Original Article

# Effects of a long-term lifestyle intervention program with Mediterranean diet and exercise for the management of patients with metabolic syndrome in a primary care setting

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## ARTICLE INFO

## ABSTRACT

*Background:* The impact of a lifestyle intervention (LSI) program for the long-term management of subjects with metabolic syndrome in a primary care setting is not known.
*Methods:* This 3-year prospective controlled trial randomized adult subjects with metabolic syndrome to receive intensive LSI or to usual care in a community health centre in Malaga, Spain. LSI subjects received instruction on Mediterranean diet and a regular aerobic exercise program by their primary care professionals. Primary outcome included changes from baseline on different components of metabolic syndrome (abdominal circumference, blood pressure, HDL-cholesterol, fasting plasma glucose and triglycerides).
*Results:* Among the 2,492 subjects screened, 601 subjects with metabolic syndrome (24.1%) were randomized to LSI ($n = 298$) or to usual care ($n = 303$); of them, a 77% and a 58%, respectively, completed the study. At the end of the study period, LSI resulted in significant differences vs. usual care in abdominal circumference ($-0.4 \pm 6$ cm vs. $+2.1 \pm 6.7$ cm, $p < 0.001$), systolic blood pressure ($-5.5 \pm 15$ mmHg vs. -0.6 $\pm$ 19 mmHg, $p = 0.004$), diastolic blood pressure ($-4.6 \pm 10$ mmHg vs. -0.2 $\pm$ 13 mmHg, $p < 0.001$) and HDL-cholesterol ($+4 \pm 12$ mg/dL vs. $+2 \pm 12$ mg/dL, $p = 0.05$); however, there were no differences in fasting plasma glucose and triglyceride concentration ($-4 \pm 35$ mg/dl vs. -1 $\pm$ 32 mg/dl, $p = 0.43$ and $-0.4 \pm 83$ mg/dl vs. $+6 \pm 113$ mg/dl, $p = 0.28$).
*Conclusion:* Intensive LSI counseling provided by primary care professionals resulted in significant improvements in abdominal circumference, blood pressure and HDL-cholesterol but had limited effects on glucose and triglyceride levels in patients with metabolic syndrome.

## 1. Introduction

In the context of the obesity pandemic, the prevalence of metabolic syndrome (MS) is increasing worldwide [1]. In Spain, the prevalence of MS is around 20% of adult population [2]. Despite certain criticism [3], MS is considered a major public health problem because it is a potent predictor of type 2 diabetes [4] and increases cardiovascular outcomes [5,6] and all-cause mortality [5].

The efficacy of lifestyle interventions (LSI) in reducing MS prevalence and improving its individual components has been established in a recent meta-analysis [7]. Nevertheless, the applicability of the current studies [8–16] in a primary care setting is quite limited, so the impact of a low-cost LSI program for the long-term management of general population with MS in a primary care setting is still not well established, and the efficacy of LSI provided by family physicians during their usual practice for reducing the prevalence of metabolic abnormalities is unknown.

On the other hand, epidemiological studies and clinical trials have showed that the adherence to a Mediterranean diet may have a potential role in preventing overweight/obesity [17,18], and that it is useful for the prevention and treatment of MS and its individual components

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[15,19,20]. Moreover, it could prevent type 2 diabetes [21] and reduce cardiovascular diseases [22,23] and overall mortality [24,25].

Our objective was to assess the long-term effects on patients with MS with an intensive LSI based on Mediterranean diet and physical exercise and delivered by primary care providers (PCPs).

## 2. Subjects and methods

A cross-sectional epidemiological study to determine the prevalence of MS in our area was initially designed. We included 2,492 subjects, stratified by age (18–80 years) and sex, which were randomly drawn from the list of the adult population assigned to a health centre in Malaga District. The selection criteria, exclusion and anthropometric and analytical determinations performed were previously described [26]. For the diagnosis of MS, the criteria of the International Diabetes Federation [27] were used. In a second phase of the study, we conducted a single-blind study with a concurrent control group (parallel) on a sample subset of subjects with MS, which were randomly distributed into an experimental group. This group was subjected to an individualized program on Mediterranean diet and aerobic exercise. Participants subjected to sham treatment were used as control group, which received some general recommendations on heart-healthy diet and exercise. The time of this intervention was 3 years.

Patients with MS of both sexes and aged between 18 and 80 years were included. All selected subjects received personalized written information explaining the objectives of the study and requesting their voluntary participation. If they accepted their participation, subjects corroborated their written consent and received a standardized questionnaire adapted from the WHO-MONICA protocol [28]. Subsequently, each participant was randomly assigned to one group (experimental or control) form.

To assess the compliance degree of LSI, a random group formed by one third of the participants in the study carried out, at baseline and at the end of the study, a 14-item validated questionnaire of adherence to the Mediterranean diet [29], a 137-item validated food frequency questionnaire [30], and the validated Spanish version [31] of the Minnesota Leisure-Time Physical Activity Questionnaire. We also administered a 17-item validated questionnaire about quality of life in obese population; each item ranges from 0 (not at all) to 6 points (a very great deal bothersomeness) [32]. The anthropometrical and blood pressure measurements and fasting blood samples were also repeated at baseline visit and 3 years later.

Intervention measures in the two groups were as follows:

- Experimental group. As a dietary intervention, a type of Mediterranean diet [15,22] was recommended, based on the use of olive oil as the main source of visible fat and a regular consumption of vegetables (≥2 servings/day), fruits (≥3 servings/day), legumes (≥3 servings/week) and fish (≥3 times per week), reducing the consumption of red meat or sausage (<2 times per week) and eliminating (or reducing to <1 time/week) the consumption of dairy milk, sugary drinks and confectionery. Patients who had overweight or were obese were suggested a diet with a caloric deficit (600 kcal/day) based on the general patterns of the Mediterranean diet, calculating a caloric deficit of following the Harris–Benedict equation, with the aim of achieving a body weight loss ≥ 5%.

As a program of physical activity, a daily exercise practice was recommended. The minimum aim was walking a mean of 150 min a week. This minimum level of defined activity was based on the cardiometabolic benefit demonstrated in other studies [33].

All the participants in the experimental group had a total of 27 visits throughout the study (9 medical visits and 18 nursing visits) by the specialist in family practice and the community nurse corresponding to each subject. According to the definition of the intensive obesity counseling of the U.S. Preventive Services Task Force (USPSTF) [34], 6 of those visits (2 medical and 4 nursing) were performed during the first 3 months after the intervention. The rest of the medical visits were performed every 3 months during the first year and then every six months. The visits were scheduled every 4 weeks during the first semester and then every 3 months until the end of the study. The health assessment lasted 15 min and included general hygiene and dietary recommendations, clinical assessment and laboratory controls. The first six nursing visits were single and had a duration of 30 min, in which the details, the goals of the diet and the exercise program were explained to the subject. In addition, they were instructed on general concepts (risk factors, Mediterranean diet, different types of fat and their food sources, the importance of physical exercise) and practical concepts (healthy cooking recipes, how to interpret the composition of food, types of exercise recommended) and were provided with educational material on the recommended diet and exercise levels adjusted to their age and physical condition. The rest of the nursing visits were conducted in groups formed by less than 10 people, and they also lasted 30 min, although a visit for individual nursing to strengthen the adhesion was performed every 6 months, receiving a total of 11 individual nursing visits and 7 other group visits. The aim was to ensure that the experimental subjects acquired a theoretical background and sufficient skills to achieve a gradual change in their habits. A nurse interviewed the people who normally bought the food and cooked at the home of the subject under study, to instruct them in practical dietary aspects.

- Control group: In this group, at least 4 medical consultations and 4 nursing visits (individual, with a duration of 10 min) were performed on an annual basis, which could be extended at the discretion of the responsible physician or nurse due to the pathology associated to the patient, and in these cases it continued at the usual clinical practice. The health assessment included general recommendations on heart-healthy diet and exercise and identical clinical and laboratory evaluations in the experimental group. In the general nursing visits, oral and written information about the diet and exercise recommended without entering individualized specifications was provided. The messages contained qualitative changes in the diet, an increase of physical activity and, if overweight or obese, a recommendation to lose weight.

During the study, the physicians responsible for the patients performed the pharmacological interventions they deemed necessary, according to standard practice.

The main outcome measures were changes from baseline to the 3-year follow-up in the mean values of components of MS.

The secondary end points were changes from baseline to the end of the study follow-up on the following: (a) prevalence of MS; (b) severity of MS (measured as the number of components of MS in a subject); (c) incidence of type 2 diabetes (criteria of American Diabetes Association) [35]; and (d) incidence of cardiovascular disease (coronary heart disease, ischemic stroke, peripheral arterial disease).

### 2.1. Statistical analysis

Qualitative variables are presented as frequency distribution; quantitative variables were summarized as mean of the standard deviation (SD). The behavior of quantitative variables for each of the independent variables categorized by the variance analysis (ANOVA) was analyzed. To analyze the differences between the groups at baseline and during the follow-up study, the chi-square test and the Wilcoxon test and the Mann–Whitney test for nonparametric variables were performed. The difference between the groups and their interaction with other variables in reducing the cumulative incidence was performed by a log-rank test and a proportional hazards Cox regression. The effect measures were expressed in terms of absolute and relative risk reduction,