IMPROVEMENT OF METABOLIC SYNDROME AFTER AN INTERVENTION BASED ON MEDITERRANEAN DIET IN PATIENTS WITH NON ALCOHOLIC FATTY LIVER DISEASE (NAFLD): A RANDOMISED CONTROLLED CLINICAL TRIAL

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INTRODUCTION:

Non-alcoholic fatty liver disease (NAFLD) is a pathologic condition which involves both hepatic steatosis and non alcoholic steatohepatitis (NASH), as the result of fat accumulation in the liver (liver fat >5% of liver weight), not due to excess alcohol consumption or other causes of steatosis [1]. NAFLD is considered as the hepatic manifestation of the metabolic syndrome [2]. At present, no medication or surgical procedure has been approved for treating NAFLD and lifestyle modifications remain the cornerstone therapy, targeting both at weight reduction for overweight subjects and at prevention of overweight for the normal weight individuals [3].

Current epidemiological data suggest that high adherence to the Mediterranean diet (MD) is associated with lower likelihood of having Metabolic syndrome (MetS) in NAFLD patients [4]. Moreover, a Mediterranean lifestyle (ML) (referring also to sleep and physical activity patterns) has been proposed for chronic disease prevention and treatment [5].

Therefore, the aim of the present study was to explore whether a MD or a ML intervention could resolve MetS and improve its components in patients with NAFLD.

METHOD – DESIGN (continues):

- **Study sample:**

This is a prospective, randomized and single blinded study. At this point, 41 overweight/obese patients (49±11 years, 68% male, BMI range >25-40kg/m^2) with NAFLD, were randomly assigned either to a MD group (n=13) or a ML group (n= 14) or to a control (C) group (n=14) for a 6-month intervention. NAFLD diagnosis was based on the presence of hepatic steatosis on ultrasound and on increased serum levels of alanine aminotransferase (ALT), with or without increased gamma-glutamyl transpeptidase (GGT) serum levels. Patients were excluded if they had a history of alcohol abuse or increased intake (>210 or >140 gr per week for men or women, respectively), other causes of hepatic steatosis, diabetes, reception of potentially hepatotoxic drugs and presence of systemic disease with potential liver involvement.

- **Study groups:**

Subjects were randomly assigned to one of 3 groups: (a) Mediterranean diet Group (MDG), (b) Mediterranean lifestyle group (MLG) or (c) Control group (CG). Participants in groups (a) and (b) attended an intense comprehensive program, comprising seven 60-min group (3-4subjects) counselling sessions, conducted biweekly for the first 2 months and monthly for the following 4 months, until the 6-month evaluation. The MD intervention aimed at increasing adherence to the MD along with 5% weight loss, whereas the ML intervention included also aims for adequate sleep (≥7 hours to ≤9 hours), as well as an increase in physical activity level (PAL). CG received only written information for a healthy diet.

- **Evaluations:**

Blood samples were collected after an overnight food deprivation for the assessment of biochemical markers, and stored at -80^{o}C. Markers of liver function were measured using automated analyzers. Adherence to the MD was assessed by MedDietScore[6] (range 0-55, higher values indicative for better adherence). Physical activity was assessed using the Athens Physical Activity Questionnaire (APAQ)[7]. Sleep duration was evaluated through the Athens Insomnia Scale (AIS)[8]. Metabolic syndrome was defined according to the criteria published by Alberti et al [9].

- **Statistical Analysis:** Results were expressed in terms of mean±standard deviation. The normality of the data was assessed using Shapiro-Wilk test. Changes over time within groups were calculated using paired t test or Wilcoxon test, whereas changes over time between groups were assessed using Repeated Measure-ANOVA. All statistical analyses were performed using SPSS version 23.0 (SPSS Inc., Chicago, IL, USA). Intention to treat analysis using the "*last observation carried forward*" method was used to include 6 dropouts from CG. Statistical significance was set at 5%.

RESULTS:

At baseline, 28.6% in CG, 30.8% in MDG and 71.4% in MLG had MetS. At 6 months, both MDG and MLG increased MedDietScore and decreased weight, whereas no changes were observed in the CG (all P between groups <0.05) (***Table 1***). MLG increased also exercise [ΔPAL:+0.07(±0.14)] (P between groups=0.05)]. At 6months, WC (P<0.001), triglycerides (P=0.05) and % hypertension (P=0.05) improved in the MLG, whereas in the MDG only reduction in WC was observed (P<0.001). In the CG, triglycerides increased, while HDL-cholesterol decreased (all P=0.05). Percentage of MetS was significantly reduced in MLG compared to CG group (P=0.03), but not compared to the MDG.

Table 1. Characteristics of NAFLD patients before and after the 6 month intervention.

	Mediterranean diet group (n=13)		P†	Mediterranean lifestyle group (n=14)		P†	Control group (n=14)		P †	P^
	baseline	6mo		baseline	6mo		baseline	6mo		
% weight loss	-4.78 ± 4.20		0.001	-5.06 ± 4.12		0.001	+1.15 ± 2.36		0.09	<0.001
WC (cm)	103.6 ±11.5	98.2 ±11.2	<0.001	105.9 ±7.81	99.60 ±8.56	<0.001	104.6 ±13.9	105.9 ±14.1	0.27	0.60
BMI (kg/m^2)	30.6 ±5.03	29.3 ±5.74	0.005	31.7 ±4.24	30.16 ±3.91	0.005	32.4 ±5.62	32.8 ±5.73	0.05	0.38
Δ PAL	-0.02±0.17		0.74	+0.07±0.15		0.10	-0.03±0.06		0.06	0.05
% Hypertension (yes), n	53.8, (7)	38.5, (5)	0.32	64.3, (9)	35.7, (5)	0.05	57.1, (8)	57.1, (8)	1.00	0.28
Triglycerides (mg/dL)	108.6 ±43.3	103.1 ±40.1	0.65	180.3 ±93.4	150.6 ±75.9	0.05	122.5 ±49.2	142.0 ±56.3	0.05	0.05
HDL-cholesterol (mg/dL)	49.5±14.5	53.1 ±13.1	0.08	46.5 ±16.3	48.86 ±21.2	0.32	51.0 ± 19.6	48.3 ±19.0	0.05	0.86
MedDietScore (0-55)	32.9 ±3.09	37.8 ±4.18	0.003	33.6 ±2.95	39.07 ±3.26	<0.001	31.1 ±4.38	31.2 ±4.25	0.83	<0.001
% MetS (yes), n	30.8, (4)	23.1, (3)	0.56	71.4, (10)	50, (7)	0.08	28.6, (4)	42.9, (6)	0.16	0.12

Total sample (n)=41, Data presented as mean ± standard deviation (SD); †change over time within group. ^change over time between group, BMI: Body mass index (kg/m^2), CG: Control group, Δ PAL: Physical activity level difference, HDL-cholesterol: high density lipoprotein-cholesterol (mg/dL), MetS: metabolic syndrome, MDG: Mediterranean diet group, MLG: Mediterranean lifestyle group, WC: waist circumference (cm).

CONCLUSIONS:

Based on our results, Mediterranean lifestyle intervention seems to provide favorable results on Metabolic syndrome and its components.

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