Effectiveness of the I²AO² interdisciplinary programme led by nurses on metabolic syndrome and cardiovascular risk: a randomized, controlled trial

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Abstract

Objective: To evaluate the effectiveness of an interdisciplinary programme led by nurses in relation to metabolic syndrome (MS) and cardiovascular risk (CVR).

Methods: This randomized, controlled, clinical trial included 74 patients diagnosed with MS (experimental group [EG], n = 37; control group [CG], n = 37). The intervention consisted of a 12-month interdisciplinary programme (pre-test, 6 months of intervention, 12 months of intervention, and 1-year follow-up post-intervention) coordinated by nursing.

Results: We found a progressive and significant reduction for all clinical, biochemical, and anthropometric parameters analysed at different time points. In the EG, remission of MS by 48.1% in the short term was observed (83.8% in the medium term) and maintained at 1 year post-intervention. In the CG, the prevalence of MS increased by 2.7% from the initial evaluation to study completion. A similar trend was observed for CVR. In the EG, 100% of subjects had a moderate-low risk of CVR at 1 year post-intervention, whereas the CG had CVR in all categories.

Conclusion: An interdisciplinary, nurse-led programme improves participants' metabolic and cardiovascular health, while maintaining long-term effects. Our findings suggest an important role of the professional nurse as a nexus between the patient, different professionals, and the community.

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Introduction

Metabolic syndrome (MS) is a multifactorial, clinical condition related to, among others factors, lifestyle and nutritional habits, such as sedentariness and superfeeding.[1] The prevalence of MS ranges from 10% to 30% in Europe, and from 34% to 42% in the United States, increasing dramatically in older groups.[2] In the most recent population analysis conducted in Murcia, Spain, a prevalence of 53.5% for MS was found, which is higher than that recorded in Europe or in the United States.[3] The prevalence of cardiovascular disease (CVD) in Murcia was 32.1%, and a substantially increased risk of CVD was found in those with MS.[3]

In management of MS, unidirectional therapies (i.e., those based on a unique intervention, such as diet, exercise, and education) have achieved unsatisfactory results, and the benefits of such therapies have not been maintained over time.[4] Therefore, an interdisciplinary approach where different therapies and professionals come together is required. This type of approach has shown a significant reduction in the overall prevalence of MS after 12 months, and more specifically, in the prevalence of its components (central obesity, hypertriglyceridemia, and diabetes mellitus).[5] Furthermore, there is evidence of the efficacy of these interventions related to cardiovascular problems[6,7] that can prevent a surgical approach.[8,9]

There are some limitations of interdisciplinary programmes, such as planning, coordination, patient follow-up, and contact. These limitations could decrease the effectiveness of interdisciplinary interventions. There have been few reports describing the involvement of nursing as a cornerstone of educational programmes on subjects with MS,[10] although the collaborative role of this discipline has been recognized in some programmes.[11]

The main aim of the present study was to determine the effectiveness of the Interdisciplinary Intervention Against Overweight and Obesity (I^2AO^2) programme on MS and cardiovascular risk (CVR). This programme is based on healthy eating, exercise, cognitive-behavioural therapy, and health education in the short (6 months) and medium (12 months) term. The long-term effect was assessed within 1 year after the intervention was finished. The secondary aim of this study was implementation of an interdisciplinary programme led by nurses.

Materials and method

Study design

A randomized, clinical trial was conducted to determine the efficacy of an interdisciplinary intervention on reduction of MS and CVR in adults. Patients were assigned at random to two groups. A 12-month intervention was applied to the experimental group (EG). In the control group (CG), the standard guidelines included in the Community Service Program of the Public Health Service of Murcia (PHSM) (internal

document) were maintained. Efficacy of the intervention was evaluated through clinical, anthropometric, and biochemical measures taken before, during, and after the intervention. The EG was expected to show decreased clinical and anthropometric values, and improved metabolic and cardiovascular measures during and after the intervention. In contrast, the CG was expected to remain unchanged. All of the patients provided written informed consent. The research was approved by the Ethics Committee of the Reina Sofía University Hospital. The research was developed under the ethical principles of the Declaration of Helsinki, ensuring the complete anonymity and confidentiality of data and information concerning the patients analysed, acting in accordance with Law 15/1999, December 13, regarding Personal Data Protection.

Participants

The I^2AO^2 programme was conducted in a Community Care Centre in the municipality of Murcia. In 2013, the population served by this health centre was 3262. A sample of 299 patients was selected through a systematic sampling procedure. We identified patients who were overweight, and then the prevalence of obesity was calculated. A total of 121 (40.5%) patients were classified as overweight and 128 (42.8%) as obese, according to the Spanish Society for the Study of the Obesity (SEEDO) criteria.[3] The criterion for participation in the I^2AO^2 programme was overweight (body mass index [BMI] between 25.0 and 29.9 kg/m^2) or obesity (BMI $\geq$ 30 kg/m^2), according to SEEDO criteria, as well as filling in an informed consent form. Of the 249 subjects who met the BMI criterion, 40 were excluded by comorbidities with other pathologies (depression, cancer, fibromyalgia, and others, which could interfere with the intervention). Finally, of 209 patients remaining,

74 signed informed consent (130 declined to participate) (Figure 1). Randomization to the EG or CG was performed by a table of numbers. A total of 37 patients were assigned to the CG and 37 to the EG, and these were randomly distributed by sex and age (Table 1).

Measures

All assessments were made at four time points as follows: 1) before starting the intervention; 2) at 6 months from the beginning of the intervention (short-term efficacy); 3) at 12 months (medium-term efficacy); and 4) 1 year after intervention had been concluded (long-term efficacy).

Sociodemographic data. Sociodemographic evaluation was carried out in which sex, age, and marital status were recorded.

Anthropometric and clinical data. Anthropometric assessment was determined by BMI and waist circumference (WC). BMI was calculated as the ratio of weight in kilograms to height in meters squared.[11] Weight and height were measured on a scale calibrated with a portable stadiometer (seca 213; seca GmbH & Co. KG, Hamburg, Germany). The guidelines used for weight and height were applied to WC measurement. The instrument used was a non-extensible or deformable steel tape measure with 1-mm divisions (Holtain model 606; Holtain Ltd., Crymych, Wales) (recommendations by SEEDO).[12]

Clinical evaluation included measurement of systolic blood pressure (SBP) and diastolic blood pressure (DBP). A stethoscope (Littmann 3200 model; 3M, Maplewood, MN, USA) and sphygmomanometer (DuraShock DS44; Welch Allyn, Skaneateles Falls, NY, USA) were used for measurement of blood pressure.

All measurements were carried out by the same nurse, who had previously received specific theoretical and practical training.
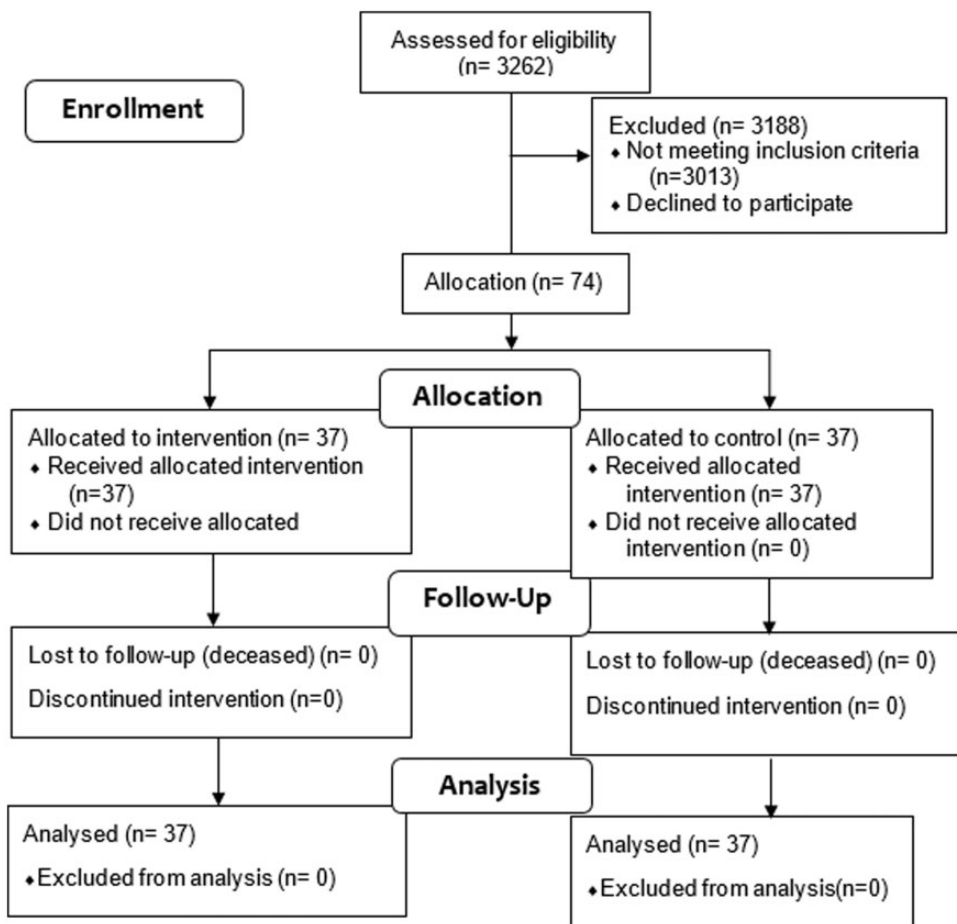
Figure 1. Flow diagram (according to Consort 2010 flow diagram model).

All measurements of anthropometric and clinical values were performed three times, and the mean value was used for analysis.

Biochemical data. Biochemical parameters that were recorded included blood glucose, glycosylated haemoglobin (HbA1c), total cholesterol (TC), triglycerides (TG), high-density lipoprotein cholesterol (HDL-C), low-density lipoprotein cholesterol (LDL-C), gamma glutamyltranspeptidase, alanine transaminase, aspartate transaminase, and total bilirubin. Blood samples were collected after a night fast of 10 to 12 hours and processed in the reference laboratory.

Metabolic and cardiovascular comorbidity data. Metabolic evaluation was performed by the diagnosis of MS according to the criteria established in the National Cholesterol Education Program - Adult Treatment, Panel III.[13] Additionally, cardiovascular evaluation was included by applying the methodology of the Framingham cohort study (CVR).[14] Once the odds of CVR were obtained, they were categorized into three

Table 1. Sociodemographic data, smoking and drinking habits, and clinical history

		CG (n = 37)		EG (n = 37)				
		M	SD	M	SD	t-test	p	d
Age	Years	62.8	8.9	59.4	9.1	1.646	0.104	0.19
		n	%	n	%	χ^2 (df)	p	
Sex	Male	18	48.6	19	51.4	0.000 (1)	1.000	
Smoking	Non-smoker	26	70.3	20	54.1	2.177 (2)	0.337	
	Former smoker	9	24.3	13	35.1			
	Smoker	2	5.4	4	10.8			
Alcohol	Yes	22	59.5	21	56.8	0.000 (1)	1.000	
Diabetes mellitus	Yes	23	62.2	16	43.2	1.952 (1)	0.162	
Hypertension	Yes	32	86.5	29	78.4	0.373 (1)	0.541	
Dyslipidaemia	Yes	21	56.8	19	51.4	0.054 (1)	0.816	

CG: control group; EG: experimental group; n: number; M: mean; SD: standard deviation; t-test: two independent samples Student's t-test; χ^2 (df): chi-squared statistic (degrees of freedom); d: Cohen's d statistic for effect size.

groups as follows: 1) <10%, low CVR; 2) 10%–19%, intermediate CVR; and 3) ≥20%, high CVR.[15]

Intervention

The EG underwent an interdisciplinary intervention (I^2AO^2) with a comprehensive approach for treatment of metabolic and cardiovascular comorbidity for 12 months with re-evaluation 1 year after completion. The project was developed and coordinated by a research team of nurses outside PHSM, and new features were included that had not been covered by the PHSM adult metabolic control programme. The interdisciplinary team was formed by physicians, qualified nurses, nutritionists, psychologists, and physical activity and sports sciences (PASC) professionals. The intervention and the interdisciplinary teams were coordinated by a qualified nurse whose management was based on the theory of activity and interprofessional education.[16,17] In particular, the role of nursing in the study was defined by the following activities: a) to create, develop and coordinate the project; b) to coordinate the intervention and action of interdisciplinary personnel; c) to implement health education, by maintaining a monthly session of 60 minutes for educational treatment of MS and CVR, modification of unhealthy dietary habits, and selection and preparation of healthy menus (12 sessions in total); d) to serve as a link between participants and interdisciplinary staff, clarifying doubts and resolving difficulties; and e) to evaluate the results of the I^2AO^2 programme. All of the above activities were under the philosophy of empowering the patient for change, respecting the patient's autonomy, and creating a health care professional–patient relationship of respect, empathy, and accompaniment for change. At all times, there was the goal of being aware of the patient's status and assessing the patient's strengths and weaknesses, in order to adapt instruction to meet the patient's needs under a joint strategy, and thus achieve real change. Continuous evaluation of the project through a meeting of the participating professionals was performed monthly. The nurses were present

in all activities that were conducted by different professionals, and were the link between all professionals and patients to clarify and solve possible difficulties.

The intervention conducted by the PASC professionals consisted of four 40-minute sessions of physical activity every week during the 12 months of intervention (208 sessions in total). Each session started with stretching exercises (10 minutes), followed by moderate aerobic work (30 minutes) consisting of fast walking or light running, with a rest period at the end. For accomplishment of these sessions, the participants were divided in three groups of ten and a group of seven. The participation rate in the physical activity component of the intervention was 88%. Participants with more than 35% of missed sessions would have been excluded from the intervention programme, but no patients were excluded for this reason. Psychologists conducted a 6-minute session of cognitive behavioural therapy on a monthly basis (12 sessions in total). The cognitive behavioural therapy component was based on psychoeducation techniques (motivation for weight loss), cognitive restructuring, problem solving (self-efficacy), and skill development. This component of the intervention was created by a team of psychologists from previous models and interventions, with the objective of maintaining a decrease in metabolic and cardiovascular parameters in the medium and long term. The sessions were applied in groups. The physician and nutritionist implemented the clinical and nutritional component. They controlled the drug–nutrient interactions and monitored any imbalance or adverse reactions that could occur in response to physical activity and dietary treatment. Energy needs and nutritional assessment were calculated using the Harris and Benedict formula[18] by professionals who were instructed individually in dietary treatment. The menus were prepared by the nutritionist from the Adult Treatment, Panel III diet with a deficit of 300 kcal/day. The nutritional classification was as follows: 55% carbohydrates, less than 30% fat, 15% protein, and less than 150 mg/day of cholesterol. The concept of consumption of vegetables and fruits was strengthened.[19] All activities were carried out at the Community Cultural Centre, with the exception of clinical, nutritional, anthropometric, and biochemical assessments, which were carried out in the Community Care Center.

In the CG, the research team performed clinical, anthropometric, and biochemical evaluations, which were carried out in the Community Care Centre at the above-mentioned time points. Additionally, continuation with the prescriptions of the standard programme was performed, and this consisted of recommendations with regard to lifestyle and dietary habits. Similar to the EG, during the year after the intervention, the research team had no contact with the participants. Patients were contacted again 1 year after completion of the intervention, for the last clinical, anthropometric, and biochemical evaluations.

The I^2AO^2 programme did not require any economic finance or additional effort from the Healthcare Service of Murcia. This programme was conducted with public resources (material as well as human) that were offered to the community by the city council, and by the support of health care professionals practicing their duties as usual. The only exception was the presence of a nurse who participated in 104 sessions with a PASC professional. The nurse controlled the attendance of the participants and the quality of the sessions during the first and last session of the week. The sessions were held in the afternoons on Mondays, Tuesdays, Wednesdays, and Thursdays; the nurse attended Monday and Thursday sessions to have direct contact with patients and PASC professionals, to attend to any incident that might arise.

Therefore, this is the only special cost for any public system in Spanish territory that wishes to carry out this programme (€5600 EUR). An estimation of the cost for implementing the I^2AO^2 in the private sector is as follows:

Human resources:

- PASC professional: €20 per session (208 sessions would be €4160).
- Psychologist: €45 per session (12 sessions would be €540).
- Nutritionist: €20 per session (24 sessions would be €480).
- Physician: €60 per session (24 sessions would be €1440, and 444 hours for personal control of EG subjects per month would be €26640, for a total of €28,080).
- Nurse: €40 per session (12 personal sessions of health education + 12 control sessions together with the psychologist + 24 control sessions with the physician and the nutritionist + 104 sessions shared with the PASC professional, for a total of €6080).

Material resources:

- Sport facility: €10 per session (208 sessions would be €2080).
- Training room €60 per session (48 sessions would be €2880)

Therefore, the economic estimation for development of this programme in the private sector would be €45,740.

Statistical analysis

Statistical analyses were performed using the IBM SPSS Statistics, version 22.0 (IBM Corp., Armonk, NY, USA). We performed a descriptive study of the variables by calculating the mean and standard deviation of the quantitative variables (age, weight, BMI, WC, SBP, DBP, heart rate [HR], CVR, TC, HDL-C, LDL-C, TG, glucose, and HbA1c). We also calculated the frequency and percentage of qualitative variables (sex, smoking, alcohol, diabetes mellitus, hypertension, dyslipidaemia, MS, and CVR). The efficacy of the intervention was analysed by analysis of variance for crossover studies, with group as a between-subjects factor and the time of the measurement of the dependent variables as an intra-subject factor (group × time). There was an effect of the intervention when the F test for the group × time interaction was significant. In this case, repeated measures analysis of variance was applied to study longitudinal development of the dependent variable in each group. Effect-size evaluation was performed using the η^2 statistic. In repeated measures tests, comparisons between pairs of time measures were performed using the post-hoc Tukey test. Bonferroni correction was applied to correct for the effect of multiple comparisons (type I error). Analysis of the effect of sex on MS and CVR was conducted using the chi-square test for qualitative variables in each group. The significance level used was $p < 0.05$.

Results

The two groups were similar regarding age and sex, as well as smoking and drinking habits and previous pathologies (Table 1).

For anthropometric measurements, there was a significant reduction in weight, BMI, and WC in the EG, with significance for group, time, and group × time interaction (all $p < 0.05$) (Table 2). There was a decrease in weight in the EG at 6 and 12 months compared with the pretest value (both $p < 0.001$). Weight loss was maintained at follow-up ($p < 0.001$). In the CG, there were no significant changes in weight at 6 and 12 months, or at follow-up. The results for BMI were similar to those for weight. In the EG, there was a decrease in BMI at 6 and 12 months compared with the pretest value (both $p < 0.001$). This decrease

Table 2. Effect of the intervention on anthropometric parameters

		CG (n = 37)		EG (n = 37)		Interaction $F_{3;216}$ P $\eta2$	Time $F_{3;216}$ P $\eta2$	Group $F_{1;72}$ P $\eta2$
		M	SD	M	SD			
Weight (kg)	Pretest[a]	88.9	13.2	86.9	11.4	78.988	65.140	6.340
	6 months	88.5	12.9	82.2	10.4	<0.001	<0.001	0.014
	12 months	88.7	12.4	79.9	9.9	0.523	0.475	0.081
	Follow-up	89.8	12.9	79.7	10.0			
BMI (kg/m^2)	Pretest[b]	34.3	4.5	32.4	3.8	77.529	64.638	16.873
	6 months	34.1	4.4	30.6	3.4	<0.001	<0.001	<0.001
	12 months	34.2	4.2	29.8	3.3	0.518	0.473	0.190
	Follow-up	34.6	4.1	29.7	3.3			
WC (cm)	Pretest[c]	108.3	8.9	106.1	9.3	123.940	82.429	17.116
	6 months	107.8	8.6	100.4	8.4	<0.001	<0.001	<0.001
	12 months	108.5	8.9	97.8	7.9	0.633	0.534	0.192
	Follow-up	109.9	8.9	97.6	7.9			

Pretest tests: [a]weight: $t_{72} = 0.721$; $p = 0.473$; [b]BMI: $t_{72} = 1.979$; $p = 0.052$; [c]WC: $t_{72} = 1.061$; $p = 0.292$.
CG: control group; EG: experimental group; n: number; M: mean; SD: standard deviation; $F_{df1;df2}$: F-statistic$_{degrees\ of\ freedom}$; η^2: effect size statistic (eta squared); BMI: body mass index; WC: waist circumference; Follow-up: 1-year post-intervention follow-up.

in BMI remained at follow-up (p < 0.001). In the CG, there were no significant changes in BMI at 6 and 12 months, or at follow-up. There was a decrease in WC in the EG at 6 and at 12 months, and at follow-up compared with the pretest value (all p < 0.001). No significant changes in WC were found in the CG at 6 or 12 months, but there was a significant increase at follow-up compared with the pretest value (p = 0.001).

Cardiovascular parameters were also improved with intervention, with significance for group, time, and group × time interaction (all parameters, p < 0.001) (Table 3). SBP was significantly decreased in both groups at 6 and 12 months, and at follow-up compared with the pretest value (all p < 0.001). However, this decrease was significantly higher in the EG at 6 months (difference = −11.757, p < 0.001), 12 months (difference = −16.757, p < 0.001), and at follow-up (difference = −17.973, p < 0.001) compared with the CG. DBP was reduced over time in both groups (6 and 12

months, and at follow-up, all p < 0.001 vs pretest values). However, this decrease was higher in the EG at 6 months (difference = −5,000, p < 0.001), 12 months (difference = −8.874, p < 0.001), and at follow-up (difference = −12.027, p < 0.001) compared with the CG. There was a significant decrease in HR in the EG at 6 and 12 months, and at follow-up compared with the pretest value (all p < 0.001). There was a tendency for an increase in HR in the CG by follow-up (p = 0.007). CVR values were decreased in the EG at 6 and 12 months, and at follow-up compared with the pretest value (all p < 0.001). In the CG, there was a significant decrease in CVR at 6 months (p = 0.001), but CVR values at 12 months and at follow-up were similar to those before the intervention.

Interdisciplinary intervention was also effective in improving the lipid and glycaemic profile, with significant time and group-× time interaction effects (both p < 0.001) (Table 4). In the EG, TC levels were decreased throughout the intervention and

Table 3. Effect of the intervention on cardiovascular parameters

		CG (n = 37)		EG (n = 37)		Interaction $F_{3;216}$ P η^2	Time $F_{3;216}$ P η^2	Group $F_{1;72}$ P η^2
		M	SD	M	SD			
SBP[a]	Pretest	152.3	11.8	150.6	12.9	34.729	135.411	47.628
(mmHg)	6 months	145.1	9.1	133.4	7.6	<0.001	<0.001	<0.001
	12 months	144.1	7.3	127.3	7.0	0.325	0.653	0.398
	Follow-up	145.5	6.6	127.6	5.8			
DBP[b]	Pretest	87.3	6.8	87.6	5.8	63.094	246.209	36.719
(mmHg)	6 months	81.4	4.8	76.4	5.1	<0.001	<0.001	<0.001
	12 months	80.3	4.7	71.5	4.2	0.467	0.774	0.338
	Follow-up	83.0	5.3	70.9	3.9			
HR[c]	Pretest	74.8	7.5	76.2	11.1	41.358	15.656	21.795
(beats/min)	6 months	74.6	7.2	70.2	6.5	<0.001	<0.001	<0.001
	12 months	76.2	6.6	66.1	5.0	0.365	0.179	0.232
	Follow-up	78.1	6.3	65.0	4.2			
CVR[d]	Pretest	9.3	7.3	8.1	3.7	35.340	40.824	19.227
(%)	6 months	7.6	4.5	4.4	2.2	<0.001	<0.001	<0.001
	12 months	8.1	5.0	3.1	1.5	0.329	0.362	0.211
	Follow-up	9.9	5.8	2.6	1.2			

Pretest tests: [a]SBP: $t_{72} = 0.603$; $p = 0.549$; [b]DBP: $t_{72} = -0.238$; $p = 0.812$; [c]HR: $t_{72} = -0.636$; $p = 0.527$; [d]$t_{72} = 0.862$; $p = 0.392$.
CG: control group; EG: experimental group; n: number; M: mean; SD: standard deviation; $F_{df1;df2}$: F-statistic$_{degrees\ of\ freedom}$; η^2: effect size statistic (eta squared); SBP: systolic blood pressure; DBP: diastolic blood pressure; HR: heart rate; CVR: cardiovascular risk; Follow-up: 1-year post-intervention follow-up.

at follow-up compared with the pretest value (p < 0.001). In the CG, TC levels were significantly decreased at 6 months compared with the pretest value (p = 0.003), although TC levels had returned to the pretest value by follow-up. In the EG, HDL-C levels were increased at 6 and 12 months, and at follow-up compared with the pretest value (p < 0.001). However, in the CG, there were no changes in HDL-C levels at 6 and 12 months, and there was a significant decrease at follow-up compared with the pretest value (p < 0.001). In contrast, in the EG, LDL-C levels were decreased at 6 and 12 months and at follow-up compared with the pretest value (p < 0.001), with no change in the CG at 6 and 12 months. However, LDL-C levels were increased at follow-up compared with the pretest value in the CG

(p = 0.002). Similar results were observed for TG levels.

In the EG, there was a significant decrease in blood glucose levels at 6 and 12 months, and at follow-up compared with the pretest value (all p < 0.001). In the CG, a significant decrease in blood glucose levels was observed at 6 (p = 0.048) and 12 months (p = 0.050) compared with the pretest value, although this improvement disappeared at follow-up. Finally, in the EG, HbAc1 values were significantly decreased at 6 and 12 months, and at follow-up compared with the pretest value (p < 0.001). However, in the CG, HbAc1 values did not vary over time.

The effect of the intervention showed a gradual reduction in the percentage of participants who were classified as having MS in the EG during treatment. This percentage

Table 4. Effect of the intervention on biochemical parameters (lipid and glycaemic profiles)

		CG (n = 37)		EG (n = 37)		Interaction $F_{3;216}$ P η^2	Time $F_{3;216}$ P η^2	Group $F_{1;72}$ P η^2
		M	SD	M	SD			
TC[a]	Pretest	214.5	26.4	217.6	40.4	77.668	62.468	36.738
(mg/dL)	6-month	200.5	32.0	177.8	27.2	<0.001	<0.001	<0.001
	12-month	207.4	32.2	157.2	24.0	0.519	0.465	0.338
	Follow-up	223.4	33.3	145.9	19.2			
HDL-C[b]	Pretest	53.5	15.4	47.2	12.3	77.895	16.635	2.297
(mg/dL)	6-month	52.5	14.1	53.1	11.3	<0.001	<0.001	0.134
	12-month	51.9	14.5	58.9	10.2	0.520	0.188	0.031
	Follow-up	46.4	13.8	62.2	9.6			
LDL-C[c]	Pretest	123.0	32.5	126.9	38.4	46.408	23.301	12.011
(mg/dL)	6-month	119.4	27.7	106.0	27.7	<0.001	<0.001	0.001
	12-month	124.3	29.1	91.0	22.0	0.392	0.245	0.143
	Follow-up	134.1	28.9	91.6	20.2			
TG[d]	Pretest	147.5	84.4	171.5	81.9	27.541	16.209	1.363
(mg/dL)	6-month	143.1	72.8	136.9	50.4	<0.001	<0.001	0.247
	12-month	143.2	62.7	115.5	36.0	0.277	0.184	0.019
	Follow-up	164.9	69.7	110.3	28.9			
Glucose[e]	Pretest	139.1	33.4	132.9	36.0	25.705	43.387	41.217
(mg/dL)	6-month	129.1	22.5	102.0	14.4	<0.001	<0.001	<0.001
	12-month	129.1	27.2	88.4	9.7	0.263	0.376	0.364
	Follow-up	136.6	31.4	86.8	6.8			
HbA1c[f]	Pretest	7.2	1.1	6.7	1.2	49.622	57.114	57.417
(mg/dL)	6-month	7.0	1.1	5.7	0.7	<0.001	<0.001	<0.001
	12-month	7.0	1.1	5.1	0.3	0.408	0.442	0.444
	Follow-up	7.3	1.1	5.1	0.2			

Pretest tests: [a]TC: $t_{72} = -0.402$; $p = 0.689$; [b]HDL-C: $t_{72} = 1.959$; $p = 0.054$; [c]LDL-C: $t_{72} = -0.474$; $p = 0.637$; [d]TG: $t_{72} = -1.244$; $p = 0.217$; [e]glucose: $t_{72} = 0.764$; $p = 0.447$; [f]HbA1c: $t_{72} = 1.897$; $p = 0.062$.

CG: control group; EG: experimental group; n: number; M: mean; SD: standard deviation; $F_{df1;df2}$: F-statistic$_{degrees\ of\ freedom}$; η^2: effect size statistic (eta squared); TC: total cholesterol; HDL-C: high-density lipoprotein cholesterol; LDL-C: low-density lipoprotein cholesterol; TG: triglycerides; HbA1c: glycosylated haemoglobin; Follow-up: 1-year post-intervention follow-up.

decreased from 100% to 51.9% at 6 months and to 16.2% at 12 months. This improvement was maintained at follow-up (Q3 = 73.132, p < 0.001; Q3 indicates that 75% of patients had a value of <73.312). In the CG, the rate of MS was also decreased from 100% to 81.1% at 6 months and 78.4% at 12 months. However, there was an increase in the rate of MS at follow-up (83.8%) (Q3 = 18,600, p < 0.001) (Figure 2). In the EG, there was no significant difference in rate of MS between men and women at

any time point. However, in the CG, women had a significantly higher rate of MS than did men at the 12-month and follow-up time points (both p < 0.05, Table 5).

With regard to classification of participants in the CVR categories, 24.3% of participants in the EG had a high risk at pretest, and 8.1% had a very high risk. The remaining participants were classified as low-moderate risk (Figure 3). These data were similar ($\chi_2^2 = 1.270$, p = 0.530) to those in the CG (low-moderate CVR:
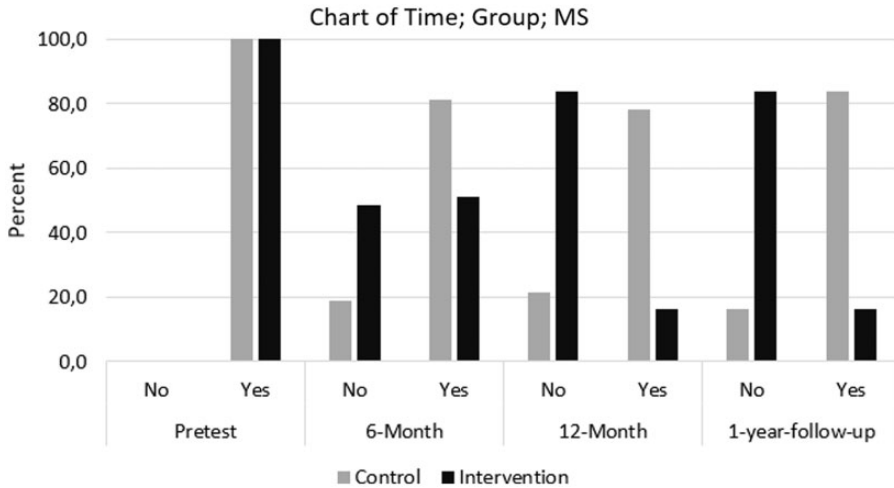
Figure 2. Classification of participants with metabolic syndrome.

Table 5. Metabolic syndrome by sex

		Men		Women		χ^2 test	
		n	%	n	%	$\chi^2(1)$	p
Control							
MS (pretest)	Yes	18	100.0	19	100.0	–	–
MS (6 months)	Yes	12	66.7	18	94.7	3.094	0.079
MS (12 months)	Yes	11	61.1	18	94.7	4.343	0.037
MS (follow-up)	Yes	12	66.7	19	100.0	5.305	0.021
Intervention							
MS (pretest)	Yes	19	100.0	18	100.0	–	–
MS (6 months)	Yes	10	52.6	9	50.0	0.000	1.000
MS (12 months)	Yes	2	10.5	4	22.2	0.269	0.604
MS (follow-up)	Yes	2	10.5	4	22.2	0.269	0.604

n: number; χ^2(df): chi-squared statistic (degrees of freedom); MS: metabolic syndrome; Follow-up: 1-year post-intervention follow-up.

64.9%, high: 18.9%, very high: 16.2%). At 6 months, in the EG, 97.3% of participants had a moderate-low risk and 2.7% had a high risk. In the CG, 8.1% of participants still had a very high risk, 18.9% had a high risk, and 73% had a low-moderate risk ($\chi^2_2 = 8.786$; p = 0.012). At 12 months, all of participants in the EG had a low-moderate risk, whereas in the CG, 21.6% had a high risk, 8.1% had a very high

risk, and 70.3% had a low-moderate risk ($\chi^2_2 = 12.921$, p = 0.002). These results were maintained after the intervention. This was shown by the finding that all of the participants remained in the low-moderate CVR group among those who had received treatment compared with 13.5% with a very high risk and 27% with a high risk in the CG ($\chi^2_2 = 18.814$; p < 0.001). Results by sex showed that at any time point, there were
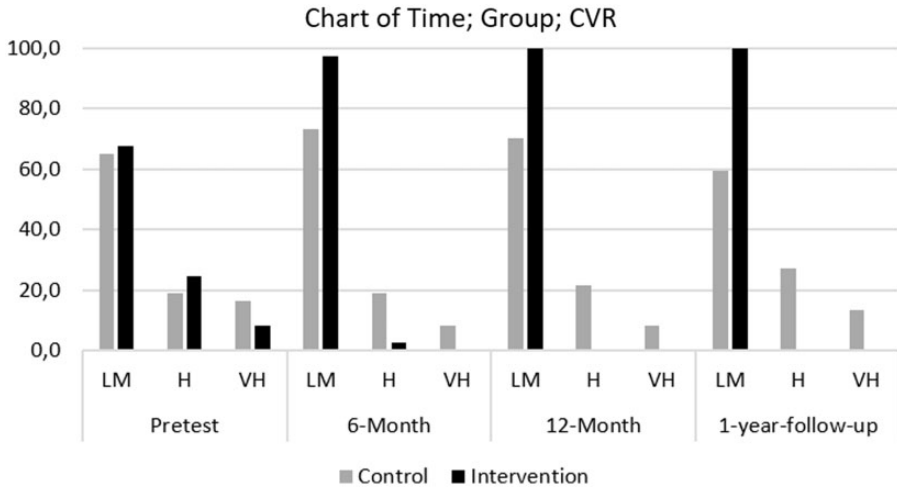
Figure 3. Classification of participants in cardiovascular risk categories.
LM: low-moderate; H: high; VH: very high.

no significant differences in CVR between men and women in the CG. However, in the EG, men showed a higher CVR than did women before the intervention (p < 0.05, Table 6).

Discussion

Widely studied metabolic disorders, such as obesity and MS, continue to be a challenge for public health in the 21st century. Some authors have described that conservative treatment of obesity and MS is a challenge in the current society.[2,20,21] Some authors have even proposed surgical management under certain conditions.[8,9]

Failure attributed to conservative treatment of MS is due to development of programmes based on unidirectional therapies, which are promoted and carried out by a single professional group.[4] Different professionals in isolation have found some beneficial short-term results of treating MS,[22–24] among them nursing.[25,26] However, recent published tendencies maintain that the approach to achieve long-term efficiency and efficacy for treating MS must be interdisciplinary.[27,28] One of the limitations

that this methodology could pose is communication and coordination over time between the different professionals to promote and maintain health care. In this capacity, nursing is important, but recognition of this importance is absent.[29,30]

The scientific literature has shown the holistic role in nursing care, recognizing its biological, psychological, and social implications.[31–33] Currently, these professionals are included in some intervention programmes to manage MS.[5,34] Unfortunately, there have been few publications that have shown the leadership capacity in terms of coordination and monitoring. This has been the case even when nursing has a privileged place as a link between different professionals, the patient, and the community, especially in primary care.[10] A recent study suggested that nursing is important for treating this metabolic disorder, with nurses as the leaders of coordination between health teams and community resources and estates.[23] Our research team aimed to work with the patient, and to understand their social, family, and personal reality. Under the philosophy of empowerment, we made the patient responsible for his/her illness,

Table 6. Cardiovascular risk classification by sex

	Men		Women		χ^2 test	
	n	%	n	%	χ^2 (df)	p
Control						
Pretest						
Low-moderate	9	50.0	15	78.9	3.428	0.180
High	5	27.8	2	10.5		
Very high	4	22.2	2	10.5		
6 months						
Low-moderate	12	66.7	15	78.9	0.783	0.676
High	4	22.2	3	15.8		
Very high	2	11.1	1	5.3		
12 months						
Low-moderate	10	55.6	16	84.2	3.694	0.158
High	6	33.3	2	10.5		
Very high	2	11.1	1	5.3		
Follow-up						
Low-moderate	9	50.0	13	68.4	1.301	0.522
High	6	33.3	4	21.1		
Very high	3	16.7	2	10.5		
Intervention						
Pretest						
Low-moderate	9	47.4	16	88.9	7.716(2)	0.021
High	7	36.8	2	11.1		
Very high	3	15.8	0	0.0		
6 months						
Low-moderate	18	94.7	18	100.0	0.000(1)	1.000
High	1	5.3	0	0.0		
12 months						
Low-moderate	19	100.0	18	100.0	–	–
Follow-up						
Low-moderate	19	100.0	18	100.0	–	–

n: number; χ^2 (df): chi-squared statistic (degrees of freedom); Follow-up: 1-year post-intervention follow-up.

and provided all of the tools required to control and improve the illness. The patient was the main protagonist of any change, and professionals served as support, accompanying them in meeting their requested. Our results obtained for the I^2AO^2 programme show the benefits of the philosophy presented in the treatment of MS, and also indicate the possibility of preventing CVD.

Our study showed the efficacy and effectiveness of the programme in the short term (6 months), medium term (12 months), and long term (24 months). In subjects who performed the intervention, a significant reduction was found in the short-term diagnosis of MS by 48.1% and in the medium term by 83.8%. This reduction was maintained for 24 months after the start of the programme. However, participants in the CG showed an increase in prevalence of MS by 2.7% from the initial evaluation to completion of the study. A programme led by Bo et al.[5] (2007)

with an interdisciplinary basis, but without nursing as an element of leadership, showed beneficial results in reduction of MS at 12 months. Their MS rates were also much lower than those in our study. The HEALTHY LIFE programme showed more similar data to our study with a reduction in all components of MS by 60% at 12 months of intervention.[35]

Our results confirmed the efficiency and efficacy of the I^2AO^2 programme, specifically for the MS components. For anthropometric parameters, a progressive reduction was observed in the three temporal time points for weight, WC, and BMI in the EG. In contrast, the CG did not show changes in these variables at 6 and 12 months of the study, and WC was even increased at the end of the study (24 months). These results are replicated by an investigation that carried out a lifestyle modification for 12 months, and obtained beneficial modifications for subjects in two components of MS, weight and blood glucose levels.[36] Another interdisciplinary programme aimed at correction of MS showed that, 12 months after the intervention, there was a reduction in WC, blood glucose levels, and TG in the EG, and an increase of these variables in the weight-control group.[5] Our results support previous results, with a progressive and significant reduction in blood glucose, HbA1c, TC, TG, and LDL-C levels over time in the EG compared with the CG. Additionally, we observed a cardio-protective effect with increasing HDL-C levels in those who were enrolled in the programme. This cardio-protective effect was found by Chang et al (2016).[25] They found an increase in HDL-C levels of 2.34 mg/dL at 6 months. The benefits of their intervention extended to a reduction in body weight, BMI, WC, blood glucose levels, and blood pressure. Another study carried out by nurses showed that at 6 months of indicating changes in habits, discrete improvements

in weight, LDL-C levels, and SBP were observed.[25] Ohno et al. (2016) recognized the preventive effect of modifying habits in cardiovascular prevention and equating it to pharmacological treatment of antihypertensives.[37] Our study showed a positive reduction in mean SBP and DBP in all study subjects at different time points. However, this observed reduction was significantly higher in the EG than in the CG in the short, medium, and long term. This was not the case with HR, which showed a significant decrease at all time points compared with the pretest value in the EG, with an increase in the CG by follow-up.

A direct relationship between previous metabolic disorders and CVR^2 has been described, with an estimation of death due to CVD for people with MS ranging from 12%–17%.[38] Therefore, the positive changes in all of the individual metabolic parameters analysed in the present study suggest an improvement in the CVR in subjects in the EG. At 12 months in the programme, 100% of the subjects had a moderate-low CVR compared with those in the CG who did not show any changes in the rates of CVR (very high, high, and moderate-low risk categories) at the end of the study. A similar trend was published by the Look AHEAD Research Group (2016), which showed a maximum reduction in the CVR rate of 24% after intervention.[39] These previous findings are supported by an important investigation with a follow-up for 23 years after lifestyle intervention.[40] This previous study showed that the cumulative incidence of CVD mortality was 11.9% in the intervention group versus 19.6% in the control group (p = 0.033), and the overall mortality rates for the intervention and control groups were 28.1% and 38.4% (p = 0.049), respectively.

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Declaration of conflicting interest

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References

1. Fernández-Ruiz VE, Paniagua-Urbano JA, Solé-Agustí M, et al. Impact of the I^2AO^2 interdisciplinary program led by nursing on psychological comorbidity and quality of life: Randomized controlled clinical trial. *Arch Psychiatr Nurs* 2017. http://dx.doi.org/10.1016/j.apnu.2017.11.014

2. Han TS and Lean ME. A clinical perspective of obesity, metabolic syndrome and cardiovascular disease. *JRSM Cardiovasc Dis* 2016; 5: 2048004016633371.

3. Fernández-Ruiz VE, Paniagua-Urbano JA, Solé-Agustí M, et al. [Prevalence of metabolic syndrome and cardiovascular risk in an urban area of Murcia]. *Nutr Hosp* 2014; 30: 1077–1083.

4. Alonso VB and Cervantes CE. [Utility of combined therapy in the prevention and treatment of the cardiovascular disease]. *Rev Clin Esp* 2010; 210: 230–236. [in Spanish, English Abstract].

5. Bo S, Ciccone G, Baldi C, et al. Effectiveness of a lifestyle intervention on metabolic syndrome. A randomized controlled trial. *J Gen Intern Med* 2007; 22: 1695–1703.

6. Kim CJ, Park JW and Park HR. Effects of a community-based intervention on cardiometabolic risk and self-care behaviour in older adults with metabolic syndrome. *Int J Nurs Pract* 2014; 20: 212–220.

7. Blackford K, Jancey J, Lee AH, et al. Home-based lifestyle intervention for rural adults improves metabolic syndrome parameters and cardiovascular risk factors: A randomised controlled trial. *Prev Med* 2016; 89: 15–22.

8. Fernández-Ruiz VE, Armero-Barranco D, Xandri-Graupera JM, et al. Roux-en-Y Gastric Bypass Effective Against Metabolic and Psychiatric Comorbidity? *Biological Research For Nursing* 2016; 7: 1–8

9. Fernández-Ruiz VE, Armero-Barranco D, Xandri-Graupera JM, et al. Bariatric and Cardiovascular Efficacy of Long-Limb Roux-en-Y Gastric Bypass: Overcoming the Limitations Inherent in Individuals. *Bariatr Surg Pract Patient Care* 2016; 11: 49–55.

10. Steinberger J, Daniels SR, Eckel RH, et al. Progress and challenges in metabolic syndrome in children and adolescents: a scientific statement from the American Heart Association Atherosclerosis, hypertension, and obesity in the young committee of the council on cardiovascular disease in the young; council on cardiovascular nursing; and council on nutrition, physical activity, and metabolism. *Circulation* 2009; 119: 628–647.

11. Nanri A, Tomita K, Matsushita Y, et al. Effect of six months lifestyle intervention in Japanese men with metabolic syndrome: randomized controlled trial. *J Occup Health* 2012; 54: 215–222.

12. Campillo JE, Carmena R, Casanueva F, et al. [SEEDO'2000 consensus for the evaluation of overweight and obesity and the establishment of criteria for therapeutic intervention. Sociedad Española para el Estudio de la Obesidad]. *Med Clin (Barc)* 2000; 115: 587–597. [in Spanish, English Abstract].

13. National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) final report. *Circulation* 2002; 106: 3143–3421.

14. Wilson PW, D'Agostino RB, Levy D, et al. Prediction of coronary heart disease using risk factor categories. *Circulation* 1998; 97: 1837–1847.

15. Masson W, Siniawski D, Krauss J, et al. [Clinical applicability of the framingham 30-year risk score. Usefulness in cardiovascular risk stratification and the diagnosis of

carotid atherosclerotic plaque]. *Rev Esp Cardiol* 2011; 64: 305–311. [in Spanish, English Abstract].

16. Steaban RL. Health care reform, care coordination, and transformational leadership. *Nurs Adm Q* 2016; 40: 153–163.

17. Kent F, Francis-Cracknell A, McDonald R, et al. How do interprofessional student teams interact in a primary care clinic? A qualitative analysis using activity theory. *Adv Health Sci Educ Theory Pract* 2016; 21: 749–760.

18. Harris JA and Benedict FG. *A biometric study of basal metabolism in man*. Carnegie Instit, 1919, p.1919.

19. Miguel Soca PE, Peña Pérez I, Niño Escofet S, et al. [Randomised controlled trial: the role of diet and exercise in women with metabolic syndrome]. *Aten Primaria* 2012; 44: 387–393. [in Spanish, English Abstract].

20. Córdova Villalobos JÁ. [Obesity: the real pandemic of the 21(st) century]. *Cir Cir* 2016; 84: 351–355. [in Spanish, English Abstract].

21. Väistö J, Eloranta AM, Viitasalo A, et al. Physical activity and sedentary behaviour in relation to cardiometabolic risk in children: cross-sectional findings from the Physical Activity and Nutrition in Children (PANIC) Study. *Int J Behav Nutr Phys Act* 2014; 11: 55.

22. Araneta MR and Tanori D. Benefits of Zumba Fitness® among sedentary adults with components of the metabolic syndrome: a pilot study. *J Sports Med Phys Fitness* 2015; 55: 1227–1233.

23. Guess N, Wijesuriya M, Vasantharajah L, et al. The effect of dietary changes on distinct components of the metabolic syndrome in a young Sri Lankan population at high risk of CVD. *Br J Nutr* 2016; 116: 719–727.

24. Lin CH, Chiang SL, Heitkemper MM, et al. Effects of telephone-based motivational interviewing in lifestyle modification program on reducing metabolic risks in middle-aged and older women with metabolic syndrome: A randomized controlled trial. *Int J Nurs Stud* 2016; 60: 12–23.

25. Ohno Y, Miyazaki T, Sato M, et al. Lifestyle modifications supported by regional health nurses lowered insulin resistance, oxidative stress and central blood pressure in subjects with metabolic syndrome. *Obes Res Clin Pract* 2015; 9: 584–591.

26. Chang SH, Chen MC, Chien NH, et al. Effectiveness of community-based exercise intervention programme in obese adults with metabolic syndrome. *J Clin Nurs* 2016; 25: 2579–2589.

27. Bischoff SC, Damms-Machado A, Betz C, et al. Multicenter evaluation of an interdisciplinary 52-week weight loss program for obesity with regard to body weight, comorbidities and quality of life–a prospective study. *Int J Obes* 2012; 36: 614–624.

28. Sanches RB, Andrade-Silva SG, Fidalgo JPN, et al. Interdisciplinary therapy improves cardiorespiratory fitness and inflammatory markers in obese adult women. *Obes Med* 2016; 2: 1–7.

29. Budd GM and Peterson JA. CE: The obesity epidemic, part 2: nursing assessment and intervention. *Am J Nurs* 2015; 115: 38–46; quiz 47-8.

30. Welbourn R, Dixon J, Barth JH, et al. NICE-accredited commissioning guidance for weight assessment and management clinics: a model for a specialist multidisciplinary team approach for people with severe obesity. *Obes Surg* 2016; 26: 649–659.

31. Henderson S. Factors impacting on nurses' transference of theoretical knowledge of holistic care into clinical practice. *Nurse Educ Pract* 2002; 2: 244–250.

32. Takase M and Teraoka S. Development of the holistic nursing competence scale. *Nurs Health Sci* 2011; 13: 396–403.

33. Zamanzadeh V, Jasemi M, Valizadeh L, et al. Effective factors in providing holistic care: a qualitative study. *Indian J Palliat Care* 2015; 21: 214–224.

34. Carey MG, Al-Zaiti SS, Liao LM, et al. A low-glycemic nutritional fitness program to reverse metabolic syndrome in professional firefighters: results of *a pilot study*. *J Cardiovasc Nurs* 2011; 26: 298–304.

35. Buckley J, Yekta S, Joseph V, et al. Vida Sana: a lifestyle intervention for uninsured, predominantly Spanish-speaking immigrants improves metabolic syndrome indicators. *J Community Health* 2015; 40: 116–123.

36. Chirinos DA, Goldberg RB, Llabre MM, et al. Lifestyle modification and weight

reduction among low-income patients with the metabolic syndrome: the CHARMS randomized controlled trial. *J Behav Med* 2016; 39: 483–492.

37. Ohno Y, Shibazaki S, Araki R, et al. Lifestyle Modifications Versus Antihypertensive Medications in Reducing Cardiovascular Events in an Aging Society: A Success Rate-oriented Simulation. *Intern Med* 2016; 55: 2185–2195.

38. Ford ES. Risks for all-cause mortality, cardiovascular disease, and diabetes associated with the metabolic syndrome: a summary of the evidence. *Diabetes Care* 2005; 28: 1769–1778.

39. Look AHEAD Research Group, Gregg EW, Jakicic JM, et al. Association of the magnitude of weight loss and changes in physical fitness with long-term cardiovascular disease outcomes in overweight or obese people with type 2 diabetes: a post-hoc analysis of the Look AHEAD randomised clinical trial. *Lancet Diabetes Endocrinol* 2016; 4: 913–921.

40. Li G, Zhang P, Wang J, et al. Cardiovascular mortality, all-cause mortality, and diabetes incidence after lifestyle intervention for people with impaired glucose tolerance in the Da Qing Diabetes Prevention Study: a 23-year follow-up study. *Lancet Diabetes Endocrinol* 2014; 2: 474–480.