patients were grouped by quartiles of body weight loss at the end of follow-up into four groups: Q1: total responders with a median weight loss of 9.5kg (-12.43;-7.73) and Q2: partial responders with a median weight loss of 4.2kg (-5.33;-3.18), Q3: no change in body weight (-1.10;1kg), and Q4: median increase in body weight of 5.0kg (3.60;7.50). Patients in groups Q1 and Q2 were classified as responders, patients in Q3 and Q 4 as non-responders. Total responders lost weight progressively through the three years of follow-up. Partial responders lost most of the weight in the first year of follow-up and then were stable in the third year. Patients in the Q3 group had mild weight loss the first year but re-gained weight afterwards. Patients with weight gain increased progressively through the three years of follow-up (Table 1).

There was a statistically significant reduction in waist circumference, total cholesterol, diastolic blood pressure, and HbA1c levels in the responder patients, as well as a lower degree of use of lipid-lowering and antihypertensive drugs. The reduction in body weight was not associated with differences in age, gender, initial BMI or the use of antihyperglycemic drug therapy (Table 2).

A higher level of physical activity was associated with greater weight loss, as were the nuts and the low density patterns, following multivariate regression analysis adjusted for basal pattern, basal BMI and basal HbA1c, taking the reduction in body weight as a continuous variable as was an increment in leisure-time activity alone (Table 3).

Both total and leisure physical activity were significantly associated with weight loss, with a reduction in body weight of 7.0 (CI 95%: -9.8;-4.18) and of 6.67kg (CI 95%: -9.65;-3.69) respectively.

A higher score for consumption of vegetables, nuts, whole grain cereals, and legumes was associated with greater weight loss, as was an increased nutrition score. An increase in the latter score >5 versus <2 was associated with a weight loss of 5.15kg (CI95%: -7.7;-2.59; p<0.001). This effect was mainly due to a higher consumption of nuts in substitution of cured sausages as snacks: 3-4 servings of nuts per week were associated with-5.52kg (CI 95%: -9.16;-2.18), and with a higher consumption of legumes and whole grain cereals instead of white cereals or potatoes, and whole fruits instead of white cereals or potatoes, and whole fruits instead of juices: 4-6 servings of legumes, whole grain cereals and whole fruits per week were associated with-5.49kg (CI 95%: -8.8;-2.18). The low fat pattern was not associated with a reduction in body weight.

Table 1. Quartiles of body weight loss during follow-up

N	All DPts	Q1 (<-6.2)	Q2 (-6.0;-2.2)	Q3 (-2.0;2.2)	Q4 (>2.3)	P trend
	185	**46**	**46**	**47**	**46**	
1st-year WL(Kg)	-2.00(-4.73;1.00)	-6.4 0(-8.77;-3.68)	-3.00(-5.00;-1.40)	-0.40(-2.00;1.00)	1.40(-0.40;3.50)	0.001
2nd-year WL(Kg)	-2.00(-5.60;1.00)	-7.00(-10.48;-5.60)	-4.25(-5.25;-2.00	-0.10(-2.0;1.00)	3.00(0.40;5.00)	0.001
3th-year WL(Kg)	-2.00(-6.00;2.30)	-9.50(-12.43;-7.73)	-4.20(-5.33;-3.18)	0.20(-1.10;1.00)	5.00(3.60;7.50)	0.001

Data are median (IQR) or number. WL: weight loss

Table 2. Changes in laboratory and clinical data after 3 years

3 year-baseline	All	Q1 (<-6.2)	Q2 (-6.0;-2.2)	Q3 (-2.0-;2.2)	Q4 (>2.3)	P trend
Weight loss (Kg)	-2.00(-6.00;2.30)	-9.50(-12.43;-7.73)	-4.20(-5.33;-3.18)	0.20(-1.10;1.00)	5.00(3.60;7.50)	0.001
WC (cm)	-4(-9;4)/	-13(-15;-8)/	-6(-9;-4)/	2(-1;4)/	9(5;12)/	0.001
Men/Women	-3(-8;4)	-12(-16;-7)	-7(-10;-4)	0(-3;2)	6(4;11)	0.001
Total Chol. (mg/dl)	-12(-34;3)	-29(-46;2)	-8(-34;4)	-8(-19;14)	-16(-38;3)	0.03
LDL Chol. (mg/dL)	-11(-32;4)	-24(-42;-4)	-11(-32;1)	-8(-22;11)	-9.6(-36;7)	0.09
HDL Cholesterol (mg/dL)	1(-4;5)	2(-4;9)	1(-4;6)	1(-5;5)	0(-6;4)	0.43
Triglycerides (mg/dL)	2(-26;27)	-1(-56;16)	-1(-30;27)	4(-9;26)	16(-27;42)	0.11
Hipolipemic treatment N (%)	125(68)	19(41)	20(43)	44(94)	42(91)	0.04
HbA1c (%)	-0.4(-0.9;0)	-0.8(-.3;0.2)	-0.7(-1.0;0.4)	0.2(-0.1;0.7)	0(-0.5;0.5)	0.001
HOMA-IR	-1(-2.4;0.1)	-2(-4.3;0.3)	-1.1(-1.7;0.2)	0.8(0.2;2.9)	1(-0.3;2.1)	0.04
Antidiabetic therapy						0.11
Metformin alone	102(55.1)	27(58.7)	32(69.6)	21(44.7)	22(47.8)	
- add Pioglitazone	4(2.1)	2(4.4)	0	2(4.4)	0	
- add DPP4-I	19(10.3)	5(10.9)	3(6.5)	7(14.9)	4(8.7)	
- add Sulfonylurea	23(12.4)	4(8.7)	0	8(17.0)	11(23.9)	
- add insulin	9(4.9)	1(2.2)	2(4.3)	3(6.4)	3(6.4)	
- triple combination	28(15.1)	7(15.2)	9(22.5)	6(12.8)	6(12.8)	
SBP (mm Hg)	-11(-22;1)	-10(-21;0)	-17(-29;9)	-15(-22;6)	6(-1;17)	0.06
DBP (mm Hg)	-6(-12;0)	-6(-14;1)	-10(-17;5)	-6(-10;1)	2(-2;8)	0.02
Antihypertensive treatment N (%)	69(37)	9(20)	12(26)	23(49)	25(54)	0.04
CRP (mg/dL)	-0.1(-0.27;0.06)	-0.16(-0.29;0.02)	-0.13(-0.36; 0.02)	0.1(-0.19;0.27)	0.02(-0.05;0.22)	0.41

Data are median (IQR) or number (%), WC, waist circumference; sBP, systolic blood pressure; dBP; diastolic blood pressure

Table 3. Multivariate linear regression analyses of food consumption patterns and physical activity adjusted by baseline pattern, BMI and HbA1c values, and 3-year weight loss as continuous variable

Model	Pattern	β coefficient	CI 95%	P
Increase in nutrition	2-5vs.≤2	-1.43	-3.96;1.10	0.26
Pattern score	>5vs.≤2	-5.15	-7.7;-2.59	0.001
Increase in	1-3vs≤0	1.66	-0.96;4.18	0.19
Low fat pattern score	4-6vs≤0	4.03	-0.22;8.29	0.06
Increase in	1-3vs≤0	-0.30	-3.30;2.69	0.84
Saturated fat pattern score	4-8vs≤0	-1.92	-6.20;2.33	0.37
Increase in	1-2vs≤0	-1.50	-4.12;1.12	0.26
Nuts pattern score	3-4vs≤0	-5.52	-9.16;-1.89	0.003
Increase in	1-3vs≤0	-4.17	-6.84;-1.50	0.002
Low density pattern score	4-6vs≤0	-5.49	-8.80;-2.18	0.001
Increase in	1-2vs≤0	-4.80	-7.14;-2.47	0.001
Leisure pattern score	3-4vs≤0	-6.67	-9.65;-3.69	0.001
Increase in physical	1-3vs≤0	-3.14	-5.56;-0.71	0.01
Activity pattern score	4-6vs≤0	-7.0	-9.80;-4.18	0.001

4. DISCUSSION

This study shows that lifestyle interventions can produce long term weight loss in type 2 diabetic patients (median 2kg), slightly lower than what has been observed in other lifestyle intervention trials [9,12]. In our study a higher consumption of nuts in substitution of cured sausages as snacks was associated with a higher degree for weight loss (Table 3). This effect may be due not only to the beneficial effects of unsaturated fatty acids, but to the reduction in consumption of cured sausages. In fact, consumption of processed meats has been associated with higher incidence of coronary heart disease and diabetes mellitus [25, 26]. Since we did not find an association between the reduction in the total fat consumption and weight loss (Table 3), we believe that recommendations that limit the intake of unsaturated fatty acids from olive oil or oily fish to reduce fat consumption are not beneficial. One group of patients lost weight progressively over the three years of follow-up (Table 1). Given the fact that maintenance of weight loss has been a major problem in behavioural treatments of obesity, with most trials indicating that weight initially lost is regained after the first year of follow-up [9,12-13], we set out to identify dietary factors associated with sustained weight loss. This study, identifying eating patterns associated with body weight loss, indicates that a Mediterranean pattern diet is able to achieve sustained weight reduction as opposed to a diet based on restriction of all fat intake. Nevertheless, eating patterns are not easy to control and subjective reports of consumption might be sometimes inaccurate.

Our study failed to identify an association between progressive weight loss and other factors such as age, gender, initial BMI or the type of antidiabetic medication. However, at the time of the study, GLP-1 analogues were not available. It is likely that the use of these drugs would have had an added effect, although experience with their long-term use is limited.

Previous studies did not find any statistically significant relationships between resistance training or aerobic exercise and changes in BMI in T2DM [27]. Nevertheless, a combination of aerobic and resistance training improves HbA1c levels in patients with T2DM [28]. Furthermore, leisure physical activity has been associated with a higher degree of weight loss [9], and walking is decreased in obesity and declines with weight gain [29]. Minimal intensity physical activity of longer duration improves insulin action and plasma lipids more than shorter periods of moderate to vigorous exercise [30]. We found that an increase in physical activity, both leisure-time activity and sports exercise, was associated with greater weight loss. But an increase in leisure physical activity (walking and climbing stairs) was independently associated with a reduction in body weight of 6.67kg (Table 3). Leisure physical activity is easier to maintain long-term in daily life, and therefore, more likely to induce beneficial effects.

In the responders group, weight loss was accompanied by improvements in cardiovascular risk factors (Table 2). Whereas drug therapy usually addresses only one risk factor, lifestyle intervention produced positive changes in glycemic control, blood pressure, and lipids simultaneously. Thus, across the time period of the study, responder patients had a lower exposure to a number of potentially negative effects of elevated cardiovascular risk factors. Furthermore, fewer patients in this group used lipid- lowering and antihypertensive drugs to achieve this control. In addition to health benefits, the intervention may have resulted in cost savings due to a reduced need for medication.

Over 50% of our type 2 diabetes study patients lost weight, a higher rate than would be expected, when comparing with results obtained in the general population [13]. Adherence to lifestyle intervention is a key factor. We have previously shown that using SMBG [20] as an educational tool improves adherence to lifestyle recommendations, since the information provided by blood glucose testing can be a powerful motivating factor, encouraging self-management of diabetes by allowing patients to measure directly the impact of their behaviour, such as the effect of eating on postprandial glucose or the glucose-lowering effect of exercise.

5. CONCLUSION AND IMPLICATIONS FOR RESEARCH AND PRACTICE

Long-term weight loss in T2DM can be achieved with dietary and exercise interventions. Improving patients' adherence to lifestyle interventions is a cornerstone in T2DM therapy. Based on our results, the best strategy would be to give simple, easily-followed recommendations that increase the consumption of vegetables, substitute nuts for snacks, fruit instead of juices, wholegrain instead of processed cereals, legumes instead of potatoes, together with climbing stairs and taking walks daily.

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COMPETING INTERESTS

There are no competing financial interests in relation to the work described. None declare duality of interest associated with the manuscript. Guarantor: Dr A.L. Calle-Pascual.

REFERENCES

1. Baliunas DO, Taylor BJ, Irving H, et al. Alcohol as a risk factor for type 2 diabetes: A systematic review and meta-analysis. Diabetes Care. 2009;32:2123-2132.
2. Nettleton JA, Steffen LM, Ni H, et al. Dietary patterns and risk of incident type 2 diabetes in the Multi-Ethnic Study of Atherosclerosis(MESA). Diabetes Care. 2008;31:1777-1782.

3. Wannamethee SG, Whincup PH, Thomas MC, et al. Associations between dietaryfiber and inflammation, hepatic function, and risk of type 2 diabetes in older men: Potential mechanisms for the benefits of fiber on diabetes risk. Diabetes Care. 2009;32:1823-1825.
4. Hu FB, Manson JE, Stampfer MJ, et al. Diet, lifestyle, and the risk of type 2 diabetesmellitus in women. New England Journal of Medicine. 2001;345:790-797.
5. Odegaard AO, Koh WP, Butler LM, et al. Dietary patterns and incident type 2 diabetes in chinese men and women: The singapore chinese health study. Diabetes Care. 2011;34:880-885.
6. Mozaffarian D, Kamineni A, Carnethon M, et al. Lifestyle risk factors and new-onsetdiabetes mellitus in older adults: The cardiovascular health study. Archives of Internal Medicine. 2009;169:798-807.
7. Martín Rojas-Marcos P, del Valle L, Fuentes Ferrer M, et al. The lifestyle patterns in a Mediterranean population and its association with diabetes mellitus. MOPOR Case Control Study. Obesity and Metabolism. 2010;6:69-75.
8. Tuomilehto J, Lindström J, Eriksson JG, et al. Finnish diabetes prevention study group. Prevention of type 2 diabetes mellitus by changes in lifestyle among subjectswith impaired glucose tolerance. New England Journal of Medicine. 2001;344:1343-1350.
9. Diabetes Prevention Program Research Group: Reduction in the incidence of type 2diabetes with lifestyle intervention or metformin. New England Journal of Medicine. 2002;346:393-403.
10. Salas-Salvadó J, Bulló M, Babio N, et al. Reduction in the incidence of type 2 diabetes with the Mediterranean diet: Results of the PREDIMED-Reus nutrition intervention randomized trial. Diabetes Care. 2011;34:14-19.
11. Bantle JP, Wylie-Rosett J, Albright AL, et al. Nutrition recommendations and interventions for diabetes: A position statement of the American Diabetes Association. Diabetes Care. 2006;29:2140-2157.
12. Wadden TA, Neiberg RH, Wing RR, et al. Four-year weight losses in the Look AHEAD study: factors associated with long-term success. Look AHEAD Research Group. Obesity. 2011;19:1987-1998.
13. Wadden TA, Volger S, Sarwer DB, et al. A two-year randomized trial of obesity treatment in primary care practice. New England Journal of Medicine. 2011;365:1969-1979.
14. Connor H, Annan F, Bunn E, et al. Nutrition. Subcommittee of the diabetes care advisory committee of diabetes UK. The implementations of nutritional advice for people with diabetes. Diabetic Medicine. 2003;20(10):786–807.
15. Canadian Diabetes Association Clinical Practice Guidelines Expert Committe Canadian Diabetes Association 2008 clinical practice guidelines for the prevention and management of diabetes in Canada. Nutrition therapy. Canadian Journal of Diabetes. 2008;(Suppl 1):40–45.
16. Wheeler ML, Dunbar SA, Jaacks LM, et al. Macronutrients, food groups, and eatingpatterns in the management of diabetes: A systematic review of the literature, 2010. Diabetes Care. 2012;35:434-445.
17. Esposito K, Maiorino MI, Ciotola M, et al. Effects of a Mediterranean-style diet on the need for antihyperglycemic drug therapy in patients with newly diagnosed type 2 diabetes: A randomized trial. Annals of Internal Medicine. 2009;151(5):306-314.
18. Estruch R, Ros E, Salas-Salvadó J, et al. The PREDIMED Study Investigators. Primary Prevention of Cardiovascular Disease with a Mediterranean Diet. New England Journal of Medicine. 2013;368:1279-1290.

19. American Diabetes Association: Standards of medical care in diabetes-2012. Diabetes Care. 2012;35(Suppl 1):11-63.
20. García de la Torre N, Durán A, Del Valle L, et al. Early management of type 2 diabetes based on a SMBG strategy: The way to diabetes regression-the St Carlos study: A 3-year, prospective, randomized, clinic-based, interventional study with parallel groups. Acta Diabetologica. 2013;50:607-614
21. Velasco V, Lecumberri E, Bordiu E, et al. Valoración del riesgo de padecer diabetes mellitus tipo 2 mediante un cuestionario de hábitos de vida. Av Diabetol. 2007;23:470-471.
22. The Diabetes and Nutrition Study Group of the Spanish Diabetes Association: Diabetes Nutrition and Complications Trial: trends in nutritional pattern between 1993 and 2000 and targets of diabetes treatment in a sample of Spanish people with diabetes. Diabetes Care. 2004;27:984–987.
23. The Diabetes and Nutrition Study Group of the Spanish Diabetes Association: Diabetes Nutrition and Complications Trial: Adherence to the ADA nutritional recommendations, targets of metabolic control, and onset of diabetes complications. A 7-year, prospective, population-based, observational multicenter study. Journal of Diabetes Complications. 2006;20(6):361–366.
24. The Diabetes and Nutrition Study Group of the Spanish Diabetes Association: Diabetes Nutrition and Complications Trial (DNCT): Diet and risk of microangiopathy progression: The role of polyunsaturated fatty acids and monounsaturated fatty acids consumption. Obesity and Metabolism. 2006;2:6–12.
25. Micha R, Wallace SK, Mozaffarian D. Red and processed meat consumption and risk of incident coronary heart disease, stroke, and diabetes mellitus: A systematic review and meta-analysis. Circulation. 2010;121:2271-2283.
26. Aune D, Ursin G, Veirod MB. Meat consumption and the risk of type 2 diabetes: Systematic review and meta-analysis of cohort studies. Diabetologia. 2009;52:2277-2287.
27. Chudyk A, Petrella RJ. Effects of exercise on cardiovascular risk factors in type 2 diabetes: A meta-analysis. Diabetes Care. 2011;34:1228-1237.
28. Church TS, Blair SN, Cocreham S, et al. Effects of aerobic and resistance trainingon hemoglobin A1c levels in patients with type 2 diabetes. JAMA. 2010;304(20):2253-2262.
29. Levine JA, McCrady SK, Lanningham-Foster LM, et al. The role of free-living daily walking in human weight gain and obesity. Diabetes. 2008;57:548-554.
30. Duvivier BM, Schaper NC, Bremers MA, et al. Minimal intensity physical activity (standing and walking) of longer duration improves insulin action and plasma lipids more than shorter periods of moderate to vigorous exercise (cycling) in sedentary subjects when energy expenditure is comparable. PLoS One. 2013;8(2):e55542. doi: 33610.1371/journal.pone.0055.

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