

# Efficacy of Cognitive Behavioral Therapy in Adherence to the Mediterranean Diet in Metabolic Syndrome Patients: A Randomized Controlled Trial

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## ABSTRACT

**Objective:** Verify the efficacy of cognitive behavioral therapy (CBT) in adherence to the Mediterranean diet (MedDiet) in metabolic syndrome (MetS) patients.

**Design, Setting, Participants, and Intervention:** In the *Multimodal Intervention Program for Patients with Metabolic Syndrome* clinical trial, 79 MetS patients completed the intervention. Of those, 48 belonged to the experimental group and 31 to the control group. The intervention received by the experimental group was CBT; the control group followed usual care and attended a workshop on healthy lifestyle.

**Main Outcome Measure(s) and Analysis:** Anthropometric, biochemical, psychological, and lifestyle measures were taken before and after the intervention at 3 and 6 months. Analyses included paired *t* tests, ANOVA, and ANCOVA.

**Results:** The ANOVA results showed a statistically significant interaction between the 2 groups in waist circumference ( $P = .009$ ), triglycerides ( $P = .015$ ), and adherence to the MedDiet ( $P = .026$ ). The ANCOVA results indicated between-group difference in waist circumference ( $P = .026$  and  $.062$  at 3 and 6 months, respectively), in triglycerides ( $P = .009$  and  $.860$  at 3 and 6 months, respectively), and in MedDiet ( $P = .024$  and  $.273$  at 3 and 6 months, respectively).

**Conclusions and Implications:** In interventions in which CBT was applied, significant improvements were observed in MetS patients, especially in adherence to the MedDiet.

**Key Words:** cardiovascular diseases, cognitive behavioral therapy, Mediterranean diet, metabolic syndrome, randomized controlled trial (*J Nutr Educ Behav.* 2018; 000:1–9.)

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## INTRODUCTION

Metabolic syndrome (MetS) is the clustering of cardiovascular risk factors such as central obesity, atherogenic dyslipidemia, high blood

pressure (BP) and hyperglycemia.<sup>1</sup> The best therapeutic strategy for MetS patients is the use of therapies that seek to reduce all risk factors simultaneously, such as lifestyle therapy.<sup>2</sup> Studies in this area indicate

that behavioral intervention programs designed to promote healthy lifestyles, including physical exercise, nutritional education, and group dynamics are not only effective in producing changes in lifestyle but also directly influence biochemical outcomes.<sup>3</sup>

Lifestyle modification based on cognitive behavioral therapy (CBT) is 1 of the most important and effective strategies for managing MetS, especially when specific recommendations regarding diet and exercise are combined with behavioral and cognitive strategies. The main challenge of this treatment lies in helping patients maintain healthy behavioral changes over the long term.<sup>4</sup>

Effective educational, behavioral, and motivational techniques are thus necessary to help patients achieve real change in the way they eat. The use of moderate

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energy-deficit diets combined with reasonable long-term weight loss goals and increased physical activity is probably the most viable intervention method for reducing body weight. Cognitive behavioral techniques such as self-control, stimulus control, cognitive restructuring, relapse prevention, and the continuation of successful changes are critical to successful treatment.<sup>5</sup>

In this regard, interventions focusing on adherence to the Mediterranean diet (MedDiet) are especially interesting. This diet is characterized by a high intake of fruits, vegetables, legumes, whole (minimally processed) foods, fish, and unsaturated fatty acids (especially olive oil); moderate consumption of alcohol (mainly wine, preferably consumed with food); and a low consumption of meat (particularly red meat), dairy products, and saturated fatty acids.<sup>3</sup>

The *Prevention with Mediterranean Diet* study revealed that participants with greater adherence to the MedDiet had higher levels of high-density lipoprotein cholesterol (HDLc) and lower levels of triglycerides. It has been found that greater adherence to the MedDiet significantly lowers the likelihood of MetS in a population with a high risk for cardiovascular diseases (CVDs)<sup>6</sup> and can counteract the effects of increased adiposity on CVD risk.<sup>7</sup> Focusing on MetS patients, a few studies evaluated the effect of adherence to the MedDiet, including a clinical trial in which improvements were observed in the intervention group in weight, high-sensitivity C-reactive protein, and insulin resistance.<sup>8</sup> It would thus seem that adherence to the MedDiet is effective in reducing the prevalence of MetS and associated cardiovascular risk.<sup>8</sup>

Despite these findings, to the authors' knowledge, no studies have performed a follow-up on the efficacy of CBT in increasing adherence to the MedDiet in MetS patients. This study was thus undertaken with a twofold objective: (1) to verify the efficacy of CBT in increasing adherence to the MedDiet, and (2) to study the cardiovascular risk factors modified as a consequence of implementing this therapeutic approach in a group of MetS patients, with a follow-up of 6 months.

## METHODS

### Design, Setting, and Participants

In the *Multimodal Intervention Program for Patients with Metabolic Syndrome* (clinical trial registered at clinicaltrials.gov, No. NCT02949622), 143 subjects who met the diagnostic criteria for MetS according to the National Cholesterol Education Program<sup>1</sup> were randomized to begin the intervention. Figure 1 shows a flowchart illustrating the progress of the patients over the course of the trial. Using intention-to-treat analysis, possible differences between subjects who completed the intervention and those who did not, such as differences in the main sociodemographic variables, lifestyle, and psychological traits were checked using Student *t* test and chi-square analysis.

Participants were blindly randomized into 2 groups. The first was the experimental group (EG) and the second was the control group (CG). A total of 79 participants (53.2% of whom were women) took part in the study, 48 in the EG and 31 in the CG. Table 1 shows the sample's main demographic variables.

Subjects were recruited over 2013–2014 from the University Hospital Virgen de las Nieves in Granada, Spain, which belongs to the Public Healthcare Service of Andalusia. This hospital serves approximately half of the population of the city of Granada and its province. All patients with a diagnosis of MetS who had consultations in the Hypertension or Rheumatology Departments during this period were assessed for possible inclusion in the study. Inclusion criteria were a diagnosis of MetS<sup>1</sup> according to the *National Cholesterol Education Program*: waist circumference > 88 cm for women and > 102 cm for men and the presence of  $\geq 2$  of the following characteristics: (1) BP: systolic  $\geq 130$  mm Hg and diastolic  $\geq 85$  mm Hg; (2) fasting glucose level  $\geq 110$  mg/dL; (3) triglycerides  $\geq 150$  mg/dL; and (4) high-density lipoprotein cholesterol (HDLc)  $\leq 40$  mg/dL in men and  $\leq 50$  mg/dL in women. Exclusion criteria were a diagnosis of advanced osteoarthritis, active inflammatory diseases, severe psychiatric disorders

and/or significant cognitive impairment (assessed through the Mini Mental State Examination), and being illiterate. Patients aged <25 or >65 years were also excluded.

After reading the study information sheet, all subjects who participated in the trial gave informed consent in writing, following the principles of the Declaration of Helsinki. The research protocol was approved by the Ethical Committee of the University Hospital Virgen de las Nieves.

### Intervention

The intervention program based on CBT, which had been assigned to the EG, consisted of the following sessions: (1) psychoeducation of the factors related to MetS and CBT; (2) dysfunctional thoughts and beliefs related to starting and maintaining a diet or exercise routine and difficulties that might hinder the process; (3) problem solving related to lifestyle change; (4) self-control and impulsivity when choosing food or planning an exercise routine; (5) stress management; (6) anger management; (7–9) social skills such as assertiveness, learning to say no effectively, and using feedback; (10) self-efficacy in relation to healthy eating and regular physical exercise; (11) social support from both family and health professionals; and (12) relapse prevention, with a view to promoting long-term maintenance of these changes.

The training was delivered by a psychologist in group format (ie, collectively), with 10–12 patients/group, during 12 weekly sessions lasting 90 minutes. Participation in the study was free of charge for the subjects. Four therapy groups were formed. The objectives of this intervention were to provide information about the disease and give patients cognitive strategies for both lifestyle changes and greater adherence to the proposed therapeutic measures.

The procedure followed for the CG consisted of a workshop with basic information about MetS and the cardiovascular risk involved. At the workshop, standard therapeutic measures were presented in accordance with the *Nutrition, Physical*

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