# Effect of Mediterranean diet adapted to the Mexican population on indicators of metabolic risk in patients with obstructive sleep apnea. MEDIMEXOSA-STUDY

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## *Abstract*

**Background:** Obstructive sleep apnea (OSA) is characterized by episodes of intermittent airway obstruction during deep sleep or REM. It is associated to cardiometabolic risk diseases. The base treatment is continuous positive airway pressure (CPAP), to which not all patients adapt. The Mediterranean diet has proven to be effective in reducing cardiovascular risk markers; however, it must be adapted to different populations. Among OSA patients, it can effectively reduce clinical entity and cardiometabolic risk, while improving quality of life and sleep.

**Objective:** To evaluate the effect of a Mediterranean diet adapted to Mexican diet versus a standard nutritional treatment on metabolic risk indicators in patients with obstructive sleep apnea.

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**Conclusions:** The results of the present RCT will contribute to evaluate the effect of a nutritional intervention adapted to OSA patients, seeking to reduce cardiovascular risk indicators in patients, improve their clinical condition, reduce OSA symptoms, and improve patients' quality of life. Clinical Trial: NCT06782737; https://clinicaltrials.gov/study/NCT06278571

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# Original Manuscript

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**Abstract**

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Trial Registration: Clinical Trials.gov. NCT06782737; https://clinicaltrials.gov/study/NCT06278571

**KEYWORDS:** obstructive sleep apnea; obesity; hyperglycemia; hypercholesterolemia; mediterranean diet; nutritional therapy.

## Introduction

Obstructive sleep apnea (OSA) is a disease characterized by the partial or total obstruction of airways during sleep (1). The global prevalence of OSA has been reported to be between 9 and 38%, considering an apnea-hypopnea index (AHI) of ≥ 5 events/h; higher in men, advancing age, and urban dwelling (3). OSA is estimated to be present in 60% of patients with metabolic syndrome, which can also include, diabetes, obesity, insulin resistance, systemic arterial hypertension, and dyslipidemia (4). Overweight and obesity contribute to higher amounts of fat in dilator muscles of neck and tongue, thus increasing OSA. A positive correlation has been found between severe OSA and obesity in adult patients (5).

Daytime symptoms of OSA patients include, excessive daytime drowsiness, complaints of unrefreshing sleep, morning headaches resolved with breathing regulation, irritability, apathy,

depression, difficulty to focus, and memory loss, among others (6). The treatment of choice for OSA patients, CPAP, generates positive air pressure to reduce negative intrathoracic and upper airway pressure, limiting the repetitive hypoxia cycle in the patients; still, adherence is limited (7).

Weight loss in OSA patients is directly proportional to reduced respiratory events measured by AHI. This was reported in 89 men with OSA who reduced body weight by 7%, fat by 19%, and visceral adipose tissue by 26%, in addition to changes in lifestyle. As a result, OSA was reduced by 15% and 45% of the patients did not need CPAP anymore (8). Evidence indicates the Mediterranean diet (MD) is widely cardioprotective, and contributes to lowering cardiovascular risk and even death (9–11). The PREDIMED study reported that an MD, mostly consisting of fruits, vegetables, white meat, and dried fruits or olive oil, reduced cardiovascular event symptoms in patients compared to those who followed a controlled diet. The MIMOSA study conducted with 187 adults with OSA showed that an intervention with MD or Mediterranean style had a better effect improving cardiometabolic indicators than a standard diet (12). Additionally, the authors report a greater reduction in metabolic syndrome with MD in OSA patients, even when adjusting fluctuations in body weight as compared against a Mediterranean style or a standard diet (13, 14). Fewer insomnia episodes have been linked to a greater adherence to MD in patients with OSA and insomnia (15). Although it has shown to be cardioprotective and improve metabolic indicators, MD must be adapted to other countries. In Mexico, there is scarce evidence on the modification of MD to the Mexican diet and its cardiometabolic effect in OSA patients. Therefore, the aim of this study was to evaluate the effect of a Mediterranean diet adapted to Mexican eating habits *versus* a standard nutritional treatment on metabolic risk indicators in patients with obstructive sleep apnea.

## Methods

### Study and population assignment

A randomized, two-arm clinical trial will be conducted with OSA patients from the Regional

Hospital, Mexican Social Security Institute (Instituto Mexicano del Seguro Social, IMSS) in Mexico City with 12-month follow-up.

The sample size was calculated using the formula for difference in proportions, considering a confidence interval of 95% and a power of 80%. Weight loss is expected in 58% of the sample corresponding to the group given a MD adapted to Mexican population and in 30% of the group consuming a standard diet, as previously reported in the literature. A sample size of 49 patients per group was obtained and, considering losses of 20%, the total number of patients will be 120 (16).

**Selection criteria**

**Inclusion criteria**

Men and women aged 30–70 years, diagnosed with moderate and severe OSA will be included. Table 1 describes the inclusion and exclusion criteria.

**Study procedures**

The study design is a randomized, two-arm clinical trial in patients with OSA. The patients will be referred by a specialist from the sleep clinic at the Hospital where the study will take place. Once the inclusion criteria are checked, the study, risks, and benefits will be explained to the patients, questions will be answered by the researchers, and the patients will sign informed consents to participate in the trial.

Software will be used for randomization, and patients will be assigned to either of the following groups:

- *Mediterranean Diet with Mexican Food (MDMF)*
- Standard diet

**Sociodemographic and clinical variables**

The medical researcher will conduct a clinical interview to obtain sociodemographic data,

pathological background, present comorbidities, and current pharmacological treatment.

A medical questionnaire will be applied by the research team to collect sociodemographic data, pathological-clinical background, and non-pathological information. The patients will answer questions regarding age; clinical history, including pathological and non-pathological background; and pharmacological and non-pharmacological treatments.

**Arterial blood pressure measurement**

Arterial blood pressure will be measured by the medical team participating in the study, using a pre-gauged blood pressure cuff, and no smoking nor consumption of coffee or cola soft drinks in the previous 30 min. The patient will sit in a chair, with the back supported and feet straight on the floor. The left arm will be uncovered and supported on a flat table at heart level. The air chamber (balloon) must cover at least ¾ of the arm's length and at least 80% of its circumference.

**Sleep variable measurement**

During the first consultation at the Sleep Clinic, measurements of AHI and oxygen desaturation index (ODI) will be recorded using CPAP, as part of the routine studies patients with OSA undergo. The study takes 7–8 h.

Polysomnography: PSG channels will be set up; they include electroencephalographic derivations and electrooculogram, electromyogram of chin and legs, respiratory flow signals from thermistor and/or nasal cannula, respiratory effort signals, continuous oxygen monitoring, electrocardiogram, and patient's body position. The study, lasting 4–6 h, will be carried out once and is part of a series of tests that OSA patients undergo.

**Biochemical indicator measurement**

Venous blood samples will be taken after fasting for 8–10 h to measure glucose, lipid profile (cholesterol, triglycerides, HDL, and LDL). Measurements will be recorded during the first consultations and after 6 and 12 months.

**Anthropometric and body composition measurements**

Body composition will be measured by bioimpedance, using an InBody 120 composition analyzer, to obtain fat percentage, fat mass, lean mass, and total body water. Body weight and height will be measured with the same analyzer. The patient must wear as little clothing as possible, without any metal objects (bracelets, earrings, rings, belt, and others). The patient will face forward, place their feet on the metal plates, and arms holding the metal bars and stretched out to the front in a 90 º angle. Height will be measured using an InBody ultrasound stadiometer while the patient is in an upright anatomical position. Anthropometry will be recorded by two nutritionists previously standardized, using the method proposed by Habitch and according with the specifications by Lohman and colleagues (17, 18). The body mass index (BMI) will be obtained from height and weight.

Waist circumference (WC) will be measured using a measuring tape halfway between the lowest rib and the top of the right hipbone. The average value of the second and third measurements will be used for analysis. Measurements will be taken during the first consultation and after 3, 6, and 12 months.

**Sleep quality measurement**

Sleep quality will be measured using Epworth sleepiness scale (ESS), which evaluates 8 items, each from 0 to 3 points, where 0 indicates the patient would never nod off, 1 indicates a small probability of nodding off or falling asleep, 2 indicates a moderate probability of nodding off or falling asleep, and 3 indicates a high probability of falling asleep. A score from 1 to 6 in the scale is considered regular sleep, one from 7 to 8 points is considered mild sleepiness, and one from 9 to 24 points at a pathological (abnormal) drowsiness (19).

**Quality of life measurement**

Quality of life will be measured using a Quebec Sleep Questionnaire (QSQ), which has been

validated for the Hispanic population. It contains 32 items focused on measuring daily sleepiness (7, 16, 20, 27, 31, and 32), daytime symptoms (1, 10, 11, 14, 17, 18, 19, 23, 26, 29), nighttime symptoms (4, 9, 21, 22, 25, 28, 30), emotions (5, 6, 8, 15, 24), and social interactions (2, 3, 12, 13). The questionnaire will be applied basally and after 12-mont follow-up (20).

**Physical activity measurement**

To measure the physical activity, the International Physical Activity Questionnaire (IPAQ) will be applied. The questionnaire contains 7 items that point at the physical activity carried out in the past seven days (hours, minutes, and days of the week). Physical activity will be classified after considering the metabolic equivalent of task (MET) values according to the activity (measurement unit of the test). Physical activity is classified in three categories: low, moderate, and high (25). It will be measured at the beginning of the trial, and after 6 and 12 months (21).

**Nutritional intervention description**

**Group with Mediterranean diet adjusted using Mexican foods**

The patients in the MDMF group will be given a normocaloric, personalized diet with the following distribution: 15–20% proteins, 50–55% carbohydrates, 25–30% fats, and <7% saturated fats, according to the recommendations for OSA patients. The Mifflin-St Jeor equation will be applied to calculate the caloric requirements. At the beginning of the intervention, 24-h reminders will be established to know dietary habits and adjust the diet to the patient’s preferences, customs, and budget. A dietary plan will be designed using equivalent foods. The equivalents will be chosen from the Mexican system of equivalent foods, considering portions, amounts and preparation of each food. In it, typical foods of the Mexican diet can be found, along with their most common preparation and presentation; for instance: grilled, fried, baked, and uncooked (raw), among others (22).

*Mediterranean Diet with Mexican Food (MDMF) Group*

The MD includes a variety of typical foods from European countries. Therefore, it is necessary to analyze their nutritional characteristics before adapting the diet to Mexican citizens particularly those OSA patients taking part in this study. After reviewing the literature, foods belonging to the Mexican diet were identified to show similar characteristics as those in the MD. As part of the adaptation, a comparative chart showing European and Mexican foods was created using the major food groups. Table 2 shows the most representative foods and their adaptation to the Mexican diet, which is explained simply to the patients.

In addition to the equivalency chart including the food groups of both diets, a healthy eating plate was also created as the strategy has been effective in Mexico, where the main foods for a healthy diet are presented in a plate (23). From this strategy, a plate of MD in Mexico was designed, adapting foods that must be consumed according to the region, culture, preferences, and budget, considering easy access for OSA patients. The proposal is shown in Figure 1.

To reinforce the meal plan given to this group, preestablished menus were designed containing foods typical in the MD, such as fruits, vegetables, whole grains, cereals, and white meat. The menus also promoted the intake of vegetable oils and common dried fruits in Mexico. The menus were designed to reach 1200, 1400, 1600, 1800, 2002, and 2200 calories. This group will also continue their common treatment with their physician or group of healthcare professionals as usual.

*MDMF adherence assessment*

Adherence to MDMF will be measured using the 14-point Mediterranean diet adherence screener (MEDAS) questionnaire, consisting of 12 questions on the consumption frequency of foods and 2 questions on intake habits of foods considered part of the MD (24). In this instrument, each question is scored 0 or 1. One point is given for using olive oil as main source of fat for cooking, preferring white meat over red meat, or for consuming: a) 4 or more spoons of olive oil/day; b) 2 or more

vegetable portions/day; c) 3 or more pieces of fruit/day; d) less than 1 portion of red meat or sausage/ day; e) less than 1 portion of animal fat/day; f) less than 1 sugary drink/day; g) 7 or fewer glasses of red wine/week; h) 3 or more portions of legumes/week; i) 3 or more portions of fish/week; j) fewer than 2 cakes or commercial baked goods/week; k) 3 or more portions of nuts/week; and l) a plate of traditional tomato, garlic and onion sauce twice or more/week. The total score ranges between 0 and 14 and allows to identify three levels of MD: low (0–6), medium (7–8), and high (≥ 9) (50).

**Standard diet group**

Patients in the control group will be given a normocaloric diet with the following energy distribution: 15–20% proteins, 50–55% carbohydrates, 25–30% fats, and < 7% saturated fats, per the guidelines for adult OSA patients. The Mifflin-St Jeor equation will be applied to identify the caloric requirements of each patient. The energy needs and distribution will be administered as individual nutritional guidance regarding sleep hygiene measures and type of diet for weight loss according to age, sex, current body weight, and present comorbidities. At the beginning of the intervention, 24-h reminders will be set to know the daily diet. Patients will be given a pamphlet to reinforce healthy eating, and they will continue nutritional consultations with their physicians. This group will also continue the traditional treatment with their physician or group of healthcare professionals as usual.

*Follow-up and study procedures*

At the beginning of the trial and after 12 months, laboratory data (glucose and lipid profiles), clinical data, arterial blood pressure records, anthropometry, body composition, and dietary records of the previous 3 days will be obtained, along with the quality of life and sleep survey. All the patients will receive the written results and explanation in each clinical consultation, as shown in Figure 2.

Follow-up will continue after 3, 6, and 12 months for *MDMF and 6 and 12* months for standard diet participants, who will attend consultation with nutritionist and medical team. Data of meals

corresponding to the previous 3 days will be collected and nutritional recommendations will be given to improve adherence to the nutritional intervention. The study follow-up is shown in Table 3.

**Primary Outcomes**

The **primary objective** of this clinical trial is to evaluate the effect of the MD adapted to the Mexican diet *versus* a standard nutritional treatment on metabolic risk indicators in OSA patients (body weight, fasting glucose, lipid profile, WC, and body composition).

The secondary outcomes are to evaluate the effect of the intervention on:

1. Sleep quality through ESS.

2. Changes in quality of life through QSQ.

3. Adherence to nutritional therapy intervention through records of meals corresponding to previous and MEDAS questionnaire.

**Statistical analysis**

The statistical analysis of the data will be carried out using SPSSv27. The study population will be described using the background, clinical, and pathological variables to characterize the sample of OSA participants. The Kolmogorov–Smirnov test will be used to identify the distribution of quantitative variables, for whose normal distribution measures of central tendency and dispersion will be estimated. For those with free distribution, mean and interquartile range will be used. Measures of frequency and percentages will be used for sociodemographic and clinical qualitative variables, as well as those of patient proportion with and without glycemic control, and with and without cognitive impairment. A chi-squared test will be used to compare the effect of MDMF *vs* that of a standard diet in studied patients compared to patients with control and decontrol of metabolic risk indicators. Depending on the data distribution, a Student’s t test will be used to compare quantitative variables with parametric distribution between groups, and a Mann–Whitney U test will be conducted for free-distribution variables. A logistic regression multivariate analysis will be carried

out, including a reduction or not of respiratory events as an outcome variable, adjusting by other variables that may be statistically significant in the bivariate analysis, such as sex, age, and comorbidities, among others.

## Ethical Considerations

This clinical trial was submitted to the Ethics and Research Committee at HGR 1 “Dr Carlos MacGregor Sánchez Navarrro”, IMSS under the registry number R-2024-3609-055. The protocol was registered at Clinical Trials.gov (NCT06782737). The aim of the study, risks, and benefits will be explained in detail to the participants who will freely chose to take part in the trial. They will provide a written consent describing each procedure in the trial and respect to information privacy. All the researchers participating receive annual training regarding better clinical practices related to research.

## Results

The protocol was approved in 2024, and funding is being sought for patient follow-up, patient inclusion and execution of RCT in 2025. Recruiting will start in March 2025, while data analysis and expected results are to be completed by February 2026.

## Discussion

This RCT seeks to measure the impact of MD adapted to the Mexican population with moderate and sever OSA. There is enough evidence on the cardioprotective effect of MD, which is not only proven in European countries: There are clinical trials evaluating MD adapted to the Chilean population suffering metabolic syndrome (25). It has been proven that interventions aimed at lifestyle improve AHI, showing a reduction by –4.55 events/h and improving weight and BMI among OSA patients; however, no effect on sleep and life quality has been found (26).

Obesity and related diseases, like diabetes, hypertension, and dyslipidemia, represent a greater risk for OSA patients. Then, CPAP treatment combined with weight loss is an effective strategy to reduce cardiovascular risk (27). Adaptation to the patient's likes, customs and budget is necessary for MDA. This study seeks to adequate MD to the Mexican diet in order to make it accessible, since typical MD includes foods considered high-priced for the population receiving care at public healthcare institutions in Mexico.

Furthermore, improvement in cardiometabolic indicators, such a glucose, lipid profile, and weight loss, is likely. Patients are expected to lose 5–10% of their initial body weight, as reported by similar interventions (12).

Sleep quality in OSA patients could improve after the proposed nutritional intervention, while the number of obstructive respiratory events could be reduced given that the size of the oropharyngeal lumen is reduced because of body fat loss (28). Besides the reduction in obesity, the diet is expected to improve fasting glucose, arterial blood pressure, and dyslipidemia in OSA patients taking part in the trial. We also expect this trial to positively affect daytime drowsiness in the patients and improve their quality of life. This clinical trial would be one of the few conducted in Mexico with OSA patients where the implementation of low-cost strategies aims at improving cardiometabolic indicators and quality of life of those OSA patients that receive care at public healthcare institutions in Mexico.

## Conclusion

This study seeks to contribute with improving the diet of patients with OSA, thus enhancing the cardiometabolic risk indicators and reducing the patients' risk of cardiovascular diseases. In addition, we expect to improve the patients' sleep quality and lifestyle. We consider this intervention will be useful to create a proposal including a Mediterranean diet adapted to Mexican habits that improves the dietary needs of OSA patients and similarly those of patients with diabetes, obesity, hypertension,

and other comorbidities.

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The authors would like to thank the authorities at Hospital Regional No 1 “Dr Carlos MacGregor Sánchez Navarro” for providing the conditions to carry out this study.

**Data availability**

The data obtained from the clinical trial will not be available publicly to protect the privacy of the patients’ information. Still, they will be available through the author via correspondence and once there is a justification for the data analysis.

**Authors' contributions**

GT and LV conceptualized the study and drafted the manuscript. MS, EL, and FF conceptualized the study and reviewed the manuscript.

**Conflicts of interest**

None declared.

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**Table 1. Selection criteria for patients with OSA included of the study**

| **Inclusion criteria:** |
| --- |
| ● Men and women<br>● Ages 30-70 years old<br>● Diagnosed with moderate or severe obstructive sleep apnea |
| **Exclusion criteria:** |
| ● Anatomic alterations of the nose, oropharynx, or maxilla<br>● Chronic kidney disease under substantive renal function treatment.<br>● Decompensated heart failure |

- Any type of cancer
- Neurological disease
- Diagnosis of depression
- Refractory dyslipidemia
- Familial dyslipidemia
- Surgeries in the last 6 months
- Body mass index (BMI) >40 kg/m²

**Table 2.** Mediterranean-Mexican Food: *Proposal for the adaptation of the Mediterranean Diet with Mexican foods.*

| **Food Group/Equivalent** | **Mediterranean Diet** | **Foods in Mexico** | **Suggested portions and frequency of consumption** |
|---|---|---|---|
| Fruits and vegetables | **Fruits:** Grapes, watermelon, strawberries, oranges **Vegetables:** Artichokes, asparagus, lettuce, bell peppers, spinach, broccoli. | **Fruits:** Guava, orange, mango, mamey, papaya, blackberry, banana **Vegetables:** Nopal, chayote, cucumber, mushrooms, purslane, quelites, chard, watercress, zucchini, bell pepper, green beans, jicama | **Fruits:** 1-2 servings per main meal **Vegetables:** >2 servings per main meal **Total:** At least 5 servings per day |
| Healthy Fats | Olive oil, olives, hazelnuts, almonds | Avocado, nuts, peanuts, corn oil, sunflower oil, pumpkin seeds, pistachios, sesame seeds | **Olive oil:** In every main meal **Nuts, seeds, olives, avocado:** 1-2 servings per day |
| Cereals | Whole wheat bread, pasta, rice, couscous | Whole wheat bread, pasta, rice, corn tortilla, oats, amaranth | **Bread, pasta, rice, tortilla, oats:** 1-2 servings per main meal |
| Tubers | Potatoes, sweet potatoes | Potatoes, sweet potatoes, yuca | **Potatoes, sweet potatoes, yuca:** <3 servings per week |
| Legumes | Lentils, chickpeas, beans, peas | Lentils, beans, chickpeas | **Lentils, beans, chickpeas:** >2 servings per week |
| Animal-based foods | **Fish and seafood:** Salmon, cod, squid, mussels, shrimp, oysters **Low-fat dairy:** Yogurt, cheese, milk **White meat:** Chicken, hen, turkey **Eggs** **Red and processed meats:** Beef, pork, | **Fish and seafood:** Tuna, sardines, trout, red snapper, tilapia **Low-fat dairy:** Yogurt, cheese, milk, cottage cheese, curd **White meat:** Chicken, hen, turkey **Red and processed meats:** Beef, pork, cold cuts | **Fish:** >2 servings per week **Low-fat dairy:** 2 servings per day **White meat:** 2 servings per week **Eggs:** 2-4 servings per week **Red meat:** <2 servings per week **Processed meats:** |

| | | | |
|---|---|---|---|
| | cold cuts | | <1 serving per week |
| *This table provides examples of foods characteristic of the general Mexican population. It may vary according to the region of Mexico, seasonality, and accessibility for each patient.* | | | |

Figure 1. Proposal of a healthy dish adapted from the Mediterranean diet with Mexican food.

Figure 2. Study follow-up and procedure.

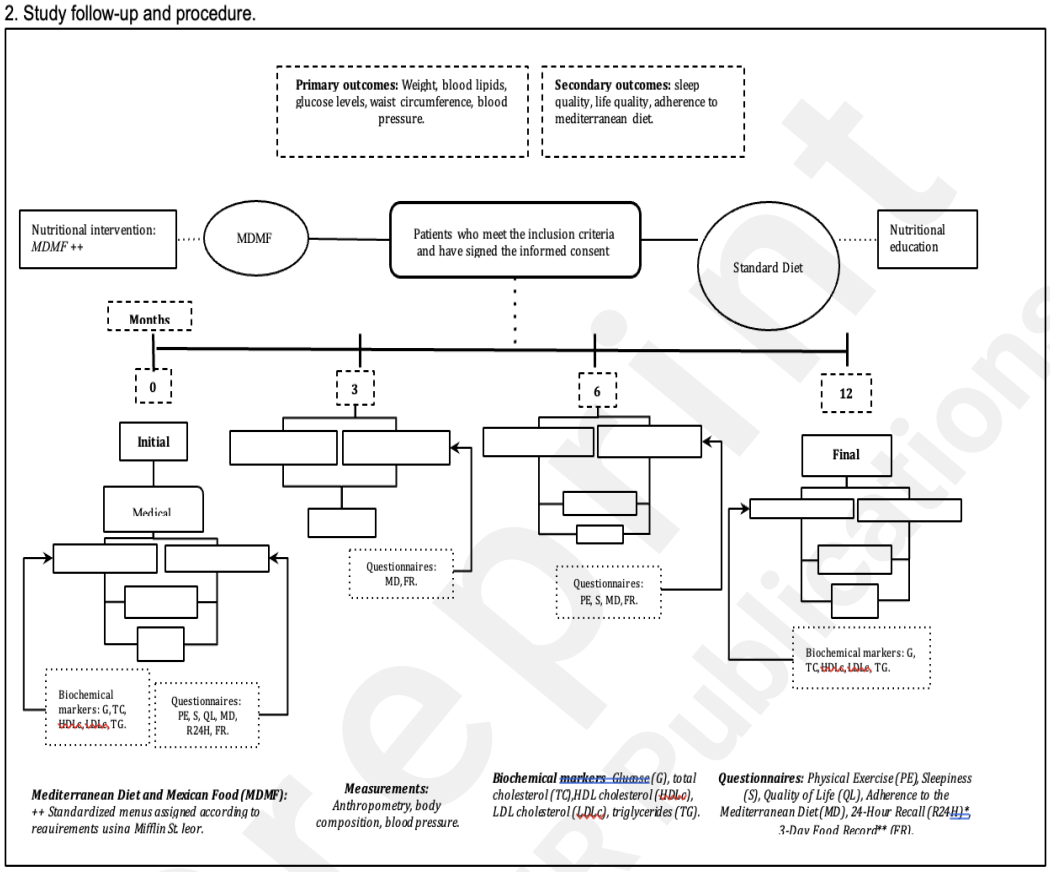


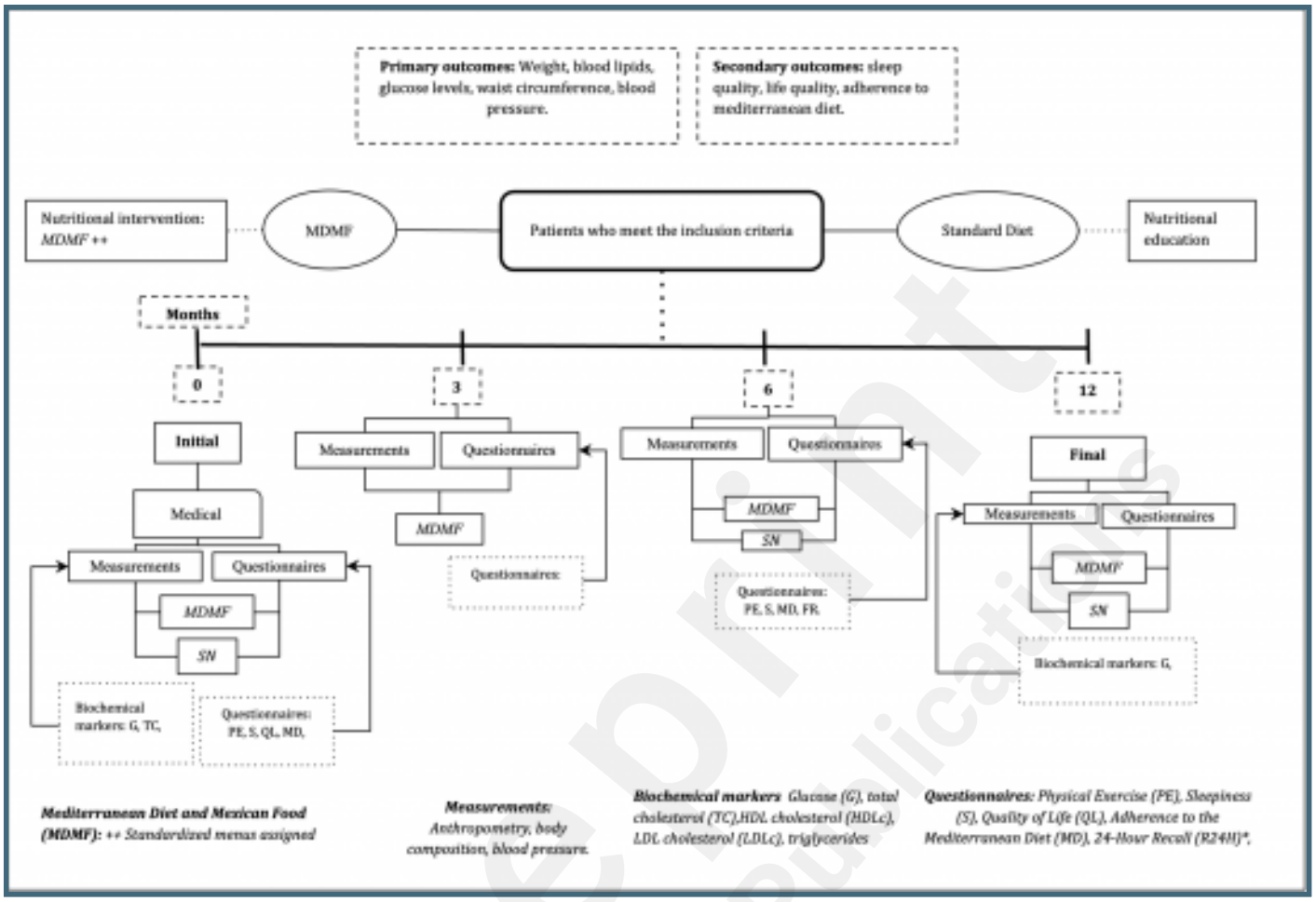
Table 3. Study Follow-Up and Procedure in Patients with OSA in Both Groups.

| | Baseline | 3 months | 6 months | 12 months |
|---|---|---|---|---|
| Collection of sociodemographic data | + ** | | | |
| Medical history | + ** | | | |
| Medical evaluation | + ** | | + | + * |
| Biochemical data | + ** | | | + * |
| Arterial blood pressure and Anthropometric and body composition measurements | + ** | + | + * | + * |
| Sleepiness with Epworth sleepiness scale | + ** | | + ** | + * |
| Quality of life with Quebec Sleep Questionnaire (QSQ) | + ** | | | + * |
| Physical activity with IPAQ Questionary | + ** | | + * | + * |
| Adherence to the diet intervention with records of the previous 3 days | +* | + | +* | +* |
| Adherence to the diet intervention with MEDAS Questionary | +* | + | +* | +* |
| Phone call follow-up | | + | | |

*+Group with Mediterranean Diet and Mexican Food (MDMF).*
** Group with Standard diet.*

# Supplementary Files

Untitled.



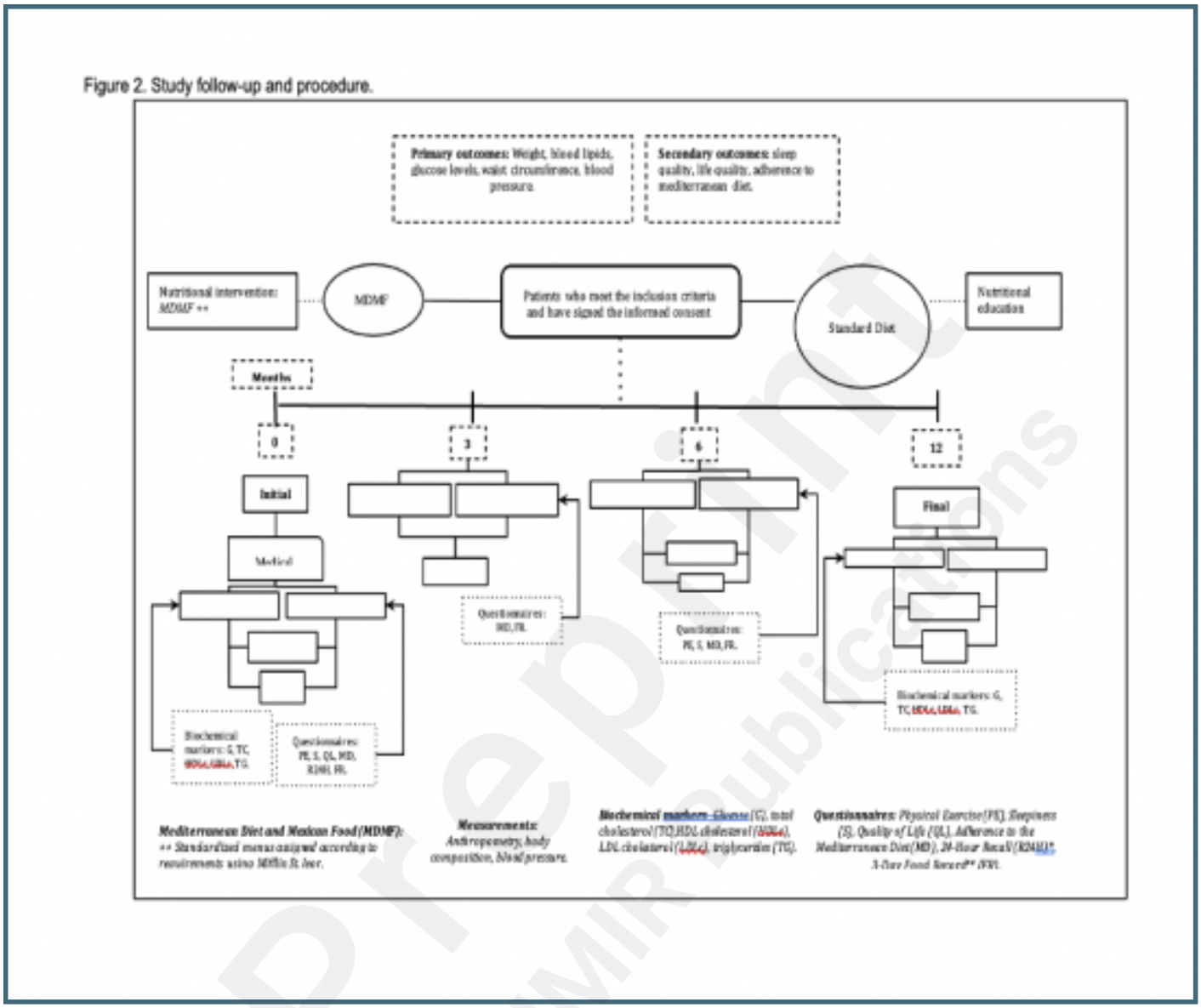
Untitled.
URL: http://asset.jmir.pub/assets/043ab69671b14dd1a8581c16f2370311.pdf

Once the modifications requested by the review of the research and ethics committee were made, this protocol was approved.
URL: http://asset.jmir.pub/assets/6d72bbd483d5334f0ffd6d971d41f0ca.pdf

# Figures

Proposal of a healthy dish adapted from the Mediterranean diet with Mexican food.

Study follow-up and procedure.



# Multimedia Appendixes

This protocol was peer-reviewed by the research committee of the host hospital.
URL: http://asset.jmir.pub/assets/c8561f562721671e5b2371b2af87f642.pdf

# Existing Peer-Review Reports from Funding Agencies (for protocols/proposals only)s

Peer review of the research protocol.
URL: http://asset.jmir.pub/assets/6bd5d6b4655fc410b5da6e4320517760.pdf