



## Effects of Time-Restricted Hypocaloric Mediterranean Diet in Patients with Non-Alcoholic Fatty Liver Disease: Preliminary Data from the CHRONO-NAFLD Project †

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Abstract: Background and objectives: Non-alcoholic fatty liver disease (NAFLD) is spreading at alarming rates, representing a serious public health problem, and it is the most common cause of chronic liver disease. This study aims to evaluate the effects of time-restricted feeding (TRF) along with a hypocaloric Mediterranean Diet (MD) on body weight and biochemical indices. Methods: This 12-week, open-label, randomized controlled trial [NCT05866744] consists of three interventional groups following a personalized diet (1500-2100 kcal/day): control group (MD without time restriction), early 14:10 TRF, and delayed 14:10 TRF. Anthropometric measurements and biochemical analyses are carried out at baseline and 12 weeks. Results: We recruited sixty NAFLD patients with a mean body mass index (BMI) of  $31.8 \pm 0.8 \text{ kg/m}^2$  and a mean age of  $51.05 \pm 2.74$  years, out of whom twenty-one (10 males, 47.6%) have completed the ongoing trial (control n = 7, early TRF n = 6, delayed TRF n = 8). There was no difference in body weight between the groups at 12 weeks, but each group lost significant body weight compared to baseline (control: 6.3%, p = 0.015; early and triglycerides, and low-density lipoprotein cholesterol levels at 12 weeks. Significant decreases in BMI, waist circumference, hip circumference, fat mass, and systolic and diastolic blood pressure were homeostatic model assessment for insulin resistance (HOMA-IR), alanine aminotransferase, and controlled attenuation parameter derived from elastography; while in the early TRF group, there was gamma-glutamyl-transferase, and alkaline phosphatase were improved compared to baseline. There These preliminary data show that 14:10 TRF led to clinically significant weight loss (>5%), mainly via fat mass loss, and to an improved lipid profile, regardless of the time restrictions placed on food

delayed TRF: 8%, p = 0.004, and p = 0.001, respectively). The three groups differed in total cholesterol, observed in all groups. Additionally, in the control group, there was a decrease in fasting insulin, a tendency for lower glycated hemoglobin A1c. Finally, in the delayed TRF group, fasting glucose, was no difference in pleasure rate between the three interventions at baseline or 12 weeks. Discussion: intake. Consequently, TRF could be an alternative weight loss strategy for individuals with NAFLD. Keywords: non-alcoholic fatty liver disease; time-restricted feeding; Mediterranean diet; glucose metabolism; weight loss



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